FETOLY

Software for fetal ultrasound imaging examination aid

Instructions For Use

IFU-WW-FETOLY-V4

March 06th, 2026

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INSTRUCTIONS FOR USE (ENGLISH)

1. Device Identification

FETOLY

Software for fetal heart and brain ultrasound imaging examination aid.

Software version linked to this IFU: V2026.02.25

2. Update

FETOLY has been updated as follows for the 2026.02.25 version:

- FETOLY is now compatible with iOS
- The following measurements have been added per Modification #4 of the PCCP: PLAS, CSP ratio, VP-ratio
- The Transventricular and Transthalamic views have been merged into the Axial view.
- The IFU has been updated to clarify the keypoint display functionality and to add a warning explaining that the software shall not be used in transvaginal scanning method
- The AI model detection performance has been improved per Modification #1 of the PCCP
- It is now possible to enable the TLS mode for DICOM export

Verification testing have been fully re-launched to verify that there is no impact of the update on device functionalities. The methodology followed is the same than for initial product version.

3. Manufacturer identification

FETOLY is manufactured by:

DIAGNOLY

2 Place de Francfort, 69003 LYON, France

Tel.: +33(0)6.58.49.07.84

Product complaints: support@diagnoly.com

Please report any serious incident to Diagnoly through product complaints e-mail address and to the Competent Authority of your country.

CE 0197

4. Device Description and presentation

Fetoly is a software that aims at helping sonographers, obstetricians, radiologists, maternal-fetal medicine specialists and pediatric cardiologists (designated as healthcare professionals i.e. HCPs) to perform fetal ultrasound examinations of the fetal brain and heart in real-time. Fetoly can be used by HCPs during fetal ultrasound examinations in the second and third trimesters (gestational age window: from 17 to 40 weeks).

The software is intended to assist HCPs in the completeness assessment of the fetal brain and heart ultrasound examination in accordance with national and international guidelines. Fetoly is also intended to be used to realize biometric measurements of the fetal brain/heart in accordance with national and internation guidelines.

To utilize Fetoly, the software needs to be installed on a hardware device which is connected to an Ultrasound Machine through an HDMI connection. The software receives ultrasound images captured by the connected Ultrasound Machine in real-time. The software's frozen deep learning algorithm, which was trained by supervised learning, analyzes images of this ultrasound image stream to detect brain/heart views, quality criteria within those views and to make biometric measurements of the heart and brain.

The software provides the following user-accessible information:

1. **Examination completeness**: the software displays in real-time which brain/heart views and quality criteria are verified by the software during the examination. The verified brain/heart views and quality criteria are accessible by clinicians at any moment of the ultrasound examination, in real-time.
2. **Biometric quantitative measurements:** The software displays in real-time which brain and heart measurements are seen and done by the software during the examination and if the measurements are in- or out-of-range in comparison with reference ranges defined per state-of-the-art. The verified heart and brain measurements are accessible by clinicians at any moment of the ultrasound examination, in the background.
3. **Examination illustration:** the software selects an image subset that illustrates
    - the verified views and quality criteria. These images can be reviewed by clinicians to verify the views and criteria's presence. Optionally, clinicians can display detected quality criteria localization on selected images.
    - each measurement. For each measurement, the software displays an image with the measurement drawn (in yellow) and the measured value (on bottom). The normal range for this measurement is also reminded to the user. The user can move the keypoints and the software update the measurements accordingly.
4. **Examination report:** The software allows the user to export an examination report which contains:
    - A summary of measurements and completeness;
    - Illustrations (images).

Definition of a complete examination

For the fetal heart

Table 1: List of 52 quality criteria defining the quality of the 5 views recommended by the International Society of Ultrasound in Obstetrics and Gynecology for the foetal heart screening of 2nd and 3rd trimesters of pregnancy.

Heart views	***Quality criteria within the views***	
 ***(A) ABD***	*(A1) Sp*	*Spine*
	(A2) lRb	*Left rib*
	(A3) rRb	*Right rib*
	(A4) Ao	*Descending aorta*
	(A5) VC	*Inferior vena cava*
	(A6) St	*Stomach*

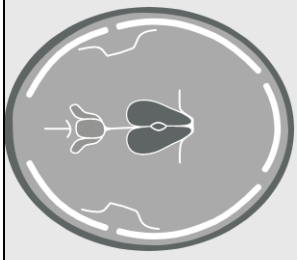
Abdomen view	*(A7) Uv*	*Umbilical vein*
(n = 8)	*(A8) aA*	*Anterior Abdomen*
	*(B1) Sp*	*Spine*
	(B2) lRb	*Left rib*
	(B3) rRb	*Right rib*
	(B4) Ao	*Descending aorta*
	(B5) lPV	*Left pulmonary vein*
	(B6) rPV	*Right pulmonary vein*
(B) 4CH	*(B7) LA*	*Left atrium*
Four chamber view	*(B8) RA*	*Right atrium*
(n = 19)	*(B9) FOF*	*Septum primum (Vieussens valve or Fo-ramen Ovale Flap)*
	(B10) FO	*Open Foramen Ovale*
	(B11) MV	*Mitral valve*
	(B12) TV	*Tricuspid valve*
	(B13) bCr	*Connection between crux and atrial septum (vestibular septum)*
	(B14) Cr	*Atrioventricular valve offset in crux*
	(B15) tCr	*Connection between interventricular septum and crux*
	(B16) IVS	*Interventricular septum*
	(B17) LV	*Left ventricle*
	(B18) RV	*Right ventricle*
	(B19) Str	*Sternum*
	*(C1) LA*	*Left atrium*
	(C2) aAo	*Proximal ascending aorta*
	(C3) SV	*Semilunar valves*
	(C4) LV	*Left ventricle*
	(C5) IVS	*Interventricular septum*
(C) LVOT	*(C6) RV*	*Right ventricle*
Left Ventricular Outflow Tract view		
(n = 6)		
	*(D1) dAo*	*Descending aorta*
	(D2) Tr	*Trachea / bronchi*
	(D3) lPA	*Left pulmonary artery*
	(D4) Du	*Ductus arteriosus*
	(D5) rPA	*Right pulmonary artery*
(D) RVOT	*(D6) Or*	*Origin of pulmonary arteries*
Right Ventricular Outflow Tract view	*(D7) S*	*Septum between pulmonary artery trunk and ascending aorta*
(n = 10)	*(D8) aAo*	*Ascending aorta*
	(D9) SVC	*Superior vena cava*

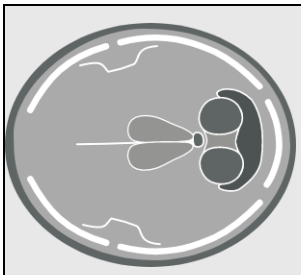
	(D10) PA	*Pulmonary trunk*
 ***(E) 3VX*** ***Three vessels view*** ***(n = 9)***	*(E1) Sp*	*Spine*
	(E2) Tr	*Trachea*
	(E3) ES	*Side space on the left of ductus / pulmonary artery*
	(E4) DuA	*Ductal arch connected to the descending aorta*
	(E5) Du	*Ductal arch not connected to the descending aorta*
	(E6) aAo	*Ascending aorta*
	(E7) aAr	*Aortic arch*
	(E8) SVC	*Superior vena cava*
	(E9) Th	*Thymus / sternum*

*International and national guidelines [Carvalho2023] recommend 5 foetal cardiac views for routine ultrasound examination of 2nd and 3rd trimesters: (A) Abdomen view, (B) Four chamber view, (C) Left Ventricular Outflow Tract view, (D) Right Ventricular Outflow Tract view, (E) Three vessels view. The quality of these 5 heart views depends on the presence of 52 anatomical quality criteria within the views (**Table 1**). Thus, an examination can be defined as complete when all 5 heart views and their quality criteria are obtained by the HCP.*

For the fetal brain

Table 2: List of 34 quality criteria defining the quality of the 3 views recommended by the International Society of Ultrasound in Obstetrics and Gynecology for the foetal brain screening of 2nd and 3rd trimesters of pregnancy.

Brain views	***Quality criteria within the views***	
 ***(F) TV*** ***Axial view*** ***(n = 18)***	*(F1) aFx*	*Anterior Falx*
	(F2) CSP	*Cavum Septum Pellucidum*
	(F3) For	*Fornix*
	(F4) dAV	*Distal Anterior Ventricle*
	(F5) pAV	*Proximal Anterior Ventricle*
	(F6) AC	*Ambient Cisterna*
	(F7) Atr	*Atrium*
	(F8) CP	*Choroid Plexus*
	(F9) POS	*Parieto Occipital Sulcus*
	(F10) pFx	*Posterior Falx*
	(F11) dCS	*Distal Coronal suture*
	(F12) pCS	*Proximal Coronal suture*
	(F13) SF	*Sylvian Fissure*
	(F14) Sk	*Skull*
	(F15) Sep	*Thalami Separation*
	(F16) 3V	*3rd Ventricle*
	(F17) dTh	*Distal Thalamus*
	(F18) pTh	*Proximal Thalamus*

 ***(G) TC*** ***Transcerebellar view*** ***(n = 8)***	*(G1) dTh*	*Distal Thalamus*
	(G2) pTh	*Proximal Thalamus*
	(G3) 4V	*4th Ventricle*
	(G4) Ver	*Vermis*
	(G5) dCH	*Distal Cerebellar Hemisphere*
	(G6) pCH	*Proximal Cerebellar Hemisphere*
	(G7) CB	*Cerebellar Border*
	(G8) CM	*Cisterna Magma*
 ***(I) SAG*** ***Sagittal/profile view*** ***(n = 8)***	*(I1) NB*	*Nose Bone*
	(I2) uVer	*Upper Part of Vermis*
	(I3) lVer	*Lower Part of Vermis*
	(I4) Fas	*Fastigium*
	(I5) rgCC	*Rostrum & Genu Corpus Callosum*
	(I6) bCC	*Body Corpus Callosum*
	(I7) sCC	*Splenium Corpus Callosum*
	(I8) CSP	*Cavum Septum Pellicidum*

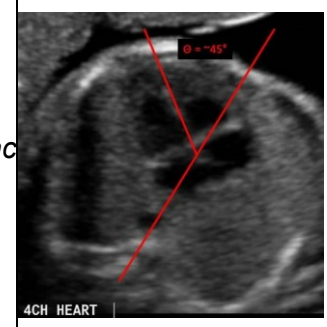
Biometric measurements and reference intervals

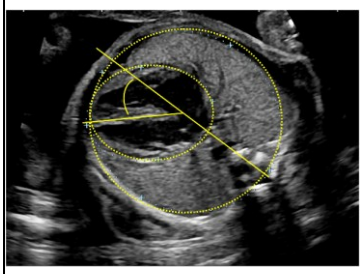
FETOLY provides three types of automated biometric measurements:

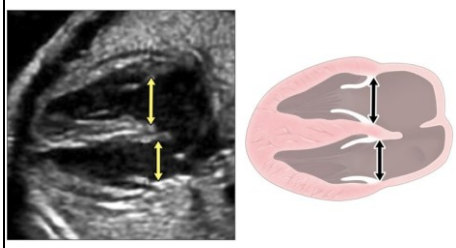
- **Angle measurement** displayed in degrees (°);
- **Ratio measurement** (a distance normalized with another distance, either represented as a ratio or a percentage);
- **Number** of anatomical landmarks detected;

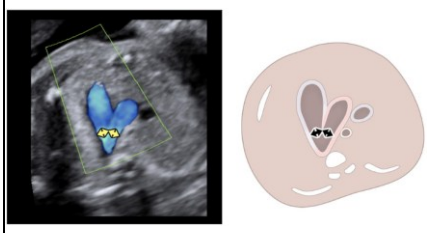
List of measurements and their reference intervals:

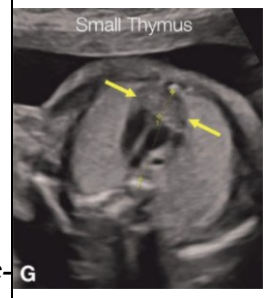
The table below details the biometric measurements provided by FETOLY and their corresponding normal reference intervals based on established literature.

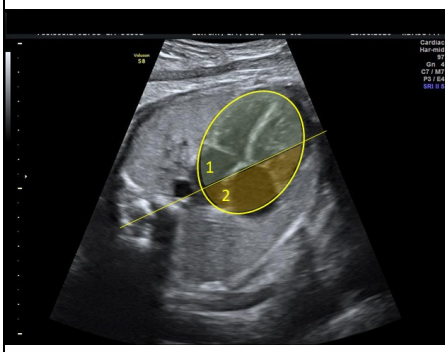
Parameter	*Information accessible in FETOLY (description and sources)*
(M1) Cardiac axis	***What is the cardiac axis (CAx)?***  *(source: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)*

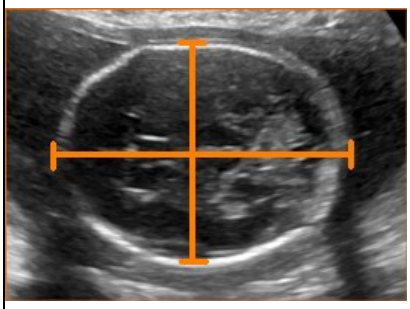
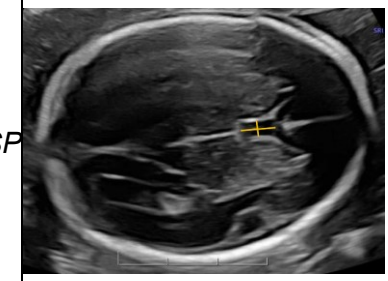
	*The **cardiac axis** (or **cardiac angle**) refers to the orientation of the heart relative to the midline of the chest measured in the four-chamber view. It is determined by the angle between a line along the interventricular septum and an anteroposterior line that bisects the thorax.* *The image should include the spine, sternum, and four chambers. The left and right ribs should be present and visible as single ribs.* ***What do the guidelines recommend?*** *ISUOG guidelines indicate that the cardiac screening examination should include the four-chamber, and its assessment should include the cardiac axis ("Normal fetal heart lies mainly on left, with cardiac apex pointing to left at an angle of 45 ± 20° in relation to anteroposterior axis of chest") (Carvalho2023). They cite (Comstock1987) which provides the reference range for the cardiac axis.* *ASE guidelines also recommend the evaluation of the cardiac axis ("Cardiac axis is a recommended component of fetal echocardiographic 2D imaging [...] normal 35–65°) (Moon-Grady2023).* ***Available reference intervals:*** • **Comstock (1987):** (Mean ± 2 SD) ○ 17-40GA: [25° - 65°]. • **ASE (2023):** (guideline-defined reference range) ○ 17-40GA: [35° - 65°]
(M2) Cardiothoracic ratio	***What is the cardiothoracic ratio?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *The fetal cardiothoracic ratio (CTR) is the ratio of the transverse circumference of the epicardial surface of the heart to the transverse circumference of the thorax measured in the four-chamber view during diastole.* *The image should include the spine, sternum, and four chambers. The left and right ribs should be present and visible as single ribs.* ***What do the guidelines recommend?*** *ASE guidelines indicate that the cardiothoracic ratio is a mandatory component of a fetal echocardiogram ("Standard biometric measurements from an axial image at the level of the four-chamber view. The cardiothoracic ratio is calculated from measurement of the inside circumference (or area) of the chest and the epicardial surface of the heart") (Moon-Grady2023).* *AIUM guidelines also indicate that the cardiothoracic ratio is a required cardiac biometry (AIUM2019). ISUOG guidelines also recommend this measurement ("The*

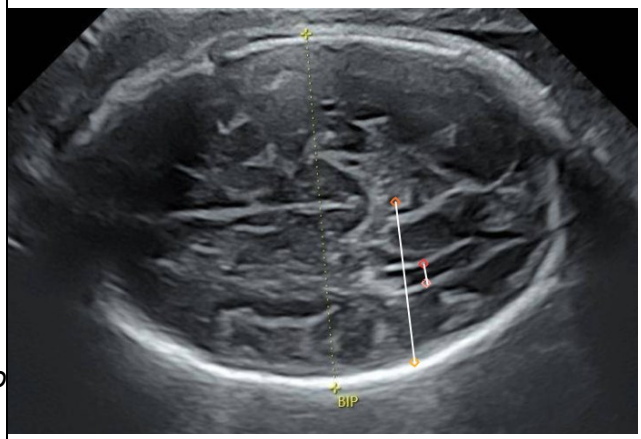
	key elements of the normal mid-trimester four-chamber view include heart area no more than one third of chest area") (Carvalho2013). The handbook by Abuhamad (2009) also recommends assessing the cardiac dimensions ("Fetal cardiac dimensions can be easily assessed by measuring the ratio of cardiac circumference or area to the chest circumference or area obtained at the level of the four-chamber view) (Abuhamad2009). AHA guidelines (Donofrio2014) and Abuhamad's handbook both cite (Paladini1990) for the reference range. ***Available reference intervals:*** • **Paladini (1990):** (2.5th and 97th percentiles for circumference) ○ 17GA: [0.40 - 0.52] ○ 18GA: [0.40 - 0.52] ○ 19GA: [0.42 - 0.51] ○ … ○ 40GA: [0.46 - 0.56] • **Garcia-Otero (2020)**: (5th and 95th percentiles for area) ○ 18GA: [0.16 - 0.25] ○ 19GA: [0,16 - 0.26] ○ … ○ 40GA: [0.21 - 0.35] • **ASE** (Moon-Grady2023): (guideline-defined range for optimal fetal score for area) ○ 17-40GA: [0.20-0.35]
(M3) Ventricular width ratio	***What is the right-left ventricular ratio?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *The **right-to-left ventricular ratio (TV/MV)** refers to the ratio of the tricuspid valve (TV) annular diameter to the mitral valve (MV) annular diameter, which is used to assess cardiac morphology in fetuses. It is determined by comparing the diameters of the TV and MV at their widest points during diastole.* *The image should include the spine and sternum. The left and right ribs should be present and visible as single ribs. The four chamber views should be visible and well contrasted.* *Note: there are two conventions to measure ventricular diameter (Schneider2005): the measurement at the level of the valves or end-diastolic dimension. Please note that the former is used for this measurement.* ***What do the guidelines recommend?***

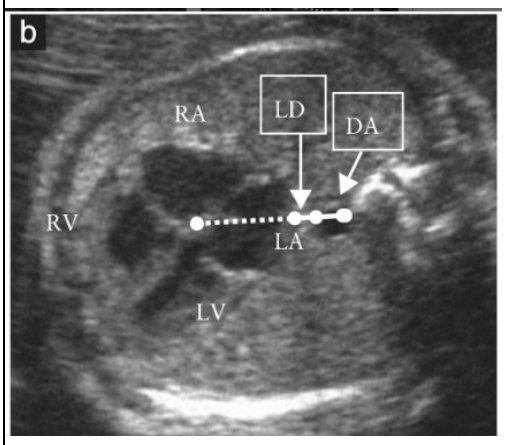
	AIUM guidelines indicate that the comparison of the tricuspid and mitral valve annulus in diastole is a required cardiac biometry ("Tricuspid and mitral valve annulus in diastole ([...] comparison of left- to right-sided valves) is a required cardiac biometry") (AIUM2019). They cite (DeVore2017), (Lee2009), and (Schneider2005) for the reference ranges. *ISUOG guidelines also indicate that right-to-left asymmetry warrants further examination ("Both ventricles should appear similar in size. Although mild ventricular disproportion can occur as a normal variant in the third trimester of pregnancy, right–left asymmetry in midgestation warrants further examination") (Carvalho2023). They cite (Kirk1999) for the reference range.* *ASE guidelines also indicate that the ventricular size relationship is a mandatory assessment of the fetal echocardiogram ("AV valve annulus in early diastole is required as part of complete echocardiography") (Moon-Grady2023). The handbook by Abuhamed (2012) also highlights the relevance of the right ventricular–to–left ventricular width ratio, of 1.19 in normal fetuses.* ***Available reference intervals:*** • **Gabbay-Benziv (2015)** (Gabbay-Benziv2015): (2.5th and 97th percentiles) ○ 17GA: [0.87 - 1.22] ○ 18GA: [0.86 - 1.22] ○ 19GA: [0.86 - 1.22] ○ … ○ 38GA: [0.87 - 1.30] • **Garcia-Otero (2020)**: (5th and 95th percentiles) ○ 18GA: [0.82 - 1.21] ○ 19GA: [0.82 - 1.22] ○ … ○ 40GA: [0.86 - 1.27]
(M4) Vessels ratio	***What is the ratio of the great vessels?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *The great vessels size ratio (Ao/Du) refers to the ratio between the diameters of the aortic isthmus (Ao) and the ductus (Du) on the three-vessel view. It is determined by measuring the diameters of the ductus and aortic arch at their base. Note that the mediastinal pulmonary artery (PA) to ascending aorta (Ao) diameter ratio is also used in literature (Slodki2009).* *The image should include the spine and sternum, with visible and distinct left and right ribs. The ductus arteriosus and ascending aorta should be clearly visible, demonstrating their connection.* ***What do the guidelines recommend?***

	The American and international, including ASE, ISUOG, AIUM, AHA, indicate the evaluation of the size relationship between the great arteries is a mandatory evaluation (Donofrio2014). ("It is important to ascertain normality of the two great arteries, including their size [...] relative to each other") (Carvalho2023). The handbook by Abuhamad (2012) also highlights the relevance of the comparison between diameters of the aortic arch to the main pulmonary artery, specifically in the isthmus region. They cite the study by Pasquini (2007) (Pasquini2007) for reference ranges. ***Available reference intervals:*** • **Pasquini (2007):** ○ Constant: [0.86 - 1.12] (mean ± SD) ○ Constant: [0.74 - 1.23] (2.5th and 97.5th percentiles) (Buyens2012)
(M5) Vessels number	***What is the number of vessels?*** *The fetal three-vessel view (3VV) is an axial plane used in prenatal imaging to assess the great vessels of the heart. This view typically shows three vessels, normally the pulmonary artery, aorta and superior vena cava. The vessels count only focuses on round or elongated anechoic structures, and excludes the trachea and the descending aorta.* *The image should highlight the vessels, with a clear contrast and distinction of the structures.* ***What do the guidelines recommend?*** *The ISUOG guidelines recommend that the evaluation of the three-vessel view should "involve an assessment of vessel number. From left to right, the vessels are the pulmonary artery, aorta and right superior vena cava" (Carvalho2023). ASE guidelines also emphasize that abnormalities in vessel number should be noted (Moon-Grady2023). As an international standard, the expected number of vessels is three.*
(M6) Thymic-thoracic ratio	***What is the thymic-thoracic ratio?***  *(source: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4th ed.). Wolters Kluwer)* *The **thymic-thoracic ratio** is the ratio of the anteroposterior thymic to the intrathoracic mediastinal diameters measured in the three vessels and trachea view.* *The image should display the spine, sternum, and ascending aorta, with the left and right ribs visible as single structures. The thymus should be clearly visible and identifiable.*

	What do the guidelines recommend? *ISUOG guidelines indicate that the "[evaluation of the three-vessel view] involves an assessment of vessel alignment." (Carvalho2023) and that it "may improve detection of outflow tract [...] anomalies". They cite (Chaoui2011) for the evaluation of the thymic-thoracic ratio to detect outflow tract anomalies. The handbook by Abuhamad (2022) also indicates the importance of assessing this parameter.* ***Available reference intervals:*** • **Chaoui (2011):** ○ Constant throughout gestation: [0.36 - 0.53] (mean ± 2 SD)
(M7) Cardiothoracic position	***What is the cardiothoracic position?***  *(image inspired by https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/)* *The **cardiothoracic position** is determined by extending the interventricular septum line posteriorly dividing the atria to a point at the base of the heart (Smith1995). This is performed on the four-chamber view by calculating the ratio of the left-part area to the total cardiac area. This process involves drawing an ellipse over the heart and dividing it with an anteroposterior line that bisects the thorax (the midline of the chest). The left (1) and right (2) areas represent the heart surfaces located on the left and right anatomical sides of the midline, respectively. The position is expressed as the ratio of the left area to the total cardiac area.* ***What do the guidelines recommend?*** *The fetal heart's position within the chest is an important parameter in fetal evaluation. Deviation from the normal position warrants further investigation of potential intrathoracic, intracardiac or extracardiac intrathoracic pathological conditions (Abdullah2000). Both American and international guidelines, including ISUOG (2008), ASE (2004), AIUM (2013), AHA (2014), recommend careful measurement of the fetal heart's position within the chest on the four-chamber view during standard obstetric scans (Donofrio2014). According to these guidelines, the normal fetal heart is primarily located on the left side of the chest, with at least 50% (ratio ≥ 0.5) of its area within the left thoracic space ("the heart is mainly on the left side") (Carvalho2013) ("careful attention should be paid to cardiac axis and position. Majority of heart [should be] in left chest") (Carvalho2023). Studies corroborate these recommendations, with Chiappa (2009) and others (Smith1995, Sever2021) stating that "two thirds of the heart [should be] in the left side of the chest".* *While the many guidelines define a normal cardiothoracic position as 0.66 (ratio ≈ 2/3) and should not fall below 0.5, the literature does not clearly define the upper*

	limit of the normal range. Users can either only visualize the measurement value without a reference range, or define their own reference range.
(M8) Cephalic index	***What is the cephalic index?***  *(source: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* *The **cephalic index** is the ratio of the biparietal diameter (BPD) to the occipitofrontal diameter (OFD) multiplied by 100. The cephalic index gives an idea of the fetal head shape. The front to back, OFD, is measured with the cursor placed on the outer edge to the outer edge of the cranial bones. A grossly decreased cephalic index suggests dolichocephaly while a grossly increased one can suggest brachycephaly. When this parameter is abnormal, other measurements, such as the HC, abdominal circumference, or femur length, should be used to predict fetal age (Timor-Tritsch2012).* *The image should display an axially symmetric view of the brain, capturing the transthalamic plane with both hemispheres visible and clear.* ***What do the guidelines recommend?*** *ISUOG guidelines indicate that "the cephalic index is a ratio of the maximum head width (BPD) to its maximum length (occipitofrontal diameter (OFD)) and this value can be used to characterize the fetal head shape. Abnormal head shape (e.g. brachycephaly or dolichocephaly) can be associated with syndromes or be the result of oligohydramnios or breech presentation. This finding can also lead to inaccurate estimates of fetal age when the BPD is used; in these cases, HC measurements are even more reliable (Hadlock1981)" (Salomon2022).* ***Available reference intervals:*** • **Hadlock (1981):** ○ Constant throughout gestation: [74 - 83] (mean ± SD)
(M9) CSP ratio	***What is the CSP ratio?***  *(source: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. In Journal of Ultrasound in Medicine (Vol. 43, Issue 8, pp. 1461–1466). Wiley)*

	Description: *The* ***Cavum Septum Pellucidum (CSP) ratio*** *is the ratio between the length and the width of the CSP. It is determined by measuring the length and width of the CSP and calculating the length-to-width ratio.* *The image should show an axially symmetric trans ventricular view of the brain, with a clear visualization of the cavum septum pellucidum (CSP) and midline anatomical structures.* ***What do the guidelines recommend?*** *The ISUOG guidelines indicate that the shape of the CSP has been described as a relatively reliable marker of partial agenesis of the corpus callosum and they cite studies by Karl (2017) and Shen (2015) for reference ranges (Malinger2020).* *The World Association of Perinatal Medicine (WAPM) guidelines indicate that the CSP must be visualized and "failure to visualize the CSP or its abnormal appearance (Karl2017) is predictive of commissural anomalies. However, the normal appearance of CSP does not exclude all [corpus callosum] abnormalities" (Robertis2021).* *This parameter can also be found in state-of-the-art Deep Learning techniques for routine biometrics (Coronado-Gutiérrez2023).* ***Available reference intervals:*** • **Karl (2017):** *Constant throughout gestation: [1.5 - 3.3] (5th and 95th percentiles)*
(M10) Posterior cerebral ventricle to hemisphere diameter ratio (VP ratio)	***What is the posterior cerebral ventricle to hemisphere diameter ratio?***  *The* ***posterior cerebral ventricle to hemisphere diameter ratio*** *is a parameter used to assess brain development; particularly ventricular size relative to the overall brain (hemisphere) size.* *It is the ratio between:* - *Posterior cerebral ventricle diameter (= atrial width) – usually referring to the atrium of the lateral ventricle (located at the junction of the occipital, temporal, and parietal horns).* - *Cerebral hemisphere diameter – the total transverse diameter of the corresponding brain hemisphere.* *This measurement shall be realized in the transventricular view.*

	What do guidelines recommend? *The ISUOG guidelines indicate that the measurement of atrial width represents an integral part of sonographic screening for CNS malformation and that atrial width should be measured inner-to-inner and should be <10 mm throughout pregnancy.* *Peer-reviewed literature (Nicolaides1994) emphasize the role of posterior cerebral ventricle to hemisphere diameter ratio in improving prenatal cerebral evaluation and fetal screening accuracy, as it is a relatively reliable marker of ventriculomegaly.* ***Available reference intervals:*** • ***Nicolaides (1994):*** *(5th and 95th percentiles)* ○ *17GA: [0.29 - 0.45]* ○ *18GA: [0.27 - 0.42]* ○ *19GA: [0.26 - 0.40]* ○ *…* *39GA: [0.15 - 0.24]*
(M11) Post-Left Atrium Space (PLAS)	***What is the Post-Left Atrium Space (PLAS) Index?***  *(Source: Kawazu2014)* *The post-left atrium space (PLAS) index is a fetal echocardiographic measurement used to assess the space posterior to the left atrium. It is calculated from a four-chamber view of the fetal heart. The measurement involves determining the distance between the posterior wall of the left atrium and the anterior wall of the descending aorta (LD) and dividing this by the diameter of the descending aorta (DA). The calculation is performed during the end-systolic phase of the cardiac cycle.* *The formula for the PLAS index is:* ***PLAS index = Left Atrium-to-Descending Aorta Distance (LD) / Descending Aorta Diameter (DA)*** ***What Do Guidelines Recommend? (Rationale and Clinical Significance)*** *Peer-reviewed literature (Kawazu2019, Anuwutnavin2023, Akkurt2015) has highlighted the importance of the PLAS index as a simple and reproducible measurement in fetal cardiac screening. Initially introduced by (Kawazu2014), the*

	PLAS index has been identified as a sensitive marker for the prenatal diagnosis of total anomalous pulmonary venous connection (TAPVC), a condition where the pulmonary veins do not connect to the left atrium. An increased PLAS index is a significant indicator of TAPVC ***Available Reference Intervals:*** *Kawazu2014 and Kawazu2019: Constant throughout gestation: An optimal cut-off value of **> 1.27** for suggesting TAPVC. For normal fetuses, the mean PLAS index was reported as **0.62 ± 0.19.***

*Each measurement requires a specific ultrasound viewpoint, referred to as '**subview**', which must meet specific image conditions to ensure accurate measurement. A subview is always derived from one of the standard screening fetal views, but also requires additional particular conditions. For example, measuring the right-to-left ventricular ratio on the four-chamber view requires visualizing correctly the ventricular borders, which is not needed for the cardiac axis.*

The table below illustrates the correspondence between subviews and the cardiac or cerebral views outlined in the ISUOG guidelines.

View	***Subview***
Four chamber view	***Subview 1 (M1):** The image should include the spine, sternum, four chambers, and interventricular septum. The left and right ribs should be present and visible as single ribs.* ***Subview 2 (M2):** The image should include the spine, sternum, and four chambers. The left and right ribs should be present and visible as single ribs.* ***Subview 3 (M3):** The image should include the spine and sternum. The left and right ribs should be present and visible as single ribs. The four chamber views should be visible and well contrasted.* ***Subview 7 (M7):** The image should include the spine, sternum, and four chambers.* ***Subview 11 (M11):** The thorax appears round, not shaped like an open « V ». The left and right ribs both appear as single structures, not multiple parallel or sequential lines. The atrium and the aorta, especially their posterior walls, as well as the space between them, is clearly visible, without shadow obstruction.*
Three vessel and three vessel and trachea views	***Subview 4 (M4):** The image should include the spine and sternum, with visible and distinct left and right ribs. The ductus arteriosus and ascending aorta should be clearly visible, demonstrating their connection.* ***Subview 5 (M5):** The image should highlight the vessels, with a clear contrast and distinction of the structures.*

	Subview 6 (M6): *The image should display the spine, sternum, and ascending aorta, with the left and right ribs visible as single structures. The thymus should be clearly visible and identifiable.*
Axial view	***Subview 8 (M8):*** *The image should display an axially symmetric view of the brain, capturing the transthalamic plane with both hemispheres visible and clear.* ***Subview 9 (M9):*** *The image should show an axially symmetric trans ventricular view of the brain, with a clear visualization of the cavum septum pellucidum (CSP) and midline anatomical structures.* ***Subview 10 (M10):*** *The image should show an axial view where the POS (Parieto Occipital Sulcus) is visible.*

Functionality 1: completeness meter

The software assesses, through a frozen deep learning algorithm which was trained by supervised learning, the completeness of the foetal ultrasound examination. It verifies whether all the information corresponding to the recommended guidelines for the foetal heart/brain examination has been acquired. This information corresponds to the presence of:

- 5 main foetal cardiac views and 52 quality criteria, detailed previously, allowing for compliance in cardiac screening;
- 4 main foetal brain views and 43 quality criteria, detailed previously, allowing for compliance in brain screening.

The completeness page (**Figure 1**) consists of:

- A **play/pause button** initiates the analysis of images acquired by the ultrasound system at the beginning of the examination,
- The **count of heart/brain views** verified by the software since the beginning of the examination. A heart view is considered verified when it is detected in at least one image,
- Individual buttons for **each of the quality criteria**, which turn **green** upon verification by the software.

Each image analysed by the software dynamically updates the completeness page as follows:

- If a quality criterion is detected in the image for the first time, the criterion is marked as **verified**, and its colour changes from white to **green**),
- If a quality criterion is detected in the image but was previously verified, no changes occur,
- If a quality criterion is not detected on the image, no changes occur.

If a quality criterion is associated with an anomaly, the detection status of the criterion depends on its visual appearance:

- If an anomaly alters a quality criterion in such way that it changes its appearance, the software may not detect the criterion and the status will remain unverified;
- If an anomaly does not impact the quality criterion appearance, the software will detect the criterion and mark it as verified, changing its colour from white to **green.**

Please note it is reminded in the labelling that no diagnostic or screening can be realized with FETOLY. A quality criterion not verified by the software does not inherently indicate a pathology.

The completeness page is continuously updated in real-time, allowing users to refer to it at any time during their examination. This allows them to glance at the page without disrupting their examination workflow or necessitating additional actions.

As a reminder and as explained in section 10, FETOLY cannot be used to realize diagnostic or screening. A quality criterion not verified by the software does not inherently indicate a pathology.

Functionality 2: completeness illustration

This functionality was developed to enhance the security of the completeness evaluation which is done by the first module. It enables clinicians to verify the examination completeness overview, i.e. verified views and quality criteria by the software through the gallery page of the software interface. Operating continuously, it evaluates each image processed by the first module in real-time, retaining an image set as visual evidence of the verified heart/brain views and quality criteria up to that moment.

FETOLY does not aim to select the 'best' or of 'high' diagnostic quality according to a given qualitative scale. Rather, FETOLY aims to select images illustrating the examination quantitative completeness in terms of verified views and quality criteria. As this module relies entirely on the first module's deep learning algorithm performance, no additional performance assessment is needed.

For example, if the user has some doubts about one of the green quality criteria, he/she can verify the presence of this criterion by clicking on it in the gallery page. The software will show images which contain this criterion (in yellow in the figure below). When a criterion is selected, the software displays the bounding box surrounding the criterion in these images. This bounding box information is part of the Fetoly-CNN's output.

Functionality 3: Biometric measurements

FETOLY-MEASURE module section is labeled with "Measure" on the analysis page and displays a list of measurements, each organized into four fields:

- **Measurement name**: Displays the name or abbreviation of the measurement along with an information icon. Clicking the icon open detailed information about the measurement, including its scientific reference.
- **Measurement value and units**: The measured value is displayed with the related units. For example, a degree symbol (°) is shown for angular measurements, a percentage symbol (%); otherwise, the field remains empty, meaning that it is a relative measurement. If the keypoints have been edited in the gallery page, a symbol appears in front of the measurement ( ).
- **Reference range**: This field provides the literature-defined reference range for the measurement, supported by its scientific reference. The source may be a guideline, peer-reviewed publication, textbook, or a custom range defined by the user. By clicking on the **new tab button**, user can manually define the reference range or update the literature reference if multiples are available. By clicking on the **information link button**, user can access to a popup with all the necessary information related to the given measurement criterion.
- **Gestational age,** that shall be set up before launching the analysis.

Functionality 4: Measurements illustration

Like the completeness illustration that selects images that demonstrate views and quality criteria, it automatically selects an image for each measurement. Both sets of images are displayed together on the Gallery page. These two sets of images are easy to distinguish: images from measurement function include a measurement value and parameter name, while completeness images do not have annotations.

Both “measurement” and “completeness” images are organized based on their corresponding ultrasound views. Please note that the view affiliation of the images selected by the measurement function is independent from the completeness function. Indeed, each measurement subview corresponds by definition to one of the 5 cardiac or 4 cerebral ultrasound views. Therefore, by knowing the subview, the images selected by the measurement function can be automatically categorized into the appropriate view that this subview belongs to.

Functionality 5: Examination report

A report can be generated from the export page. It will include results and images from FETOLY and will be sent to an external device.

Associated devices

To use the FETOLY device, you need to have the following associated devices:

- An ultrasound machine.
- A tablet and, optionally, a DICOM server, a computer with an FTP server or Bluetooth capabilities, as specified in section 10 “interaction with other equipment”.
- An UVC dongle and an HDMI cable to connect the tablet with the ultrasound machine.

5. Intended use and indications for use

FETOLY is intended to analyze fetal ultrasound image sequences using machine learning techniques to automatically:

- detect brain and heart views and quality criteria within the views;
- detect images suitable for measuring biometric parameters of the fetal heart and brain and provide quantitative measurements of these parameters.

The device is intended for use as a concurrent reading aid during the acquisition and interpretation of fetal ultrasound images.

FETOLY is indicated for use during routine fetal heart and brain examination of 2nd and 3rd trimester pregnancy (gestational age: from 17 to 40 weeks).

6. Intended Users

The product must be used by qualified healthcare professional specialized in prenatal ultrasound imaging.

7. Targeted patient population

Pregnant women during the 2nd and 3rd trimester of pregnancy.

8. Clinical benefits and performances

For this type of device, a SWMD that is a concurrent reading aid used during routine fetal heart and brain examination, the following clinical benefit has been showed:

- Standardization of the routine fetal heart and brain examination as required by the recognized international guidelines

Performance outcomes are detailed in the tables below. The results of the standalone performance testing demonstrate that FETOLY automatically:

- detects fetal heart and brain ultrasound views with a sensitivity ≥ 85% (acceptance criterion) and specificity ≥ 85% (acceptance criterion),
- detects quality criteria within heart views with a sensitivity ≥ 90% (acceptance criterion) and a specificity ≥ 90% (acceptance criterion),
- detects quality criteria within brain views with a sensitivity ≥ 85% (acceptance criterion) and a specificity ≥ 85% (acceptance criterion),
- localizes bounding boxes of quality criteria with a mean intersection over union (IoU) of ≥ 50% (acceptance criterion),
- detects fetal heart and brain ultrasound subviews with a sensitivity ≥ 70% (acceptance criterion) and specificity ≥ 70% (acceptance criterion), and
- realizes fetal heart and brain measurement according to each LOA defined per study endpoints.

For overall results

Fetal view	***Sensitivity***			***Specificity***		
	N(positive)	***Point estimate***	***Bootstrap CI (95%)***	***N(negative)***	***Point estimate***	***Bootstrap CI (95%)***
Abdomen view	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Four chamber view	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Left ventricular outflow tract view	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Right ventricular outflow tract view	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Three vessels view	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Axial view	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Transcerebellar view	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Sagittal/profile view	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Other view	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Quality criterion	***Sensitivity***			***Specificity***			***mIoU***	
	N	***Point estimate***	***Bootstrap CI (95%)***	***N***	***Point estimate***	***Bootstrap CI (95%)***	***Point estimate***	***Bootstrap CI (95%)***
Abdomen view								

Spine	*678*	*0.99*	*(0.983,0.998)*	*4531*	*0.998*	*(0.996,0.999)*	*0.71*	*(0.70,0.73)*
Left rib	*632*	*0.967*	*(0.953,0.980)*	*4577*	*0.993*	*(0.991,0.995)*	*0.58*	*(0.56,0.59)*
Right rib	*627*	*0.951*	*(0.934,0.967)*	*4582*	*0.994*	*(0.992,0.996)*	*0.55*	*(0.53,0.57)*
Descending aorta	*673*	*0.972*	*(0.959,0.984)*	*4536*	*0.998*	*(0.996,0.999)*	*0.52*	*(0.51,0.54)*
Inferior vena cava	*550*	*0.939*	*(0.917,0.958)*	*4659*	*0.987*	*(0.983,0.990)*	*0.5*	*(0.49,0.52)*
Stomach	*675*	*0.983*	*(0.973,0.992)*	*4534*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.75)*
Umbilical vein	*552*	*0.973*	*(0.958,0.986)*	*4657*	*0.99*	*(0.988,0.993)*	*0.64*	*(0.62,0.65)*
Anterior Abdomen	*643*	*0.969*	*(0.954,0.983)*	*4566*	*0.993*	*(0.990,0.995)*	*0.5*	*(0.49,0.52)*
Four chamber view								
Spine	*595*	*0.969*	*(0.955,0.982)*	*4614*	*0.998*	*(0.996,0.999)*	*0.74*	*(0.73,0.75)*
Left rib	*536*	*0.945*	*(0.924,0.963)*	*4673*	*0.99*	*(0.987,0.993)*	*0.64*	*(0.63,0.66)*
Right rib	*548*	*0.948*	*(0.926,0.965)*	*4661*	*0.993*	*(0.991,0.996)*	*0.68*	*(0.66,0.69)*
Descending aorta	*608*	*0.968*	*(0.952,0.981)*	*4601*	*0.997*	*(0.995,0.998)*	*0.66*	*(0.65,0.67)*
Left pulmonary vein	*240*	*0.925*	*(0.889,0.958)*	*4969*	*0.975*	*(0.971,0.979)*	*0.51*	*(0.48,0.53)*
Right pulmonary vein	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*
Left atrium	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Right atrium	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Septum primum (Vieussens valve or Fo-ramen Ovale Flap)	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Open Foramen Ovale	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Mitral valve	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Tricuspid valve	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Connection between crux and atrial septum (vestibular septum)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Atrioventricular valve offset in crux	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Connection between interventricular septum and crux	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Interventricular septum	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*

Left ventricle	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Right ventricle	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Sternum	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Left ventricular outflow tract view								
Left atrium	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Proximal ascending aorta	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Semilunar valves	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Left ventricle	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Interventricular septum	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Right ventricle	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Right ventricular outflow tract view								
Descending aorta	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Trachea / bronchi	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Left pulmonary artery	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*
Ductus arteriosus	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Right pulmonary artery	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Origin of pulmonary arteries	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Septum between pulmonary artery trunk and ascending aorta	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Ascending aorta	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Superior vena cava	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Pulmonary trunk	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Three vessels views								
Spine	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Trachea	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Side space on the left of ductus / pulmonary artery	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Ductal arch connected to the descending aorta	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*

Ductal arch not connected to the descending aorta	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Ascending aorta	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Aortic arch	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Superior vena cava	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Thymus / sternum	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Axial view								
Anterior Falx	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavum Septum Pellucidum	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Fornix	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Distal Anterior Ventricle	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Proximal Anterior Ventricle	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Ambient Cisterna	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Atrium	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Choroid Plexus	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Parieto Occipital Sulcus	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Posterior Falx	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Distal Coronal suture	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Proximal Coronal suture	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Sylvian Fissure	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Skull	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Thalami Separation	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
3rd Ventricul	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Proximal Thalamus	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Distal Thalamus	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Transcerebellar view								
Distal Thalamus	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Proximal Thalamus	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
4th Ventricle	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*

Vermis	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Distal Cerebellar Hemisphere	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Proximal Cerebellar Hemisphere	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Cerebellar Border	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Cisterna Magma	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Sagittal/Profile view								
Nose Bone	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Upper Part of Vermis	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Lower Part of Vermis	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastigium	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Rostrum & Genu Corpus Callosum	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Body Corpus Callosum	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Splenium Corpus Callosum	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavum Septum Pellicidum	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Measurement	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	LOA	LOA CI
thymic-thoracic_ratio	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
cardiothoracic_ratio	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
vessels_ratio	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
cephalic_index	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
vessels_number	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
cardiothoracic_position	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
right-left_ventricular_ratio	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
cardiac_angle	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
CSP ratio	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
VP-ratio	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
Post-Left Atrium Space	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Measurement	slope	intercept	slope CI	intercept CI
thymic-thoracic_ratio	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
cardiothoracic_ratio	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
vessels_ratio	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
cephalic_index	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*

vessels_number	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
cardiothoracic_position	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
right-left_ventricular_ratio	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
cardiac_angle	*0.9197936528230518*	*3.114077691538199*	*(0.888,0.945)*	*(2.023,4.477)*
CSP ratio	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
VP-ratio	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
Post-Left Atrium Space	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

For ultrasound system manufacturer results

Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
I	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
I	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)
X	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
X	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
X	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)

Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*

A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*
A.Sp	*Samsung*	*296*	*0.984*	*(0.967,0.994)*	*1708*	*0.999*	*(0.997,1.000)*	*0.7*	*(0.68,0.71)*
A.St	*Canon*	*29*	*0.966*	*(0.893,1.000)*	*207*	*0.991*	*(0.975,1.000)*	*0.72*	*(0.67,0.76)*
A.St	*GE*	*279*	*0.993*	*(0.983,1.000)*	*2261*	*1.0*	*(1.000,1.000)*	*0.79*	*(0.77,0.80)*
A.St	*Samsung*	*293*	*0.973*	*(0.954,0.990)*	*1711*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
A.Uv	*Canon*	*25*	*0.96*	*(0.870,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.6*	*(0.51,0.67)*
A.Uv	*GE*	*217*	*0.977*	*(0.955,0.996)*	*2323*	*0.991*	*(0.988,0.995)*	*0.67*	*(0.65,0.70)*
A.Uv	*Samsung*	*240*	*0.967*	*(0.944,0.988)*	*1764*	*0.989*	*(0.984,0.993)*	*0.62*	*(0.59,0.64)*
A.VC	*Canon*	*26*	*0.885*	*(0.750,1.000)*	*210*	*0.986*	*(0.970,1.000)*	*0.46*	*(0.40,0.52)*
A.VC	*GE*	*221*	*0.973*	*(0.950,0.992)*	*2319*	*0.987*	*(0.983,0.991)*	*0.54*	*(0.52,0.57)*
A.VC	*Samsung*	*247*	*0.903*	*(0.864,0.939)*	*1757*	*0.989*	*(0.984,0.994)*	*0.49*	*(0.47,0.51)*
B.Ao	*Canon*	*27*	*0.926*	*(0.808,1.000)*	*209*	*0.996*	*(0.985,1.000)*	*0.71*	*(0.66,0.77)*
B.Ao	*GE*	*247*	*0.956*	*(0.926,0.980)*	*2293*	*0.997*	*(0.994,0.999)*	*0.73*	*(0.71,0.75)*
B.Ao	*Samsung*	*255*	*0.977*	*(0.956,0.993)*	*1749*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.58,0.62)*
B.bCr	*Canon*	*25*	*0.92*	*(0.800,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.65*	*(0.58,0.72)*
B.bCr	*GE*	*202*	*0.892*	*(0.849,0.932)*	*2338*	*0.992*	*(0.989,0.996)*	*0.61*	*(0.57,0.64)*
B.bCr	*Samsung*	*216*	*0.926*	*(0.889,0.959)*	*1788*	*0.984*	*(0.979,0.989)*	*0.54*	*(0.52,0.57)*
B.Cr	*Canon*	*7*	*0.715*	*(0.334,1.000)*	*229*	*0.983*	*(0.967,0.996)*	*0.62*	*(nan,nan)*
B.Cr	*GE*	*52*	*0.885*	*(0.789,0.961)*	*2488*	*0.989*	*(0.985,0.993)*	*0.52*	*(0.46,0.58)*
B.Cr	*Samsung*	*76*	*0.974*	*(0.933,1.000)*	*1928*	*0.977*	*(0.971,0.983)*	*0.57*	*(0.52,0.61)*
B.FO	*Canon*	*26*	*0.962*	*(0.880,1.000)*	*210*	*1.0*	*(1.000,1.000)*	*0.7*	*(0.62,0.78)*
B.FO	*GE*	*215*	*0.935*	*(0.899,0.965)*	*2325*	*0.994*	*(0.991,0.997)*	*0.64*	*(0.62,0.67)*
B.FO	*Samsung*	*257*	*0.965*	*(0.941,0.985)*	*1747*	*0.994*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
B.FOF	*Canon*	*8*	*0.75*	*(0.375,1.000)*	*228*	*1.0*	*(1.000,1.000)*	*0.56*	*(0.42,0.67)*
B.FOF	*GE*	*108*	*0.899*	*(0.841,0.949)*	*2432*	*0.998*	*(0.996,1.000)*	*0.5*	*(0.47,0.53)*
B.FOF	*Samsung*	*63*	*0.921*	*(0.845,0.984)*	*1941*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.47,0.55)*
B.IVS	*Canon*	*15*	*0.934*	*(0.770,1.000)*	*221*	*0.982*	*(0.965,0.996)*	*0.65*	*(0.53,0.75)*
B.IVS	*GE*	*165*	*0.867*	*(0.806,0.915)*	*2375*	*0.992*	*(0.988,0.995)*	*0.62*	*(0.59,0.66)*
B.IVS	*Samsung*	*152*	*0.922*	*(0.872,0.962)*	*1852*	*0.984*	*(0.978,0.989)*	*0.64*	*(0.61,0.67)*
B.LA	*Canon*	*30*	*0.934*	*(0.834,1.000)*	*206*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.71,0.79)*
B.LA	*GE*	*264*	*0.966*	*(0.942,0.986)*	*2276*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.78,0.81)*
B.LA	*Samsung*	*274*	*0.997*	*(0.989,1.000)*	*1730*	*0.999*	*(0.996,1.000)*	*0.71*	*(0.70,0.73)*
B.lPV	*Canon*	*14*	*1.0*	*(1.000,1.000)*	*222*	*0.982*	*(0.965,0.996)*	*0.47*	*(0.34,0.60)*
B.lPV	*GE*	*109*	*0.881*	*(0.816,0.937)*	*2431*	*0.981*	*(0.976,0.986)*	*0.51*	*(0.47,0.55)*
B.lPV	*Samsung*	*85*	*0.965*	*(0.924,1.000)*	*1919*	*0.97*	*(0.963,0.977)*	*0.55*	*(0.51,0.59)*
B.lRb	*Canon*	*21*	*0.953*	*(0.850,1.000)*	*215*	*0.996*	*(0.986,1.000)*	*0.67*	*(0.58,0.77)*
B.lRb	*GE*	*220*	*0.9*	*(0.861,0.940)*	*2320*	*0.993*	*(0.989,0.996)*	*0.67*	*(0.64,0.70)*
B.lRb	*Samsung*	*219*	*0.978*	*(0.957,0.996)*	*1785*	*0.988*	*(0.983,0.993)*	*0.66*	*(0.63,0.68)*

B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)
B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)

C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)
D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)

E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)
F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)

F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)
G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Samsung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Samsung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)
G.pCH	Samsung	182	0.94	(0.905,0.973)	1822	0.999	(0.998,1.000)	0.74	(0.72,0.77)
G.pTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.58	(0.51,0.65)
G.pTh	GE	216	0.922	(0.884,0.954)	2324	0.995	(0.992,0.998)	0.62	(0.60,0.64)
G.pTh	Samsung	119	0.95	(0.905,0.984)	1885	0.998	(0.996,1.000)	0.59	(0.57,0.62)
G.Ver	Canon	23	0.914	(0.783,1.000)	213	1.0	(1.000,1.000)	0.62	(0.54,0.70)
G.Ver	GE	288	0.893	(0.859,0.928)	2252	0.996	(0.993,0.999)	0.61	(0.59,0.63)
G.Ver	Samsung	138	0.892	(0.840,0.942)	1866	0.997	(0.994,0.999)	0.52	(0.49,0.55)

I.bCC	*Canon*	*15*	*1.0*	*(1.000,1.000)*	*221*	*0.987*	*(0.971,1.000)*	*0.59*	*(0.51,0.67)*
I.bCC	*GE*	*168*	*0.923*	*(0.878,0.962)*	*2372*	*0.995*	*(0.993,0.998)*	*0.57*	*(0.54,0.60)*
I.bCC	*Samsung*	*54*	*0.815*	*(0.699,0.910)*	*1950*	*0.996*	*(0.994,0.999)*	*0.57*	*(0.52,0.62)*
I.CSP	*Canon*	*20*	*0.95*	*(0.824,1.000)*	*216*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.69,0.81)*
I.CSP	*GE*	*196*	*0.888*	*(0.841,0.928)*	*2344*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.69,0.74)*
I.CSP	*Samsung*	*79*	*0.849*	*(0.760,0.924)*	*1925*	*1.0*	*(1.000,1.000)*	*0.7*	*(0.66,0.75)*
I.Fas	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.63*	*(0.46,0.79)*
I.Fas	*GE*	*99*	*0.889*	*(0.819,0.951)*	*2441*	*1.0*	*(0.999,1.000)*	*0.56*	*(0.52,0.60)*
I.Fas	*Samsung*	*33*	*0.97*	*(0.900,1.000)*	*1971*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.49,0.61)*
I.lVer	*Canon*	*14*	*0.929*	*(0.750,1.000)*	*222*	*1.0*	*(1.000,1.000)*	*0.69*	*(0.60,0.77)*
I.lVer	*GE*	*102*	*0.912*	*(0.850,0.960)*	*2438*	*0.999*	*(0.998,1.000)*	*0.7*	*(0.66,0.73)*
I.lVer	*Samsung*	*41*	*0.927*	*(0.834,1.000)*	*1963*	*1.0*	*(0.999,1.000)*	*0.64*	*(0.59,0.69)*
I.NB	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.71*	*(0.61,0.82)*
I.NB	*GE*	*115*	*0.905*	*(0.844,0.955)*	*2425*	*0.992*	*(0.989,0.996)*	*0.63*	*(0.59,0.67)*
I.NB	*Samsung*	*60*	*0.917*	*(0.837,0.982)*	*1944*	*0.998*	*(0.996,1.000)*	*0.64*	*(0.58,0.69)*
I.rgCC	*Canon*	*18*	*0.945*	*(0.824,1.000)*	*218*	*0.991*	*(0.978,1.000)*	*0.48*	*(0.41,0.56)*
I.rgCC	*GE*	*177*	*0.888*	*(0.833,0.930)*	*2363*	*0.998*	*(0.996,1.000)*	*0.56*	*(0.54,0.59)*
I.rgCC	*Samsung*	*65*	*0.893*	*(0.808,0.965)*	*1939*	*1.0*	*(0.999,1.000)*	*0.48*	*(0.43,0.53)*
I.sCC	*Canon*	*13*	*0.847*	*(0.616,1.000)*	*223*	*0.992*	*(0.978,1.000)*	*0.48*	*(0.36,0.61)*
I.sCC	*GE*	*114*	*0.922*	*(0.868,0.964)*	*2426*	*0.992*	*(0.988,0.995)*	*0.51*	*(0.48,0.54)*
I.sCC	*Samsung*	*40*	*0.9*	*(0.796,1.000)*	*1964*	*0.998*	*(0.996,1.000)*	*0.45*	*(0.39,0.53)*
I.uVer	*Canon*	*14*	*1.0*	*(1.000,1.000)*	*222*	*0.991*	*(0.978,1.000)*	*0.57*	*(0.49,0.65)*
I.uVer	*GE*	*116*	*0.88*	*(0.815,0.931)*	*2424*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.63)*
I.uVer	*Samsung*	*48*	*0.938*	*(0.861,1.000)*	*1956*	*0.999*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	LOA	LOA CI
cardiac_angle	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
cardiac_angle	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
cardiac_angle	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
cardiothoracic_position	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
cardiothoracic_position	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
cardiothoracic_position	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*
cardiothoracic_ratio	Canon	*23*	*1.0*	*(1.000,1.000)*	*37*	*0.946*	*(0.865,1.000)*	*0.078*	*(0.041,0.117)*
cardiothoracic_ratio	GE	*225*	*0.969*	*(0.944,0.991)*	*262*	*0.908*	*(0.874,0.943)*	*0.059*	*(0.049,0.073)*
cardiothoracic_ratio	Samsung	*105*	*0.952*	*(0.909,0.989)*	*232*	*0.776*	*(0.724,0.828)*	*0.051*	*(0.042,0.061)*
cephalic_index	Canon	*28*	*0.929*	*(0.821,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.026*	*(0.021,0.032)*
cephalic_index	GE	*195*	*0.944*	*(0.909,0.974)*	*262*	*0.943*	*(0.916,0.969)*	*0.03*	*(0.026,0.036)*

cephalic_index	Samsung	90	0.989	(0.964,1.000)	232	0.909	(0.871,0.944)	0.023	(0.020,0.026)
right-left_ventricular_ratio	Canon	28	1.0	(1.000,1.000)	37	0.865	(0.757,0.973)	0.106	(0.080,0.128)
right-left_ventricular_ratio	GE	235	0.923	(0.883,0.957)	262	0.901	(0.859,0.939)	0.127	(0.090,0.173)
right-left_ventricular_ratio	Samsung	93	0.978	(0.943,1.000)	232	0.931	(0.901,0.961)	0.099	(0.087,0.115)
thymic-thoracic_ratio	Canon	19	1.0	(1.000,1.000)	37	1.0	(1.000,1.000)	0.047	(0.039,0.059)
thymic-thoracic_ratio	GE	174	0.902	(0.856,0.944)	262	0.924	(0.889,0.954)	0.051	(0.045,0.059)
thymic-thoracic_ratio	Samsung	138	0.942	(0.900,0.978)	232	0.892	(0.853,0.931)	0.059	(0.049,0.070)
vessels_number	Canon	21	0.905	(0.760,1.000)	37	1.0	(1.000,1.000)	0.0	(0.000,0.000)
vessels_number	GE	209	0.933	(0.895,0.966)	262	0.969	(0.947,0.989)	0.281	(0.138,0.406)
vessels_number	Samsung	113	0.929	(0.879,0.974)	232	0.966	(0.940,0.987)	0.329	(0.000,0.491)
vessels_ratio	Canon	28	1.0	(1.000,1.000)	37	0.892	(0.784,0.973)	0.112	(0.091,0.145)
vessels_ratio	GE	194	0.979	(0.956,0.995)	262	0.977	(0.954,0.992)	0.109	(0.099,0.121)
vessels_ratio	Samsung	122	0.984	(0.958,1.000)	232	0.922	(0.888,0.953)	0.111	(0.100,0.125)
CSP ratio	Canon	25	1.0	(1.000,1.000)	37	1.0	(1.000,1.000)	0.842	(0.608,1.028)
CSP ratio	GE	226	0.854	(0.805,0.899)	262	0.977	(0.954,0.992)	0.826	(0.753,0.889)
CSP ratio	Samsung	107	0.879	(0.821,0.935)	232	0.991	(0.978,1.000)	0.835	(0.755,0.907)
VP-ratio	Canon	22	0.909	(0.773,1.000)	37	1.0	(1.000,1.000)	0.064	(0.043,0.084)
VP-ratio	GE	206	0.956	(0.925,0.981)	262	1.0	(1.000,1.000)	0.065	(0.059,0.071)
VP-ratio	Samsung	91	0.956	(0.910,0.990)	232	1.0	(1.000,1.000)	0.066	(0.056,0.075)
Post-Left Atrium Space	Canon	16	0.938	(0.800,1.000)	37	0.919	(0.837,1.000)	0.094	(0.067,0.114)
Post-Left Atrium Space	GE	181	0.978	(0.953,0.995)	262	0.924	(0.889,0.954)	0.086	(0.079,0.091)
Post-Left Atrium Space	Samsung	159	0.981	(0.957,1.000)	232	0.953	(0.922,0.978)	0.07	(0.065,0.078)

For US vs. EU subgroup results

Class	Continent	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI
A	EU	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	US	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	EU	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	US	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	EU	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	US	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	EU	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	US	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	EU	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)

E	US	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	EU	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	US	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	EU	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	US	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	EU	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
I	US	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)
X	EU	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
X	US	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)

Class	Continent	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
A.aA	EU	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	US	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	EU	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	US	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	EU	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	US	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	EU	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	US	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	EU	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*
A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*

B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*
C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	US	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	EU	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	US	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	EU	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	US	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*
D.rPA	EU	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	US	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	EU	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*

D.S	US	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	EU	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	US	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	EU	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	US	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	EU	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	US	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	EU	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	US	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	EU	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	US	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	EU	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	US	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	EU	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	US	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	EU	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	US	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	EU	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	US	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	EU	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	US	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*
E.Tr	EU	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*
E.Tr	US	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	EU	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	US	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	EU	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	US	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	EU	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*
F.aFx	US	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	EU	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	US	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	EU	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	US	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	EU	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	US	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	EU	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	US	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	EU	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*

F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*
G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Class	Conti-nent	n(posi-tive)	Se	Se CI	n(nega-tive)	Sp	Sp CI	LOA	LOA CI
cardiac_angle	EU	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
cardiac_angle	US	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
cardiothoracic_position	EU	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
cardiothoracic_position	US	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
cardiothoracic_ratio	EU	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
cardiothoracic_ratio	US	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
cephalic_index	EU	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
cephalic_index	US	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
right-left_ventricu-lar_ratio	EU	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
right-left_ventricu-lar_ratio	US	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
thymic-thoracic_ratio	EU	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
thymic-thoracic_ratio	US	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)
vessels_number	EU	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
vessels_number	US	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
vessels_ratio	EU	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
vessels_ratio	US	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
CSP ratio	EU	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
CSP ratio	US	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
VP-ratio	EU	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
VP-ratio	US	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
Post-Left Atrium Space	EU	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
Post-Left Atrium Space	US	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Contraindications

There is no contraindication linked to FETOLY device.

10. Warning, precautions, interactions with other equipment

Warnings and precautions from risk management file:

- The user shall zoom in of at least 30% to avoid software false-negative;

- The user shall systematically review the images set selected before export;
- Reset function oversight may lead to patient mix-up and contribute to false negative screening;
- Images deleted within image selection are definitively lost;
- Video stream input configuration may contribute to false negative screening;
- Incompatible video stream can lead to error in examination documentation. The video stream shall have the following characteristics:
    - At least 24 frame per second (fps);
    - A resolution inferior to 1280*720.
- Tablet incompatibility can lead to error in examination documentation;
- Export failure leads to examination report loss;
- Please verify the patient name chosen before DICOM export on the export page to avoid patient file mix-up;
- Use on 1st trimester pregnancy leads to error in completeness function;
- The examination shall be done on one foetus at a time;
- If the tablet starts to overheat, stop the use of the software;
- Please verify the battery level of your tablet before examination. Software shut-down can lead to examination data loss;
- The software cannot be used for screening purpose as it can lead to false negative screening contribution;
- Use the tablet alone and do not allow unauthorized person to access to your tablet to avoid security risks;
- Please be aware that when the data are exported on your device, they are under your responsibility;
- Do not use any other tablet application in parallel to FETOLY to avoid interference on the image stream reception process or machine learning calculation execution;
- Do not use the application while scanning with a transvaginal probe, as the product has not been tested with transvaginal images.

Warnings and precautions from software performance study:

- The software's sensitivity may be lower for the detection of:
    - The following heart quality criteria: Atrioventricular valve offset in crux (Four chamber view)
    - The following brain quality criteria:
        - Proximal Coronal suture (Axial view)
        - Cavum Septum Pellucidum (Axial view)
        - 3rd ventricle (Axial view)

  Users should exercise caution for this view and these quality criteria and verify results.

Interactions with other equipment

FETOLY software is designed to run on a wide range of tablets without relying on external cloud computation. FETOLY is configured to receive an ultrasound video stream, which can be achieved by an ultrasound system equipped with an HDMI output to the hardware running the software.

The software is compatible with ultrasound machines from General Electric, Samsung and Canon.

The software requires the following minimal tablet configuration:

- CPU architecture ARMv8
- A Snapdragon 8 processor, or

- A M1 processor or higher, or
- A A14 processor of higher, and
- At least 8GB of RAM capacity
- At least 1GB of storage capacity
- Android in version 13/ iOS in version 17 or higher

The following tablet models are advised:

- Samsung Galaxy Tab S8 or higher
- Ipad Air 5 or higher
- Ipad 10 or higher
- Ipad mini 7 or higher
- Ipad Pro 3 or higher

Feel free to contact Diagnoly support at support@diagnoly.com if you have any doubt on tablet model choice.

Images labeled by FETOLY can be saved directly on the tablet or sent to another device on the same network as the device running FETOLY. To utilize this option, the software requires an FTP server on the target device, a DICOM Store server or a Bluetooth connection.

11. Undesirable effects

There is no undesirable effect linked to the FETOLY device.

12. Cybersecurity instructions

12.1. High-level Critical Functionality Protection Description

This section provides a high-level description of the device features that protect critical functionality. The image stream reception and image analysis features rely on local resources (physical cable, edge AI model) and do not require the internet to function. The software does not store or manage any patient data but allows the user to export, after an examination, an examination report to a third-party device. A fallback export mode is available if the local network is compromised to allow users to save reports on the tablet's filesystem.

12.2. Inherent cybersecurity risks of the device

Inherent cybersecurity risks of FETOLY include:

- Patient data theft
- Less performant patient care due to corrupted AI operation, such as tampered model weights or software/operating system modifications
- Misuse of the device, leading to different results than intended by the manufacturer or expected by the user
- Loss of time for the user.

These risks are controlled by the risk analysis.

11.3. Diagram of recommended cybersecurity controls



The diagram describes the environment of the FETOLY software running on the user's tablet and the input/output communications with the ultrasound system and third-party device.

It includes the references to recommended cybersecurity controls for the intended use environment described in **section 12.4**:

- G1: Secure operation with third-party systems via FTP over SSL/TLS
- G2: Secure operation with third-party systems via Bluetooth (Android only)
- G3: Secure device access control
- G4: Secure operation with third-party systems via DICOM over SSL/TLS

12.4. Device instructions and product specifications related to recommended cybersecurity controls appropriate for the intended use environment

Guidelines for secure operation with third-party systems via FTP over SSL/TLS (G1):

- Minimum networking requirements: the network infrastructure must support FTP over SSL/TLS (FTPS) and the FTP server must be compatible with FTPS. Implement network segmentation and firewall rules to restrict access to necessary services and IP addresses.
- Installing an FTP over SSL/TLS server, such as:
    a. Windows 10/11 using IIS: Refer to Microsoft's documentation for setting up FTP over TLS/SSL with IIS.
    b. FileZilla Server (cross-platform): Configure FTPES 'Require explicit FTP over TLS', create a user with a strong password*, define a data storage path (e.g., 'C:\FetolyData` or `/home/shared/FetolyData'), and configure firewall rules for the specific program or port used by the FTP server.

Guidelines for secure operation with third-party systems via Bluetooth (G2, Android only):

- Minimum networking requirements: Bluetooth version 5 or higher.
- Define a strong password within the software to protect the exported patient data*.

Guidelines on secure device access control (G3):

- Set up a lock screen with a strong password*, PIN, or biometric authentication.
- Enable automatic updates for the operating system and all installed applications.
- Disable any unused network interfaces (e.g., NFC, IR).

Guidelines for secure operation with third-party systems via DICOM (G4):

- Ensure that communication occurs over a secured and segmented network, restricting access through robust firewall configurations and access control mechanisms.

*Use strong passwords on your tablet and for any device (i.e. third-party device for FTP export) or configuration linked to FETOLY (i.e. Bluetooth configuration) per America's cyber defense agency recommendations:

- Long—at least 16 characters long (even longer is better).
- Random—like a string of mixed-case letters, numbers and symbols (the strongest!) or a passphrase of 5 –7 random words.
- Unique—used for one and only one account.

If a cybersecurity vulnerability or incident is detected, immediately report to your IT security team and Diagnoly (support@diagnoly.com). On the tablet:

- Reset: Restore factory settings to erase all data and configurations.
- Reinstall application: Download the latest, secure application version from the Google Play Store.
- Fallback option: Use local export to an SD card if network-based exports are compromised.

12.5. A list of network ports and other interfaces

The FETOLY software receives input stream data via a cable connected between the ultrasound system's external monitor output to the tablet's USB-C input. The software can be configured to export examination reports to a third-party device via TCP/IP FTPS or Bluetooth.

For the data export via network TCP IP/FTPS:

- Protocol: FTPS
- Incoming ports: The software does not open any incoming ports itself as it functions solely as a client, not a server.
- Outgoing ports: The software uses a dynamically assigned ephemeral port (range: 1024-65535) to establish connection to the FTPS server at a specified IP address. The incoming port of the third-party FTPS server is user-defined.
- Firewall rules: Firewalls on both client and server sides must allow outgoing connections from the client to the server's port.

For the data export via Bluetooth/OBEX (Android only):

- Encryption: the data is zipped and password-encrypted.

For the data export via DICOM:

- Protocol: DICOM

- Incoming ports: The software does not open any incoming ports itself as it functions solely as a client, not a server.
- Outgoing ports: The software uses a dynamically assigned ephemeral port (Android: 32768 to 60999) to establish connection to the DICOM server at a specified IP address. The incoming port of the third-party DICOM server is user-defined.
- Firewall rules: Firewalls on both client and server sides must allow outgoing connections from the client to the server's port.

12.6. Supporting infrastructure requirements

Refer to section 10 for supporting infrastructure requirements, including minimal tablet configuration, compatible ultrasound systems.

12.7. SBOM

A software Bill of Materials (sBoM) is available for users to manage their assets, understand the potential impact of identified vulnerabilities, and deploy countermeasures to maintain the device's safety and effectiveness. The sBoM is downloadable within the software's 'About' page, in a machine-readable format (.csv), by clicking on 'show' in front of 'Third-Party Notice'.

12.8. Update / Patch Instructions

Refer to section 13 'Software and licence update' for update instructions.

12.9. Description of how the device responds when anomalous conditions are detected

This section describes how the software responds to security events. All crashes of the software are exported through a crash log to Firebase. The following warnings may appear when using FETOLY:

- Export failure: network anomaly leading to failure of report export via TCP/IP FTPS, DICOM or Bluetooth.
- USB connection failure: no USB-C cable connected to the tablet or failure of USB-C video stream receipt.
- License validation failure: user attempts license validation without an internet connection, automatic time activation, or a valid license.
- Tablet overheating.
- Tablet compatibility issue: video stream frame rate below 24 fps.
- Tablet low battery.

12.10. Backup and Restore

To restore the device features and default configuration, uninstall and re-install the device through Google Play/App Store.

12.11. Description of methods for retention and recovery of device configuration by an authenticated authorized user

Export settings, such as third-party credentials, and video capture settings, such as input video ratio, are retained in the tablet's data storage cache, securely isolated by Android/iOS. Given that the aforementioned configurations are quick to set up, no specific recovery methodology

is implemented. Users are prompted to re-enter settings manually during re-installation or new device installation.

12.12. Secure Configuration

This section provides instructions to ensure the FETOLY software is securely configured and maintained.

Initial setup: Download and install the latest version from the Google Play/App Store. Verify the app name and icon matches the one provided in section 13. Perform all export setup steps over a secure network connection as per guidelines G1/2/4 in section 12.4. Ensure device running FETOLY is secure as per guideline G3 in section 12.4.

Incident response: Enable internet connection to log crashes and anomalous activities, as described in section 12.13. Report any detected vulnerability as per guidelines in section 12.4.

12.13. Forensic Evidence Collection, where appropriate for the intended use environment

A crash report system is integrated into the software. Crash reports are sent in case of application crash or anomalous event if an internet connection is enabled.

12.14. End-of-life and end-of-support Information for system or components, if known or anticipated

End-of-life and end-of-support rely on the license validity. The licence will be renewed automatically with an internet connection as soon as the licence contract is still valid. If the contract is expired or the end-of-life is reached, you will be asked to enter a new registration code.

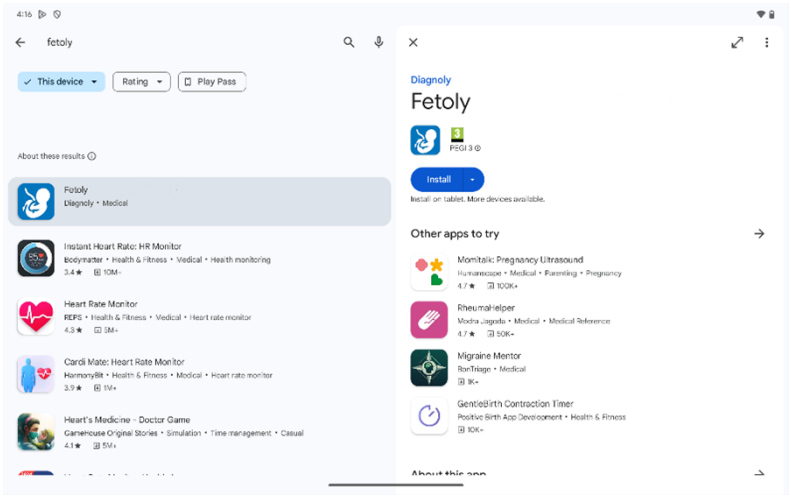
12.15. Secure Decommissioning

To decommission and dispose of the software, uninstall the application through the Android/iOS system as any application on your tablet, in the app's parameters, as illustrated in section 13 in the ‘software uninstallation’ paragraph. This uninstallation will remove any data linked to the use of FETOLY, including license, from your tablet.

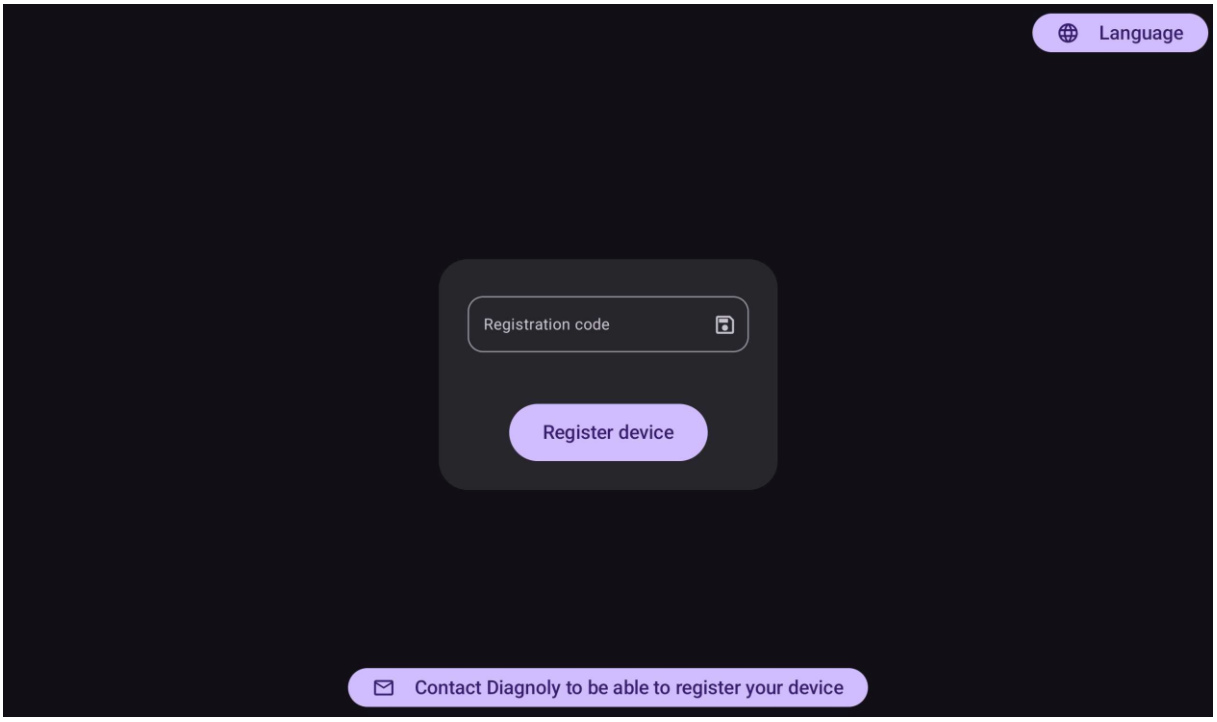
13. Direction for use

Software installation and launch

1. Go to Google Play or App Store, write FETOLY in the search bar and launch the automatic download and installation



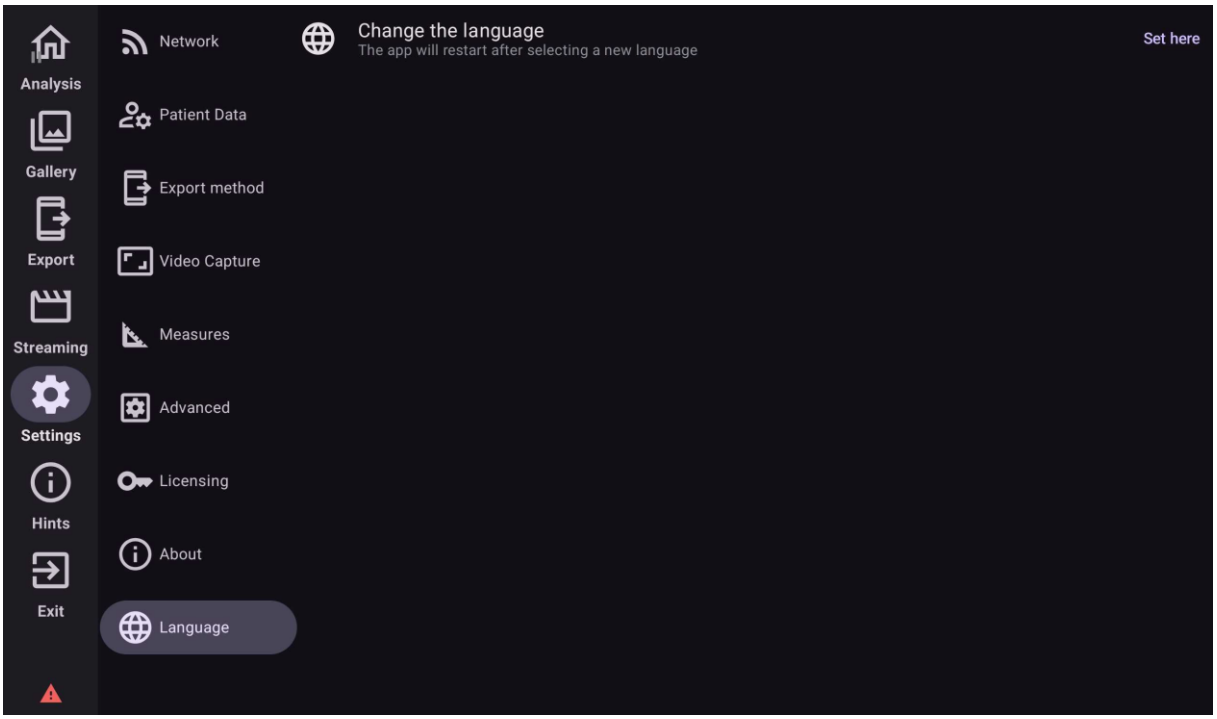
2. Click on the icon of FETOLY on your tablet
3. **Licence validation**: If needed, enter the licence registration code as showed below. Diagnoly is responsible to provide you a licence. You can contact Diagnoly for licence edition by clicking directly on the displayed button on the bottom of the welcoming page. The Licence is linked to your device ID which is available in the licence settings page.

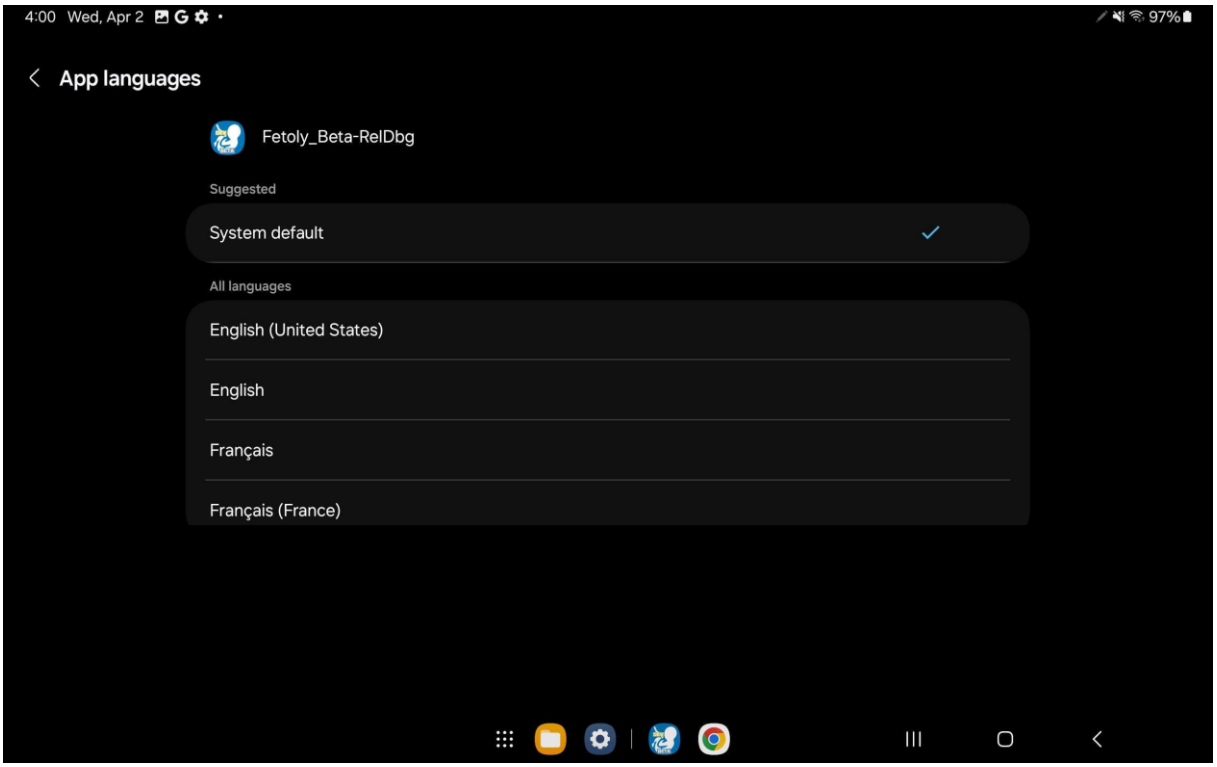


4. **Establish a Wi-Fi connection:** If you want to receive the ultrasound data to your personal computer, please, connect the tablet to your Wi-Fi spot.

Language settings

By default, the software is set up in the same language than your tablet. However, you can choose the language that you need within ‘Settings’ > ‘Language’. This will lead you to the app languages settings on Android. Once the needed language is selected, the application will be translated in this language at re-launch.



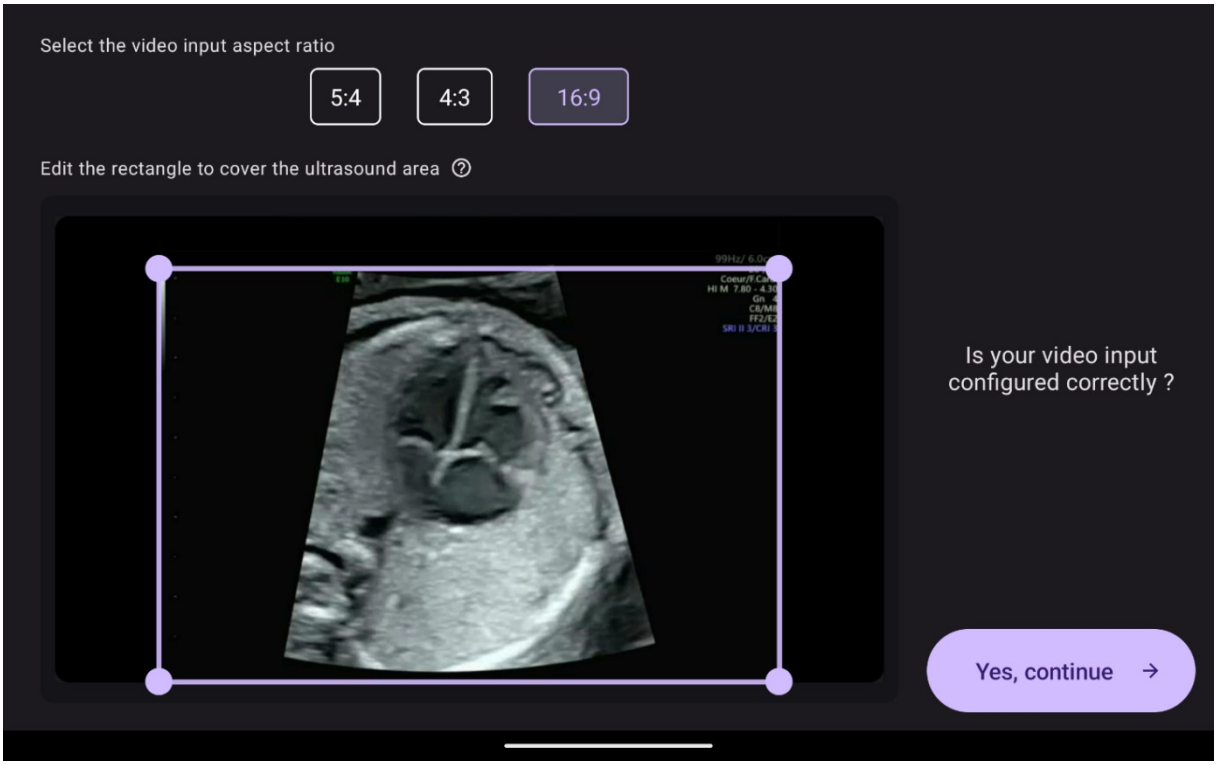


Ultrasound machine connection

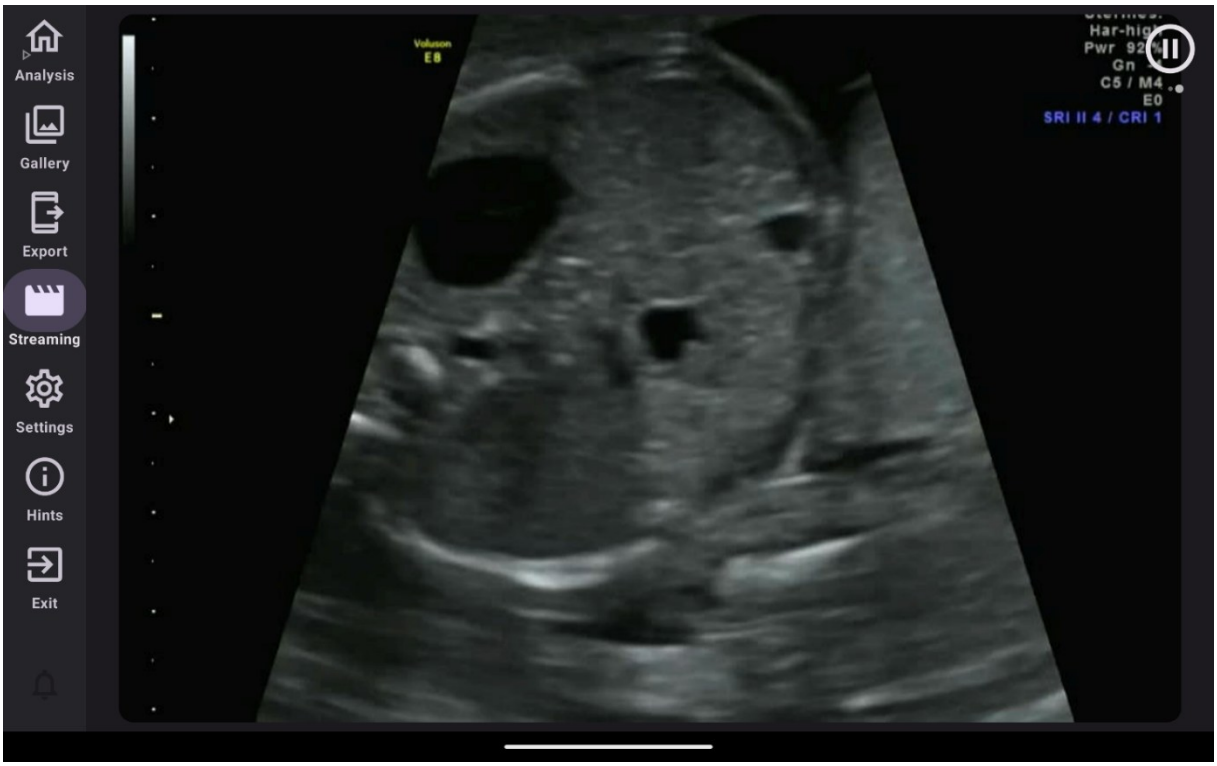
1. **Power on the ultrasound system:** Before connecting your tablet, ensure that the ultrasound system is powered on and in working condition.
2. **Connect your tablet to your ultrasound system:** To connect, simply plug the USB (Type C) end of an UVC dongle into your tablet and the HDMI end into your ultrasound machine.
3. **Verification:** To verify the connection between the ultrasound system and the tablet, open FETOLY software. If a new USB source has been connected, the software shall display the video stream configuration page automatically.

Video stream configuration

1. Begin configuring the video stream in the application:
    a. When the software opens automatically the video configuration page, select the video aspect ratio to be aligned with ultrasound machine output ratio and select the region of ultrasound. In other situations, go to ‘settings’ > ‘video capture’ to configure the video stream, with the same methodology.



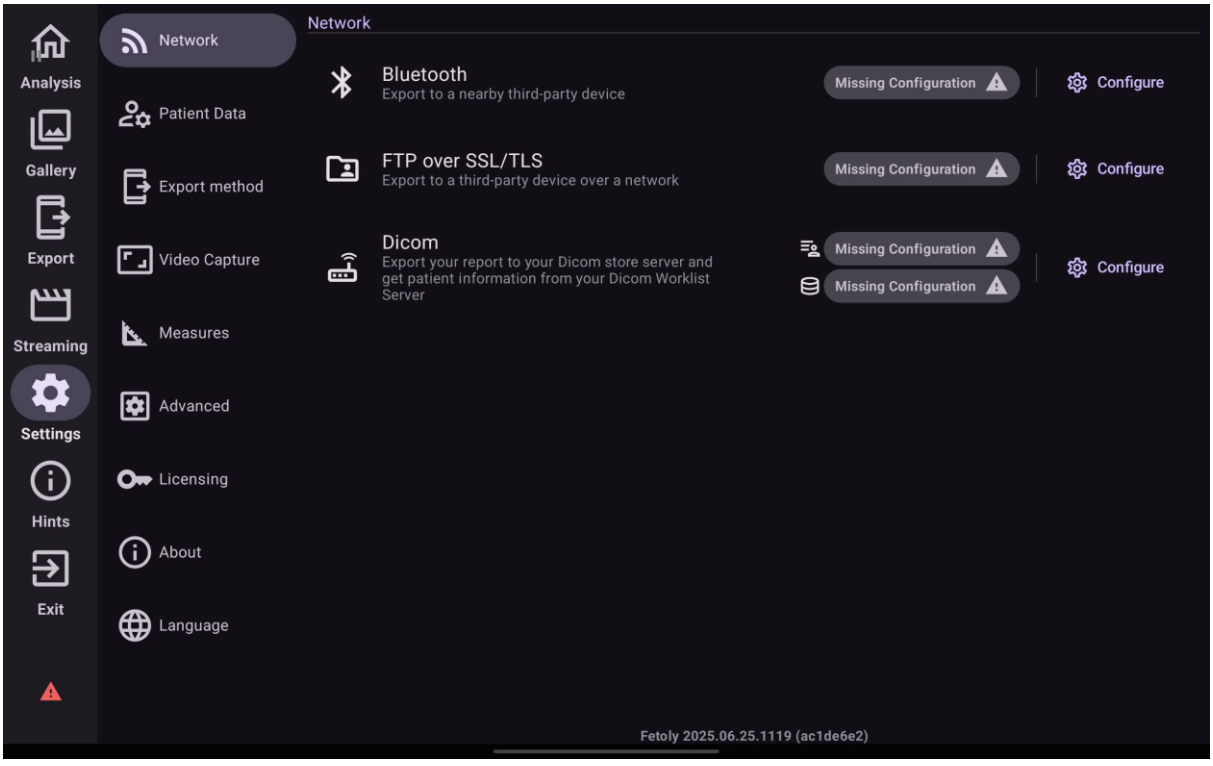
    b. The selected region appears in real-time in the streaming page. The play button can be used on the streaming page to launch the analysis.
    c. Verify that the microphone is not deactivated on your tablet as it will lead to video stream input blocking.



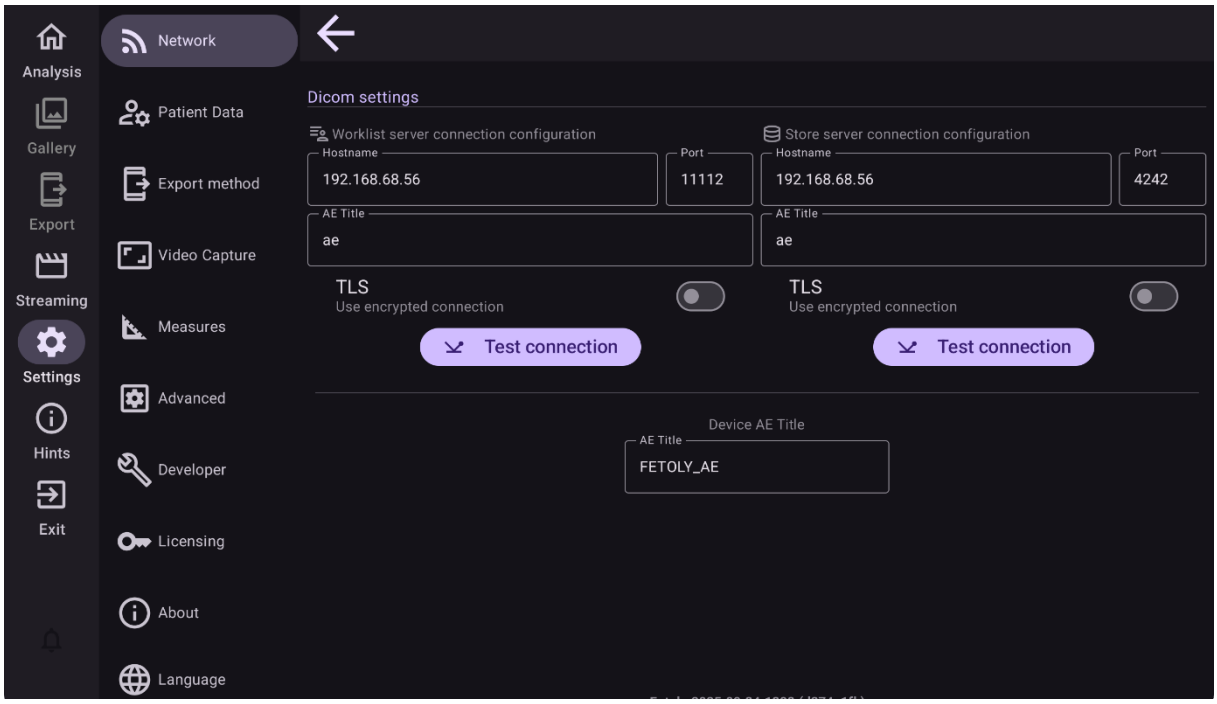
[OPTIONAL] Configuration of the ultrasound machine

Some ultrasound systems enable the configuration of the size of the ultrasound region in the video output. If this is the case, it is advised to select the largest possible region.

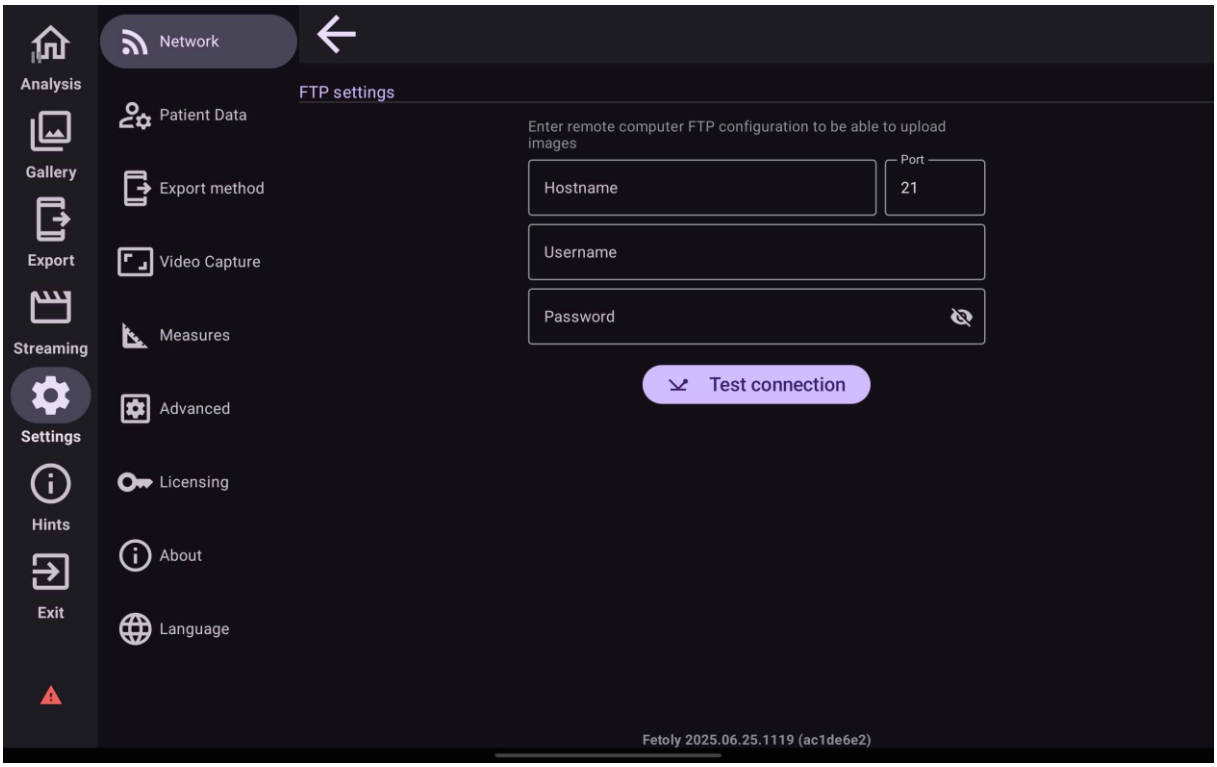
Export configuration



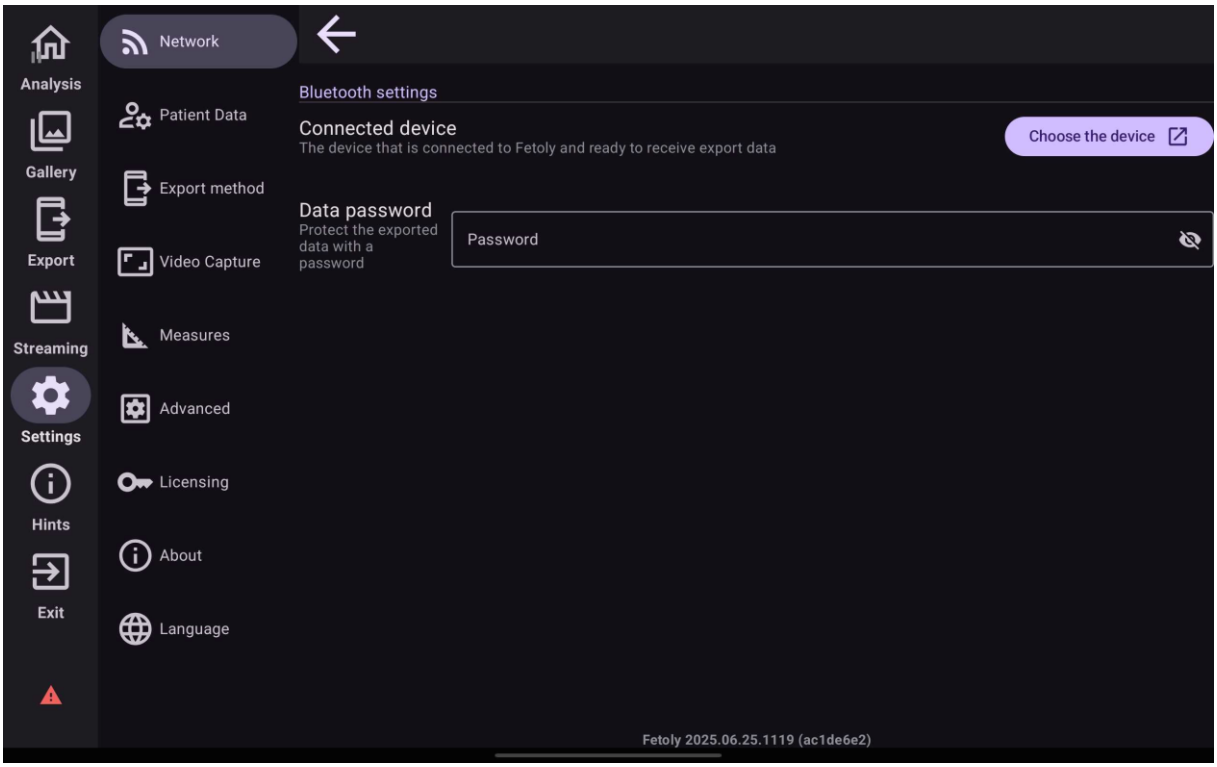
1. Configure the remote DICOM server for exporting images captured by FETOLY. Please note that this step requires the presence of a DICOM server running on a device connected to the same network as the tablet running FETOLY.
    a. Then go to Settings' > 'Network Settings', select configure DICOM and enter the required information for your DICOM store server: worklist hostname (IP address) and AE title, DICOM Store hostname (IP address) and AE title, Device AE title. To verify the connection, click the 'Test connection' button for each DICOM server. This ensures the connection is valid and ready for exporting images. You can also optionally enable the TLS option.

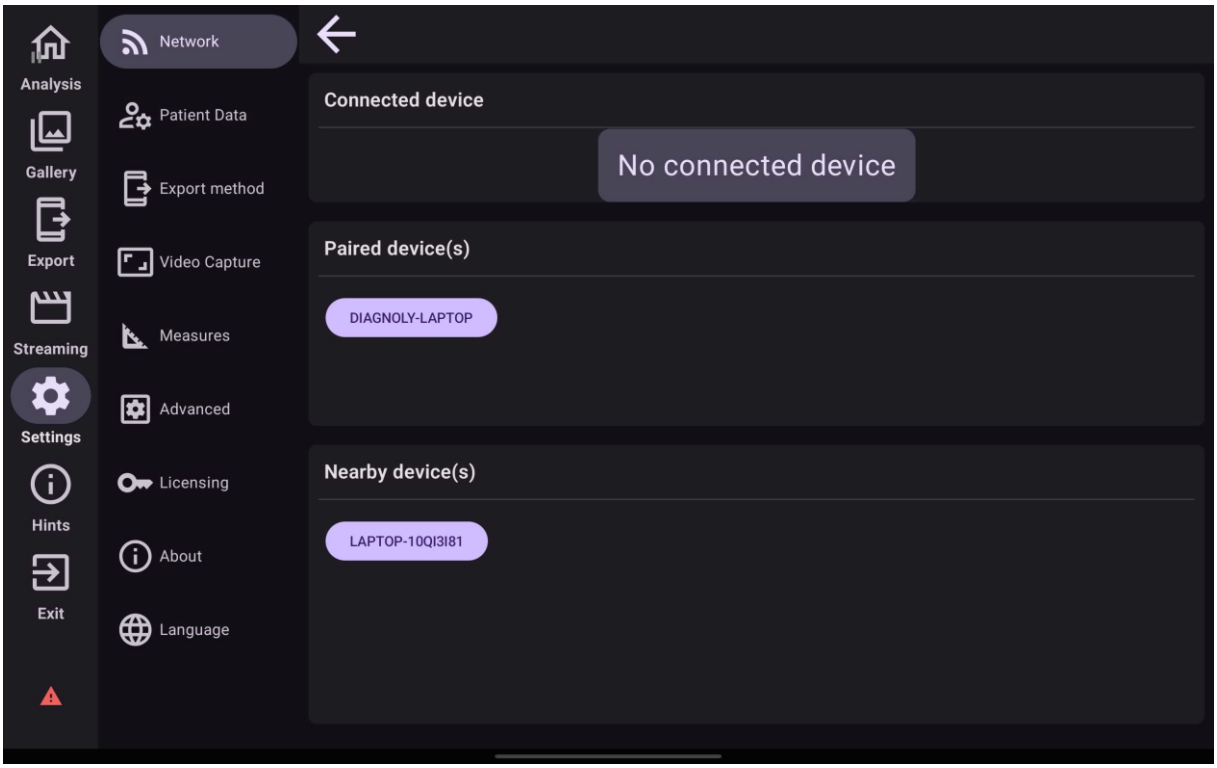


2. Alternatively, configure the remote FTP server for exporting images captured by FETOLY. Please note that this step requires the presence of an FTP server running on a device connected to the same network as the tablet running FETOLY.
    a. Go to 'Settings' > 'Network Settings', select configure FTP and enter the required information for your FTP client: hostname (IP address), username and password. To verify the connection, click the 'Test connection' button. This ensures the connection is valid and ready for exporting images.

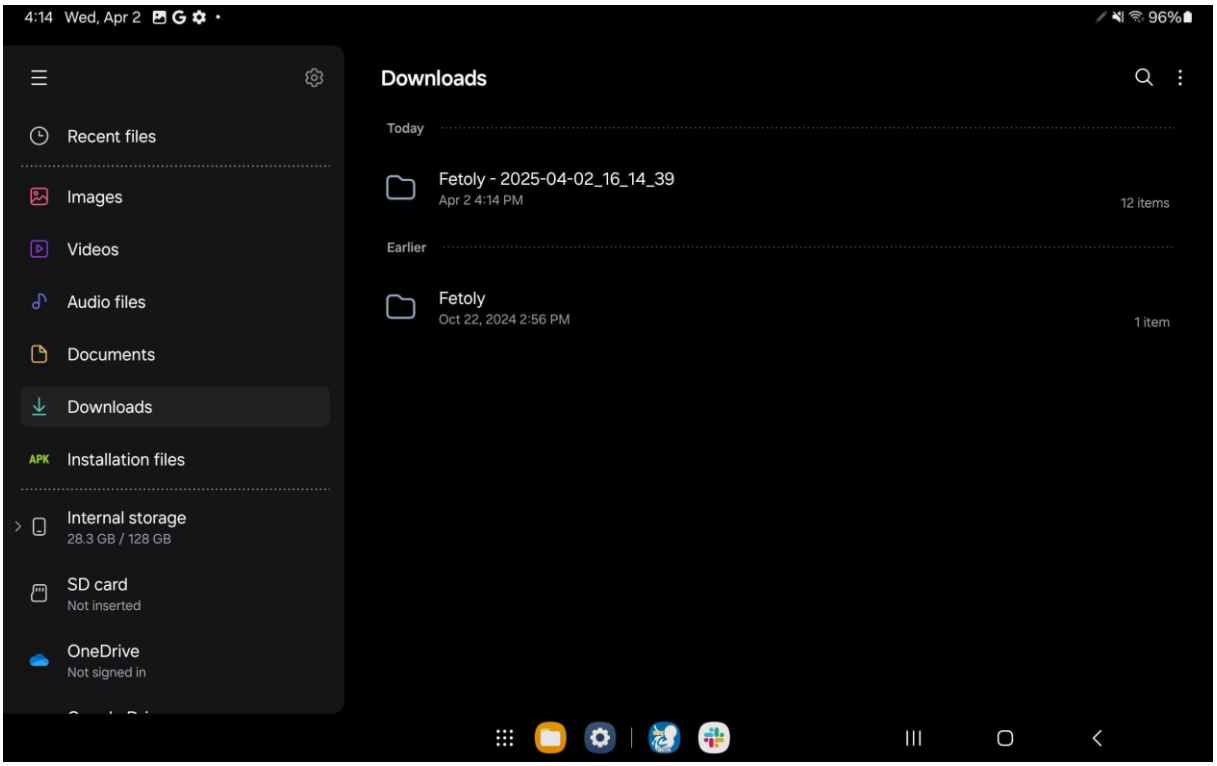


3. Alternatively, you can use Bluetooth connection (Android only):
    a. Settings' > 'Network Settings', select Bluetooth. To choose the device on which you export the data, you need to pair the device by selecting it in the 'nearby device' section. Then, choose the device to connect within the 'paired device' section. Once the device is chosen, you can test the connection within the 'connected device' section. The device selection page is accessible by clicking on the button on the right of 'Bluetooth settings' > 'connected device'.
    b. To export the file, you shall set up additionally a password. This password will be affixed to the .zip file exported on the third-party device

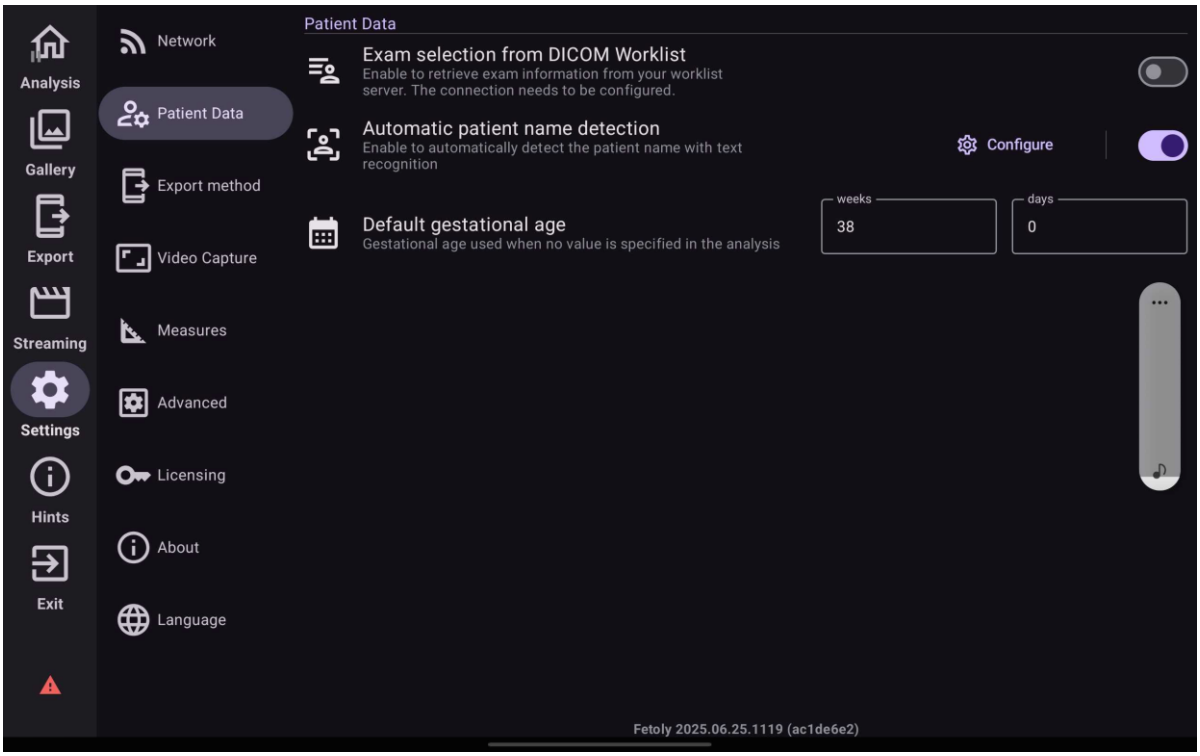


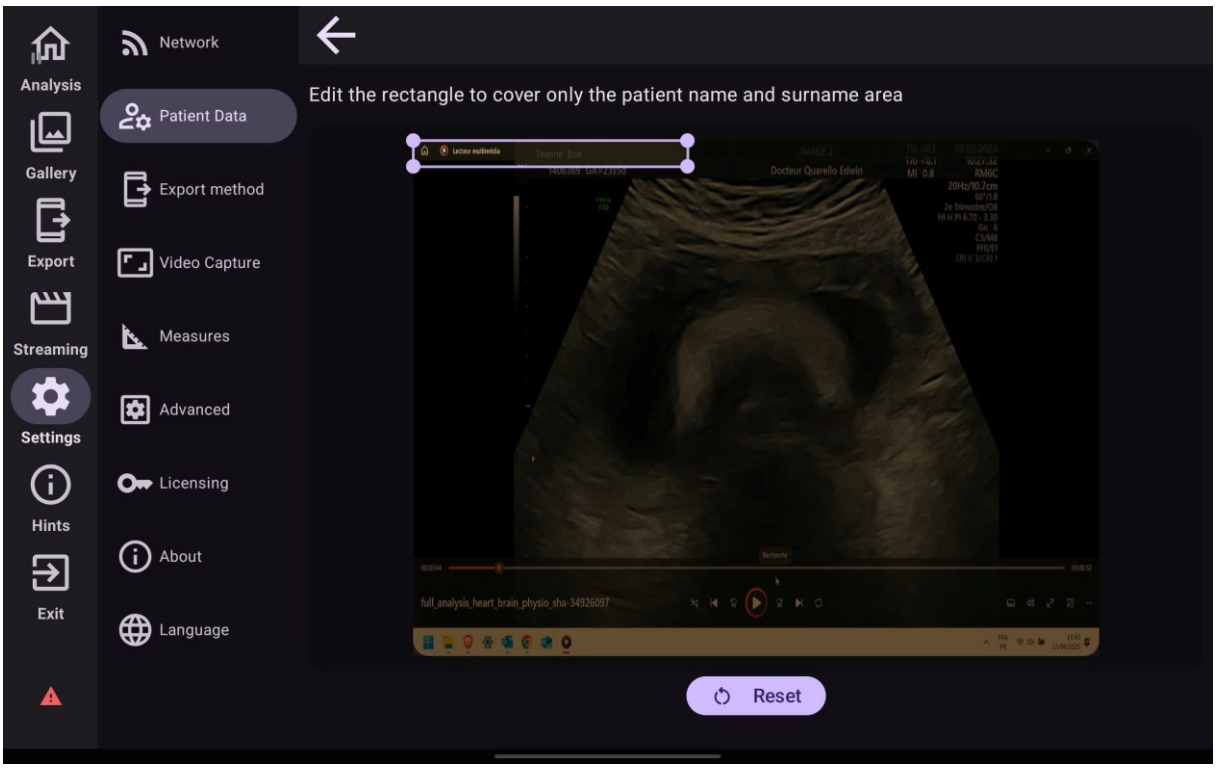


4. If you don’t want to use a wireless connection, you can export the data directly on the tablet:
    a. Go to ‘Settings’ > ‘Export method’, select local. The file will be saved on a location already defined by the tablet.
    b. To reach the defined location, go on your tablet desktop, select the ‘Files’ icon, then go to ‘Downloads’ > ‘Fetoly’.



5. If you want to add the name of the patient in the name of the file exported or if you want to select the patient examination from DICOM worklist:
    a. Fill directly the patient's name with the gestational age on the analysis page, or
    b. Go to 'settings' > 'Patient data' and activate 'exam selection from DICOM worklist'. Notice that this function works only if you are connected to a PACS with DICOM worklist parameters configured. Notice also that in DICOM export mode, you are forced to use this setting.
    c. Optionally, go to 'settings' > 'Patient data' and activate 'automatic patient name detection'. You can then go to 'configure' and select the area on the ultrasound video stream where the patient's name appears. The patient's name will be then filled automatically at examination launch or by clicking on the refresh button on the right of the patient's name on the analysis page.

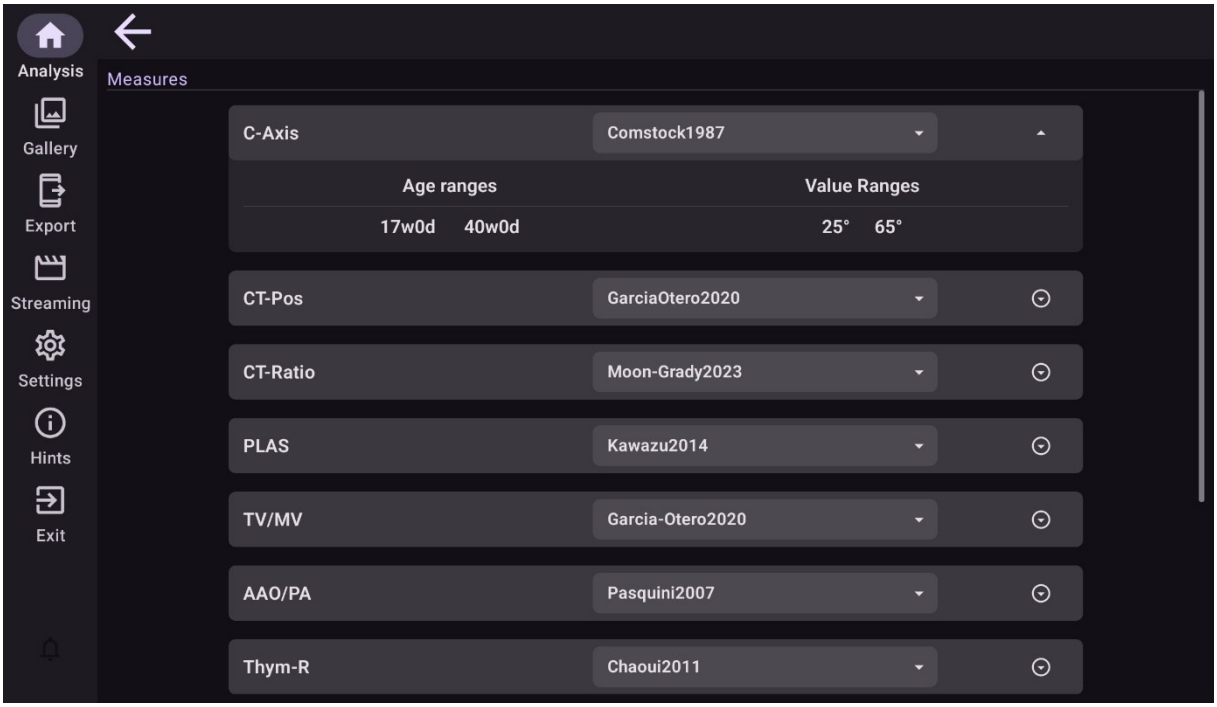




Use

1. Follow these steps to realize examination completeness and measurements:
    a. Enter the gestational age on the analysis page with the patient's name or select the patient examination from the DICOM worklist.
    b. You can configure the default gestational age by going to 'Settings' > 'Patient data'.

c. For the measurement function, if multiple literature sources are available, chose the one that you prefer. You can also set up manually reference ranges by selecting custom. This is done by clicking on the new tab button on the right of the measurement on the analysis page or by going to ‘Settings’ > ‘Measures Settings’. That will redirect you on the measurement settings page.



d. Press Play on the analysis page

e. Do the examination as usual

f. The examination is considered as complete when all the views and criteria are verified and when all the measurements are done

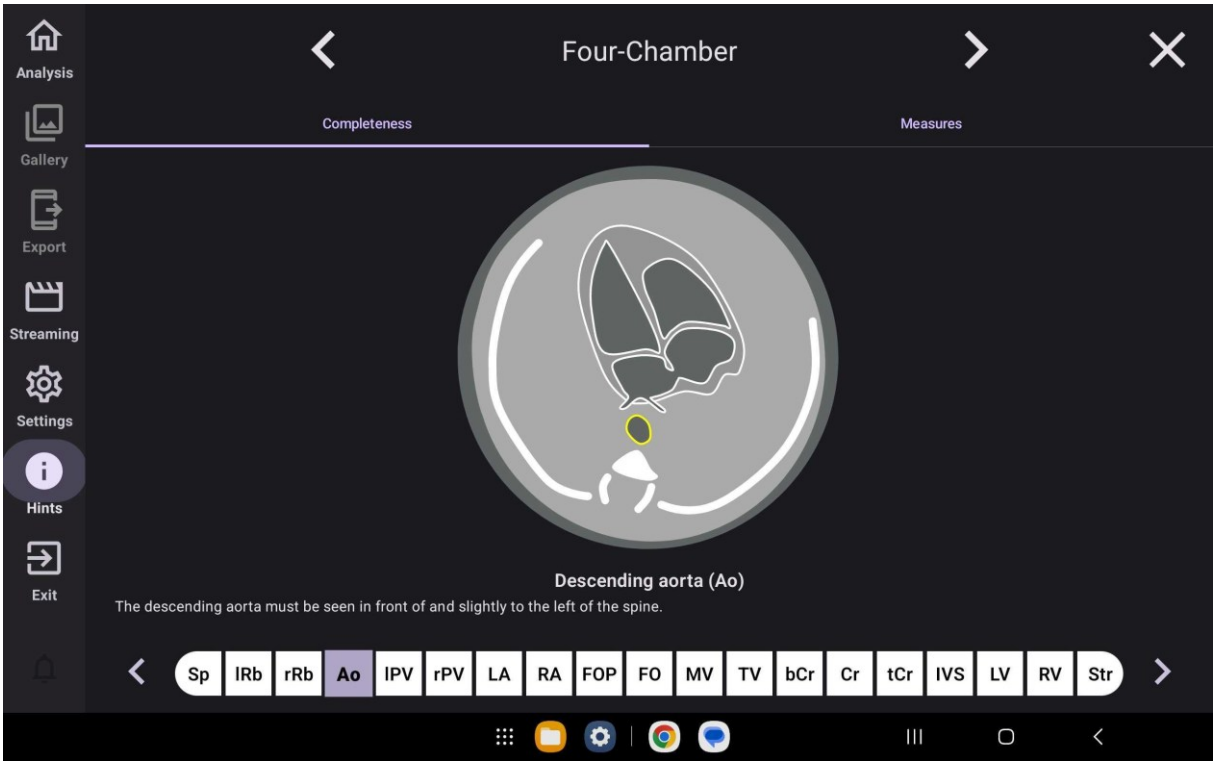
g. The measurements are displayed as “out-of-range” if they are out of the reference range defined

h. When the examination is complete, the analysis page indicates it and allows you to go directly to the gallery page to check images suggested

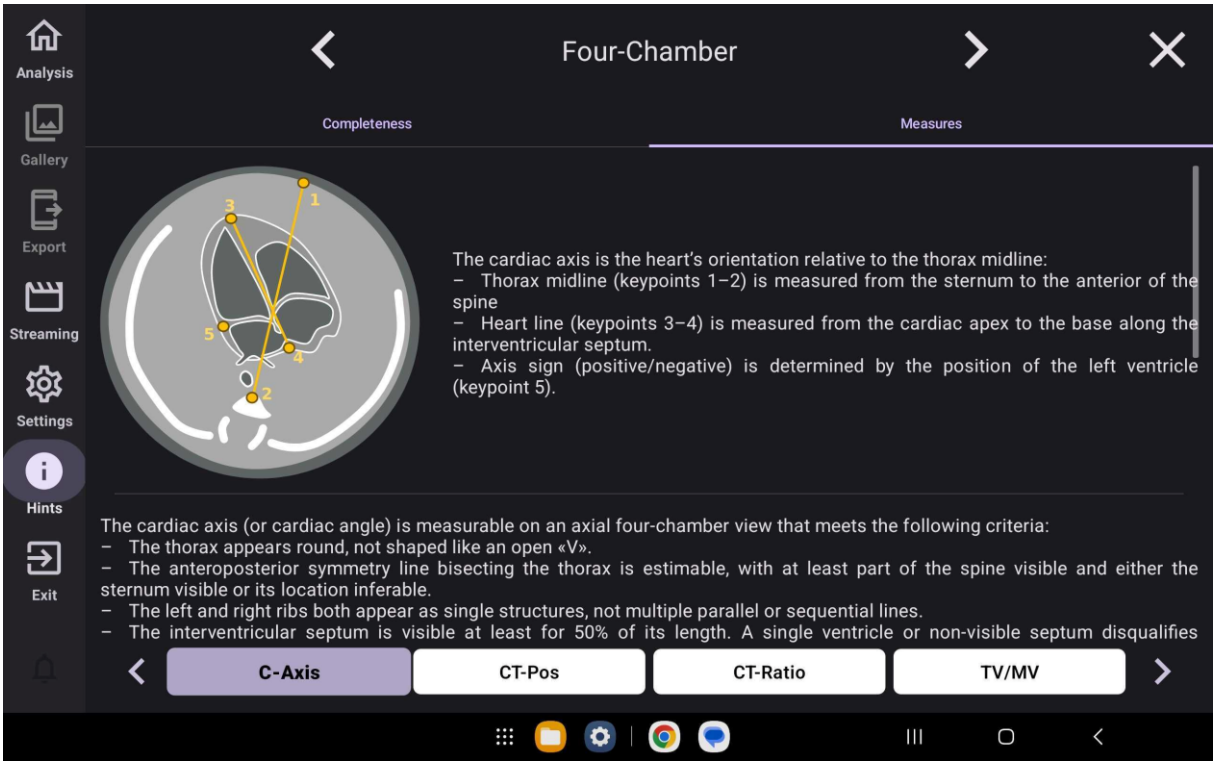


2. Please find hereafter a list of tips to be sure to realize easily the examination completeness and measures:

    a. Quality criteria and views detected by the software are based on the ISUOG guideline for fetal cardiac and cerebral screening. Please read this guidance if needed as a reminder for fetal cardiac/cerebral screening good practices. You can also go to the Hints page to have an explanation of all quality criteria



b. Biometric measurements done by the software are based on international guideline and well-known literature for fetal cardiac and cerebral screening. Please read the literature articles referred by the software if needed as a reminder for fetal cardiac/cerebral screening good practices. You can also go to the Hints page to have an explanation of all measurements done.



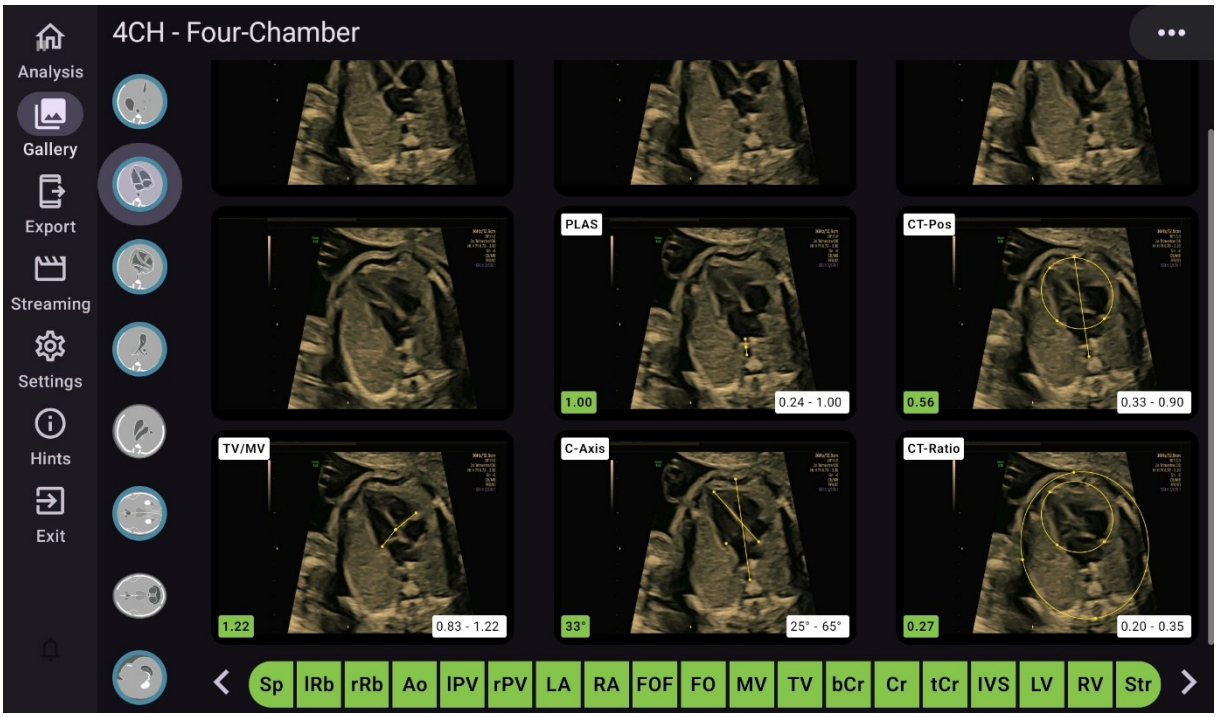
c. Be sure that all the configuration steps explained above are correctly done to avoid detection issues.

d. Be sure that you use compatible equipment per section 10 of this IFU.

e. There is a warning on the export page if quality criteria/measures are not contained in the image set selected.

f. Once all criteria are verified and all the measurements done on the analysis page, verify if all the corresponding criteria and measures are well identifiable on the images set selected in the Gallery page.

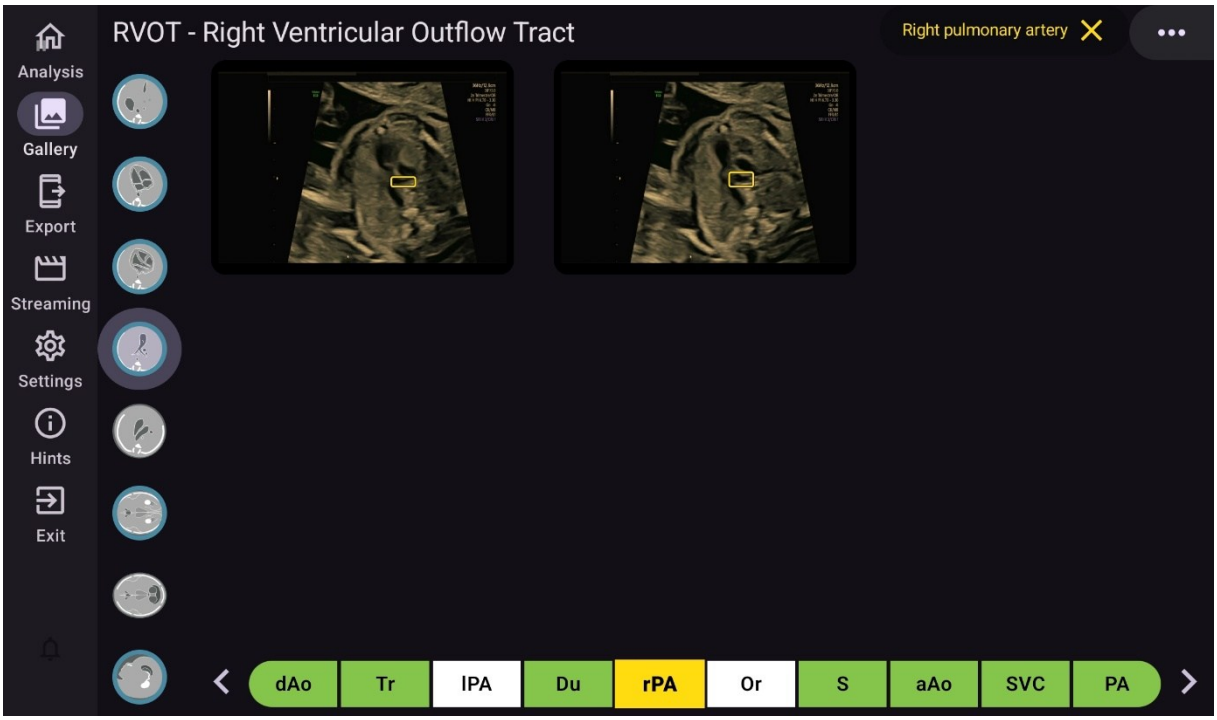
3. Once your video stream is over, go to the 'Gallery' section to explore the selected images. To facilitate navigation within the image set, the images are categorized by plane.



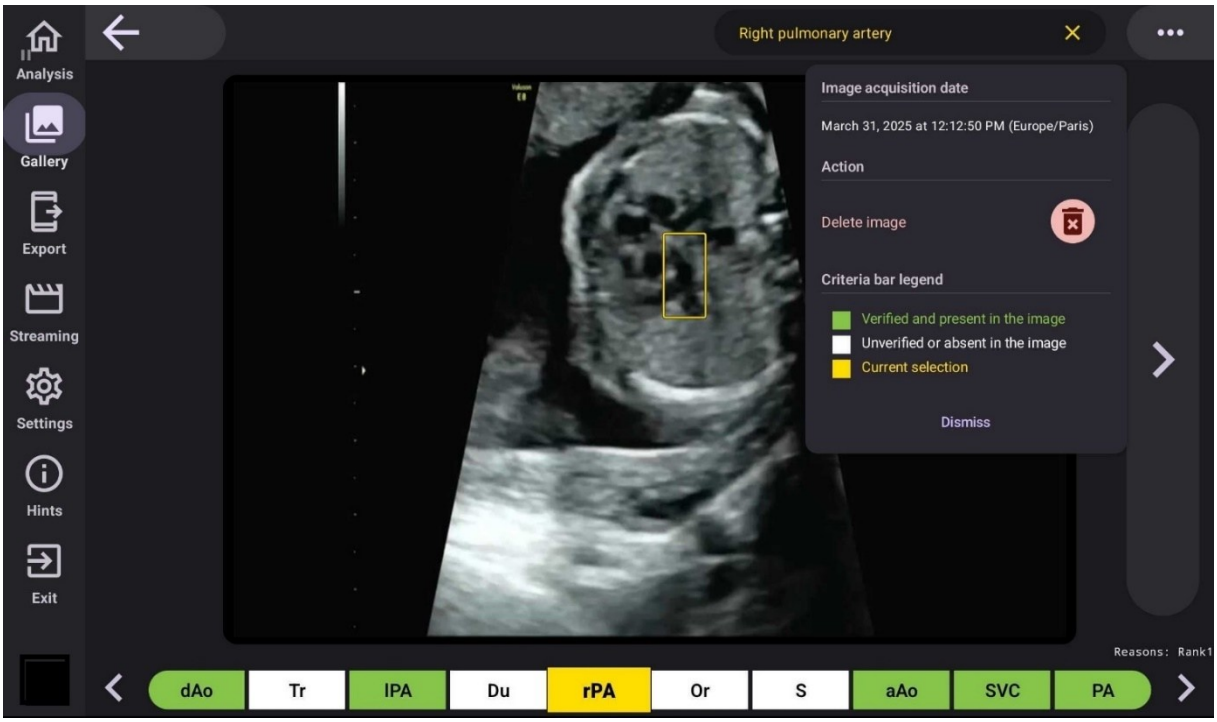
a. Click on a specific plane (left panel) to view selected images related to this plane. Criteria in green are verified and criteria in white are not verified.

b. The images selected for biometric measurements contain the following information: measurement name, value, reference range, and out-of-range status if applicable. The measurement keypoints and shapes are in yellow.

c. Click on a specific structure to view selected images containing this structure. The selected quality criterion is in yellow and the bounding box surrounding the criterion is displayed on the images.

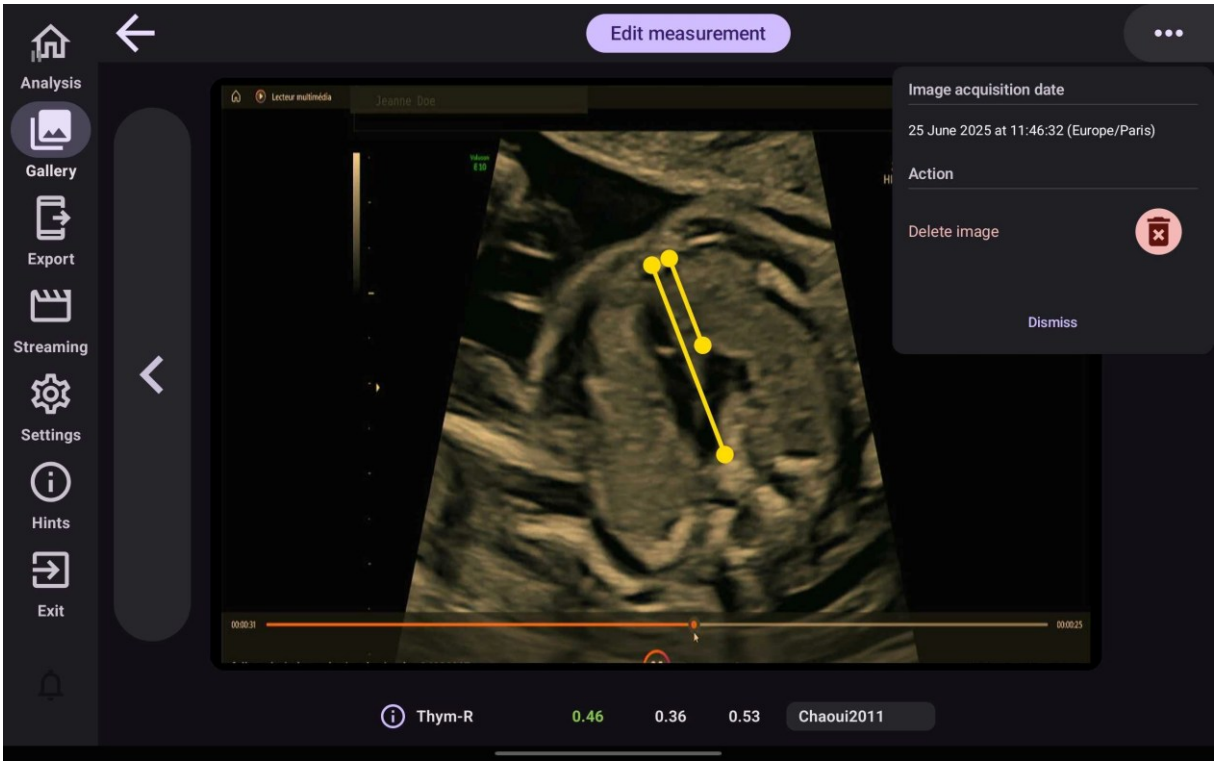


d. Click on a completeness image to zoom on it. You can click on a quality criterion in green to display the bounding box surrounding the quality criterion. The quality criterion chosen is in yellow. White boxes mean that the quality criteria are present on other images of the gallery or unverified. Click on the trash symbol to delete the image. You can directly swipe on the sides of the image to go through other images of the view.



e. Click on a measurement image to zoom on it. The measurement keypoints and shapes are in yellow. Note that the measurement keypoints are not designed to be on the exact location but to be enough accurate to display the good

measurement value. The value and the “out-of-range” status if applicable are displayed, along with reference range and bibliographical source selected. Click on the trash symbol to delete the image. You can directly swipe on the sides of the image to go through other images of the view. You can edit the keypoints for a measure on measurement images, by clicking on the ‘edit measurement’ button. The measurement value will then be updated accordingly and the software prevent any automatic modification by rescanning after the edition. The edited measurement will be marked with the following symbol: .

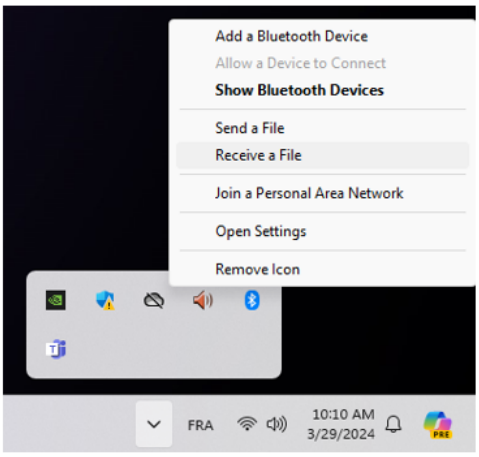


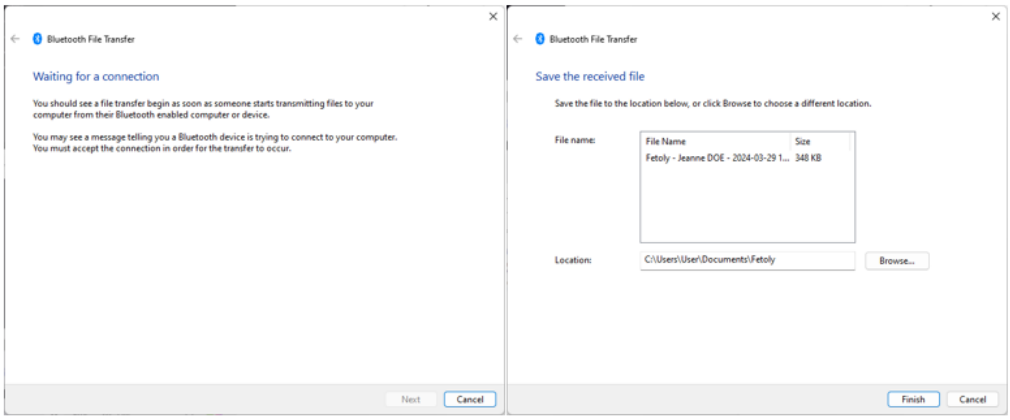


f. If needed, you can go back on the analysis page to re-launch the analysis and obtain additional images.

Export images

1. Go to the ‘Export method’ section in ‘Settings’ to select the export mode that you want to use.
2. Go to the ‘Export’ section to export the selected images:
    a. If you have chosen Bluetooth connection (Android only), go on your PC and select ‘receive a file’ in Bluetooth configuration.

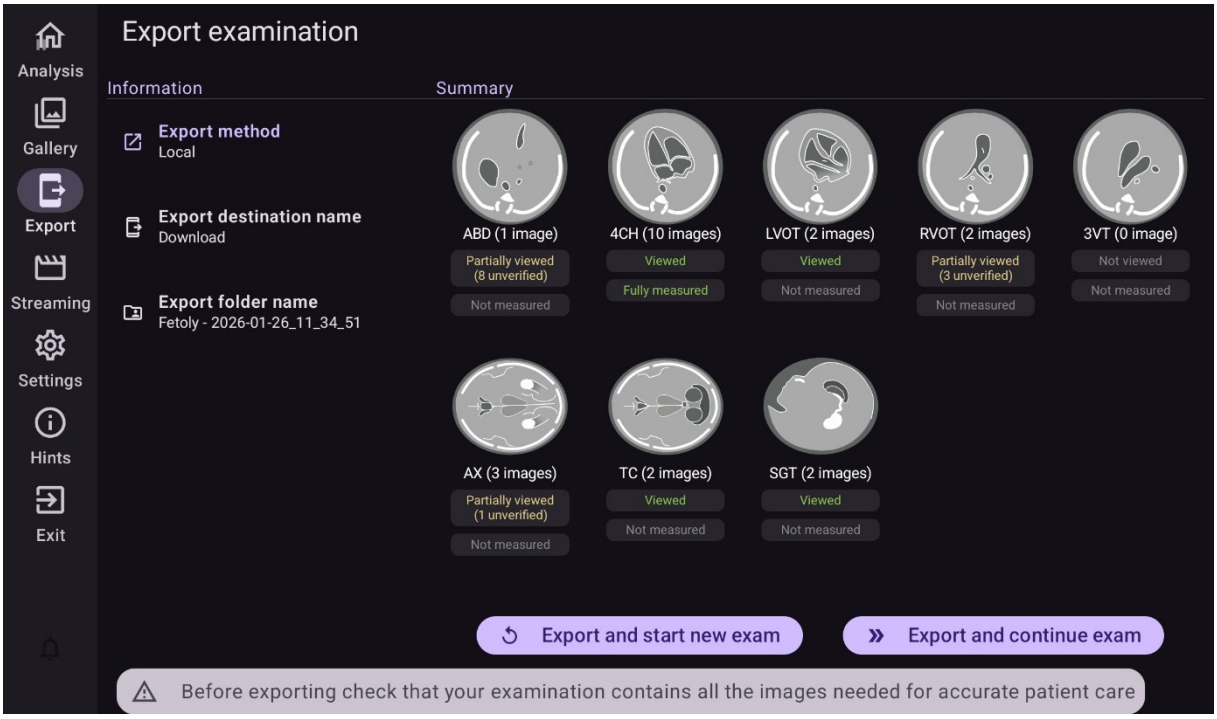




    b. If you have chosen DICOM connection, you can verify if the patient selected for export is the good one and select another patient if there is a mistake by using the DICOM worklist on the analysis page.
    c. The export page displays a summary of the examination and reminds you to verify if you have all the images needed for efficient patient care before export.
    d. The export page displays the export methodology chosen. If you want to change settings, you can go directly to export settings page by clicking on ‘export method’.
    e. The export page displays the export file location on the chosen device and the file name set up for local export.
    f. Click the ‘Export and start a new exam’ button to export images and clear the examination before beginning a new exam.

g. Or, click the ‘Export and continue exam’ button to export images without erasing the current selected set of images and completeness analysis.

h. The software will indicate you if the export has been successful or has failed.



Re-initialization (clear)

If you didn’t use the clear function on the export page, go to ‘Analysis’ and click the ‘Clear’ button to reinitialize the set of selected images and the examination.

Advanced settings

If you want to disable the measurement function, go to ‘Settings’ > ‘Advanced’ and click on the button.

Software and licence update

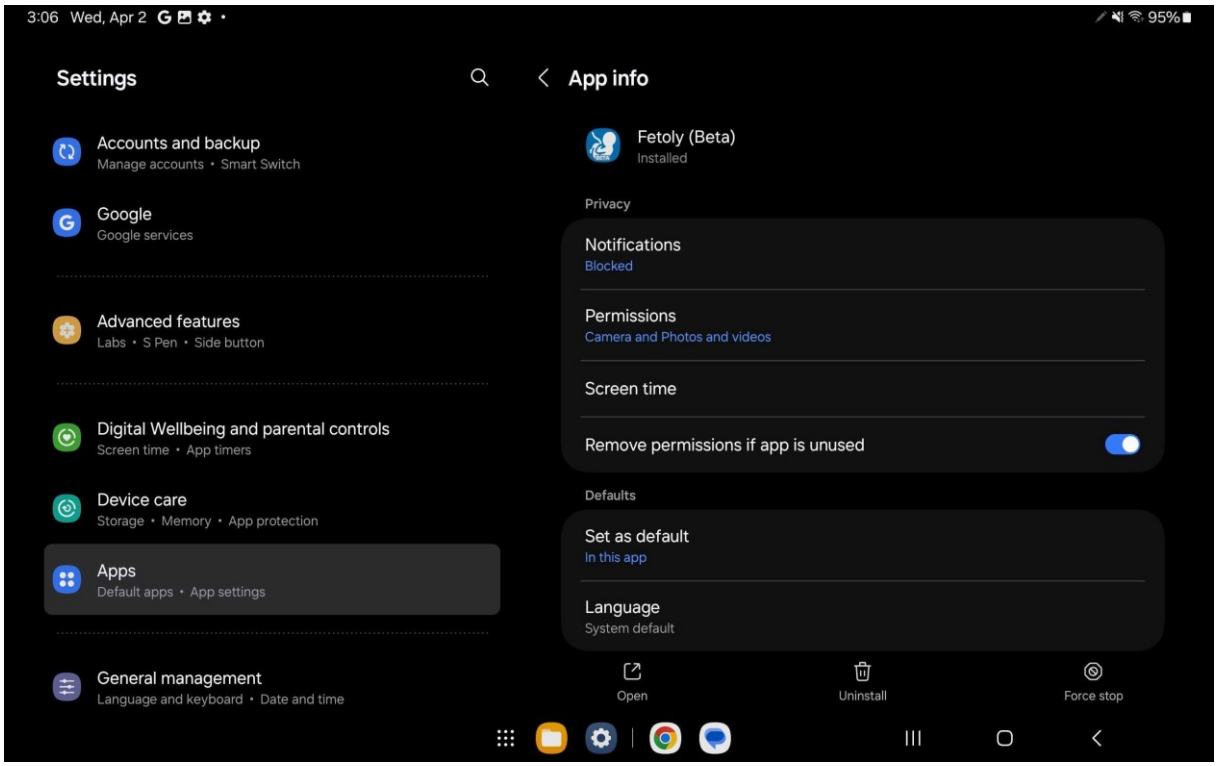
The software checks periodically for new app updates. To ensure immediate availability of new updates, enable background updates for FETOLY in Google Play/App Store settings. When an update is available, the software will display a blocking page at launch, requiring the user to update and restart the app in order to continue using it. After accepting the update, Google Play/App store handles the update installation and app restart. An internet connection is required to check for updates and to renew automatically the licence. If the device is not connected to the internet for a period of 30 days, the software will be blocked.

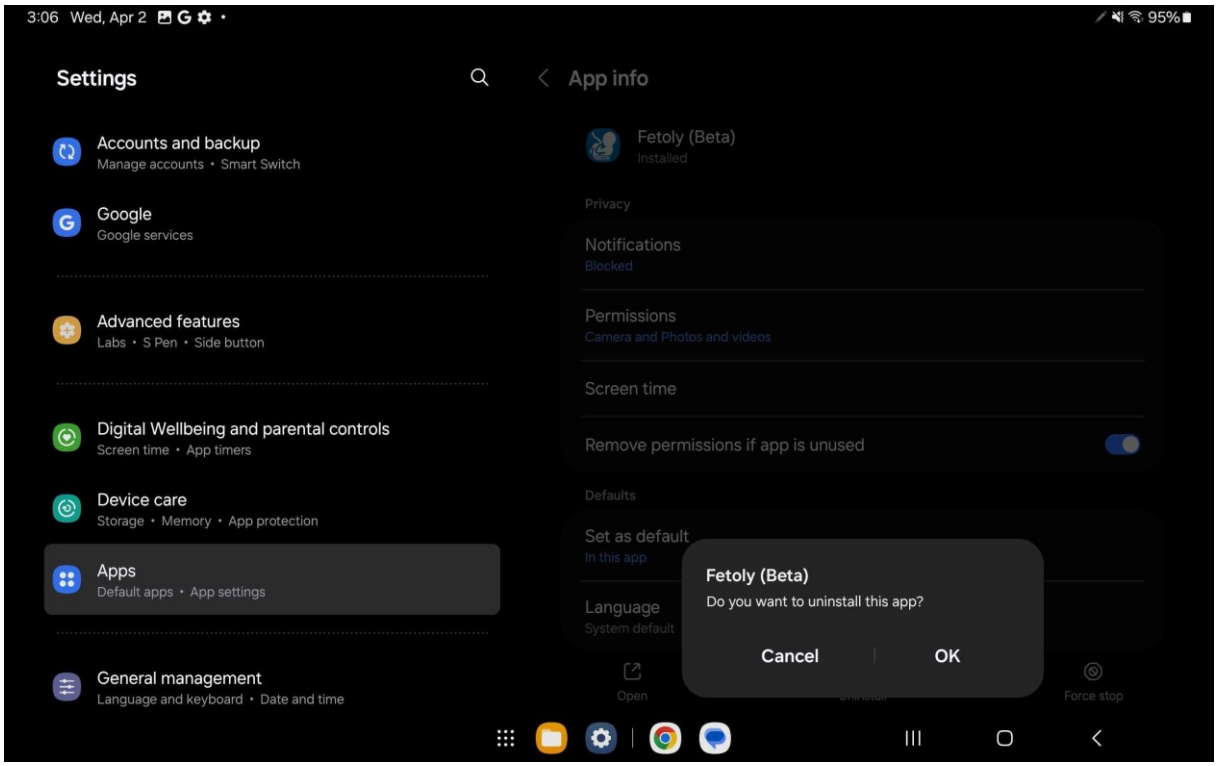
Your licence is verified and renewed automatically when an internet connection is activated until the licence contract is expired. The licence expiration date is displayed in the licence

settings page. When the licence contract is expired, if no renewal of the contract is done, the software will ask to enter a new registration code and block functionalities.

Software uninstallation

Uninstall the application as any app on your tablet as illustrated below:





14. Maintenance, handling and disposal

- The instructions must be read before use.
- Please launch updates when asked by the software at launch.
- Please notice that, for the United States of America market, a Predetermined Change Control Plan (PCCP) has been included. This PCCP is implemented for the Machine Learning model incorporated in the FETOLY device that could modify the device's performance, inputs, or use. It is therefore strongly recommended to be regularly connected to the internet to allow automatic update installation.
- Please enter the registration code when asked by the software at launch.
- To decommission and dispose of the software, please uninstall the application through the Android system as any application on your tablet, in the app's parameters, as illustrated above in the 'software uninstallation' paragraph. This uninstallation will remove any data linked to the use of FETOLY, including licence, on your tablet.

Symbols used on labelling (about page):

	Manufacturer (filled factory symbol)
	CE marked device
	Unique Device Identifier 01: UDI-DI 11: Manufacturing date 8012: Software version
	Consult Instruction for Use
	Federal law restricts this device to sale on or by the order of a physician
	Medical Device
	Manufacturing date (empty factory symbol)
	Swiss representative name and address

Instructions d'utilisation (Français)

1. Identification du dispositif

FETOLY

Logiciel d'aide à l'examen échographique fœtal.

Version du logiciel liée à cette notice : V2026.02.25

2. Mise à jour

FETOLY a été mis à jour comme suit :

- FETOLY est désormais compatible avec iOS
- Les mesures suivantes ont été ajoutées selon la Modification#4 du PCCP: PLAS, CSP ratio, VP-ratio
- Les vues Transventriculaire et Transthalamique ont été fusionnées en la vue Axiale.
- La notice a été mise à jour pour clarifier la fonctionnalité d'affichage des points clés et pour ajouter un avertissement expliquant que le logiciel ne peut pas être utilisé si l'échographie est réalisée avec une sonde transvaginale.
- Les performances de détection du modèle d'IA ont été améliorées selon la modification #1 du PCCP.
- Il est désormais possible d'activer TLS en mode DICOM pour l'export.

Les tests de vérification ont été complètement rejoués pour vérifier qu'il n'y a pas d'impact sur les fonctionnalités du dispositif. La méthodologie suivie est la même que pour la version initiale du produit.

3. Identification du fabricant

FETOLY est fabriqué par :

DIAGNOLY

2 Place de Francfort, 69003 LYON, France

Tel.: +33(0)6.58.49.07.84

Réclamations produit : support@diagnoly.com

Veuillez signaler tout incident grave à Diagnoly via l'adresse e-mail ci-dessus, ainsi qu'à l'autorité compétente de votre pays.

CE 0197

4. Description et présentation du dispositif

Fetoly est un logiciel conçu pour aider les échographistes, obstétriciens, radiologues, spécialistes en médecine materno-fœtale et cardiologues pédiatriques (désignés comme professionnels de santé, c'est-à-dire PS) à réaliser en temps réel des examens échographiques du cerveau et du cœur fœtaux. **Fetoly** peut être utilisé par les PS lors des

examens échographiques fœtaux au cours du deuxième et du troisième trimestre de grossesse (fenêtre d'âge gestationnel : de 17 à 40 semaines).

Le logiciel est destiné à assister les PS dans l'évaluation de la complétude de l'examen échographique du cerveau et du cœur fœtaux, conformément aux recommandations nationales et internationales. **Fetoly** est également destiné à être utilisé pour effectuer des mesures biométriques du cerveau et du cœur fœtaux, conformément aux recommandations nationales et internationales.

Pour utiliser **Fetoly**, le logiciel doit être installé sur un dispositif matériel connecté à un appareil d'échographie via une connexion HDMI. Le logiciel reçoit en temps réel les images échographiques capturées par l'appareil d'échographie connecté. L'algorithme d'apprentissage profond figé du logiciel, entraîné par apprentissage supervisé, analyse les images de ce flux échographique pour détecter les vues du cerveau et du cœur, les critères de qualité au sein de ces vues, et pour réaliser des mesures biométriques du cerveau et du cœur.

Le logiciel fournit les informations suivantes accessibles à l'utilisateur :

1. **Évaluation de la complétude de l'examen** : le logiciel affiche en temps réel les vues cérébrales et cardiaques ainsi que les critères de qualité qui sont vérifiés par le logiciel pendant l'examen. Les vues et critères de qualité vérifiés sont accessibles aux cliniciens à tout moment de l'examen échographique, en temps réel.
2. **Mesures biométriques quantitatives** : le logiciel affiche en temps réel les mesures cérébrales et cardiaques détectées et effectuées par le logiciel pendant l'examen, ainsi que l'indication si ces mesures sont dans les valeurs de référence ou en dehors de celles-ci, selon les normes de l'état de l'art. Les mesures vérifiées du cerveau et du cœur sont accessibles aux cliniciens à tout moment de l'examen échographique, en arrière-plan.
3. **Illustration de l'examen** : le logiciel sélectionne un sous-ensemble d'images qui illustre :
    - les vues et critères de qualité vérifiés. Ces images peuvent être revues par les cliniciens afin de confirmer la présence des vues et critères. De manière optionnelle, les cliniciens peuvent afficher la localisation des critères de qualité détectés sur les images sélectionnées ;
    - chaque mesure. Pour chaque mesure, le logiciel affiche une image avec les points clés de mesure tracés (en jaune) ainsi que la valeur mesurée (en bas de l'image). La plage de référence normale pour cette mesure est également rappelée à l'utilisateur. L'utilisateur peut éditer les points clés et le logiciel met à jour la mesure en fonction.
4. **Rapport d'examen** : le logiciel permet à l'utilisateur d'exporter un rapport d'examen contenant :
    - un résumé des mesures et de la complétude de l'examen ;
    - des illustrations (images.

Definition d'un examen complet

Pour le cœur fœtal

Vue cardiaque	***Critères qualité dans les vues***	
	(A1) Sp	*Spine* ***(rachis)***
	(A2) lRb	*Left rib* ***(côte gauche)***
	(A3) rRb	*Right rib* ***(côte droite)***

 ***(A) ABD*** ***Abdomen view (Vue abdominale)*** ***(n = 8)***	*(A4) Ao*	*Descending aorta* ***(aorte descendante)***
	(A5) VC	*Inferior vena cava* ***(veine cave inféreure)***
	(A6) St	*Stomach* ***(estomac)***
	(A7) Uv	*Umbilical vein* ***(veine ombilicale)***
	(A8) aA	*Anterior abdomen* ***(abdomen antérieur)***
 ***(B) 4CH*** ***Four chamber view (Vue des quatre cavités)*** ***(n = 19)***	*(B1) Sp*	*Spine* ***(rachis)***
	(B2) lRb	*Left rib* ***(côte gauche)***
	(B3) rRb	*Right rib* ***(côte droite)***
	(B4) Ao	*Descending aorta* ***(aorte descendante)***
	(B5) lPV	*Left pulmonary vein* ***(veine pulmonaire gauche)***
	(B6) rPV	*Right pulmonary vein* ***(veine pulmonaire droite)***
	(B7) LA	*Left atrium* ***(oreillette gauche)***
	(B8) RA	*Right atrium* ***(oreillette droite)***
	(B9) FOF	*Foramen Ovale flap* ***(Valve de Vieussens)***
	(B10) FO	*Open Foramen Ovale* ***(foramen ovale ouvert)***
	(B11) MV	*Mitral valve* ***(valve mitrale)***
	(B12) TV	*Tricuspid valve* ***(valve tricuspide)***
	(B13) bCr	*Connection between crux and atrial septum (vestibular septum)* ***Connexion entre la croix du coeur et le septum interauriculaire (septum vestibulaire intact)***
	(B14) Cr	*Atrioventricular valve offset in crux* ***Décalage des valves auriculo-ventriculaires au niveau de la croix du cœur***
	(B15) tCr	*Connection between interventricular septum and crux* ***(continuité du septum interventriculaire membraneux)***
	(B16) IVS	*Interventricular septum* ***(continuité du septum interventriculaire musculaire)***
	(B17) LV	*Left ventricle* ***(ventricule gauche)***
	(B18) RV	*Right ventricle* ***(ventricule droit)***
	(B19) Str	*Sternum* ***(Sternum)***
	*(C1) LA*	*Left atrium* ***(oreillette gauche)***
	(C2) aAo	*Proximal ascending aorta* ***(aorte ascendante proximale)***
	(C3) SV	*Semilunar valves* ***(valves semi-lunaires)***
	(C4) LV	*Left ventricle* ***(ventricule gauche)***
	(C5) IVS	*Interventricular septum* ***(septum interventriculaire – continuité septo aortique)***

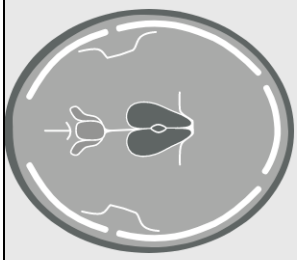
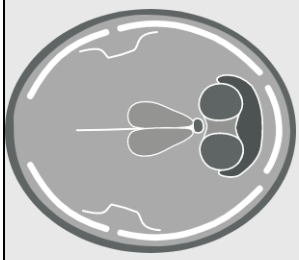
(C) LVOT ***Left Ventricular Outflow Tract view*** ***(Vue de la voie d'éjection gauche)*** ***(n = 6)***	*(C6) RV*	*Right ventricle* ***(ventricule droit)***
 ***(D) RVOT*** ***Right Ventricular Outflow Tract view*** ***(Vue de la voie d'éjection droite)*** ***(n = 10)***	*(D1) dAo*	*Descending aorta* ***(aorte descendante)***
	(D2) Tr	*Trachea / bronchi* ***(trachée/bronches)***
	(D3) lPA	*Left pulmonary artery* ***(artère pulmonaire gauche)***
	(D4) Du	*Ductus arteriosus* ***(canal artériel)***
	(D5) rPA	*Right pulmonary artery* ***(artère pulmonaire droite)***
	(D6) Or	*Origin of pulmonary arteries* ***(origine des artères pulmonaires)***
	(D7) S	*Septum between pulmonary artery trunk and ascending aorta* ***(Continuité du septum entre le tronc pulmonaire et l'aorte ascendante)***
	(D8) aAo	*Ascending aorta* ***(aorte ascendante)***
	(D9) SVC	*Superior vena cava* ***(veine cave supérieure)***
	(D10) PA	*Pulmonary trunk* ***(tronc de l'artère pulmonaire)***
 ***(E) 3VX*** ***Three vessels view*** ***(Vue des trois vaisseaux)*** ***(n = 9)***	*(E1) Sp*	*Spine* ***(rachis)***
	(E2) Tr	*Trachea* ***(trachée)***
	(E3) ES	*Side space on the left of ductus / pulmonary artery* ***(Espace latéral à gauche du canal artériel / de l'origine de l'artère pulmonaire)***
	(E4) DuA	*Ductal arch connected to the descending aorta* ***(Crosse du canal artériel relié à l'aorte descendante)***
	(E5) Du	*Ductal arch not connected to the descending aorta* ***(Crosse du canal artériel non relié à l'aorte descendante)***
	(E6) aAo	*Ascending aorta* ***(aorte ascendante)***
	(E7) aAr	*Aortic arch* ***(arc aortique)***
	(E8) SVC	*Superior vena cava* ***(veine cave supérieure)***
	(E9) Th	*Thymus and Sternum* ***(Thymus et Sternum)***

Tableau 1. Liste des 52 critères qualité définissant la qualité des 5 vues recommandées par l'ISUOG (International Society of Ultrasound in Obstetrics and Gynecology) pour l'examen du cœur foetal lors des 2e et 3e trimestres de grossesse. Les abréviations du tableau correspondent aux abréviations utilisées dans le logiciel.

For the fetal brain

Tableau 3: Liste des 34 critères de qualité définissant la qualité des 3 vues recommandées par la Société Internationale d'Échographie en Gynécologie et Obstétrique (ISUOG) pour le dépistage du cerveau fœtal aux 2e et 3e trimestres de la grossesse.

Brain views	***Quality criteria within the views***	
	(F1) aFx	*Anterior Falx* ***(Faux antérieure du cerveau)***
	(F2) CSP	*Cavum Septum Pellucidum* ***(Cavum Septum Pellucidum)***
	(F3) For	*Fornix* ***(Fornix)***

 ***(F) TV*** ***Axial view*** ***Vue axiale*** ***(n = 15)***	*(F4) dAV*	*Distal Anterior Ventricle* ***(Ventricule antérieur distal)***
	(F5) pAV	*Proximal Anterior Ventricle* ***(Ventricule antérieur proximal)***
	(F6) AC	*Ambient Cisterna* ***(Citerne ambiante)***
	(F7) Atr	*Atrium* ***(Atrium)***
	(F8) CP	*Choroid Plexus* ***(Plexus choroïde)***
	(F9) POS	*Parieto Occipital Sulcus* ***(Sillon pariéto-occipital)***
	(F10) pFx	*Posterior Falx* ***(Faux postérieure du cerveau)***
	(F11) dCS	*Distal Coronal suture* ***(Suture coronale distale)***
	(F12) pCS	*Proximal Coronal suture* ***(Suture coronale proximale)***
	(F13) SF	*Sylvian Fissure* ***(Vallée Sylvienne)***
	(F14) Sk	*Skull* ***(Crâne)***
	(F15) Sep	*Thalami Separation* ***(Séparation des thalami)***
	(F16) 3V	*3rd Ventricle* ***(3e Ventricule)***
	(F17) dTh	*Distal Thalamus* ***(Thalamus Distal)***
	(F18) pTh	*Proximal Thalamus* ***(Thalamus Proximal)***
 ***(G) TC*** ***Transcerebellar view*** ***Vue transcérébelleuse*** ***(n = 8)***	*(G1) dTh*	*Distal Thalamus* ***(Thalamus Distal)***
	(G2) pTh	*Proximal Thalamus* ***(Thalamus Proximal)***
	(G3) 4V	*4th Ventricle* ***(4e Ventricule)***
	(G4) Ver	*Vermis* ***(Vermis)***
	(G5) dCH	*Distal Cerebellar Hemisphere* ***(Hémisphère Cérébelleux Distal)***
	(G6) pCH	*Proximal Cerebellar Hemisphere* ***(Hémisphère Cérébelleux Proximal)***
	(G7) CB	*Cerebellar Border* ***(Bord du cervelet)***
	(G8) CM	*Cisterna Magma* ***(Grande citerne)***
 ***(I) SAG*** ***Sagittal/profile view*** ***Vue sagittale*** ***(n = 8)***	*(I1) NB*	*Nose Bone* ***(Os Nasal)***
	(I2) uVer	*Upper Part of Vermis* ***(Partie Supérieure du Vermis)***
	(I3) lVer	*Lower Part of Vermis* ***(Partie Inférieure du Vermis)***
	(I4) Fas	*Fastigium* ***(Fastigium)***
	(I5) rgCC	*Rostrum & Genu Corpus Callosum* ***(Rostrum & Genu du Corps Calleux)***
	(I6) bCC	*Body Corpus Callosum* ***(Corps du Corps Calleux)***
	(I7) sCC	*Splenium Corpus Callosum* ***(Splenium du Corps Calleux)***
	(I8) CSP	*Cavum Septum Pellicidum* ***(Cavum Septum Pellucidum)***

Mesures biométriques et intervalles de référence

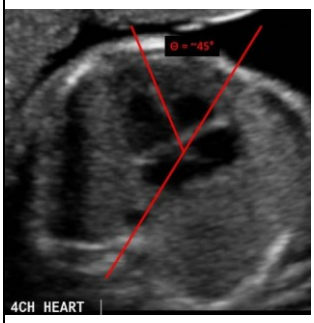
FETOLY fournit trois types de mesures biométriques automatisées :

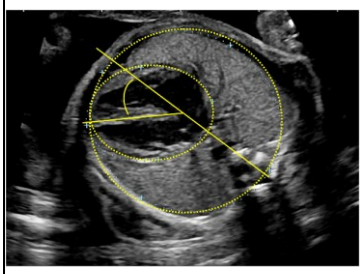
- Mesure d'angle affichée en degrés (°) ;

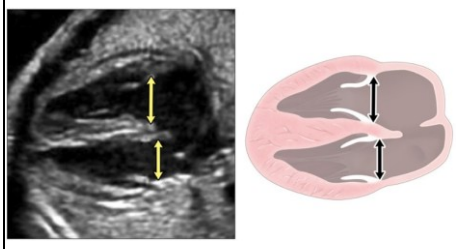
- Mesure de rapport (une distance normalisée par une autre distance, représentée soit sous forme de rapport, soit en pourcentage) ;
- Nombre de repères anatomiques détectés.

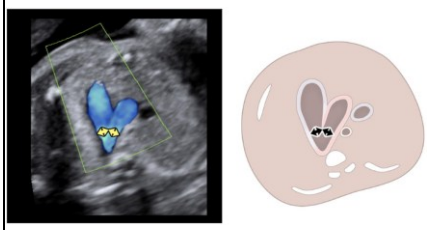
Liste des mesures et de leurs intervalles de référence :

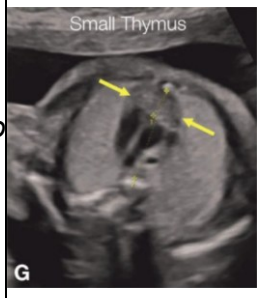
Le tableau ci-dessous détaille les mesures biométriques fournies par FETOLY ainsi que leurs intervalles de référence normaux, basés sur la littérature scientifique établie.

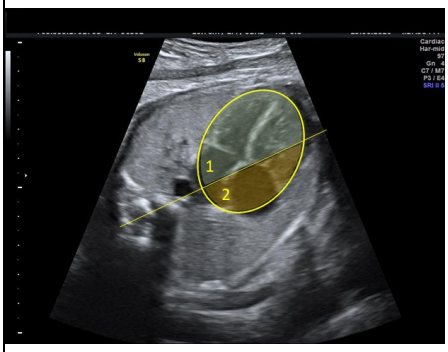
Paramètre	*Information accessible dans FETOLY (description et sources)*
(M1) Axe cardiaque	***Quest-ce que l'axe cardiaque (CAx) ?***  *(source: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* ***L'axe cardiaque (ou angle cardiaque)** fait référence à l'orientation du cœur par rapport à la ligne médiane du thorax, mesurée dans la vue des quatre cavités. Il est déterminé par l'angle entre une ligne suivant le septum interventriculaire et une ligne antéropostérieure qui divise le thorax en deux.* *L'image doit inclure le rachis, le sternum et les quatre cavités cardiaques. Les côtes gauche et droite doivent être présentes et visibles comme des côtes simples.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'**ISUOG** indiquent que l'examen de dépistage cardiaque doit inclure la vue des quatre cavités, et que son évaluation doit comporter la mesure de l'axe cardiaque :* *« Le cœur fœtal normal est situé principalement à gauche, avec l'apex cardiaque pointant vers la gauche selon un angle de **45° ± 20°** par rapport à l'axe antéropostérieur du thorax » (Carvalho2023).* *Elles citent Comstock1987, qui fournit les intervalles de référence pour l'axe cardiaque.* *Les recommandations de l'**ASE** recommandent également l'évaluation de l'axe cardiaque :* *« L'axe cardiaque est un élément recommandé de l'imagerie échocardiographique fœtale en 2D […] normal : **35–65°** » (Moon-Grady2023).* ***Intervalles de référence disponibles :*** • **Comstock (1987):** (Moyenne ± 2 DS)

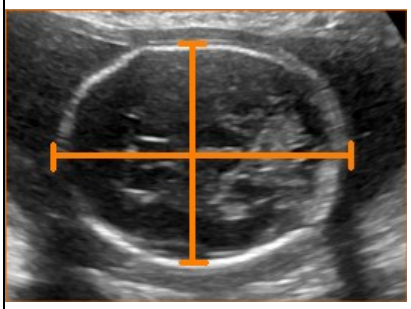
	○ 17-40AG: [25° - 65°]. • **ASE (2023):** ○ 17-40AG: [35° - 65°]
(M2) Ratio cardiothoracique	***Qu'est-ce que le ratio cardiothoracique ?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* ***Le rapport cardiothoracique fœtal (CTR)** est le rapport entre la circonférence transversale de la surface épicardique du cœur et la circonférence transversale du thorax, mesuré dans la vue des quatre cavités pendant la diastole.* *L'image doit inclure le rachis, le sternum et les quatre cavités cardiaques. Les côtes gauche et droite doivent être présentes et visibles comme des côtes simples.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'**ASE** indiquent que le rapport cardiothoracique est un composant obligatoire de l'échocardiographie fœtale :* *« Mesures biométriques standard à partir d'une image axiale au niveau de la vue des quatre cavités. Le rapport cardiothoracique est calculé à partir de la mesure de la circonférence intérieure (ou de la surface) de la poitrine et de la surface épicardique du cœur » (Moon-Grady2023).* *Les recommandations de l'**AIUM** indiquent aussi que le rapport cardiothoracique est une biométrie cardiaque requise (AIUM2019). L'**ISUOG** recommande également cette mesure :* *« Les éléments clés de la vue normale des quatre cavités au milieu du deuxième trimestre incluent une surface cardiaque ne dépassant pas un tiers de la surface thoracique » (Carvalho2013).* *Le manuel d'Abuhamad (2009) recommande aussi d'évaluer les dimensions cardiaques :* *« Les dimensions cardiaques fœtales peuvent être facilement évaluées en mesurant le rapport de la circonférence ou de la surface cardiaque à la circonférence ou surface thoracique obtenues au niveau de la vue des quatre cavités » (Abuhamad, 2009).* *Les recommandations de l'**AHA** (Donofrio2014) et le manuel d'Abuhamad citent tous deux (Paladini, 1990) pour les intervalles de référence.* ***Intervalles de référence disponibles :*** • ***Paladini (1990)** : (2,5e et 97e percentiles pour la circonférence)* ○ *17 SA : [0,40 - 0,52]*

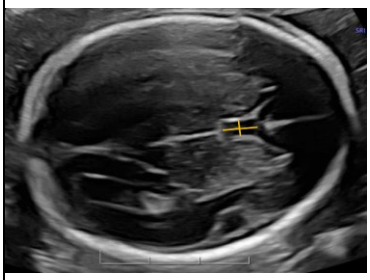
	○ *18 SA : [0,40 - 0,52]* ○ *19 SA : [0,42 - 0,51]* ○ *…* ○ *40 SA : [0,46 - 0,56]* • ***Garcia-Otero (2020)** : (5e et 95e percentiles pour la surface)* ○ *18 SA : [0,16 - 0,25]* ○ *19 SA : [0,16 - 0,26]* ○ *…* ○ *40 SA : [0,21 - 0,35]* • ***ASE (Moon-Grady, 2023)** : (intervalle défini par les recommandations pour un score fœtal optimal basé sur la surface)* ○ *17-40 SA : [0,20 - 0,35]*
(M3) Ratio de la largeur ventriculaire	***Qu'est ce que le ratio de la largeur ventriculaire ?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* ***Le rapport ventriculaire droit-gauche (TV/MV)** correspond au rapport entre le diamètre annulaire de la valve tricuspide (TV) et celui de la valve mitrale (MV), utilisé pour évaluer la morphologie cardiaque chez le fœtus. Il est déterminé en comparant les diamètres de la TV et de la MV à leurs points les plus larges pendant la diastole.* *L'image doit inclure le rachis et le sternum. Les côtes gauche et droite doivent être présentes et visibles comme des côtes simples. La vue des quatre cavités doit être visible et bien contrastée.* ***Note :** Il existe deux conventions pour mesurer le diamètre ventriculaire (Schneider2005) : la mesure au niveau des valves ou la dimension en fin de diastole. Pour cette mesure, c'est la première qui est utilisée.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'**AIUM** indiquent que la comparaison des anneaux des valves tricuspide et mitrale en diastole est une biométrie cardiaque obligatoire :* *« Les anneaux des valves tricuspide et mitrale en diastole ([...] comparaison des valves gauche et droite) constituent une biométrie cardiaque requise » (AIUM2019).* *Ils citent (DeVore2017), (Lee2009) et (Schneider2005) pour les intervalles de référence.* *Les recommandations de l'**ISUOG** indiquent également qu'une asymétrie droite-gauche justifie un examen complémentaire :*

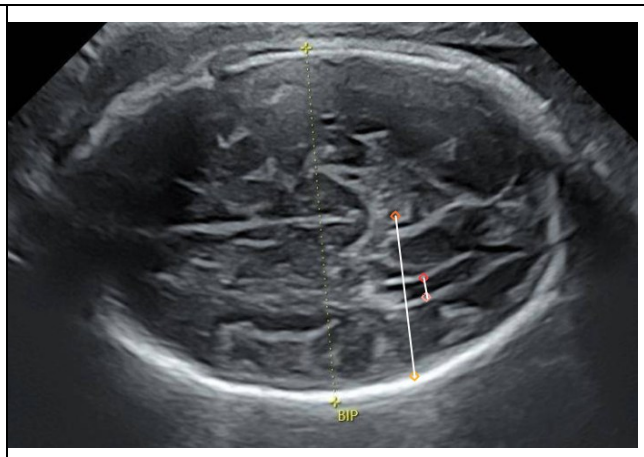
	« Les deux ventricules doivent apparaître de taille similaire. Bien qu'une légère disproportion ventriculaire puisse être une variante normale au troisième trimestre, une asymétrie droite-gauche au milieu de la grossesse nécessite un examen approfondi » (Carvalho2023). *Ils citent (Kirk, 1999) pour les intervalles de référence.* *Les recommandations de l'**ASE** indiquent que l'évaluation de la relation des tailles ventriculaires est une étape obligatoire de l'échocardiogramme fœtal :* *« L'anneau des valves atrioventriculaires en début de diastole est requis dans le cadre d'une échocardiographie complète » (Moon-Grady2023).* *Le manuel d'Abuhamad (2012) souligne également la pertinence du rapport largeur ventriculaire droite/gauche, évalué à 1,19 chez les fœtus normaux.* ***Intervalles de référence disponibles :*** • ***Gabbay-Benziv** (Gabbay-Benziv2015): (2,5e et 97e percentiles)* ○ *17 SA : [0,87 - 1,22]* ○ *18 SA : [0,86 - 1,22]* ○ *19 SA : [0,86 - 1,22]* ○ *…* ○ *38 SA : [0,87 - 1,30]* • ***Garcia-Otero (2020)** : (5e et 95e percentiles)* ○ *18 SA : [0,82 - 1,21]* ○ *19 SA : [0,82 - 1,22]* ○ *…* ○ *40 SA : [0,86 - 1,27]*
(M4) Ratio des gros vaisseaux	***Qu'est ce que le ratio des gros vaisseaux ?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* ***Le rapport de taille des gros vaisseaux (Ao/Du)** correspond au rapport entre les diamètres de l'isthme aortique (Ao) et du canal artériel (Du) sur la vue des trois vaisseaux. Il est déterminé en mesurant les diamètres du canal artériel et de l'arc aortique à leur base. Notez que le rapport diamètre de l'artère pulmonaire médiastinale (AP) sur l'aorte ascendante (Ao) est également utilisé dans la littérature (Slodki, 2009).* *L'image doit inclure le rachis et le sternum, avec des côtes gauches et droites visibles et distinctes. Le canal artériel et l'aorte ascendante doivent être clairement visibles, montrant leur connexion.*

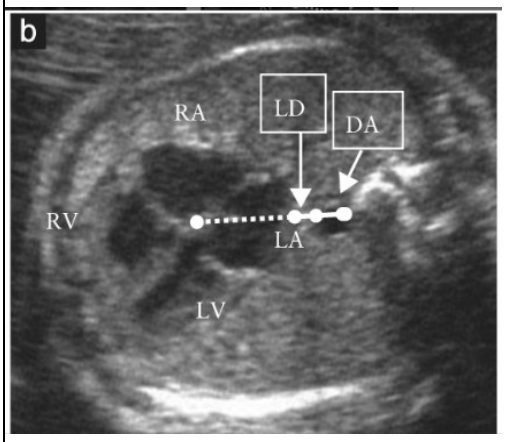
	Que recommandent les lignes directrices ? *Les recommandations américaines et internationales, y compris celles de l'ASE, ISUOG, AIUM, et AHA, indiquent que l'évaluation de la relation de taille entre les gros vaisseaux est une évaluation obligatoire (Donofrio2014).* *« Il est important de vérifier la normalité des deux gros vaisseaux, y compris leur taille [...] relative l'un à l'autre » (Carvalho2023).* *Le manuel d'Abuhamad (2012) souligne également la pertinence de la comparaison entre les diamètres de l'arc aortique et de l'artère pulmonaire principale, en particulier dans la région de l'isthme. Ils citent l'étude de Pasquini (Pasquini2007) pour les intervalles de référence.* ***Intervalles de référence disponibles :*** • ***Pasquini (Pasquini2007) :*** o *Constante : [0,86 - 1,12] (moyenne ± écart-type)* o *Constante : [0,74 - 1,23] (2,5e et 97,5e percentiles) (Buyens, 2012)*
(M5) Nombre de vaisseaux	***Qu'est-ce que le nombre de vaisseaux ?*** ***La vue fœtale des trois vaisseaux (3VV)*** *est un plan axial utilisé en imagerie prénatale pour évaluer les gros vaisseaux du cœur. Cette vue montre généralement trois vaisseaux, normalement l'artère pulmonaire, l'aorte et la veine cave supérieure. Le comptage des vaisseaux se concentre uniquement sur les structures anéchogènes rondes ou allongées, en excluant la trachée et l'aorte descendante.* *L'image doit mettre en évidence les vaisseaux, avec un contraste clair et une distinction nette des structures.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'****ISUOG*** *indiquent que l'évaluation de la vue des trois vaisseaux doit « inclure une évaluation du nombre de vaisseaux. De gauche à droite, les vaisseaux sont l'artère pulmonaire, l'aorte et la veine cave supérieure droite » (Carvalho2023).* *Les recommandations de l'****ASE*** *insistent également sur le fait que toute anomalie dans le nombre de vaisseaux doit être notée (Moon-Grady2023). En tant que standard international, le nombre attendu de vaisseaux est de trois.*
(M6) Ratio thymique-thoracique	***Qu'est-ce que le ratio thymique-thoracique?***  *(source: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4th ed.). Wolters Kluwer)*

	Le ratio thymique-thoracique *correspond au rapport entre le diamètre thymique antéropostérieur et le diamètre médiastinal intrathoracique, mesurés sur la vue des trois vaisseaux et de la trachée.* *L'image doit afficher le rachis, le sternum et l'aorte ascendante, avec les côtes gauche et droite visibles en tant que structures distinctes. Le thymus doit être clairement visible et identifiable.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'**ISUOG** indiquent que l'« [évaluation de la vue des trois vaisseaux] inclut une appréciation de l'alignement des vaisseaux » (Carvalho2023) et que cela « peut améliorer la détection des anomalies des voies de sortie [...] ». Ils citent (Chaoui2011) pour l'évaluation du rapport thymique-thoracique dans la détection des anomalies des voies de sortie.* *Le manuel d'Abuhamad (2022) souligne également l'importance d'évaluer ce paramètre.* ***Intervalles de référence disponibles :*** • ***Chaoui (2011)*** *:* ○ *Constant tout au long de la grossesse : [0,36 - 0,53] (moyenne ± 2 écarts-types)*
(M7) Position cardiothoracique	***Qu'est-ce que la position cardiothoracique ?***  *(image inspired by https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/)* ***La position cardiothoracique*** *est déterminée en prolongeant la ligne du septum interventriculaire vers l'arrière, divisant les oreillettes jusqu'à un point à la base du cœur (Smith, 1995). Cela se réalise sur la vue des quatre cavités en calculant le rapport entre la surface située à gauche et la surface cardiaque totale. Ce procédé consiste à dessiner une ellipse sur le cœur et à la diviser par une ligne antéropostérieure qui coupe en deux le thorax (la ligne médiane de la poitrine). Les surfaces gauche (1) et droite (2) représentent respectivement les parties du cœur situées à gauche et à droite de la ligne médiane anatomique. La position est exprimée par le rapport entre la surface gauche et la surface cardiaque totale.* ***Que recommandent les lignes directrices ?*** *La position du cœur fœtal dans la cage thoracique est un paramètre important dans l'évaluation fœtale. Toute déviation par rapport à la position normale justifie une investigation approfondie de possibles pathologies intrathoraciques, intracardiaques ou extracardiaques intrathoraciques (Abdullah, 2000).* *Les lignes directrices américaines et internationales, y compris celles de l'ISUOG (2008), ASE (2004), AIUM (2013), AHA (2014), recommandent une mesure*

	attentive de la position du cœur fœtal dans le thorax lors de la vue des quatre cavités pendant les échographies obstétricales standard (Donofrio2014). *Selon ces recommandations, le cœur fœtal normal est principalement situé sur le côté gauche de la cage thoracique, avec au moins 50 % (rapport ≥ 0,5) de sa surface dans l'espace thoracique gauche (« le cœur est principalement du côté gauche ») (Carvalho2013) (« une attention particulière doit être portée à l'axe et à la position cardiaque. La majorité du cœur [doit être] dans la cage thoracique gauche ») (Carvalho2023).* *Les études confirment ces recommandations, Chiappa (2009) et d'autres (Smith, 1995 ; Sever, 2021) affirmant que « les deux tiers du cœur [doivent être] du côté gauche de la cage thoracique ».* *Bien que plusieurs recommandations définissent une position cardiothoracique normale autour de 0,66 (rapport ≈ 2/3) et qui ne devrait pas descendre en dessous de 0,5, la littérature ne définit pas clairement la limite supérieure de la normale. Les utilisateurs peuvent soit visualiser uniquement la valeur mesurée sans intervalle de référence, soit définir leur propre intervalle de référence.*
(M8) Indice céphalique	***Qu'est-ce que l'indice céphalique ?***  *(source: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* ***L'indice céphalique** est le rapport du diamètre biparié tal (BPD) au diamètre occipitofrontal (OFD), multiplié par 100. L'indice céphalique donne une idée de la forme de la tête fœtale. La mesure de l'OFD, de l'avant vers l'arrière, se fait en plaçant le curseur du bord externe au bord externe des os crâniens. Un indice céphalique très diminué suggère une dolichocéphalie, tandis qu'un indice très augmenté peut suggérer une brachycéphalie. Lorsque ce paramètre est anormal, d'autres mesures, comme le périmètre crânien (HC), le périmètre abdominal ou la longueur du fémur, doivent être utilisées pour estimer l'âge fœtal (Timor-Tritsch, 2012).* *L'image doit afficher une vue axiale symétrique du cerveau, capturant le plan transthalamique avec les deux hémisphères visibles et nets.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'**ISUOG** indiquent que « l'indice céphalique est le rapport entre la largeur maximale de la tête (BPD) et sa longueur maximale (diamètre occipitofrontal (OFD)) et cette valeur peut être utilisée pour caractériser la forme de la tête fœtale. Une forme anormale de la tête (par exemple brachycéphalie ou dolichocéphalie) peut être associée à des syndromes ou résulter d'oligohydramnios ou de présentation du siège. Cette anomalie peut aussi conduire à une estimation inexacte de l'âge fœtal lorsque le BPD est utilisé ;*

	dans ces cas, les mesures du périmètre crânien (HC) sont plus fiables (Hadlock1981) » (Salomon2022).
(M9) Ratio du CSP	***Qu'est-ce que le ratio du CSP ?***  *(source: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. In Journal of Ultrasound in Medicine (Vol. 43, Issue 8, pp. 1461–1466). Wiley)* ***Description :*** *Le ratio du cavum septum pellucidum (CSP) correspond au rapport entre la longueur et la largeur du CSP. Il est déterminé en mesurant la longueur et la largeur du CSP, puis en calculant le rapport longueur/largeur.* *L'image doit montrer une vue transventriculaire axiale et symétrique du cerveau, avec une visualisation claire du cavum septum pellucidum (CSP) et des structures anatomiques de la ligne médiane.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'ISUOG indiquent que la forme du CSP a été décrite comme un marqueur relativement fiable de l'agénésie partielle du corps calleux, et elles citent les études de Karl (2017) et Shen (2015) pour les plages de référence (Malinger2020).* *Les recommandations de la World Association of Perinatal Medicine (WAPM) indiquent que le CSP doit être visualisé et que « l'absence de visualisation du CSP ou son aspect anormal (Karl2017) est prédictif d'anomalies commissurales. Toutefois, l'aspect normal du CSP n'exclut pas toutes les anomalies du corps calleux » (Robertis2021).* *Ce paramètre est également utilisé dans des techniques de deep learning de pointe appliquées aux biométries de routine (Coronado-Gutiérrez2023).* ***Intervalles de référence disponibles :*** • ***Karl (2017) :*** *Constante tout au long de la gestation : [1,5 – 3,3] (5e et 95e percentiles)*
(M10) Rapport entre le ventricule cérébral postérieur et le diamètre de	***Qu'est-ce que le rapport entre le ventricule cérébral postérieur et le diamètre de l'hémisphère ?***

l'hémisphère (VP ratio)	 ***Le rapport ventricule cérébral postérieur / diamètre de l'hémisphère** est un paramètre utilisé pour évaluer le développement cérébral, en particulier la taille ventriculaire par rapport à la taille globale du cerveau (hémisphère).* *Il correspond au rapport entre :* • *Diamètre du ventricule cérébral postérieur (= largeur de l'atrium) – fait généralement référence à l'atrium du ventricule latéral (situé à la jonction des cornes occipitale, temporale et pariétale).* • *Diamètre de l'hémisphère cérébral – le diamètre transverse total de l'hémisphère cérébral correspondant.* *Cette mesure doit être réalisée en vue transventriculaire.* ***Que recommandent les lignes directrices ?*** *Les recommandations de l'ISUOG indiquent que la mesure de la largeur de l'atrium fait partie intégrante du dépistage échographique des malformations du système nerveux central, et que la largeur de l'atrium doit être mesurée bord interne au bord interne et rester <10 mm tout au long de la grossesse.* *La littérature évaluée par les pairs (Nicolaides1994) souligne le rôle du rapport ventricule cérébral postérieur / diamètre de l'hémisphère dans l'amélioration de l'évaluation cérébrale prénatale et de la précision du dépistage fœtal, car il constitue un marqueur relativement fiable de ventriculomégalie.* ***Plages de référence disponibles :*** • ***Nicolaides (1994) : (5e et 95e percentiles)*** ○ *17 SA : [0,29 – 0,45]* ○ *18 SA : [0,27 – 0,42]* ○ *19 SA : [0,26 – 0,40]* ○ *…* ○ *39 SA : [0,15 – 0,24]*
(M11) Indice de l'Espace Post-Atrium	***Qu'est-ce que l'Indice de l'Espace Post-Atrium Gauche (PLAS) ?***

Gauche (PLAS)	
	(Source: Kawazu2014)
	
	L'indice de l'espace post-atrial gauche (PLAS) *est une mesure échocardiographique fœtale utilisée pour évaluer l'espace situé derrière l'oreillette gauche. Il se calcule à partir d'une* ***vue des quatre cavités du cœur fœtal****.*
	
	La mesure consiste à déterminer la ***distance entre la paroi postérieure de l'oreillette gauche et la paroi antérieure de l'aorte descendante (LD)****, puis à la diviser par le* ***diamètre de l'aorte descendante (DA)****. Le calcul est réalisé pendant la* ***phase de fin de systole*** *du cycle cardiaque.*
	
	Formule de l'indice PLAS :
	
	$$\text{Indice PLAS} = \frac{\text{Distance Oreillette Gauche – Aorte Descendante (LD)}}{\text{Diamètre de l'Aorte Descendante (DA)}}$$
	
	Recommandations des lignes directrices (justification et importance clinique)
	La littérature évaluée par les pairs (Kawazu2019, Anuwutnavin2023, Akkurt2015) souligne l'importance de l'indice PLAS comme ***mesure simple et reproductible*** *pour le dépistage cardiaque fœtal. Initialement introduit par Kawazu2014, l'indice PLAS a été identifié comme un* ***marqueur sensible pour le diagnostic prénatal de la connexion veineuse pulmonaire anormale totale (TAPVC)****, une pathologie où les veines pulmonaires ne se connectent pas correctement à l'oreillette gauche.* ***Un indice PLAS augmenté constitue un indicateur significatif de TAPVC.***
	
	Plages de référence disponibles :
	• *Kawazu2014 et Kawazu2019 : constante tout au long de la gestation*
	  ○ ***Valeur seuil optimale*** *pour suggérer une TAPVC : > 1,27*
	  ○ *Pour les fœtus normaux : indice PLAS moyen = 0,62 ± 0,19*

Chaque mesure nécessite un point de vue échographique spécifique, appelé « sous-vue », qui doit répondre à des conditions d'image particulières pour garantir une mesure précise. Une sous-vue est toujours dérivée d'une des vues fœtales standards de dépistage, mais requiert également des conditions additionnelles spécifiques. Par exemple, la mesure du rapport ventriculaire droit-gauche sur la vue des quatre cavités exige une visualisation correcte des contours ventriculaires, ce qui n'est pas nécessaire pour l'axe cardiaque.

Le tableau ci-dessous illustre la correspondance entre les sous-vues et les vues cardiaques ou cérébrales décrites dans les recommandations de l'ISUOG.

View	***Subview***
Vue des 4 cavités	***Sous-vue 1 (M1) :*** *L'image doit inclure le rachis, le sternum, les quatre cavités et le septum interventriculaire. Les côtes gauche et droite doivent être présentes et visibles individuellement.* ***Sous-vue 2 (M2) :*** *L'image doit inclure le rachis, le sternum et les quatre cavités. Les côtes gauche et droite doivent être présentes et visibles individuellement.* ***Sous-vue 3 (M3) :*** *L'image doit inclure le rachis et le sternum. Les côtes gauche et droite doivent être présentes et visibles individuellement. La vue des quatre cavités doit être visible et bien contrastée.* ***Sous-vue 7 (M7) :*** *L'image doit inclure le rachis, le sternum et les quatre cavités.* ***Sous-vue 11 (M11) :*** *Le thorax apparaît rond, et non en forme de « V » ouvert. Les côtes gauche et droite apparaissent comme des structures uniques, et non comme des lignes parallèles ou séquentielles multiples. L'atrium et l'aorte, en particulier leurs parois postérieures, ainsi que l'espace entre eux, sont clairement visibles, sans obstruction par des ombres.*
Vue des trois vaisseaux et vue des trois vaisseaux avec la trachée.	***Sous-vue 4 (M4) :*** *L'image doit inclure le rachis et le sternum, avec des côtes gauches et droites visibles et distinctes. Le canal artériel et l'aorte ascendante doivent être clairement visibles, montrant leur connexion.* ***Sous-vue 5 (M5) :*** *L'image doit mettre en évidence les vaisseaux, avec un contraste clair et une distinction nette des structures.* ***Sous-vue 6 (M6) :*** *L'image doit afficher le rachis, le sternum et l'aorte ascendante, avec les côtes gauche et droite visibles individuellement. Le thymus doit être clairement visible et identifiable.*
Vue Axiale	***Sous-vue 8 (M8) :*** *L'image doit présenter une vue axiale symétrique du cerveau, capturant le plan transthalamique avec les deux hémisphères visibles et nets.* ***Sous-vue 9 (M9) :*** *L'image doit montrer une vue transventriculaire axiale et symétrique du cerveau, avec une visualisation claire du cavum septum pellucidum (CSP) et des structures anatomiques de la ligne médiane.* ***Sous-vue 10 (M10) :*** *L'image doit montrer une vue axiale où le sillon pariéto-occipital (POS) est visible.*

Fonctionnalité 1 : complétude

Le logiciel évalue la complétude de l'examen échographique fœtal. Il vérifie si toutes les informations correspondant directives recommandées pour l'examen du cœur et du cerveau fœtal ont été acquises. Ces informations correspondent à la présence de 5 vues principales du cœur fœtal avec les 52 critères qualité et des 4 vues principales du cerveau fœtal avec les 43 critères qualité, détaillés dans la section ci-dessus, permettant de garantir la conformité au dépistage cardiaque et cérébral.

La page de complétude (voir la section 12 pour les instructions d'utilisation) se compose de :

- Un bouton **play/pause**, qui lance l'analyse des images acquises par la machine échographique au début de l'examen.
- Le **compteur des vues du cœur/du cerveau** vérifiées par le logiciel depuis le début de l'examen. Une vue est considérée comme vérifiée quand elle est détectée sur au moins une image.
- Le **compteur des critères qualité** vérifiés par le logiciel depuis le début de l'examen. Un critère est vérifié quand il a été détecté sur au moins une image.
- Des **boutons individuels** pour chaque critère qualité, qui deviennent verts après vérification par le logiciel.

Chaque image analysée par le logiciel met à jour dynamiquement la page de complétude comme suit :

- Si un critère qualité est détecté dans l'image pour la première fois, le critère est marqué comme **vérifié,** et sa couleur change du blanc au **vert.**
- Si un critère qualité est détecté sur une image mais a déjà été vérifié précédemment, il n'y a aucun changement,
- Si un critère qualité n'est pas détecté sur une image, il n'y a aucun changement.

Si un critère de qualité est associé à une anomalie, le statut de détection du critère dépend de son apparence visuelle :

- Si une anomalie altère l'apparence du critère qualité, le logiciel peut ne pas détecter ce critère et le statut restera non vérifié ;
- Si une anomalie n'impacte pas l'apparence du critère qualité, le logiciel détectera le critère et l'indiquera comme vérifié, changeant la couleur du blanc au **vert**.

Pour rappel, comme expliqué dans la section 10, FETOLY ne peut pas être utilisé pour réaliser un diagnostic ou un dépistage. Un critère de qualité non vérifié par le logiciel n'indique pas nécessairement une pathologie.

Fonctionnalité 2 : illustration de la complétude

Cette fonctionnalité a été développée pour améliorer la sécurité de l'évaluation de la complétude réalisée par le premier module. Elle permet aux cliniciens de vérifier l'aperçu de la compéltude de l'examen, c'est-à-dire les vues et critères de qualité vérifiés par le logiciel via la page galerie de l'interface du logiciel. Fonctionnant en continu, elle évalue chaque image traitée par le premier module en temps réel, en conservant un ensemble d'images comme preuve visuelle des vues du cœur et des critères de qualité vérifiés jusqu'à ce moment-là.

FETOLY n'a pas pour objectif de sélectionner la « meilleure » ou l'image de « haute » qualité diagnostique selon une échelle qualitative donnée. Au contraire, FETOLY vise à sélectionner des images illustrant la complétude quantitative de l'examen en termes de vues et de critères de qualité vérifiés. Étant donné que ce module repose entièrement sur la performance de l'algorithme d'apprentissage profond du premier module, aucune évaluation de performance supplémentaire n'est nécessaire.

Par exemple, si l'utilisateur a des doutes sur l'un des critères de qualité verts, il/elle peut vérifier la présence de ce critère en cliquant dessus dans la page galerie. Le logiciel affichera les images contenant ce critère. Lorsqu'un critère est sélectionné, le logiciel affiche la boîte de délimitation entourant ce critère dans ces images. Cette information de boîte de délimitation fait partie de la sortie de Fetoly-CNN.

Fonctionnalité 3 : Mesures biométriques

La section du module **FETOLY-MEASURE** est intitulée « **Mesure** » sur la page d'analyse et affiche une liste de mesures, chacune organisée en quatre champs :

- **Nom de la mesure** : Affiche le nom ou l'abréviation de la mesure accompagné d'une icône d'information. Cliquer sur cette icône ouvre des informations détaillées sur la mesure, y compris sa référence scientifique.
- **Valeur mesurée et unités** : La valeur mesurée est affichée avec ses unités correspondantes. Par exemple, un symbole de degré (°) est utilisé pour les mesures angulaires, un symbole de pourcentage (%) pour les ratios ; sinon, le champ reste vide, indiquant qu'il s'agit d'une mesure relative. Si les points clés ont été édités dans la page galerie, un symbole apparaît devant la mesure ( ).
- **Plage de référence** : Ce champ fournit la plage de référence définie dans la littérature pour la mesure, avec sa source scientifique. Celle-ci peut être une recommandation officielle, une publication évaluée par des pairs, un manuel, ou une plage personnalisée définie par l'utilisateur. En cliquant sur le bouton « nouvel onglet », l'utilisateur peut définir manuellement la plage de référence ou mettre à jour la source s'il en existe plusieurs. En cliquant sur le bouton « lien d'information », l'utilisateur accède à une fenêtre contextuelle contenant toutes les informations nécessaires concernant le critère de mesure donné.
- **Âge gestationnel**, qui doit être renseigné avant de lancer l'analyse.

Fonctionnalité 4 : illustration des mesures

Tout comme l'**illustration de complétude**, qui sélectionne des images démontrant les vues et les critères de qualité, une image est automatiquement sélectionnée pour chaque **mesure**. Les deux ensembles d'images sont affichés ensemble sur la page **Galerie**. Les images sélectionnées par la fonction de mesure sont toujours présentées en premier, suivies des images sélectionnées pour l'illustration de complétude. Ces deux ensembles d'images sont faciles à distinguer : les images issues de la fonction de mesure incluent une **valeur de mesure** et le **nom du paramètre**, tandis que les images de complétude ne comportent **aucune annotation**.

Si un seul module est accessible à l'utilisateur, l'autre restera désactivé et son résumé d'images restera vide.

Les images de « **mesure** » et de « **complétude** » sont organisées en fonction de leurs **vues échographiques correspondantes**. Veuillez noter que l'affiliation des vues des images sélectionnées par la fonction de mesure est **indépendante** de celle de la fonction de complétude. En effet, chaque **sous-vue de mesure** correspond par définition à l'une des **5**

vues cardiaques ou **4 vues cérébrales** échographiques. Ainsi, en connaissant la sous-vue, les images sélectionnées par la fonction de mesure peuvent être automatiquement **catégorisées** dans la **vue appropriée** à laquelle cette sous-vue appartient.

Fonctionnalité 5 : rapport d'examen

Un rapport peut être généré depuis la page d'exportation. Il inclura les résultats et les images issus de FETOLY et sera envoyé vers un dispositif externe.

Dispositifs associés

Pour utiliser le dispositif **FETOLY**, vous devez disposer des équipements associés suivants :

- Une **machine d'échographie**.
- Une **tablette** et, en option, un **serveur DICOM**, un **ordinateur avec un serveur FTP** ou des **capacités Bluetooth**, comme spécifié dans la section 10 « Interaction avec d'autres équipements ».
- Une **clé UVC** et un **câble HDMI** pour connecter la tablette à la machine d'échographie.

5. Destination prévue et indications

FETOLY est conçu pour analyser des séquences d'images échographiques fœtales à l'aide de techniques d'apprentissage automatique afin de :

- détecter les vues du cerveau et du cœur ainsi que les critères de qualité associés à ces vues ;
- détecter les images adaptées à la mesure des paramètres biométriques du cœur et du cerveau fœtaux, et fournir des mesures quantitatives de ces paramètres.

Le dispositif est destiné à être utilisé comme outil d'aide à la lecture simultanée lors de l'acquisition et de l'interprétation des images échographiques fœtales.

FETOLY est indiqué pour l'examen de routine du cœur et du cerveau fœtal au cours du 2e et du 3e trimestre de la grossesse (âge gestationnel : de 17 à 40 semaines).

6. Utilisateurs attendus

Le dispositif doit être utilisé par des professionnels de santé qualifiés et spécialisés en imagerie échographique prénatale.

7. Groupes cibles de patients

Femmes enceintes pendant les 2e et 3e trimestres de grossesse.

8. Bénéfices et performances cliniques

Pour ce type de dispositif, un logiciel dispositif médical, qui est un outil d'aide à la lecture simultanée utilisé lors de l'examen échographique cardiaque/cérébral fœtal de routine, le bénéfice clinique suivant a été démontré :

- Standardisation de l'examen échographique cardiaque/cérébral fœtal de routine comme l'exigent les lignes directrices internationales reconnues.

Les résultats de performance sont détaillés dans les tableaux ci-dessous. Les résultats des tests de performance démontrent que FETOLY permet automatiquement :

- de détecter les vues échographiques du cœur et du cerveau fœtaux avec une sensibilité ≥ 85 % (critère d'acceptation) et une spécificité ≥ 85 % (critère d'acceptation),
- de détecter les critères de qualité dans les vues cardiaques avec une sensibilité ≥ 90 % (critère d'acceptation) et une spécificité ≥ 90 % (critère d'acceptation),
- de détecter les critères de qualité dans les vues cérébrales avec une sensibilité ≥ 85 % (critère d'acceptation) et une spécificité ≥ 85 % (critère d'acceptation),
- de localiser les boîtes englobantes des critères de qualité avec une intersection moyenne sur union (IoU) ≥ 50 % (critère d'acceptation),
- de détecter les sous-vues échographiques du cœur et du cerveau fœtaux avec une sensibilité ≥ 70 % (critère d'acceptation) et une spécificité ≥ 70 % (critère d'acceptation),
- et de réaliser les mesures du cœur et du cerveau fœtal conformément aux limites d'accord (LOA) définies pour chaque critère d'évaluation de l'étude.

Pour les résultats globaux

Vue foetale	***Sensitivité***			***Specificité***		
	N (positif)	***Estimation ponctuelle***	***Bootstrap CI (95%)***	***N (négatif)***	***Estimation ponctuelle***	***Bootstrap CI (95%)***
Vue abdominale	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Vue 4 cavités	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Vue voie d'éjection gauche	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Vue voie d'éjection droite	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Vue 3 vaisseaux	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Vue Axiale	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Vue transcérébelleuse	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Vue sagittale	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Autre vue	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Critère qualité	***Sensitivité***			***Specificité***			***mIoU***	
	N	***Estimation ponctuelle***	***Bootstrap CI (95%)***	***N***	***Estimation ponctuelle***	***Bootstrap CI (95%)***	***Estimation ponctuelle***	***Bootstrap CI (95%)***

Vue abdominale								
Rachis	*678*	*0.99*	*(0.983,0.998)*	*4531*	*0.998*	*(0.996,0.999)*	*0.71*	*(0.70,0.73)*
Côte gauche	*632*	*0.967*	*(0.953,0.980)*	*4577*	*0.993*	*(0.991,0.995)*	*0.58*	*(0.56,0.59)*
Côte droite	*627*	*0.951*	*(0.934,0.967)*	*4582*	*0.994*	*(0.992,0.996)*	*0.55*	*(0.53,0.57)*
Aorte descendante	*673*	*0.972*	*(0.959,0.984)*	*4536*	*0.998*	*(0.996,0.999)*	*0.52*	*(0.51,0.54)*
Veine cave inférieure	*550*	*0.939*	*(0.917,0.958)*	*4659*	*0.987*	*(0.983,0.990)*	*0.5*	*(0.49,0.52)*
Estomac	*675*	*0.983*	*(0.973,0.992)*	*4534*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.75)*
Veine ombilicale	*552*	*0.973*	*(0.958,0.986)*	*4657*	*0.99*	*(0.988,0.993)*	*0.64*	*(0.62,0.65)*
Abdomène antérieur	*643*	*0.969*	*(0.954,0.983)*	*4566*	*0.993*	*(0.990,0.995)*	*0.5*	*(0.49,0.52)*
Vue des 4 cavités								
Rachis	*595*	*0.969*	*(0.955,0.982)*	*4614*	*0.998*	*(0.996,0.999)*	*0.74*	*(0.73,0.75)*
Côte gauche	*536*	*0.945*	*(0.924,0.963)*	*4673*	*0.99*	*(0.987,0.993)*	*0.64*	*(0.63,0.66)*
Côte droite	*548*	*0.948*	*(0.926,0.965)*	*4661*	*0.993*	*(0.991,0.996)*	*0.68*	*(0.66,0.69)*
Aorte descendante	*608*	*0.968*	*(0.952,0.981)*	*4601*	*0.997*	*(0.995,0.998)*	*0.66*	*(0.65,0.67)*
Veine pulmonaire gauche	*240*	*0.925*	*(0.889,0.958)*	*4969*	*0.975*	*(0.971,0.979)*	*0.51*	*(0.48,0.53)*
Veine pulmonaire droite	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*
Oreillette gauche	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Oreillette droite	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Valve de Vieussens	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Foramen oval ouvert	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Valve mitrale	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Valve tricuspide	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Connexion entre la croix du coeur et le septum interauriculaire	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Atrioventricular valve offset in crux	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Décalage des valves auriculo-ventriculaires au niveau de la croix du cœur	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*

Continuité du septum ventriculaire membraneux	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Ventricule gauche	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Ventricule droit	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Sternum	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Vue de la voie d'éjection gauche								
Oreillette gauche	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Aorte ascendante proximale	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Valves semi-lunaires	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Ventricule gauche	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Septum interventriculaire – continuité septo aortique	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Ventricule droit	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Vue de la voie d'éjection droite								
Aorte descendante	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Trachée/bronches	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Artère pulmonaire gauche	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*
Canal artériel	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Artère pulmonaire droite	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Origine des artères pulmonaires	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Continuité du septum entre le tronc pulmonaire et l'aorte ascendante	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Aorte ascendante	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Veine cave supérieure	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Tronc de l'artère pulmonaire	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Vue des 3 vaisseaux								
Rachis	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*

Trachée	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Espace latéral à gauche du canal artériel / de l'origine de l'artère pulmonaire	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Crosse du canal artériel relié à l'aorte descendante	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Crosse du canal artériel non relié à l'aorte descendante	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Aorte ascendante	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Arc aortique	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Veine cave supérieure	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Thymus et Sternum	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Vue Axiale								
Faux antérieure du cerveau	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavum Septum Pellucidum	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Fornix	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Ventricule antérieur distal	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Ventricule antérieur proximal	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Citerne ambiante	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Atrium	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Plexus Choroïdes	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Sillon pariéto-occipital	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Faux postérieure du cerveau	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Suture coronale distale	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Suture coronale proximale	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Vallée sylvienne	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*

Crâne	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Séparation des thalami	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
3e ventricule	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Thalamus distal	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Thalamus proximal	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Vue transcérébelleuse								
Thalamus distal	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Thalamus proximal	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
4e ventricule	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Vermis	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Hémisphère cérébelleux distal	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Hémisphère cérébelleux proximal	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Bord du cervelet	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Grande citerne	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Vue Sagittale								
Os nasal	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Partie supérieure du vermis	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Partie inférieure du vermis	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastigium	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Rostrum et Genu du corps calleux	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Corps du corps calleux	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Splenium du corps calleux	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavum Septum Pellicidum	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Mesure	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	LOA	LOA CI
Ratio thymique-thoracique	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
Ratio cardiothoracique	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)

Ratio des gros vaisseaux	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
Indice céphalique	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
Nombre de vaisseaux	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
Position cardiothoracique	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
Ratio de la largeur ventriculaire	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
Axe cardiaque	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
Ratio du CSP	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
VP-ratio	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
Indice de l'Espace Post-Atrium Gauche	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Measure	Pente	Ordonnée à l'origine	Pente CI	Ordonnée à l'origine CI
Ratio thymique-thoracique	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
Ratio cardiothoracique	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
Ratio des gros vaisseaux	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
Indice céphalique	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
Nombre de vaisseaux	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
Position cardiothoracique	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
Ratio de la largeur ventricu-laire	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
Axe cardiaque	*0.9197936528230518*	*3.1140776915381 99*	*(0.888,0.945)*	*(2.023,4.477)*
Ratio du CSP	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
VP-ratio	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
Indice de l'Espace Post-Atrium Gauche	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Pour les résultats par fabricant de machine ultrasons

Classe	Système	n(positif)	Se	Se CI	n(negatif)	Sp	Sp CI
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)

E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
I	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)
I	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)
X	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
X	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
X	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)

Classe	Système	n(positif)	Se	Se CI	n(negatif)	Sp	Sp CI	mIoU	mIoU CI
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*
A.Sp	*Samsung*	*296*	*0.984*	*(0.967,0.994)*	*1708*	*0.999*	*(0.997,1.000)*	*0.7*	*(0.68,0.71)*
A.St	*Canon*	*29*	*0.966*	*(0.893,1.000)*	*207*	*0.991*	*(0.975,1.000)*	*0.72*	*(0.67,0.76)*
A.St	*GE*	*279*	*0.993*	*(0.983,1.000)*	*2261*	*1.0*	*(1.000,1.000)*	*0.79*	*(0.77,0.80)*
A.St	*Samsung*	*293*	*0.973*	*(0.954,0.990)*	*1711*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
A.Uv	*Canon*	*25*	*0.96*	*(0.870,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.6*	*(0.51,0.67)*
A.Uv	*GE*	*217*	*0.977*	*(0.955,0.996)*	*2323*	*0.991*	*(0.988,0.995)*	*0.67*	*(0.65,0.70)*
A.Uv	*Samsung*	*240*	*0.967*	*(0.944,0.988)*	*1764*	*0.989*	*(0.984,0.993)*	*0.62*	*(0.59,0.64)*
A.VC	*Canon*	*26*	*0.885*	*(0.750,1.000)*	*210*	*0.986*	*(0.970,1.000)*	*0.46*	*(0.40,0.52)*
A.VC	*GE*	*221*	*0.973*	*(0.950,0.992)*	*2319*	*0.987*	*(0.983,0.991)*	*0.54*	*(0.52,0.57)*
A.VC	*Samsung*	*247*	*0.903*	*(0.864,0.939)*	*1757*	*0.989*	*(0.984,0.994)*	*0.49*	*(0.47,0.51)*
B.Ao	*Canon*	*27*	*0.926*	*(0.808,1.000)*	*209*	*0.996*	*(0.985,1.000)*	*0.71*	*(0.66,0.77)*
B.Ao	*GE*	*247*	*0.956*	*(0.926,0.980)*	*2293*	*0.997*	*(0.994,0.999)*	*0.73*	*(0.71,0.75)*
B.Ao	*Samsung*	*255*	*0.977*	*(0.956,0.993)*	*1749*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.58,0.62)*
B.bCr	*Canon*	*25*	*0.92*	*(0.800,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.65*	*(0.58,0.72)*
B.bCr	*GE*	*202*	*0.892*	*(0.849,0.932)*	*2338*	*0.992*	*(0.989,0.996)*	*0.61*	*(0.57,0.64)*
B.bCr	*Samsung*	*216*	*0.926*	*(0.889,0.959)*	*1788*	*0.984*	*(0.979,0.989)*	*0.54*	*(0.52,0.57)*

B.Cr	Canon	7	0.715	(0.334,1.000)	229	0.983	(0.967,0.996)	0.62	(nan,nan)
B.Cr	GE	52	0.885	(0.789,0.961)	2488	0.989	(0.985,0.993)	0.52	(0.46,0.58)
B.Cr	Samsung	76	0.974	(0.933,1.000)	1928	0.977	(0.971,0.983)	0.57	(0.52,0.61)
B.FO	Canon	26	0.962	(0.880,1.000)	210	1.0	(1.000,1.000)	0.7	(0.62,0.78)
B.FO	GE	215	0.935	(0.899,0.965)	2325	0.994	(0.991,0.997)	0.64	(0.62,0.67)
B.FO	Samsung	257	0.965	(0.941,0.985)	1747	0.994	(0.991,0.998)	0.58	(0.55,0.60)
B.FOF	Canon	8	0.75	(0.375,1.000)	228	1.0	(1.000,1.000)	0.56	(0.42,0.67)
B.FOF	GE	108	0.899	(0.841,0.949)	2432	0.998	(0.996,1.000)	0.5	(0.47,0.53)
B.FOF	Samsung	63	0.921	(0.845,0.984)	1941	0.993	(0.989,0.996)	0.51	(0.47,0.55)
B.IVS	Canon	15	0.934	(0.770,1.000)	221	0.982	(0.965,0.996)	0.65	(0.53,0.75)
B.IVS	GE	165	0.867	(0.806,0.915)	2375	0.992	(0.988,0.995)	0.62	(0.59,0.66)
B.IVS	Samsung	152	0.922	(0.872,0.962)	1852	0.984	(0.978,0.989)	0.64	(0.61,0.67)
B.LA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.75	(0.71,0.79)
B.LA	GE	264	0.966	(0.942,0.986)	2276	0.999	(0.997,1.000)	0.79	(0.78,0.81)
B.LA	Samsung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Samsung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Samsung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)
B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)

B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)
D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)

D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)
F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)

F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)
G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)

G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Samsung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Samsung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)
G.pCH	Samsung	182	0.94	(0.905,0.973)	1822	0.999	(0.998,1.000)	0.74	(0.72,0.77)
G.pTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.58	(0.51,0.65)
G.pTh	GE	216	0.922	(0.884,0.954)	2324	0.995	(0.992,0.998)	0.62	(0.60,0.64)
G.pTh	Samsung	119	0.95	(0.905,0.984)	1885	0.998	(0.996,1.000)	0.59	(0.57,0.62)
G.Ver	Canon	23	0.914	(0.783,1.000)	213	1.0	(1.000,1.000)	0.62	(0.54,0.70)
G.Ver	GE	288	0.893	(0.859,0.928)	2252	0.996	(0.993,0.999)	0.61	(0.59,0.63)
G.Ver	Samsung	138	0.892	(0.840,0.942)	1866	0.997	(0.994,0.999)	0.52	(0.49,0.55)
I.bCC	Canon	15	1.0	(1.000,1.000)	221	0.987	(0.971,1.000)	0.59	(0.51,0.67)
I.bCC	GE	168	0.923	(0.878,0.962)	2372	0.995	(0.993,0.998)	0.57	(0.54,0.60)
I.bCC	Samsung	54	0.815	(0.699,0.910)	1950	0.996	(0.994,0.999)	0.57	(0.52,0.62)
I.CSP	Canon	20	0.95	(0.824,1.000)	216	1.0	(1.000,1.000)	0.75	(0.69,0.81)
I.CSP	GE	196	0.888	(0.841,0.928)	2344	1.0	(0.999,1.000)	0.72	(0.69,0.74)
I.CSP	Samsung	79	0.849	(0.760,0.924)	1925	1.0	(1.000,1.000)	0.7	(0.66,0.75)
I.Fas	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.63	(0.46,0.79)
I.Fas	GE	99	0.889	(0.819,0.951)	2441	1.0	(0.999,1.000)	0.56	(0.52,0.60)
I.Fas	Samsung	33	0.97	(0.900,1.000)	1971	0.999	(0.997,1.000)	0.55	(0.49,0.61)
I.lVer	Canon	14	0.929	(0.750,1.000)	222	1.0	(1.000,1.000)	0.69	(0.60,0.77)
I.lVer	GE	102	0.912	(0.850,0.960)	2438	0.999	(0.998,1.000)	0.7	(0.66,0.73)
I.lVer	Samsung	41	0.927	(0.834,1.000)	1963	1.0	(0.999,1.000)	0.64	(0.59,0.69)
I.NB	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.71	(0.61,0.82)
I.NB	GE	115	0.905	(0.844,0.955)	2425	0.992	(0.989,0.996)	0.63	(0.59,0.67)
I.NB	Samsung	60	0.917	(0.837,0.982)	1944	0.998	(0.996,1.000)	0.64	(0.58,0.69)
I.rgCC	Canon	18	0.945	(0.824,1.000)	218	0.991	(0.978,1.000)	0.48	(0.41,0.56)
I.rgCC	GE	177	0.888	(0.833,0.930)	2363	0.998	(0.996,1.000)	0.56	(0.54,0.59)
I.rgCC	Samsung	65	0.893	(0.808,0.965)	1939	1.0	(0.999,1.000)	0.48	(0.43,0.53)
I.sCC	Canon	13	0.847	(0.616,1.000)	223	0.992	(0.978,1.000)	0.48	(0.36,0.61)
I.sCC	GE	114	0.922	(0.868,0.964)	2426	0.992	(0.988,0.995)	0.51	(0.48,0.54)
I.sCC	Samsung	40	0.9	(0.796,1.000)	1964	0.998	(0.996,1.000)	0.45	(0.39,0.53)
I.uVer	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.57	(0.49,0.65)
I.uVer	GE	116	0.88	(0.815,0.931)	2424	0.999	(0.998,1.000)	0.6	(0.56,0.63)
I.uVer	Samsung	48	0.938	(0.861,1.000)	1956	0.999	(0.998,1.000)	0.52	(0.48,0.56)

Mesure	Système	n(positif)	Se	Se CI	n(negatif)	Sp	Sp CI	LOA	LOA CI
Axe cardiaque	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
Axe cardiaque	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
Axe cardiaque	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
Position cardiothoracique	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
Position cardiothoracique	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
Position cardiothoracique	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*
Ratio cardiothoracique	Canon	*23*	*1.0*	*(1.000,1.000)*	*37*	*0.946*	*(0.865,1.000)*	*0.078*	*(0.041,0.117)*
Ratio cardiothoracique	GE	*225*	*0.969*	*(0.944,0.991)*	*262*	*0.908*	*(0.874,0.943)*	*0.059*	*(0.049,0.073)*
Ratio cardiothoracique	Samsung	*105*	*0.952*	*(0.909,0.989)*	*232*	*0.776*	*(0.724,0.828)*	*0.051*	*(0.042,0.061)*
Indice céphalique	Canon	*28*	*0.929*	*(0.821,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.026*	*(0.021,0.032)*
Indice céphalique	GE	*195*	*0.944*	*(0.909,0.974)*	*262*	*0.943*	*(0.916,0.969)*	*0.03*	*(0.026,0.036)*
Indice céphalique	Samsung	*90*	*0.989*	*(0.964,1.000)*	*232*	*0.909*	*(0.871,0.944)*	*0.023*	*(0.020,0.026)*
Ratio de la largeur ventriculaire	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.865*	*(0.757,0.973)*	*0.106*	*(0.080,0.128)*
Ratio de la largeur ventriculaire	GE	*235*	*0.923*	*(0.883,0.957)*	*262*	*0.901*	*(0.859,0.939)*	*0.127*	*(0.090,0.173)*
Ratio de la largeur ventriculaire	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.931*	*(0.901,0.961)*	*0.099*	*(0.087,0.115)*
Ratio thymique-thoracique	Canon	*19*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.047*	*(0.039,0.059)*
Ratio thymique-thoracique	GE	*174*	*0.902*	*(0.856,0.944)*	*262*	*0.924*	*(0.889,0.954)*	*0.051*	*(0.045,0.059)*
Ratio thymique-thoracique	Samsung	*138*	*0.942*	*(0.900,0.978)*	*232*	*0.892*	*(0.853,0.931)*	*0.059*	*(0.049,0.070)*
Nombre de vaisseaux	Canon	*21*	*0.905*	*(0.760,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.0*	*(0.000,0.000)*
Nombre de vaisseaux	GE	*209*	*0.933*	*(0.895,0.966)*	*262*	*0.969*	*(0.947,0.989)*	*0.281*	*(0.138,0.406)*
Nombre de vaisseaux	Samsung	*113*	*0.929*	*(0.879,0.974)*	*232*	*0.966*	*(0.940,0.987)*	*0.329*	*(0.000,0.491)*
Ratio des gros vaisseaux	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.112*	*(0.091,0.145)*
Ratio des gros vaisseaux	GE	*194*	*0.979*	*(0.956,0.995)*	*262*	*0.977*	*(0.954,0.992)*	*0.109*	*(0.099,0.121)*
Ratio des gros vaisseaux	Samsung	*122*	*0.984*	*(0.958,1.000)*	*232*	*0.922*	*(0.888,0.953)*	*0.111*	*(0.100,0.125)*
Ratio du CSP	Canon	*25*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.842*	*(0.608,1.028)*
Ratio du CSP	GE	*226*	*0.854*	*(0.805,0.899)*	*262*	*0.977*	*(0.954,0.992)*	*0.826*	*(0.753,0.889)*
Ratio du CSP	Samsung	*107*	*0.879*	*(0.821,0.935)*	*232*	*0.991*	*(0.978,1.000)*	*0.835*	*(0.755,0.907)*
VP-ratio	Canon	*22*	*0.909*	*(0.773,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.064*	*(0.043,0.084)*
VP-ratio	GE	*206*	*0.956*	*(0.925,0.981)*	*262*	*1.0*	*(1.000,1.000)*	*0.065*	*(0.059,0.071)*
VP-ratio	Samsung	*91*	*0.956*	*(0.910,0.990)*	*232*	*1.0*	*(1.000,1.000)*	*0.066*	*(0.056,0.075)*
Indice de l'Espace Post-Atrium Gauche	Canon	*16*	*0.938*	*(0.800,1.000)*	*37*	*0.919*	*(0.837,1.000)*	*0.094*	*(0.067,0.114)*
Indice de l'Espace Post-Atrium Gauche	GE	*181*	*0.978*	*(0.953,0.995)*	*262*	*0.924*	*(0.889,0.954)*	*0.086*	*(0.079,0.091)*
Indice de l'Espace Post-Atrium Gauche	Samsung	*159*	*0.981*	*(0.957,1.000)*	*232*	*0.953*	*(0.922,0.978)*	*0.07*	*(0.065,0.078)*

Pour les résultats des sous-groupes EU vs. US

Classe	Continent	n(positif)	Se	Se CI	n(negatif)	Sp	Sp CI
A	EU	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	US	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	EU	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	US	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	EU	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	US	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)

D	EU	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	US	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	EU	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	US	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	EU	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	US	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	EU	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	US	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	EU	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	US	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	EU	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	US	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Classe	Continent	n(positif)	Se	Se CI	n(negatif)	Sp	Sp CI	mIoU	mIoU CI
A.aA	EU	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	US	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	EU	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	US	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	EU	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	US	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	EU	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	US	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	EU	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*
A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*

B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*
C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	US	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	EU	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	US	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	EU	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	US	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*

D.rPA	EU	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	US	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	EU	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*
D.S	US	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	EU	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	US	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	EU	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	US	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	EU	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	US	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	EU	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	US	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	EU	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	US	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	EU	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	US	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	EU	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	US	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	EU	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	US	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	EU	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	US	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	EU	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	US	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*
E.Tr	EU	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*
E.Tr	US	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	EU	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	US	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	EU	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	US	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	EU	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*
F.aFx	US	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	EU	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	US	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	EU	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	US	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	EU	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	US	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	EU	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	US	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	EU	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*

F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*
G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*

I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Mesure	Continent	n(positif)	Se	Se CI	n(negatif)	Sp	Sp CI	LOA	LOA CI
Axe cardiaque	EU	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
Axe cardiaque	US	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
Position cardiothoracique	EU	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
Position cardiothoracique	US	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
Ratio cardiothoracique	EU	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
Ratio cardiothoracique	US	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
Indice céphalique	EU	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
Indice céphalique	US	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
Ratio de la largeur ventriculaire	EU	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
Ratio de la largeur ventriculaire	US	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
Ratio thymique-thoracique	EU	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
Ratio thymique-thoracique	US	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)
Nombre de vaisseaux	EU	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
Nombre de vaisseaux	US	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
Ratio des gros vaisseaux	EU	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
Ratio des gros vaisseaux	US	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
Ratio du CSP	EU	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
Ratio du CSP	US	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
VP-ratio	EU	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
VP-ratio	US	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
Indice de l'Espace Post-Atrium Gauche	EU	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
Indice de l'Espace Post-Atrium Gauche	US	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Contre-indications

Il n'y a pas de contre-indication liée à FETOLY.

10. Risques résiduels, précautions, interactions avec d'autres équipements

Risques résiduels et précautions issus du dossier de management des risques :

- L'utilisateur doit zoomer d'au moins 30 % pour éviter les faux négatifs du logiciel ;
- L'utilisateur doit systématiquement examiner l'ensemble des images sélectionnées avant l'exportation ;
- Une négligence de la fonction de réinitialisation peut entraîner une confusion des dossiers patients et contribuer à des faux négatifs dans le dépistage ;
- Les images supprimées lors de la sélection des images sont définitivement perdues ;
- La configuration de l'entrée du flux vidéo peut contribuer à des faux négatifs dans le dépistage ;

- Un flux vidéo incompatible peut entraîner une erreur dans la documentation de l'examen. Le flux vidéo doit avoir les caractéristiques suivantes :
    - Au moins 24 images par seconde (ips) ;
    - Une résolution inférieure à 1280*720.
- L'incompatibilité de la tablette peut entraîner une erreur dans la documentation de l'examen ;
- Un échec d'exportation entraîne la perte du rapport d'examen ;
- Veuillez vérifier le nom du patient choisi avant l'exportation DICOM sur la page d'exportation pour éviter la confusion des dossiers patients ;
- L'utilisation lors du 1er trimestre de grossesse entraîne des erreurs dans la fonction de complétude ;
- L'examen doit être réalisé sur un seul fœtus à la fois ;
- Si la tablette commence à surchauffer, arrêtez d'utiliser le logiciel ;
- Veuillez vérifier le niveau de la batterie de votre tablette avant l'examen. L'arrêt du logiciel peut entraîner la perte des données de l'examen ;
- Le logiciel ne peut pas être utilisé à des fins de dépistage, car cela peut contribuer à des faux négatifs dans le dépistage ;
- Utilisez la tablette seule et ne permettez pas à une personne non autorisée d'accéder à votre tablette pour éviter les risques de cybersécurité ;
- Veuillez noter que lorsque les données sont exportées sur votre appareil, elles sont sous votre responsabilité ;
- Ne pas utiliser d'autres applications sur la tablette en parallèle à FETOLY afin d'éviter toute interférence avec le processus de réception du flux d'images ou l'exécution des calculs d'apprentissage automatique.
- Ne pas utiliser l'application lors d'un examen avec une sonde transvaginale, car le produit n'a pas été testé avec des images transvaginales.

Avertissements et précautions issus de l'étude de performance du logiciel :

- La sensibilité du logiciel peut être plus faible pour la détection de :
    - Les critères de qualité du cœur suivants : Décalage des valves auriculo-ventriculaires au niveau de la croix du cœur (vue 4-cavités)
    - Les critères de qualité cérébrale suivants :
        - Suture coronale proximale (vue axiale)
        - Cavum Septum Pellucidum (vue axiale)
        - 3e ventricule (vue axiale)

  Les utilisateurs doivent faire preuve de prudence pour cette vue et ces critères de qualité, et vérifier les résultats.

Interactions avec d'autres équipements

Le logiciel FETOLY est conçu pour fonctionner sur une large gamme de tablettes sans dépendre du calcul dans le cloud externe. FETOLY est configuré pour recevoir un flux vidéo d'échographie, ce qui peut être réalisé par un système d'échographie équipé d'une sortie HDMI connectée au matériel exécutant le logiciel.

Le logiciel est compatible avec les appareils d'échographie des marques General Electric, Samsung et Canon.

Le logiciel nécessite la configuration minimale suivante pour la tablette :

- Architecture CPU ARMv8
- Processeur Snapdragon 8, ou

- Processeur M1, ou
- Processeur A14, et
- Au moins 8 Go de RAM
- Au moins 1 Go de capacité de stockage
- Android version 13/ iOS version 17 ou supérieure

Les modèles de tablettes recommandés sont :
- Samsung Galaxy Tab S8 ou supérieure
- Ipad Air 5 ou supérieure
- Ipad 10 ou supérieure
- Ipad mini 7 ou supérieure
- Ipad Pro 3 ou supérieure

N'hésitez pas à contacter le support Diagnoly à support@diagnoly.com en cas de doute sur le choix du modèle de tablette.

Les images étiquetées par FETOLY peuvent être sauvegardées directement sur la tablette ou envoyées à un autre appareil connecté au même réseau que celui exécutant FETOLY. Pour utiliser cette option, le logiciel nécessite un serveur FTP sur l'appareil cible, un serveur DICOM Store ou une connexion Bluetooth.

11. Effets indésirables

Il n'y a pas d'effet indésirable lié à FETOLY.

12. Informations de cybersécurité

12.1. Description de la Protection des Fonctionnalités Critiques à Haut Niveau

Cette section fournit une description générale des fonctionnalités du dispositif qui protègent les fonctionnalités critiques. La réception du flux d'images et les fonctionnalités d'analyse d'images dépendent des ressources locales (câble physique, modèle d'IA en périphérie) et ne nécessitent pas internet pour fonctionner. Le logiciel ne stocke ni ne gère les données des patients, mais permet à l'utilisateur d'exporter, après un examen, un rapport d'examen vers un dispositif tiers. Un mode d'exportation de secours est disponible si le réseau local est compromis, permettant aux utilisateurs de sauvegarder les rapports sur le système de fichiers de la tablette.

12.2. Risques de cybersécurité inhérents au dispositif

Les risques inhérents à la cybersécurité de FETOLY incluent :

- Le vol de données patients
- Des soins moins performants pour le patient en raison d'un dysfonctionnement de l'IA, tels que des modifications des poids du modèle ou des modifications du logiciel/système d'exploitation
- Une mauvaise utilisation de l'appareil, entraînant des résultats différents de ceux prévus par le fabricant ou attendus par l'utilisateur
- La perte de temps pour l'utilisateur.

Ces risques sont contrôlés par l'analyse des risques.

12.3. Diagramme des contrôles de cybersécurité recommandés



Le diagramme décrit l'environnement du logiciel FETOLY fonctionnant sur la tablette de l'utilisateur ainsi que les communications d'entrée/sortie avec le système d'échographie et le dispositif tiers.

Il inclut les références aux contrôles de cybersécurité recommandés pour l'environnement d'utilisation prévu décrit dans la section 12.4 :

- G1 : Fonctionnement sécurisé avec des systèmes tiers via FTP sur SSL/TLS
- G2 : Fonctionnement sécurisé avec des systèmes tiers via Bluetooth (Android seulement)
- G3 : Contrôle sécurisé de l'accès au dispositif
- G4 : Fonctionnement sécurisé avec des systèmes tiers via DICOM sur SSL/TLS

12.4. Instructions relatives au dispositif et spécifications du produit concernant les contrôles de cybersécurité recommandés adaptés à l'environnement d'utilisation prévu

Directives pour un fonctionnement sécurisé avec des systèmes tiers via FTP sur SSL/TLS (G1) :

- Exigences réseau minimales : L'infrastructure réseau doit prendre en charge FTP sur SSL/TLS (FTPS) et le serveur FTP doit être compatible avec FTPS. Implémentez une segmentation réseau et des règles de pare-feu pour restreindre l'accès aux services et adresses IP nécessaires.
- Installation d'un serveur FTP sur SSL/TLS, tel que :
    - Windows 10/11 avec IIS : Référez-vous à la documentation de Microsoft pour configurer FTP sur TLS/SSL avec IIS.
    - FileZilla Server (multiplateforme) : Configurez FTPES « Require explicit FTP over TLS », créez un utilisateur avec un mot de passe robuste*, définissez un chemin de stockage des données (par exemple, C:\FetolyData ou /home/shared/FetolyData), et configurez les règles de pare-feu pour le programme ou le port spécifique utilisé par le serveur FTP.

Directives pour un fonctionnement sécurisé avec des systèmes tiers via Bluetooth (G2, Android seulement) :

- Exigences réseau minimales : Version Bluetooth 5 ou supérieure.

- Définissez un mot de passe robuste dans le logiciel pour protéger les données patient exportées*.

Directives pour un contrôle sécurisé de l'accès au dispositif (G3) :

- Configurez un écran de verrouillage avec un mot de passe robuste*, un code PIN ou une authentification biométrique.
- Activez les mises à jour automatiques pour le système d'exploitation et toutes les applications installées.
- Désactivez toutes les interfaces réseau inutilisées (par exemple, NFC, IR).

Directives pour une utilisation sécurisée avec des systèmes tiers via DICOM (G4) :

- Assurez-vous que les communications s'effectuent sur un réseau sécurisé et segmenté, en limitant l'accès grâce à des configurations de pare-feu robustes et des mécanismes de contrôle d'accès efficaces.

Recommandations pour des mots de passe robustes :

- Long : Au moins 16 caractères (plus long si possible).
- Aléatoire : Une chaîne de lettres majuscules et minuscules, chiffres et symboles mélangés (le plus fort !) ou une phrase secrète composée de 5 à 7 mots aléatoires.
- Unique : Utilisé pour un seul compte ou appareil.

En cas de vulnérabilité ou d'incident de cybersécurité détecté :

- Signalez immédiatement l'incident à votre équipe de sécurité informatique et à Diagnoly (support@diagnoly.com).
- Sur la tablette :
    - Réinitialisation : Restaurez les paramètres d'usine pour effacer toutes les données et configurations.
    - Réinstallation de l'application : Téléchargez la dernière version sécurisée de l'application depuis le Google Play Store.
    - Option de secours : Utilisez l'exportation locale sur une carte SD si les exportations via le réseau sont compromises.

12.5. Liste des ports réseau et autres interfaces

Le logiciel FETOLY reçoit les données du flux d'entrée via un câble connecté entre la sortie de moniteur externe du système d'échographie et l'entrée USB-C de la tablette. Le logiciel peut être configuré pour exporter des rapports d'examen vers un dispositif tiers via TCP/IP FTPS, DICOM ou Bluetooth.

Pour l'exportation de données via le réseau TCP/IP FTPS :

- Protocole : FTPS
- Ports entrants : Le logiciel n'ouvre aucun port entrant lui-même, car il fonctionne uniquement en tant que client, et non en tant que serveur.
- Ports sortants : Le logiciel utilise un port éphémère assigné dynamiquement (plage : 1024-65535) pour établir une connexion avec le serveur FTPS à une adresse IP spécifiée. Le port entrant du serveur FTPS tiers est défini par l'utilisateur.
- Règles de pare-feu : Les pare-feux côté client et serveur doivent autoriser les connexions sortantes du client vers le port du serveur.

Pour l'exportation de données via Bluetooth/OBEX (Android seulement) :

- Chiffrement : Les données sont compressées (zippées) et protégées par un mot de passe.

Exportation des données via DICOM :

- **Protocole :** DICOM
- **Ports entrants :** Le logiciel n'ouvre aucun port entrant, car il fonctionne uniquement comme client et non comme serveur.
- **Ports sortants :** Le logiciel utilise un port éphémère attribué dynamiquement pour établir une connexion au serveur DICOM à une adresse IP spécifiée :
    - **Android :** de 32 768 à 60 999

      Le port entrant du serveur DICOM tiers est défini par l'utilisateur.
- **Règles de pare-feu :** Les pares-feux, côté client et côté serveur, doivent autoriser les connexions sortantes du client vers le port du serveur DICOM.

12.6. Exigences relatives à l'infrastructure de support

Reportez-vous à la section 9 pour connaître les exigences relatives à l'infrastructure, y compris la configuration minimale de la tablette et les systèmes d'échographie compatibles.

12.7. Nomenclature du logiciel (sBoM)

Une nomenclature est disponible pour les utilisateurs afin de gérer leurs actifs, comprendre l'impact potentiel des vulnérabilités identifiées et déployer des contre-mesures pour maintenir la sécurité et l'efficacité du dispositif. La sBoM est téléchargeable depuis la page « À propos » du logiciel, dans un format lisible par machine (.csv), en cliquant sur « afficher » devant « Avis de tiers ».

12.8. Instructions de mises à jour

Reportez-vous à la section 13 « Mise à jour du logiciel et de la licence » pour les instructions de mise à jour.

12.9. Description de la réponse du dispositif en cas de détection de conditions anormales

Cette section décrit la réponse du logiciel aux événements de sécurité. Tous les crashs du logiciel sont exportés via un journal de crash vers Firebase. Les avertissements suivants peuvent apparaître lors de l'utilisation de FETOLY :

- Échec de l'exportation : anomalie réseau entraînant l'échec de l'exportation du rapport via TCP/IP FTPS, DICOM ou Bluetooth.
- Échec de la connexion USB : aucun câble USB-C connecté à la tablette ou échec de la réception du flux vidéo USB-C.
- Échec de la validation de la licence : tentative de validation de la licence par l'utilisateur sans connexion Internet, activation automatique de l'heure ou licence valide.
- Surchauffe de la tablette.
- Problème de compatibilité de la tablette : fréquence d'images du flux vidéo inférieure à 24 fps.
- Batterie faible de la tablette.

12.10. Sauvegarde et Restauration

Pour restaurer les fonctionnalités et la configuration par défaut du dispositif, désinstallez et réinstallez le dispositif via le Google Play/ App Store.

12.11. Description des méthodes de conservation et de récupération de la configuration du dispositif par un utilisateur autorisé authentifié

Les paramètres d'exportation, tels que les identifiants des dispositifs tiers, et les paramètres de capture vidéo, tels que le ratio vidéo d'entrée, sont conservés dans le cache de stockage de données de la tablette, isolés de manière sécurisée par Android. Étant donné que les configurations mentionnées ci-dessus sont rapides à configurer, aucune méthodologie spécifique de récupération n'est mise en place. Les utilisateurs sont invités à saisir à nouveau les paramètres manuellement lors de la réinstallation ou de l'installation d'un nouveau dispositif.

12.12. Configuration de la sécurité

Cette section fournit des instructions pour garantir que le logiciel FETOLY est configuré et maintenu de manière sécurisée.

Configuration initiale : Téléchargez et installez la dernière version depuis le Google Play/ App Store. Vérifiez que le nom et l'icône de l'application correspondent à ceux fournis dans la section 13. Effectuez toutes les étapes de configuration de l'exportation via une connexion réseau sécurisée conformément aux directives G1, G2 de la section 12.4. Assurez-vous que le dispositif exécutant FETOLY est sécurisé conformément à la directive G3 de la section 12.4.

Réponse aux incidents : Activez la connexion Internet pour enregistrer les crashs et les activités anormales, comme décrit dans la section 12.13. Signalez toute vulnérabilité détectée conformément aux directives de la section 12.4.

12.13. Collecte de preuves judiciaires, si approprié, pour l'environnement d'utilisation prévu

Un système de rapport d’accident est intégré au logiciel. Les rapports d’accident sont envoyés en cas d’échec de l'application ou d'événement anormal si une connexion Internet est activée.

12.14. Informations sur la fin de vie et la fin du support pour le système ou les composants, si elles sont connues ou anticipées.

La fin de vie et la fin du support dépendent de la validité de la licence. La licence sera renouvelée automatiquement via une connexion Internet tant que le contrat de licence est toujours valide. Si le contrat est expiré ou que la fin de vie du produit est atteinte, un nouveau code d’enregistrement vous sera demandé.

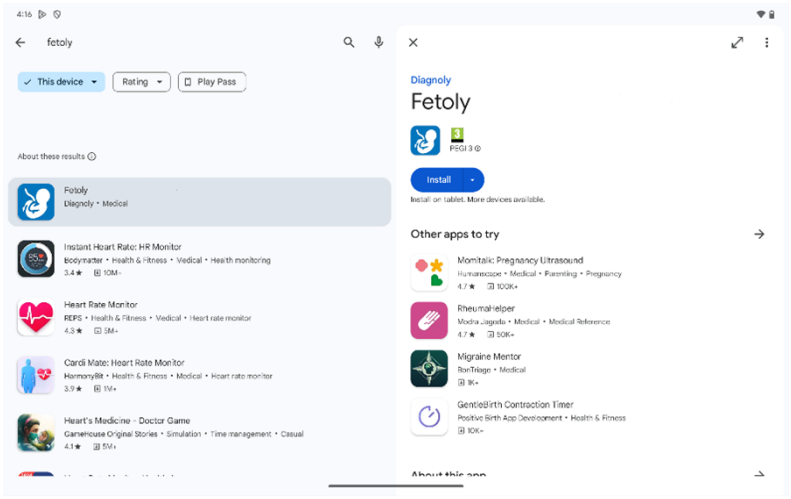
12.15. Désinstallation sécurisée

Pour mettre hors service et disposer du logiciel, désinstallez l'application via le système Android comme toute autre application sur votre tablette, dans les paramètres de l'application, comme illustré dans la section 13 au paragraphe "désinstallation du logiciel". Cette désinstallation supprimera toutes les données liées à l'utilisation de FETOLY, y compris la licence, de votre tablette.

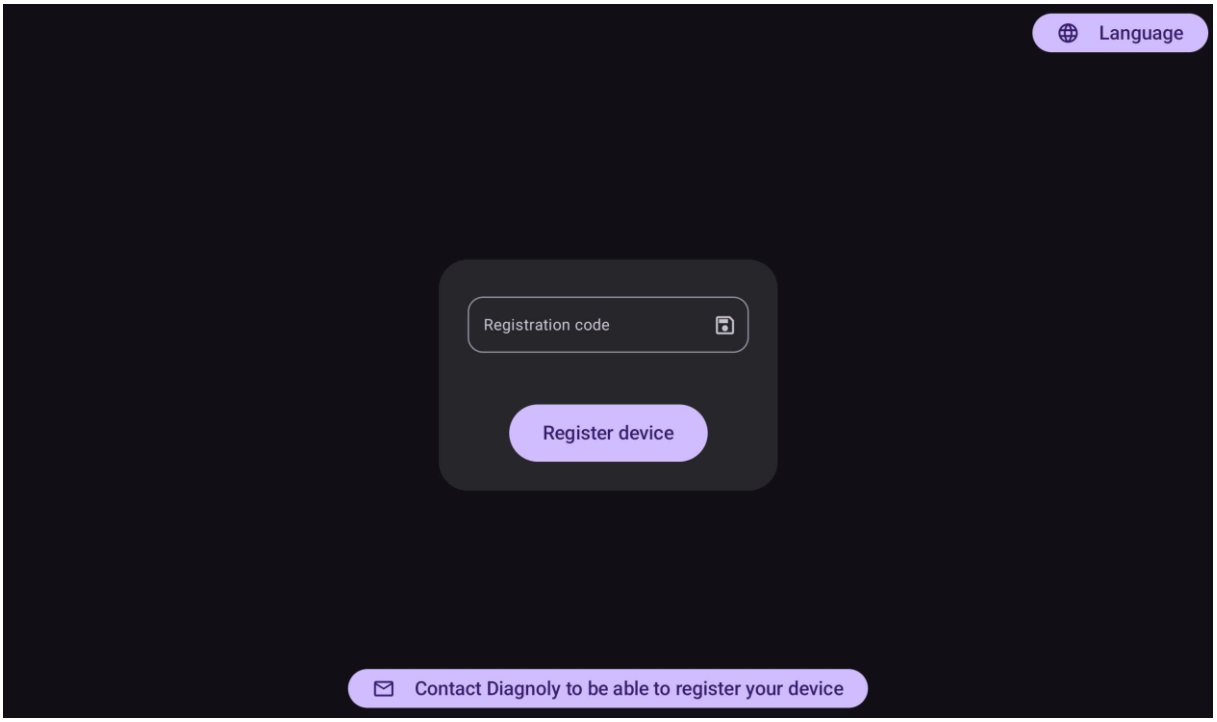
13. Instructions d’utilisation

Installation et lancement du logiciel

1. Aller sur Google Play ou l'App Store, écrire FETOLY dans la barre de recherche et lancer le téléchargement et l'installation automatiques



2. Cliquer sur l'icône FETOLY sur la tablette
3. **Validation de la licence** : si nécessaire, entrez le code d'enregistrement comme montré ci-dessous. Diagnoly est responsable de la fourniture de la licence. Vous pouvez contacter Diagnoly pour l'édition de la licence en cliquant directement sur le bouton affiché en bas de la page d'accueil. La licence est liée à l'ID de votre dispositif, qui est disponible dans la page des paramètres de licence.

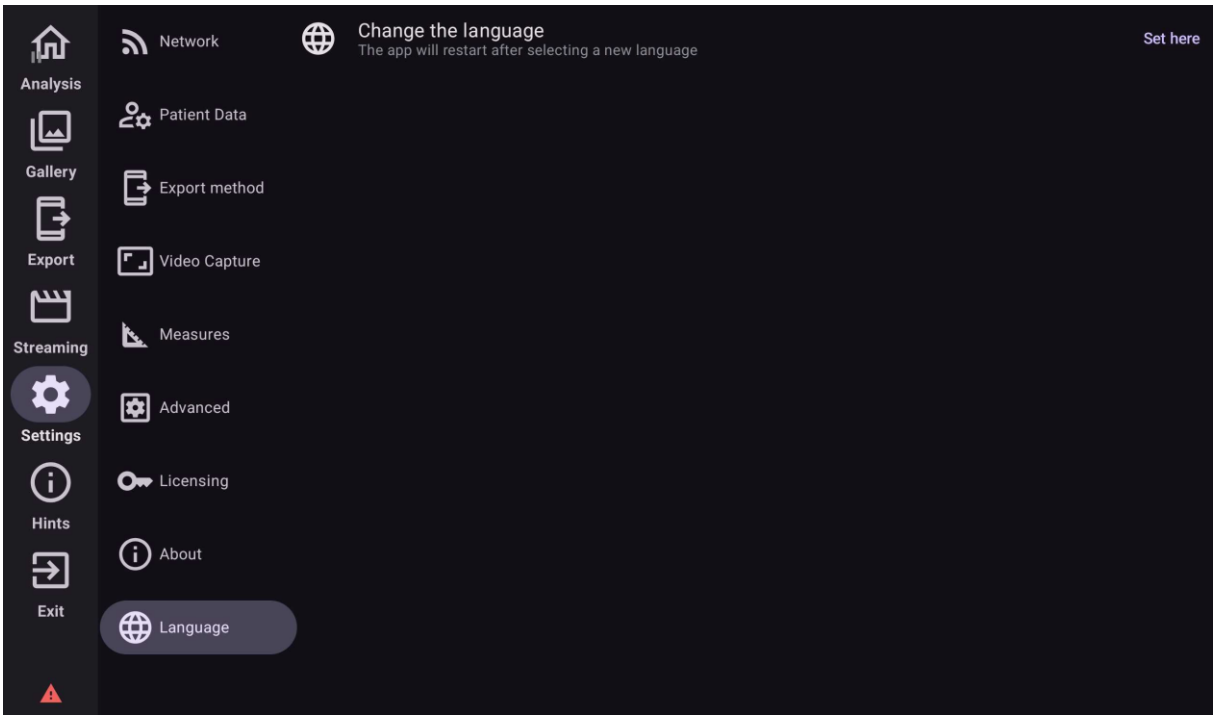


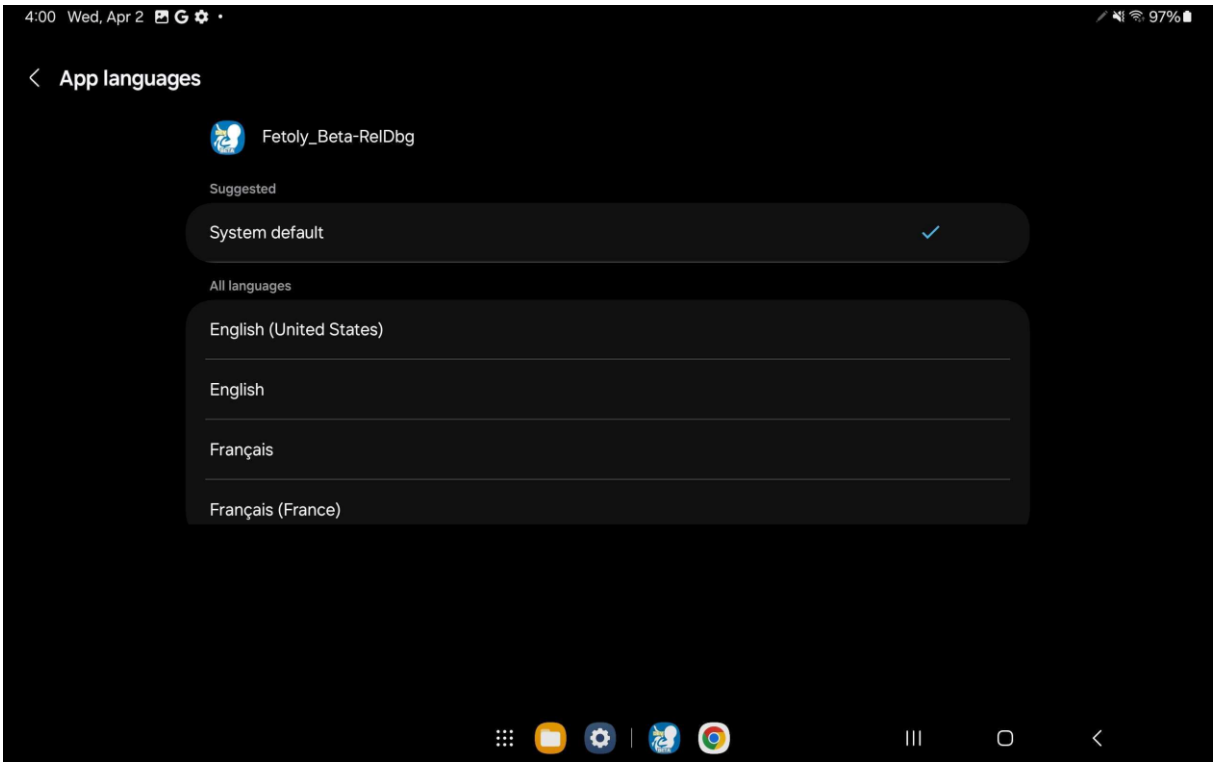
4. **Connexion au réseau WIFI :** si vous désirez recevoir les données échographiques sur votre ordinateur personnel, connectez votre tablette sur votre réseau WIFI.

Choix de la langue

Par défaut, le logiciel est configuré dans la même langue que celle de votre tablette. Cependant, vous pouvez choisir la langue de votre choix dans « Paramètres » > « Langue ».

Cela vous dirigera vers les paramètres de langue de l'application sur Android. Une fois la langue souhaitée sélectionnée, l'application sera traduite dans cette langue lors du prochain lancement.





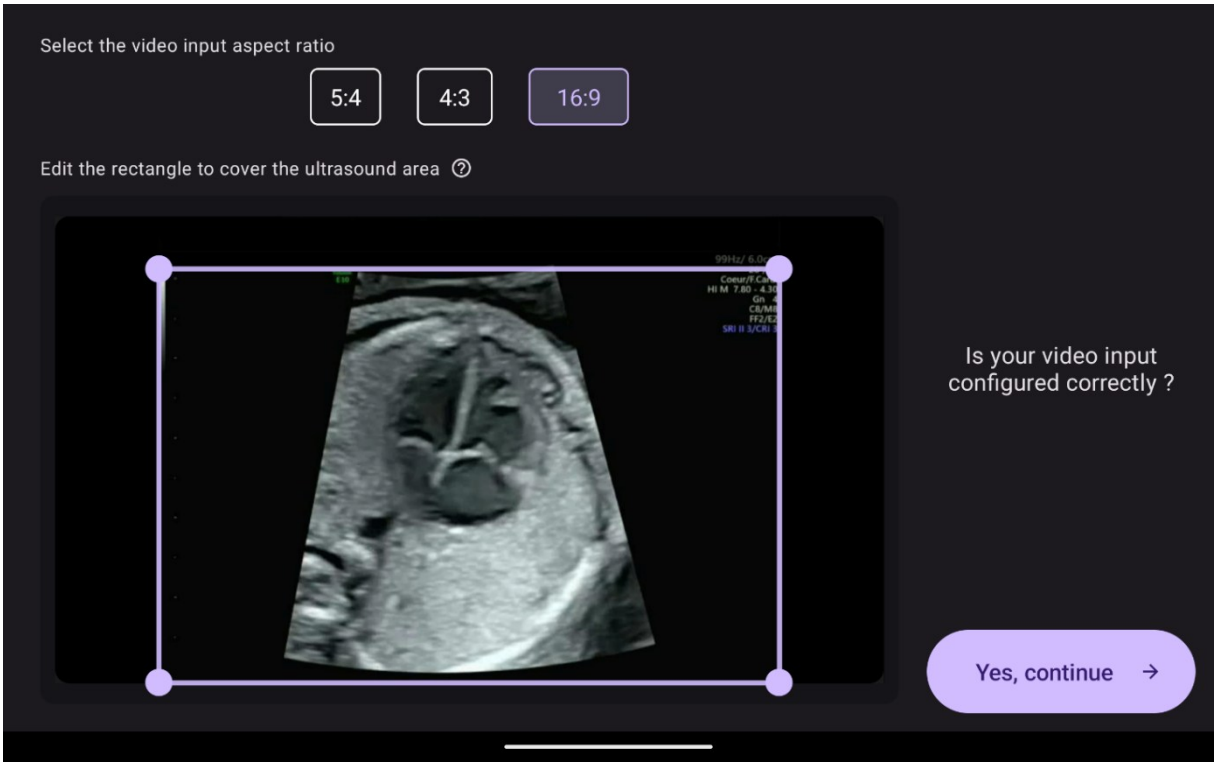
Connexion de la machine d'échographie

1. **Allumer le système d'échographie** : Avant de connecter votre tablette, assurez-vous que le système d'échographie est allumé et en bon état de fonctionnement.

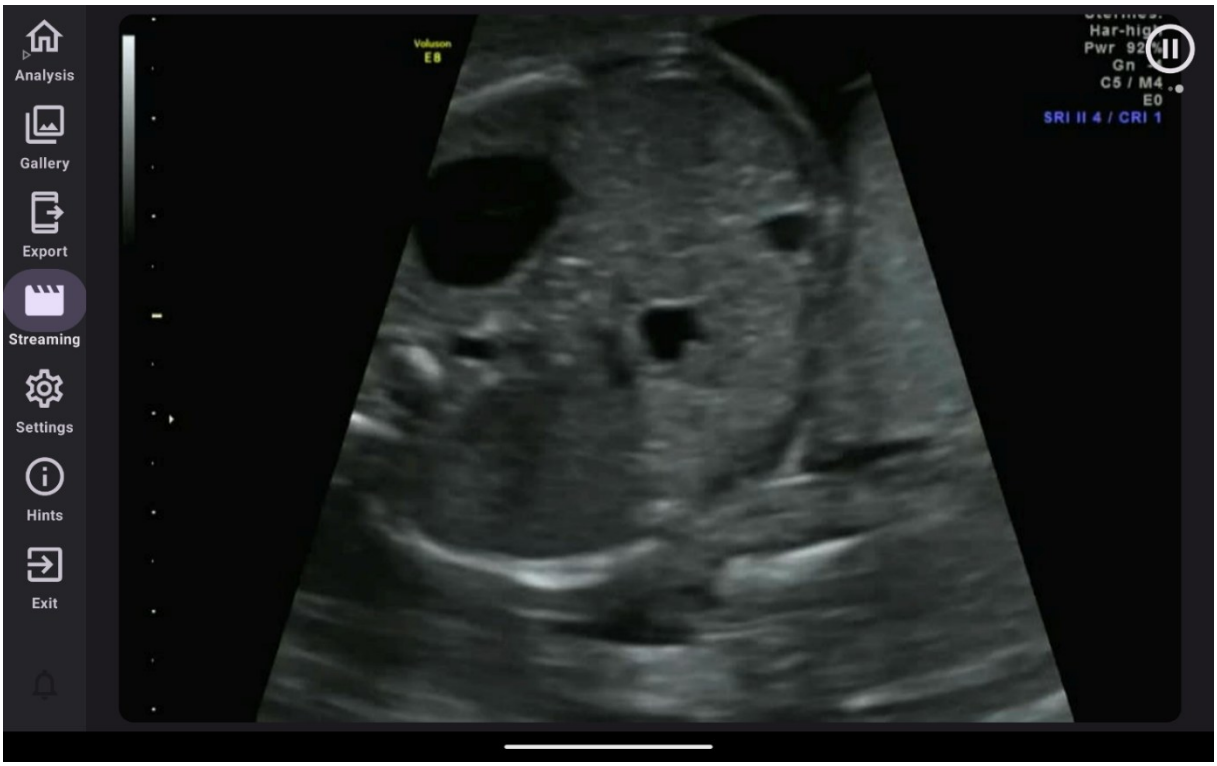
2. **Connecter votre tablette au système d'échographie** : Pour connecter, il suffit de brancher l'extrémité USB (Type C) d'un adaptateur UVC sur votre tablette et l'extrémité HDMI sur votre machine à ultrasons.
3. **Vérification :** Pour vérifier la connexion entre le système d'échographie et la tablette, ouvrez le logiciel FETOLY. Si une nouvelle source USB a été connectée, le logiciel affichera automatiquement la page de configuration du flux vidéo.

Configuration du flux vidéo :

1. Commencez par configure le flux vidéo dans le logiciel :
    a. Quand le logiciel ouvre automatiquement la page de configuration du flux vidéo, choisissez le ratio en alignement avec le ratio de sortie de votre machine échographique et sélectionnez la zone échographique à analyser. Dans d'autres situations, allez dans 'paramètres' > 'capture vidéo' pour configure le flux vidéo, avec la même méthodologie.



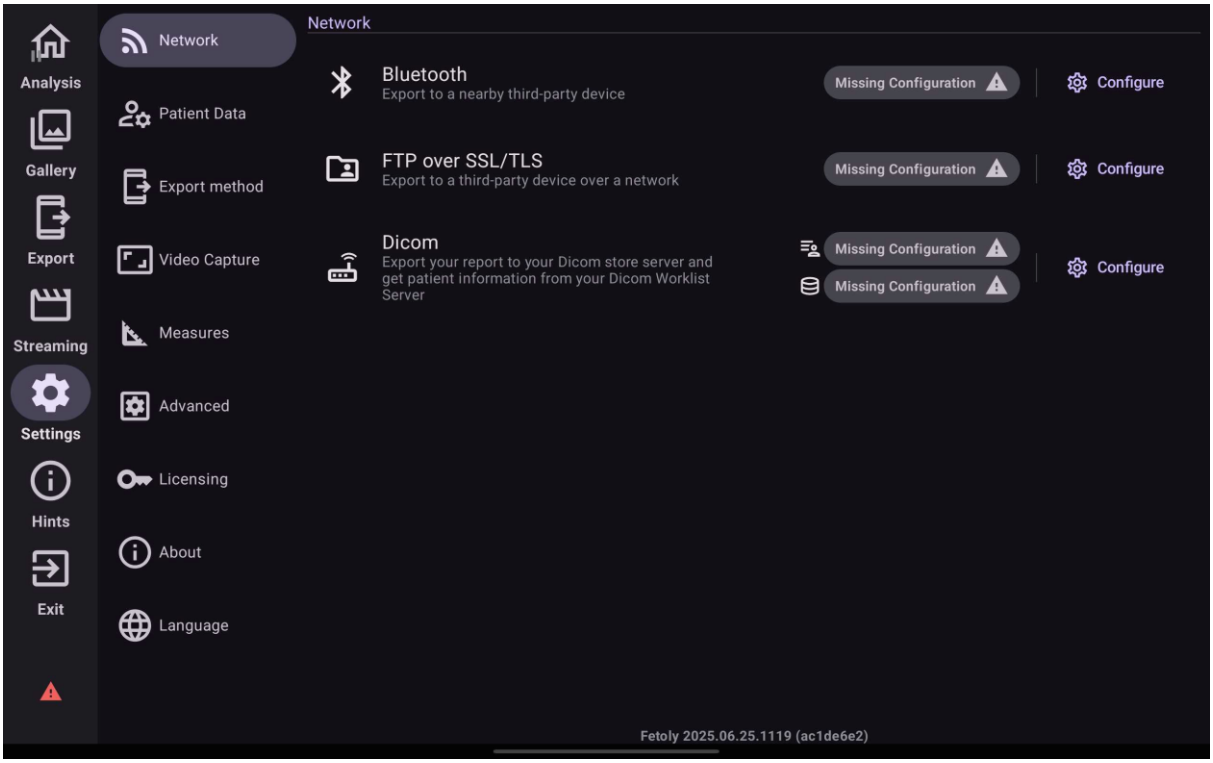
    b. La zone sélectionnée apparaît en temps réel sur la page de vidéo (streaming). Le bouton de lecture peut être utilisé sur la page de vidéo (streaming) pour lancer l'analyse
    c. Vérifiez que le microphone n'est pas désactivé sur votre tablette car cela bloquerait aussi le flux vidéo.



[OPTIONEL] Configuration de la machine échographique

Certains systèmes à ultrasons permettent de configurer la taille de la zone à ultrasons dans la sortie vidéo. Dans ce cas, il est conseillé de sélectionner la plus grande zone possible.

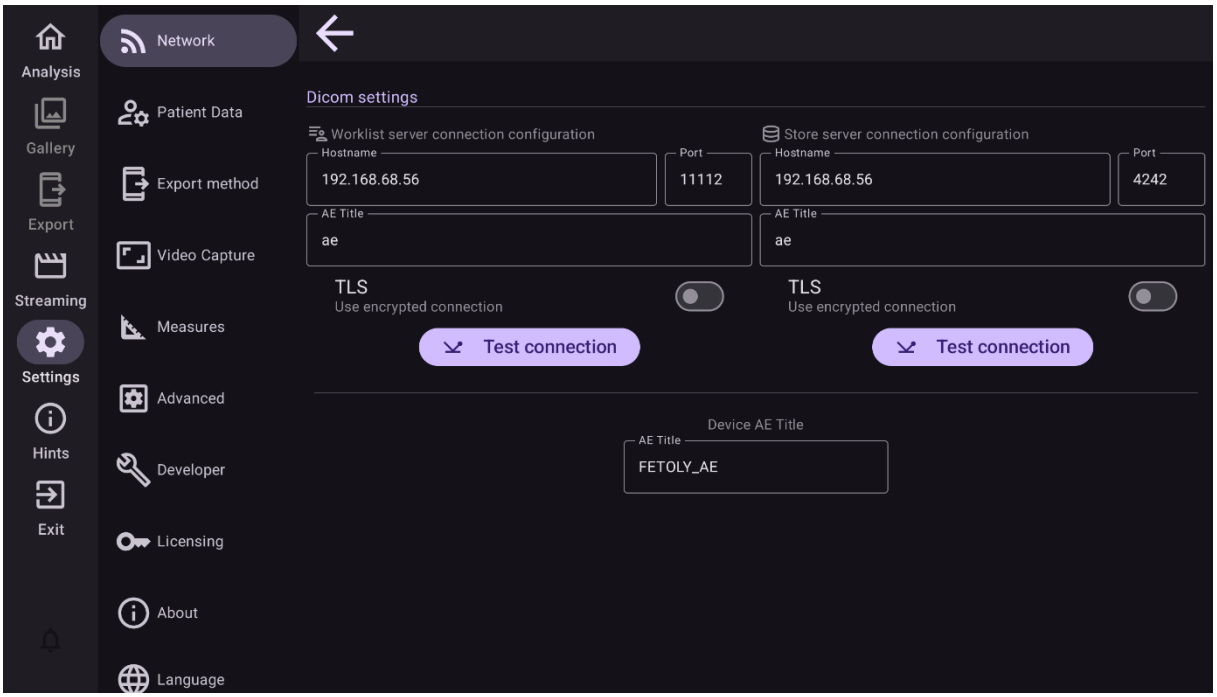
Configuration de l'exportation



1. Configurez le serveur DICOM distant pour l'exportation des images capturées par FETOLY. Veuillez noter que cette étape nécessite la présence d'un serveur DICOM

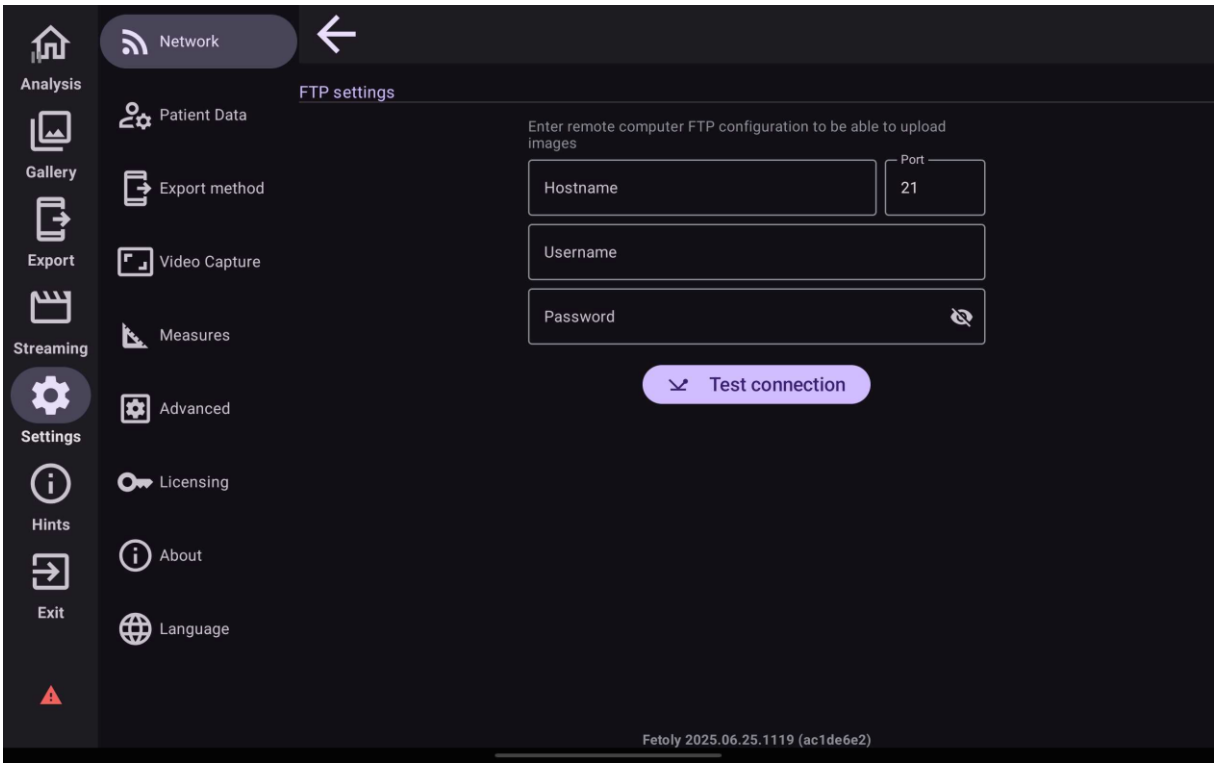
fonctionnant sur un appareil connecté au même réseau que la tablette exécutant FETOLY.

a. Allez dans « Paramètres » > « Paramètres de réseau », sélectionnez configurer DICOM et entrez les informations requises pour votre serveur stockage DICOM : hôte de la liste des tâches (adresse IP) et titre AE, hôte du stockage DICOM (adresse IP) et titre AE, titre AE du dispositif. Pour vérifier la connexion, cliquez sur le bouton « Tester la connexion » pour chaque serveur DICOM. Cela garantit que la connexion est valide et prête pour l'exportation des images. Vous pouvez aussi activer optionnellement l'option TLS.

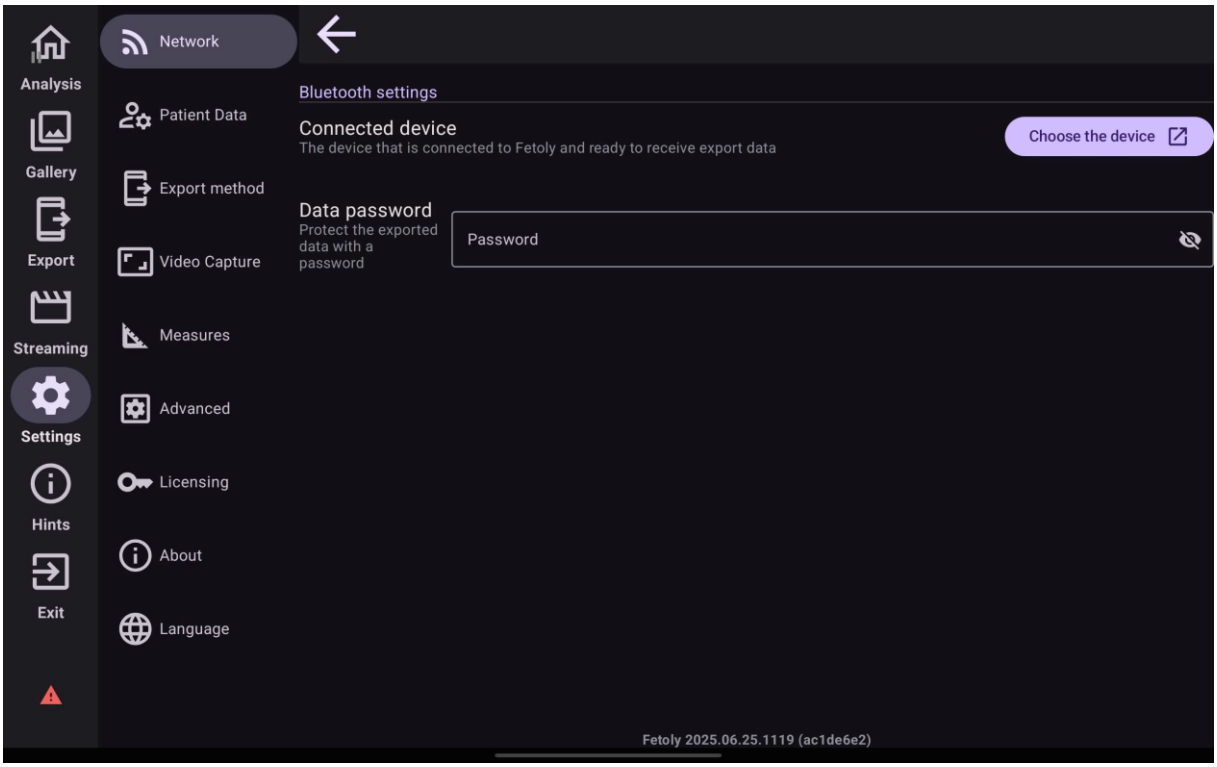


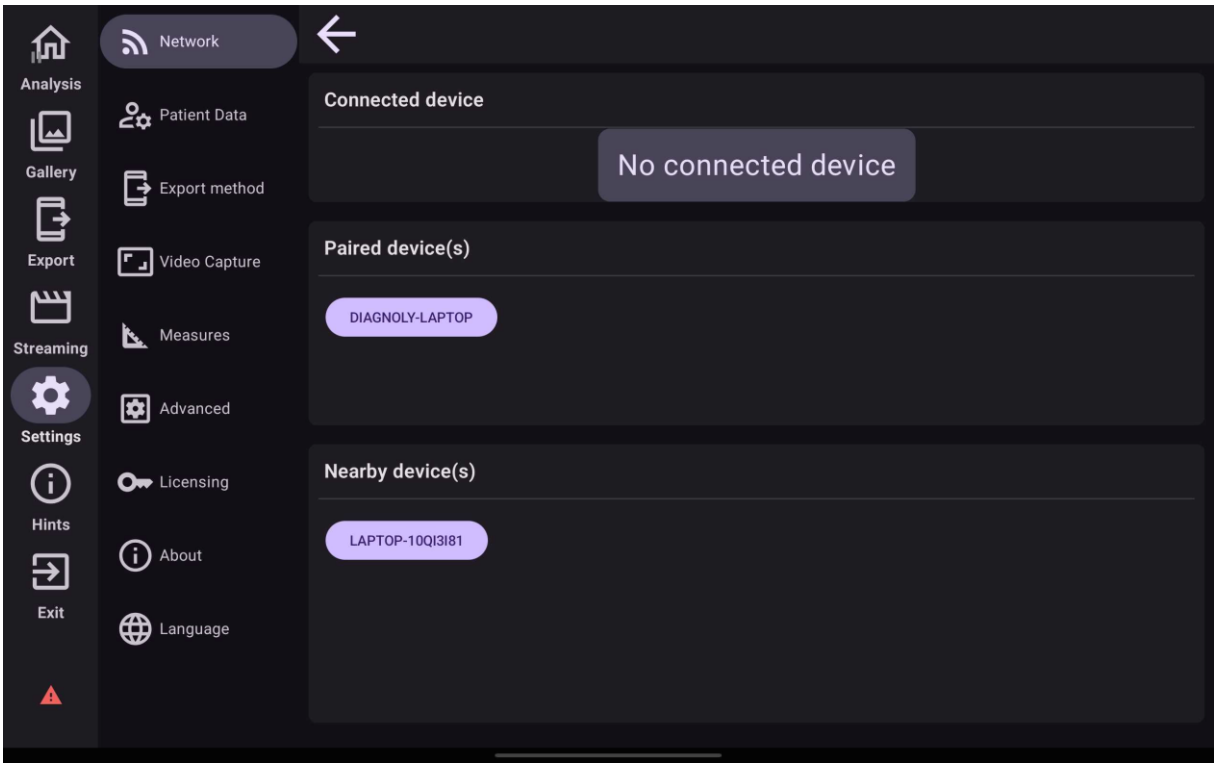
2. De manière alternative, configurez le serveur distant pour l'exportation des images capturées par FETOLY. Veuillez noter que cette étape nécessite la présence d'un serveur FTP fonctionnant sur un dispositif connecté au même réseau que la tablette exécutant FETOLY.

b. Allez dans « Paramètres » > « Paramètres de réseau », sélectionnez configurer FTP et entrez les informations requises pour votre client FTP : nom d'hôte (adresse IP), nom d'utilisateur et mot de passe. Pour vérifier la connexion, cliquez sur le bouton « Tester la connexion ». Cela garantit que la connexion est valide et prête pour l'exportation des images.

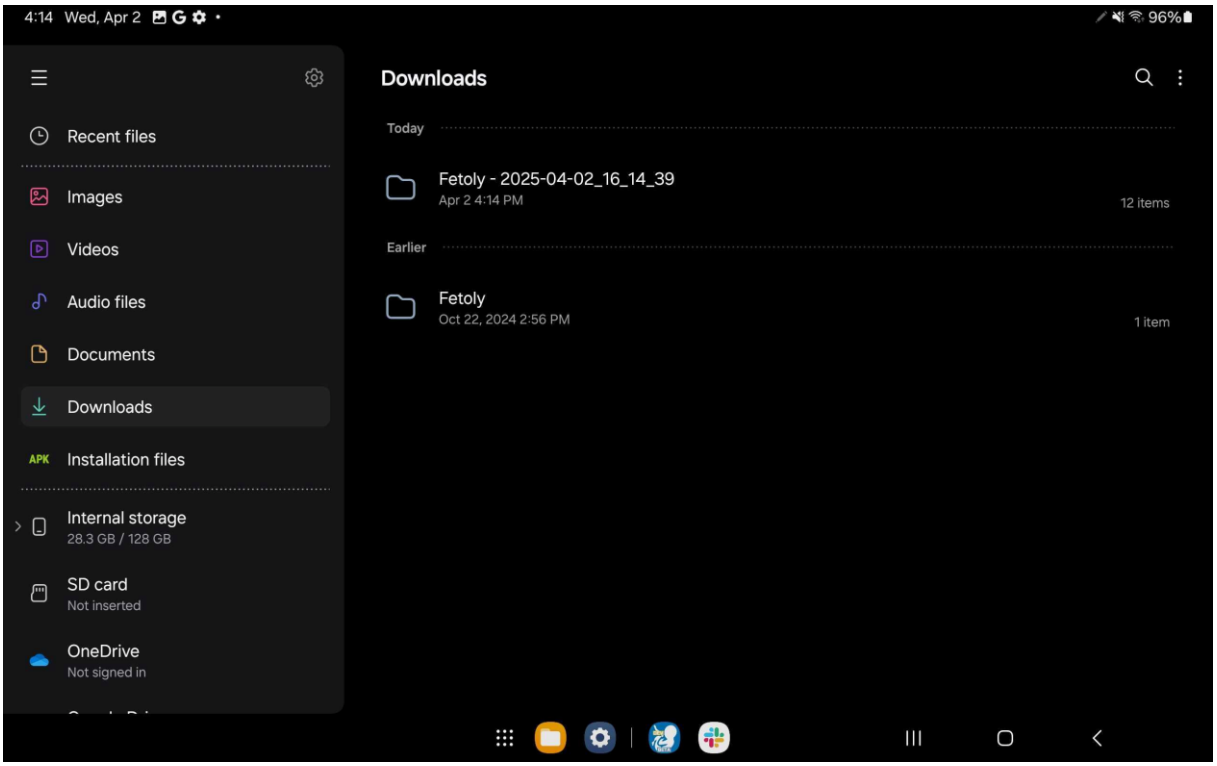


3. Vous pouvez également utiliser une connexion Bluetooth (Android seulement) :
    a. Allez dans « Paramètres » > « Paramètres de réseau », sélectionnez Bluetooth. Pour choisir le dispositif sur lequel vous exportez les données, vous devez associer le dispositif en le sélectionnant dans la section « appareil à proximité ». Ensuite, choisissez le dispositif à connecter dans la section « appareil apparié ». Une fois le dispositif sélectionné, vous pouvez tester la connexion dans la section « appareil connecté ». La page de sélection du dispositif est accessible en cliquant sur le bouton à droite de « Paramètres Bluetooth » > « appareil connecté ».
    b. Pour exporter le fichier, vous devrez également configurer un mot de passe. Ce mot de passe sera apposé sur le fichier .zip exporté sur le dispositif tiers.

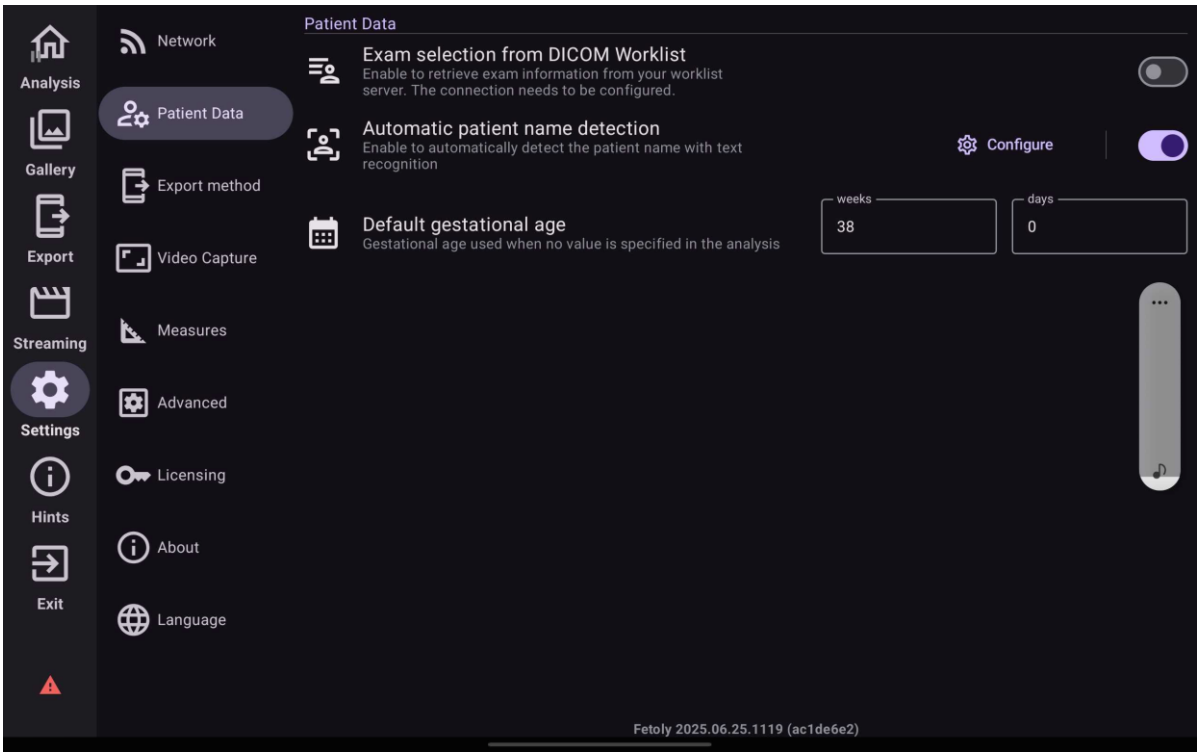


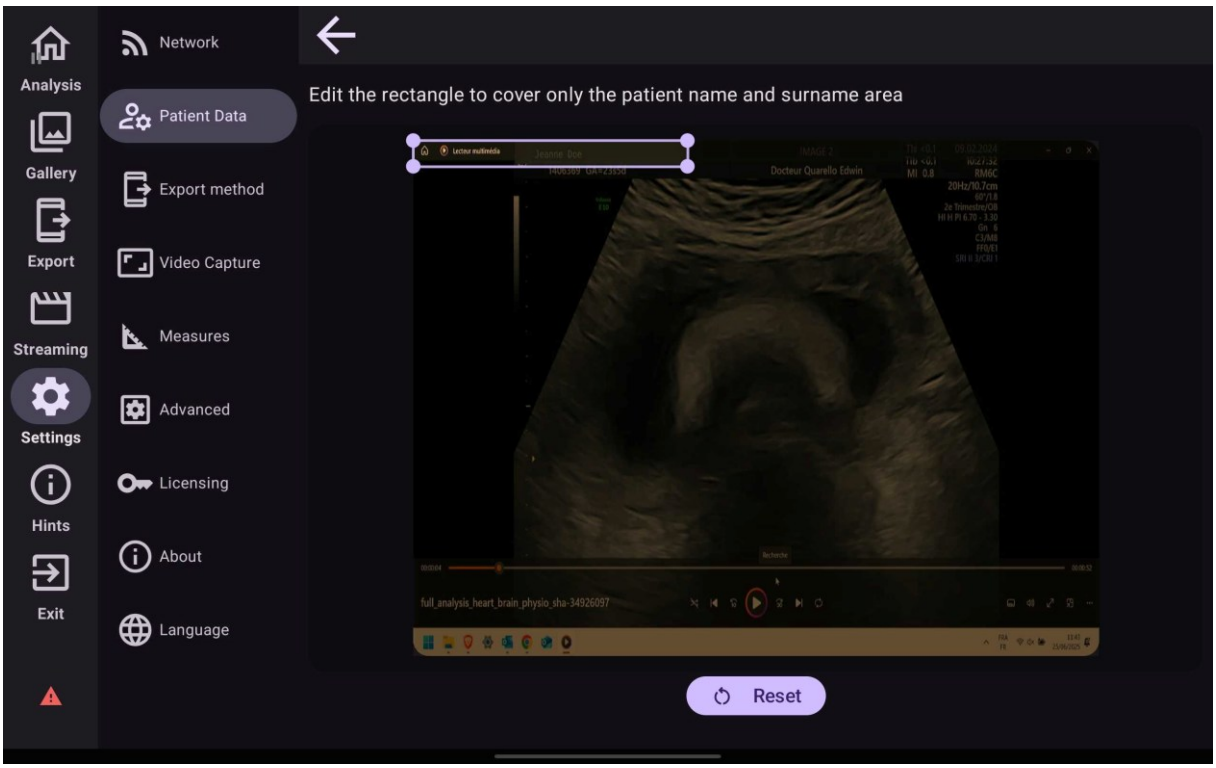


4. Si vous ne voulez pas utiliser de connexion sans fil, vous pouvez directement exporter les données sur la tablette :
    a. Allez dans ‘Paramètres’ > ‘Méthode d’exportation’, et sélectionnez local. Le fichier sera sauvegardé à un emplacement déjà défini par la tablette.
    b. Pour trouver l’emplacement, allez sur le bureau de la tablette, sélectionnez “fichiers” et allez dans ‘Téléchargements’ > ‘Fetoly’.



5. Si vous souhaitez ajouter le nom du patient dans le nom du fichier exporté ou si vous souhaitez sélectionner l'examen du patient à partir de la worklist DICOM :
    a. Renseignez directement le nom du patient ainsi que l'âge gestationnel sur la page d'analyse, ou ;
    b. Allez dans « paramètres » > « Données patient » et activez « sélection de l'examen depuis la worklist DICOM ». Veuillez noter que cette fonction ne fonctionne que si vous êtes connecté à un PACS avec des paramètres DICOM worklist configurés. Notez également qu'en mode d'exportation DICOM, cette configuration est obligatoire.
    c. Facultativement, allez dans « paramètres » > « Données patient » et activez la détection automatique du nom du patient. Vous pouvez ensuite cliquer sur « configurer » et sélectionner la zone du flux vidéo échographique où apparaît le nom du patient. Le nom du patient sera alors automatiquement renseigné au lancement de l'examen ou en cliquant sur le bouton de rafraîchissement à droite du nom du patient sur la page d'analyse.

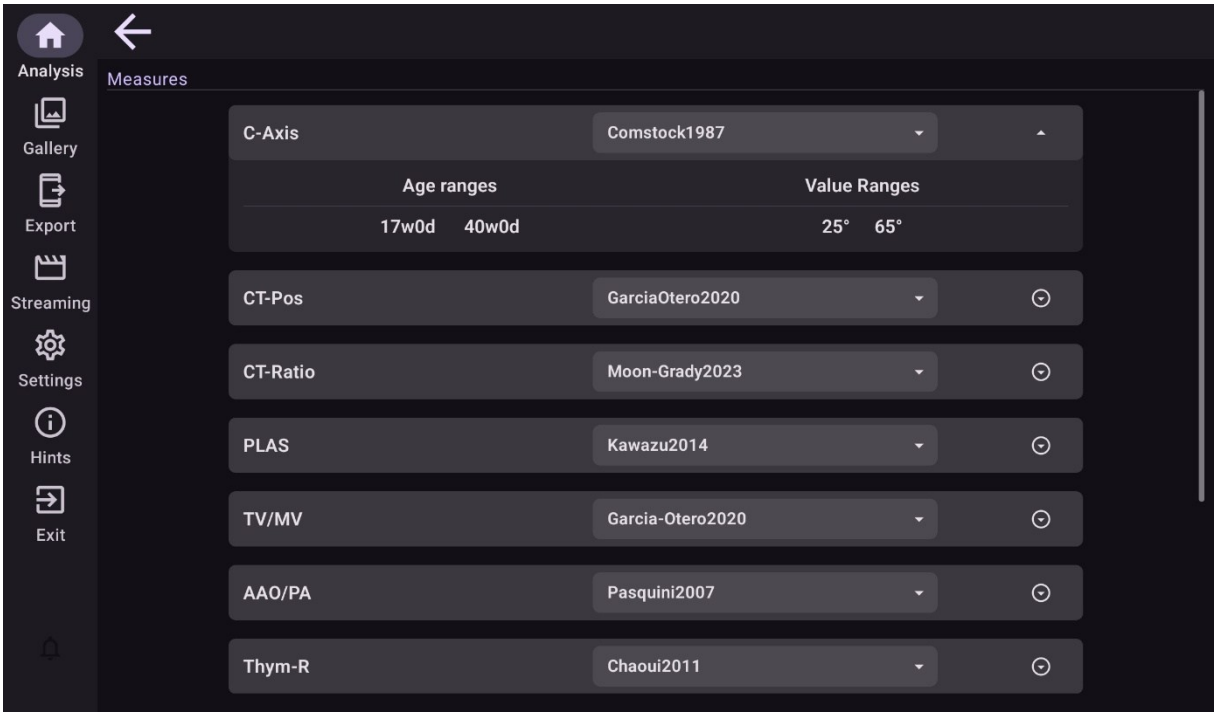




Utilisation

1. Suivez ces étapes pour réaliser la complétude de l'examen et les mesures:
    a. Entrer l'âge gestationnel sur la page d'analyse avec le nom du patient ou en sélectionnant l'examen du patient depuis la worklist DICOM.
    b. Vous pouvez configurer l'âge gestationnel par défaut en allant dans « Paramètres » > « Données patient ».

c. Pour la fonction de mesure, si plusieurs sources bibliographiques sont disponibles, choisissez celle que vous préférez. Vous pouvez également configurer manuellement les plages de référence. Cela se fait en cliquant sur le bouton « nouvel onglet » à droite de la mesure sur la page d'analyse ou en allant dans « Paramètres » > « Paramètres des mesures ». Cela vous redirigera vers la page des paramètres de mesure.



d. Appuyez sur le bouton démarrer sur la page d'analyse

e. Faites l'examen comme d'habitude

f. L'examen est considéré comme complet quand toutes les vues et tous les critères sont verts et quand toutes les mesures sont réalisées

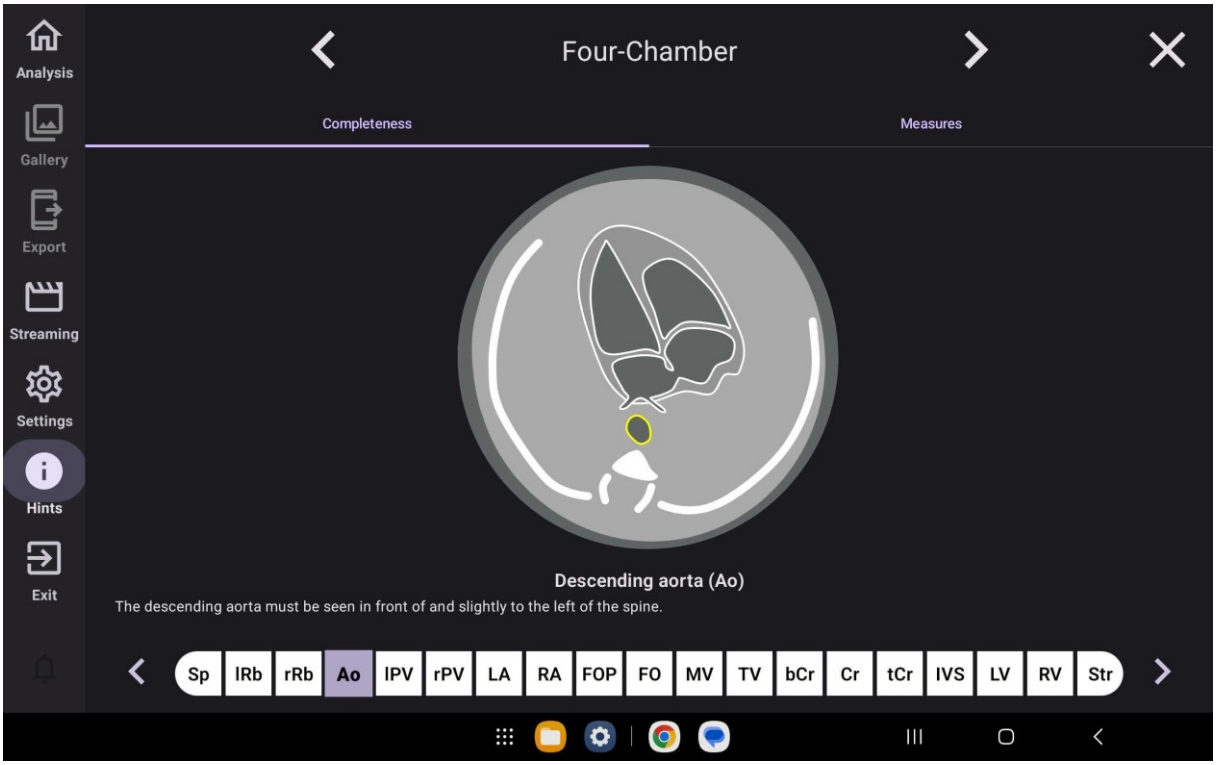
g. Les mesures sont affichées comme « hors intervalle » si elles sont en dehors de la plage de référence définie

h. Quand l'examen est complet, la page d'analyse l'indique et vous permet d'aller directement sur la page galerie pour vérifier les images suggérées

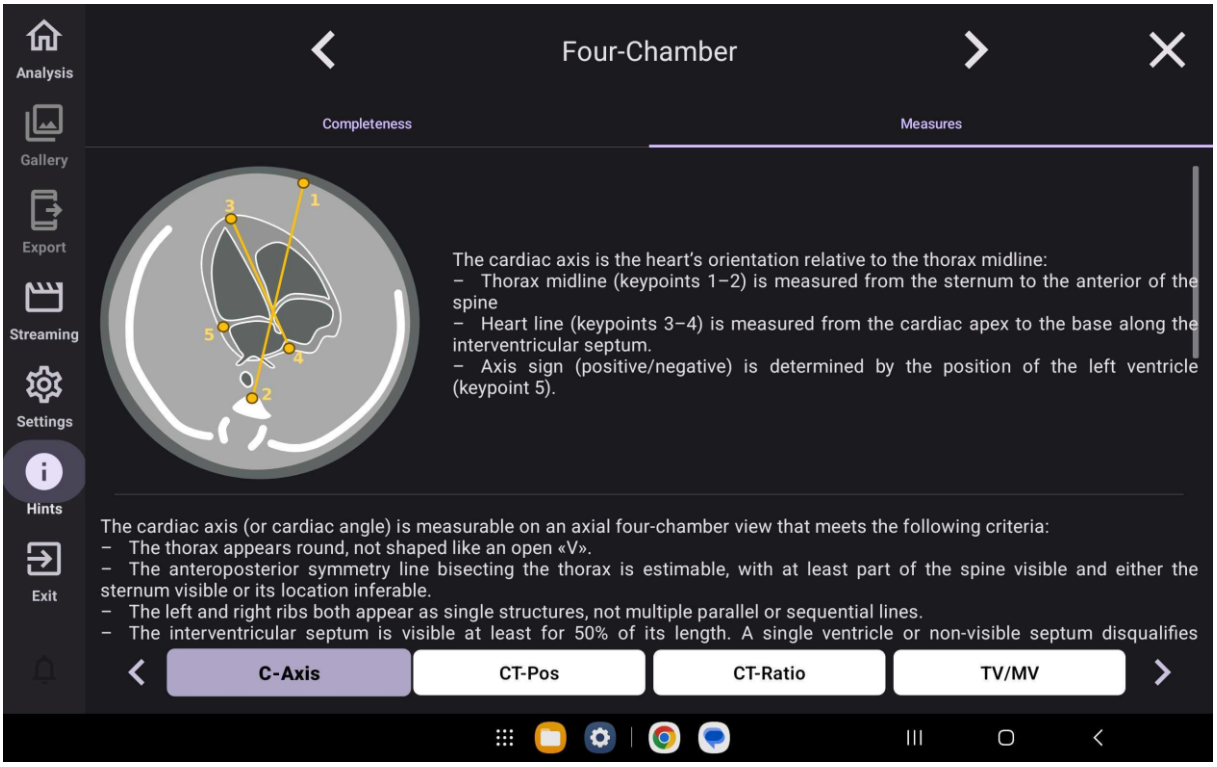


2. Veuillez trouver ci-après une liste de conseils pour être sûr de réaliser correctement la complétude de l'examen et les mesures :

    a. Les critères de qualité et les vues détectées par le logiciel sont basés sur les recommandations de l'ISUOG pour le dépistage cardiaque et cérébral fœtal. Veuillez consulter ce guide si nécessaire, comme rappel des bonnes pratiques de dépistage cardiaque/cérébral fœtal. Vous pouvez également consulter la page « Conseils » pour obtenir une explication de tous les critères de qualité.



b. Les mesures biométriques réalisées par le logiciel sont basées sur des recommandations internationales et des publications reconnues pour le dépistage cardiaque et cérébral fœtal. Veuillez consulter les articles scientifiques référencés par le logiciel si nécessaire, en guise de rappel des bonnes pratiques de dépistage cardiaque/cérébral fœtal. Vous pouvez également consulter la page « Conseils » pour obtenir une explication de toutes les mesures effectuées.



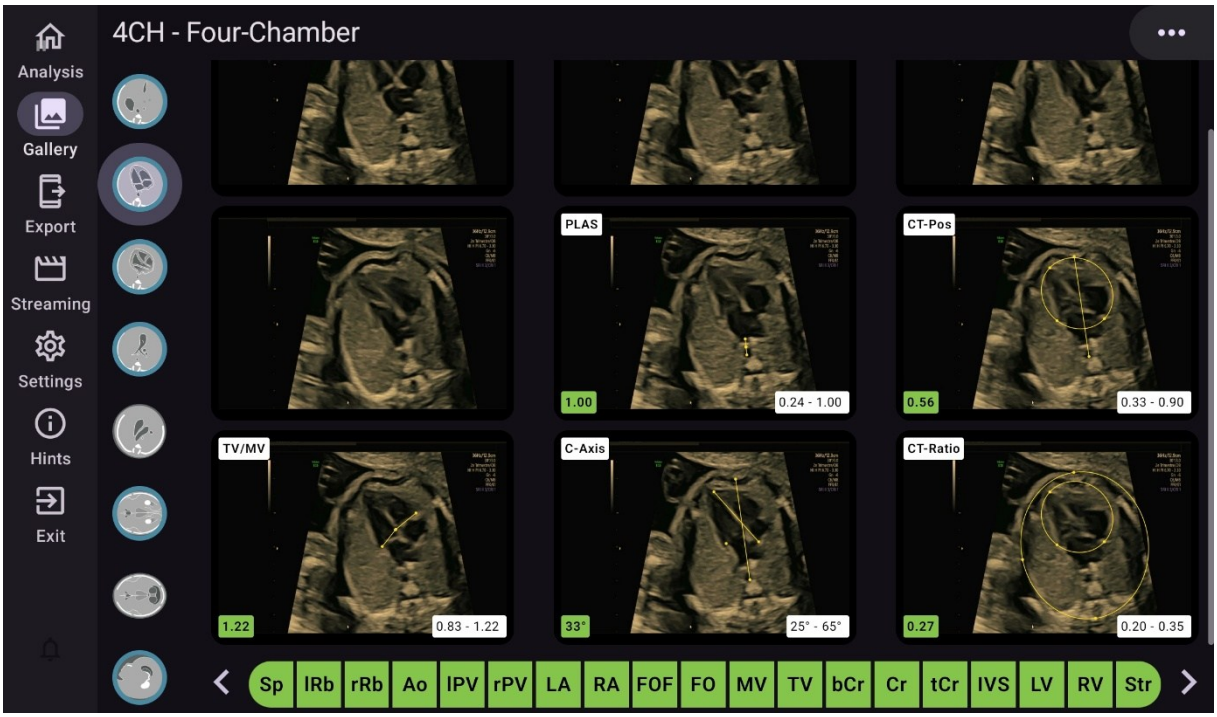
c. Assurez-vous que les étapes de configuration expliquées ci-dessus sont faites correctement pour éviter des erreurs de détection.

d. Assurez-vous d'utiliser des équipements compatibles selon la section 9 de cette notice.

e. Un avertissement apparaît sur la page d'exportation si les critères de qualité/mesures ne sont pas inclus dans l'ensemble d'images sélectionné.

f. Une fois que tous les critères sont vérifiés et que toutes les mesures sont effectuées sur la page d'analyse, vérifiez si tous les critères et mesures correspondants sont bien identifiables dans l'ensemble d'images sélectionné sur la page Galerie.

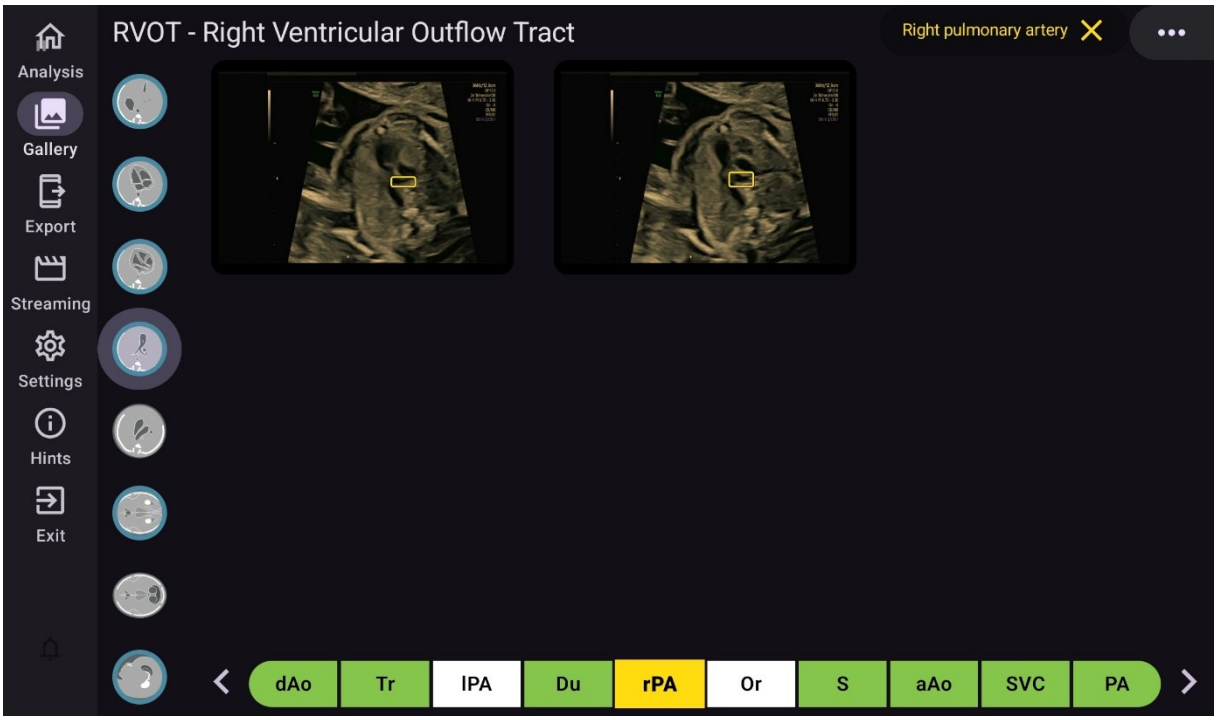
3. Une fois votre flux vidéo terminé, allez dans la section « Galerie » pour explorer les images sélectionnées. Pour faciliter la navigation dans l'ensemble des images, celles-ci sont catégorisées par plan.



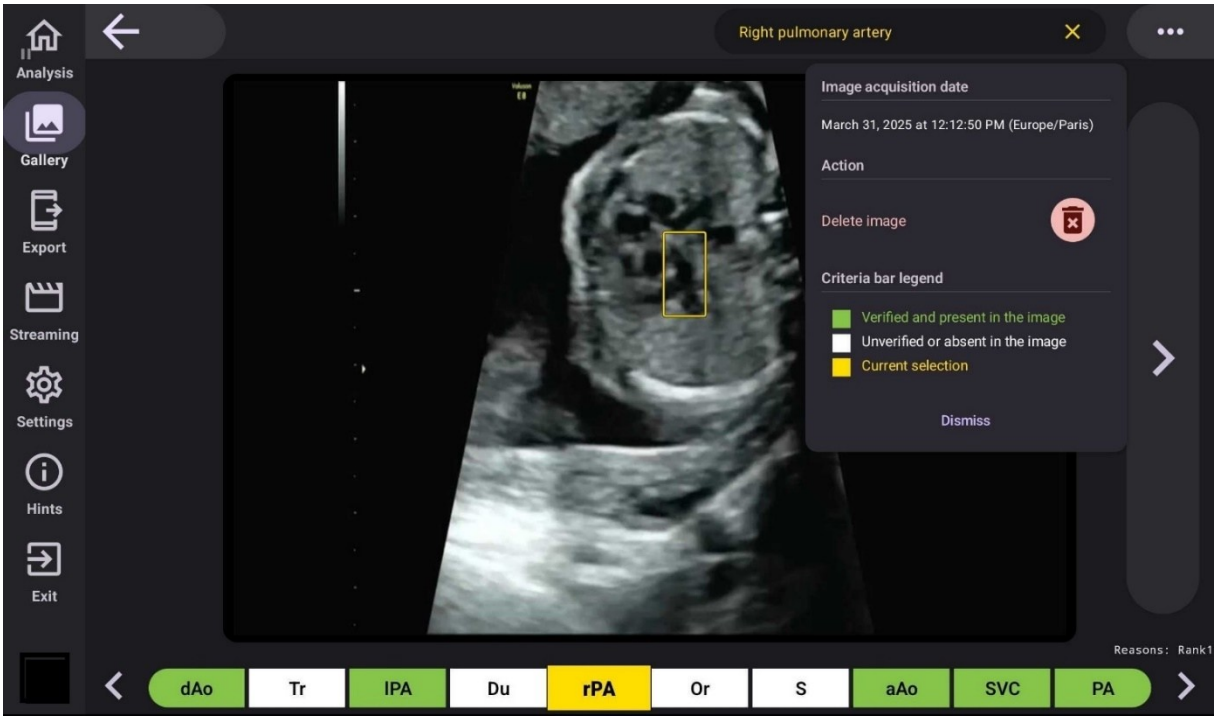
a. Cliquez sur un plan spécifique (panneau de gauche) pour afficher les images sélectionnées liées à ce plan. Les critères en vert sont vérifiés et les critères en blanc ne le sont pas.

b. Les images sélectionnées pour les mesures biométriques contiennent les informations suivantes : nom de la mesure, valeur, plage de référence, et statut hors plage si applicable. Les points clés et le tracé de la mesure sont en jaune.

c. Cliquez sur une structure spécifique pour afficher les images sélectionnées contenant cette structure. Le critère de qualité sélectionné est en jaune et la zone délimitée entourant le critère est affichée sur les images.

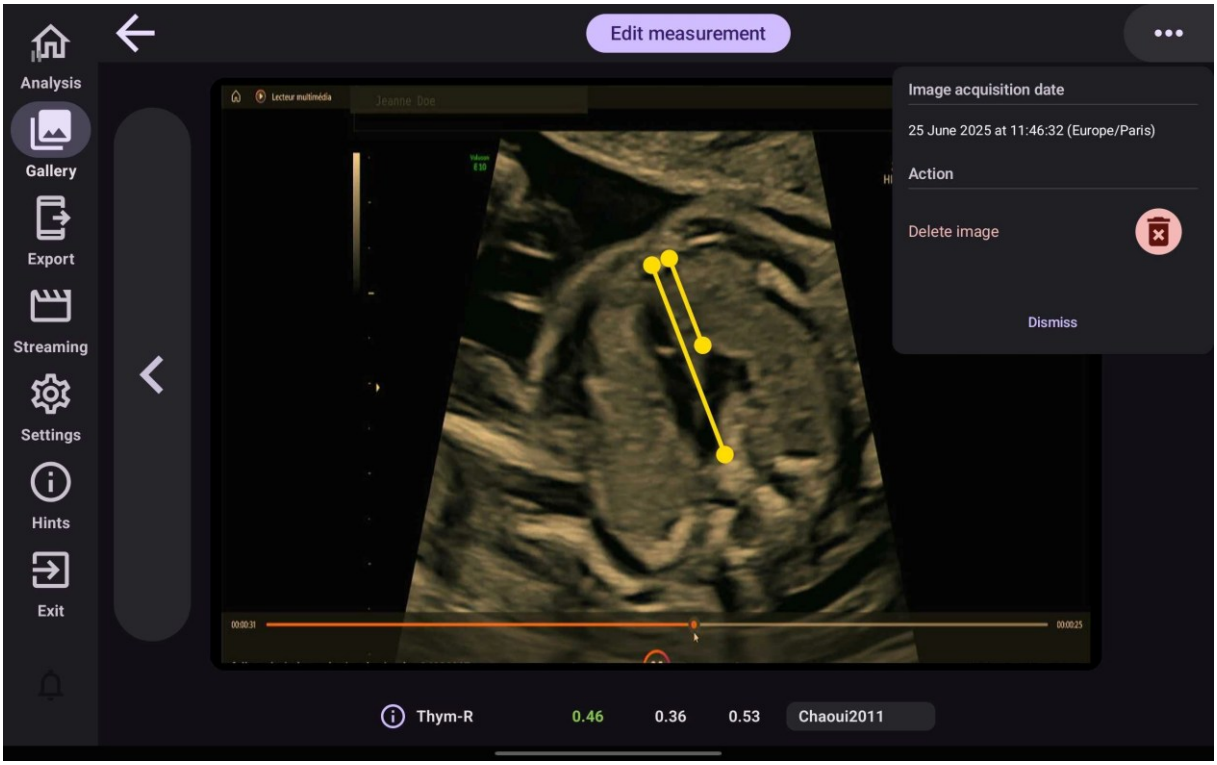


d. Cliquez sur une image de complétude pour zoomer dessus. Vous pouvez cliquer sur un critère de qualité en vert pour afficher la zone délimitée entourant ce critère de qualité. Le critère de qualité sélectionné est en jaune. Les encadrés blancs signifient que les critères de qualité sont présents sur d'autres images de la galerie ou non vérifiés. Cliquez sur le symbole de la corbeille pour supprimer l'image. Vous pouvez glisser directement sur les côtés de l'image pour parcourir les autres images de la vue.



e. Cliquez sur une image de mesure pour zoomer dessus. Les points clés et le tracé de la mesure sont en jaune. Notez que les points clés de mesure ne sont pas conçus pour

être placés à l'emplacement exact, mais doivent être suffisamment précis pour afficher la valeur de mesure correcte. La valeur et le statut « hors plage » le cas échéant sont affichés, ainsi que la plage de référence et la source bibliographique sélectionnée. Cliquez sur le symbole de la corbeille pour supprimer l'image. Vous pouvez glisser directement sur les côtés de l'image pour parcourir les autres images de la vue. Vous pouvez modifier les points clés d'une mesure sur les images de mesure en cliquant sur le bouton « modifier la mesure ». La valeur de la mesure sera alors mise à jour en conséquence, et le logiciel empêchera toute modification automatique par re-scannage après l'édition. La mesure modifiée sera marquée avec le symbole suivant : .

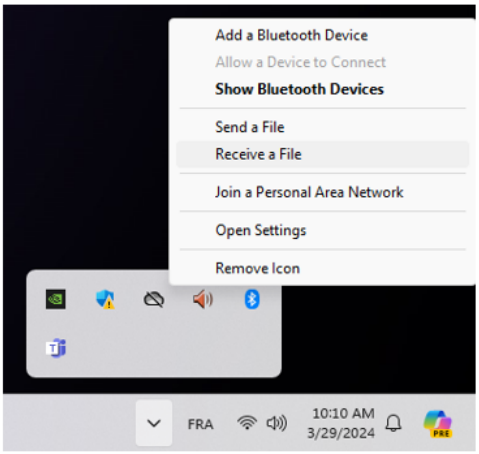


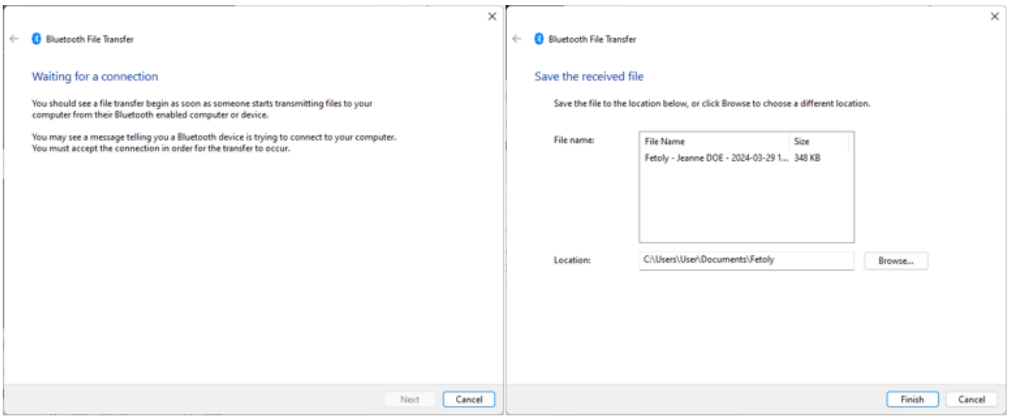


f. Si besoin, vous pouvez retourner sur la page d'analyse pour relancer l'analyse et obtenir de nouvelles images.

Export images

1. Allez dans la section « Méthode d'exportation » des « Paramètres » pour sélectionner le mode d'exportation que vous souhaitez utiliser.
2. Allez dans la page Exporter pour exporter les images sélectionnées :
    a. Si vous avez choisi la connexion Bluetooth, allez sur votre PC et sélectionnez « recevoir un fichier » dans la configuration Bluetooth.





b. Si vous avez choisi la connexion DICOM, vous pouvez vérifier si le patient sélectionné pour l'exportation est le bon et sélectionner un autre patient en cas d'erreur en utilisant la worklist DICOM sur la page d'analyse.

c. La page d'exportation affiche un résumé des critères manquants, s'il y en a, et vous rappelle de vérifier si vous disposez de toutes les images nécessaires pour une prise en charge efficace du patient avant l'exportation.

d. La page d'exportation affiche la méthodologie d'exportation choisie. Si vous souhaitez modifier les paramètres, vous pouvez accéder directement à la page des paramètres d'exportation en cliquant sur « méthode d'exportation ».

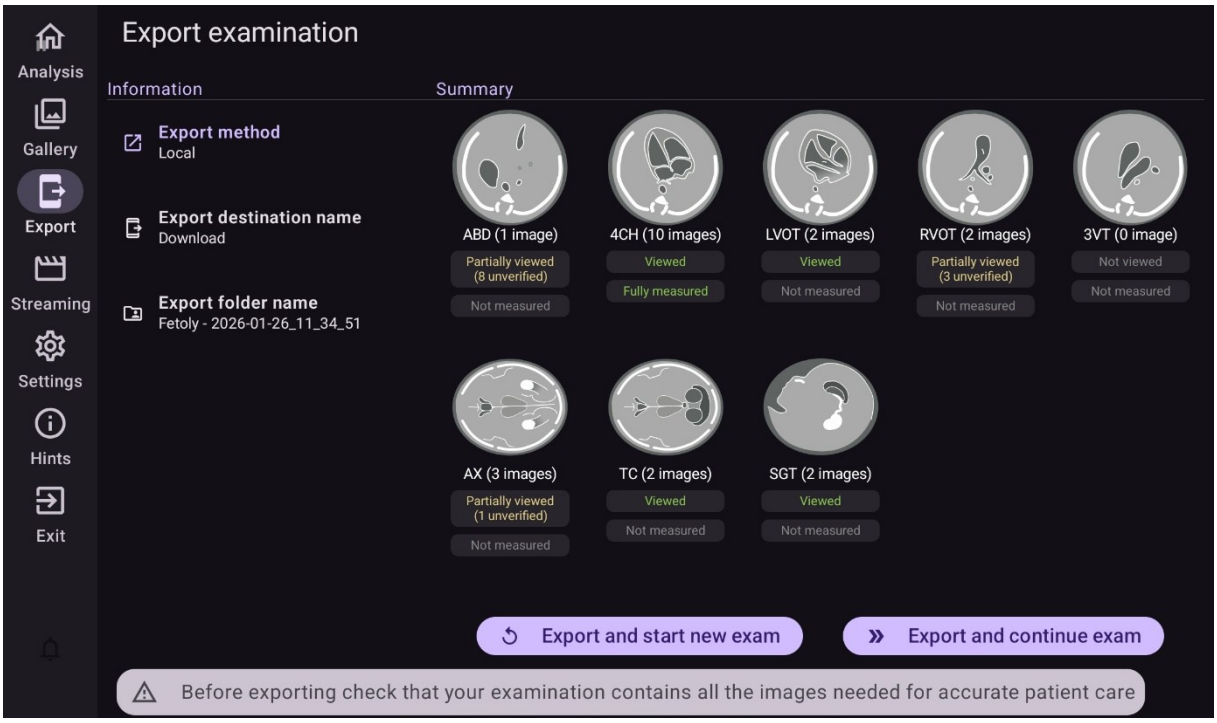
e. La page d'exportation affiche l'emplacement du fichier exporté sur le dispositif choisi et le nom du fichier configuré pour l'export local.

f. Lorsque la détection automatique du nom est sélectionnée, la zone choisie sur le flux vidéo de l'échographie est affichée.

g. Cliquez sur le bouton « Exporter et commencer un nouvel examen » pour exporter les images et effacer l'examen avant de commencer un nouvel examen.

h. Ou cliquez sur le bouton « Exporter et continuer l'examen » pour exporter les images sans effacer l'ensemble d'images sélectionné et l'analyse de complétude actuelle.

i. Le logiciel vous indiquera si l'exportation a été réussie ou a échoué.



Réinitialisation (effacer)

Si vous n'avez pas utilisé la fonction d'effacement sur la page d'exportation, allez dans « Analyse » et cliquez sur le bouton « Effacer » pour réinitialiser l'ensemble des images sélectionnées et la complétude de l'examen.

Paramètres avancés

Si vous souhaitez désactiver la fonction de mesure, allez dans « Paramètres » > « Avancé » et cliquez sur le bouton.

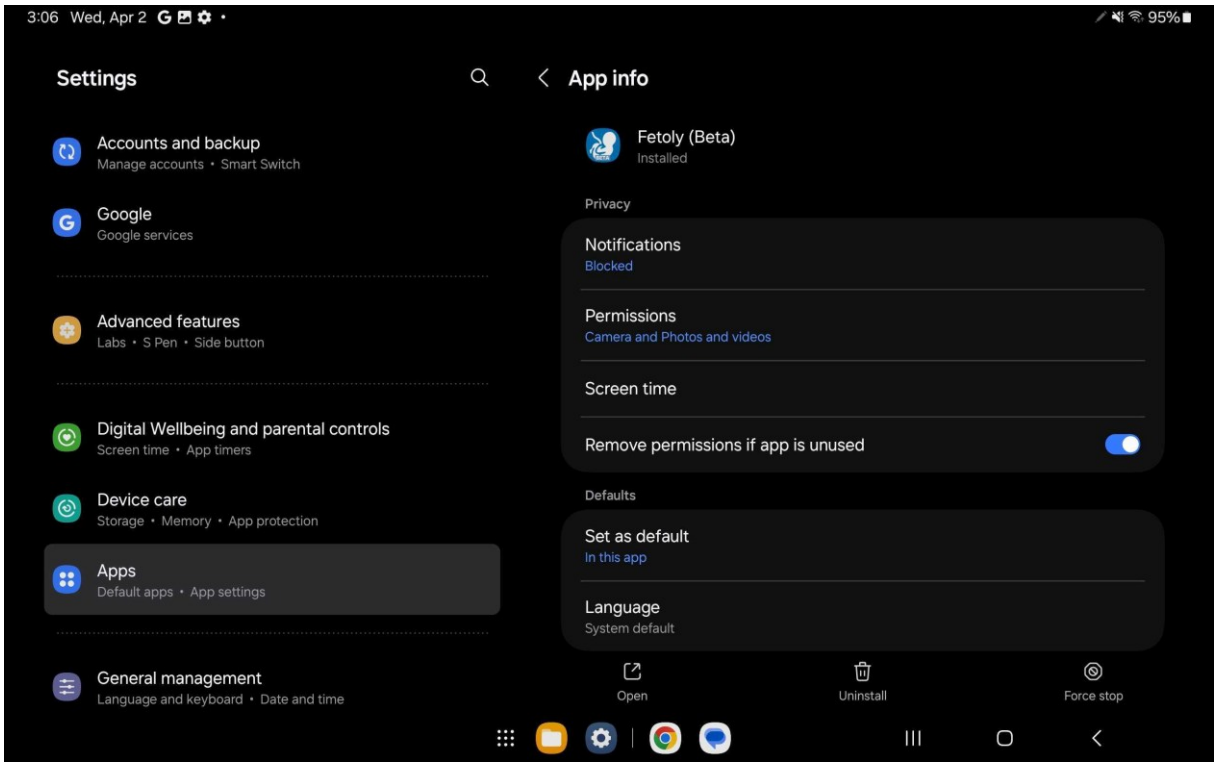
Mise à jour de la licence et du logiciel

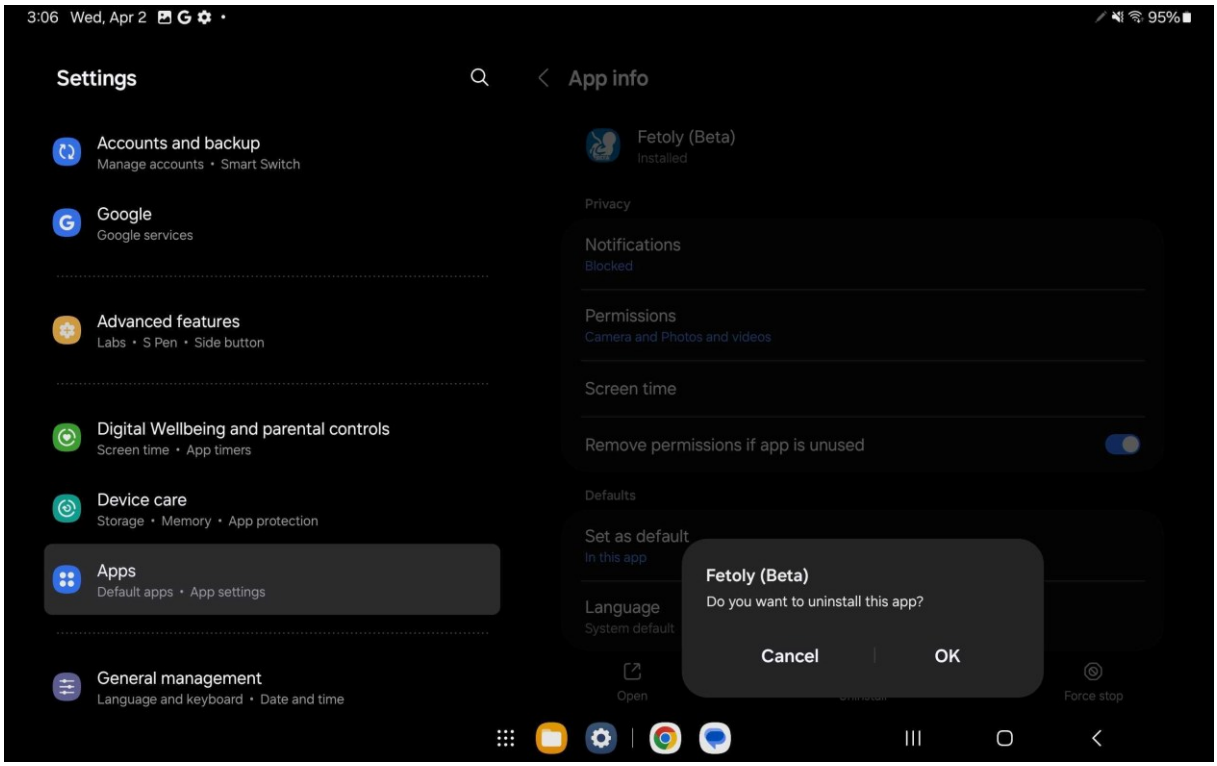
Le logiciel vérifie périodiquement la disponibilité de nouvelles mises à jour. Pour garantir la disponibilité immédiate des mises à jour, activez les mises à jour en arrière-plan pour FETOLY dans les paramètres du Google Play/ App Store. Lorsqu'une mise à jour est disponible, le logiciel affichera une page bloquante au lancement, obligeant l'utilisateur à mettre à jour et redémarrer l'application pour pouvoir continuer à l'utiliser. Après avoir accepté la mise à jour, Google Play s'occupe de l'installation de la mise à jour et du redémarrage de l'application. Une connexion internet est nécessaire pour vérifier les mises à jour et renouveler automatiquement la licence. Si l'appareil n'est pas connecté à Internet pendant une période de 30 jours, le logiciel sera bloqué.

Votre licence est vérifiée et renouvelée automatiquement lorsque la connexion Internet est activée, tant que le contrat de licence est valide. La date d’expiration de la licence est affichée dans la page des paramètres de la licence. Lorsque le contrat de licence est expiré, si aucun renouvellement n’est effectué, le logiciel vous demandera de saisir un nouveau code d’enregistrement et bloquera certaines fonctionnalités.

Désinstallation du logiciel

Désinstallez l'application comme n'importe quelle autre application sur votre tablette, comme illustré ci-dessous :





14. Maintenance, manipulation et elimination

- Les instructions doivent être lues avant utilisation.
- Veuillez lancer les mises à jour lorsque le logiciel vous le demande au démarrage.
- Veuillez noter que, pour le marché des États-Unis d'Amérique, un Plan de Contrôle de Changement Prédéterminé (PCCP) a été inclus. Ce PCCP est mis en œuvre pour le modèle d'apprentissage automatique intégré dans le dispositif FETOLY, qui pourrait modifier les performances, les entrées ou l'utilisation de l'appareil. Il est donc fortement recommandé d'être régulièrement connecté à Internet afin de permettre l'installation automatique des mises à jour.
- Veuillez entrer le code d'enregistrement lorsque le logiciel vous le demande au démarrage.
- Pour désactiver et éliminer le logiciel, veuillez désinstaller l'application via le système Android, comme n'importe quelle application sur votre tablette, dans les paramètres de l'application, comme illustré ci-dessus dans le paragraphe « désinstallation du logiciel ». Cette désinstallation supprimera toutes les données liées à l'utilisation de FETOLY, y compris la licence, de votre tablette.

Symboles utilisés dans les informations fournies par le fabricant (page « à propos ») :

	Fabricant (symbole usine pleine)
	Dispositif marqué CE
	Identifiant Unique du Dispositif 01: UDI-ID 11: date de fabrication 8012: version du logiciel
	Consulter les instructions d'utilisation
	La loi fédérale limite la vente de ce dispositif à la demande d'un médecin.
	Dispositif Médical
	Date de fabrication (symbole usine vide)
	Représentant Suisse

INSTRUCCIONES DE USO (ESPAÑOL)

1. Identificación del dispositivo

FETOLY

Software de ayuda a la exploración ecográfica cardíaca y cerebral del feto

Versión de software vinculada a estas instrucciones de uso: V2026.02.25

2. Actualización

La versión V2026.02.25 de FETOLY se ha actualizado de la siguiente manera:

- FETOLY ahora es compatible con iOS.
- Se han añadido las siguientes mediciones según la modificación n.º 4 del PCCP: PLAS, índice CSP, índice VP.
- Las vistas transventricular y transtálamica se han fusionado en la vista axial.
- Se han actualizado las instrucciones de uso para aclarar la funcionalidad de visualización de puntos clave y añadir una advertencia en la que se explica que el software no debe utilizarse en el método de exploración transvaginal.
- Se ha mejorado el rendimiento de detección del modelo de IA según la modificación n.º 1 del PCCP.
- Ahora es posible habilitar el modo TLS para la exportación DICOM.

Se han vuelto a realizar pruebas de verificación completas para comprobar que la actualización no afecta a las funciones del dispositivo. La metodología que se ha seguido es la misma que la utilizada para la versión inicial del producto.

3. Identificación del fabricante

FETOLY está fabricado por:

DIAGNOLY

2 Place de Francfort, 69003 LYON, Francia

Tel.: +33(0)6.58.49.07.84

Reclamaciones de productos: support@diagnoly.com

Notifique los incidentes graves a Diagnoly a través de la dirección de correo electrónico de reclamaciones de productos y a la autoridad competente de su país.

CE 0197

4. Descripción y presentación del dispositivo

Fetoly es un software cuyo objetivo es ayudar a ecografistas, obstetras, radiólogos, especialistas en medicina maternofetal y cardiólogos pediátricos (designados como profesionales sanitarios) a realizar ecografías cerebrales y cardíacas del feto en tiempo real.

Los profesionales sanitarios pueden utilizar Fetoly durante las ecografías del feto en el segundo y tercer trimestres (intervalo de edad gestacional: de 17 a 40 semanas).

El software tiene por objeto ayudar a los profesionales sanitarios en la evaluación exhaustiva de la ecografía cerebral y cardíaca del feto de conformidad con las directrices nacionales e internacionales. Fetoly también puede utilizarse para realizar mediciones biométricas cerebrales y cardíacas del feto de acuerdo con las directrices nacionales e internacionales.

Para utilizar Fetoly, es necesario instalar el software en un dispositivo de hardware que se conecta a un ecógrafo a través de una conexión HDMI. El software recibe en tiempo real las imágenes ecográficas captadas por el ecógrafo conectado. El algoritmo de aprendizaje profundo integrado en el software, entrenado mediante aprendizaje supervisado, analiza las imágenes de esta secuencia de imágenes ecográficas para detectar vistas cerebrales y cardíacas, criterios de calidad dentro de esas vistas y realizar mediciones biométricas cardíacas y cerebrales.

El software proporciona la siguiente información disponible para el usuario:

5. **Exhaustividad de la exploración**: el software muestra en tiempo real las vistas cerebrales y cardíacas, y los criterios de calidad verificados por el software durante la exploración. Los médicos pueden acceder a las vistas cerebrales y cardíacas verificadas, y a los criterios de calidad en cualquier momento de la exploración ecográfica, en tiempo real.
6. **Mediciones biométricas cuantitativas:** el software muestra en tiempo real qué mediciones cerebrales y cardíacas se observan y se realizan durante la exploración, y si dichas mediciones se encuentran dentro o fuera del intervalo de referencia definido según los últimos avances tecnológicos. Los médicos pueden acceder a las mediciones cardíacas y cerebrales verificadas en cualquier momento de la exploración ecográfica, en segundo plano.
7. **Ilustración de la exploración:** el software selecciona un subconjunto de imágenes que ilustran:
    - Las vistas verificadas y los criterios de calidad. Estas imágenes las pueden revisar los médicos para verificar las vistas y la presencia de criterios. Opcionalmente, los médicos pueden visualizar la localización de los criterios de calidad detectados en las imágenes seleccionadas.
    - Cada medición. Para cada medición, el software muestra una imagen con la medición dibujada (en amarillo) y el valor medido (en la parte inferior). También se recuerda al usuario el intervalo normal para esta medición. El usuario puede mover los puntos clave y el software actualiza las mediciones según corresponda.
8. **Informe de la exploración:** el software permite al usuario exportar el informe de exploración que contiene:
    - Resumen de mediciones y exhaustividad
    - Ilustraciones (imágenes)

Definición de una exploración completa

Para el corazón del feto

Tabla 4: Lista de 52 criterios de calidad que definen la calidad de las 5 vistas recomendadas por la International Society of Ultrasound in Obstetrics and Gynecology para el cribado cardíaco del feto en el segundo y tercer trimestres del embarazo.

Vistas cardíacas	***Criterios de calidad en las vistas***	
	(A1) Sp	*Columna vertebral*
	(A2) IRb	*Costilla izquierda*

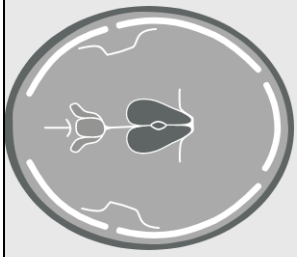
 **(A) ABD** **Vista del abdomen** **(n = 8)**	*(A3) rRb*	*Costilla derecha*
	(A4) Ao	*Aorta descendente*
	(A5) VC	*Vena cava inferior*
	(A6) St	*Estómago*
	(A7) Uv	*Vena umbilical*
	(A8) aA	*Abdomen anterior*
 **(B) 4CH** **Vista de cuatro cavidades** **(n = 19)**	*(B1) Sp*	*Columna vertebral*
	(B2) lRb	*Costilla izquierda*
	(B3) rRb	*Costilla derecha*
	(B4) Ao	*Aorta descendente*
	(B5) lPV	*Vena pulmonar izquierda*
	(B6) rPV	*Vena pulmonar derecha*
	(B7) LA	*Aurícula izquierda*
	(B8) RA	*Aurícula derecha*
	(B9) FOF	*Septum primum (válvula de Vieussens o colgajo del foramen oval)*
	(B10) FO	*Foramen oval abierto*
	(B11) MV	*Válvula mitral*
	(B12) TV	*Válvula tricúspide*
	(B13) bCr	*Conexión entre la cruz y el tabique interauricular (tabique vestibular)*
	(B14) Cr	*Desplazamiento de la válvula auriculoventricular en la cruz*
	(B15) tCr	*Conexión entre el tabique interventricular y la cruz*
	(B16) IVS	*Tabique interventricular*
	(B17) LV	*Ventrículo izquierdo*
	(B18) RV	*Ventrículo derecho*
	(B19) Str	*Esternón*
 **(C) LVOT** **Vista del tracto de salida del ventrículo izquierdo** **(n = 6)**	*(C1) LA*	*Aurícula izquierda*
	(C2) aAo	*Aorta ascendente proximal*
	(C3) SV	*Válvulas semilunares*
	(C4) LV	*Ventrículo izquierdo*
	(C5) IVS	*Tabique interventricular*
	(C6) RV	*Ventrículo derecho*
	(D1) dAo	*Aorta descendente*
	(D2) Tr	*Tráquea/bronquios*
	(D3) lPA	*Arteria pulmonar izquierda*

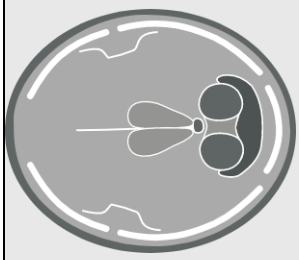
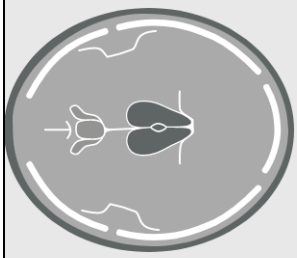
 **(D) RVOT** **Vista del tracto de salida del ventrículo derecho** **(n = 10)**	*(D4) Du*	*Conducto arterial*
	(D5) rPA	*Arteria pulmonar derecha*
	(D6) O	*Origen de las arterias pulmonares*
	(D7) S	*Tabique entre el tronco de la arteria pulmonar y la aorta ascendente*
	(D8) aAo	*Aorta ascendente*
	(D9) SVC	*Vena cava superior*
	(D10) PA	*Tronco pulmonar*
 **(E) 3VX** **Vista de tres vasos** **(n = 9)**	*(E1) Sp*	*Columna vertebral*
	(E2) Tr	*Tráquea*
	(E3) ES	*Espacio lateral a la izquierda del conducto/arteria pulmonar*
	(E4) DuA	*Arco ductal conectado a la aorta descendente*
	(E5) Du	*Arco ductal no conectado a la aorta descendente*
	(E6) aAo	*Aorta ascendente*
	(E7) aAr	*Arco aórtico*
	(E8) SVC	*Vena cava superior*
	(E9) Th	*Timo/esternón*

*En las directrices internacionales y nacionales [Carvalho2023] se recomiendan 5 vistas cardíacas del feto para la exploración ecográfica habitual en el segundo y tercer trimestres del embarazo: (A) Vista del abdomen, (B) Vista de cuatro cavidades, (C) Vista del tracto de salida del ventrículo izquierdo, (D) Vista del tracto de salida del ventrículo derecho y (E) Vista de tres vasos. La calidad de estas 5 vistas cardíacas depende de la presencia de 52 criterios de calidad anatómica dentro de las vistas (**Tabla 1**). Así pues, una exploración puede definirse como completa cuando el profesional sanitario obtiene las 5 vistas cardíacas y sus criterios de calidad.*

Para el cerebro fetal

Tabla 5: Lista de 34 criterios de calidad que definen la calidad de las 3 vistas recomendadas por la International Society of Ultrasound in Obstetrics and Gynecology para el cribado cerebral del feto en el segundo y tercer trimestres del embarazo.

Vistas cerebrales	***Criterios de calidad en las vistas***	
 **(F) TV** **Vista axial** **(n = 18)**	*(F1) aFx*	*Hoz anterior*
	(F2) CSP	*Cavum Septum Pellucidum*
	(F3) For	*Trígono cerebral*
	(F4) dAV	*Ventrículo anterior distal*
	(F5) pAV	*Ventrículo anterior proximal*
	(F6) AC	*Cisterna ambiens*
	(F7) Atr	*Trígono colateral*
	(F8) CP	*Plexo coroideo*
	(F9) POS	*Surco parietooccipital*

	(F10) pFx	*Hoz posterior*
	(F11) dCS	*Sutura coronal distal*
	(F12) pCS	*Sutura coronal proximal*
	(F13) SF	*Cisura de Silvio*
	(F14) Sk	*Cráneo*
	(F15) Sep	*Separación de tálamos*
	(F16) 3V	*Tercer ventrículo*
	(F17) dTh	*Tálamo distal*
	(F18) pTh	*Tálamo proximal*
 ***(G) TC*** ***Vista transcerebelosa*** ***(n = 8)***	*(G1) dTh*	*Tálamo distal*
	(G2) pTh	*Tálamo proximal*
	(G3) 4V	*Cuarto ventrículo*
	(G4) Ver	*Vermis*
	(G5) dCH	*Hemisferio cerebeloso distal*
	(G6) pCH	*Hemisferio cerebeloso proximal*
	(G7) CB	*Borde cerebeloso*
	(G8) CM	*Cisterna Magma*
 ***(H) TT*** ***Vista transtalámica*** ***(n = 12)***	*(H1) aFx*	*Hoz anterior*
	(H2) CSP	*Cavum Septum Pellicidum*
	(H3) dAV	*Ventrículo anterior distal*
	(H4) pAV	*Ventrículo anterior proximal*
	(H5) dTh	*Tálamo distal*
	(H6) pTh	*Tálamo proximal*
	(H7) Sep	*Separación de tálamos*
	(H8) 3V	*Tercer ventrículo*
	(H9) dCS	*Sutura coronal distal*
	(H10) pCS	*Sutura coronal proximal*
	(H11) SF	*Cisura de Silvio*
	(H12) Sk	*Cráneo*
 ***(I) SAG*** ***Vista sagital/de perfil*** ***(n = 8)***	*(I1) NB*	*Hueso de la nariz*
	(I2) uVer	*Parte superior del vermis*
	(I3) lVer	*Parte inferior del vermis*
	(I4) Fas	*Fastigio*
	(I5) rgCC	*Rostro y genu del cuerpo calloso*
	(I6) bCC	*Cuerpo del cuerpo calloso*
	(I7) sCC	*Esplenio del cuerpo calloso*
	(I8) CSP	*Cavum Septum Pellicidum*

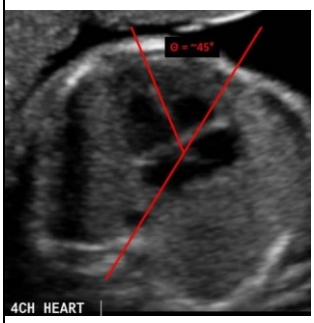
Medidas biométricas e intervalos de referencia

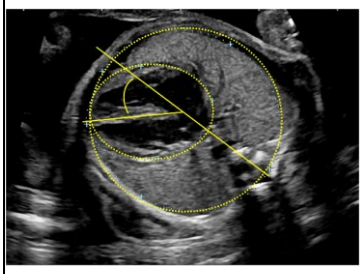
FETOLY proporciona tres tipos de mediciones biométricas automatizadas:

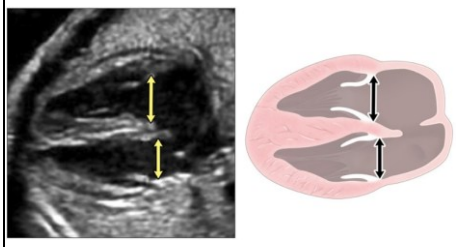
- **Medición del ángulo** mostrada en grados (°)
- **Medición del índice** (una distancia normalizada con otra distancia, representada como un índice o un porcentaje)
- **Número** de puntos de referencia anatómicos detectados

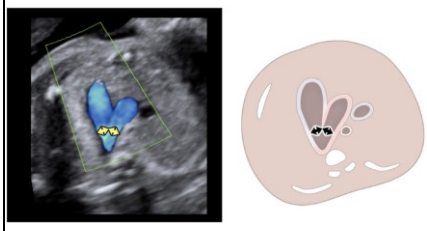
Lista de mediciones y sus intervalos de referencia:

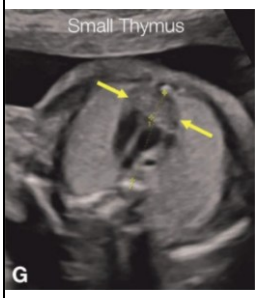
En la tabla siguiente se detallan las mediciones biométricas proporcionadas por FETOLY y sus correspondientes intervalos normales de referencia basados en la bibliografía establecida.

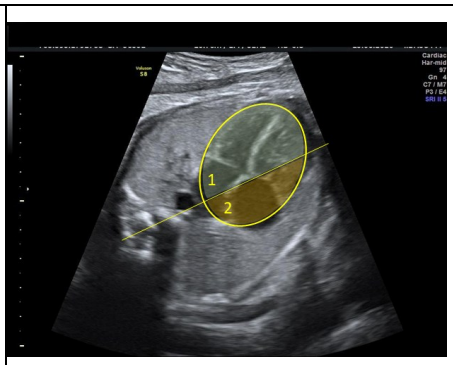
Parámetro	*Información disponible en FETOLY (descripción y fuentes)*
(M1) Eje cardíaco	***¿Qué es el eje cardíaco (CAx)?***  *(fuente: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* *El **eje cardíaco** (o **ángulo cardíaco**) se refiere a la orientación del corazón en relación con la línea media del tórax medida en la vista de cuatro cavidades. Se determina por el ángulo entre una línea a lo largo del tabique interventricular y una línea anteroposterior que biseca el tórax.* *La imagen debe incluir la columna vertebral, el esternón y las cuatro cavidades. Las costillas izquierda y derecha deben estar presentes y ser visibles como costillas individuales.* ***¿Qué se recomienda en las directrices?*** *En las directrices de la ISUOG se indica que la exploración de detección cardíaca debe incluir la vista de cuatro cavidades y su evaluación debe incluir el eje cardíaco ("El corazón del feto normal se sitúa principalmente a la izquierda, con el ápice cardíaco apuntando hacia la izquierda en un ángulo de 45 ± 20° en relación con el eje anteroposterior del tórax") (Carvalho2023). Citan a(Comstock1987) que proporciona el intervalo de referencia para el eje cardíaco.* *En las directrices de la ASE también se recomienda la evaluación del eje cardíaco ("El eje cardíaco es un componente recomendado de las imágenes bidimensionales ecocardiográficas del feto [...] normal 35-65°)(Moon-Grady2023).* ***Intervalos de referencia disponibles:*** • **Comstock (1987):** (Media ± 2 DE)

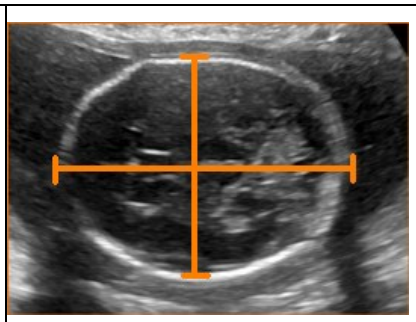
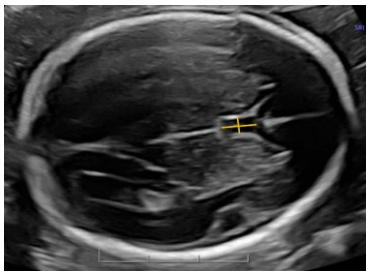
	○ 17-40GA: [25° - 65°]. • **ASE (2023):** (intervalo de referencia definido en las directrices) ○ 17-40GA: [35° - 65°]
(M2) Índice cardiotorácico	***¿Qué es el índice cardiotorácico?***  *(fuente: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *El índice cardiotorácico fetal (CTR) se refiere al índice que se obtiene entre la circunferencia transversal de la superficie epicárdica del corazón y la circunferencia transversal del tórax medida en la vista de cuatro cavidades durante la diástole.* *La imagen debe incluir la columna vertebral, el esternón y las cuatro cavidades. Las costillas izquierda y derecha deben estar presentes y ser visibles como costillas individuales.* ***¿Qué se recomienda en las directrices?*** *En las directrices de la ASE se indica que el índice cardiotorácico es un componente obligatorio de un ecocardiograma fetal ("Mediciones biométricas estándar a partir de una imagen axial a nivel de la vista de cuatro cavidades. El índice cardiotorácico se calcula a partir de la medición de la circunferencia interior (o área) del tórax y la superficie epicárdica del corazón") (Moon-Grady2023).* *En las directrices de la AIUM también se indica que el índice cardiotorácico es una biometría cardíaca obligatoria (AIUM2019). En las directrices de la ISUOG también se recomienda esta medición ("Los elementos clave de la vista normal de cuatro cavidades en el segundo trimestre incluyen un área cardíaca no superior a un tercio del área torácica") (Carvalho2013). En el manual de Abuhamad (2009) también se recomienda evaluar las dimensiones cardíacas ("Las dimensiones cardíacas del feto pueden evaluarse fácilmente midiendo el índice entre la circunferencia o área cardíaca y la circunferencia o área torácica obtenido a nivel de la vista de cuatro cavidades) (Abuhamad2009). En las directrices de la AHA(Donofrio2014) y en el manual de Abuhamad se cita (Paladini1990) para el intervalo de referencia.* ***Intervalos de referencia disponibles:*** • **Paladini (1990):** (percentiles 2,5 y 97 para la circunferencia) ○ 17GA: [0,40 - 0,52] ○ 18GA: [0,40 - 0,52] ○ 19GA: [0,42 - 0,51] ○ … ○ 40GA: [0,46 - 0,56] • **García-Otero (2020)**: (percentiles 5 y 95 para el área) ○ 18GA: [0,16 - 0,25]

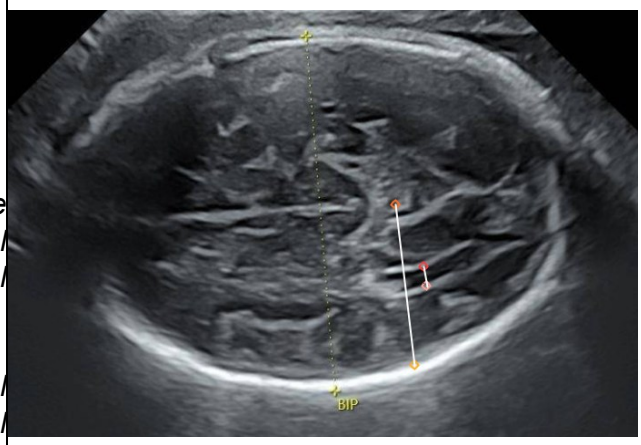
	○ 19GA: [0,16 - 0,26] ○ … ○ 40GA: [0,21 - 0,35] • **ASE** (Moon-Grady2023): (intervalo definido por las directrices para la puntuación del área fetal óptima) ○ 17-40GA: [0,20-0,35]
(M3) Índice del ancho ventricular	***¿Qué es el índice ventrículo derecho/ventrículo izquierdo?***  *(fuente: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *El **índice ventrículo derecho/ventrículo izquierdo (TV/MV)** se refiere al índice entre el diámetro anular de la válvula tricúspide (TV) y el diámetro anular de la válvula mitral (MV), que se utiliza para evaluar la morfología cardíaca en los fetos. Se determina comparando los diámetros de la TV y la MV en sus puntos más anchos durante la diástole.* *La imagen debe incluir la columna vertebral y el esternón. Las costillas izquierda y derecha deben estar presentes y ser visibles como costillas individuales. Las vistas de las cuatro cavidades deben ser visibles y estar bien contrastadas.* *Nota: existen dos convenciones para medir el diámetro ventricular (Schneider2005): la medición a nivel de las válvulas o la dimensión telediastólica. Obsérvese que para esta medición se utiliza la primera.* ***¿Qué se recomienda en las directrices?*** *En las directrices de la AIUM se indica que la comparación de los anillos de las válvulas tricúspide y mitral en la diástole es una biometría cardíaca obligatoria ("Anillos de las válvulas tricúspide y mitral en la diástole ([...] comparación de las válvulas del lado izquierdo con las del lado derecho) es una biometría cardíaca obligatoria") (AIUM2019). Citan a (DeVore2017), (Lee2009) y (Schneider2005) para los intervalos de referencia.* *En las directrices de la ISUOG también se indica que la asimetría de derecha a izquierda justifica una exploración más exhaustiva ("Ambos ventrículos deben parecer similares en tamaño. Aunque una desproporción ventricular leve puede ocurrir como una variante normal en el tercer trimestre del embarazo, la asimetría derecha-izquierda en la mitad de la gestación justifica una exploración más exhaustiva") (Carvalho2023). Citan a (Kirk1999) para el intervalo de referencia.* *En las directrices de la ASE también se indica que el índice del tamaño ventricular es una evaluación obligatoria del ecocardiograma fetal ("el anillo de la válvula AV en la diástole temprana es necesario como parte de la ecocardiografía completa") (Moon-Grady2023). En el manual de Abuhamed (2012) también se destaca la*

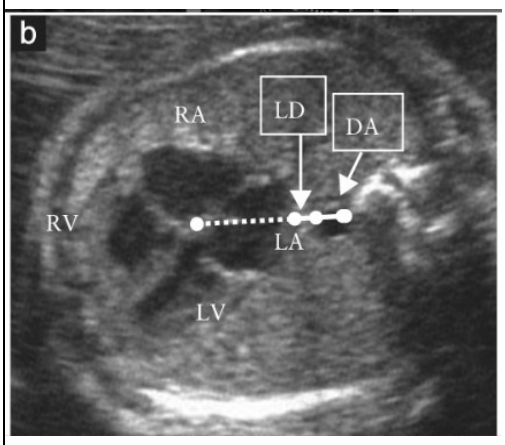
	importancia del índice del ancho ventricular derecho a izquierdo, de 1,19 en fetos normales. ***Intervalos de referencia disponibles:*** • **Gabbay-Benziv (2015)** (Gabbay-Benziv2015): (percentiles 2,5 y 97) ○ 17GA: [0,87 - 1,22] ○ 18GA: [0,86 - 1,22] ○ 19GA: [0,86 - 1,22] ○ … ○ 38GA: [0,87 - 1,30] • **García-Otero (2020)**: (percentiles 5 y 95) ○ 18GA: [0,82 - 1,21] ○ 19GA: [0,82 - 1,22] ○ … ○ 40GA: [0,86 - 1,27]
(M4) Índice de vasos	***¿Cuál es el índice de los grandes vasos?***  *(fuente: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *El índice de tamaño de los grandes vasos (Ao/Du) se refiere a el índice entre los diámetros del istmo aórtico (Ao) y el conducto (Du) en la vista de tres vasos. Se determina midiendo los diámetros del conducto y del arco aórtico en su base. Obsérvese que el índice entre el diámetro de la arteria pulmonar (AP) mediastínica y la aorta ascendente (Ao) también se utiliza en la bibliografía (Slodki2009).* *La imagen debe incluir la columna vertebral y el esternón, con las costillas izquierda y derecha visibles y diferenciadas. El conducto arterial y la aorta ascendente deben ser claramente visibles, demostrando su conexión.* ***¿Qué se recomienda en las directrices?*** *En las asociaciones estadounidenses e internacionales, como la ASE, la ISUOG, la AIUM y la AHA, se indica que la evaluación del índice de tamaño entre las grandes arterias es obligatoria (Donofrio2014). ("Es importante determinar la normalidad de las dos grandes arterias, incluido su tamaño relativo entre sí") (Carvalho2023). En el manual de Abuhamad (2012) también se destaca la importancia de la comparación entre los diámetros del arco aórtico y la arteria pulmonar principal, específicamente en la región del istmo. Citan el estudio de Pasquini (2007) (Pasquini2007) para los intervalos de referencia.* ***Intervalos de referencia disponibles:*** • **Pasquini (2007):** ○ Constante: [0,86 - 1,12] (media ± DE) ○ Constante: [0,74 - 1,23] (percentiles 2,5 y 97,5) (Buyens2012)

(M5) Número de vasos	***¿Cuál es el número de vasos?*** *La vista fetal de tres vasos (3VV) es un plano axial utilizado en las imágenes prenatales para evaluar los grandes vasos del corazón. Esta vista suele mostrar tres vasos, normalmente la arteria pulmonar, la aorta y la vena cava superior. El recuento de vasos solo se centra en las estructuras anecoicas redondas o alargadas, y excluye la tráquea y la aorta descendente.* *La imagen debe resaltar los vasos, con un claro contraste y distinción de las estructuras.* ***¿Qué se recomienda en las directrices?*** *En las directrices de la ISUOG se recomienda que la evaluación de la vista de tres vasos "incluya una evaluación del número de vasos. De izquierda a derecha, los vasos son la arteria pulmonar, la aorta y la vena cava superior derecha" (Carvalho2023). En las directrices de la ASE también se hace hincapié en que deben señalarse las anomalías en el número de vasos (Moon-Grady2023). Como norma internacional, el número previsto de vasos es de tres.*
(M6) Índice timo-torácico	***¿Cuál es el índice timo-torácico?***  *(fuente: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4.ª ed.). Wolters Kluwer)* *El **índice timo-torácico** es el índice entre los diámetros anteroposterior del timo y mediastínico intratorácico medidos en la vista de los tres vasos y la tráquea.* *La imagen debe mostrar la columna vertebral, el esternón y la aorta ascendente, con las costillas izquierda y derecha visibles como estructuras individuales. El timo debe ser claramente visible e identificable.* ***¿Qué se recomienda en las directrices?*** *En las directrices de la ISUOG se indica que la "[evaluación de la vista de tres vasos] implica una evaluación de la alineación de los vasos". (Carvalho2023) y que "puede mejorar la detección de anomalías del tracto de salida [...]". Citan a (Chaoui2011) para la evaluación del índice timo-torácico para detectar anomalías del tracto de salida. En el manual de Abuhamad (2022) también se indica la importancia de evaluar este parámetro.* ***Intervalos de referencia disponibles:*** • **Chaoui (2011):** o Constante durante toda la gestación: [0,36 - 0,53] (media ± 2 DE)
(M7) Posición	***¿Qué es la posición cardiotorácica?***

cardiotorácica	 *(imagen inspirada en https://obgynkey.com/cardíac-chambers-the-four-chamber-and-short-axis-views/)* *La **posición cardiotorácica** se determina extendiendo posteriormente la línea del tabique interventricular que divide las aurículas hasta un punto en la base del corazón (Smith1995). Esto se realiza en la vista de cuatro cavidades calculando el índice entre el área de la parte izquierda y el área cardíaca total. Este proceso consiste en dibujar una elipse sobre el corazón y dividirla con una línea anteroposterior que biseca el tórax (la línea media del tórax). Las áreas izquierda (1) y derecha (2) representan las superficies cardíacas situadas en los lados anatómicos izquierdo y derecho de la línea media, respectivamente. La posición se expresa como el índice entre el área izquierda y el área cardíaca total.* ***¿Qué se recomienda en las directrices?*** *La posición del corazón del feto dentro del tórax es un parámetro importante en la evaluación del feto. La desviación de la posición normal justifica una investigación más exhaustiva de las posibles patologías intratorácicas, intracardíacas o extracardíacas (Abdullah2000). Tanto en las directrices estadounidenses como en las internacionales, incluidas las de la ISUOG (2008), la ASE (2004), la AIUM (2013) y la AHA (2014), se recomienda medir con atención la posición del corazón del feto dentro del tórax en la vista de cuatro cavidades durante las ecografías obstétricas estándar (Donofrio2014). Según estas directrices, el corazón del feto normal se localiza principalmente en el lado izquierdo del tórax, con al menos el 50 % (índice ≥0,5) de su superficie dentro del espacio torácico izquierdo ("el corazón está principalmente en el lado izquierdo") (Carvalho2013) ("debe prestarse especial atención al eje cardíaco y a la posición. La mayor parte del corazón [debe estar] en el tórax izquierdo") (Carvalho2023). En los estudios se corroboran estas recomendaciones y Chiappa (2009) y otros (Smith1995, Sever2021) afirman que "dos tercios del corazón [deben estar] en el lado izquierdo del tórax".* *Aunque las numerosas directrices definen la posición cardiotorácica normal como 0,66 (índice ≈ 2/3) y no debe ser inferior a 0,5, la bibliografía no define claramente el límite superior del intervalo normal. Los usuarios pueden visualizar únicamente el valor medido sin un intervalo de referencia o definir su propio intervalo de referencia.*
(M8) Índice cefálico	***¿Qué es el índice cefálico?***

	 *(fuente: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* *El **índice cefálico** es el índice entre el diámetro biparietal (BPD) y el diámetro occipitofrontal (OFD) multiplicado por 100. El índice cefálico da una idea de la forma de la cabeza del feto. La distancia de delante hacia atrás, OFD, se mide colocando el cursor en el borde exterior de los huesos craneales. Un índice cefálico muy reducido sugiere dolicocefalia, mientras que uno muy elevado puede sugerir braquicefalia. Cuando este parámetro es anómalo, se deben utilizar otras mediciones, como el HC, la circunferencia abdominal o la longitud del fémur, para predecir la edad del feto (Timor-Tritsch2012).* *La imagen debe mostrar una vista axialmente simétrica del cerebro, capturando el plano transtalámico con ambos hemisferios visibles y nítidos.* ***¿Qué se recomienda en las directrices?*** *En las directrices de la ISUOG se indica que "el índice cefálico es una relación entre el ancho máximo de la cabeza (BPD) y su longitud máxima (diámetro occipitofrontal (OFD) y este valor puede utilizarse para caracterizar la forma de la cabeza del feto. La forma anómala de la cabeza (p. ej., braquicefalia o dolicocefalia) puede estar asociada a síndromes o ser consecuencia de oligohidramnios o presentación podálica. Este hallazgo también puede dar lugar a estimaciones inexactas de la edad del feto cuando se utiliza el BPD; en estos casos, las mediciones del HC son aún más fiables (Hadlock1981)" (Salomon2022).* ***Intervalos de referencia disponibles:*** • **Hadlock (1981):** o Constante durante toda la gestación: [74 - 83] (media ± DE)
(M9) Índice CSP	***¿Qué es el índice CSP?***  ***(fuente: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. En Journal of Ultrasound in Medicine (Vol. 43, Número 8, pp. 1461–1466). Wiley)*** ***Descripción:** El **índice del cavum septum pellucidum (CSP)** es el índice entre la longitud y la anchura del CSP. Se determina midiendo la longitud y la anchura del CSP y calculando el índice entre ambas.*

	La imagen debe mostrar una vista transventricular axialmente simétrica del cerebro, con una visualización clara del cavum septum pellucidum (CSP) y las estructuras anatómicas de la línea media. ***¿Qué recomiendan las directrices?*** *Las directrices de la ISUOG indican que la forma del CSP se ha descrito como un marcador relativamente fiable de la agenesia parcial del cuerpo calloso y citan los estudios de Karl (2017) y Shen (2015) para los intervalos de referencia (Malinger2020).* *Las directrices de la Asociación Mundial de Medicina Perinatal (WAPM) indican que el CSP debe visualizarse y que «la imposibilidad de visualizar el CSP o su aspecto anormal (Karl2017) es predictivo de anomalías comisurales. Sin embargo, el aspecto normal del CSP no excluye todas las anomalías [del cuerpo calloso]» (Robertis2021).* *Este parámetro también se puede encontrar en las técnicas de aprendizaje profundo de última generación para la biometría rutinaria (Coronado-Gutiérrez2023).* ***Intervalos de referencia disponibles:*** • **Karl (2017):** *Constante durante toda la gestación: [1,5 - 3,3] (percentiles 5 y 95)*
(M10) Índice entre el diámetro del ventrículo cerebral posterior y el diámetro del hemisferio (índice VP)	***¿Qué es el índice entre el diámetro del ventrículo cerebral posterior y el diámetro del hemisferio?***  *El **índice entre el diámetro del ventrículo cerebral posterior y el diámetro del hemisferio** es un parámetro utilizado para evaluar el desarrollo cerebral, en particular el tamaño ventricular en relación con el tamaño total del cerebro (hemisferio).* *Es el índice entre:* - *El diámetro del ventrículo cerebral posterior (= anchura auricular), que suele referirse a la aurícula del ventrículo lateral (situada en la unión de los cuernos occipital, temporal y parietal).*

	- *El diámetro del hemisferio cerebral, es decir, el diámetro transversal total del hemisferio cerebral correspondiente.* *Esta medición se realizará en la vista transventricular.* ***¿Qué recomiendan las directrices?*** *Las directrices de la ISUOG indican que la medición del ancho auricular es una parte integral de la ecografía de cribado de malformaciones del SNC y que el ancho auricular debe medirse de interior a interior y debe ser <10 mm durante todo el embarazo.* *La literatura revisada por pares (Nicolaides, 1994) destaca la importancia del índice entre el diámetro del ventrículo cerebral posterior y el diámetro del hemisferio en la mejora de la evaluación cerebral prenatal y la precisión del cribado fetal, ya que es un marcador relativamente fiable de ventriculomegalia.* ***Intervalos de referencia disponibles:*** • ***Nicolaides (1994):*** *(percentiles 5 y 95)* o *17 GA: [0,29 - 0,45]* o *18 GA: [0,27 - 0,42]* o *19 GA: [0,26 - 0,40]* o *…* *39 GA: [0,15 - 0,24]*
(M11) Espacio posauricular izquierdo (PLAS)	***¿Qué es el índice del espacio posauricular izquierdo (PLAS)?***  *(Fuente: Kawazu2014)* *El índice del espacio posterior a la aurícula izquierda (PLAS) es una medida ecocardiográfica fetal que se utiliza para evaluar el espacio posterior a la aurícula izquierda. Se calcula a partir de una vista de cuatro cámaras del corazón fetal. La medida consiste en determinar la distancia entre la pared posterior de la aurícula izquierda y la pared anterior de la aorta descendente (LD) y dividirla por el diámetro de la aorta descendente (DA). El cálculo se realiza durante la fase telesistólica del ciclo cardíaco.* *La fórmula para el índice PLAS es:*

	Índice PLAS = Distancia entre la aurícula izquierda y la aorta descendente (LD) / Diámetro de la aorta descendente (DA) ***¿Qué recomiendan las directrices? (Fundamento y relevancia clínica)*** *La literatura revisada por pares (Kawazu2019, Anuwutnavin2023 y Akkurt2015) ha destacado la importancia del índice PLAS como una medición sencilla y reproducible en el cribado cardíaco fetal. Introducido inicialmente por (Kawazu2014), el índice PLAS se ha identificado como un marcador sensible para el diagnóstico prenatal de la conexión venosa pulmonar anómala total (TAPVC), una afección en la que las venas pulmonares no se conectan a la aurícula izquierda. Un aumento del índice PLAS es un indicador significativo de TAPVC* ***Intervalos de referencia disponibles:*** *Kawazu2014 y Kawazu2019: Constante durante todo el embarazo: un valor de corte óptimo **>1,27** para sugerir TAPVC. Para los fetos normales, el índice PLAS medio fue de **0,62 ± 0,19**.*

*Cada medición requiere un punto de vista ecográfico específico, denominado "**subvista**", que debe cumplir unas condiciones de imagen concretas para garantizar una medición precisa. Una subvista siempre se deriva de una de las vistas fetales de cribado estándar, pero también requiere otras condiciones particulares. Por ejemplo, la medición del índice ventricular derecho-izquierdo en la vista de las cuatro cavidades requiere visualizar correctamente los bordes ventriculares, lo que no es necesario para el eje cardíaco.*

En la tabla siguiente se ilustra la correspondencia entre las subvistas y las vistas cardíacas o cerebrales descritas en las directrices de la ISUOG.

Vista	***Subvista***
Vista de cuatro cavidades	***Subvista 1 (M1):** La imagen debe incluir la columna vertebral, el esternón, las cuatro cavidades y el tabique interventricular. Las costillas izquierda y derecha deben estar presentes y ser visibles como costillas individuales.* ***Subvista 2 (M2):** La imagen debe incluir la columna vertebral, el esternón y las cuatro cavidades. Las costillas izquierda y derecha deben estar presentes y ser visibles como costillas individuales.* ***Subvista 3 (M3):** La imagen debe incluir la columna vertebral y el esternón. Las costillas izquierda y derecha deben estar presentes y ser visibles como costillas individuales. Las vistas de las cuatro cavidades deben ser visibles y estar bien contrastadas.* ***Subvista 7 (M7):** La imagen debe incluir la columna vertebral, el esternón y las cuatro cavidades.* ***Subvista 11 (M11):** El tórax aparece redondeado, sin forma de «V» abierta. Las costillas izquierda y derecha aparecen como estructuras únicas, sin líneas múltiples paralelas o*

	secuenciales. La aurícula y la aorta, especialmente sus paredes posteriores, así como el espacio entre ellas, son claramente visibles, sin obstrucción por sombras.
Vistas de tres vasos y de tres vasos y tráquea	***Subvista 4 (M4):** La imagen debe incluir la columna vertebral y el esternón, con las costillas izquierda y derecha visibles y diferenciadas. El conducto arterial y la aorta ascendente deben ser claramente visibles, demostrando su conexión.* ***Subvista 5 (M5):** La imagen debe resaltar los vasos, con un claro contraste y distinción de las estructuras.* ***Subvista 6 (M6):** La imagen debe mostrar la columna vertebral, el esternón y la aorta ascendente, con las costillas izquierda y derecha visibles como estructuras individuales. El timo debe ser claramente visible e identificable.*
Vista axial	***Subvista 8 (M8):** La imagen debe mostrar una vista axialmente simétrica del cerebro, capturando el plano transtalámico con ambos hemisferios visibles y nítidos.* ***Subvista 9 (M9):** La imagen debe mostrar una vista transventricular axialmente simétrica del cerebro, con una visualización clara del cavum septum pellucidum (CSP) y las estructuras anatómicas de la línea media.* ***Subvista 10 (M10):** La imagen debe mostrar una vista axial en la que sea visible el POS (surco parietooccipital).*

Funcionalidad 1: medidor de exhaustividad

El software evalúa, mediante un algoritmo de aprendizaje profundo integrado entrenado mediante aprendizaje supervisado, la exhaustividad de la exploración ecográfica del feto. Verifica si se ha obtenido toda la información correspondiente a las directrices recomendadas para la exploración cardíaca y cerebral fetal. Esta información corresponde a la presencia de:

- 5 vistas cardíacas del feto principales y 52 criterios de calidad, detallados anteriormente, que permiten el cumplimiento en el cribado cardíaco;
- 4 vistas principales cerebrales del feto y 43 criterios de calidad, detallados anteriormente, que permiten el cumplimiento en el cribado cerebral.

La página de exhaustividad **(Figura 1**) consta de:

- Un **botón de reproducción/pausa** inicia el análisis de las imágenes obtenidas por el ecógrafo al principio de la exploración,
- El **recuento de vistas cardíacas o cerebrales** verificadas por el software desde el inicio de la exploración. Una vista del corazón se considera verificada cuando se detecta en al menos una imagen,
- Botones individuales para **cada uno de los criterios de calidad**, que se iluminan **en color verde** tras la verificación por parte del software.

La página de exhaustividad se actualiza automáticamente con cada imagen que analiza el software de la siguiente manera:

- Si se detecta un criterio de calidad en la imagen por primera vez, el criterio se marca como **verificado** y su color cambia de blanco a **verde**).

- Si se detecta un criterio de calidad en la imagen que ya se había verificado anteriormente, no se produce ningún cambio.
- Si no se detecta un criterio de calidad en la imagen, no se produce ningún cambio.

Si un criterio de calidad está asociado a una anomalía, el estado de detección del criterio depende de su aspecto visual:

- Si una anomalía altera un criterio de calidad cambiando su aspecto, es posible que el software no detecte el criterio y el estado permanecerá sin verificar.
- Si una anomalía no afecta al aspecto del criterio de calidad, el software lo detectará y lo marcará como verificado, cambiando su color de blanco a **verde.**

Téngase en cuenta que en el etiquetado se recuerda que FETOLY no permite realizar diagnósticos ni pruebas de detección. Un criterio de calidad no verificado por el software no indica intrínsecamente una patología.

La página de exhaustividad se actualiza continuamente en tiempo real, lo que permite a los usuarios consultarla en cualquier momento de la exploración. De este modo, pueden mirar la página sin interrumpir su trabajo durante la exploración ni tener que atender a otras acciones.

A modo de recordatorio y tal como se explica en la sección 10, FETOLY no puede utilizarse para realizar diagnósticos o cribados. Un criterio de calidad no verificado por el software no indica intrínsecamente una patología.

Funcionalidad 2: ilustración de exhaustividad

Esta funcionalidad se desarrolló para mejorar la seguridad de la evaluación de exhaustividad que realiza el primer módulo. Permite a los médicos verificar el resumen de la exhaustividad de la exploración, es decir, las vistas verificadas y los criterios de calidad por el software a través de la página de galería de la interfaz del software. De funcionamiento continuo, evalúa cada imagen procesada por el primer módulo en tiempo real, conservando un conjunto de imágenes como prueba visual de las vistas cardíacas o cerebrales verificadas y los criterios de calidad hasta ese momento.

FETOLY no tiene como objetivo seleccionar las "mejores" o las de "alta" calidad diagnóstica según una escala cualitativa determinada. FETOLY tiene más bien como objetivo seleccionar imágenes que ilustren la exhaustividad cuantitativa de la exploración en cuanto a vistas verificadas y criterios de calidad. Dado que este módulo se basa por completo en el rendimiento del algoritmo de aprendizaje profundo del primer módulo, no es necesaria ninguna evaluación adicional del rendimiento.

Por ejemplo, si el usuario tiene dudas sobre uno de los criterios de calidad verde, puede verificar la presencia de ese criterio haciendo clic sobre él en la página de galería. El programa mostrará las imágenes que contengan este criterio (en amarillo en la figura siguiente). Cuando se selecciona un criterio, el programa muestra el cuadro delimitador que rodea al criterio en estas imágenes. Esta información forma parte de los resultados de Fetoly-CNN.

Funcionalidad 3: Mediciones biométricas

La sección del módulo **FETOLY-MEDICIÓN** está etiquetada con "Medición" en la página de análisis y muestra una lista de mediciones, cada una organizada en cuatro campos:

- **Nombre de la medición**: Muestra el nombre o la abreviatura de la medición junto con un icono de información. Al hacer clic en el icono se abre información detallada sobre la medición, incluida su referencia científica.
- **Valor de la medición y unidades de medida**: El valor medido se muestra con las unidades correspondientes. Por ejemplo, se muestra un símbolo de grado (°) para las mediciones angulares y un símbolo de porcentaje (%); de lo contrario, el campo permanece vacío, lo que significa que se trata de una medición relativa. Si los puntos clave se han editado en la página de galería, aparecerá un símbolo delante de la medición ( ).
- **Intervalo de referencia**: Este campo proporciona el intervalo de referencia definido por la bibliografía para la medición, respaldado por su referencia científica. La fuente puede ser una directriz, una publicación revisada por pares, un libro de texto o un intervalo personalizado definido por el usuario. Haciendo clic en el **botón de nueva pestaña**, el usuario puede definir manualmente el intervalo de referencia o actualizar la referencia bibliográfica si se dispone de múltiplos. Al hacer clic en el **botón de enlace de información**, el usuario puede acceder a una ventana emergente con toda la información necesaria relacionada con el criterio de medición dado.
- **Edad gestacional,** que se establecerá antes de iniciar el análisis.

Funcionalidad 4: Ilustración de mediciones

Al igual que la ilustración de exhaustividad que selecciona imágenes que demuestran vistas y criterios de calidad, selecciona automáticamente una imagen para cada medición. Ambos conjuntos de imágenes se muestran juntos en la página de galería. Estos dos conjuntos de imágenes son fáciles de distinguir: las imágenes de la función de medición incluyen un valor de medición y el nombre del parámetro, mientras que las imágenes de exhaustividad no tienen anotaciones.

Tanto las imágenes de "medición" como las de "exhaustividad" se organizan en función de sus correspondientes vistas ecográficas. Obsérvese que la afiliación de vista de las imágenes seleccionadas por la función de medición es independiente de la función de exhaustividad. De hecho, cada subvista de medición corresponde por definición a una de las 5 vistas ecográficas cardíacas o 4 vistas ecográficas cerebrales. Por lo tanto, conociendo la subvista, las imágenes seleccionadas por la función de medición pueden clasificarse automáticamente en la vista adecuada a la que pertenece esta subvista.

Funcionalidad 5: Informe de la exploración

Puede generarse un informe desde la página de exportación. Incluirá resultados e imágenes de FETOLY y se enviará a un dispositivo externo.

Dispositivos asociados

Para utilizar el dispositivo FETOLY, es necesario disponer de los siguientes dispositivos asociados:

- Un ecógrafo.
- Una tableta y, opcionalmente, un servidor DICOM, un ordenador con un servidor FTP o capacidades Bluetooth, como se especifica en la sección 10 "Interacción con otros equipos".
- Un dongle UVC y un cable HDMI para conectar la tableta con el ecógrafo.

5. Uso previsto e indicaciones de uso

El objetivo de FETOLY es analizar secuencias de imágenes ecográficas del feto mediante técnicas de aprendizaje automático:

- detectar vistas cerebrales y cardíacas, además de los criterios de calidad dentro de las vistas;
- detectar imágenes adecuadas para medir parámetros biométricos cardíacos y cerebrales del feto y proporcionar mediciones cuantitativas de estos parámetros.

El dispositivo está destinado a utilizarse como ayuda de lectura simultánea durante la adquisición e interpretación de imágenes de ecografía del feto.

FETOLY está indicado para su uso durante la exploración habitual cardíaca y cerebral del feto durante el segundo y el tercer trimestres del embarazo (edad gestacional: de 17 a 40 semanas).

6. Usuarios previstos

El producto debe ser utilizado por profesionales sanitarios cualificados especializados en ecografía prenatal.

7. Población de pacientes destinataria

Mujeres embarazadas en el segundo y el tercer trimestres del embarazo.

8. Beneficios y resultados clínicos

Para este tipo de dispositivo, un SWMD que es una ayuda de lectura concurrente utilizada durante la exploración habitual cardíaca y cerebral del feto, se ha demostrado el siguiente beneficio clínico:

- Normalización de la exploración habitual cardíaca y cerebral del feto, tal como exigen las directrices internacionales reconocidas.

Los resultados se detallan en las tablas siguientes. Los resultados de las pruebas de rendimiento autónomo demuestran que FETOLY automáticamente:

- detecta las vistas ecográficas cardíacas y cerebrales del feto con una sensibilidad ≥85 % (criterio de aceptación) y una especificidad ≥85 % (criterio de aceptación);
- detecta criterios de calidad dentro de las vistas cardíacas con una sensibilidad ≥90 % (criterio de aceptación) y una especificidad ≥90 % (criterio de aceptación);
- detecta criterios de calidad dentro de las vistas cerebrales con una sensibilidad ≥85 % (criterio de aceptación) y una especificidad ≥85 % (criterio de aceptación);
- localiza las cajas delimitadoras de los criterios de calidad con una intersección media sobre la unión (IoU) de ≥50 % (criterio de aceptación):
- detecta las subvistas ecográficas cardíacas y cerebrales del feto con una sensibilidad ≥70 % (criterio de aceptación) y una especificidad ≥70 % (criterio de aceptación); y
- realiza la medición del corazón y el cerebro del feto de acuerdo con cada LOA definido por los criterios de valoración del estudio.

En cuanto a los resultados generales

Vista fetal	Sensibilidad			Especificidad		
	N(positivo)	Estimación puntual	IC de Bootstrap (95 %)	N(negativo)	Estimación puntual	IC de Bootstrap (95 %)
Vista del abdomen	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Vista de cuatro cavidades	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Vista del tracto de salida ventricular izquierdo	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Vista del tracto de salida ventricular derecho	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Vista de tres vasos	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Vista axial	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Vista transcerebelosa	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Vista sagital/de perfil	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Otra vista	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Criterio de calidad	Sensibilidad			Especificidad			mIoU	
	N	Estimación puntual	IC de Bootstrap (95 %)	N	Estimación puntual	IC de Bootstrap (95 %)	Estimación puntual	IC de Bootstrap (95 %)
Vista del abdomen								
Columna vertebral	678	0.99	(0.983,0.998)	4531	0.998	(0.996,0.999)	0.71	(0.70,0.73)
Costilla izquierda	632	0.967	(0.953,0.980)	4577	0.993	(0.991,0.995)	0.58	(0.56,0.59)
Costilla derecha	627	0.951	(0.934,0.967)	4582	0.994	(0.992,0.996)	0.55	(0.53,0.57)
Aorta descendente	673	0.972	(0.959,0.984)	4536	0.998	(0.996,0.999)	0.52	(0.51,0.54)
Vena cava inferior	550	0.939	(0.917,0.958)	4659	0.987	(0.983,0.990)	0.5	(0.49,0.52)
Estómago	675	0.983	(0.973,0.992)	4534	0.999	(0.998,1.000)	0.74	(0.72,0.75)
Vena umbilical	552	0.973	(0.958,0.986)	4657	0.99	(0.988,0.993)	0.64	(0.62,0.65)
Abdomen anterior	643	0.969	(0.954,0.983)	4566	0.993	(0.990,0.995)	0.5	(0.49,0.52)
Vista de cuatro cavidades								
Columna vertebral	595	0.969	(0.955,0.982)	4614	0.998	(0.996,0.999)	0.74	(0.73,0.75)
Costilla izquierda	536	0.945	(0.924,0.963)	4673	0.99	(0.987,0.993)	0.64	(0.63,0.66)
Costilla derecha	548	0.948	(0.926,0.965)	4661	0.993	(0.991,0.996)	0.68	(0.66,0.69)
Aorta descendente	608	0.968	(0.952,0.981)	4601	0.997	(0.995,0.998)	0.66	(0.65,0.67)
Vena pulmonar izquierda	240	0.925	(0.889,0.958)	4969	0.975	(0.971,0.979)	0.51	(0.48,0.53)

Vena pulmonar derecha	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*
Aurícula izquierda	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Aurícula derecha	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Septum primum (válvula de Vieussens o colgajo del foramen oval)	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Foramen oval abierto	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Válvula mitral	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Válvula tricúspide	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Conexión entre la cruz y el tabique interauricular (tabique vestibular)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Desplazamiento de la válvula auriculoventricular en la cruz	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Conexión entre el tabique interventricular y la cruz	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Tabique interventricular	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Ventrículo izquierdo	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Ventrículo derecho	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Esternón	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Vista del tracto de salida ventricular izquierdo								
Aurícula izquierda	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Aorta ascendente proximal	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Válvulas semilunares	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Ventrículo izquierdo	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Tabique interventricular	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Ventrículo derecho	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*

Vista del tracto de salida ventricular derecho								
Aorta descendente	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Tráquea/bronquios	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Arteria pulmonar izquierda	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*
Conducto arterial	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Arteria pulmonar derecha	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Origen de las arterias pulmonares	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Tabique entre el tronco de la arteria pulmonar y la aorta ascendente	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Aorta ascendente	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Vena cava superior	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Tronco pulmonar	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Vistas de tres vasos								
Columna vertebral	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Tráquea	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Espacio lateral a la izquierda del conducto/arteria pulmonar	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Arco ductal conectado a la aorta descendente	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Arco ductal no conectado a la aorta descendente	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Aorta ascendente	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Arco aórtico	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Vena cava superior	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Timo/esternón	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Vista axial								

Hoz anterior	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavum Septum Pellucidum	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Trígono cerebral	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Ventrículo anterior distal	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Ventrículo anterior proximal	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cisterna ambiens	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Trígono colateral	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Plexo coroideo	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Surco parietooccipital	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Hoz posterior	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Sutura coronal distal	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Sutura coronal proximal	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Cisura de Silvio	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Cráneo	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Separación de tálamos	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
Tercer ventrículo	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Tálamo distal	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Tálamo proximal	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Vista transcerebelosa								
Tálamo distal	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Tálamo proximal	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
Cuarto ventrículo	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Vermis	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Hemisferio cerebeloso distal	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Hemisferio cerebeloso proximal	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Borde cerebeloso	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Cisterna Magma	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Vista sagital/de perfil								
Hueso de la nariz	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*

Parte superior del vermis	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Parte inferior del vermis	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastigio	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Rostro y genu del cuerpo calloso	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Cuerpo del cuerpo calloso	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Esplenio del cuerpo calloso	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavum Septum Pellicidum	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Medición	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp	LOA	IC de LOA
índice_timo-torácico	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
índice_cardiotorácico	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
índice_vasos	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
índice_cefálico	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
número_de_vasos	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
posición_cardiotorácica	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
índice_ventricular_derecha-izquierda	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
ángulo_cardíaco	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
Índice CSP	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
Índice VP	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
Espacio auricular posterior izquierdo	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Medición	pendiente	intercepción	IC de pendiente	IC de intercepción
índice_timo-torácico	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
índice_cardiotorácico	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
índice_vasos	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
índice_cefálico	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
número_de_vasos	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
posición_cardiotorácica	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
índice_ventricular_derecha-izquierda	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
ángulo_cardíaco	*0.9197936528230518*	*3.114077691538199*	*(0.888,0.945)*	*(2.023,4.477)*
Índice CSP	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
Índice VP	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
Espacio auricular posterior izquierdo	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Resultados del fabricante del ecógrafo

Clase	Sistema	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
I	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)
I	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)
X	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
X	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
X	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)

Clase	Sistema	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp	mIoU	IC de mIoU
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*

A.Sp	Samsung	296	0.984	(0.967,0.994)	1708	0.999	(0.997,1.000)	0.7	(0.68,0.71)
A.St	Canon	29	0.966	(0.893,1.000)	207	0.991	(0.975,1.000)	0.72	(0.67,0.76)
A.St	GE	279	0.993	(0.983,1.000)	2261	1.0	(1.000,1.000)	0.79	(0.77,0.80)
A.St	Samsung	293	0.973	(0.954,0.990)	1711	0.998	(0.996,1.000)	0.7	(0.68,0.72)
A.Uv	Canon	25	0.96	(0.870,1.000)	211	0.986	(0.969,1.000)	0.6	(0.51,0.67)
A.Uv	GE	217	0.977	(0.955,0.996)	2323	0.991	(0.988,0.995)	0.67	(0.65,0.70)
A.Uv	Samsung	240	0.967	(0.944,0.988)	1764	0.989	(0.984,0.993)	0.62	(0.59,0.64)
A.VC	Canon	26	0.885	(0.750,1.000)	210	0.986	(0.970,1.000)	0.46	(0.40,0.52)
A.VC	GE	221	0.973	(0.950,0.992)	2319	0.987	(0.983,0.991)	0.54	(0.52,0.57)
A.VC	Samsung	247	0.903	(0.864,0.939)	1757	0.989	(0.984,0.994)	0.49	(0.47,0.51)
B.Ao	Canon	27	0.926	(0.808,1.000)	209	0.996	(0.985,1.000)	0.71	(0.66,0.77)
B.Ao	GE	247	0.956	(0.926,0.980)	2293	0.997	(0.994,0.999)	0.73	(0.71,0.75)
B.Ao	Samsung	255	0.977	(0.956,0.993)	1749	0.999	(0.998,1.000)	0.6	(0.58,0.62)
B.bCr	Canon	25	0.92	(0.800,1.000)	211	0.986	(0.969,1.000)	0.65	(0.58,0.72)
B.bCr	GE	202	0.892	(0.849,0.932)	2338	0.992	(0.989,0.996)	0.61	(0.57,0.64)
B.bCr	Samsung	216	0.926	(0.889,0.959)	1788	0.984	(0.979,0.989)	0.54	(0.52,0.57)
B.Cr	Canon	7	0.715	(0.334,1.000)	229	0.983	(0.967,0.996)	0.62	(nan,nan)
B.Cr	GE	52	0.885	(0.789,0.961)	2488	0.989	(0.985,0.993)	0.52	(0.46,0.58)
B.Cr	Samsung	76	0.974	(0.933,1.000)	1928	0.977	(0.971,0.983)	0.57	(0.52,0.61)
B.FO	Canon	26	0.962	(0.880,1.000)	210	1.0	(1.000,1.000)	0.7	(0.62,0.78)
B.FO	GE	215	0.935	(0.899,0.965)	2325	0.994	(0.991,0.997)	0.64	(0.62,0.67)
B.FO	Samsung	257	0.965	(0.941,0.985)	1747	0.994	(0.991,0.998)	0.58	(0.55,0.60)
B.FOF	Canon	8	0.75	(0.375,1.000)	228	1.0	(1.000,1.000)	0.56	(0.42,0.67)
B.FOF	GE	108	0.899	(0.841,0.949)	2432	0.998	(0.996,1.000)	0.5	(0.47,0.53)
B.FOF	Samsung	63	0.921	(0.845,0.984)	1941	0.993	(0.989,0.996)	0.51	(0.47,0.55)
B.IVS	Canon	15	0.934	(0.770,1.000)	221	0.982	(0.965,0.996)	0.65	(0.53,0.75)
B.IVS	GE	165	0.867	(0.806,0.915)	2375	0.992	(0.988,0.995)	0.62	(0.59,0.66)
B.IVS	Samsung	152	0.922	(0.872,0.962)	1852	0.984	(0.978,0.989)	0.64	(0.61,0.67)
B.LA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.75	(0.71,0.79)
B.LA	GE	264	0.966	(0.942,0.986)	2276	0.999	(0.997,1.000)	0.79	(0.78,0.81)
B.LA	Samsung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Samsung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Samsung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)

B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)
B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)

D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)
D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)

E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)
F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)

F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)
G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Samsung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Samsung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)
G.pCH	Samsung	182	0.94	(0.905,0.973)	1822	0.999	(0.998,1.000)	0.74	(0.72,0.77)
G.pTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.58	(0.51,0.65)
G.pTh	GE	216	0.922	(0.884,0.954)	2324	0.995	(0.992,0.998)	0.62	(0.60,0.64)
G.pTh	Samsung	119	0.95	(0.905,0.984)	1885	0.998	(0.996,1.000)	0.59	(0.57,0.62)
G.Ver	Canon	23	0.914	(0.783,1.000)	213	1.0	(1.000,1.000)	0.62	(0.54,0.70)
G.Ver	GE	288	0.893	(0.859,0.928)	2252	0.996	(0.993,0.999)	0.61	(0.59,0.63)
G.Ver	Samsung	138	0.892	(0.840,0.942)	1866	0.997	(0.994,0.999)	0.52	(0.49,0.55)
I.bCC	Canon	15	1.0	(1.000,1.000)	221	0.987	(0.971,1.000)	0.59	(0.51,0.67)
I.bCC	GE	168	0.923	(0.878,0.962)	2372	0.995	(0.993,0.998)	0.57	(0.54,0.60)
I.bCC	Samsung	54	0.815	(0.699,0.910)	1950	0.996	(0.994,0.999)	0.57	(0.52,0.62)
I.CSP	Canon	20	0.95	(0.824,1.000)	216	1.0	(1.000,1.000)	0.75	(0.69,0.81)
I.CSP	GE	196	0.888	(0.841,0.928)	2344	1.0	(0.999,1.000)	0.72	(0.69,0.74)
I.CSP	Samsung	79	0.849	(0.760,0.924)	1925	1.0	(1.000,1.000)	0.7	(0.66,0.75)
I.Fas	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.63	(0.46,0.79)
I.Fas	GE	99	0.889	(0.819,0.951)	2441	1.0	(0.999,1.000)	0.56	(0.52,0.60)
I.Fas	Samsung	33	0.97	(0.900,1.000)	1971	0.999	(0.997,1.000)	0.55	(0.49,0.61)

I.lVer	*Canon*	*14*	*0.929*	*(0.750,1.000)*	*222*	*1.0*	*(1.000,1.000)*	*0.69*	*(0.60,0.77)*
I.lVer	*GE*	*102*	*0.912*	*(0.850,0.960)*	*2438*	*0.999*	*(0.998,1.000)*	*0.7*	*(0.66,0.73)*
I.lVer	*Samsung*	*41*	*0.927*	*(0.834,1.000)*	*1963*	*1.0*	*(0.999,1.000)*	*0.64*	*(0.59,0.69)*
I.NB	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.71*	*(0.61,0.82)*
I.NB	*GE*	*115*	*0.905*	*(0.844,0.955)*	*2425*	*0.992*	*(0.989,0.996)*	*0.63*	*(0.59,0.67)*
I.NB	*Samsung*	*60*	*0.917*	*(0.837,0.982)*	*1944*	*0.998*	*(0.996,1.000)*	*0.64*	*(0.58,0.69)*
I.rgCC	*Canon*	*18*	*0.945*	*(0.824,1.000)*	*218*	*0.991*	*(0.978,1.000)*	*0.48*	*(0.41,0.56)*
I.rgCC	*GE*	*177*	*0.888*	*(0.833,0.930)*	*2363*	*0.998*	*(0.996,1.000)*	*0.56*	*(0.54,0.59)*
I.rgCC	*Samsung*	*65*	*0.893*	*(0.808,0.965)*	*1939*	*1.0*	*(0.999,1.000)*	*0.48*	*(0.43,0.53)*
I.sCC	*Canon*	*13*	*0.847*	*(0.616,1.000)*	*223*	*0.992*	*(0.978,1.000)*	*0.48*	*(0.36,0.61)*
I.sCC	*GE*	*114*	*0.922*	*(0.868,0.964)*	*2426*	*0.992*	*(0.988,0.995)*	*0.51*	*(0.48,0.54)*
I.sCC	*Samsung*	*40*	*0.9*	*(0.796,1.000)*	*1964*	*0.998*	*(0.996,1.000)*	*0.45*	*(0.39,0.53)*
I.uVer	*Canon*	*14*	*1.0*	*(1.000,1.000)*	*222*	*0.991*	*(0.978,1.000)*	*0.57*	*(0.49,0.65)*
I.uVer	*GE*	*116*	*0.88*	*(0.815,0.931)*	*2424*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.63)*
I.uVer	*Samsung*	*48*	*0.938*	*(0.861,1.000)*	*1956*	*0.999*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Clase	Sistema	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp	LOA	IC de LOA
ángulo_cardíaco	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
ángulo_cardíaco	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
ángulo_cardíaco	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
posición_cardiotorácica	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
posición_cardiotorácica	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
posición_cardiotorácica	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*
índice_cardiotorácico	Canon	*23*	*1.0*	*(1.000,1.000)*	*37*	*0.946*	*(0.865,1.000)*	*0.078*	*(0.041,0.117)*
índice_cardiotorácico	GE	*225*	*0.969*	*(0.944,0.991)*	*262*	*0.908*	*(0.874,0.943)*	*0.059*	*(0.049,0.073)*
índice_cardiotorácico	Samsung	*105*	*0.952*	*(0.909,0.989)*	*232*	*0.776*	*(0.724,0.828)*	*0.051*	*(0.042,0.061)*
índice_cefálico	Canon	*28*	*0.929*	*(0.821,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.026*	*(0.021,0.032)*
índice_cefálico	GE	*195*	*0.944*	*(0.909,0.974)*	*262*	*0.943*	*(0.916,0.969)*	*0.03*	*(0.026,0.036)*
índice_cefálico	Samsung	*90*	*0.989*	*(0.964,1.000)*	*232*	*0.909*	*(0.871,0.944)*	*0.023*	*(0.020,0.026)*
índice_ventricular_derecha-izquierda	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.865*	*(0.757,0.973)*	*0.106*	*(0.080,0.128)*
índice_ventricular_derecha-izquierda	GE	*235*	*0.923*	*(0.883,0.957)*	*262*	*0.901*	*(0.859,0.939)*	*0.127*	*(0.090,0.173)*
índice_ventricular_derecha-izquierda	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.931*	*(0.901,0.961)*	*0.099*	*(0.087,0.115)*
índice_timo-torácico	Canon	*19*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.047*	*(0.039,0.059)*
índice_timo-torácico	GE	*174*	*0.902*	*(0.856,0.944)*	*262*	*0.924*	*(0.889,0.954)*	*0.051*	*(0.045,0.059)*
índice_timo-torácico	Samsung	*138*	*0.942*	*(0.900,0.978)*	*232*	*0.892*	*(0.853,0.931)*	*0.059*	*(0.049,0.070)*
número_de_vasos	Canon	*21*	*0.905*	*(0.760,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.0*	*(0.000,0.000)*
número_de_vasos	GE	*209*	*0.933*	*(0.895,0.966)*	*262*	*0.969*	*(0.947,0.989)*	*0.281*	*(0.138,0.406)*
número_de_vasos	Samsung	*113*	*0.929*	*(0.879,0.974)*	*232*	*0.966*	*(0.940,0.987)*	*0.329*	*(0.000,0.491)*
índice_vasos	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.112*	*(0.091,0.145)*
índice_vasos	GE	*194*	*0.979*	*(0.956,0.995)*	*262*	*0.977*	*(0.954,0.992)*	*0.109*	*(0.099,0.121)*
índice_vasos	Samsung	*122*	*0.984*	*(0.958,1.000)*	*232*	*0.922*	*(0.888,0.953)*	*0.111*	*(0.100,0.125)*
Índice CSP	Canon	*25*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.842*	*(0.608,1.028)*

Índice CSP	GE	*226*	*0.854*	*(0.805,0.899)*	*262*	*0.977*	*(0.954,0.992)*	*0.826*	*(0.753,0.889)*
Índice CSP	Samsung	*107*	*0.879*	*(0.821,0.935)*	*232*	*0.991*	*(0.978,1.000)*	*0.835*	*(0.755,0.907)*
Índice VP	Canon	*22*	*0.909*	*(0.773,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.064*	*(0.043,0.084)*
Índice VP	GE	*206*	*0.956*	*(0.925,0.981)*	*262*	*1.0*	*(1.000,1.000)*	*0.065*	*(0.059,0.071)*
Índice VP	Samsung	*91*	*0.956*	*(0.910,0.990)*	*232*	*1.0*	*(1.000,1.000)*	*0.066*	*(0.056,0.075)*
Espacio auricular posterior izquierdo	Canon	*16*	*0.938*	*(0.800,1.000)*	*37*	*0.919*	*(0.837,1.000)*	*0.094*	*(0.067,0.114)*
Espacio auricular posterior izquierdo	GE	*181*	*0.978*	*(0.953,0.995)*	*262*	*0.924*	*(0.889,0.954)*	*0.086*	*(0.079,0.091)*
Espacio auricular posterior izquierdo	Samsung	*159*	*0.981*	*(0.957,1.000)*	*232*	*0.953*	*(0.922,0.978)*	*0.07*	*(0.065,0.078)*

Para los resultados del subgrupo de EE. UU. vs. UE

Clase	Continente	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp
A	UE	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	EE. UU.	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	UE	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	EE. UU.	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	UE	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	EE. UU.	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	UE	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	EE. UU.	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	UE	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	EE. UU.	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	UE	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	EE. UU.	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	UE	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	EE. UU.	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	UE	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	EE. UU.	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	UE	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	EE. UU.	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Clase	Continente	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp	mIoU	IC de mIoU
A.aA	UE	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	EE. UU.	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	UE	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	EE. UU.	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	UE	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	EE. UU.	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	UE	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	EE. UU.	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	UE	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	EE. UU.	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*
A.St	UE	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*

A.St	EE. UU.	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	UE	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	EE. UU.	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	UE	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	EE. UU.	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	UE	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	EE. UU.	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	UE	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	EE. UU.	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	UE	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	EE. UU.	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	UE	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	EE. UU.	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	UE	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	EE. UU.	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	UE	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	EE. UU.	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	UE	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	EE. UU.	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	UE	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	EE. UU.	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	UE	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	EE. UU.	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	UE	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	EE. UU.	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	UE	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	EE. UU.	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	UE	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	EE. UU.	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	UE	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	EE. UU.	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	UE	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	EE. UU.	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	UE	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	EE. UU.	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	UE	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	EE. UU.	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	UE	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	EE. UU.	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	UE	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	EE. UU.	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	UE	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	EE. UU.	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	UE	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	EE. UU.	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*
C.IVS	UE	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*

C.IVS	EE. UU.	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	UE	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	EE. UU.	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	UE	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	EE. UU.	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	UE	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EE. UU.	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	UE	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	EE. UU.	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	UE	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	EE. UU.	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	UE	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	EE. UU.	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	UE	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	EE. UU.	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	UE	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	EE. UU.	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	UE	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	EE. UU.	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	UE	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	EE. UU.	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*
D.rPA	UE	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	EE. UU.	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	UE	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*
D.S	EE. UU.	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	UE	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	EE. UU.	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	UE	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	EE. UU.	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	UE	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	EE. UU.	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	UE	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	EE. UU.	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	UE	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	EE. UU.	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	UE	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	EE. UU.	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	UE	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	EE. UU.	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	UE	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	EE. UU.	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	UE	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	EE. UU.	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	UE	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	EE. UU.	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*
E.Tr	UE	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*

E.Tr	EE. UU.	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	UE	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	EE. UU.	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	UE	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	EE. UU.	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	UE	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*
F.aFx	EE. UU.	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	UE	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	EE. UU.	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	UE	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	EE. UU.	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	UE	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	EE. UU.	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	UE	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	EE. UU.	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	UE	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	EE. UU.	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	UE	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	EE. UU.	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	UE	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	EE. UU.	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	UE	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	EE. UU.	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	UE	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	EE. UU.	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	UE	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	EE. UU.	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	UE	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	EE. UU.	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	UE	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	EE. UU.	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	UE	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	EE. UU.	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	UE	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	EE. UU.	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	UE	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	EE. UU.	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	UE	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	EE. UU.	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	UE	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	EE. UU.	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	UE	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	EE. UU.	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	UE	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	EE. UU.	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*
G.dTh	UE	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*

G.dTh	EE. UU.	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	UE	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	EE. UU.	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	UE	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	EE. UU.	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	UE	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	EE. UU.	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	UE	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	EE. UU.	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	UE	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	EE. UU.	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	UE	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EE. UU.	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	UE	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	EE. UU.	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	UE	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	EE. UU.	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	UE	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	EE. UU.	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	UE	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	EE. UU.	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	UE	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	EE. UU.	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Clase	Continente	n(positivo)	Se	IC de Se	n(negativo)	Sp	IC de Sp	LOA	IC de LOA
ángulo_cardíaco	UE	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
ángulo_cardíaco	EE. UU.	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
posición_cardiotorácica	UE	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
posición_cardiotorácica	EE. UU.	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
índice_cardiotorácico	UE	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
índice_cardiotorácico	EE. UU.	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
índice_cefálico	UE	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
índice_cefálico	EE. UU.	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
índice_ventricular_derecha-izquierda	UE	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
índice_ventricular_derecha-izquierda	EE. UU.	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
índice_timo-torácico	UE	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
índice_timo-torácico	EE. UU.	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)
número_de_vasos	UE	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
número_de_vasos	EE. UU.	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
índice_vasos	UE	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
índice_vasos	EE. UU.	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
Índice CSP	UE	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
Índice CSP	EE. UU.	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)

Índice VP	UE	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
Índice VP	EE. UU.	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
Espacio auricular posterior izquierdo	UE	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
Espacio auricular posterior izquierdo	EE. UU.	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Contraindicaciones

No existe ninguna contraindicación relacionada con el dispositivo FETOLY.

10. Advertencias, precauciones e interacciones con otros equipos

Advertencias y precauciones del archivo de gestión de riesgos:

- El usuario deberá hacer un zoom de al menos el 30 % para evitar falsos negativos de software.
- El usuario deberá revisar sistemáticamente el conjunto de imágenes seleccionadas antes de la exportación.
- El uso incorrecto de la función de reinicio puede provocar confusiones entre pacientes y contribuir a falsos negativos en las pruebas de detección.
- Las imágenes borradas dentro de la selección de imágenes se pierden de forma permanente.
- La configuración de entrada de la transmisión de vídeo puede contribuir a un cribado falso negativo.
- Una transmisión de vídeo incompatible puede llevar a errores en la documentación de la exploración. La transmisión de vídeo tendrá las siguientes características:
    - Al menos 24 fotogramas por segundo (fps)
    - Una resolución inferior a 1280*720
- La incompatibilidad de las tabletas puede dar lugar a errores en la documentación de las exploraciones.
- Un fallo en la exportación provoca la pérdida del informe de exploración.
- Verifique el nombre del paciente seleccionado antes de la exportación DICOM en la página de exportación para evitar confusiones en los archivos de las pacientes.
- Su uso en el primer trimestre de embarazo provoca errores en la función de exhaustividad.
- La exploración se realizará en un feto cada vez.
- Si la tableta empieza a sobrecalentarse, interrumpa el uso del software.
- Compruebe el nivel de batería de su tableta antes de la exploración. El cierre del software puede provocar la pérdida de datos de la exploración.
- El software no puede utilizarse con fines de detección, ya que puede dar lugar a falsos negativos en la detección.
- Utilice la tableta solo usted y no permita que personas no autorizadas accedan a ella para evitar riesgos de seguridad.
- Tenga en cuenta que cuando los datos se exportan a su dispositivo, están bajo su responsabilidad.
- No utilice ninguna otra aplicación de tableta en paralelo con FETOLY para evitar interferencias en el proceso de recepción de la secuencia de imágenes o en la ejecución de los cálculos de aprendizaje automático.

- *No utilice la aplicación mientras realiza una ecografía con una sonda transvaginal, ya que el producto no ha sido probado con imágenes transvaginales.*

Advertencias y precauciones del estudio de rendimiento del software:

- La sensibilidad del software puede ser menor para la detección de:
  - La visión transtalámica del cerebro;
  - Los siguientes criterios de calidad cardíacos: Desplazamiento de la válvula auriculoventricular en la cruz (vista de las cuatro cavidades)
  - Los siguientes criterios de calidad cerebrales:
    - Sutura coronal proximal (vista axial)
    - *Cavum Septum Pellucidum* (vista axial)
    - Tercer ventrículo (vista axial)

  Los usuarios deben actuar con precaución con esta vista y estos criterios de calidad, y verificar los resultados.

Interacciones con otros equipos

El software FETOLY está diseñado para ejecutarse en una amplia gama de tabletas sin depender de la computación externa en la nube. FETOLY está configurado para recibir una transmisión del vídeo de la ecografía, lo que puede conseguirse mediante un ecógrafo equipado con una salida HDMI al hardware que ejecuta el software.

El software es compatible con ecógrafos de General Electric, Samsung y Canon.

El software requiere la siguiente configuración mínima de la tableta:

- Arquitectura de CPU ARMv8
- Un procesador Snapdragon 8 o
- Un procesador M1 o superior, o
- Un procesador A14 o superior y
- Al menos 8 GB de RAM
- Al menos 1 GB de capacidad de almacenamiento
- Android en versión 13 o superior

Se aconsejan los siguientes modelos de tabletas:

- Samsung Galaxy Tab S8 o superior
- Ipad Air 5 o superior
- Ipad 10 o superior
- Ipad mini 7 o superior
- Ipad Pro 3 o superior

No dude en contactar con el soporte de Diagnoly en support@diagnoly.com si tiene alguna duda sobre la elección del modelo de tableta.

Las imágenes etiquetadas por FETOLY pueden guardarse directamente en la tableta o enviarse a otro dispositivo en la misma red que el dispositivo en el que se ejecuta FETOLY. Para utilizar esta opción, el software requiere un servidor FTP en el dispositivo de destino, un servidor DICOM Store o una conexión Bluetooth.

11. Efectos no deseados

No existen efectos no deseados relacionados con el dispositivo FETOLY.

12. Instrucciones de ciberseguridad

12,1. Descripción de alto nivel de la protección de funciones críticas

En esta sección se proporciona una descripción de alto nivel de las características del dispositivo que protegen las funciones críticas. Las funciones de recepción de secuencias de imágenes y análisis de imágenes se basan en recursos locales (cable físico y modelo de IA periférico) y no requieren Internet para funcionar. El software no almacena ni gestiona ningún dato de las pacientes, pero permite al usuario exportar, tras una exploración, un informe de esta a un dispositivo de terceros. Si la red local se ve comprometida, existe un modo de exportación alternativo que permite a los usuarios guardar los informes en el sistema de archivos de la tableta.

12,2. Riesgos de ciberseguridad inherentes al dispositivo

Entre los riesgos de ciberseguridad inherentes a FETOLY se incluyen:

- Robo de datos de las pacientes.
- Menor rendimiento en la atención al paciente debido al mal funcionamiento de la IA, como la manipulación de los pesos de los modelos o las modificaciones del software o del sistema operativo.
- Uso indebido del dispositivo, que da lugar a resultados diferentes a los previstos por el fabricante o a los esperados por el usuario.
- Pérdida de tiempo para el usuario.

Estos riesgos se controlan mediante el análisis de riesgos.

11,3. Diagrama de controles de ciberseguridad recomendados



El diagrama describe el entorno del software FETOLY que se ejecuta en la tableta del usuario y las comunicaciones de entrada/salida con el ecógrafo y el dispositivo de terceros.

Incluye las referencias a los controles de ciberseguridad recomendados para el entorno de uso previsto descrito en la **sección 12,4**:

- G1: Funcionamiento seguro con sistemas de terceros mediante FTP sobre SSL/TLS
- G2: Funcionamiento seguro con sistemas de terceros mediante Bluetooth (solo Android)
- G3: Control de acceso seguro a dispositivos
- G4: Funcionamiento seguro con sistemas de terceros a través de DICOM sobre SSL/TLS

12,4. Instrucciones del dispositivo y especificaciones del producto relacionadas con los controles de ciberseguridad recomendados y adecuados para el entorno de uso previsto

Directrices para el funcionamiento seguro con sistemas de terceros a través de FTP sobre SSL/TLS (G1):

- Requisitos mínimos de red: la infraestructura de red debe soportar FTP sobre SSL/TLS (FTPS) y el servidor FTP debe ser compatible con FTPS. Implementar la segmentación de la red y las reglas del cortafuegos para restringir el acceso a los servicios y direcciones IP necesarios.
- Instalar un servidor FTP sobre SSL/TLS, como:
    c. Windows 10/11 utilizando IIS: Consulte la documentación de Microsoft para configurar FTP sobre TLS/SSL con IIS.
    d. Servidor FileZilla (multiplataforma): Configure FTPES "Requerir FTP explícito sobre TLS", cree un usuario con una contraseña segura*, defina una ruta de almacenamiento de datos (p. ej., "C:\FetolyData" o "/home/shared/FetolyData") y configure las reglas del cortafuegos para el programa o puerto específico utilizado por el servidor FTP.

Directrices para el funcionamiento seguro con sistemas de terceros a través de Bluetooth (G2, solo Android):

- Requisitos mínimos de red: Bluetooth versión 5 o superior.
- Defina una contraseña segura dentro del software para proteger los datos exportados de la paciente*.

Directrices sobre control de acceso seguro a dispositivos (G3):

- Configure una pantalla de bloqueo con una contraseña* segura, un PIN o autenticación biométrica.
- Active las actualizaciones automáticas del sistema operativo y de todas las aplicaciones instaladas.
- Desactive las interfaces de red no utilizadas (p. ej., NFC, IR).

Directrices para el funcionamiento seguro con sistemas de terceros a través de DICOM (G4):

- Asegúrese de que la comunicación se produce a través de una red segura y segmentada, restringiendo el acceso mediante sólidas configuraciones de cortafuegos y mecanismos de control de acceso.

*Utilice contraseñas seguras en su tableta y para cualquier dispositivo (es decir, dispositivo de terceros para exportación FTP) o configuración vinculada a FETOLY (es decir, configuración Bluetooth) según las recomendaciones de la agencia de ciberdefensa estadounidense:

- Larga: al menos 16 caracteres (cuanto más larga, mejor).
- Al azar, como una cadena de letras, números y símbolos mixtos (la más fuerte) o una frase de contraseña de 5-7 palabras aleatorias.
- Único: se utiliza única y exclusivamente para una cuenta.

Si se detecta una vulnerabilidad o un incidente de ciberseguridad, informe de inmediato a su equipo de seguridad informática y a Diagnoly (support@diagnoly.com). En la tableta:

- Reiniciar: Restaure los ajustes de fábrica para borrar todos los datos y configuraciones.
- Reinstalar la aplicación: Descargue la versión más reciente y segura de la aplicación desde Google Play Store.
- Opción alternativa: Utilice la exportación local a una tarjeta SD si las exportaciones basadas en red están comprometidas.

12,5. Una lista de puertos de red y otras interfaces

El software FETOLY recibe los datos del flujo de entrada a través de un cable conectado entre la salida del monitor externo del ecógrafo y la entrada USB-C de la tableta. El software puede configurarse para exportar informes de exploración a un dispositivo de terceros a través de TCP/IP FTPS o Bluetooth.

Para la exportación de datos a través de la red TCP IP/FTPS:

- Protocolo: FTPS
- Puertos de entrada: El software no abre ningún puerto de entrada por sí mismo, ya que funciona únicamente como cliente, no como servidor.
- Puertos de salida: El software utiliza un puerto efímero asignado dinámicamente (intervalo: 1024-65535) para establecer la conexión con el servidor FTPS en una dirección IP especificada. El puerto de entrada del servidor FTPS de terceros lo define el usuario.
- Reglas del cortafuegos: Los cortafuegos, tanto del lado del cliente como del servidor, deben permitir las conexiones salientes del cliente al puerto del servidor.

Para la exportación de datos vía Bluetooth/OBEX (solo Android):

- Cifrado: los datos se comprimen y cifran con contraseña.

Para la exportación de datos a través de DICOM:

- Protocolo: DICOM
- Puertos de entrada: El software no abre ningún puerto de entrada por sí mismo, ya que funciona únicamente como cliente, no como servidor.
- Puertos de salida: El software utiliza un puerto efímero asignado dinámicamente (Android: de 32768 a 60999) para establecer la conexión con el servidor DICOM en una dirección IP especificada. El puerto de entrada del servidor DICOM de terceros lo define el usuario.

- Reglas del cortafuegos: Los cortafuegos, tanto del lado del cliente como del servidor, deben permitir las conexiones salientes del cliente al puerto del servidor.

12,6. Necesidades de infraestructuras de apoyo

Consulte la sección 10 para conocer los requisitos de la infraestructura de apoyo, incluida la configuración mínima de la tableta y los ecógrafos compatibles.

12,7. SBOM

Los usuarios disponen de una lista de materiales de software (sBoM) para gestionar sus activos, comprender el impacto potencial de las vulnerabilidades identificadas y desplegar contramedidas para mantener la seguridad y eficacia del dispositivo. El sBoM puede descargarse desde la página "Acerca de" del programa, en formato legible por máquina (.csv), haciendo clic en "mostrar" delante de "Aviso a terceros".

12,8. Instrucciones de actualización/parche

Consulte la sección 13 "Actualización del software y la licencia" para obtener instrucciones de actualización.

12,9. Descripción de cómo responde el dispositivo cuando se detectan condiciones anómalas

En esta sección se describe cómo responde el software a los eventos de seguridad. Todas las caídas del software se exportan mediante un registro de caídas a Firebase. Al utilizar FETOLY pueden aparecer las siguientes advertencias:

- Fallo de exportación: anomalía en la red que provoca un fallo en la exportación de informes a través de TCP/IP FTPS, DICOM o Bluetooth.
- Fallo de conexión USB: no hay ningún cable USB-C conectado a la tableta o fallo en la recepción de la transmisión de vídeo USB-C.
- Fallo de validación de licencia: el usuario intenta validar la licencia sin conexión a Internet, activación automática por tiempo o licencia válida.
- Sobrecalentamiento de la tableta.
- Problema de compatibilidad con tabletas: velocidad de fotogramas de la transmisión de vídeo inferior a 24 fps.
- Batería baja de la tableta.

12,10. Copia de seguridad y restauración

Para restaurar las funciones del dispositivo y la configuración predeterminada, desinstálelo y vuelva a instalarlo a través de Google Play/App Store.

12,11. Descripción de métodos para la retención y recuperación de la configuración del dispositivo por un usuario autorizado autenticado

Los ajustes de exportación, como las credenciales de terceros, y los ajustes de captura de vídeo, como la relación de aspecto del vídeo de entrada, se conservan en la caché de almacenamiento de datos de la tableta, aisladas de forma segura por Android/iOS. Dado que las configuraciones mencionadas son rápidas de poner en marcha, no se aplica ninguna metodología de recuperación específica. Se pide a los usuarios que vuelvan a introducir los ajustes manualmente durante la reinstalación o la instalación de un nuevo dispositivo.

12,12. Configuración segura

En esta sección se proporcionan instrucciones para garantizar la configuración y el mantenimiento seguros del software FETOLY.

Ajustes iniciales: Descargue e instale la última versión desde Google Play/App Store. Verifique que el nombre y el icono de la aplicación coincidan con los proporcionados en la sección 13. Realice todos los pasos de configuración de la exportación a través de una conexión de red segura según las directrices G1/2/4 de la sección 12,4. Asegúrese de que el dispositivo en el que se ejecuta FETOLY es seguro según la directriz G3 de la sección 12,4.

Respuesta a incidentes: Habilite la conexión a Internet para registrar caídas y actividades anómalas, como se describe en la sección 12,13. Notifique cualquier vulnerabilidad detectada según las directrices de la sección 12,4.

12,13. Recogida de pruebas legales, cuando sea apropiado para el entorno de uso previsto

El software integra un sistema de informes de accidentes. Los informes de fallos se envían en caso de que se produzca un fallo en la aplicación o un evento anómalo si la conexión a Internet está habilitada.

12,14. Información sobre el fin de la vida útil y el fin del soporte técnico del sistema o los componentes, si se conoce o se prevé

El fin de la vida útil y del soporte técnico dependen de la validez de la licencia. La licencia se renovará automáticamente con una conexión a Internet en cuanto el contrato de licencia siga siendo válido. Si el contrato ha vencido o ha alcanzado el fin de su vida útil, se le pedirá que introduzca un nuevo código de registro.

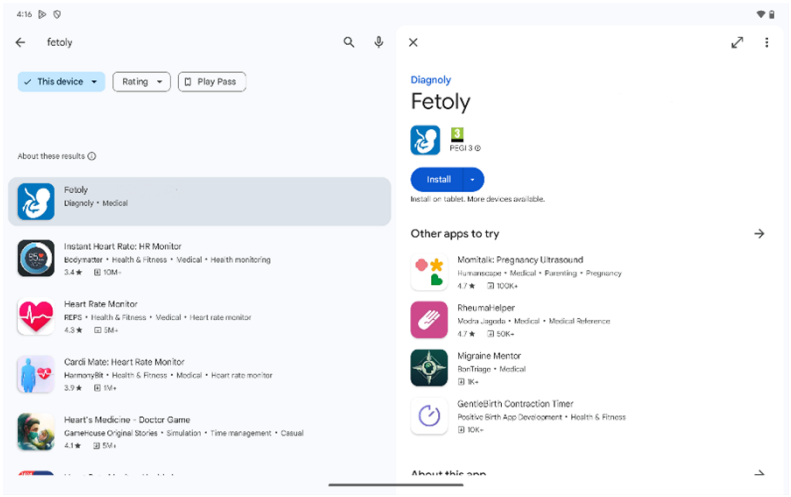
12,15. Desactivación segura

Para desactivar y eliminar el software, desinstale la aplicación a través del sistema Android/iOS como cualquier otra aplicación de su tableta, en los parámetros de la aplicación, tal y como se ilustra en la sección 13 del apartado "desinstalación del software". Esta desinstalación eliminará de su tableta todos los datos relacionados con el uso de FETOLY, incluida la licencia.

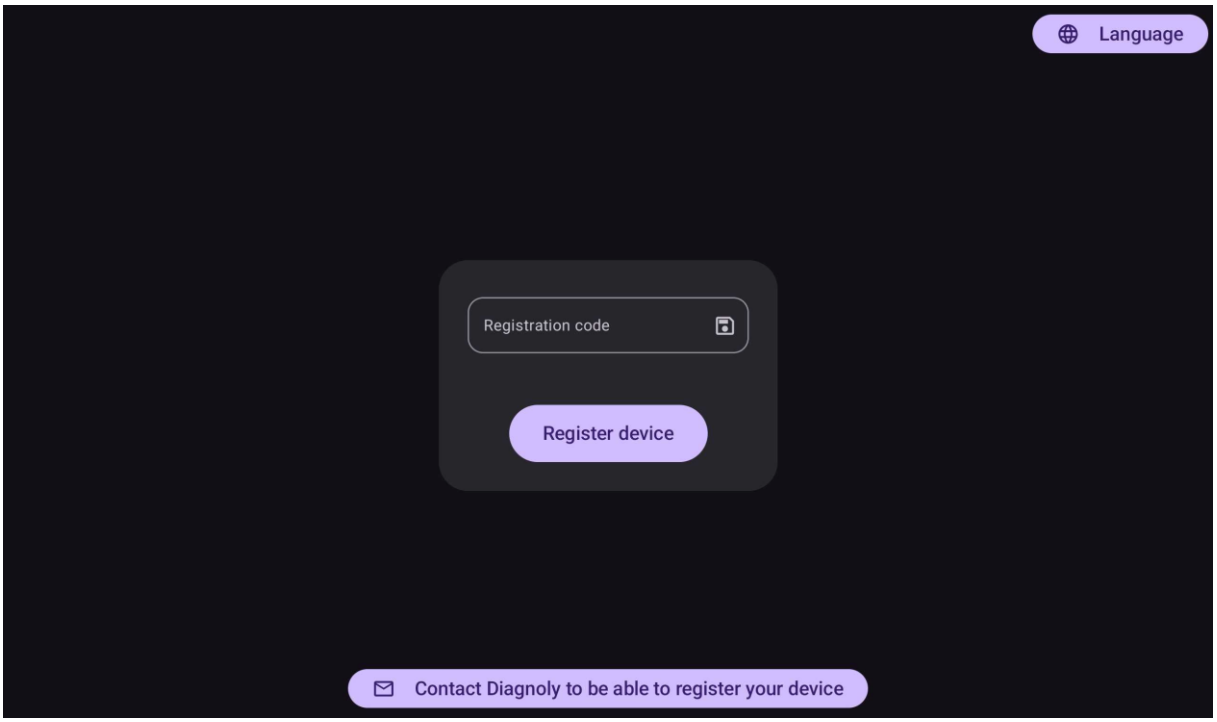
13. Instrucciones de uso

Instalación y puesta en marcha del software

5. Vaya a Google Play o a la App Store, escriba FETOLY en la barra de búsqueda e inicie la descarga e instalación automáticas



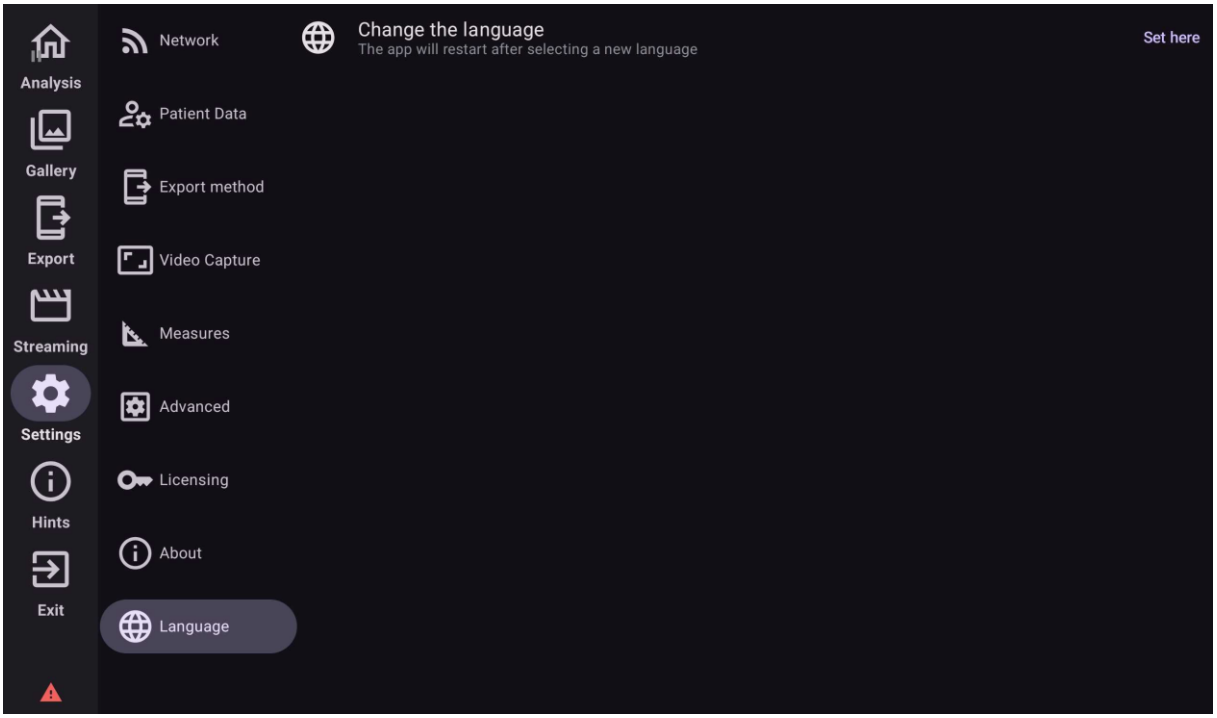
6. Haga clic en el icono de FETOLY en su tableta
7. **Validación de la licencia**: Si es necesario, introduzca el código de registro de la licencia como se muestra a continuación. Diagnoly es responsable de proporcionarle una licencia. Puede ponerse en contacto con Diagnoly para la edición de la licencia haciendo clic directamente en el botón que aparece en la parte inferior de la página de bienvenida. La licencia está vinculada al ID de su dispositivo, disponible en la página de ajustes de la licencia.

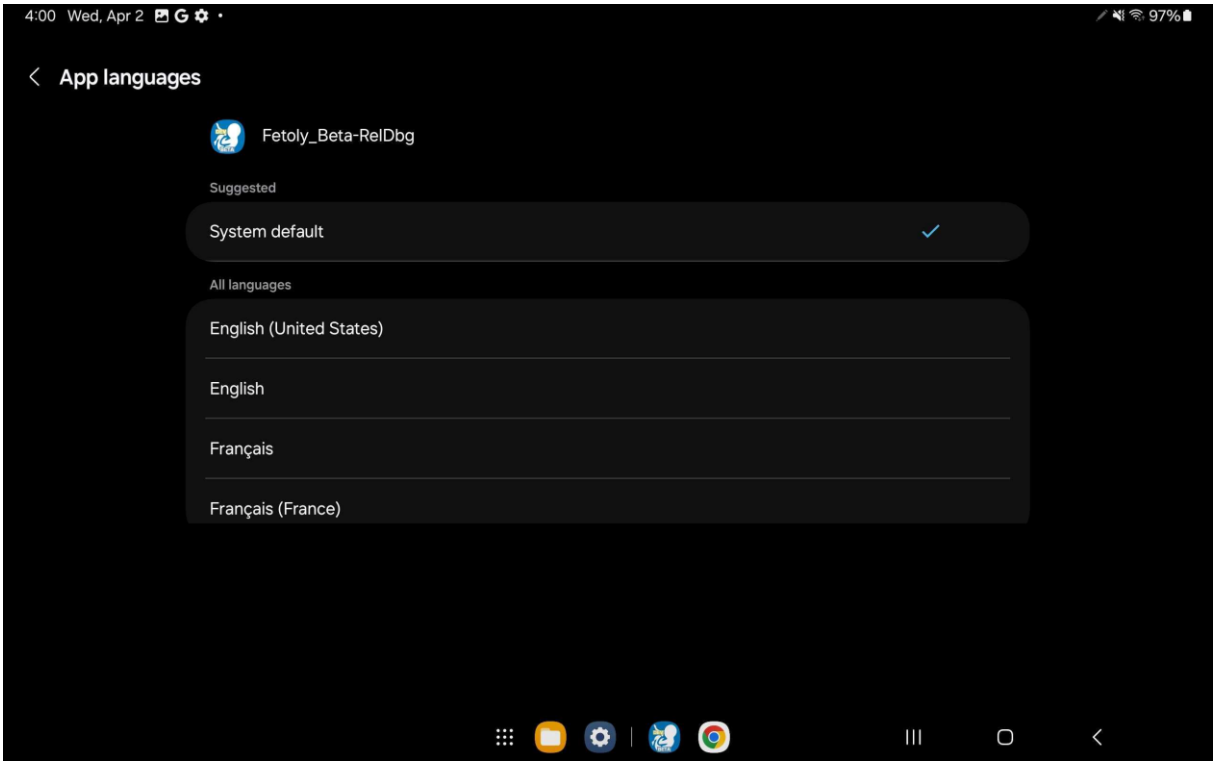


8. **Establezca una conexión Wi-Fi:** Si desea recibir los datos ecográficos en su ordenador personal, conecte la tableta a su punto Wi-Fi.

Ajustes de idioma

Por defecto, el software está configurado en el mismo idioma que su tableta. Sin embargo, puede elegir el idioma que necesite en "Ajustes" > "Idioma". Esto le llevará a la configuración de idiomas de la aplicación en Android. Una vez seleccionado el idioma necesario, la aplicación se traducirá a ese idioma al volver a iniciarse.





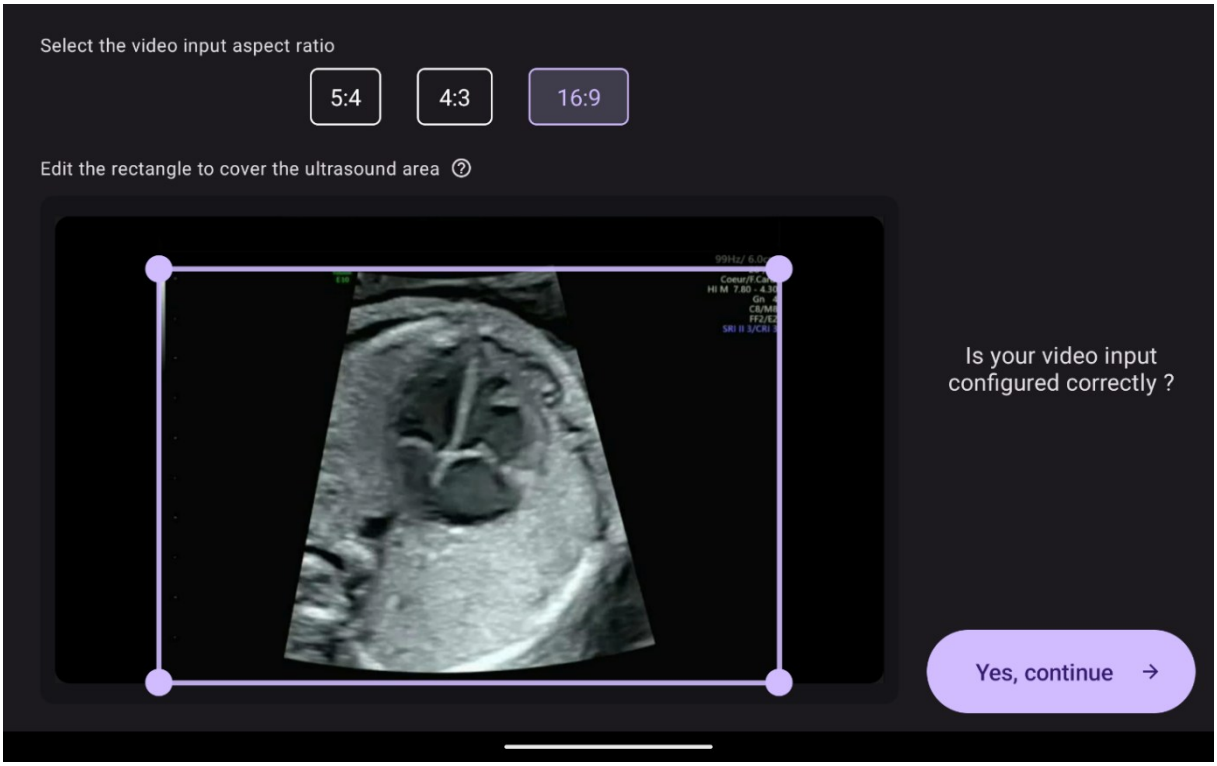
Conexión del ecógrafo

4. **Encienda el ecógrafo:** Antes de conectar la tableta, asegúrese de que el ecógrafo esté encendido y en condiciones de funcionamiento.
5. **Conecte su tableta a su ecógrafo:** Para conectarla, simplemente enchufe el extremo USB (tipo C) de un adaptador UVC en su tableta y el extremo HDMI en su ecógrafo.
6. **Verificación:** Para verificar la conexión entre el ecógrafo y la tableta, abra el software FETOLY. Si se ha conectado una nueva fuente USB, el software mostrará automáticamente la página de configuración de la transmisión de vídeo.

Configuración de la transmisión de vídeo

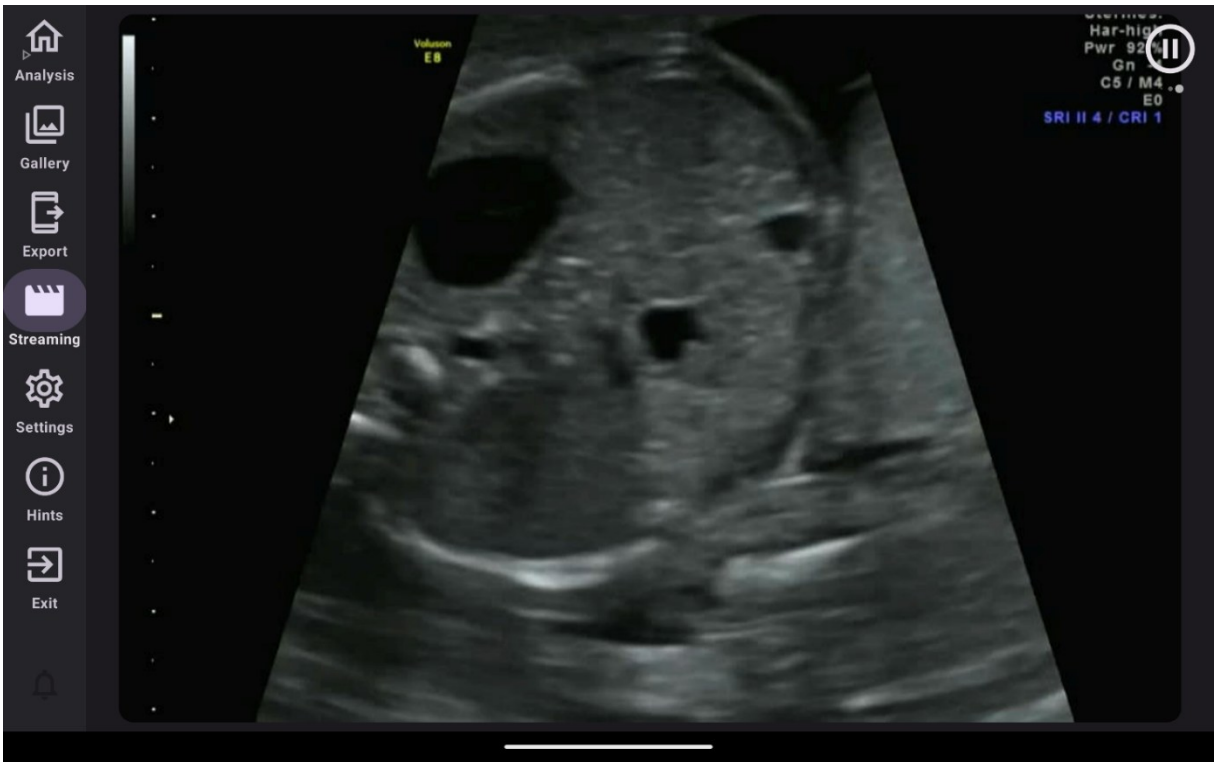
2. Empiece a configurar la transmisión de vídeo en la aplicación:

    a. Cuando el software abra automáticamente la página de configuración de vídeo, seleccione la relación de aspecto de vídeo que se alinee con el índice de salida del ecógrafo y seleccione la región correspondiente. En otras situaciones, vaya a 'ajustes' > 'captura de vídeo' para configurar la transmisión de vídeo, con la misma metodología.



    d. La región seleccionada aparece en tiempo real en la página de transmisión. El botón de reproducción puede utilizarse en la página de transmisión para iniciar el análisis.

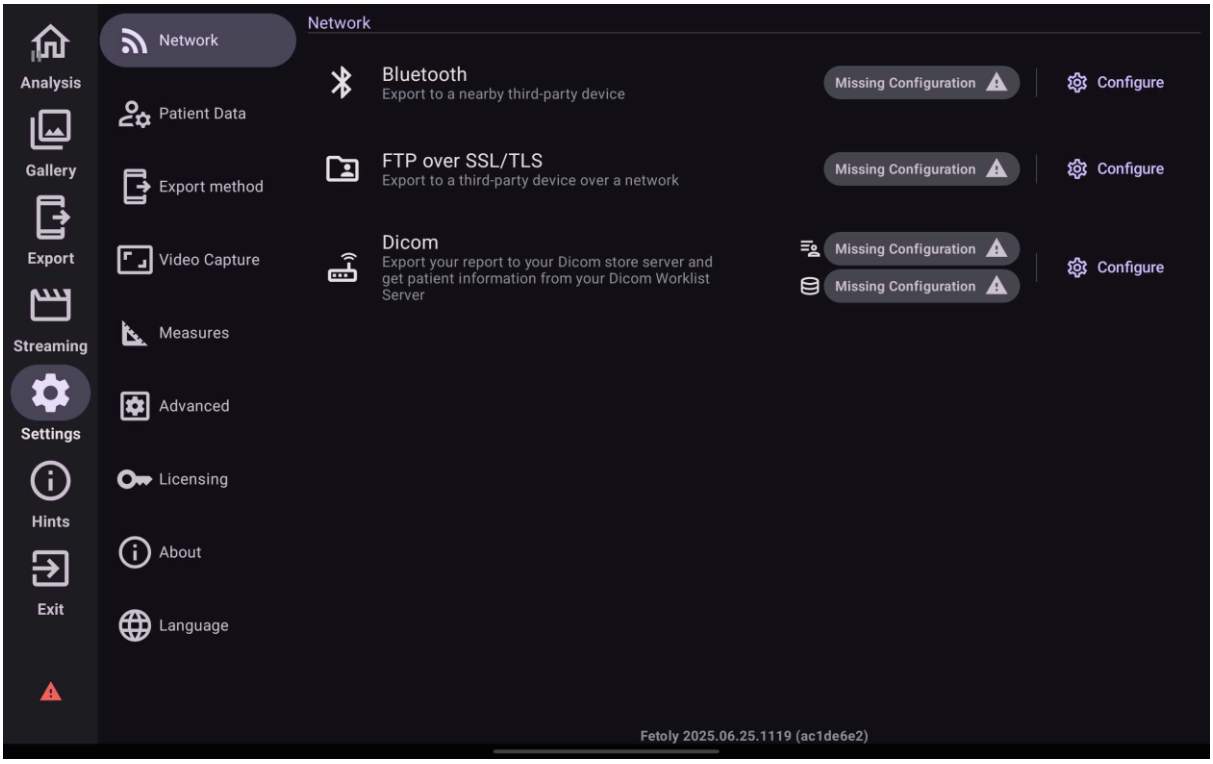
    e. Compruebe que el micrófono no esté desactivado en su tableta, ya que provocará el bloqueo de la entrada de la transmisión de vídeo.



[OPCIONAL] Configuración del ecógrafo

Algunos ecógrafos permiten configurar el tamaño de la región ecográfica en la salida de vídeo. En ese caso, se aconseja seleccionar la región más grande posible.

Exportar configuración



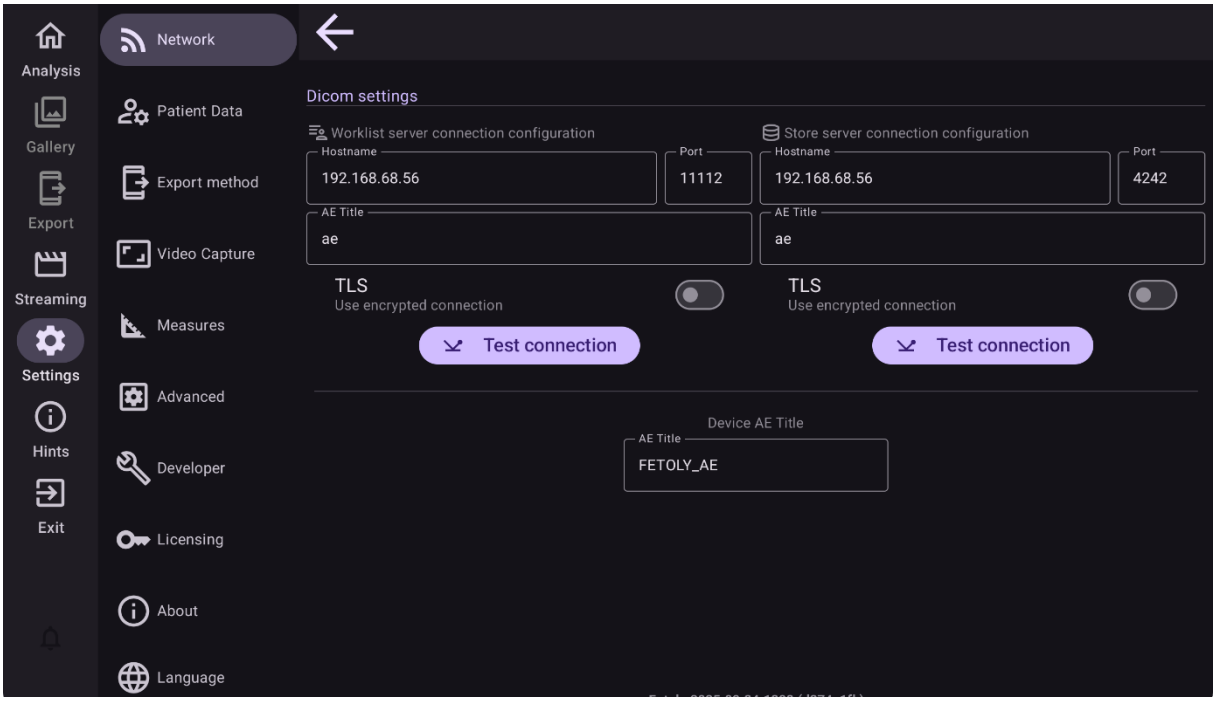
2. Configure el servidor DICOM remoto para exportar las imágenes capturadas por FETOLY. Obsérvese que este paso requiere la presencia de un servidor DICOM que se ejecute en un dispositivo conectado a la misma red que la tableta en la que se ejecuta FETOLY.

   A continuación, vaya a "Ajustes" > "Ajustes de red", seleccione "configurar DICOM" e introduzca la información necesaria para su servidor de almacenamiento DICOM: nombre de host de la lista de trabajo (dirección IP) y título AE, nombre de host del almacenamiento DICOM (dirección IP) y título AE, título AE del dispositivo. Para verificar la conexión, haga clic en el botón "Probar conexión" para cada servidor DICOM. Esto garantiza que la conexión es válida y está lista para exportar imágenes. También puede habilitar opcionalmente la opción TLS.

   a.

3. Como alternativa, configure el servidor FTP remoto para exportar las imágenes capturadas por FETOLY. Obsérvese que este paso requiere la presencia de un servidor FTP ejecutándose en un dispositivo conectado a la misma red que la tableta en la que se ejecuta FETOLY.

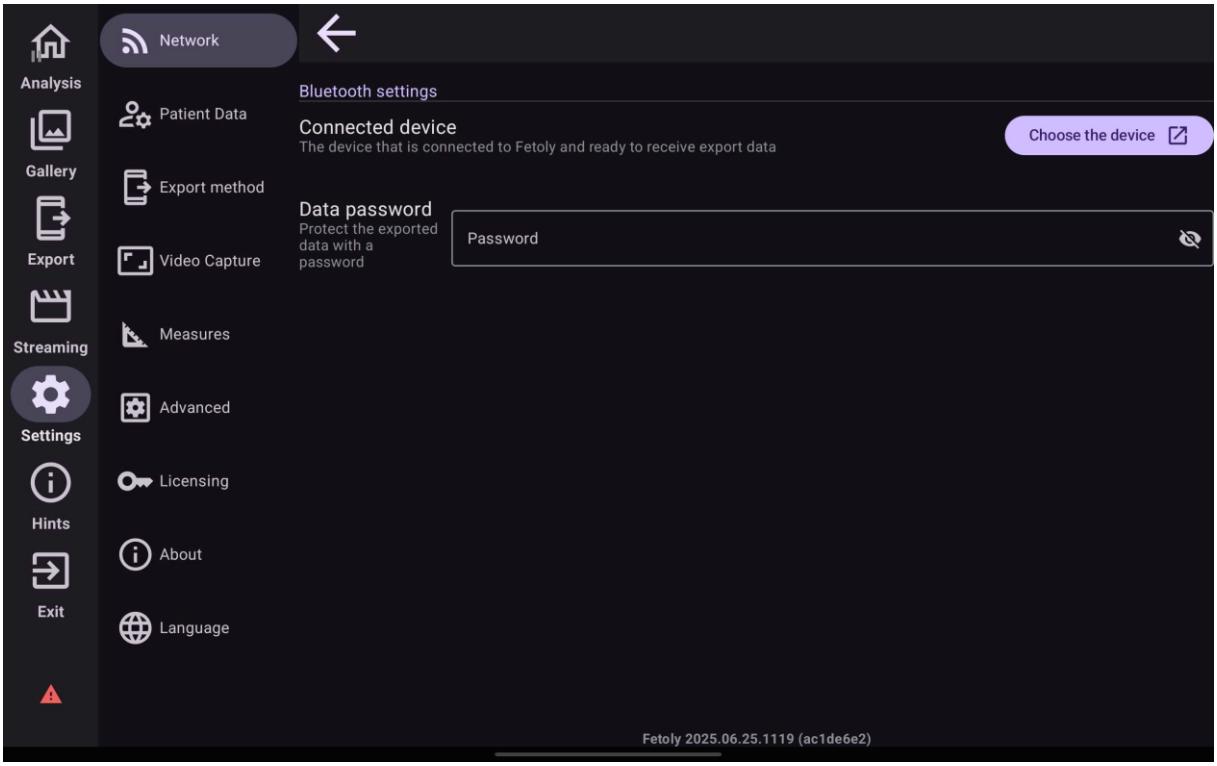
   b. Vaya a "Ajustes" > "Ajustes de red", seleccione configurar FTP e introduzca la información necesaria para su cliente FTP: nombre de host (dirección IP), nombre de usuario y contraseña. Para verificar la conexión, haga clic en el botón "Probar conexión". Esto garantiza que la conexión es válida y está lista para exportar imágenes.

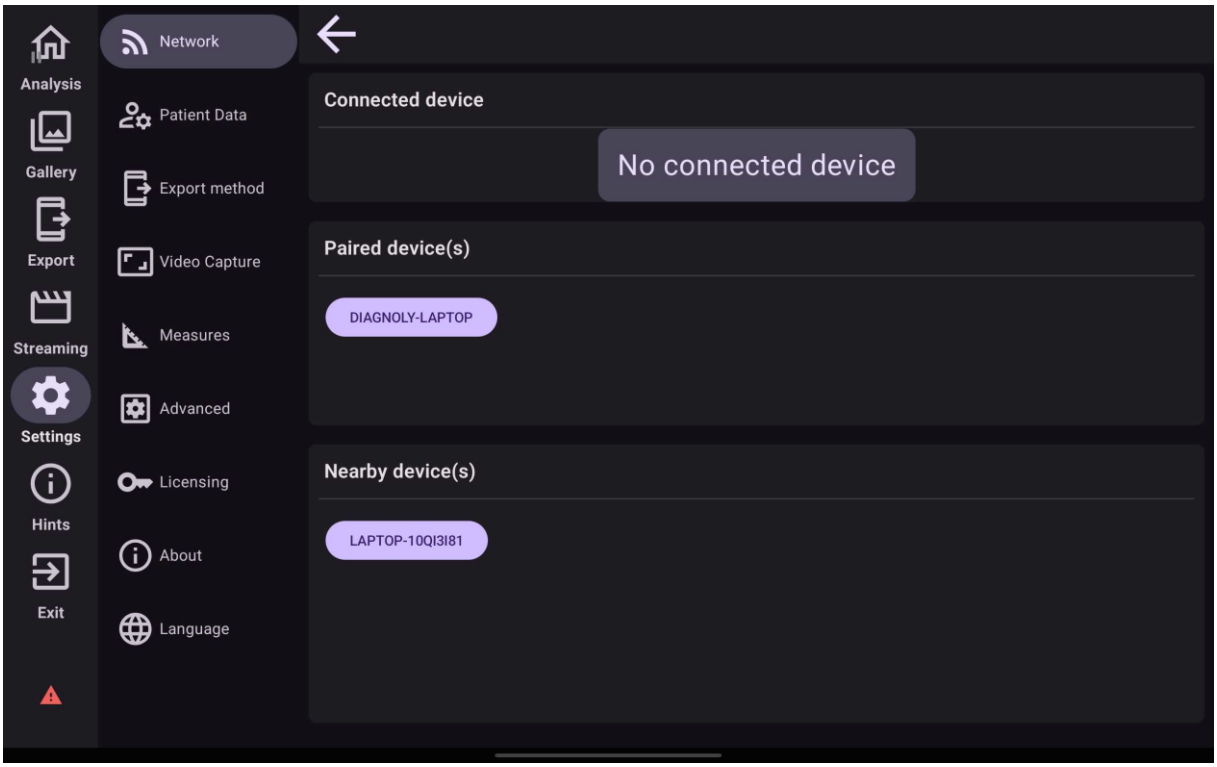


6. También puede utilizar la conexión Bluetooth (solo Android):

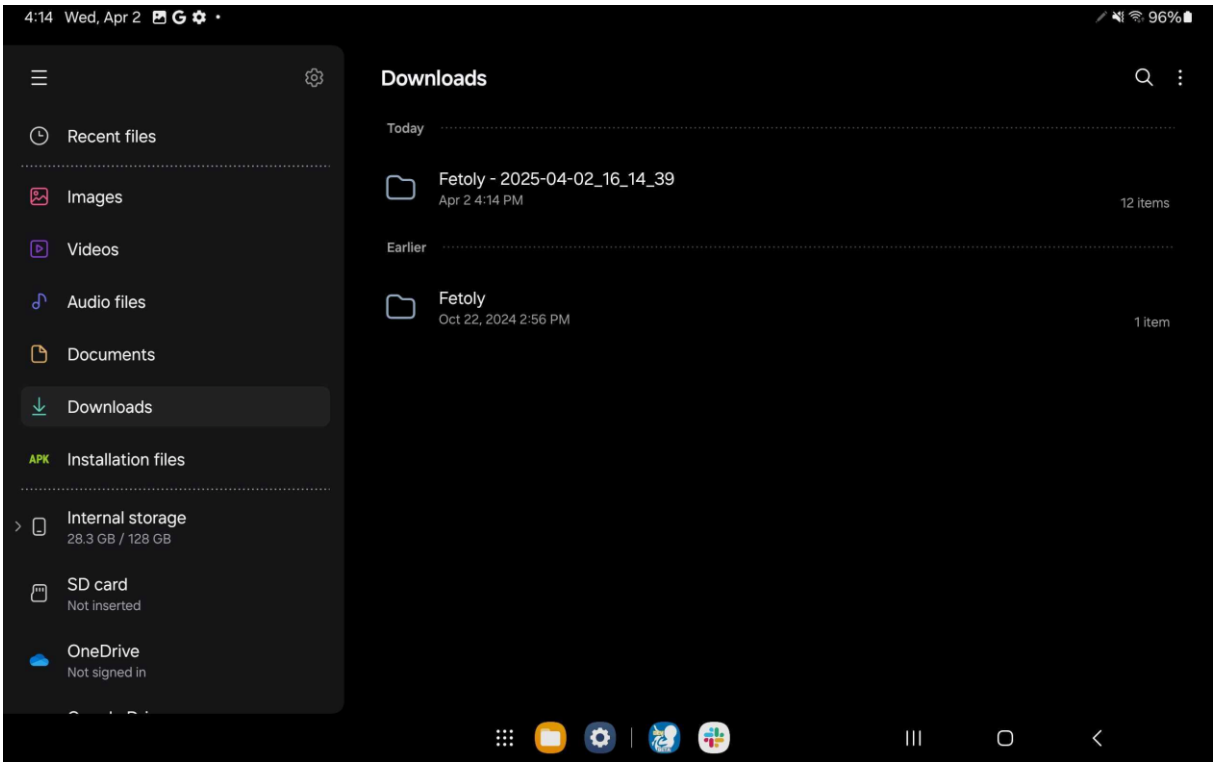
a. Ajustes" > "Ajustes de red" y seleccione Bluetooth. Para elegir el dispositivo al que exportar los datos, debe emparejarlo seleccionándolo en la sección "dispositivo cercano". A continuación, seleccione el dispositivo que desea conectar en la sección "dispositivo emparejado". Una vez elegido el dispositivo, puede probar la conexión en la sección "dispositivo conectado". Para acceder a la página de selección de dispositivos, haga clic en el botón situado a la derecha de "Configuración de Bluetooth" > "dispositivo conectado".

b. Para exportar el archivo, deberá establecer además una contraseña. Esta contraseña se adjuntará al archivo .zip exportado en el dispositivo de terceros

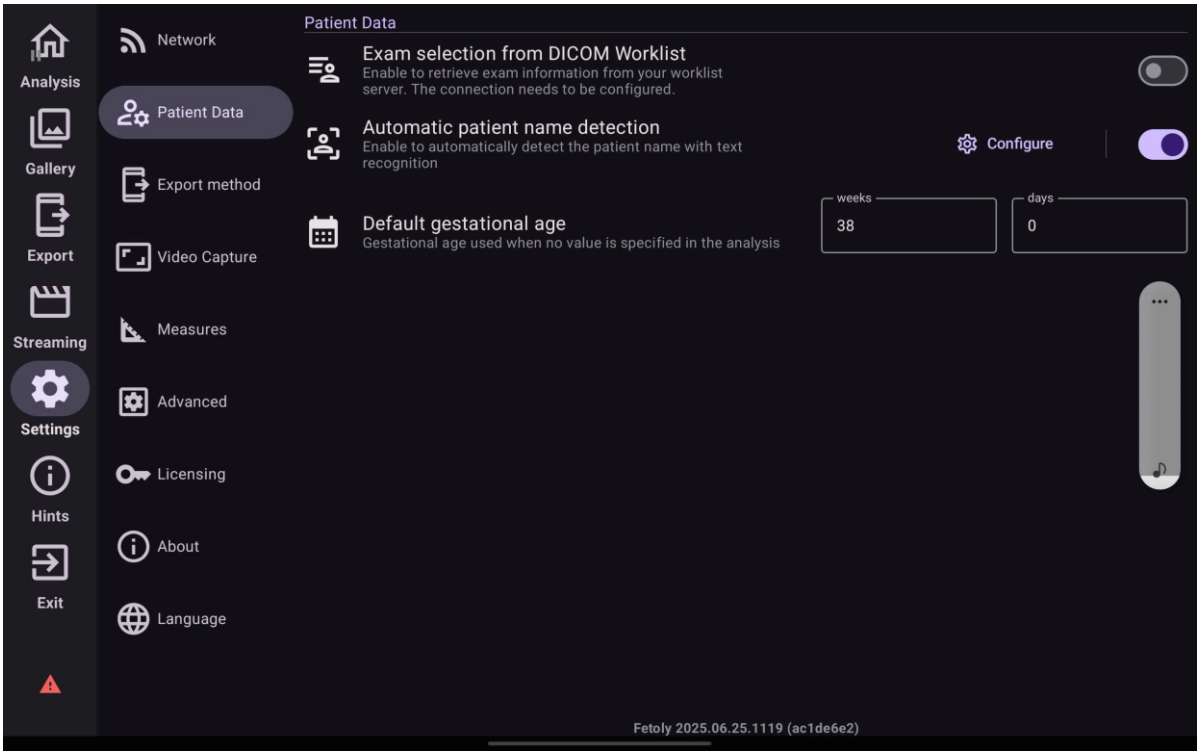




7. Si no quiere utilizar una conexión inalámbrica, puede exportar los datos directamente en la tableta:
    a. Vaya a "Ajustes" > "Método de exportación" y seleccione local. El archivo se guardará en una ubicación ya definida por la tableta.
    b. Para acceder a la ubicación definida, vaya al escritorio de su tableta, seleccione el icono "Archivos" y, a continuación, vaya a "Descargas" > "Fetoly".



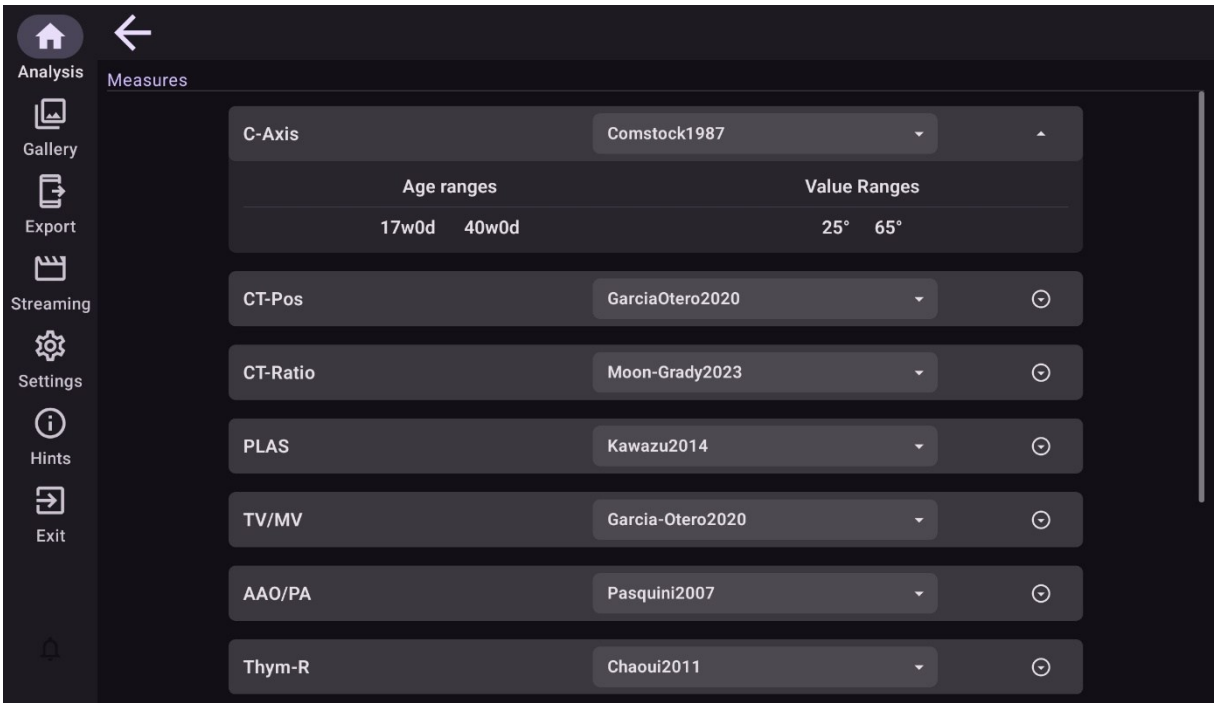
8. Si desea añadir el nombre de la paciente en el nombre del archivo exportado o si desea seleccionar la exploración de la paciente de la lista de trabajo DICOM:
    a. Rellene directamente el nombre de la paciente con la edad gestacional en la página de análisis: o bien
    b. Vaya a "ajustes" > "Datos de la paciente" y active "selección de exámenes de la lista de trabajo DICOM" Obsérvese que esta función solo funciona si está conectado a un PACS con los parámetros de la lista de trabajo DICOM configurados. Téngase también en cuenta que en el modo de exportación DICOM, está obligado a utilizar estos ajustes.
    c. Opcionalmente, vaya a "ajustes" > "Datos de la paciente" y active la "detección automática del nombre de la paciente". A continuación, puede ir a "configurar" y seleccionar la zona de la transmisión de vídeo de la ecografía en la que aparece el nombre de la paciente. A continuación, el nombre de la paciente se rellenará automáticamente al iniciar la exploración o pulsando el botón de actualización situado a la derecha del nombre de la paciente en la página de análisis.





Uso

4. Siga estos pasos para realizar la comprobación de la exhaustividad y las mediciones:
    a. Introduzca la edad gestacional en la página de análisis con el nombre de la paciente o seleccione la exploración de la paciente en la lista de trabajo DICOM.
    b. Puede configurar la edad gestacional por defecto accediendo a "Ajustes" > "Datos de la paciente".
    c. Para la función de medición, si hay varias fuentes bibliográficas disponibles, elija la que prefiera. También puede configurar manualmente intervalos de referencia seleccionando el ajuste de personalizados. Para ello, haga clic en el botón de nueva pestaña situado a la derecha de la medición en la página de análisis o vaya a "Ajustes" > "Ajustes de medidas". Esto le redirigirá a la página de ajustes de las mediciones.



d. Pulse Reproducir en la página de análisis.

e. Realice la exploración como de costumbre.

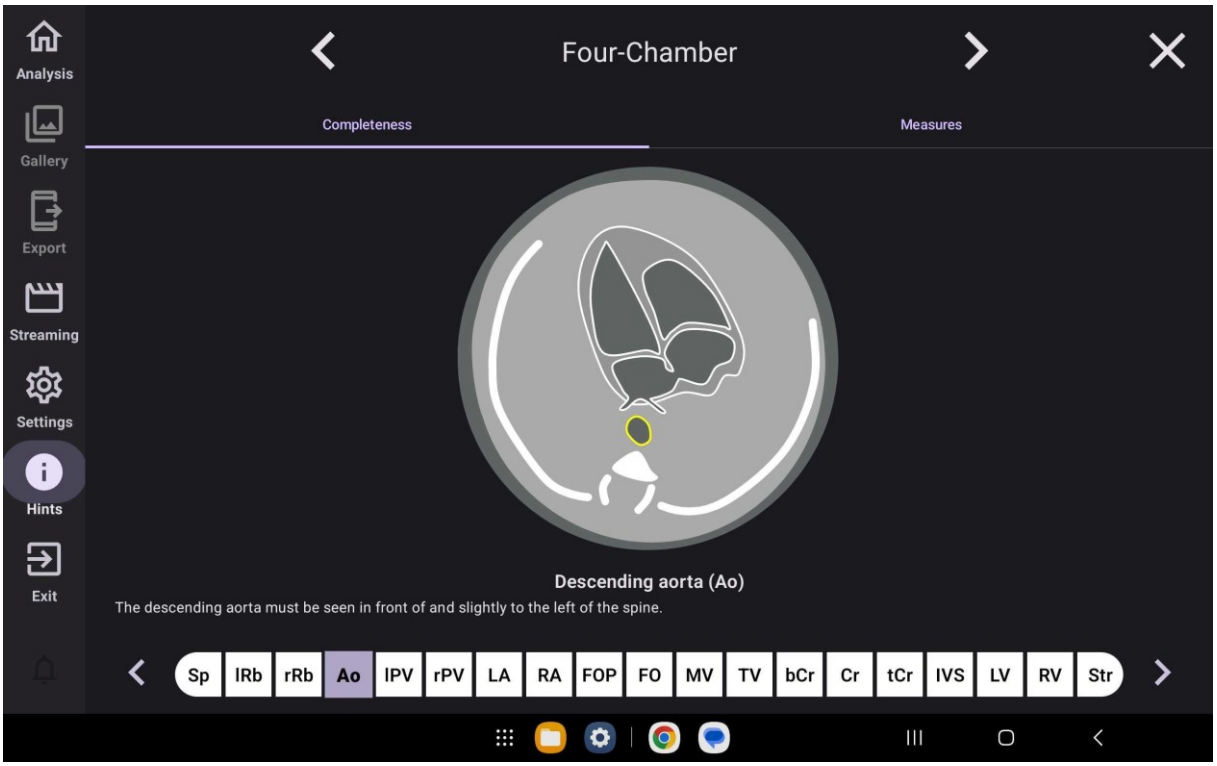
f. La exploración se considera completa cuando se han verificado todas las opiniones y criterios, y se han realizado todas las mediciones

g. Las mediciones se muestran como "fuera de intervalo" si están fuera del intervalo de referencia definido.

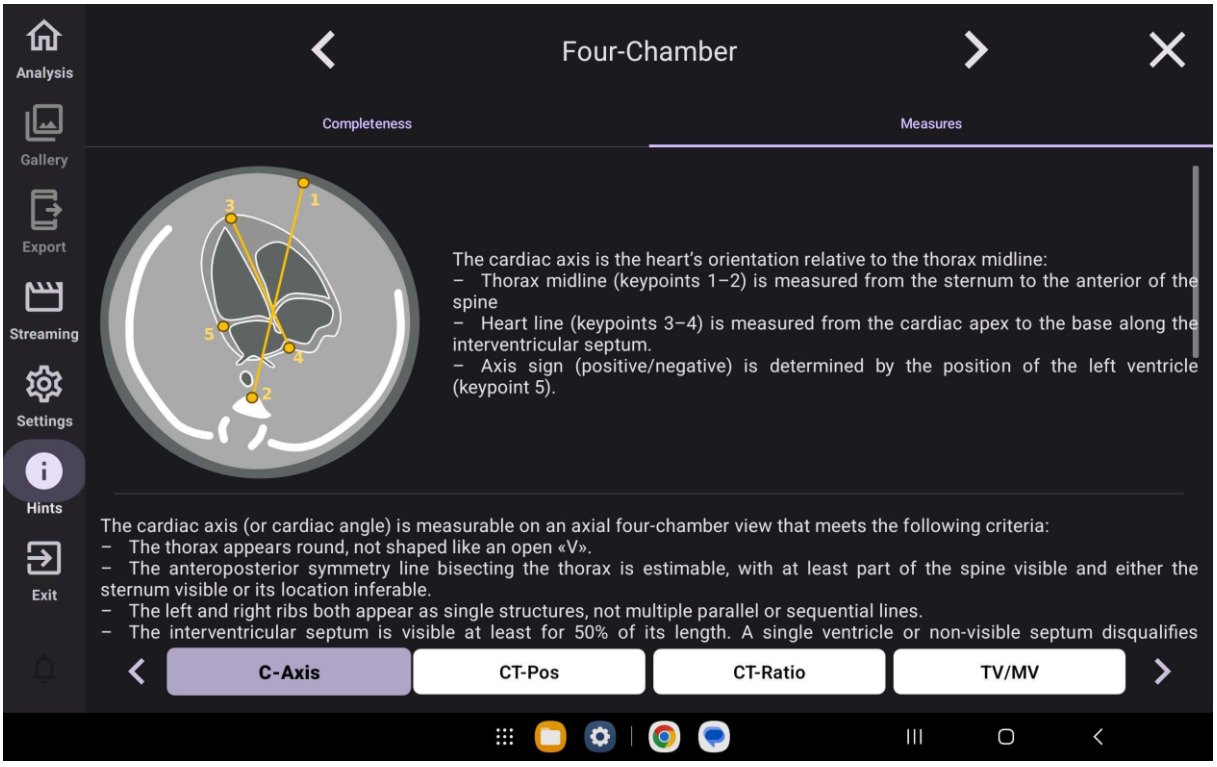
h. Una vez finalizado la exploración, la página de análisis lo indica y permite ir directamente a la página de galería para consultar las imágenes propuestas.



5. A continuación, encontrará una lista de consejos para poder completar fácilmente la exploración y las medidas:
    a. Los criterios de calidad y las opiniones detectadas por el software se basan en la guía de la ISUOG para el cribado cardíaco y cerebral del feto. Lea esta guía si lo necesita como recordatorio de las buenas prácticas en el cribado cardíaco y cerebral del feto. También puede ir a la página de Consejos para obtener una explicación de todos los criterios de calidad



b. Las mediciones biométricas realizadas por el software se basan en directrices internacionales y en bibliografía reconocida sobre el cribado cardíaco y cerebral del feto. Si es necesario, lea los artículos científicos a los que hace referencia el software como recordatorio de las buenas prácticas en el cribado cardíaco y cerebral del feto. También puede ir a la página Consejos para obtener una explicación de todas las mediciones realizadas.



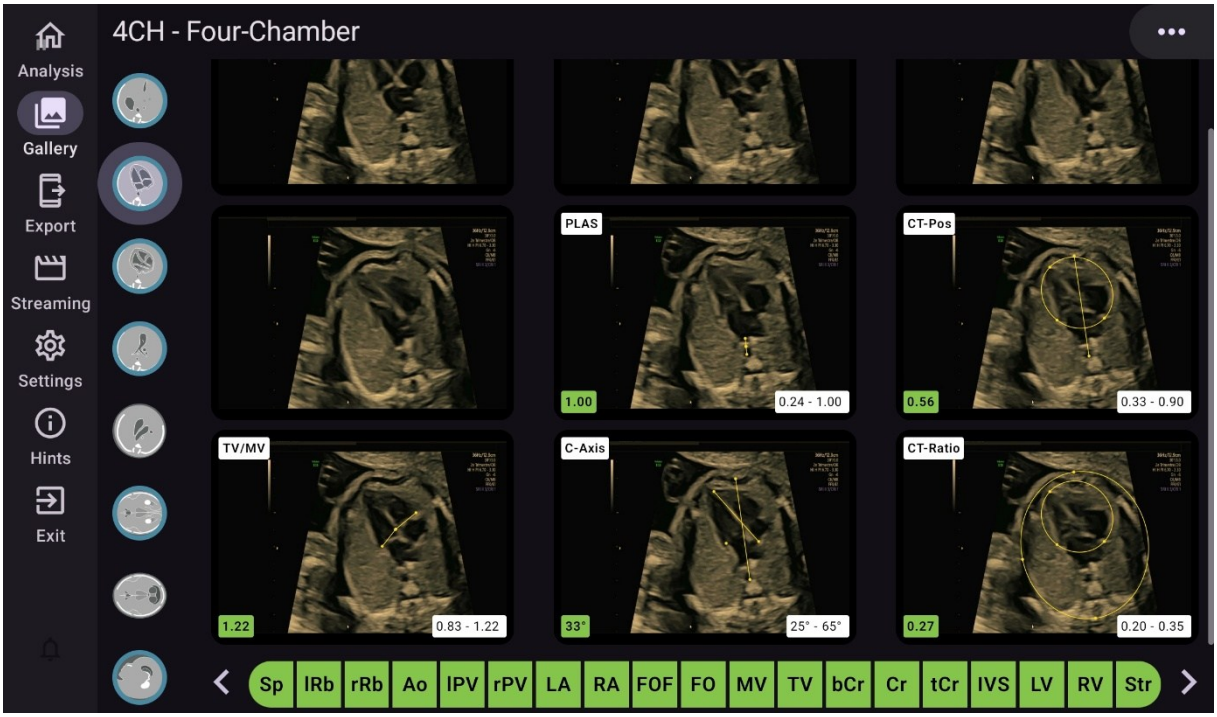
c. Asegúrese de que todos los pasos de configuración explicados anteriormente se realizan correctamente para evitar problemas de detección.

d. Asegúrese de utilizar equipos compatibles según la sección 10 de estas instrucciones de uso.

e. Aparece una advertencia en la página de exportación si los criterios y medidas de calidad no están incluidos en el conjunto de imágenes seleccionado.

f. Una vez verificados todos los criterios y realizadas todas las mediciones en la página de análisis, compruebe si la totalidad de criterios y mediciones correspondientes son fácilmente identificables en el conjunto de imágenes seleccionado en la página de galería.

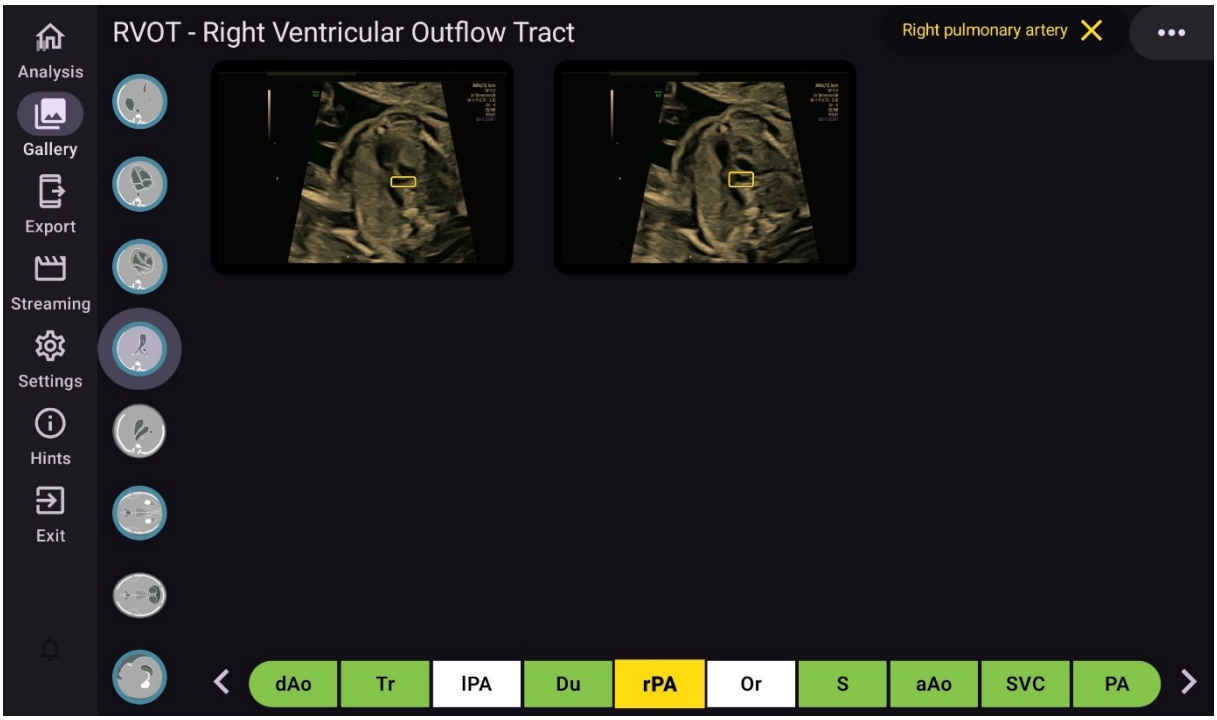
6. Una vez finalizada la transmisión de vídeo, vaya a la sección "Galería" para explorar las imágenes seleccionadas. Para facilitar la navegación dentro del conjunto de imágenes, estas se clasifican por planos.



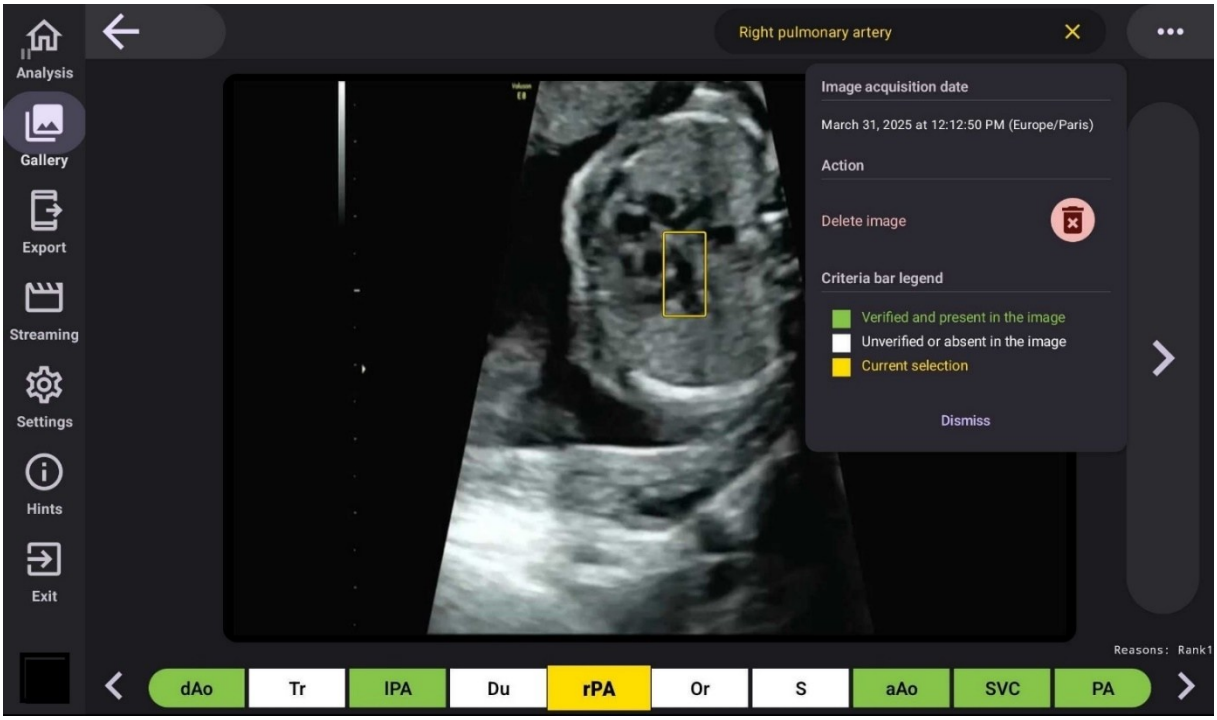
a. Haga clic en un plano concreto (panel izquierdo) para ver las imágenes seleccionadas relacionadas con ese plano. Los criterios en verde están verificados y los criterios en blanco no están verificados.

b. Las imágenes seleccionadas para las mediciones biométricas contienen la siguiente información: nombre de la medición, valor, intervalo de referencia y estado fuera de intervalo, si procede. Los puntos clave de medición y las formas aparecen en amarillo.

c. Haga clic en una estructura específica para ver las imágenes seleccionadas que contienen esta estructura. El criterio de calidad seleccionado aparece en amarillo y el cuadro delimitador que rodea al criterio se muestra en las imágenes.

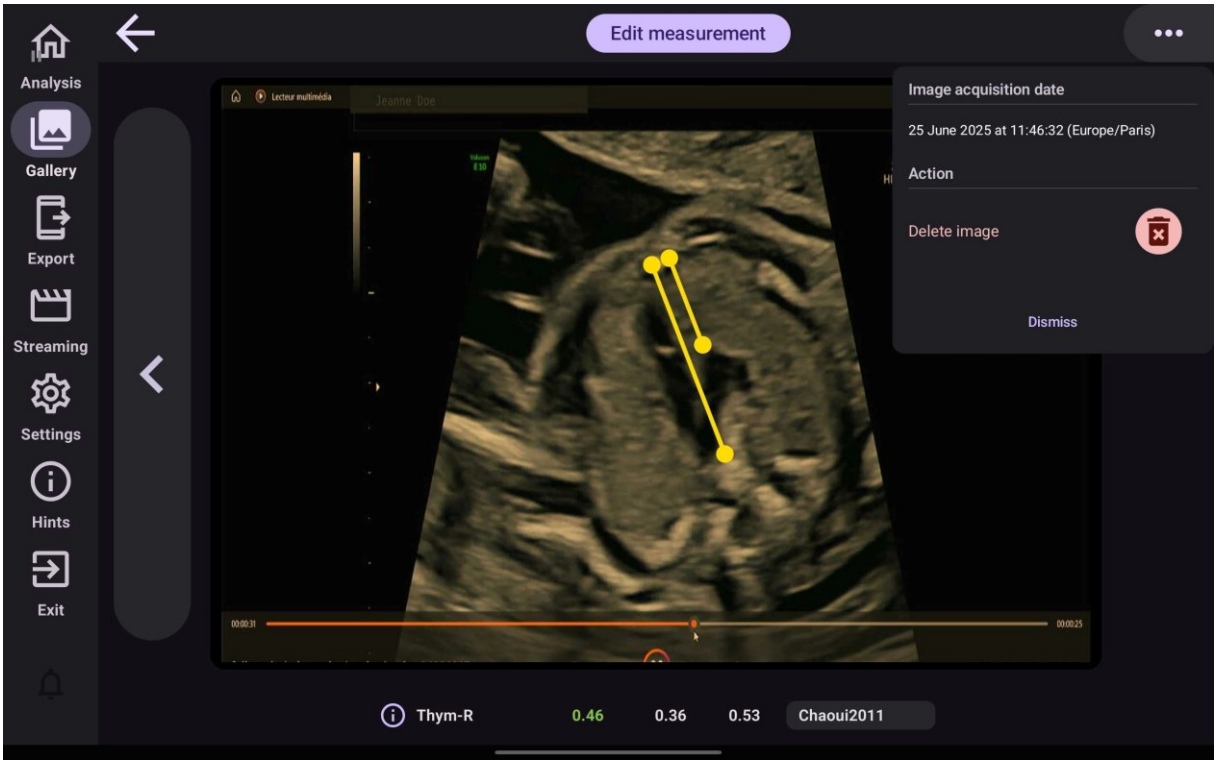


d. Haga clic en una imagen completa para ampliarla. Puede hacer clic en un criterio de calidad en verde para visualizar el cuadro delimitador que rodea al criterio de calidad. El criterio de calidad elegido aparece en amarillo. Los cuadros blancos significan que los criterios de calidad están presentes en otras imágenes de la galería o no están verificados. Haga clic en el símbolo de la papelera para borrar la imagen. Puede deslizar directamente el dedo por los laterales de la imagen para ver otras imágenes de la vista.



e. Haga clic en una imagen de medición para ampliarla. Los puntos clave de medición y las formas aparecen en amarillo. Tenga en cuenta que los puntos

clave de medición no están diseñados para estar en la ubicación exacta, sino para ser lo suficientemente precisos como para mostrar el valor de medición correcto. Se muestra el valor y el estado "fuera de intervalo" si procede, junto con el intervalo de referencia y la fuente bibliográfica seleccionada. Haga clic en el símbolo de la papelera para borrar la imagen. Puede deslizar directamente el dedo por los laterales de la imagen para ver otras imágenes de la vista. Puede editar los puntos clave de una medida en las imágenes de medición, haciendo clic en el botón "editar medición". A continuación, el valor de medición se actualizará en consecuencia y el software evitará cualquier modificación automática mediante un nuevo escaneo después de la edición. La medición editada se marcará con el siguiente símbolo: .

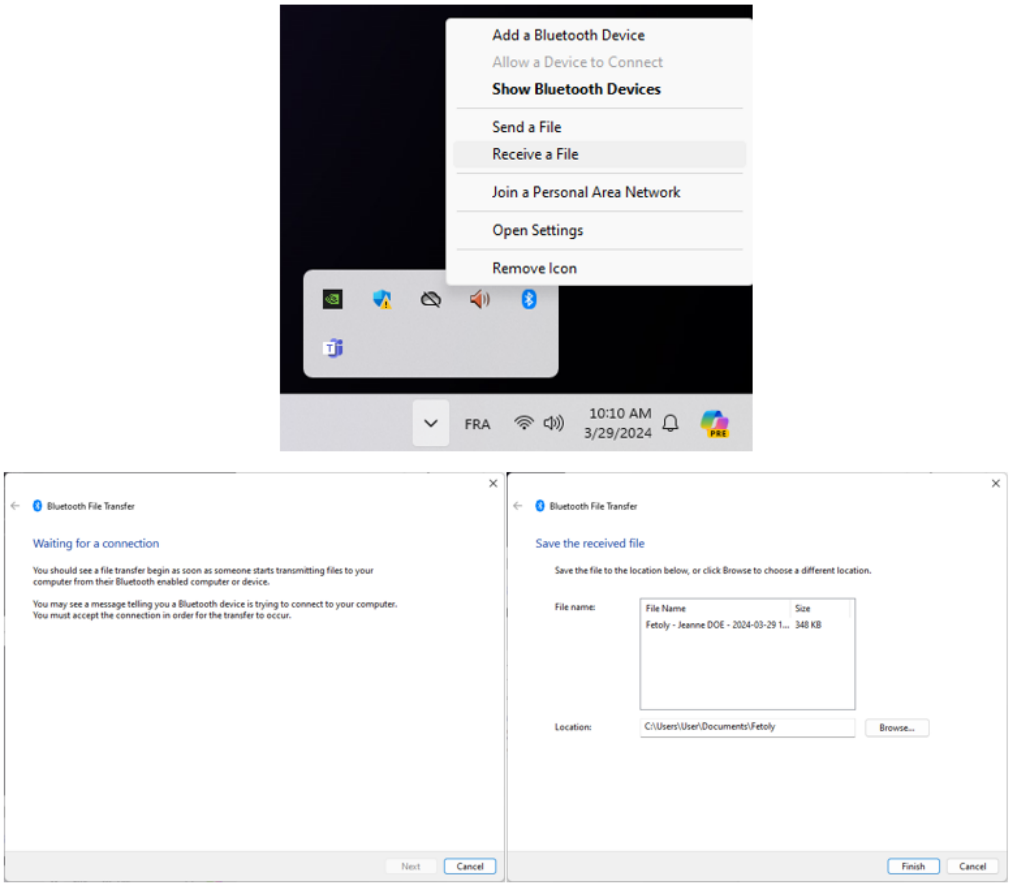




f. En caso necesario, puede volver a la página de análisis para relanzar el análisis y obtener imágenes adicionales.

Exportar imágenes

3. Vaya a la sección "Método de exportación" en "Ajustes" para seleccionar el modo de exportación que desea utilizar.
4. Vaya a la sección "Exportar" para exportar las imágenes seleccionadas:
    c. Si ha elegido la conexión Bluetooth (solo Android), vaya a su PC y seleccione "recibir un archivo" en la configuración Bluetooth.



i. Si ha elegido la conexión DICOM, puede verificar si la paciente seleccionada para la exportación es la correcta y seleccionar otra paciente si existe un error utilizando la lista de trabajo DICOM en la página de análisis.

j. En la página de exportación se muestra un resumen de la exploración y le recuerda que debe comprobar si dispone de todas las imágenes necesarias para una atención eficaz de la paciente antes de exportarlas.

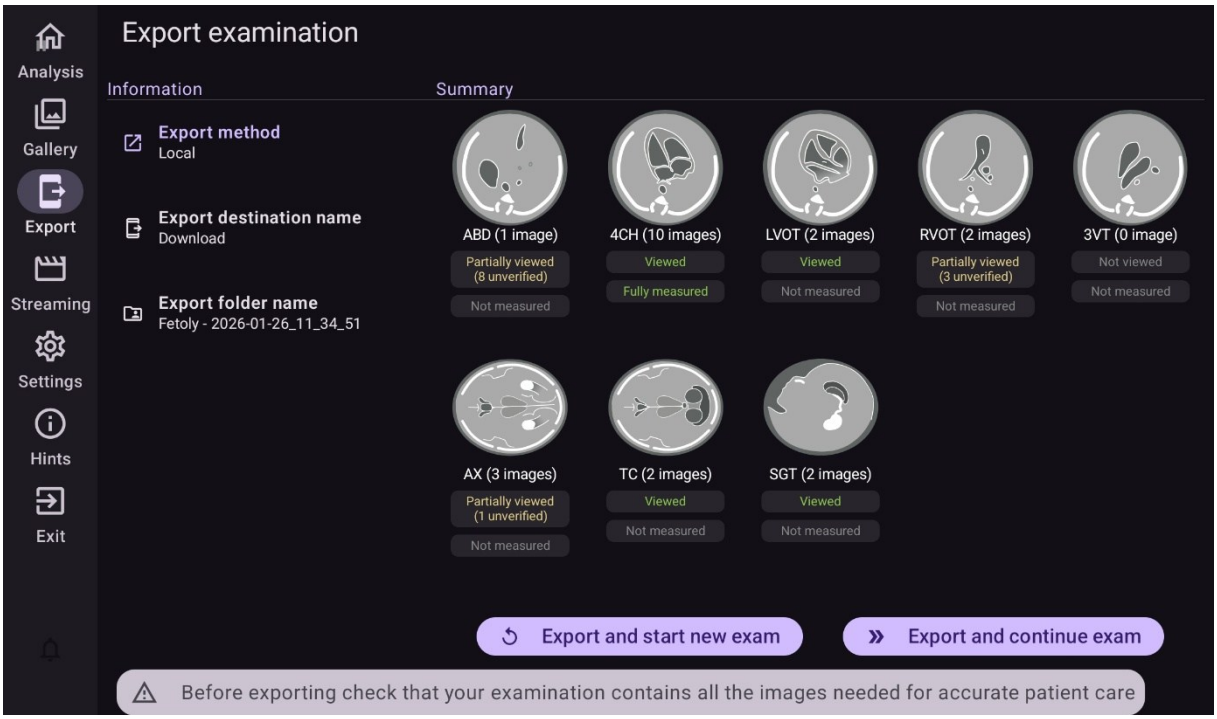
k. La página de exportación muestra la metodología de exportación elegida. Si desea cambiar los ajustes, puede ir directamente a la página de ajustes de exportación haciendo clic en "método de exportación".

l. La página de exportación muestra la ubicación del archivo de exportación en el dispositivo elegido y el nombre de archivo configurado para la exportación local.

m. Haga clic en el botón "Exportar e iniciar una nueva exploración" para exportar las imágenes y borrar la exploración antes de iniciar una nueva exploración.

n. O bien, haga clic en el botón "Exportar y continuar la exploración" para exportar las imágenes sin borrar el conjunto de imágenes seleccionado actualmente ni el análisis de exhaustividad.

o. El programa le indicará si la exportación se ha realizado correctamente o ha fallado.



Reinicialización (borrar)

Si no ha utilizado la función de borrado en la página de exportación, vaya a "Análisis" y haga clic en el botón "Borrar" para reinicializar el conjunto de imágenes seleccionadas y la exploración.

Ajustes avanzados

Si desea desactivar la función de medición, vaya a "Ajustes" > "Avanzado" y haga clic en el botón.

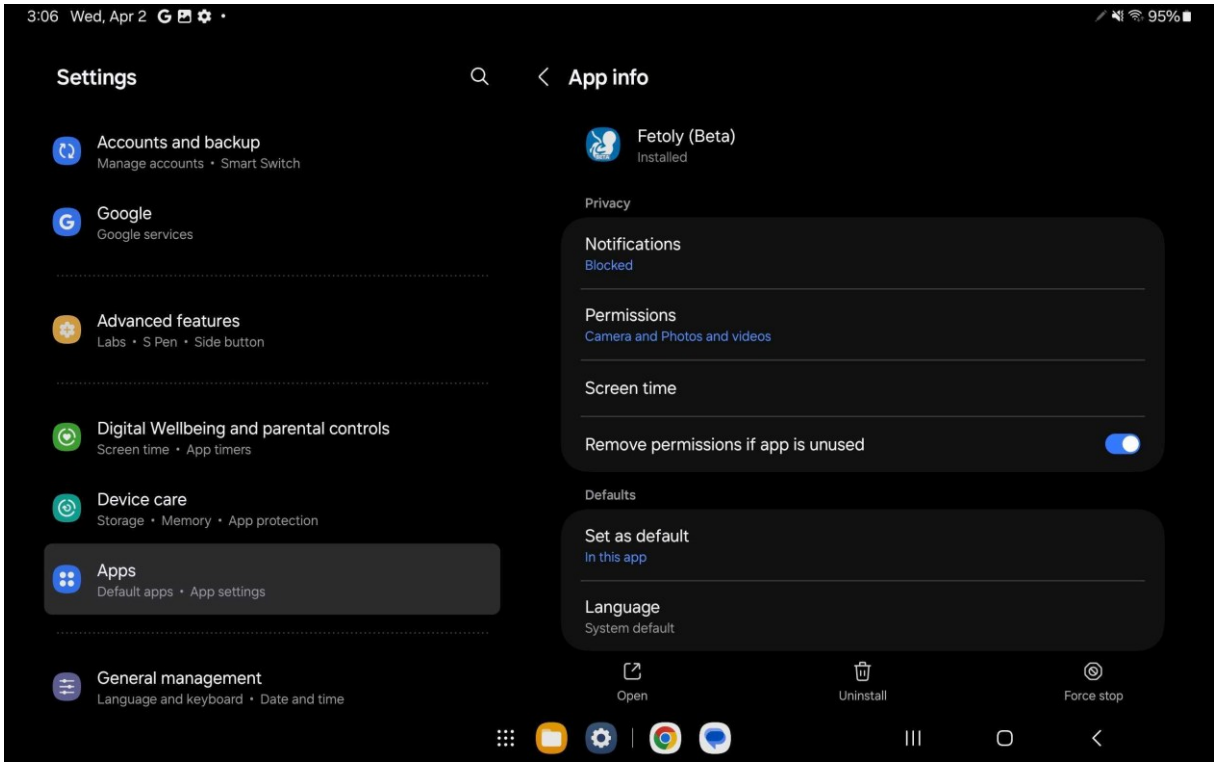
Actualización de software y licencias

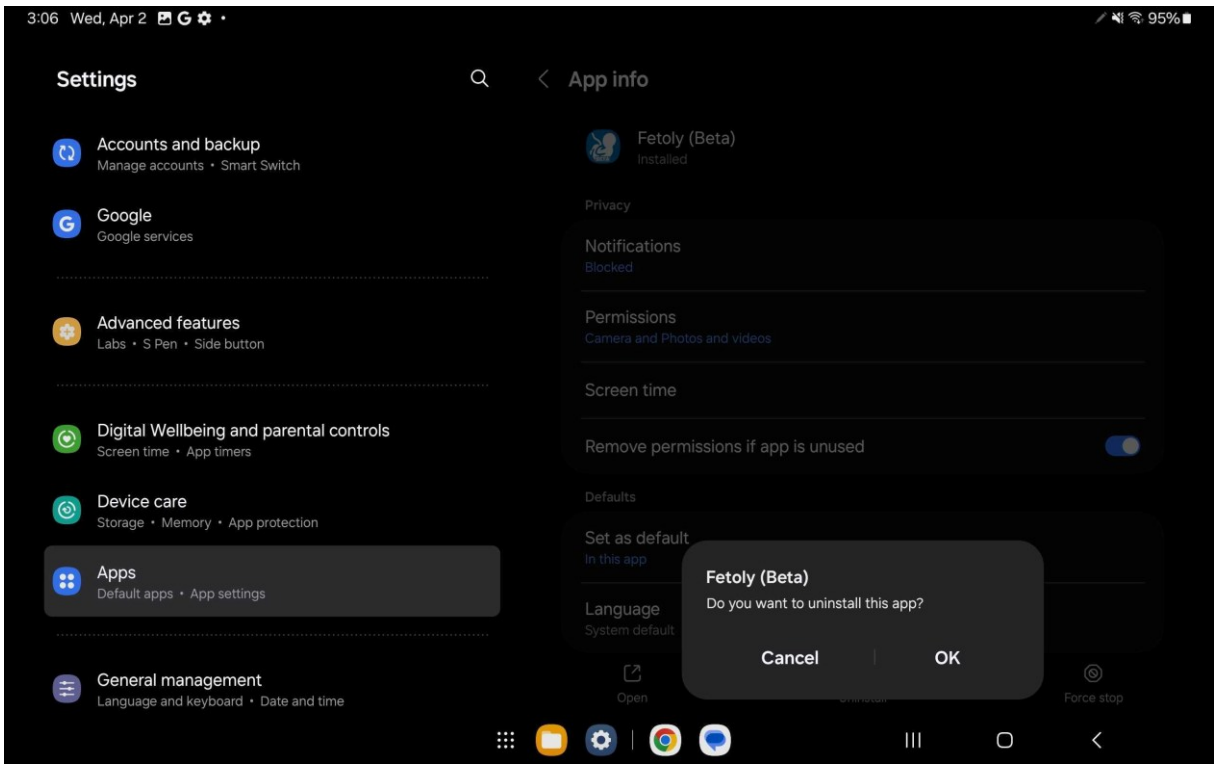
El software comprueba periódicamente si hay nuevas actualizaciones de la aplicación. Para garantizar la disponibilidad inmediata de las nuevas actualizaciones, active las actualizaciones en segundo plano para FETOLY en los ajustes de Google Play/App Store. Cuando haya una actualización disponible, el software mostrará una página de bloqueo al iniciarse, en la que se pedirá al usuario que actualice y reinicie la aplicación para poder seguir utilizándola. Tras aceptar la actualización, Google Play/App store se encarga de la instalación de la actualización y del reinicio de la aplicación. Se necesita una conexión a Internet para comprobar si hay actualizaciones y para renovar automáticamente la licencia. Si el dispositivo no se conecta a Internet durante un periodo de 30 días, el software se bloqueará.

Su licencia se verifica y renueva automáticamente cuando se activa una conexión a Internet hasta que vence el contrato de licencia. La fecha de caducidad de la licencia se muestra en la página de ajustes de la licencia. Cuando venza el contrato de licencia, si no se renueva el contrato, el programa pedirá que se introduzca un nuevo código de registro y bloqueará las funcionalidades.

Desinstalación de programas

Desinstale la aplicación como cualquier aplicación de su tableta, tal y como se muestra a continuación:





14. Mantenimiento, manipulación y eliminación

- Deben leerse las instrucciones antes de su uso.

- Por favor, inicie las actualizaciones cuando se lo solicite el software al iniciarse.
- Téngase en cuenta que, para el mercado de los Estados Unidos de América, se ha incluido un Plan de control de cambios predeterminados (PCCP). Este PCCP se implementa para el modelo de aprendizaje automático incorporado en el dispositivo FETOLY que podría modificar el rendimiento, las entradas o el uso del dispositivo. Por lo tanto, se recomienda encarecidamente estar conectado regularmente a Internet para permitir la instalación automática de actualizaciones.
- Introduzca el código de registro cuando se lo pida el programa al iniciarlo.
- Para desactivar y eliminar el software, desinstale la aplicación a través del sistema Android como cualquier otra aplicación de su tableta, en los parámetros de la aplicación, tal y como se ilustra anteriormente en el apartado "desinstalación del software". Esta desinstalación eliminará todos los datos relacionados con el uso de FETOLY, incluida la licencia, en su tableta.

Símbolos utilizados en el etiquetado (acerca de la página):

	Fabricante (símbolo de fábrica rellenado)
	Dispositivo con marcado CE
	Identificador único de dispositivo 01: UDI-DI 11: Fecha de fabricación 8012: Versión de software
	Consulte las instrucciones de uso
	La ley federal restringe la venta de este dispositivo a médicos o por prescripción médica
	Productos sanitarios
	Fecha de fabricación (símbolo de fábrica vacío)
	Nombre y dirección del representante suizo

NÁVOD K POUŽITÍ (ČESKY)

1. Identifikace prostředku

FETOLY

Software určený k asistenci při ultrazvukovém vyšetření srdce a mozku plodu.

Verze softwaru spojená s tímto návodem k použití: V2026.02.25

2. Aktualizace

FETOLY byl ve verzi V2026.02.25 aktualizován takto:

- FETOLY je nyní kompatibilní s iOS
- Následující měření byla přidána dle modifikace č. 4 PCCP: PLAS, CSP poměr, VP poměr
- Transventrikulární a transtalamické zobrazení byly sloučeny do axiálního zobrazení.Návod k použití byl aktualizován, aby se objasnila funkce zobrazení klíčových bodů a bylo přidáno varování vysvětlující, že software by se neměl používat při transvaginální skenovací metodě.
- Výkon detekce modelů umělé inteligence byl vylepšen dle modifikace č. 1 PCCP.
- Nyní je možné povolit režim TLS pro export DICOM.

Byly znovu plně zahájeny ověřovací testy, aby se ověřilo, že aktualizace nemá žádný dopad na fungování prostředku. Použitá metodika je stejná jako u původní verze výrobku.

3. Identifikace výrobce

FETOLY vyrábí:

DIAGNOLY

2 Place de Francfort, 69003 LYON, Francie

Tel.: +33(0)6.58.49.07.84

Reklamace výrobku: support@diagnoly.com

Veškeré závažné incidenty hlaste společnosti Diagnoly prostřednictvím e-mailové adresy pro stížnosti na výrobky a příslušnému úřadu ve vaší zemi.

CE 0197

4. Popis a prezentace prostředku

Fetoly je software, jehož cílem je asistovat sonografistům, porodníkům, radiologům, specialistům na mateřskou a fetální medicínu a dětským kardiologům (označovaným jako

zdravotničtí pracovníci, tj. ZP) při ultrazvukovém vyšetření mozku a srdce plodu v reálném čase. Software Fetoly můžou ZP používat při ultrazvukovém vyšetření plodu ve druhém a třetím trimestru (rozmezí gestačního stáří: od 17. do 40. týdne).

Tento software je určen k tomu, aby pomáhal ZP při posuzování úplnosti ultrazvukového vyšetření mozku a srdce plodu v souladu s národními a mezinárodními pokyny. Software Fetoly je také určen k provádění biometrických měření mozku/srdce plodu v souladu s národními a mezinárodními pokyny.

Pro použití je třeba software Fetoly nainstalovat do hardwarového zařízení, které je připojeno k ultrazvukovému přístroji prostřednictvím připojení HDMI. Software přijímá ultrazvukové snímky pořízené připojeným ultrazvukovým přístrojem v reálném čase. Software využívá algoritmus fixního hlubokého učení, který byl vycvičen pomocí učení pod dohledem, k analýze snímků z tohoto ultrazvukového obrazového toku za účelem detekce pohledů na mozek/srdce, kritérií kvality v rámci těchto pohledů a provádění biometrických měření srdce a mozku.
Software poskytuje uživateli následující informace:

9. **Úplnost vyšetření**: software v reálném čase ukazuje, které pohledy na mozek/srdce a kritéria kvality jsou během vyšetření softwarem ověřovány. Ověřené pohledy na mozek/srdce a kritéria kvality jsou klinickým lékařům přístupná v kterémkoli okamžiku ultrazvukového vyšetření, a to v reálném čase.
10. **Biometrická kvantitativní měření:** Software v reálném čase ukazuje, která měření mozku a srdce během vyšetření software provedl a zda jsou tato měření v rozmezí nebo mimo něj ve srovnání s referenčními rozsahy definovanými podle aktuálních standardů. Ověřená měření srdce a mozku jsou lékařům přístupná kdykoli během ultrazvukového vyšetření, a to na pozadí.
11. **Znázornění při vyšetření:** software vybere podmnožinu snímků znázorňujících
    - Ověřené pohledy a kritéria kvality: Tyto snímky si mohou kliničtí lékaři prohlédnout a ověřit pohledy a přítomnost kritérií. Volitelně si mohou lékaři zobrazit zjištěná kritéria kvality lokalizace na vybraných snímcích.
    - Každé měření: U každého měření software zobrazí snímek s nakresleným měřením (žlutě) a naměřenou hodnotou (dole). Uživateli se rovněž připomene normální rozsah tohoto měření. Uživatel může přesouvat klíčové body a software podle toho aktualizuje měření.
12. **Zpráva o vyšetření:** Software umožňuje uživateli exportovat zprávu o vyšetření, která obsahuje:
    - Souhrn měření a úplnost;
    - Znázornění (snímky).

Definice úplného vyšetření

Srdce plodu

Tabulka 6: Seznam 52 kritérií kvality definujících kvalitu 5 pohledů doporučených Mezinárodní společností pro ultrazvuk v porodnictví a gynekologii u screeningu srdce plodu ve 2. a 3. trimestru těhotenství.

Zobrazení srdce	***Kritéria kvality v rámci pohledů***	
	(A1) Sp	*Páteř*
	(A2) lRb	*Levé žebro*
	(A3) rRb	*Pravé žebro*

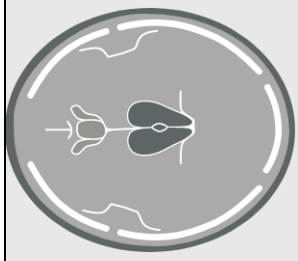
 ***(A) ABD*** ***Pohled na břicho*** ***(n = 8)***	*(A4) Ao*	*Sestupná aorta*
	(A5) VC	*Dolní dutá žíla*
	(A6) St	*Žaludek*
	(A7) Uv	*Pupeční žíla*
	(A8) aA	*Přední část břicha*
 ***(B) 4CH*** ***Čtyřkomorový pohled*** ***(n = 19)***	*(B1) Sp*	*Páteř*
	(B2) lRb	*Levé žebro*
	(B3) rRb	*Pravé žebro*
	(B4) Ao	*Sestupná aorta*
	(B5) lPV	*Levá plicní žíla*
	(B6) rPV	*Pravá plicní žíla*
	(B7) LA	*Levá síň*
	(B8) RA	*Pravá síň*
	(B9) FOF	*Septum primum (Vieussensova chlopeň neboli foramen ovale)*
	(B10) FO	*Otevřené foramen ovale*
	(B11) MV	*Mitrální chlopeň*
	(B12) TV	*Trikuspidální chlopeň*
	(B13) bCr	*Spojení mezi křížem a síňovým septem (vestibulární septum)*
	(B14) Cr	*Posun atrioventrikulární chlopně v kříži*
	(B15) tCr	*Spojení mezi interventrikulárním septem a křížem*
	(B16) IVS	*Interventrikulární septum*
	(B17) LV	*Levá komora*
	(B18) RV	*Pravá komora*
	(B19) Str	*Sternum*
 ***(C) LVOT*** ***Pohled na výtokový trakt levé komory*** ***(n = 6)***	*(C1) LA*	*Levá síň*
	(C2) aAo	*Proximální vzestupná aorta*
	(C3) SV	*Poloměsíčité chlopně*
	(C4) LV	*Levá komora*
	(C5) IVS	*Interventrikulární septum*
	(C6) RV	*Pravá komora*
	(D1) dAo	*Sestupná aorta*
	(D2) Tr	*Průdušnice / průdušky*
	(D3) lPA	*Levá plicní tepna*

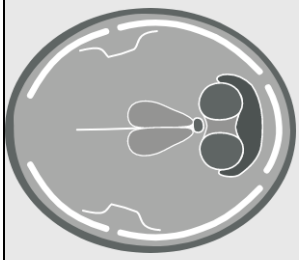
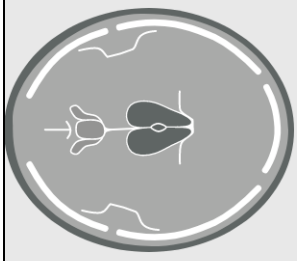
 ***(D) RVOT*** ***Pohled na výtokový trakt pravé komory*** ***(n = 10)***	*(D4) Du*	*Botallova dučej*
	(D5) rPA	*Pravá plicní tepna*
	(D6) Or	*Začátek plicních tepen*
	(D7) S	*Septum mezi kmenem plicní tepny a vzestupnou aortou*
	(D8) aAo	*Vzestupná aorta*
	(D9) SVC	*Horní dutá žíla*
	(D10) PA	*Plicní kmen*
 ***(E) 3VX*** ***Pohled na tři cévy*** ***(n = 9)***	*(E1) Sp*	*Páteř*
	(E2) Tr	*Průdušnice*
	(E3) ES	*Boční prostor vlevo od Botallovy dučeje*
	(E4) DuA	*Oblouk chámovodu napojený na sestupnou aortu*
	(E5) Du	*Oblouk chámovodu, který není spojen se sestupnou aortou*
	(E6) aAo	*Vzestupná aorta*
	(E7) aAr	*Aortální oblouk*
	(E8) SVC	*Horní dutá žíla*
	(E9) Th	*Brzlík / hrudní kost*

Mezinárodní a národní pokyny [Carvalho2023] doporučují u běžného ultrazvukového vyšetření ve 2. a 3. trimestru 5 pohledů na srdeční činnost plodu: (A) pohled na břicho, (B) čtyřkomorový pohled, (C) pohled na výtokový trakt levé komory, (D) pohled na výtokový trakt pravé komory, (E) pohled na tři cévy. Kvalita těchto 5 pohledů na srdce závisí na přítomnosti 52 anatomických kritérií kvality v rámci zobrazení ***(tabulka 1)****. Vyšetření lze tedy považovat za kompletní, pokud ZP pořídí všech 5 pohledů na srdce a splní jejich kritéria kvality.*

Mozek plodu

Tabulka 7: Seznam 34 kritérií kvality definujících kvalitu 3 pohledů doporučených Mezinárodní společností pro ultrazvuk v porodnictví a gynekologii u screeningu mozku plodu ve 2. a 3. trimestru těhotenství.

Zobrazení mozku	***Kritéria kvality v rámci pohledů***	
 ***(F) TV*** ***Axiální pohled*** ***(n = 18)***	*(F1) aFx*	*Přední falx*
	(F2) CSP	*Cavum septum pellucidum*
	(F3) For	*Fornix*
	(F4) dAV	*Distální přední komora*
	(F5) pAV	*Proximální přední komora*
	(F6) AC	*Cisterna ambiens*
	(F7) Atr	*Atrium*
	(F8) CP	*Plexus chorioideus*
	(F9) POS	*Sulcus parietooccipitalis*
	(F10) pFx	*Zadní falx*

	(F11) dCS	*Distální koronární šev*
	(F12) pCS	*Proximální koronární šev*
	(F13) SF	*Sylviova brázda*
	(F14) Sk	*Lebka*
	(F15) Sep	*Hranice mezi thalamy*
	(F16) 3V	*3. komora*
	(F17) dTh	*Distální thalamus*
	(F18) pTh	*Proximální thalamus*
 ***(G) TC Transcerebelární pohled (n = 8)***	*(G1) dTh*	*Distální thalamus*
	(G2) pTh	*Proximální thalamus*
	(G3) 4V	*4. komora*
	(G4) Ver	*Vermis*
	(G5) dCH	*Distální mozečková hemisféra*
	(G6) pCH	*Proximální mozečková hemisféra*
	(G7) CB	*Okraj mozečku*
	(G8) CM	*Cisterna magma*
 ***(H) TT Transthalamický pohled (n = 12)***	*(H1) aFx*	*Přední falx*
	(H2) CSP	*Cavum Septum Pellicidum*
	(H3) dAV	*Distální přední komora*
	(H4) pAV	*Proximální přední komora*
	(H5) dTh	*Distální thalamus*
	(H6) pTh	*Proximální thalamus*
	(H7) Sep	*Hranice mezi thalamy*
	(H8) 3V	*3. komora*
	(H9) dCS	*Distální koronární šev*
	(H10) pCS	*Proximální koronární šev*
	(H11) SF	*Sylviova brázda*
	(H12) Sk	*Lebka*
 ***(I) SAG Sagitální/profilový pohled (n = 8)***	*(I1) NB*	*Kost nosní*
	(I2) uVer	*Horní část vermis*
	(I3) lVer	*Dolní část vermis*
	(I4) Fas	*Fastigium*
	(I5) rgCC	*Rostrum a genu corpus callosum*
	(I6) bCC	*Tělo corpus callosum*
	(I7) sCC	*Splenium corpus callosum*
	(I8) CSP	*Cavum Septum Pellicidum*

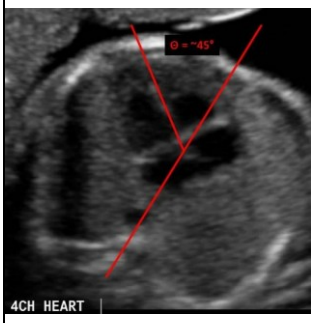
Biometrická měření a referenční intervaly

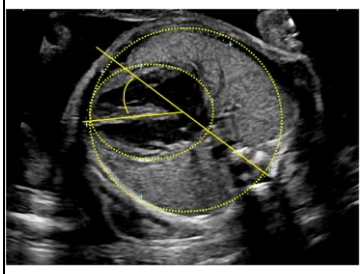
Software FETOLY poskytuje tři typy automatizovaných biometrických měření:

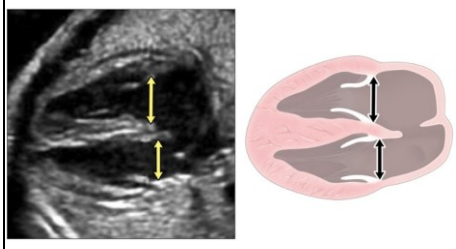
- **Měření úhlů** se zobrazuje ve stupních (°);
- **Poměrové měření** (vzdálenost v poměru k jiné vzdálenosti, vyjádřená buď jako poměr nebo v procentech);
- **Počet** zjištěných anatomických orientačních bodů;

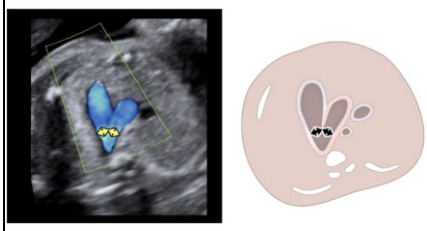
Seznam měření a jejich referenčních intervalů:

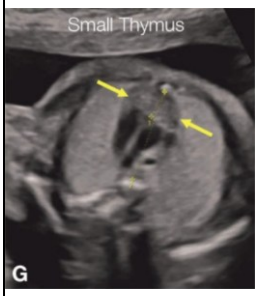
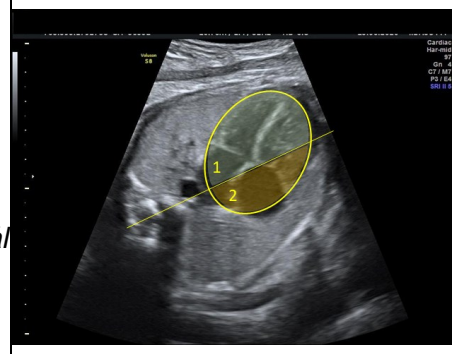
V následující tabulce jsou podrobně uvedena biometrická měření prováděná softwarem FETOLY a jim odpovídající standardní referenční intervaly čerpající z ověřené literatury.

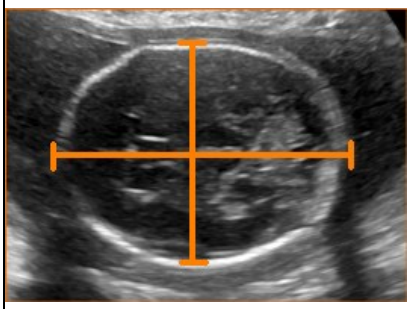
Parametr	*Informace dostupné ve FETOLY (popis a zdroje)*
(M1) Srdeční osa	***Co je to srdeční osa (CAx)?***  *(zdroj: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* ***Srdeční osa** (neboli **úhel srdce**) označuje orientaci srdce vzhledem ke středové čáře hrudníku měřenou ve čtyřkomorovém pohledu. Určuje se podle úhlu mezi přímkou podél interventrikulárního septa a předozadní přímkou, která protíná hrudník.* *Snímek má zahrnovat páteř, hrudní kost a čtyři komory. Levá a pravá žebra mají být přítomna a mají být rozeznatelná jako jednotlivá žebra.* ***Co doporučují pokyny?*** *Pokyny ISUOG uvádějí, že screeningové vyšetření srdce má zahrnovat čtyřkomorový pohled a jeho vyhodnocení má zahrnovat srdeční osu („Normální srdce plodu leží převážně vlevo, přičemž srdeční hrot směřuje doleva pod úhlem 45 ± 20° vzhledem k předozadní ose hrudníku.“) (Carvalho 2023). Je citován Comstock (1987), který uvádí referenční rozmezí pro srdeční osu.* *Pokyny ASE rovněž doporučují vyhodnocení srdeční osy („Srdeční osa je doporučenou součástí fetálního echokardiografického 2D zobrazení [...], v běžném rozmezí 35–65°)“ (Moon-Grady 2023).* ***Dostupné referenční intervaly:*** • **Comstock (1987):** (průměr ± 2 SD) o Gestační stáří 17–40: [25–65°]. • **ASE (2023):** (referenční rozmezí definované v pokynech)

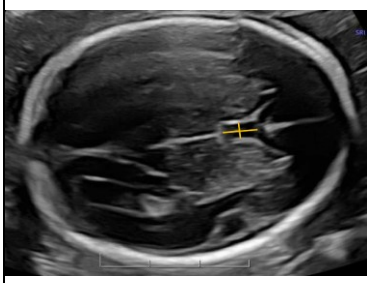
	○ Gestační stáří 17–40: [35–65°]
(M2) Kardiotorakální index	***Co je to kardiotorakální index?***  *(zdroj: https: //www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Kardiotorakální index plodu (CTR) je poměr šířky srdečního stínu k šířce hrudníku měřený na čtyřkomorovém pohledu během diastoly.* *Snímek má zahrnovat páteř, hrudní kost a čtyři komory. Levá a pravá žebra mají být přítomna a mají být rozeznatelná jako jednotlivá žebra.* ***Co doporučují pokyny?*** *Pokyny ASE uvádějí, že kardiotorakální index je povinnou součástí fetálního echokardiogramu („Standardní biometrická měření z axiálního snímku na úrovni čtyřkomorového pohledu. Kardiotorakální index se vypočítá na základě měření vnitřního obvodu (nebo plochy) hrudníku a epikardiální plochy srdce.“) (Moon-Grady 2023).* *Pokyny institutu AIUM rovněž uvádějí, že kardiotorakální index je povinnou součástí biometriky srdce (AIUM 2019). Toto měření doporučují i pokyny ISUOG („Klíčové prvky standardního čtyřkomorového pohledu v polovině druhého trimestru zahrnují plochu srdce nepřesahující jednu třetinu plochy hrudníku.“) (Carvalho 2013). V příručce od Abuhamada (2009) se rovněž doporučuje posoudit rozměry srdce („Rozměry srdce plodu lze snadno posoudit měřením poměru obvodu nebo plochy srdce k obvodu nebo ploše hrudníku získanému na úrovni čtyřkomorového pohledu.“) (Abuhamad 2009). Pokyny AHA (Donofrio 2014) i Abuhamadova příručka citují u referenčního rozmezí Paladiniho (1990).* ***Dostupné referenční intervaly:*** • **Paladini (1990):** (2,5. a 97. percentil u obvodu) ○ Gestační stáří 17: [0,40–0,52] ○ Gestační stáří 18: [0,40–0,52] ○ Gestační stáří 19: [0,42–0,51] ○ … ○ Gestační stáří 40: [0,46–0,56] • **Garcia-Otero (2020)**: (5. a 95. percentil u dané oblasti) ○ Gestační stáří 18: [0,16–0,25] ○ Gestační stáří 19: [0,16–0,26] ○ … ○ Gestační stáří 40: [0,21–0,35]

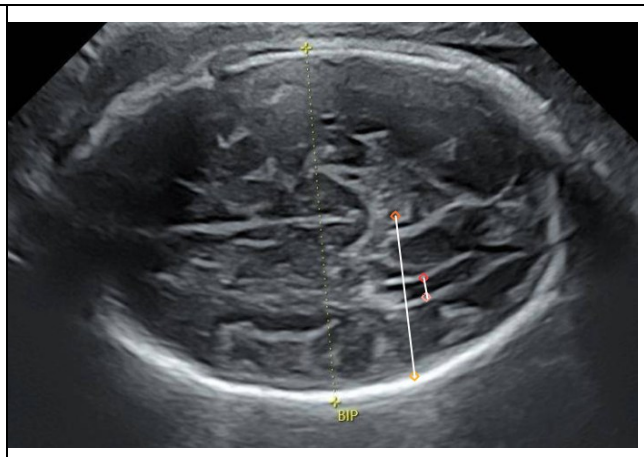
	• **ASE** (Moon-Grady 2023): (rozsah definovaný pokyny pro optimální skóre plodu u dané oblasti) o Gestační stáří 17–40: [0,20–0,35]
(M3) Poměr šířky komor	***Jaký je poměr pravé a levé komory?***  *(zdroj: https: //www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* ***Poměr pravé a levé komory (TV/MV**) označuje poměr průměru prstence trikuspidální chlopně (TV) k průměru prstence mitrální chlopně (MV), který se používá k hodnocení srdeční morfologie u plodu. Určuje se porovnáním průměrů TV a MV v jejich nejširším bodě během diastoly.* *Snímek zahrnuje páteř a hrudní kost. Levá a pravá žebra mají být přítomna a mají být rozeznatelná jako jednotlivá žebra. Čtyřkomorové pohledy mají být vidět a mají být dobře kontrastní.* *Poznámka: při měření průměru komor existují dvě konvence (Schneider 2005): měření na úrovni chlopní nebo enddiastolický rozměr. Vezměte prosím na vědomí, že u tohoto měření se používá první možnost.* ***Co doporučují pokyny?*** *Pokyny AIUM uvádějí, že porovnání anulu trikuspidální a mitrální chlopně během diastoly je povinnou srdeční biometrií („Anulus trikuspidální a mitrální chlopně při diastole ([...] srovnání levostranných a pravostranných chlopní) je nezbytnou součástí biometriky srdce.“) (AIUM 2019). U referenčních rozsahů se citují DeVore (2017), Lee (2009) a Schneider (2005).* *Pokyny ISUOG také uvádějí, že pravolevá asymetrie je důvodem k dalšímu vyšetření („Obě komory mají mít podobnou velikost. Ačkoli mírná komorová disproporce může být ve třetím trimestru těhotenství normální variantou, asymetrie mezi pravou a levou stranou v polovině těhotenství vyžaduje další vyšetření.“) (Carvalho 2023). U referenčního rozsahu se cituje Kirk (1999).* *Pokyny organizace ASE také uvádějí, že poměr velikosti komor je při echokardiografickém vyšetření plodu povinným ukazatelem („Anulus chlopně AV při časné diastole je nezbytnou součástí kompletní echokardiografie.“) (Moon-Grady 2023). Příručka od Abuhameda (2012) rovněž zdůrazňuje význam poměru šířky pravé a levé komory, který je u normálního plodu 1,19.* ***Dostupné referenční intervaly:*** • **Gabbay-Benziv (2015)** (Gabbay-Benziv 2015): (2,5. a 97. percentil) o Gestační stáří 17: [0,87–1,22] o Gestační stáří 18: [0,86–1,22] o Gestační stáří 19: [0,86–1,22] o …

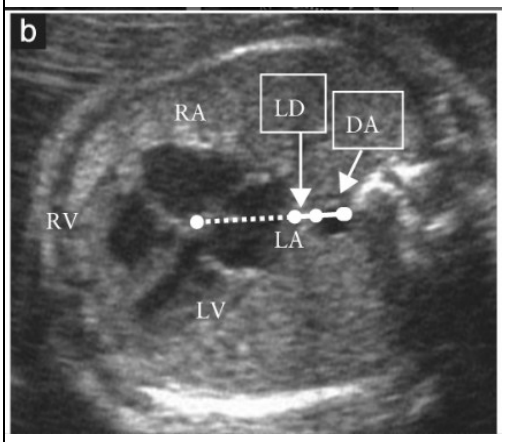
	○ Gestační stáří 38: [0,87–1,30] • **Garcia-Otero (2020)**: (5. a 95. percentil) ○ Gestační stáří 18: [0,82–1,21] ○ Gestační stáří 19: [0,82–1,22] ○ … ○ Gestační stáří 40: [0,86–1,27]
(M4) Poměr cév	***Jaký je poměr velkých cév?***  *(zdroj: https: //www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Poměr rozměrů velkých cév (Ao/Du) označuje poměr mezi průměry aortálního isthmu (Ao) a Botallovy dučeje (Du) v pohledu na tři cévy. Určuje se změřením průměrů dučeje a aortálního oblouku u jejich báze. Poměr průměru mediastinální plicní tepny (PA) k průměru vzestupné aorty (Ao) se využívá i v literatuře (Slodki2009).* *Snímek má zahrnovat páteř a hrudní kost se zřetelně viditelnými levými a pravými žebry. Botallova dučej a vzestupná aorta mají být zřetelně viditelné, aby bylo patrné jejich spojení.* ***Co doporučují pokyny?*** *Americké a mezinárodní pokyny, např. od organizací ASE, ISUOG, AIUM či AHA, uvádějí, že hodnocení poměru rozměrů velkých tepen je povinným ukazatelem (Donofrio 2014). („Je důležité ověřit normální stav obou velkých tepen, včetně jejich velikosti [...] ve vzájemném poměru.“) (Carvalho 2023). Příručka od Abuhamada (2012) rovněž zdůrazňuje význam srovnání průměrů aortálního oblouku s hlavní plicní tepnou, konkrétně v oblasti isthmu. U referenčního rozmezí je citován Pasquini (2007) (Pasquini 2007).* ***Dostupné referenční intervaly:*** • **Pasquini (2007):** ○ Konstantní: [0,86–1,12] (průměr ± SD) ○ Konstantní: [0,74–1,23] (2,5. a 97,5. percentil) (Buyens 2012)
(M5) Počet cév	***Jaký je počet cév?*** *Pohled na tři cévy plodu (3VV) je axiální rovina používaná při prenatálním zobrazování k posouzení velkých cév srdce. Tento pohled obvykle zobrazuje tři cévy, obvykle plicní tepnu, aortu a horní dutou žílu. Počet cév se zaměřuje pouze na kulaté nebo podlouhlé anechogenní struktury a nezahrnuje tracheu a sestupnou aortu.* *Na snímku mají být zřetelně vidět cévy s jasným kontrastem a rozlišením struktur.* ***Co doporučují pokyny?***

	Pokyny ISUOG doporučují, aby hodnocení pohledu na tři cévy „zahrnovalo posouzení počtu cév. Zleva doprava jsou to plicní tepna, aorta a pravá horní dutá žíla.“ (Carvalho 2023). Pokyny ASE rovněž zdůrazňují, že je třeba zaznamenat abnormality v počtu cév (Moon-Grady 2023). Podle mezinárodního standardu se očekává, že cévy budou tři.
(M6) Poměr brzlíku a hrudníku	***Jaký je poměr brzlíku a hrudníku?***  *(zdroj: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4th ed.). Wolters Kluwer)* ***Poměr brzlíku a hrudníku** je poměr předozadního průměru brzlíku a intratorakálního průměru mediastina měřený při pohledu na tři cévy a tracheu.* *Na snímku má být zobrazena páteř, hrudní kost a vzestupná aorta, přičemž levá a pravá žebra mají být vidět jako oddělené struktury. Brzlík má být jasně viditelný a identifikovatelný.* ***Co doporučují pokyny?*** *Pokyny ISUOG uvádějí, že „[vyhodnocení pohledu na tři cévy] zahrnuje posouzení uspořádání cév.“ (Carvalho 2023) a že „může zlepšit detekci anomálií výtokového traktu [...]“. U vyhodnocení poměru brzlíku a hrudníku k detekci anomálií výtokového traktu se cituje (Chaoui 2011). Příručka od Abuhamada (2022) rovněž poukazuje na důležitost hodnocení tohoto parametru.* ***Dostupné referenční intervaly:*** • **Chaoui (2011):** o Konstantní po celou dobu těhotenství: [0,36–0,53] (průměr ± 2 SD)
(M7) Kardiotorakální poloha	***Co je to kardiotorakální poloha?***  *(snímek inspirovaný https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/)* ***Kardiotorakální poloha** je určena prodloužením linie interventrikulárního septa směrem dozadu. Tato linie pak rozděluje síně a vede do bodu na bázi srdce (Smith*

	1995). Provádí se na čtyřkomorovém pohledu výpočtem poměru plochy levé části k celkové ploše srdce. Postup zahrnuje nakreslení elipsy nad srdcem a její rozdělení předozadní linií, která protíná hrudník (středovou čáru hrudníku). Levá (1) a pravá (2) oblast představují srdeční plochy nacházející se na levé, resp. pravé anatomické straně střední čáry. Poloha je vyjádřena jako poměr levé plochy k celkové ploše srdce. ***Co doporučují pokyny?*** *Poloha srdce plodu v hrudníku je důležitým parametrem při hodnocení plodu. Odchylka od normální polohy je důvodem k dalšímu vyšetření možných intratorakálních, intrakardiálních nebo extrakardiálních intratorakálních patologických stavů (Abdullah 2000). Americká i mezinárodní doporučení, např. od organizací ISUOG (2008), ASE (2004), AIUM (2013) či AHA (2014), doporučují pečlivé měření polohy srdce plodu v hrudníku pomocí čtyřkomorového pohledu během standardních porodnických vyšetření (Donofrio 2014). Podle těchto pokynů se normální srdce plodu nachází především na levé straně hrudníku, přičemž nejméně 50 % (poměr ≥ 0,5) jeho plochy se nachází v levém hrudním prostoru („srdce se nachází převážně na levé straně“) (Carvalho 2013) („Pečlivou pozornost je třeba věnovat srdeční ose a poloze. Většina srdce [má být] v levé části hrudníku.“) (Carvalho 2023). Studie tato doporučení potvrzují: Chiappa (2009) a další (Smith 1995, Sever 2021) uvádějí, že „dvě třetiny srdce by se měly nacházet na levé straně hrudníku“.* *Zatímco mnohé pokyny definují normální kardiotorakální polohu jako 0,66 (poměr ≈ 2/3) a neměla by klesnout pod 0,5, v literatuře není jasně definována horní hranice normálního rozmezí. Uživatelé mohou buď pouze vizualizovat naměřenou hodnotu bez referenčního rozsahu, nebo si definovat vlastní referenční rozmezí.*
(M8) Cefalický index	***Co je to cefalický index?***  *(zdroj: https: //obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* ***Cefalický index** je poměr biparietálního průměru (BPD) a okcipitofrontálního průměru (OFD) vynásobený 100. Cefalický index poskytuje představu o tvaru hlavy plodu. Rozměr od přední části k zadní části (OFD) se měří pomocí kurzoru umístěného na vnějším okraji lebky. Výrazně snížený cefalický index naznačuje dolichocefalii, zatímco výrazně zvýšený index může naznačovat brachycefalii. Pokud je tento parametr abnormální, je třeba k odhadu stáří plodu použít jiné měření, např. HC, obvod břicha nebo délku stehenní kosti (Timor-Tritsch 2012).* *Snímek má zobrazovat axiálně symetrický pohled na mozek zachycující transthalamickou rovinu s jasně zřetelnými oběma hemisférami.* ***Co doporučují pokyny?***

	Pokyny ISUOG uvádějí, že „cefalický index je poměr maximální šířky hlavy (BPD) k její maximální délce (okcipitofrontální průměr (OFD)) a tato hodnota se dá použít k identifikaci tvaru hlavy plodu. Abnormální tvar hlavy (např. brachycefalie nebo dolichocefalie) může souviset se syndromy nebo může mít za následek oligohydramnion či porod koncem pánevním. Toto zjištění může vést k nepřesným odhadům stáří plodu, pokud se používá BPD; v těchto případech je spolehlivější měření HC (Hadlock 1981).“ (Salomon 2022). ***Dostupné referenční intervaly:*** • **Hadlock (1981):** ○ Konstantní po celou dobu těhotenství: [74–83] (průměr ± SD)
(M9) CSP poměr	***Co je CSP poměr?***  *(zdroj: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. In Journal of Ultrasound in Medicine (Vol. 43, Issue 8, pp. 1461–1466). Wiley)* ***Popis: Poměr Cavum Septum Pellucidum (CSP)** je poměr mezi délkou a šířkou CSP. Stanovuje se změřením délky a šířky CSP a výpočtem poměru délky k šířce.* *Snímek by měl ukazovat axiálně symetrický transventrikulární pohled na mozek s jasnou vizualizací cavum septum pellucidum (CSP) a anatomických struktur ve střední čáře.* ***Co doporučují směrnice?*** *Pokyny ISUOG uvádějí, že tvar CSP byl popsán jako relativně spolehlivý marker parciální ageneze corpus callosum a citují studie Karla (2017) a Shena (2015) jako referenční rozmezí (Malinger2020).* *Pokyny Světové asociace perinatální medicíny (WAPM) uvádějí, že CSP musí být vizualizováno a „neschopnost vizualizovat CSP nebo jeho abnormální vzhled (Karl2017) je prediktivní pro komisurální anomálie. Normální vzhled CSP však nevylučuje všechny abnormality [corpus callosum]“ (Robertis2021).* *Tento parametr lze nalézt také v nejmodernějších technikách hlubokého učení pro rutinní biometrii (Coronado-Gutiérrez2023).* ***Dostupné referenční intervaly:*** • **Karl (2017):** *Konstantní po celou dobu těhotenství: [1,5 - 3,3] (5. a 95. percentil)*
(M10) Poměr průměru zadní mozkové komory k průměru	***Co je poměr průměru zadní mozkové komory k průměru hemisféry?***

hemisféry (VP poměr)	 ***Poměr průměru zadní mozkové komory k průměru hemisféry*** *je parametr používaný k posouzení vývoje mozku, zejména velikosti komor v poměru k celkové velikosti mozku (hemisféry).* *Jedná se o poměr mezi:* - *Průměr zadní mozkové komory (= šířka síně) – obvykle se vztahuje k síni laterální komory (umístěné na spojení týlního, temporálního a temenního rohu).* - *Průměr mozkové hemisféry – celkový příčný průměr odpovídající mozkové hemisféry.* *Toto měření má být provedeno v transventrikulárním pohledu.* ***Co doporučují směrnice?*** *Pokyny ISUOG uvádějí, že měření šířky síní představuje nedílnou součást sonografického screeningu malformací CNS a že šířka síní má být měřena zevnitř dovnitř a měla by být <10 mm po celou dobu těhotenství.* *Recenzovaná literatura (Nicolaides 1994) zdůrazňuje roli poměru průměru zadní mozkové komory k průměru hemisféry při zlepšování prenatálního vyšetření mozku a přesnosti fetálního screeningu, protože je relativně spolehlivým markerem ventrikulomegalie.* ***Dostupné referenční intervaly:*** • ***Nicolaides (1994):*** *(5. a 95. percentily)* ○ *17GA: [0,29–0,45]* ○ *18GA: [0,27–0,42]* ○ *19GA: [0,26–0,40]* ○ *…* *39GA: [0,15–0,24]*
(M11) Prostor za levou síní (PLAS)	***Co je index prostoru za levou síní (PLAS)?***



(Zdroj: Kawazu2014)

Index prostoru za levou síní (PLAS) je fetální echokardiografické měření používané k posouzení prostoru za levou síní. Vypočítává se ze čtyřdutinového pohledu na srdce plodu. Měření zahrnuje určení vzdálenosti mezi zadní stěnou levé síně a přední stěnou sestupné aorty (LD) a vydělení této hodnoty průměrem sestupné aorty (DA). Výpočet se provádí během endsystolické fáze srdečního cyklu.
Vzorec pro výpočet indexu PLAS je:
Index PLAS = Vzdálenost levé síně od sestupné aorty (LD) / Průměr sestupné aorty (DA)

Co doporučují směrnice? (Odůvodnění a klinický význam)
Recenzovaná literatura (Kawazu2019, Anuwutnavin2023, Akkurt2015) zdůraznila důležitost PLAS indexu jako jednoduchého a reprodukovatelného měření při screeningu srdečních funkcí plodu. PLAS index, původně zavedený (Kawazu2014), byl identifikován jako citlivý marker pro prenatální diagnostiku totálního anomálního plicního žilního spojení (TAPVC), což je stav, kdy plicní žíly nejsou spojeny s levou síní. Zvýšený PLAS index je významným indikátorem TAPVC.

Dostupné referenční intervaly:

*Kawazu2014 a Kawazu2019: Konstantní po celou dobu těhotenství: Optimální hraniční hodnota **> 1,27** pro naznačení TAPVC. U normálních plodů byl průměrný PLAS index hlášen jako **0,62 ± 0,19**.*

*Každé měření vyžaduje specifický ultrazvukový pohled, označovaný jako „**dílčí pohled**“, které musí u každého snímku splňovat specifické podmínky, aby bylo zajištěno přesné měření. Dílčí pohled je vždy odvozen od jednoho ze standardních screeningových zobrazení plodu, ale vyžaduje také další konkrétní podmínky. Například měření poměru pravé a levé komory pomocí čtyřkomorového pohledu vyžaduje správné zobrazení hranic komor, což není nutné u srdeční osy.*

Níže uvedená tabulka znázorňuje shodu mezi dílčími pohledy a pohledy na srdce nebo mozek uvedenými v pokynech ISUOG.

Pohled	***Dílčí pohled***

Čtyřkomorový pohled	***Dílčí pohled 1 (M1):*** *Snímek má zahrnovat páteř, hrudní kost, čtyři komory a interventrikulární septum. Levá a pravá žebra mají být přítomna a mají být rozeznatelná jako jednotlivá žebra.* ***Dílčí pohled 2 (M2):*** *Snímek má zahrnovat páteř, hrudní kost a čtyři komory. Levá a pravá žebra mají být přítomna a mají být rozeznatelná jako jednotlivá žebra.* ***Dílčí pohled 3 (M3):*** *Snímek zahrnuje páteř a hrudní kost. Levá a pravá žebra mají být přítomna a mají být rozeznatelná jako jednotlivá žebra. Čtyřkomorové pohledy mají být vidět a mají být dobře kontrastní.* ***Dílčí pohled 7 (M7):*** *Snímek má zahrnovat páteř, hrudní kost a čtyři komory.* ***Dílčí pohled 11 (M11):*** *Hrudník se jeví jako kulatý, nemá tvar otevřeného písmene «V». Levé i pravé žebro se jeví jako samostatné struktury, nikoli jako více rovnoběžných nebo po sobě jdoucích linií. Síň a aorta, zejména jejich zadní stěny, a také prostor mezi nimi, jsou jasně viditelné bez stínu.*
Pohledy na tři cévy a pohled na tři cévy a průdušnici	***Dílčí pohled 4 (M4):*** *Snímek má zahrnovat páteř a hrudní kost se zřetelně viditelnými levými a pravými žebry. Botallova dučej a vzestupná aorta mají být zřetelně viditelné, aby bylo patrné jejich spojení.* ***Dílčí pohled 5 (M5):*** *Na snímku mají být zřetelně vidět cévy s jasným kontrastem a rozlišením struktur.* ***Dílčí pohled 6 (M6):*** *Na snímku má být zobrazena páteř, hrudní kost a vzestupná aorta, přičemž levá a pravá žebra mají být vidět jako oddělené struktury. Brzlík má být jasně viditelný a identifikovatelný.*
Axiální pohled	***Dílčí pohled 8 (M8):*** *Snímek má zobrazovat axiálně symetrický pohled na mozek zachycující transthalamickou rovinu s jasně zřetelnými oběma hemisférami.* ***Dílčí pohled 9 (M9):*** *Snímek by měl ukazovat axiálně symetrický transventrikulární pohled na mozek s jasnou vizualizací cavum septum pellucidum (CSP) a anatomických struktur ve střední čáře.* ***Dílčí pohled 10 (M10):*** *Obrázek by měl ukazovat axiální pohled, kde je viditelný POS (parieto occipital sulcus).*

Funkce 1: Měření úplnosti

Software vyhodnocuje úplnost ultrazvukového vyšetření plodu pomocí fixního algoritmu hlubokého učení, který byl vycvičen pomocí učení pod dohledem. Ověřuje, zda byly získány všechny informace odpovídající doporučeným pokynům u vyšetření srdce/mozku plodu. Tyto informace zahrnují přítomnost:

- 5 hlavních pohledů na srdce plodu a 52 kritérií kvality, která byla podrobně popsána dříve a která umožňují dodržovat pravidla pro screening srdce;

- 4 hlavních pohledů na mozek plodu a 43 kritérií kvality, která byla podrobně popsána dříve a která umožňují dodržovat pravidla pro screening mozku.

Na stránce značící úplnost **(obrázek 1)** najdete:

- **Tlačítko přehrávání/pauzy** pro spuštění analýzy snímků pořízených ultrazvukovým systémem na začátku vyšetření.
- **Počet pohledů na srdce/mozek** ověřených softwarem od začátku vyšetření. Pohled na srdce se považuje za ověřený, pokud je detekováno alespoň na jednom snímku.
- Samostatná tlačítka pro **každé kritérium kvality**, která se po ověření softwarem zbarví **zeleně**.

Každý snímek analyzovaný softwarem dynamicky aktualizuje stránku značící úplnost následujícím způsobem:

- Pokud je kritérium kvality zjištěno na snímku poprvé, je označeno jako **ověřené** a jeho barva se změní z bílé na **zelenou**).
- Pokud je na snímku zjištěno kritérium kvality, které bylo již dříve ověřeno, nedojde k žádným změnám.
- Pokud na snímku není zjištěno kritérium kvality, nedojde k žádným změnám.

Pokud je kritérium kvality spojeno s anomálií, závisí stav detekce kritéria na jeho vizuálním vzhledu:

- Pokud anomálie změní kritérium kvality takovým způsobem, že změní jeho vzhled, software nemusí kritérium odhalit a stav zůstane neověřený;
- Pokud anomálie nemá vliv na vzhled kritéria kvality, software kritérium rozpozná a označí ho jako ověřené, přičemž změní jeho barvu z bílé na **zelenou.**

Vezměte prosím na vědomí, že značení na prostředku upozorňuje, že se softwarem FETOLY nelze provádět žádnou diagnostiku ani screening. Kritérium kvality, které není ověřeno softwarem, samo o sobě neznamená patologii.

Stránka značící úplnost se průběžně aktualizuje v reálném čase, uživatelé se na ni tedy mohou dívat kdykoli během vyšetření. Díky tomu mohou na stránku nahlížet, aniž by to narušilo jejich pracovní postup při vyšetření nebo vyžadovalo další akce.

Připomínáme, jak je vysvětleno v oddíle 10, že software FETOLY nelze použít k diagnostice ani screeningu. Kritérium kvality, které není ověřeno softwarem, samo o sobě neznamená patologii.

Funkce 2: Znázornění úplnosti

Tato funkce byla vyvinuta za účelem bezpečnějšího vyhodnocení úplnosti, které provádí první modul. Zajišťuje lékařům neustálý přehled o úplnosti vyšetření, tj. ukazuje jim zobrazení a kritéria kvality ověřená softwarem na stránce galerie v rozhraní softwaru. Funguje nepřetržitě a vyhodnocuje každý snímek zpracovaný prvním modulem v reálném čase, přičemž uchovává sadu snímků jako vizuální důkaz ověřených pohledů na srdce/mozek a kritérií kvality až do daného okamžiku.

Software FETOLY si neklade za cíl vybrat „nejlepší“ nebo „vysoce kvalitní“ diagnostiku podle dané kvalitativní škály. Cílem softwaru FETOLY je spíše výběr snímků znázorňujících kvantitativní úplnost vyšetření z hlediska ověřených pohledů a kritérií kvality. Protože tento modul zcela závisí na výkonu algoritmu hlubokého učení prvního modulu, není třeba provádět žádné další hodnocení funkční způsobilosti.

Pokud má uživatel například pochybnosti o některém z kritérií kvality označeném zeleně, může si přítomnost tohoto kritéria ověřit kliknutím na něj na stránce galerie. Software zobrazí snímky, které toto kritérium obsahují (na obrázku níže žlutě). Po výběru kritéria zobrazí software na těchto snímcích rámeček kolem daného kritéria. Tyto informace v podobě orámovaných kritérií jsou součástí výstupu Fetoly-CNN.

Funkce 3: Biometrická měření

Sekce modulu **FETOLY-MEASURE** je na stránce analýzy označena „Measure“ (měření) a zobrazuje seznam měření, z nichž každé je uspořádáno do čtyř polí:

- **Název měření**: Zobrazí název nebo zkratku měření spolu s informační ikonou. Kliknutím na ikonu se otevřou podrobné informace o měření, včetně odkazu na vědecké publikace.
- **Hodnota měření a jednotky**: Zobrazí se naměřená hodnota s příslušnými jednotkami. Například u měření úhlů se zobrazuje symbol stupně (°), u procentuálních měření symbol procenta (%); jinak zůstává pole prázdné, což znamená, že se jedná o relativní měření. Pokud byly na stránce galerie upraveny klíčové body, zobrazí se před měřením symbol ( ).
- **Referenční rozsah**: V tomto poli je uveden referenční rozsah měření definovaný v literatuře a podložený vědeckými výzkumy. Zdrojem může být pokyn, recenzovaná publikace, učebnice nebo vlastní rozsah definovaný uživatelem. Kliknutím na **tlačítko nové karty** může uživatel ručně definovat referenční rozsah nebo aktualizovat odkaz na odbornou literaturu, pokud je k dispozici více odkazů. Kliknutím na **tlačítko odkazu s informacemi** se uživateli zobrazí vyskakovací okno se všemi potřebnými informacemi týkajícími se daného kritéria měření.
- **Gestační stáří,** které se stanoví před zahájením analýzy.

Funkce 4: Znázornění měření

Stejně jako u znázornění úplnosti, kdy se vybírají snímky potvrzující dané pohledy a kritéria kvality, automaticky vybírá ke každému měření vhodný snímek. Obě sady snímků se na stránce galerie zobrazí společně. Tyto dvě sady snímků lze snadno rozlišit: snímky z funkce měření obsahují hodnotu měření a název parametru, zatímco snímky úplnosti nemají anotace.

Snímky „měření“ i „úplnosti“ jsou uspořádány na základě odpovídajících ultrazvukových pohledů. Vezměte prosím na vědomí, že propojení s pohledovými snímky pomocí funkce měření je nezávislé na funkci úplnosti. Každý dílčí pohled na měření odpovídá podle definice jednomu z 5 srdečních nebo 4 mozkových ultrazvukových pohledů. Proto lze na základě znalosti dílčího pohledu automaticky přiřadit snímky vybrané funkcí měření k příslušnému pohledu, pod který tento dílčí pohled patří.

Funkce 5: Zpráva o vyšetření

Na stránce exportu lze vygenerovat zprávu. Ta zahrnuje výsledky a snímky ze softwaru FETOLY a bude odeslána do externího zařízení.

Přidružená zařízení

Abyste mohli používat prostředek FETOLY, je třeba mít k dispozici následující přidružená zařízení:

- Ultrazvukový přístroj.

- Tablet a případně server DICOM, počítač se serverem FTP nebo s funkcí Bluetooth, jak je uvedeno v oddíle 10 „interakce s jinými zařízeními“.
- Disk UVC a kabel HDMI k propojení tabletu s ultrazvukovým přístrojem.

5. Určené použití a indikace k použití

Software FETOLY je určen k automatické analýze ultrazvukových snímků plodu pomocí technik strojového učení:

- detekce pohledů na mozek a srdce a ověřování kritérií kvality v rámci těchto pohledů;
- detekce snímků vhodných k měření biometrických parametrů srdce a mozku plodu a kvantitativní měření těchto parametrů.

Prostředek slouží jako pomůcka k souběžnému čtení během pořizování a interpretace ultrazvukových snímků plodu.

Přípravek FETOLY je indikován k použití při běžném vyšetření srdce a mozku plodu ve 2. a 3. trimestru těhotenství (gestační stáří: od 17. do 40. týdne).

6. Zamýšlení uživatelé

Výrobek smí používat kvalifikovaný zdravotnický personál specializovaný na prenatální ultrazvukové zobrazování.

7. Cílová populace pacientů

Těhotné ženy během 2. a 3. trimestru těhotenství.

8. Klinické přínosy a funkční způsobilost

U tohoto typu prostředku, který je označován jako software jako zdravotnický prostředek (SWMD), je souběžnou pomůckou pro čtení a používá se při běžném vyšetření srdce a mozku plodu, byl prokázán následující klinický přínos:

- Standardizace běžného vyšetření srdce a mozku plodu podle požadavků uznávaných mezinárodních pokynů.

Výsledky funkční způsobilosti jsou podrobně uvedeny v níže uvedených tabulkách. Výsledky samostatného testování funkční způsobilosti ukazují, že software FETOLY automaticky:

- detekuje ultrazvukové pohledy na srdce a mozek plodu s citlivostí ≥ 85 % (kritérium přijatelnosti) a specifičností ≥ 85 % (kritérium přijatelnosti),
- detekuje kritéria kvality v rámci pohledů na srdce s citlivostí ≥ 90 % (kritérium přijatelnosti) a specifičností ≥ 90 % (kritérium přijatelnosti),
- detekuje kritéria kvality v rámci pohledu na mozek s citlivostí ≥ 85 % (kritérium přijatelnosti) a specifičností ≥ 85 % (kritérium přijatelnosti),
- lokalizuje rámečky kolem kritérií kvality se středním průnikem nad sjednocením (IoU) ≥ 50 % (kritérium přijatelnosti),
- detekuje ultrazvukové podhledy na srdce a mozek plodu s citlivostí ≥ 70 % (kritérium přijatelnosti) a specifičností ≥ 70 % (kritérium přijatelnosti) a
- realizuje měření srdce a mozku plodu podle jednotlivých LOA definovaných pro jednotlivé cílové parametry studie.

Celkové výsledky

Pohled na plod	Citlivost			Specifičnost		
	N (pozitivní)	Bodový odhad	Bootstrap CI (95%)	N (negativní)	Bodový odhad	Bootstrap CI (95%)
Pohled na břicho	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Čtyřkomorový pohled	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Pohled na výtokový trakt levé komory	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Pohled na výtokový trakt pravé komory	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Pohled na tři cévy	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Axiální pohled	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Transcerebelární pohled	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Sagitální/profilový pohled	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Jiný pohled	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Kritérium kvality	Citlivost			Specifičnost			mIoU	
	N	Bodový odhad	Bootstrap CI (95%)	N	Bodový odhad	Bootstrap CI (95%)	Bodový odhad	Bootstrap CI (95%)
Pohled na břicho								
Páteř	678	0.99	(0.983,0.998)	4531	0.998	(0.996,0.999)	0.71	(0.70,0.73)
Levé žebro	632	0.967	(0.953,0.980)	4577	0.993	(0.991,0.995)	0.58	(0.56,0.59)
Pravé žebro	627	0.951	(0.934,0.967)	4582	0.994	(0.992,0.996)	0.55	(0.53,0.57)
Sestupná aorta	673	0.972	(0.959,0.984)	4536	0.998	(0.996,0.999)	0.52	(0.51,0.54)
Dolní dutá žíla	550	0.939	(0.917,0.958)	4659	0.987	(0.983,0.990)	0.5	(0.49,0.52)
Žaludek	675	0.983	(0.973,0.992)	4534	0.999	(0.998,1.000)	0.74	(0.72,0.75)
Pupeční žíla	552	0.973	(0.958,0.986)	4657	0.99	(0.988,0.993)	0.64	(0.62,0.65)
Přední část břicha	643	0.969	(0.954,0.983)	4566	0.993	(0.990,0.995)	0.5	(0.49,0.52)
Čtyřkomorový pohled								
Páteř	595	0.969	(0.955,0.982)	4614	0.998	(0.996,0.999)	0.74	(0.73,0.75)
Levé žebro	536	0.945	(0.924,0.963)	4673	0.99	(0.987,0.993)	0.64	(0.63,0.66)
Pravé žebro	548	0.948	(0.926,0.965)	4661	0.993	(0.991,0.996)	0.68	(0.66,0.69)
Sestupná aorta	608	0.968	(0.952,0.981)	4601	0.997	(0.995,0.998)	0.66	(0.65,0.67)
Levá plicní žíla	240	0.925	(0.889,0.958)	4969	0.975	(0.971,0.979)	0.51	(0.48,0.53)
Pravá plicní žíla	351	0.929	(0.902,0.955)	4858	0.981	(0.978,0.984)	0.53	(0.50,0.55)

Levá síň	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Pravá síň	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Septum primum (Vieussensova chlopeň neboli foramen ovale)	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Otevřené foramen ovale	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Mitrální chlopeň	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Trikuspidální chlopeň	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Spojení mezi křížem a síňovým septem (vestibulární septum)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Posun atrioventrikulární chlopně v kříži	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Spojení mezi interventrikulárním septem a křížem	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Interventrikulární septum	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Levá komora	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Pravá komora	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Sternum	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Pohled na výtokový trakt levé komory								
Levá síň	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Proximální vzestupná aorta	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Poloměsíčité chlopně	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Levá komora	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Interventrikulární septum	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Pravá komora	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Pohled na výtokový trakt pravé komory								
Sestupná aorta	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Průdušnice / průdušky	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Levá plicní tepna	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*

Botallova dučej	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Pravá plicní tepna	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Začátek plicních tepen	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Septum mezi kmenem plicní tepny a vzestupnou aortou	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Vzestupná aorta	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Horní dutá žíla	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Plicní kmen	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Pohledy na tři cévy								
Páteř	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Průdušnice	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Boční prostor vlevo od Botallovy dučeje	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Oblouk chámovodu napojený na sestupnou aortu	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Oblouk chámovodu, který není spojen se sestupnou aortou	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Vzestupná aorta	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Aortální oblouk	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Horní dutá žíla	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Brzlík / hrudní kost	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Axiální pohled								
Přední falx	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavum septum pellucidum	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Fornix	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Distální přední komora	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Proximální přední komora	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cisterna ambiens	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Atrium	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*

Plexus chorioideus	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Sulcus parietooccipitalis	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Zadní falx	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Distální koronární šev	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Proximální koronární šev	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Sylviova brázda	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Lebka	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Hranice mezi thalamy	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
3. komora	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Distální thalamus	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Proximální thalamus	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Transcerebelární pohled								
Distální thalamus	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Proximální thalamus	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
4. komora	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Vermis	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Distální mozečková hemisféra	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Proximální mozečková hemisféra	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Okraj mozečku	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Cisterna magma	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Sagitální/profilový pohled								
Kost nosní	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Horní část vermis	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Dolní část vermis	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastigium	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Rostrum a genu corpus callosum	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Tělo corpus callosum	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*

Splenium corpus callosum	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavum Septum Pellicidum	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Měření	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI	LOA	LOA CI
poměr_brzlíku-a-hrudníku	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
kardiotorakální_index	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
poměr_cév	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
cefalický_index	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
počet_cév	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
kardiotorakální_poloha	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
poměr_pravé-a-levé_komory	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
úhel_srdce	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
CSP poměr	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
VP-poměr	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
Prostor za levou síní	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Měření	sklon	zachycení	sklon CI	zachycení CI
poměr_brzlíku-a-hrudníku	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
kardiotorakální_index	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
poměr_cév	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
cefalický_index	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
počet_cév	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
kardiotorakální_poloha	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
poměr_pravé-a-levé_komory	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
úhel_srdce	*0.9197936528230518*	*3.114077691538199*	*(0.888,0.945)*	*(2.023,4.477)*
CSP poměr	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
VP-poměr	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
Prostor za levou síní	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Výsledky výrobce ultrazvukového systému

Třída	Systém	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)

D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
I	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)
I	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)
X	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
X	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
X	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)

Třída	Systém	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI	mIoU	mIoU CI
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*
A.Sp	*Samsung*	*296*	*0.984*	*(0.967,0.994)*	*1708*	*0.999*	*(0.997,1.000)*	*0.7*	*(0.68,0.71)*
A.St	*Canon*	*29*	*0.966*	*(0.893,1.000)*	*207*	*0.991*	*(0.975,1.000)*	*0.72*	*(0.67,0.76)*
A.St	*GE*	*279*	*0.993*	*(0.983,1.000)*	*2261*	*1.0*	*(1.000,1.000)*	*0.79*	*(0.77,0.80)*
A.St	*Samsung*	*293*	*0.973*	*(0.954,0.990)*	*1711*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
A.Uv	*Canon*	*25*	*0.96*	*(0.870,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.6*	*(0.51,0.67)*
A.Uv	*GE*	*217*	*0.977*	*(0.955,0.996)*	*2323*	*0.991*	*(0.988,0.995)*	*0.67*	*(0.65,0.70)*
A.Uv	*Samsung*	*240*	*0.967*	*(0.944,0.988)*	*1764*	*0.989*	*(0.984,0.993)*	*0.62*	*(0.59,0.64)*
A.VC	*Canon*	*26*	*0.885*	*(0.750,1.000)*	*210*	*0.986*	*(0.970,1.000)*	*0.46*	*(0.40,0.52)*
A.VC	*GE*	*221*	*0.973*	*(0.950,0.992)*	*2319*	*0.987*	*(0.983,0.991)*	*0.54*	*(0.52,0.57)*
A.VC	*Samsung*	*247*	*0.903*	*(0.864,0.939)*	*1757*	*0.989*	*(0.984,0.994)*	*0.49*	*(0.47,0.51)*
B.Ao	*Canon*	*27*	*0.926*	*(0.808,1.000)*	*209*	*0.996*	*(0.985,1.000)*	*0.71*	*(0.66,0.77)*
B.Ao	*GE*	*247*	*0.956*	*(0.926,0.980)*	*2293*	*0.997*	*(0.994,0.999)*	*0.73*	*(0.71,0.75)*
B.Ao	*Samsung*	*255*	*0.977*	*(0.956,0.993)*	*1749*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.58,0.62)*

B.bCr	Canon	25	0.92	(0.800,1.000)	211	0.986	(0.969,1.000)	0.65	(0.58,0.72)
B.bCr	GE	202	0.892	(0.849,0.932)	2338	0.992	(0.989,0.996)	0.61	(0.57,0.64)
B.bCr	Samsung	216	0.926	(0.889,0.959)	1788	0.984	(0.979,0.989)	0.54	(0.52,0.57)
B.Cr	Canon	7	0.715	(0.334,1.000)	229	0.983	(0.967,0.996)	0.62	(nan,nan)
B.Cr	GE	52	0.885	(0.789,0.961)	2488	0.989	(0.985,0.993)	0.52	(0.46,0.58)
B.Cr	Samsung	76	0.974	(0.933,1.000)	1928	0.977	(0.971,0.983)	0.57	(0.52,0.61)
B.FO	Canon	26	0.962	(0.880,1.000)	210	1.0	(1.000,1.000)	0.7	(0.62,0.78)
B.FO	GE	215	0.935	(0.899,0.965)	2325	0.994	(0.991,0.997)	0.64	(0.62,0.67)
B.FO	Samsung	257	0.965	(0.941,0.985)	1747	0.994	(0.991,0.998)	0.58	(0.55,0.60)
B.FOF	Canon	8	0.75	(0.375,1.000)	228	1.0	(1.000,1.000)	0.56	(0.42,0.67)
B.FOF	GE	108	0.899	(0.841,0.949)	2432	0.998	(0.996,1.000)	0.5	(0.47,0.53)
B.FOF	Samsung	63	0.921	(0.845,0.984)	1941	0.993	(0.989,0.996)	0.51	(0.47,0.55)
B.IVS	Canon	15	0.934	(0.770,1.000)	221	0.982	(0.965,0.996)	0.65	(0.53,0.75)
B.IVS	GE	165	0.867	(0.806,0.915)	2375	0.992	(0.988,0.995)	0.62	(0.59,0.66)
B.IVS	Samsung	152	0.922	(0.872,0.962)	1852	0.984	(0.978,0.989)	0.64	(0.61,0.67)
B.LA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.75	(0.71,0.79)
B.LA	GE	264	0.966	(0.942,0.986)	2276	0.999	(0.997,1.000)	0.79	(0.78,0.81)
B.LA	Samsung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Samsung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Samsung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)

B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)

D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)

F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)

G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Samsung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Samsung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)
G.pCH	Samsung	182	0.94	(0.905,0.973)	1822	0.999	(0.998,1.000)	0.74	(0.72,0.77)
G.pTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.58	(0.51,0.65)
G.pTh	GE	216	0.922	(0.884,0.954)	2324	0.995	(0.992,0.998)	0.62	(0.60,0.64)
G.pTh	Samsung	119	0.95	(0.905,0.984)	1885	0.998	(0.996,1.000)	0.59	(0.57,0.62)
G.Ver	Canon	23	0.914	(0.783,1.000)	213	1.0	(1.000,1.000)	0.62	(0.54,0.70)
G.Ver	GE	288	0.893	(0.859,0.928)	2252	0.996	(0.993,0.999)	0.61	(0.59,0.63)
G.Ver	Samsung	138	0.892	(0.840,0.942)	1866	0.997	(0.994,0.999)	0.52	(0.49,0.55)
I.bCC	Canon	15	1.0	(1.000,1.000)	221	0.987	(0.971,1.000)	0.59	(0.51,0.67)
I.bCC	GE	168	0.923	(0.878,0.962)	2372	0.995	(0.993,0.998)	0.57	(0.54,0.60)
I.bCC	Samsung	54	0.815	(0.699,0.910)	1950	0.996	(0.994,0.999)	0.57	(0.52,0.62)
I.CSP	Canon	20	0.95	(0.824,1.000)	216	1.0	(1.000,1.000)	0.75	(0.69,0.81)
I.CSP	GE	196	0.888	(0.841,0.928)	2344	1.0	(0.999,1.000)	0.72	(0.69,0.74)
I.CSP	Samsung	79	0.849	(0.760,0.924)	1925	1.0	(1.000,1.000)	0.7	(0.66,0.75)
I.Fas	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.63	(0.46,0.79)
I.Fas	GE	99	0.889	(0.819,0.951)	2441	1.0	(0.999,1.000)	0.56	(0.52,0.60)
I.Fas	Samsung	33	0.97	(0.900,1.000)	1971	0.999	(0.997,1.000)	0.55	(0.49,0.61)
I.lVer	Canon	14	0.929	(0.750,1.000)	222	1.0	(1.000,1.000)	0.69	(0.60,0.77)
I.lVer	GE	102	0.912	(0.850,0.960)	2438	0.999	(0.998,1.000)	0.7	(0.66,0.73)
I.lVer	Samsung	41	0.927	(0.834,1.000)	1963	1.0	(0.999,1.000)	0.64	(0.59,0.69)
I.NB	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.71	(0.61,0.82)
I.NB	GE	115	0.905	(0.844,0.955)	2425	0.992	(0.989,0.996)	0.63	(0.59,0.67)
I.NB	Samsung	60	0.917	(0.837,0.982)	1944	0.998	(0.996,1.000)	0.64	(0.58,0.69)
I.rgCC	Canon	18	0.945	(0.824,1.000)	218	0.991	(0.978,1.000)	0.48	(0.41,0.56)
I.rgCC	GE	177	0.888	(0.833,0.930)	2363	0.998	(0.996,1.000)	0.56	(0.54,0.59)
I.rgCC	Samsung	65	0.893	(0.808,0.965)	1939	1.0	(0.999,1.000)	0.48	(0.43,0.53)
I.sCC	Canon	13	0.847	(0.616,1.000)	223	0.992	(0.978,1.000)	0.48	(0.36,0.61)
I.sCC	GE	114	0.922	(0.868,0.964)	2426	0.992	(0.988,0.995)	0.51	(0.48,0.54)
I.sCC	Samsung	40	0.9	(0.796,1.000)	1964	0.998	(0.996,1.000)	0.45	(0.39,0.53)
I.uVer	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.57	(0.49,0.65)

I.uVer	*GE*	*116*	*0.88*	*(0.815,0.931)*	*2424*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.63)*
I.uVer	*Samsung*	*48*	*0.938*	*(0.861,1.000)*	*1956*	*0.999*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Třída	Systém	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI	LOA	LOA CI
úhel_srdce	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
úhel_srdce	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
úhel_srdce	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
kardiotorakální_poloha	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
kardiotorakální_poloha	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
kardiotorakální_poloha	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*
kardiotorakální_index	Canon	*23*	*1.0*	*(1.000,1.000)*	*37*	*0.946*	*(0.865,1.000)*	*0.078*	*(0.041,0.117)*
kardiotorakální_index	GE	*225*	*0.969*	*(0.944,0.991)*	*262*	*0.908*	*(0.874,0.943)*	*0.059*	*(0.049,0.073)*
kardiotorakální_index	Samsung	*105*	*0.952*	*(0.909,0.989)*	*232*	*0.776*	*(0.724,0.828)*	*0.051*	*(0.042,0.061)*
cefalický_index	Canon	*28*	*0.929*	*(0.821,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.026*	*(0.021,0.032)*
cefalický_index	GE	*195*	*0.944*	*(0.909,0.974)*	*262*	*0.943*	*(0.916,0.969)*	*0.03*	*(0.026,0.036)*
cefalický_index	Samsung	*90*	*0.989*	*(0.964,1.000)*	*232*	*0.909*	*(0.871,0.944)*	*0.023*	*(0.020,0.026)*
poměr_pravé-a-levé_komory	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.865*	*(0.757,0.973)*	*0.106*	*(0.080,0.128)*
poměr_pravé-a-levé_komory	GE	*235*	*0.923*	*(0.883,0.957)*	*262*	*0.901*	*(0.859,0.939)*	*0.127*	*(0.090,0.173)*
poměr_pravé-a-levé_komory	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.931*	*(0.901,0.961)*	*0.099*	*(0.087,0.115)*
poměr_brzlíku-a-hrudníku	Canon	*19*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.047*	*(0.039,0.059)*
poměr_brzlíku-a-hrudníku	GE	*174*	*0.902*	*(0.856,0.944)*	*262*	*0.924*	*(0.889,0.954)*	*0.051*	*(0.045,0.059)*
poměr_brzlíku-a-hrudníku	Samsung	*138*	*0.942*	*(0.900,0.978)*	*232*	*0.892*	*(0.853,0.931)*	*0.059*	*(0.049,0.070)*
počet_cév	Canon	*21*	*0.905*	*(0.760,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.0*	*(0.000,0.000)*
počet_cév	GE	*209*	*0.933*	*(0.895,0.966)*	*262*	*0.969*	*(0.947,0.989)*	*0.281*	*(0.138,0.406)*
počet_cév	Sam-sung	*113*	*0.929*	*(0.879,0.974)*	*232*	*0.966*	*(0.940,0.987)*	*0.329*	*(0.000,0.491)*
poměr_cév	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.112*	*(0.091,0.145)*
poměr_cév	GE	*194*	*0.979*	*(0.956,0.995)*	*262*	*0.977*	*(0.954,0.992)*	*0.109*	*(0.099,0.121)*
poměr_cév	Sam-sung	*122*	*0.984*	*(0.958,1.000)*	*232*	*0.922*	*(0.888,0.953)*	*0.111*	*(0.100,0.125)*
CSP poměr	Canon	*25*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.842*	*(0.608,1.028)*
CSP poměr	GE	*226*	*0.854*	*(0.805,0.899)*	*262*	*0.977*	*(0.954,0.992)*	*0.826*	*(0.753,0.889)*

CSP poměr	Sam-sung	*107*	*0.879*	*(0.821,0.935)*	*232*	*0.991*	*(0.978,1.000)*	*0.835*	*(0.755,0.907)*
VP-poměr	Canon	*22*	*0.909*	*(0.773,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.064*	*(0.043,0.084)*
VP-poměr	GE	*206*	*0.956*	*(0.925,0.981)*	*262*	*1.0*	*(1.000,1.000)*	*0.065*	*(0.059,0.071)*
VP-poměr	Sam-sung	*91*	*0.956*	*(0.910,0.990)*	*232*	*1.0*	*(1.000,1.000)*	*0.066*	*(0.056,0.075)*
Prostor za levou síní	Canon	*16*	*0.938*	*(0.800,1.000)*	*37*	*0.919*	*(0.837,1.000)*	*0.094*	*(0.067,0.114)*
Prostor za levou síní	GE	*181*	*0.978*	*(0.953,0.995)*	*262*	*0.924*	*(0.889,0.954)*	*0.086*	*(0.079,0.091)*
Prostor za levou síní	Sam-sung	*159*	*0.981*	*(0.957,1.000)*	*232*	*0.953*	*(0.922,0.978)*	*0.07*	*(0.065,0.078)*

Výsledky podskupin USA vs. EU

Třída	Oblast	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI
A	EU	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	USA	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	EU	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	USA	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	EU	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	USA	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	EU	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	USA	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	EU	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	USA	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	EU	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	USA	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	EU	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	USA	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	EU	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	USA	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	EU	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	USA	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Třída	Oblast	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI	mIoU	mIoU CI
A.aA	EU	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	US	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	EU	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	US	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	EU	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	US	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	EU	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	US	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	EU	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*

A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*

C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	US	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	EU	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	US	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	EU	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	US	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*
D.rPA	EU	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	US	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	EU	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*
D.S	US	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	EU	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	US	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	EU	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	US	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	EU	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	US	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	EU	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	US	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	EU	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	US	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	EU	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	US	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	EU	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	US	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	EU	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	US	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	EU	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	US	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	EU	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	US	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*

E.Tr	EU	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*
E.Tr	US	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	EU	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	US	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	EU	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	US	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	EU	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*
F.aFx	US	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	EU	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	US	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	EU	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	US	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	EU	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	US	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	EU	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	US	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	EU	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*

G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Třída	Oblast	n (pozitivní)	Se	Se CI	n (negativní)	Sp	Sp CI	LOA	LOA CI
úhel_srdce	EU	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
úhel_srdce	USA	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
kardiotorakální_poloha	EU	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
kardiotorakální_poloha	USA	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
kardiotorakální_index	EU	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
kardiotorakální_index	USA	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
cefalický_index	EU	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
cefalický_index	USA	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
poměr_pravé-a-levé_komory	EU	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
poměr_pravé-a-levé_komory	USA	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
poměr_brzlíku-a-hrudníku	EU	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
poměr_brzlíku-a-hrudníku	USA	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)

počet_cév	EU	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
počet_cév	USA	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
poměr_cév	EU	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
poměr_cév	USA	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
CSP poměr	EU	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
CSP poměr	USA	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
VP-poměr	EU	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
VP-poměr	USA	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
Prostor za levou síní	EU	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
Prostor za levou síní	USA	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Kontraindikace

S prostředkem FETOLY není spojena žádná kontraindikace.

10. Upozornění, bezpečnostní opatření, interakce s jinými zařízeními

Varování a bezpečnostní opatření ze souboru řízení rizik:

- Uživatel musí zvětšit obraz alespoň o 30 %, aby se zabránilo falešně negativním výsledkům softwaru.
- Uživatel musí systematicky kontrolovat vybranou sadu snímků před exportem.
- Nepoužití funkce vymazání může vést k záměně pacientů a přispět k falešně negativnímu screeningu.
- Snímky odstraněné v rámci výběru snímků jsou definitivně ztraceny.
- Konfigurace vstupu video streamu může přispět k falešně negativnímu screeningu.
- Nekompatibilní video stream může vést k chybám v dokumentaci vyšetření. Video stream musí mít následující vlastnosti:
    - Nejméně 24 snímků za sekundu (fps);
    - Rozlišení nižší než 1280*720.
- Nekompatibilita tabletů může vést k chybám v dokumentaci vyšetření.
- Selhání exportu vede ke ztrátě zprávy o vyšetření.
- Před exportem DICOM na stránce exportu zkontrolujte zvolené jméno pacienta, aby nedošlo k záměně souborů s jiným pacientem.
- Použití v 1. trimestru těhotenství vede k chybě ve funkci úplnosti.
- Vyšetření se provádí vždy u jednoho plodu.
- Pokud se tablet začne přehřívat, přestaňte software používat.
- Před vyšetřením zkontrolujte stav baterie tabletu. Vypnutí softwaru může vést ke ztrátě dat.
- Tento software nelze použít ke screeningovým účelům, protože může vést k falešně negativním výsledkům screeningu.

- Abyste předešli bezpečnostním rizikům, používejte tablet sami a neumožňujte přístup k tabletu neoprávněným osobám.
- Upozorňujeme, že po exportu dat na vaše zařízení nesete za data odpovědnost vy.
- Nepoužívejte souběžně se softwarem FETOLY žádnou jinou aplikaci pro tablety, aby nedocházelo k rušení procesu příjmu obrazového toku nebo provádění výpočtu strojového učení;
- Nepoužívejte aplikaci během skenování transvaginální sondou, protože produkt nebyl testován s transvaginálními snímky.

Upozornění a bezpečnostní opatření ze studie funkční způsobilosti softwaru:

- Citlivost softwaru může být nižší u detekce:
    - transthalamického pohledu na mozek;
    - následujících kritérií kvality srdce: Posun atrioventrikulární chlopně v kříži (čtyřkomorový pohled).
    - následujících kritérií kvality mozku:
        - Proximální koronární šev (axiální pohled)
        - Cavum septum pellucidum (axiální pohled)
        - 3. komory (axiální pohled)

Uživatelé musí být u těchto pohledů a kritérií kvality obezřetní a výsledky si ověřit.

Interakce s jinými zařízeními

Software FETOLY je navržen tak, aby mohl běžet na široké škále tabletů bez závislosti na externích cloudových serverech. Software FETOLY je nakonfigurován tak, aby přijímal ultrazvukový video stream, čehož lze dosáhnout pomocí ultrazvukového systému vybaveného výstupem HDMI na hardware, na kterém software běží.

Software je kompatibilní s ultrazvukovými přístroji společností General Electric, Samsung a Canon.

Software vyžaduje následující minimální konfiguraci tabletu:

- Architektura procesoru ARMv8
- Procesor Snapdragon 8 nebo
- Procesor M1 nebo novější nebo
- Procesor A14 nebo novější nebo
- Alespoň 8 GB paměti RAM
- Alespoň 1 GB úložné kapacity
- Android ve verzi 13/iOS ve verzi 17 nebo novější

Doporučujeme následující modely tabletů:

- Samsung Galaxy Tab S8 nebo novější
- Ipad Air 5 nebo novější
- Ipad 10 nebo novější
- Ipad mini 7 nebo novější
- Ipad Pro 3 nebo novější

Vpřípadě jakýchkoli pochybností ohledně výběru modelu tabletu se obraťte na podporu společnosti Diagnoly na adrese support@diagnoly.com.

Snímky označené softwarem FETOLY lze uložit přímo do tabletu nebo odeslat do jiného zařízení ve stejné síti jako zařízení se spuštěným softwarem FETOLY. Při použití této možnosti

vyžaduje software server FTP v cílovém zařízení, server DICOM Store nebo připojení Bluetooth.

11. Nežádoucí účinky

Se softwarem FETOLY nejsou spojeny žádné nežádoucí účinky.

12. Pokyny pro kybernetickou bezpečnost

12.1. Popis vysoké úrovně ochrany kritických funkcí

Tato část obsahuje stručný popis funkcí prostředku, které chrání kritické funkce. Funkce příjmu obrazového toku a analýzy obrazu využívají místní zdroje (fyzický kabel, model Edge AI) a nevyžadují ke svému fungování internet. Software neukládá ani nespravuje žádné údaje o pacientovi, ale umožňuje uživateli po vyšetření exportovat zprávu o vyšetření na zařízení třetí strany. V případě narušení místní sítě je k dispozici záložní režim exportu, který uživatelům umožňuje ukládat zprávy do složek v tabletu.

12.2. Kybernetická rizika související s prostředkem

K rizikům kybernetické bezpečnosti softwaru FETOLY patří:

- Krádež údajů o pacientech.
- Zhoršená péče o pacienty v důsledku narušeného fungování umělé inteligence, jakým jsou například zmanipulované váhové modely nebo změny softwaru / operačního systému.
- Nesprávné použití prostředku, které vede k jiným výsledkům, než výrobce zamýšlel nebo uživatel očekával.
- Ztráta času pro uživatele.

Tato rizika jsou kontrolována analýzou rizik.

11.3. Schéma doporučených kontrol kybernetické bezpečnosti



Schéma popisuje prostředí softwaru FETOLY spuštěného na tabletu uživatele a vstupní/výstupní komunikaci s ultrazvukovým systémem a zařízením třetí strany.

Obsahuje odkazy na doporučené kontroly kybernetické bezpečnosti v prostředí zamýšleného použití popsané v **oddíle 12.4**:

- G1: Zabezpečený provoz se systémy třetích stran prostřednictvím protokolu FTP přes SSL/TLS
- G2: Zabezpečený provoz se systémy třetích stran přes Bluetooth (pouze pro Android)
- G3: Zabezpečené řízení přístupu k zařízení
- G4: Zabezpečený provoz se systémy třetích stran prostřednictvím protokolu DICOM přes SSL/TLS

12.4. Návody k použití prostředku a specifikace výrobku týkající se doporučených kontrol kybernetické bezpečnosti vhodných v zamýšleném prostředí použití

Pokyny pro bezpečný provoz se systémy třetích stran prostřednictvím protokolu FTP přes SSL/TLS (G1):

- Minimální požadavky na síť: síťová infrastruktura musí podporovat protokol FTP přes SSL/TLS (FTPS) a server FTP musí být kompatibilní s FTPS. Implementujte segmentaci sítě a pravidla brány firewall, abyste omezili přístup jen na potřebné služby a IP adresy.
- Instalace serveru FTP přes SSL/TLS, např.:
    e. Windows 10/11 pomocí služby IIS: Informace o nastavení protokolu FTP přes TLS/SSL pomocí služby IIS najdete v dokumentaci společnosti Microsoft.
    f. FileZilla Server (multiplatformní): Nakonfigurujte FTPES „Require explicit FTP over TLS“ (vyžadovat explicitní FTP přes TLS), vytvořte uživatele se silným heslem*, definujte cestu pro ukládání dat (např. „C:\FetolyData“ nebo „/home/shared/FetolyData“) a nakonfigurujte pravidla brány firewall pro konkrétní program nebo port používaný serverem FTP.

Pokyny pro bezpečný provoz se systémy třetích stran přes Bluetooth (G2, pouze pro Android):

- Minimální požadavky na síť: Bluetooth verze 5 nebo vyšší.
- Definujte v softwaru silné heslo pro ochranu exportovaných dat pacientů*.

Pokyny pro bezpečné řízení přístupu k zařízením (G3):

- Nastavte si zamykací obrazovku se silným heslem*, kódem PIN nebo biometrickým ověřením.
- Povolte automatické aktualizace operačního systému a všech nainstalovaných aplikací.
- Vypněte všechna nepoužívaná síťová rozhraní (např. NFC, IR).

Pokyny pro bezpečný provoz se systémy třetích stran prostřednictvím DICOM (G4):

- Zajistěte, aby komunikace probíhala přes zabezpečenou a segmentovanou síť a omezte přístup pomocí robustních konfigurací brány firewall a mechanismů řízení přístupu.

* Používejte silná hesla na tabletu i u všech dalších zařízení (např. zařízení třetí strany pro export FTP) nebo konfigurací propojených s FETOLY (např. konfigurace Bluetooth) podle doporučení americké agentury pro kybernetickou obranu:

- Dlouhá – alespoň 16 znaků (čím delší, tím lepší).
- Náhodná – např. řetězec smíšených písmen, číslic a symbolů (nejsilnější!) nebo heslo složené z 5–7 náhodných slov.
- Jedinečná – používaná pouze pro jeden účet.

Pokud zjistíte zranitelnost kybernetické bezpečnosti nebo incident, okamžitě to nahlaste svému týmu IT bezpečnosti a společnosti Diagnoly (support@diagnoly.com). Na tabletu:

- Obnovení: Obnovení továrního nastavení pro vymazání všech dat a konfigurací.
- Opětovná instalace aplikace: Stáhněte si nejnovější zabezpečenou verzi aplikace z obchodu Google Play.
- Náhradní možnost: Pokud je síťový export ohrožen, použijte místní export na kartu SD.

12.5. Seznam síťových portů a dalších rozhraní

Software FETOLY přijímá vstupní data prostřednictvím kabelu připojeného mezi výstupem externího monitoru ultrazvukového systému a vstupem USB-C tabletu. Software lze nakonfigurovat tak, aby exportoval zprávy o vyšetření do zařízení třetí strany prostřednictvím protokolu TCP/IP FTPS nebo Bluetooth.

Export dat přes síť TCP IP/FTPS:

- Protokol: FTPS
- Příchozí porty: Software sám neotevírá žádné příchozí porty, protože funguje pouze jako klient, nikoli jako server.
- Odchozí porty: Software používá dynamicky přiřazený efemérní port (rozsah: 1024-65535) pro navázání spojení se serverem FTPS na zadané IP adrese. Příchozí port serveru FTPS třetí strany je definován uživatelem.

- Pravidla brány firewall: Brány firewall na straně klienta i serveru musí povolit odchozí připojení z klienta na port serveru.

Export dat přes Bluetooth/OBEX (pouze pro Android):

- Šifrování: data jsou zazipována a zašifrována heslem.

Export dat prostřednictvím DICOM:

- Protokol: DICOM
- Příchozí porty: Software sám neotevírá žádné příchozí porty, protože funguje pouze jako klient, nikoli jako server.
- Odchozí porty: Software používá dynamicky přiřazený efemérní port (Android: 32768 až 60999) pro navázání spojení se serverem DICOM na zadané IP adrese. Příchozí port serveru DICOM třetí strany je definován uživatelem.
- Pravidla brány firewall: Brány firewall na straně klienta i serveru musí povolit odchozí připojení z klienta na port serveru.

12.6. Požadavky na podpůrnou infrastrukturu

Požadavky na podpůrnou infrastrukturu, včetně minimální konfigurace tabletu a kompatibilních ultrazvukových systémů, najdete v části 10.

12.7. SBOM

Uživatelé mají k dispozici softwarový kusovník (sBoM), který jim umožňuje spravovat svá aktiva, porozumět potenciálnímu dopadu zjištěných zranitelností a nasadit protiopatření pro zachování bezpečnosti a účinnosti prostředku. SBoM lze stáhnout na stránce „About“ (O softwaru) ve strojově čitelném formátu (.csv) kliknutím na „show“ (zobrazit) před „Third-Party Notice“ (Oznámení třetí strany).

12.8. Pokyny k aktualizaci/opravám

Pokyny k aktualizaci najdete v části 13 „Aktualizace softwaru a licence“.

12.9. Popis způsobu reakce zařízení při zjištění anomálních podmínek

Tato část popisuje, jak software reaguje na události ohrožující zabezpečení. Všechny pády softwaru jsou exportovány prostřednictvím protokolu o pádu do databáze Firebase. Při používání softwaru FETOLY se mohou objevit následující varování:

- Selhání exportu: síťová anomálie vedoucí k selhání exportu zprávy přes TCP/IP FTPS, DICOM nebo Bluetooth.
- Porucha připojení USB: k tabletu není připojen kabel USB-C nebo došlo k poruše příjmu video streamu USB-C.
- Selhání ověření licence: uživatel se pokusil ověřit licenci bez připojení k internetu, automatické časové aktivace nebo platné licence.
- Přehřívání tabletu.
- Problém s kompatibilitou s tabletem: snímková frekvence video streamu je nižší než 24 snímků za sekundu.
- Vybitá baterie tabletu.

12.10. Zálohování a obnovení

Chcete-li obnovit funkce prostředku a výchozí konfiguraci, odinstalujte a znovu nainstalujte prostředek prostřednictvím obchodu Google Play/App store.

12.11. Popis metod uchovávání a obnovy konfigurace prostředku ověřeným oprávněným uživatelem

Nastavení exportu, jako jsou pověření třetích stran, a nastavení snímání videa, jako je vstupní poměr videa, se uchovávají v mezipaměti dat tabletu, bezpečně izolované systémem Android/iOS. Vzhledem k tomu, že výše uvedené konfigurace lze rychle nastavit, není zavedena žádná zvláštní metodika obnovy. Při opětovné instalaci nebo instalaci nového prostředku jsou uživatelé vyzváni k ručnímu zadání nastavení.

12.12. Zabezpečená konfigurace

Tato část obsahuje pokyny k zajištění bezpečné konfigurace a údržby softwaru FETOLY.

Počáteční nastavení: Stáhněte si a nainstalujte nejnovější verzi z obchodu Google Play/App store. Zkontrolujte, zda název a ikona aplikace odpovídají názvu a ikoně uvedené v části 13. Všechny kroky nastavení exportu provádějte přes zabezpečené síťové připojení podle pokynů G1/2/4 v části 12.4. Zajistěte, aby zařízení se systémem FETOLY bylo zabezpečeno podle pokynu G3 v části 12.4.

Reakce na incident: Povolte připojení k internetu, abyste mohli zaznamenávat pády a anomální aktivity, jak je popsáno v části 12.13. Nahlásit jakoukoli zjištěnou zranitelnost podle pokynů v části 12.4.

12.13. Shromažďování forenzních důkazů, pokud je to vhodné v zamýšleném prostředí použití

Do softwaru je integrován systém hlášení pádů. V případě pádu aplikace nebo anomální události se odešle hlášení o pádu, pokud je povoleno připojení k internetu.

12.14. Informace o konci životnosti a ukončení podpory systému nebo komponent, pokud je znám nebo se předpokládá

Konec životnosti a podpory závisí na platnosti licence. Licence bude automaticky obnovena pomocí internetového připojení, pokud bude licenční smlouva stále platná. Pokud smlouva vypršela nebo skončila její platnost, budete vyzváni k zadání nového registračního kódu.

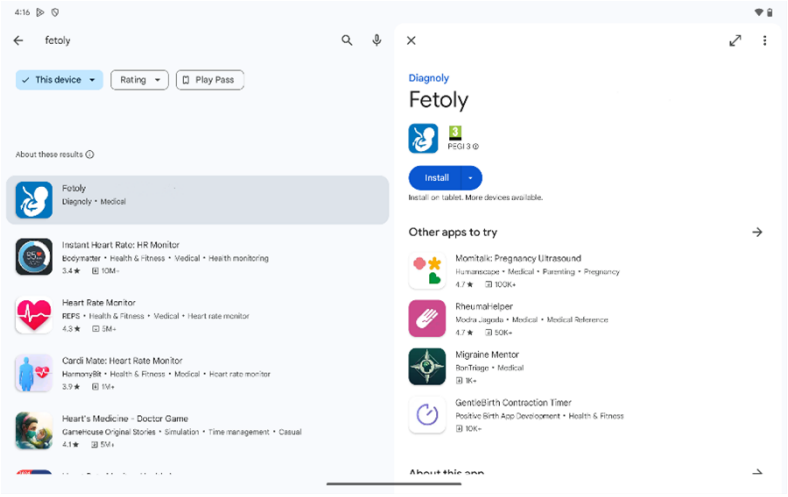
12.15. Bezpečné vyřazení z provozu

Chcete-li software vyřadit z provozu a zlikvidovat ho, odinstalujte aplikaci prostřednictvím systému Android/iOS jako jakoukoli jinou aplikaci v tabletu, a to v parametrech aplikace, jak je znázorněno v části 13 v odstavci „Odinstalace softwaru“. Odinstalací se z tabletu odstraní veškerá data spojená s používáním softwaru FETOLY, včetně licence.

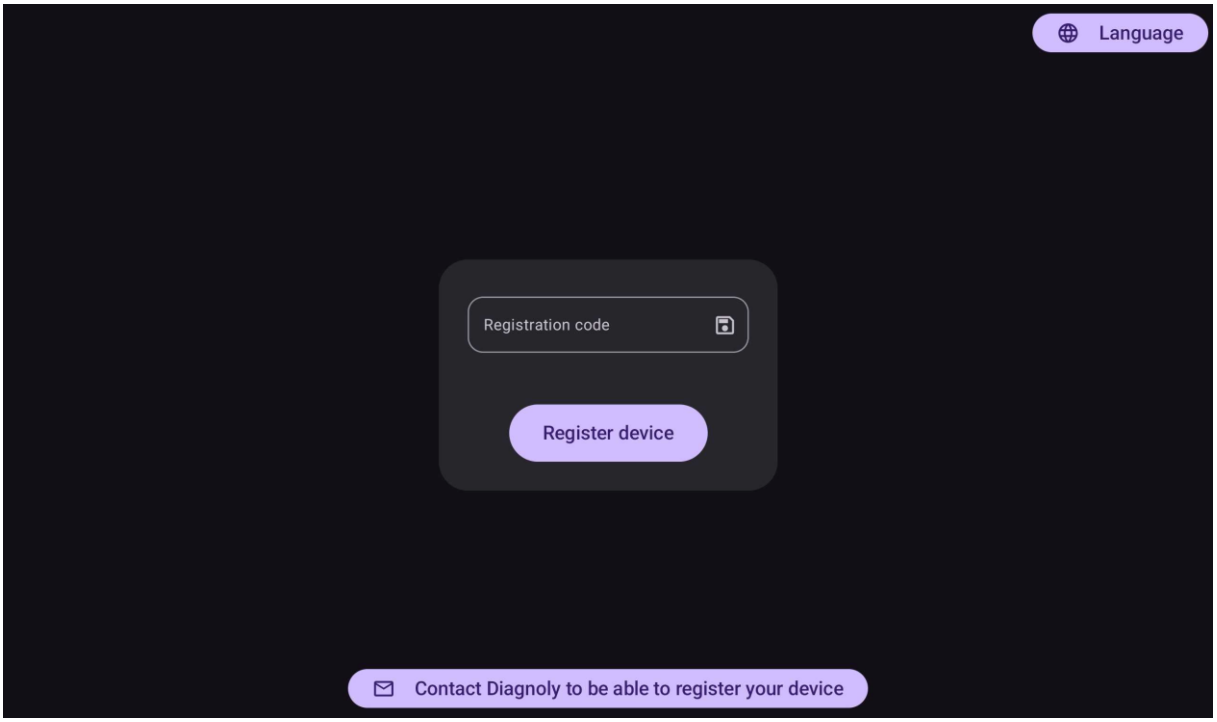
13. Návod k použití

Instalace a spuštění softwaru

9. Přejděte na Google Play nebo App Store, do vyhledávacího řádku napište FETOLY a spusťte automatické stahování a instalaci.



10. Klikněte na ikonu FETOLY na tabletu.
11. **Ověření platnosti licence**: V případě potřeby zadejte registrační kód licence, jak je uvedeno níže. Společnost Diagnoly je odpovědná za poskytnutí licence. Společnost Diagnoly můžete kontaktovat pro vydání licence kliknutím přímo na zobrazené tlačítko v dolní části uvítací stránky. Licence je spojena s ID vašeho prostředku, které je k dispozici na stránce nastavení licence.

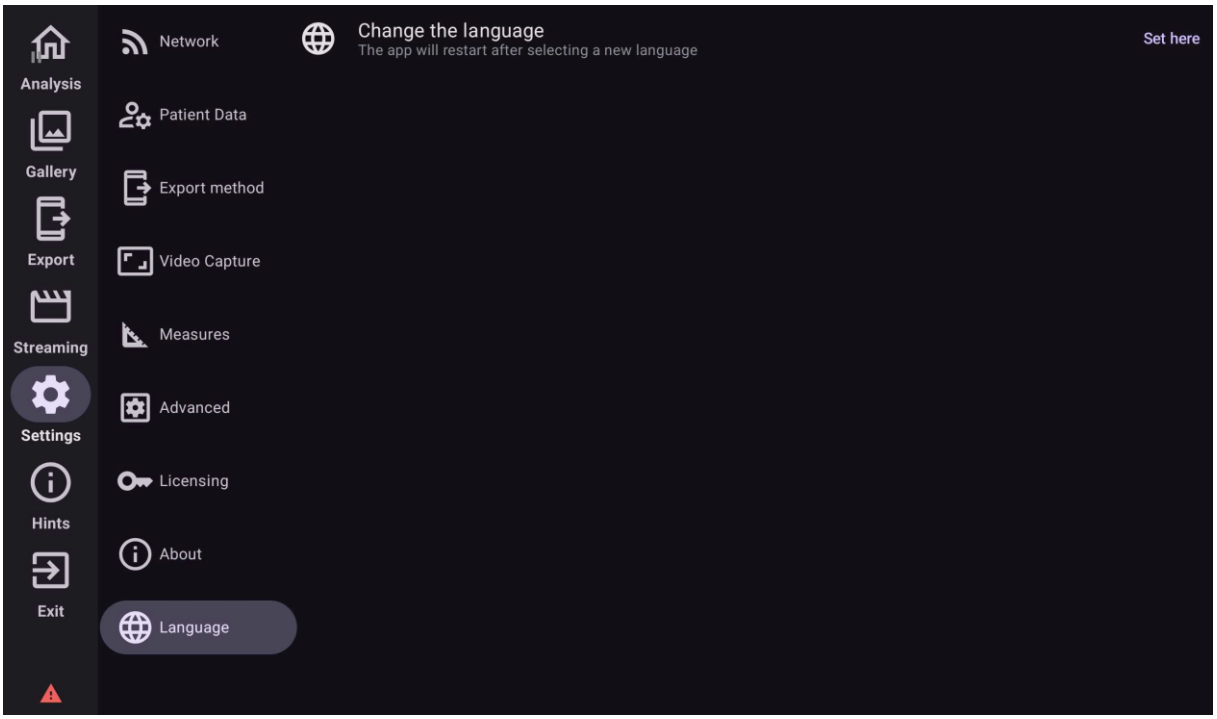


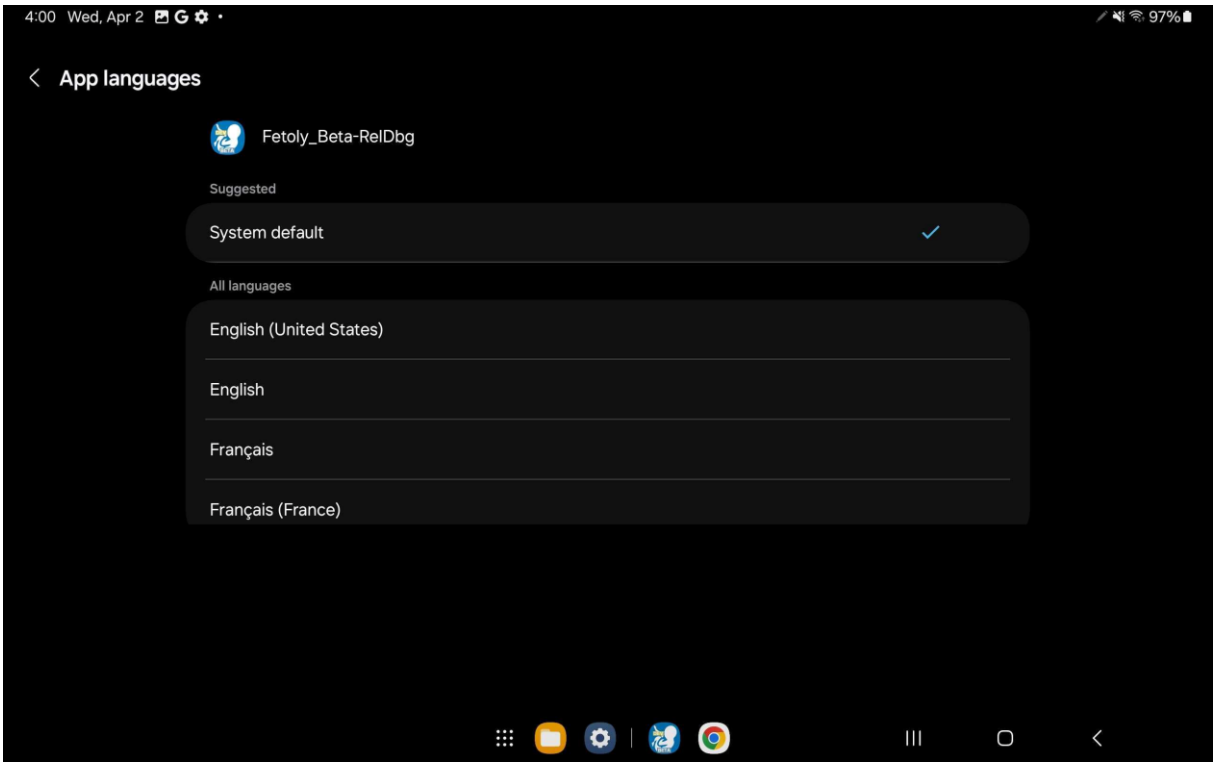
12. **Připojení k Wi-Fi:** Pokud chcete přijímat ultrazvuková data do osobního počítače, připojte tablet k síti Wi-Fi.

Nastavení jazyka

Ve výchozím nastavení je software nastaven ve stejném jazyce jako tablet. Vybraný jazyk si však můžete zvolit v nabídce „Settings“ > „Language“ (Nastavení > Jazyk). Tím se dostanete

do nastavení jazyků aplikací v systému Android. Po výběru požadovaného jazyka bude aplikace při opětovném spuštění přeložena do tohoto jazyka.





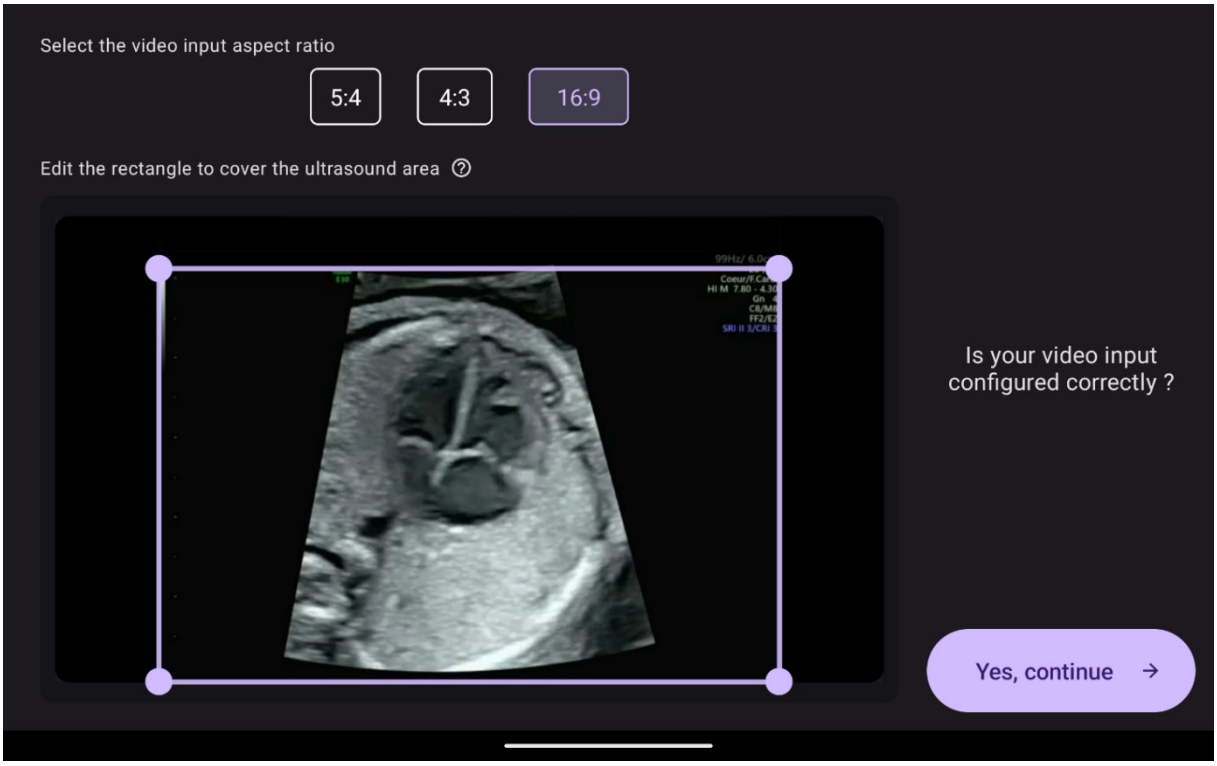
Připojení ultrazvukového přístroje

7. **Zapněte ultrazvukový systém:** Před připojením tabletu se ujistěte, že je ultrazvukový systém zapnutý a v provozuschopném stavu.
8. **Připojte tablet k ultrazvukovému systému:** Pro připojení stačí zasunout konektor USB (typ C) adaptéru UVC do tabletu a konektor HDMI do ultrazvukového přístroje.

9. **Ověření:** Chcete-li ověřit spojení mezi ultrazvukovým systémem a tabletem, spusťte software FETOLY. Pokud byl připojen nový zdroj USB, software automaticky zobrazí stránku konfigurace video streamu.

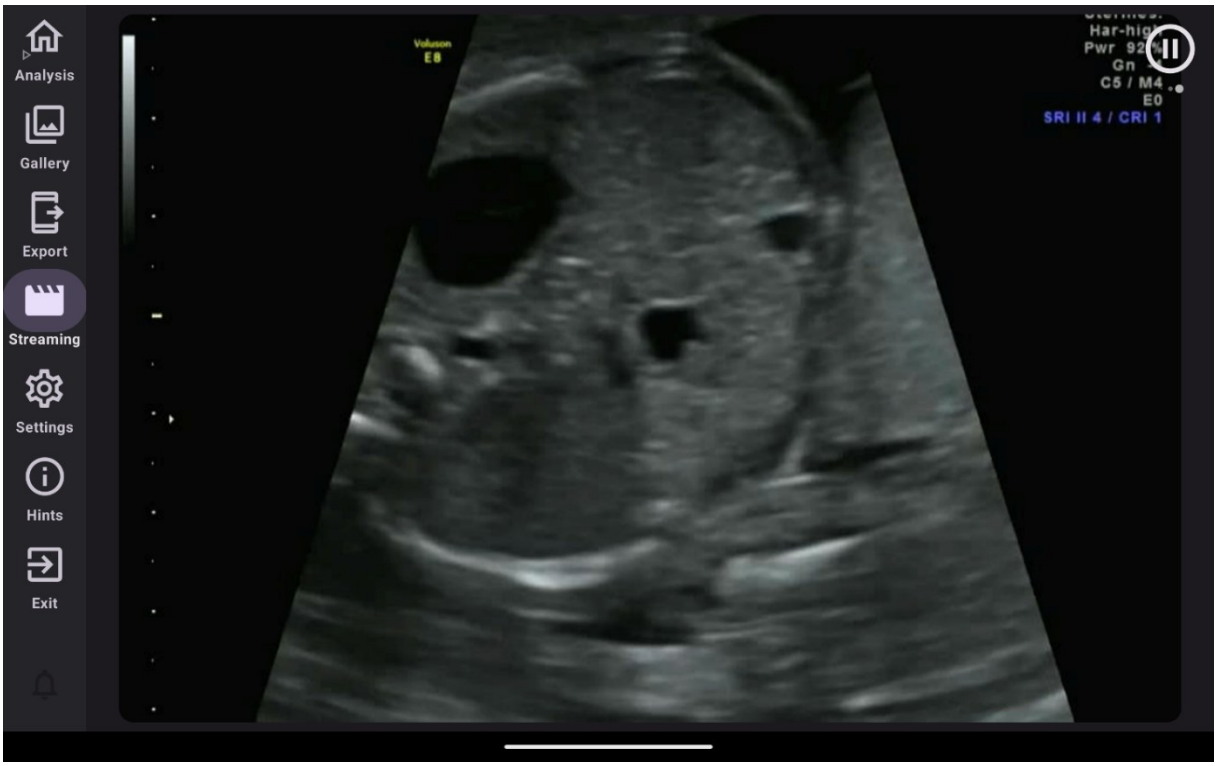
Konfigurace video streamu

3. Spusťte konfiguraci video streamu v aplikaci:
    a. Až se automaticky otevře stránka konfigurace videa, vyberte poměr stran videa, který má být sladěn s výstupním poměrem ultrazvukového přístroje, a vyberte oblast ultrazvuku. V ostatních situacích přejděte do „settings“ (nastavení) > „video capture“ (snímání videa) a nakonfigurujte video stream stejným způsobem.



    f. Vybraná oblast se na stránce streamování zobrazí v reálném čase. Tlačítko přehrát lze použít na stránce streamování ke spuštění analýzy.

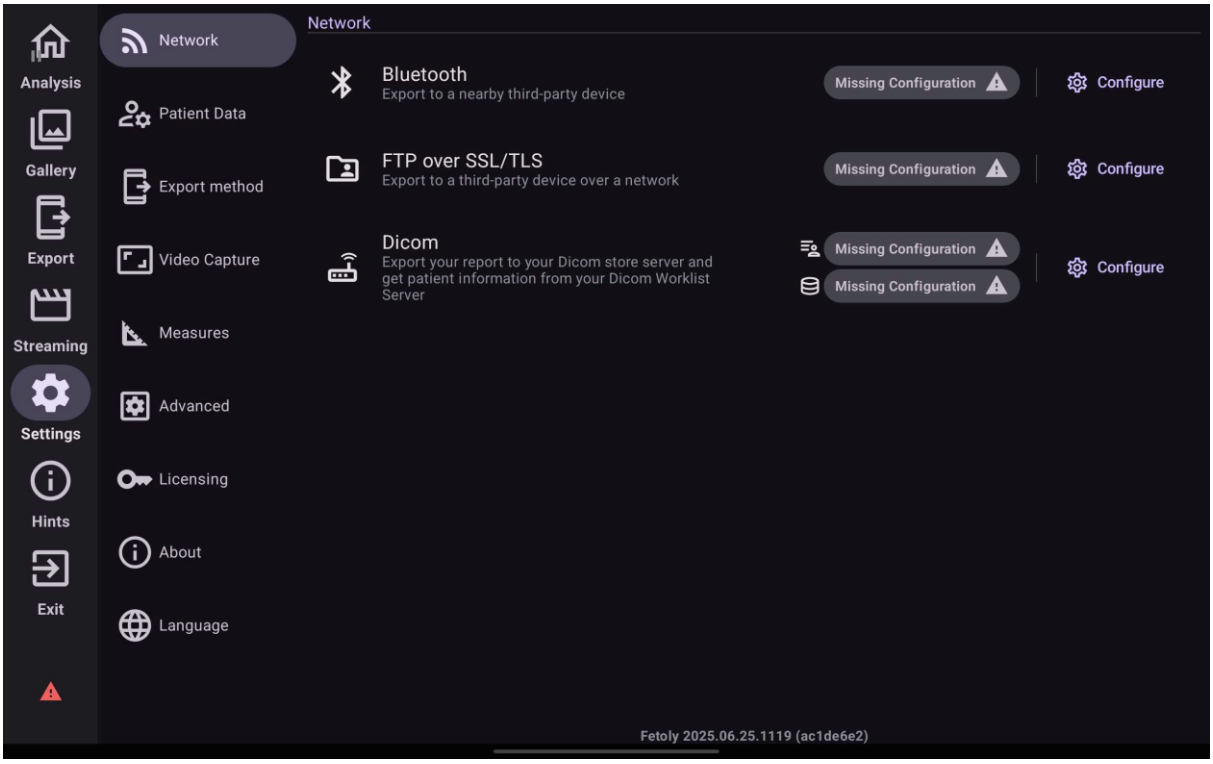
    g. Zkontrolujte, zda není na tabletu deaktivován mikrofon, protože to vede k blokování vstupu video streamu.



[VOLITELNĚ] Konfigurace ultrazvukového přístroje

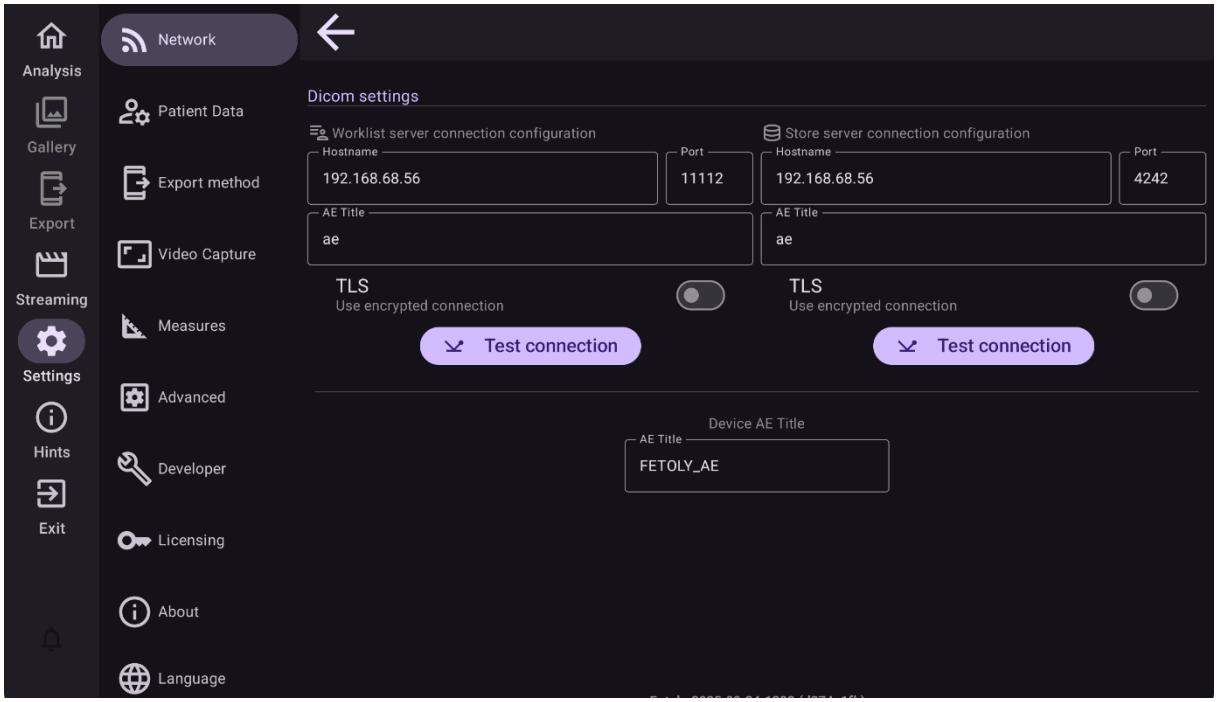
Některé ultrazvukové systémy umožňují konfiguraci velikosti ultrazvukové oblasti na videovýstupu. V takovém případě se doporučuje vybrat co největší oblast.

Konfigurace exportu



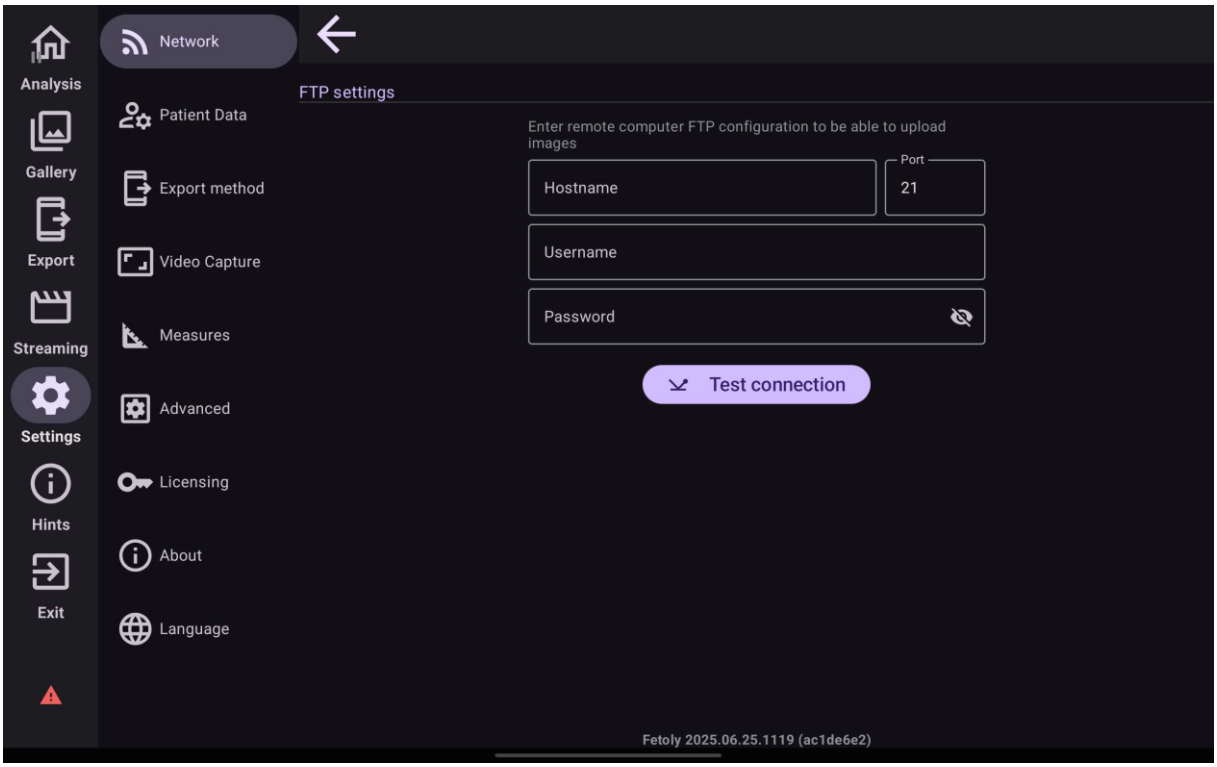
3. Konfigurace vzdáleného serveru DICOM pro export snímků pořízených pomocí FETOLY. Upozorňujeme, že tento krok vyžaduje spuštění serveru DICOM na zařízení připojeném ke stejné síti jako tablet se spuštěným softwarem FETOLY.

   Přejděte do „Settings“ (Nastavení) > „Network Settings“ (Síťová nastavení), vyberte „Configure DICOM“ (Konfigurace DICOM) a zadejte požadované informace pro DICOM server: Worklist hostname (IP address) (jméno hostitele (IP adresa) pro pracovní seznam) a AE title (AE název), DICOM Store hostname (IP address) (jméno hostitele (IP adresa) pro DICOM úložiště) a AE title (AE název), Device AE title (AE název zařízení). Chcete-li ověřit připojení, klikněte u každého serveru DICOM na tlačítko „Test connection“ (Otestovat připojení). Tím se zajistí, že připojení je platné a připravené na export snímků. Volitelně můžete také povolit možnost TLS.

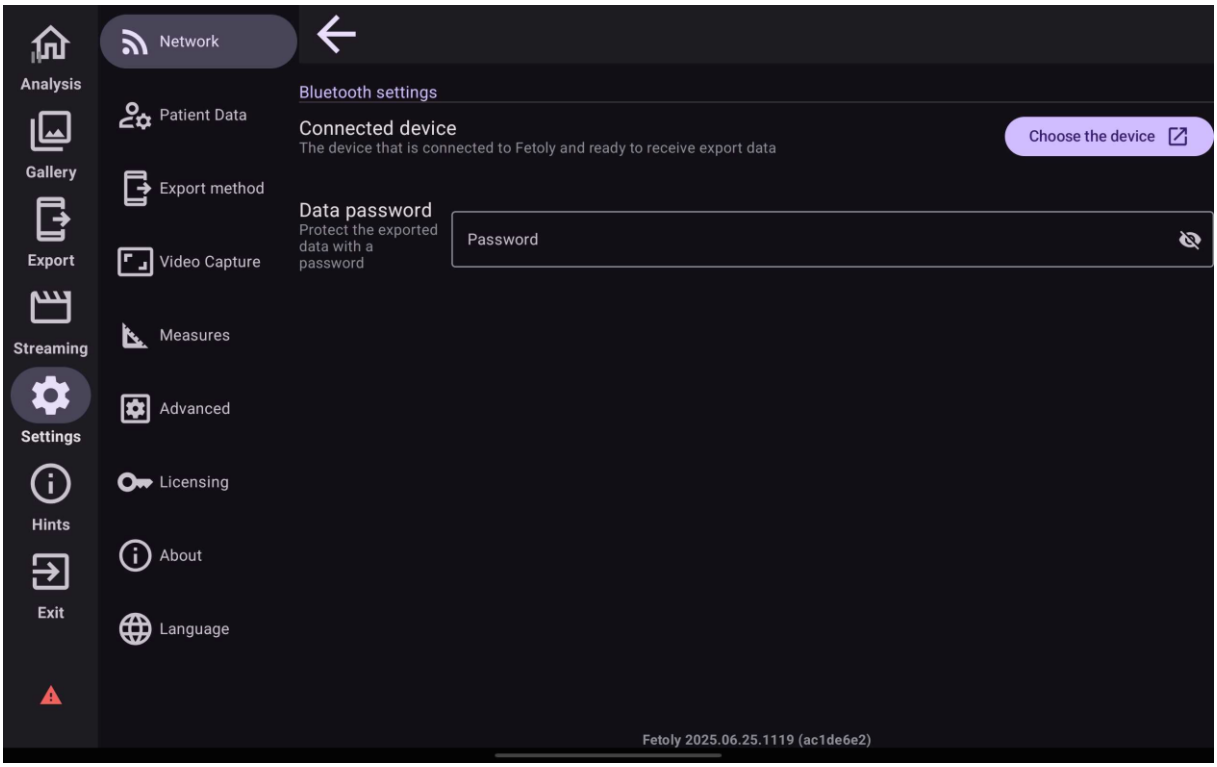


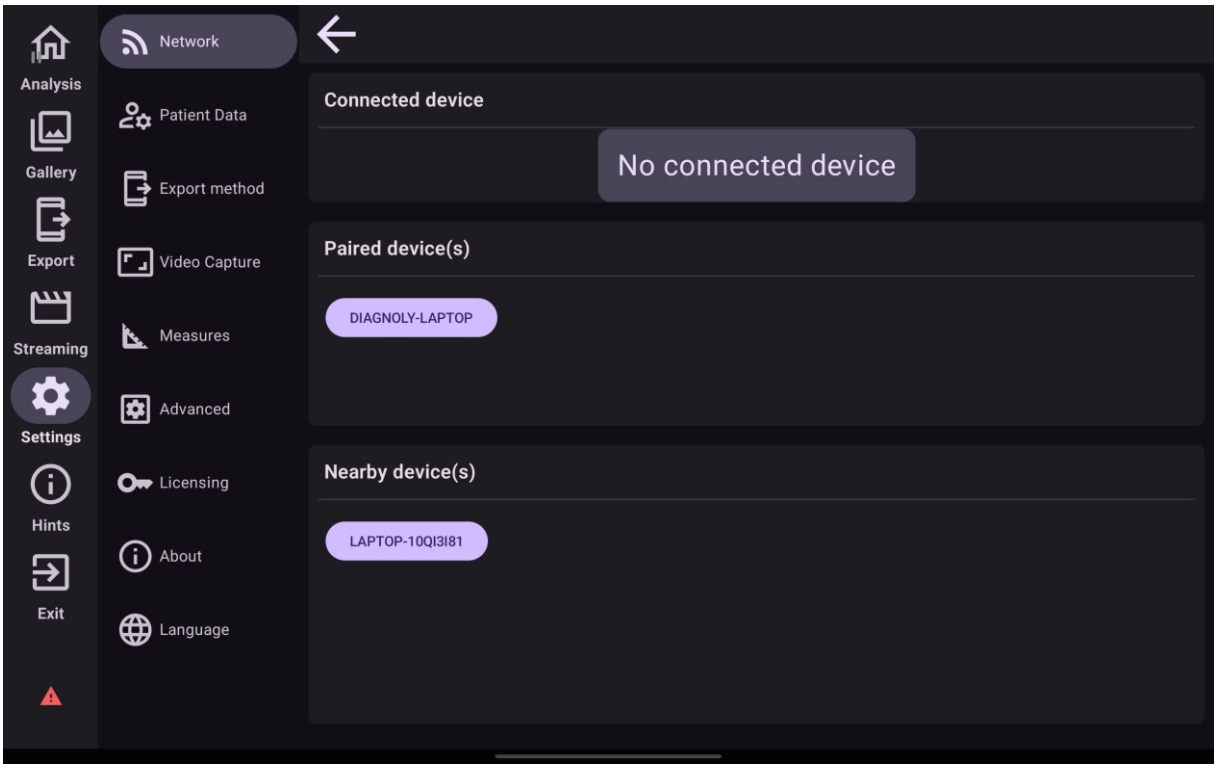
4. Případně nakonfigurujte vzdálený server FTP pro export snímků nasnímaných softwarem FETOLY. Upozorňujeme, že tento krok vyžaduje spuštění serveru FTP na zařízení připojeném ke stejné síti jako tablet se spuštěným softwarem FETOLY.

   c. Přejděte do „Settings“ (Nastavení) > „Network Settings“ (Nastavení sítě), vyberte možnost „Configure FTP“ (Konfigurace FTP) a zadejte požadované informace pro klienta FTP: jméno hostitele (IP adresa), uživatelské jméno a heslo. Chcete-li ověřit připojení, klikněte na tlačítko „Test connection“ (Otestovat připojení). Tím se zajistí, že připojení je platné a připravené na export snímků.



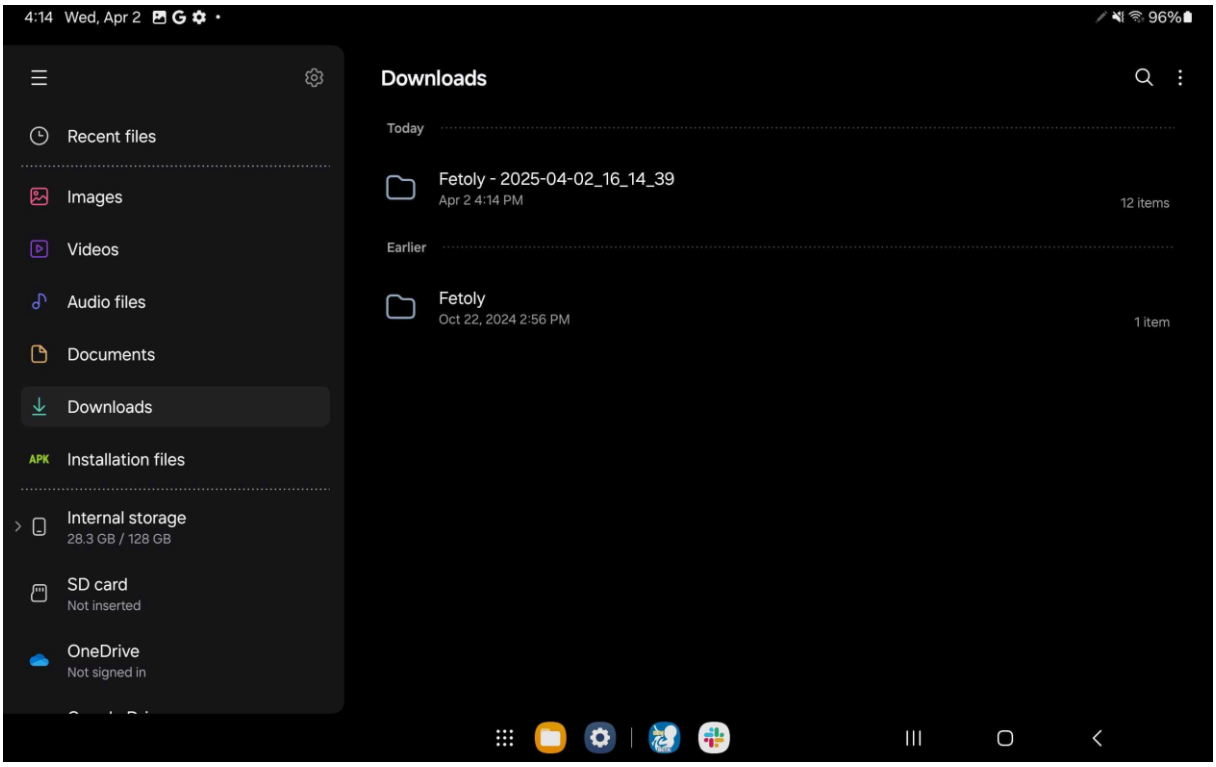
9. Můžete také použít připojení Bluetooth (pouze pro Android):
    a. Přejděte do „Settings“ (Nastavení) > „Network Settings“ (Síťová nastavení) a vyberte možnost Bluetooth. Chcete-li vybrat zařízení, do kterého budete exportovat data, musíte zařízení spárovat výběrem v části „nearby device“ (blízké zařízení). Poté v části „paired device“ (spárované zařízení) vyberte zařízení, které chcete připojit. Po výběru zařízení můžete připojení otestovat v části „connected device“ (připojené zařízení). Stránka pro výběr zařízení je přístupná kliknutím na tlačítko napravo od „Bluetooth settings“ (Nastavení Bluetooth) > „connected device“ (připojené zařízení).
    b. Chcete-li soubor exportovat, musíte dodatečně nastavit heslo. Toto heslo bude připojeno k souboru .zip exportovanému na zařízení třetí strany.



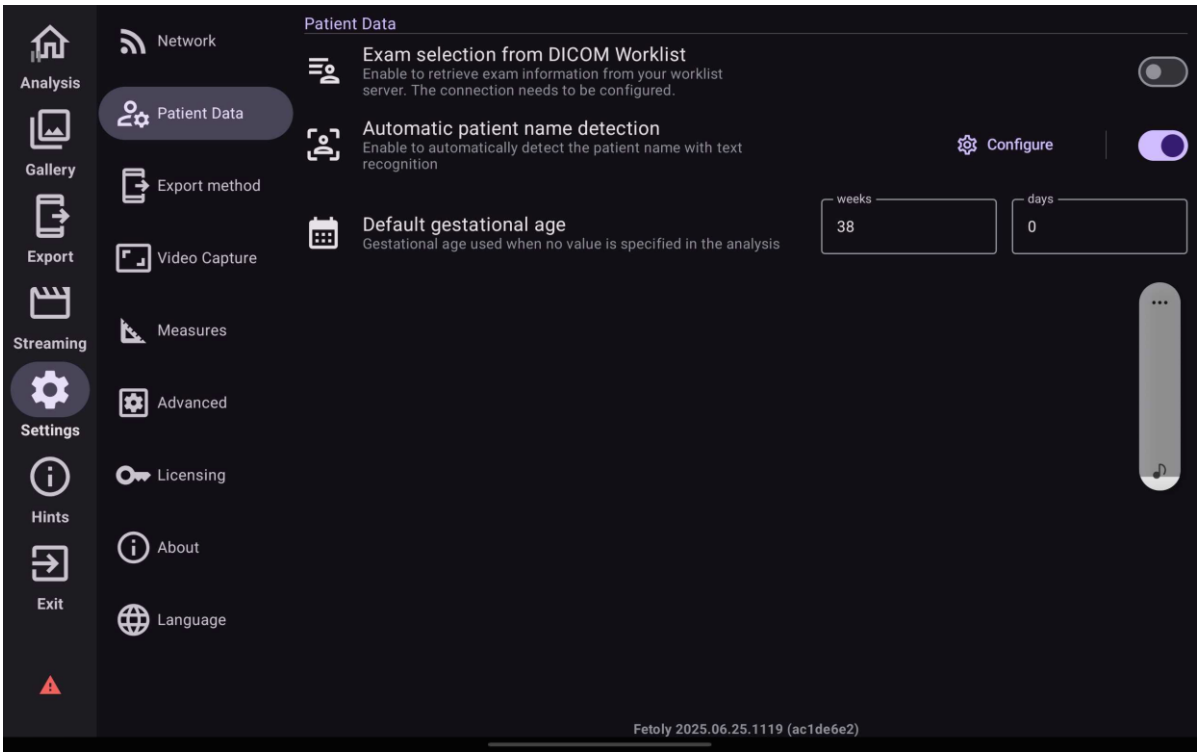


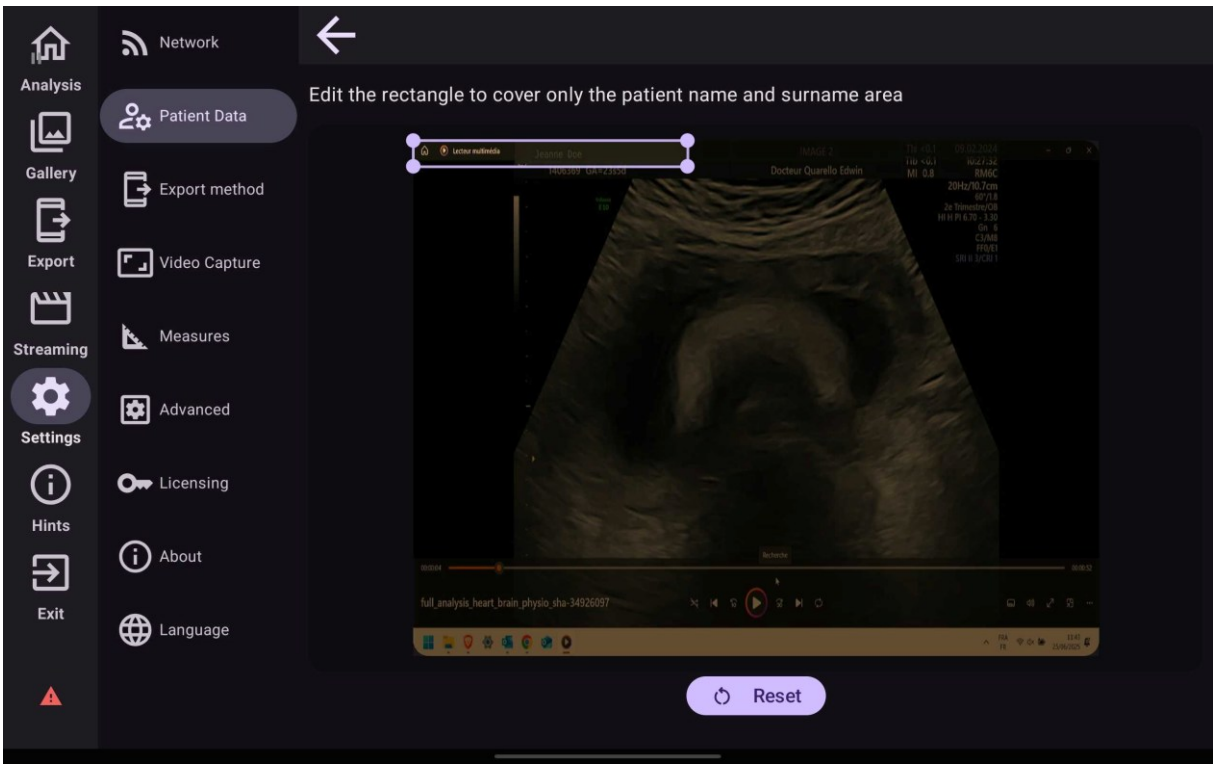
10. Pokud nechcete používat bezdrátové připojení, můžete data exportovat přímo do tabletu:
    a. Přejděte do „Settings“ (Nastavení) > „Export method“ (Způsob exportu) a vyberte Local (Místní). Soubor se uloží do umístění, které již bylo definováno tabletem.

b. Chcete-li se dostat do definovaného umístění, přejděte na plochu tabletu, vyberte ikonu „Files“ (Soubory), poté přejděte do „Downloads“ (Stažené soubory) > „Fetoly“.



11. Chcete-li do názvu exportovaného souboru přidat jméno pacienta nebo chcete-li vybrat vyšetření pacienta z pracovního seznamu DICOM:
    a. Vyplňte jméno pacienta a gestační stáří přímo na stránce analýzy, nebo
    b. Přejděte do „Settings“ (Nastavení) > „Patient data“ (Údaje o pacientovi) a aktivujte „exam selection from DICOM worklist“ (výběr vyšetření z pracovního seznamu DICOM). Upozorňujeme, že tato funkce funguje pouze v případě, že jste připojeni k systému PACS s nakonfigurovanými parametry pracovního seznamu DICOM. Rovněž upozorňujeme, že v režimu exportu DICOM jste nuceni použít toto nastavení.
    c. Volitelně můžete přejít do „Settings“ (Nastavení) > „Patient data“ (Údaje o pacientovi) a aktivovat „automatic patient name detection“ (automatické rozpoznávání jména pacienta). Poté můžete přejít do „Configure“ (Konfigurace) a vybrat oblast na ultrazvukovém video streamu, kde se zobrazuje jméno pacienta. Jméno pacienta se pak vyplní automaticky při spuštění vyšetření nebo po kliknutí na tlačítko obnovit vpravo od jména pacienta na stránce analýzy.

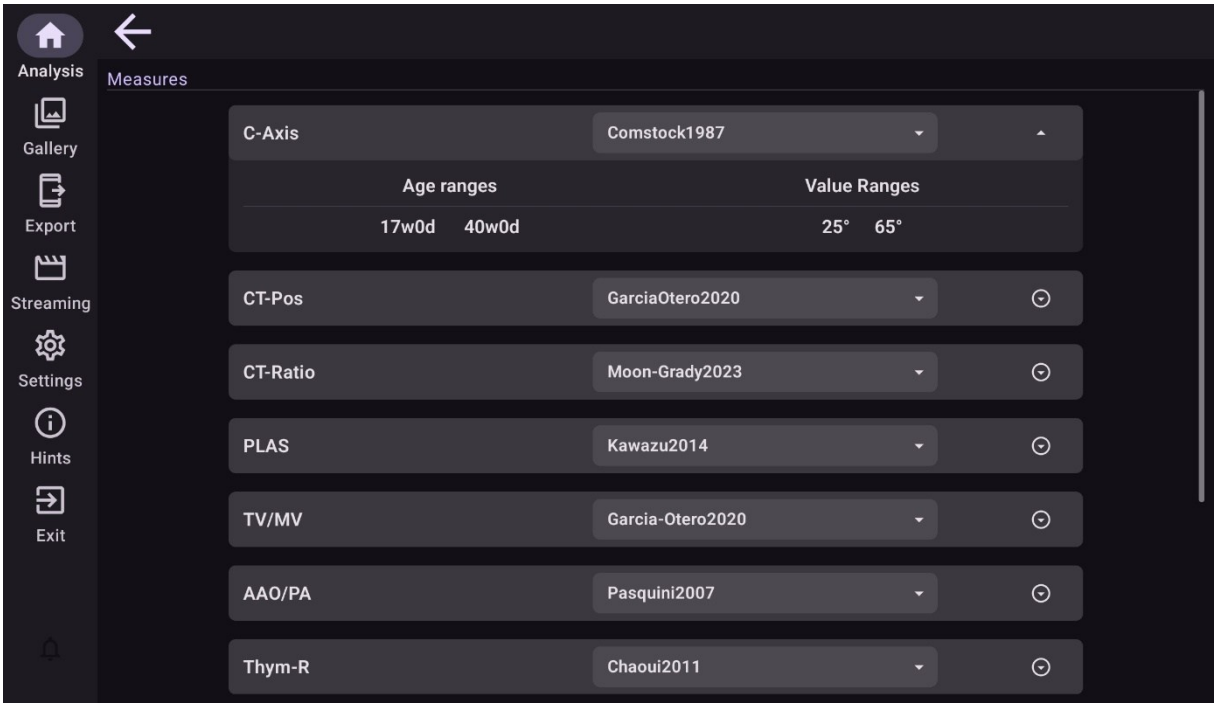




Použití

7. Postupujte podle následujících kroků, abyste dosáhli úplnosti vyšetření a měření:
    a. Zadejte gestační stáří na stránce analýzy se jménem pacienta nebo vyberte vyšetření pacienta z pracovního seznamu DICOM.
    b. Výchozí gestační stáří můžete nastavit v nabídce „Settings“ (Nastavení) > „Patient data“ (Údaje o pacientovi).

c. Pokud je u funkce měření k dispozici více zdrojů literatury, vyberte ten, který upřednostňujete. Referenční rozsahy můžete nastavit také ručně výběrem možnosti „vlastní“. To lze provést kliknutím na tlačítko nové karty vpravo od měření na stránce analýzy nebo v části „Settings“ (Nastavení) > „Measures Settings“ (Nastavení měření). To vás přesměruje na stránku nastavení měření.



d. Stiskněte tlačítko „Play“ (přehrát) na stránce analýzy.

e. Proveďte vyšetření jako obvykle.

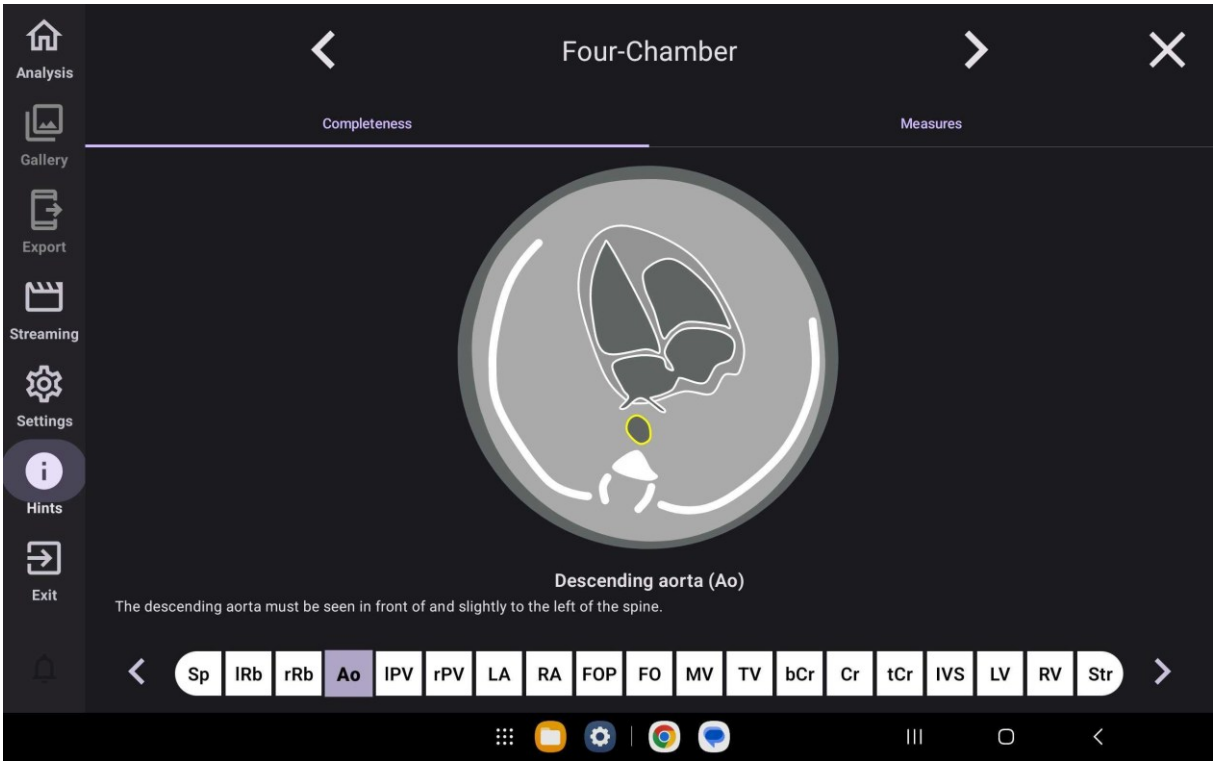
f. Vyšetření je považováno za úplné, když jsou ověřeny všechny pohledy a kritéria a když jsou provedena všechna měření.

g. Měření se zobrazí jako „out-of-range“ (mimo rozsah), pokud jsou mimo definovaný referenční rozsah.

h. Po dokončení vyšetření ho stránka s analýzou označí a umožní vám přejít přímo na stránku galerie a zkontrolovat navržené snímky.

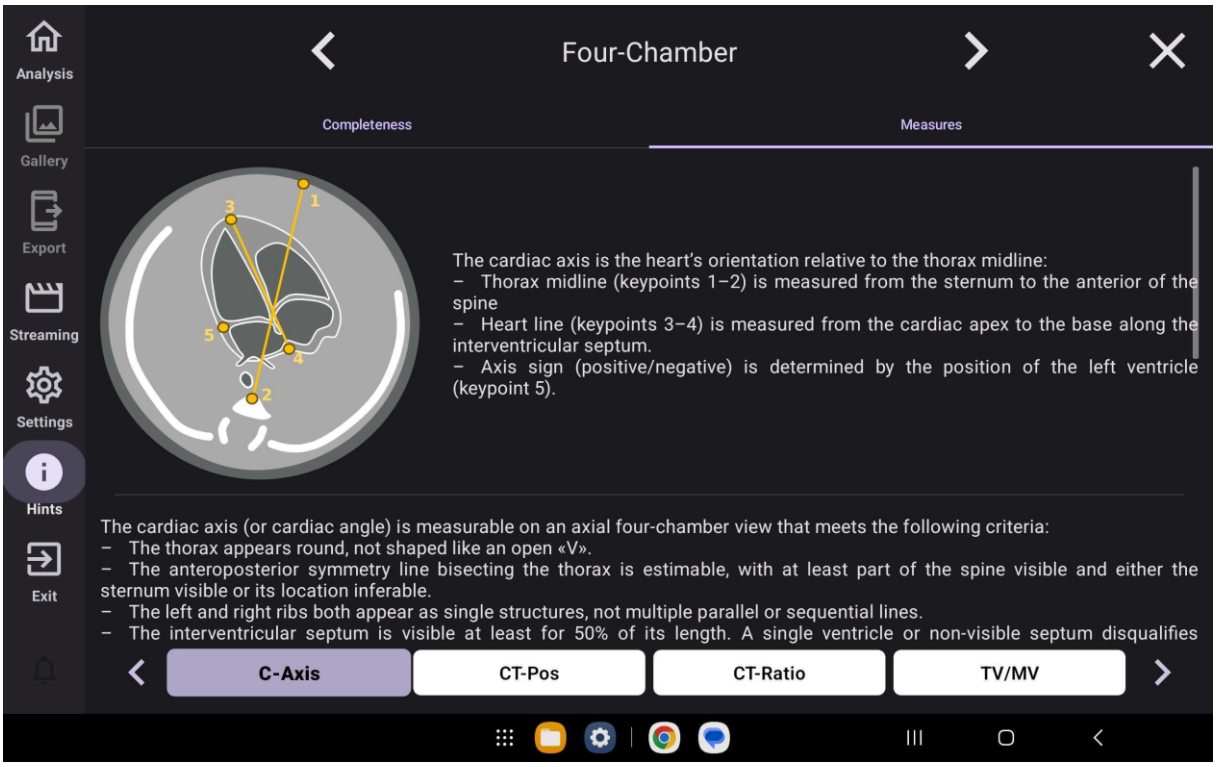


8. Níže najdete seznam tipů, jak si snadno ověřit úplnost vyšetření a měření:
    a. Kritéria kvality a pohledy zjištěné softwarem vycházejí z pokynů organizace ISUOG pro screening srdce a mozku plodu. V případě potřeby si prosím přečtěte tyto pokyny jako připomínku správných postupů pro screening srdce a mozku plodu. Můžete také přejít na stránku „Hints“ (nápověda), kde najdete vysvětlení všech kritérií kvality.



    b. Biometrická měření prováděná softwarem jsou založena na mezinárodních pokynech a dostupné odborné literatuře na téma screening srdce a mozku plodu. V případě potřeby si přečtěte články uvedené v literatuře, na které

odkazuje software, jako připomenutí správných postupů při screeningu srdce/mozku plodu. Můžete také přejít na stránku „Hints“ (nápověda), kde najdete vysvětlení všech provedených měření.



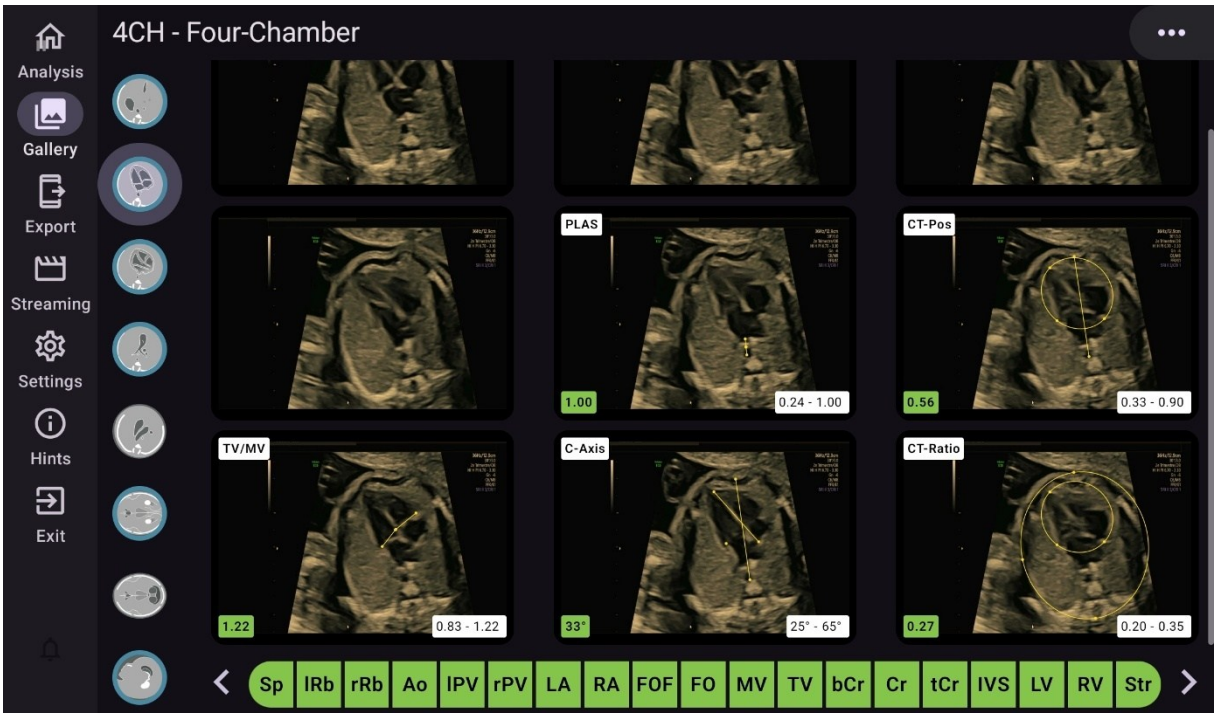
c. Ujistěte se, že všechny výše uvedené kroky konfigurace byly provedeny správně, abyste se vyhnuli problémům s detekcí.

d. Ujistěte se, že používáte kompatibilní zařízení podle oddílu 10 tohoto návodu.

e. Na stránce exportu se zobrazí varování, pokud vybraná sada snímků neobsahuje kritéria kvality / měření.

f. Po ověření všech kritérií a všech měření na stránce analýzy ověřte, zda jsou všechna odpovídající kritéria a měření dobře identifikovatelná v sadě vybraných snímků na stránce galerie.

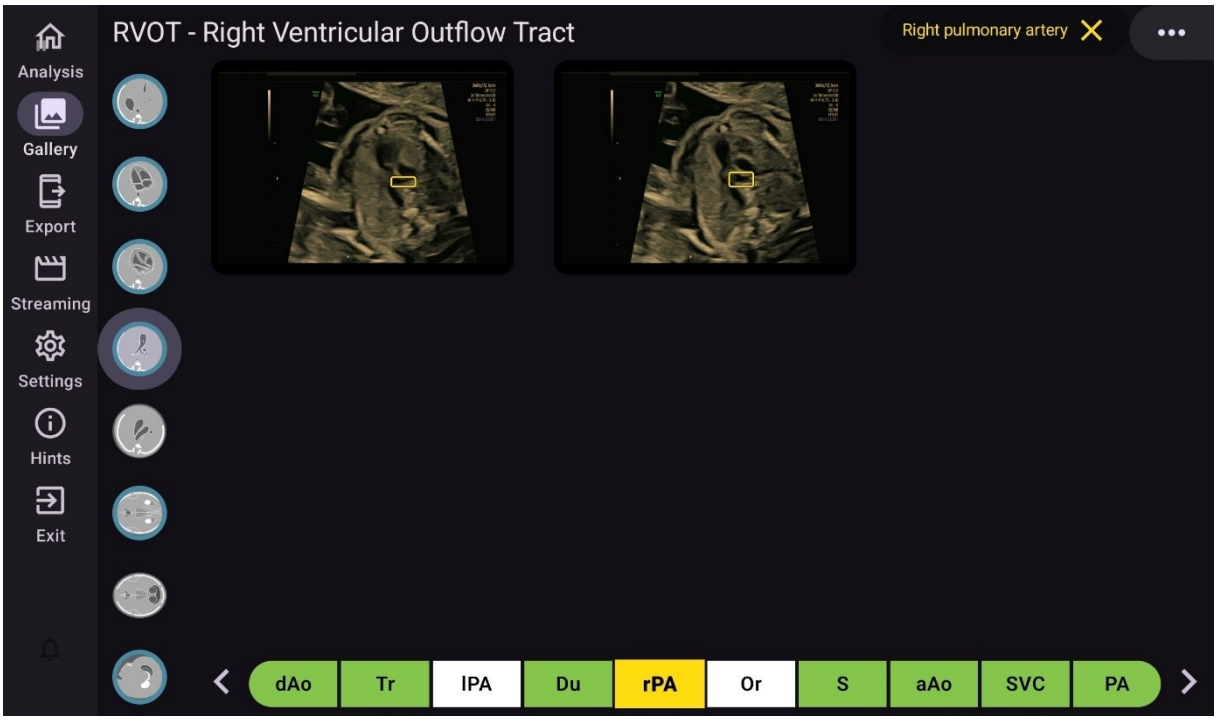
9. Po skončení video streamu přejděte do sekce galerie a prohlédněte si vybrané snímky. Pro usnadnění orientace v souboru snímků jsou snímky roztříděny podle rovin.



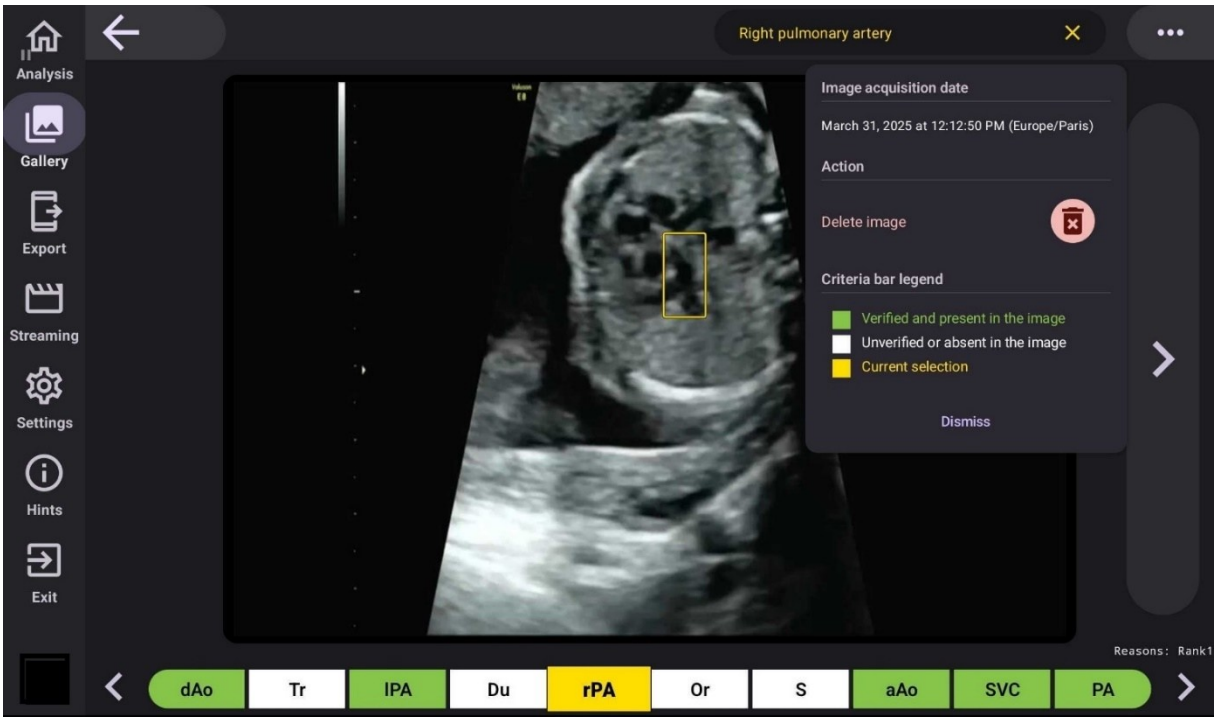
a. Kliknutím na konkrétní rovinu (levý panel) zobrazíte vybrané snímky týkající se této roviny. Zeleně označená kritéria jsou ověřená a bíle označená kritéria nejsou ověřená.

b. Snímky vybrané pro biometrická měření obsahují následující informace: název měření, hodnotu, referenční rozsah a případně stav mimo rozsah. Klíčové body a tvary měření jsou vyznačeny žlutě.

c. Kliknutím na konkrétní strukturu zobrazíte vybrané snímky obsahující tuto strukturu. Vybrané kritérium kvality je vyznačeno žlutě a na snímcích je zobrazen rámeček ohraničující toto kritérium.

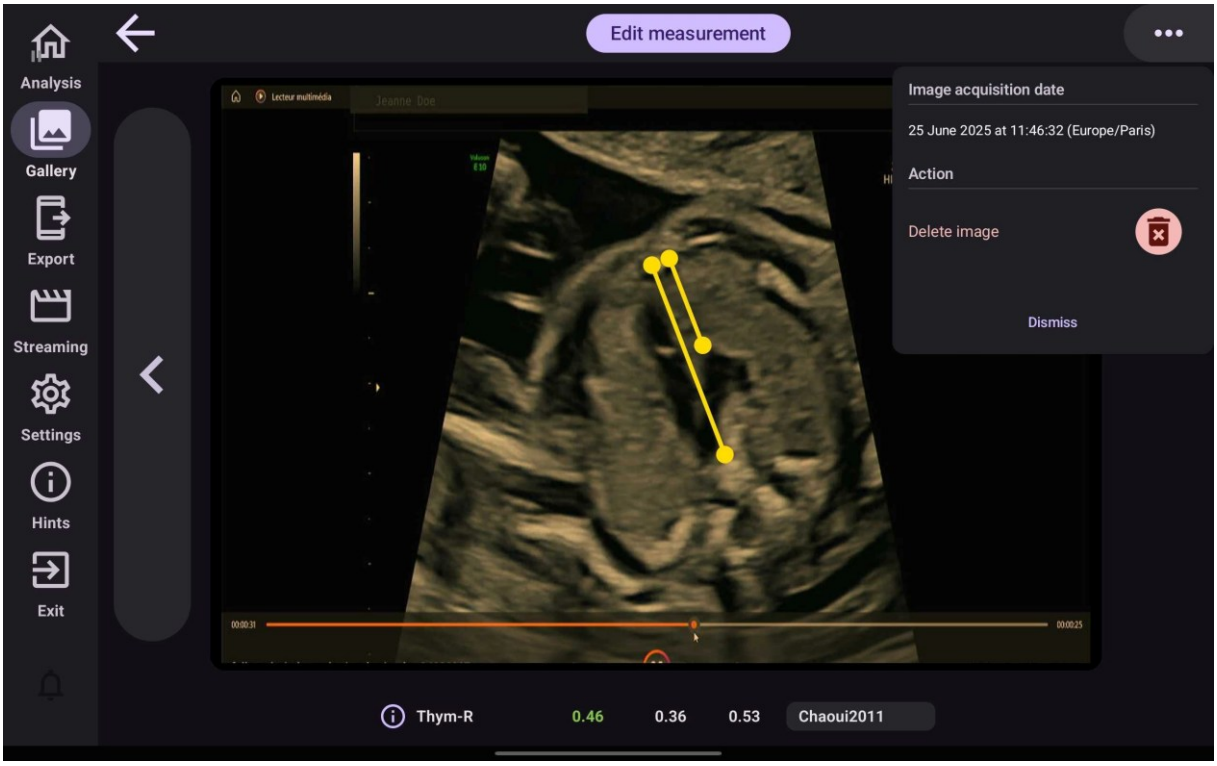


d. Kliknutím na snímek úplnosti snímek přiblížíte. Kliknutím na kritérium kvality v zelené barvě se zobrazí rámeček ohraničující kritérium kvality. Zvolené kritérium kvality je vyznačeno žlutě. Bílá pole znamenají, že kritéria kvality jsou přítomna i na jiných snímcích v galerii nebo nejsou ověřena. Kliknutím na symbol koše snímek odstraníte. Přejetím prstem do stran snímku můžete rovnou procházet další snímky pohledu.



e. Kliknutím na snímek měření snímek přiblížíte. Klíčové body a tvary měření jsou vyznačeny žlutě. Upozorňujeme, že klíčové body měření nejsou navrženy tak, aby byly na přesném místě, ale aby byly dostatečně přesné pro zobrazení správné naměřené hodnoty. Zobrazí se hodnota a případný stav mimo rozsah,

referenční rozsah a vybraný zdroj literatury. Kliknutím na symbol koše snímek odstraníte. Přejetím prstem do stran snímku můžete rovnou procházet další snímky pohledu. Klíčové body pro měření na snímcích měření můžete upravit kliknutím na tlačítko „upravit měření“. Hodnota měření se pak odpovídajícím způsobem aktualizuje a software zabrání jakékoli automatické úpravě opětovným skenováním po editaci. Upravené měření bude označeno následujícím symbolem: .



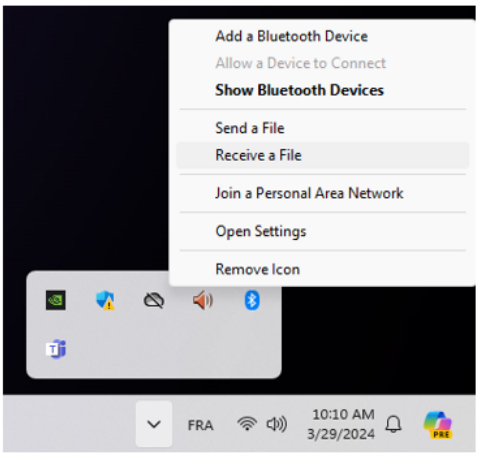


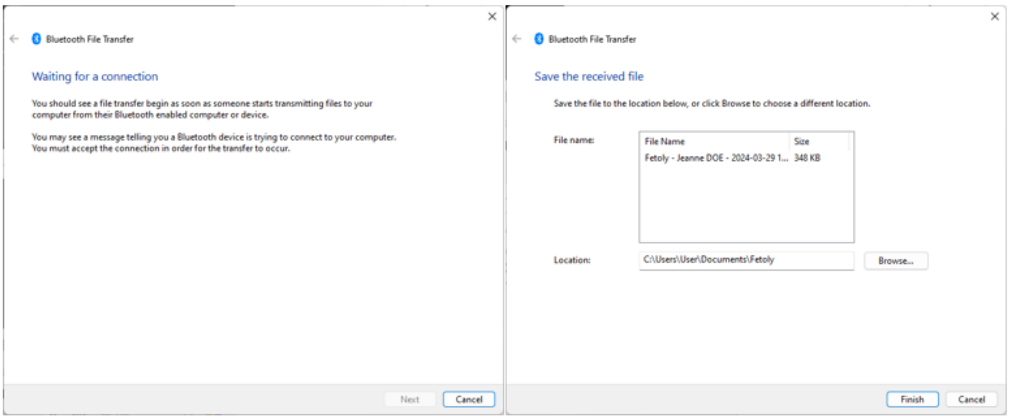
f. V případě potřeby se můžete vrátit na stránku analýzy, znovu ji spustit a pořídit další snímky.

Export snímků

5. V části „Settings“ (Nastavení) přejděte do části „Export method“ (Způsob exportu) a vyberte režim exportu, který chcete použít.
6. Přejděte do sekce „Export“ a exportujte vybrané snímky:

d. Pokud jste zvolili připojení Bluetooth (pouze pro Android), přejděte do počítače a v konfiguraci Bluetooth vyberte možnost „receive a file“ (přijmout soubor).





p. Pokud jste zvolili připojení DICOM, můžete pomocí pracovního seznamu DICOM na stránce analýzy ověřit, zda je pacient vybraný k exportu správný, a v případě chyby vybrat jiného pacienta.

q. Na stránce exportu se zobrazí souhrn vyšetření a připomene vám, abyste před exportem zkontrolovali, zda máte všechny snímky potřebné k náležité péči o pacienta.

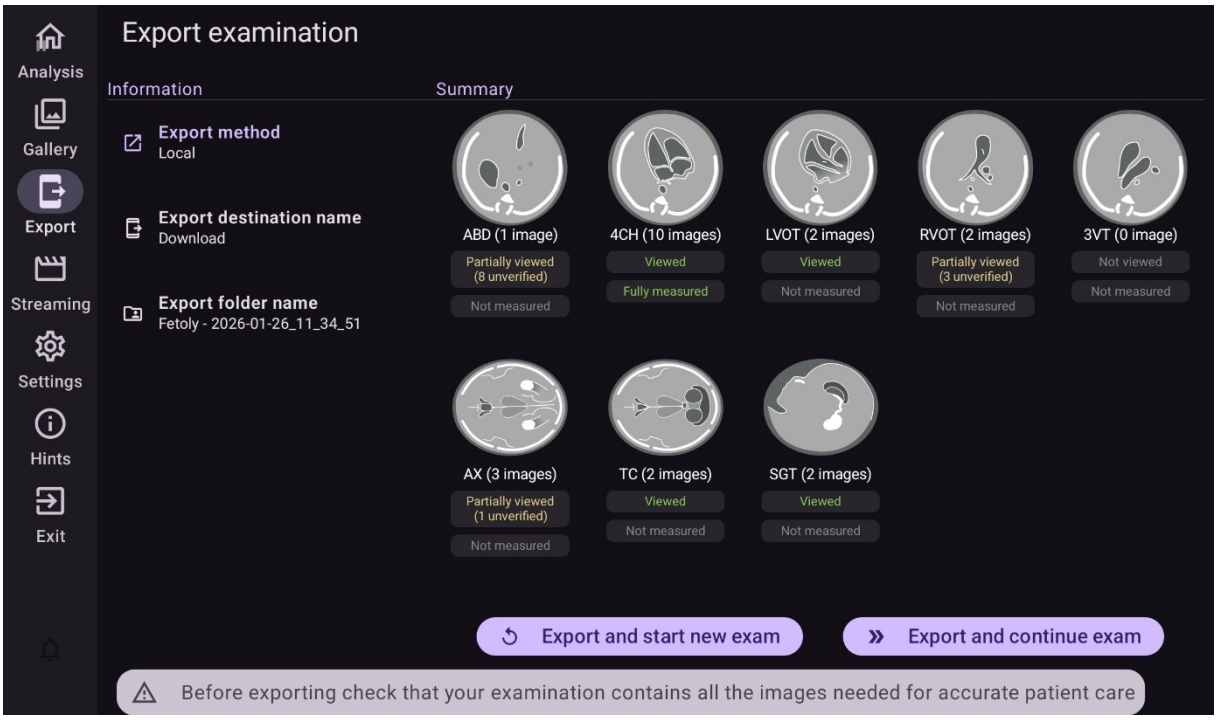
r. Na stránce exportu se zobrazí zvolený způsob exportu. Pokud chcete změnit nastavení, můžete přejít přímo na stránku nastavení exportu kliknutím na „Export method“ (Způsob exportu).

s. Na stránce exportu se zobrazí umístění exportního souboru ve vybraném zařízení a název souboru nastavený pro místní export.

t. Kliknutím na tlačítko „Export and start a new exam“ (Exportovat a zahájit nové vyšetření) vyexportujete snímky a vymažete vyšetření před zahájením nového vyšetření.

u. Nebo klikněte na tlačítko „Export and continue exam“ (Exportovat a pokračovat ve vyšetření), chcete-li exportovat snímky bez vymazání aktuálně vybrané sady snímků a analýzy úplnosti.

v. Software vám oznámí, zda byl export úspěšný, nebo neúspěšný.



Reset (vymazání)

Pokud jste nepoužili funkci vymazání na stránce exportu, přejděte na stránku „Analysis“ (Analýza) a kliknutím na tlačítko „Clear“ (Vymazat) znovu resetujete sadu vybraných snímků a vyšetření.

Rozšířená nastavení

Pokud chcete deaktivovat funkci měření, přejděte do „Settings“ (Nastavení) > „Advanced“ (Pokročilé) a klikněte na dané tlačítko.

Aktualizace softwaru a licencí

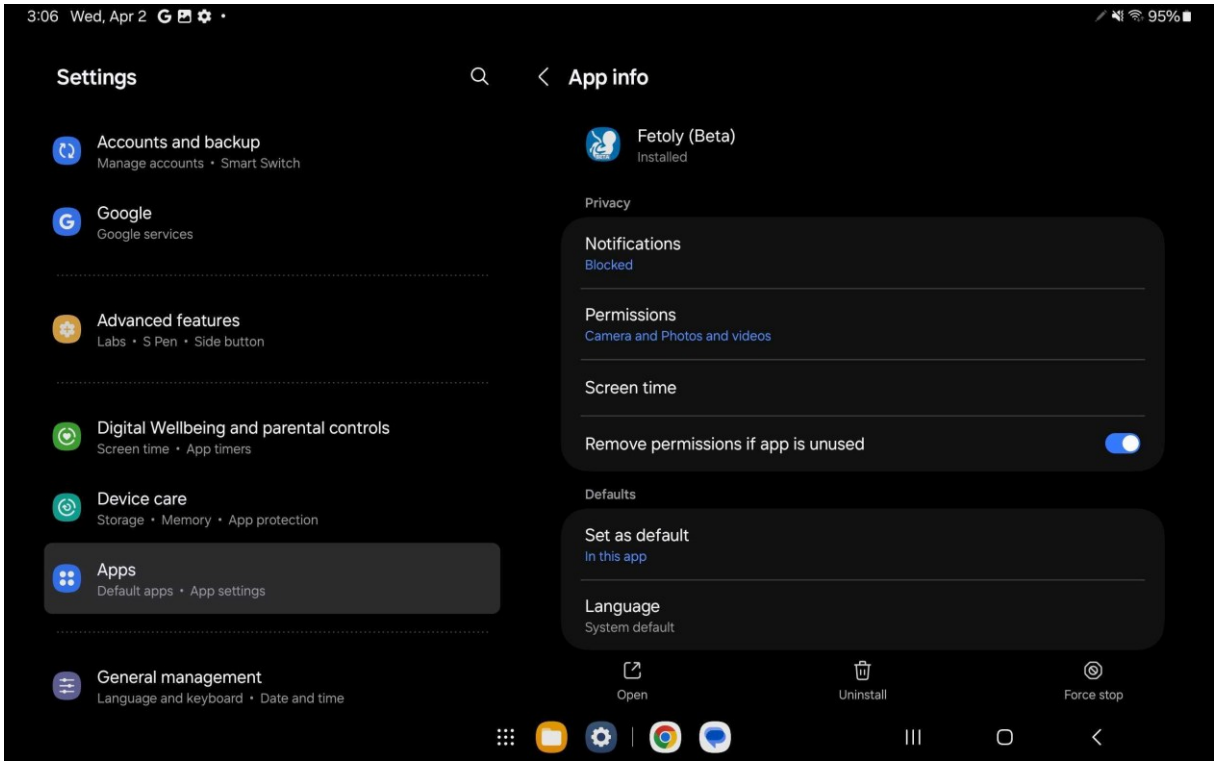
Software pravidelně kontroluje, zda jsou k dispozici nové aktualizace aplikací. Chcete-li zajistit okamžitou dostupnost nových aktualizací, povolte aktualizace na pozadí pro software FETOLY v nastavení obchodu Google Play/App store. Pokud je k dispozici aktualizace, software při spuštění zobrazí stránku s blokováním, která vyžaduje, aby uživatel aplikaci aktualizoval a

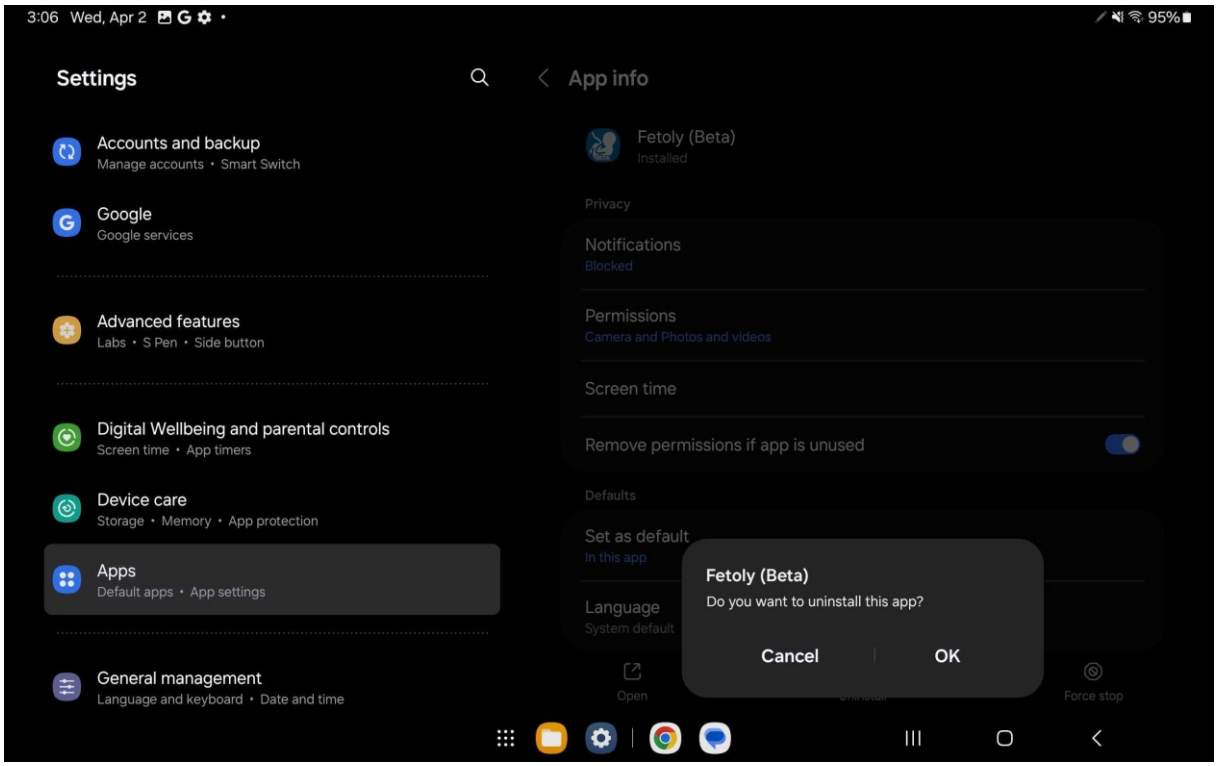
restartoval zařízení, aby mohl aplikaci dál používat. Po přijetí aktualizace se obchod Google Play/App store postará o instalaci aktualizace a restart aplikace. Pro kontrolu aktualizací a automatické obnovování licence je nutné připojení k internetu. Pokud zařízení nebude po dobu 30 dnů připojeno k internetu, software bude zablokován.

Vaše licence se ověřuje a obnovuje automaticky po aktivaci internetového připojení až do vypršení licenční smlouvy. Datum vypršení platnosti licence se zobrazuje na stránce nastavení licence. Pokud nedojde k obnovení licenční smlouvy, software vás po vypršení její platnosti požádá o zadání nového registračního kódu a zablokuje funkce.

Odinstalace softwaru

Odinstalujte aplikaci jako jakoukoli jinou aplikaci v tabletu, jak je znázorněno níže:





14. Údržba, manipulace a likvidace

- Před použitím je třeba si přečíst návod k použití.
- Spusťte aktualizace, jakmile vás o to software při spuštění požádá.
- Upozorňujeme, že na trhu v USA byl přijat plán řízení předem stanovených změn (PCCP). Tento PCCP je implementován v modelu strojového učení zabudovaném do prostředku FETOLY, a mohl by měnit výkon, vstupy nebo použití prostředku. Proto se důrazně doporučuje pravidelné připojení k internetu, aby byla umožněna automatická instalace aktualizací.
- Na výzvu softwaru při spuštění zadejte registrační kód.
- Chcete-li software vyřadit z provozu a zlikvidovat, odinstalujte aplikaci prostřednictvím systému Android jako jakoukoli jinou aplikaci v tabletu, a to v parametrech aplikace, jak je znázorněno výše v odstavci „Odinstalace softwaru“. Odinstalací odstraníte z tabletu veškerá data spojená s používáním softwaru FETOLY, včetně licence.

Symboly používané na značení prostředku (stránka „O softwaru“):

	Výrobce (vyplněný tovární symbol)
CE 0197	Prostředek s označením CE
UDI	Jedinečný identifikátor prostředku 01: UDI-DI

	11: Datum výroby 8012: Verze softwaru
	Přečtěte si návod k použití
	Federální zákon omezuje prodej tohoto prostředku pouze na lékaře nebo na základě jeho pověření.
	Zdravotnický prostředek
	Datum výroby (prázdný výrobní symbol)
	Jméno a adresa švýcarského zástupce

INSTRUCȚIUNI DE UTILIZARE (ROMÂNĂ)

1. Identificarea dispozitivului

FETOLY

Software de asistență pentru ecografii cardiace și cerebrale fetale.

Versiunea software asociată cu aceste instrucțiuni de utilizare: V2026.02.25

2. Actualizare

FETOLY a fost actualizat după cum urmează pentru versiunea 2026.02.25:

- FETOLY este compatibil acum cu iOS
- Următoarele măsurători au fost adăugate conform Modificării nr. 4 a PCCP: PLAS, raportul CSP, raportul VP.
- Planul transventricular și planul transtalamic au fost combinate în planul axial.
- Instrucțiunile de utilizare au fost actualizate pentru a clarifica funcționalitatea afișării punctelor cheie și pentru a adăuga un avertisment care explică faptul că software-ul nu trebuie utilizat în metoda de scanare transvaginală.
- Performanța modelului de detectare AI a fost îmbunătățită conform Modificării nr. 1 a PCCP.
- Acum este posibil activarea modului TLS pentru export DICOM.

Testele de verificare au fost relansate complet pentru a verifica dacă actualizarea are vreun impact asupra funcționalității dispozitivului. Metodologia urmată este aceeași ca pentru versiunea inițială a produsului.

3. Identificarea producătorului

FETOLY este fabricat de:

DIAGNOLY

2 Place de Francfort, 69003 LYON, Franța

Tel.: +33(0)6.58.49.07.84

Reclamații privind produsele: support@diagnoly.com

Vă rugăm să raportați orice incident grav către Diagnoly utilizând adresa de e-mail pentru reclamații privind produsele și către autoritatea competentă din țara dumneavoastră.

CE 0197

4. Descrierea și prezentarea dispozitivului

Fetoly este un software care își propune să asiste specialiștii în ecografie, medicii obstetricieni, medicii radiologi, specialiștii în medicina materno-fetală și medicii cardiologii pediatri (denumiți

cadre medicale) în efectuarea ecografiilor cardiace și cerebrale fetale în timp real. Fetoly poate fi utilizat de cadrele medicale în timpul ecografiilor fetale în trimestrele 2 și 3 de sarcină (vârsta gestațională: între 17 și 40 de săptămâni).

Software-ul este destinat să asiste cadrele medicale în evaluarea completitudinii ecografiilor cardiace și cerebrale fetale, în conformitate cu orientările naționale și internaționale. De asemenea, Fetoly este destinat utilizării pentru realizarea de măsurători biometrice ale creierului/cordului fătului, în conformitate cu orientările naționale și internaționale.

Pentru a utiliza Fetoly, software-ul trebuie să fie instalat pe un dispozitiv hardware care este conectat la un ecograf printr-o conexiune HDMI. Software-ul primește imagini ultrasonografice captate de ecograful conectat în timp real. Algoritmul de învățare aprofundată al software-ului, care a fost antrenat prin învățare supravegheată, analizează imaginile din acest flux de imagini ultrasonografice pentru a detecta planuri de vizualizare ale creierului/cordului, criteriile de calitate din cadrul acestor planuri de vizualizare și pentru a efectua măsurători biometrice ale cordului și creierului.

Software-ul îi furnizează utilizatorului următoarele informații accesibile:

1. **Completitudinea examinării**: software-ul afișează în timp real planurile de vizualizare ale creierului/cordului și criteriile de calitate verificate de software în timpul examinării. Planurile de vizualizare ale creierului/cordului și criteriile de calitate verificate sunt accesibile clinicienilor în orice moment al ecografiei, în timp real.
2. **Măsurători biometrice cantitative:** software-ul afișează în timp real măsurătorile creierului și cordului înregistrate și efectuate de software în timpul examinării și dacă măsurătorile se încadrează sau nu în intervalele de referință definite conform standardelor actuale. Măsurătorile verificate ale cordului și creierului sunt accesibile clinicienilor în fundal în orice moment al ecografiei.
3. **Ilustrația examinării:** software-ul selectează un subset de imagini care ilustrează
    - planurile de vizualizare și criteriile de calitate verificate. Aceste imagini pot fi revizuite de clinicieni pentru a verifica prezența planurilor de vizualizare și a criteriilor. Opțional, clinicienii pot afișa localizarea criteriilor de calitate detectate pe imaginile selectate.
    - fiecare măsurătoare. Pentru fiecare măsurătoare, software-ul afișează o imagine cu măsurătoarea trasată (în galben) și valoarea măsurată (în partea de jos). De asemenea, utilizatorului i se reamintește intervalul normal pentru această măsurătoare. Utilizatorul poate muta punctele cheie, iar software-ul actualizează măsurătorile în consecință.
4. **Raport de examinare:** software-ul îi permite utilizatorului să exporte un raport de examinare care conține:
    - Un rezumat al măsurătorilor și al completitudinii;
    - Ilustrații (imagini).

Definiția unei examinări complete

Pentru ecografia fetală cardiacă

Tabelul 8: Lista celor 52 de criterii de calitate care definesc calitatea celor 5 planuri de vizualizare recomandate de Societatea Internațională de Ultrasonografie în Obstetrică și Ginecologie (International Society of Ultrasound in Obstetrics and Gynecology – ISUOG) pentru screeningul cardiac fetal în trimestrele 2 și 3 de sarcină.

Planurile de vizualizare cardiace	***Criteriile de calitate în cadrul planurilor de vizualizare***	
	(A1) Sp	*Coloana vertebrală*

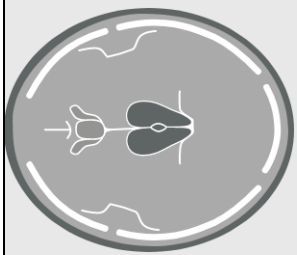
 ***(A) ABD*** ***Planul abdominal*** ***(n = 8)***	*(A2) lRb*	*Coasta stângă*
	(A3) rRb	*Coasta dreaptă*
	(A4) Ao	*Aorta descendentă*
	(A5) VC	*Vena cavă inferioară*
	(A6) St	*Stomac*
	(A7) Uv	*Vena ombilicală*
	(A8) aA	*Regiunea abdominală anterioară*
 ***(B) 4CH*** ***Planul de vizualizare a celor patru camere*** ***(n = 19)***	*(B1) Sp*	*Coloana vertebrală*
	(B2) lRb	*Coasta stângă*
	(B3) rRb	*Coasta dreaptă*
	(B4) Ao	*Aorta descendentă*
	(B5) lPV	*Vena pulmonară stângă*
	(B6) rPV	*Vena pulmonară dreaptă*
	(B7) LA	*Atriul stâng*
	(B8) RA	*Atriul drept*
	(B9) FOF	*Septum primum (valvula lui Vieussens sau foramen oval)*
	(B10) FO	*Foramen oval deschis*
	(B11) MV	*Valva mitrală*
	(B12) TV	*Valva tricuspidă*
	(B13) bCr	*Legătura dintre crux cordis și septul atrial (septul vestibular)*
	(B14) Cr	*Deplasarea valvei atrioventriculare în crux cordis*
	(B15) tCr	*Legătura dintre septul interventricular și crux cordis*
	(B16) IVS	*Septul interventricular*
	(B17) LV	*Ventriculul stâng*
	(B18) RV	*Ventriculul drept*
	(B19) Str	*Sternul*
 ***(C) LVOT*** ***Planul tractului de ejecție al ventriculului stâng*** ***(n = 6)***	*(C1) LA*	*Atriul stâng*
	(C2) aAo	*Aorta ascendentă proximală*
	(C3) SV	*Valvele semilunare*
	(C4) LV	*Ventriculul stâng*
	(C5) IVS	*Septul interventricular*
	(C6) RV	*Ventriculul drept*
	(D1) dAo	*Aorta descendentă*
	(D2) Tr	*Traheea/bronhiile*
	(D3) lPA	*Artera pulmonară stângă*

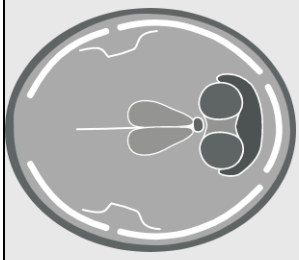
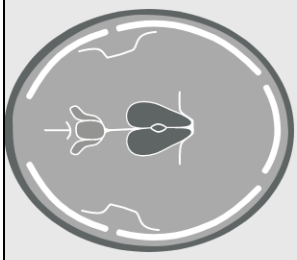
 ***(D) RVOT*** ***Planul tractului de ejecție al ventriculului drept*** ***(n = 10)***	*(D4) Du*	*Canalul arterial*
	(D5) rPA	*Artera pulmonară dreaptă*
	(D6) Or	*Originea arterelor pulmonare*
	(D7) S	*Septul dintre trunchiul arterei pulmonare și aorta ascendentă*
	(D8) aAo	*Aorta ascendentă*
	(D9) SVC	*Vena cavă superioară*
	(D10) PA	*Trunchiul pulmonar*
 ***(E) 3VX*** ***Planul de vizualizare a celor trei vase*** ***(n = 9)***	*(E1) Sp*	*Coloana vertebrală*
	(E2) Tr	*Traheea*
	(E3) ES	*Spațiul lateral din stânga canalului/arterei pulmonare*
	(E4) DuA	*Arcul ductal conectat la aorta descendentă*
	(E5) Du	*Arcul ductal neconectat la aorta descendentă*
	(E6) aAo	*Aorta ascendentă*
	(E7) aAr	*Arcul aortic*
	(E8) SVC	*Vena cavă superioară*
	(E9) Th	*Timusul/sternul*

*Orientările internaționale și naționale [Carvalho2023] recomandă 5 planuri de vizualizare cardiace fetale pentru examinarea ecografică de rutină în trimestrele 2 și 3 de sarcină: (A) planul abdominal, (B) planul de vizualizare a celor patru camere, (C) planul tractului de ejecție al ventriculului stâng, (D) planul tractului de ejecție al ventriculului drept, (E) planul de vizualizare a celor trei vase. Calitatea acestor 5 planuri de vizualizare cardiace depinde de prezența a 52 de criterii anatomice de calitate în cadrul planurilor (**Tabelul 1**). Astfel, o examinare poate fi definită ca fiind completă atunci când toate cele 5 planuri de vizualizare cardiace și criteriile de calitate ale acestora sunt obținute de către cadrele medicale.*

Pentru ecografia fetală cerebrală

Tabelul 9: Lista celor 34 de criterii de calitate care definesc calitatea celor 3 planuri de vizualizare recomandate de Societatea Internațională de Ultrasonografie în Obstetrică și Ginecologie (International Society of Ultrasound in Obstetrics and Gynecology – ISUOG) pentru screeningul cerebral fetal în trimestrele 2 și 3 de sarcină.

Planurile de vizualizare cerebrale	***Criteriile de calitate în cadrul planurilor de vizualizare***	
 ***(F) TV*** *Planul axial (n=18)*	*(F1) aFx*	*Falxul anterior*
	(F2) CSP	*Cavitatea septului pelucid*
	(F3) For	*Fornix*
	(F4) dAV	*Ventriculul anterior distal*
	(F5) pAV	*Ventriculul anterior proximal*
	(F6) AC	*Ambient Cisterna*
	(F7) Atr	*Atrium*
	(F8) CP	*Plexul coroid*

	(F9) POS	*Șanțul parietooccipital*
	(F10) pFx	*Falxul posterior*
	(F11) dCS	*Sutura coronară distală*
	(F12) pCS	*Sutura coronară proximală*
	(F13) SF	*Fisura silviană*
	(F14) Sk	*Craniul*
	(F15) Sep	*Despărțitura talamusului*
	(F16) 3V	*Ventriculul 3*
	(F17) dTh	*Talamusul distal*
	(F18) pTh	*Talamusul proximal*
 ***(G) TC*** ***Planul transcerebelos*** ***(n = 8)***	*(G1) dTh*	*Talamusul distal*
	(G2) pTh	*Talamusul proximal*
	(G3) 4V	*Ventriculul 4*
	(G4) Ver	*Vermisul*
	(G5) dCH	*Emisfera cerebeloasă distală*
	(G6) pCH	*Emisfera cerebeloasă proximală*
	(G7) CB	*Marginea cerebelului*
	(G8) CM	*Cisterna Magma*
 ***(H) TT*** ***Planul transtalamic*** ***(n = 12)***	*(H1) aFx*	*Falxul anterior*
	(H2) CSP	*Cavitatea septului pelucid*
	(H3) dAV	*Ventriculul anterior distal*
	(H4) pAV	*Ventriculul anterior proximal*
	(H5) dTh	*Talamusul distal*
	(H6) pTh	*Talamusul proximal*
	(H7) Sep	*Despărțitura talamusului*
	(H8) 3V	*Ventriculul 3*
	(H9) dCS	*Sutura coronară distală*
	(H10) pCS	*Sutura coronară proximală*
	(H11) SF	*Fisura silviană*
	(H12) Sk	*Craniul*
 ***(I) SAG*** ***Planul sagital/profil***	*(I1) NB*	*Osul nasului*
	(I2) uVer	*Partea superioară a vermisului*
	(I3) lVer	*Partea inferioară a vermisului*
	(I4) Fas	*Fastigium*
	(I5) rgCC	*Rostul și genunchiul corpului calos*
	(I6) bCC	*Trunchiul corpului calos*
	(I7) sCC	*Spleniul corpului calos*
	(I8) CSP	*Cavitatea septului pelucid*

(n = 8)		

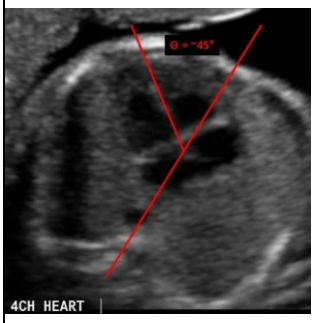
Măsurători biometrice și intervale de referință

FETOLY oferă trei tipuri de măsurători biometrice automate:

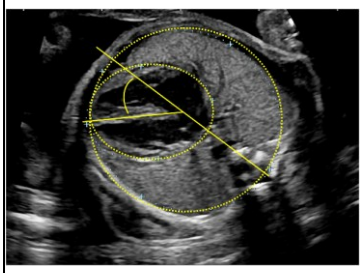
- **Măsurarea unghiului** afișată în grade (°);
- **Măsurarea raportului** (o distanță normalizată în raport cu o altă distanță, reprezentată fie ca raport, fie ca procent);
- **Numărul** de repere anatomice detectate;

Lista măsurătorilor și a intervalelor de referință ale acestora:

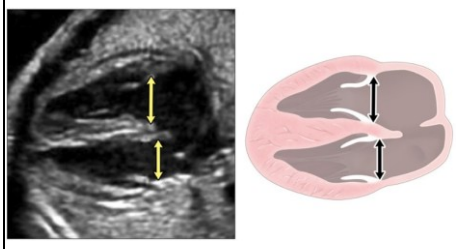
Tabelul de mai jos detaliază măsurătorile biometrice furnizate de FETOLY și intervalele normale de referință corespunzătoare ale acestora, bazate pe literatura de specialitate.

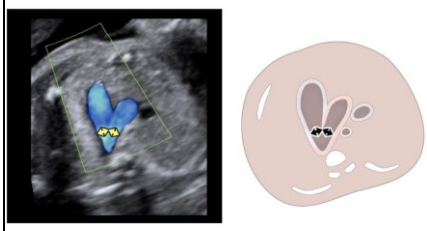
Parametru	*Informații accesibile în FETOLY (descriere și surse)*
(M1) Axa cardiacă	***Ce este axa cardiacă (CAx)?***  *(sursa: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* ***Axa cardiacă** (sau **unghiul cardiac**) se referă la orientarea cordului în raport cu linia mediană a toracelui, măsurată în planul de vizualizare a celor patru camere. Aceasta este determinată de unghiul dintre o linie de-a lungul septului interventricular și o linie anteroposterioară care intersectează toracele.* *Imaginea trebuie să includă coloana vertebrală, sternul și cele patru camere. Coasta stângă și coasta dreaptă trebuie să fie prezente și vizibile drept coaste individuale.* ***Ce recomandă orientările?*** *Orientările ISUOG indică faptul că examinarea cardiacă de screening trebuie să includă cele patru camere, iar evaluarea acesteia trebuie să includă axa cardiacă („Cordul fetal normal se află în principal în partea stângă, cu apexul cardiac îndreptat spre stânga la un unghi de 45±20° în raport cu axa anteroposterioră a toracelui”) (Carvalho2023). Acestea citează (Comstock1987), care indică intervalul de referință pentru axa cardiacă.* *Orientările ASE recomandă, de asemenea, evaluarea axei cardiace („Axa cardiacă este o componentă recomandată a ecocardiografiei fetale 2D [...] normal de 35-65°) (Moon-Grady2023).* ***Intervale de referință disponibile:***

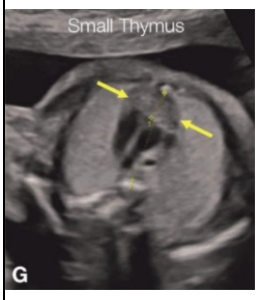
	• **Comstock (1987):** (medie ± 2 AS)
	  ○ 17-40GA: [25° - 65°].
	• **ASE (2023):** (interval de referință definit de orientări)
	  ○ 17-40GA: [35° - 65°]

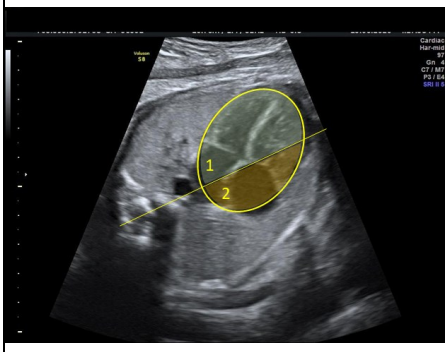
(M2) Raportul cardiotoracic	***Ce este raportul cardiotoracic?***
	 
	(sursa: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)
	Raportul cardiotoracic fetal (CTR) este raportul dintre circumferința transversală a suprafeței epicardice a cordului și circumferința transversală a toracelui, măsurat în planul de vizualizare a celor patru camere în timpul diastolei.
	Imaginea trebuie să includă coloana vertebrală, sternul și cele patru camere. Coasta stângă și coasta dreaptă trebuie să fie prezente și vizibile drept coaste individuale.
	Ce recomandă orientările?
	Orientările ASE indică faptul că raportul cardiotoracic este o componentă obligatorie a unei ecocardiografii fetale („Măsurători biometrice standard dintr-o imagine axială la nivelul planului de vizualizare a celor patru camere. Raportul cardiotoracic se calculează prin măsurarea circumferinței interioare (sau a zonei) a toracelui și a suprafeței epicardice a cordului") (Moon-Grady2023).
	Orientările AIUM indică, de asemenea, că raportul cardiotoracic este o biometrie cardiacă obligatorie (AIUM2019). Orientările ISUOG recomandă, de asemenea, această măsurătoare („Elementele cheie ale planului normal de vizualizare a celor patru camere la mijlocul trimestrului includ suprafața cordului care nu depășește o treime din suprafața toracelui") (Carvalho2013). Manualul elaborat de Abuhamad (2009) recomandă, de asemenea, evaluarea dimensiunilor cardiace („Dimensiunile cardiace fetale pot fi evaluate cu ușurință prin măsurarea raportului dintre circumferința sau suprafața cardiacă și circumferința sau suprafața toracică obținută la nivelul planului de vizualizare a celor patru camere) (Abuhamad2009). Orientările AHA (Donofrio2014) și manualul Abuhamad citează (Paladini1990) pentru intervalul de referință.
	Intervale de referință disponibile:
	• **Paladini (1990):** (percentilele 2,5 și 97 pentru circumferință)
	  ○ 17GA: [0,40 - 0,52]
	  ○ 18GA: [0,40 - 0,52]
	  ○ 19GA: [0,42 - 0,51]
	  ○ …
	  ○ 40GA: [0,46 - 0,56]

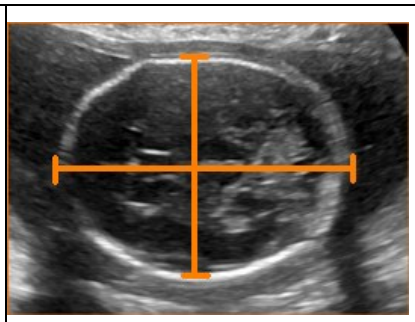
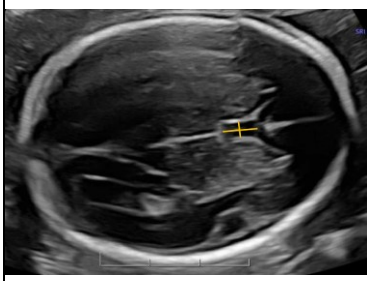
	• **Garcia-Otero (2020)**: (percentilele 5 și 95 pentru suprafață)
	  ○ 18GA: [0,16 - 0,25]
	  ○ 19GA: [0,16 - 0,26]
	  ○ …
	  ○ 40GA: [0,21 - 0,35]
	• **ASE** (Moon-Grady2023): (interval definit de orientări pentru scorul fetal optim pentru zonă)
	  ○ 17-40GA: [0,20 - 0,35]

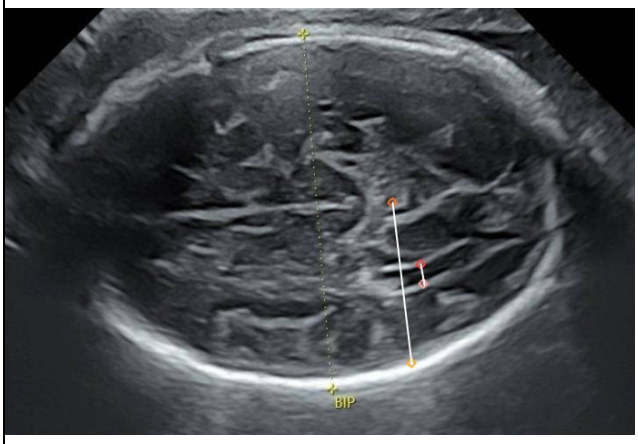
(M3) Raportul lățimii ventriculare	***Ce este raportul lățimii ventriculare dreapta/stânga?***  *(sursa: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Raportul **ventricul drept/ventricul stâng (TV/MV)** se referă la raportul dintre diametrul inelului valvei tricuspide (TV) și diametrul inelului valvei mitrale (MV), care este utilizat pentru evaluarea morfologiei cardiace la feți. Se determină prin compararea diametrelor TV și MV în punctele cele mai largi în timpul diastolei.* *Imaginea trebuie să includă coloana vertebrală și sternul. Coasta stângă și coasta dreaptă trebuie să fie prezente și vizibile drept coaste individuale. Planul de vizualizare a celor patru camere trebuie să fie vizibil, cu un contrast adecvat.* *Notă: există două convenții pentru măsurarea diametrului ventricular (Schneider2005): măsurarea la nivelul valvelor sau dimensiunea la sfârșitul diastolei. Vă rugăm să rețineți că pentru această măsurătoare se utilizează prima convenție.* ***Ce recomandă orientările?*** *Orientările AIUM indică faptul că compararea inelului valvei tricuspide și a inelului valvei mitrale în diastolă reprezintă o biometrie cardiacă obligatorie („Compararea inelului valvei tricuspide și a inelului valvei mitrale în diastolă ([...] compararea valvei drepte cu valva stângă) reprezintă o biometrie cardiacă obligatorie”) (AIUM2019). Acestea citează (DeVore2017), (Lee2009) și (Schneider2005) pentru intervalele de referință.* *Orientările ISUOG indică, de asemenea, că asimetria dreapta-stânga justifică o examinare suplimentară („Ambele ventricule ar trebui să aibă dimensiuni similare. Deși o disproporție ventriculară ușoară poate apărea ca o variantă normală în al treilea trimestru de sarcină, asimetria dreapta-stânga la mijlocul sarcinii justifică o examinare suplimentară”) (Carvalho2023). Acestea citează (Kirk1999) pentru intervalul de referință.* *Orientările ASE indică, de asemenea, că relația dintre dimensiunile ventriculelor este o evaluare obligatorie în cadrul ecocardiografiei fetale („Măsurarea inelului*

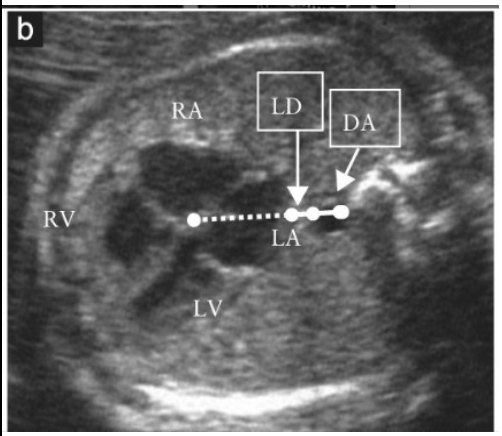
	valvei atrioventriculare la începutul diastolei este necesară ca parte a ecocardiografiei complete") (Moon-Grady2023). Manualul lui Abuhamed (2012) subliniază, de asemenea, relevanța raportului lățimii ventriculare dreapta/stânga, evaluat la 1,19 la fețiinormali. ***Intervale de referință disponibile:*** • **Gabbay-Benziv (2015)** (Gabbay-Benziv2015): (percentilele 2,5 și 97) o 17GA: [0,87 - 1,22] o 18GA: [0,86 - 1,22] o 19GA: [0,86 - 1,22] o … o 38GA: [0,87 - 1,30] • **Garcia-Otero (2020)**: (percentilele 5 și 95) o 18GA: [0,82 - 1,21] o 19GA: [0,82 - 1,22] o … o 40GA: [0,86 - 1,27]
(M4) Raportul vaselor mari	***Ce este raportul vaselor mari?***  *(sursa: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Raportul dimensiunii vaselor mari (Ao/Du) se referă la raportul dintre diametrul istmului aortic (Ao) și diametrul canalului arterial (Du) în planul de vizualizare a celor trei vase. Se determină prin măsurarea diametrului canalului și a arcului aortic la baza acestora. Rețineți că raportul dintre diametrul arterei pulmonare mediastinale (PA) și diametrul aortei ascendente (Ao) este, de asemenea, utilizat în literatura de specialitate (Slodki2009).* *Imaginea trebuie să includă coloana vertebrală și sternul, cu coastele stânga și dreapta vizibile și distincte. Canalul arterial și aorta ascendentă trebuie să fie clar vizibile, demonstrând legătura acestora.* ***Ce recomandă orientările?*** *Orientările americane și internaționale, inclusiv ASE, ISUOG, AIUM, AHA, indică faptul că evaluarea relației dimensiunilor vaselor mari este o evaluare obligatorie (Donofrio2014). („Este important să se stabilească normalitatea celor două vase mari, inclusiv dimensiunea acestora [...] una în raport cu cealaltă") (Carvalho2023). Manualul elaborat de Abuhamad (2012) subliniază, de asemenea, relevanța comparației dintre diametrul arcului aortic și diametrul arterei pulmonare principale, în special în regiunea istmului. Orientările citează studiul realizat de Pasquini (2007) (Pasquini2007) pentru intervalele de referință.* ***Intervale de referință disponibile:*** • **Pasquini (2007):**

	○ Constantă: [0,86 - 1,12] (medie ± AS) ○ Constantă: [0,74 - 1,23] (percentilele 2,5 și 97,5) (Buyens2012)
(M5) Numărul de vase	***Ce este numărul de vase?*** *Planul de vizualizare fetală a celor trei vase (3VV) este un plan axial utilizat în imagistica prenatală pentru a evalua vasele mari ale cordului. Acest plan de vizualizare prezintă, în general, trei vase, în mod normal artera pulmonară, aorta și vena cavă superioară. Numărarea vaselor se concentrează doar pe structurile anecoice rotunde sau alungite și exclude traheea și aorta descendentă.* *Imaginea trebuie să evidențieze vasele, cu un contrast și o distincție clară a structurilor.* ***Ce recomandă orientările?*** *Orientările ISUOG recomandă ca evaluarea planului de vizualizare a celor trei vase să „implice o evaluare a numărului de vase. De la stânga la dreapta, vasele sunt artera pulmonară, aorta și vena cavă superioară dreaptă" (Carvalho2023). Orientările ASE subliniază, de asemenea, că trebuie să se noteze anomaliile observate în ceea ce privește numărul de vase (Moon-Grady2023). Ca standard internațional, numărul preconizat de vase este de trei.*
(M6) Raportul timico-toracic	***Care este raportul timico-toracic?***  *(sursa: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (Ed. 4). Wolters Kluwer)* ***Raportul timico-toracic** este raportul dintre diametrul timic anteroposterior și diametrul mediastinal intratoracic, măsurat în planul de vizualizare a celor trei vase și a traheei.* *Imaginea trebuie să prezinte coloana vertebrală, sternul și aorta ascendentă, cu coastele din stânga și dreapta vizibile ca structuri distincte. Timusul trebuie să fie clar vizibil și identificabil.* ***Ce recomandă orientările?*** *Orientările ISUOG indică faptul că „[evaluarea planului de vizualizare a celor trei vase] implică o evaluare a alinierii vaselor". (Carvalho2023) și că aceasta „poate îmbunătăți detectarea anomaliilor [...] la nivelul tractului de ejecție". Acestea citează (Chaoui2011) pentru evaluarea raportului timico-toracic în vederea detectării anomaliilor la nivelul tractului de ejecție. Manualul elaborat de Abuhamad (2022) indică, de asemenea, importanța evaluării acestui parametru.* ***Intervale de referință disponibile:*** • **Chaoui (2011):** ○ Constantă pe parcursul sarcinii: [0,36 - 0,53] (medie ± 2 AS)

(M7) Poziția cardiotoracică	***Ce este poziția cardiotoracică?***  *(imagine inspirată de https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/)* ***Poziția cardiotoracică** este determinată prin prelungirea liniei septului interventricular care împarte posterior atriile până la un punct situat la baza cordului (Smith1995). Acest lucru se realizează pe planul de vizualizare a celor patru camere prin calcularea raportului dintre suprafața stângă și suprafața cardiacă totală. Acest proces implică desenarea unei elipse deasupra cordului și împărțirea acesteia cu o linie anteroposterioară care intersectează toracele (linia mediană a toracelui). Zona stângă (1) și zona dreaptă (2) reprezintă suprafețele cordului situate la stânga și la dreapta liniei mediane anatomice. Poziția este exprimată ca raport între suprafața stângă și suprafața cardiacă totală.* ***Ce recomandă orientările?*** *Poziția cordului fetal în cutia toracică este un parametru important în evaluarea fetală. Abaterea de la poziția normală justifică investigarea suplimentară a potențialelor afecțiuni patologice intratoracice, intracardiace sau extracardiace (Abdullah2000). Atât orientările americane, cât și cele internaționale, inclusiv ISUOG (2008), ASE (2004), AIUM (2013), AHA (2014), recomandă măsurarea atentă a poziției cordului fetal în cutia toracică pe planul de vizualizare a celor patru camere în timpul scanărilor obstetrice standard (Donofrio2014). Conform acestor orientări, cordul fetal normal este localizat în principal pe partea stângă a cutiei toracice, cu cel puțin 50% (raport ≥ 0,5) din suprafața acestuia în spațiul toracic stâng („cordul este situat în principal pe partea stângă”) (Carvalho2013) („trebuie să se acorde o atenție deosebită axei și poziției cardiace. Cea mai mare parte a cordului [ar trebui să fie] în partea stângă a cutiei toracice”) (Carvalho2023). Studiile coroborează aceste recomandări, Chiappa (2009) și alții (Smith1995, Sever2021) afirmând că „două treimi din cord [ar trebui să fie] în partea stângă a cutiei toracice”.* *Deși numeroase orientări definesc o poziție cardiotoracică normală ca fiind 0,66 (raport ≈ 2/3) și care nu ar trebui să scadă sub 0,5, literatura de specialitate nu definește în mod clar limita superioară a intervalului normal. Utilizatorii pot fie să vizualizeze doar valoarea de măsurare fără un interval de referință, fie să își definească propriul interval de referință.*
(M8) Indicele cefalic	***Ce este indicele cefalic?***

	 *(sursa: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* ***Indicele cefalic** este raportul dintre diametrul biparietal (BPD) și diametrul occipitofrontal (OFD) înmulțit cu 100. Indicele cefalic oferă o idee asupra formei capului fetal. Din față în spate, OFD se măsoară cu cursorul plasat pe marginea exterioară până la marginea exterioară a oaselor craniene. Un indice cefalic redus semnificativ sugerează dolicocefalie, în timp ce unul crescut semnificativ poate sugera brahicefalie. Atunci când acest parametru este anormal, ar trebui utilizate alte măsurători, cum ar fi HC, circumferința abdominală sau lungimea femurului, pentru a prezice vârsta fetală (Timor-Tritsch2012).* *Imaginea trebuie să prezinte un plan axial simetric al creierului, capturând planul transtalamic cu ambele emisfere vizibile și clare.* ***Ce recomandă orientările?*** *Orientările ISUOG indică faptul că „indicele cefalic este un raport între lățimea maximă a capului (BPD) și lungimea maximă a acestuia [diametrul occipitofrontal (OFD)], iar această valoare poate fi utilizată pentru a caracteriza forma capului fetal. Forma anormală a capului (de exemplu, brahicefalia sau dolicocefalia) poate fi asociată cu sindroame sau poate fi rezultatul oligohidramniosului sau al prezentării pelviene. Această constatare poate duce, de asemenea, la estimări inexacte ale vârstei fetale atunci când se utilizează BPD; în aceste cazuri, măsurătorile HC sunt și mai fiabile (Hadlock1981)" (Salomon2022).* ***Intervale de referință disponibile:*** • **Hadlock (1981):** o Constantă pe parcursul sarcinii: [74 - 83] (medie ± AS)
(M9) Raportul CSP	***Ce este raportul CSP?***  *(sursa: Sichitiu et al. (2024). Revizuirea implicațiilor unui cavum septi pellucidi fetal larg sau îngust. În Journal of Ultrasound in Medicine (Vol. 43, Numărul 8, pp. 1461–1466). Wiley)* ***Descriere: Raportul Cavum Septum Pellucidum (CSP)** este raportul dintre lungimea și lățimea CSP. Acesta se determină prin măsurarea lungimii și lățimii CSP și prin calcularea raportului lungime-lățime.*

	Imaginea trebuie să prezinte un plan de vizualizare transventricular axial simetric al creierului, cu o vizualizare clară a cavum septum pellucidum (CSP) și a structurilor anatomice mediane. ***Ce recomandă orientările?*** *Orientările ISUOG indică faptul că forma CSP a fost descrisă ca un marker relativ fiabil al agenezieiparțiale a corpului calos și citează studiile realizate de Karl (2017) și Shen (2015) pentru intervalele de referință (Malinger2020).* *Orientările Asociației Mondiale de Medicină Perinatală (WAPM) indică faptul că CSP trebuie vizualizat și că „nevizualizarea CSP sau aspectul anormal al acestuia (Karl2017) prognozează anomalii comisurale. Cu toate acestea, aspectul normal al CSP nu exclude toate anomaliile [corpului calos]” (Robertis2021).* *Acest parametru se regăsește și în tehnicile de ultimă generație de învățare profundă pentru biometria de rutină (Coronado-Gutiérrez2023).* ***Intervale de referință disponibile:*** • **Karl (2017):** *Constant pe toată durata sarcinii: [1,5 - 3,3] (percentilele 5 și 95)*
(M10) Raportul dintre diametrul ventriculului cerebral posterior și diametrul emisferei cerebrale	***Ce este raportul dintre diametrul ventriculului cerebral posterior și diametrul emisferei cerebrale?***  ***Raportul dintre diametrul ventriculului cerebral posterior și diametrul emisferei cerebrale** este un parametru utilizat pentru evaluarea dezvoltării creierului, în special a dimensiunii ventriculului în raport cu dimensiunea totală a creierului (emisfera cerebrală).* *Este raportul dintre:* - *Diametrul ventriculului cerebral posterior (= lățimea atrială) – referindu-se, de obicei, la atriul ventriculului lateral (situat la joncțiunea cornurilor occipitale, temporale și parietale).* - *Diametrul emisferei cerebrale – diametrul transversal total al emisferei cerebrale corespunzătoare.* *Această măsurătoare se realizează în plan transventricular.* ***Ce recomandă orientările?***

	Orientările ISUOG indică faptul că măsurarea lățimii atriale reprezintă o parte integrantă a screeningului ecografic pentru malformații ale SNC și că lățimea atrială trebuie măsurată de la interior la interior și trebuie să fie <10 mm pe toată durata sarcinii. *Literatura de specialitate (Nicolaides1994) subliniază rolul raportului dintre diametrul ventriculului cerebral posterior și diametrul emisferei cerebrale în îmbunătățirea evaluării cerebrale prenatale și a preciziei screeningului fetal, deoarece este un marker relativ fiabil al ventriculomegaliei.* ***Intervale de referință disponibile:*** • ***Nicolaides (1994):*** *(percentilele 5 și 95)* ○ *17VG: [0,29 - 0,45]* ○ *18VG: [0,27 - 0,42]* ○ *19VG: [0,26 - 0,40]* ○ *…* *39GVG: [0,15 - 0,24]*
(M11) Spațiul atrial stâng posterior (PLAS)	***Ce este indicele spațiului atrial stâng posterior (PLAS)?***  *(Sursă: Kawazu2014)* *Indicele spațiului atrial stâng posterior (PLAS) este o măsurătoare ecocardiografică fetală utilizată pentru a evalua spațiul posterior al atriului stâng. Acesta se calculează pe baza planului de vizualizare a celor patru camere ale inimii fetale. Măsurătoarea implică determinarea distanței dintre peretele posterior al atriului stâng și peretele anterior al aortei descendente (LD) și împărțirea acesteia la diametrul aortei descendente (DA). Calculul se efectuează în faza sistolică finală a ciclului cardiac.* *Formula pentru indicele PLAS este:* ***Indicele PLAS = Distanța dintre atriul stâng și aorta descendentă (LD) / Diametrul aortei descendente (DA)*** ***Ce recomandă orientările? (Justificare și semnificație clinică)***

	Literatura de specialitate (Kawazu2019, Anuwutnavin2023, Akkurt2015) a subliniat importanța indicelui PLAS ca măsurătoare simplă și reproductibilă în screeningul cardiac fetal. Introdus inițial de (Kawazu2014), indicele PLAS a fost identificat ca un marker sensibil pentru diagnosticul prenatal de retur venos total anormal (TAPVC), o afecțiune în care venele pulmonare nu se conectează la atriul stâng. Un indice PLAS crescut este un indicator semnificativ al TAPVC ***Intervale de referință disponibile:*** *Kawazu2014 și Kawazu2019: Constantă pe toată durata sarcinii: o valoare optimă de **> 1,27** pentru a sugera TAPVC. Pentru fetușii normali, indicele PLAS mediu a fost raportat ca fiind **0,62 ± 0,19.***

*Fiecare măsurătoare necesită un punct de vedere ecografic specific, denumit „**subsecțiune**”, care trebuie să îndeplinească condiții specifice de imagine pentru a asigura o măsurătoare precisă. O subsecțiune este întotdeauna derivată din unul dintre planurile de vizualizare fetale de screening standard, dar necesită și condiții speciale suplimentare. De exemplu, măsurarea raportului ventricular dreapta-stânga pe planul de vizualizare a celor patru camere necesită vizualizarea corectă a marginilor ventriculare, ceea ce nu este necesar pentru axa cardiacă.*

Tabelul de mai jos ilustrează corespondența dintre subsecțiuni și planurile de vizualizare cardiace sau cerebrale descrise în orientările ISUOG.

Plan de vizualizare	***Subsecțiune***
Planul de vizualizare a celor patru camere	***Subsecțiunea 1 (M1):** imaginea trebuie să includă coloana vertebrală, sternul, cele patru camere și septul interventricular. Coasta stângă și coasta dreaptă trebuie să fie prezente și vizibile drept coaste individuale.* ***Subsecțiunea 2 (M2):** Imaginea trebuie să includă coloana vertebrală, sternul și cele patru camere. Coasta stângă și coasta dreaptă trebuie să fie prezente și vizibile drept coaste individuale.* ***Subsecțiunea 3 (M3):** Imaginea trebuie să includă coloana vertebrală și sternul. Coasta stângă și coasta dreaptă trebuie să fie prezente și vizibile drept coaste individuale. Planul de vizualizare a celor patru camere trebuie să fie vizibil, cu un contrast adecvat.* ***Subsecțiunea 7 (M7):** Imaginea trebuie să includă coloana vertebrală, sternul și cele patru camere.* ***Subsecțiunea 11 (M11):** Toracele are un aspect rotund, nu în formă de „V” deschis. Coastele stângi și drepte apar ca structuri unice, nu ca linii multiple paralele sau secvențiale. Atriul și aorta, în special pereții posteriori ai acestora, precum și spațiul dintre acestea, sunt clar vizibile, fără obstrucții ale umbrelor.*

Planul de vizualizare a celor trei vase și planul de vizualizare a celor trei vase și al traheei	***Subsecțiunea 4 (M4):*** *Imaginea trebuie să includă coloana vertebrală și sternul, cu coastele stânga și dreapta vizibile și distincte. Canalul arterial și aorta ascendentă trebuie să fie clar vizibile, demonstrând legătura acestora.* ***Subsecțiunea 5 (M5):*** *Imaginea trebuie să evidențieze vasele, cu un contrast și o distincție clară a structurilor.* ***Subsecțiunea 6 (M6):*** *Imaginea trebuie să prezinte coloana vertebrală, sternul și aorta ascendentă, cu coastele din stânga și dreapta vizibile ca structuri distincte. Timusul trebuie să fie clar vizibil și identificabil.*
Planul axial	***Subsecțiunea 8 (M8):*** *Imaginea trebuie să prezinte un plan axial simetric al creierului, capturând planul transtalamic cu ambele emisfere vizibile și clare.* ***Subsecțiunea 9 (M9):*** *Imaginea trebuie să prezinte un plan transventricular axial simetric al creierului, cu o vizualizare clară a cavum septum pellucidum (CSP) și a structurilor anatomice mediane.* ***Subsecțiunea 10 (M10):*** *Imaginea trebuie să prezinte un plan axial în care POS (șanțul parietooccipital) este vizibil.*

Funcționalitatea 1: completitudinea

Software-ul evaluează, prin intermediul unui algoritm de învățare aprofundată care a fost antrenat prin învățare supravegheată, completitudinea ecografiei fetale. Acesta verifică dacă au fost obținute toate informațiile corespunzătoare orientărilor recomandate pentru examinarea cordului/creierului fetal. Aceste informații corespund prezenței:

- unui număr de 5 planuri de vizualizare cardiace fetale principale și a unui număr de 52 de criterii de calitate, detaliate anterior, care permit asigurarea conformității în screeningul cardiac;
- unui număr de 4 planuri de vizualizare cerebrale fetale principale și a unui număr de 43 de criterii de calitate, detaliate anterior, care permit asigurarea conformității în screeningul cerebral.

Pagina de completitudine (**Figura 1**) include:

- Un **buton de redare/pauză** care inițiază analiza imaginilor obținute de sistemul ecografic la începutul examinării;
- **Numărul de planuri de vizualizare cardiace/cerebrale** verificate de software de la începutul examinării. Un plan de vizualizare cardiac este considerat verificat atunci când este detectat în cel puțin o imagine;
- Butoane individuale pentru **fiecare dintre criteriile de calitate**, care devin **verzi** după verificarea de către software.

Fiecare imagine analizată de software actualizează dinamic pagina de completitudine după cum urmează:

- Dacă un criteriu de calitate este detectat pentru prima dată în imagine, criteriul este marcat ca fiind **verificat**, iar culoarea acestuia se schimbă de la alb la **verde**);
- Dacă un criteriu de calitate este detectat în imagine, dar a fost verificat anterior, nu are loc nicio modificare;

- Dacă un criteriu de calitate nu este detectat pe imagine, nu are loc nicio modificare.

Dacă un criteriu de calitate este asociat cu o anomalie, starea de detectare a criteriului depinde de aspectul vizual al acestuia:

- Dacă o anomalie modifică un criteriu de calitate în așa fel încât îi schimbă aspectul, este posibil ca software-ul să nu detecteze criteriul, iar starea să rămână neverificată;
- Dacă o anomalie nu afectează aspectul criteriului de calitate, software-ul va detecta criteriul și îl va marca drept verificat, schimbându-i culoarea din alb în **verde**.

Vă rugăm să rețineți că pe etichetă se reamintește faptul că FETOLY nu poate fi utilizat pentru diagnosticare sau screening. Un criteriu de calitate care nu este verificat de software nu indică în mod intrinsec o patologie.

Pagina de completitudine este actualizată permanent în timp real, permițându-le utilizatorilor să o consulte în orice moment în timpul examinării. Acest lucru le permite acestora să arunce o privire asupra paginii fără a întrerupe fluxul de lucru al examinării sau fără a necesita acțiuni suplimentare.

Ca o reamintire și așa cum se explică în secțiunea 10, FETOLY nu poate fi utilizat pentru diagnosticare sau screening. Un criteriu de calitate care nu este verificat de software nu indică în mod intrinsec o patologie.

Funcționalitatea 2: ilustrarea completitudinii

Această funcționalitate a fost dezvoltată pentru a spori securitatea evaluării completitudinii care este efectuată de primul modul. Acesta permite medicilor să consulte, prin intermediul paginii Gallery (Galerie) a interfeței software-ului, o prezentare generală a completitudinii examinării și anume, planurile de vizualizare și criteriile de calitate verificate de software. Funcționând continuu, acesta evaluează în timp real fiecare imagine prelucrată de primul modul, păstrând un set de imagini ca dovadă vizuală a planurilor de vizualizare cardiace/toracice și a criteriilor de calitate verificate până la momentul respectiv.

FETOLY nu are ca obiectiv selectarea celei mai „bune” imagini sau a imaginii de „înaltă” calitate diagnostică în funcție de o anumită scară calitativă. Mai degrabă, FETOLY urmărește să selecteze imagini care ilustrează completitudinea cantitativă a examinării în ceea ce privește planurile de vizualizare și criteriile de calitate verificate. Deoarece acest modul se bazează în întregime pe performanța algoritmului de învățare aprofundată al primului modul, nu este necesară nicio evaluare suplimentară a performanței.

De exemplu, dacă utilizatorul are îndoieli cu privire la unul dintre criteriile de calitate de culoare verde, poate verifica prezența criteriului făcând clic pe acesta în pagina Gallery (Galerie). Software-ul va afișa imaginile care conțin acest criteriu (în galben în figura de mai jos). Atunci când se selectează un criteriu, software-ul afișează caseta de delimitare care încadrează criteriul în aceste imagini. Aceste informații din caseta de delimitare fac parte din rezultatul Fetoly-CNN.

Funcționalitatea 3: măsurătorile biometrice

Secțiunea modulului **FETOLY-MEASURE** este etichetată cu „Measure” (Măsurătoare) pe pagina de analiză și afișează o listă de măsurători, fiecare organizată în patru câmpuri:

- **Denumirea măsurătorii**: afișează numele sau abrevierea măsurătorii împreună cu o pictogramă de informare. Făcând clic pe pictogramă, se deschid informații detaliate despre măsurătoare, inclusiv referința științifică a acesteia.

- **Valoarea și unitățile de măsură**: valoarea măsurată este afișată împreună cu unitățile aferente. De exemplu, un simbol de grad (°) este afișat pentru măsurătorile unghiulare, un simbol de procent (%) pentru raporturi; în caz contrar, câmpul rămâne gol, ceea ce înseamnă că este vorba de o măsurătoare relativă. Dacă punctele cheie au fost editate în pagina Gallery (Galerie), în fața măsurătorii apare un simbol ( ).
- **Interval de referință**: acest câmp furnizează intervalul de referință definit în literatura de specialitate pentru măsurătoare, susținut de referința științifică a acestuia. Sursa poate fi o orientare, o publicație evaluată inter pares, un manual sau un interval personalizat definit de utilizator. Făcând clic pe **butonul New Tab** (Filă nouă), utilizatorul poate defini manual intervalul de referință sau poate actualiza referința din literatura de specialitate, dacă sunt disponibile mai multe. Făcând clic pe **butonul Information Link** (Link de informare), utilizatorul poate accesa o fereastră pop-up cu toate informațiile necesare referitoare la criteriul de măsurare dat.
- **Vârsta gestațională,** care va fi stabilită înainte de lansarea analizei.

Funcționalitatea 4: ilustrarea măsurătorilor

La fel ca în cazul ilustrării completitudinii, care selectează imagini care demonstrează planurile de vizualizare și criteriile de calitate, aceasta selectează automat o imagine pentru fiecare măsurătoare. Ambele seturi de imagini sunt afișate împreună pe pagina Gallery (Galerie). Aceste două seturi de imagini sunt ușor de distins: imaginile generate de funcția de măsurare includ o valoare de măsurare și numele parametrului, în timp ce imaginile de completitudine nu au adnotări.

Atât imaginile de „măsurare”, cât și cele de „completitudine” sunt organizate pe baza planurilor de vizualizare ecografice corespunzătoare. Vă rugăm să rețineți că afilierea cu planurile a imaginilor selectate de funcția de măsurare este independentă de funcția de completitudine. Într-adevăr, fiecare subsecțiune de măsurare corespunde prin definiție unuia dintre cele 5 planuri ecografice cardiace sau unuia dintre cele 4 planuri ecografice cerebrale. Prin urmare, prin cunoașterea subsecțiunii, imaginile selectate de funcția de măsurare pot fi categorisite automat în planul de vizualizare corespunzător căruia îi aparține subsecțiunea respectivă.

Funcționalitatea 5: raportul de examinare

Un raport poate fi generat de pe pagina de export. Acesta va include rezultate și imagini generate de FETOLY și va fi trimis către un dispozitiv extern.

Dispozitive asociate

Pentru a utiliza dispozitivul FETOLY, trebuie să aveți următoarele dispozitive asociate:

- Un ecograf.
- O tabletă și, opțional, un server DICOM, un computer cu un server FTP sau capabilități Bluetooth, așa cum se specifică în secțiunea 10 „Interacțiunea cu alte echipamente”.
- Un dongle UVC și un cablu HDMI pentru a conecta tableta la ecograf.

5. Utilizarea prevăzută și indicații de utilizare

FETOLY este destinat să analizeze secvențele de imagini ecografice fetale utilizând tehnici de învățare automată pentru:

- detectarea automată a planurilor de vizualizare cerebrale și cardiace și a criteriilor de calitate din cadrul planurilor;

- detectarea automată a imaginilor adecvate pentru măsurarea parametrilor biometrici ai cordului și creierului fetal și pentru a furniza măsurători cantitative ale acestor parametri.

Dispozitivul este destinat utilizării ca ajutor pentru citirea concomitentă în timpul achiziționării și interpretării imaginilor ecografice fetale.

FETOLY este indicat pentru utilizare în timpul examinării de rutină a cordului și creierului fetal în trimestrul 2 și 3 de sarcină (vârsta gestațională: de la 17 la 40 de săptămâni).

6. Utilizatori vizați

Produsul trebuie utilizat de cadre medicale calificate, specializate în imagistica ecografică prenatală.

7. Populația de pacienți vizată

Femeile gravide în timpul trimestrelor 2 și 3 de sarcină.

8. Beneficii și performanțe clinice

Pentru acest tip de dispozitiv, un software pentru dispozitive medicale, care este un instrument de asistență la citire utilizat în timpul ecografiei cardiace/cerebrale fetale de rutină, s-a demonstrat următorul beneficiu clinic:

- Standardizarea ecografiei cardiace/cerebrale fetale de rutină, în conformitate cu orientările internaționale recunoscute

Rezultatele legate de performanță sunt detaliate în tabelele de mai jos. Rezultatele testelor de performanță independente demonstrează că FETOLY:

- detectează planurile ecografice cardiace și cerebrale fetale cu o sensibilitate ≥ 85% (criteriu de acceptare) și o specificitate ≥ 85% (criteriu de acceptare);
- detectează criteriile de calitate în cadrul planurilor de vizualizare cardiace cu o sensibilitate ≥ 90% (criteriu de acceptare) și o specificitate ≥ 90% (criteriu de acceptare);
- detectează criteriile de calitate în cadrul planurilor de vizualizare cerebrale cu o sensibilitate ≥ 85% (criteriu de acceptare) și o specificitate ≥ 85% (criteriu de acceptare);
- localizează casete de delimitare a criteriilor de calitate cu o intersecție medie peste uniune (IoU) ≥ 50% (criteriu de acceptare);
- detectează subsecțiunile ecografice ale cordului și creierului fetal cu o sensibilitate ≥ 70% (criteriu de acceptare) și o specificitate ≥ 70% (criteriu de acceptare); și
- realizează măsurători ale cordului și creierului fetal în conformitate cu limitele de acord (LOA) definite pentru fiecare criteriu final de evaluare al studiului.

Pentru rezultate generale

Plan de vizualizare fetal	***Sensibilitate***			***Specificitate***		
	N(pozitiv)	***Estimare punctuală***	***IÎ Bootstrap (95%)***	***N(negativ)***	***Estimare punctuală***	***IÎ Bootstrap (95%)***
Planul abdominal	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)

Planul de vizualizare a celor patru camere	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Planul tractului de ejecție al ventriculului stâng	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Planul tractului de ejecție al ventriculului drept	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Planul de vizualizare a celor trei vase	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Planul axial	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Planul transcerebelos	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Planul sagital/profil	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Alt plan de vizualizare	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Criterii de calitate	***Sensibilitate***			***Specificitate***			***mIoU***	
	N	***Estimare punctuală***	***IÎ Bootstrap (95%)***	***N***	***Estimare punctuală***	***IÎ Bootstrap (95%)***	***Estimare punctuală***	***IÎ Bootstrap (95%)***
Planul abdominal								
Coloana vertebrală	*678*	*0.99*	*(0.983,0.998)*	*4531*	*0.998*	*(0.996,0.999)*	*0.71*	*(0.70,0.73)*
Coasta stângă	*632*	*0.967*	*(0.953,0.980)*	*4577*	*0.993*	*(0.991,0.995)*	*0.58*	*(0.56,0.59)*
Coasta dreaptă	*627*	*0.951*	*(0.934,0.967)*	*4582*	*0.994*	*(0.992,0.996)*	*0.55*	*(0.53,0.57)*
Aorta descendentă	*673*	*0.972*	*(0.959,0.984)*	*4536*	*0.998*	*(0.996,0.999)*	*0.52*	*(0.51,0.54)*
Vena cavă inferioară	*550*	*0.939*	*(0.917,0.958)*	*4659*	*0.987*	*(0.983,0.990)*	*0.5*	*(0.49,0.52)*
Stomac	*675*	*0.983*	*(0.973,0.992)*	*4534*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.75)*
Vena ombilicală	*552*	*0.973*	*(0.958,0.986)*	*4657*	*0.99*	*(0.988,0.993)*	*0.64*	*(0.62,0.65)*
Regiunea abdominală anterioară	*643*	*0.969*	*(0.954,0.983)*	*4566*	*0.993*	*(0.990,0.995)*	*0.5*	*(0.49,0.52)*
Planul de vizualizare a celor patru camere								
Coloana vertebrală	*595*	*0.969*	*(0.955,0.982)*	*4614*	*0.998*	*(0.996,0.999)*	*0.74*	*(0.73,0.75)*
Coasta stângă	*536*	*0.945*	*(0.924,0.963)*	*4673*	*0.99*	*(0.987,0.993)*	*0.64*	*(0.63,0.66)*
Coasta dreaptă	*548*	*0.948*	*(0.926,0.965)*	*4661*	*0.993*	*(0.991,0.996)*	*0.68*	*(0.66,0.69)*
Aorta descendentă	*608*	*0.968*	*(0.952,0.981)*	*4601*	*0.997*	*(0.995,0.998)*	*0.66*	*(0.65,0.67)*
Vena pulmonară stângă	*240*	*0.925*	*(0.889,0.958)*	*4969*	*0.975*	*(0.971,0.979)*	*0.51*	*(0.48,0.53)*
Vena pulmonară dreaptă	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*

Atriul stâng	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Atriul drept	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Septum primum (valvula lui Vieussens sau foramen oval)	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Foramen oval deschis	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Valva mitrală	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Valva tricuspidă	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Legătura dintre crux cordis și septul atrial (septul vestibular)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Deplasarea valvei atrioventriculare în crux cordis	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Legătura dintre septul interventricular și crux cordis	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Septul interventricular	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Ventriculul stâng	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Ventriculul drept	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Sternul	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Planul tractului de ejecție al ventriculului stâng								
Atriul stâng	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Aorta ascendentă proximală	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Valvele semilunare	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Ventriculul stâng	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Septul interventricular	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Ventriculul drept	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Planul tractului de ejecție al ventriculului drept								
Aorta descendentă	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Traheea/bronhiile	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Artera pulmonară stângă	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*

Canalul arterial	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Artera pulmonară dreaptă	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Originea arterelor pulmonare	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Septul dintre trunchiul arterei pulmonare și aorta ascendentă	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Aorta ascendentă	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Vena cavă superioară	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Trunchiul pulmonar	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Planurile de vizualizare ale celor trei vase								
Coloana vertebrală	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Traheea	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Spațiul lateral din stânga canalului/arterei pulmonare	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Arcul ductal conectat la aorta descendentă	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Arcul ductal neconectat la aorta descendentă	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Aorta ascendentă	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Arcul aortic	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Vena cavă superioară	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Timusul/sternul	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Planul axial								
Falxul anterior	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavitatea septului pelucid	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Fornix	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Ventriculul anterior distal	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Ventriculul anterior proximal	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*

Ambient Cisterna	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Atrium	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Plexul coroid	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Șanțul parietooccipital	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Falxul posterior	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Sutura coronară distală	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Sutura coronară proximală	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Fisura silviană	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Craniul	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Despărțitura talamusului	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
Ventriculul 3	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Talamusul distal	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Talamusul proximal	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Planul transcerebelos								
Talamusul distal	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Talamusul proximal	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
Ventriculul 4	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Vermisul	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Emisfera cerebeloasă distală	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Emisfera cerebeloasă proximală	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Marginea cerebelului	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Cisterna Magma	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Planul sagital/profil								
Osul nasului	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Partea superioară a vermisului	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Partea inferioară a vermisului	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastigium	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*

Rostul și genunchiul corpului calos	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Trunchiul corpului calos	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Spleniul corpului calos	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavitatea septului pelucid	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Măsurătoare	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp	LOA	IÎ LOA
raport_timico-toracic	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
raport_cardiotoracic	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
raport_vase	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
indice_cefalic	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
număr_vase	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
poziție_cardiotoracică	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
raport_ventricular_dreapta-stânga	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
unghi_cardiac	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
raport CSP	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
raport VP	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
spațiu atrial stâng posterior	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Măsurătoare	înclinare	interceptare	IÎ înclinare	IÎ interceptare
raport_timico-toracic	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
raport_cardiotoracic	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
raport_vase	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
indice_cefalic	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
număr_vase	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
poziție_cardiotoracică	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
raport_ventricular_dreapta-stânga	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
unghi_cardiac	*0.9197936528230518*	*3.114077691538199*	*(0.888,0.945)*	*(2.023,4.477)*
raport CSP	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
raport VP	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
spațiu atrial stâng posterior	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Pentru rezultatele producătorului sistemului ecografic

Clasa	Sistem	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)

A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
I	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)
I	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)
X	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
X	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
X	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)

Clasa	Sistem	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp	mIoU	IÎ mIoU
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Sam-sung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Sam-sung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*

A.lRb	Sam-sung	280	0.947	(0.919,0.971)	1724	0.995	(0.991,0.998)	0.58	(0.55,0.60)
A.rRb	Canon	28	0.893	(0.759,1.000)	208	1.0	(1.000,1.000)	0.54	(0.45,0.63)
A.rRb	GE	267	0.974	(0.954,0.993)	2273	0.996	(0.993,0.998)	0.58	(0.55,0.61)
A.rRb	Sam-sung	269	0.922	(0.889,0.953)	1735	0.994	(0.990,0.998)	0.53	(0.51,0.56)
A.Sp	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)	0.63	(0.56,0.71)
A.Sp	GE	276	0.997	(0.989,1.000)	2264	0.997	(0.994,0.999)	0.75	(0.74,0.77)
A.Sp	Sam-sung	296	0.984	(0.967,0.994)	1708	0.999	(0.997,1.000)	0.7	(0.68,0.71)
A.St	Canon	29	0.966	(0.893,1.000)	207	0.991	(0.975,1.000)	0.72	(0.67,0.76)
A.St	GE	279	0.993	(0.983,1.000)	2261	1.0	(1.000,1.000)	0.79	(0.77,0.80)
A.St	Sam-sung	293	0.973	(0.954,0.990)	1711	0.998	(0.996,1.000)	0.7	(0.68,0.72)
A.Uv	Canon	25	0.96	(0.870,1.000)	211	0.986	(0.969,1.000)	0.6	(0.51,0.67)
A.Uv	GE	217	0.977	(0.955,0.996)	2323	0.991	(0.988,0.995)	0.67	(0.65,0.70)
A.Uv	Sam-sung	240	0.967	(0.944,0.988)	1764	0.989	(0.984,0.993)	0.62	(0.59,0.64)
A.VC	Canon	26	0.885	(0.750,1.000)	210	0.986	(0.970,1.000)	0.46	(0.40,0.52)
A.VC	GE	221	0.973	(0.950,0.992)	2319	0.987	(0.983,0.991)	0.54	(0.52,0.57)
A.VC	Sam-sung	247	0.903	(0.864,0.939)	1757	0.989	(0.984,0.994)	0.49	(0.47,0.51)
B.Ao	Canon	27	0.926	(0.808,1.000)	209	0.996	(0.985,1.000)	0.71	(0.66,0.77)
B.Ao	GE	247	0.956	(0.926,0.980)	2293	0.997	(0.994,0.999)	0.73	(0.71,0.75)
B.Ao	Sam-sung	255	0.977	(0.956,0.993)	1749	0.999	(0.998,1.000)	0.6	(0.58,0.62)
B.bCr	Canon	25	0.92	(0.800,1.000)	211	0.986	(0.969,1.000)	0.65	(0.58,0.72)
B.bCr	GE	202	0.892	(0.849,0.932)	2338	0.992	(0.989,0.996)	0.61	(0.57,0.64)
B.bCr	Sam-sung	216	0.926	(0.889,0.959)	1788	0.984	(0.979,0.989)	0.54	(0.52,0.57)
B.Cr	Canon	7	0.715	(0.334,1.000)	229	0.983	(0.967,0.996)	0.62	(nan,nan)
B.Cr	GE	52	0.885	(0.789,0.961)	2488	0.989	(0.985,0.993)	0.52	(0.46,0.58)
B.Cr	Sam-sung	76	0.974	(0.933,1.000)	1928	0.977	(0.971,0.983)	0.57	(0.52,0.61)
B.FO	Canon	26	0.962	(0.880,1.000)	210	1.0	(1.000,1.000)	0.7	(0.62,0.78)
B.FO	GE	215	0.935	(0.899,0.965)	2325	0.994	(0.991,0.997)	0.64	(0.62,0.67)
B.FO	Sam-sung	257	0.965	(0.941,0.985)	1747	0.994	(0.991,0.998)	0.58	(0.55,0.60)
B.FOF	Canon	8	0.75	(0.375,1.000)	228	1.0	(1.000,1.000)	0.56	(0.42,0.67)
B.FOF	GE	108	0.899	(0.841,0.949)	2432	0.998	(0.996,1.000)	0.5	(0.47,0.53)
B.FOF	Sam-sung	63	0.921	(0.845,0.984)	1941	0.993	(0.989,0.996)	0.51	(0.47,0.55)

B.IVS	Canon	15	0.934	(0.770,1.000)	221	0.982	(0.965,0.996)	0.65	(0.53,0.75)
B.IVS	GE	165	0.867	(0.806,0.915)	2375	0.992	(0.988,0.995)	0.62	(0.59,0.66)
B.IVS	Sam-sung	152	0.922	(0.872,0.962)	1852	0.984	(0.978,0.989)	0.64	(0.61,0.67)
B.LA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.75	(0.71,0.79)
B.LA	GE	264	0.966	(0.942,0.986)	2276	0.999	(0.997,1.000)	0.79	(0.78,0.81)
B.LA	Sam-sung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Sam-sung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Sam-sung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Sam-sung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Sam-sung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Sam-sung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Sam-sung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Sam-sung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Sam-sung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)

B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)
B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)

D.aAo	Sam-sung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Sam-sung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Sam-sung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Sam-sung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Sam-sung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Sam-sung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)
D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Sam-sung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Sam-sung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Sam-sung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Sam-sung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Sam-sung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)

E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Sam-sung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Sam-sung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Sam-sung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Sam-sung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Sam-sung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Sam-sung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Sam-sung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Sam-sung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Sam-sung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Sam-sung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)

F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)
F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)

F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Sam-sung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Sam-sung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Sam-sung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Sam-sung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Sam-sung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)
G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Sam-sung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Sam-sung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Sam-sung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Sam-sung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Sam-sung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)

G.pCH	Sam-sung	182	0.94	(0.905,0.973)	1822	0.999	(0.998,1.000)	0.74	(0.72,0.77)
G.pTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.58	(0.51,0.65)
G.pTh	GE	216	0.922	(0.884,0.954)	2324	0.995	(0.992,0.998)	0.62	(0.60,0.64)
G.pTh	Sam-sung	119	0.95	(0.905,0.984)	1885	0.998	(0.996,1.000)	0.59	(0.57,0.62)
G.Ver	Canon	23	0.914	(0.783,1.000)	213	1.0	(1.000,1.000)	0.62	(0.54,0.70)
G.Ver	GE	288	0.893	(0.859,0.928)	2252	0.996	(0.993,0.999)	0.61	(0.59,0.63)
G.Ver	Sam-sung	138	0.892	(0.840,0.942)	1866	0.997	(0.994,0.999)	0.52	(0.49,0.55)
I.bCC	Canon	15	1.0	(1.000,1.000)	221	0.987	(0.971,1.000)	0.59	(0.51,0.67)
I.bCC	GE	168	0.923	(0.878,0.962)	2372	0.995	(0.993,0.998)	0.57	(0.54,0.60)
I.bCC	Sam-sung	54	0.815	(0.699,0.910)	1950	0.996	(0.994,0.999)	0.57	(0.52,0.62)
I.CSP	Canon	20	0.95	(0.824,1.000)	216	1.0	(1.000,1.000)	0.75	(0.69,0.81)
I.CSP	GE	196	0.888	(0.841,0.928)	2344	1.0	(0.999,1.000)	0.72	(0.69,0.74)
I.CSP	Sam-sung	79	0.849	(0.760,0.924)	1925	1.0	(1.000,1.000)	0.7	(0.66,0.75)
I.Fas	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.63	(0.46,0.79)
I.Fas	GE	99	0.889	(0.819,0.951)	2441	1.0	(0.999,1.000)	0.56	(0.52,0.60)
I.Fas	Sam-sung	33	0.97	(0.900,1.000)	1971	0.999	(0.997,1.000)	0.55	(0.49,0.61)
I.lVer	Canon	14	0.929	(0.750,1.000)	222	1.0	(1.000,1.000)	0.69	(0.60,0.77)
I.lVer	GE	102	0.912	(0.850,0.960)	2438	0.999	(0.998,1.000)	0.7	(0.66,0.73)
I.lVer	Sam-sung	41	0.927	(0.834,1.000)	1963	1.0	(0.999,1.000)	0.64	(0.59,0.69)
I.NB	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.71	(0.61,0.82)
I.NB	GE	115	0.905	(0.844,0.955)	2425	0.992	(0.989,0.996)	0.63	(0.59,0.67)
I.NB	Sam-sung	60	0.917	(0.837,0.982)	1944	0.998	(0.996,1.000)	0.64	(0.58,0.69)
I.rgCC	Canon	18	0.945	(0.824,1.000)	218	0.991	(0.978,1.000)	0.48	(0.41,0.56)
I.rgCC	GE	177	0.888	(0.833,0.930)	2363	0.998	(0.996,1.000)	0.56	(0.54,0.59)
I.rgCC	Sam-sung	65	0.893	(0.808,0.965)	1939	1.0	(0.999,1.000)	0.48	(0.43,0.53)
I.sCC	Canon	13	0.847	(0.616,1.000)	223	0.992	(0.978,1.000)	0.48	(0.36,0.61)
I.sCC	GE	114	0.922	(0.868,0.964)	2426	0.992	(0.988,0.995)	0.51	(0.48,0.54)
I.sCC	Sam-sung	40	0.9	(0.796,1.000)	1964	0.998	(0.996,1.000)	0.45	(0.39,0.53)
I.uVer	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.57	(0.49,0.65)
I.uVer	GE	116	0.88	(0.815,0.931)	2424	0.999	(0.998,1.000)	0.6	(0.56,0.63)
I.uVer	Sam-sung	48	0.938	(0.861,1.000)	1956	0.999	(0.998,1.000)	0.52	(0.48,0.56)

Clasa	Sistem	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp	LOA	IÎ LOA
unghi_cardiac	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
unghi_cardiac	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
unghi_cardiac	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
poziție_cardiotoracică	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
poziție_cardiotoracică	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
poziție_cardiotoracică	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*
raport_cardiotoracic	Canon	*23*	*1.0*	*(1.000,1.000)*	*37*	*0.946*	*(0.865,1.000)*	*0.078*	*(0.041,0.117)*
raport_cardiotoracic	GE	*225*	*0.969*	*(0.944,0.991)*	*262*	*0.908*	*(0.874,0.943)*	*0.059*	*(0.049,0.073)*
raport_cardiotoracic	Samsung	*105*	*0.952*	*(0.909,0.989)*	*232*	*0.776*	*(0.724,0.828)*	*0.051*	*(0.042,0.061)*
indice_cefalic	Canon	*28*	*0.929*	*(0.821,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.026*	*(0.021,0.032)*
indice_cefalic	GE	*195*	*0.944*	*(0.909,0.974)*	*262*	*0.943*	*(0.916,0.969)*	*0.03*	*(0.026,0.036)*
indice_cefalic	Samsung	*90*	*0.989*	*(0.964,1.000)*	*232*	*0.909*	*(0.871,0.944)*	*0.023*	*(0.020,0.026)*
raport_ventricular_dreapta-stânga	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.865*	*(0.757,0.973)*	*0.106*	*(0.080,0.128)*
raport_ventricular_dreapta-stânga	GE	*235*	*0.923*	*(0.883,0.957)*	*262*	*0.901*	*(0.859,0.939)*	*0.127*	*(0.090,0.173)*
raport_ventricular_dreapta-stânga	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.931*	*(0.901,0.961)*	*0.099*	*(0.087,0.115)*
raport_timico-toracic	Canon	*19*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.047*	*(0.039,0.059)*
raport_timico-toracic	GE	*174*	*0.902*	*(0.856,0.944)*	*262*	*0.924*	*(0.889,0.954)*	*0.051*	*(0.045,0.059)*
raport_timico-toracic	Samsung	*138*	*0.942*	*(0.900,0.978)*	*232*	*0.892*	*(0.853,0.931)*	*0.059*	*(0.049,0.070)*
număr_vase	Canon	*21*	*0.905*	*(0.760,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.0*	*(0.000,0.000)*
număr_vase	GE	*209*	*0.933*	*(0.895,0.966)*	*262*	*0.969*	*(0.947,0.989)*	*0.281*	*(0.138,0.406)*
număr_vase	Sam-sung	*113*	*0.929*	*(0.879,0.974)*	*232*	*0.966*	*(0.940,0.987)*	*0.329*	*(0.000,0.491)*
raport_vase	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.112*	*(0.091,0.145)*
raport_vase	GE	*194*	*0.979*	*(0.956,0.995)*	*262*	*0.977*	*(0.954,0.992)*	*0.109*	*(0.099,0.121)*
raport_vase	Sam-sung	*122*	*0.984*	*(0.958,1.000)*	*232*	*0.922*	*(0.888,0.953)*	*0.111*	*(0.100,0.125)*
raport CSP	Canon	*25*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.842*	*(0.608,1.028)*
raport CSP	GE	*226*	*0.854*	*(0.805,0.899)*	*262*	*0.977*	*(0.954,0.992)*	*0.826*	*(0.753,0.889)*
raport CSP	Sam-sung	*107*	*0.879*	*(0.821,0.935)*	*232*	*0.991*	*(0.978,1.000)*	*0.835*	*(0.755,0.907)*
raport VP	Canon	*22*	*0.909*	*(0.773,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.064*	*(0.043,0.084)*

raport VP	GE	206	0.956	(0.925,0.981)	262	1.0	(1.000,1.000)	0.065	(0.059,0.071)
raport VP	Sam-sung	91	0.956	(0.910,0.990)	232	1.0	(1.000,1.000)	0.066	(0.056,0.075)
spațiu atrial stâng posterior	Canon	16	0.938	(0.800,1.000)	37	0.919	(0.837,1.000)	0.094	(0.067,0.114)
spațiu atrial stâng posterior	GE	181	0.978	(0.953,0.995)	262	0.924	(0.889,0.954)	0.086	(0.079,0.091)
spațiu atrial stâng posterior	Sam-sung	159	0.981	(0.957,1.000)	232	0.953	(0.922,0.978)	0.07	(0.065,0.078)

Pentru rezultatele subgrupurilor din SUA și UE

Clasa	Continent	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp
A	UE	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	SUA	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	UE	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	SUA	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	UE	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	SUA	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	UE	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	SUA	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	UE	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	SUA	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	UE	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	SUA	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	UE	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	SUA	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	UE	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	SUA	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	UE	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	SUA	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Clasa	Continent	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp	mIoU	IÎ mIoU
A.aA	EU	270	0.971	(0.949,0.989)	2201	0.99	(0.985,0.993)	0.49	(0.47,0.51)
A.aA	US	205	0.976	(0.954,0.995)	1441	0.997	(0.994,1.000)	0.55	(0.52,0.58)
A.Ao	EU	295	0.967	(0.946,0.984)	2176	0.999	(0.997,1.000)	0.56	(0.54,0.58)
A.Ao	US	203	0.986	(0.968,1.000)	1443	0.996	(0.993,0.999)	0.54	(0.51,0.57)
A.lRb	EU	270	0.96	(0.936,0.982)	2201	0.992	(0.988,0.995)	0.56	(0.54,0.59)
A.lRb	US	198	0.97	(0.945,0.991)	1448	0.994	(0.990,0.998)	0.59	(0.56,0.62)
A.rRb	EU	271	0.953	(0.927,0.975)	2200	0.995	(0.993,0.998)	0.55	(0.52,0.58)
A.rRb	US	203	0.956	(0.924,0.982)	1443	0.998	(0.996,1.000)	0.58	(0.54,0.62)
A.Sp	EU	291	0.987	(0.973,0.997)	2180	0.996	(0.994,0.999)	0.71	(0.70,0.73)

A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*
A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*

B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*
C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*

D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	US	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	EU	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	US	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	EU	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	US	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*
D.rPA	EU	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	US	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	EU	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*
D.S	US	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	EU	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	US	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	EU	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	US	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	EU	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	US	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	EU	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	US	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	EU	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	US	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	EU	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	US	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	EU	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	US	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	EU	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	US	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	EU	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	US	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	EU	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	US	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*

E.Tr	EU	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*
E.Tr	US	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	EU	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	US	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	EU	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	US	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	EU	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*
F.aFx	US	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	EU	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	US	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	EU	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	US	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	EU	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	US	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	EU	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	US	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	EU	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*

F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*
G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*

I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Clasa	Continent	n(pozitiv)	Se	IÎ Se	n(negativ)	Sp	IÎ Sp	LOA	IÎ LOA
unghi_cardiac	UE	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
unghi_cardiac	SUA	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
poziție_cardiotoracică	UE	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
poziție_cardiotoracică	SUA	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
raport_cardiotoracic	UE	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
raport_cardiotoracic	SUA	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
indice_cefalic	UE	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
indice_cefalic	SUA	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
raport_ventricular_dreapta-stânga	UE	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
raport_ventricular_dreapta-stânga	SUA	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
raport_timico-toracic	UE	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
raport_timico-toracic	SUA	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)
număr_vase	UE	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
număr_vase	SUA	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
raport_vase	UE	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
raport_vase	SUA	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
raport CSP	UE	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
raport CSP	SUA	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
raport VP	UE	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)

raport VP	SUA	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
spațiu atrial stâng posterior	UE	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
spațiu atrial stâng posterior	SUA	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Contraindicații

Nu există nicio contraindicație legată de dispozitivul FETOLY.

10. Avertismente, precauții, interacțiuni cu alte echipamente

Avertismente și precauții din dosarul de gestionare a riscurilor:

- Utilizatorul trebuie să mărească imaginea cu cel puțin 30% pentru a evita rezultatele fals-negative ale software-ului;
- Utilizatorul trebuie să examineze sistematic setul de imagini selectate înainte de export;
- Neglijarea funcției de resetare poate conduce la confuzie în fișele pacienților și poate contribui la rezultate fals-negative în procesul de screening;
- Imaginile șterse în cadrul selecției de imagini sunt pierdute definitiv;
- Configurația intrării fluxului video poate contribui la apariția unor rezultate fals-negative în procesul de screening;
- Fluxul video incompatibil poate conduce la erori în documentația de examinare. Fluxul video trebuie să aibă următoarele caracteristici:
  - Cel puțin 24 de cadre pe secundă (fps);
  - O rezoluție mai mică de 1280*720.
- Incompatibilitatea tabletei poate duce la erori în documentația de examinare;
- Eșecul exportului duce la pierderea raportului de examinare;
- Vă rugăm să verificați numele pacientului ales înainte de exportul DICOM pe pagina de export, pentru a evita confuzia în ceea ce privește fișele pacienților;
- Utilizarea în primul trimestru de sarcină conduce la o eroare a funcției de completitudine;
- Examinarea se va efectua pe rând pentru fiecare făt;
- Dacă tableta începe să se supraîncălzească, opriți utilizarea software-ului;
- Verificați nivelul bateriei tabletei înainte de examinare. Oprirea software-ului poate duce la pierderea datelor de examinare;
- Software-ul nu poate fi utilizat în scopuri de screening, deoarece poate contribui la rezultate fals- negative în procesul de screening;
- Utilizați numai dvs. tableta și nu permiteți accesul persoanelor neautorizate la tableta dvs., pentru a evita riscurile de securitate;
- Vă rugăm să rețineți că atunci când datele sunt exportate pe dispozitivul dvs., acestea constituie responsabilitatea dvs;
- Nu utilizați nicio altă aplicație pe tabletă în paralel cu FETOLY, pentru a evita interferențele în procesul de recepție a fluxului de imagini sau de executare a calculelor de învățare automată;
- Nu utilizați aplicația în timpul scanării cu o sondă transvaginală, deoarece produsul nu a fost testat cu imagini transvaginale.

Avertismente și precauții generate de testul de performanță a software-ului:

- Sensibilitatea software-ului poate fi mai scăzută pentru detectarea:
    - Planului de vizualizare cerebral transtalamic;
    - Următoarelor criterii de calitate cardiace: deplasarea valvei atrioventriculare în crux cordis (planul de vizualizare a celor patru camere)
    - Următoarelor criterii de calitate cerebrale:
        - Sutura coronară proximală (planul de vizualizare axial)
        - Cavitatea septului pelucid (planul de vizualizare axial)
        - Al treilea ventricul (planul de vizualizare axial)

  Utilizatorii trebuie să acorde atenție sporită acestui plan de vizualizare și criteriilor de calitate asociate și să confirme corectitudinea rezultatelor.

Interacțiuni cu alte echipamente

Software-ul FETOLY este conceput pentru a funcționa pe o gamă largă de tablete, fără a depinde de un cloud extern. FETOLY este configurat pentru a primi un flux video de ecografie, ceea ce poate fi realizat de un ecograf echipat cu o ieșire HDMI conectată la hardware-ul pe care rulează software-ul.

Software-ul este compatibil cu ecografele de la General Electric, Samsung și Canon.

Software-ul necesită următoarea configurație minimă pentru tabletă:

- Arhitectură CPU ARMv8
- Procesor Snapdragon 8 sau
- Procesor M1 sau un model ulterior sau
- Procesor A14 sau un model ulterior și
- Capacitate RAM de cel puțin 8 GB
- Capacitate de stocare de cel puțin 1 GB
- Android versiunea 13/iOS versiunea 17 sau superioară

Modelele de tablete recomandate sunt:

- Samsung Galaxy Tab S8 sau modelele ulterioare
- Ipad Air 5 sau un model ulterior
- Ipad 10 sau un model ulterior
- Ipad mini 7 sau un model ulterior
- Ipad Pro 3 sau un model ulterior

Nu ezitați să contactați serviciul de asistență Diagnoly la support@diagnoly.com dacă aveți îndoieli cu privire la alegerea modelului de tabletă.

Imaginile etichetate de FETOLY pot fi salvate direct pe tabletă sau pot fi trimise către un alt dispozitiv din aceeași rețea cu dispozitivul pe care rulează FETOLY. Pentru a utiliza această opțiune, software-ul necesită un server FTP pe dispozitivul țintă, un server DICOM Store sau o conexiune Bluetooth.

11. Efecte nedorite

Nu există niciun efect nedorit legat de dispozitivul FETOLY.

12. Instrucțiuni privind securitatea cibernetică

12.1. Descrierea protecției funcționalității critice la nivel înalt

Această secțiune oferă o descriere la nivel înalt a caracteristicilor dispozitivului care protejează funcționalitatea critică. Recepția fluxului de imagini și funcțiile de analiză a imaginilor depind

de resursele locale (cablu fizic, model AI integrat) și nu necesită internet pentru a funcționa. Software-ul nu stochează și nu gestionează datele pacienților, însă îi permite utilizatorului să exporte, după o examinare, un raport de examinare către un dispozitiv terț. Un mod de export de rezervă este disponibil dacă rețeaua locală este compromisă, permițându-le utilizatorilor să salveze rapoartele în sistemul de fișiere al tabletei.

12.2. Riscurile inerente de securitate cibernetică ale dispozitivului

Riscurile inerente de securitate cibernetică ale FETOLY includ:

- Furtul datelor pacienților;
- Îngrijiri medicale mai puțin eficiente pentru pacient din cauza unei disfuncționalități a AI, cum ar fi modificări ale greutății modelului sau modificări ale software-ului/sistemului de operare;
- Utilizarea incorectă a dispozitivului, care conduce la rezultate diferite de cele prevăzute de producător sau așteptate de utilizator;
- Pierderea de timp pentru utilizator.

Aceste riscuri sunt controlate prin analiza riscurilor.

11.3. Diagrama controalelor de securitate cibernetică recomandate



Diagrama descrie mediul software-ului FETOLY care rulează pe tableta utilizatorului, precum și comunicațiile de intrare/ieșire cu sistemul ecografic și dispozitivul terț.

Aceasta include referințe la controalele de securitate cibernetică recomandate pentru mediul de utilizare prevăzut descris în **secțiunea 12.4**:

- G1: Funcționarea sigură cu sistemele terțe prin FTP pe SSL/TLS
- G2: Funcționarea sigură cu sistemele terțe prin Bluetooth (doar pentru Android)
- G3: Controlul securizat al accesului la dispozitiv

- G4: Funcționarea sigură cu sistemele terțe prin DICOM pe SSL/TLS

12.4. Instrucțiuni privind dispozitivul și specificațiile produsului referitoare la controalele de securitate cibernetică recomandate, adaptate mediului de utilizare prevăzut

Orientări pentru funcționarea în siguranță cu sistemele terțe prin FTP pe SSL/TLS (G1):

- Cerințe minime de rețea: infrastructura de rețea trebuie să suporte FTP pe SSL/TLS (FTPS), iar serverul FTP trebuie să fie compatibil cu FTPS. Implementați segmentarea rețelei și reguli de firewall pentru a restricționa accesul la serviciile și adresele IP necesare.
- Instalarea unui server FTP pe SSL/TLS, cum ar fi:
    a. Windows 10/11 cu IIS: consultați documentația Microsoft pentru a configura FTP pe TLS/SSL cu IIS.
    b. FileZilla Server (toate platformele): configurați FTPES „Require explicit FTP over TLS”, creați un utilizator cu o parolă puternică*, definiți o cale de stocare a datelor (de exemplu, „C:\FetolyData” sau „/home/shared/FetolyData”) și configurați regulile firewall-ului pentru programul sau portul specific utilizat de serverul FTP.

Orientări pentru funcționarea în siguranță cu sistemele terțe prin Bluetooth (G2, doar pentru Android):

- Cerințe minime de rețea: Bluetooth versiunea 5 sau superioară.
- Setați o parolă puternică în software pentru a proteja datele exportate ale pacientului*.

Orientări pentru controlul securizat al accesului la dispozitiv (G3):

- Configurați un ecran de blocare cu o parolă puternică*, un cod PIN sau autentificarea biometrică.
- Activați actualizările automate pentru sistemul de operare și toate aplicațiile instalate.
- Dezactivați toate interfețele de rețea neutilizate (de exemplu, NFC, IR).

Orientări pentru funcționarea sigură cu sistemele terțe prin DICOM (G4):

- Asigurați-vă că comunicațiile se efectuează într-o rețea securizată și segmentată, limitând accesul prin configurații robuste de firewall și mecanisme eficiente de control al accesului.

*Utilizați parole puternice pe tabletă și pentru orice dispozitiv (de exemplu, dispozitive terțe pentru export FTP) sau o configurație conectată la FETOLY (de exemplu, configurația Bluetooth), conform recomandărilor Agenției americane de apărare cibernetică:

- Lungă: cel puțin 16 caractere (mai lungă, dacă este posibil).
- Aleatorie: precum un șir de litere majuscule și minuscule, cifre și simboluri amestecate (cea mai puternică!) sau o frază secretă compusă din 5-7 cuvinte aleatorii.
- Unică: utilizată pentru un singur cont sau dispozitiv.

Dacă se detectează o vulnerabilitate sau un incident de securitate cibernetică, raportați imediat echipei de securitate IT și Diagnoly (support@diagnoly.com). Pe tabletă:

- Resetare: restabiliți setările din fabrică pentru a șterge toate datele și configurațiile.

- Reinstalarea aplicației: descărcați cea mai recentă versiune securizată a aplicației din Google Play Store.
- Opțiune de rezervă: utilizați exportul local pe un card SD dacă exporturile în rețea sunt compromise.

12.5. Lista porturilor de rețea și alte interfețe

Software-ul FETOLY primește datele fluxului de intrare printr-un cablu conectat între ieșirea monitorului extern al sistemului ecografic și intrarea USB-C a tabletei. Software-ul poate fi configurat pentru a exporta rapoarte de examinare către un dispozitiv terț prin TCP/IP FTPS, DICOM sau Bluetooth.

Pentru exportul de date prin rețeaua TCP/IP FTPS:

- Protocol: FTPS
- Porturi de intrare: software-ul nu deschide niciun port de intrare, deoarece funcționează doar ca client, nu ca server.
- Porturi de ieșire: software-ul utilizează un port efemer alocat dinamic (interval: 1024-65535) pentru a stabili o conexiune cu serverul FTPS la o adresă IP specificată. Portul de intrare al serverului FTPS terț este definit de utilizator.
- Reguli de firewall: Firewall-urile de pe partea clientului și de pe partea serverului trebuie să permită conexiunile de ieșire de la client la portul serverului.

Pentru exportul de date prin Bluetooth/OBEX (doar pentru Android):

- Criptare: datele sunt comprimate și criptate prin parolă.

Pentru exportul de date prin DICOM:

- Protocol: DICOM
- Porturi de intrare: software-ul nu deschide niciun port de intrare, deoarece funcționează doar ca client, nu ca server.
- Porturi de ieșire: software-ul utilizează un port efemer alocat dinamic (Android: 32768-60999) pentru a stabili conexiunea la serverul DICOM la o adresă IP specificată. Portul de intrare al serverului DICOM terț este definit de utilizator.
- Reguli de firewall: Firewall-urile de pe partea clientului și de pe partea serverului trebuie să permită conexiunile de ieșire de la client la portul serverului.

12.6. Cerințe privind infrastructura de sprijin

Consultați secțiunea 10 pentru cerințele privind infrastructura, inclusiv configurația minimă a tabletei și sistemele ecografice compatibile.

12.7. Lista de materiale software (sBoM)

O listă de materiale software (sBoM) este disponibilă pentru ca utilizatorii să își gestioneze activele, să înțeleagă impactul potențial al vulnerabilităților identificate și să implementeze contramăsuri pentru a menține siguranța și eficiența dispozitivului. sBoM poate fi descărcată de pe pagina „About” (Despre) a software-ului, într-un format care poate fi citit automat (.csv), făcând clic pe „Show” (Afișare) în fața opțiunii „Third-Party Notice” (Notificare pentru terți).

12.8. Instrucțiuni de actualizare/patch-uri

Consultați secțiunea 13 „Actualizarea software-ului și a licenței” pentru instrucțiuni de actualizare.

12.9. Descrierea răspunsului dispozitivului în cazul detectării unor condiții anormale

Această secțiune descrie modul în care software-ul reacționează la evenimentele de securitate. Toate erorile fatale ale software-ului sunt exportate prin intermediul unui jurnal de erori fatale în Firebase. Următoarele avertismente pot apărea la utilizarea FETOLY:

- Eșecul exportului: anomalie de rețea care conduce la eșecul exportului raportului prin TCP/IP FTPS, DICOM sau Bluetooth.
- Eșecul conexiunii USB: niciun cablu USB-C conectat la tabletă sau eșecul recepționării fluxului video prin USB-C.
- Eșecul validării licenței: încercare de validare a licenței de către utilizator fără conexiune la internet, fără activarea automată a orei sau fără o licență validă.
- Supraîncălzirea tabletei.
- Problemă de compatibilitate a tabletei: frecvența cadrelor fluxului video este mai mică de 24 fps.
- Nivel scăzut al bateriei.

12.10. Backup și restabilire

Pentru a restabili funcțiile dispozitivului și configurația implicită, dezinstalați și reinstalați dispozitivul prin intermediul Google Play/App Store.

12.11. Descrierea metodelor de păstrare și recuperare a configurației dispozitivului de către un utilizator autorizat autentificat

Setările de export, precum acreditările terțe, și setările de captură video, precum raportul de intrare video, sunt păstrate în memoria cache de stocare a datelor tabletei, izolate în siguranță de Android/iOS. Deoarece configurațiile menționate mai sus sunt rapid de setat, nu este implementată nicio metodologie specifică de recuperare. Utilizatorii sunt rugați să introducă din nou parametrii manual la reinstalare sau la instalarea unui dispozitiv nou.

12.12. Configurarea securizată

Această secțiune oferă instrucțiuni pentru a vă asigura că software-ul FETOLY este configurat și întreținut în condiții de siguranță.

Configurarea inițială: descărcați și instalați cea mai recentă versiune din Google Play/App Store. Verificați dacă numele și pictograma aplicației corespund celor furnizate în secțiunea 13. Efectuați toate etapele de configurare a exportului printr-o conexiune de rețea securizată, în conformitate cu instrucțiunile G1/2/4 din secțiunea 12.4. Asigurați-vă că dispozitivul pe care rulează FETOLY este securizat în conformitate cu instrucțiunea G3 din secțiunea 12.4.

Răspunsul la incidente: activați conexiunea la internet pentru a înregistra erorile fatale și activitățile anormale, așa cum este descris în secțiunea 12.13. Raportați orice vulnerabilitate detectată în conformitate cu instrucțiunile din secțiunea 12.4.

12.13. Colectarea de probe judiciare, dacă este cazul, pentru mediul de utilizare prevăzut

Un sistem de raportare a erorilor fatale este integrat în software. Rapoartele de erori fatale sunt trimise în cazul unei defecțiuni a aplicației sau al unui eveniment anormal, dacă conexiunea la internet este activată.

12.14. Informații privind sfârșitul ciclului de viață și sfârșitul asistenței pentru sistem sau componente, dacă sunt cunoscute sau anticipate

Sfârșitul ciclului de viață și sfârșitul asistenței depind de valabilitatea licenței. Licența va fi reînnoită automat prin intermediul unei conexiuni la internet, atâta timp cât contractul de licență este încă valabil. În cazul în care contractul a expirat sau produsul a ajuns la sfârșitul ciclului de viață, vi se va solicita un nou cod de înregistrare.

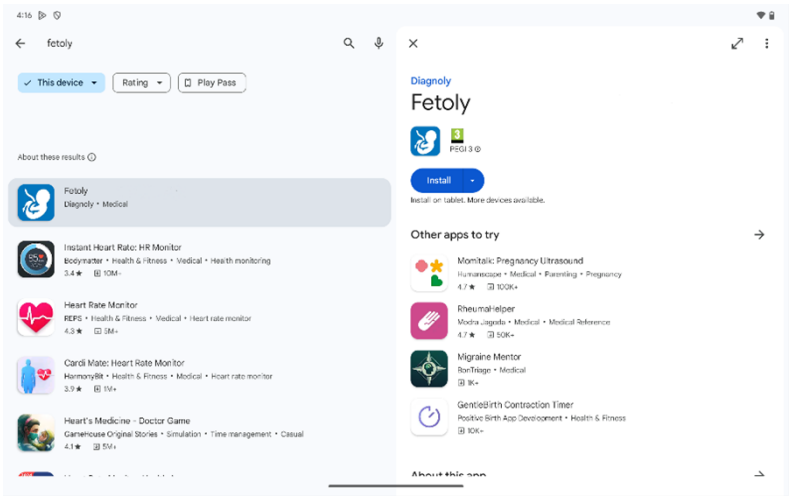
12.15. Scoaterea din uz securizată

Pentru a scoate din uz și a elimina software-ul, dezinstalați aplicația prin intermediul sistemului Android/iOS ca orice altă aplicație de pe tabletă, în setările aplicației, așa cum este ilustrat în secțiunea 13, în paragraful „Dezinstalarea software-ului”. Această dezinstalare va șterge toate datele legate de utilizarea FETOLY, inclusiv licența, de pe tabletă.

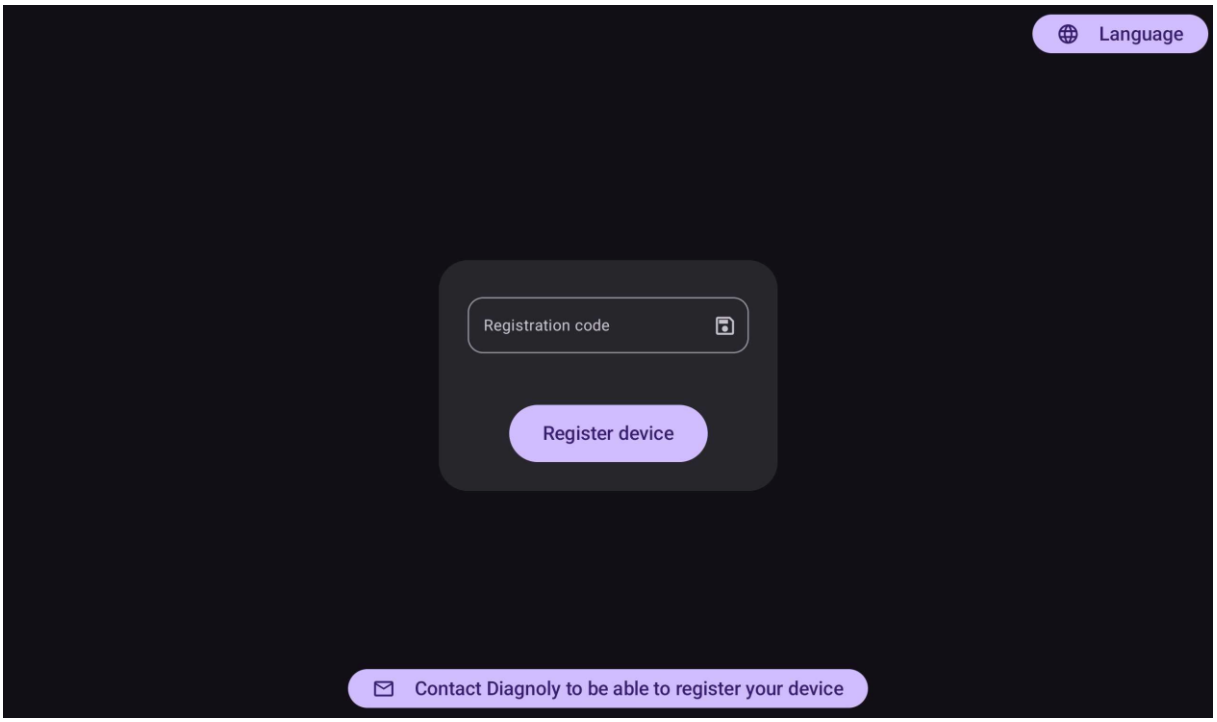
13. Instrucțiuni de utilizare

Instalarea și lansarea software-ului

1. Accesați Google Play sau App Store, scrieți FETOLY în bara de căutare și lansați descărcarea și instalarea automată



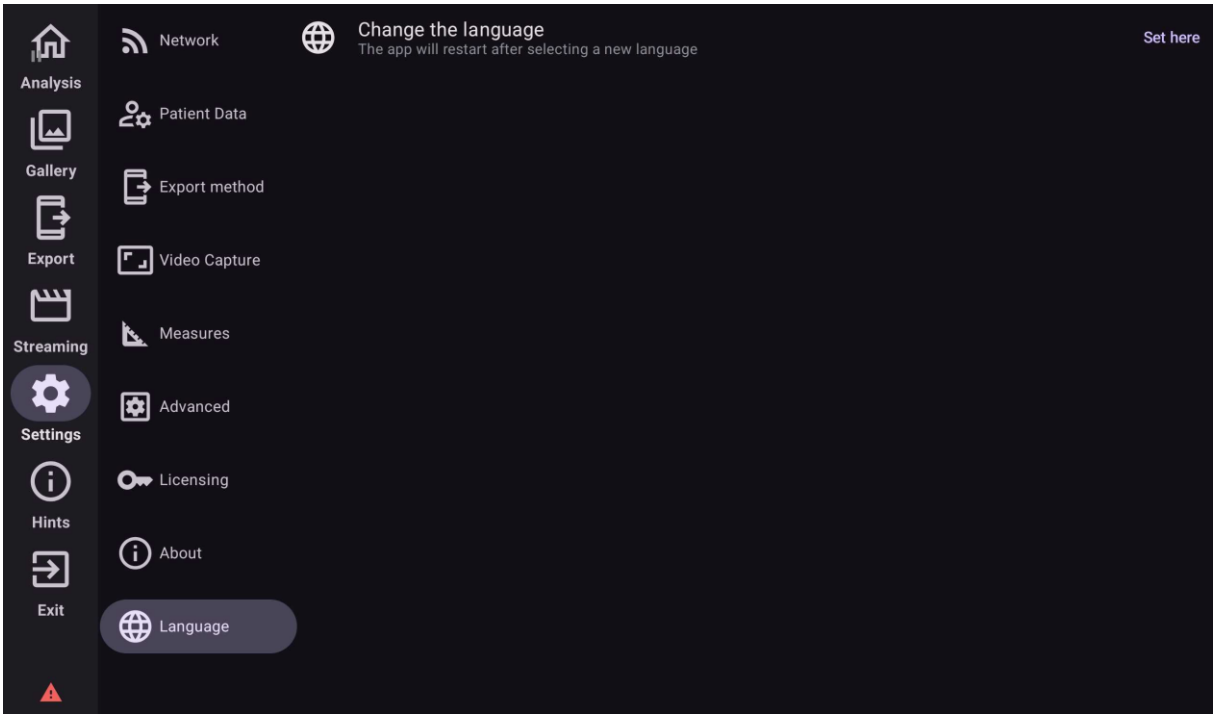
2. Faceți clic pe pictograma FETOLY de pe tabletă
3. **Validarea licenței**: dacă este necesar, introduceți codul de înregistrare a licenței, după cum se arată mai jos. Diagnoly este responsabilă pentru furnizarea licenței. Puteți contacta Diagnoly pentru editarea licenței făcând clic direct pe butonul afișat în partea de jos a paginii de pornire. Licența este asociată cu ID-ul dispozitivului dvs., care este disponibil pe pagina de setări a licenței.

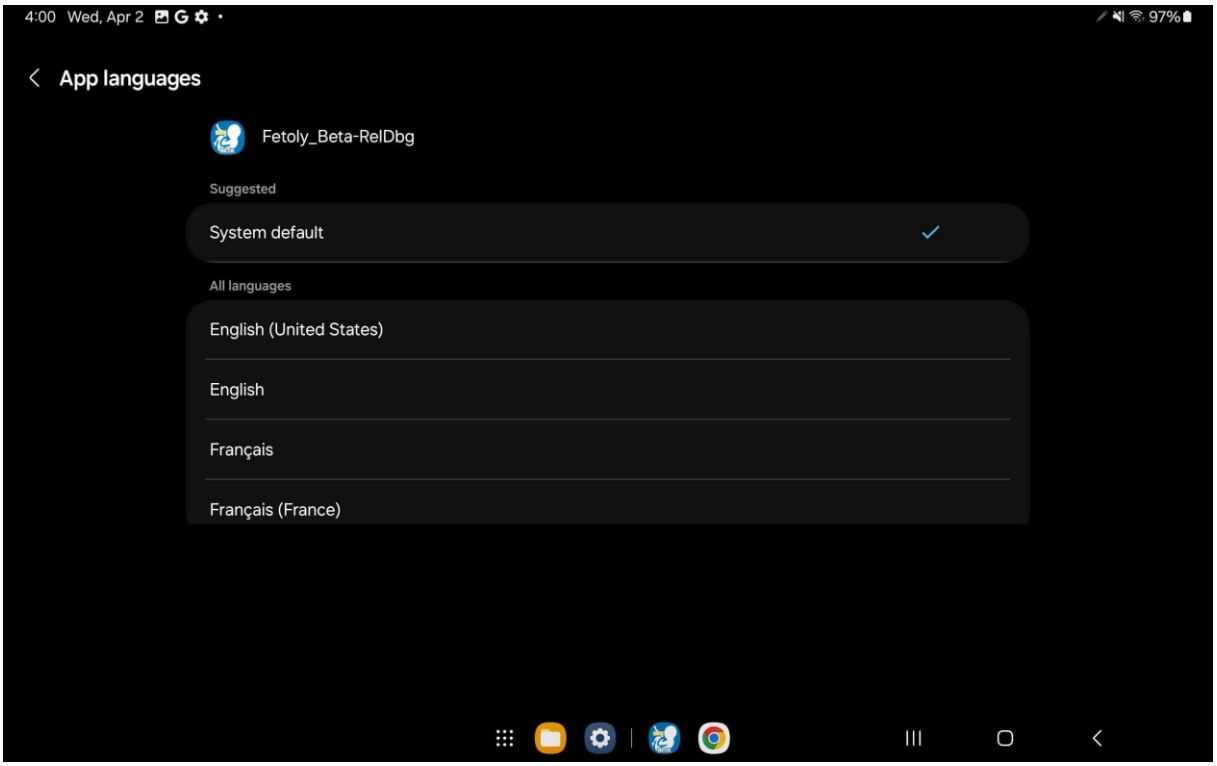


4. **Conectarea la rețeaua Wi-Fi:** dacă doriți să primiți datele ecografice pe computerul dvs. personal, vă rugăm să conectați tableta la rețeaua Wi-Fi.

Setări de limbă

În mod implicit, software-ul este configurat în aceeași limbă ca și tableta dvs. Cu toate acestea, puteți alege limba dorită în „Settings” > „Language” (Setări > Limbă). Aceasta vă va direcționa către setările de limbă ale aplicației pe Android. După selectarea limbii dorite, aplicația va fi tradusă în această limbă la următoarea lansare.



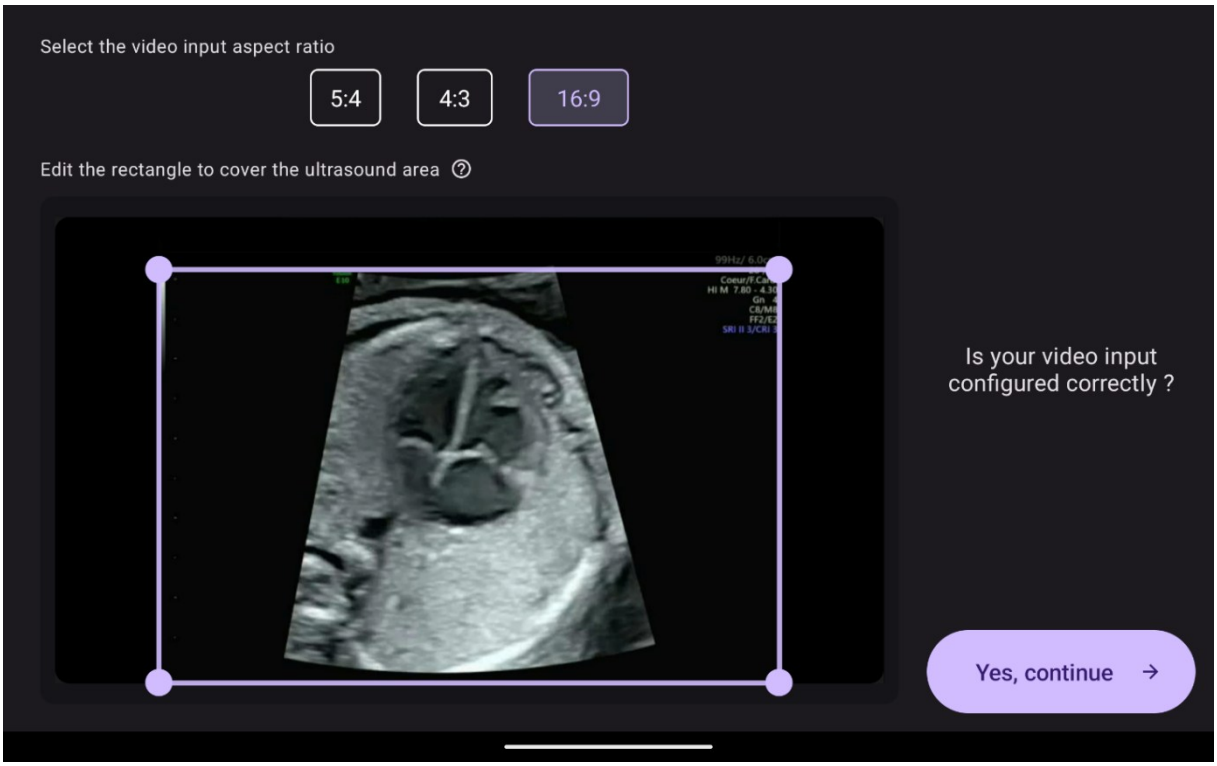


Conectarea ecografului

1. **Pornirea sistemului ecografic:** înainte de a conecta tableta, asigurați-vă că sistemul ecografic este pornit și în stare de funcționare.
2. **Conectarea tabletei la sistemul ecografic:** pentru conectare, conectați pur și simplu capătul USB (Type C) al unui dongle UVC la tabletă și capătul HDMI la ecograf.
3. **Verificare:** pentru a verifica conexiunea dintre sistemul ecografic și tabletă, deschideți software-ul FETOLY. Dacă a fost conectată o nouă sursă USB, software-ul va afișa automat pagina de configurare a fluxului video.

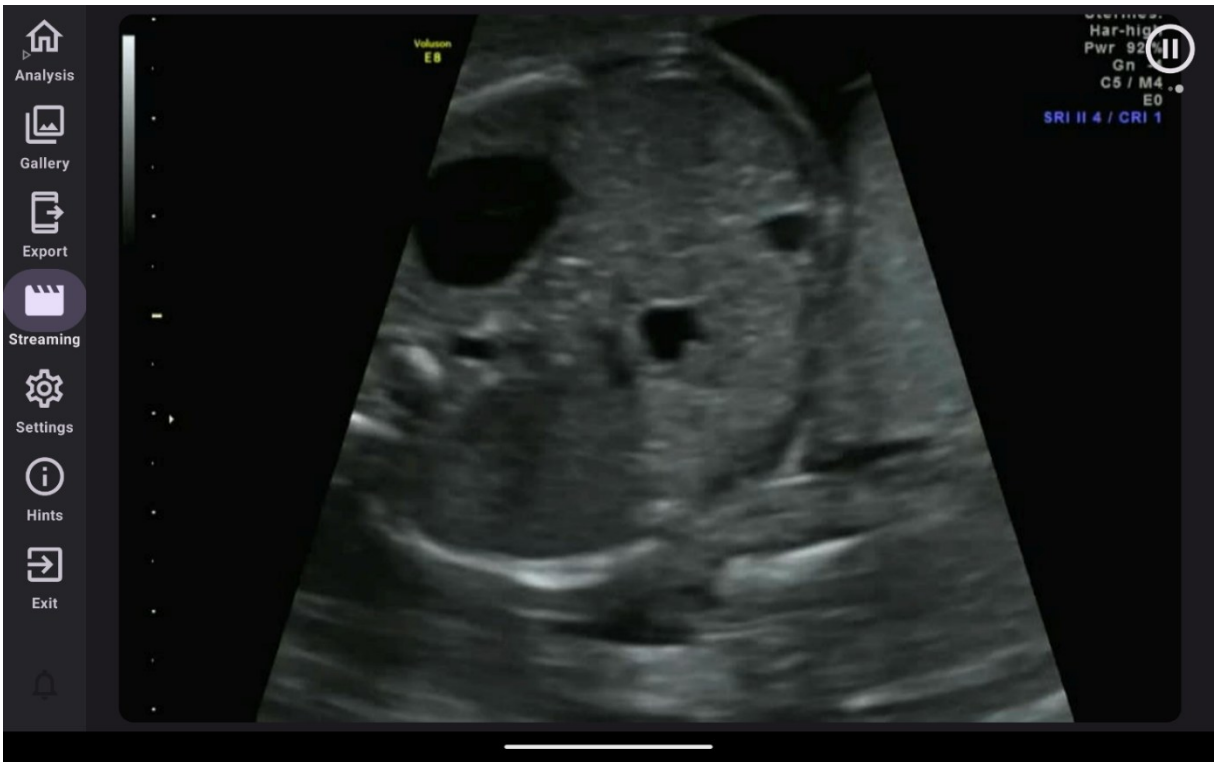
Configurarea fluxului video

1. Începeți configurarea fluxului video în aplicație:
    a. Când software-ul deschide automat pagina de configurare a fluxului video, selectați raportul de aspect video pentru a corespunde raportului de ieșire al ecografului și selectați regiunea ecografică. În alte situații, accesați „Settings” > „Video Capture” (Setări > Captură video) pentru a configura fluxul video, cu aceeași metodologie.



b. Regiunea selectată apare în timp real în pagina de streaming. Butonul de redare poate fi utilizat pe pagina de streaming pentru a lansa analiza.

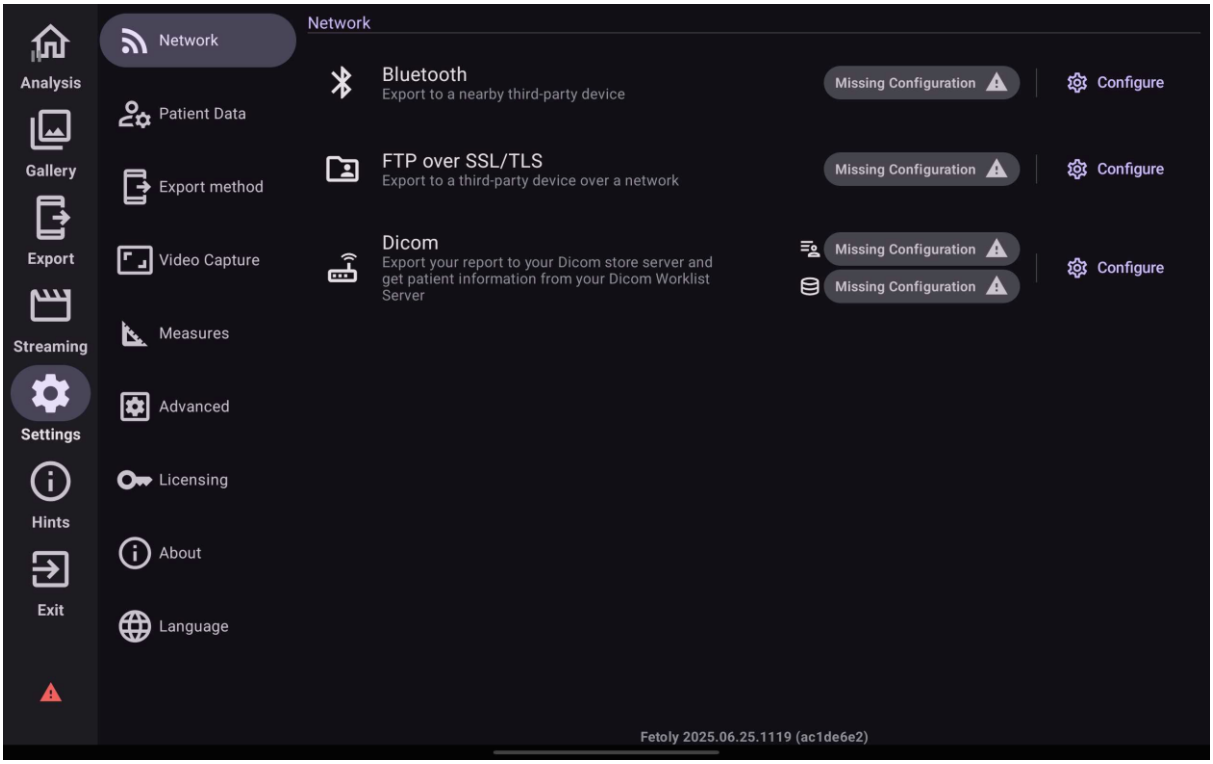
c. Verificați dacă microfonul este dezactivat pe tabletă, deoarece acest lucru va bloca fluxul video.



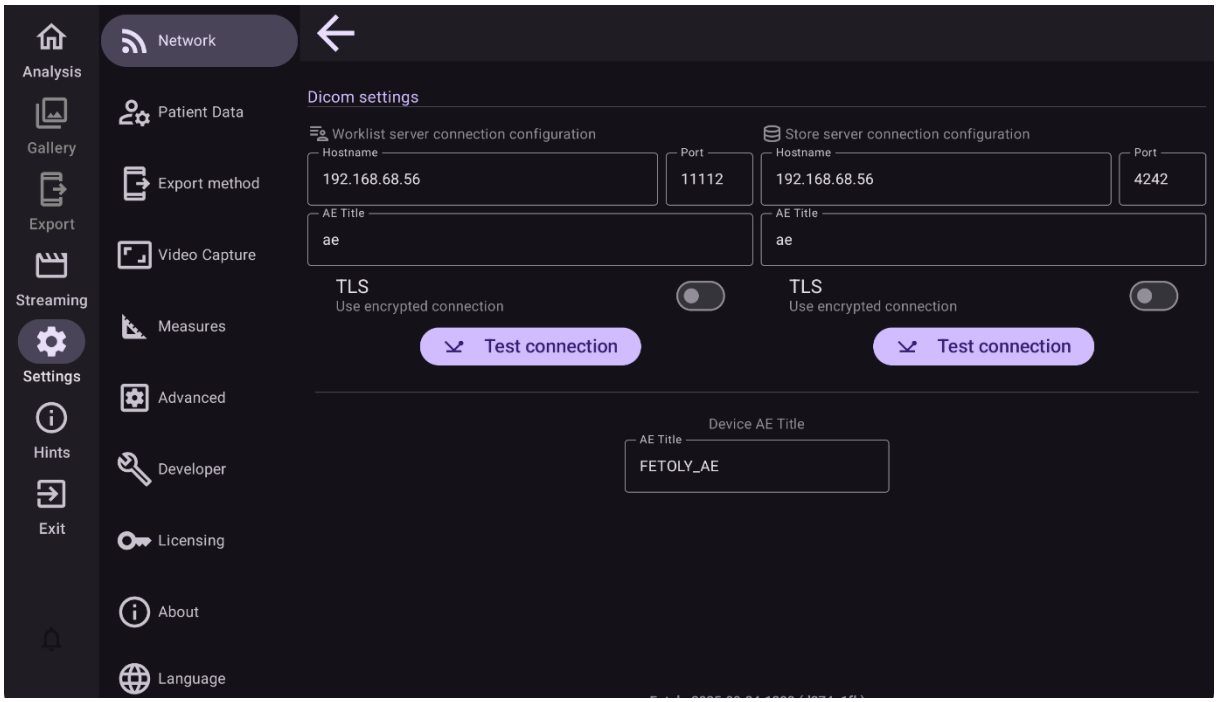
[OPȚIONAL] Configurarea ecografului

Unele sisteme ecografice permit configurarea dimensiunii regiunii ecografice în ieșirea video. În acest caz, se recomandă să selectați cea mai mare regiune posibilă.

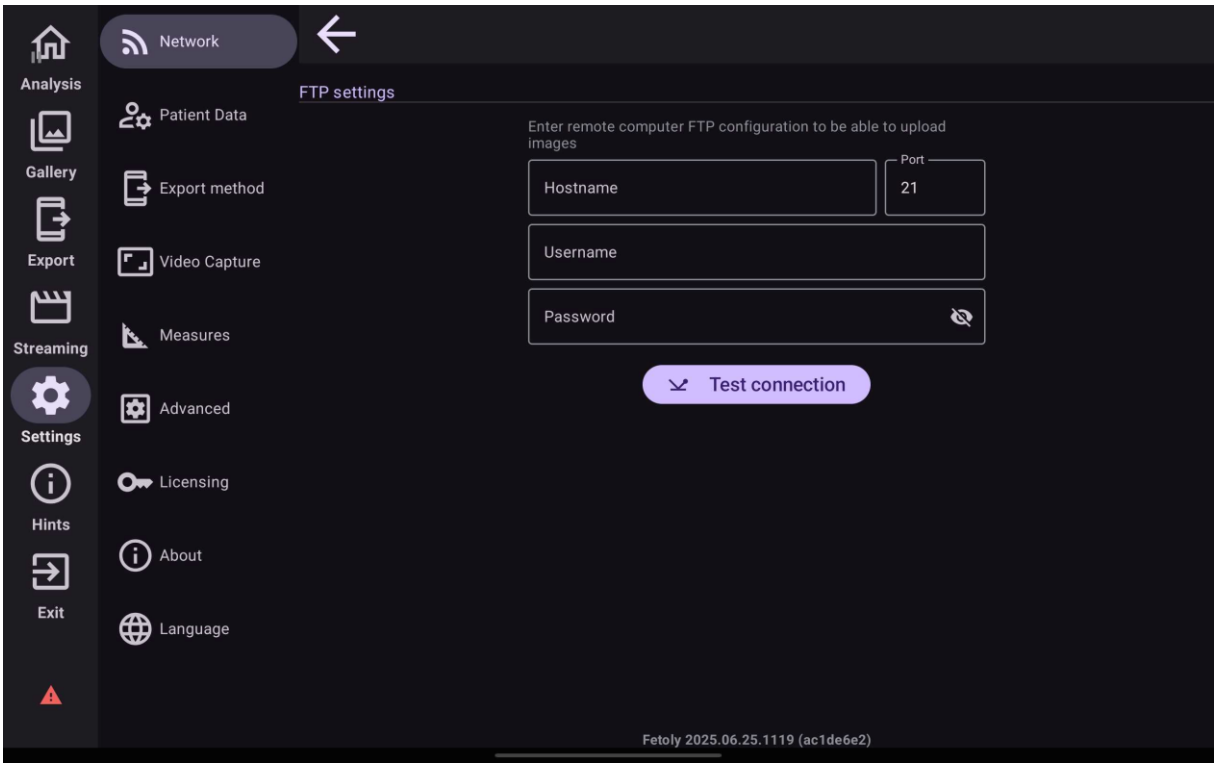
Configurarea exportului



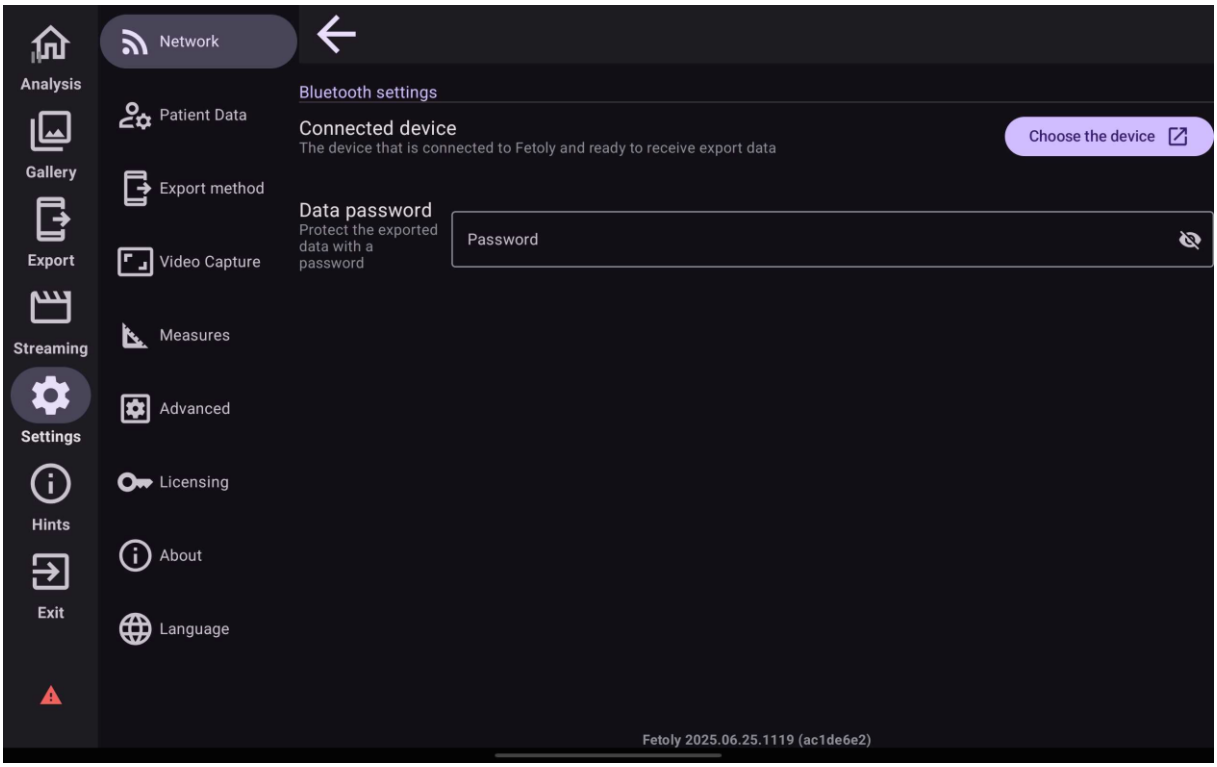
1. Configurați serverul DICOM la distanță pentru exportul imaginilor captate de FETOLY. Vă rugăm să rețineți că acest pas necesită prezența unui server DICOM care rulează pe un dispozitiv conectat la aceeași rețea precum tableta pe care rulează FETOLY.
    a. Apoi accesați „Settings” > „Network Settings” (Setări > Setări rețea), selectați opțiunea de configurare DICOM și introduceți informațiile necesare pentru serverul DICOM Store: numele gazdei pentru lista de lucru (adresa IP) și titlul AE, numele gazdei DICOM Store (adresa IP) și titlul AE, titlul AE al dispozitivului. Pentru a verifica conexiunea, faceți clic pe butonul „Test Connection” (Testare conexiune) pentru fiecare server DICOM. Acest lucru asigură că conexiunea este validă și pregătită pentru exportul imaginilor. Opțional, puteți să activați opțiunea TLS.

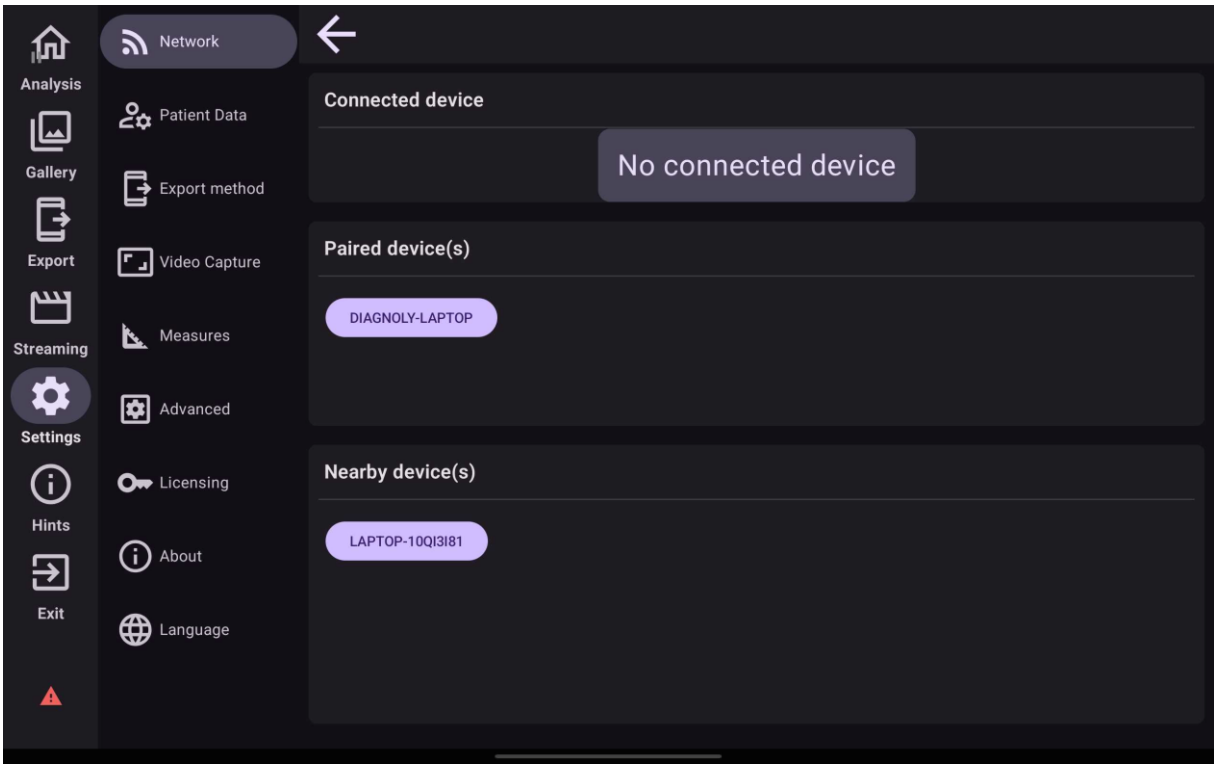


2. Alternativ, configurați serverul FTP la distanță pentru exportul imaginilor captate de FETOLY. Vă rugăm să rețineți că acest pas necesită prezența unui server FTP care rulează pe un dispozitiv conectat la aceeași rețea precum tableta pe care rulează FETOLY.
    a. Accesați „Settings” > „Network Settings” (Setări > Setări rețea), selectați opțiunea de configurare FTP și introduceți informațiile necesare pentru clientul FTP: numele gazdei (adresa IP), numele de utilizator și parola. Pentru a verifica conexiunea, faceți clic pe butonul „Test Connection” (Testare conexiune). Acest lucru asigură că conexiunea este validă și pregătită pentru exportul imaginilor.

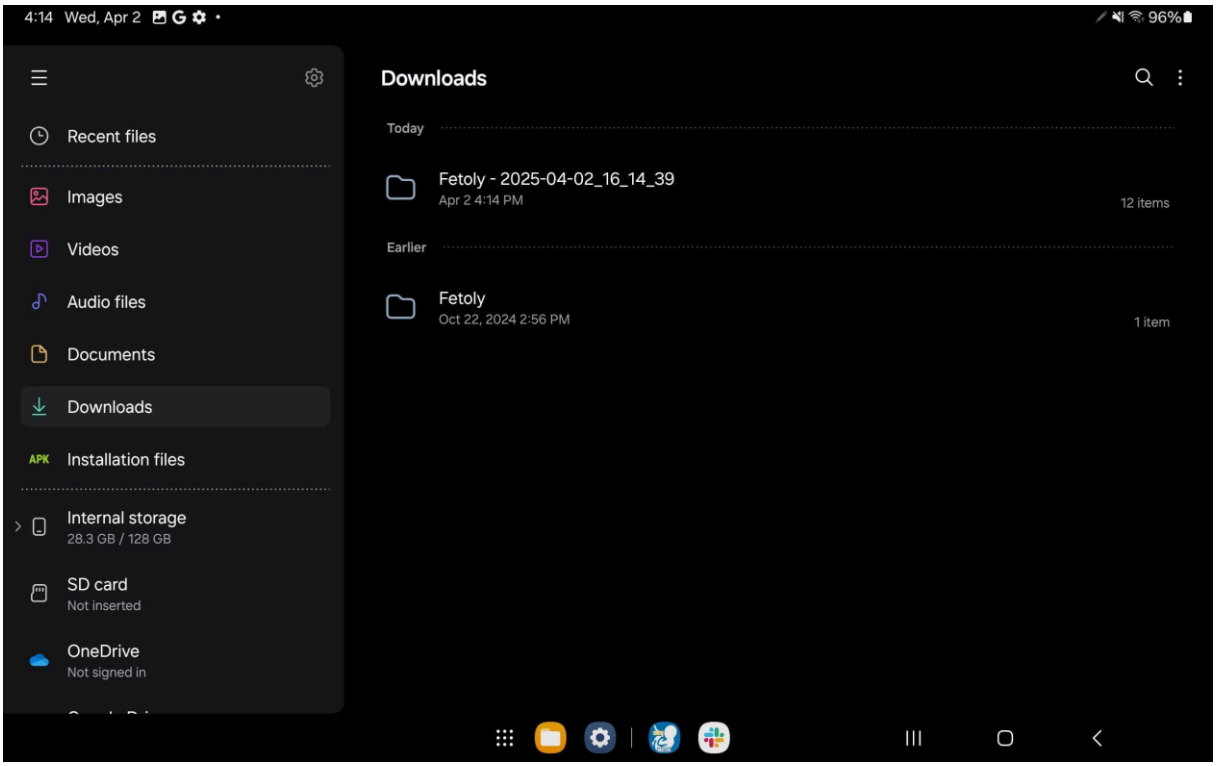


3. Alternativ, puteți utiliza conexiunea Bluetooth (doar pentru Android):
    a. „Settings” > „Network Settings” (Setări > Setări rețea), selectați Bluetooth. Pentru a alege dispozitivul pe care exportați datele, trebuie să asociați dispozitivul selectându-l în secțiunea „Nearby Device” (Dispozitiv din apropiere). Apoi, alegeți dispozitivul care trebuie conectat în secțiunea „Paired Device” (Dispozitiv asociat). Odată ce dispozitivul este ales, puteți testa conexiunea în secțiunea „Connected Device” (Dispozitiv conectat). Pagina de selectare a dispozitivului poate fi accesată făcând clic pe butonul din dreapta „Bluetooth Settings” > „Connected Device” (Setări Bluetooth > Dispozitiv conectat).
    b. Pentru a exporta fișierul, trebuie să configurați suplimentar o parolă. Această parolă va fi atașată la fișierul .zip exportat pe dispozitivul terț.

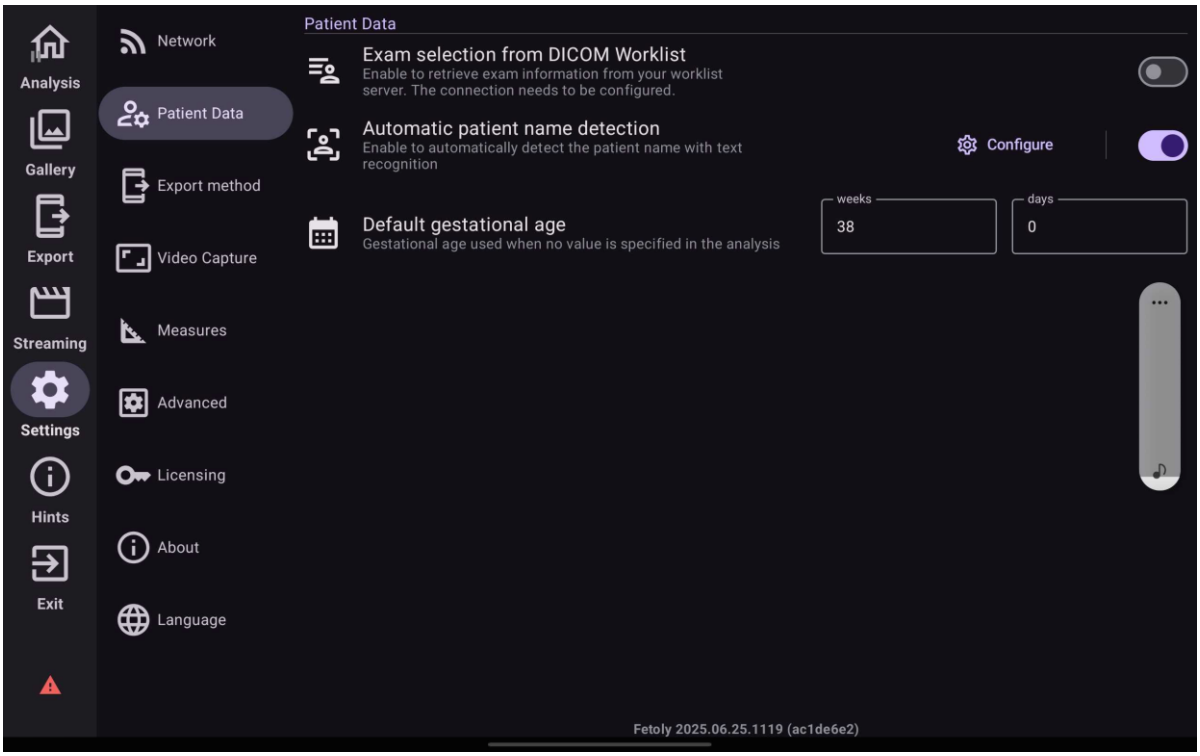


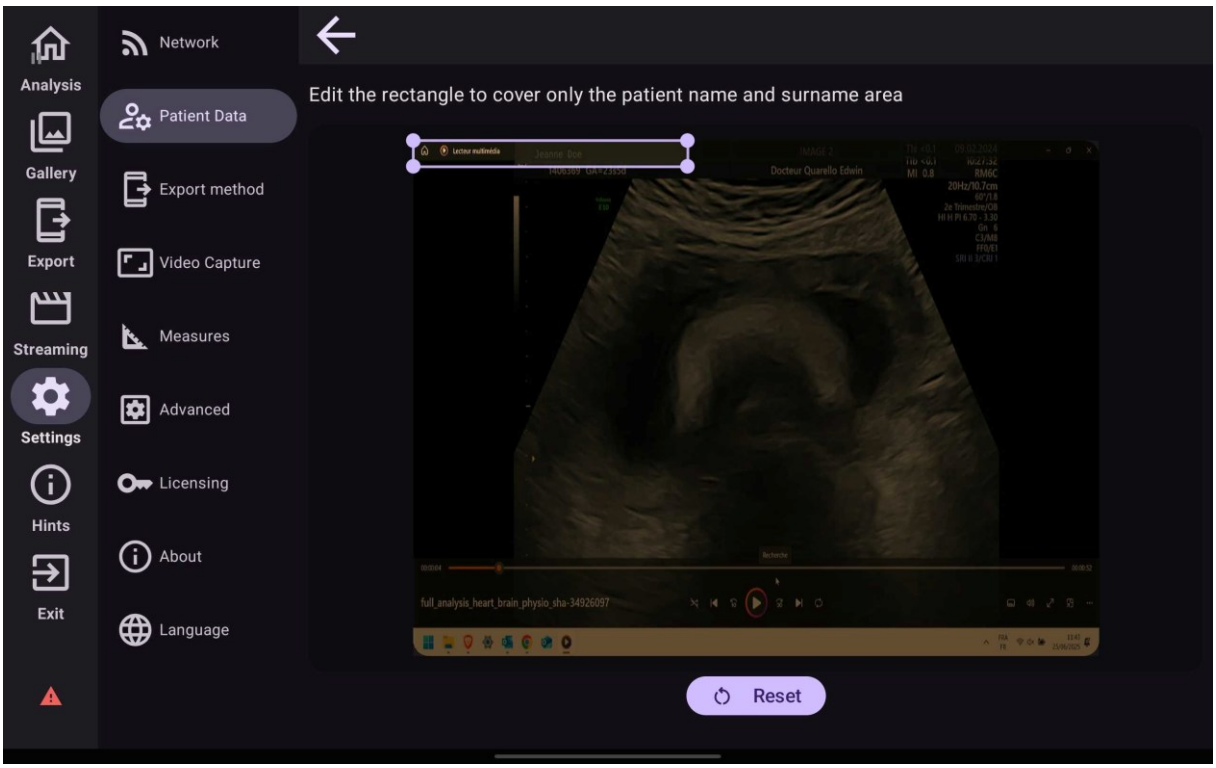


4. Dacă nu doriți să utilizați o conexiune wireless, puteți exporta datele direct pe tabletă:
    a. Accesați „Settings” > „Export Method” (Setări > Metodă de export), selectați locația. Fișierul va fi salvat într-o locație deja definită de tabletă.
    b. Pentru a ajunge la locația definită, accesați desktopul tabletei, selectați pictograma „Files” (Fișiere), apoi accesați „Downloads” > „Fetoly” (Descărcări > Fetoly).



5. Dacă doriți să adăugați numele pacientului în numele fișierului exportat sau dacă doriți să selectați examinarea pacientului din lista de lucru DICOM:
    a. Completați direct numele pacientului cu vârsta gestațională pe pagina de analiză sau
    b. Accesați „Settings” > „Patient Data” (Setări > Date pacient) și activați „Exam Selection from DICOM Worklist” (Selectare examinare din lista de lucru DICOM). Rețineți că această funcție funcționează doar dacă sunteți conectat(ă) la un PACS cu setările listei de lucru DICOM configurate. De asemenea, rețineți că în modul de export DICOM, sunteți obligat(ă) să utilizați această setare.
    c. Opțional, accesați „Settings” > „Patient Data” (Setări > Date pacient) și activați „Automatic Patient Name Detection” (Detectare automată nume pacient). Apoi puteți să accesați „Configure” (Configurare) și să selectați zona de pe fluxul video de ecografie în care apare numele pacientului. Numele pacientului va fi apoi completat automat la lansarea examinării sau făcând clic pe butonul de reîmprospătare din dreapta numelui pacientului de pe pagina de analiză.

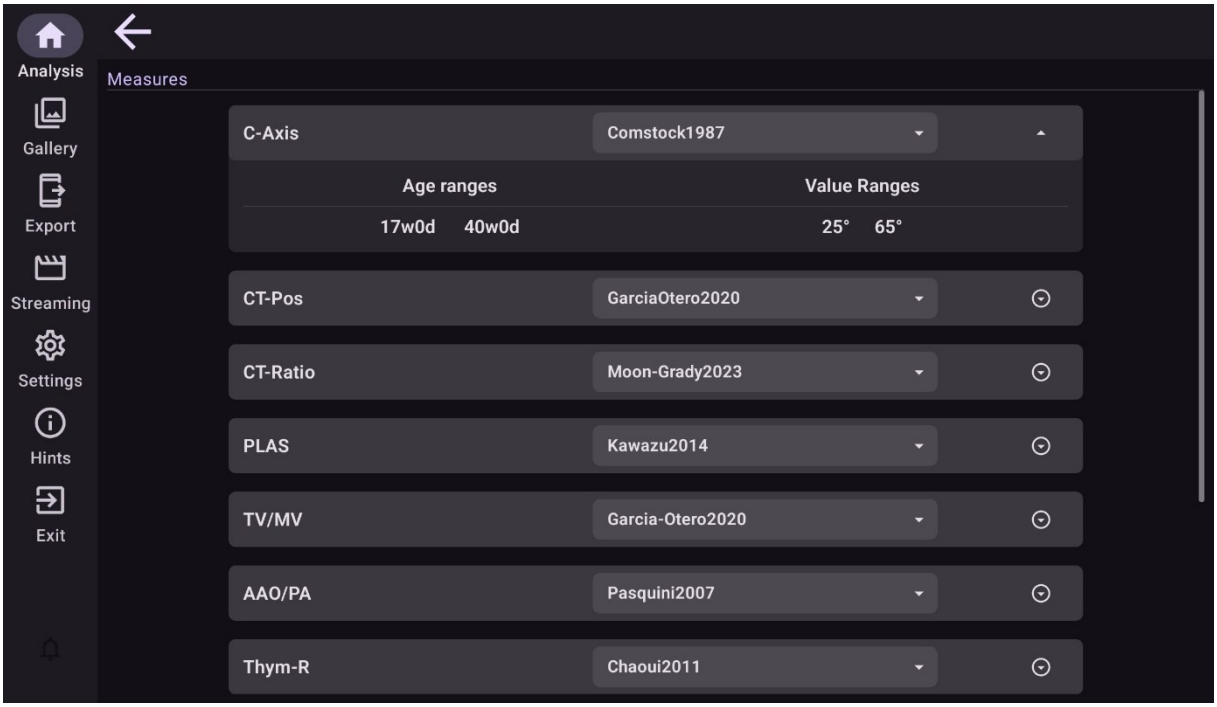




Utilizare

1. Urmați acești pași pentru a asigura completitudinea examinării și a măsurătorilor:
    a. Introduceți vârsta gestațională pe pagina de analiză cu numele pacientului sau selectați examinarea pacientului din lista de lucru DICOM.
    b. Puteți configura vârsta gestațională implicită accesând „Settings” > „Patient Data” (Setări > Date pacient).

c. Pentru funcția de măsurare, dacă sunt disponibile mai multe surse bibliografice, alegeți-o pe cea pe care o preferați. De asemenea, puteți configura manual intervalele de referință prin selectarea personalizată. Pentru aceasta, faceți clic pe butonul New Tab (Filă nouă) din dreapta măsurătorii pe pagina de analiză sau accesând „Settings” > „Measures Settings” (Setări > Setări măsurători). Aceasta vă va redirecționa către pagina de setări ale măsurătorilor.



d. Apăsați Play (Redare) pe pagina de analiză.

e. Efectuați examinarea ca de obicei.

f. Examinarea este considerată completă atunci când toate planurile de vizualizare și criteriile sunt verificate și când toate măsurătorile sunt efectuate.

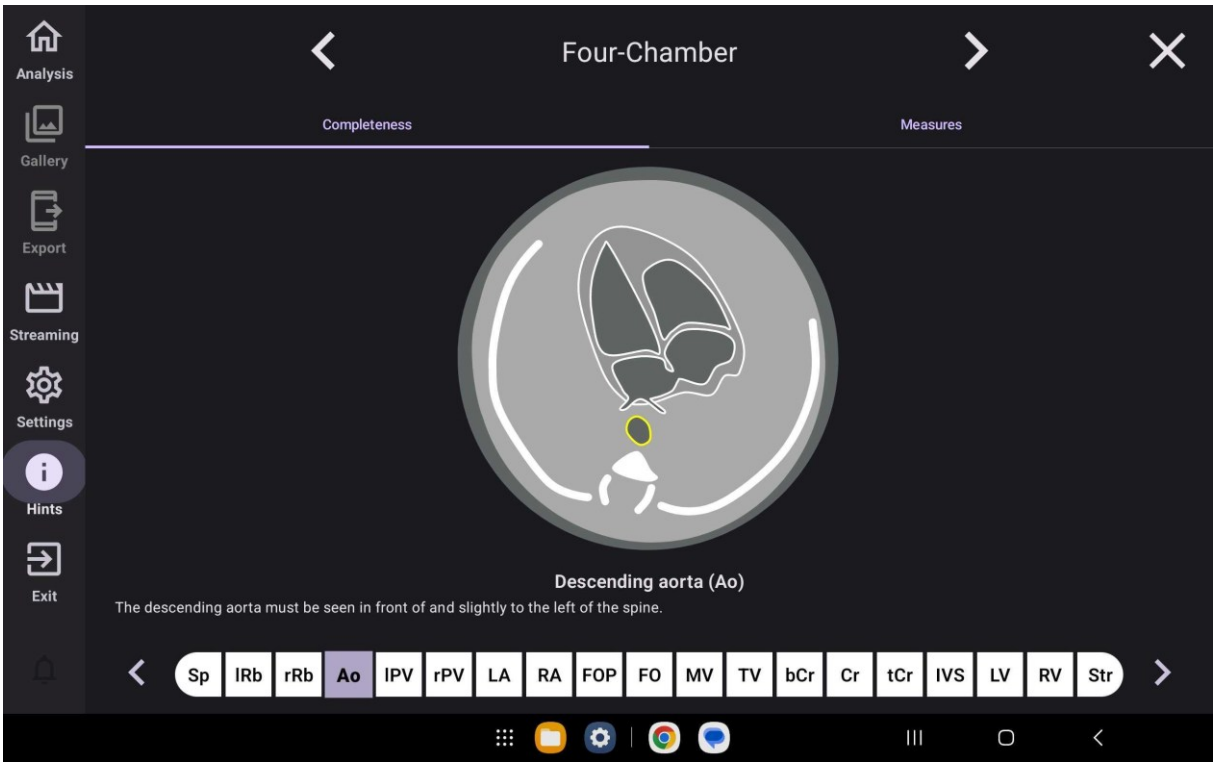
g. Măsurătorile sunt afișate ca fiind „în afara intervalului” dacă nu se încadrează în intervalul de referință definit.

h. Când examinarea este finalizată, pagina de analiză indică acest lucru și vă permite să accesați direct pagina Gallery (Galerie) pentru a verifica imaginile sugerate

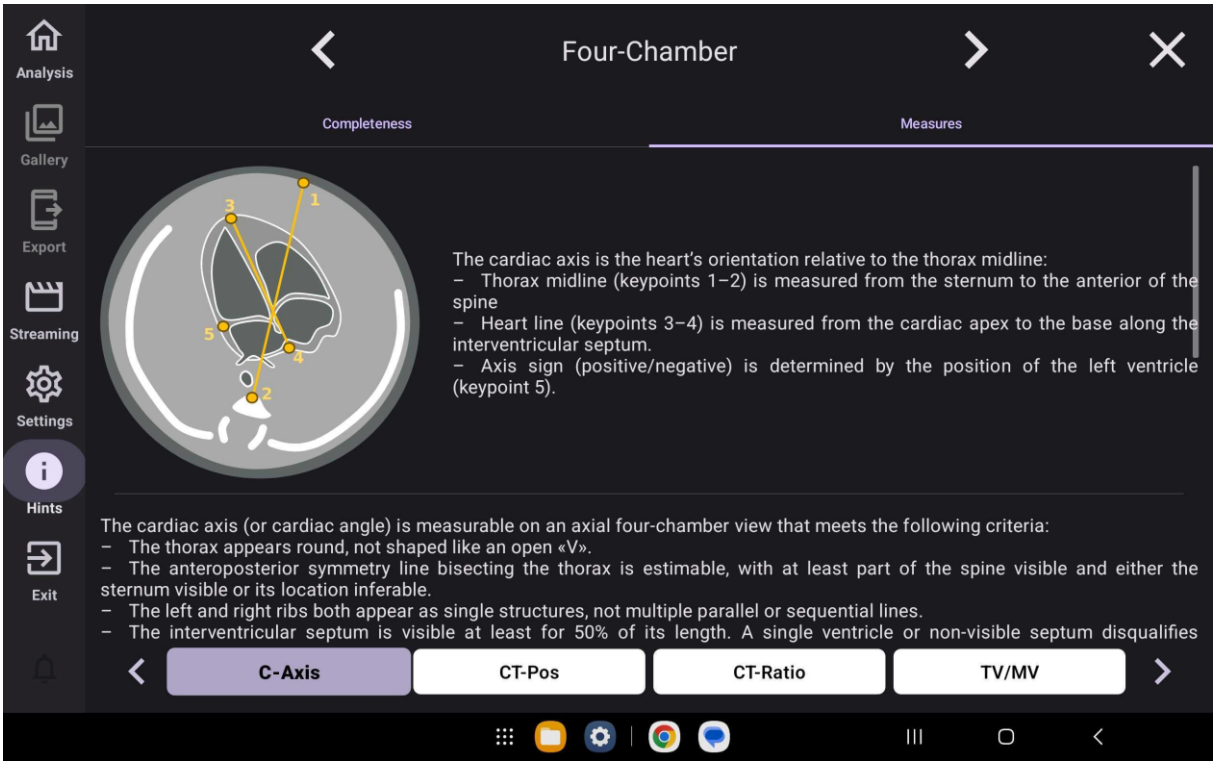


2. Mai jos este o listă de recomandări pentru a vă asigura că realizați cu ușurință completitudinea examinării și măsurătorile:

    a. Criteriile de calitate și planurile de vizualizare detectate de software se bazează pe orientările ISUOG pentru screeningul cardiac și cerebral fetal. Vă rugăm să citiți aceste orientări, dacă este necesar, ca o recapitulare a bunelor practici de screening cardiac/cerebral fetal. De asemenea, puteți accesa pagina Hints (Sugestii) pentru a obține o explicație a tuturor criteriilor de calitate.



b. Măsurătorile biometrice efectuate de software se bazează pe orientările internaționale și pe literatura de specialitate pentru screeningul cardiac și cerebral fetal. Vă rugăm să citiți articolele din literatura de specialitate menționate de software, dacă este necesar, ca o recapitulare a bunelor bunele practici de screening cardiac/cerebral fetal. De asemenea, puteți accesa pagina Hints (Sugestii) pentru a obține o explicație a tuturor măsurătorilor efectuate.



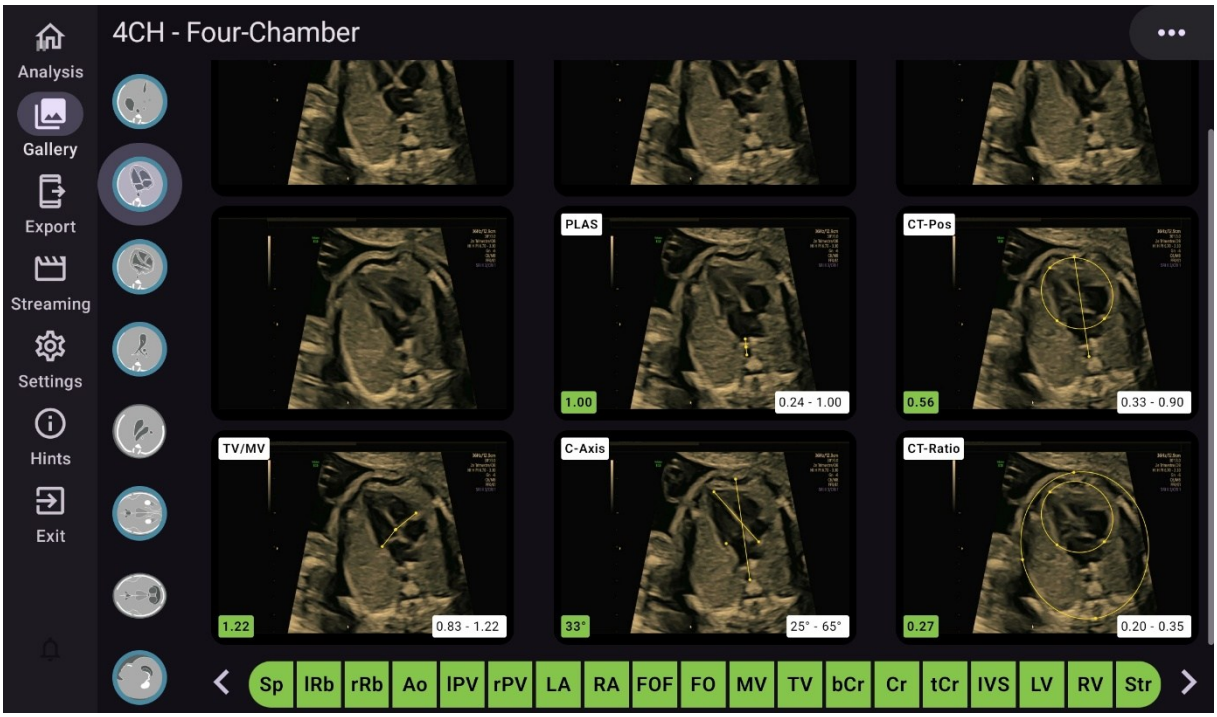
c. Asigurați-vă că toți pașii de configurare explicați mai sus sunt efectuați corect, pentru a evita problemele de detectare.

d. Asigurați-vă că utilizați echipamente compatibile conform secțiunii 10 din aceste instrucțiuni de utilizare.

e. Există un avertisment pe pagina de export în cazul în care criteriile de calitate/măsurătorile nu sunt prezente în setul de imagini selectat.

f. Odată ce toate criteriile sunt verificate și toate măsurătorile sunt efectuate pe pagina de analiză, verificați dacă toate criteriile și măsurătorile corespunzătoare sunt bine identificabile pe setul de imagini selectat în pagina Gallery (Galerie).

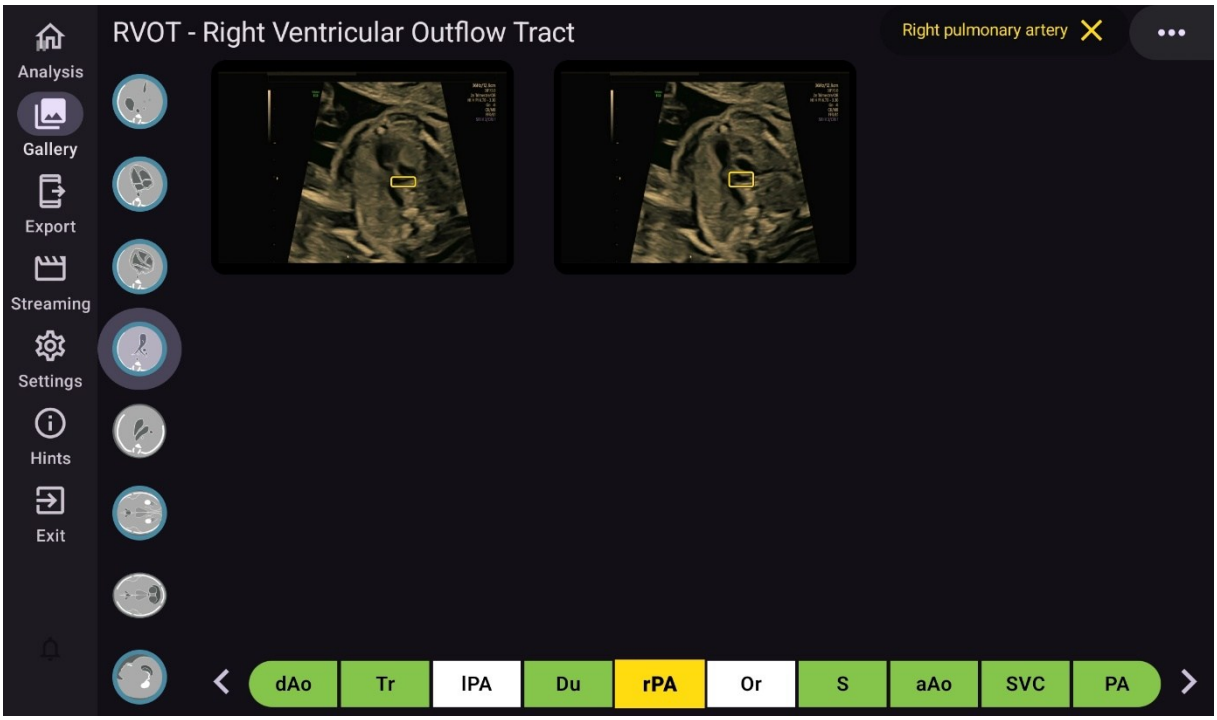
3. După încheierea fluxului video, accesați secțiunea „Gallery” (Galerie) pentru a examina imaginile selectate. Pentru a facilita navigarea în cadrul setului de imagini, imaginile sunt clasificate în funcție de plan.



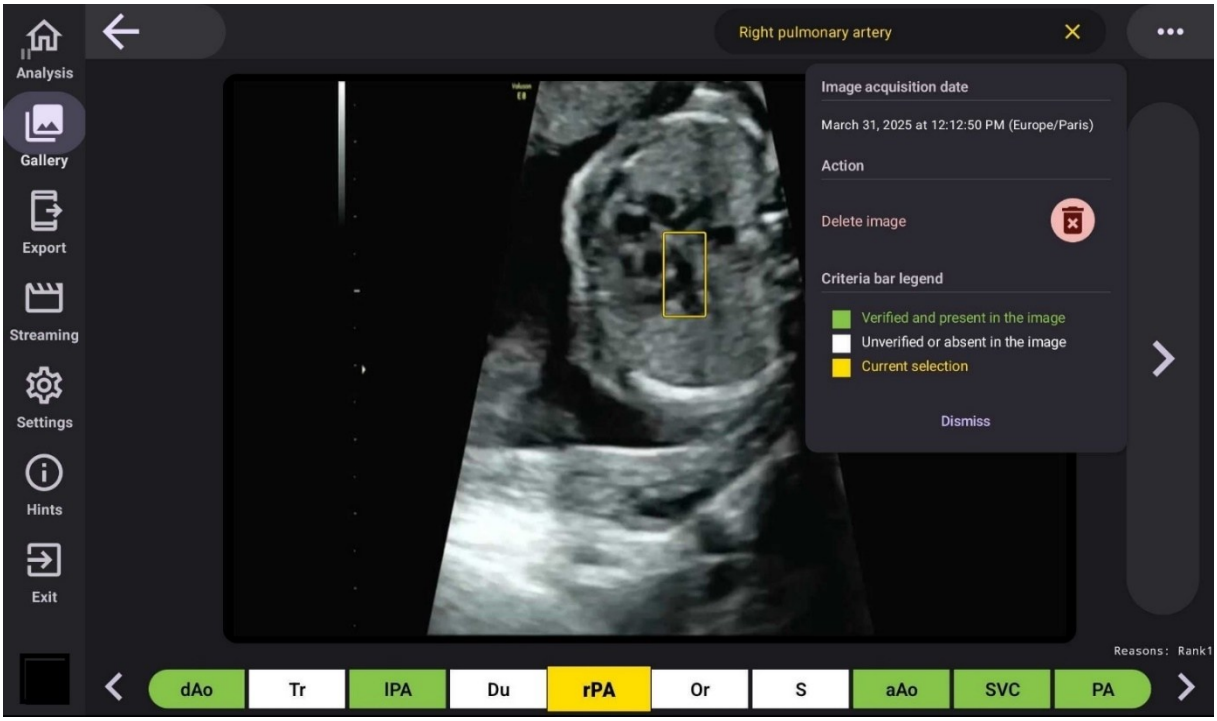
a. Faceți clic pe un anumit plan (panoul din stânga) pentru a vizualiza imaginile selectate referitoare la planul respectiv. Criteriile de culoare verde sunt verificate, iar criteriile de culoare albă nu sunt verificate.

b. Imaginile selectate pentru măsurătorile biometrice conțin următoarele informații: numele măsurătorii, valoarea, intervalul de referință și starea „în afara intervalului”, dacă este cazul. Punctele cheie ale măsurătorii și formele sunt afișate cu galben.

c. Faceți clic pe o anumită structură pentru a vizualiza imaginile selectate care conțin această structură. Criteriul de calitate selectat este de culoare galbenă, iar caseta de delimitare care încadrează criteriul este afișată pe imagini.

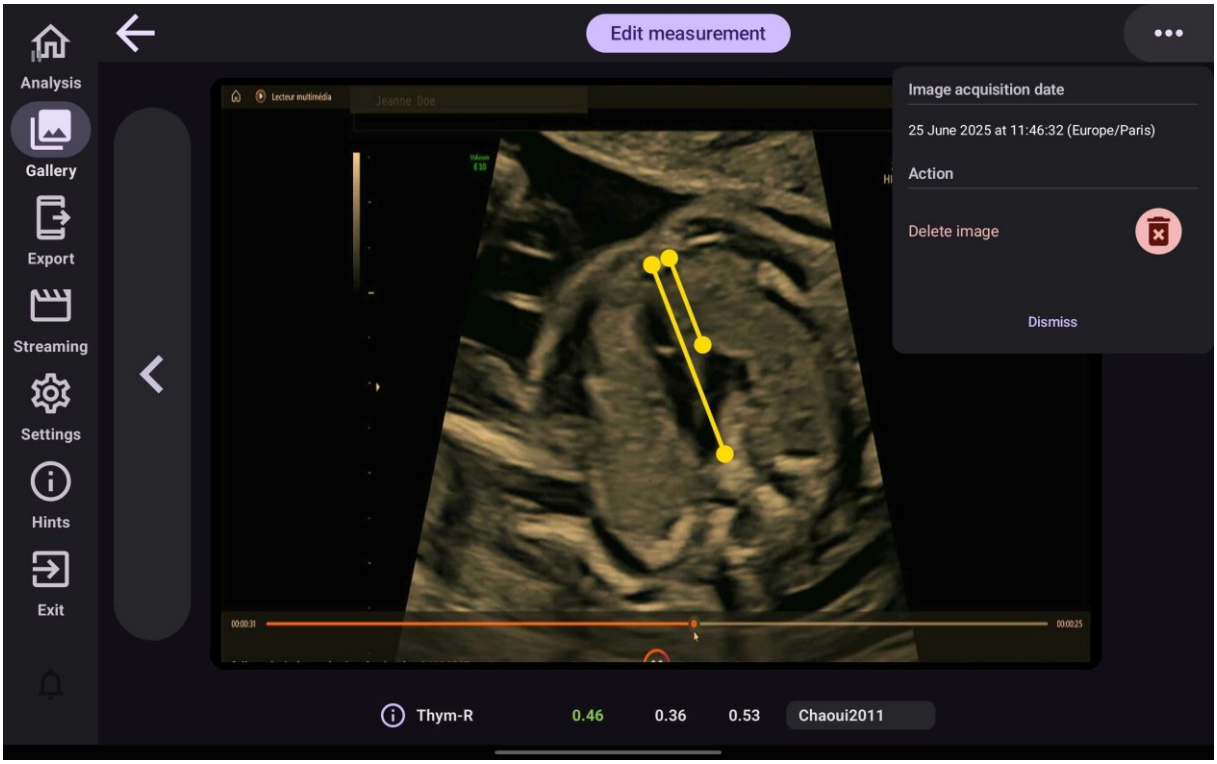


d. Faceți clic pe o imagine de completitudine pentru a o mări. Puteți face clic pe un criteriu de calitate de culoare verde pentru a afișa caseta de delimitare care încadrează criteriul de calitate. Criteriul de calitate ales este afișat cu galben. Casetele albe înseamnă că criteriile de calitate sunt prezente pe alte imagini din galerie sau sunt neverificate. Faceți clic pe simbolul coșului de gunoi pentru a șterge imaginea. Puteți glisa direct pe părțile laterale ale imaginii pentru a naviga prin alte imagini ale planului de vizualizare.



e. Faceți clic pe o imagine de măsurare pentru a o mări. Punctele cheie ale măsurătorii și formele sunt afișate cu galben. Rețineți că punctele cheie ale

măsurătorii nu sunt concepute pentru a fi amplasate în locația exactă, ci pentru a fi suficient de precise pentru a afișa valoarea corectă a măsurătorii. Sunt afișate valoarea și starea „în afara intervalului”, dacă este cazul, împreună cu intervalul de referință și sursa bibliografică selectată. Faceți clic pe simbolul coșului de gunoi pentru a șterge imaginea. Puteți glisa direct pe părțile laterale ale imaginii pentru a naviga prin alte imagini ale planului de vizualizare. Puteți edita punctele cheie pentru o măsurătoare pe imaginile de măsurare, făcând clic pe butonul „Edit Measurement” (Editare măsurătoare). Valoarea măsurătorii va fi apoi actualizată în consecință, iar software-ul va împiedica orice modificare automată prin rescanare după editare. Măsurătoarea editată va fi marcată cu următorul simbol: .

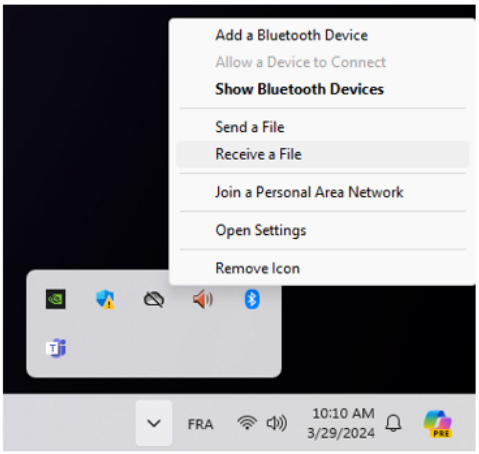


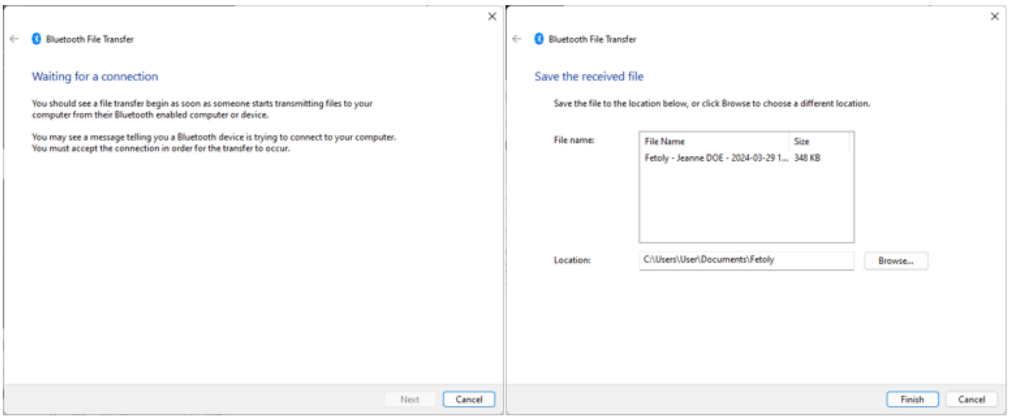


f. Dacă este necesar, puteți reveni la pagina de analiză pentru a relansa analiza și a obține imagini suplimentare.

Exportul imaginilor

1. Accesați secțiunea „Export Method” (Metodă de export) din „Settings” (Setări) pentru a selecta modul de export pe care doriți să îl utilizați.
2. Accesați secțiunea „Export” (Export) pentru a exporta imaginile selectate:
    a. Dacă ați ales conexiunea Bluetooth (doar pentru Android), accesați PC-ul și selectați „Receive a File” (Primire fișier) în configurația Bluetooth.





b. Dacă ați ales conexiunea DICOM, puteți verifica dacă pacientul selectat pentru export este cel corect și puteți selecta un alt pacient în cazul unei erori, utilizând lista de lucru DICOM de pe pagina de analiză.

c. Pagina de export afișează un rezumat al examinării și vă reamintește să verificați dacă aveți toate imaginile necesare pentru gestionarea eficientă a pacientului înainte de export.

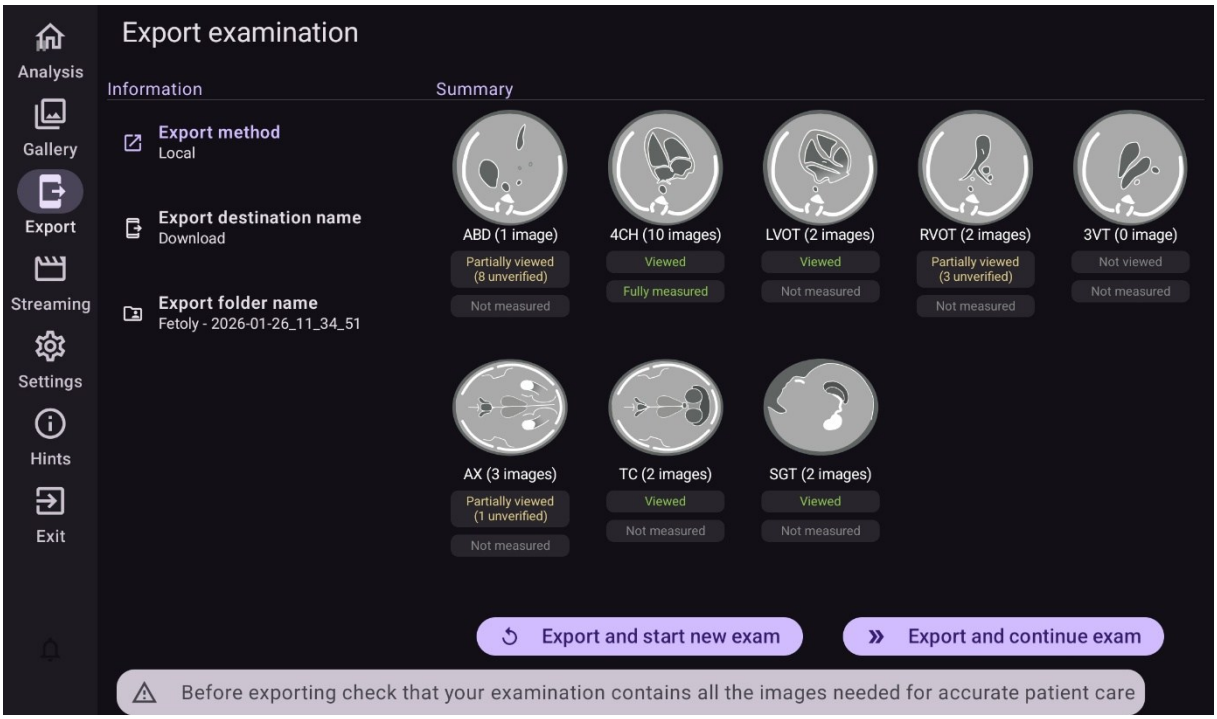
d. Pagina de export afișează metodologia de export aleasă. Dacă doriți să modificați setările, puteți accesa direct pagina cu setările de export făcând clic pe „Export Method” (Metodă de export).

e. Pagina de export afișează locația fișierului de export de pe dispozitivul ales și numele fișierului configurat pentru exportul local.

f. Faceți clic pe butonul „Export and Start a New Exam” (Exportați și începeți o nouă examinare) pentru a exporta imaginile și a șterge examinarea înainte de a începe o nouă examinare.

g. Sau, faceți clic pe butonul „Export and Continue Exam” (Exportați și continuați examinarea) pentru a exporta imaginile fără a șterge setul curent de imagini selectate și analiza completitudinii.

h. Software-ul vă va indica dacă exportul a reușit sau a eșuat.



Reinițializare (ștergere)

Dacă nu ați utilizat funcția de ștergere de pe pagina de export, accesați „Analysis” (Analiză) și faceți clic pe butonul „Clear” (Ștergere) pentru a reinițializa setul de imagini selectate și examinarea.

Setări avansate

Dacă doriți să dezactivați funcția de măsurare, accesați „Settings” > „Advanced” (Setări > Avansate) și faceți clic pe buton.

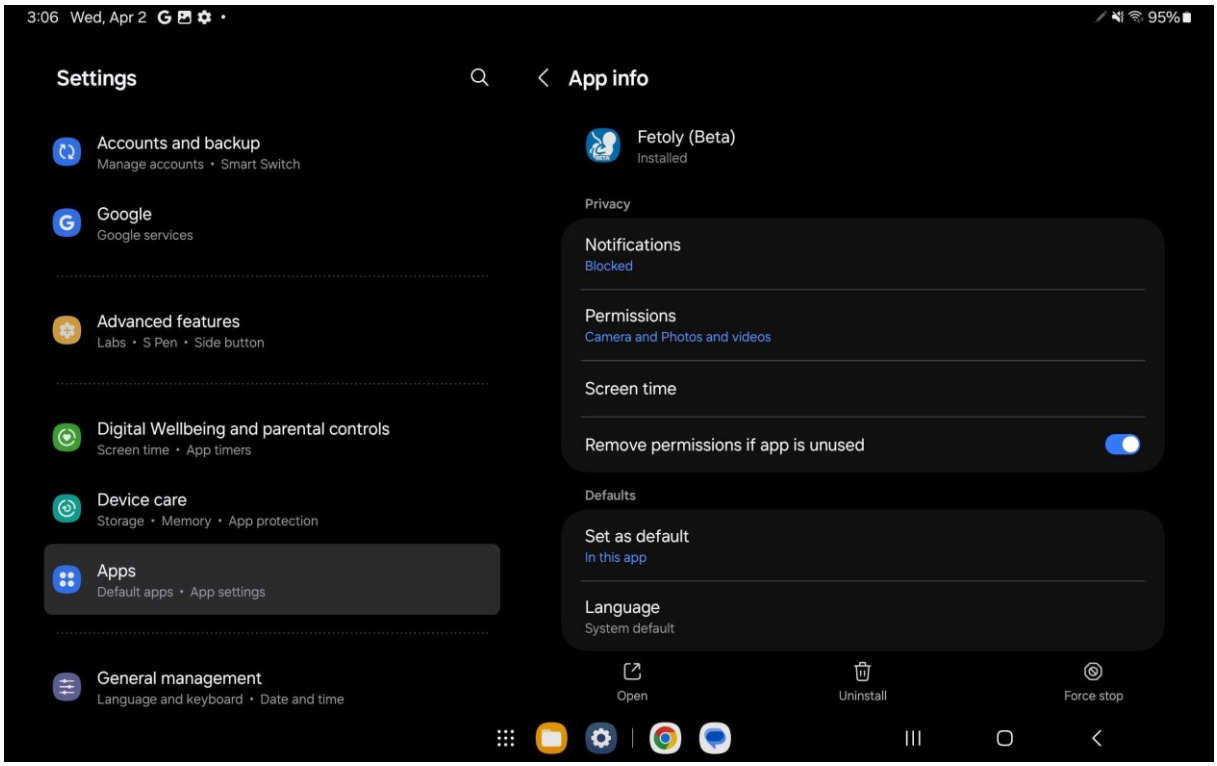
Actualizarea software-ului și a licenței

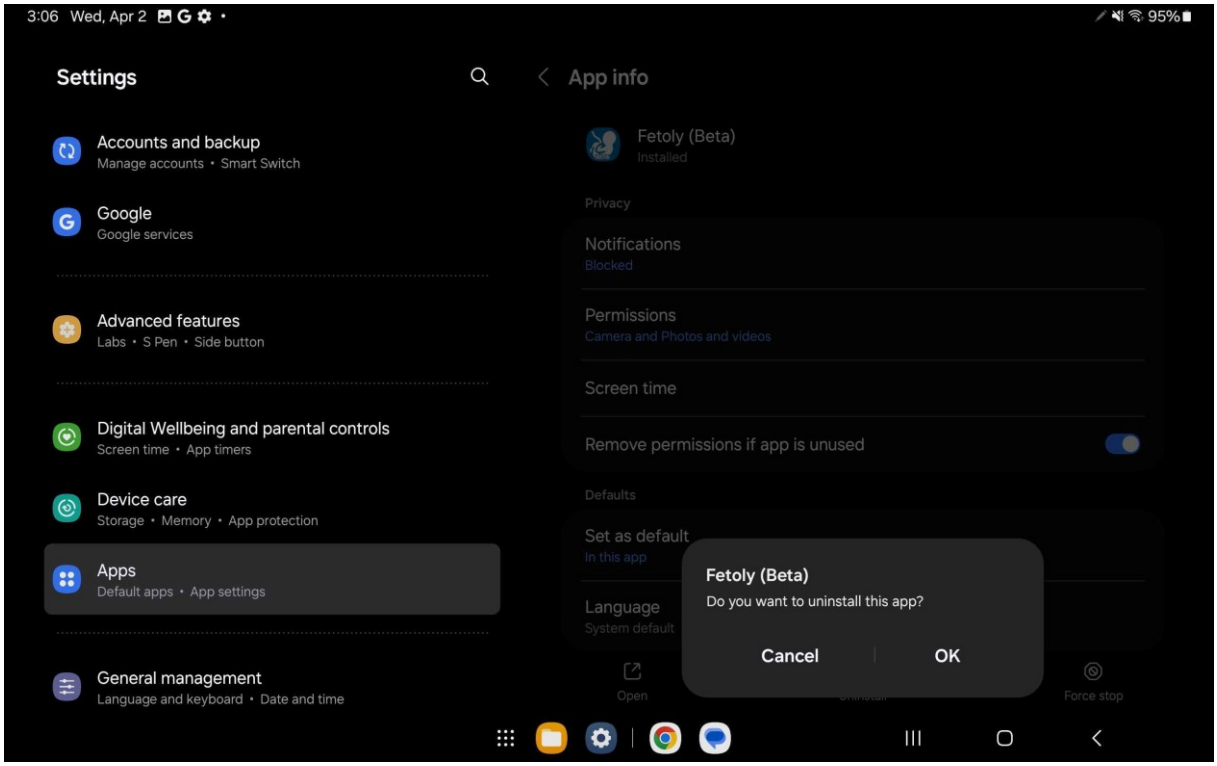
Software-ul verifică periodic disponibilitatea actualizărilor noi pentru aplicație. Pentru a asigura disponibilitatea imediată a actualizărilor noi, activați actualizările în fundal pentru FETOLY în setările Google Play/App Store. Atunci când este disponibilă o actualizare, software-ul va afișa o pagină de blocare la lansare, solicitându-i utilizatorului să actualizeze și să repornească aplicația pentru a o putea utiliza în continuare. După acceptarea actualizării, Google Play/App Store instalează actualizarea și repornește aplicația. Este necesară o conexiune la internet pentru a verifica actualizările și pentru a reînnoi automat licența. Dacă dispozitivul nu este conectat la internet pentru o perioadă de 30 de zile, software-ul va fi blocat.

Licența dvs. este verificată și reînnoită automat atunci când conexiunea la internet este activată, până la expirarea contractului de licență. Data expirării licenței este afișată în pagina de setări a licenței. La expirarea contractului de licență, dacă nu se reînnoiește contractul, software-ul va solicita introducerea unui nou cod de înregistrare și va bloca funcționalitățile.

Dezinstalarea software-ului

Dezinstalați aplicația ca orice altă aplicație de pe tabletă, după cum se arată mai jos:





14. Întreținere, manipulare și eliminare

- Instrucțiunile trebuie citite înainte de utilizare.
- Lansați actualizările atunci când software-ul solicită acest lucru la lansare.

- Pentru piața din Statele Unite ale Americii a fost inclus un plan predeterminat de control al modificărilor (PCCP). Acest PCCP este implementat pentru modelul de învățare automată încorporat în dispozitivul FETOLY, care ar putea modifica performanța, intrările sau utilizarea dispozitivului. Prin urmare, se recomandă insistent să fiți conectat(ă) în mod regulat la internet pentru a permite instalarea automată a actualizărilor.
- Introduceți codul de înregistrare atunci când este solicitat de software la lansare.
- Pentru a scoate din uz și a elimina software-ul, dezinstalați aplicația prin intermediul sistemului Android ca orice altă aplicație de pe tabletă, în setările aplicației, așa cum este ilustrat în paragraful „Dezinstalarea software-ului" de mai sus. Această dezinstalare va șterge toate datele legate de utilizarea FETOLY, inclusiv licența, de pe tabletă.

Simboluri utilizate pe etichetă (pagina About [Despre]):

	Producător (simbol de fabrică compact)
	Dispozitiv marcat CE
	Identificatorul unic al dispozitivului 01: UDI-DI 11: Data fabricației 8012: Versiunea software
	Consultați instrucțiunile de utilizare
	Legea federală restricționează vânzarea acestui dispozitiv exclusiv cadrelor medicale sau la indicația acestora
	Dispozitiv medical
	Data fabricației (simbol de fabrică gol)
	Numele și adresa reprezentantului din Elveția

FETOLY

Softvér na podporu ultrazvukového vyšetrenia plodu

Návod na použitie

IFU-WW-FETOLY-V4

21. október 2025

NÁVOD NA POUŽITIE (SLOVENČINA)

1. Identifikácia zariadenia

FETOLY

Softvér na podporu ultrazvukového vyšetrenia srdca a mozgu plodu.

Verzia softvéru pre ktorú je tento návod na použitie určený: V2026.02.25

2. Aktualizácia

FETOLY bol aktualizovaný na verziu 2026.02.25 nasledovne:

- FETOLY je teraz kompatibilný s iOS
- Na základe modifikácie č. 4 PCCP boli pridané nasledujúce merania: PLAS, pomer CSP, pomer VP
- Transventrikulárne a transthalamické pohľady boli zlúčené do axiálneho pohľadu.
- Návod na použitie bol aktualizovaný s cieľom objasniť funkciu zobrazenia kľúčových bodov a pridať varovanie, že softvér sa nesmie používať pri transvaginálnej metóde skenovania
- Výkon detekcie AI modelu bol vylepšený podľa modifikácie č. 1 PCCP.
- Teraz je možné aktivovať režim TLS pre export DICOM.

Overovacie testy boli úplne znovu spustené, aby sa overilo, že aktualizácia nemá žiadny vplyv na funkcie zariadenia. Použitá metodika je rovnaká ako pri pôvodnej verzii produktu.

3. Identifikácia výrobcu

FETOLY je vyrábaný spoločnosťou:

DIAGNOLY

2 Place de Francfort, 69003 LYON, Francúzsko

Tel: +33(0)6.58.49.07.84

Reklamácie výrobku: support@diagnoly.com

Každý závažný incident nahláste spoločnosti Diagnoly prostredníctvom e-mailovej adresy pre reklamácie na produkty a príslušnému orgánu vo vašej krajine.

CE 0197

4. Opis a prezentácia zariadenia

Fetoly je softvér, ktorý pomáha sonografom, pôrodníkom, rádiológom, špecialistom na matersko-fetálnu medicínu a detským kardiológom (označovaným ako zdravotnícki pracovníci, t. j. ZP) vykonávať ultrazvukové vyšetrenia mozgu a srdca plodu v reálnom čase. Fetoly môžu zdravotnícki pracovníci používať počas ultrazvukových vyšetrení plodu v druhom a treťom trimestri (rozsah gestačného veku: od 17. do 40. týždňa).

Tento softvér je určený na pomoc zdravotníckym pracovníkom pri hodnotení úplnosti ultrazvukového vyšetrenia mozgu a srdca plodu v súlade s národnými a medzinárodnými usmerneniami. Fetoly je tiež určený na realizáciu biometrických meraní mozgu/srdca plodu v súlade s národnými a medzinárodnými usmerneniami.

Na používanie softvéru Fetoly je potrebné nainštalovať softvér na hardvérové zariadenie, ktoré je pripojené k ultrazvukovému prístroju prostredníctvom HDMI pripojenia. Softvér prijíma ultrazvukové obrazy zachytené pripojeným ultrazvukovým prístrojom v reálnom čase. Softvérový zmrazený algoritmus hlbokého učenia, ktorý bol vyškolený prostredníctvom učenia pod dohľadom, analyzuje obrazy tohto toku ultrazvukových snímok s cieľom detegovať pohľady na mozog/srdce, kritériá kvality v rámci týchto pohľadov a vykonať biometrické merania srdca a mozgu.

Softvér poskytuje tieto používateľsky prístupné informácie:

13. **Úplnosť vyšetrenia**: softvér v reálnom čase zobrazuje, ktoré zobrazenia mozgu/srdca a kritériá kvality sú počas vyšetrenia overované softvérom. Overené zobrazenia mozgu/srdca a kritériá kvality sú lekárom prístupné v ktoromkoľvek okamihu ultrazvukového vyšetrenia v reálnom čase.
14. **Biometrické kvantitatívne merania:** Softvér v reálnom čase zobrazuje, ktoré merania mozgu a srdca softvér počas vyšetrenia vidí a vykonáva a či sú merania v rozsahu alebo mimo rozsahu v porovnaní s referenčnými rozsahmi definovanými podľa stavu techniky. Overené merania srdca a mozgu sú lekárom prístupné na pozadí kedykoľvek počas ultrazvukového vyšetrenia.
15. **Ilustrácia vyšetrenia:** softvér vyberie podmnožinu obrazov, ktoré ilustrujú
    - overené pohľady a kritériá kvality. Tieto obrazy môžu prezerať lekári, aby overili zobrazenia a prítomnosť kritérií. Voliteľne môžu lekári na vybraných obrazoch zobraziť lokalizáciu zistených kritérií kvality
    - každého merania. Pri každom meraní softvér zobrazí obraz s nakresleným meraním (žltou farbou) a nameranou hodnotou (v spodnej časti). Používateľovi je tiež pripomenutý normálny rozsah tohto merania. Používateľ môže presúvať kľúčové body a softvér podľa toho aktualizuje merania.
16. **Správa o vyšetrení:** Softvér umožňuje používateľovi exportovať správu o vyšetrení, ktorá obsahuje:
    - zhrnutie meraní a úplnosti,
    - ilustrácie (obrazy).

Definíciu úplného vyšetrenia

Pre fetálne srdce

Tabuľka 10: Zoznam 52 kritérií kvality definujúcich kvalitu 5 zobrazení odporúčaných Medzinárodnou spoločnosťou pre ultrazvuk v pôrodníctve a gynekológii (International Society of Ultrasound in Obstetrics and Gynecology) na skríning srdca plodu v 2. a 3. trimestri tehotenstva.

Pohľady na srdce	***Kritériá kvality v rámci zobrazení***	
 ***(A) ABD*** ***Pohľad z brušnej dutiny***	*(A1) Sp*	*Chrbtica*
	(A2) lRb	*Ľavé rebro*
	(A3) rRb	*Pravé rebro*
	(A4) Ao	*Aorta descendens*
	(A5) VC	*Vena cava inferior*
	(A6) St	*Žalúdok*
	(A7) Uv	*Pupočníková žila*

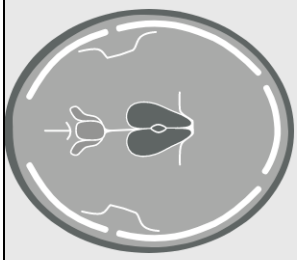
(n = 8)	*(A8) aA*	*Predná časť brušnej dutiny*
 ***(B) 4CH*** ***Štvorkomorové zobrazenie*** ***(n = 19)***	*(B1) Sp*	*Chrbtica*
	(B2) lRb	*Ľavé rebro*
	(B3) rRb	*Pravé rebro*
	(B4) Ao	*Aorta descendens*
	(B5) lPV	*Ľavá pľúcna žila*
	(B6) rPV	*Pravá pľúcna žila*
	(B7) LA	*Ľavá predsieň*
	(B8) RA	*Pravá predsieň*
	(B9) FOF	*Septum primum (Vieussensova chlopňa alebo foramen ovale)*
	(B10) FO	*Otvorené foramen ovale*
	(B11) MV	*Mitrálna chlopňa*
	(B12) TV	*Trikuspidálna chlopňa*
	(B13) bCr	*Spojenie medzi crux cordis a predsieňovým septom (septum vestibulare)*
	(B14) Cr	*Posun atrioventrikulárnej chlopne v crux cordis*
	(B15) tCr	*Spojenie medzi interventrikulárnym septom a crux cordis*
	(B16) IVS	*Interventrikulárne septum*
	(B17) LV	*Ľavá komora*
	(B18) RV	*Pravá komora*
	(B19) Str	*Sternum*
 ***(C) LVOT*** ***Pohľad na výtokový trakt ľavej komory*** ***(n = 6)***	*(C1) LA*	*Ľavá predsieň*
	(C2) aAo	*Proximálna aorta ascendens*
	(C3) SV	*Semilunárne chlopne*
	(C4) LV	*Ľavá komora*
	(C5) IVS	*Interventrikulárne septum*
	(C6) RV	*Pravá komora*
 ***(D) RVOT*** ***Pohľad na výtokový trakt pravej komory*** ***(n = 10)***	*(D1) dAo*	*Aorta descendens*
	(D2) Tr	*Priedušnica/priedušky*
	(D3) lPA	*Ľavá pľúcna artéria*
	(D4) Du	*Ductus arteriosus*
	(D5) rPA	*Pravá pľúcna artéria*
	(D6) Or	*Odstup pľúcnych artérií*
	(D7) S	*Septum medzi kmeňom pľúcnej tepny a aortou ascendens*
	(D8) aAo	*Aorta ascendens*
	(D9) SVC	*Vena cava superior*
	(D10) PA	*Pľúcny kmeň*

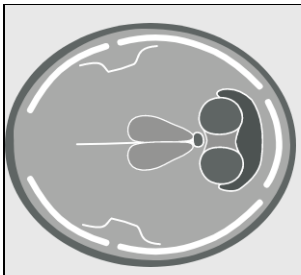
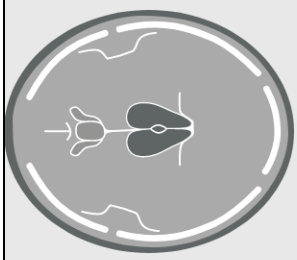
 ***(E) 3VX*** ***Pohľad na tri cievy*** ***(n = 9)***	*(E1) Sp*	*Chrbtica*
	(E2) Tr	*Trachea*
	(E3) ES	*Bočný priestor vľavo od ductus/pľúcnej artérie*
	(E4) DuA	*Duktálny oblúk napojený na aortu descendens*
	(E5) Du	*Duktálny oblúk, ktorý nie je spojený s aortou descendens*
	(E6) aAo	*Aorta ascendens*
	(E7) aAr	*Aortálny oblúk*
	(E8) SVC	*Vena cava superior*
	(E9)	*Týmus/hrudná kosť*

*Medzinárodné a národné usmernenia [Carvalho, 2023] odporúčajú pri rutinnom ultrazvukovom vyšetrení v 2. a 3. trimestri 5 pohľadov na fetálne srdce: (A) pohľad z brušnej dutiny, (B) štvorkomorové zobrazenie, (C) pohľad na výtokový trakt ľavej komory, (D) pohľad na výtokový trakt pravej komory, (E) pohľad na tri cievy. Kvalita týchto 5 pohľadov na srdce závisí od prítomnosti 52 anatomických kritérií kvality v rámci pohľadov (**Tabuľka 1**). Vyšetrenie teda možno považovať za kompletné, ak zdravotnícky pracovník získa všetkých 5 pohľadov na srdce a ich kvalitatívne kritériá.*

Pre fetálny mozog

Tabuľka 11: Zoznam 34 kritérií kvality definujúcich kvalitu 3 zobrazení odporúčaných Medzinárodnou spoločnosťou pre ultrazvuk v pôrodníctve a gynekológii (Society of Ultrasound in Obstetrics and Gynecology) na skríning mozgu plodu v 2. a 3. trimestri tehotenstva.

Pohľady na mozog	***Kritériá kvality v rámci zobrazení***	
 ***(F) TV*** ***Axiálny pohľad*** ***(n = 18)***	*(F1) aFx*	*Predný falx cerebri*
	(F2) CSP	*Cavum septi pellucidi*
	(F3) Pre	*Fornix*
	(F4) dAV	*Distálna predná komora*
	(F5) pAV	*Proximálna predná komora*
	(F6) AC	*Cisterna ambiens*
	(F7) Atr	*Atrium*
	(F8) CP	*Choroidálny plexus*
	(F9) POS	*Sulcus parieto-occipitalis*
	(F10) pFx	*Zadný falx cerebri*
	(F11) dCS	*Distálna koronárna sutúra*
	(F12) pCS	*Proximálna koronárna sutúra*
	(F13) SF	*Sylvianova fisúra*
	(F14) Sk	*Lebka*
	(F15) Sep	*Oddelenie polovíc thalamu*
	(F16) 3V	*3. komora*
	(F17) dTh	*Distálny thalamus*
	(F18) pTh	*Proximálny thalamus*

 ***(G) TC*** ***Transcerebelárny pohľad*** ***(n = 8)***	*(G1) dTh*	*Distálny thalamus*
	(G2) pTh	*Proximálny thalamus*
	(G3) 4V	*4. komora*
	(G4) Ver	*Vermis*
	(G5) dCH	*Distálna hemisféra cerebella*
	(G6) pCH	*Proximálna hemisféra cerebella*
	(G7) CB	*Cerebelárny okraj*
	(G8) CM	*Cisterna magna*
 ***(H) TT*** ***Transtalamický pohľad*** ***(n = 12)***	*(H1) aFx*	*Predný falx cerebri*
	(H2) CSP	*Cavum septi pellucidi*
	(H3) dAV	*Distálna predná komora*
	(H4) pAV	*Proximálna predná komora*
	(H5) dTh	*Distálny thalamus*
	(H6) pTh	*Proximálny thalamus*
	(H7) Sep	*Oddelenie polovíc thalamu*
	(H8) 3V	*3. komora*
	(H9) dCS	*Distálna koronárna sutúra*
	(H10) pCS	*Proximálna koronárna sutúra*
	(H11) SF	*Sylvianova fisúra*
	(H12) Sk	*Lebka*
 ***(I) SAG*** ***Sagitálny/profilový pohľad*** ***(n = 8)***	*(I1) NB*	*Nosová kosť*
	(I2) uVer	*Horná časť vermisu*
	(I3) lVer	*Dolná časť vermisu*
	(I4) Fas	*Fastigium*
	(I5) rgCC	*Rostrum a genu corpus callosum*
	(I6) bCC	*Telo corpus callosum*
	(I7) sCC	*Splenium corpus callosum*
	(I8) CSP	*Cavum septi pellucidi*

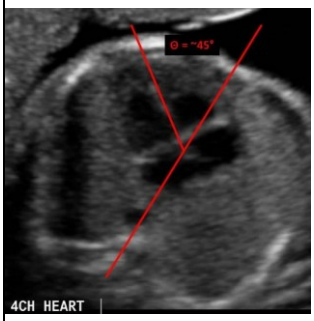
Biometrické merania a referenčné intervaly

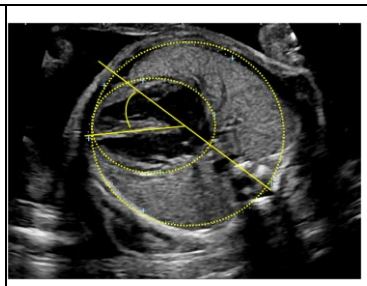
Softvér FETOLY poskytuje tri typy automatizovaných biometrických meraní:

- **Meranie uhla** zobrazené v stupňoch (°);
- **Meranie pomeru** (vzdialenosť normalizovaná s inou vzdialenosťou, buď vyjadrená ako pomer, alebo v percentách);
- **Počet** zistených anatomických orientačných bodov;

Zoznam meraní a ich referenčných intervalov:

V nasledujúcej tabuľke sú podrobne uvedené biometrické merania poskytované softvérom FETOLY a ich zodpovedajúce normálne referenčné intervaly na základe uznávanej literatúry.

Parameter	*Informácie dostupné v softvére FETOLY (opis a zdroje)*
(M1) Srdcová os	***Čo je to srdcová os (CAx)?***  *(zdroj: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* ***Os srdca** (alebo **srdcový uhol**) označuje orientáciu srdca vzhľadom na stredovú líniu hrudníka meranú v štvorkomorovom zobrazení. Stanovuje sa uhlom medzi čiarou pozdĺž interventrikulárneho septa a anteroposteriórnou čiarou, ktorá pretína hrudník.* *Obraz by mal obsahovať chrbticu, hrudnú kosť a štyri komory. Ľavé a pravé rebrá by mali byť prítomné a viditeľné ako jednotlivé rebrá.* ***Čo sa odporúča v usmerneniach?*** *Usmernenia ISUOG uvádzajú, že kardiologické vyšetrenie by malo zahŕňať štvorkomorové zobrazenie a jeho hodnotenie by malo zahŕňať srdcovú os („Normálne fetálne srdce leží hlavne na ľavej strane, s vrcholom srdca smerujúcim doľava v uhle 45 ± 20° vo vzťahu k anteroposteriórnej osi hrudníka“) (Carvalho, 2023). Citujú (Comstock, 1987), v ktorom sa uvádza referenčný rozsah pre srdcovú os.* *Usmernenia ASE odporúčajú aj hodnotenie srdcovej osi („Srdcová os je odporúčanou súčasťou echokardiografického 2D zobrazenia plodu [...] normálna 35 – 65°) (Moon-Grady, 2023).* ***Dostupné referenčné intervaly:*** • **Comstock (1987):** (Priemer ± 2 SD) o 17 – 40 GA: [25° – 65°]. • **ASE (2023):** (referenčný rozsah definovaný v usmernení) o 17 – 40 GA: [35° – 65°]
(M2) Kardiotorakálny pomer	***Čo je kardiotorakálny pomer?***



(zdroj: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)

Kardiotorakálny pomer plodu (CTR) je pomer priečneho obvodu epikardiálneho povrchu srdca k priečnemu obvodu hrudníka meraný v štvorkomorovom zobrazení počas diastoly.

Obraz by mal obsahovať chrbticu, hrudnú kosť a štyri komory. Ľavé a pravé rebrá by mali byť prítomné a viditeľné ako jednotlivé rebrá.

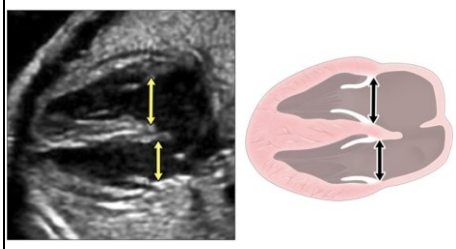
Čo sa odporúča v usmerneniach?

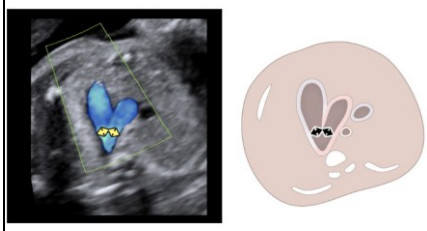
V usmerneniach ASE sa uvádza, že kardiotorakálny pomer je povinnou súčasťou echokardiografického vyšetrenia plodu („Štandardné biometrické merania z axiálneho obraze na úrovni štvorkomorového zobrazenia. Kardiotorakálny pomer sa vypočíta z merania vnútorného obvodu (alebo plochy) hrudníka a epikardiálneho povrchu srdca“) (Moon-Grady, 2023).

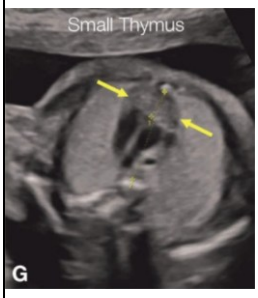
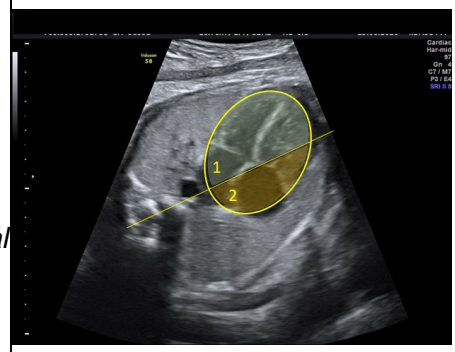
V usmerneniach AIUM sa tiež uvádza, že kardiotorakálny pomer je povinnou srdcovou biometriou (AIUM, 2019). Toto meranie odporúčajú aj usmernenia ISUOG („Medzi kľúčové prvky normálneho štvorkomorového zobrazenia v polovici trimestra patrí plocha srdca, ktorá nepresahuje jednu tretinu plochy hrudníka“) (Carvalho, 2013). V príručke od Abuhamada (2009) sa tiež odporúča posúdiť rozmery srdca („Rozmery srdca plodu možno ľahko posúdiť zmeraním pomeru obvodu alebo plochy srdca k obvodu alebo ploche hrudníka získanej na úrovni štvorkomorového pohľadu“) (Abuhamad, 2009). Pokiaľ ide o referenčný rozsah, usmernenia AHA (Donofrio, 2014) a aj Abuhamadova príručka citujú (Paladini, 1990).

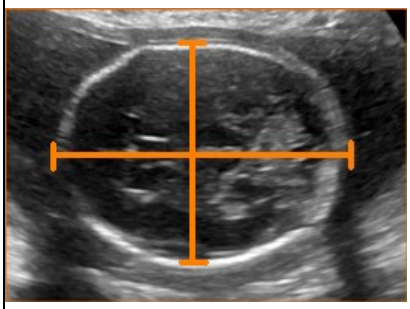
Dostupné referenčné intervaly:

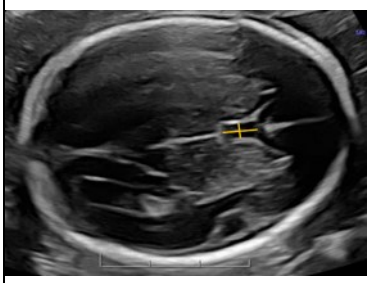
- **Paladini (1990):** (2,5. a 97. percentil pre obvod)
    - 17 GA: [0,40 – 0,52]
    - 18 GA: [0,40 – 0,52]
    - 19 GA: [0,42 – 0,51]
    - …
    - 40 GA: [0,46 – 0,56]
- **Garcia-Otero (2020)**: (5. a 95. percentil pre plochu)
    - 18 GA: [0,16 – 0,25]
    - 19 GA: [0,16 – 0,26]
    - …
    - 40 GA: [0,21 – 0,35]
- **ASE** (Moon-Grady, 2023): (usmernením definovaný rozsah optimálneho skóre plodu pre oblasť)

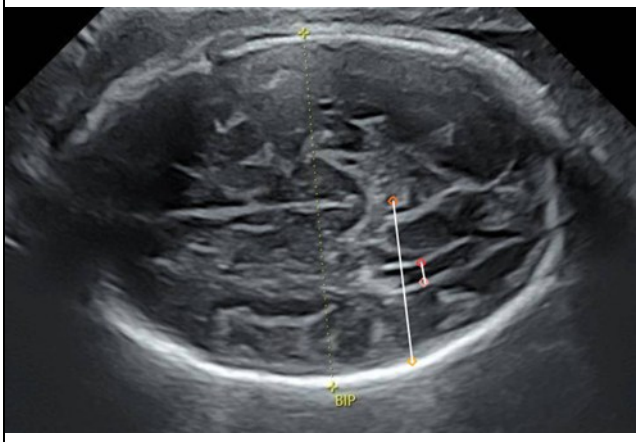
	○ 17 – 40 GA: [0,20 – 0,35]
(M3) Pomer šírky komôr	***Čo je pomer pravej a ľavej komory?***  *(zdroj: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* ***Pomer pravej a ľavej komory (TV/MV)** sa vzťahuje na pomer priemeru prstenca trikuspidálnej chlopne (TV) k priemeru prstenca mitrálnej chlopne (MV), ktorý sa používa na hodnotenie morfológie srdca plodu. Určuje sa porovnaním priemerov TV a MV v ich najširších bodoch počas diastoly.* *Obraz by mal obsahovať chrbticu a hrudnú kosť. Ľavé a pravé rebrá by mali byť prítomné a viditeľné ako jednotlivé rebrá. Štvorkomorové zobrazenie by malo byť viditeľné a dobre kontrastné.* *Poznámka: existujú dve konvencie na meranie komorového priemeru (Schneider, 2005): meranie na úrovni chlopní alebo rozmer na konci diastoly. Upozorňujeme, že pri tomto meraní sa používa prvý z nich.* ***Čo sa odporúča v usmerneniach?*** *Usmernenia AIUM uvádzajú, že porovnanie trikuspidálneho a mitrálneho chlopňového prstenca v diastole je požadovanou kardiologickou biometriou („Trikuspidálny a mitrálny chlopňový prstenec v diastole ([...] porovnanie ľavostranných a pravostranných chlopní) je požadovanou kardiologickou biometriou“) (AIUM, 2019). Pokiaľ ide o referenčné rozsahy, citujú sa (DeVore, 2017), (Lee, 2009) a (Schneider, 2005).* *V usmerneniach ISUOG sa tiež uvádza, že pravo-ľavá asymetria si vyžaduje ďalšie vyšetrenie („Obe komory by mali mať podobnú veľkosť. Hoci sa mierna komorová disproporcia môže vyskytnúť ako normálny variant v treťom trimestri tehotenstva, pravo-ľavá asymetria v polovici gravidity si vyžaduje ďalšie vyšetrenie“) (Carvalho, 2023). Pokiaľ ide o referenčný rozsah, cituje sa (Kirk, 1999).* *Usmernenia ASE tiež uvádzajú, že vzťah medzi veľkosťou komôr je povinnou súčasťou hodnotenia echokardiogramu plodu („Súčasťou kompletného echokardiografického vyšetrenia je nevyhnutné zmerať AV chlopňový prstenec v rannej diastole“) (Moon-Grady, 2023). Príručka Abuhameda (2012) tiež zdôrazňuje význam pomeru šírky pravej a ľavej komory, ktorý je u normálnych plodov 1,19.* ***Dostupné referenčné intervaly:*** • **Gabbay-Benziv (2015)** (Gabbay-Benziv, 2015): (2,5. a 97. percentil) ○ 17 GA: [0,87 –1,22] ○ 18 GA: [0,86 – 1,22] ○ 19 GA: [0,86 – 1,22] ○ … ○ 38 GA: [0,87 – 1,30]

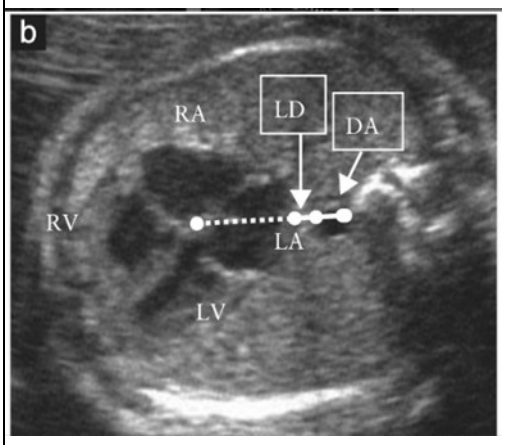
	• **Garcia-Otero (2020)**: (5. a 95. percentil) ○ 18 GA: [0,82 – 1,21] ○ 19 GA: [0,82 – 1,22] ○ … ○ 40 GA: [0,86 – 1,27]
(M4) Pomer ciev	***Čo je pomer veľkých ciev?***  *(zdroj: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Pomer veľkosti veľkých ciev (Ao/Du) označuje pomer medzi priemermi aortálneho istmu (Ao) a duktu (Du) pri zobrazení troch ciev. Určuje sa meraním priemerov duktu a aortálneho oblúka pri ich základni. Všimnite si, že v literatúre sa používa aj pomer priemeru mediastinálnej pľúcnej tepny (PA) k aorte ascendens (Ao) (Slodki, 2009).* *Obraz by mal obsahovať chrbticu a hrudnú kosť s viditeľnými a zreteľnými ľavými a pravými rebrami. Ductus arteriosus a aorta ascendens by mali byť jasne viditeľné, čo dokazuje ich spojenie.* ***Čo sa odporúča v usmerneniach?*** *Americké a medzinárodné organizácie, vrátane ASE, ISUOG, AIUM, AHA, uvádzajú, že hodnotenie veľkostného pomeru medzi veľkými tepnami je povinné hodnotenie (Donofrio, 2014). („Je dôležité zistiť normálnosť oboch veľkých tepien vrátane ich veľkosti [...] vo vzájomnom vzťahu“) (Carvalho, 2023). Príručka od Abuhamada (2012) tiež zdôrazňuje význam porovnania priemerov aortálneho oblúka s hlavnou pľúcnou tepnou, konkrétne v oblasti istmu. Pokiaľ ide o referenčné rozsahy, cituje sa štúdia od Pasquiniho (2007) (Pasquini, 2007).* ***Dostupné referenčné intervaly:*** • **Pasquini (2007):** ○ Konštanta: [0,86 – 1,12] (priemer ± SD) ○ Konštanta: [0,74 – 1,23] (2,5. a 97,5. percentil) (Buyens, 2012)
(M5) Počet ciev	***Čo je počet ciev?*** *Zobrazenie troch ciev plodu (3VV) je axiálna rovina používaná pri prenatálnom zobrazovaní na posúdenie veľkých ciev srdca. Tento pohľad zvyčajne zobrazuje tri cievy, zvyčajne pľúcnu tepnu, aortu a hornú dutú žilu. Počet ciev sa zameriava iba na guľaté alebo podlhovasté anechoické štruktúry a nezahŕňa priedušnicu a aortu descendens.* *Na obraze by mali byť zvýraznené cievy s jasným kontrastom a odlíšením štruktúr.* ***Čo sa odporúča v usmerneniach?*** *Usmernenia ISUOG odporúčajú, aby hodnotenie pri zobrazení troch ciev zahŕňalo „posúdenie počtu ciev. Zľava doprava sú to pľúcna tepna, aorta a pravá horná dutá*

	žila“ (Carvalho, 2023). Usmernenia ASE tiež zdôrazňujú, že je potrebné zaznamenať abnormality v počte ciev (Moon-Grady, 2023). Ako medzinárodný štandard sa očakáva počet troch ciev.
(M6) Pomer medzi týmusom a hrudníkom	***Čo je pomer medzi týmusom a hrudníkom?***  *(zdroj: Abuhamad, A. Z. a Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4th ed.). Wolters Kluwer)* ***Pomer medzi týmusom a hrudníkom** je pomer anteroposteriórneho priemeru týmusu a vnútrohrudného priemeru mediastína meraný pri zobrazení troch ciev a priedušnice.* *Na obraze by sa mala zobrazovať chrbtica, hrudná kosť a vzostupná aorta, pričom ľavé a pravé rebro by mali byť viditeľné ako jednotlivé štruktúry. Týmus by mal byť jasne viditeľný a identifikovateľný.* ***Čo sa odporúča v usmerneniach?*** *V usmerneniach ISUOG sa uvádza, že „[hodnotenie pri zobrazení troch ciev] zahŕňa posúdenie usporiadania ciev“. (Carvalho, 2023) a že „môže zlepšiť detekciu anomálií odtokového traktu [...]“. V rámci hodnotenia pomeru medzi týmusom a hrudníkom na odhalenie anomálií odtokového traktu sa cituje (Chaoui, 2011). Príručka od Abuhamada (2022) takisto poukazuje na dôležitosť hodnotenia tohto parametra.* ***Dostupné referenčné intervaly:*** • **Chaoui (2011):** o Konštanta počas celej gravidity: [0,36 – 0,53] (priemer ± 2 SD)
(M7) Kardiotorakálna poloha	***Čo je to kardiotorakálna poloha?***  *(obraz inšpirovaný stránkou https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/)* ***Kardiotorakálna poloha** sa stanovuje predĺžením línie interventrikulárneho septa smerom dozadu, ktorá rozdeľuje predsiene, až k bodu na spodnej časti srdca*

	(Smith, 1995). Toto sa vykonáva na štvorkomorovom zobrazení výpočtom pomeru plochy ľavej časti k celkovej ploche srdca. Tento postup zahŕňa nakreslenie elipsy nad srdcom a jej rozdelenie anteroposteriórnou čiarou, ktorá pretína hrudník (strednú líniu hrudníka). Ľavá (1) a pravá (2) oblasť predstavujú povrchy srdca nachádzajúce sa na ľavej a pravej anatomickej strane od stredovej čiary. Poloha je vyjadrená ako pomer ľavej plochy k celkovej ploche srdca. ***Čo sa odporúča v usmerneniach?*** *Poloha srdca plodu v hrudníku je dôležitým parametrom pri hodnotení plodu. Odchýlka od normálnej polohy je dôvodom na ďalšie vyšetrenie potenciálnych intrathorakálnych, intrakardiálnych alebo extrakardiálnych intrathorakálnych patologických stavov (Abdullah, 2000). Americké aj medzinárodné usmernenia, vrátane ISUOG (2008), ASE (2004), AIUM (2013), AHA (2014), odporúčajú starostlivé meranie polohy srdca plodu v hrudníku na štvorkomorovom zobrazení počas štandardného pôrodníckeho vyšetrenia (Donofrio, 2014). Podľa týchto usmernení sa normálne fetálne srdce nachádza predovšetkým na ľavej strane hrudníka, pričom najmenej 50 % (pomer ≥ 0,5) jeho plochy sa nachádza v ľavom hrudnom priestore („srdce je prevažne na ľavej strane“) (Carvalho, 2013) („je potrebné venovať zvláštnu pozornosť srdcovej osi a polohe. Väčšina srdca [by sa mala nachádzať] v ľavej časti hrudníka“) (Carvalho, 2023). Štúdie potvrdzujú tieto odporúčania, pričom Chiappa (2009) a ďalší (Smith, 1995, Sever, 2021) uvádzajú, že „dve tretiny srdca by sa mala nachádzať na ľavej strane hrudníka“.* *Hoci mnohé smernice definujú normálnu kardiotorakálnu polohu ako 0,66 (pomer ≈ 2/3) a nemala by klesnúť pod 0,5, literatúra jasne nedefinuje hornú hranicu normálneho rozsahu. Používatelia môžu buď len vizualizovať nameranú hodnotu bez referenčného rozsahu, alebo definovať vlastný referenčný rozsah.*
(M8) Cefalický index	***Čo je to cefalický index?***  *(zdroj: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* ***Cefalický index** je pomer biparietálneho priemeru (BPD) a okcipitofrontálneho priemeru (OFD) vynásobený 100. Cefalický index poskytuje predstavu o tvare hlavy plodu. Predná a zadná časť, OFD, sa meria pomocou kurzora umiestneného na vonkajšom okraji lebečných kostí. Výrazne znížený cefalický index naznačuje dolichocefáliu, zatiaľ čo hrubo zvýšený index môže naznačovať brachycefáliu. Ak je tento parameter abnormálny, na predpovedanie veku plodu by sa mali použiť iné merania, napríklad HC (obvod hlavy), obvod brucha alebo dĺžka stehennej kosti (Timor-Tritsch, 2012).* *Na obraze by sa mal zobrazovať osovo symetrický pohľad na mozog, zachytávajúci transthalamickú rovinu s viditeľnými a jasnými oboma hemisférami.* ***Čo sa odporúča v usmerneniach?***

	V usmerneniach ISUOG sa uvádza, že „cefalický index je pomer maximálnej šírky hlavy (BPD) k jej maximálnej dĺžke (okcipitofrontálny priemer (OFD)) a táto hodnota sa môže použiť na charakterizovanie tvaru hlavy plodu. Abnormálny tvar hlavy (napr. brachycefália alebo dolichocefália) môže súvisieť so syndrómami alebo byť dôsledkom oligohydramniónu či panvového predloženia plodu. Toto zistenie môže viesť aj k nepresným odhadom veku plodu, keď sa používa BPD; v týchto prípadoch sú merania HC ešte spoľahlivejšie (Hadlock, 1981)" (Salomon, 2022). ***Dostupné referenčné intervaly:*** • **Hadlock (1981):** o Konštanta počas celej gravidity: [74 – 83] (priemer ± SD)
(M9) Pomer CSP	***Čo je pomer CSP?***  *(zdroj: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. In Journal of Ultrasound in Medicine (Vol. 43, Issue 8, pp. 1461–1466). Wiley)* **Opis:** pomer **Cavum Septum Pellucidum (CSP)** je pomer medzi dĺžkou a šírkou CSP. Určuje sa meraním dĺžky a šírky CSP a výpočtom pomeru dĺžky k šírke. Obraz by mal zobrazovať axiálne symetrický transventrikulárny pohľad na mozog s jasnou vizualizáciou cavum septum pellucidum (CSP) a anatomických štruktúr stredovej línie. **Čo odporúčajú usmernenia?** Usmernenia ISUOG uvádzajú, že tvar CSP bol opísaný ako relatívne spoľahlivý marker čiastočnej agenézy corpus callosum a ako referenčné rozsahy citujú štúdie Karla (2017) a Shena (2015) (Malinger, 2020). Usmernenia Svetovej asociácie perinatálnej medicíny (WAPM) uvádzajú, že CSP musí byť vizualizované a „neúspech vizualizácie CSP alebo jeho abnormálny vzhľad (Karl, 2017) predikuje anomálie komisúry. Normálny vzhľad CSP však nevylučuje všetky abnormality [corpus callosum]" (Robertis, 2021). Tento parameter sa nachádza aj v najmodernejších technikách strojového hlbokého učenia pre rutinnú biometriu (Coronado-Gutiérrez, 2023). **Dostupné referenčné intervaly:** · **Karl (2017):** *Konštantný počas celého tehotenstva: [1,5 – 3,3] (5. a 95. percentil)*

(M10) Pomer zadnej mozgovej komory k priemeru hemisféry (pomer VP)	***Aký je pomer zadnej mozgovej komory k priemeru hemisféry?***  Pomer **zadnej mozgovej komory k priemeru hemisféry** je parameter používaný na posúdenie vývoja mozgu, najmä veľkosti komory vo vzťahu k celkovej veľkosti mozgu (hemisféry). Je to pomer medzi: - Priemerom zadnej mozgovej komory (= šírka predsiene) – zvyčajne sa vzťahuje na predsieň laterálnej komory (nachádzajúcu sa na spojení okcipitálneho, temporálneho a parietálneho rohu). - Priemer mozgovej hemisféry – celkový priečny priemer príslušnej mozgovej hemisféry. Toto meranie sa vykonáva v transventrikulárnom pohľade. **Čo odporúčajú usmernenia?** Usmernenia ISUOG uvádzajú, že meranie šírky predsiene je neoddeliteľnou súčasťou sonografického skríningu malformácií CNS a že šírka predsiene by sa mala merať od vnútornej strany k vnútornej strane a mala by byť < 10 mm počas celého tehotenstva. Recenzovaná literatúra (Nicolaides, 1994) zdôrazňuje úlohu pomeru zadnej mozgovej komory k priemeru hemisféry pri zlepšovaní prenatálneho hodnotenia mozgu a presnosti fetálneho skríningu, pretože je to relatívne spoľahlivý marker ventrikulomegálie. **Dostupné referenčné intervaly:** • **Nicolaides (1994):** (5. a 95. percentil) ○ 17GA: [0,29 – 0,45] ○ 18GA: [0,27 – 0,42] ○ 19GA: [0,26 – 0,40] ○ … *39GA: [0,15 – 0,24]*

(M11) Priestor za ľavou predsieňou (PLAS)	***Čo je index priestoru za ľavou predsieňou (PLAS)?***  *(zdroj: Kawazu, 2014*) Index priestoru za ľavou predsieňou (PLAS) je fetálne echokardiografické meranie používané na posúdenie priestoru za ľavou predsieňou. Vypočíta sa zo štvorkomorového pohľadu na srdce plodu. Meranie zahŕňa určenie vzdialenosti medzi zadnou stenou ľavej predsiene a prednou stenou zostupnej aorty (LD) a vydelenie tejto vzdialenosti priemerom zostupnej aorty (DA). Výpočet sa vykonáva počas koncovej systolickej fázy srdcového cyklu. Vzorec pre index PLAS je: **Index PLAS = vzdialenosť medzi ľavou predsieňou a zostupnou aortou (LD) / priemer zostupnej aorty (DA)** **Čo odporúčajú usmernenia? (Odôvodnenie a klinický význam)** Recenzovaná literatúra (Kawazu, 2019, Anuwutnavin, 2023, Akkurt, 2015) zdôraznila význam indexu PLAS ako jednoduchého a reprodukovateľného merania pri skríningu srdca plodu. Index PLAS, ktorý pôvodne zaviedol (Kawazu, 2014), bol identifikovaný ako citlivý marker pre prenatálnu diagnostiku totálneho anomálneho pľúcneho venózneho spojenia (TAPVC), stavu, pri ktorom pľúcne žily nie sú spojené s ľavou predsieňou. Zvýšený index PLAS je významným indikátorom TAPVC ***Dostupné referenčné intervaly:*** *Kawazu, 2014 a Kawazu, 2019: Konštantný počas celého tehotenstva: Optimálna hraničná hodnota **> 1,27** pre podozrenie na TAPVC. U normálnych plodov bol priemerný index PLAS **0,62 ± 0,19.***

*Každé meranie si vyžaduje špecifický ultrazvukový pohľad, označovaný ako „**podhľad“**, ktorý musí na zabezpečenie presného merania spĺňať špecifické podmienky zobrazenia. Podhľad je vždy odvodený od jedného zo štandardných pohľadov na plod, ale vyžaduje aj dodatočné osobitné podmienky. Napríklad meranie pomeru pravej a ľavej komory na štvorkomorovom zobrazení si vyžaduje správne zobrazenie hraníc komôr, čo nie je potrebné pri meraní srdcovej osi.*

Nasledujúca tabuľka znázorňuje zhodu medzi čiastkovými pohľadmi a srdcovými alebo mozgovými pohľadmi uvedenými v usmerneniach ISUOG.

Pohľad	***Podhľad***
Štvorkomorové zobrazenie	***Podhľad 1 (M1):** obraz by mal zahŕňať chrbticu, hrudnú kosť, štyri komory a interventrikulárne septum. Ľavé a pravé rebrá by mali byť prítomné a viditeľné ako jednotlivé rebrá.* ***Podhľad 2 (M2):** Obraz by mal obsahovať chrbticu, hrudnú kosť a štyri komory. Ľavé a pravé rebrá by mali byť prítomné a viditeľné ako jednotlivé rebrá.* ***Podhľad 3 (M3):** Obraz by mal obsahovať chrbticu a hrudnú kosť. Ľavé a pravé rebrá by mali byť prítomné a viditeľné ako jednotlivé rebrá. Štvorkomorové zobrazenie by malo byť viditeľné a dobre kontrastné.* ***Podhľad 7 (M7):** Obraz by mal obsahovať chrbticu, hrudnú kosť a štyri komory.* ***Podhľad 11 (M11):** Hrudník vyzerá zaoblený, nemá tvar otvoreného „V“. Ľavé a pravé rebrá vyzerajú ako samostatné štruktúry, nie ako viacero paralelných alebo postupných línií. Predsieň a aorta, najmä ich zadné steny, ako aj priestor medzi nimi, sú jasne viditeľné bez zakrytia tieňom.*
Pohľad na tri cievy a tri cievy a priedušnicu	***Podhľad 4 (M4):** Obraz by mal obsahovať chrbticu a hrudnú kosť s viditeľnými a zreteľnými ľavými a pravými rebrami. Ductus arteriosus a aorta ascendens by mali byť jasne viditeľné, čo dokazuje ich spojenie.* ***Podhľad 5 (M5):** Na obraze by mali byť zvýraznené cievy s jasným kontrastom a odlíšením štruktúr.* ***Podhľad 6 (M6):** Na obraze by sa mala zobrazovať chrbtica, hrudná kosť a vzostupná aorta, pričom ľavé a pravé rebro by mali byť viditeľné ako jednotlivé štruktúry. Týmus by mal byť jasne viditeľný a identifikovateľný.*
Axiálny pohľad	***Podhľad 8 (M8):** Na obraze by sa mal zobrazovať osovo symetrický pohľad na mozog, zachytávajúci transthalamickú rovinu s viditeľnými a jasnými oboma hemisférami.* ***Podhľad 9 (M9):** Obraz by mal zobrazovať axiálne symetrický transventrikulárny pohľad na mozog s jasnou vizualizáciou*

	cavum septum pellucidum (CSP) a anatomických štruktúr strednej línie. ***Podhľad 10 (M10):*** *Obraz by mal zobrazovať axiálny pohľad, kde je viditeľný POS (parieto-okcipitálny sulkus).*

Funkcia 1: Meranie úplnosti

Softvér pomocou zmrazeného algoritmu hlbokého učenia, ktorý bol vycvičený pomocou učenia pod dohľadom, hodnotí úplnosť ultrazvukového vyšetrenia plodu. Overuje, či boli získané všetky informácie zodpovedajúce odporúčaným usmerneniam pre vyšetrenie srdca/mozgu plodu. Tieto informácie zodpovedajú prítomnosti:

- 5 hlavných kardiologických zobrazení plodu a 52 kritérií kvality, ktoré boli podrobne opísané vyššie a ktoré umožňujú dodržiavanie kardiologického skríningu;
- 4 hlavných pohľadov na mozog plodu a 43 kritérií kvality, ktoré boli podrobne opísané vyššie, čo umožňuje dodržiavanie súladu pri skríningu mozgu.

Stránka úplnosti **(obraz 1)** pozostáva z/zo:

- **Tlačidla prehrávania/pauzy** spúšťa analýzu obrazov získaných ultrazvukovým systémom na začiatku vyšetrenia,
- **Počtu pohľadov srdca/mozgu** overených softvérom od začiatku vyšetrenia. Pohľad na srdce sa považuje za overený, ak je detegované aspoň na jednom obraze.
- Tlačidiel pre **jednotlivé kritériá kvality**, ktorých farba sa po overení softvérom zmení na **zelenú**.

Každý obraz analyzovaný softvérom dynamicky aktualizuje úplnosť stránky nasledovne:

- ak sa kritérium kvality zistí na obraze prvýkrát, označí sa ako **overené** a jeho farba sa zmení z bielej na **zelenú**),
- ak sa na obraze zistí kritérium kvality, ktoré už bolo overené, nedôjde k žiadnym zmenám,
- ak sa na obraze nezistí kritérium kvality, nedôjde k žiadnym zmenám.

Ak je kritérium kvality spojené s anomáliou, stav detekcie kritéria závisí od jeho vizuálneho vzhľadu:

- ak anomália zmení kritérium kvality takým spôsobom, že sa zmení jeho vzhľad, softvér nemusí toto kritérium zistiť a stav zostane neoverený,
- ak anomália nemá vplyv na vzhľad kritéria kvality, softvér zistí kritérium a označí ho ako overené, pričom jeho farba sa zmení z bielej na **zelenú**.

Upozorňujeme, že na etikete je uvedené, že pomocou softvéru FETOLY nie je možné realizovať žiadnu diagnostiku ani skríning. Kritérium kvality, ktoré softvér neoveril, samo o sebe neznamená patológiu.

Stránka úplnosti sa priebežne aktualizuje v reálnom čase, čo používateľom umožňuje na ňu kedykoľvek počas vyšetrenia nahliadnuť. Takto môžu na túto stránku nahliadnuť bez toho, aby sa narušil ich pracovný postup vyšetrenia alebo aby bolo potrebné vykonať ďalšie činnosti.

Pripomíname, že ako je vysvetlené v časti 10, softvér FETOLY sa nemôže používať na diagnostiku ani skríning. Kritérium kvality, ktoré nie je overené softvérom, samo o sebe neznamená patológiu.

Funkcia 2: Ilustrácia úplnosti

Táto funkcia bola vyvinutá na zvýšenie bezpečnosti hodnotenia úplnosti, ktoré sa vykonáva v prvom module. Umožňuje lekárom overiť prehľad úplnosti vyšetrenia, t. j. overené zobrazenia a kritériá kvality softvérom prostredníctvom stránky galérie v rozhraní softvéru. Pracuje nepretržite, v reálnom čase vyhodnocuje každý obraz spracovaný prvým modulom a uchováva súbor obrazov ako vizuálny dôkaz overených pohľadov na srdce/mozog a kritérií kvality k danému okamihu.

Cieľom FETOLY nie je vybrať „najlepšiu“ alebo „vysokú“ diagnostickú kvalitu podľa danej kvalitatívnej stupnice. Cieľom FETOLY je skôr výber obrazov ilustrujúcich kvantitatívnu úplnosť vyšetrenia z hľadiska overených zobrazení a kritérií kvality. Keďže tento modul sa úplne spolieha na výkon algoritmu hlbokého učenia prvého modulu, nie je potrebné žiadne ďalšie hodnotenie výkonu.

Napríklad, ak má používateľ akékoľvek pochybnosti o jednom zo zelených kritérií kvality, toto kritérium môže overiť kliknutím naň na stránke galérie. Softvér zobrazí obrazy, ktoré obsahujú toto kritérium (na obraze nižšie žltou farbou). Keď je vybrané kritérium, softvér zobrazí ohraničujúci rámček obklopujúci kritérium na týchto obrazoch. Tieto informácie o ohraničujúcom rámčeku sú súčasťou výstupu Fetoly-CNN.

Funkcia 3: Biometrické merania

Časť modulu **FETOLY-MEASURE** je na stránke analýzy označená ako „Measure“ (Meranie) a zobrazuje zoznam meraní, z ktorých každé je usporiadané do štyroch polí:

- **Názov merania**: zobrazuje názov alebo skratku merania spolu s informačnou ikonou. Kliknutím na ikonu sa otvoria podrobné informácie o meraní vrátane jeho vedeckého odkazu.
- **Hodnota merania a jednotky**: nameraná hodnota sa zobrazí s príslušnými jednotkami. Napríklad pri uhlových meraniach sa zobrazuje symbol stupňa (°), pri percentuálnych meraniach symbol percenta (%); inak zostáva pole prázdne, čo znamená, že ide o relatívne meranie. Ak došlo k úprave kľúčových bodov na stránke galérie, pred meraním sa zobrazí symbol ( ).
- **Referenčný rozsah**: v tomto poli sa uvádza referenčný rozsah merania definovaný v literatúre a podložený vedeckou referenciou. Zdrojom môže byť usmernenie, recenzovaná publikácia, učebnica alebo vlastný rozsah definovaný používateľom. Kliknutím na **tlačidlo novej karty** môže používateľ manuálne definovať referenčný rozsah alebo aktualizovať literárnu referenciu, ak je k dispozícii viacero odkazov. Kliknutím na **tlačidlo s odkazom na informácie** sa používateľ dostane do vyskakovacieho okna so všetkými potrebnými informáciami týkajúcimi sa daného kritéria merania.
- **Gestačný vek,** ktorý sa stanoví pred spustením analýzy.

Funkcia 4: Ilustrácia meraní

Podobne ako ilustrácia úplnosti, ktorá vyberá obrazy, ktoré demonštrujú zobrazenia a kritériá kvality, automaticky vyberá obraz pre každé meranie. Oba súbory obrazov sa zobrazia spoločne na stránke Galéria. Tieto dva súbory obrazov sa dajú ľahko rozlíšiť: obrazy z funkcie merania obsahujú hodnotu merania a názov parametra, zatiaľ čo obrazy úplnosti neobsahujú anotácie.

Obrazy „merania“ aj „úplnosti“ sú usporiadané na základe príslušných ultrazvukových zobrazení. Upozorňujeme, že príslušnosť zobrazenia obrazov vybraných funkciou merania je

nezávislá od funkcie úplnosti. Každé čiastkové meranie zodpovedá podľa definície jednému z 5 ultrazvukových zobrazení srdca alebo 4 ultrazvukovým zobrazeniam mozgu. Znalosťou podhľadu možno preto obrazy vybrané funkciou merania automaticky zaradiť do príslušného podhľadu, ku ktorému tento podhľad patrí.

Funkcia 5: Správa o vyšetrení

Správa môže byť vygenerovaná z exportnej stránky. Bude obsahovať výsledky a obrazy zo softvéru FETOLY a bude odoslaná do externého zariadenia.

Súvisiace zariadenia

Ak chcete používať zariadenie FETOLY, musíte mať tieto pridružené zariadenia:

- Ultrazvukový prístroj.
- Tablet a prípadne server DICOM, počítač so serverom FTP alebo funkciou Bluetooth, ako je uvedené v časti 10 „interakcia s inými zariadeniami“.
- Kľúč UVC a kábel HDMI na prepojenie tabletu s ultrazvukovým prístrojom.

5. Určené použitie a indikácie na použitie

Softvér FETOLY je určený na analýzu sekvencií ultrazvukových obrazov plodu pomocou techník strojového učenia na automatickú analýzu:

- detekovania pohľadov mozgu a srdca a kritérií kvality v rámci týchto pohľadov;
- detekovania obrazov vhodných na meranie biometrických parametrov srdca a mozgu plodu a poskytovania kvantitatívneho merania týchto parametrov.

Zariadenie je určené na použitie ako pomôcka na súčasné čítanie počas získavania a interpretácie ultrazvukových obrazov plodu.

FETOLY je indikovaný na použitie počas rutinného vyšetrenia srdca a mozgu plodu v 2. a 3. trimestri tehotenstva (gestačný vek: od 17. do 40. týždňa).

6. Zamýšľaní používatelia

Výrobok musí používať kvalifikovaný zdravotnícky pracovník špecializovaný na prenatálne ultrazvukové zobrazovanie.

7. Cieľová skupina pacientov

Tehotné ženy počas 2. a 3. trimestra tehotenstva.

8. Klinické výhody a výkony

Pre tento typ zariadenia, SWMD, ktoré je súbežnou pomôckou na čítanie údajov používanou počas bežného vyšetrenia srdca a mozgu plodu, sa preukázal nasledujúci klinický prínos:

- štandardizácia rutinného vyšetrenia srdca a mozgu plodu podľa požiadaviek uznávaných medzinárodných usmernení.

Výsledky výkonnosti sú podrobne uvedené v tabuľkách nižšie. Výsledky samostatného testovania výkonu ukazujú, že FETOLY automaticky:

- detekuje ultrazvukové pohľady srdca a mozgu plodu s citlivosťou ≥ 85 % (kritérium prijateľnosti) a špecifickosťou ≥ 85 % (kritérium prijateľnosti),
- detekuje kritériá kvality v rámci pohľadov srdca s citlivosťou ≥ 90 % (kritérium prijateľnosti) a špecifickosťou ≥ 90 % (kritérium prijateľnosti),
- detekuje kritériá kvality v rámci pohľadov mozgu s citlivosťou ≥ 85 % (kritérium prijateľnosti) a špecifickosťou ≥ 85 % (kritérium prijateľnosti),
- lokalizuje ohraničujúce polia kritérií kvality s priemerným priesečníkom nad zjednotením (IoU) ≥ 50 % (kritérium prijateľnosti),
- odhalí ultrazvukové podhľady srdca a mozgu plodu s citlivosťou ≥ 70 % (kritérium prijateľnosti) a špecifickosťou ≥ 70 % (kritérium prijateľnosti) a
- realizuje meranie srdca a mozgu plodu podľa jednotlivých LOA definovaných na koncové body štúdie.

Celkové výsledky

Pohľad na plod	***Citlivosť***			***Špecifickosť***		
	n (pozitívne)	***Bodový odhad***	***Bootstrap IS (95 %)***	***n (negatívne)***	***Bodový odhad***	***Bootstrap IS (95 %)***
Pohľad z brušnej dutiny	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Štvorkomorové zobrazenie	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Pohľad na výtokový trakt ľavej komory	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Pohľad na výtokový trakt pravej komory	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Pohľad na tri cievy	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Axiálny pohľad	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Transcerebelárny pohľad	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Sagitálny/profilový pohľad	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Iný pohľad	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Kritérium kvality	***Citlivosť***			***Špecifickosť***			***mIoU***	
	poč.	***Bodový odhad***	***Bootstrap IS (95 %)***	***poč.***	***Bodový odhad***	***Bootstrap IS (95 %)***	***Bodový odhad***	***Bootstrap IS (95 %)***
Pohľad z brušnej dutiny								
Chrbtica	*678*	*0.99*	*(0.983,0.998)*	*4531*	*0.998*	*(0.996,0.999)*	*0.71*	*(0.70,0.73)*
Ľavé rebro	*632*	*0.967*	*(0.953,0.980)*	*4577*	*0.993*	*(0.991,0.995)*	*0.58*	*(0.56,0.59)*
Pravé rebro	*627*	*0.951*	*(0.934,0.967)*	*4582*	*0.994*	*(0.992,0.996)*	*0.55*	*(0.53,0.57)*
Aorta descendens	*673*	*0.972*	*(0.959,0.984)*	*4536*	*0.998*	*(0.996,0.999)*	*0.52*	*(0.51,0.54)*
Vena cava inferior	*550*	*0.939*	*(0.917,0.958)*	*4659*	*0.987*	*(0.983,0.990)*	*0.5*	*(0.49,0.52)*

Žalúdok	*675*	*0.983*	*(0.973,0.992)*	*4534*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.75)*
Pupočníková žila	*552*	*0.973*	*(0.958,0.986)*	*4657*	*0.99*	*(0.988,0.993)*	*0.64*	*(0.62,0.65)*
Predná časť brušnej dutiny	*643*	*0.969*	*(0.954,0.983)*	*4566*	*0.993*	*(0.990,0.995)*	*0.5*	*(0.49,0.52)*
Štvorkomorové zobrazenie								
Chrbtica	*595*	*0.969*	*(0.955,0.982)*	*4614*	*0.998*	*(0.996,0.999)*	*0.74*	*(0.73,0.75)*
Ľavé rebro	*536*	*0.945*	*(0.924,0.963)*	*4673*	*0.99*	*(0.987,0.993)*	*0.64*	*(0.63,0.66)*
Pravé rebro	*548*	*0.948*	*(0.926,0.965)*	*4661*	*0.993*	*(0.991,0.996)*	*0.68*	*(0.66,0.69)*
Aorta descendens	*608*	*0.968*	*(0.952,0.981)*	*4601*	*0.997*	*(0.995,0.998)*	*0.66*	*(0.65,0.67)*
Ľavá pľúcna žila	*240*	*0.925*	*(0.889,0.958)*	*4969*	*0.975*	*(0.971,0.979)*	*0.51*	*(0.48,0.53)*
Pravá pľúcna žila	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*
Ľavá predsieň	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Pravá predsieň	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Septum primum (Vieussensova chlopňa alebo foramen ovale)	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Otvorené foramen ovale	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Mitrálna chlopňa	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Trikuspidálna chlopňa	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Spojenie medzi crux cordis a predsieňovým septom (septum vestibulare)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Posun atrioventrikulárnej chlopne v crux cordis	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Spojenie medzi interventrikulárnym septom a crux cordis	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Interventrikulárne septum	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Ľavá komora	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Pravá komora	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Sternum	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Pohľad na výtokový trakt ľavej komory								
Ľavá predsieň	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*

Proximálna aorta ascendens	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Semilunárne chlopne	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Ľavá komora	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Interventrikulárne septum	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Pravá komora	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Pohľad na výtokový trakt pravej komory								
Aorta descendens	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Priedušnica/priedušky	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Ľavá pľúcna artéria	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*
Ductus arteriosus	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Pravá pľúcna artéria	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Odstup pľúcnych artérií	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Septum medzi kmeňom pľúcnej tepny a aortou ascendens	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Aorta ascendens	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Vena cava superior	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Pľúcny kmeň	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Pohľad na tri cievy								
Chrbtica	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Trachea	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Bočný priestor vľavo od ductus/pľúcnej artérie	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Duktálny oblúk napojený na aortu descendens	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Duktálny oblúk, ktorý nie je spojený s aortou descendens	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Aorta ascendens	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Aortálny oblúk	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*

Vena cava superior	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Týmus/hrudná kosť	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Axiálny pohľad								
Predný falx cerebri	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavum septi pellucidi	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Fornix	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Distálna predná komora	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Proximálna predná komora	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cisterna ambiens	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Atrium	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Choroidálny plexus	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Sulcus parieto-occipitalis	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Zadný falx cerebri	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Distálna koronárna sutúra	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Proximálna koronárna sutúra	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Sylvianova fisúra	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Lebka	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Oddelenie polovíc thalamu	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
3. komora	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Distálny thalamus	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Proximálny thalamus	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Transcerebelárny pohľad								
Distálny thalamus	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Proximálny thalamus	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
4. komora	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Vermis	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*

Distálna hemisféra cerebella	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Proximálna hemisféra cerebella	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Cerebelárny okraj	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Cisterna magna	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Sagitálny/profilový pohľad								
Nosová kosť	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Horná časť vermisu	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Dolná časť vermisu	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastigium	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Rostrum a genu corpus callosum	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Telo corpus callosum	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Splenium corpus callosum	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavum septi pellucidi	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Meranie	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI	LOA	LOA CI
thymic-thoracic_ratio (pomer_týmus-hrudník)	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
cardiothoracic_ratio (kardiotorakálny_pomer)	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
vessels_ratio (pomer_ciev)	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
cephalic_index (cefalický_index)	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
vessels_number (počet_ciev)	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
cardiothoracic_position (kardiotorakálna_poloha)	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
cardiac_angle (srdcový uhol)	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
Pomer CSP	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
Pomer VP	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
Priestor za ľavou predsieňou	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Meranie	sklon	zachytenie	IS sklonu	IS zachytenia
thymic-thoracic_ratio (pomer_týmus-hrudník)	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
cardiothoracic_ratio (kardiotorakálny_pomer)	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
vessels_ratio (pomer_ciev)	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
cephalic_index (cefalický_index)	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
vessels_number (počet_ciev)	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
cardiothoracic_position (kardiotorakálna_poloha)	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
cardiac_angle (srdcový_uhol)	*0.9197936528230518*	*3.114077691538199*	*(0.888,0.945)*	*(2.023,4.477)*
Pomer CSP	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
Pomer VP	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
Priestor za ľavou predsieňou	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Výsledky pre výrobcov ultrazvukových systémov

Trieda	Systém	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
X	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
X	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)
X	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)

Trieda	Systém	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI	mIoU	mIoU CI
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*
A.Sp	*Samsung*	*296*	*0.984*	*(0.967,0.994)*	*1708*	*0.999*	*(0.997,1.000)*	*0.7*	*(0.68,0.71)*
A.St	*Canon*	*29*	*0.966*	*(0.893,1.000)*	*207*	*0.991*	*(0.975,1.000)*	*0.72*	*(0.67,0.76)*
A.St	*GE*	*279*	*0.993*	*(0.983,1.000)*	*2261*	*1.0*	*(1.000,1.000)*	*0.79*	*(0.77,0.80)*
A.St	*Samsung*	*293*	*0.973*	*(0.954,0.990)*	*1711*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
A.Uv	*Canon*	*25*	*0.96*	*(0.870,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.6*	*(0.51,0.67)*
A.Uv	*GE*	*217*	*0.977*	*(0.955,0.996)*	*2323*	*0.991*	*(0.988,0.995)*	*0.67*	*(0.65,0.70)*
A.Uv	*Samsung*	*240*	*0.967*	*(0.944,0.988)*	*1764*	*0.989*	*(0.984,0.993)*	*0.62*	*(0.59,0.64)*
A.VC	*Canon*	*26*	*0.885*	*(0.750,1.000)*	*210*	*0.986*	*(0.970,1.000)*	*0.46*	*(0.40,0.52)*
A.VC	*GE*	*221*	*0.973*	*(0.950,0.992)*	*2319*	*0.987*	*(0.983,0.991)*	*0.54*	*(0.52,0.57)*
A.VC	*Samsung*	*247*	*0.903*	*(0.864,0.939)*	*1757*	*0.989*	*(0.984,0.994)*	*0.49*	*(0.47,0.51)*
B.Ao	*Canon*	*27*	*0.926*	*(0.808,1.000)*	*209*	*0.996*	*(0.985,1.000)*	*0.71*	*(0.66,0.77)*
B.Ao	*GE*	*247*	*0.956*	*(0.926,0.980)*	*2293*	*0.997*	*(0.994,0.999)*	*0.73*	*(0.71,0.75)*
B.Ao	*Samsung*	*255*	*0.977*	*(0.956,0.993)*	*1749*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.58,0.62)*
B.bCr	*Canon*	*25*	*0.92*	*(0.800,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.65*	*(0.58,0.72)*
B.bCr	*GE*	*202*	*0.892*	*(0.849,0.932)*	*2338*	*0.992*	*(0.989,0.996)*	*0.61*	*(0.57,0.64)*
B.bCr	*Samsung*	*216*	*0.926*	*(0.889,0.959)*	*1788*	*0.984*	*(0.979,0.989)*	*0.54*	*(0.52,0.57)*
B.Cr	*Canon*	*7*	*0.715*	*(0.334,1.000)*	*229*	*0.983*	*(0.967,0.996)*	*0.62*	*(nan,nan)*
B.Cr	*GE*	*52*	*0.885*	*(0.789,0.961)*	*2488*	*0.989*	*(0.985,0.993)*	*0.52*	*(0.46,0.58)*
B.Cr	*Samsung*	*76*	*0.974*	*(0.933,1.000)*	*1928*	*0.977*	*(0.971,0.983)*	*0.57*	*(0.52,0.61)*
B.FO	*Canon*	*26*	*0.962*	*(0.880,1.000)*	*210*	*1.0*	*(1.000,1.000)*	*0.7*	*(0.62,0.78)*
B.FO	*GE*	*215*	*0.935*	*(0.899,0.965)*	*2325*	*0.994*	*(0.991,0.997)*	*0.64*	*(0.62,0.67)*
B.FO	*Samsung*	*257*	*0.965*	*(0.941,0.985)*	*1747*	*0.994*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
B.FOF	*Canon*	*8*	*0.75*	*(0.375,1.000)*	*228*	*1.0*	*(1.000,1.000)*	*0.56*	*(0.42,0.67)*
B.FOF	*GE*	*108*	*0.899*	*(0.841,0.949)*	*2432*	*0.998*	*(0.996,1.000)*	*0.5*	*(0.47,0.53)*
B.FOF	*Samsung*	*63*	*0.921*	*(0.845,0.984)*	*1941*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.47,0.55)*
B.IVS	*Canon*	*15*	*0.934*	*(0.770,1.000)*	*221*	*0.982*	*(0.965,0.996)*	*0.65*	*(0.53,0.75)*
B.IVS	*GE*	*165*	*0.867*	*(0.806,0.915)*	*2375*	*0.992*	*(0.988,0.995)*	*0.62*	*(0.59,0.66)*
B.IVS	*Samsung*	*152*	*0.922*	*(0.872,0.962)*	*1852*	*0.984*	*(0.978,0.989)*	*0.64*	*(0.61,0.67)*
B.LA	*Canon*	*30*	*0.934*	*(0.834,1.000)*	*206*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.71,0.79)*
B.LA	*GE*	*264*	*0.966*	*(0.942,0.986)*	*2276*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.78,0.81)*

B.LA	Samsung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Samsung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Samsung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)
B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)

C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)
D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)

E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)
F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)

F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)
G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Samsung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Samsung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)

G.pCH	*Samsung*	*182*	*0.94*	*(0.905,0.973)*	*1822*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.77)*
G.pTh	*Canon*	*13*	*1.0*	*(1.000,1.000)*	*223*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.51,0.65)*
G.pTh	*GE*	*216*	*0.922*	*(0.884,0.954)*	*2324*	*0.995*	*(0.992,0.998)*	*0.62*	*(0.60,0.64)*
G.pTh	*Samsung*	*119*	*0.95*	*(0.905,0.984)*	*1885*	*0.998*	*(0.996,1.000)*	*0.59*	*(0.57,0.62)*
G.Ver	*Canon*	*23*	*0.914*	*(0.783,1.000)*	*213*	*1.0*	*(1.000,1.000)*	*0.62*	*(0.54,0.70)*
G.Ver	*GE*	*288*	*0.893*	*(0.859,0.928)*	*2252*	*0.996*	*(0.993,0.999)*	*0.61*	*(0.59,0.63)*
G.Ver	*Samsung*	*138*	*0.892*	*(0.840,0.942)*	*1866*	*0.997*	*(0.994,0.999)*	*0.52*	*(0.49,0.55)*
I.bCC	*Canon*	*15*	*1.0*	*(1.000,1.000)*	*221*	*0.987*	*(0.971,1.000)*	*0.59*	*(0.51,0.67)*
I.bCC	*GE*	*168*	*0.923*	*(0.878,0.962)*	*2372*	*0.995*	*(0.993,0.998)*	*0.57*	*(0.54,0.60)*
I.bCC	*Samsung*	*54*	*0.815*	*(0.699,0.910)*	*1950*	*0.996*	*(0.994,0.999)*	*0.57*	*(0.52,0.62)*
I.CSP	*Canon*	*20*	*0.95*	*(0.824,1.000)*	*216*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.69,0.81)*
I.CSP	*GE*	*196*	*0.888*	*(0.841,0.928)*	*2344*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.69,0.74)*
I.CSP	*Samsung*	*79*	*0.849*	*(0.760,0.924)*	*1925*	*1.0*	*(1.000,1.000)*	*0.7*	*(0.66,0.75)*
I.Fas	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.63*	*(0.46,0.79)*
I.Fas	*GE*	*99*	*0.889*	*(0.819,0.951)*	*2441*	*1.0*	*(0.999,1.000)*	*0.56*	*(0.52,0.60)*
I.Fas	*Samsung*	*33*	*0.97*	*(0.900,1.000)*	*1971*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.49,0.61)*
I.lVer	*Canon*	*14*	*0.929*	*(0.750,1.000)*	*222*	*1.0*	*(1.000,1.000)*	*0.69*	*(0.60,0.77)*
I.lVer	*GE*	*102*	*0.912*	*(0.850,0.960)*	*2438*	*0.999*	*(0.998,1.000)*	*0.7*	*(0.66,0.73)*
I.lVer	*Samsung*	*41*	*0.927*	*(0.834,1.000)*	*1963*	*1.0*	*(0.999,1.000)*	*0.64*	*(0.59,0.69)*
I.NB	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.71*	*(0.61,0.82)*
I.NB	*GE*	*115*	*0.905*	*(0.844,0.955)*	*2425*	*0.992*	*(0.989,0.996)*	*0.63*	*(0.59,0.67)*
I.NB	*Samsung*	*60*	*0.917*	*(0.837,0.982)*	*1944*	*0.998*	*(0.996,1.000)*	*0.64*	*(0.58,0.69)*
I.rgCC	*Canon*	*18*	*0.945*	*(0.824,1.000)*	*218*	*0.991*	*(0.978,1.000)*	*0.48*	*(0.41,0.56)*
I.rgCC	*GE*	*177*	*0.888*	*(0.833,0.930)*	*2363*	*0.998*	*(0.996,1.000)*	*0.56*	*(0.54,0.59)*
I.rgCC	*Samsung*	*65*	*0.893*	*(0.808,0.965)*	*1939*	*1.0*	*(0.999,1.000)*	*0.48*	*(0.43,0.53)*
I.sCC	*Canon*	*13*	*0.847*	*(0.616,1.000)*	*223*	*0.992*	*(0.978,1.000)*	*0.48*	*(0.36,0.61)*
I.sCC	*GE*	*114*	*0.922*	*(0.868,0.964)*	*2426*	*0.992*	*(0.988,0.995)*	*0.51*	*(0.48,0.54)*
I.sCC	*Samsung*	*40*	*0.9*	*(0.796,1.000)*	*1964*	*0.998*	*(0.996,1.000)*	*0.45*	*(0.39,0.53)*
I.uVer	*Canon*	*14*	*1.0*	*(1.000,1.000)*	*222*	*0.991*	*(0.978,1.000)*	*0.57*	*(0.49,0.65)*
I.uVer	*GE*	*116*	*0.88*	*(0.815,0.931)*	*2424*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.63)*
I.uVer	*Samsung*	*48*	*0.938*	*(0.861,1.000)*	*1956*	*0.999*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Trieda	Systém	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI	LOA	LOA CI
cardiac_angle (srdcový_uhol)	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
cardiac_angle (srdcový_uhol)	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
cardiac_angle (srdcový_uhol)	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
cardiothoracic_position (kardiotorakálna_poloha)	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
cardiothoracic_position (kardiotorakálna_poloha)	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
cardiothoracic_position (kardiotorakálna_poloha)	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*

cardiothoracic_ratio (kardiotorakálny_pomer)	Canon	23	1.0	(1.000,1.000)	37	0.946	(0.865,1.000)	0.078	(0.041,0.117)
cardiothoracic_ratio (kardiotorakálny_pomer)	GE	225	0.969	(0.944,0.991)	262	0.908	(0.874,0.943)	0.059	(0.049,0.073)
cardiothoracic_ratio (kardiotorakálny_pomer)	Samsung	105	0.952	(0.909,0.989)	232	0.776	(0.724,0.828)	0.051	(0.042,0.061)
cephalic_index (cefalický_index)	Canon	28	0.929	(0.821,1.000)	37	0.892	(0.784,0.973)	0.026	(0.021,0.032)
cephalic_index (cefalický_index)	GE	195	0.944	(0.909,0.974)	262	0.943	(0.916,0.969)	0.03	(0.026,0.036)
cephalic_index (cefalický_index)	Samsung	90	0.989	(0.964,1.000)	232	0.909	(0.871,0.944)	0.023	(0.020,0.026)
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	Canon	28	1.0	(1.000,1.000)	37	0.865	(0.757,0.973)	0.106	(0.080,0.128)
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	GE	235	0.923	(0.883,0.957)	262	0.901	(0.859,0.939)	0.127	(0.090,0.173)
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	Samsung	93	0.978	(0.943,1.000)	232	0.931	(0.901,0.961)	0.099	(0.087,0.115)
thymic-thoracic_ratio (pomer_týmus-hrudník)	Canon	19	1.0	(1.000,1.000)	37	1.0	(1.000,1.000)	0.047	(0.039,0.059)
thymic-thoracic_ratio (pomer_týmus-hrudník)	GE	174	0.902	(0.856,0.944)	262	0.924	(0.889,0.954)	0.051	(0.045,0.059)
thymic-thoracic_ratio (pomer_týmus-hrudník)	Samsung	138	0.942	(0.900,0.978)	232	0.892	(0.853,0.931)	0.059	(0.049,0.070)
vessels_number (počet_ciev)	Canon	21	0.905	(0.760,1.000)	37	1.0	(1.000,1.000)	0.0	(0.000,0.000)
vessels_number (počet_ciev)	GE	209	0.933	(0.895,0.966)	262	0.969	(0.947,0.989)	0.281	(0.138,0.406)
vessels_number (počet_ciev)	Samsung	113	0.929	(0.879,0.974)	232	0.966	(0.940,0.987)	0.329	(0.000,0.491)
vessels_ratio (pomer_ciev)	Canon	28	1.0	(1.000,1.000)	37	0.892	(0.784,0.973)	0.112	(0.091,0.145)
vessels_ratio (pomer_ciev)	GE	194	0.979	(0.956,0.995)	262	0.977	(0.954,0.992)	0.109	(0.099,0.121)
vessels_ratio (pomer_ciev)	Samsung	122	0.984	(0.958,1.000)	232	0.922	(0.888,0.953)	0.111	(0.100,0.125)
Pomer CSP	Canon	25	1.0	(1.000,1.000)	37	1.0	(1.000,1.000)	0.842	(0.608,1.028)
Pomer CSP	GE	226	0.854	(0.805,0.899)	262	0.977	(0.954,0.992)	0.826	(0.753,0.889)
Pomer CSP	Samsung	107	0.879	(0.821,0.935)	232	0.991	(0.978,1.000)	0.835	(0.755,0.907)
Pomer VP	Canon	22	0.909	(0.773,1.000)	37	1.0	(1.000,1.000)	0.064	(0.043,0.084)
Pomer VP	GE	206	0.956	(0.925,0.981)	262	1.0	(1.000,1.000)	0.065	(0.059,0.071)
Pomer VP	Samsung	91	0.956	(0.910,0.990)	232	1.0	(1.000,1.000)	0.066	(0.056,0.075)
Priestor za ľavou predsieňou	Canon	16	0.938	(0.800,1.000)	37	0.919	(0.837,1.000)	0.094	(0.067,0.114)
Priestor za ľavou predsieňou	GE	181	0.978	(0.953,0.995)	262	0.924	(0.889,0.954)	0.086	(0.079,0.091)
Priestor za ľavou predsieňou	Samsung	159	0.981	(0.957,1.000)	232	0.953	(0.922,0.978)	0.07	(0.065,0.078)

Výsledky podskupiny USA vs. EÚ

Trieda	Kontinent	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI
A	EÚ	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)

A	USA	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	EÚ	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	USA	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	EÚ	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	USA	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	EÚ	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	USA	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	EÚ	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	USA	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	EÚ	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	USA	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	EÚ	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	USA	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	EÚ	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	USA	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	EÚ	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	USA	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Trieda	Kontinent	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI	mIoU	mIoU CI
A.aA	EU	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	US	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	EU	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	US	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	EU	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	US	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	EU	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	US	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	EU	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*
A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*

B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*
C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*

D.lPA	US	65	0.847	(0.747,0.932)	1581	0.994	(0.990,0.998)	0.63	(0.57,0.69)
D.Or	EU	199	0.965	(0.937,0.990)	2272	0.989	(0.984,0.993)	0.59	(0.56,0.62)
D.Or	US	105	0.915	(0.860,0.962)	1541	0.992	(0.987,0.997)	0.49	(0.44,0.53)
D.PA	EU	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)	0.77	(0.76,0.79)
D.PA	US	138	0.928	(0.883,0.970)	1508	0.998	(0.995,1.000)	0.7	(0.67,0.73)
D.rPA	EU	247	0.972	(0.948,0.992)	2224	0.999	(0.997,1.000)	0.69	(0.66,0.71)
D.rPA	US	134	0.911	(0.860,0.958)	1512	0.996	(0.992,0.999)	0.64	(0.60,0.68)
D.S	EU	204	0.971	(0.945,0.991)	2267	0.988	(0.983,0.992)	0.67	(0.64,0.70)
D.S	US	82	0.952	(0.898,0.989)	1564	0.984	(0.978,0.990)	0.59	(0.55,0.63)
D.SVC	EU	206	0.947	(0.916,0.976)	2265	0.991	(0.986,0.994)	0.6	(0.56,0.63)
D.SVC	US	86	0.896	(0.834,0.956)	1560	0.991	(0.986,0.996)	0.55	(0.50,0.60)
D.Tr	EU	145	0.876	(0.822,0.929)	2326	0.982	(0.976,0.987)	0.51	(0.48,0.53)
D.Tr	US	72	0.903	(0.824,0.968)	1574	0.983	(0.976,0.989)	0.52	(0.48,0.56)
E.aAo	EU	142	0.937	(0.891,0.973)	2329	0.995	(0.992,0.998)	0.68	(0.65,0.71)
E.aAo	US	99	0.91	(0.851,0.966)	1547	0.996	(0.992,0.999)	0.67	(0.62,0.71)
E.aAr	EU	126	0.961	(0.924,0.992)	2345	0.997	(0.995,0.999)	0.8	(0.76,0.83)
E.aAr	US	48	0.917	(0.830,0.982)	1598	0.995	(0.992,0.999)	0.69	(0.64,0.72)
E.Du	EU	131	0.955	(0.918,0.986)	2340	0.998	(0.995,1.000)	0.77	(0.74,0.80)
E.Du	US	44	0.887	(0.783,0.975)	1602	0.995	(0.991,0.998)	0.64	(0.57,0.70)
E.ES	EU	243	0.947	(0.917,0.973)	2228	0.992	(0.988,0.996)	0.72	(0.70,0.74)
E.ES	US	132	0.902	(0.848,0.949)	1514	0.994	(0.990,0.998)	0.66	(0.63,0.69)
E.PA	EU	134	0.933	(0.888,0.972)	2337	0.994	(0.990,0.997)	0.72	(0.69,0.75)
E.PA	US	96	0.917	(0.858,0.971)	1550	0.997	(0.993,0.999)	0.71	(0.66,0.75)
E.Sp	EU	229	0.957	(0.925,0.980)	2242	0.992	(0.989,0.996)	0.73	(0.71,0.75)
E.Sp	US	139	0.914	(0.867,0.961)	1507	0.999	(0.996,1.000)	0.68	(0.65,0.71)
E.SVC	EU	260	0.947	(0.918,0.973)	2211	0.996	(0.994,0.999)	0.6	(0.57,0.63)
E.SVC	US	142	0.909	(0.859,0.955)	1504	0.997	(0.994,1.000)	0.61	(0.57,0.64)
E.Th	EU	178	0.899	(0.854,0.942)	2293	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	US	98	0.878	(0.805,0.938)	1548	0.993	(0.989,0.997)	0.55	(0.50,0.60)
E.Tr	EU	180	0.923	(0.883,0.961)	2291	0.985	(0.980,0.990)	0.53	(0.50,0.56)
E.Tr	US	106	0.887	(0.825,0.942)	1540	0.989	(0.984,0.994)	0.5	(0.46,0.53)
F.3V	EU	77	0.78	(0.689,0.859)	2394	0.995	(0.992,0.998)	0.59	(0.55,0.63)
F.3V	US	73	0.781	(0.680,0.869)	1573	0.994	(0.989,0.997)	0.6	(0.55,0.64)
F.AC	EU	176	0.938	(0.901,0.971)	2295	0.995	(0.992,0.998)	0.73	(0.71,0.75)
F.AC	US	145	0.959	(0.923,0.987)	1501	0.997	(0.994,1.000)	0.76	(0.73,0.78)
F.aFx	EU	163	0.988	(0.968,1.000)	2308	0.996	(0.993,0.999)	0.62	(0.59,0.64)
F.aFx	US	146	0.905	(0.849,0.946)	1500	0.998	(0.996,1.000)	0.63	(0.60,0.66)
F.Atr	EU	272	0.964	(0.940,0.984)	2199	1.0	(1.000,1.000)	0.71	(0.69,0.73)
F.Atr	US	224	0.92	(0.881,0.952)	1422	1.0	(0.998,1.000)	0.73	(0.70,0.75)
F.CP	EU	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	US	239	0.908	(0.868,0.941)	1407	1.0	(1.000,1.000)	0.65	(0.63,0.68)
F.CSP	EU	184	0.962	(0.933,0.985)	2287	1.0	(1.000,1.000)	0.58	(0.55,0.60)
F.CSP	US	128	0.907	(0.850,0.955)	1518	1.0	(1.000,1.000)	0.53	(0.50,0.56)
F.dAV	EU	104	0.991	(0.969,1.000)	2367	0.998	(0.995,1.000)	0.61	(0.58,0.64)
F.dAV	US	89	0.911	(0.842,0.966)	1557	0.998	(0.995,1.000)	0.65	(0.61,0.70)
F.dCS	EU	115	0.948	(0.906,0.984)	2356	0.998	(0.995,0.999)	0.58	(0.55,0.61)

F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*
G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*

I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Trieda	Kontinent	n (pozitívne)	Se	Se CI	n (negatívne)	Sp	Sp CI	LOA	LOA CI
cardiac_angle (srdcový_uhol)	EÚ	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
cardiac_angle (srdcový_uhol)	USA	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
cardiothoracic_position (kardiotorakálna_poloha)	EÚ	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
cardiothoracic_position (kardiotorakálna_poloha)	USA	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
cardiothoracic_ratio (kardiotorakálny_pomer)	EÚ	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
cardiothoracic_ratio (kardiotorakálny_pomer)	USA	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
cephalic_index (cefalický_index)	EÚ	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
cephalic_index (cefalický_index)	USA	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	EÚ	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
right-left_ventricular_ratio (pomer_pravá_ľavá_komora)	USA	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
thymic-thoracic_ratio (pomer_týmus-hrudník)	EÚ	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
thymic-thoracic_ratio (pomer_týmus-hrudník)	USA	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)
vessels_number (počet_ciev)	EÚ	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
vessels_number (počet_ciev)	USA	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
vessels_ratio (pomer_ciev)	EÚ	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
vessels_ratio (pomer_ciev)	USA	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
Pomer CSP	EÚ	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
Pomer CSP	USA	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
Pomer VP	EÚ	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
Pomer VP	USA	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
Priestor za ľavou predsieňou	EÚ	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
Priestor za ľavou predsieňou	USA	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Kontraindikácie

Neexistuje žiadna kontraindikácia spojená so zariadením FETOLY.

10. Varovania, bezpečnostné opatrenia, interakcie s inými zariadeniami

Varovania a bezpečnostné opatrenia zo súboru pre riadenie rizík:

- Používateľ musí zväčšiť obraz najmenej o 30 %, aby sa zabránilo falošným negatívnym výsledkom softvéru;
- Používateľ musí pred exportom systematicky skontrolovať vybraný súbor obrazov;
- Prehliadnutie funkcie resetovania môže viesť k zámene pacientov a prispieť k falošne negatívnemu skríningu;
- Obrazy vymazané v rámci výberu obrazov sú definitívne stratené;
- Konfigurácia vstupu videoprenosu môže prispieť k falošne negatívnemu skríningu;
- Nekompatibilný prenos videa môže viesť k chybám v dokumentácii o vyšetrení. Videoprenos musí mať nasledujúce vlastnosti:
    - Minimálne 24 snímok za sekundu (fps);
    - Rozlíšenie nižšie ako 1280*720.
- Nekompatibilita tabletov môže viesť k chybám v dokumentácii o vyšetrení;
- Zlyhanie exportu vedie k strate správy o vyšetrení;
- Pred exportom DICOM na stránke exportu skontrolujte zvolené meno pacienta, aby nedošlo k zámene súborov pacientov;
- Použitie v 1. trimestri tehotenstva vedie k chybe vo funkcii úplnosti;
- Vyšetrenie sa vykonáva vždy na jednom plode;
- Ak sa tablet začne prehrievať, ukončite používanie softvéru;
- Pred vyšetrovaním skontrolujte úroveň nabitia batérie tabletu. Vypnutie softvéru môže viesť k strate údajov o vyšetrení;
- Tento softvér sa nemôže používať na skríningové účely, pretože môže viesť k falošne negatívnemu skríningu;
- Aby ste predišli bezpečnostným rizikám, používajte tablet len vy, a neumožnite prístup k tabletu neoprávnenej osobe;
- Upozorňujeme, že keď sa údaje exportujú do vášho zariadenia, nesiete za ne zodpovednosť;
- S FETOLY nepoužívajte súbežne žiadnu inú aplikáciu pre tablety, aby nedochádzalo k rušeniu procesu prijímania obrazového toku alebo vykonávaniavýpočtov strojového učenia;
- Nepoužívajte aplikáciu počas skenovania transvaginálnou sondou, pretože produkt nebol testovaný s transvaginálnymi snímkami.

Varovania a bezpečnostné opatrenia vyplývajúce zo štúdie výkonu softvéru:

- Citlivosť softvéru môže byť nižšia pri detekcii:
    - transthalamického pohľadu na mozog;
    - nasledujúceho kritéria kvality srdca: Posun atrioventrikulárnej chlopne v crux cordis (štvorkomorové zobrazenie).
    - nasledujúcich kritérií kvality mozgu:
        - Proximálny koronálny šev (axiálny pohľad),
        - Cavum septi pellucidi (axiálny pohľad),
        - 3. komora (axiálny pohľad).

Používatelia by mali byť pri tomto pohľade a týchto kritériách kvality opatrní a overovať výsledky.

Interakcie s inými zariadeniami

Softvér FETOLY je navrhnutý tak, aby fungoval na širokej škále tabletov bez nutnosti využívať externé cloudové výpočty. FETOLY je nakonfigurovaný na príjem ultrazvukového prenosu videa, čo je možné dosiahnuť pomocou ultrazvukového systému vybaveného výstupom HDMI do hardvéru, na ktorom je spustený softvér.

Tento softvér je kompatibilný s ultrazvukovými prístrojmi od spoločností General Electric, Samsung a Canon.

Softvér vyžaduje nasledujúcu minimálnu konfiguráciu tabletu:

- Architektúra CPU ARMv8
- Procesor Snapdragon 8 alebo
- Procesor M1 alebo vyšší, alebo
- Procesor A14 alebo vyšší, a
- Aspoň 8 GB pamäte RAM
- Aspoň 1 GB úložnej kapacity
- Android vo verzii 13/ iOS vo verzii 17 alebo vyššej

Odporúčame tieto modely tabletov:

- Samsung Galaxy Tab S8 alebo novší
- Ipad Air 5 alebo vyšší
- Ipad 10 alebo vyšší
- Ipad mini 7 alebo vyšší
- Ipad Pro 3 alebo vyšší

Ak máte akékoľvek pochybnosti o výbere modelu tabletu, neváhajte kontaktovať podporu spoločnosti Diagnoly na adrese support@diagnoly.com.

Obrazy označené softvérom FETOLY je možné uložiť priamo do tabletu alebo odoslať do iného zariadenia v tej istej sieti, v akej je zariadenie so softvérom FETOLY. Na využitie tejto možnosti softvér vyžaduje server FTP v cieľovom zariadení, server DICOM Store alebo pripojenie Bluetooth.

11. Nežiaduce účinky

So zariadením FETOLY nie sú spojené žiadne nežiaduce účinky.

12. Pokyny týkajúce sa kybernetickej bezpečnosti

12.1. Opis ochrany kritických funkcií na vysokej úrovni

V tejto časti je uvedený stručný popis funkcií zariadenia, ktoré chránia kritické funkcie. Funkcie prijímania obrazového toku a analýzy obrazov sa spoliehajú na miestne zdroje (fyzický kábel, model edge AI) a na svoju činnosť nevyžadujú internet. Softvér neukladá ani nespravuje žiadne údaje o pacientovi, ale umožňuje používateľovi po vyšetrení exportovať správu o vyšetrení do zariadenia tretej strany. V prípade narušenia miestnej siete je k dispozícii záložný režim exportu, ktorý používateľom umožňuje ukladať správy do súborového systému tabletu.

12.2. Riziká súvisiace s kybernetickou bezpečnosťou priamo na zariadení

Medzi riziká kybernetickej bezpečnosti FETOLY patria:

- Krádež údajov o pacientovi
- Znížená výkonnosť manažmentu pacienta v dôsledku poškodenej činnosti umelej inteligencie, ako napríklad manipulácia s modelovými váhami alebo úpravy softvéru/operačného systému
- Nesprávne používanie zariadenia, ktoré vedie k iným výsledkom, než zamýšľal výrobca alebo očakával používateľ
- Strata času pre používateľa.

Tieto riziká sú kontrolované analýzou rizík.

11.3. Schéma odporúčaných kontrol kybernetickej bezpečnosti



Schéma opisuje prostredie softvéru FETOLY spusteného na tablete používateľa a vstupnú/výstupnú komunikáciu s ultrazvukovým systémom a zariadením tretej strany.

Obsahuje odkazy na odporúčané kontroly kybernetickej bezpečnosti pre prostredie zamýšľaného použitia opísané v **časti 12.4**:

- G1: Zabezpečená prevádzka so systémami tretích strán prostredníctvom protokolu FTP so zabezpečením SSL/TLS
- G2: Zabezpečená prevádzka so systémami tretích strán cez Bluetooth (len Android)
- G3: Bezpečné riadenie prístupu k zariadeniam
- G4: Zabezpečená prevádzka so systémami tretích strán prostredníctvom protokolu DICOM so zabezpečením SSL/TLS

12.4. Návod na použitie zariadenia a špecifikácie výrobku týkajúce sa odporúčaných kontrol kybernetickej bezpečnosti vhodných pre prostredie zamýšľaného použitia

Usmernenia pre bezpečnú prevádzku so systémami tretích strán prostredníctvom protokolu FTP so zabezpečením SSL/TLS (G1):

- Minimálne sieťové požiadavky: sieťová infraštruktúra musí podporovať protokol FTP so zabezpečením SSL/TLS (FTPS) a server FTP musí byť kompatibilný s FTPS. Implementujte segmentáciu siete a pravidlá brány firewall, aby ste obmedzili prístup k potrebným službám a IP adresám.
- Inštalácia servera FTP so zabezpečením SSL/TLS, ako napr:
    g. Windows 10/11 použitím IIS: Pozrite si dokumentáciu spoločnosti Microsoft týkajúcu sa nastavenia protokolu FTP so zabezpečením TLS/SSL so službou IIS.
    h. FileZilla Server (multiplatformový): Nakonfigurujte FTPES „Vyžadovať explicitné FTP so zabezpečením TLS“, vytvorte používateľa s silným heslom*, definujte cestu na ukladanie údajov (napr. „C:\FetolyData“ alebo „/home/shared/FetolyData“) a nakonfigurujte pravidlá brány firewall pre konkrétny program alebo port používaný serverom FTP.

Pokyny na bezpečnú prevádzku so systémami tretích strán prostredníctvom Bluetooth (G2, len Android):

- Minimálne sieťové požiadavky: Bluetooth verzia 5 alebo vyššia.
- Definujte silné heslo v softvéri na ochranu exportovaných údajov pacienta*.

Usmernenia o bezpečnom riadení prístupu k zariadeniam (G3):

- Nastavte uzamknutie obrazovky pomocou silného hesla*, kódu PIN alebo biometrického overovania.
- Povoľte automatické aktualizácie operačného systému a všetkých nainštalovaných aplikácií.
- Zakážte všetky nepoužívané sieťové rozhrania (napr. NFC, IR).

Usmernenia pre bezpečnú prevádzku so systémami tretích strán prostredníctvom DICOM (G4):

- Zabezpečte, aby komunikácia prebiehala cez zabezpečenú a segmentovanú sieť, obmedzte prístup pomocou spoľahlivých konfigurácií brány firewall a mechanizmov kontroly prístupu.

*Používajte silné heslá na tablete a pre akékoľvek zariadenie (napr. zariadenie tretej strany pre export FTP) alebo konfiguráciu prepojenú s FETOLY (napr. konfigurácia Bluetooth) podľa odporúčaní americkej agentúry pre kybernetickú obranu:

- dlhé – aspoň 16 znakov (lepšie je ešte dlhšie),
- náhodné znaky – ako reťazec zmiešaných písmen, číslic a symbolov (najsilnejšie!) alebo prístupová fráza zložená z 5 – 7 náhodných slov,
- jedinečné – používa sa len pre jeden účet.

Ak zistíte zraniteľnosť alebo incident týkajúci sa kybernetickej bezpečnosti, okamžite to nahláste svojmu tímu IT bezpečnosti a spoločnosti Diagnoly (support@diagnoly.com). Na tablete:

- resetovanie: obnovenie továrenských nastavení na vymazanie všetkých údajov a konfigurácií,

- preinštalovanie aplikácie: stiahnite si najnovšiu zabezpečenú verziu aplikácie z obchodu Google Play,
- náhradná možnosť: ak je sieťový export ohrozený, použite miestny export na kartu SD.

12.5. Zoznam sieťových portov a iných rozhraní

Softvér FETOLY prijíma vstupný dátový tok prostredníctvom kábla pripojeného medzi výstupom externého monitora ultrazvukového systému a vstupom USB-C tabletu. Softvér možno nakonfigurovať tak, aby exportoval správy o vyšetrení do zariadenia tretej strany prostredníctvom protokolu TCP/IP FTPS alebo Bluetooth.

Pre export údajov cez sieť TCP IP/FTPS:

- Protokol: FTPS
- Porty prichádzajúcej premávky: Softvér sám neotvára žiadne porty prichádzajúcej premávky, pretože funguje výlučne ako klient, nie ako server.
- Porty odchádzajúcej premávky: Softvér používa dynamicky priradený efemérny port (rozsah: 1024-65535) na vytvorenie spojenia so serverom FTPS na zadanej IP adrese. Port prichádzajúcej premávky FTPS servera tretej strany je definovaný používateľom.
- Pravidlá brány firewall: Firewally na strane klienta aj servera musia povoliť odchádzajúce spojenia z klienta na port servera.

Pre export údajov cez Bluetooth/OBEX (len Android):

- Šifrovanie: údaje sú zazipované a zašifrované heslom.

Pre export údajov prostredníctvom DICOM:

- Protokol: DICOM
- Porty prichádzajúcej premávky: Softvér sám neotvára žiadne porty prichádzajúcej premávky, pretože funguje výlučne ako klient, nie ako server.
- Porty odchádzajúcej premávky: Softvér používa dynamicky priradený efemérny port (Android: 32768 až 60999) na vytvorenie spojenia so serverom DICOM na zadanej adrese IP. Vstupný port servera DICOM tretej strany je definovaný používateľom.
- Pravidlá brány firewall: Firewally na strane klienta aj servera musia povoliť odchádzajúce spojenia z klienta na port servera.

12.6. Požiadavky týkajúce sa podpornej infraštruktúry

Požiadavky týkajúce sa podpornej infraštruktúry vrátane minimálnej konfigurácie tabletu a kompatibilných ultrazvukových systémov nájdete v časti 10.

12.7. SBOM

Používatelia majú k dispozícii softvérový zoznam materiálov (sBoM) na správu svojich prostriedkov, pochopenie potenciálneho vplyvu identifikovaných zraniteľností a zavedenie protiopatrení na zachovanie bezpečnosti a účinnosti zariadenia. SBoM je možné stiahnuť v ponuke softvéru „O programe“ v strojovo čitateľnom formáte (.csv) kliknutím na „zobraziť“ pred „Oznámenie tretej strany“.

12.8. Pokyny týkajúce sa aktualizácií/opráv

Pokyny týkajúce sa aktualizácií nájdete v časti 13 „Aktualizácia softvéru a licencie“.

12.9. Opis spôsobu reakcie zariadenia pri zistení anomálnych podmienok

Táto časť opisuje, ako softvér reaguje na bezpečnostné udalosti. Všetky zlyhania softvéru sa exportujú do databázy Firebase prostredníctvom protokolu o zlyhaniach. Pri používaní FETOLY sa môžu objaviť nasledujúce varovania:

- Zlyhanie exportu: sieťová anomália, ktorá vedie k zlyhaniu exportu správy cez TCP/IP FTPS, DICOM alebo Bluetooth.
- Zlyhanie pripojenia USB: k tabletu nie je pripojený kábel USB-C alebo nedošlo k prijatiu USB-C videoprenosu.
- Zlyhanie overenia licencie: používateľ sa pokúša overiť licenciu bez pripojenia k internetu, automatickej časovej aktivácie alebo platnej licencie.
- Prehrievanie tabletu.
- Problém s kompatibilitou tabletu: rýchlosť prenosu obrazu videa nižšia ako 24 fps.
- Tablet má vybitú batériu.

12.10. Zálohovanie a obnova

Ak chcete obnoviť funkcie zariadenia a predvolenú konfiguráciu, odinštalujte a znovu nainštalujte zariadenie prostredníctvom obchodu Google Play/App.

12.11. Opis metód uchovávania a obnovy konfigurácie zariadenia autorizovaným používateľom

Nastavenia exportu, ako sú poverenia tretích strán, a nastavenia snímania videa, ako je pomer vstupného videa, sa uchovávajú v cache pamäti tabletu, bezpečne izolovanej systémom Android/iOS. Vzhľadom na to, že vyššie uvedené konfigurácie sa dajú rýchlo nastaviť, nie je implementovaná žiadna špecifická metodika obnovy. Pri opätovnej inštalácii alebo inštalácii nového zariadenia sú používatelia vyzvaní na manuálne zadanie nastavení.

12.12. Zabezpečená konfigurácia

Táto časť obsahuje pokyny na zabezpečenie bezpečnej konfigurácie a údržby softvéru FETOLY.

Počiatočné nastavenie: Stiahnite si a nainštalujte najnovšiu verziu z obchodu Google Play/App. Skontrolujte, či sa názov a ikona aplikácie zhodujú s názvom a ikonou uvedenými v časti 13. Všetky kroky nastavenia exportu vykonajte cez zabezpečené sieťové pripojenie podľa pokynov G1/2/4 v časti 12.4. Uistite sa, že zariadenie so systémom FETOLY je zabezpečené podľa usmernenia G3 v časti 12.4.

Reakcia na incident: Povoľte pripojenie k internetu na zaznamenávanie zlyhaní a neobvyklých aktivít, ako je opísané v časti 12.13. Nahláste všetky zistené zraniteľnosti podľa pokynov v časti 12.4.

12.13. Zber forenzných dôkazov, ak je to potrebné v zamýšľanom prostredí použitia

Do softvéru je integrovaný systém hlásenia zlyhaní. Hlásenia o zlyhaní sa odosielajú v prípade zlyhania aplikácie alebo anomálnej udalosti, ak je povolené internetové pripojenie.

12.14. Informácie o ukončení životnosti a ukončení podpory systému alebo komponentov, ak sú známe alebo predpokladané

Ukončenie životnosti a ukončenie podpory závisí od platnosti licencie. Ak je licenčná zmluva stále platná, licencia sa automaticky obnoví pri získaní internetového pripojenia. Ak zmluva vyprší alebo sa dosiahne koniec životnosti, budete požiadaní o zadanie nového registračného kódu.

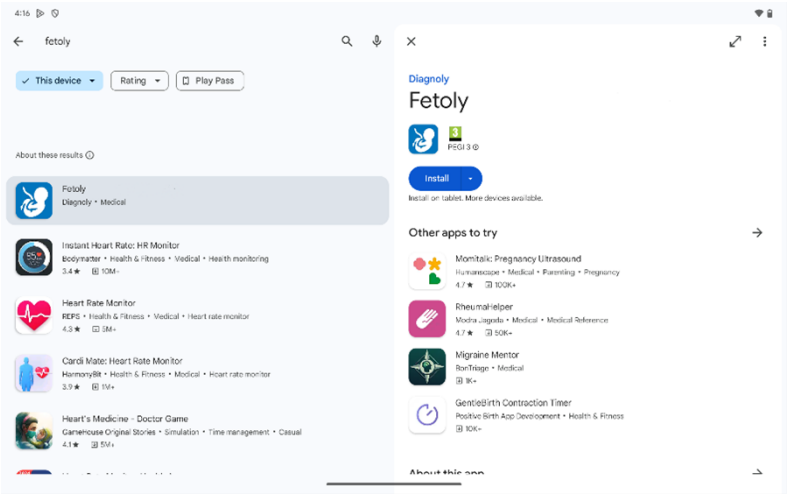
12.15. Bezpečné vyradenie z prevádzky

Ak chcete softvér vyradiť z prevádzky a zlikvidovať, odinštalujte aplikáciu prostredníctvom systému Android/iOS ako akúkoľvek inú aplikáciu v tablete, v parametroch aplikácie, ako je znázornené v časti 13 v odseku „odinštalovanie softvéru“. Odinštalovaním sa z tabletu odstránia všetky údaje súvisiace s používaním aplikácie FETOLY vrátane licencie.

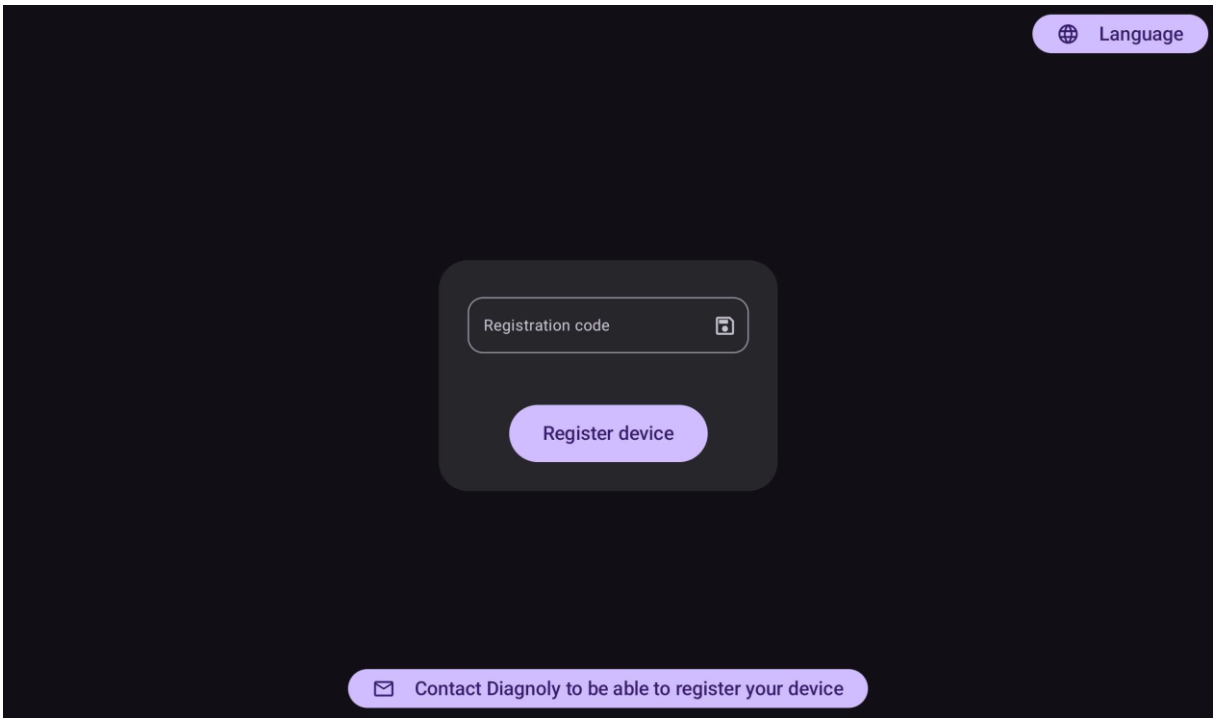
13. Návod na použitie

Inštalácia a spustenie softvéru

1. Prejdite do obchodu Google Play alebo App, do vyhľadávacieho riadku napíšte FETOLY a spustite automatické sťahovanie a inštaláciu.



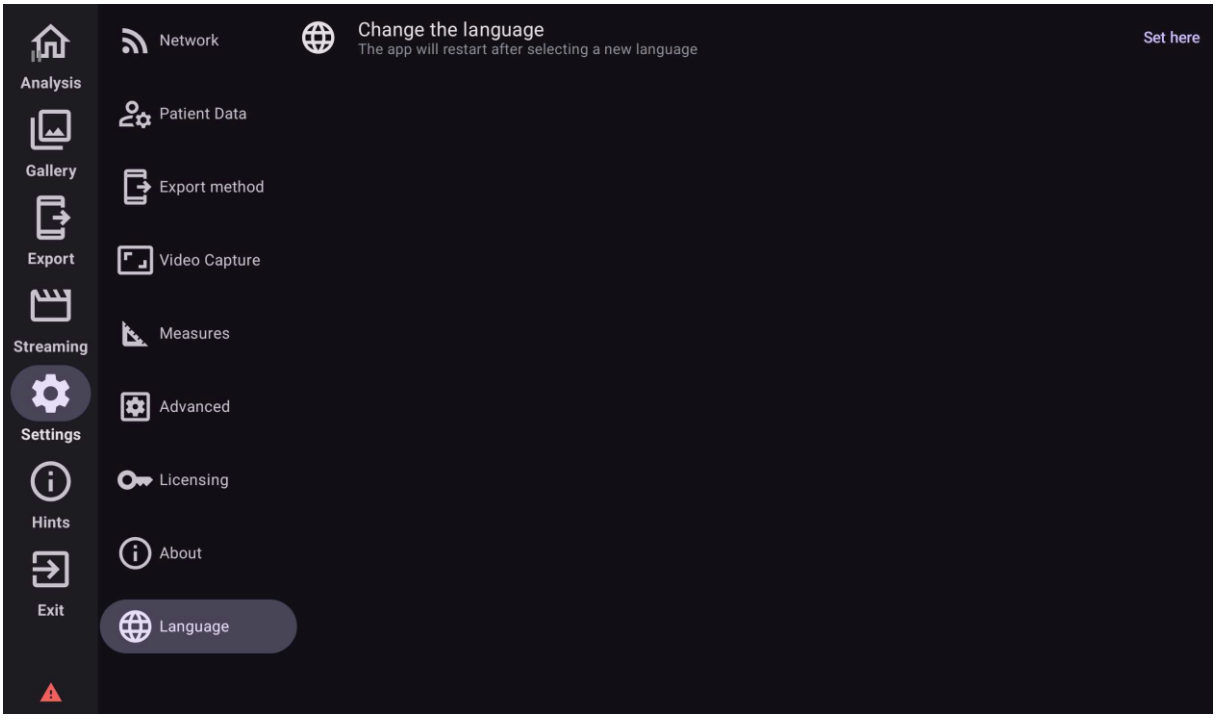
2. Kliknite na ikonu FETOLY na svojom tablete
3. **Overenie platnosti licencie**: v prípade potreby zadajte registračný kód licencie, ako je uvedené nižšie. Za poskytnutie licencie je zodpovedná spoločnosť Diagnoly. Spoločnosť Diagnoly môžete vo veci poskytnutia licencie kontaktovať priamo na zobrazené tlačidlo v dolnej časti uvítacej stránky. Licencia je prepojená s ID zariadenia, ktoré je k dispozícii na stránke nastavení licencie.

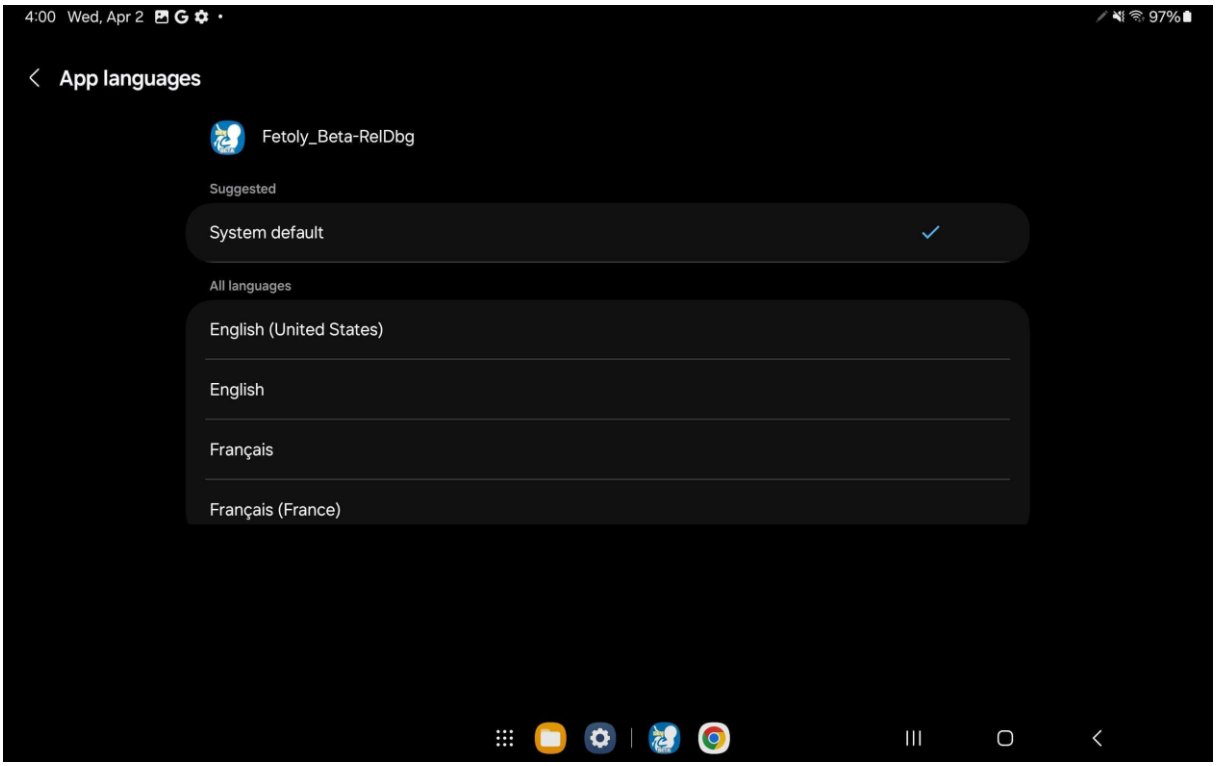


4. **Vytvorenie pripojenia Wi-Fi:** ak chcete prijímať ultrazvukové údaje do osobného počítača, pripojte tablet k sieti Wi-Fi.

Nastavenia jazyka

Jazyk softvéru je predvolene rovnaký, ako jazyk tabletu. Potrebný jazyk si však môžete vybrať v ponuke „Nastavenia“ > „Jazyk“. Tým sa dostanete do nastavení jazykov aplikácie v systéme Android. Po výbere potrebného jazyka sa aplikácia pri opätovnom spustení zobrazí v zvolenom jazyku.



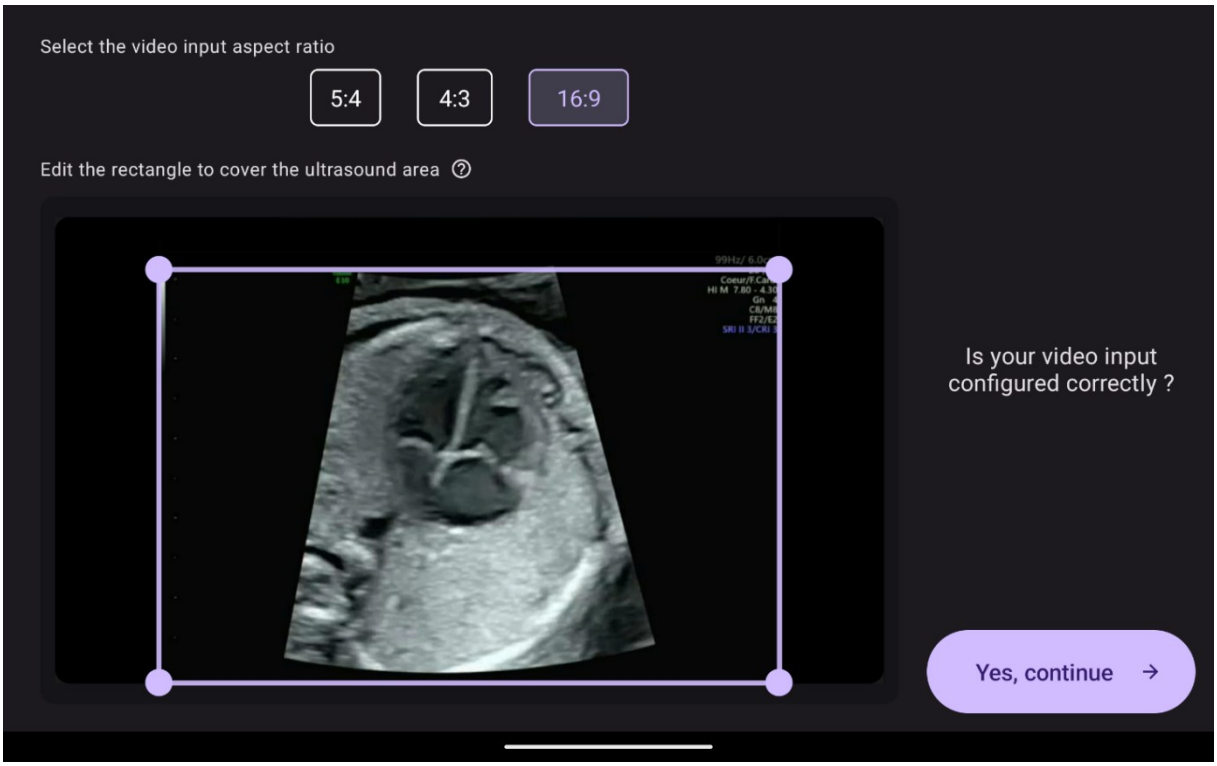


Pripojenie ultrazvukového prístroja

10. **Zapnite ultrazvukový systém:** pred pripojením tabletu sa uistite, že je ultrazvukový systém zapnutý a funkčný.
11. **Pripojte tablet k ultrazvukovému systému:** na pripojenie stačí pripojiť koniec USB (typ C) kľúča UVC k tabletu a koniec HDMI k ultrazvukovému prístroju.
12. **Overenie:** ak chcete overiť pripojenie medzi ultrazvukovým systémom a tabletom, otvorte softvér FETOLY. Ak bol pripojený nový zdroj USB, softvér automaticky zobrazí stránku s konfiguráciou videoprenosu.

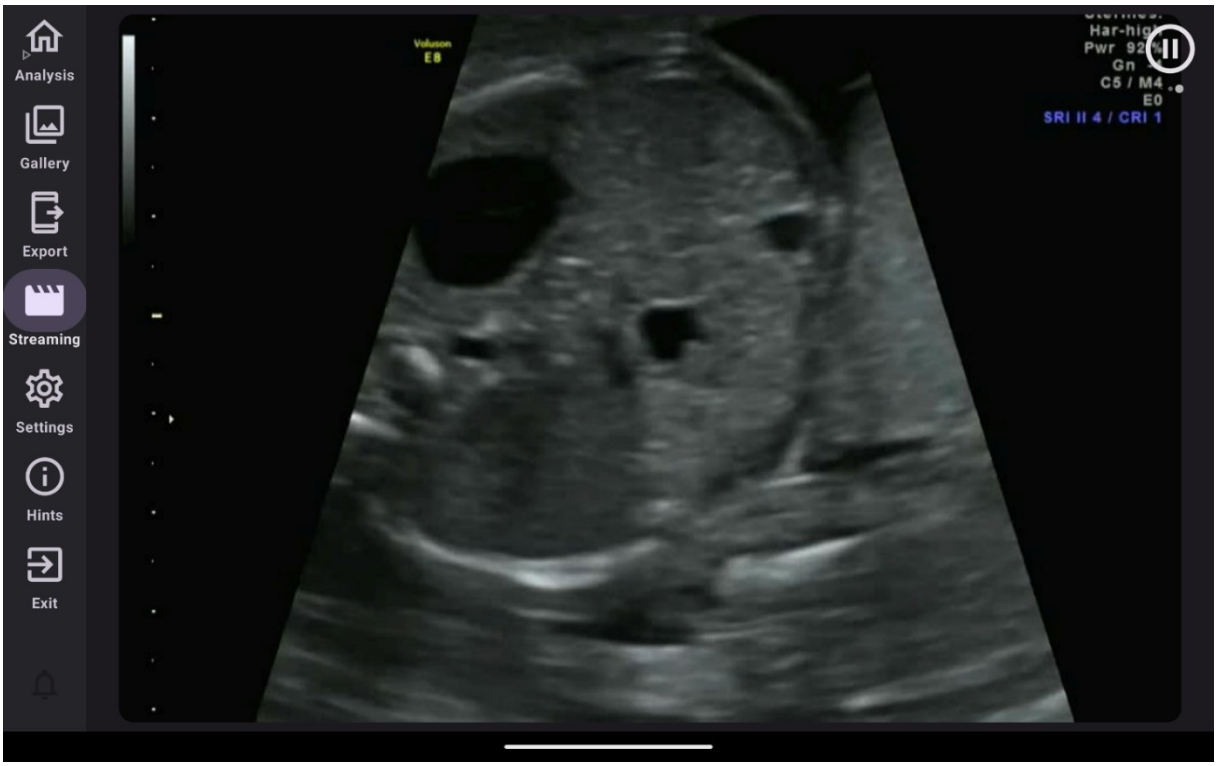
Konfigurácia videoprenosu

4. Začnite konfigurovať videoprenos v aplikácii:
    a. Keď sa automaticky otvorí stránka konfigurácie videa, vyberte pomer strán videa, ktorý sa má zosúladiť s výstupným pomerom ultrazvukového prístroja, a vyberte oblasť ultrazvuku. V iných situáciách prejdite do ponuky „Nastavenia“ > „Zachytávanie videa“ a nakonfigurujte videoprenos rovnakou metodikou.



h. Vybraná oblasť sa zobrazí v reálnom čase na stránke prenosu. Tlačidlo prehrávania na stránke prenosu slúži na spustenie analýzy.

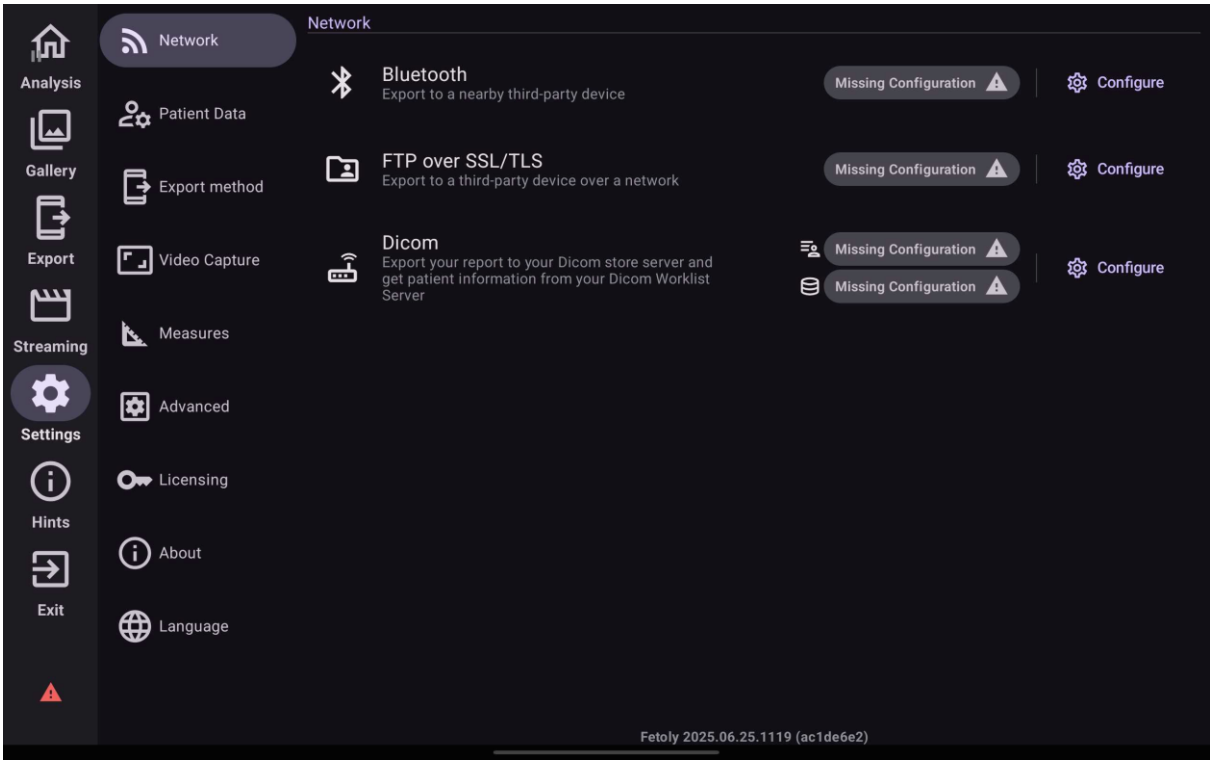
i. Skontrolujte, či na tablete nie je deaktivovaný mikrofón, pretože to vedie k blokovaniu vstupu videoprenosu.



[VOLITEĽNÉ] Konfigurácia ultrazvukového prístroja

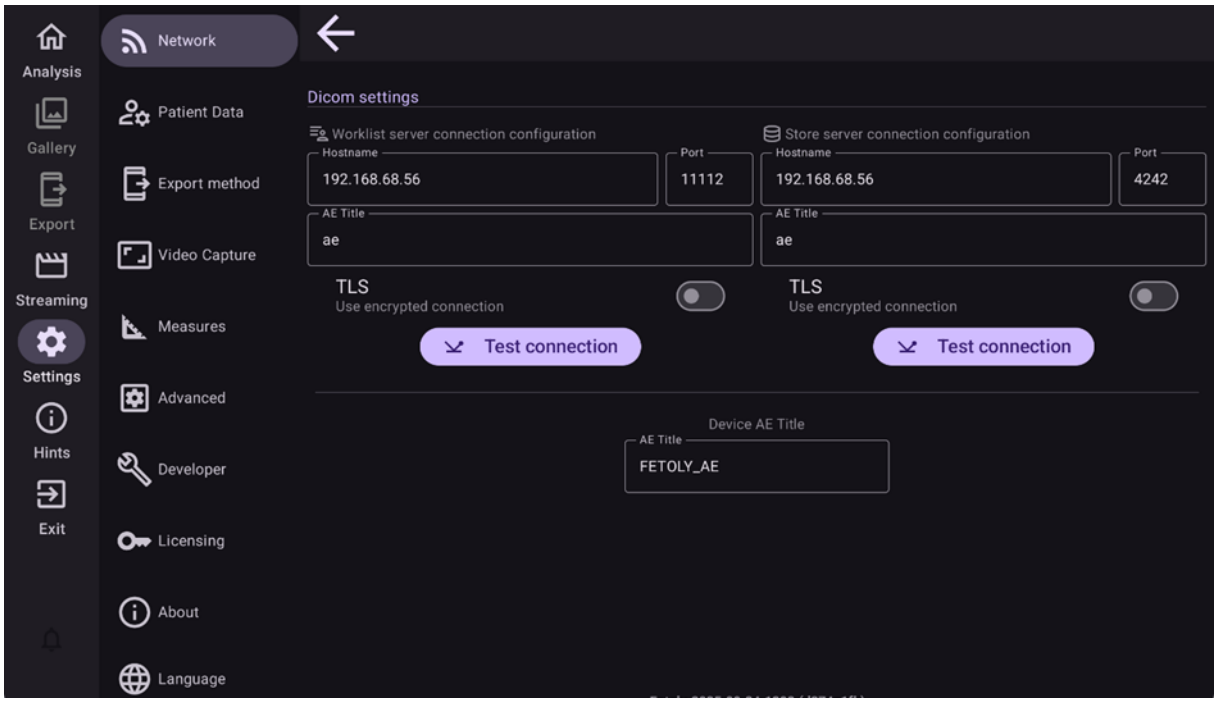
Niektoré ultrazvukové systémy umožňujú konfiguráciu veľkosti ultrazvukovej oblasti vo video výstupe. V takom prípade sa odporúča vybrať čo najväčšiu oblasť.

Konfigurácia exportu



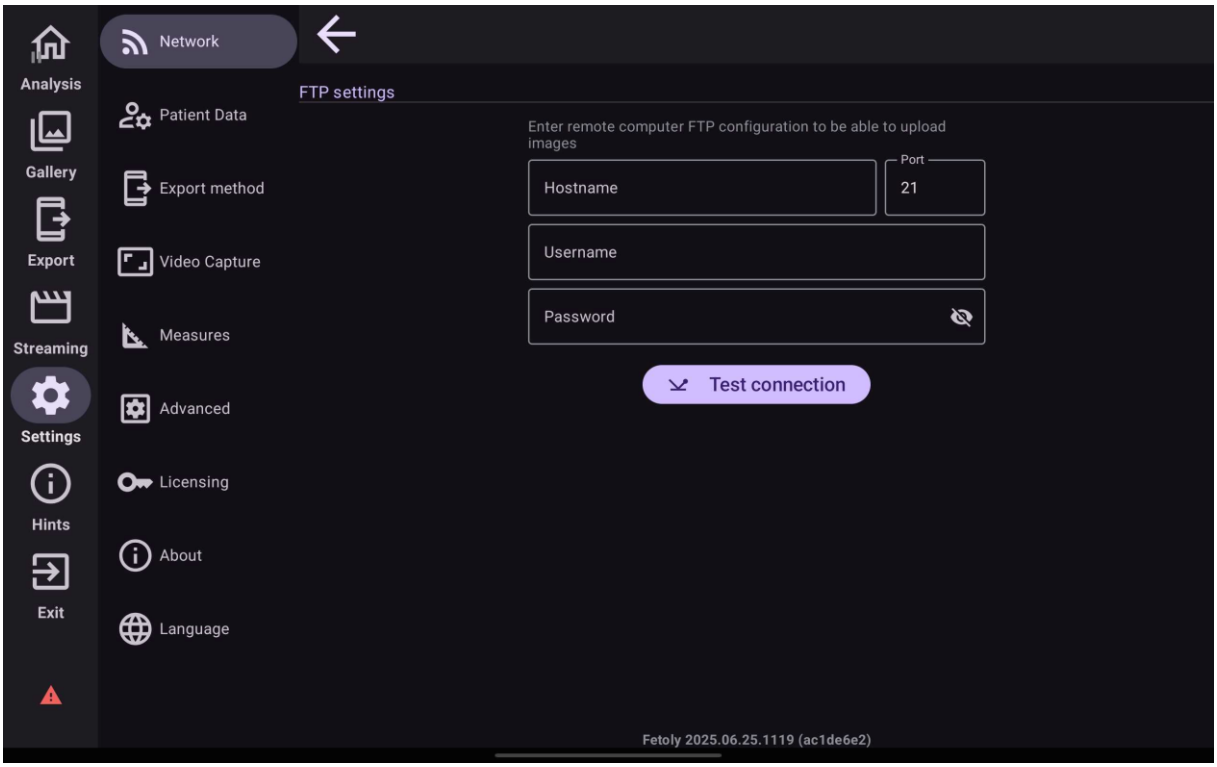
4. Konfigurácia vzdialeného servera DICOM na exportovanie obrazov zachytených programom FETOLY. Upozorňujeme, že tento krok si vyžaduje prítomnosť servera DICOM spusteného na zariadení pripojenom k rovnakej sieti ako tablet so spustenou aplikáciou FETOLY.

   Potom prejdite do Nastavenia > Nastavenia siete, vyberte položku Konfigurovať DICOM a zadajte požadované informácie pre váš server DICOM Store: názov hostiteľa pracovného zoznamu (IP adresa) a názov AE, názov hostiteľa DICOM Store (IP adresa) a názov AE, názov AE zariadenia. Ak chcete overiť pripojenie jednotlivých serverov DICOM, kliknite na tlačidlo „Testovať pripojenie“. Tým sa zabezpečí, že pripojenie je platné a pripravené na export obrazov. Môžete tiež voliteľne aktivovať možnosť TLS.

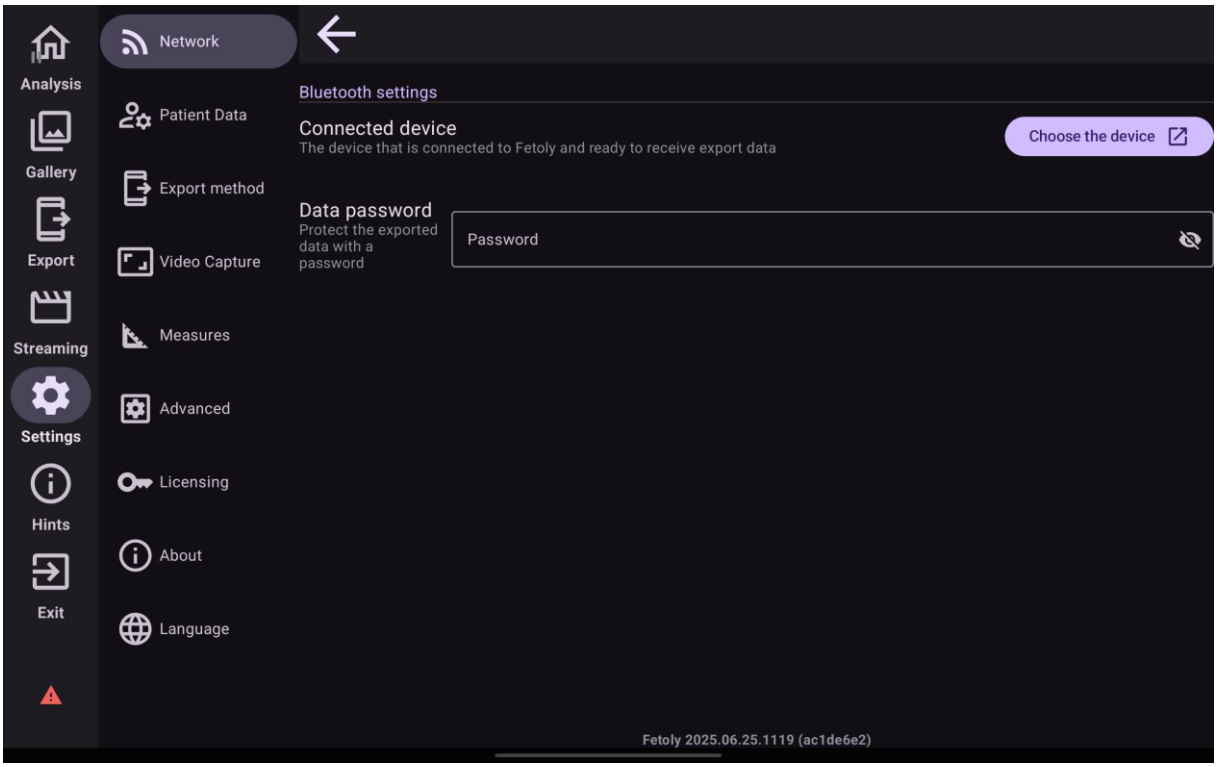


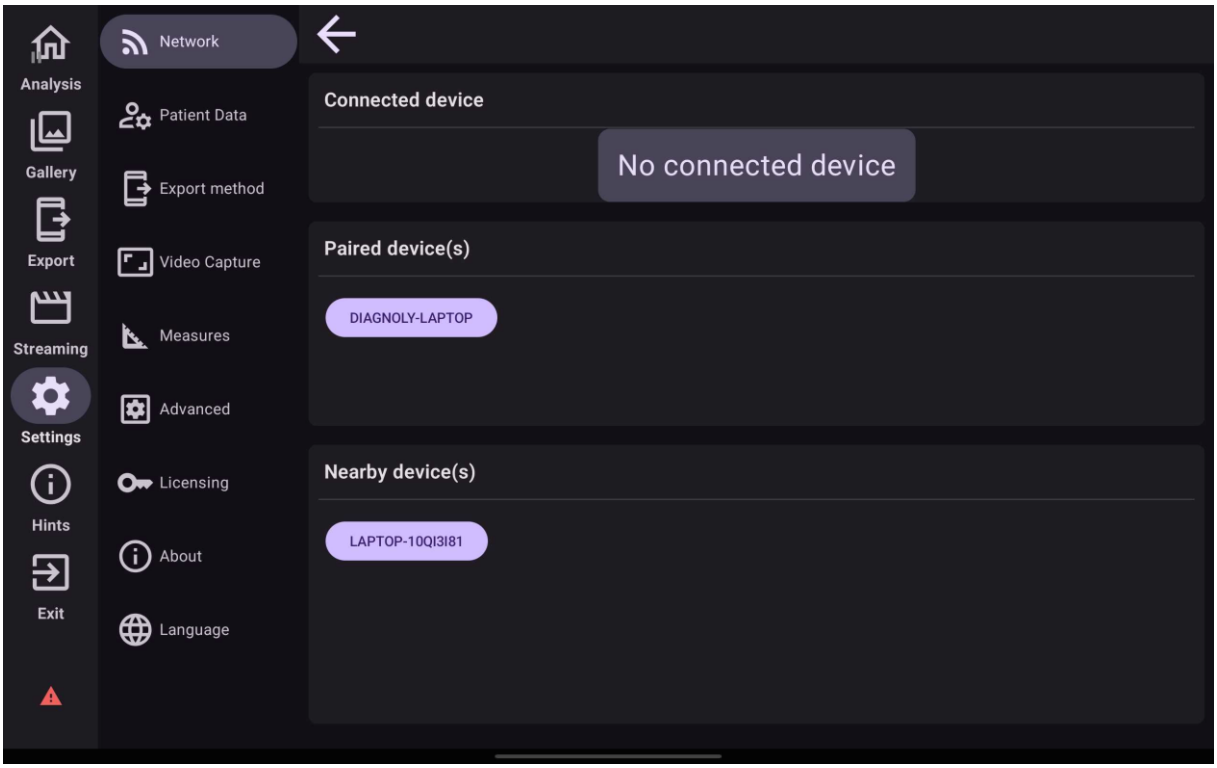
5. Prípadne nakonfigurujte vzdialený server FTP na export obrazov zachytených programom FETOLY. Upozorňujeme, že tento krok vyžaduje prítomnosť FTP servera spusteného na zariadení pripojenom k tej istej sieti ako tablet s nainštalovanou aplikáciou FETOLY.

    d. Prejdite do časti „Nastavenia“ > „Sieťové nastavenia“, vyberte možnosť Konfigurovať FTP a zadajte požadované informácie pre klienta FTP: názov hostiteľa (IP adresa), používateľské meno a heslo. Ak chcete overiť pripojenie, kliknite na tlačidlo „Otestovať pripojenie“. Tým sa zabezpečí, že pripojenie je platné a pripravené na export obrazov.



12. Prípadne môžete použiť pripojenie Bluetooth (len Android):
    a. „Nastavenia“ > „Nastavenia siete“ vyberte položku Bluetooth. Ak chcete vybrať zariadenie, do ktorého chcete exportovať údaje, musíte ho spárovať výberom v časti „Blízke zariadenie“. Potom v časti „Spárované zariadenie“ vyberte zariadenie, ktoré chcete pripojiť. Po výbere zariadenia môžete v časti „Pripojené zariadenie“ otestovať pripojenie. Stránka s výberom zariadenia je prístupná kliknutím na tlačidlo vpravo od položky „Nastavenia Bluetooth“ > „Pripojené zariadenie“.
    b. Ak chcete súbor exportovať, musíte dodatočne nastaviť heslo. Toto heslo bude pripojené k súboru .zip exportovanému do zariadenia tretej strany.

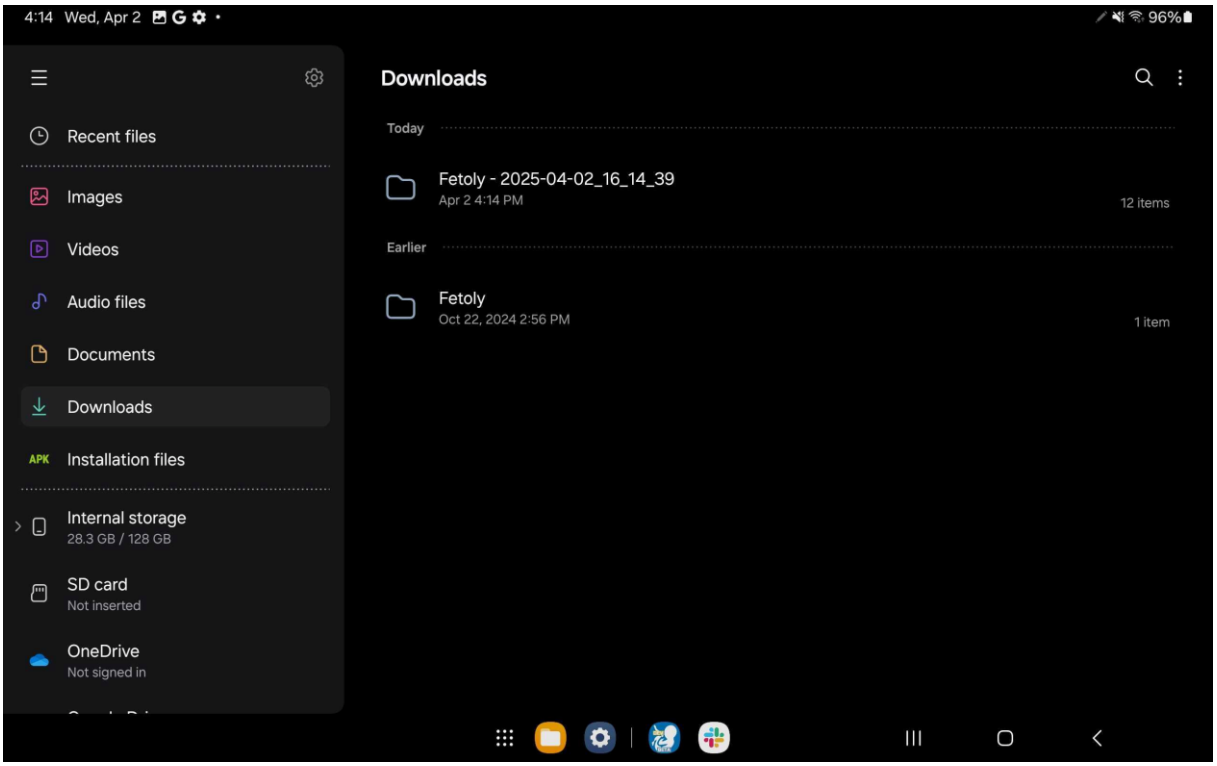




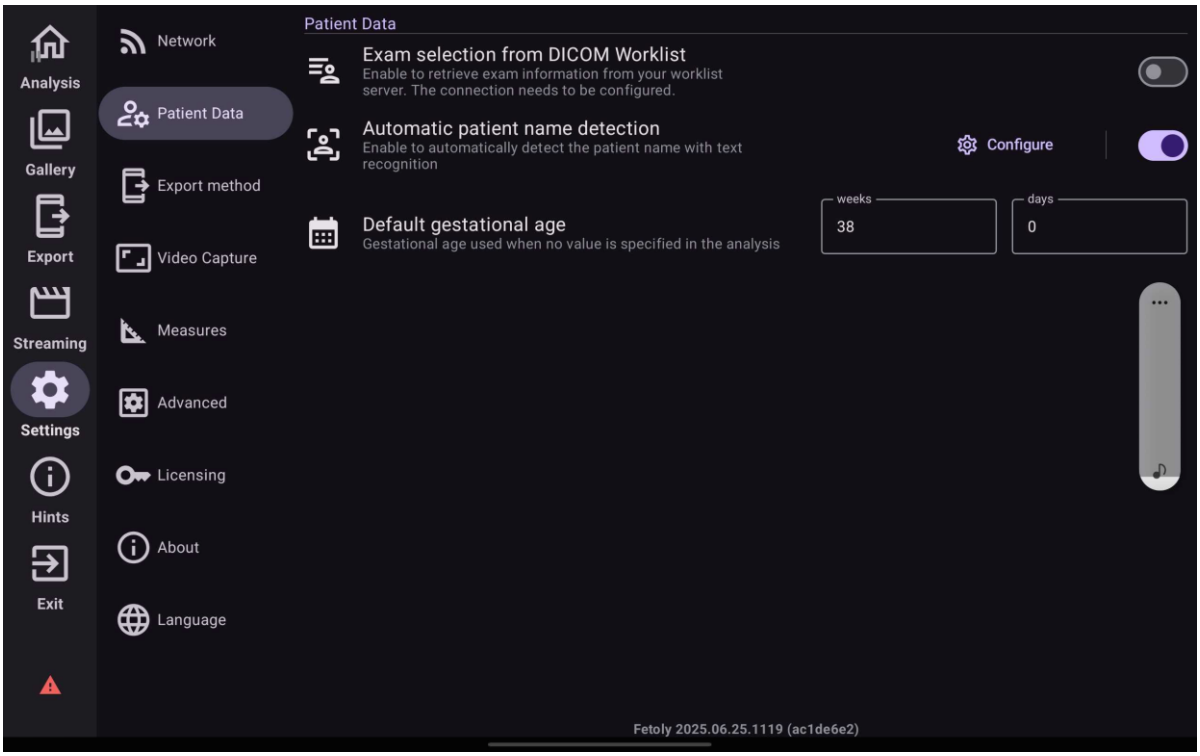
13. Ak nechcete používať bezdrôtové pripojenie, môžete údaje exportovať priamo do tabletu:

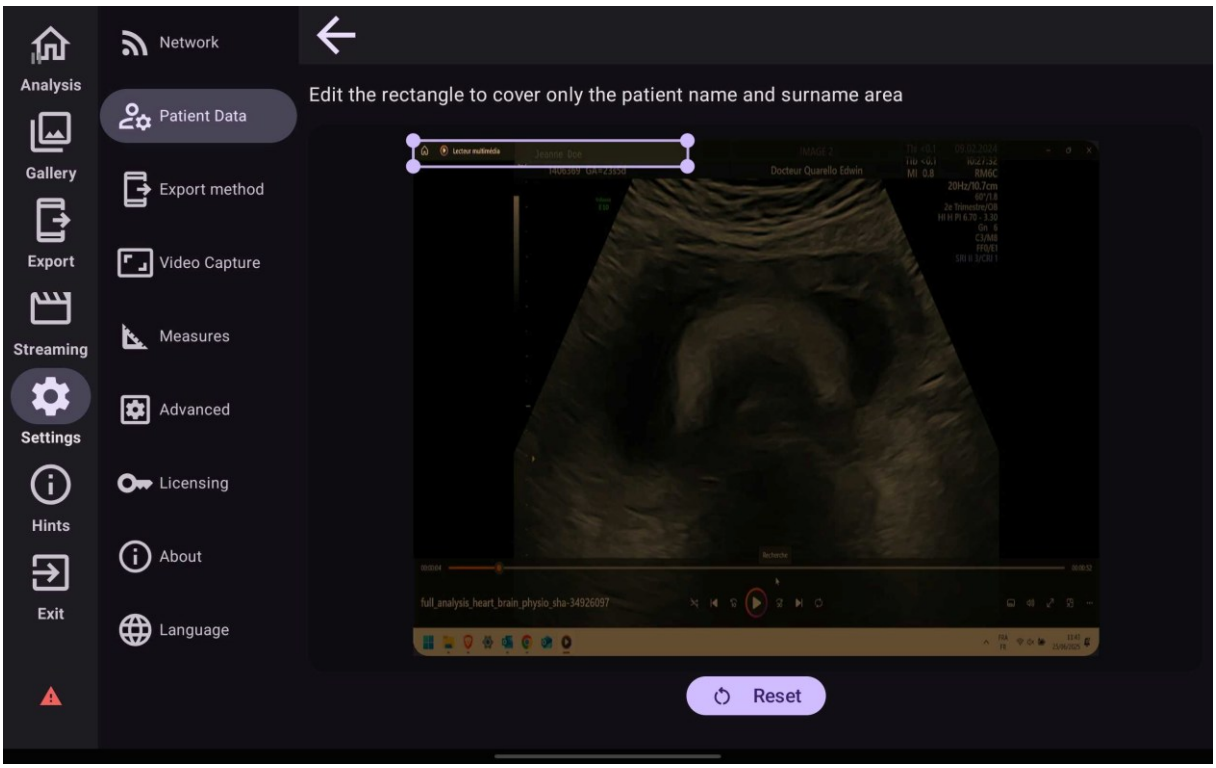
    a. Prejdite na položky „Nastavenia“ > „Spôsob exportu“ a vyberte možnosť Lokálne. Súbor sa uloží na miesto už definované tabletom.

    b. Ak sa chcete dostať do definovaného umiestnenia, prejdite na plochu tabletu, vyberte ikonu „Súbory“ a potom prejdite na „Stiahnuté súbory“ > „Fetoly“.



14. Ak chcete pridať meno pacienta do názvu exportovaného súboru alebo ak chcete vybrať vyšetrenie pacienta z pracovného zoznamu DICOM:
    a. Priamo vyplňte meno pacienta a gestačný vek na stránke analýzy alebo
    b. Prejdite na položku „Nastavenia“ > „Údaje o pacientovi“ a aktivujte „výber vyšetrenia z pracovného zoznamu DICOM“. Všimnite si, že táto funkcia funguje len vtedy, ak ste pripojení k systému PACS s nakonfigurovanými parametrami pracovného zoznamu DICOM. Takisto si všimnite, že v režime exportu DICOM ste nútení použiť toto nastavenie.
    c. Prípadne prejdite do časti „Nastavenia“ > „Údaje o pacientovi“ a aktivujte funkciu „automatické zisťovanie mena pacienta“. Potom môžete prejsť na položku „Konfigurovať“ a vybrať oblasť na ultrazvukovom videoprenose, kde sa zobrazuje meno pacienta. Meno pacienta sa potom vyplní automaticky pri spustení vyšetrenia alebo kliknutím na tlačidlo obnovenia vpravo od mena pacienta na stránke analýzy.

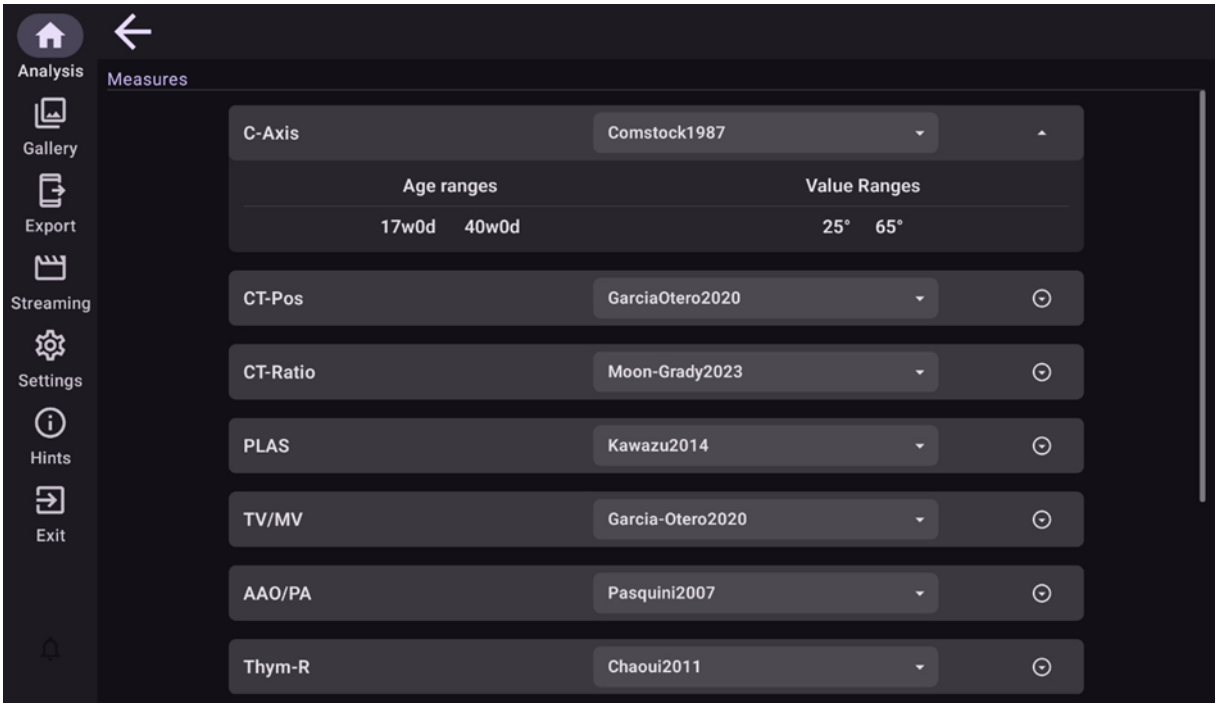




Použite

10. Na realizáciu úplnosti vyšetrenia a meraní postupujte podľa týchto krokov:
    a. Zadajte gestačný vek na stránke analýzy s menom pacientky alebo vyberte vyšetrenie pacientky z pracovného zoznamu DICOM.
    b. Predvolený gestačný vek môžete nakonfigurovať v časti „Nastavenia“ > „Údaje pacienta“.

c. Pokiaľ ide o funkciu merania, ak je k dispozícii viacero literárnych zdrojov, vyberte ten, ktorý vám najviac vyhovuje. Referenčné rozsahy môžete nastaviť aj manuálne výberom vlastnej možnosti. Toto sa vykoná kliknutím na tlačidlo novej karty vpravo od merania na stránke analýzy alebo prejdením do časti „Nastavenia“ > „Nastavenia meraní“. To vás presmeruje na stránku s nastaveniami merania.



d. Stlačte tlačidlo Play na stránke analýzy

e. Vykonajte vyšetrenie ako zvyčajne

f. Vyšetrenie sa považuje za úplné, keď sú overené všetky pohľady a kritériá a keď sú vykonané všetky merania.

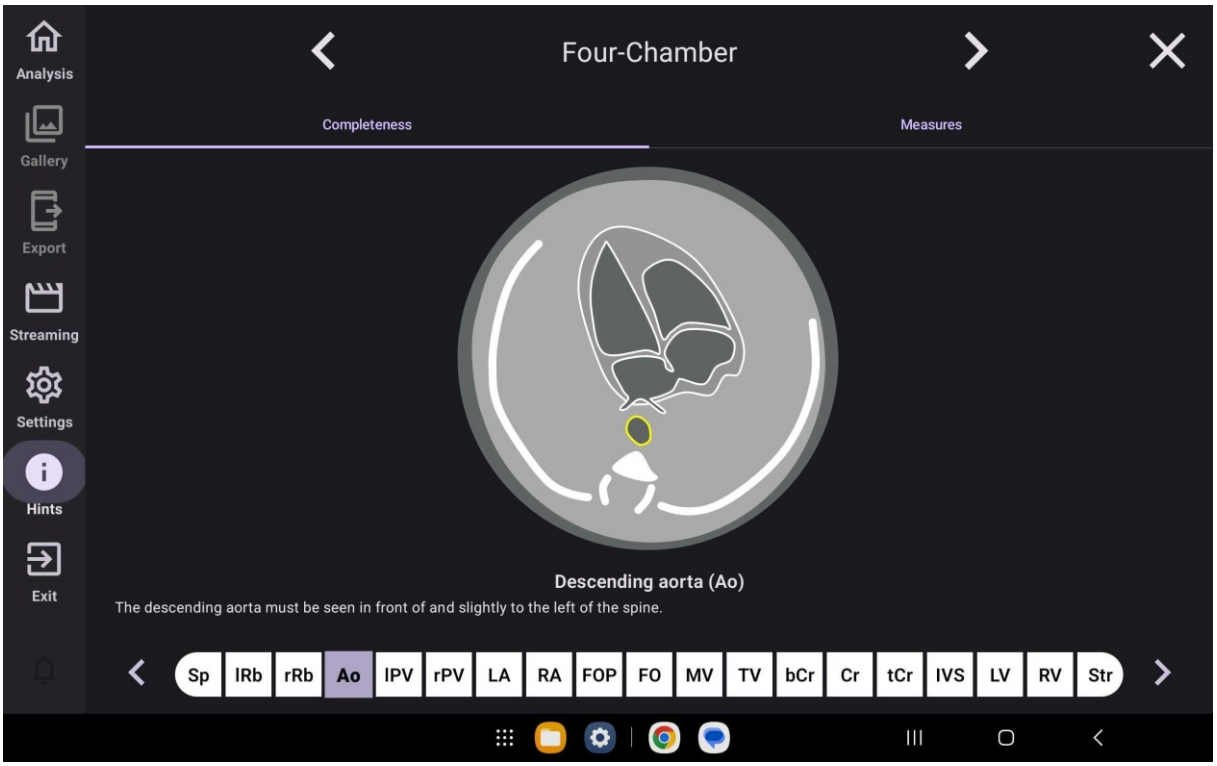
g. Ak sú merania mimo definovaného referenčného rozsahu, zobrazia sa ako „mimo rozsahu“.

h. Po dokončení skúmania sa o tom zobrazí informácia na stránke analýzy a umožní vám prejsť priamo na stránku galérie a skontrolovať navrhnuté obrazy.

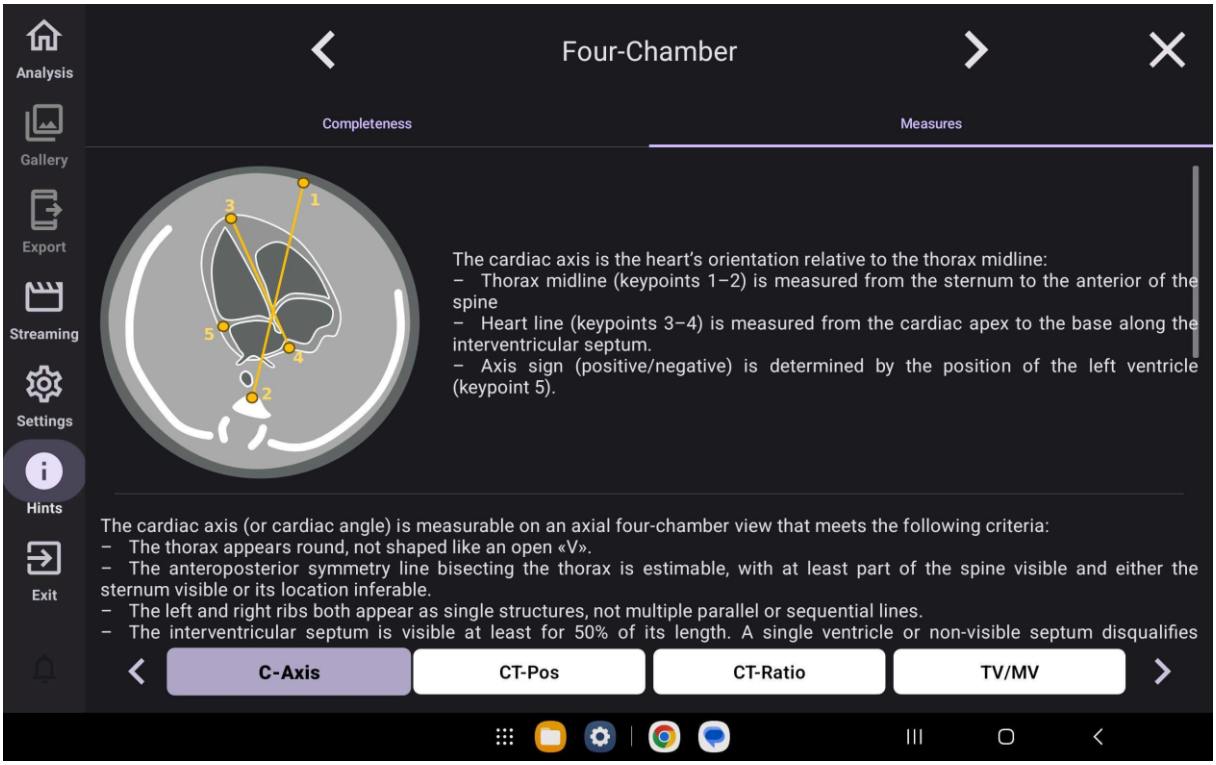


11. Nižšie nájdete zoznam tipov, ktoré vám pomôžu ľahko dosiahnuť úplnosť a opatrenia pri vyšetrení:

    a. kritériá kvality a pohľady detekované softvérom sú založené na usmerneniach ISUOG pre fetálny skríning srdca a mozgu. V prípade potreby si prečítajte toto usmernenie ako pripomienku správnych postupov pri fetálnom skríningu srdca/ mozgu. Môžete tiež prejsť na stránku Tipy, kde nájdete vysvetlenie všetkých kritérií kvality.



b. Biometrické merania vykonávané softvérom sú založené na medzinárodných usmerneniach a známej literatúre venovanej fetálnemu skríningu srdca a mozgu. V prípade potreby si prečítajte články z literatúry, na ktoré odkazuje softvér, ako pripomienku správnych postupov pri fetálnom skríningu srdca/mozgu. Môžete tiež prejsť na stránku Tipy, kde nájdete vysvetlenie všetkých uskutočňovaných meraní.



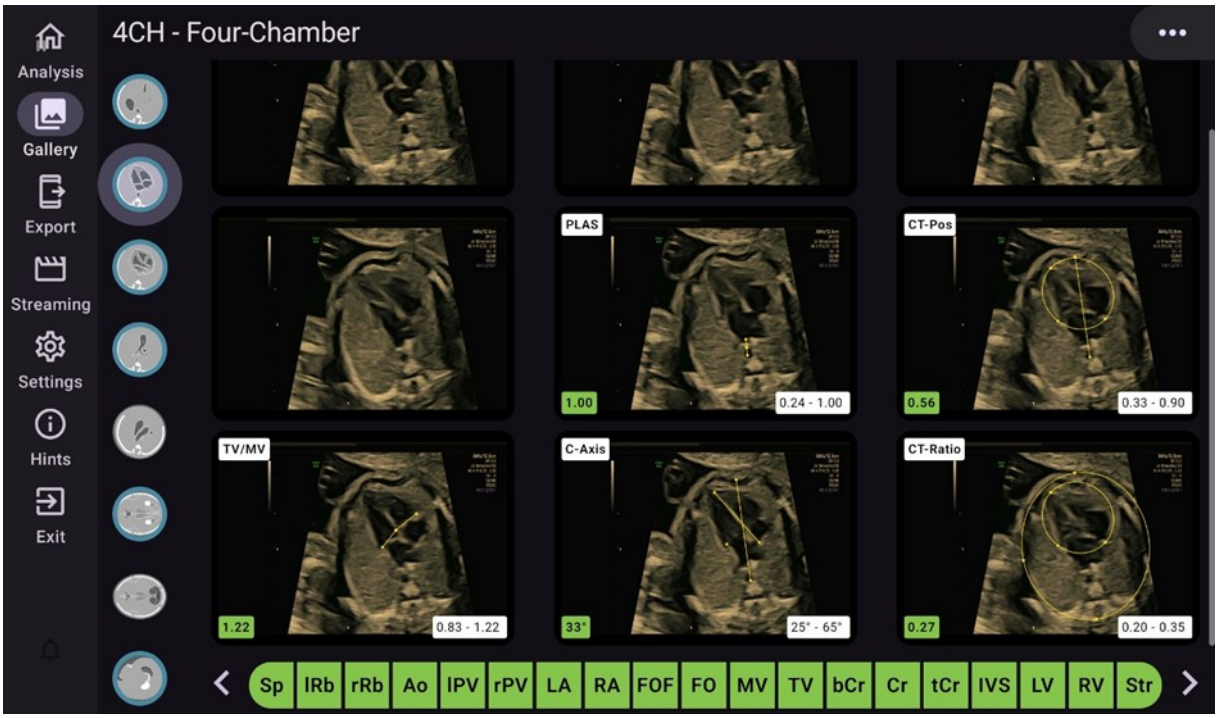
c. Uistite sa, že všetky vyššie uvedené kroky konfigurácie sú vykonané správne, aby ste sa vyhli problémom s detekciou.

d. Uistite sa, že používate kompatibilné zariadenie podľa časti 10 tohto návodu na použitie.

e. Ak kritériá kvality/merania nie sú obsiahnuté vo vybranom súbore obrazov, na stránke exportu sa zobrazí varovanie.

f. Po overení všetkých kritérií a vykonaní všetkých meraní na stránke analýzy overte, či sú všetky príslušné kritériá a merania dobre identifikovateľné na súbore obrazov vybraných na stránke Galéria.

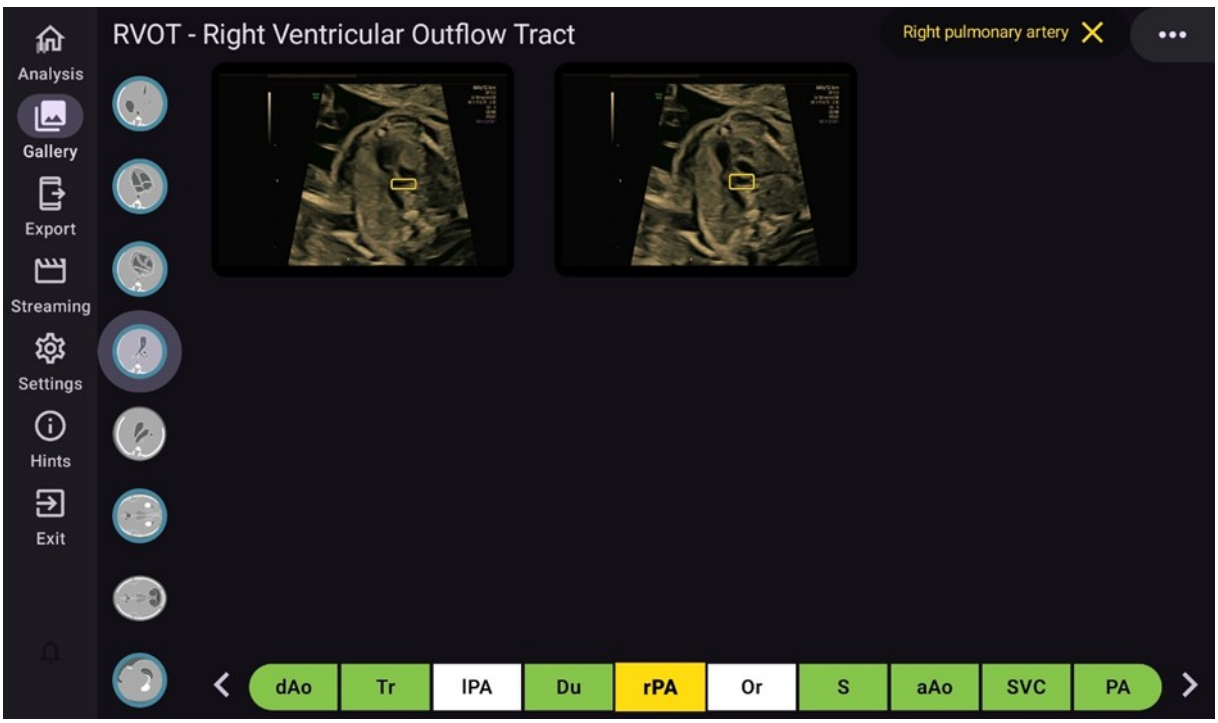
12. Po skončení videoprenosu prejdite do časti „Galéria“ a prezrite si vybrané obrazy. Na uľahčenie navigácie v súbore obrazov sú obrazy rozdelené do kategórií podľa roviny.



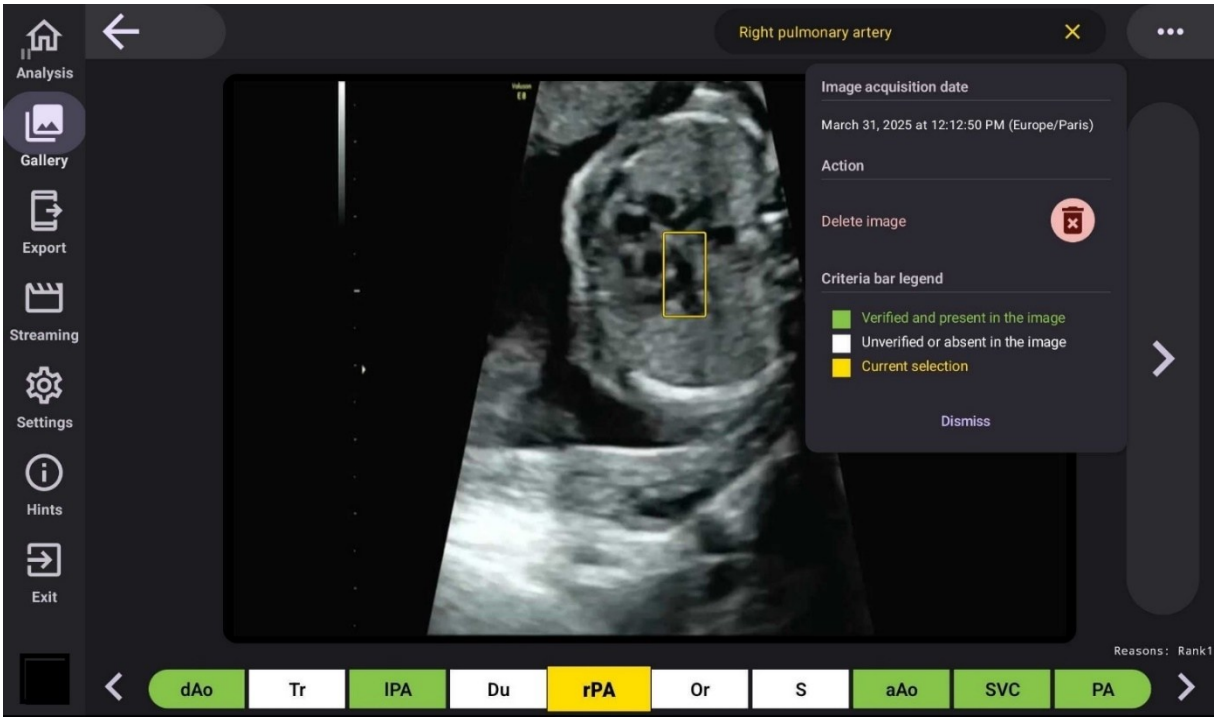
a. Kliknutím na konkrétnu rovinu (ľavý panel) zobrazíte vybrané obrazy týkajúce sa tejto roviny. Kritériá označené zelenou farbou sú overené a kritériá označené bielou farbou nie sú overené.

b. Obrázky vybrané pre biometrické merania obsahujú tieto informácie: názov merania, hodnotu, referenčný rozsah a prípadne stav mimo rozsahu. Kľúčové body a tvary merania sú označené žltou farbou.

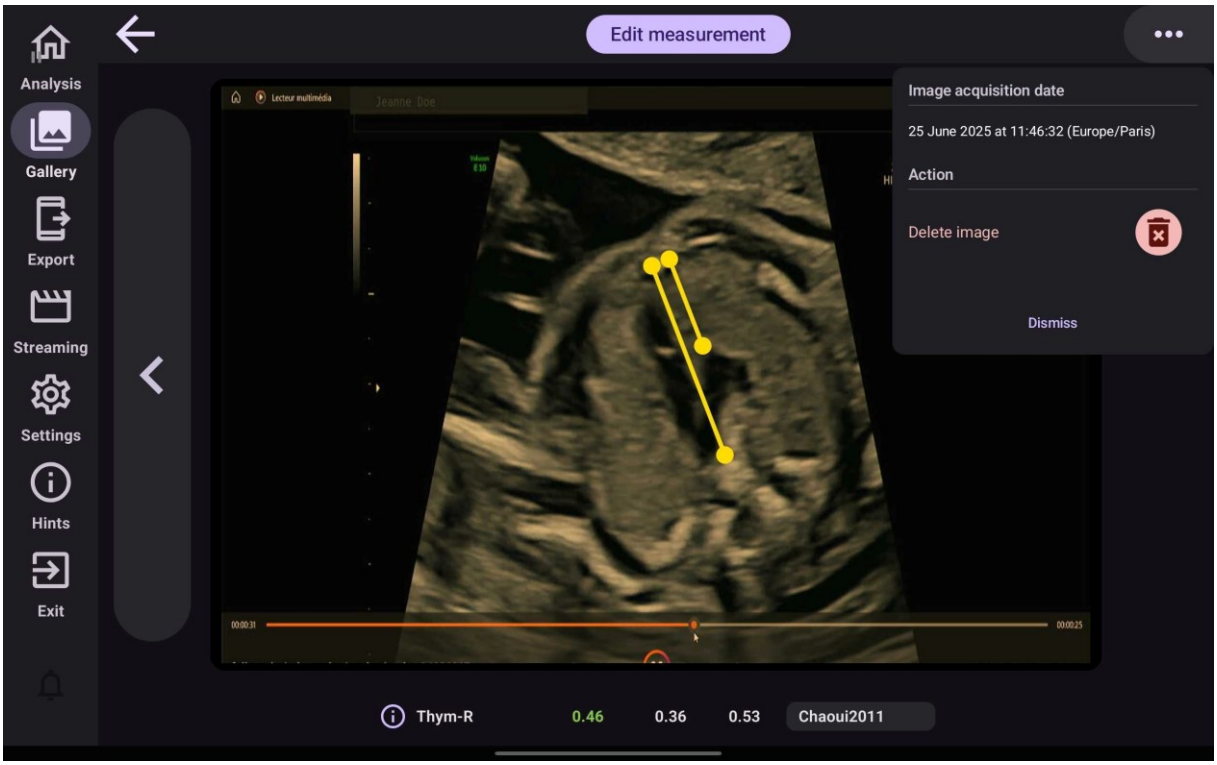
c. Kliknutím na konkrétnu štruktúru zobrazíte vybrané obrazy obsahujúce túto štruktúru. Vybrané kritérium kvality je označené žltou farbou a na obrazoch je zobrazený ohraničujúci rámček okolo kritéria.



d. Kliknutím na celý obraz ho zväčšíte. Kliknutím na kritérium kvality zelenou farbou zobrazíte ohraničujúci rámček okolo kritéria kvality. Vybrané kritérium kvality je vyznačené žltou farbou. Biele políčka znamenajú, že kritériá kvality sú prítomné aj na iných obrazoch galérie alebo nie sú overené. Kliknutím na symbol koša obraz odstránite. Môžete priamo potiahnuť prstom po bokoch obrazu, aby ste prešli na ďalšie obrazy v rámci pohľadu.



e. Kliknutím na obraz merania ho zväčšíte. Kľúčové body a tvary merania sú označené žltou farbou. Upozorňujeme, že meracie body nie sú navrhnuté tak, aby sa nachádzali na presnom mieste, ale aby boli dostatočne presné na zobrazenie správnej hodnoty merania. Zobrazí sa hodnota a prípadný stav „mimo rozsahu“ spolu s referenčným rozsahom a vybraným bibliografickým zdrojom. Kliknutím na symbol koša obraz odstránite. Môžete priamo potiahnuť prstom po bokoch obrazu, aby ste prešli na ďalšie obrazy v rámci pohľadu. Kľúčové body pre meranie na obrazoch merania môžete upraviť kliknutím na tlačidlo „Upraviť meranie“. Hodnota merania sa potom zodpovedajúcim spôsobom aktualizuje a softvér zabráni akejkoľvek automatickej úprave opätovným skenovaním po úprave. Upravené meranie sa označí nasledujúcim symbolom: .



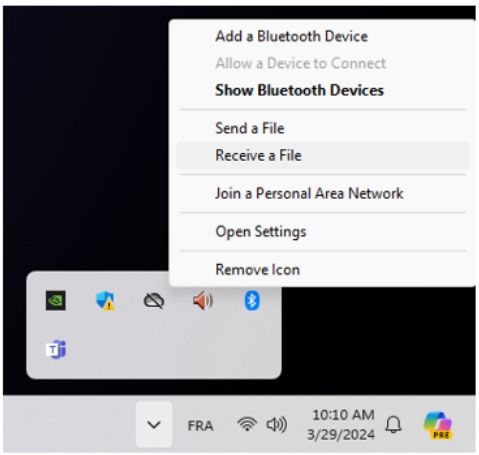


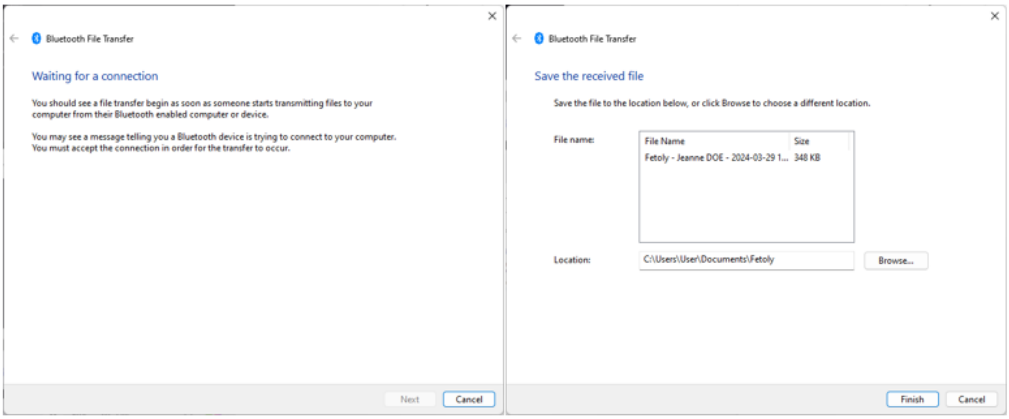
f. V prípade potreby sa môžete vrátiť na stránku analýzy a znovu spustiť analýzu a získať ďalšie obrazy.

Export obrazov

7. Prejdite do časti „Spôsob exportu“ v časti „Nastavenia“ a vyberte režim exportu, ktorý chcete použiť.
8. Ak chcete exportovať vybrané obrazy, prejdite do časti „Export“:

e. Ak ste si vybrali pripojenie Bluetooth (len Android), prejdite do počítača a v konfigurácii Bluetooth vyberte možnosť „Prijať súbor“.





w. Ak ste vybrali pripojenie DICOM, môžete pomocou pracovného zoznamu DICOM na stránke analýzy overiť, či je pacient vybraný na export správny, a v prípade chyby vybrať iného pacienta.

x. Na stránke exportu sa zobrazí súhrn vyšetrenia a pripomenie vám, aby ste pred exportom overili, či máte všetky obrazy potrebné na efektívnu starostlivosť o pacienta.

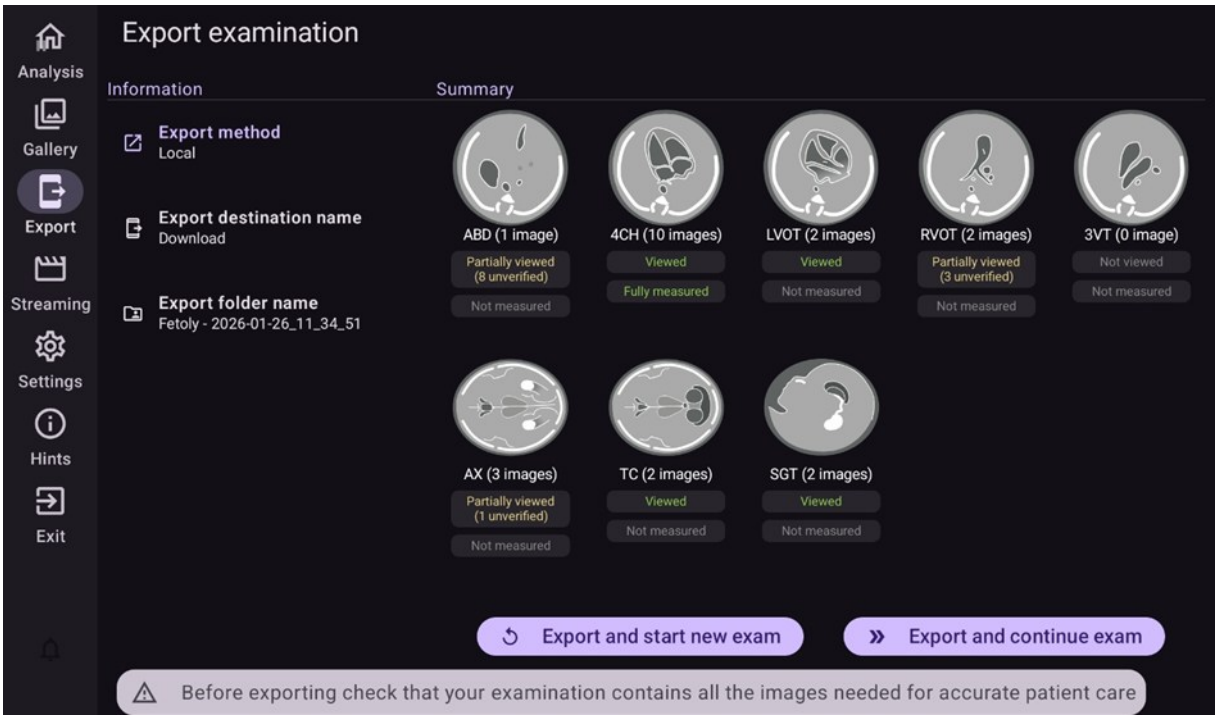
y. Na stránke exportu sa zobrazí zvolená metodika exportu. Ak chcete zmeniť nastavenia, môžete prejsť priamo na stránku s nastaveniami exportu kliknutím na „Spôsob exportu“.

z. Na stránke exportu sa zobrazí umiestnenie exportného súboru vo vybranom zariadení a názov súboru nastavený pre miestny export.

aa. Kliknutím na tlačidlo „Exportovať a začať nové vyšetrenie“ exportujete obrazy a vymažete vyšetrenie pred začatím nového vyšetrenia.

bb. Alebo kliknite na tlačidlo „Exportovať a pokračovať vo vyšetrení“ na exportovanie obrazov bez vymazania aktuálne zvoleného súboru obrazov a analýzy kompletnosti.

cc. Softvér vám oznámi, či bol export úspešný alebo neúspešný.



Opätovná inicializácia (vymazať)

Ak ste nepoužili funkciu vymazania na stránke exportu, prejdite do časti „Analýza“ a kliknutím na tlačidlo „Vymazať“ znovu inicializujte súbor vybraných obrazov a vyšetrenie.

Rozšírené nastavenia

Ak chcete funkciu merania vypnúť, prejdite do časti „Nastavenia“ > „Rozšírené“ a kliknite na tlačidlo.

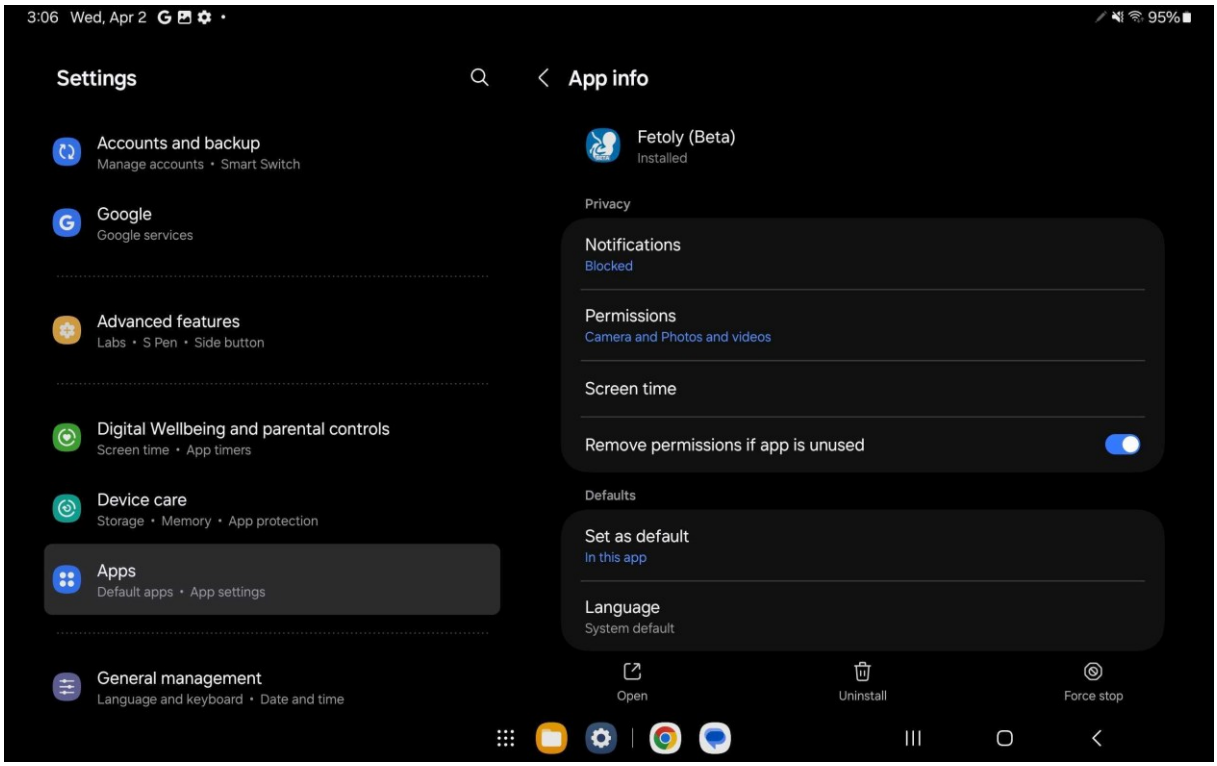
Aktualizácia softvéru a licencie

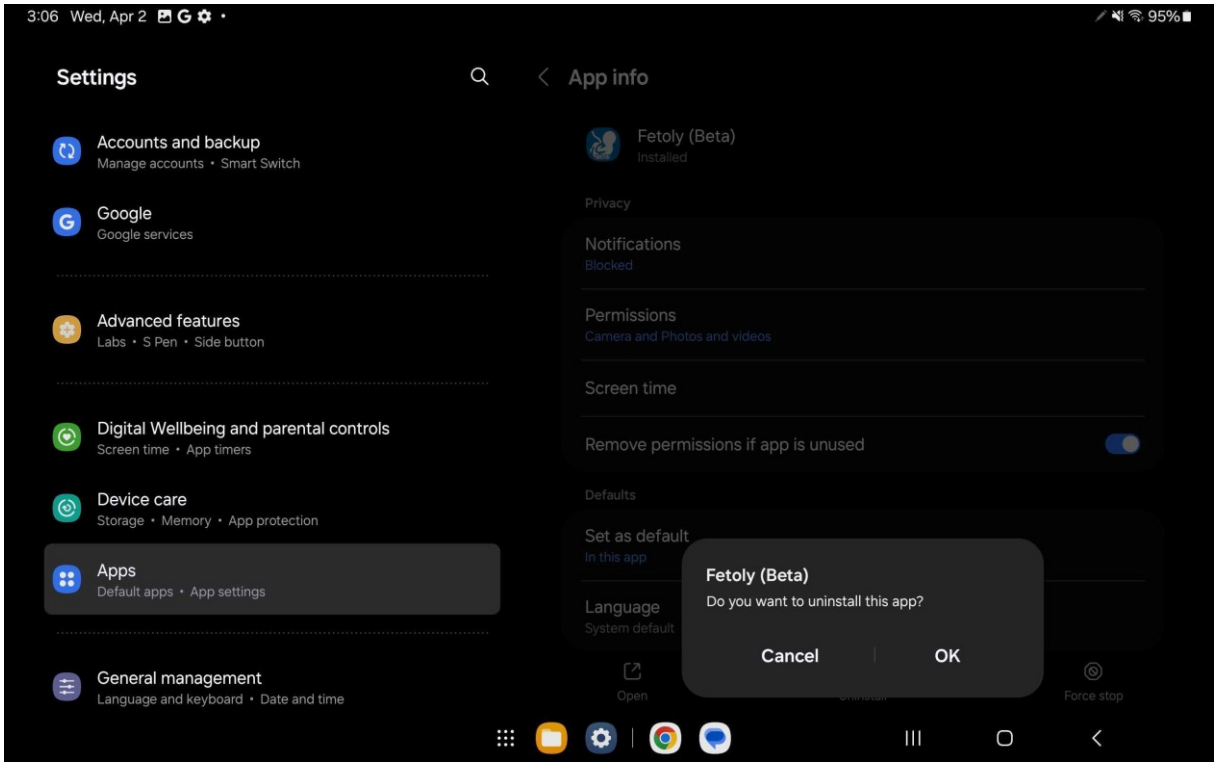
Softvér pravidelne kontroluje nové aktualizácie aplikácie. Ak chcete zabezpečiť okamžitú dostupnosť nových aktualizácií, povoľte aktualizácie na pozadí pre FETOLY v nastaveniach obchodu Google Play/App. Ak je k dispozícii aktualizácia, softvér pri spustení zobrazí blokovaciu stránku, ktorá od používateľa vyžaduje aktualizáciu a reštartovanie aplikácie, aby ju mohol ďalej používať. Po prijatí aktualizácie sa obchod Google Play/App postará o inštaláciu aktualizácie a reštart aplikácie. Na kontrolu aktualizácií a automatické obnovenie licencie je potrebné internetové pripojenie. Ak zariadenie nie je 30 dní pripojené k internetu, softvér sa zablokuje.

Vaša licencia sa overuje a obnovuje automaticky po aktivácii internetového pripojenia až do vypršania licenčnej zmluvy. Dátum skončenia platnosti licencie sa zobrazuje na stránke s nastaveniami licencie. Po uplynutí platnosti licenčnej zmluvy, ak nedôjde k jej obnoveniu, softvér požiada o zadanie nového registračného kódu a zablokuje funkcie.

Odinštalovanie softvéru

Aplikáciu odinštalujte ako akúkoľvek aplikáciu v tablete, ako je znázornené nižšie:





14. Údržba, manipulácia a likvidácia

- Pred použitím je potrebné si prečítať návod na použitie.
- Ak vás softvér pri spustení požiada o aktualizáciu, spustite ju.

- Upozorňujeme, že pre trh Spojených štátov amerických bol zahrnutý plán kontroly vopred stanovených zmien (PCCP). Tento PCCP je implementovaný pre model strojového učenia integrovaný v zariadení FETOLY, ktorý by mohol mať vplyv na výkon, vstupy alebo používanie zariadenia. Preto sa dôrazne odporúča byť pravidelne pripojený na internet, aby sa umožnila automatická inštalácia aktualizácií.
- Pri spustení softvéru zadajte registračný kód.
- Ak chcete softvér vyradiť z prevádzky a zlikvidovať, odinštalujte aplikáciu prostredníctvom systému Android ako akúkoľvek inú aplikáciu v tablete, v parametroch aplikácie, ako je znázornené vyššie v odseku „Odinštalovanie softvéru“. Odinštalovaním sa z tabletu odstránia všetky údaje súvisiace s používaním aplikácie FETOLY vrátane licencie.

Symboly používané na označovaní (o stránke):

	Výrobca (vyplnený továrenský symbol)
	Zariadenie s označením CE
	Jedinečný identifikátor zariadenia 01: UDI-DI 11: Dátum výroby 8012: Verzia softvéru
	Prečítajte si návod na použitie
	Federálny zákon obmedzuje predaj tohto zariadenia na základe objednávky lekára alebo na jeho pokyn.
	Zdravotnícka pomôcka
	Dátum výroby (symbol prázdnej továrne)
	Názov a adresa zástupcu vo Švajčiarsku

INSTRUÇÕES DE UTILIZAÇÃO (PORTUGUÊS)

1. Identificação do Dispositivo

FETOLY

Software de apoio ao exame de imagiologia por ultrassons do coração e do cérebro fetal.

Versão do software associada a este IFU: V2026.02.25

2. Atualização

O FETOLY foi atualizado da seguinte forma para a versão 2026.02.25:

- O FETOLY é agora compatível com iOS.
- As seguintes medições foram adicionadas de acordo com a Modificação n.º 4 do Plano de Controlo de Alterações Predeterminadas (PCCP): Espaço Posterior do Átrio esquerdo, rácio Cavum do Septo Pelúcido (CSP), rácio Ventrículo Posterior (VP).
- As vistas Transventricular e Transtalâmica foram fundidas na vista Axial.
- O IFU foi atualizado para clarificar a funcionalidade de apresentação dos pontos-chave e para adicionar um aviso explicando que o software não deve ser utilizado no método de ecografia pélvica endovaginal.
- O desempenho de deteção do modelo de IA foi melhorado de acordo com a Modificação n.º 1 do PCCP.
- É agora possível ativar o modo Segurança da Camada de Transporte (SMT) para exportação DICOM.

Os ensaios de verificação foram totalmente relançados para confirmar que a atualização não tem impacto nas funcionalidades do dispositivo. A metodologia seguida é a mesma da versão inicial do produto.

3. Identificação do Fabricante

O FETOLY é fabricado por:

DIAGNOLY

2 Place de Francfort,

69003 LYON, França

Tel.: +33(0)6.58.49.07.84

Reclamações de produto: support@diagnoly.com

Qualquer incidente grave deve ser comunicado à Diagnoly através do endereço de e-mail de reclamações de produto e à Autoridade Competente do seu país.

CE 0197

4. Descrição e Apresentação do Dispositivo

O Fetoly é um software destinado a auxiliar ecografistas, obstetras, radiologistas, especialistas em medicina materno-fetal e cardiologistas pediátricos (designados como profissionais de saúde – HCPs) na realização, em tempo real, de exames de ultrassons do cérebro e do coração fetal. O Fetoly pode ser utilizado por HCPs durante exames ecográficos fetais no segundo e terceiro trimestres (janela de idade gestacional: de 17 a 40 semanas).

O software destina-se a apoiar os HCPs na avaliação da completude do exame ecográfico do cérebro e do coração fetal, de acordo com as orientações nacionais e internacionais. O Fetoly destina-se igualmente à realização de medições biométricas do cérebro e do coração fetal, de acordo com as orientações nacionais e internacionais.

Para utilizar o Fetoly, o software deve ser instalado num dispositivo de hardware ligado a um equipamento de ecografia através de uma ligação HDMI. O software recebe, em tempo real, as imagens de ultrassons captadas pelo equipamento de ecografia ligado. O algoritmo de aprendizagem profunda do software, congelado e treinado por aprendizagem supervisionada, analisa este fluxo de imagens para detetar vistas do cérebro e do coração, critérios de qualidade nessas vistas e para realizar medições biométricas do coração e do cérebro.

O software fornece ao utilizador as seguintes informações acessíveis:

1. Completude do exame: o software apresenta, em tempo real, quais as vistas do cérebro/coração e critérios de qualidade que são verificados durante o exame. As vistas e critérios verificados estão acessíveis aos clínicos em qualquer momento do exame ecográfico, em tempo real.
2. Medições biométricas quantitativas: o software apresenta, em tempo real, quais as medições do cérebro e do coração detetadas e realizadas durante o exame e se estas se encontram dentro ou fora dos intervalos de referência definidos de acordo com o estado da arte. As medições verificadas do coração e do cérebro estão acessíveis aos clínicos em qualquer momento do exame, em segundo plano.
3. Ilustração do exame: o software seleciona um subconjunto de imagens que ilustra:
    a. as vistas e critérios de qualidade verificados. Estas imagens podem ser revistas pelos clínicos para confirmar a presença das vistas e dos critérios. Opcionalmente, os clínicos podem visualizar a localização dos critérios de qualidade detetados nas imagens selecionadas;
    b. cada medição. Para cada medição, o software apresenta uma imagem com a medição desenhada (a amarelo) e o valor medido (na parte inferior). O intervalo normal para essa medição é também apresentado ao utilizador. O utilizador

pode mover os pontos-chave e o software atualiza as medições em conformidade.

4. Relatório do exame: o software permite ao utilizador exportar um relatório do exame que contém:
    a. um resumo das medições e da completude;
    b. ilustrações (imagens).

Definição de um Exame Completo

Para o coração fetal

Tabela 1: Lista dos 52 critérios de qualidade que definem a qualidade das 5 vistas recomendadas pela International Society of Ultrasound in Obstetrics and Gynecology para o rastreio do coração fetal no 2.º e 3.º trimestres da gravidez.

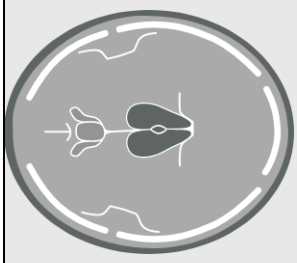
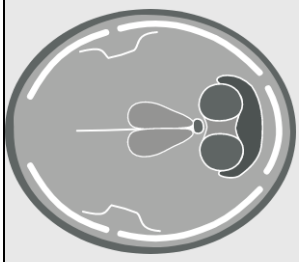
Vistas cardíacas	***Critérios de qualidade na vista***	
 ***(A) ABD*** ***Vista abdominal*** ***(n = 8)***	*(A1) Sp*	*Coluna vertebral*
	(A2) lRb	*Costela esquerda*
	(A3) rRb	*Costela direita*
	(A4) Ao	*Aaorta descendente*
	(A5) VC	*Veia cava inferior*
	(A6) St	*Estômago*
	(A7) Uv	*Veia umbilical*
	(A8) aA	*Abdómen anterior*
 ***(B) 4CH*** ***Vista cardíaca das quatro câmaras*** ***(n = 19)***	*(B1) Sp*	*Coluna vertebral*
	(B2) lRb	*Costela esquerda*
	(B3) rRb	*Costela direita*
	(B4) Ao	*Aorta descendente*
	(B5) lPV	*Veia pulmonar esquerda*
	(B6) rPV	*Veia pulmonar direita*
	(B7) LA	*Átrio esquerdo*
	(B8) RA	*Átrio direito*
	(B9) FOF	*Séptum primum (válvula de Vieussens / aba do forame oval)*
	(B10) FO	*Forame oval aberto*
	(B11) MV	*Válvula mitral*
	(B12) TV	*Válvula tricúspide*
	(B13) bCr	*Ligação entre o crux e o septo auricular (septo vestibular)*
	(B14) Cr	*Desalinhamento das válvulas auriculoventriculares no crux*
	(B15) tCr	*Ligação entre o septo interventricular e o crux*
	(B16) IVS	*Septo interventricular*

	(B17) LV	*Ventrículo esquerdo*
	(B18) RV	*Ventrículo direito*
	(B19) Str	*Esterno*
 ***(C) LVOT*** ***Trato de saída do ventrículo esquerdo*** ***(n = 6)***	*(C1) LA*	*Átrio esquerdo*
	(C2) aAo	*Aorta ascendente proximal*
	(C3) SV	*Válvulas semilunares*
	(C4) LV	*Ventrículo esquerdo*
	(C5) IVS	*Septo interventricular*
	(C6) RV	*Ventrículo direito*
 ***(D) RVOT*** ***Vista do trato de saída do ventrículo direito*** ***(n = 10)***	*(D1) dAo*	*Aorta descendente*
	(D2) Tr	*Traqueia / brônquios*
	(D3) lPA	*Artéria pulmonar esquerda*
	(D4) Du	*Canal arterial (ductus arteriosus)*
	(D5) rPA	*Artéria pulmonar direita*
	(D6) Or	*Origem das artérias pulmonares*
	(D7) S	*Septo entre o tronco pulmonar e a aorta ascendente*
	(D8) aAo	*Aorta ascendente*
	(D9) SVC	*Veia cava superior*
	(D10) PA	*Tronco pulmonar*
 ***(E) 3VX*** ***Vista dos três vasos*** ***(n = 9)***	*(E1) Sp*	*Coluna vertebral*
	(E2) Tr	*Traqueia*
	(E3) ES	*Espaço à esquerda do canal arterial / artéria pulmonar*
	(E4) DuA	*Arco ductal ligado à aorta descendente*
	(E5) Du	*Arco ductal não ligado à aorta descendente*
	(E6) aAo	*Aorta ascendente*
	(E7) aAr	*Arco aórtico*
	(E8) SVC	*Veia cava superior*
	(E9) Th	*Timo / esterno*

*As orientações internacionais e nacionais [Carvalho2023] recomendam cinco vistas cardíacas fetais para o exame ecográfico de rotina do 2.º e 3.º trimestres: (A) Vista abdominal, (B) Vista das quatro câmaras, (C) Vista do trato de saída do ventrículo esquerdo, (D) Vista do trato de saída do ventrículo direito, (E) Vista dos três vasos. A qualidade destas cinco vistas cardíacas depende da presença de 52 critérios anatómicos de qualidade no interior das vistas (**Tabela 1**). Assim, um exame pode ser considerado completo quando as cinco vistas cardíacas e os respetivos critérios de qualidade são obtidos pelo profissional de saúde (HCP).*

Para o cérebro fetal

Tabela 2: Lista de 34 critérios de qualidade que definem a qualidade das três vistas recomendadas pela International Society of Ultrasound in Obstetrics and Gynecology para o rastreio do cérebro fetal no 2.º e 3.º trimestres da gravidez.

Vistas do cérebro	***Critérios de qualidade nas vistas***	
 ***(F) TV*** *Plano axial* ***(n = 18)***	*(F1) aFx*	*Foice anterior*
	(F2) CSP	*Cavum do septo pelúcido*
	(F3) For	*Fórnix*
	(F4) dAV	*Ventrículo anterior distal*
	(F5) pAV	*Ventrículo anterior proximal*
	(F6) AC	*Cisterna ambiente*
	(F7) Atr	*Átrio*
	(F8) CP	*Plexo coroide*
	(F9) POS	*Sulco parieto-occipital*
	(F10) pFx	*Foice posterior*
	(F11) dCS	*Sutura coronal distal*
	(F12) pCS	*Sutura coronal proximal*
	(F13) SF	*Fissura de Sylvius*
	(F14) Sk	*Crânio*
	(F15) Sep	*Separação dos tálamos*
	(F16) 3V	*Terceiro ventrículo*
	(F17) dTh	*Tálamo distal*
	(F18) pTh	*Tálamo proximal*
 ***(G) TC*** ***Plano transcerebeloso*** ***(n = 8)***	*(G1) dTh*	*Tálamo distal*
	(G2) pTh	*Tálamo proximal*
	(G3) 4V	*Quarto ventrículo*
	(G4) Ver	*Vermis*
	(G5) dCH	*Hemisfério cerebeloso distal*
	(G6) pCH	*Hemisfério cerebeloso proximal*
	(G7) CB	*Contorno cerebeloso*
	(G8) CM	*Cisterna magna*
 ***(I) SAG***	*(I1) NB*	*Osso nasal*
	(I2) uVer	*Porção superior do vermis*
	(I3) lVer	*Porção inferior do vermis*
	(I4) Fas	*Fastígio*
	(I5) rgCC	*Rostro e joelho do corpo caloso*
	(I6) bCC	*Corpo do corpo caloso*
	(I7) sCC	*Esplénio do corpo caloso*

Plano sagital / vista de perfil (n = 8)	*(I8) CSP*	*Cavum do septo pelúcido*

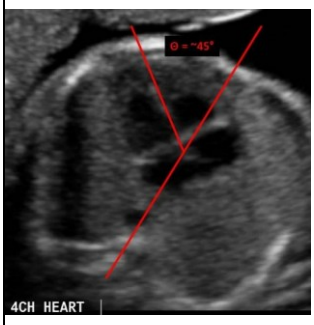
Medições biométricas e intervalos de referência

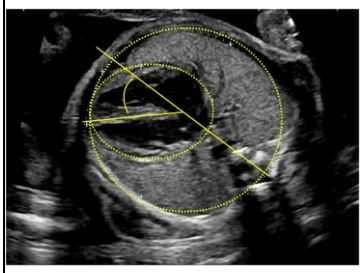
O FETOLY disponibiliza três tipos de medições biométricas automatizadas:

- **Medições angulares**, apresentadas em graus (°);
- **Medições por razão** (uma distância normalizada por outra distância, apresentada como razão ou percentagem);
- **Número** de marcos anatómicos detetados.

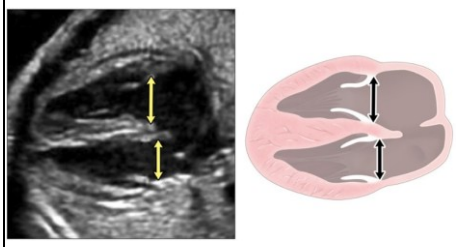
Lista de medições e respetivos intervalos de referência:

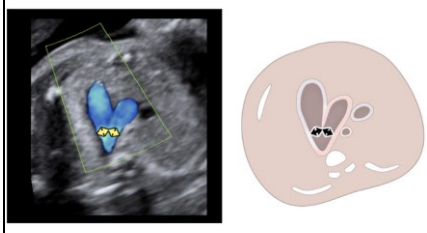
A tabela abaixo descreve as medições biométricas fornecidas pelo FETOLY e os respetivos intervalos de referência normais, com base na literatura científica estabelecida.

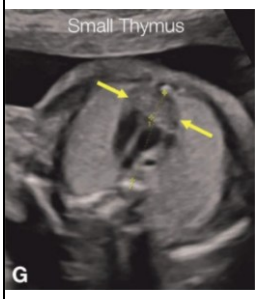
Parâmetro	*Informação disponível no FETOLY (descrição e fontes)*
(M1) Eixo cardíaco	*O que é o eixo cardíaco (CAx)?*  *(Fonte: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* *O **eixo cardíaco** (ou **ângulo cardíaco**) refere-se à orientação do coração em relação à linha média do tórax, medida na vista das quatro câmaras. É determinado pelo ângulo entre uma linha ao longo do septo interventricular e uma linha anteroposterior que divide o tórax ao meio.* *A imagem deve incluir a coluna vertebral, o esterno e as quatro câmaras. As costelas esquerda e direita devem estar presentes e visíveis como costelas únicas.* ***O que recomendam as diretrizes?*** *As diretrizes da ISUOG indicam que o rastreio cardíaco deve incluir a vista das quatro câmaras, e que a sua avaliação deve incluir o eixo cardíaco ("O coração fetal normal localiza-se maioritariamente à esquerda, com o ápice cardíaco orientado para a esquerda, formando um ângulo de 45 ± 20° em relação ao eixo anteroposterior do tórax") (Carvalho 2023). Citam o estudo de Comstock (1987), que fornece o intervalo de referência para o eixo cardíaco.*

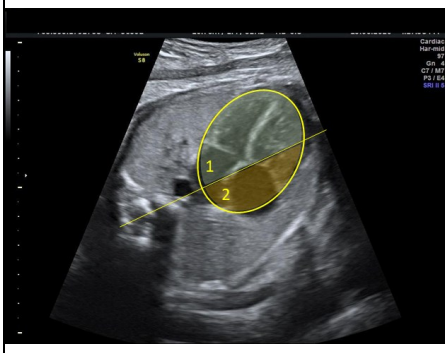
	As diretrizes da ASE também recomendam a avaliação do eixo cardíaco ("O eixo cardíaco é um componente recomendado da imagiologia ecocardiográfica fetal bidimensional […] normal 35–65°") (Moon-Grady 2023). ***Intervalos de referência disponíveis:*** • ***Comstock (1987)** – média ± 2 DP* o *17–40 semanas de gestação (SG): [25° – 65°]* • ***ASE (2023)** – intervalo definido por diretriz* o *17–40 SG: [35° – 65°]*
(M2) Rácio cardiotorácico	***O que é o rácio cardiotorácico?***  (Fonte: *https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext*) *O rácio cardiotorácico fetal (CTR) é a razão entre a circunferência transversal da superfície epicárdica do coração e a circunferência transversal do tórax, medida na vista das quatro câmaras durante a diástole.* *A imagem deve incluir a coluna vertebral, o esterno e as quatro câmaras. As costelas esquerda e direita devem estar presentes e visíveis como costelas únicas.* ***O que recomendam as diretrizes?*** *As diretrizes da ASE indicam que o rácio cardiotorácico é um componente obrigatório de um ecocardiograma fetal ("Medições biométricas padrão a partir de uma imagem axial ao nível da vista das quatro câmaras. O rácio cardiotorácico é calculado a partir da medição da circunferência (ou área) interna do tórax e da superfície epicárdica do coração") (Moon-Grady 2023).* *As diretrizes da AIUM também indicam que o rácio cardiotorácico é uma biometria cardíaca obrigatória (AIUM 2019). As diretrizes da ISUOG recomendam igualmente esta medição ("Os elementos-chave da vista normal das quatro câmaras no segundo trimestre incluem uma área cardíaca não superior a um terço da área torácica") (Carvalho 2013).* *O manual de Abuhamad (2009) também recomenda a avaliação das dimensões cardíacas ("As dimensões cardíacas fetais podem ser facilmente avaliadas medindo o rácio da circunferência ou área cardíaca em relação à circunferência ou área torácica ao nível da vista das quatro câmaras"). As diretrizes da AHA (Donofrio 2014) e o manual de Abuhamad citam Paladini (1990) como referência.*

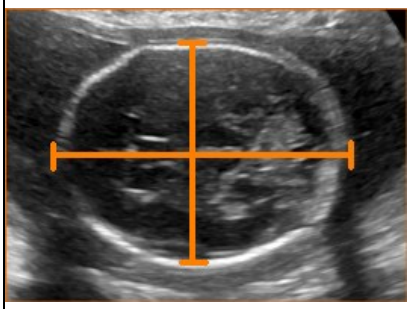
	Intervalos de referência disponíveis:
	
	• *Paladini (1990) – percentis 2,5 e 97,5 (circunferência)*
	  ○ *17 SG: [0,40 – 0,52]*
	  ○ *18 SG: [0,40 – 0,52]*
	  ○ *19 SG: [0,42 – 0,51]*
	  ○ *…*
	  ○ *40 SG: **[0,46 – 0,56]***
	• ***García-Otero (2020)** – percentis 5 e 95 (área)*
	  ○ *18 SG: [0,16 – 0,25]*
	  ○ *19 SG: [0,16 – 0,26]*
	  ○ *…*
	  ○ *40 SG: **[0,21 – 0,35]***
	• ***ASE (Moon-Grady 2023)** – intervalo definido por diretriz (área)*
	  ○ *17–40 SG: [0,20 – 0,35]*

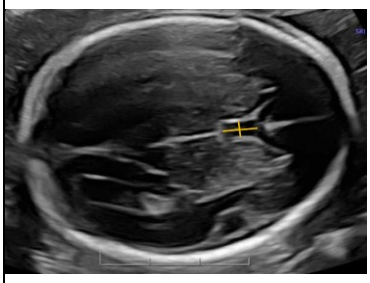
(M3) Rácio da largura ventricular	***O que é o rácio ventrículo direito–esquerdo?***  (Fonte: *https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext*) *O **rácio ventrículo direito–esquerdo (TV/MV)** refere-se à razão entre o diâmetro do anel da válvula tricúspide (TV) e o diâmetro do anel da válvula mitral (MV), sendo utilizado para avaliar a morfologia cardíaca fetal. É determinado comparando os diâmetros máximos da TV e da MV durante a diástole.* *A imagem deve incluir a coluna vertebral e o esterno. As costelas esquerda e direita devem estar presentes e visíveis como costelas únicas. A vista das quatro câmaras deve estar bem contrastada.* *Nota**:** existem duas convenções para medir o diâmetro ventricular (Schneider 2005): medição ao nível das válvulas ou dimensão telediastólica. Para este parâmetro, utiliza-se a medição ao nível das válvulas.* ***O que recomendam as diretrizes?*** *As diretrizes da AIUM indicam que a comparação dos anéis das válvulas tricúspide e mitral em diástole é uma biometria cardíaca obrigatória (AIUM 2019), citando DeVore (2017), Lee (2009) e Schneider (2005) para os intervalos de referência.* *As diretrizes da ISUOG indicam que a assimetria direita–esquerda justifica investigação adicional (“Ambos os ventrículos devem parecer semelhantes em tamanho. Embora uma ligeira desproporção ventricular possa ocorrer como variante normal no terceiro trimestre, a assimetria direita–esquerda na metade da*

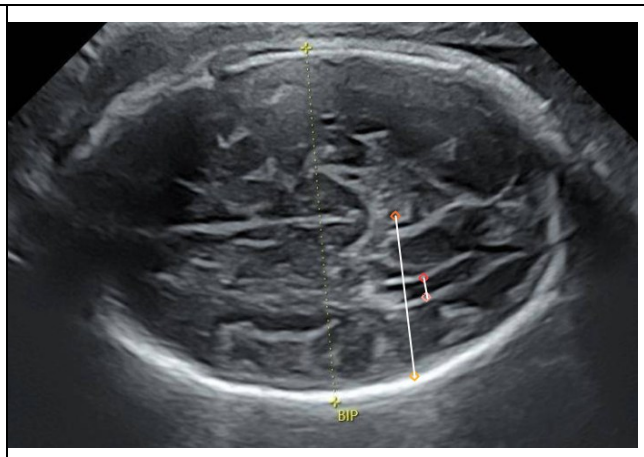
	gestação requer avaliação adicional") (Carvalho 2023), citando Kirk (1999) para o intervalo de referência. *As diretrizes da ASE indicam igualmente que a relação entre os tamanhos ventriculares é uma avaliação obrigatória no ecocardiograma fetal (Moon-Grady 2023). O manual de Abuhamad (2012) refere um rácio normal ventrículo direito/esquerdo de 1,19.* ***Intervalos de referência disponíveis:*** • ***Gabbay-Benziv (2015)*** *(Gabbay-Benziv2015) – percentis 2,5 e 97,5* o *17 SG: [0,87 – 1,22]* o *18 SG: [0,86 – 1,22]* o *19 SG: [0,86 – 1,22]* o *…* o *38 SG: [0,87 – 1,30]* • ***García-Otero (2020)*** *– percentis 5 e 95* o *18 SG: [0,82 – 1,21]* o *19 SG: [0,82 – 1,22]* o *…* o *40 SG: [0,86 – 1,27]*
(M4) Rácio dos vasos	***O que é o rácio dos grandes vasos?***  (Fonte: *https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext*) *O rácio do tamanho dos grandes vasos (Ao/Du) refere-se à razão entre os diâmetros do istmo aórtico (Ao) e do ducto arterioso (Du), medidos na vista dos três vasos. É determinado medindo os diâmetros do ducto arterioso e do arco aórtico na sua base.* *Note-se que o rácio entre o diâmetro da artéria pulmonar mediastínica (AP) e o da aorta ascendente (Ao) também é utilizado na literatura (Slodki 2009).* *A imagem deve incluir a coluna vertebral e o esterno, com as costelas esquerda e direita visíveis e bem definidas. O ducto arterioso e a aorta ascendente devem estar claramente visíveis, demonstrando a sua ligação.* ***O que recomendam as diretrizes?*** *As diretrizes americanas e internacionais, incluindo ASE, ISUOG, AIUM e AHA, indicam que a avaliação da relação de tamanho entre as grandes artérias é obrigatória (Donofrio 2014). "Assegurar a normalidade das duas grandes artérias, incluindo o seu tamanho […] relativo entre si" (Carvalho 2023). O manual de Abuhamad (2012) também destaca a relevância da comparação entre os diâmetros do arco aórtico e da artéria pulmonar principal, especificamente na*

	região do istmo. Estas referências citam o estudo de Pasquini (2007) para os intervalos de referência. ***Intervalos de referência disponíveis:*** • ***Pasquini (2007):*** o *Constante: [0,86 – 1,12] (média ± DP)* o *Constante: [0,74 – 1,23] (percentis 2,5 e 97,5) (Buyens 2012)*
(M5) Vessels number	***O que é o número de vasos?*** *A vista fetal dos três vasos (3VV) é um plano axial utilizado na imagiologia pré-natal para avaliar os grandes vasos do coração. Esta vista apresenta tipicamente três vasos, normalmente a artéria pulmonar, a aorta e a veia cava superior. A contagem dos vasos incide apenas sobre estruturas anecoicas arredondadas ou alongadas, excluindo a traqueia e a aorta descendente.* *A imagem deve realçar os vasos, com contraste e distinção claros entre as estruturas.* ***O que recomendam as diretrizes?*** *As diretrizes da ISUOG recomendam que a avaliação da vista dos três vasos "envolva a análise do número de vasos. Da esquerda para a direita, os vasos são a artéria pulmonar, a aorta e a veia cava superior direita" (Carvalho 2023). As diretrizes da ASE também enfatizam que anomalias no número de vasos devem ser registadas (Moon-Grady 2023). Como padrão internacional, o número esperado de vasos é três.*
(M6) Rácio timo-torácico	*O que é o rácio timo-torácico?*  (Fonte: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4th ed.). Wolters Kluwer) *O* ***rácio timo-torácico*** *é a razão entre o diâmetro anteroposterior do timo e o diâmetro mediastínico intratorácico, medidos na vista dos três vasos e da traqueia.* *A imagem deve mostrar a coluna vertebral, o esterno e a aorta ascendente, com as costelas esquerda e direita visíveis como estruturas únicas. O timo deve estar claramente visível e identificável.* ***O que recomendam as diretrizes?*** *As diretrizes da ISUOG indicam que a "avaliação da vista dos três vasos envolve a análise do alinhamento dos vasos" (Carvalho 2023) e que esta pode "melhorar*

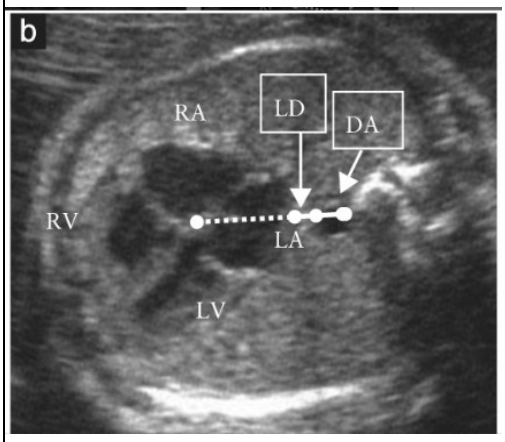
	a deteção de anomalias do trato de saída". Citam Chaoui (2011) para a avaliação do rácio timo-torácico na deteção de anomalias do trato de saída. O manual de Abuhamad (2022) também refere a importância da avaliação deste parâmetro. ***Intervalos de referência disponíveis:*** • ***Chaoui (2011):*** o *Constante ao longo da gestação: [0,36 – 0,53] (média ± 2 DP)*
(M7) Posição cardiotorácica	**What is the cardiothoracic position?**  (imagem inspirada em *https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/*) *A posição cardiotorácica é determinada prolongando posteriormente a linha do septo interventricular, dividindo as aurículas até um ponto na base do coração (Smith 1995).* *Esta medição é realizada na vista das quatro câmaras, calculando o rácio entre a área localizada à esquerda e a área cardíaca total. Para tal, desenha-se uma elipse sobre o coração e divide-se com uma linha anteroposterior que bissecta o tórax (linha média do tórax).* *As áreas esquerda (1) e direita (2) representam as superfícies cardíacas localizadas nos lados anatómicos esquerdo e direito da linha média, respetivamente. A posição é expressa como o rácio da área esquerda sobre a área cardíaca total.* ***O que recomendam as diretrizes?*** *A posição do coração fetal no interior do tórax é um parâmetro importante na avaliação fetal. Um desvio da posição normal justifica investigação adicional de possíveis patologias intratorácicas, intracardíacas ou extracardíacas intratorácicas (Abdullah 2000).* *Diretrizes americanas e internacionais, incluindo ISUOG (2008), ASE (2004), AIUM (2013) e AHA (2014), recomendam a medição cuidadosa da posição cardíaca fetal na vista das quatro câmaras durante o exame obstétrico de rotina (Donofrio 2014).* *De acordo com estas diretrizes, o coração fetal normal localiza-se predominantemente no lado esquerdo do tórax, com pelo menos 50% (rácio ≥ 0,5) da sua área no espaço torácico esquerdo ("o coração está maioritariamente do lado esquerdo") (Carvalho 2013); "deve ser dada especial atenção ao eixo e à*

	posição cardíaca. A maior parte do coração deve estar no hemitórax esquerdo" (Carvalho 2023). *Estudos corroboram estas recomendações, com **Chiappa (2009)** e outros (**Smith 1995, Sever 2021**) a referirem que "dois terços do coração devem localizar-se no lado esquerdo do tórax".* *Embora várias diretrizes definam uma posição cardiotorácica normal como 0,66 (rácio ≈ 2/3) e indiquem que não deve ser inferior a 0,5, a literatura não define claramente o limite superior da normalidade. Os utilizadores podem apenas visualizar o valor da medição sem intervalo de referência ou definir o seu próprio intervalo.*
(M8) Índice cefálico	*O que é o índice cefálico?*  *(fonte: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* *O **índice cefálico** é o rácio entre o diâmetro biparietal (**DBP**) e o diâmetro occipitofrontal (DOF), multiplicado por 100. Este índice fornece uma estimativa da forma da cabeça fetal.* *O DOF, correspondente à dimensão anteroposterior, é medido com os cursores colocados de bordo externo a bordo externo dos ossos cranianos. Um índice cefálico marcadamente diminuído sugere dolicocefalia, enquanto um valor marcadamente aumentado pode sugerir braquicefalia. Quando este parâmetro é anómalo, outras medições, como o perímetro cefálico (PC), o perímetro abdominal ou o comprimento do fémur, devem ser utilizadas para estimar a idade gestacional (Timor-Tritsch 2012).* *A imagem deve apresentar uma vista axial simétrica do cérebro, captando o plano transtálamico, com ambos os hemisférios claramente visíveis.* ***O que recomendam as diretrizes?*** *As diretrizes da ISUOG indicam que "o índice cefálico é o rácio entre a largura máxima da cabeça (DBP) e o seu comprimento máximo (diâmetro occipitofrontal (DOF)) e pode ser utilizado para caracterizar a forma da cabeça fetal. Uma forma craniana anómala (por exemplo, braquicefalia ou dolicocefalia) pode estar associada a síndromes ou ser resultado de oligohidrâmnios ou apresentação pélvica. Este achado pode também conduzir a estimativas incorretas da idade fetal quando se utiliza o DBP; nestes casos, as medições do PC são mais fiáveis" (Hadlock 1981) (Salomon 2022).*

	Intervalos de referência disponíveis • **Hadlock (1981):** o *Constante ao longo da gestação:* [74 – 83] *(média ± DP)*
(M9) Rácio do CSP	***O que é o rácio do CSP?***  (Fonte: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. In Journal of Ultrasound in Medicine (Vol. 43, Issue 8, pp. 1461–1466). Wiley) ***Descrição: O rácio do Cavum Septum Pellucidum (CSP)*** *é a razão entre o comprimento e a largura do CSP. É determinado medindo o comprimento e a largura do CSP e calculando o rácio comprimento/largura.* *A imagem deve mostrar uma vista transventricular axialmente simétrica do cérebro, com visualização clara do CSP e das estruturas da linha média.* ***O que recomendam as diretrizes?*** *As diretrizes da ISUOG indicam que a forma do CSP foi descrita como um marcador relativamente fiável de agenesia parcial do corpo caloso, citando os estudos de Karl (2017) e Shen (2015) para os intervalos de referência (Malinger 2020).* *As diretrizes da World Association of Perinatal Medicine (WAPM) indicam que o CSP deve ser visualizado e que "a não visualização do CSP ou a sua aparência anómala (Karl 2017) é preditiva de anomalias comissurais. No entanto, a aparência normal do CSP não exclui todas as anomalias do corpo caloso" (Robertis 2021).* *Este parâmetro também é utilizado em técnicas avançadas de Deep Learning para biometria fetal de rotina (Coronado-Gutiérrez 2023).* ***Intervalos de referência disponíveis*** • ***Karl (2017):*** o *Constante ao longo da gestação: [1,5 – 3,3] (percentis 5 e 95)*
(M10) Rácio ventrículo posterior / hemisfério cerebral (rácio VP)	***O que é o rácio do ventrículo cerebral posterior em relação ao hemisfério?***

	
	
	*O **rácio ventrículo cerebral posterior / hemisfério** é um parâmetro utilizado para avaliar o desenvolvimento cerebral, particularmente o tamanho ventricular em relação ao tamanho global do cérebro (hemisfério).*
	
	É a razão entre:
	
	• *o diâmetro do ventrículo cerebral posterior (= largura atrial), geralmente referente ao átrio do ventrículo lateral (localizado na junção dos cornos occipital, temporal e parietal);*
	• *o diâmetro do hemisfério cerebral correspondente (diâmetro transversal total).*
	
	Esta medição deve ser realizada na vista transventricular.
	
	O que recomendam as diretrizes?
	
	As diretrizes da ISUOG indicam que a medição da largura atrial é parte integrante do rastreio ecográfico de malformações do SNC e que deve ser medida de bordo interno a bordo interno, devendo ser < 10 mm ao longo de toda a gravidez.
	
	A literatura científica (Nicolaides 1994) enfatiza o papel do rácio ventrículo posterior / hemisfério na melhoria da avaliação cerebral pré-natal e da precisão do rastreio fetal, sendo um marcador relativamente fiável de ventriculomegalia.
	
	Intervalos de referência disponíveis
	
	• ***Nicolaides (1994):** percentis 5 e 95*
	  ○ *17 SG: [0,29 – 0,45]*
	  ○ *18 SG: [0,27 – 0,42]*
	  ○ *19 SG: [0,26 – 0,40]*
	  ○ *…*
	
	39 SG: [0,15 – 0,24]

(M11) Espaço pós-átrio	***O que é o índice de Espaço Pós-Átrio Esquerdo (PLAS)?***

esquerdo (PLAS)	 *(Fonte:* ***Kawazu2014****)* *O índice de espaço pós-átrio esquerdo (PLAS) é uma medição ecocardiográfica fetal utilizada para avaliar o espaço posterior ao átrio esquerdo. É calculado a partir da vista das quatro câmaras do coração fetal. A medição envolve a determinação da distância entre a parede posterior do átrio esquerdo e a parede anterior da aorta descendente (LD), dividida pelo diâmetro da aorta descendente (DA). A medição é realizada no fim da sístole.* *A fórmula do índice PLAS é:* ***Índice PLAS = Distância Átrio Esquerdo–Aorta Descendente (LD) / Diâmetro da Aorta Descendente (DA)*** ***O que recomendam as diretrizes? (Justificação e relevância clínica)*** *A literatura científica (Kawazu 2019, Anuwutnavin 2023, Akkurt 2015) destaca a importância do índice PLAS como uma medição simples e reprodutível no rastreio cardíaco fetal. Introduzido inicialmente por* ***Kawazu (2014)****, o índice PLAS foi identificado como um marcador sensível para o diagnóstico pré-natal de drenagem venosa pulmonar anómala total (TAPVC), uma condição em que as veias pulmonares não se ligam ao átrio esquerdo. Um índice PLAS aumentado é um indicador significativo de TAPVC.* ***Intervalos de referência disponíveis*** • ***Kawazu (2014) e Kawazu (2019):*** o *Constante ao longo da gestação: valor de corte ótimo* ***> 1,27*** *para sugestão de TAPVC* o *Em fetos normais, o índice PLAS médio foi* ***0,62 ± 0,19***

Cada medição requer um ponto de vista ecográfico específico, designado por "subview", que deve cumprir condições de imagem específicas para garantir a exatidão da medição. Uma subview é sempre derivada de uma das vistas fetais padrão de rastreio, mas exige também condições adicionais particulares.

Por exemplo, a medição do rácio ventrículo direito/ventrículo esquerdo na vista de quatro câmaras requer a visualização correta dos limites ventriculares, o que não é necessário para a avaliação do eixo cardíaco.

A tabela abaixo ilustra a correspondência entre as subviews e as vistas cardíacas ou cerebrais descritas nas diretrizes da ISUOG.

Vista	***Subvista***
Vista de quatro câmaras	***Subvista 1 (M1):*** *A imagem deve incluir a coluna vertebral, o esterno, as quatro câmaras e o septo interventricular. As costelas esquerda e direita devem estar presentes e visíveis como estruturas únicas.* ***Subvista 2 (M2):*** *A imagem deve incluir a coluna vertebral, o esterno e as quatro câmaras. As costelas esquerda e direita devem estar presentes e visíveis como estruturas únicas.* ***Subvista 3 (M3):*** *A imagem deve incluir a coluna vertebral e o esterno. As costelas esquerda e direita devem estar presentes e visíveis como estruturas únicas. As quatro câmaras devem ser visíveis e bem contrastadas.* ***Subvista 7 (M7):*** *A imagem deve incluir a coluna vertebral, o esterno e as quatro câmaras.* ***Subvista 11 (M11):*** *O tórax deve apresentar-se com forma arredondada, e não em "V" aberto. As costelas esquerda e direita devem aparecer como estruturas únicas, e não como múltiplas linhas paralelas ou sequenciais. O átrio e a aorta, especialmente as suas paredes posteriores, bem como o espaço entre ambos, devem estar claramente visíveis, sem obstrução por sombras.*
Vistas dos três vasos e dos três vasos com traqueia	***Subvista 4 (M4):*** *A imagem deve incluir a coluna vertebral e o esterno, com costelas esquerda e direita visíveis e distintas. O ducto arterioso e a aorta ascendente devem estar claramente visíveis, demonstrando a sua conexão.* ***Subvista 5 (M5):*** *A imagem deve destacar os vasos, com contraste claro e distinção adequada das estruturas.* ***Subvista 6 (M6):*** *A imagem deve mostrar a coluna vertebral, o esterno e a aorta ascendente, com as costelas esquerda e direita visíveis como estruturas únicas. O timo deve estar claramente visível e identificável.*
Vista axial	***Subvista 8 (M8):*** *A imagem deve apresentar uma vista axialmente simétrica do cérebro, captando o plano transtalâmico, com ambos os hemisférios visíveis e bem definidos.* ***Subvista 9 (M9):*** *A imagem deve mostrar uma vista axial transventricular do cérebro, com visualização clara do cavum do septo pelúcido (CSP) e das estruturas anatómicas da linha média.*

	Subvista 10 (M10): *A imagem deve mostrar uma vista axial em que o sulco parieto-occipital (POS) seja visível.*

Funcionalidade 1: Medidor de completude

O software avalia, através de um algoritmo de deep learning congelado, treinado por aprendizagem supervisionada, a completude do exame ecográfico fetal. Verifica se toda a informação correspondente às recomendações das diretrizes para o exame do coração e do cérebro fetal foi adquirida. Esta informação corresponde à presença de:

- **5 vistas cardíacas fetais principais** e **52 critérios de qualidade**, detalhados anteriormente, permitindo a conformidade com o rastreio cardíaco;
- **4 vistas cerebrais fetais principais** e **43 critérios de qualidade**, detalhados anteriormente, permitindo a conformidade com o rastreio cerebral.

A página de completude **(Figura 1)** é constituída por:

- Um botão **play/pausa** que inicia a análise das imagens adquiridas pelo sistema de ecografia no início do exame;
- A **contagem das vistas cardíacas/cerebrais** verificadas pelo software desde o início do exame. Uma vista cardíaca é considerada verificada quando é detetada em pelo menos uma imagem;
- **Botões individuais para cada critério de qualidade**, que ficam verdes após verificação pelo software.

Cada imagem analisada pelo software atualiza dinamicamente a página de completude da seguinte forma:

- Se um critério de qualidade for detetado numa imagem pela primeira vez, o critério é marcado como **verificado** e a sua cor muda de branco para **verde**;
- Se um critério de qualidade for detetado numa imagem mas já tiver sido previamente verificado, não ocorre qualquer alteração;
- Se um critério de qualidade não for detetado na imagem, não ocorre qualquer alteração.

Se um critério de qualidade estiver associado a uma anomalia, o estado de deteção do critério depende do seu aspeto visual:

- Se uma anomalia alterar um critério de qualidade de forma a modificar o seu aspeto, o software poderá não detetar o critério e o estado permanecerá como não verificado;
- Se uma anomalia não impactar o aspeto do critério de qualidade, o software irá detetar o critério e marcá-lo como verificado, mudando a sua cor de branco para **verde**.

Note-se que é recordado na rotulagem que **nenhum diagnóstico ou rastreio pode ser realizado com o FETOLY**. Um critério de qualidade não verificado pelo software não indica, por si só, a presença de uma patologia.

A página de completude é continuamente atualizada em tempo real, permitindo aos utilizadores consultá-la em qualquer momento durante o exame. Isto permite uma consulta rápida sem interromper o fluxo de trabalho do exame ou exigir ações adicionais.

Como lembrete, e conforme explicado na secção 10, o FETOLY não pode ser utilizado para realizar diagnóstico ou rastreio. Um critério de qualidade não verificado pelo software não indica, por si só, a presença de uma patologia.

Funcionalidade 2: Ilustração da completude

Esta funcionalidade foi desenvolvida para reforçar a segurança da avaliação de completude realizada pelo primeiro módulo. Permite aos clínicos verificar a visão geral da completude do exame — isto é, as vistas e critérios de qualidade verificados pelo software — através da página da galeria da interface do software.

Funcionando de forma contínua, avalia cada imagem processada pelo primeiro módulo em tempo real, retendo um conjunto de imagens como evidência visual das vistas cardíacas/cerebrais e critérios de qualidade verificados até esse momento.

O FETOLY não tem como objetivo selecionar as imagens “melhores” ou de “elevada” qualidade diagnóstica segundo uma escala qualitativa específica. Em vez disso, o FETOLY visa selecionar imagens que ilustrem a **completude quantitativa do exame**, em termos de vistas e critérios de qualidade verificados. Como este módulo depende inteiramente do desempenho do algoritmo de deep learning do primeiro módulo, não é necessária uma avaliação adicional de desempenho.

Por exemplo, se o utilizador tiver dúvidas relativamente a um critério de qualidade assinalado a verde, pode verificar a presença desse critério clicando sobre ele na página da galeria. O software mostrará as imagens que contêm esse critério (assinalado a amarelo na figura abaixo). Quando um critério é selecionado, o software apresenta a *bounding box* que envolve o critério nessas imagens. Esta informação da *bounding box* faz parte da saída da Fetoly-CNN.

Funcionalidade 3: Medições biométricas

A secção do módulo **FETOLY-MEASURE** é identificada com a designação “Measure” na página de análise e apresenta uma lista de medições, cada uma organizada em quatro campos:

- **Nome da medição:** apresenta o nome ou abreviatura da medição, juntamente com um ícone de informação. Ao clicar no ícone, são apresentadas informações detalhadas sobre a medição, incluindo a sua referência científica;
- **Valor da medição e unidades:** o valor medido é apresentado com as unidades correspondentes. Por exemplo, é apresentado o símbolo de graus (°) para medições angulares ou o símbolo de percentagem (%). Caso contrário, o campo permanece vazio, significando que se trata de uma medição relativa. Se os *keypoints* tiverem sido editados na página da galeria, surge um símbolo à frente da medição;
- **Intervalo de referência:** este campo fornece o intervalo de referência definido na literatura para a medição, suportado pela respetiva referência científica. A fonte pode ser uma diretriz, uma publicação científica com revisão por pares, um livro de referência ou um intervalo personalizado definido pelo utilizador. Ao clicar no botão de novo separador, o utilizador pode definir manualmente o intervalo de referência ou atualizar a referência bibliográfica, caso existam múltiplas disponíveis. Ao clicar

no botão de ligação de informação, o utilizador pode aceder a uma janela pop-up com toda a informação necessária relacionada com o critério de medição;
- **Idade gestacional**, que deve ser definida antes do início da análise.

Funcionalidade 4: Ilustração das medições

Tal como a ilustração da completude seleciona imagens que demonstram vistas e critérios de qualidade, esta funcionalidade seleciona automaticamente uma imagem para cada medição. Ambos os conjuntos de imagens são apresentados em conjunto na página da Galeria. Estes dois conjuntos de imagens são facilmente distinguíveis: as imagens provenientes da função de medição incluem o valor da medição e o nome do parâmetro, enquanto as imagens de completude não apresentam anotações.

Tanto as imagens de “medição” como as de “completude” são organizadas com base nas respetivas vistas ecográficas correspondentes. Note-se que a associação das imagens selecionadas pela função de medição a uma vista é independente da função de completude. De facto, cada *subview* de medição corresponde, por definição, a uma das 5 vistas cardíacas ou 4 vistas cerebrais de ecografia. Assim, conhecendo o *subview*, as imagens selecionadas pela função de medição podem ser automaticamente categorizadas na vista apropriada a que esse *subview* pertence.

Funcionalidade 5: Relatório do exame

Um relatório pode ser gerado a partir da página de exportação. Este incluirá resultados e imagens do FETOLY e será enviado para um dispositivo externo.

Dispositivos associados

Para utilizar o dispositivo FETOLY, é necessário dispor dos seguintes dispositivos associados:

- Um equipamento de ecografia;
- Um tablet e, opcionalmente, um servidor DICOM, um computador com servidor FTP ou capacidades Bluetooth, conforme especificado na secção 10 “interação com outros equipamentos”;
- Um *dongle* UVC e um cabo HDMI para ligar o tablet ao equipamento de ecografia.

5. Utilização prevista e indicações de utilização

O FETOLY destina-se a analisar sequências de imagens de ecografia fetal utilizando técnicas de *machine learning* para automaticamente:

- detetar vistas e critérios de qualidade do cérebro e do coração fetal dentro das vistas;
- detetar imagens adequadas para a medição de parâmetros biométricos do coração e do cérebro fetal e fornecer medições quantitativas desses parâmetros.

O dispositivo destina-se a ser utilizado como **auxiliar de leitura concomitante** durante a aquisição e interpretação de imagens de ecografia fetal.

O FETOLY está indicado para utilização durante o exame de rotina do coração e do cérebro fetal no **2.º e 3.º trimestres da gravidez** (idade gestacional: 17 a 40 semanas).

6. Utilizadores previstos

O produto deve ser utilizado por profissionais de saúde qualificados, especializados em imagiologia ecográfica pré-natal.

7. População-alvo de doentes

Mulheres grávidas durante o 2.º e 3.º trimestres da gravidez.

8. Benefícios clínicos e desempenho

Para este tipo de dispositivo, um **software como dispositivo médico (SWMD)** utilizado como auxiliar de leitura concomitante durante o exame de rotina do coração e do cérebro fetal, foi demonstrado o seguinte benefício clínico:

- **Normalização do exame de rotina do coração e do cérebro fetal**, conforme exigido pelas diretrizes internacionais reconhecidas.

Os resultados de desempenho estão detalhados nas tabelas abaixo. Os resultados dos testes de desempenho *standalone* demonstram que o FETOLY automaticamente:

- deteta vistas ecográficas do coração e do cérebro fetal com uma sensibilidade ≥ 85% (critério de aceitação) e especificidade ≥ 85% (critério de aceitação);
- deteta critérios de qualidade nas vistas cardíacas com uma sensibilidade ≥ 90% (critério de aceitação) e especificidade ≥ 90% (critério de aceitação);
- deteta critérios de qualidade nas vistas cerebrais com uma sensibilidade ≥ 85% (critério de aceitação) e especificidade ≥ 85% (critério de aceitação);
- localiza *bounding boxes* dos critérios de qualidade com um *intersection over union* (IoU) médio ≥ 50% (critério de aceitação);
- deteta *subviews* ecográficos do coração e do cérebro fetal com uma sensibilidade ≥ 70% (critério de aceitação) e especificidade ≥ 70% (critério de aceitação);
- realiza medições do coração e do cérebro fetal de acordo com cada **LOA** definida por estudo.

Resultados globais

Vista fetal	***Sensibilidade***			***Especificidade***		
	N(positivos)	***Estimativa pontual***	***IC Bootstrap (95%)***	***N(negativos)***	***Estimativa pontual***	***IC Bootstrap (95%)***
Vista do abdómen	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Vista das quatro câmaras	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Vista do trato de saída do ventrículo esquerdo	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Vista do trato de saída do ventrículo direito	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)

Vista dos três vasos	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Vista axial	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)
Vista transcerebelosa	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Vista sagital / perfil	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Outras vistas	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Critério de qualidade	*Sensibilidade*			*Estimativa pontual*			*mIoU*	
	N	*Estimativa pontual*	*IC Bootstrap (95%)*	*N*	*Estimativa pontual*	*IC Bootstrap (95%)*	*Estimativa pontual*	*IC Bootstrap (95%)*
Vista abdominal								
Coluna vertebral	*678*	*0.99*	*(0.983,0.998)*	*4531*	*0.998*	*(0.996,0.999)*	*0.71*	*(0.70,0.73)*
Costela esquerda	*632*	*0.967*	*(0.953,0.980)*	*4577*	*0.993*	*(0.991,0.995)*	*0.58*	*(0.56,0.59)*
Costela direita	*627*	*0.951*	*(0.934,0.967)*	*4582*	*0.994*	*(0.992,0.996)*	*0.55*	*(0.53,0.57)*
Aorta descendente	*673*	*0.972*	*(0.959,0.984)*	*4536*	*0.998*	*(0.996,0.999)*	*0.52*	*(0.51,0.54)*
Veia cava inferior	*550*	*0.939*	*(0.917,0.958)*	*4659*	*0.987*	*(0.983,0.990)*	*0.5*	*(0.49,0.52)*
Estômago	*675*	*0.983*	*(0.973,0.992)*	*4534*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.75)*
Veia umbilical	*552*	*0.973*	*(0.958,0.986)*	*4657*	*0.99*	*(0.988,0.993)*	*0.64*	*(0.62,0.65)*
Abdómen anterior	*643*	*0.969*	*(0.954,0.983)*	*4566*	*0.993*	*(0.990,0.995)*	*0.5*	*(0.49,0.52)*
Vista de quatro câmaras								
Coluna vertebral	*595*	*0.969*	*(0.955,0.982)*	*4614*	*0.998*	*(0.996,0.999)*	*0.74*	*(0.73,0.75)*
Costela esquerda	*536*	*0.945*	*(0.924,0.963)*	*4673*	*0.99*	*(0.987,0.993)*	*0.64*	*(0.63,0.66)*
Costela direita	*548*	*0.948*	*(0.926,0.965)*	*4661*	*0.993*	*(0.991,0.996)*	*0.68*	*(0.66,0.69)*
Aorta descendente	*608*	*0.968*	*(0.952,0.981)*	*4601*	*0.997*	*(0.995,0.998)*	*0.66*	*(0.65,0.67)*
Veia pulmonar esquerda	*240*	*0.925*	*(0.889,0.958)*	*4969*	*0.975*	*(0.971,0.979)*	*0.51*	*(0.48,0.53)*
Veia pulmonar direita	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*
Átrio esquerdo	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Átrio direito	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Septo primum (válvula de Vieussens ou retalho do forame oval)	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*
Forame oval aberto	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Válvula mitral	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*

Válvula tricúspide	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Conexão entre o crux e o septo auricular (septo vestibular)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Desfasamento das válvulas auriculoventriculares no crux	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Conexão entre o septo interventricular e o crux	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Septo interventricular	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Ventrículo esquerdo	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Ventrículo direito	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Esterno	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Vista do trato de saída do ventrículo esquerdo								
Átrio esquerdo	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Aorta ascendente proximal	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Válvulas semilunares	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Ventrículo esquerdo	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Septo interventricular	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Ventrículo direito	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Vista do trato de saída do ventrículo direito								
Aorta descendente	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Traqueia / brônquios	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*
Artéria pulmonar esquerda	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*
Ducto arterioso	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Artéria pulmonar direita	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Origem das artérias pulmonares	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*

Septo entre o tronco da artéria pulmonar e a aorta ascendente	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Aorta ascendente	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Veia cava superior	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Tronco pulmonar	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Vista dos três vasos								
Coluna vertebral	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Traqueia	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Espaço lateral à esquerda do ducto / artéria pulmonar	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Arco ductal ligado à aorta descendente	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Arco ductal não ligado à aorta descendente	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Aorta ascendente	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Arco aórtico	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Veia cava superior	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Timo / esterno	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Vista axial								
Foice anterior	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cavum do septo pelúcido	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Fórnix	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Ventrículo anterior distal	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Ventrículo anterior proximal	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Cisterna ambiens	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Átrio	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Plexo coroide	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Sulco parieto-occipital	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Foice posterior	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*

Sutura coronária distal	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Sutura coronária proximal	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Fissura de Sylvius	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Crânio	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Separação dos tálamos	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
Foice anterior	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Cavum do septo pelúcido	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Fórnix	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Vista transcerebelosa								
Tálamo distal	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Tálamo proximal	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
Quarto ventrículo	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Vérmis	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Hemisfério cerebeloso distal	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Hemisfério cerebeloso proximal	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Limite cerebeloso	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Cisterna magna	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Vista sagital / perfil								
Osso nasal	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Parte superior do vérmis	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Parte inferior do vérmis	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Fastígio	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Rostro e joelho do corpo caloso	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Corpo do corpo caloso	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Esplénio do corpo caloso	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Cavum do septo pelúcido	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Medição	n(positivo)	Se	IC Se	n(negativo)	Sp	IC Sp	LOA	LIC OA
razão tímica-torácica	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
razão cardio-torácica	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
razão dos vasos	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
índice cefálico	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
número de vasos	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
posição cardio-torácica	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
razão ventrículo direito-esquerdo	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
ângulo cardíaco	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
razão do CSP	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
razão VP	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
espaço pós-auricular esquerdo	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Medição	Inclinação	Interceção	IC da Inclinação	IC da Interceção
razão tímica-torácica	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
razão cardio-torácica	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
razão dos vasos	*1.020704625736053*	*-0.02037929987663466*	*(0.975,1.070)*	*(-0.063,0.020)*
índice cefálico	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
número de vasos	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
posição cardio-torácica	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
razão ventrículo direito-esquerdo	*1.0111269484433731*	*-0.0054679878902589504*	*(0.992,1.040)*	*(-0.033,0.016)*
ângulo cardíaco	*0.9197936528230518*	*3.114077691538199*	*(0.888,0.945)*	*(2.023,4.477)*
razão do CSP	*0.6801357222664575*	*0.44007609936523384*	*(0.638,0.722)*	*(0.352,0.532)*
razão VP	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
espaço pós-auricular esquerdo	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Resultados do fabricante do sistema de ultrassom

Classe	Sistema	n(positivo)	Se	IC da Se	n(negativo)	Sp	IC da Sp
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)

D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
I	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)
I	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)
X	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
X	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
X	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)

Classe	Sistema	n(positivo)	Se	IC da Se	n(negativo)	Sp	IC da Sp	mIoU	IC do mIoU
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*
A.Sp	*Samsung*	*296*	*0.984*	*(0.967,0.994)*	*1708*	*0.999*	*(0.997,1.000)*	*0.7*	*(0.68,0.71)*
A.St	*Canon*	*29*	*0.966*	*(0.893,1.000)*	*207*	*0.991*	*(0.975,1.000)*	*0.72*	*(0.67,0.76)*
A.St	*GE*	*279*	*0.993*	*(0.983,1.000)*	*2261*	*1.0*	*(1.000,1.000)*	*0.79*	*(0.77,0.80)*
A.St	*Samsung*	*293*	*0.973*	*(0.954,0.990)*	*1711*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
A.Uv	*Canon*	*25*	*0.96*	*(0.870,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.6*	*(0.51,0.67)*
A.Uv	*GE*	*217*	*0.977*	*(0.955,0.996)*	*2323*	*0.991*	*(0.988,0.995)*	*0.67*	*(0.65,0.70)*
A.Uv	*Samsung*	*240*	*0.967*	*(0.944,0.988)*	*1764*	*0.989*	*(0.984,0.993)*	*0.62*	*(0.59,0.64)*
A.VC	*Canon*	*26*	*0.885*	*(0.750,1.000)*	*210*	*0.986*	*(0.970,1.000)*	*0.46*	*(0.40,0.52)*
A.VC	*GE*	*221*	*0.973*	*(0.950,0.992)*	*2319*	*0.987*	*(0.983,0.991)*	*0.54*	*(0.52,0.57)*
A.VC	*Samsung*	*247*	*0.903*	*(0.864,0.939)*	*1757*	*0.989*	*(0.984,0.994)*	*0.49*	*(0.47,0.51)*
B.Ao	*Canon*	*27*	*0.926*	*(0.808,1.000)*	*209*	*0.996*	*(0.985,1.000)*	*0.71*	*(0.66,0.77)*
B.Ao	*GE*	*247*	*0.956*	*(0.926,0.980)*	*2293*	*0.997*	*(0.994,0.999)*	*0.73*	*(0.71,0.75)*
B.Ao	*Samsung*	*255*	*0.977*	*(0.956,0.993)*	*1749*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.58,0.62)*

B.bCr	Canon	25	0.92	(0.800,1.000)	211	0.986	(0.969,1.000)	0.65	(0.58,0.72)
B.bCr	GE	202	0.892	(0.849,0.932)	2338	0.992	(0.989,0.996)	0.61	(0.57,0.64)
B.bCr	Samsung	216	0.926	(0.889,0.959)	1788	0.984	(0.979,0.989)	0.54	(0.52,0.57)
B.Cr	Canon	7	0.715	(0.334,1.000)	229	0.983	(0.967,0.996)	0.62	(nan,nan)
B.Cr	GE	52	0.885	(0.789,0.961)	2488	0.989	(0.985,0.993)	0.52	(0.46,0.58)
B.Cr	Samsung	76	0.974	(0.933,1.000)	1928	0.977	(0.971,0.983)	0.57	(0.52,0.61)
B.FO	Canon	26	0.962	(0.880,1.000)	210	1.0	(1.000,1.000)	0.7	(0.62,0.78)
B.FO	GE	215	0.935	(0.899,0.965)	2325	0.994	(0.991,0.997)	0.64	(0.62,0.67)
B.FO	Samsung	257	0.965	(0.941,0.985)	1747	0.994	(0.991,0.998)	0.58	(0.55,0.60)
B.FOF	Canon	8	0.75	(0.375,1.000)	228	1.0	(1.000,1.000)	0.56	(0.42,0.67)
B.FOF	GE	108	0.899	(0.841,0.949)	2432	0.998	(0.996,1.000)	0.5	(0.47,0.53)
B.FOF	Samsung	63	0.921	(0.845,0.984)	1941	0.993	(0.989,0.996)	0.51	(0.47,0.55)
B.IVS	Canon	15	0.934	(0.770,1.000)	221	0.982	(0.965,0.996)	0.65	(0.53,0.75)
B.IVS	GE	165	0.867	(0.806,0.915)	2375	0.992	(0.988,0.995)	0.62	(0.59,0.66)
B.IVS	Samsung	152	0.922	(0.872,0.962)	1852	0.984	(0.978,0.989)	0.64	(0.61,0.67)
B.LA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.75	(0.71,0.79)
B.LA	GE	264	0.966	(0.942,0.986)	2276	0.999	(0.997,1.000)	0.79	(0.78,0.81)
B.LA	Samsung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Samsung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Samsung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)

B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)

D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)
D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)

F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)
F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)

G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)
G.dCH	GE	345	0.974	(0.955,0.989)	2195	0.999	(0.997,1.000)	0.75	(0.74,0.77)
G.dCH	Samsung	181	0.94	(0.903,0.973)	1823	0.999	(0.998,1.000)	0.73	(0.71,0.76)
G.dTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.6	(0.52,0.69)
G.dTh	GE	205	0.937	(0.902,0.967)	2335	0.993	(0.989,0.996)	0.65	(0.63,0.67)
G.dTh	Samsung	114	0.957	(0.916,0.991)	1890	0.997	(0.994,0.999)	0.61	(0.59,0.63)
G.pCH	Canon	26	1.0	(1.000,1.000)	210	0.996	(0.986,1.000)	0.73	(0.68,0.78)
G.pCH	GE	347	0.975	(0.956,0.992)	2193	1.0	(0.998,1.000)	0.76	(0.74,0.77)
G.pCH	Samsung	182	0.94	(0.905,0.973)	1822	0.999	(0.998,1.000)	0.74	(0.72,0.77)
G.pTh	Canon	13	1.0	(1.000,1.000)	223	1.0	(1.000,1.000)	0.58	(0.51,0.65)
G.pTh	GE	216	0.922	(0.884,0.954)	2324	0.995	(0.992,0.998)	0.62	(0.60,0.64)
G.pTh	Samsung	119	0.95	(0.905,0.984)	1885	0.998	(0.996,1.000)	0.59	(0.57,0.62)
G.Ver	Canon	23	0.914	(0.783,1.000)	213	1.0	(1.000,1.000)	0.62	(0.54,0.70)
G.Ver	GE	288	0.893	(0.859,0.928)	2252	0.996	(0.993,0.999)	0.61	(0.59,0.63)
G.Ver	Samsung	138	0.892	(0.840,0.942)	1866	0.997	(0.994,0.999)	0.52	(0.49,0.55)
I.bCC	Canon	15	1.0	(1.000,1.000)	221	0.987	(0.971,1.000)	0.59	(0.51,0.67)
I.bCC	GE	168	0.923	(0.878,0.962)	2372	0.995	(0.993,0.998)	0.57	(0.54,0.60)
I.bCC	Samsung	54	0.815	(0.699,0.910)	1950	0.996	(0.994,0.999)	0.57	(0.52,0.62)
I.CSP	Canon	20	0.95	(0.824,1.000)	216	1.0	(1.000,1.000)	0.75	(0.69,0.81)
I.CSP	GE	196	0.888	(0.841,0.928)	2344	1.0	(0.999,1.000)	0.72	(0.69,0.74)
I.CSP	Samsung	79	0.849	(0.760,0.924)	1925	1.0	(1.000,1.000)	0.7	(0.66,0.75)
I.Fas	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.63	(0.46,0.79)
I.Fas	GE	99	0.889	(0.819,0.951)	2441	1.0	(0.999,1.000)	0.56	(0.52,0.60)
I.Fas	Samsung	33	0.97	(0.900,1.000)	1971	0.999	(0.997,1.000)	0.55	(0.49,0.61)
I.lVer	Canon	14	0.929	(0.750,1.000)	222	1.0	(1.000,1.000)	0.69	(0.60,0.77)
I.lVer	GE	102	0.912	(0.850,0.960)	2438	0.999	(0.998,1.000)	0.7	(0.66,0.73)
I.lVer	Samsung	41	0.927	(0.834,1.000)	1963	1.0	(0.999,1.000)	0.64	(0.59,0.69)
I.NB	Canon	11	1.0	(1.000,1.000)	225	0.992	(0.979,1.000)	0.71	(0.61,0.82)
I.NB	GE	115	0.905	(0.844,0.955)	2425	0.992	(0.989,0.996)	0.63	(0.59,0.67)
I.NB	Samsung	60	0.917	(0.837,0.982)	1944	0.998	(0.996,1.000)	0.64	(0.58,0.69)
I.rgCC	Canon	18	0.945	(0.824,1.000)	218	0.991	(0.978,1.000)	0.48	(0.41,0.56)
I.rgCC	GE	177	0.888	(0.833,0.930)	2363	0.998	(0.996,1.000)	0.56	(0.54,0.59)
I.rgCC	Samsung	65	0.893	(0.808,0.965)	1939	1.0	(0.999,1.000)	0.48	(0.43,0.53)
I.sCC	Canon	13	0.847	(0.616,1.000)	223	0.992	(0.978,1.000)	0.48	(0.36,0.61)
I.sCC	GE	114	0.922	(0.868,0.964)	2426	0.992	(0.988,0.995)	0.51	(0.48,0.54)
I.sCC	Samsung	40	0.9	(0.796,1.000)	1964	0.998	(0.996,1.000)	0.45	(0.39,0.53)
I.uVer	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.57	(0.49,0.65)

I.uVer	*GE*	*116*	*0.88*	*(0.815,0.931)*	*2424*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.63)*
I.uVer	*Samsung*	*48*	*0.938*	*(0.861,1.000)*	*1956*	*0.999*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Classe	Sistema	n(positivo)	Se	IC da Se	n(negativo)	Sp	IC da Sp	LOA	IC do LOA
ângulo cardíaco	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
ângulo cardíaco	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*
ângulo cardíaco	Samsung	*93*	*0.989*	*(0.966,1.000)*	*232*	*0.866*	*(0.823,0.909)*	*6.321*	*(5.318,7.723)*
posição cardio-torácica	Canon	*28*	*0.893*	*(0.750,1.000)*	*37*	*0.973*	*(0.919,1.000)*	*0.089*	*(0.067,0.120)*
posição cardio-torácica	GE	*233*	*0.931*	*(0.900,0.964)*	*262*	*0.912*	*(0.878,0.947)*	*0.051*	*(0.046,0.058)*
posição cardio-torácica	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.772*	*(0.716,0.819)*	*0.077*	*(0.067,0.086)*
razão cardio-torácica	Canon	*23*	*1.0*	*(1.000,1.000)*	*37*	*0.946*	*(0.865,1.000)*	*0.078*	*(0.041,0.117)*
razão cardio-torácica	GE	*225*	*0.969*	*(0.944,0.991)*	*262*	*0.908*	*(0.874,0.943)*	*0.059*	*(0.049,0.073)*
razão cardio-torácica	Samsung	*105*	*0.952*	*(0.909,0.989)*	*232*	*0.776*	*(0.724,0.828)*	*0.051*	*(0.042,0.061)*
índice cefálico	Canon	*28*	*0.929*	*(0.821,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.026*	*(0.021,0.032)*
índice cefálico	GE	*195*	*0.944*	*(0.909,0.974)*	*262*	*0.943*	*(0.916,0.969)*	*0.03*	*(0.026,0.036)*
índice cefálico	Samsung	*90*	*0.989*	*(0.964,1.000)*	*232*	*0.909*	*(0.871,0.944)*	*0.023*	*(0.020,0.026)*
razão ventrículo direito-esquerdo	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.865*	*(0.757,0.973)*	*0.106*	*(0.080,0.128)*
razão ventrículo direito-esquerdo	GE	*235*	*0.923*	*(0.883,0.957)*	*262*	*0.901*	*(0.859,0.939)*	*0.127*	*(0.090,0.173)*
razão ventrículo direito-esquerdo	Samsung	*93*	*0.978*	*(0.943,1.000)*	*232*	*0.931*	*(0.901,0.961)*	*0.099*	*(0.087,0.115)*
razão tímica-torácica	Canon	*19*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.047*	*(0.039,0.059)*
razão tímica-torácica	GE	*174*	*0.902*	*(0.856,0.944)*	*262*	*0.924*	*(0.889,0.954)*	*0.051*	*(0.045,0.059)*
razão tímica-torácica	Samsung	*138*	*0.942*	*(0.900,0.978)*	*232*	*0.892*	*(0.853,0.931)*	*0.059*	*(0.049,0.070)*
número de vasos	Canon	*21*	*0.905*	*(0.760,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.0*	*(0.000,0.000)*
número de vasos	GE	*209*	*0.933*	*(0.895,0.966)*	*262*	*0.969*	*(0.947,0.989)*	*0.281*	*(0.138,0.406)*
número de vasos	Samsung	*113*	*0.929*	*(0.879,0.974)*	*232*	*0.966*	*(0.940,0.987)*	*0.329*	*(0.000,0.491)*
razão dos vasos	Canon	*28*	*1.0*	*(1.000,1.000)*	*37*	*0.892*	*(0.784,0.973)*	*0.112*	*(0.091,0.145)*
razão dos vasos	GE	*194*	*0.979*	*(0.956,0.995)*	*262*	*0.977*	*(0.954,0.992)*	*0.109*	*(0.099,0.121)*
razão dos vasos	Samsung	*122*	*0.984*	*(0.958,1.000)*	*232*	*0.922*	*(0.888,0.953)*	*0.111*	*(0.100,0.125)*
razão do CSP	Canon	*25*	*1.0*	*(1.000,1.000)*	*37*	*1.0*	*(1.000,1.000)*	*0.842*	*(0.608,1.028)*
razão do CSP	GE	*226*	*0.854*	*(0.805,0.899)*	*262*	*0.977*	*(0.954,0.992)*	*0.826*	*(0.753,0.889)*

razão do CSP	Sam-sung	107	0.879	(0.821,0.935)	232	0.991	(0.978,1.000)	0.835	(0.755,0.907)
razão VP	Canon	22	0.909	(0.773,1.000)	37	1.0	(1.000,1.000)	0.064	(0.043,0.084)
razão VP	GE	206	0.956	(0.925,0.981)	262	1.0	(1.000,1.000)	0.065	(0.059,0.071)
razão VP	Sam-sung	91	0.956	(0.910,0.990)	232	1.0	(1.000,1.000)	0.066	(0.056,0.075)
espaço pós-auricular esquerdo	Canon	16	0.938	(0.800,1.000)	37	0.919	(0.837,1.000)	0.094	(0.067,0.114)
espaço pós-auricular esquerdo	GE	181	0.978	(0.953,0.995)	262	0.924	(0.889,0.954)	0.086	(0.079,0.091)
espaço pós-auricular esquerdo	Sam-sung	159	0.981	(0.957,1.000)	232	0.953	(0.922,0.978)	0.07	(0.065,0.078)

Resultados por subgrupo EUA vs. UE

Classe	Continente	n(positivo)	Se	IC da Se	n(negativo)	Sp	IC da Sp
A	UE	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	EUA	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	UE	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	EUA	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	UE	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	EUA	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	UE	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	EUA	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	UE	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	EUA	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	UE	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	EUA	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	UE	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	EUA	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	UE	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	EUA	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	UE	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	EUA	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Classe	Continente	n(positivo)	Se	IC da Se	n(negativo)	Sp	IC da Sp	mIoU	IC do mIoU
A.aA	EU	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	US	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	EU	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	US	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	EU	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	US	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	EU	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	US	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	EU	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*

A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*
B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*

C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	US	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	EU	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	US	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	EU	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	US	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*
D.rPA	EU	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	US	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	EU	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*
D.S	US	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	EU	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	US	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	EU	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	US	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	EU	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	US	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	EU	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	US	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	EU	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	US	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	EU	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	US	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	EU	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	US	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	EU	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	US	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	EU	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	US	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	EU	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	US	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*

E.Tr	EU	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*
E.Tr	US	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	EU	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	US	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	EU	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	US	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	EU	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*
F.aFx	US	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	EU	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	US	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	EU	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	US	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	EU	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	US	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	EU	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	US	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	EU	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*

G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*
G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Classe	Continente	n(positivo)	Se	IC da Se	n(negativo)	Sp	IC da Sp	LOA	IC do LOA
ângulo cardíaco	EU	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
ângulo cardíaco	US	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
posição cardio-torácica	EU	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
posição cardio-torácica	US	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
razão cardio-torácica	EU	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
razão cardio-torácica	US	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
índice cefálico	EU	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
índice cefálico	US	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
razão ventrículo direito-esquerdo	EU	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
razão ventrículo direito-esquerdo	US	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
razão tímica-torácica	EU	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
razão tímica-torácica	US	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)

número de vasos	EU	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
número de vasos	US	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
razão dos vasos	EU	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
razão dos vasos	US	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
razão do CSP	EU	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)
razão do CSP	US	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
razão VP	EU	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
razão VP	US	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
espaço pós-auricular esquerdo	EU	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
espaço pós-auricular esquerdo	US	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Contraindicações

Não existe nenhuma contraindicação associada ao dispositivo **FETOLY**.

10. Avisos, precauções e interações com outros equipamentos

Avisos e precauções do ficheiro de gestão de risco:

- O utilizador deve aumentar o zoom em pelo menos 30% para evitar falsos negativos do software;
- O utilizador deve rever sistematicamente o conjunto de imagens selecionadas antes da exportação;
- A negligência na função de redefinir (*reset*) pode levar a troca de pacientes e contribuir para falsos negativos;
- As imagens eliminadas durante a seleção de imagens são perdidas definitivamente;
- A configuração da entrada do fluxo de vídeo pode contribuir para falsos negativos;
- Um fluxo de vídeo incompatível pode causar erro na documentação do exame. O fluxo de vídeo deve ter as seguintes características:
    - Pelo menos 24 frames por segundo (fps);
    - Resolução inferior a 1280 × 720;
- Incompatibilidade do tablet pode causar erro na documentação do exame;
- Falha na exportação leva à perda do relatório do exame;
- Verifique o nome do paciente escolhido antes da exportação DICOM na página de exportação para evitar troca de ficheiros;
- O uso na gravidez do 1º trimestre pode causar erro na função de completude;
- O exame deve ser feito num feto de cada vez;
- Se o tablet começar a sobreaquecer, interrompa o uso do software;
- Verifique o nível da bateria do tablet antes do exame, pois desligamentos podem causar perda de dados;
- O software **não pode ser usado para fins de rastreio**, pois pode contribuir para falsos negativos;

- Use o tablet sozinho e não permita acesso a terceiros não autorizados, para evitar riscos de segurança;
- Quando os dados são exportados para o dispositivo, ficam sob sua responsabilidade;
- Não use nenhuma outra aplicação no tablet em paralelo com o **FETOLY** para evitar interferência na recepção do fluxo de imagens ou na execução do cálculo do *machine learning*;
- Não utilize a aplicação enquanto estiver a realizar varredura com sonda transvaginal, pois o produto não foi testado com imagens transvaginais.

Avisos e precauções do estudo de desempenho do software:

- A sensibilidade do software pode ser menor para a deteção de:
    - Critérios de qualidade cardíaca: *Deslocamento da válvula atrioventricular no crux* (vista de quatro câmaras);
    - Critérios de qualidade cerebral:
        - Suturas coronais proximais (vista axial)
        - Cavum Septum Pellucidum (vista axial)
        - 3º ventrículo (vista axial)

Os utilizadores devem ter cautela nesta vista e com estes critérios de qualidade e verificar os resultados.

Interações com outros equipamentos:

O software **FETOLY** foi concebido para funcionar numa ampla gama de tablets sem depender de computação em nuvem externa. Ele é configurado para receber um fluxo de vídeo de ultrassom, o que pode ser feito a partir de um sistema de ultrassom com saída HDMI para o hardware que executa o software.

O software é compatível com máquinas de ultrassom da **General Electric**, **Samsung** e **Canon**.

Requisitos mínimos do tablet:

- Arquitetura CPU ARMv8
- Processador Snapdragon 8 ou
- Processador M1 ou superior ou
- Processador A14 ou superior
- Pelo menos 8 GB de RAM
- Pelo menos 1 GB de armazenamento
- Android versão 13 / iOS versão 17 ou superior

Modelos de tablet aconselhados:

- Samsung Galaxy Tab S8 ou superior
- iPad Air 5 ou superior
- iPad 10 ou superior
- iPad mini 7 ou superior
- iPad Pro 3 ou superior

Para dúvidas sobre a escolha do modelo de tablet, contacte o suporte da Diagnoly: **support@diagnoly.com**.

As imagens etiquetadas pelo **FETOLY** podem ser guardadas diretamente no tablet ou enviadas para outro dispositivo na mesma rede. Para isso, o software requer um servidor FTP no dispositivo de destino, um servidor DICOM Store ou ligação Bluetooth.

11. Efeitos indesejáveis

Não existem efeitos indesejáveis associados ao dispositivo **FETOLY**.

12. Instruções de Cibersegurança

12.1. Descrição de proteção de funcionalidades críticas

Esta secção fornece uma descrição de alto nível das funcionalidades do dispositivo que protegem funções críticas. A receção do fluxo de imagens e a análise de imagens dependem de recursos locais (cabo físico, modelo de IA no dispositivo) e não requerem internet para funcionar.

O software não armazena nem gere dados de pacientes, mas permite ao utilizador exportar, após um exame, o relatório do exame para um dispositivo de terceiros. Um modo de exportação alternativo está disponível caso a rede local seja comprometida, permitindo guardar os relatórios no sistema de ficheiros do tablet.

12.2. Riscos inerentes de cibersegurança do dispositivo

Os riscos inerentes ao **FETOLY** incluem:

- Roubo de dados do paciente;
- Cuidados de saúde menos eficazes devido a operação de IA corrompida, como pesos do modelo alterados ou modificações no software/sistema operativo;
- Uso indevido do dispositivo, levando a resultados diferentes dos pretendidos pelo fabricante ou esperados pelo utilizador;
- Perda de tempo do utilizador.

Estes riscos são controlados pela análise de risco.

12.3. Diagrama de controlos de cibersegurança recomendados



O diagrama descreve o ambiente do software **FETOLY** a correr no tablet do utilizador e as comunicações de entrada/saída com o sistema de ultrassom e dispositivos de terceiros.

Inclui referências aos controlos de cibersegurança recomendados para o ambiente de utilização pretendido, conforme descrito na secção 12.4:

- **G1**: Operação segura com sistemas de terceiros via FTP sobre SSL/TLS
- **G2**: Operação segura com sistemas de terceiros via Bluetooth (apenas Android)
- **G3**: Controlo seguro de acesso ao dispositivo
- **G4**: Operação segura com sistemas de terceiros via DICOM sobre SSL/TLS

12.4. Instruções do dispositivo e especificações do produto relacionadas com os controlos de cibersegurança recomendados para o ambiente de utilização pretendido

Diretrizes para operação segura com sistemas de terceiros via FTP sobre SSL/TLS (G1):

- Requisitos mínimos de rede: a infraestrutura de rede deve suportar FTP sobre SSL/TLS (FTPS) e o servidor FTP deve ser compatível com FTPS. Implementar segmentação de rede e regras de firewall para restringir o acesso aos serviços e endereços IP necessários.
- Instalação de servidor FTP sobre SSL/TLS, como:

  i) Windows 10/11 com IIS: consultar a documentação da Microsoft para configurar FTP sobre TLS/SSL com IIS.
  ii) FileZilla Server (multi-plataforma): configurar FTPES 'Exigir FTP explícito sobre TLS', criar um utilizador com senha forte*, definir um caminho de armazenamento de dados (ex.: 'C:\FetolyData' ou /home/shared/FetolyData), e configurar regras de firewall para o programa ou porta específica usada pelo servidor FTP.

Diretrizes para operação segura com sistemas de terceiros via Bluetooth (G2, apenas Android):

- Requisitos mínimos de rede: versão Bluetooth 5 ou superior.
- Definir uma senha forte no software para proteger os dados do paciente exportados*.

Diretrizes para controlo seguro de acesso ao dispositivo (G3):

- Configurar ecrã de bloqueio com senha forte*, PIN ou autenticação biométrica.
- Ativar atualizações automáticas para o sistema operativo e todas as aplicações instaladas.
- Desativar interfaces de rede não utilizadas (ex.: NFC, IR).

Diretrizes para operação segura com sistemas de terceiros via DICOM (G4):

- Garantir que a comunicação ocorre numa rede segura e segmentada, restringindo o acesso através de configurações robustas de firewall e mecanismos de controlo de acesso.

*Utilize senhas fortes no seu tablet e em qualquer dispositivo (ex.: dispositivo de terceiros para exportação FTP) ou configuração ligada ao **FETOLY** (ex.: configuração Bluetooth), conforme recomendações da agência de defesa cibernética dos EUA:

- **Longa** – pelo menos 16 caracteres (mais longa é melhor);
- **Aleatória** – combinação de letras maiúsculas/minúsculas, números e símbolos (a mais forte!) ou uma frase-passe com 5 a 7 palavras aleatórias;
- **Única** – usada apenas para uma conta.

Se for detetada qualquer vulnerabilidade ou incidente de cibersegurança, reporte imediatamente à sua equipa de segurança informática e à Diagnoly (**support@diagnoly.com**).

No tablet:

- **Reset**: Restaurar definições de fábrica para apagar todos os dados e configurações.
- **Reinstalar a aplicação**: descarregar a versão mais recente e segura da Google Play Store.
- **Opção alternativa**: usar exportação local para cartão SD se a exportação baseada em rede estiver comprometida.

12.5. Lista de portas de rede e outras interfaces

O software **FETOLY** recebe dados de entrada via cabo conectado entre a saída externa do monitor do sistema de ultrassom e a entrada USB-C do tablet. O software pode ser configurado para exportar relatórios de exame para um dispositivo de terceiros via TCP/IP FTPS ou Bluetooth.

Para exportação de dados via rede TCP/IP FTPS:

- Protocolo: FTPS
- Portas de entrada: o software não abre portas de entrada, funcionando apenas como cliente, não servidor.

- Portas de saída: usa uma porta efémera dinâmica (intervalo: 1024-65535) para estabelecer ligação ao servidor FTPS num endereço IP especificado. A porta de entrada do servidor FTPS de terceiros é definida pelo utilizador.
- Regras de firewall: firewalls do cliente e do servidor devem permitir conexões de saída do cliente para a porta do servidor.

Para exportação de dados via Bluetooth/OBEX (apenas Android):

- Criptografia: os dados são comprimidos e encriptados com senha.

Para exportação de dados via DICOM:

- Protocolo: DICOM
- Portas de entrada: o software não abre portas de entrada, funcionando apenas como cliente, não servidor.
- Portas de saída: usa uma porta efémera dinâmica (Android: 32768 a 60999) para estabelecer ligação ao servidor DICOM em endereço IP especificado. A porta de entrada do servidor DICOM de terceiros é definida pelo utilizador.
- Regras de firewall: firewalls do cliente e do servidor devem permitir conexões de saída do cliente para a porta do servidor.

12.6. Requisitos de infraestrutura de suporte

Consultar secção 10 para requisitos de infraestrutura de suporte, incluindo configuração mínima do tablet e sistemas de ultrassom compatíveis.

12.7. SBOM

Um *Software Bill of Materials* (sBoM) está disponível para os utilizadores gerirem os seus ativos, compreenderem o impacto potencial de vulnerabilidades identificadas e aplicarem contramedidas para manter a segurança e eficácia do dispositivo. O sBoM pode ser descarregado dentro da página “Sobre” do software, em formato legível por máquina (.csv), clicando em “mostrar” em frente de “Aviso de Terceiros”.

12.8. Instruções de atualização / patch

Consultar secção 13 “Atualização de software e licença” para instruções de atualização.

12.9. Descrição da resposta do dispositivo quando são detetadas condições anómalas

O software responde a eventos de segurança. Todos os crashes são exportados através de um log para o Firebase. Os seguintes avisos podem surgir ao usar o **FETOLY**:

- Falha na exportação: anomalia de rede levando à falha na exportação de relatório via TCP/IP FTPS, DICOM ou Bluetooth.
- Falha na ligação USB: cabo USB-C não conectado ou falha na receção do fluxo de vídeo.
- Falha de validação de licença: tentativas de validação sem ligação à internet, ativação automática do tempo ou licença válida.
- Sobre-aquecimento do tablet.

- Problema de compatibilidade do tablet: taxa de frames do fluxo de vídeo abaixo de 24 fps.
- Bateria baixa do tablet.

12.10. Backup e restauração

Para restaurar funcionalidades e configuração padrão, desinstale e reinstale a aplicação através da Google Play/App Store.

12.11. Métodos para retenção e recuperação de configuração do dispositivo por utilizador autenticado

As configurações de exportação (como credenciais de terceiros) e captura de vídeo (como proporção de entrada de vídeo) são guardadas no cache de dados do tablet, isoladas de forma segura pelo Android/iOS. Como estas configurações são rápidas de configurar, não existe método de recuperação específico. Os utilizadores devem reintroduzir as configurações manualmente durante reinstalação ou nova instalação do dispositivo.

12.12. Configuração segura

Esta secção fornece instruções para garantir que o software **FETOLY** está configurado e mantido de forma segura.

- **Configuração inicial**: descarregar e instalar a versão mais recente da Google Play/App Store. Verificar nome e ícone da app conforme secção 13. Executar todos os passos de configuração de exportação sobre ligação de rede segura (G1/2/4, secção 12.4). Garantir segurança do dispositivo (G3, secção 12.4).
- **Resposta a incidentes**: ativar ligação à internet para registo de crashes e atividades anómalas, conforme secção 12.13. Reportar vulnerabilidades detetadas conforme secção 12.4.

12.13. Recolha de evidência forense, quando apropriado

Um sistema de relatórios de crashes está integrado no software. Relatórios são enviados em caso de crash da aplicação ou evento anómalo, se a ligação à internet estiver ativa.

12.14. Informação sobre fim de vida e fim de suporte do sistema ou componentes

O fim de vida e fim de suporte depende da validade da licença. A licença é renovada automaticamente se houver ligação à internet e o contrato ainda for válido. Se o contrato expirar ou o fim de vida for atingido, será solicitado um novo código de registo.

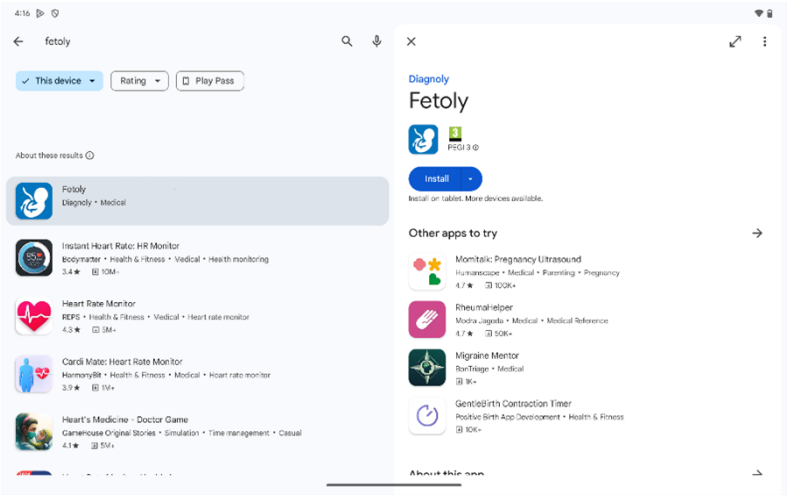
12.15. Desativação segura

Para desativar e eliminar o software, desinstale a aplicação através do sistema Android/iOS como qualquer outra app, nas definições da aplicação, conforme ilustra a secção 13 em “desinstalação de software”. Esta desinstalação remove todos os dados ligados ao uso do **FETOLY**, incluindo a licença, do tablet.

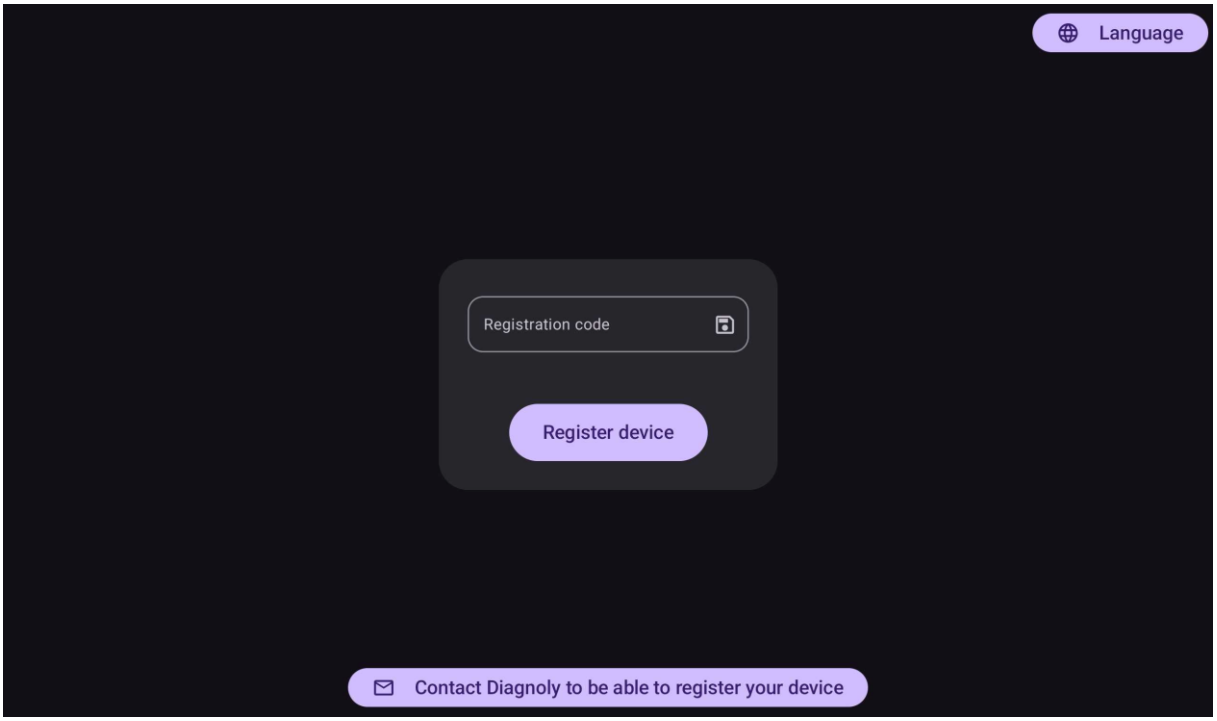
13. Direção de utilização

Instalação e lançamento do software:

1. Aceder à Google Play ou App Store, escrever **FETOLY** na barra de pesquisa e iniciar o download e instalação automática.



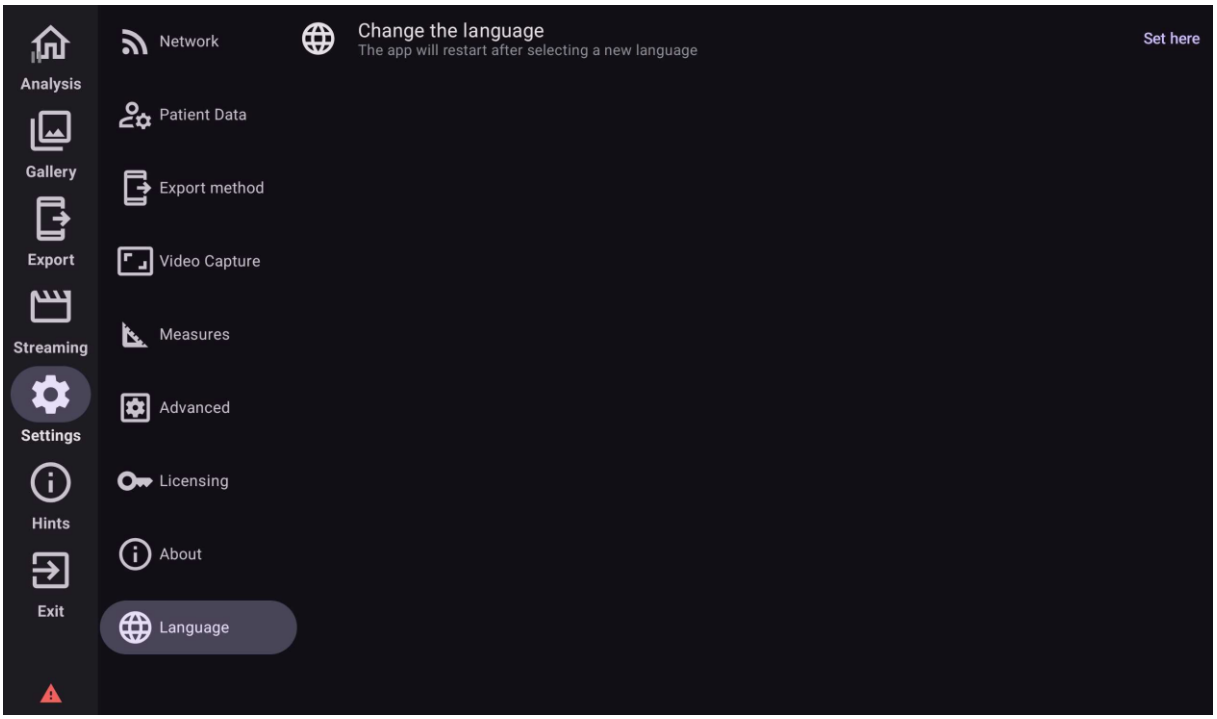
2. Clique no ícone do FETOLY no seu tablet
3. Validação da licença: Se necessário, introduza o código de registo da licença conforme indicado abaixo. A Diagnoly é responsável por fornecer a licença. Pode contactar a Diagnoly para edição da licença clicando diretamente no botão exibido na parte inferior da página de boas-vindas. A licença está ligada ao ID do seu dispositivo, disponível na página de definições da licença.

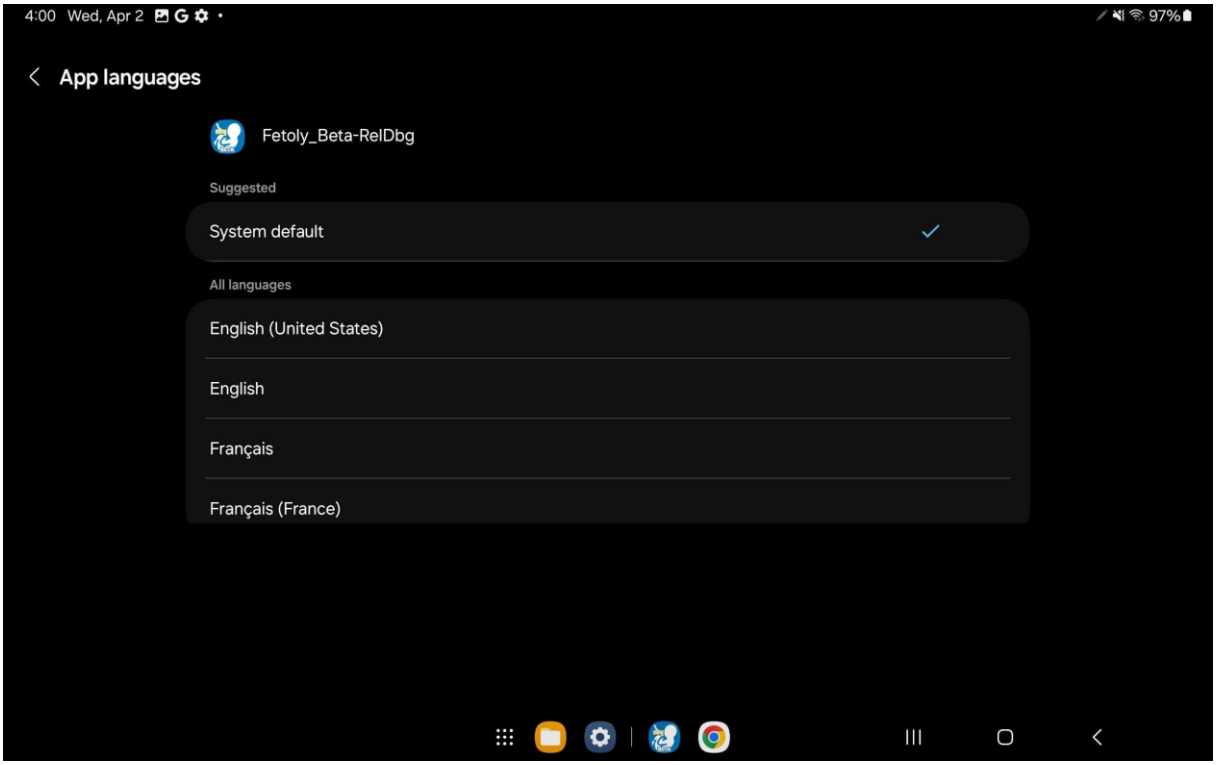


4. Estabelecer ligação Wi-Fi: Se pretender receber os dados de ultrassom no seu computador pessoal, ligue o tablet à sua rede Wi-Fi.

Configurações de idioma

Por defeito, o software está configurado no mesmo idioma do tablet. No entanto, pode escolher o idioma pretendido em ‘Definições’ > ‘Idioma’. Isto irá levá-lo às definições de idioma da aplicação no Android. Depois de selecionado o idioma desejado, a aplicação será traduzida ao relançar.



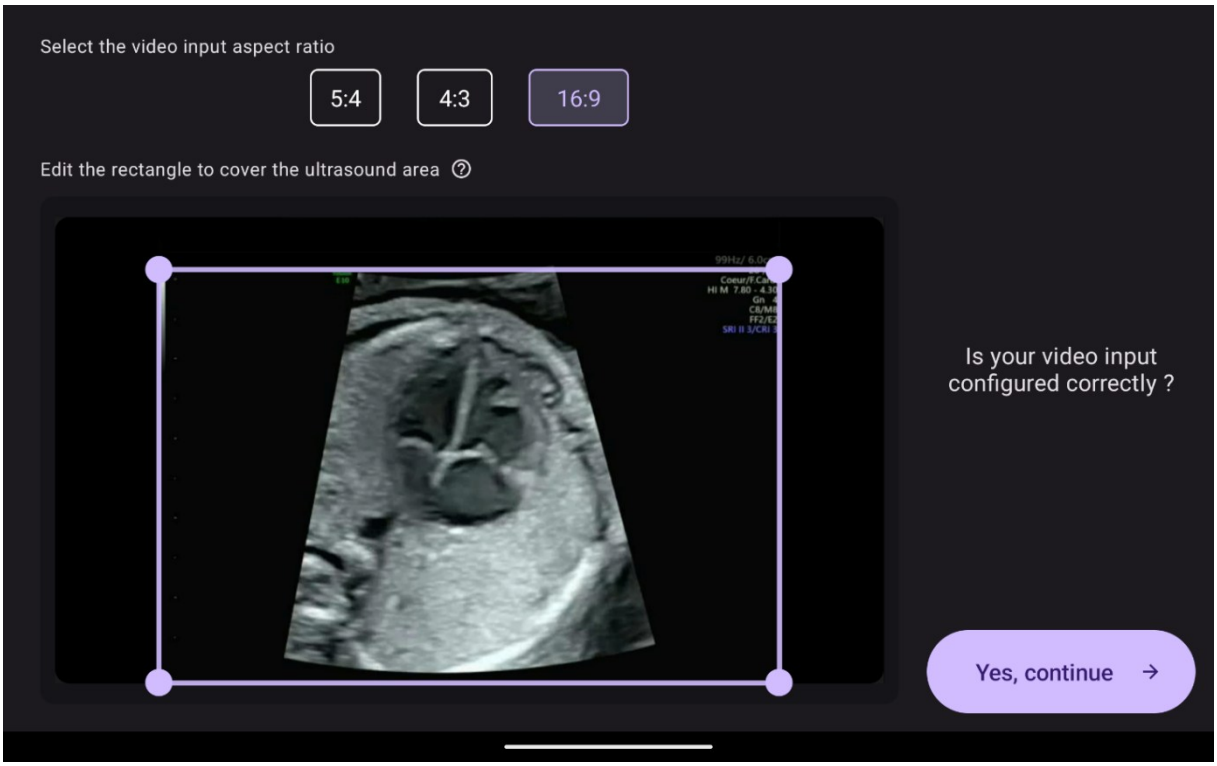


Ligação ao sistema de ultrassom

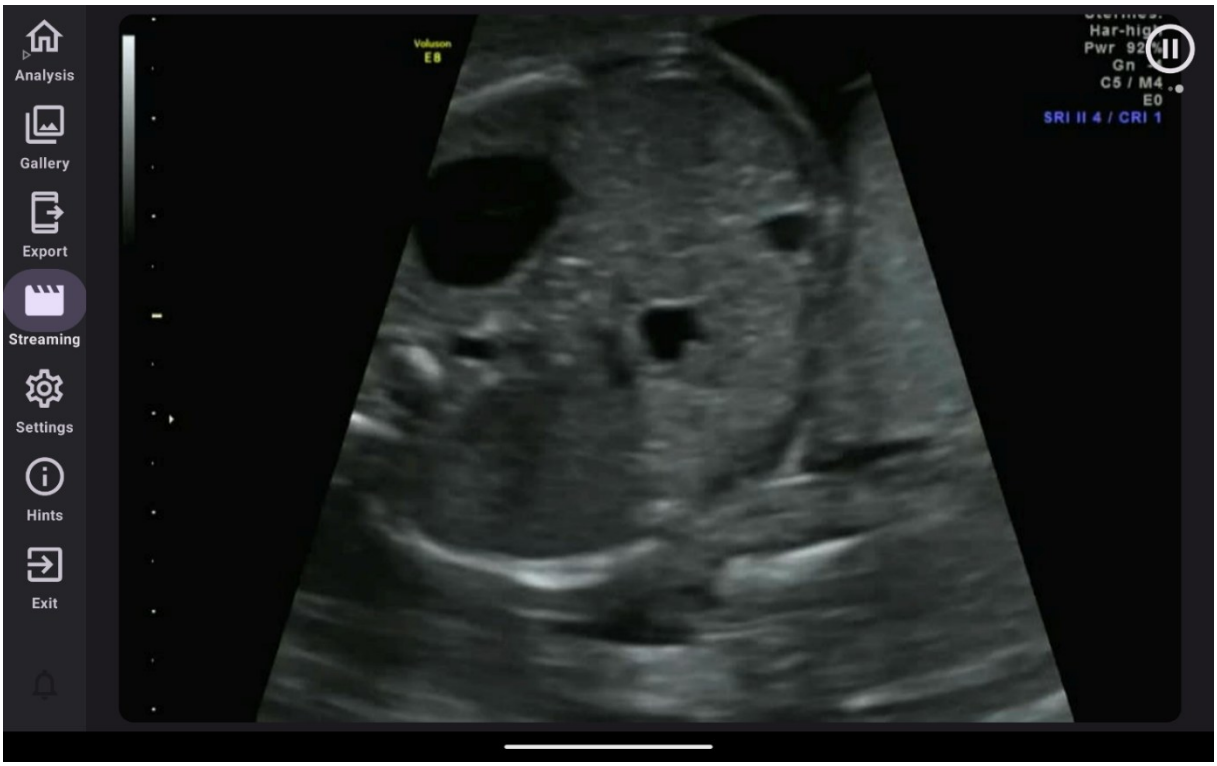
13. Ligar o sistema de ultrassom: Antes de ligar o tablet, certifique-se de que o sistema de ultrassom está ligado e em funcionamento.
14. Ligar o tablet ao sistema de ultrassom: Para ligar, basta conectar a extremidade USB (Tipo C) de um dongle UVC ao tablet e a extremidade HDMI à máquina de ultrassom.
15. Verificação: Para verificar a ligação entre o sistema de ultrassom e o tablet, abra o software FETOLY. Se uma nova fonte USB tiver sido ligada, a aplicação exibirá automaticamente a página de configuração do fluxo de vídeo.

Configuração do fluxo de vídeo

1. Iniciar a configuração do fluxo de vídeo na aplicação:
    a. Quando o software abrir automaticamente a página de configuração de vídeo, selecione a proporção de aspeto do vídeo para coincidir com a saída da máquina de ultrassom e selecione a região do ultrassom. Em outras situações, vá a 'Definições' > 'Captura de vídeo' para configurar o fluxo de vídeo, seguindo a mesma metodologia.



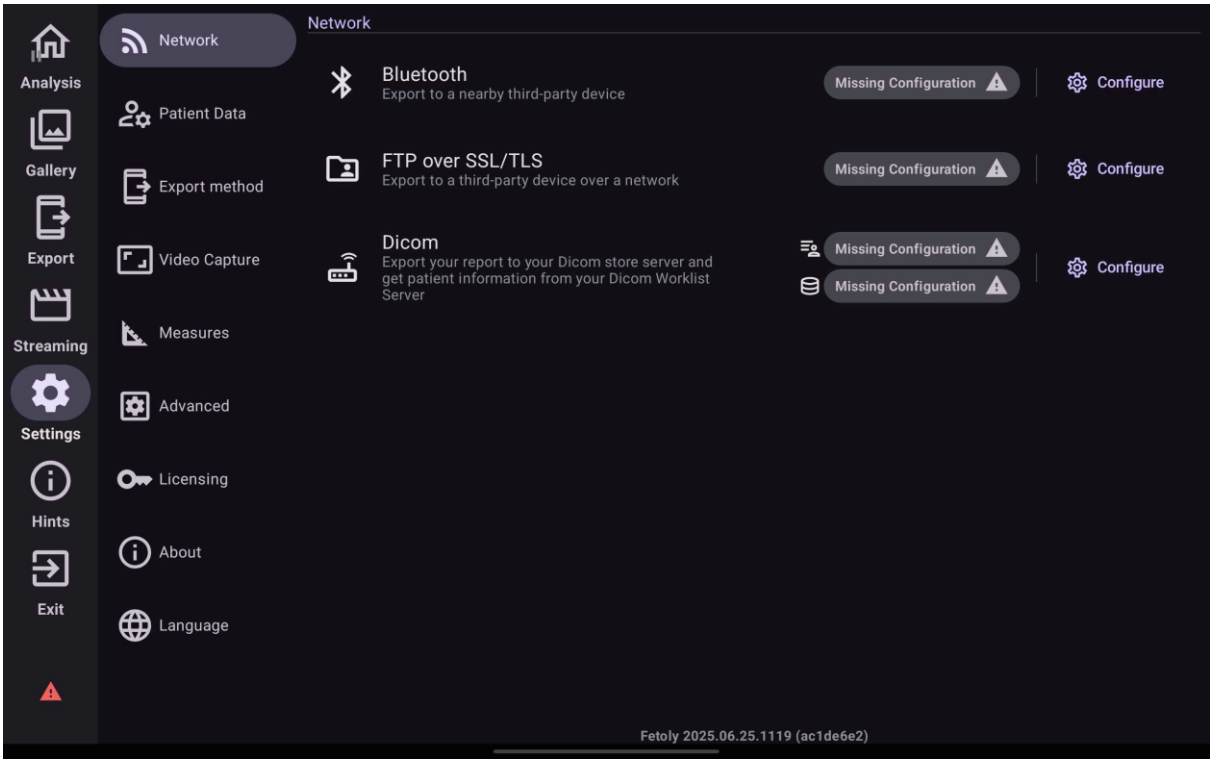
    j. A região selecionada aparece em tempo real na página de streaming. O botão de reprodução pode ser usado para iniciar a análise.
    k. Verifique se o microfone não está desativado no tablet, pois isso bloqueará a entrada do fluxo de vídeo.



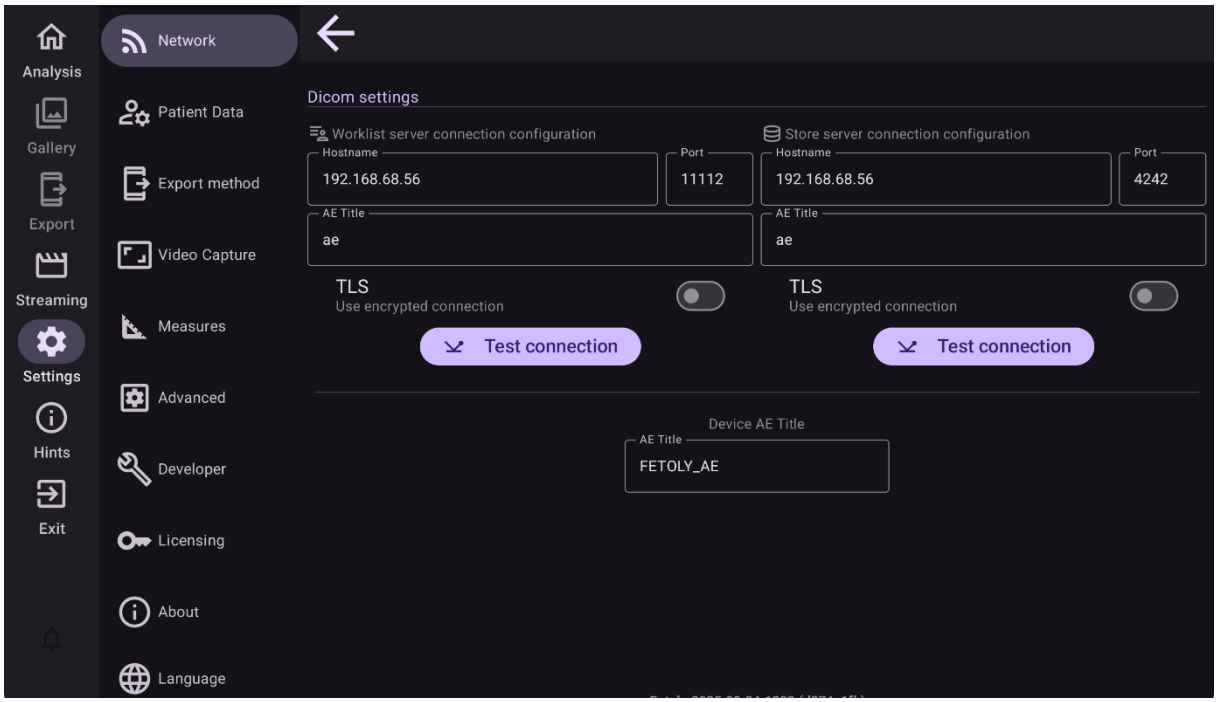
[OPCIONAL] Configuração da máquina de ultrassom:

Alguns sistemas permitem configurar o tamanho da região de ultrassom na saída de vídeo. Se for o caso, recomenda-se selecionar a maior região possível.

Configuração de exportação

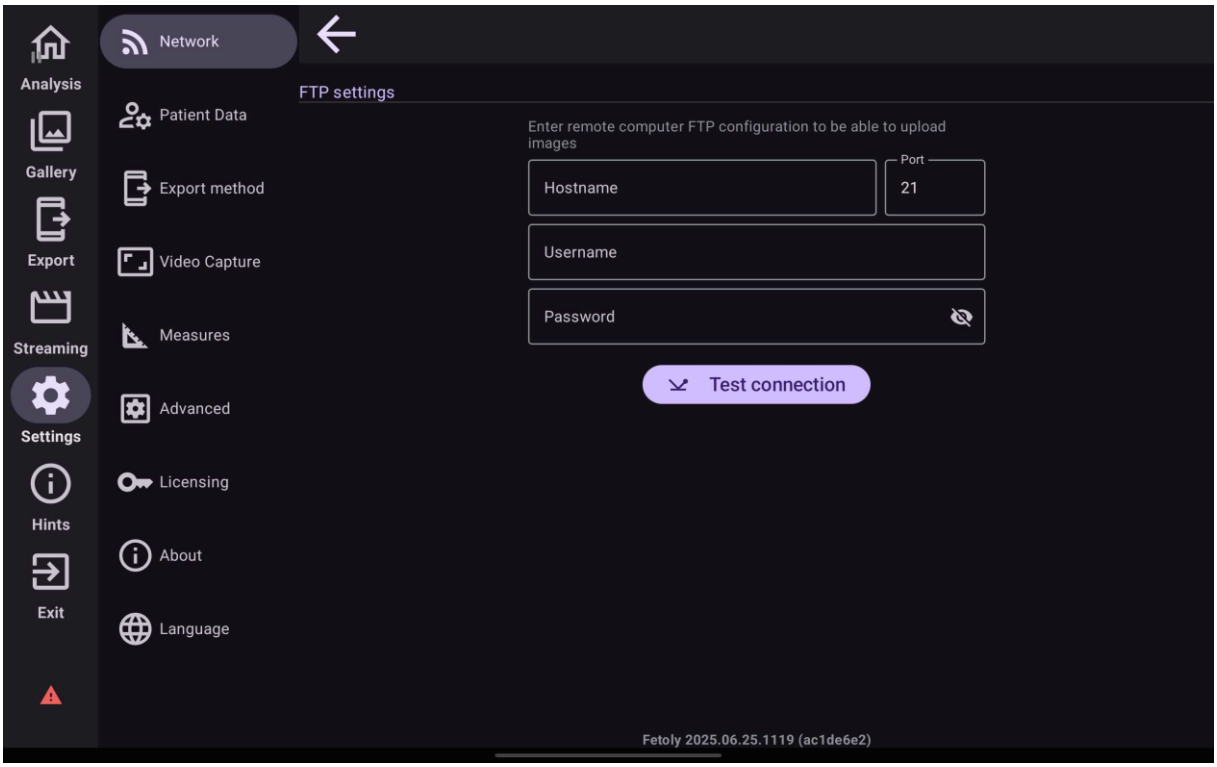


1. Configurar o servidor DICOM remoto para exportar imagens capturadas pelo FETOLY. Este passo requer um servidor DICOM num dispositivo ligado à mesma rede do tablet.
    a. Vá a ‘Definições’ > ‘Definições de Rede’, selecione Configurar DICOM e introduza as informações necessárias: hostname da worklist (endereço IP) e título AE, hostname do DICOM Store (endereço IP) e título AE, título AE do dispositivo. Para verificar a ligação, clique no botão ‘Testar ligação’ para cada servidor DICOM. Também pode ativar a opção TLS opcionalmente.



6. Em alternativa, configure o servidor FTP remoto para exportar as imagens captadas pelo FETOLY. Note que este passo requer a existência de um servidor FTP ativo num dispositivo ligado à mesma rede que o tablet onde o FETOLY está a ser executado.

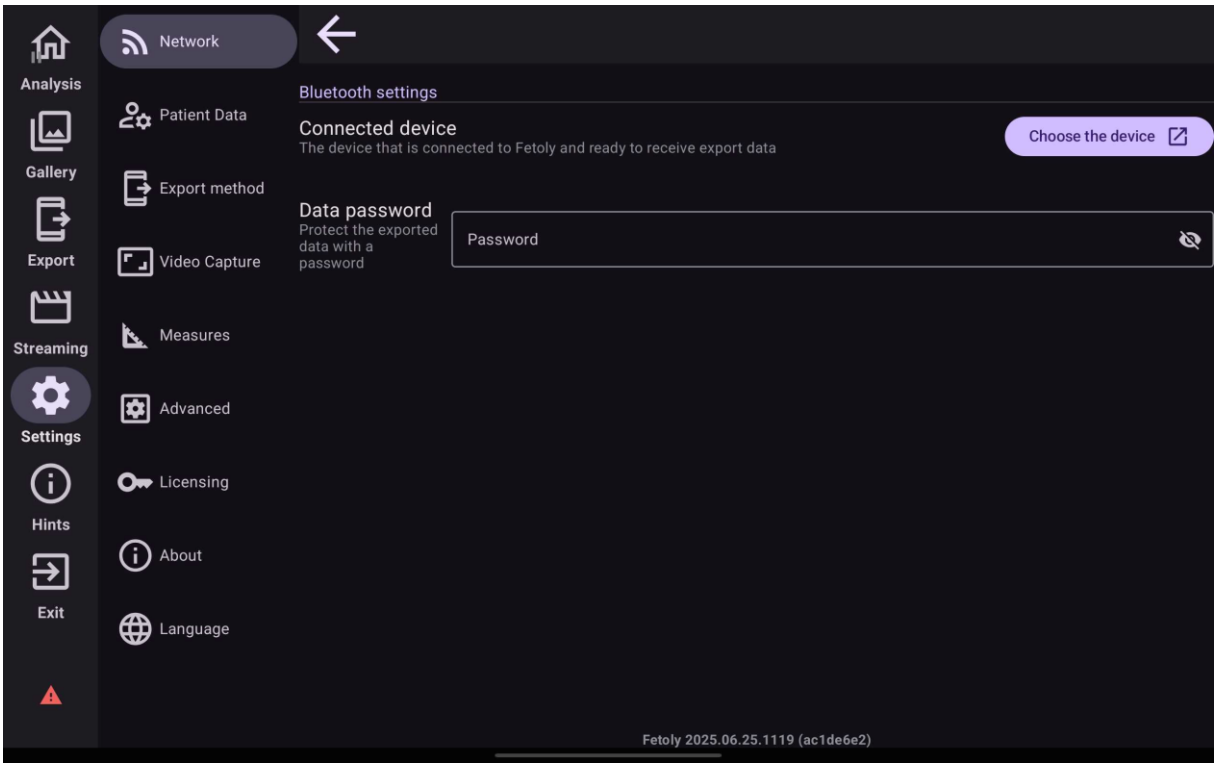
    a. Vá a ‘Definições’ > ‘Definições de Rede’, selecione Configurar FTP e introduza hostname (endereço IP), nome de utilizador e senha. Clique em ‘Testar ligação’ para verificar.

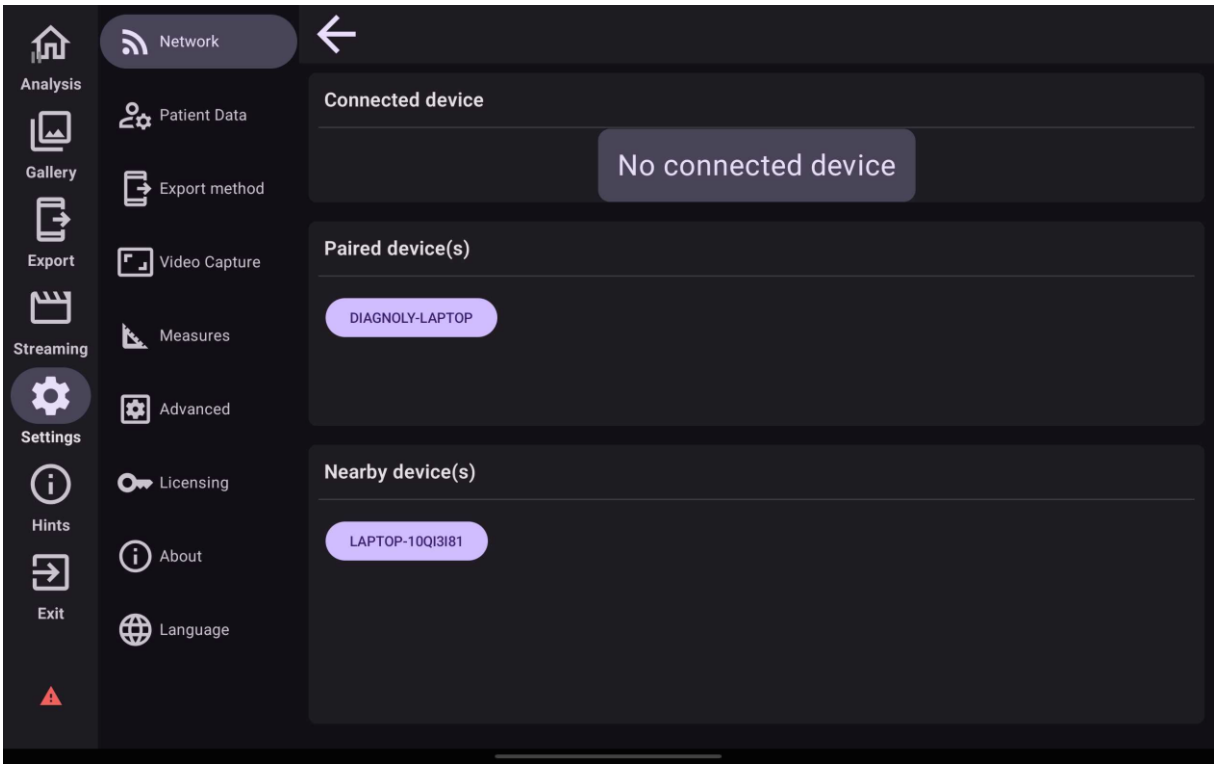


15. Em alternativa, use ligação Bluetooth (apenas Android):

    a. Em Definições > Definições de Rede, selecione Bluetooth. Para escolher o dispositivo para o qual pretende exportar os dados, é necessário emparelhar o dispositivo selecionando-o na secção dispositivos próximos. Em seguida, escolha o dispositivo ao qual pretende ligar-se na secção dispositivos emparelhados. Depois de o dispositivo estar selecionado, pode testar a ligação na secção dispositivo ligado. A página de seleção de dispositivo pode ser acedida clicando no botão à direita de Definições de Bluetooth > dispositivo ligado.

    b. Para exportar o ficheiro, deve configurar uma senha que será aplicada ao ficheiro .zip exportado no dispositivo de terceiros.

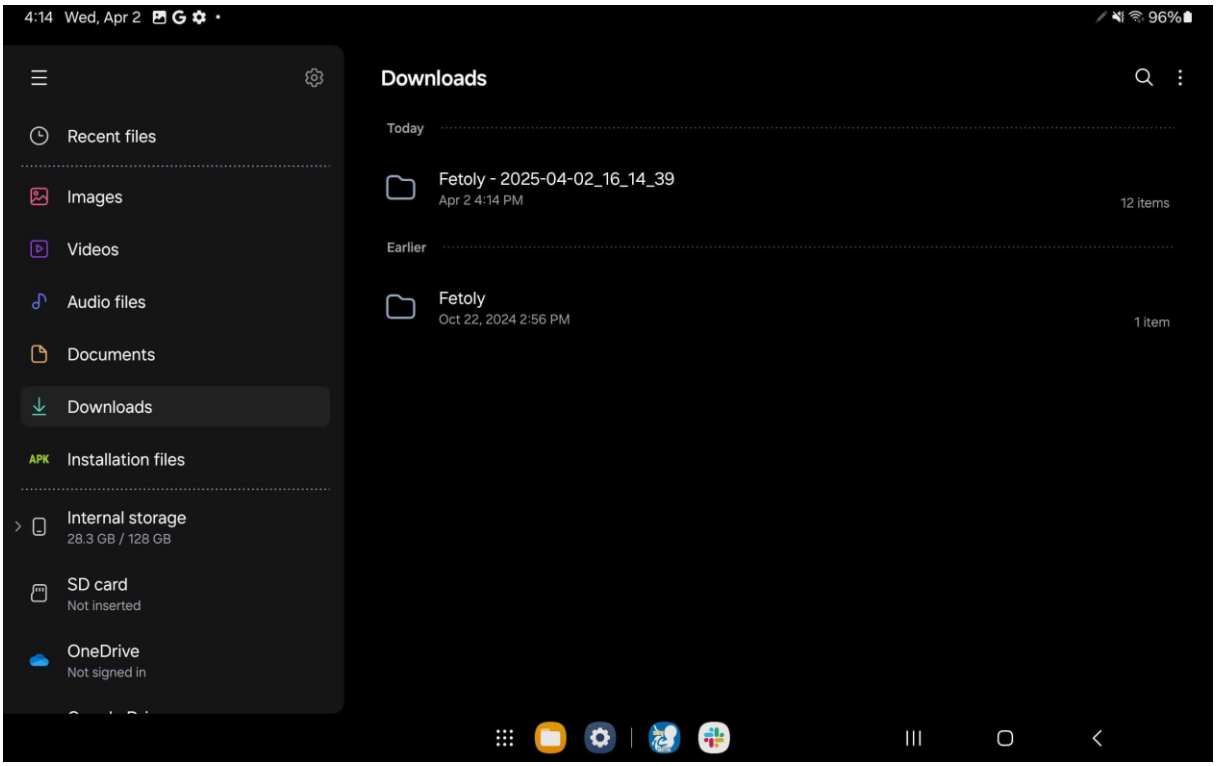




16. Se não pretender utilizar uma ligação sem fios, pode exportar os dados diretamente no tablet:

    a. Vá a ‘Definições’ > ‘Método de exportação’, selecione Local. O ficheiro será guardado num local pré-definido pelo tablet.

    b. Para aceder ao local, vá à área de trabalho do tablet, selecione o ícone ‘Ficheiros’, depois ‘Downloads’ > ‘Fetoly’.

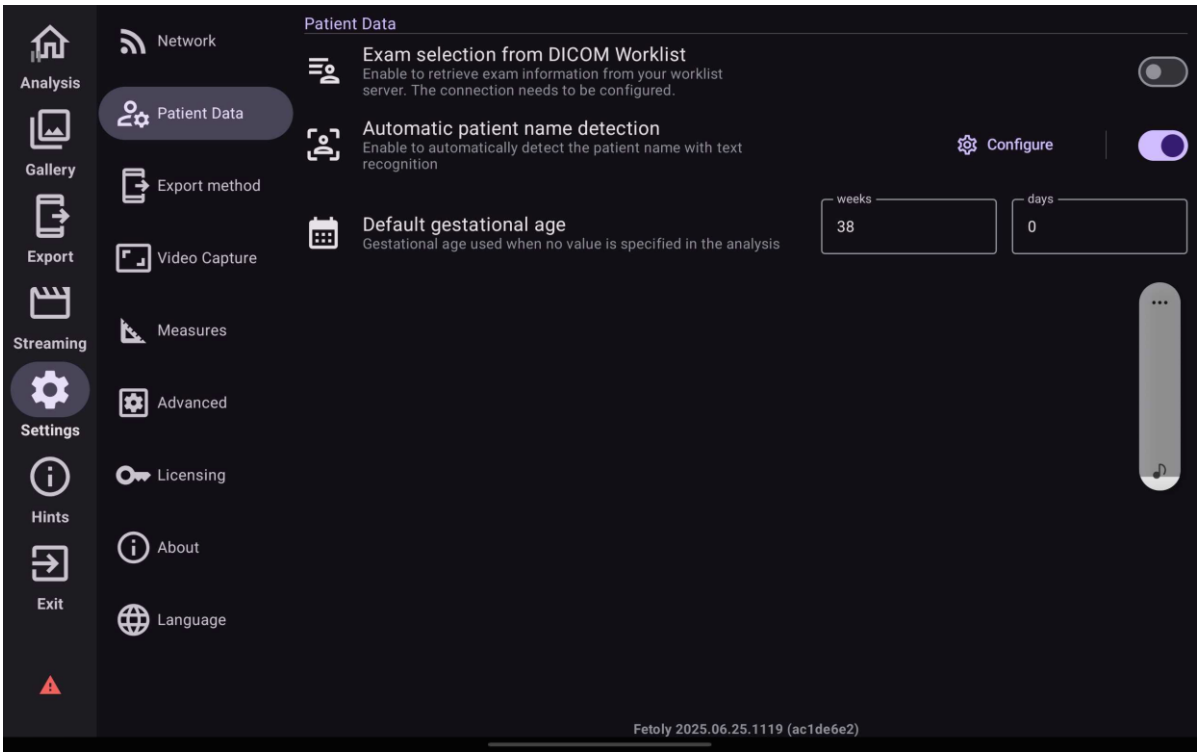


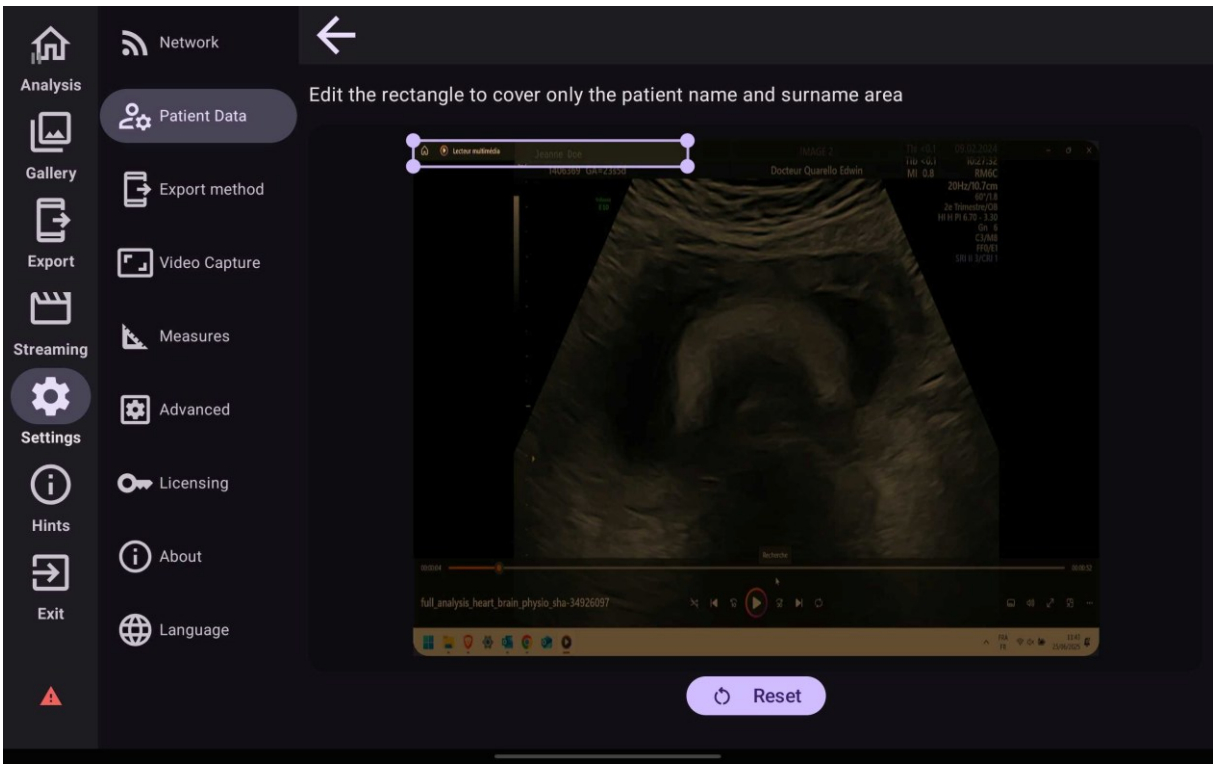
17. Se pretender adicionar o nome do paciente ao nome do ficheiro exportado ou selecionar o exame do paciente a partir da lista de trabalho DICOM:

    a. Preencha o nome do paciente e a idade gestacional na página de análise, ou

    b. Vá a ‘Definições’ > ‘Dados do paciente’ e ative ‘Seleção de exame a partir da worklist DICOM’ (funciona apenas se estiver ligado a um PACS com parâmetros DICOM configurados).

    c. Opcionalmente, ative ‘Deteção automática do nome do paciente’ e configure a área no fluxo de vídeo onde o nome aparece. O nome será preenchido automaticamente ao iniciar o exame ou ao clicar no botão de atualizar ao lado do nome do paciente.

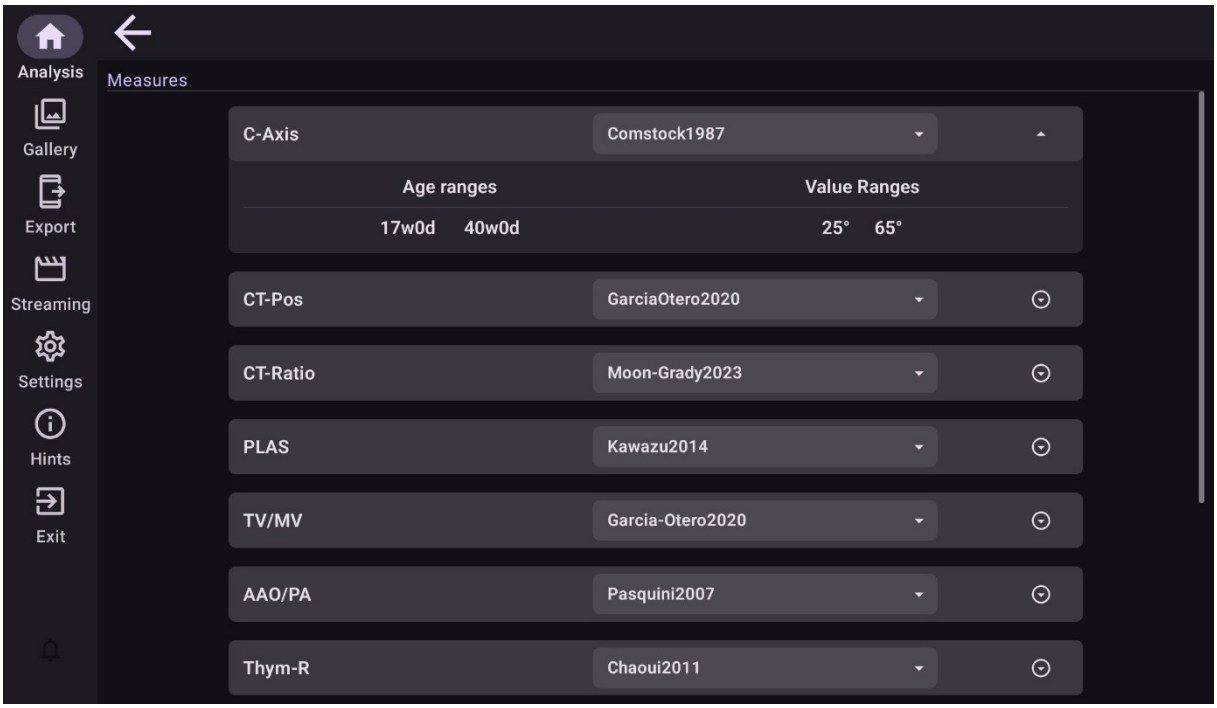




Utilização

1. Passos para realizar exame completo e medições:
    a. Introduza a idade gestacional na página de análise com o nome do paciente ou selecione o exame na worklist DICOM.
    b. Configure a idade gestacional por defeito em ‘Definições’ > ‘Dados do paciente’.

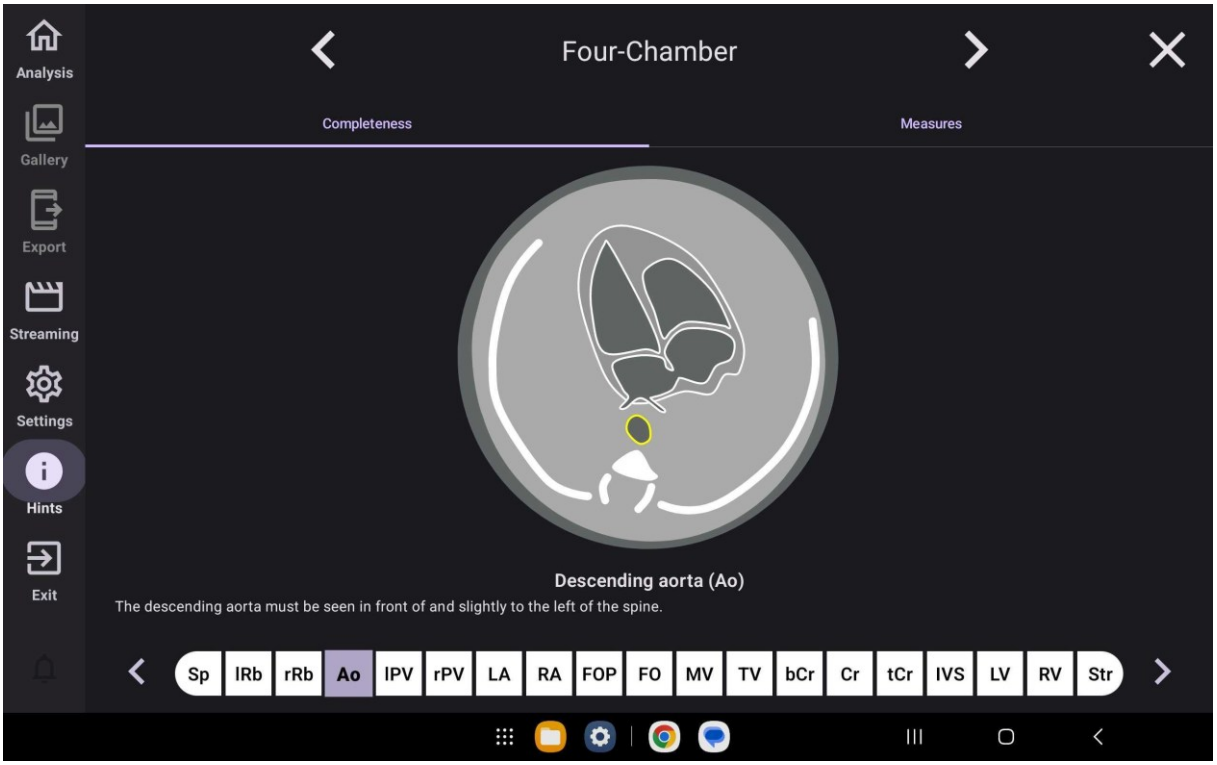
c. Para medições, se existirem múltimas fontes bibliográficas, escolha a preferida. Pode também definir intervalos de referência manualmente, selecionando Personalizado em ‘Definições’ > ‘Definições de Medidas’.



d. Pressione Play na página de análise
e. Realize o exame normalmente
f. O exame é considerado completo quando todas as vistas e critérios são verificados e todas as medições realizadas
g. As medições fora do intervalo são exibidas como “fora do intervalo”
h. Ao completar o exame, a página de análise indica e permite ir diretamente à Galeria para verificar as imagens sugeridas

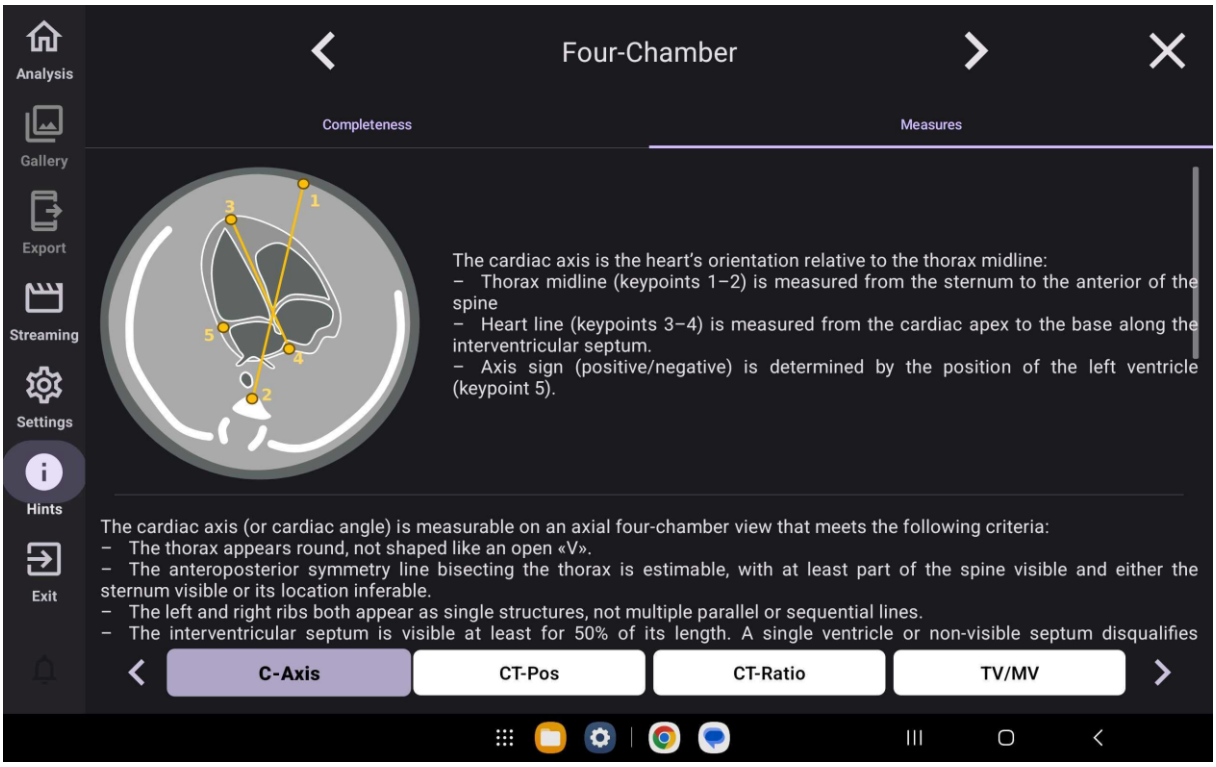


2. Dicas para assegurar a realização correta do exame e das medições:
    a. Os critérios de qualidade e as vistas detetadas pelo software baseiam-se nas orientações da ISUOG para rastreio cardíaco e cerebral fetal. Leia estas orientações, se necessário, como lembrete das boas práticas no rastreio cardíaco/cerebral fetal. Pode também consultar a página de Dicas para obter uma explicação de todos os critérios de qualidade.



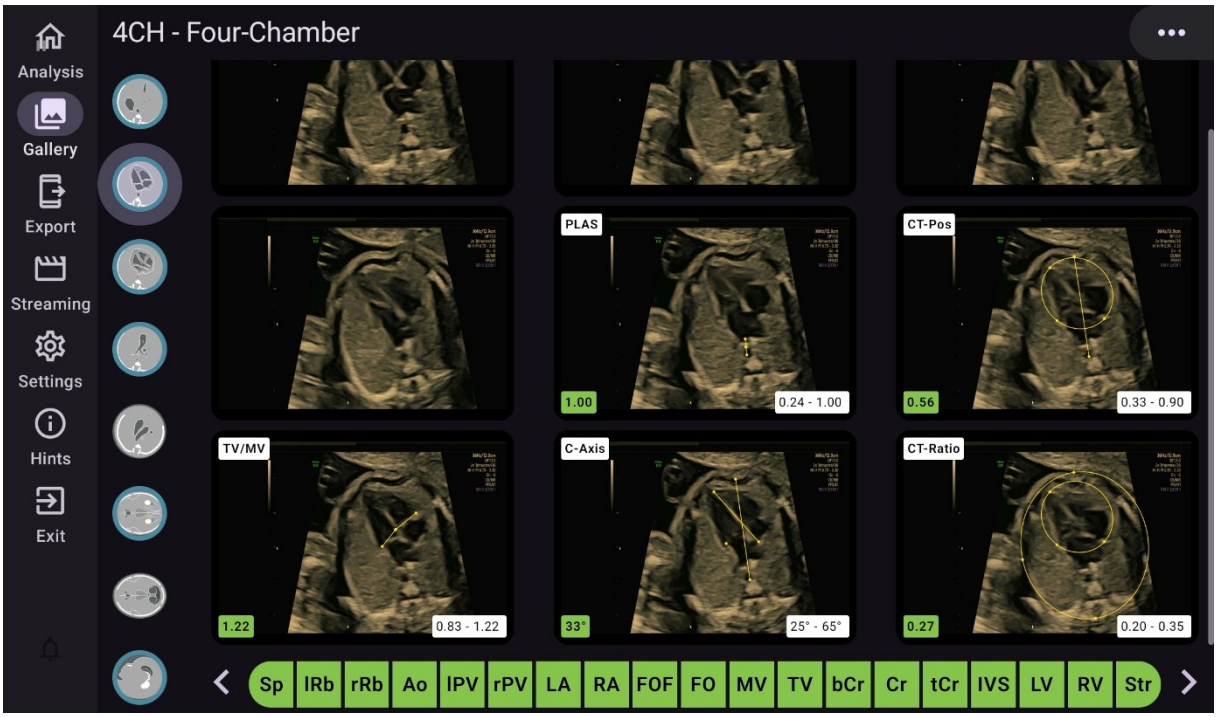
    b. As medições biométricas efetuadas pelo software baseiam-se em orientações internacionais e literatura reconhecida para o rastreio cardíaco e cerebral

fetal. Leia os artigos da literatura referidos pelo software, se necessário, como lembrete das boas práticas no rastreio cardíaco/cerebral fetal. Pode também consultar a página de Dicas para obter uma explicação de todas as medições efetuadas.

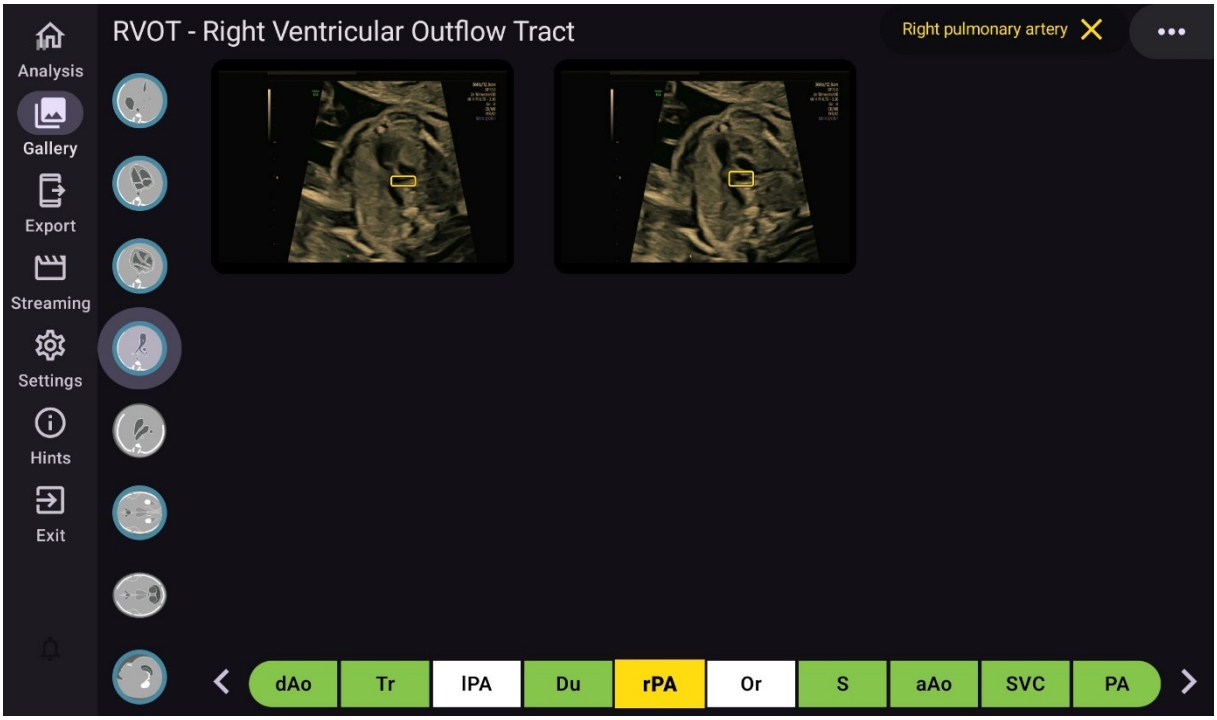


c. Certifique-se de que todos os passos de configuração explicados acima estão corretamente realizados para evitar problemas de deteção.
d. Certifique-se de que utiliza equipamento compatível conforme a secção 10 deste IFU.
e. Existe um aviso na página de exportação caso os critérios de qualidade/medidas não estejam presentes no conjunto de imagens selecionado.
f. Uma vez verificados todos os critérios e efetuadas todas as medições na página de análise, confirme se todos os critérios e medidas correspondentes são claramente identificáveis no conjunto de imagens selecionado na página Galeria.

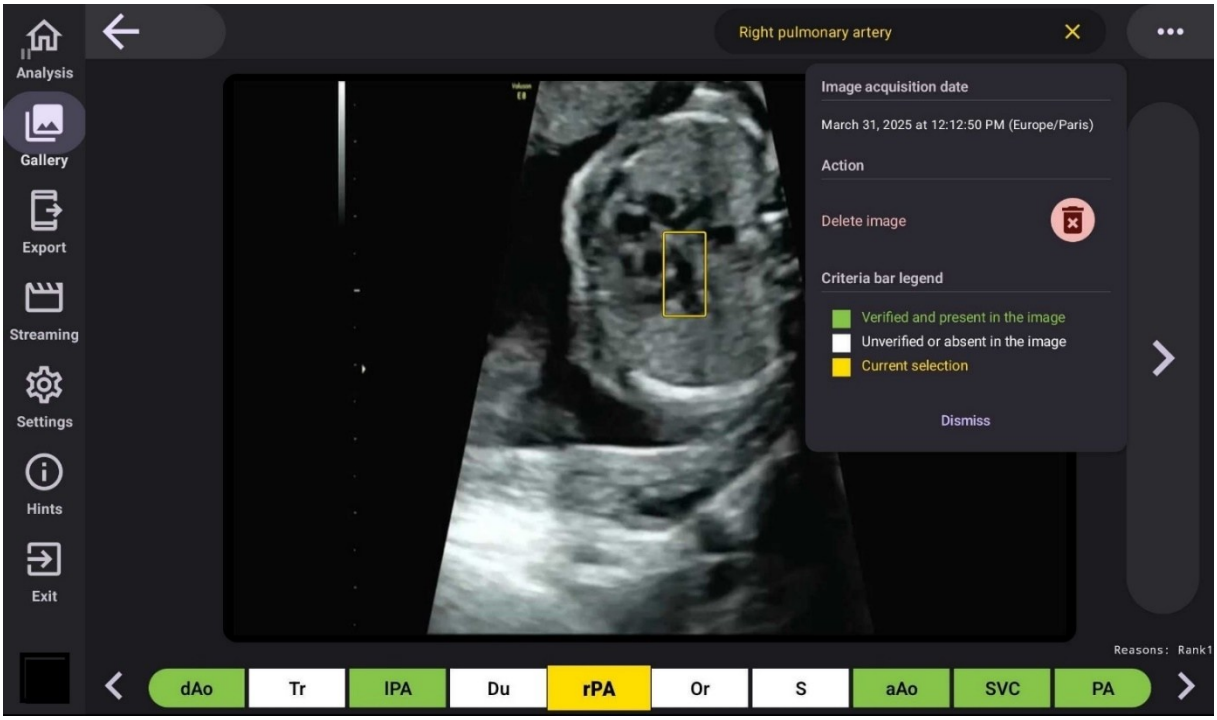
3. Após terminar a transmissão de video, vá à secção Galeria para explorar as imagens selecionadas. Para facilitar a navegação dentro do conjunto de imagens, estas estão categorizadas por plano.



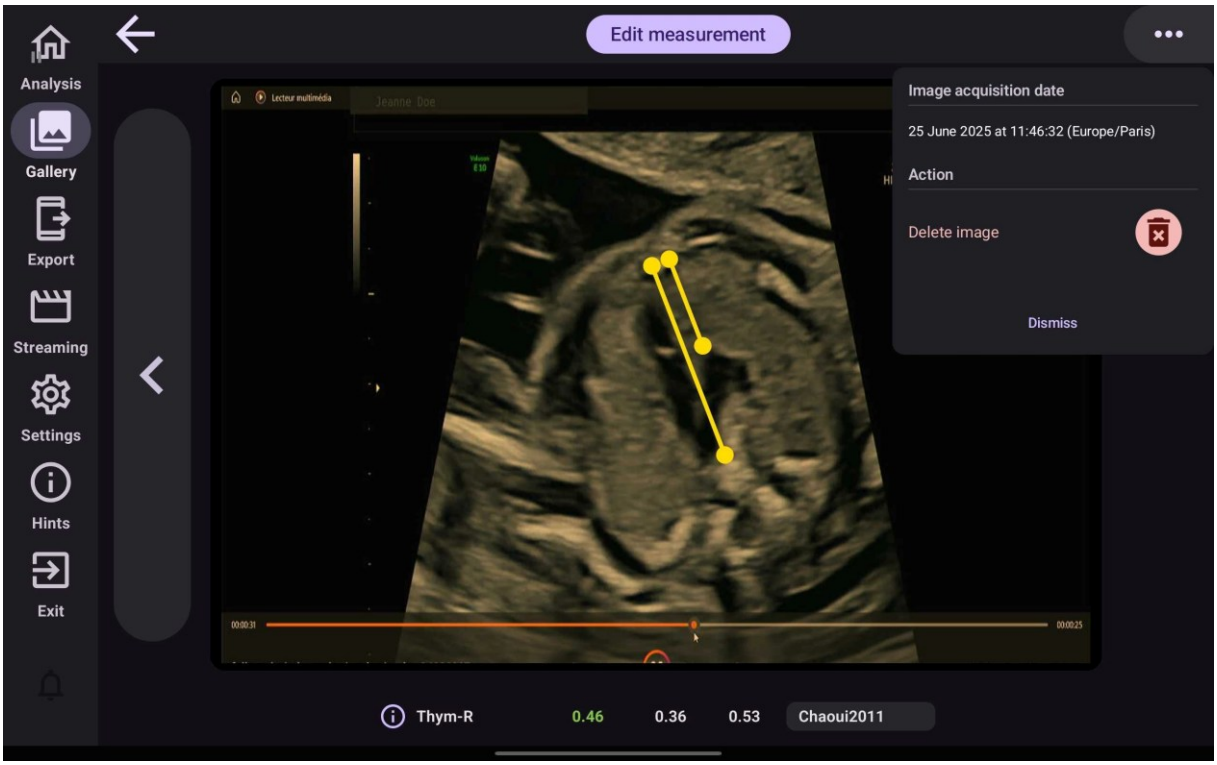
a) Clique num plano específico (painel esquerdo) para visualizar as imagens selecionadas relativas a esse plano. Os critérios em verde estão verificados e os critérios em branco não estão verificados.
b) As imagens selecionadas para medições biométricas contêm a seguinte informação: nome da medição, valor, intervalo de referência e estado fora do intervalo, se aplicável. Os pontos-chave e formas da medição estão a amarelo.
c) Clique numa estrutura específica para visualizar imagens selecionadas que contenham essa estrutura. O critério de qualidade selecionado aparece a amarelo e a caixa delimitadora em torno do critério é exibida nas imagens.



d) Clique numa imagem de completude para ampliar. Pode clicar num critério de qualidade em verde para mostrar a caixa delimitadora em torno do critério. O critério de qualidade escolhido aparece a amarelo. Caixas brancas significam que os critérios de qualidade estão presentes noutras imagens da galeria ou não foram verificados. Clique no símbolo da lixeira para apagar a imagem. Pode deslizar diretamente nas laterais da imagem para percorrer outras imagens da mesma vista.



e) Clique numa imagem de medição para ampliar. Os pontos-chave e formas da medição estão a amarelo. Note que os pontos-chave da medição não estão posicionados no local exato, mas são suficientemente precisos para mostrar o valor correto da medição. O valor e o estado “fora do intervalo”, se aplicável, são exibidos, juntamente com o intervalo de referência e a fonte bibliográfica selecionada. Clique no símbolo da lixeira para apagar a imagem. Pode deslizar diretamente nas laterais da imagem para percorrer outras imagens da mesma vista. Pode editar os pontos-chave de uma medição nas imagens de medição clicando no botão editar medição. O valor da medição será atualizado em conformidade e o software impede qualquer modificação automática após a edição. A medição editada será marcada com o seguinte símbolo: .



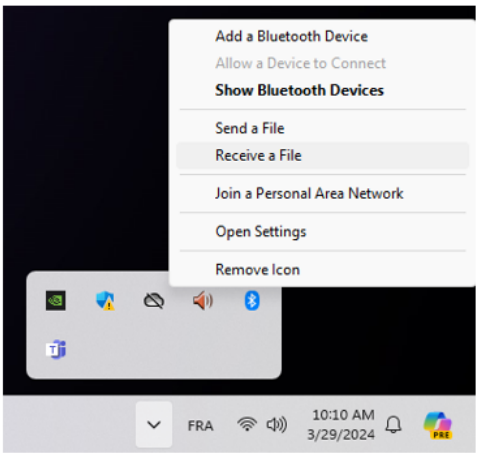


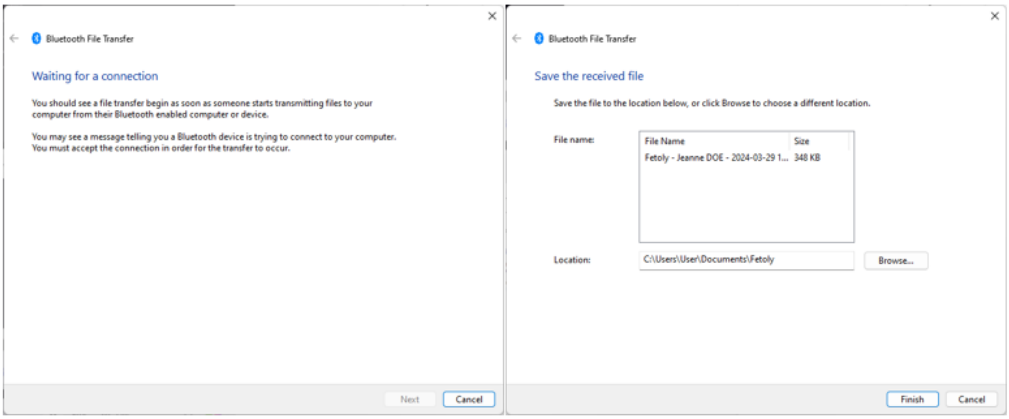
f) Se necessário, pode voltar à página de análise para relançar a análise e obter imagens adicionais.

Exportação de imagens

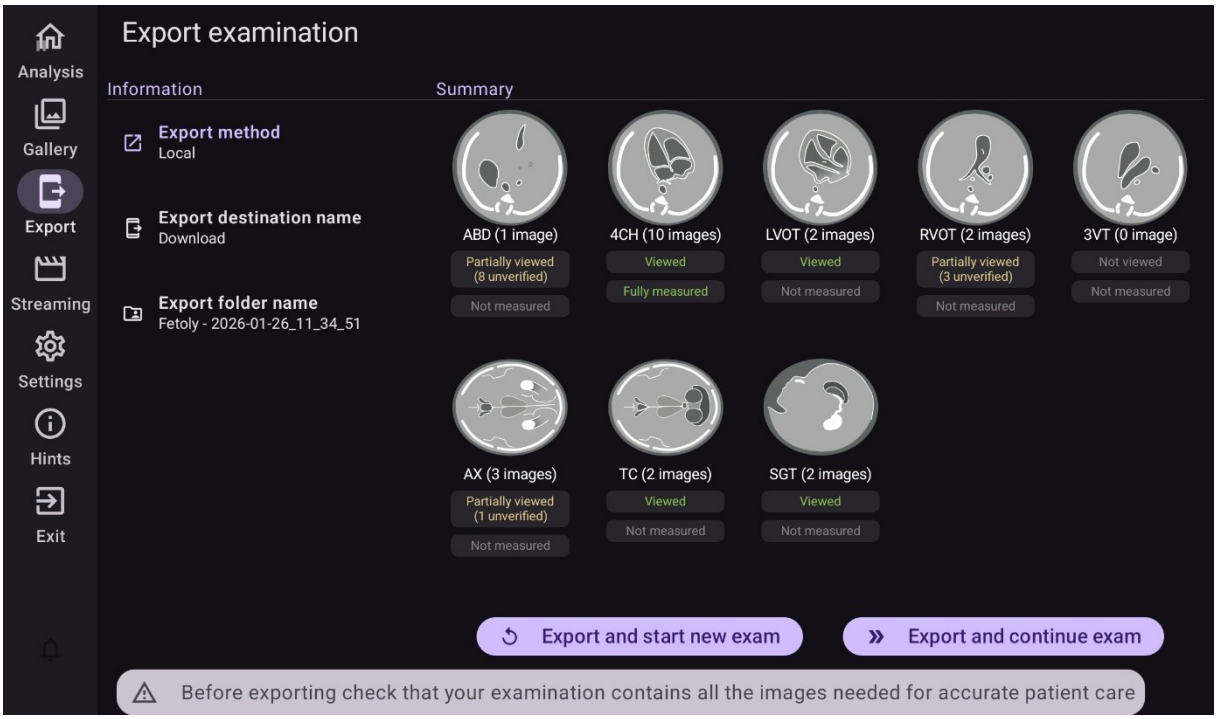
1. Vá à secção Método de Exportação em Definições para selecionar o modo de exportação que pretende utilizar.
2. Vá à secção Exportar para exportar as imagens selecionadas:

a. Se escolheu conexão Bluetooth (apenas Android), vá para o seu PC e selecione receber um ficheiro nas configurações de Bluetooth.





b. Se escolheu conexão DICOM, pode verificar se o paciente selecionado para exportação é o correto e selecionar outro paciente, se houver engano, utilizando a lista de trabalho DICOM na página de análise.
c. A página de exportação exibe um resumo do exame e lembra-o de verificar se possui todas as imagens necessárias para um cuidado eficiente do paciente antes da exportação.
d. A página de exportação mostra a metodologia de exportação escolhida. Se quiser alterar as definições, pode ir diretamente à página de definições de exportação clicando em método de exportação.
e. A página de exportação exibe a localização do ficheiro de exportação no dispositivo escolhido e o nome do ficheiro definido para exportação local.
f. Clique no botão Exportar e iniciar novo exame para exportar imagens e limpar o exame antes de iniciar um novo.
g. Ou clique no botão Exportar e continuar exame para exportar imagens sem apagar o conjunto atual de imagens selecionadas e a análise de completude.
h. O software indicará se a exportação foi bem-sucedida ou falhou.



Re-inicialização (limpar)

Se não utilizou a função limpar na página de exportação, vá a Análise e clique no botão Limpar para reinicializar o conjunto de imagens selecionadas e o exame.

Definições avançadas

Se quiser desativar a função de medição, vá a Definições > Avançado e clique no botão correspondente.

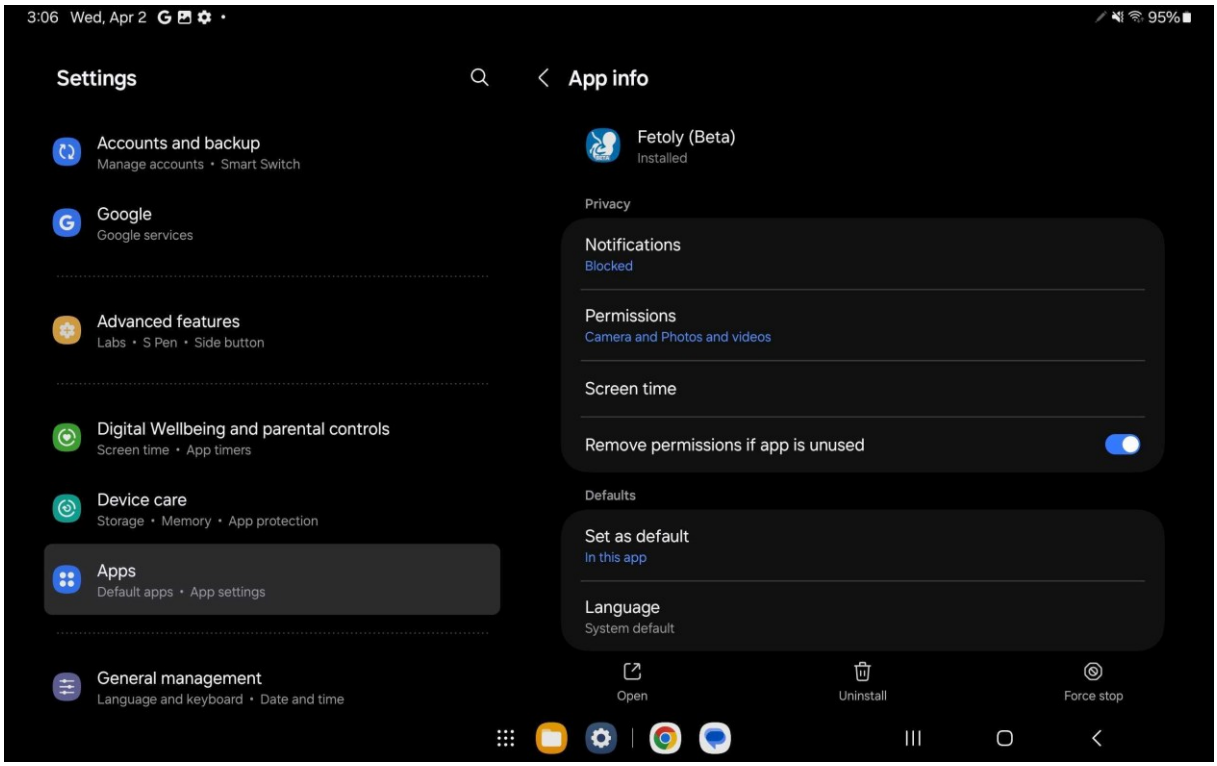
Atualização do software e licença

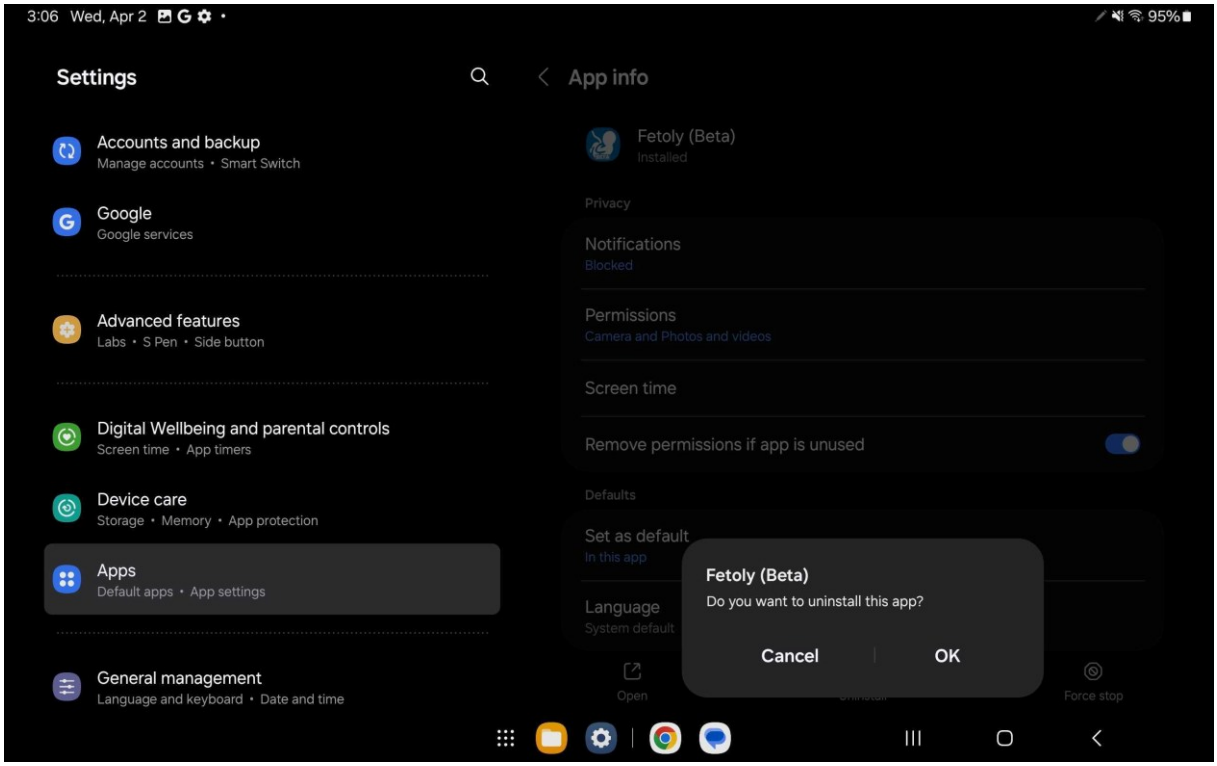
O software verifica periodicamente se existem atualizações. Para garantir a disponibilidade imediata de novas atualizações, ative as atualizações em segundo plano para o FETOLY nas definições da Google Play/App Store. Quando uma atualização estiver disponível, o software exibirá uma página bloqueadora ao iniciar, solicitando ao utilizador que atualize e reinicie a app para continuar a utilizá-la. Após aceitar a atualização, a Google Play/App Store trata da instalação e reinício da app. É necessária uma ligação à internet para verificar atualizações e renovar automaticamente a licença. Se o dispositivo não estiver ligado à internet por 30 dias, o software será bloqueado.

A sua licença é verificada e renovada automaticamente quando a ligação à internet está ativa, até à expiração do contrato de licença. A data de expiração da licença é exibida na página de definições da licença. Quando o contrato expira e não houver renovação, o software solicitará um novo código de registo e bloqueará funcionalidades.

Desinstalação do software

Desinstale a aplicação como qualquer outra app no seu tablet, conforme ilustrado abaixo:





14. Manutenção, manuseamento e eliminação

- As instruções devem ser lidas antes da utilização.
- Lance as atualizações quando solicitado pelo software ao iniciar.
- Note que, para o mercado dos Estados Unidos da América, foi incluído um Plano de Controlo de Alterações Predeterminado (PCCP). Este PCCP é implementado para o modelo de Machine Learning incorporado no dispositivo FETOLY, que pode modificar o desempenho, os dados de entrada ou o uso do dispositivo. É, portanto, fortemente

recomendado manter o dispositivo regularmente ligado à internet para permitir a instalação automática de atualizações.

- Insira o código de registo quando solicitado pelo software ao iniciar.
- Para descomissionar e eliminar o software, desinstale a aplicação através do sistema Android, como faria com qualquer aplicação no seu tablet, nas definições da app, conforme ilustrado acima no parágrafo Desinstalação do software. Esta desinstalação removerá todos os dados ligados à utilização do FETOLY, incluindo a licença, no seu tablet.

Símbolos utilizados na rotulagem (página "sobre"):

	Fabricante (símbolo da fábrica preenchido)
	Dispositivo marcado CE
	Identificador Único do Dispositivo (UDI) 01: UDI-DI 11: Data de fabrico 8012: Versão do software
	Consultar Instruções de Utilização
	A lei federal restringe este dispositivo à venda sob prescrição de um médico
	Dispositivo Médico
	Data de fabrico (símbolo da fábrica vazio)
	Nome e endereço do representante suíço

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ (ΕΛΛΗΝΙΚΑ)

1. Ταυτοποίηση συσκευής

FETOLY

Λογισμικό υποβοήθησης υπερηχογραφικής απεικόνισης της καρδιάς και του εγκεφάλου του εμβρύου.

Έκδοση λογισμικού που συνδέεται με τις παρούσες οδηγίες χρήσης (IFU): V2026.02.25

2. Ενημέρωση

Το FETOLY έχει επικαιροποιηθεί ως εξής για την Έκδοση V2026.02.25:

- Το FETOLY είναι πλέον συμβατό με iOS
- Οι ακόλουθες μετρήσεις προστέθηκαν βάσει της Τροποποίησης #4 του Σχεδίου Ελέγχου Προκαθορισμένων Αλλαγών (PCCP): PLAS, λόγος CSP, λόγος VP
- Η Διακοιλιακή και η Διαθαλαμική όψη έχουν συγχωνευθεί στην Αξονική όψη.
- Οι Οδηγίες χρήσης επικαιροποιήθηκαν ώστε να αποσαφηνίζεται η λειτουργικότητα της προβολής των σημείων-κλειδιών και να προστεθεί μια προειδοποίηση που εξηγεί ότι το λογισμικό δεν πρέπει να χρησιμοποιείται με τη μέθοδο της διακολπικής σάρωσης
- Η απόδοση ανίχνευσης μοντέλου AI έχει βελτιωθεί σύμφωνα με την Τροποποίηση #1 του PCCP
- Είναι πλέον δυνατή η ενεργοποίηση της λειτουργίας TLS (Ασφάλεια στο επίπεδο μεταφοράς) για την εξαγωγή DICOM (Ψηφιακή απεικόνιση και επικοινωνία στην ιατρική)

Οι δοκιμές επαλήθευσης έχουν ξεκινήσει εκ νέου πλήρως για να επαληθευτεί ότι δεν υπάρχει αντίκτυπος της ενημέρωσης στις λειτουργικότητες της συσκευής. Η μεθοδολογία που ακολουθείται είναι η ίδια όπως και για την αρχική έκδοση του προϊόντος.

3. Ταυτοποίηση κατασκευαστή

Το FETOLY κατασκευάζεται από την:

DIAGNOLY

2 Place de Francfort, 69003 LYON, Γαλλία

Τηλ.: +33(0)6.58.49.07.84

Email παραπόνων για τα προϊόντα: support@diagnoly.com

Παρακαλούμε να αναφέρετε οποιοδήποτε σοβαρό περιστατικό στην Diagnoly μέσω της διεύθυνσης ηλεκτρονικού ταχυδρομείου παραπόνων για τα προϊόντα και στην Αρμόδια Αρχή της χώρας σας.

CE 0197

4. Περιγραφή και παρουσίαση της συσκευής

Το Fetoly είναι ένα λογισμικό που στοχεύει να βοηθήσει τους χειριστές υπερηχογράφων, τους μαιευτήρες, τους ακτινολόγους, τους ειδικούς της μητρικής-εμβρυϊκής ιατρικής και τους παιδοκαρδιολόγους (που ορίζονται ως επαγγελματίες υγείας, δηλαδή ΕΥ) να πραγματοποιούν εμβρυϊκές υπερηχογραφικές εξετάσεις του εγκεφάλου και της καρδιάς του εμβρύου σε πραγματικό χρόνο. Το Fetoly μπορεί να χρησιμοποιηθεί από τους ΕΥ κατά τη διάρκεια υπερηχογραφικών εξετάσεων εμβρύου στο δεύτερο και το τρίτο τρίμηνο (παράθυρο ηλικίας κύησης: από τις 17 έως τις 40 εβδομάδες).

Το λογισμικό προορίζεται να βοηθήσει τους ΕΥ στην αξιολόγηση της πληρότητας της εξέτασης υπερήχων εγκεφάλου και καρδιάς του εμβρύου σύμφωνα με τις εθνικές και διεθνείς κατευθυντήριες οδηγίες. Το Fetoly προορίζεται επίσης να χρησιμοποιηθεί για την πραγματοποίηση βιομετρικών μετρήσεων του εγκεφάλου/της καρδιάς του εμβρύου σύμφωνα με τις εθνικές και διεθνείς κατευθυντήριες οδηγίες.

Για να χρησιμοποιηθεί το Fetoly, το λογισμικό πρέπει να εγκατασταθεί σε μια συσκευή υλικού η οποία είναι συνδεδεμένη με ένα μηχάνημα υπερηχογραφίας μέσω σύνδεσης HDMI. Το λογισμικό λαμβάνει εικόνες υπερήχων που καταγράφονται από το συνδεδεμένο μηχάνημα υπερηχογραφίας σε πραγματικό χρόνο. Ο αλγόριθμος βαθιάς μάθησης παγωμένου μοντέλου του λογισμικού, ο οποίος εκπαιδεύτηκε με εποπτευόμενη μάθηση, αναλύει εικόνες αυτής της ροής εικόνων υπερήχων για να ανιχνεύσει όψεις εγκεφάλου/καρδιάς, τα κριτήρια ποιότητας σε αυτές τις προβολές και για να κάνει βιομετρικές μετρήσεις της καρδιάς και του εγκεφάλου.

Το λογισμικό παρέχει τις ακόλουθες πληροφορίες, που είναι προσβάσιμες για τον χρήστη:

17. **Πληρότητα εξέτασης**: Το λογισμικό εμφανίζει σε πραγματικό χρόνο ποιες όψεις εγκεφάλου/καρδιάς και ποια κριτήρια ποιότητας επαληθεύονται από το λογισμικό κατά τη διάρκεια της εξέτασης. Οι επαληθευμένες όψεις εγκεφάλου/καρδιάς και τα κριτήρια ποιότητας είναι προσβάσιμα από τους κλινικούς ιατρούς ανά πάσα στιγμή στη διάρκεια της υπερηχογραφικής εξέτασης, σε πραγματικό χρόνο.
18. **Βιομετρικές ποσοτικές μετρήσεις:** Το λογισμικό εμφανίζει σε πραγματικό χρόνο ποιες μετρήσεις εγκεφάλου και καρδιάς προβάλλονται και εκτελούνται από το λογισμικό κατά τη διάρκεια της εξέτασης, καθώς και αν οι μετρήσεις είναι εντός ή εκτός εύρους σε σύγκριση με τα εύρη αναφοράς που ορίζονται σύμφωνα με την τεχνολογία αιχμής. Οι επαληθευμένες μετρήσεις καρδιάς και εγκεφάλου είναι προσβάσιμες για τους κλινικούς ιατρούς ανά πάσα στιγμή στη διάρκεια της υπερηχογραφικής εξέτασης, στο παρασκήνιο.
19. **Απεικόνιση εξέτασης:** Το λογισμικό επιλέγει ένα υποσύνολο εικόνων που απεικονίζει
    - τις επαληθευμένες όψεις και τα κριτήρια ποιότητας. Αυτές οι εικόνες μπορούν να ελεγχθούν από κλινικούς ιατρούς για να επαληθευτεί η παρουσία των όψεων και των κριτηρίων. Προαιρετικά, οι κλινικοί ιατροί μπορούν να εμφανίσουν τον εντοπισμό των κριτηρίων ποιότητας που ανιχνεύθηκαν σε επιλεγμένες εικόνες.
    - κάθε μέτρηση. Για κάθε μέτρηση, το λογισμικό εμφανίζει μια εικόνα με τη μέτρηση σχεδιασμένη (με κίτρινο χρώμα) και τη μετρούμενη τιμή (στο κάτω μέρος). Το φυσιολογικό εύρος για τη συγκεκριμένη μέτρηση υπενθυμίζεται επίσης στον χρήστη. Ο χρήστης μπορεί να μετακινήσει τα σημεία-κλειδιά και το λογισμικό ενημερώνει τις μετρήσεις αναλόγως.
20. **Αναφορά εξέτασης:** Το λογισμικό επιτρέπει στον χρήστη να εξαγάγει μια αναφορά εξέτασης η οποία περιλαμβάνει:
    - Περίληψη των μετρήσεων και της πληρότητας.
    - Απεικονίσεις (εικόνες).

Ορισμός πλήρους εξέτασης

Για την εμβρυϊκή καρδιά

Πίνακας 12: Κατάλογος των 52 κριτηρίων ποιότητας που καθορίζουν την ποιότητα των 5 όψεων, τα οποία συνιστώνται από τη Διεθνή Εταιρεία Υπερήχων στη Μαιευτική και τη Γυναικολογία για τον έλεγχο της καρδιάς του εμβρύου κατά το 2ο και το 3ο τρίμηνο της κύησης.

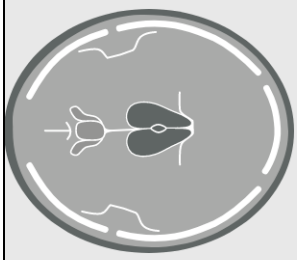
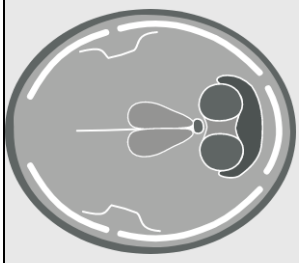
Όψεις της καρδιάς	***Κριτήρια ποιότητας για τις όψεις***	
 ***(A) ABD Κοιλιακή όψη (n = 8)***	*(A1) Sp*	*Σπονδυλική στήλη*
	(A2) lRb	*Αριστερή πλευρά*
	(A3) rRb	*Δεξιά πλευρά*
	(A4) Ao	*Κατιούσα αορτή*
	(A5) VC	*Κάτω κοίλη φλέβα*
	(A6) St	*Στόμαχος*
	(A7) Uv	*Ομφαλική φλέβα*
	(A8) aA	*Πρόσθια κοιλιακή χώρα*
 ***(B) 4CH Όψη τεσσάρων θαλάμων (n = 19)***	*(B1) Sp*	*Σπονδυλική στήλη*
	(B2) lRb	*Αριστερή πλευρά*
	(B3) rRb	*Δεξιά πλευρά*
	(B4) Ao	*Κατιούσα αορτή*
	(B5) lPV	*Αριστερή πνευμονική φλέβα*
	(B6) rPV	*Δεξιά πνευμονική φλέβα*
	(B7) LA	*Αριστερός κόλπος*
	(B8) RA	*Δεξιός κόλπος*
	(B9) FOF	*Πρωτογενές διάφραγμα (βαλβίδα του Vieussens ή πτερύγιο του ωοειδούς τρήματος)*
	(B10) FO	*Ανοικτό ωοειδές τρήμα*
	(B11) MV	*Μιτροειδής βαλβίδα*
	(B12) TV	*Τριγλώχινα βαλβίδα*
	(B13) bCr	*Σύνδεση μεταξύ καρδιακού σταυρού και κολπικού διαφράγματος (διάφραγμα του κώνου)*
	(B14) Cr	*Μετατόπιση της κολποκοιλιακής βαλβίδας στον καρδιακό σταυρό*
	(B15) tCr	*Σύνδεση μεταξύ μεσοκοιλιακού διαφράγματος και καρδιακού σταυρού*
	(B16) IVS	*Μεσοκοιλιακό διάφραγμα*
	(B17) LV	*Αριστερή κοιλία*
	(B18) RV	*Δεξιά κοιλία*
	(B19) Str	*Στέρνο*
	(C1) LA	*Αριστερός κόλπος*
	(C2) aAo	*Εγγύς ανιούσα αορτή*
	(C3) SV	*Μηνοειδείς βαλβίδες*
	(C4) LV	*Αριστερή κοιλία*

 ***(C) LVOT*** ***Όψη οδού εκροής αριστερής κοιλίας*** ***(n = 6)***	*(C5) IVS*	*Μεσοκοιλιακό διάφραγμα*
	(C6) RV	*Δεξιά κοιλία*
 ***(D) RVOT*** ***Όψη οδού εκροής δεξιάς κοιλίας*** ***(n = 10)***	*(D1) dAo*	*Κατιούσα αορτή*
	(D2) Tr	*Τραχεία / βρόγχοι*
	(D3) lPA	*Αριστερή πνευμονική αρτηρία*
	(D4) Du	*Αρτηριακός πόρος*
	(D5) rPA	*Δεξιά πνευμονική αρτηρία*
	(D6) Or	*Έκφυση των πνευμονικών αρτηριών*
	(D7) S	*Διάφραγμα μεταξύ στελέχους πνευμονικής αρτηρίας και ανιούσας αορτής*
	(D8) aAo	*Ανιούσα αορτή*
	(D9) SVC	*Άνω κοίλη φλέβα*
	(D10) PA	*Πνευμονικό στέλεχος*
 ***(E) 3VX*** ***Όψη τριών αγγείων*** ***(n = 9)***	*(E1) Sp*	*Σπονδυλική στήλη*
	(E2) Tr	*Τραχεία*
	(E3) ES	*Πλευρικός χώρος στα αριστερά του πόρου / της πνευμονικής αρτηρίας*
	(E4) DuA	*Τόξο αρτηριακού πόρου συνδεδεμένο με την κατιούσα αορτή*
	(E5) Du	*Τόξο αρτηριακού πόρου μη συνδεδεμένο με την κατιούσα αορτή*
	(E6) aAo	*Ανιούσα αορτή*
	(E7) aAr	*Αορτικό τόξο*
	(E8) SVC	*Άνω κοίλη φλέβα*
	(E9) Th	*Θύμος αδένας / στέρνο*

*Οι διεθνείς και εθνικές κατευθυντήριες οδηγίες [Carvalho2023] συνιστούν 5 εμβρυϊκές καρδιακές όψεις για την τυπική υπερηχογραφική εξέταση 2ου και 3ου τριμήνου: (Α) Κοιλιακή όψη, (Β) Όψη τεσσάρων θαλάμων, (Γ) Όψη οδού εκροής αριστερής κοιλίας, (Δ) Όψη οδού εκροής δεξιάς κοιλίας, (Ε) Όψη τριών αγγείων. Η ποιότητα αυτών των 5 όψεων της καρδιάς εξαρτάται από την παρουσία 52 ανατομικών κριτηρίων ποιότητας εντός των όψεων (**Πίνακας 1**). Έτσι, μια εξέταση μπορεί να οριστεί ως πλήρης όταν και οι 5 καρδιακές όψεις και τα ποιοτικά τους κριτήρια λαμβάνονται από τον ΕΥ.*

Για τον εγκέφαλο του εμβρύου

Πίνακας 13: Κατάλογος των 34 κριτηρίων ποιότητας που καθορίζουν την ποιότητα των 3 όψεων, τα οποία συνιστώνται από τη Διεθνή Εταιρεία Υπερήχων στη Μαιευτική και τη Γυναικολογία για τον έλεγχο του εγκεφάλου του εμβρύου κατά το 2ο και το 3ο τρίμηνο της κύησης.

Όψεις του εγκεφάλου	***Κριτήρια ποιότητας για τις όψεις***	
 ***(F) TV*** ***Αξονική όψη*** ***(n = 18)***	*(F1) aFx*	*Πρόσθιο δρέπανο*
	(F2) CSP	*Κοιλότητα του διαφανούς διαφράγματος*
	(F3) For	*Ψαλίδα*
	(F4) dAV	*Άπω πρόσθια κοιλία*
	(F5) pAV	*Εγγύς πρόσθια κοιλία*
	(F6) AC	*Αμφιμηνοειδής δεξαμενή*
	(F7) Atr	*Κόλπος*
	(F8) CP	*Χοριοειδές πλέγμα*
	(F9) POS	*Βρεγματοϊνιακή αύλακα*
	(F10) pFx	*Οπίσθιο δρέπανο*
	(F11) dCS	*Άπω στεφανιαία ραφή*
	(F12) pCS	*Εγγύς στεφανιαία ραφή*
	(F13) SF	*Σχισμή του Sylvius*
	(F14) Sk	*Κρανίο*
	(ΣT15) Sep	*Διαχωρισμός των θαλάμων*
	(F16) 3V	*3η Κοιλία*
	(F17) dTh	*Άπω τμήμα του θαλάμου*
	(F18) pTh	*Εγγύς τμήμα του θαλάμου*
 ***(G) TC*** ***Διαπαρεγκεφαλιδική όψη*** ***(n = 8)***	*(G1) dTh*	*Άπω τμήμα του θαλάμου*
	(G2) pTh	*Εγγύς τμήμα του θαλάμου*
	(G3) 4V	*4η Κοιλία*
	(G4) Ver	*Σκώληκας της παρεγκεφαλίδας*
	(G5) dCH	*Άπω ημισφαίριο της παρεγκεφαλίδας*
	(G6) pCH	*Εγγύς ημισφαίριο της παρεγκεφαλίδας*
	(G7) CB	*Όριο της παρεγκεφαλίδας*
	(G8) CM	*Μεγάλη δεξαμενή*
 ***(I) SAG*** ***Οβελιαία όψη (προφίλ)*** ***(n = 8)***	*(I1) NB*	*Ρινικό οστό*
	(I2) uVer	*Άνω τμήμα του σκώληκα*
	(I3)	*Κάτω τμήμα του σκώληκα*
	(I4) Fas	*Αέτωμα της οροφής της τέταρτης κοιλίας*
	(I5) rgCC	*Ρύγχος και γόνυ του μεσολοβίου*
	(I6) bCC	*Σώμα του μεσολοβίου*
	(I7) sCC	*Σπληνίο του μεσολοβίου*
	(I8) CSP	*Κοιλότητα του διαφανούς διαφράγματος*

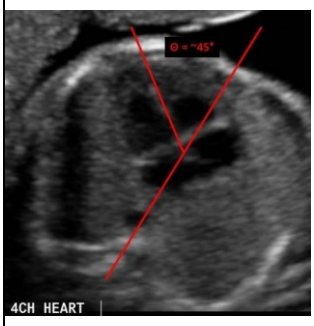
Βιομετρικές μετρήσεις και διαστήματα αναφοράς

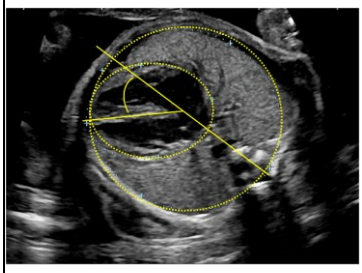
Το FETOLY παρέχει τρεις τύπους αυτοματοποιημένων βιομετρικών μετρήσεων:

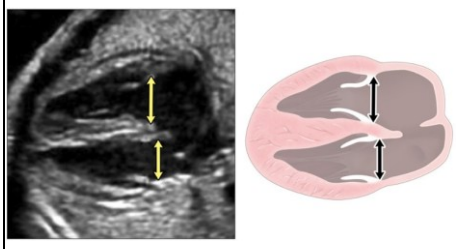
- **Μέτρηση γωνίας** που εμφανίζεται σε μοίρες (°).
- **Μέτρηση αναλογίας** (μια απόσταση κανονικοποιημένη ως προς μια άλλη απόσταση, που μπορεί να παρουσιάζεται είτε ως λόγος είτε ως ποσοστό).
- **Αριθμός** των ανατομικών ορόσημων που εντοπίστηκαν.

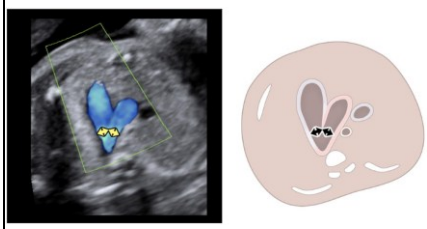
Κατάλογος των μετρήσεων και των διαστημάτων αναφοράς τους:

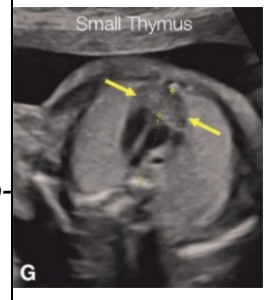
Ο παρακάτω πίνακας περιγράφει λεπτομερώς τις βιομετρικές μετρήσεις που παρέχονται από το FETOLY και τα αντίστοιχα κανονικά διαστήματα αναφοράς τους με βάση την καθιερωμένη βιβλιογραφία.

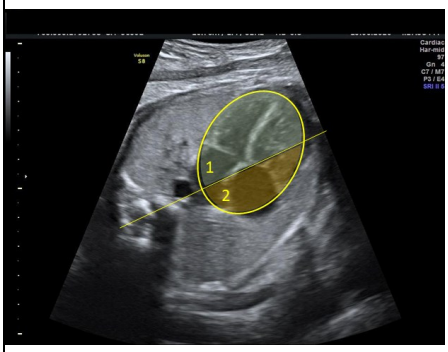
Παράμετρος	*Πληροφορίες προσβάσιμες στο FETOLY (περιγραφή και πηγές)*
(M1) Καρδιακός άξονας	***Τι είναι ο καρδιακός άξονας (CAx);***  *(πηγή: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* *Ο **καρδιακός άξονας** (ή **καρδιακή γωνία**) αναφέρεται στον προσανατολισμό της καρδιάς σε σχέση με τη μέση γραμμή του θώρακα, που μετράται στην όψη τεσσάρων θαλάμων. Καθορίζεται από τη γωνία μεταξύ μιας γραμμής κατά μήκος του μεσοκοιλιακού διαφράγματος και μιας προσθιοπίσθιας γραμμής που διχοτομεί τον θώρακα.* *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη, το στέρνο και τους τέσσερις θαλάμους. Οι αριστερές και οι δεξιές πλευρές θα πρέπει να είναι παρούσες και ορατές ως μεμονωμένες πλευρές.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες της Διεθνούς Εταιρείας Υπερήχων στη Μαιευτική και τη Γυναικολογία (ISUOG) υποδεικνύουν ότι η εξέταση του καρδιακού ελέγχου θα πρέπει να περιλαμβάνει τους τέσσερις θαλάμους και η αξιολόγησή της θα πρέπει να περιλαμβάνει τον καρδιακό άξονα («Η φυσιολογική εμβρυϊκή καρδιά βρίσκεται κυρίως στα αριστερά, με την καρδιακή κορυφή να δείχνει προς τα αριστερά υπό γωνία 45 ± 20° σε σχέση με τον προσθιοπίσθιο άξονα του θώρακα») (Carvalho2023). Παραπέμπουν στο (Comstock1987), όπου παρέχεται το εύρος αναφοράς για τον καρδιακό άξονα.* *Οι κατευθυντήριες οδηγίες της Αμερικανικής Εταιρείας Ηχοκαρδιογραφίας (ASE) επίσης συνιστούν την αξιολόγηση του καρδιακού άξονα («Ο καρδιακός άξονας είναι*

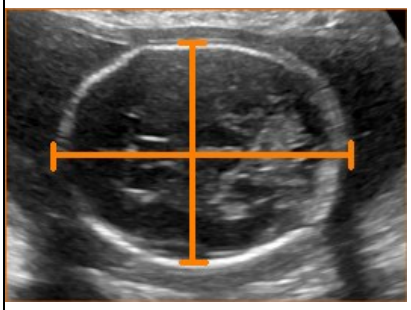
	μια συνιστώμενη συνιστώσα της εμβρυϊκής ηχοκαρδιογραφικής δισδιάστατης απεικόνισης [...] φυσιολογικές τιμές 35–65°) (Moon-Grady2023). ***Διαθέσιμα διαστήματα αναφοράς:*** • **Comstock (1987):** (Μέση τιμή ± 2 SD) o 17-40GA: [25° - 65°]. • **ASE (2023):** (εύρος αναφοράς καθοριζόμενο από κατευθυντήριες οδηγίες) o 17-40GA: [35° - 65°]
(M2) Καρδιοθωρακική αναλογία	***Τι είναι η καρδιοθωρακική αναλογία;***  *(πηγή: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Η εμβρυϊκή καρδιοθωρακική αναλογία (CTR) είναι ο λόγος της εγκάρσιας περιμέτρου της επικαρδιακής επιφάνειας της καρδιάς προς την εγκάρσια περίμετρο του θώρακα που μετράται στην όψη τεσσάρων θαλάμων κατά τη διάρκεια της διαστολής.* *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη, το στέρνο και τους τέσσερις θαλάμους. Οι αριστερές και οι δεξιές πλευρές θα πρέπει να είναι παρούσες και ορατές ως μεμονωμένες πλευρές.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες της ASE υποδεικνύουν ότι η καρδιοθωρακική αναλογία είναι υποχρεωτική συνιστώσα ενός εμβρυϊκού ηχοκαρδιογραφήματος («Τυπικές βιομετρικές μετρήσεις από μια αξονική εικόνα στο επίπεδο της όψης τεσσάρων θαλάμων. Η καρδιοθωρακική αναλογία υπολογίζεται από τη μέτρηση της εσωτερικής περιμέτρου (ή του εμβαδού) του θώρακα και της επικαρδιακής επιφάνειας της καρδιάς») (Moon-Grady2023).* *Οι κατευθυντήριες οδηγίες του Αμερικανικού Ινστιτούτου Υπερήχων στην Ιατρική (AIUM) επίσης υποδεικνύουν ότι η καρδιοθωρακική αναλογία είναι μια απαιτούμενη καρδιακή βιομετρική μέτρηση (AIUM2019). Οι κατευθυντήριες οδηγίες της ISUOG επίσης συνιστούν αυτή τη μέτρηση («Τα βασικά στοιχεία της φυσιολογικής όψης τεσσάρων θαλάμων στο δεύτερο τρίμηνο περιλαμβάνουν καρδιακή περιοχή που δεν υπερβαίνει το ένα τρίτο της θωρακικής περιοχής») (Carvalho2013). Το εγχειρίδιο του Abuhamad (2009) επίσης συνιστά την αξιολόγηση των καρδιακών διαστάσεων («Οι καρδιακές διαστάσεις του εμβρύου μπορούν εύκολα να αξιολογηθούν μετρώντας την αναλογία της καρδιακής περιμέτρου ή περιοχής προς τη θωρακική περίμετρο ή περιοχή που λαμβάνονται στο επίπεδο της όψης τεσσάρων θαλάμων) (Abuhamad2009). Οι κατευθυντήριες οδηγίες της Αμερικανικής Καρδιολογικής Εταιρείας (Donofrio2014) και το εγχειρίδιο του Abuhamad παραπέμπουν αμφότερες στο (Paladini1990) για το εύρος αναφοράς.*

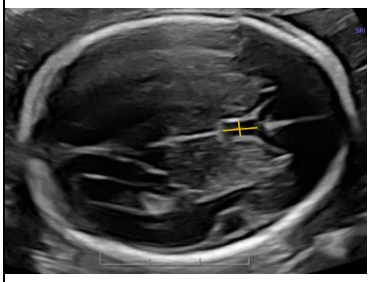
	Διαθέσιμα διαστήματα αναφοράς: • **Paladini (1990):** (2,5ο και 97ο εκατοστημόριο όσον αφορά την περίμετρο) ○ 17GA: [0,40 - 0,52] ○ 18GA: [0,40 - 0,52] ○ 19GA: [0,42 - 0,51] ○ … ○ 40GA: [0,46 - 0,56] • **Garcia-Otero (2020)**: (5ο και 95ο εκατοστημόριο όσον αφορά το εμβαδόν) ○ 18GA: [0,16 - 0,25] ○ 19GA: [0,16 - 0,26] ○ … ○ 40GA: [0,21 - 0,35] • **ASE** (Moon-Grady2023): (εύρος καθορισμένο από τις κατευθυντήριες οδηγίες για τη βέλτιστη βαθμολογία εμβρύου όσον αφορά το εμβαδόν) ○ 17-40GA: [0,20-0,35]
(M3) Λόγος πλατών των κοιλιών	***Τι είναι ο λόγος της δεξιάς προς την αριστερή κοιλία;***  *(πηγή: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Ο **λόγος δεξιάς-αριστερής κοιλία (TV/MV)** αναφέρεται στην αναλογία της δακτυλιοειδούς διαμέτρου της τριγλώχινας βαλβίδας (TV) προς τη δακτυλιοειδή διάμετρο της μιτροειδούς βαλβίδας (MV), η οποία χρησιμοποιείται για την αξιολόγηση της καρδιακής μορφολογίας στα έμβρυα. Προσδιορίζεται συγκρίνοντας τις διαμέτρους της TV και της MV στα σημεία τους με το μεγαλύτερο πλάτος, κατά τη διάρκεια της διαστολής.* *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη και το στέρνο. Οι αριστερές και οι δεξιές πλευρές θα πρέπει να είναι παρούσες και ορατές ως μεμονωμένες πλευρές. Οι όψεις τεσσάρων θαλάμων πρέπει να είναι ορατές και να έχουν καλή αντίθεση.* *Σημείωση: Υπάρχουν δύο συμβάσεις για τη μέτρηση της κοιλιακής διαμέτρου (Schneider2005): η μέτρηση στο επίπεδο των βαλβίδων ή της τελοδιαστολικής διάστασης. Λάβετε υπόψη ότι για αυτή τη μέτρηση χρησιμοποιείται η πρώτη.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες του AIUM υποδεικνύουν ότι η σύγκριση των δακτυλίων της τριγλώχινας και της μιτροειδούς βαλβίδας στη διαστολή είναι μια απαιτούμενη καρδιακή βιομετρική μέτρηση («Δακτύλιος της τριγλώχινας και της μιτροειδούς βαλβίδας σε διαστολή ([...] σύγκριση βαλβίδων αριστερής-δεξιάς πλευράς) είναι μια*

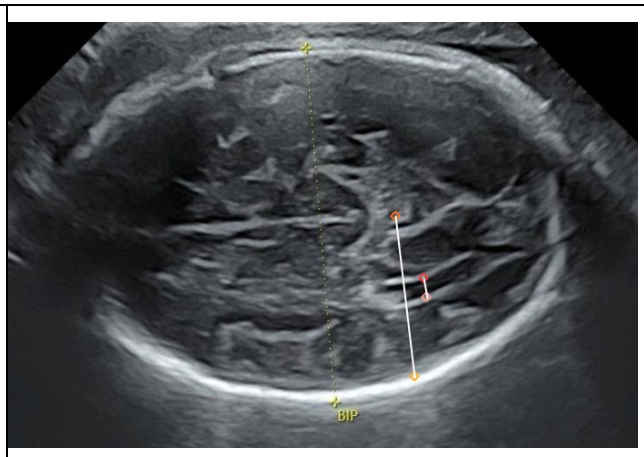
	απαιτούμενη καρδιακή βιομετρική μέτρηση») (AIUM2019). Παραπέμπουν στο (DeVore2017), (Lee2009) και (Schneider2005) για τα εύρη τιμών. *Οι κατευθυντήριες οδηγίες της ISUOG επίσης υποδεικνύουν ότι η ασυμμετρία δεξιάς-αριστερής πλευράς απαιτεί περαιτέρω διερεύνηση («Οι δύο κοιλίες θα πρέπει να φαίνονται παρόμοιες σε μέγεθος. Αν και μια ήπια κοιλιακή δυσαναλογία μπορεί να εμφανιστεί ως φυσιολογική παραλλαγή στο τρίτο τρίμηνο της κύησης, η ασυμμετρία δεξιάς-αριστερής πλευράς στο μέσο της κύησης απαιτεί περαιτέρω διερεύνηση») (Carvalho2023). Γίνεται παραπομπή στο (Kirk1999) για το εύρος αναφοράς.* *Οι κατευθυντήριες οδηγίες της ASE επίσης υποδεικνύουν ότι η σχέση μεγέθους της κοιλίας είναι μια υποχρεωτική αξιολόγηση του εμβρυϊκού ηχοκαρδιογραφήματος («Ο δακτύλιος της κολποκοιλιακής βαλβίδας στην πρώιμη διαστολή απαιτείται ως μέρος του πλήρους υπερηχοκαρδιογραφήματος») (Moon-Grady2023). Στο εγχειρίδιο του Abuhamed (2012) επισημαίνεται επίσης η σημασία του λόγου μεταξύ του πλάτους της δεξιάς κοιλίας και εκείνου της αριστερής κοιλίας, με τιμή 1,19 σε φυσιολογικά έμβρυα.* ***Διαθέσιμα διαστήματα αναφοράς:*** • **Gabbay-Benziv (2015)** (Gabbay-Benziv2015): (2,5ο και 97ο εκατοστημόριο) ○ 17GA: [0,87 - 1,22] ○ 18GA: [0,86 - 1,22] ○ 19GA: [0,86 - 1,22] ○ … ○ 38GA: [0,87 - 1,30] • **Garcia-Otero (2020)**: (5ο και 95ο εκατοστημόριο) ○ 18GA: [0,82 - 1,21] ○ 19GA: [0,82 - 1,22] ○ … ○ 40GA: [0,86 - 1,27]
(M4) Αναλογία αγγείων	***ΤΙ είναι η αναλογία μεγάλων αγγείων;***  *(πηγή: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *Η αναλογία των αγγείων μεγάλου μεγέθους (Ao/Du) αναφέρεται στον λόγο μεταξύ της διαμέτρου του ισθμού της αορτής (Ao) και της διαμέτρου του πόρου (Du), στην όψη των τριών αγγείων. Προσδιορίζεται με μέτρηση της διαμέτρου του πόρου και της διαμέτρου του αορτικού τόξου στη βάση τους. Σημειώστε ότι ο λόγος διαμέτρου της μεσοθωρακικής πνευμονικής αρτηρίας (PA) προς την ανιούσα αορτή (Ao) χρησιμοποιείται επίσης στη βιβλιογραφία (Slodki2009).* *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη και το στέρνο, με ορατές και ευδιάκριτες τις αριστερές και δεξιές πλευρές. Ο αρτηριακός πόρος και η ανιούσα αορτή θα πρέπει να είναι ευδιάκριτα, και να επιδεικνύεται η σύνδεσή τους.*

	Τι συνιστούν οι κατευθυντήριες οδηγίες; *Οι αμερικανικές και διεθνείς εταιρείες, συμπεριλαμβανομένων των ASE, ISUOG, AIUM, AHA, υποδεικνύουν ότι η αξιολόγηση της σχέσης μεγέθους μεταξύ των μεγάλων αρτηριών είναι μια υποχρεωτική αξιολόγηση (Donofrio2014). («Είναι σημαντικό να εξακριβωθεί η κανονικότητα των δύο μεγάλων αρτηριών, συμπεριλαμβανομένου του μεγέθους τους [...] σε σχέση μεταξύ τους») (Carvalho2023). Στο εγχειρίδιο του Abuhamad (2012) επισημαίνεται επίσης η σημασία της σύγκρισης μεταξύ της διαμέτρου του αορτικού τόξου και εκείνης της κύριας πνευμονικής αρτηρίας, ειδικά στην περιοχή του ισθμού. Γίνεται παραπομπή στη μελέτη του Pasquini (2007) (Pasquini2007) για τα εύρη τιμών.* ***Διαθέσιμα διαστήματα αναφοράς:*** • **Pasquini (2007):** ○ Σταθερά: [0,86 - 1,12] (μέση τιμή ± SD) ○ Σταθερά: [0,74 - 1,23] (2,5ο και 97,5ο εκατοστημόριο) (Buyens2012)
(M5) Αριθμός αγγείων	***Τι είναι ο αριθμός των αγγείων;*** *Η εμβρυϊκή όψη τριών αγγείων (3VV) είναι ένα αξονικό επίπεδο που χρησιμοποιείται στην προγεννητική απεικόνιση για την αξιολόγηση των μεγάλων αγγείων της καρδιάς. Κατά κανόνα, αυτή η όψη δείχνει τρία αγγεία, συνήθως την πνευμονική αρτηρία, την αορτή και την άνω κοίλη φλέβα. Ο αριθμός των αγγείων επικεντρώνεται μόνο σε στρογγυλές ή επιμήκεις ανηχοϊκές δομές και αποκλείει την τραχεία και την κατιούσα αορτή.* *Η εικόνα θα πρέπει να αναδεικνύει τα αγγεία, με σαφή αντίθεση και διάκριση των δομών.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες της ISUOG συνιστούν ότι η αξιολόγηση της όψης των τριών αγγείων θα πρέπει να «περιλαμβάνει αξιολόγηση του αριθμού του αγγείου. Από τα αριστερά προς τα δεξιά, τα αγγεία είναι η πνευμονική αρτηρία, η αορτή και η δεξιά άνω κοίλη φλέβα» (Carvalho2023). Οι κατευθυντήριες οδηγίες της ASE επίσης τονίζουν ότι θα πρέπει να επισημαίνονται οι ανωμαλίες στον αριθμό των αγγείων (Moon-Grady2023). Σύμφωνα με το διεθνές πρότυπο, ο αναμενόμενος αριθμός αγγείων είναι τρία.*
(M6) Θυμο-θωρακικός λόγος	***Τι είναι ο θυμο-θωρακικός λόγος;***  *(πηγή: Abuhamad, A. Z., & Chaoui, R. (2022). A practical guide to fetal echocardiography: Normal and abnormal hearts (4th ed.). Wolters Kluwer)* *Ο **θυμο-θωρακικός λόγος** είναι ο λόγος της προσθιοπίσθιας διαμέτρου του θύμου προς την ενδοθωρακική διάμετρο του μεσοθωρακίου, όπως μετράται στην όψη τριών αγγείων και τραχείας.*

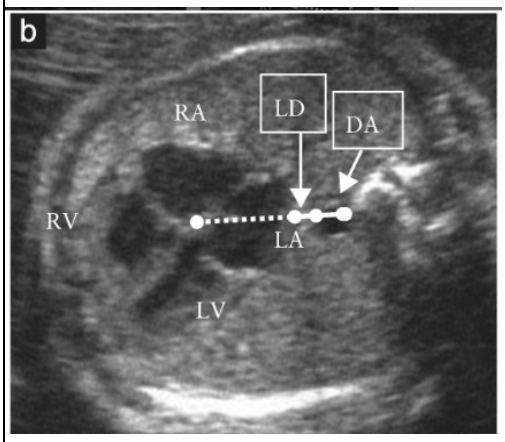
	Η εικόνα θα πρέπει να εμφανίζει τη σπονδυλική στήλη, το στέρνο και την ανιούσα αορτή, με τις αριστερές και τις δεξιές πλευρές ορατές ως μεμονωμένες δομές. Ο θύμος αδένας πρέπει να είναι ευδιάκριτος και αναγνωρίσιμος. ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες της ISUOG υποδεικνύουν ότι η «[αξιολόγηση της όψης τριών αγγείων] περιλαμβάνει αξιολόγηση της ευθυγράμμισης των αγγείων». (Carvalho2023) και ότι «μπορεί να βελτιώσει την ανίχνευση ανωμαλιών [...] της οδού εκροής». Παραπέμπουν στο (Chaoui2011) για την αξιολόγηση του θυμο-θωρακικού λόγου, για την ανίχνευση ανωμαλιών της οδού εκροής. Το εγχειρίδιο του Abuhamad (2022) υποδεικνύει επίσης τη σημασία της αξιολόγησης αυτής της παραμέτρου.* ***Διαθέσιμα διαστήματα αναφοράς:*** • **Chaoui (2011):** o Σταθερά καθ' όλη τη διάρκεια της κύησης: [0,36 - 0,53] (μέση τιμή ± 2 SD)
(M7) Καρδιοθωρακική θέση	***Τι είναι η καρδιοθωρακική θέση;***  *(εικόνα εμπνευσμένη από https://obgynkey.com/cardiac-chambers-the-four-chamber-and-short-axis-views/)* *Η **καρδιοθωρακική θέση** προσδιορίζεται με επέκταση της γραμμής του μεσοκοιλιακού διαφράγματος που διαιρεί τους κόλπους προς τα πίσω, έως ένα σημείο στη βάση της καρδιάς (Smith1995). Αυτό πραγματοποιείται στην όψη τεσσάρων θαλάμων υπολογίζοντας την αναλογία της περιοχής του αριστερού μέρους προς τη συνολική καρδιακή περιοχή. Αυτή η διαδικασία περιλαμβάνει τη σχεδίαση μιας έλλειψης πάνω από την καρδιά και τη διαίρεση της με μια προσθιοπίσθια γραμμή που διχοτομεί τον θώρακα (τη μέση γραμμή του θώρακα). Η αριστερή (1) και η δεξιά (2) περιοχή αντιπροσωπεύουν τις καρδιακές επιφάνειες που βρίσκονται στην αριστερή και δεξιά ανατομική πλευρά της μέσης γραμμής, αντίστοιχα. Η θέση εκφράζεται ως ο λόγος της αριστερής περιοχής προς τη συνολική καρδιακή περιοχή.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Η θέση της καρδιάς του εμβρύου μέσα στον θώρακα είναι μια σημαντική παράμετρος στην αξιολόγηση του εμβρύου. Η απόκλιση από τη φυσιολογική θέση δικαιολογεί την περαιτέρω διερεύνηση πιθανών ενδοθωρακικών, ενδοκαρδιακών ή εξωκαρδιακών ενδοθωρακικών παθολογικών καταστάσεων (Abdullah2000). Τόσο οι αμερικανικές όσο και οι διεθνείς κατευθυντήριες οδηγίες, συμπεριλαμβανομένων των ISUOG (2008), ASE (2004), AIUM (2013), AHA (2014), συνιστούν προσεκτική μέτρηση της θέσης της καρδιάς του εμβρύου μέσα στον θώρακα στην όψη τεσσάρων*

	θαλάμων κατά τη διάρκεια τυπικών μαιευτικών σαρώσεων (Donofrio2014). Σύμφωνα με αυτές τις κατευθυντήριες οδηγίες, η φυσιολογική καρδιά του εμβρύου βρίσκεται κυρίως στην αριστερή πλευρά του θώρακα, με τουλάχιστον το 50% (λόγος ≥ 0,5) της έκτασής της εντός του αριστερού θωρακικού χώρου («η καρδιά βρίσκεται κυρίως στην αριστερή πλευρά») (Carvalho2013) («πρέπει να δοθεί ιδιαίτερη προσοχή στον άξονα και τη θέση της καρδιάς. Το μεγαλύτερο μέρος της καρδιάς [θα πρέπει να βρίσκεται] στον αριστερό θώρακα») (Carvalho2023). Μελέτες επιβεβαιώνουν αυτές τις συστάσεις, με τον Chiappa (2009) και άλλους (Smith1995, Sever2021) να δηλώνουν ότι «τα δύο τρίτα της καρδιάς [θα πρέπει να βρίσκονται] στην αριστερή πλευρά του θώρακα». *Ενώ πολλές κατευθυντήριες οδηγίες ορίζουν ότι η φυσιολογική καρδιοθωρακική θέση ισούται με 0,66 (λόγος ≈ 2/3) και δεν πρέπει να υπολείπεται του 0,5, η βιβλιογραφία δεν ορίζει με σαφήνεια το ανώτερο όριο του φυσιολογικού εύρους. Οι χρήστες μπορούν είτε να οπτικοποιήσουν μόνο την τιμή μέτρησης χωρίς εύρος αναφοράς είτε να ορίσουν το δικό τους εύρος αναφοράς.*
(M8) Κεφαλικός δείκτης	***Τι είναι ο κεφαλικός δείκτης;***  *(πηγή: https://obimages.net/take-a-tour/normal-fetal-ultrasound-biometry/)* *Ο **κεφαλικός δείκτης** είναι ο λόγος της αμφιβρεγματικής διαμέτρου (BPD) προς την ινιομετωπική διάμετρο (OFD) πολλαπλασιασμένος επί 100. Ο κεφαλικός δείκτης δίνει μια ιδέα για το σχήμα της κεφαλής του εμβρύου. Η προσθιοπίσθια διάμετρος (OFD) μετράται με την τοποθέτηση του δρομέα από το εξωτερικό χείλος έως το εξωτερικό χείλος των κρανιακών οστών. Ένας πολύ χαμηλός κεφαλικός δείκτης υποδηλώνει δολιχοκεφαλία, ενώ ένας πολύ υψηλός κεφαλικός δείκτης μπορεί να υποδηλώνει βραχυκεφαλία. Όταν αυτή η παράμετρος είναι μη φυσιολογική, άλλες μετρήσεις, όπως η περίμετρος κεφαλής (HC), η περίμετρος της κοιλιακής χώρας ή το μήκος του μηριαίου οστού, θα πρέπει να χρησιμοποιούνται για την πρόβλεψη της ηλικίας του εμβρύου (Timor-Tritsch2012).* *Η εικόνα θα πρέπει να εμφανίζει μια αξονικά συμμετρική όψη του εγκεφάλου, καταγράφοντας το διαθαλαμικό επίπεδο με τα δύο ημισφαίρια ορατά και ευδιάκριτα.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες της ISUOG υποδεικνύουν ότι «ο κεφαλικός δείκτης είναι η αναλογία μεταξύ του μέγιστου πλάτους της κεφαλής (BPD) και του μέγιστου μήκους της (ινιομετωπική διάμετρος ή OFD), και αυτή η τιμή μπορεί να χρησιμοποιηθεί για τον χαρακτηρισμό του σχήματος της κεφαλής του εμβρύου. Το μη φυσιολογικό σχήμα της κεφαλής (π.χ. βραχυκεφαλία ή δολιχοκεφαλία) μπορεί να συσχετίζεται με σύνδρομα ή να είναι αποτέλεσμα ολιγοϋδραμνίου ή ισχιακής προβολής. Αυτό το εύρημα μπορεί επίσης να οδηγήσει σε ανακριβείς εκτιμήσεις της ηλικίας του εμβρύου όταν χρησιμοποιείται η BPD. Σε αυτές τις περιπτώσεις, οι μετρήσεις της HC είναι ακόμη πιο αξιόπιστες (Hadlock1981)» (Salomon2022).*

	Διαθέσιμα διαστήματα αναφοράς: • **Hadlock (1981):** o Σταθερά καθ' όλη τη διάρκεια της κύησης: [74 - 83] (μέση τιμή ± SD)
(M9) Λόγος CSP	***Τι είναι ο λόγος CSP;***  *(πηγή: Sichitiu et al. (2024). Revisiting the Implications of a Wide or Narrow Fetal Cavum Septi Pellucidi. In Journal of Ultrasound in Medicine (Vol. 43, Issue 8, pp. 1461–1466). Wiley)* ***Περιγραφή:*** *Ο **λόγος της κοιλότητας του διαφανούς διαφράγματος (CSP)** είναι ο λόγος μεταξύ του μήκους και του πλάτους της CSP. Προσδιορίζεται με μέτρηση του μήκους και του πλάτους της CSP και με υπολογισμό του λόγου του μήκους προς το πλάτος.* *Η εικόνα θα πρέπει να δείχνει μια αξονικά συμμετρική διακοιλιακή όψη του εγκεφάλου, με σαφή οπτικοποίηση της κοιλότητας του διαφανούς διαφράγματος (CSP) και των ανατομικών δομών της μέσης γραμμής.* ***Τι συνιστούν οι κατευθυντήριες οδηγίες;*** *Οι κατευθυντήριες οδηγίες της ISUOG υποδεικνύουν ότι το σχήμα της CSP έχει περιγραφεί ως ένας σχετικά αξιόπιστος δείκτης μερικής αγενεσίας του μεσολοβίου και παραθέτουν τις μελέτες των Karl (2017) και Shen (2015) για τα εύρη αναφοράς (Malinger2020).* *Οι κατευθυντήριες οδηγίες της Παγκόσμιας Ένωσης Περιγεννητικής Ιατρικής (WAPM) υποδεικνύουν ότι η CSP πρέπει να οπτικοποιηθεί και «η αποτυχία οπτικοποίησης της CSP ή ανώμαλη εμφάνισή του (Karl2017) είναι προγνωστική για ανωμαλίες των συνδέσμων. Ωστόσο, η φυσιολογική εμφάνιση της CSP δεν αποκλείει όλες τις ανωμαλίες [του μεσολοβίου]» (Robertis2021).* *Αυτή η παράμετρος μπορεί επίσης να βρεθεί σε υπερσύγχρονες τεχνικές βαθιάς μάθησης για τυπικά βιομετρικά στοιχεία (Coronado-Gutiérrez2023).* ***Διαθέσιμα διαστήματα αναφοράς:*** • **Karl (2017):** *Σταθερά καθ' όλη τη διάρκεια της κύησης: [1,5 - 3,3] (5ο και 95ο εκατοστημόριο)*
(M10) Λόγος της διαμέτρου της οπίσθιας εγκεφαλικής κοιλίας προς τη διάμετρο του	***Τι είναι ο λόγος της διαμέτρου της οπίσθιας εγκεφαλικής κοιλίας προς τη διάμετρο του ημισφαιρίου;***

ημισφαιρίου (λόγος VP)	
	
	*Η **λόγος της διαμέτρου της οπίσθιας εγκεφαλικής κοιλίας προς τη διάμετρο του ημισφαιρίου** είναι μια παράμετρος που χρησιμοποιείται για την αξιολόγηση της ανάπτυξης του εγκεφάλου, και συγκεκριμένα το μέγεθος της κοιλίας σε σχέση με το συνολικό μέγεθος του εγκεφάλου (ημισφαίριο).*
	
	Είναι η αναλογία μεταξύ των εξής:
	- *Διάμετρος οπίσθιας εγκεφαλικής κοιλίας (= πλάτος κόλπου) – συνήθως αναφέρεται στον κόλπο της πλάγιας κοιλίας (που βρίσκεται στη συμβολή του ινιακού, του κροταφικού και του βρεγματικού κέρατος).*
	- *Διάμετρος εγκεφαλικού ημισφαιρίου – η συνολική εγκάρσια διάμετρος του αντίστοιχου ημισφαιρίου του εγκεφάλου.*
	
	Η μέτρηση αυτή πρέπει να πραγματοποιείται στη διακοιλιακή όψη.
	
	Τι προτείνουν οι κατευθυντήριες οδηγίες;
	
	Οι κατευθυντήριες οδηγίες της ISUOG υποδεικνύουν ότι η μέτρηση του κολπικού πλάτους αποτελεί αναπόσπαστο μέρος του υπερηχογραφικού ελέγχου για δυσπλασία του ΚΝΣ και ότι το κολπικό πλάτος θα πρέπει να μετράται από το εσωτερικό έως το εσωτερικό και να είναι <10 mm καθ' όλη τη διάρκεια της κύησης.
	
	Η έγκριτη βιβλιογραφία (Nicolaides1994) τονίζει τον ρόλο του λόγου της διαμέτρου της οπίσθιας εγκεφαλικής κοιλίας προς τη διάμετρο του ημισφαιρίου στη βελτίωση της προγεννητικής εγκεφαλικής αξιολόγησης και της ακρίβειας του εμβρυϊκού ελέγχου, καθώς είναι ένας σχετικά αξιόπιστος δείκτης κοιλιομεγαλίας.
	
	Διαθέσιμα διαστήματα αναφοράς:
	- ***Nicolaides (1994):** (5ο και 95ο εκατοστημόριο)*
	  - *17GA: [0,29 - 0,45]*
	  - *18GA: [0,27 - 0,42]*
	  - *19GA: [0,26 - 0,40]*
	  - *…*
	
	39GA: [0,15 - 0,24]

(M11) PLAS (Οπίσθιος χώρος	***Τι είναι ο δείκτης PLAS (οπίσθιος χώρος αριστερού κόλπου);***

αριστερού κόλπου)	 *(Πηγή: Kawazu2014)* *Ο δείκτης PLAS είναι μια ηχοκαρδιογραφική μέτρηση που διενεργείται στα έμβρυα για την εκτίμηση του χώρου πίσω από τον αριστερό κόλπο. Υπολογίζεται από μια όψη τεσσάρων θαλάμων της καρδιάς του εμβρύου. Η μέτρηση περιλαμβάνει τον προσδιορισμό της απόστασης μεταξύ του οπίσθιου τοιχώματος του αριστερού κόλπου και του πρόσθιου τοιχώματος της κατιούσας αορτής (LD) και τη διαίρεση αυτής με τη διάμετρο της κατιούσας αορτής (DA). Ο υπολογισμός πραγματοποιείται κατά την τελοσυστολική φάση του καρδιακού κύκλου.* *Ο τύπος για τον δείκτη PLAS είναι:* ***Δείκτης PLAS = Απόσταση του αριστερού κόλπου από την φθίνουσα αορτή (LD) / Διάμετρος φθίνουσας αορτής (DA)*** ***Τι προτείνουν οι κατευθυντήριες οδηγίες; (Σκεπτικό και κλινική σημασία)*** *Η έγκριτη βιβλιογραφία (Kawazu2019, Anuwutnavin2023, Akkurt2015) έχει τονίσει τη σημασία του δείκτη PLAS ως μιας απλής και αναπαραγώγιμης μέτρησης στον εμβρυϊκό καρδιακό έλεγχο. Ο δείκτης PLAS, που αρχικά εισήχθη από τον (Kawazu2014), έχει αναγνωριστεί ως ένας ευαίσθητος δείκτης για την προγεννητική διάγνωση της ολικής ανώμαλης πνευμονικής φλεβικής σύνδεσης (TAPVC), μιας κατάστασης όπου οι πνευμονικές φλέβες δεν συνδέονται με τον αριστερό κόλπο. Αυξημένος δείκτης PLAS είναι ένας σημαντικός δείκτης της TAPVC* ***Διαθέσιμα διαστήματα αναφοράς:*** *Kawazu2014 και Kawazu2019: Σταθερά καθ' όλη τη διάρκεια της κύησης: Βέλτιστη τιμή αποκοπής* ***> 1,27*** *για την υποδήλωση TAPVC. Για τα φυσιολογικά έμβρυα, ο μέσος δείκτης PLAS αναφέρθηκε ως* ***0,62 ± 0,19.***

*Κάθε μέτρηση απαιτεί μια συγκεκριμένη οπτική γωνία υπερήχων, που αναφέρεται ως «**επιμέρους όψη**», η οποία πρέπει να πληροί συγκεκριμένες συνθήκες απεικόνισης ώστε να εξασφαλίζεται ακριβής μέτρηση. Μια επιμέρους όψη προκύπτει πάντα από μία από τις τυπικές όψεις ελέγχου των εμβρύων, αλλά απαιτεί επίσης πρόσθετες ειδικές συνθήκες. Για παράδειγμα, η μέτρηση του λόγου της δεξιάς προς την αριστερή κοιλία στην όψη τεσσάρων θαλάμων απαιτεί σωστή οπτικοποίηση των κοιλιακών ορίων, κάτι που είναι απαραίτητο για τον καρδιακό άξονα.*

Στον παρακάτω πίνακα αποτυπώνεται η αντιστοιχία μεταξύ των επιμέρους όψεων και των καρδιακών ή εγκεφαλικών όψεων που περιγράφονται στις κατευθυντήριες οδηγίες της ISUOG.

Όψη	*Επιμέρους όψη*
Όψη τεσσάρων θαλάμων	***Επιμέρους όψη 1 (M1):*** *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη, το στέρνο, τους τέσσερις θαλάμους και το μεσοκοιλιακό διάφραγμα. Οι αριστερές και οι δεξιές πλευρές θα πρέπει να είναι παρούσες και ορατές ως μεμονωμένες πλευρές.* ***Επιμέρους όψη 2 (M2):*** *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη, το στέρνο και τους τέσσερις θαλάμους. Οι αριστερές και οι δεξιές πλευρές θα πρέπει να είναι παρούσες και ορατές ως μεμονωμένες πλευρές.* ***Επιμέρους όψη 3 (M3):*** *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη και το στέρνο. Οι αριστερές και οι δεξιές πλευρές θα πρέπει να είναι παρούσες και ορατές ως μεμονωμένες πλευρές. Οι όψεις τεσσάρων θαλάμων πρέπει να είναι ορατές και να έχουν καλή αντίθεση.* ***Επιμέρους όψη 7 (M7):*** *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη, το στέρνο και τους τέσσερις θαλάμους.* ***Επιμέρους όψη 11 (M11):*** *Ο θώρακας φαίνεται στρογγυλεμένος, δεν έχει σχήμα ανοιχτού «V». Οι αριστερές και οι δεξιές πλευρές εμφανίζονται αμφότερες ως μεμονωμένες δομές, όχι ως πολλαπλές παράλληλες ή διαδοχικές γραμμές. Ο κόλπος και η αορτή, ειδικά τα οπίσθια τοιχώματά τους, καθώς και ο χώρος μεταξύ τους, είναι ευδιάκριτα, χωρίς παρεμπόδιση λόγω σκιάς.*
Όψη τριών αγγείων και όψη τριών αγγείων και τραχείας	***Επιμέρους όψη 4 (M4):*** *Η εικόνα θα πρέπει να περιλαμβάνει τη σπονδυλική στήλη και το στέρνο, με ορατές και ευδιάκριτες τις αριστερές και δεξιές πλευρές. Ο αρτηριακός πόρος και η ανιούσα αορτή θα πρέπει να είναι ευδιάκριτα, και να επιδεικνύεται η σύνδεσή τους.* ***Επιμέρους όψη 5 (M5):*** *Η εικόνα θα πρέπει να αναδεικνύει τα αγγεία, με σαφή αντίθεση και διάκριση των δομών.* ***Επιμέρους όψη 6 (M6):*** *Η εικόνα θα πρέπει να εμφανίζει τη σπονδυλική στήλη, το στέρνο και την ανιούσα αορτή, με τις αριστερές και τις δεξιές πλευρές ορατές ως μεμονωμένες δομές. Ο θύμος αδένας πρέπει να είναι ευδιάκριτος και αναγνωρίσιμος.*
Αξονική όψη	***Επιμέρους όψη 8 (M8):*** *Η εικόνα θα πρέπει να εμφανίζει μια αξονικά συμμετρική όψη του εγκεφάλου, καταγράφοντας το διαθαλαμικό επίπεδο με τα δύο ημισφαίρια ορατά και ευδιάκριτα.* ***Επιμέρους όψη 9 (M9):*** *Η εικόνα θα πρέπει να δείχνει μια αξονικά συμμετρική διακοιλιακή όψη του εγκεφάλου, με σαφή οπτικοποίηση της κοιλότητας του διαφανούς διαφράγματος (CSP) και των ανατομικών δομών της μέσης γραμμής.* ***Επιμέρους όψη 10 (M10):*** *Η εικόνα θα πρέπει να δείχνει μια αξονική όψη όπου είναι ορατή η βρεγματοϊνιακή αύλακα (POS).*

Λειτουργικότητα 1: μέτρηση πληρότητας

Το λογισμικό αξιολογεί, μέσω ενός αλγορίθμου βαθιάς μάθησης παγωμένου μοντέλου που εκπαιδεύτηκε με εποπτευόμενη μάθηση, την πληρότητα της υπερηχογραφικής εξέτασης του εμβρύου. Επαληθεύει εάν έχουν συγκεντρωθεί όλες οι πληροφορίες που αντιστοιχούν στις συνιστώμενες κατευθυντήριες οδηγίες για την εξέταση της καρδιάς/του εγκεφάλου του εμβρύου. Αυτές οι πληροφορίες αντιστοιχούν στην παρουσία:

- 5 κύριων όψεων της καρδιάς του εμβρύου και 52 κριτηρίων ποιότητας, που αναλύθηκαν προηγουμένως, επιτρέποντας τη συμμόρφωση στον έλεγχο της καρδιάς.
- 4 κύριων όψεων του εγκεφάλου του εμβρύου και 43 κριτηρίων ποιότητας, που αναλύθηκαν προηγουμένως, επιτρέποντας τη συμμόρφωση στον έλεγχο του εγκεφάλου.

Η σελίδα πληρότητας (**Σχήμα 1**) αποτελείται από:

- Ένα **κουμπί αναπαραγωγής/παύσης** που ξεκινά την ανάλυση των εικόνων που λαμβάνονται από το σύστημα υπερήχων στην αρχή της εξέτασης,
- Τον **αριθμό όψεων καρδιάς/εγκεφάλου** που επαληθεύεται από το λογισμικό από την αρχή της εξέτασης. Μια όψη της καρδιάς θεωρείται επαληθευμένη όταν ανιχνεύεται σε τουλάχιστον μία εικόνα,
- Μεμονωμένα κουμπιά για **καθένα από τα κριτήρια ποιότητας**, τα οποία αποκτούν **πράσινο χρώμα** κατόπιν επαλήθευσης από το λογισμικό.

Κάθε εικόνα που αναλύεται από το λογισμικό ενημερώνει δυναμικά τη σελίδα πληρότητας ως εξής:

- Εάν ένα κριτήριο ποιότητας εντοπιστεί στην εικόνα για πρώτη φορά, το κριτήριο επισημαίνεται ως **επαληθευμένο**, και το χρώμα του αλλάζει από λευκό σε **πράσινο**),
- Εάν εντοπιστεί ένα κριτήριο ποιότητας στην εικόνα αλλά έχει επαληθευτεί προηγουμένως, δεν επέρχονται αλλαγές,
- Εάν δεν εντοπιστεί ένα κριτήριο ποιότητας στην εικόνα, δεν πραγματοποιούνται αλλαγές.

Εάν ένα κριτήριο ποιότητας συσχετίζεται με μια ανωμαλία, η κατάσταση ανίχνευσης του κριτηρίου εξαρτάται από την οπτική του εμφάνιση:

- Εάν μια ανωμαλία μεταβάλλει ένα κριτήριο ποιότητας με τέτοιο τρόπο ώστε να αλλάξει την εμφάνισή του, το λογισμικό ενδέχεται να μην εντοπίσει το κριτήριο και η κατάσταση θα παραμείνει μη επαληθευμένη.
- Εάν μια ανωμαλία δεν επηρεάζει την εμφάνιση του κριτηρίου ποιότητας, το λογισμικό θα εντοπίσει το κριτήριο και θα το επισημάνει ως επαληθευμένο, αλλάζοντας το χρώμα του από λευκό σε **πράσινο.**

Λάβετε υπόψη ότι υπενθυμίζεται στην επισήμανση ότι δεν μπορεί να πραγματοποιηθεί διάγνωση ή έλεγχος με το FETOLY. Η μη επαλήθευση ενός κριτηρίου ποιότητας από το λογισμικό δεν υποδηλώνει εξ ορισμού παθολογική κατάσταση.

Η σελίδα πληρότητας ενημερώνεται συνεχώς σε πραγματικό χρόνο, επιτρέποντας στους χρήστες να ανατρέχουν σε αυτήν ανά πάσα στιγμή κατά τη διάρκεια της εξέτασής τους. Αυτό τους επιτρέπει να κάνουν γρήγορη επισκόπηση της σελίδας χωρίς να διαταραχθεί η ροή εργασιών της εξέτασης ή να απαιτηθούν πρόσθετες ενέργειες.

Υπενθυμίζουμε πως, όπως εξηγείται και στην ενότητα 10, το FETOLY δεν μπορεί να χρησιμοποιηθεί για την πραγματοποίηση διαγνωστικού ή προσυμπτωματικού ελέγχου. Η μη επαλήθευση ενός κριτηρίου ποιότητας από το λογισμικό δεν υποδηλώνει εξ ορισμού παθολογική κατάσταση.

Λειτουργικότητα 2: απεικόνιση πληρότητας

Αυτή η λειτουργικότητα αναπτύχθηκε για να ενισχύσει την ασφάλεια της αξιολόγησης πληρότητας, που εκτελείται από την πρώτη μονάδα. Επιτρέπει στους κλινικούς ιατρούς να επαληθεύουν την επισκόπηση πληρότητας της εξέτασης, δηλαδή επαληθευμένες όψεις και κριτήρια ποιότητας από το λογισμικό μέσω της σελίδας συλλογής της διεπαφής λογισμικού. Λειτουργεί συνεχώς, αξιολογώντας κάθε εικόνα που υποβάλλεται σε επεξεργασία από την πρώτη μονάδα σε πραγματικό χρόνο και διατηρώντας ένα σύνολο εικόνων ως οπτική απόδειξη των επαληθευμένων όψεων καρδιάς/εγκεφάλου και των κριτηρίων ποιότητας μέχρι εκείνη τη στιγμή.

Το FETOLY δεν αποσκοπεί στην επιλογή της «βέλτιστης» ή «υψηλής» διαγνωστικής ποιότητας σύμφωνα με μια δεδομένη ποιοτική κλίμακα. Αντίθετα, το FETOLY αποσκοπεί στην επιλογή εικόνων που απεικονίζουν την ποσοτική πληρότητα της εξέτασης όσον αφορά τις επαληθευμένες προβολές και τα κριτήρια ποιότητας. Καθώς αυτή η ενότητα βασίζεται εξ ολοκλήρου στην απόδοση του αλγορίθμου βαθιάς μάθησης της πρώτης ενότητας, δεν απαιτείται πρόσθετη αξιολόγηση της απόδοσης.

Για παράδειγμα, εάν ο χρήστης έχει κάποιες αμφιβολίες σχετικά με ένα από τα πράσινα κριτήρια ποιότητας, μπορεί να επαληθεύσει την παρουσία αυτού του κριτηρίου κάνοντας κλικ σε αυτό στη σελίδα της συλλογής. Το λογισμικό θα εμφανίσει εικόνες που περιέχουν αυτό το κριτήριο (με κίτρινο χρώμα στο παρακάτω σχήμα). Όταν επιλέγεται ένα κριτήριο, το λογισμικό εμφανίζει το πλαίσιο οριοθέτησης που περιβάλλει το κριτήριο σε αυτές τις εικόνες. Αυτές οι πληροφορίες πλαισίου οριοθέτησης αποτελούν μέρος της εξόδου του Fetoly-CNN (συνελικτικό νευρωνικό δίκτυο).

Λειτουργικότητα 3: Βιομετρικές μετρήσεις

Η ενότητα της μονάδας **FETOLY-MEASURE** φέρει την ετικέτα «Μέτρηση» στη σελίδα ανάλυσης και εμφανίζει μια λίστα μετρήσεων, καθεμία οργανωμένη σε τέσσερα πεδία:

- **Όνομα μέτρησης**: Εμφανίζει το όνομα ή τη συντομογραφία της μέτρησης μαζί με ένα εικονίδιο πληροφοριών. Κάνοντας κλικ στο εικονίδιο ανοίγετε λεπτομερείς πληροφορίες σχετικά με τη μέτρηση, συμπεριλαμβανομένης της επιστημονικής της αναφοράς.
- **Τιμή μέτρησης και μονάδες**: Η μετρούμενη τιμή εμφανίζεται με τις σχετικές μονάδες. Για παράδειγμα, εμφανίζεται το σύμβολο των μοιρών (°) για τις γωνιακές μετρήσεις, το σύμβολο του ποσοστού (%). Διαφορετικά, το πεδίο παραμένει κενό, γεγονός που σημαίνει ότι πρόκειται για σχετική μέτρηση. Εάν τα σημεία-κλειδιά έχουν υποστεί επεξεργασία στη σελίδα της συλλογής, εμφανίζεται ένα σύμβολο μπροστά από τη μέτρηση ( ).
- **Εύρος αναφοράς**: Αυτό το πεδίο παρέχει το εύρος αναφοράς που ορίζεται στη βιβλιογραφία για τη μέτρηση, υποστηριζόμενο από την επιστημονική του αναφορά. Η πηγή μπορεί να είναι μια κατευθυντήρια οδηγία, μια δημοσίευση με αξιολόγηση από ομότιμους, ένα εγχειρίδιο ή ένα προσαρμοσμένο εύρος που ορίζεται από τον χρήστη. Κάνοντας κλικ στο **κουμπί νέας καρτέλας**, ο χρήστης μπορεί να ορίσει μη αυτόματα το εύρος αναφοράς ή να ενημερώσει τη βιβλιογραφική αναφορά εάν υπάρχουν διαθέσιμα πολλαπλάσια. Κάνοντας κλικ στο **κουμπί σύνδεσης πληροφοριών**, ο χρήστης αποκτά πρόσβαση σε ένα αναδυόμενο παράθυρο με όλες τις απαραίτητες πληροφορίες που σχετίζονται με το δεδομένο κριτήριο μέτρησης.
- **Ηλικία κύησης,** που πρέπει να δημιουργηθεί πριν από την έναρξη της ανάλυσης.

Λειτουργικότητα 4: Απεικόνιση μετρήσεων

Όπως και η απεικόνιση πληρότητας που επιλέγει εικόνες οι οποίες επιδεικνύουν προβολές και κριτήρια ποιότητας, επιλέγει αυτόματα μια εικόνα για κάθε μέτρηση. Και τα δύο σύνολα εικόνων εμφανίζονται μαζί στη σελίδα Συλλογή. Αυτά τα δύο σύνολα εικόνων είναι εύκολο να διακριθούν: οι εικόνες από τη λειτουργία μέτρησης περιλαμβάνουν μια τιμή μέτρησης και ένα όνομα παραμέτρου, ενώ οι εικόνες πληρότητας δεν έχουν σχολιασμούς.

Τόσο οι εικόνες «μέτρησης» όσο και οι εικόνες «πληρότητας» οργανώνονται με βάση τις αντίστοιχες υπερηχογραφικές όψεις τους. Λάβετε υπόψη ότι η συσχέτιση όψης των εικόνων που επιλέγονται από τη λειτουργία μέτρησης είναι ανεξάρτητη από τη λειτουργία πληρότητας. Πράγματι, κάθε επιμέρους όψη μέτρησης αντιστοιχεί εξ ορισμού σε μία από τις 5 καρδιολογικές ή 4 εγκεφαλικές υπερηχογραφικές όψεις. Επομένως, γνωρίζοντας τη δευτερεύουσα όψη, οι εικόνες που επιλέγονται από τη λειτουργία μέτρησης μπορούν να κατηγοριοποιηθούν αυτόματα στην κατάλληλη όψη στην οποία ανήκει αυτή η δευτερεύουσα όψη.

Λειτουργικότητα 5: Αναφορά εξέτασης

Μια αναφορά μπορεί να δημιουργηθεί από τη σελίδα εξαγωγής. Θα περιλαμβάνει αποτελέσματα και εικόνες από το FETOLY και θα σταλεί σε εξωτερική συσκευή.

Συσχετιζόμενες συσκευές

Για να χρησιμοποιήσετε τη συσκευή FETOLY, πρέπει να έχετε τις ακόλουθες συσχετιζόμενες συσκευές:

- Ένα μηχάνημα υπερηχογραφίας.
- Ένα tablet και, προαιρετικά, έναν διακομιστή DICOM, έναν υπολογιστή με διακομιστή FTP ή δυνατότητες Bluetooth, όπως ορίζεται στην ενότητα 10 «Αλληλεπιδράσεις με άλλο εξοπλισμό».
- Έναν προσαρμογέα UVC και ένα καλώδιο HDMI για τη σύνδεση του tablet με το μηχάνημα υπερηχογραφίας.

5. Προβλεπόμενη χρήση και ενδείξεις χρήσης

Το FETOLY προορίζεται να αναλύσει τις ακολουθίες εικόνων υπερήχων του εμβρύου χρησιμοποιώντας τεχνικές μηχανικής μάθησης για να κάνει αυτόματα:

- ανίχνευση όψεων εγκεφάλου και καρδιάς και κριτηρίων ποιότητας εντός των όψεων.
- ανίχνευση εικόνων κατάλληλων για τη μέτρηση βιομετρικών παραμέτρων της καρδιάς και του εγκεφάλου του εμβρύου και να παρέχει ποσοτικές μετρήσεις αυτών των παραμέτρων.

Η συσκευή προορίζεται για χρήση ως ταυτόχρονο βοήθημα ανάγνωσης κατά τη λήψη και ερμηνεία εικόνων υπερήχων εμβρύου.

Το FETOLY ενδείκνυται για χρήση κατά τη διάρκεια της τυπικής εξέτασης εμβρυϊκής καρδιάς και εγκεφάλου 2^{ου} και 3^{ου} τριμήνου κύησης (ηλικία κύησης: από 17 έως 40 εβδομάδες).

6. Προβλεπόμενοι χρήστες

Το προϊόν πρέπει να χρησιμοποιείται από πιστοποιημένο επαγγελματία υγείας εξειδικευμένο στην προγεννητική υπερηχογραφική απεικόνιση.

7. Στοχευμένος πληθυσμός ασθενών

Έγκυες γυναίκες κατά το 2ο και 3ο τρίμηνο της κύησης.

8. Κλινικά οφέλη και επιδόσεις

Για αυτόν τον τύπο συσκευής, δηλαδή για ένα αυτοτελές λογισμικό ιατροτεχνολογικού προϊόντος (SWMD) που είναι ένα ταυτόχρονο βοήθημα ανάγνωσης που χρησιμοποιείται κατά τη διάρκεια της τυπικής εξέτασης της καρδιάς και του εγκεφάλου του εμβρύου, έχει αποδειχθεί το ακόλουθο κλινικό όφελος:

- Τυποποίηση της τυπικής εξέτασης της καρδιάς και του εγκεφάλου στα έμβρυα όπως απαιτείται από τις αναγνωρισμένες διεθνείς κατευθυντήριες οδηγίες

Τα αποτελέσματα απόδοσης περιγράφονται λεπτομερώς στους παρακάτω πίνακες. Τα αποτελέσματα των αυτόνομων δοκιμών απόδοσης δείχνουν ότι το FETOLY αυτόματα:

- ανιχνεύει υπερηχογραφικές όψεις εμβρυϊκής καρδιάς και εμβρυϊκού εγκεφάλου με ευαισθησία ≥ 85% (κριτήριο αποδοχής) και ειδικότητα ≥ 85% (κριτήριο αποδοχής),
- ανιχνεύει κριτήρια ποιότητας στις προβολές της καρδιάς με ευαισθησία ≥ 90% (κριτήριο αποδοχής) και ειδικότητα ≥ 90% (κριτήριο αποδοχής),
- ανιχνεύει κριτήρια ποιότητας στις προβολές του εγκεφάλου με ευαισθησία ≥ 85% (κριτήριο αποδοχής) και ειδικότητα ≥ 85% (κριτήριο αποδοχής),
- εντοπίζει πλαίσια οριοθέτησης κριτηρίων ποιότητας με μέσο λόγο τομής προς ένωση (IoU) ≥ 50% (κριτήριο αποδοχής),
- ανιχνεύει δευτερεύουσες υπερηχογραφικές όψεις εμβρυϊκής καρδιάς και εμβρυϊκού εγκεφάλου με ευαισθησία ≥ 70% (κριτήριο αποδοχής) και ειδικότητα ≥ 70% (κριτήριο αποδοχής) και
- πραγματοποιεί μέτρηση της εμβρυϊκής καρδιάς και του εμβρυϊκού εγκεφάλου σύμφωνα με κάθε επίπεδο ακρίβειας (LOA) που ορίζεται ανά καταληκτικά σημεία της μελέτης.

Για τα συνολικά αποτελέσματα

Εμβρυϊκή όψη	***Ευαισθησία***			***Ειδικότητα***		
	Ν(θετικό)	***Σημειακή εκτίμηση***	***Διάστημα εμπιστοσύνης με επαναδειγματοληψία bootstrap (95%)***	***Ν(αρνητικό)***	***Σημειακή εκτίμηση***	***Διάστημα εμπιστοσύνης με επαναδειγματοληψία bootstrap (95%)***
Κοιλιακή όψη	691	0.989	(0.980,0.996)	4518	1.0	(1.000,1.000)
Όψη τεσσάρων θαλάμων	669	0.983	(0.972,0.991)	4540	1.0	(0.999,1.000)
Όψη οδού εκροής αριστερής κοιλίας	553	0.955	(0.935,0.971)	4656	1.0	(0.999,1.000)
Όψη οδού εκροής δεξιάς κοιλίας	513	0.952	(0.932,0.970)	4696	0.998	(0.997,0.999)
Όψη τριών αγγείων	554	0.961	(0.945,0.977)	4655	1.0	(0.999,1.000)
Αξονική όψη	570	0.946	(0.927,0.963)	4639	1.0	(1.000,1.000)

Διαπαρεγκεφαλιδική όψη	560	0.965	(0.949,0.979)	4649	1.0	(1.000,1.000)
Οβελιαία όψη (προφίλ)	311	0.885	(0.850,0.918)	4898	1.0	(1.000,1.000)
Άλλη όψη	788	0.993	(0.987,0.998)	4421	0.963	(0.957,0.969)

Κριτήριο ποιότητας	***Ευαισθησία***			***Ειδικότητα***			***Μέσος λόγος τομής προς ένωση (mIoU)***	
	N	***Σημειακή εκτίμηση***	***Διάστημα εμπιστοσύνης με επαναδειγματοληψία bootstrap (95%)***	***N***	***Σημειακή εκτίμηση***	***Διάστημα εμπιστοσύνης με επαναδειγματοληψία bootstrap (95%)***	***Σημειακή εκτίμηση***	***Διάστημα εμπιστοσύνης με επαναδειγματοληψία bootstrap (95%)***
Κοιλιακή όψη								
Σπονδυλική στήλη	*678*	*0.99*	*(0.983,0.998)*	*4531*	*0.998*	*(0.996,0.999)*	*0.71*	*(0.70,0.73)*
Αριστερή πλευρά	*632*	*0.967*	*(0.953,0.980)*	*4577*	*0.993*	*(0.991,0.995)*	*0.58*	*(0.56,0.59)*
Δεξιά πλευρά	*627*	*0.951*	*(0.934,0.967)*	*4582*	*0.994*	*(0.992,0.996)*	*0.55*	*(0.53,0.57)*
Κατιούσα αορτή	*673*	*0.972*	*(0.959,0.984)*	*4536*	*0.998*	*(0.996,0.999)*	*0.52*	*(0.51,0.54)*
Κάτω κοίλη φλέβα	*550*	*0.939*	*(0.917,0.958)*	*4659*	*0.987*	*(0.983,0.990)*	*0.5*	*(0.49,0.52)*
Στόμαχος	*675*	*0.983*	*(0.973,0.992)*	*4534*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.75)*
Ομφαλική φλέβα	*552*	*0.973*	*(0.958,0.986)*	*4657*	*0.99*	*(0.988,0.993)*	*0.64*	*(0.62,0.65)*
Πρόσθια κοιλιακή χώρα	*643*	*0.969*	*(0.954,0.983)*	*4566*	*0.993*	*(0.990,0.995)*	*0.5*	*(0.49,0.52)*
Όψη τεσσάρων θαλάμων								
Σπονδυλική στήλη	*595*	*0.969*	*(0.955,0.982)*	*4614*	*0.998*	*(0.996,0.999)*	*0.74*	*(0.73,0.75)*
Αριστερή πλευρά	*536*	*0.945*	*(0.924,0.963)*	*4673*	*0.99*	*(0.987,0.993)*	*0.64*	*(0.63,0.66)*
Δεξιά πλευρά	*548*	*0.948*	*(0.926,0.965)*	*4661*	*0.993*	*(0.991,0.996)*	*0.68*	*(0.66,0.69)*
Κατιούσα αορτή	*608*	*0.968*	*(0.952,0.981)*	*4601*	*0.997*	*(0.995,0.998)*	*0.66*	*(0.65,0.67)*
Αριστερή πνευμονική φλέβα	*240*	*0.925*	*(0.889,0.958)*	*4969*	*0.975*	*(0.971,0.979)*	*0.51*	*(0.48,0.53)*
Δεξιά πνευμονική φλέβα	*351*	*0.929*	*(0.902,0.955)*	*4858*	*0.981*	*(0.978,0.984)*	*0.53*	*(0.50,0.55)*
Αριστερός κόλπος	*662*	*0.976*	*(0.963,0.987)*	*4547*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*
Δεξιός κόλπος	*668*	*0.975*	*(0.963,0.985)*	*4541*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.76,0.78)*
Πρωτογενές διάφραγμα (βαλβίδα του Vieussens ή πτερύγιο του	*185*	*0.903*	*(0.860,0.944)*	*5024*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.48,0.53)*

ωοειδούς τρήματος)								
Ανοικτό ωοειδές τρήμα	*578*	*0.954*	*(0.935,0.971)*	*4631*	*0.993*	*(0.991,0.995)*	*0.59*	*(0.57,0.60)*
Μιτροειδής βαλβίδα	*343*	*0.925*	*(0.896,0.953)*	*4866*	*0.991*	*(0.988,0.994)*	*0.62*	*(0.60,0.63)*
Τριγλώχινα βαλβίδα	*424*	*0.927*	*(0.903,0.951)*	*4785*	*0.994*	*(0.992,0.996)*	*0.65*	*(0.63,0.67)*
Σύνδεση μεταξύ καρδιακού σταυρού και κολπικού διαφράγματος (διάφραγμα του κώνου)	*503*	*0.905*	*(0.878,0.929)*	*4706*	*0.988*	*(0.985,0.991)*	*0.56*	*(0.54,0.58)*
Μετατόπιση της κολποκοιλιακής βαλβίδας στον καρδιακό σταυρό	*159*	*0.938*	*(0.897,0.973)*	*5050*	*0.981*	*(0.978,0.985)*	*0.54*	*(0.51,0.58)*
Σύνδεση μεταξύ μεσοκοιλιακού διαφράγματος και καρδιακού σταυρού	*271*	*0.901*	*(0.864,0.935)*	*4938*	*0.991*	*(0.988,0.993)*	*0.52*	*(0.49,0.54)*
Μεσοκοιλιακό διάφραγμα	*402*	*0.901*	*(0.869,0.929)*	*4807*	*0.988*	*(0.985,0.991)*	*0.61*	*(0.58,0.63)*
Αριστερή κοιλία	*657*	*0.961*	*(0.945,0.975)*	*4552*	*0.999*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
Δεξιά κοιλία	*655*	*0.932*	*(0.911,0.950)*	*4554*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.76)*
Στέρνο	*582*	*0.925*	*(0.903,0.945)*	*4627*	*0.993*	*(0.991,0.996)*	*0.54*	*(0.52,0.56)*
Όψη οδού εκροής αριστερής κοιλίας								
Αριστερός κόλπος	*548*	*0.955*	*(0.934,0.971)*	*4661*	*0.999*	*(0.998,1.000)*	*0.65*	*(0.63,0.67)*
Εγγύς ανιούσα αορτή	*554*	*0.955*	*(0.935,0.971)*	*4655*	*1.0*	*(1.000,1.000)*	*0.68*	*(0.67,0.70)*
Μηνοειδείς βαλβίδες	*245*	*0.939*	*(0.907,0.966)*	*4964*	*0.991*	*(0.988,0.993)*	*0.51*	*(0.49,0.53)*
Αριστερή κοιλία	*552*	*0.955*	*(0.935,0.971)*	*4657*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.71,0.73)*
Μεσοκοιλιακό διάφραγμα	*284*	*0.937*	*(0.908,0.962)*	*4925*	*0.987*	*(0.984,0.990)*	*0.64*	*(0.61,0.66)*
Δεξιά κοιλία	*552*	*0.953*	*(0.933,0.970)*	*4657*	*1.0*	*(0.999,1.000)*	*0.71*	*(0.69,0.73)*
Όψη οδού εκροής δεξιάς κοιλίας								
Κατιούσα αορτή	*481*	*0.915*	*(0.890,0.939)*	*4728*	*0.998*	*(0.996,0.999)*	*0.63*	*(0.61,0.65)*
Τραχεία / βρόγχοι	*287*	*0.903*	*(0.869,0.936)*	*4922*	*0.982*	*(0.979,0.986)*	*0.5*	*(0.48,0.52)*

Αριστερή πνευμονική αρτηρία	*221*	*0.915*	*(0.875,0.950)*	*4988*	*0.991*	*(0.988,0.994)*	*0.61*	*(0.58,0.63)*
Αρτηριακός πόρος	*283*	*0.905*	*(0.870,0.935)*	*4926*	*0.994*	*(0.991,0.996)*	*0.62*	*(0.59,0.64)*
Δεξιά πνευμονική αρτηρία	*500*	*0.946*	*(0.926,0.965)*	*4709*	*0.998*	*(0.996,0.999)*	*0.66*	*(0.64,0.67)*
Έκφυση των πνευμονικών αρτηριών	*396*	*0.94*	*(0.917,0.961)*	*4813*	*0.989*	*(0.986,0.992)*	*0.53*	*(0.50,0.55)*
Διάφραγμα μεταξύ στελέχους πνευμονικής αρτηρίας και ανιούσας αορτής	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*
Ανιούσα αορτή	*510*	*0.936*	*(0.914,0.957)*	*4699*	*0.998*	*(0.997,0.999)*	*0.66*	*(0.65,0.68)*
Άνω κοίλη φλέβα	*365*	*0.927*	*(0.898,0.951)*	*4844*	*0.989*	*(0.986,0.992)*	*0.56*	*(0.54,0.59)*
Πνευμονικό στέλεχος	*510*	*0.955*	*(0.935,0.973)*	*4699*	*0.998*	*(0.996,0.999)*	*0.73*	*(0.71,0.74)*
Όψεις τριών αγγείων								
Σπονδυλική στήλη	*498*	*0.932*	*(0.911,0.953)*	*4711*	*0.996*	*(0.994,0.998)*	*0.7*	*(0.68,0.71)*
Τραχεία	*380*	*0.916*	*(0.888,0.942)*	*4829*	*0.987*	*(0.983,0.990)*	*0.51*	*(0.49,0.53)*
Πλευρικός χώρος στα αριστερά του πόρου / της πνευμονικής αρτηρίας	*492*	*0.933*	*(0.912,0.954)*	*4717*	*0.993*	*(0.990,0.995)*	*0.68*	*(0.67,0.70)*
Τόξο αρτηριακού πόρου συνδεδεμένο με την κατιούσα αορτή	*281*	*0.926*	*(0.893,0.955)*	*4928*	*0.995*	*(0.993,0.997)*	*0.7*	*(0.67,0.73)*
Τόξο αρτηριακού πόρου μη συνδεδεμένο με την κατιούσα αορτή	*253*	*0.941*	*(0.912,0.968)*	*4956*	*0.996*	*(0.994,0.998)*	*0.73*	*(0.71,0.75)*
Ανιούσα αορτή	*293*	*0.919*	*(0.889,0.949)*	*4916*	*0.996*	*(0.994,0.998)*	*0.66*	*(0.63,0.68)*
Αορτικό τόξο	*258*	*0.946*	*(0.917,0.973)*	*4951*	*0.996*	*(0.994,0.998)*	*0.75*	*(0.72,0.77)*
Άνω κοίλη φλέβα	*537*	*0.933*	*(0.912,0.953)*	*4672*	*0.998*	*(0.996,0.999)*	*0.58*	*(0.56,0.61)*
Θύμος αδένας / στέρνο	*363*	*0.904*	*(0.872,0.932)*	*4846*	*0.992*	*(0.990,0.995)*	*0.57*	*(0.54,0.59)*
Αξονική όψη								
Πρόσθιο δρέπανο	*341*	*0.951*	*(0.928,0.974)*	*4868*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*

Κοιλότητα του διαφανούς διαφράγματος	*352*	*0.935*	*(0.907,0.960)*	*4857*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.53,0.56)*
Ψαλίδα	*116*	*0.888*	*(0.828,0.941)*	*5093*	*0.999*	*(0.997,1.000)*	*0.53*	*(0.50,0.56)*
Άπω πρόσθια κοιλία	*203*	*0.951*	*(0.921,0.978)*	*5006*	*0.998*	*(0.996,0.999)*	*0.62*	*(0.60,0.65)*
Εγγύς πρόσθια κοιλία	*247*	*0.928*	*(0.895,0.958)*	*4962*	*0.998*	*(0.996,0.999)*	*0.61*	*(0.59,0.63)*
Αμφιμηνοειδής δεξαμενή	*357*	*0.947*	*(0.923,0.969)*	*4852*	*0.997*	*(0.995,0.998)*	*0.74*	*(0.72,0.75)*
Κόλπος	*554*	*0.939*	*(0.919,0.958)*	*4655*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.72)*
Χοριοειδές πλέγμα	*569*	*0.941*	*(0.920,0.958)*	*4640*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.64,0.67)*
Βρεγματοϊνιακή αύλακα	*274*	*0.946*	*(0.919,0.970)*	*4935*	*0.994*	*(0.991,0.996)*	*0.55*	*(0.53,0.57)*
Οπίσθιο δρέπανο	*283*	*0.933*	*(0.904,0.959)*	*4926*	*0.994*	*(0.991,0.996)*	*0.53*	*(0.51,0.55)*
Άπω στεφανιαία ραφή	*215*	*0.907*	*(0.867,0.945)*	*4994*	*0.998*	*(0.996,0.999)*	*0.59*	*(0.56,0.61)*
Εγγύς στεφανιαία ραφή	*343*	*0.872*	*(0.837,0.906)*	*4866*	*0.997*	*(0.996,0.999)*	*0.6*	*(0.58,0.62)*
Σχισμή του Sylvius	*243*	*0.906*	*(0.868,0.941)*	*4966*	*0.998*	*(0.997,0.999)*	*0.75*	*(0.73,0.77)*
Κρανίο	*501*	*0.947*	*(0.926,0.965)*	*4708*	*0.994*	*(0.992,0.996)*	*0.96*	*(0.96,0.96)*
Διαχωρισμός των θαλάμων	*475*	*0.933*	*(0.909,0.954)*	*4734*	*0.995*	*(0.992,0.997)*	*0.65*	*(0.64,0.67)*
3η Κοιλία	*162*	*0.784*	*(0.719,0.841)*	*5047*	*0.994*	*(0.992,0.996)*	*0.58*	*(0.55,0.61)*
Άπω τμήμα του θαλάμου	*464*	*0.908*	*(0.882,0.932)*	*4745*	*0.995*	*(0.993,0.997)*	*0.68*	*(0.67,0.69)*
Εγγύς τμήμα του θαλάμου	*428*	*0.895*	*(0.866,0.925)*	*4781*	*0.995*	*(0.993,0.997)*	*0.67*	*(0.66,0.69)*
Διαπαρεγκεφαλιδική όψη								
Άπω τμήμα του θαλάμου	*332*	*0.946*	*(0.921,0.970)*	*4877*	*0.995*	*(0.993,0.997)*	*0.63*	*(0.62,0.65)*
Εγγύς τμήμα του θαλάμου	*348*	*0.934*	*(0.905,0.957)*	*4861*	*0.997*	*(0.995,0.998)*	*0.61*	*(0.59,0.62)*
4η Κοιλία	*215*	*0.917*	*(0.878,0.950)*	*4994*	*0.994*	*(0.992,0.996)*	*0.54*	*(0.51,0.56)*
Σκώληκας της παρεγκεφαλίδας	*449*	*0.894*	*(0.865,0.921)*	*4760*	*0.997*	*(0.995,0.998)*	*0.58*	*(0.56,0.60)*
Άπω ημισφαίριο της παρεγκεφαλίδας	*553*	*0.964*	*(0.949,0.979)*	*4656*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.73,0.75)*

Εγγύς ημισφαίριο της παρεγκεφαλίδας	*555*	*0.964*	*(0.949,0.979)*	*4654*	*0.999*	*(0.998,1.000)*	*0.75*	*(0.74,0.76)*
Όριο της παρεγκεφαλίδας	*451*	*0.923*	*(0.899,0.946)*	*4758*	*0.99*	*(0.987,0.993)*	*0.53*	*(0.51,0.55)*
Μεγάλη δεξαμενή	*526*	*0.93*	*(0.909,0.953)*	*4683*	*0.998*	*(0.997,1.000)*	*0.65*	*(0.63,0.67)*
Οβελιαία όψη (προφίλ)								
Ρινικό οστό	*186*	*0.914*	*(0.870,0.953)*	*5023*	*0.995*	*(0.993,0.997)*	*0.64*	*(0.61,0.67)*
Άνω τμήμα του σκώληκα	*178*	*0.905*	*(0.860,0.945)*	*5031*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.55,0.60)*
Κάτω τμήμα του σκώληκα	*157*	*0.918*	*(0.875,0.958)*	*5052*	*1.0*	*(0.999,1.000)*	*0.68*	*(0.65,0.71)*
Αέτωμα της οροφής της τέταρτης κοιλίας	*143*	*0.917*	*(0.868,0.958)*	*5066*	*0.999*	*(0.998,1.000)*	*0.57*	*(0.53,0.60)*
Ρύγχος και γόνυ του μεσολοβίου	*260*	*0.893*	*(0.854,0.928)*	*4949*	*0.999*	*(0.998,1.000)*	*0.54*	*(0.51,0.56)*
Σώμα του μεσολοβίου	*237*	*0.903*	*(0.866,0.937)*	*4972*	*0.996*	*(0.994,0.998)*	*0.57*	*(0.55,0.60)*
Σπληνίο του μεσολοβίου	*167*	*0.911*	*(0.862,0.950)*	*5042*	*0.995*	*(0.993,0.997)*	*0.5*	*(0.46,0.52)*
Κοιλότητα του διαφανούς διαφράγματος	*295*	*0.882*	*(0.844,0.915)*	*4914*	*1.0*	*(1.000,1.000)*	*0.72*	*(0.69,0.74)*

Μέτρηση	n(θετικό)	Se	Se CI	n(αρνητικό)	Sp	Sp CI	LOA	LOA CI
θυμο-θωρακικός_λόγος	331	0.925	(0.894,0.953)	531	0.916	(0.891,0.938)	0.053	(0.048,0.059)
καρδιοθωρακικός_λόγος	353	0.967	(0.946,0.984)	531	0.854	(0.825,0.886)	0.057	(0.049,0.068)
αναλογία_αγγείων	343	0.931	(0.904,0.957)	531	0.97	(0.955,0.984)	0.288	(0.157,0.389)
κεφαλικός_δείκτης	313	0.956	(0.931,0.976)	531	0.925	(0.901,0.946)	0.028	(0.024,0.032)
αριθμός_αγγείων	344	0.983	(0.968,0.995)	531	0.948	(0.929,0.965)	0.109	(0.102,0.118)
καρδιοθωρακική_θέση	354	0.941	(0.914,0.963)	531	0.855	(0.825,0.884)	0.062	(0.056,0.067)
αναλογία_δεξιάς-προς-αριστερή_κοιλία	356	0.944	(0.919,0.966)	531	0.912	(0.888,0.936)	0.118	(0.093,0.150)
καρδιακή_γωνία	355	0.967	(0.947,0.983)	531	0.884	(0.855,0.910)	6.536	(6.014,7.206)
Λόγος CSP	358	0.872	(0.834,0.903)	531	0.985	(0.974,0.995)	0.834	(0.784,0.879)
Λόγος VP	319	0.953	(0.928,0.974)	531	1.0	(1.000,1.000)	0.065	(0.059,0.070)
Οπίσθιος χώρος αριστερού κόλπου	356	0.978	(0.961,0.992)	531	0.936	(0.914,0.957)	0.078	(0.073,0.082)

Μέτρηση	κλίση	τεταγμένη επί την αρχή	CI κλίσης	CI τεταγμένης επί την αρχή
θυμο-θωρακικός_λόγος	*0.9193728700913325*	*0.036831145919916715*	*(0.867,0.974)*	*(0.012,0.061)*
καρδιοθωρακικός_λόγος	*0.876712772545025*	*0.031190882303024643*	*(0.805,0.937)*	*(0.016,0.049)*
αναλογία_αγγείων	*1.020704625736053*	*-0.020379299876634666*	*(0.975,1.070)*	*(-0.063,0.020)*
κεφαλικός_δείκτης	*0.947817675762887*	*0.0419878759388707*	*(0.908,0.984)*	*(0.014,0.074)*
αριθμός_αγγείων	*0.9599365750528535*	*0.13033826638477716*	*(0.874,1.003)*	*(-0.010,0.400)*
καρδιοθωρακική_θέση	*0.9714247040194667*	*0.01579493110578061*	*(0.948,0.989)*	*(0.006,0.031)*
αναλογία_δεξιάς-προς-αριστερή_κοιλία	*1.0111269484433731*	*-0.005467987890258950 4*	*(0.992,1.040)*	*(-0.033,0.016)*
καρδιακή_γωνία Λόγος CSP	*0.9197936528230518* *0.6801357222664575*	*3.114077691538199* *0.44007609936523384*	*(0.888,0.945)* *(0.638,0.722)*	*(2.023,4.477)* *(0.352,0.532)*
Λόγος VP	*0.9509744900822699*	*0.016521822338360265*	*(0.910,0.987)*	*(0.011,0.025)*
Οπίσθιος χώρος αριστερού κόλπου	*1.0129714823586744*	*-0.011022639305439475*	*(1.001,1.028)*	*(-0.021,-0.003)*

Για τα αποτελέσματα του κατασκευαστή του συστήματος υπερήχων

Κατηγορία	Σύστημα	n(θετικό)	Se	Se CI	n(αρνητικό)	Sp	Sp CI
A	Canon	31	0.968	(0.900,1.000)	205	1.0	(1.000,1.000)
A	GE	284	0.997	(0.990,1.000)	2256	1.0	(0.999,1.000)
A	Samsung	301	0.981	(0.964,0.994)	1703	1.0	(1.000,1.000)
B	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)
B	GE	267	0.971	(0.946,0.989)	2273	1.0	(0.998,1.000)
B	Samsung	278	0.993	(0.982,1.000)	1726	1.0	(1.000,1.000)
C	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)
C	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)
C	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)
D	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)
D	GE	239	0.954	(0.923,0.980)	2301	0.999	(0.997,1.000)
D	Samsung	198	0.94	(0.904,0.971)	1806	0.997	(0.993,0.999)
E	Canon	23	1.0	(1.000,1.000)	213	1.0	(1.000,1.000)
E	GE	270	0.971	(0.949,0.989)	2270	0.999	(0.998,1.000)
E	Samsung	183	0.935	(0.899,0.967)	1821	1.0	(0.999,1.000)
F	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)
F	GE	336	0.935	(0.909,0.960)	2204	1.0	(1.000,1.000)
F	Samsung	205	0.957	(0.928,0.982)	1799	1.0	(1.000,1.000)
G	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)
G	GE	349	0.975	(0.957,0.989)	2191	1.0	(0.999,1.000)
G	Samsung	184	0.941	(0.906,0.973)	1820	1.0	(1.000,1.000)
I	Canon	21	0.953	(0.840,1.000)	215	1.0	(1.000,1.000)
I	GE	206	0.884	(0.835,0.924)	2334	1.0	(1.000,1.000)

I	Samsung	84	0.87	(0.789,0.937)	1920	1.0	(1.000,1.000)
X	Canon	32	1.0	(1.000,1.000)	204	0.976	(0.955,0.991)
X	GE	340	0.986	(0.974,0.998)	2200	0.96	(0.952,0.968)
X	Samsung	336	1.0	(1.000,1.000)	1668	0.96	(0.950,0.970)

Κατηγορία	Σύστημα	N (θετικό)	Se	Se CI	n(αρνητικό)	Sp	Sp CI	Μέσος λόγος τομής προς ένωση (mIoU)	mIoU CI
A.aA	*Canon*	*28*	*0.965*	*(0.889,1.000)*	*208*	*0.991*	*(0.976,1.000)*	*0.44*	*(0.36,0.53)*
A.aA	*GE*	*265*	*0.982*	*(0.964,0.997)*	*2275*	*0.992*	*(0.988,0.995)*	*0.53*	*(0.51,0.55)*
A.aA	*Samsung*	*280*	*0.95*	*(0.924,0.975)*	*1724*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.47,0.51)*
A.Ao	*Canon*	*31*	*0.904*	*(0.782,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.49,0.60)*
A.Ao	*GE*	*277*	*0.986*	*(0.972,0.997)*	*2263*	*0.998*	*(0.996,1.000)*	*0.57*	*(0.55,0.60)*
A.Ao	*Samsung*	*291*	*0.963*	*(0.940,0.983)*	*1713*	*0.998*	*(0.995,1.000)*	*0.5*	*(0.48,0.51)*
A.lRb	*Canon*	*28*	*0.929*	*(0.822,1.000)*	*208*	*0.996*	*(0.986,1.000)*	*0.49*	*(0.42,0.57)*
A.lRb	*GE*	*256*	*0.985*	*(0.969,0.997)*	*2284*	*0.993*	*(0.989,0.996)*	*0.58*	*(0.56,0.61)*
A.lRb	*Samsung*	*280*	*0.947*	*(0.919,0.971)*	*1724*	*0.995*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
A.rRb	*Canon*	*28*	*0.893*	*(0.759,1.000)*	*208*	*1.0*	*(1.000,1.000)*	*0.54*	*(0.45,0.63)*
A.rRb	*GE*	*267*	*0.974*	*(0.954,0.993)*	*2273*	*0.996*	*(0.993,0.998)*	*0.58*	*(0.55,0.61)*
A.rRb	*Samsung*	*269*	*0.922*	*(0.889,0.953)*	*1735*	*0.994*	*(0.990,0.998)*	*0.53*	*(0.51,0.56)*
A.Sp	*Canon*	*31*	*0.968*	*(0.900,1.000)*	*205*	*1.0*	*(1.000,1.000)*	*0.63*	*(0.56,0.71)*
A.Sp	*GE*	*276*	*0.997*	*(0.989,1.000)*	*2264*	*0.997*	*(0.994,0.999)*	*0.75*	*(0.74,0.77)*
A.Sp	*Samsung*	*296*	*0.984*	*(0.967,0.994)*	*1708*	*0.999*	*(0.997,1.000)*	*0.7*	*(0.68,0.71)*
A.St	*Canon*	*29*	*0.966*	*(0.893,1.000)*	*207*	*0.991*	*(0.975,1.000)*	*0.72*	*(0.67,0.76)*
A.St	*GE*	*279*	*0.993*	*(0.983,1.000)*	*2261*	*1.0*	*(1.000,1.000)*	*0.79*	*(0.77,0.80)*
A.St	*Samsung*	*293*	*0.973*	*(0.954,0.990)*	*1711*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
A.Uv	*Canon*	*25*	*0.96*	*(0.870,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.6*	*(0.51,0.67)*
A.Uv	*GE*	*217*	*0.977*	*(0.955,0.996)*	*2323*	*0.991*	*(0.988,0.995)*	*0.67*	*(0.65,0.70)*
A.Uv	*Samsung*	*240*	*0.967*	*(0.944,0.988)*	*1764*	*0.989*	*(0.984,0.993)*	*0.62*	*(0.59,0.64)*
A.VC	*Canon*	*26*	*0.885*	*(0.750,1.000)*	*210*	*0.986*	*(0.970,1.000)*	*0.46*	*(0.40,0.52)*
A.VC	*GE*	*221*	*0.973*	*(0.950,0.992)*	*2319*	*0.987*	*(0.983,0.991)*	*0.54*	*(0.52,0.57)*
A.VC	*Samsung*	*247*	*0.903*	*(0.864,0.939)*	*1757*	*0.989*	*(0.984,0.994)*	*0.49*	*(0.47,0.51)*
B.Ao	*Canon*	*27*	*0.926*	*(0.808,1.000)*	*209*	*0.996*	*(0.985,1.000)*	*0.71*	*(0.66,0.77)*
B.Ao	*GE*	*247*	*0.956*	*(0.926,0.980)*	*2293*	*0.997*	*(0.994,0.999)*	*0.73*	*(0.71,0.75)*
B.Ao	*Samsung*	*255*	*0.977*	*(0.956,0.993)*	*1749*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.58,0.62)*
B.bCr	*Canon*	*25*	*0.92*	*(0.800,1.000)*	*211*	*0.986*	*(0.969,1.000)*	*0.65*	*(0.58,0.72)*
B.bCr	*GE*	*202*	*0.892*	*(0.849,0.932)*	*2338*	*0.992*	*(0.989,0.996)*	*0.61*	*(0.57,0.64)*
B.bCr	*Samsung*	*216*	*0.926*	*(0.889,0.959)*	*1788*	*0.984*	*(0.979,0.989)*	*0.54*	*(0.52,0.57)*
B.Cr	*Canon*	*7*	*0.715*	*(0.334,1.000)*	*229*	*0.983*	*(0.967,0.996)*	*0.62*	*(nan,nan)*
B.Cr	*GE*	*52*	*0.885*	*(0.789,0.961)*	*2488*	*0.989*	*(0.985,0.993)*	*0.52*	*(0.46,0.58)*
B.Cr	*Samsung*	*76*	*0.974*	*(0.933,1.000)*	*1928*	*0.977*	*(0.971,0.983)*	*0.57*	*(0.52,0.61)*
B.FO	*Canon*	*26*	*0.962*	*(0.880,1.000)*	*210*	*1.0*	*(1.000,1.000)*	*0.7*	*(0.62,0.78)*
B.FO	*GE*	*215*	*0.935*	*(0.899,0.965)*	*2325*	*0.994*	*(0.991,0.997)*	*0.64*	*(0.62,0.67)*
B.FO	*Samsung*	*257*	*0.965*	*(0.941,0.985)*	*1747*	*0.994*	*(0.991,0.998)*	*0.58*	*(0.55,0.60)*
B.FOF	*Canon*	*8*	*0.75*	*(0.375,1.000)*	*228*	*1.0*	*(1.000,1.000)*	*0.56*	*(0.42,0.67)*

B.FOF	GE	108	0.899	(0.841,0.949)	2432	0.998	(0.996,1.000)	0.5	(0.47,0.53)
B.FOF	Samsung	63	0.921	(0.845,0.984)	1941	0.993	(0.989,0.996)	0.51	(0.47,0.55)
B.IVS	Canon	15	0.934	(0.770,1.000)	221	0.982	(0.965,0.996)	0.65	(0.53,0.75)
B.IVS	GE	165	0.867	(0.806,0.915)	2375	0.992	(0.988,0.995)	0.62	(0.59,0.66)
B.IVS	Samsung	152	0.922	(0.872,0.962)	1852	0.984	(0.978,0.989)	0.64	(0.61,0.67)
B.LA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.75	(0.71,0.79)
B.LA	GE	264	0.966	(0.942,0.986)	2276	0.999	(0.997,1.000)	0.79	(0.78,0.81)
B.LA	Samsung	274	0.997	(0.989,1.000)	1730	0.999	(0.996,1.000)	0.71	(0.70,0.73)
B.lPV	Canon	14	1.0	(1.000,1.000)	222	0.982	(0.965,0.996)	0.47	(0.34,0.60)
B.lPV	GE	109	0.881	(0.816,0.937)	2431	0.981	(0.976,0.986)	0.51	(0.47,0.55)
B.lPV	Samsung	85	0.965	(0.924,1.000)	1919	0.97	(0.963,0.977)	0.55	(0.51,0.59)
B.lRb	Canon	21	0.953	(0.850,1.000)	215	0.996	(0.986,1.000)	0.67	(0.58,0.77)
B.lRb	GE	220	0.9	(0.861,0.940)	2320	0.993	(0.989,0.996)	0.67	(0.64,0.70)
B.lRb	Samsung	219	0.978	(0.957,0.996)	1785	0.988	(0.983,0.993)	0.66	(0.63,0.68)
B.LV	Canon	30	0.9	(0.782,1.000)	206	1.0	(1.000,1.000)	0.77	(0.70,0.83)
B.LV	GE	257	0.95	(0.920,0.974)	2283	0.998	(0.996,1.000)	0.8	(0.78,0.82)
B.LV	Samsung	276	0.982	(0.963,0.997)	1728	1.0	(0.999,1.000)	0.73	(0.72,0.75)
B.MV	Canon	11	0.819	(0.556,1.000)	225	0.983	(0.966,0.996)	0.65	(0.54,0.79)
B.MV	GE	123	0.919	(0.865,0.963)	2417	0.995	(0.992,0.998)	0.66	(0.62,0.70)
B.MV	Samsung	146	0.939	(0.897,0.973)	1858	0.989	(0.984,0.994)	0.6	(0.57,0.62)
B.RA	Canon	30	0.934	(0.834,1.000)	206	1.0	(1.000,1.000)	0.82	(0.78,0.87)
B.RA	GE	266	0.967	(0.940,0.986)	2274	1.0	(0.998,1.000)	0.82	(0.80,0.83)
B.RA	Samsung	278	0.986	(0.971,0.997)	1726	1.0	(1.000,1.000)	0.74	(0.72,0.75)
B.rPV	Canon	20	0.85	(0.667,1.000)	216	0.982	(0.962,0.996)	0.57	(0.49,0.64)
B.rPV	GE	152	0.935	(0.889,0.973)	2388	0.987	(0.982,0.991)	0.53	(0.49,0.56)
B.rPV	Samsung	126	0.929	(0.879,0.971)	1878	0.975	(0.968,0.982)	0.54	(0.51,0.58)
B.rRb	Canon	27	0.852	(0.715,0.966)	209	0.996	(0.986,1.000)	0.73	(0.67,0.80)
B.rRb	GE	235	0.928	(0.896,0.958)	2305	0.997	(0.994,0.999)	0.7	(0.67,0.72)
B.rRb	Samsung	208	0.976	(0.953,0.996)	1796	0.99	(0.986,0.995)	0.68	(0.65,0.70)
B.RV	Canon	29	0.932	(0.822,1.000)	207	1.0	(1.000,1.000)	0.73	(0.67,0.78)
B.RV	GE	255	0.918	(0.879,0.952)	2285	0.998	(0.996,1.000)	0.79	(0.77,0.81)
B.RV	Samsung	278	0.954	(0.929,0.976)	1726	1.0	(1.000,1.000)	0.72	(0.71,0.74)
B.Sp	Canon	26	0.885	(0.759,1.000)	210	1.0	(1.000,1.000)	0.76	(0.71,0.82)
B.Sp	GE	233	0.97	(0.947,0.988)	2307	0.997	(0.995,0.999)	0.78	(0.76,0.80)
B.Sp	Samsung	243	0.98	(0.961,0.996)	1761	0.998	(0.995,1.000)	0.72	(0.70,0.73)
B.Str	Canon	25	0.8	(0.630,0.959)	211	0.986	(0.970,1.000)	0.51	(0.43,0.60)
B.Str	GE	230	0.909	(0.869,0.943)	2310	0.994	(0.990,0.997)	0.64	(0.61,0.66)
B.Str	Samsung	235	0.941	(0.912,0.970)	1769	0.993	(0.989,0.997)	0.45	(0.43,0.47)
B.tCr	Canon	10	0.9	(0.666,1.000)	226	0.992	(0.979,1.000)	0.48	(0.30,0.64)
B.tCr	GE	110	0.873	(0.810,0.932)	2430	0.991	(0.988,0.995)	0.56	(0.52,0.61)
B.tCr	Samsung	126	0.913	(0.861,0.960)	1878	0.995	(0.991,0.998)	0.51	(0.48,0.54)
B.TV	Canon	14	1.0	(1.000,1.000)	222	0.987	(0.971,1.000)	0.68	(0.60,0.76)
B.TV	GE	160	0.882	(0.826,0.927)	2380	0.996	(0.993,0.999)	0.68	(0.65,0.72)
B.TV	Samsung	174	0.96	(0.929,0.988)	1830	0.992	(0.988,0.996)	0.65	(0.63,0.68)
C.aAo	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.68	(0.62,0.75)
C.aAo	GE	249	0.956	(0.930,0.979)	2291	1.0	(0.999,1.000)	0.71	(0.70,0.73)

C.aAo	Samsung	235	0.949	(0.922,0.975)	1769	1.0	(1.000,1.000)	0.66	(0.64,0.68)
C.IVS	Canon	11	1.0	(1.000,1.000)	225	0.987	(0.971,1.000)	0.63	(0.47,0.77)
C.IVS	GE	125	0.952	(0.912,0.985)	2415	0.988	(0.984,0.992)	0.66	(0.63,0.69)
C.IVS	Samsung	123	0.952	(0.912,0.985)	1881	0.988	(0.983,0.992)	0.63	(0.59,0.67)
C.LA	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.71	(0.64,0.79)
C.LA	GE	244	0.955	(0.928,0.979)	2296	0.998	(0.996,1.000)	0.67	(0.64,0.70)
C.LA	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.63	(0.60,0.66)
C.LV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.72	(0.68,0.78)
C.LV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.72,0.76)
C.LV	Samsung	234	0.949	(0.922,0.975)	1770	1.0	(0.999,1.000)	0.71	(0.70,0.73)
C.RV	Canon	22	1.0	(1.000,1.000)	214	1.0	(1.000,1.000)	0.8	(0.75,0.86)
C.RV	GE	248	0.956	(0.929,0.979)	2292	1.0	(0.998,1.000)	0.74	(0.71,0.76)
C.RV	Samsung	234	0.945	(0.915,0.971)	1770	1.0	(0.999,1.000)	0.69	(0.66,0.71)
C.SV	Canon	6	1.0	(nan,nan)	230	0.987	(0.973,1.000)	0.49	(nan,nan)
C.SV	GE	140	0.958	(0.921,0.987)	2400	0.991	(0.988,0.995)	0.51	(0.49,0.54)
C.SV	Samsung	81	0.902	(0.829,0.962)	1923	0.99	(0.985,0.994)	0.49	(0.46,0.52)
Class	System	n(positive)	Se	Se CI	n(negative)	Sp	Sp CI	mIoU	mIoU CI
D.aAo	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.64	(0.55,0.74)
D.aAo	GE	237	0.941	(0.911,0.970)	2303	0.999	(0.997,1.000)	0.73	(0.70,0.75)
D.aAo	Samsung	198	0.91	(0.870,0.944)	1806	0.997	(0.993,0.999)	0.6	(0.57,0.63)
D.dAo	Canon	19	0.895	(0.762,1.000)	217	1.0	(1.000,1.000)	0.68	(0.57,0.80)
D.dAo	GE	223	0.92	(0.881,0.952)	2317	0.997	(0.994,0.999)	0.69	(0.67,0.72)
D.dAo	Samsung	185	0.914	(0.871,0.953)	1819	0.998	(0.996,1.000)	0.6	(0.57,0.63)
D.Du	Canon	16	0.938	(0.810,1.000)	220	1.0	(1.000,1.000)	0.7	(0.59,0.80)
D.Du	GE	88	0.91	(0.837,0.965)	2452	0.996	(0.993,0.998)	0.67	(0.63,0.72)
D.Du	Samsung	139	0.878	(0.821,0.931)	1865	0.991	(0.987,0.996)	0.59	(0.56,0.63)
D.lPA	Canon	6	0.834	(nan,nan)	230	0.996	(0.987,1.000)	0.61	(nan,nan)
D.lPA	GE	150	0.92	(0.872,0.962)	2390	0.994	(0.991,0.997)	0.63	(0.60,0.67)
D.lPA	Samsung	52	0.924	(0.843,0.982)	1952	0.989	(0.984,0.993)	0.57	(0.52,0.62)
D.Or	Canon	17	0.942	(0.813,1.000)	219	0.987	(0.971,1.000)	0.59	(0.49,0.70)
D.Or	GE	181	0.962	(0.930,0.988)	2359	0.991	(0.987,0.995)	0.58	(0.54,0.61)
D.Or	Samsung	163	0.915	(0.869,0.954)	1841	0.992	(0.987,0.996)	0.5	(0.47,0.53)
D.PA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.82	(0.77,0.87)
D.PA	GE	238	0.958	(0.928,0.983)	2302	0.999	(0.997,1.000)	0.77	(0.75,0.79)
D.PA	Samsung	197	0.94	(0.903,0.971)	1807	0.996	(0.993,0.999)	0.7	(0.67,0.72)
D.rPA	Canon	21	0.953	(0.850,1.000)	215	1.0	(1.000,1.000)	0.74	(0.66,0.81)
D.rPA	GE	237	0.95	(0.919,0.976)	2303	0.999	(0.998,1.000)	0.69	(0.66,0.71)
D.rPA	Samsung	187	0.931	(0.892,0.964)	1817	0.995	(0.991,0.998)	0.62	(0.59,0.65)
D.S	Canon	15	1.0	(1.000,1.000)	221	0.991	(0.978,1.000)	0.61	(0.49,0.72)
D.S	GE	185	0.957	(0.927,0.985)	2355	0.989	(0.984,0.993)	0.68	(0.64,0.70)
D.S	Samsung	133	0.94	(0.898,0.976)	1871	0.981	(0.975,0.987)	0.58	(0.55,0.61)
D.SVC	Canon	13	0.924	(0.750,1.000)	223	0.987	(0.972,1.000)	0.51	(0.34,0.68)
D.SVC	GE	195	0.913	(0.871,0.951)	2345	0.993	(0.989,0.996)	0.61	(0.57,0.65)
D.SVC	Samsung	127	0.945	(0.898,0.980)	1877	0.988	(0.983,0.992)	0.52	(0.49,0.56)
D.Tr	Canon	13	1.0	(1.000,1.000)	223	0.996	(0.987,1.000)	0.66	(0.59,0.75)
D.Tr	GE	141	0.837	(0.778,0.898)	2399	0.982	(0.976,0.987)	0.52	(0.49,0.55)

D.Tr	Samsung	102	0.951	(0.909,0.990)	1902	0.983	(0.977,0.989)	0.46	(0.43,0.49)
E.aAo	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.67	(nan,nan)
E.aAo	GE	160	0.932	(0.891,0.967)	2380	0.996	(0.993,0.998)	0.69	(0.66,0.72)
E.aAo	Samsung	102	0.883	(0.818,0.940)	1902	0.995	(0.992,0.998)	0.62	(0.59,0.66)
E.aAr	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.84	(0.77,0.90)
E.aAr	GE	108	0.954	(0.912,0.989)	2432	0.995	(0.991,0.997)	0.78	(0.75,0.81)
E.aAr	Samsung	80	0.938	(0.883,0.988)	1924	0.997	(0.995,0.999)	0.69	(0.66,0.72)
E.Du	Canon	18	0.945	(0.819,1.000)	218	1.0	(1.000,1.000)	0.82	(0.78,0.86)
E.Du	GE	106	0.953	(0.909,0.990)	2434	0.994	(0.990,0.997)	0.75	(0.71,0.78)
E.Du	Samsung	83	0.916	(0.852,0.976)	1921	1.0	(0.999,1.000)	0.68	(0.64,0.72)
E.ES	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.71	(0.62,0.79)
E.ES	GE	252	0.941	(0.908,0.968)	2288	0.995	(0.992,0.998)	0.71	(0.69,0.73)
E.ES	Samsung	148	0.919	(0.870,0.958)	1856	0.989	(0.984,0.994)	0.67	(0.64,0.70)
E.PA	Canon	5	1.0	(nan,nan)	231	0.996	(0.987,1.000)	0.77	(nan,nan)
E.PA	GE	153	0.929	(0.887,0.966)	2387	0.995	(0.992,0.998)	0.73	(0.70,0.77)
E.PA	Samsung	96	0.896	(0.834,0.955)	1908	0.995	(0.991,0.998)	0.67	(0.63,0.71)
E.Sp	Canon	18	0.945	(0.824,1.000)	218	1.0	(1.000,1.000)	0.71	(0.65,0.77)
E.Sp	GE	240	0.955	(0.928,0.979)	2300	0.994	(0.990,0.997)	0.73	(0.71,0.75)
E.Sp	Samsung	162	0.908	(0.863,0.947)	1842	0.996	(0.993,0.999)	0.67	(0.64,0.69)
E.SVC	Canon	21	0.953	(0.843,1.000)	215	0.996	(0.986,1.000)	0.65	(0.55,0.76)
E.SVC	GE	265	0.944	(0.915,0.969)	2275	0.998	(0.996,1.000)	0.62	(0.59,0.65)
E.SVC	Samsung	173	0.914	(0.870,0.952)	1831	0.997	(0.993,0.999)	0.54	(0.51,0.57)
E.Th	Canon	10	0.9	(0.667,1.000)	226	0.987	(0.972,1.000)	0.56	(0.48,0.64)
E.Th	GE	180	0.889	(0.842,0.933)	2360	0.99	(0.986,0.994)	0.61	(0.58,0.65)
E.Th	Samsung	128	0.899	(0.839,0.950)	1876	0.996	(0.992,0.998)	0.54	(0.51,0.58)
E.Tr	Canon	15	0.867	(0.667,1.000)	221	0.987	(0.973,1.000)	0.65	(0.52,0.77)
E.Tr	GE	201	0.921	(0.884,0.957)	2339	0.989	(0.984,0.993)	0.52	(0.49,0.55)
E.Tr	Samsung	109	0.909	(0.850,0.961)	1895	0.985	(0.979,0.990)	0.47	(0.44,0.50)
F.3V	Canon	6	0.667	(0.250,1.000)	230	1.0	(1.000,1.000)	0.61	(nan,nan)
F.3V	GE	104	0.818	(0.742,0.889)	2436	0.994	(0.991,0.997)	0.61	(0.57,0.64)
F.3V	Samsung	52	0.731	(0.611,0.848)	1952	0.992	(0.988,0.996)	0.52	(0.48,0.57)
F.AC	Canon	25	0.96	(0.875,1.000)	211	1.0	(1.000,1.000)	0.7	(0.66,0.75)
F.AC	GE	202	0.941	(0.908,0.970)	2338	0.995	(0.991,0.997)	0.75	(0.73,0.77)
F.AC	Samsung	130	0.954	(0.915,0.986)	1874	0.998	(0.996,1.000)	0.72	(0.70,0.74)
F.aFx	Canon	12	1.0	(1.000,1.000)	224	0.983	(0.963,0.996)	0.53	(0.44,0.62)
F.aFx	GE	208	0.933	(0.895,0.965)	2332	0.997	(0.995,0.999)	0.64	(0.61,0.66)
F.aFx	Samsung	121	0.976	(0.945,1.000)	1883	0.999	(0.998,1.000)	0.59	(0.55,0.62)
F.Atr	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.72	(0.66,0.78)
F.Atr	GE	320	0.932	(0.905,0.958)	2220	1.0	(0.999,1.000)	0.73	(0.71,0.75)
F.Atr	Samsung	205	0.942	(0.909,0.972)	1799	1.0	(1.000,1.000)	0.67	(0.65,0.69)
F.CP	Canon	29	1.0	(1.000,1.000)	207	1.0	(1.000,1.000)	0.64	(0.58,0.70)
F.CP	GE	336	0.929	(0.903,0.955)	2204	1.0	(1.000,1.000)	0.68	(0.66,0.69)
F.CP	Samsung	204	0.951	(0.922,0.981)	1800	1.0	(1.000,1.000)	0.61	(0.58,0.63)
F.CSP	Canon	13	0.924	(0.750,1.000)	223	1.0	(1.000,1.000)	0.53	(0.47,0.60)
F.CSP	GE	199	0.935	(0.897,0.967)	2341	1.0	(1.000,1.000)	0.58	(0.56,0.61)
F.CSP	Samsung	140	0.936	(0.890,0.972)	1864	1.0	(1.000,1.000)	0.49	(0.47,0.52)

F.dAV	Canon	7	1.0	(nan,nan)	229	1.0	(1.000,1.000)	0.48	(nan,nan)
F.dAV	GE	127	0.969	(0.935,0.993)	2413	0.998	(0.996,1.000)	0.66	(0.63,0.69)
F.dAV	Samsung	69	0.914	(0.840,0.972)	1935	0.996	(0.993,0.999)	0.57	(0.53,0.62)
F.dCS	Canon	13	0.924	(0.734,1.000)	223	0.996	(0.986,1.000)	0.58	(0.49,0.66)
F.dCS	GE	139	0.893	(0.840,0.941)	2401	0.998	(0.996,1.000)	0.61	(0.59,0.64)
F.dCS	Samsung	63	0.937	(0.871,0.987)	1941	0.997	(0.995,0.999)	0.53	(0.49,0.57)
F.dTh	Canon	22	0.864	(0.706,1.000)	214	0.986	(0.969,1.000)	0.63	(0.59,0.67)
F.dTh	GE	276	0.885	(0.846,0.922)	2264	0.995	(0.992,0.998)	0.7	(0.69,0.72)
F.dTh	Samsung	166	0.952	(0.920,0.982)	1838	0.996	(0.992,0.998)	0.65	(0.63,0.67)
F.For	Canon	7	0.858	(0.555,1.000)	229	1.0	(1.000,1.000)	0.53	(0.42,0.61)
F.For	GE	78	0.898	(0.824,0.961)	2462	0.999	(0.997,1.000)	0.53	(0.49,0.58)
F.For	Samsung	31	0.871	(0.737,0.971)	1973	0.997	(0.995,0.999)	0.53	(0.46,0.59)
F.pAV	Canon	11	0.91	(0.700,1.000)	225	1.0	(1.000,1.000)	0.59	(nan,nan)
F.pAV	GE	152	0.922	(0.878,0.961)	2388	0.999	(0.998,1.000)	0.63	(0.59,0.66)
F.pAV	Samsung	84	0.941	(0.885,0.988)	1920	0.995	(0.992,0.998)	0.58	(0.54,0.62)
F.pCS	Canon	14	1.0	(1.000,1.000)	222	0.991	(0.978,1.000)	0.44	(0.33,0.54)
F.pCS	GE	209	0.852	(0.802,0.900)	2331	0.998	(0.996,1.000)	0.65	(0.63,0.67)
F.pCS	Samsung	120	0.892	(0.835,0.946)	1884	0.996	(0.993,0.998)	0.54	(0.50,0.57)
F.pFx	Canon	20	1.0	(1.000,1.000)	216	0.991	(0.978,1.000)	0.48	(0.40,0.55)
F.pFx	GE	154	0.923	(0.877,0.960)	2386	0.992	(0.988,0.995)	0.55	(0.53,0.58)
F.pFx	Samsung	109	0.936	(0.888,0.980)	1895	0.995	(0.992,0.998)	0.52	(0.49,0.55)
F.POS	Canon	13	0.847	(0.600,1.000)	223	0.996	(0.987,1.000)	0.47	(0.40,0.54)
F.POS	GE	180	0.95	(0.918,0.979)	2360	0.995	(0.993,0.998)	0.57	(0.54,0.60)
F.POS	Samsung	81	0.951	(0.898,0.989)	1923	0.99	(0.985,0.994)	0.51	(0.47,0.55)
F.pTh	Canon	20	0.95	(0.827,1.000)	216	0.987	(0.972,1.000)	0.62	(0.55,0.68)
F.pTh	GE	260	0.9	(0.864,0.936)	2280	0.997	(0.995,1.000)	0.69	(0.67,0.70)
F.pTh	Samsung	148	0.879	(0.824,0.928)	1856	0.991	(0.986,0.995)	0.66	(0.64,0.67)
F.Sep	Canon	23	1.0	(1.000,1.000)	213	0.991	(0.976,1.000)	0.65	(0.57,0.73)
F.Sep	GE	291	0.928	(0.900,0.956)	2249	0.994	(0.991,0.997)	0.67	(0.65,0.69)
F.Sep	Samsung	161	0.932	(0.895,0.970)	1843	0.994	(0.990,0.997)	0.62	(0.59,0.65)
F.SF	Canon	16	1.0	(1.000,1.000)	220	0.996	(0.986,1.000)	0.77	(0.71,0.82)
F.SF	GE	150	0.88	(0.826,0.928)	2390	0.997	(0.994,0.999)	0.76	(0.74,0.78)
F.SF	Samsung	77	0.936	(0.883,0.987)	1927	0.999	(0.998,1.000)	0.73	(0.69,0.75)
F.Sk	Canon	21	1.0	(1.000,1.000)	215	0.987	(0.971,1.000)	0.95	(0.93,0.97)
F.Sk	GE	281	0.929	(0.899,0.957)	2259	0.989	(0.985,0.993)	0.96	(0.96,0.97)
F.Sk	Samsung	199	0.965	(0.938,0.990)	1805	0.999	(0.998,1.000)	0.96	(0.95,0.96)
G.4V	Canon	9	1.0	(1.000,1.000)	227	1.0	(1.000,1.000)	0.52	(0.39,0.64)
G.4V	GE	131	0.955	(0.916,0.986)	2409	0.992	(0.988,0.995)	0.59	(0.56,0.62)
G.4V	Samsung	75	0.84	(0.750,0.918)	1929	0.995	(0.991,0.998)	0.44	(0.40,0.48)
G.CB	Canon	18	1.0	(1.000,1.000)	218	0.964	(0.942,0.986)	0.53	(0.44,0.61)
G.CB	GE	287	0.927	(0.896,0.955)	2253	0.989	(0.985,0.993)	0.54	(0.51,0.57)
G.CB	Samsung	146	0.905	(0.854,0.947)	1858	0.991	(0.987,0.995)	0.52	(0.49,0.55)
G.CM	Canon	27	0.963	(0.880,1.000)	209	1.0	(1.000,1.000)	0.68	(0.62,0.74)
G.CM	GE	320	0.935	(0.904,0.960)	2220	0.996	(0.994,0.999)	0.65	(0.62,0.67)
G.CM	Samsung	179	0.917	(0.875,0.956)	1825	1.0	(0.999,1.000)	0.64	(0.61,0.68)
G.dCH	Canon	27	1.0	(1.000,1.000)	209	1.0	(1.000,1.000)	0.69	(0.62,0.76)

G.dCH	*GE*	*345*	*0.974*	*(0.955,0.989)*	*2195*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.74,0.77)*
G.dCH	*Samsung*	*181*	*0.94*	*(0.903,0.973)*	*1823*	*0.999*	*(0.998,1.000)*	*0.73*	*(0.71,0.76)*
G.dTh	*Canon*	*13*	*1.0*	*(1.000,1.000)*	*223*	*1.0*	*(1.000,1.000)*	*0.6*	*(0.52,0.69)*
G.dTh	*GE*	*205*	*0.937*	*(0.902,0.967)*	*2335*	*0.993*	*(0.989,0.996)*	*0.65*	*(0.63,0.67)*
G.dTh	*Samsung*	*114*	*0.957*	*(0.916,0.991)*	*1890*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.59,0.63)*
G.pCH	*Canon*	*26*	*1.0*	*(1.000,1.000)*	*210*	*0.996*	*(0.986,1.000)*	*0.73*	*(0.68,0.78)*
G.pCH	*GE*	*347*	*0.975*	*(0.956,0.992)*	*2193*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	*Samsung*	*182*	*0.94*	*(0.905,0.973)*	*1822*	*0.999*	*(0.998,1.000)*	*0.74*	*(0.72,0.77)*
G.pTh	*Canon*	*13*	*1.0*	*(1.000,1.000)*	*223*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.51,0.65)*
G.pTh	*GE*	*216*	*0.922*	*(0.884,0.954)*	*2324*	*0.995*	*(0.992,0.998)*	*0.62*	*(0.60,0.64)*
G.pTh	*Samsung*	*119*	*0.95*	*(0.905,0.984)*	*1885*	*0.998*	*(0.996,1.000)*	*0.59*	*(0.57,0.62)*
G.Ver	*Canon*	*23*	*0.914*	*(0.783,1.000)*	*213*	*1.0*	*(1.000,1.000)*	*0.62*	*(0.54,0.70)*
G.Ver	*GE*	*288*	*0.893*	*(0.859,0.928)*	*2252*	*0.996*	*(0.993,0.999)*	*0.61*	*(0.59,0.63)*
G.Ver	*Samsung*	*138*	*0.892*	*(0.840,0.942)*	*1866*	*0.997*	*(0.994,0.999)*	*0.52*	*(0.49,0.55)*
I.bCC	*Canon*	*15*	*1.0*	*(1.000,1.000)*	*221*	*0.987*	*(0.971,1.000)*	*0.59*	*(0.51,0.67)*
I.bCC	*GE*	*168*	*0.923*	*(0.878,0.962)*	*2372*	*0.995*	*(0.993,0.998)*	*0.57*	*(0.54,0.60)*
I.bCC	*Samsung*	*54*	*0.815*	*(0.699,0.910)*	*1950*	*0.996*	*(0.994,0.999)*	*0.57*	*(0.52,0.62)*
I.CSP	*Canon*	*20*	*0.95*	*(0.824,1.000)*	*216*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.69,0.81)*
I.CSP	*GE*	*196*	*0.888*	*(0.841,0.928)*	*2344*	*1.0*	*(0.999,1.000)*	*0.72*	*(0.69,0.74)*
I.CSP	*Samsung*	*79*	*0.849*	*(0.760,0.924)*	*1925*	*1.0*	*(1.000,1.000)*	*0.7*	*(0.66,0.75)*
I.Fas	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.63*	*(0.46,0.79)*
I.Fas	*GE*	*99*	*0.889*	*(0.819,0.951)*	*2441*	*1.0*	*(0.999,1.000)*	*0.56*	*(0.52,0.60)*
I.Fas	*Samsung*	*33*	*0.97*	*(0.900,1.000)*	*1971*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.49,0.61)*
I.lVer	*Canon*	*14*	*0.929*	*(0.750,1.000)*	*222*	*1.0*	*(1.000,1.000)*	*0.69*	*(0.60,0.77)*
I.lVer	*GE*	*102*	*0.912*	*(0.850,0.960)*	*2438*	*0.999*	*(0.998,1.000)*	*0.7*	*(0.66,0.73)*
I.lVer	*Samsung*	*41*	*0.927*	*(0.834,1.000)*	*1963*	*1.0*	*(0.999,1.000)*	*0.64*	*(0.59,0.69)*
I.NB	*Canon*	*11*	*1.0*	*(1.000,1.000)*	*225*	*0.992*	*(0.979,1.000)*	*0.71*	*(0.61,0.82)*
I.NB	*GE*	*115*	*0.905*	*(0.844,0.955)*	*2425*	*0.992*	*(0.989,0.996)*	*0.63*	*(0.59,0.67)*
I.NB	*Samsung*	*60*	*0.917*	*(0.837,0.982)*	*1944*	*0.998*	*(0.996,1.000)*	*0.64*	*(0.58,0.69)*
I.rgCC	*Canon*	*18*	*0.945*	*(0.824,1.000)*	*218*	*0.991*	*(0.978,1.000)*	*0.48*	*(0.41,0.56)*
I.rgCC	*GE*	*177*	*0.888*	*(0.833,0.930)*	*2363*	*0.998*	*(0.996,1.000)*	*0.56*	*(0.54,0.59)*
I.rgCC	*Samsung*	*65*	*0.893*	*(0.808,0.965)*	*1939*	*1.0*	*(0.999,1.000)*	*0.48*	*(0.43,0.53)*
I.sCC	*Canon*	*13*	*0.847*	*(0.616,1.000)*	*223*	*0.992*	*(0.978,1.000)*	*0.48*	*(0.36,0.61)*
I.sCC	*GE*	*114*	*0.922*	*(0.868,0.964)*	*2426*	*0.992*	*(0.988,0.995)*	*0.51*	*(0.48,0.54)*
I.sCC	*Samsung*	*40*	*0.9*	*(0.796,1.000)*	*1964*	*0.998*	*(0.996,1.000)*	*0.45*	*(0.39,0.53)*
I.uVer	*Canon*	*14*	*1.0*	*(1.000,1.000)*	*222*	*0.991*	*(0.978,1.000)*	*0.57*	*(0.49,0.65)*
I.uVer	*GE*	*116*	*0.88*	*(0.815,0.931)*	*2424*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.63)*
I.uVer	*Samsung*	*48*	*0.938*	*(0.861,1.000)*	*1956*	*0.999*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Κατηγορία	Σύστημα	η(θετικό)	Se	Se CI	η(αρνητικό)	Sp	Sp CI	LOA	LOA CI
καρδιακή_γωνία	Canon	*27*	*0.963*	*(0.884,1.000)*	*37*	*0.811*	*(0.676,0.919)*	*5.968*	*(4.696,7.732)*
καρδιακή_γωνία	GE	*235*	*0.957*	*(0.930,0.979)*	*262*	*0.908*	*(0.870,0.943)*	*6.792*	*(6.000,7.671)*

καρδιακή_γωνία	Samsung	93	0.989	(0.966,1.000)	232	0.866	(0.823,0.909)	6.321	(5.318,7.723)
καρδιοθωρακική_θέση	Canon	28	0.893	(0.750,1.000)	37	0.973	(0.919,1.000)	0.089	(0.067,0.120)
καρδιοθωρακική_θέση	GE	233	0.931	(0.900,0.964)	262	0.912	(0.878,0.947)	0.051	(0.046,0.058)
καρδιοθωρακική_θέση	Samsung	93	0.978	(0.943,1.000)	232	0.772	(0.716,0.819)	0.077	(0.067,0.086)
καρδιοθωρακικός_λόγος	Canon	23	1.0	(1.000,1.000)	37	0.946	(0.865,1.000)	0.078	(0.041,0.117)
καρδιοθωρακικός_λόγος	GE	225	0.969	(0.944,0.991)	262	0.908	(0.874,0.943)	0.059	(0.049,0.073)
καρδιοθωρακικός_λόγος	Samsung	105	0.952	(0.909,0.989)	232	0.776	(0.724,0.828)	0.051	(0.042,0.061)
κεφαλικός_δείκτης	Canon	28	0.929	(0.821,1.000)	37	0.892	(0.784,0.973)	0.026	(0.021,0.032)
κεφαλικός_δείκτης	GE	195	0.944	(0.909,0.974)	262	0.943	(0.916,0.969)	0.03	(0.026,0.036)
κεφαλικός_δείκτης	Samsung	90	0.989	(0.964,1.000)	232	0.909	(0.871,0.944)	0.023	(0.020,0.026)
αναλογία_δεξιάς-προς-αριστερή_κοιλία	Canon	28	1.0	(1.000,1.000)	37	0.865	(0.757,0.973)	0.106	(0.080,0.128)
αναλογία_δεξιάς-προς-αριστερή_κοιλία	GE	235	0.923	(0.883,0.957)	262	0.901	(0.859,0.939)	0.127	(0.090,0.173)
αναλογία_δεξιάς-προς-αριστερή_κοιλία	Samsung	93	0.978	(0.943,1.000)	232	0.931	(0.901,0.961)	0.099	(0.087,0.115)
θυμο-θωρακικός_λόγος	Canon	19	1.0	(1.000,1.000)	37	1.0	(1.000,1.000)	0.047	(0.039,0.059)
θυμο-θωρακικός_λόγος	GE	174	0.902	(0.856,0.944)	262	0.924	(0.889,0.954)	0.051	(0.045,0.059)
θυμο-θωρακικός_λόγος	Samsung	138	0.942	(0.900,0.978)	232	0.892	(0.853,0.931)	0.059	(0.049,0.070)
αριθμός_αγγείων	Canon	21	0.905	(0.760,1.000)	37	1.0	(1.000,1.000)	0.0	(0.000,0.000)
αριθμός_αγγείων	GE	209	0.933	(0.895,0.966)	262	0.969	(0.947,0.989)	0.281	(0.138,0.406)
αριθμός_αγγείων	Sam-sung	113	0.929	(0.879,0.974)	232	0.966	(0.940,0.987)	0.329	(0.000,0.491)
αναλογία_αγγείων	Canon	28	1.0	(1.000,1.000)	37	0.892	(0.784,0.973)	0.112	(0.091,0.145)
αναλογία_αγγείων	GE	194	0.979	(0.956,0.995)	262	0.977	(0.954,0.992)	0.109	(0.099,0.121)
αναλογία_αγγείων	Sam-sung	122	0.984	(0.958,1.000)	232	0.922	(0.888,0.953)	0.111	(0.100,0.125)
Λόγος CSP	Canon	25	1.0	(1.000,1.000)	37	1.0	(1.000,1.000)	0.842	(0.608,1.028)
Λόγος CSP	GE	226	0.854	(0.805,0.899)	262	0.977	(0.954,0.992)	0.826	(0.753,0.889)
Λόγος CSP	Sam-sung	107	0.879	(0.821,0.935)	232	0.991	(0.978,1.000)	0.835	(0.755,0.907)
Λόγος VP	Canon	22	0.909	(0.773,1.000)	37	1.0	(1.000,1.000)	0.064	(0.043,0.084)
Λόγος VP	GE	206	0.956	(0.925,0.981)	262	1.0	(1.000,1.000)	0.065	(0.059,0.071)
Λόγος VP	Sam-sung	91	0.956	(0.910,0.990)	232	1.0	(1.000,1.000)	0.066	(0.056,0.075)
Οπίσθιος χώρος αριστερού κόλπου	Canon	16	0.938	(0.800,1.000)	37	0.919	(0.837,1.000)	0.094	(0.067,0.114)
Οπίσθιος χώρος αριστερού κόλπου	GE	181	0.978	(0.953,0.995)	262	0.924	(0.889,0.954)	0.086	(0.079,0.091)
Οπίσθιος χώρος αριστερού κόλπου	Sam-sung	159	0.981	(0.957,1.000)	232	0.953	(0.922,0.978)	0.07	(0.065,0.078)

Για τα αποτελέσματα υποομάδων ΗΠΑ έναντι ΕΕ

Κατηγορία	Ήπειρος	n(θετικό)	Se	Se CI	n(αρνητικό)	Sp	Sp CI
A	ΕΕ	302	0.984	(0.968,0.997)	2169	1.0	(1.000,1.000)
A	ΗΠΑ	210	1.0	(1.000,1.000)	1436	1.0	(0.998,1.000)
B	ΕΕ	271	0.982	(0.965,0.997)	2200	1.0	(1.000,1.000)
B	ΗΠΑ	203	0.966	(0.938,0.990)	1443	0.999	(0.997,1.000)
C	ΕΕ	245	0.984	(0.967,0.997)	2226	1.0	(1.000,1.000)
C	ΗΠΑ	169	0.924	(0.879,0.962)	1477	1.0	(0.998,1.000)
D	ΕΕ	251	0.977	(0.955,0.993)	2220	0.998	(0.996,1.000)
D	ΗΠΑ	140	0.922	(0.875,0.966)	1506	0.999	(0.996,1.000)
E	ΕΕ	268	0.974	(0.955,0.990)	2203	0.999	(0.997,1.000)
E	ΗΠΑ	150	0.947	(0.909,0.981)	1496	1.0	(0.998,1.000)
F	ΕΕ	272	0.971	(0.950,0.989)	2199	1.0	(1.000,1.000)
F	ΗΠΑ	240	0.921	(0.885,0.951)	1406	1.0	(1.000,1.000)
G	ΕΕ	309	0.949	(0.923,0.971)	2162	1.0	(1.000,1.000)
G	ΗΠΑ	206	0.981	(0.962,0.996)	1440	1.0	(0.998,1.000)
I	ΕΕ	204	0.922	(0.882,0.960)	2267	1.0	(1.000,1.000)
I	ΗΠΑ	87	0.794	(0.703,0.877)	1559	1.0	(1.000,1.000)
X	ΕΕ	349	0.998	(0.992,1.000)	2122	0.972	(0.964,0.979)
X	ΗΠΑ	241	0.984	(0.967,0.997)	1405	0.947	(0.934,0.959)

Κατηγορία	Ήπειρος	n(θετικό)	Se	Se CI	n(αρνητικό)	Sp	Sp CI	Μέσος λόγος τομής προς ένωση (mIoU)	mIoU CI
A.aA	EU	*270*	*0.971*	*(0.949,0.989)*	*2201*	*0.99*	*(0.985,0.993)*	*0.49*	*(0.47,0.51)*
A.aA	US	*205*	*0.976*	*(0.954,0.995)*	*1441*	*0.997*	*(0.994,1.000)*	*0.55*	*(0.52,0.58)*
A.Ao	EU	*295*	*0.967*	*(0.946,0.984)*	*2176*	*0.999*	*(0.997,1.000)*	*0.56*	*(0.54,0.58)*
A.Ao	US	*203*	*0.986*	*(0.968,1.000)*	*1443*	*0.996*	*(0.993,0.999)*	*0.54*	*(0.51,0.57)*
A.lRb	EU	*270*	*0.96*	*(0.936,0.982)*	*2201*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
A.lRb	US	*198*	*0.97*	*(0.945,0.991)*	*1448*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.56,0.62)*
A.rRb	EU	*271*	*0.953*	*(0.927,0.975)*	*2200*	*0.995*	*(0.993,0.998)*	*0.55*	*(0.52,0.58)*
A.rRb	US	*203*	*0.956*	*(0.924,0.982)*	*1443*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.54,0.62)*
A.Sp	EU	*291*	*0.987*	*(0.973,0.997)*	*2180*	*0.996*	*(0.994,0.999)*	*0.71*	*(0.70,0.73)*
A.Sp	US	*210*	*1.0*	*(1.000,1.000)*	*1436*	*1.0*	*(0.998,1.000)*	*0.75*	*(0.72,0.77)*
A.St	EU	*295*	*0.98*	*(0.963,0.994)*	*2176*	*1.0*	*(0.999,1.000)*	*0.77*	*(0.75,0.78)*
A.St	US	*207*	*0.991*	*(0.976,1.000)*	*1439*	*0.999*	*(0.997,1.000)*	*0.73*	*(0.71,0.76)*
A.Uv	EU	*223*	*0.983*	*(0.964,0.996)*	*2248*	*0.988*	*(0.984,0.992)*	*0.65*	*(0.63,0.68)*
A.Uv	US	*178*	*0.978*	*(0.954,0.995)*	*1468*	*0.996*	*(0.993,0.999)*	*0.64*	*(0.62,0.67)*
A.VC	EU	*238*	*0.946*	*(0.918,0.972)*	*2233*	*0.988*	*(0.984,0.992)*	*0.52*	*(0.50,0.54)*
A.VC	US	*171*	*0.948*	*(0.915,0.977)*	*1475*	*0.985*	*(0.979,0.991)*	*0.53*	*(0.50,0.56)*
B.Ao	EU	*252*	*0.957*	*(0.932,0.980)*	*2219*	*0.998*	*(0.996,1.000)*	*0.69*	*(0.67,0.71)*

B.Ao	US	*184*	*0.979*	*(0.955,0.995)*	*1462*	*0.996*	*(0.993,0.999)*	*0.7*	*(0.67,0.73)*
B.bCr	EU	*226*	*0.912*	*(0.872,0.947)*	*2245*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.64)*
B.bCr	US	*142*	*0.902*	*(0.847,0.946)*	*1504*	*0.989*	*(0.982,0.994)*	*0.56*	*(0.53,0.60)*
B.Cr	EU	*71*	*0.888*	*(0.810,0.956)*	*2400*	*0.988*	*(0.984,0.993)*	*0.55*	*(0.50,0.60)*
B.Cr	US	*46*	*0.957*	*(0.889,1.000)*	*1600*	*0.979*	*(0.973,0.985)*	*0.57*	*(0.51,0.63)*
B.FO	EU	*230*	*0.957*	*(0.930,0.982)*	*2241*	*0.996*	*(0.994,0.999)*	*0.64*	*(0.61,0.67)*
B.FO	US	*182*	*0.935*	*(0.893,0.968)*	*1464*	*0.995*	*(0.991,0.998)*	*0.61*	*(0.58,0.63)*
B.FOF	EU	*86*	*0.896*	*(0.832,0.956)*	*2385*	*0.997*	*(0.995,0.999)*	*0.51*	*(0.48,0.55)*
B.FOF	US	*72*	*0.889*	*(0.814,0.958)*	*1574*	*0.995*	*(0.991,0.998)*	*0.49*	*(0.45,0.53)*
B.IVS	EU	*168*	*0.887*	*(0.834,0.934)*	*2303*	*0.99*	*(0.986,0.993)*	*0.66*	*(0.63,0.69)*
B.IVS	US	*116*	*0.888*	*(0.825,0.941)*	*1530*	*0.99*	*(0.985,0.995)*	*0.58*	*(0.54,0.63)*
B.LA	EU	*271*	*0.982*	*(0.965,0.997)*	*2200*	*1.0*	*(1.000,1.000)*	*0.78*	*(0.77,0.79)*
B.LA	US	*198*	*0.965*	*(0.937,0.990)*	*1448*	*0.997*	*(0.994,1.000)*	*0.75*	*(0.73,0.77)*
B.lPV	EU	*109*	*0.918*	*(0.866,0.965)*	*2362*	*0.978*	*(0.972,0.983)*	*0.52*	*(0.48,0.55)*
B.lPV	US	*81*	*0.914*	*(0.847,0.971)*	*1565*	*0.981*	*(0.975,0.988)*	*0.54*	*(0.50,0.59)*
B.lRb	EU	*212*	*0.925*	*(0.885,0.959)*	*2259*	*0.992*	*(0.988,0.996)*	*0.68*	*(0.65,0.71)*
B.lRb	US	*162*	*0.926*	*(0.886,0.964)*	*1484*	*0.99*	*(0.985,0.995)*	*0.65*	*(0.62,0.68)*
B.LV	EU	*270*	*0.956*	*(0.930,0.978)*	*2201*	*1.0*	*(0.999,1.000)*	*0.79*	*(0.77,0.80)*
B.LV	US	*193*	*0.959*	*(0.929,0.985)*	*1453*	*0.997*	*(0.994,1.000)*	*0.77*	*(0.74,0.79)*
B.MV	EU	*125*	*0.936*	*(0.888,0.977)*	*2346*	*0.996*	*(0.993,0.998)*	*0.65*	*(0.61,0.67)*
B.MV	US	*112*	*0.902*	*(0.845,0.955)*	*1534*	*0.988*	*(0.983,0.993)*	*0.62*	*(0.58,0.66)*
B.RA	EU	*271*	*0.975*	*(0.955,0.993)*	*2200*	*1.0*	*(1.000,1.000)*	*0.81*	*(0.80,0.82)*
B.RA	US	*202*	*0.961*	*(0.932,0.986)*	*1444*	*0.999*	*(0.997,1.000)*	*0.79*	*(0.77,0.80)*
B.rPV	EU	*157*	*0.937*	*(0.897,0.974)*	*2314*	*0.984*	*(0.979,0.989)*	*0.55*	*(0.52,0.58)*
B.rPV	US	*107*	*0.907*	*(0.848,0.957)*	*1539*	*0.99*	*(0.984,0.995)*	*0.52*	*(0.48,0.57)*
B.rRb	EU	*226*	*0.934*	*(0.902,0.965)*	*2245*	*0.996*	*(0.993,0.998)*	*0.7*	*(0.68,0.73)*
B.rRb	US	*166*	*0.94*	*(0.900,0.976)*	*1480*	*0.995*	*(0.991,0.998)*	*0.7*	*(0.67,0.73)*
B.RV	EU	*266*	*0.937*	*(0.908,0.963)*	*2205*	*1.0*	*(0.998,1.000)*	*0.78*	*(0.76,0.80)*
B.RV	US	*195*	*0.924*	*(0.885,0.961)*	*1451*	*0.998*	*(0.995,1.000)*	*0.75*	*(0.73,0.77)*
B.Sp	EU	*231*	*0.97*	*(0.948,0.992)*	*2240*	*0.997*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Sp	US	*180*	*0.962*	*(0.932,0.989)*	*1466*	*0.998*	*(0.995,1.000)*	*0.76*	*(0.74,0.78)*
B.Str	EU	*225*	*0.889*	*(0.844,0.930)*	*2246*	*0.992*	*(0.988,0.995)*	*0.56*	*(0.54,0.59)*
B.Str	US	*178*	*0.939*	*(0.902,0.972)*	*1468*	*0.996*	*(0.993,0.999)*	*0.58*	*(0.54,0.61)*
B.tCr	EU	*111*	*0.928*	*(0.879,0.975)*	*2360*	*0.991*	*(0.987,0.994)*	*0.59*	*(0.55,0.63)*
B.tCr	US	*86*	*0.838*	*(0.756,0.915)*	*1560*	*0.996*	*(0.993,0.999)*	*0.5*	*(0.46,0.55)*
B.TV	EU	*160*	*0.919*	*(0.879,0.960)*	*2311*	*0.997*	*(0.994,0.999)*	*0.68*	*(0.65,0.71)*
B.TV	US	*134*	*0.933*	*(0.888,0.972)*	*1512*	*0.991*	*(0.986,0.996)*	*0.67*	*(0.63,0.70)*
C.aAo	EU	*245*	*0.984*	*(0.967,0.997)*	*2226*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
C.aAo	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.67*	*(0.64,0.69)*
C.IVS	EU	*133*	*0.963*	*(0.925,0.993)*	*2338*	*0.99*	*(0.986,0.994)*	*0.65*	*(0.62,0.68)*
C.IVS	US	*83*	*0.928*	*(0.867,0.977)*	*1563*	*0.985*	*(0.980,0.990)*	*0.65*	*(0.60,0.70)*
C.LA	EU	*240*	*0.984*	*(0.966,0.997)*	*2231*	*0.998*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
C.LA	US	*168*	*0.923*	*(0.878,0.962)*	*1478*	*0.999*	*(0.997,1.000)*	*0.64*	*(0.61,0.67)*
C.LV	EU	*244*	*0.984*	*(0.966,0.997)*	*2227*	*1.0*	*(0.999,1.000)*	*0.73*	*(0.71,0.75)*
C.LV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*
C.RV	EU	*243*	*0.984*	*(0.966,0.997)*	*2228*	*1.0*	*(0.998,1.000)*	*0.74*	*(0.71,0.76)*

C.RV	US	*169*	*0.924*	*(0.879,0.962)*	*1477*	*1.0*	*(0.998,1.000)*	*0.71*	*(0.68,0.73)*
C.SV	EU	*142*	*0.951*	*(0.913,0.986)*	*2329*	*0.993*	*(0.989,0.996)*	*0.51*	*(0.48,0.53)*
C.SV	US	*56*	*0.911*	*(0.822,0.982)*	*1590*	*0.99*	*(0.985,0.995)*	*0.5*	*(0.46,0.54)*
D.aAo	EU	*250*	*0.98*	*(0.961,0.996)*	*2221*	*0.998*	*(0.996,1.000)*	*0.71*	*(0.68,0.73)*
D.aAo	US	*139*	*0.871*	*(0.811,0.925)*	*1507*	*0.999*	*(0.996,1.000)*	*0.63*	*(0.58,0.67)*
D.dAo	EU	*234*	*0.941*	*(0.908,0.968)*	*2237*	*0.997*	*(0.994,0.999)*	*0.69*	*(0.66,0.72)*
D.dAo	US	*129*	*0.892*	*(0.836,0.944)*	*1517*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.57,0.65)*
D.Du	EU	*122*	*0.91*	*(0.858,0.959)*	*2349*	*0.994*	*(0.991,0.997)*	*0.67*	*(0.63,0.71)*
D.Du	US	*75*	*0.92*	*(0.858,0.975)*	*1571*	*0.995*	*(0.990,0.999)*	*0.59*	*(0.55,0.63)*
D.lPA	EU	*125*	*0.952*	*(0.912,0.985)*	*2346*	*0.991*	*(0.988,0.995)*	*0.62*	*(0.58,0.65)*
D.lPA	US	*65*	*0.847*	*(0.747,0.932)*	*1581*	*0.994*	*(0.990,0.998)*	*0.63*	*(0.57,0.69)*
D.Or	EU	*199*	*0.965*	*(0.937,0.990)*	*2272*	*0.989*	*(0.984,0.993)*	*0.59*	*(0.56,0.62)*
D.Or	US	*105*	*0.915*	*(0.860,0.962)*	*1541*	*0.992*	*(0.987,0.997)*	*0.49*	*(0.44,0.53)*
D.PA	EU	*251*	*0.977*	*(0.955,0.993)*	*2220*	*0.998*	*(0.996,1.000)*	*0.77*	*(0.76,0.79)*
D.PA	US	*138*	*0.928*	*(0.883,0.970)*	*1508*	*0.998*	*(0.995,1.000)*	*0.7*	*(0.67,0.73)*
D.rPA	EU	*247*	*0.972*	*(0.948,0.992)*	*2224*	*0.999*	*(0.997,1.000)*	*0.69*	*(0.66,0.71)*
D.rPA	US	*134*	*0.911*	*(0.860,0.958)*	*1512*	*0.996*	*(0.992,0.999)*	*0.64*	*(0.60,0.68)*
D.S	EU	*204*	*0.971*	*(0.945,0.991)*	*2267*	*0.988*	*(0.983,0.992)*	*0.67*	*(0.64,0.70)*
D.S	US	*82*	*0.952*	*(0.898,0.989)*	*1564*	*0.984*	*(0.978,0.990)*	*0.59*	*(0.55,0.63)*
D.SVC	EU	*206*	*0.947*	*(0.916,0.976)*	*2265*	*0.991*	*(0.986,0.994)*	*0.6*	*(0.56,0.63)*
D.SVC	US	*86*	*0.896*	*(0.834,0.956)*	*1560*	*0.991*	*(0.986,0.996)*	*0.55*	*(0.50,0.60)*
D.Tr	EU	*145*	*0.876*	*(0.822,0.929)*	*2326*	*0.982*	*(0.976,0.987)*	*0.51*	*(0.48,0.53)*
D.Tr	US	*72*	*0.903*	*(0.824,0.968)*	*1574*	*0.983*	*(0.976,0.989)*	*0.52*	*(0.48,0.56)*
E.aAo	EU	*142*	*0.937*	*(0.891,0.973)*	*2329*	*0.995*	*(0.992,0.998)*	*0.68*	*(0.65,0.71)*
E.aAo	US	*99*	*0.91*	*(0.851,0.966)*	*1547*	*0.996*	*(0.992,0.999)*	*0.67*	*(0.62,0.71)*
E.aAr	EU	*126*	*0.961*	*(0.924,0.992)*	*2345*	*0.997*	*(0.995,0.999)*	*0.8*	*(0.76,0.83)*
E.aAr	US	*48*	*0.917*	*(0.830,0.982)*	*1598*	*0.995*	*(0.992,0.999)*	*0.69*	*(0.64,0.72)*
E.Du	EU	*131*	*0.955*	*(0.918,0.986)*	*2340*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.74,0.80)*
E.Du	US	*44*	*0.887*	*(0.783,0.975)*	*1602*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.57,0.70)*
E.ES	EU	*243*	*0.947*	*(0.917,0.973)*	*2228*	*0.992*	*(0.988,0.996)*	*0.72*	*(0.70,0.74)*
E.ES	US	*132*	*0.902*	*(0.848,0.949)*	*1514*	*0.994*	*(0.990,0.998)*	*0.66*	*(0.63,0.69)*
E.PA	EU	*134*	*0.933*	*(0.888,0.972)*	*2337*	*0.994*	*(0.990,0.997)*	*0.72*	*(0.69,0.75)*
E.PA	US	*96*	*0.917*	*(0.858,0.971)*	*1550*	*0.997*	*(0.993,0.999)*	*0.71*	*(0.66,0.75)*
E.Sp	EU	*229*	*0.957*	*(0.925,0.980)*	*2242*	*0.992*	*(0.989,0.996)*	*0.73*	*(0.71,0.75)*
E.Sp	US	*139*	*0.914*	*(0.867,0.961)*	*1507*	*0.999*	*(0.996,1.000)*	*0.68*	*(0.65,0.71)*
E.SVC	EU	*260*	*0.947*	*(0.918,0.973)*	*2211*	*0.996*	*(0.994,0.999)*	*0.6*	*(0.57,0.63)*
E.SVC	US	*142*	*0.909*	*(0.859,0.955)*	*1504*	*0.997*	*(0.994,1.000)*	*0.61*	*(0.57,0.64)*
E.Th	EU	*178*	*0.899*	*(0.854,0.942)*	*2293*	*0.99*	*(0.986,0.994)*	*0.61*	*(0.58,0.65)*
E.Th	US	*98*	*0.878*	*(0.805,0.938)*	*1548*	*0.993*	*(0.989,0.997)*	*0.55*	*(0.50,0.60)*
E.Tr	EU	*180*	*0.923*	*(0.883,0.961)*	*2291*	*0.985*	*(0.980,0.990)*	*0.53*	*(0.50,0.56)*
E.Tr	US	*106*	*0.887*	*(0.825,0.942)*	*1540*	*0.989*	*(0.984,0.994)*	*0.5*	*(0.46,0.53)*
F.3V	EU	*77*	*0.78*	*(0.689,0.859)*	*2394*	*0.995*	*(0.992,0.998)*	*0.59*	*(0.55,0.63)*
F.3V	US	*73*	*0.781*	*(0.680,0.869)*	*1573*	*0.994*	*(0.989,0.997)*	*0.6*	*(0.55,0.64)*
F.AC	EU	*176*	*0.938*	*(0.901,0.971)*	*2295*	*0.995*	*(0.992,0.998)*	*0.73*	*(0.71,0.75)*
F.AC	US	*145*	*0.959*	*(0.923,0.987)*	*1501*	*0.997*	*(0.994,1.000)*	*0.76*	*(0.73,0.78)*
F.aFx	EU	*163*	*0.988*	*(0.968,1.000)*	*2308*	*0.996*	*(0.993,0.999)*	*0.62*	*(0.59,0.64)*

F.aFx	US	*146*	*0.905*	*(0.849,0.946)*	*1500*	*0.998*	*(0.996,1.000)*	*0.63*	*(0.60,0.66)*
F.Atr	EU	*272*	*0.964*	*(0.940,0.984)*	*2199*	*1.0*	*(1.000,1.000)*	*0.71*	*(0.69,0.73)*
F.Atr	US	*224*	*0.92*	*(0.881,0.952)*	*1422*	*1.0*	*(0.998,1.000)*	*0.73*	*(0.70,0.75)*
F.CP	EU	*272*	*0.971*	*(0.950,0.989)*	*2199*	*1.0*	*(1.000,1.000)*	*0.67*	*(0.65,0.69)*
F.CP	US	*239*	*0.908*	*(0.868,0.941)*	*1407*	*1.0*	*(1.000,1.000)*	*0.65*	*(0.63,0.68)*
F.CSP	EU	*184*	*0.962*	*(0.933,0.985)*	*2287*	*1.0*	*(1.000,1.000)*	*0.58*	*(0.55,0.60)*
F.CSP	US	*128*	*0.907*	*(0.850,0.955)*	*1518*	*1.0*	*(1.000,1.000)*	*0.53*	*(0.50,0.56)*
F.dAV	EU	*104*	*0.991*	*(0.969,1.000)*	*2367*	*0.998*	*(0.995,1.000)*	*0.61*	*(0.58,0.64)*
F.dAV	US	*89*	*0.911*	*(0.842,0.966)*	*1557*	*0.998*	*(0.995,1.000)*	*0.65*	*(0.61,0.70)*
F.dCS	EU	*115*	*0.948*	*(0.906,0.984)*	*2356*	*0.998*	*(0.995,0.999)*	*0.58*	*(0.55,0.61)*
F.dCS	US	*88*	*0.853*	*(0.770,0.924)*	*1558*	*0.997*	*(0.994,0.999)*	*0.61*	*(0.58,0.65)*
F.dTh	EU	*224*	*0.898*	*(0.854,0.934)*	*2247*	*0.993*	*(0.989,0.996)*	*0.68*	*(0.66,0.69)*
F.dTh	US	*195*	*0.903*	*(0.858,0.940)*	*1451*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.68,0.72)*
F.For	EU	*53*	*0.906*	*(0.827,0.977)*	*2418*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.51,0.60)*
F.For	US	*56*	*0.875*	*(0.770,0.956)*	*1590*	*0.999*	*(0.996,1.000)*	*0.53*	*(0.48,0.57)*
F.pAV	EU	*123*	*0.968*	*(0.933,0.993)*	*2348*	*1.0*	*(0.998,1.000)*	*0.6*	*(0.57,0.63)*
F.pAV	US	*103*	*0.884*	*(0.819,0.943)*	*1543*	*0.995*	*(0.991,0.998)*	*0.64*	*(0.60,0.68)*
F.pCS	EU	*163*	*0.908*	*(0.861,0.950)*	*2308*	*0.998*	*(0.996,1.000)*	*0.58*	*(0.56,0.61)*
F.pCS	US	*150*	*0.827*	*(0.765,0.885)*	*1496*	*0.994*	*(0.990,0.998)*	*0.65*	*(0.62,0.68)*
F.pFx	EU	*146*	*0.946*	*(0.907,0.980)*	*2325*	*0.994*	*(0.991,0.997)*	*0.53*	*(0.50,0.55)*
F.pFx	US	*112*	*0.929*	*(0.872,0.973)*	*1534*	*0.99*	*(0.985,0.995)*	*0.56*	*(0.53,0.59)*
F.POS	EU	*135*	*0.956*	*(0.916,0.986)*	*2336*	*0.995*	*(0.992,0.998)*	*0.51*	*(0.48,0.53)*
F.POS	US	*122*	*0.935*	*(0.888,0.975)*	*1524*	*0.993*	*(0.988,0.996)*	*0.61*	*(0.58,0.65)*
F.pTh	EU	*201*	*0.906*	*(0.863,0.943)*	*2270*	*0.994*	*(0.990,0.997)*	*0.67*	*(0.66,0.69)*
F.pTh	US	*185*	*0.898*	*(0.854,0.940)*	*1461*	*0.994*	*(0.990,0.998)*	*0.68*	*(0.66,0.70)*
F.Sep	EU	*227*	*0.956*	*(0.929,0.979)*	*2244*	*0.992*	*(0.988,0.996)*	*0.67*	*(0.64,0.69)*
F.Sep	US	*197*	*0.904*	*(0.855,0.941)*	*1449*	*0.994*	*(0.989,0.998)*	*0.65*	*(0.62,0.68)*
F.SF	EU	*128*	*0.946*	*(0.903,0.983)*	*2343*	*0.998*	*(0.995,1.000)*	*0.77*	*(0.75,0.79)*
F.SF	US	*93*	*0.85*	*(0.773,0.922)*	*1553*	*0.997*	*(0.994,1.000)*	*0.74*	*(0.71,0.77)*
F.Sk	EU	*208*	*0.972*	*(0.947,0.991)*	*2263*	*0.987*	*(0.983,0.992)*	*0.95*	*(0.95,0.96)*
F.Sk	US	*237*	*0.92*	*(0.883,0.951)*	*1409*	*1.0*	*(1.000,1.000)*	*0.97*	*(0.97,0.98)*
G.4V	EU	*118*	*0.907*	*(0.853,0.958)*	*2353*	*0.995*	*(0.992,0.998)*	*0.54*	*(0.51,0.58)*
G.4V	US	*77*	*0.923*	*(0.856,0.983)*	*1569*	*0.989*	*(0.984,0.994)*	*0.56*	*(0.51,0.60)*
G.CB	EU	*249*	*0.932*	*(0.900,0.961)*	*2222*	*0.985*	*(0.980,0.990)*	*0.46*	*(0.43,0.48)*
G.CB	US	*167*	*0.917*	*(0.870,0.957)*	*1479*	*0.993*	*(0.988,0.997)*	*0.67*	*(0.64,0.70)*
G.CM	EU	*292*	*0.942*	*(0.915,0.967)*	*2179*	*0.997*	*(0.995,0.999)*	*0.62*	*(0.59,0.65)*
G.CM	US	*190*	*0.916*	*(0.872,0.952)*	*1456*	*0.998*	*(0.996,1.000)*	*0.7*	*(0.67,0.73)*
G.dCH	EU	*305*	*0.951*	*(0.925,0.974)*	*2166*	*0.999*	*(0.997,1.000)*	*0.75*	*(0.73,0.76)*
G.dCH	US	*203*	*0.981*	*(0.960,0.996)*	*1443*	*0.998*	*(0.996,1.000)*	*0.76*	*(0.73,0.78)*
G.dTh	EU	*143*	*0.924*	*(0.874,0.965)*	*2328*	*0.994*	*(0.990,0.997)*	*0.62*	*(0.59,0.64)*
G.dTh	US	*156*	*0.962*	*(0.927,0.988)*	*1490*	*0.996*	*(0.992,0.999)*	*0.66*	*(0.64,0.68)*
G.pCH	EU	*306*	*0.951*	*(0.927,0.974)*	*2165*	*1.0*	*(0.998,1.000)*	*0.76*	*(0.74,0.77)*
G.pCH	US	*205*	*0.976*	*(0.955,0.996)*	*1441*	*0.999*	*(0.997,1.000)*	*0.76*	*(0.74,0.78)*
G.pTh	EU	*152*	*0.895*	*(0.842,0.941)*	*2319*	*0.996*	*(0.993,0.998)*	*0.6*	*(0.58,0.63)*
G.pTh	US	*161*	*0.969*	*(0.940,0.994)*	*1485*	*0.997*	*(0.994,1.000)*	*0.62*	*(0.61,0.64)*
G.Ver	EU	*256*	*0.879*	*(0.839,0.917)*	*2215*	*0.997*	*(0.994,0.999)*	*0.57*	*(0.54,0.59)*

G.Ver	US	*162*	*0.908*	*(0.861,0.947)*	*1484*	*0.995*	*(0.991,0.998)*	*0.62*	*(0.59,0.65)*
I.bCC	EU	*181*	*0.94*	*(0.905,0.974)*	*2290*	*0.997*	*(0.995,1.000)*	*0.6*	*(0.57,0.62)*
I.bCC	US	*44*	*0.773*	*(0.642,0.895)*	*1602*	*0.991*	*(0.986,0.995)*	*0.46*	*(0.42,0.50)*
I.CSP	EU	*199*	*0.925*	*(0.884,0.961)*	*2272*	*1.0*	*(1.000,1.000)*	*0.75*	*(0.73,0.78)*
I.CSP	US	*78*	*0.783*	*(0.685,0.872)*	*1568*	*1.0*	*(0.999,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	EU	*88*	*0.955*	*(0.909,0.990)*	*2383*	*0.999*	*(0.998,1.000)*	*0.6*	*(0.56,0.64)*
I.Fas	US	*47*	*0.83*	*(0.721,0.934)*	*1599*	*0.999*	*(0.997,1.000)*	*0.51*	*(0.46,0.56)*
I.lVer	EU	*93*	*0.957*	*(0.911,0.990)*	*2378*	*1.0*	*(0.998,1.000)*	*0.72*	*(0.68,0.75)*
I.lVer	US	*53*	*0.831*	*(0.724,0.928)*	*1593*	*1.0*	*(0.999,1.000)*	*0.61*	*(0.57,0.65)*
I.NB	EU	*109*	*0.945*	*(0.899,0.982)*	*2362*	*0.994*	*(0.990,0.997)*	*0.66*	*(0.62,0.69)*
I.NB	US	*59*	*0.848*	*(0.750,0.933)*	*1587*	*0.994*	*(0.990,0.998)*	*0.59*	*(0.54,0.64)*
I.rgCC	EU	*186*	*0.925*	*(0.886,0.963)*	*2285*	*0.999*	*(0.997,1.000)*	*0.55*	*(0.53,0.58)*
I.rgCC	US	*60*	*0.784*	*(0.676,0.883)*	*1586*	*0.998*	*(0.995,1.000)*	*0.49*	*(0.44,0.54)*
I.sCC	EU	*130*	*0.947*	*(0.904,0.984)*	*2341*	*0.992*	*(0.988,0.995)*	*0.5*	*(0.47,0.53)*
I.sCC	US	*29*	*0.759*	*(0.600,0.914)*	*1617*	*0.997*	*(0.994,0.999)*	*0.43*	*(0.35,0.52)*
I.uVer	EU	*106*	*0.934*	*(0.881,0.981)*	*2365*	*0.998*	*(0.996,1.000)*	*0.61*	*(0.58,0.64)*
I.uVer	US	*59*	*0.831*	*(0.728,0.921)*	*1587*	*1.0*	*(0.998,1.000)*	*0.52*	*(0.48,0.56)*

Κατηγορία	Ήπειρος	η(θετικό)	Se	Se CI	η(αρνητικό)	Sp	Sp CI	LOA	LOA CI
καρδιακή_γωνία	EU	173	0.942	(0.908,0.976)	266	0.906	(0.868,0.940)	6.167	(5.437,6.897)
καρδιακή_γωνία	US	182	0.989	(0.972,1.000)	265	0.86	(0.815,0.902)	7.411	(6.440,8.394)
καρδιοθωρακική_θέση	EU	167	0.934	(0.894,0.969)	266	0.944	(0.914,0.970)	0.066	(0.059,0.075)
καρδιοθωρακική_θέση	ΗΠΑ	187	0.947	(0.913,0.979)	265	0.766	(0.713,0.819)	0.059	(0.051,0.067)
καρδιοθωρακικός_λόγος	ΕΕ	158	0.994	(0.977,1.000)	266	0.921	(0.883,0.951)	0.062	(0.046,0.084)
καρδιοθωρακικός_λόγος	ΗΠΑ	195	0.944	(0.910,0.975)	265	0.785	(0.736,0.834)	0.057	(0.050,0.066)
κεφαλικός_δείκτης	ΕΕ	154	0.955	(0.916,0.982)	266	0.917	(0.883,0.947)	0.032	(0.028,0.037)
κεφαλικός_δείκτης	ΗΠΑ	159	0.956	(0.924,0.986)	265	0.932	(0.898,0.962)	0.025	(0.021,0.030)
αναλογία_δεξιάς-προς-αριστερή_κοιλία	ΕΕ	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
αναλογία_δεξιάς-προς-αριστερή_κοιλία	ΗΠΑ	182	0.907	(0.863,0.947)	265	0.917	(0.883,0.947)	0.137	(0.092,0.188)
θυμο-θωρακικός_λόγος	ΕΕ	170	0.959	(0.928,0.987)	266	0.962	(0.940,0.981)	0.051	(0.045,0.057)
θυμο-θωρακικός_λόγος	ΗΠΑ	161	0.888	(0.836,0.937)	265	0.868	(0.823,0.909)	0.057	(0.048,0.067)
αριθμός_αγγείων	ΕΕ	187	0.947	(0.911,0.978)	266	0.974	(0.955,0.992)	0.203	(0.000,0.330)
αριθμός_αγγείων	ΗΠΑ	156	0.91	(0.865,0.952)	265	0.966	(0.943,0.985)	0.369	(0.164,0.520)
αναλογία_αγγείων	ΕΕ	195	0.979	(0.958,0.995)	266	0.936	(0.906,0.962)	0.12	(0.112,0.134)
αναλογία_αγγείων	ΗΠΑ	149	0.987	(0.966,1.000)	265	0.958	(0.932,0.981)	0.092	(0.081,0.102)
Λόγος CSP	ΕΕ	181	0.923	(0.879,0.961)	266	0.974	(0.955,0.992)	0.841	(0.777,0.904)

Λόγος CSP	ΗΠΑ	177	0.819	(0.762,0.876)	265	0.996	(0.989,1.000)	0.82	(0.740,0.887)
Λόγος VP	ΕΕ	158	0.949	(0.911,0.981)	266	1.0	(1.000,1.000)	0.061	(0.053,0.068)
Λόγος VP	ΗΠΑ	161	0.957	(0.922,0.983)	265	1.0	(1.000,1.000)	0.069	(0.061,0.075)
Οπίσθιος χώρος αριστερού κόλπου	ΕΕ	159	0.969	(0.936,0.994)	266	0.929	(0.895,0.959)	0.082	(0.075,0.089)
Οπίσθιος χώρος αριστερού κόλπου	ΗΠΑ	197	0.985	(0.966,1.000)	265	0.943	(0.913,0.970)	0.075	(0.070,0.081)

9. Αντενδείξεις

Δεν υπάρχει αντένδειξη που να συνδέεται με τη συσκευή FETOLY.

10. Προειδοποίηση, προφυλάξεις, αλληλεπιδράσεις με άλλο εξοπλισμό

Προειδοποιήσεις και προφυλάξεις από το αρχείο διαχείρισης κινδύνων:

- Ο χρήστης πρέπει να μεγεθύνει τουλάχιστον 30% για να αποφύγει το ψευδώς αρνητικό αποτέλεσμα λόγω λογισμικού.
- Ο χρήστης πρέπει να επανεξετάζει συστηματικά το σύνολο των εικόνων που έχουν επιλεγεί πριν από την εξαγωγή.
- Η επίβλεψη της λειτουργίας επαναφοράς μπορεί να οδηγήσει σε σύγχυση των ασθενών και να συμβάλει σε ψευδώς αρνητικό έλεγχο.
- Οι εικόνες που διαγράφονται κατά την επιλογή εικόνων χάνονται οριστικά.
- Η διαμόρφωση της εισόδου ροής βίντεο μπορεί να συμβάλει σε ψευδώς αρνητικό έλεγχο.
- Η μη συμβατή ροή βίντεο μπορεί να οδηγήσει σε σφάλμα στην τεκμηρίωση της εξέτασης. Η ροή βίντεο πρέπει να έχει τα ακόλουθα χαρακτηριστικά:
    - Τουλάχιστον 24 καρέ ανά δευτερόλεπτο (fps).
    - Ανάλυση κατώτερη από 1280*720.
- Η ασυμβατότητα του tablet μπορεί να οδηγήσει σε σφάλμα στην τεκμηρίωση της εξέτασης.
- Η αποτυχία εξαγωγής οδηγεί σε απώλεια της αναφοράς εξέτασης.
- Επαληθεύστε το όνομα ασθενούς που επιλέξατε πριν από την εξαγωγή DICOM στη σελίδα εξαγωγής ,για να αποφύγετε τη σύγχυση του φακέλου ασθενούς.
- Χρήση κατά το 1ο τρίμηνο της κύησης οδηγεί σε σφάλμα στη λειτουργία πληρότητας.
- Η εξέταση πρέπει να γίνεται σε ένα έμβρυο κάθε φορά.
- Εάν το tablet αρχίσει να υπερθερμαίνεται, σταματήστε τη χρήση του λογισμικού.
- Επαληθεύστε τη στάθμη της μπαταρίας του tablet σας πριν από την εξέταση. Ο τερματισμός λειτουργίας του λογισμικού μπορεί να οδηγήσει σε απώλεια των δεδομένων της εξέτασης.
- Το λογισμικό δεν μπορεί να χρησιμοποιηθεί για σκοπούς ελέγχου, καθώς μπορεί να οδηγήσει σε ψευδώς αρνητική συνεισφορά ελέγχου.
- Χρησιμοποιήστε το tablet μόνο του και μην επιτρέπετε σε μη εξουσιοδοτημένα άτομα να έχουν πρόσβαση στο tablet σας για να αποφύγετε κινδύνους ασφαλείας.
- Παρακαλούμε να έχετε υπόψη πως όταν τα δεδομένα εξάγονται στη συσκευή σας, βρίσκονται πλέον υπό την ευθύνη σας.

- Μην χρησιμοποιείτε καμία άλλη εφαρμογή tablet παράλληλα με το FETOLY, ώστε να αποφύγετε παρεμβολές στη διαδικασία λήψης ροής εικόνων ή στην εκτέλεση του υπολογισμού μηχανικής μάθησης.
- Μην χρησιμοποιείτε την εφαρμογή κατά τη σάρωση με διακολπική κεφαλή υπερήχων, καθώς το προϊόν δεν έχει δοκιμαστεί με διακολπικές εικόνες.

Προειδοποιήσεις και προφυλάξεις από τη μελέτη απόδοσης λογισμικού:

- Η ευαισθησία του λογισμικού μπορεί να είναι χαμηλότερη για την ανίχνευση:
    - Των ακόλουθων κριτηρίων ποιότητας λήψεων καρδιάς: Μετατόπιση της κολποκοιλιακής βαλβίδας στον καρδιακό σταυρό (Όψη τεσσάρων θαλάμων)
    - Των ακόλουθων κριτηρίων ποιότητας λήψεων εγκεφάλου:
        - Εγγύς στεφανιαία ραφή (Αξονική όψη)
        - Κοιλότητα του διαφανούς διαφράγματος (Αξονική όψη)
        - 3η κοιλία (Αξονική όψη)

    Οι χρήστες θα πρέπει να είναι προσεκτικοί με αυτή την όψη και αυτά τα κριτήρια ποιότητας και να επαληθεύουν τα αποτελέσματα.

Αλληλεπιδράσεις με άλλο εξοπλισμό

Το λογισμικό FETOLY έχει σχεδιαστεί για να λειτουργεί σε ένα ευρύ φάσμα tablet χωρίς να βασίζεται σε εξωτερικούς υπολογισμούς cloud. Το FETOLY έχει διαμορφωθεί ώστε να λαμβάνει μια ροή βίντεο υπερήχων, η οποία μπορεί να επιτευχθεί από ένα σύστημα υπερήχων εξοπλισμένο με έξοδο HDMI προς το υλικό που εκτελεί το λογισμικό.

Το λογισμικό είναι συμβατό με μηχανήματα υπερηχογραφίας της General Electric, της Samsung και της Canon.

Το λογισμικό απαιτεί την ακόλουθη ελάχιστη διαμόρφωση tablet:

- Αρχιτεκτονική CPU ARMv8
- Επεξεργαστής Snapdragon 8 ή
- Επεξεργαστής M1 ή μεταγενέστερος, ή
- Επεξεργαστής A14 ή μεταγενέστερος και
- Χωρητικότητα RAM τουλάχιστον 8 GB
- Χωρητικότητα αποθήκευσης τουλάχιστον 1 GB
- Android σε έκδοση 13/ iOS σε έκδοση 17 ή μεταγενέστερη

Συνιστώνται τα ακόλουθα μοντέλα tablet:

- Samsung Galaxy Tab S8 ή νεότερη έκδοση
- Ipad Air 5 ή νεότερη έκδοση
- Ipad 10 ή νεότερη έκδοση
- Ipad mini 7 ή νεότερη έκδοση
- Ipad Pro 3 ή νεότερη έκδοση

Μη διστάσετε να επικοινωνήσετε με την υποστήριξη πελατών της Diagnoly στο support@diagnoly.com εάν έχετε οποιαδήποτε αμφιβολία σχετικά με την επιλογή μοντέλου tablet.

Οι εικόνες με ετικέτα από το FETOLY μπορούν να αποθηκευτούν απευθείας στο tablet ή να σταλούν σε άλλη συσκευή στο ίδιο δίκτυο με τη συσκευή που εκτελεί το FETOLY. Για να χρησιμοποιήσετε αυτή την επιλογή, το λογισμικό απαιτεί έναν διακομιστή FTP στη συσκευή προορισμού, έναν διακομιστή DICOM Store ή μια σύνδεση Bluetooth.

11. Ανεπιθύμητες ενέργειες

Δεν υπάρχει ανεπιθύμητη ενέργεια που να συνδέεται με τη συσκευή FETOLY.

12. Οδηγίες για την ασφάλεια στον κυβερνοχώρο

12.1. Περιγραφή της υψηλού επιπέδου προστασίας κρίσιμης λειτουργικότητας

Αυτή η ενότητα παρέχει μια υψηλού επιπέδου περιγραφή των δυνατοτήτων της συσκευής που προστατεύουν κρίσιμες λειτουργικότητες. Οι δυνατότητες λήψης ροής εικόνων και ανάλυσης εικόνων βασίζονται σε τοπικούς πόρους (ενσύρματο καλώδιο, μοντέλο τεχνητής νοημοσύνης αιχμής) και δεν απαιτούν τη λειτουργία του Διαδικτύου. Το λογισμικό δεν αποθηκεύει ούτε διαχειρίζεται δεδομένα ασθενούς, αλλά επιτρέπει στον χρήστη να εξαγάγει, μετά από μια εξέταση, μια αναφορά εξέτασης σε συσκευή τρίτου κατασκευαστή. Μια εναλλακτική λειτουργία εξαγωγής είναι διαθέσιμη εάν το τοπικό δίκτυο έχει παραβιαστεί για να επιτρέψει στους χρήστες να αποθηκεύουν αναφορές στο σύστημα αρχείων του tablet.

12.2. Εγγενείς κίνδυνοι κυβερνοασφάλειας της συσκευής

Οι εγγενείς κίνδυνοι κυβερνοασφάλειας του FETOLY περιλαμβάνουν:

- Κλοπή δεδομένων ασθενούς
- Λιγότερο αποδοτική φροντίδα ασθενών λόγω κατεστραμμένης λειτουργίας τεχνητής νοημοσύνης, όπως παραποιημένα βάρη μοντέλου ή τροποποιήσεις λογισμικού/λειτουργικού συστήματος
- Κακή χρήση της συσκευής, που οδηγεί σε διαφορετικά αποτελέσματα από αυτά που επιδιώκει ο κατασκευαστής ή αναμένει ο χρήστης
- Απώλεια χρόνου για τον χρήστη.

Αυτοί οι κίνδυνοι ελέγχονται από την ανάλυση κινδύνου.

12.3. Διάγραμμα συνιστώμενων ελέγχων κυβερνοασφάλειας



Το διάγραμμα περιγράφει το περιβάλλον του λογισμικού FETOLY που εκτελείται στο tablet του χρήστη και τις επικοινωνίες εισόδου/εξόδου με το σύστημα υπερήχων και τη συσκευή τρίτου κατασκευαστή.

Περιλαμβάνει τις παραπομπές σε συνιστώμενους ελέγχους κυβερνοασφάλειας για το περιβάλλον προβλεπόμενης χρήσης που περιγράφεται στην **ενότητα 12.4**:

- G1: Ασφαλής λειτουργία με συστήματα τρίτων μέσω FTP με SSL/TLS
- G2: Ασφαλής λειτουργία με συστήματα τρίτων μέσω Bluetooth (μόνο για Android)
- G3: Έλεγχος ασφαλούς πρόσβασης της συσκευής
- G4: Ασφαλής λειτουργία με συστήματα τρίτων μέσω DICOM με SSL/TLS

12.4. Οδηγίες συσκευής και προδιαγραφές προϊόντος που σχετίζονται με συνιστώμενους ελέγχους κυβερνοασφάλειας κατάλληλους για το περιβάλλον προβλεπόμενης χρήσης

Κατευθυντήριες οδηγίες για ασφαλή λειτουργία με συστήματα τρίτων μέσω FTP με SSL/TLS (G1):

- Ελάχιστες απαιτήσεις δικτύωσης: η υποδομή δικτύου πρέπει να υποστηρίζει FTP με SSL/TLS (FTPS) και ο διακομιστής FTP πρέπει να είναι συμβατός με FTPS. Εφαρμόστε κανόνες τμηματοποίησης δικτύου και τείχους προστασίας για να περιορίσετε την πρόσβαση στις απαραίτητες υπηρεσίες και διευθύνσεις IP.
- Εγκατάσταση FTP μέσω διακομιστή SSL/TLS, όπως:
    i. Windows 10/11 με χρήση των υπηρεσιών IIS: Ανατρέξτε στην τεκμηρίωση της Microsoft για τη ρύθμιση του FTP μέσω TLS/SSL με τις υπηρεσίες IIS.
    j. Διακομιστής FileZilla (ανεξαρτήτως πλατφόρμας): Διαμορφώστε το FTPES ως εξής: «Απαιτείται ρητό FTP μέσω TLS», δημιουργήστε έναν χρήστη με ισχυρό κωδικό πρόσβασης*, ορίστε μια διαδρομή αποθήκευσης δεδομένων (π.χ. «C:\FetolyData» ή «/home/shared/FetolyData») και διαμορφώστε τους κανόνες τείχους προστασίας για το συγκεκριμένο πρόγραμμα ή τη θύρα που χρησιμοποιείται από τον διακομιστή FTP.

Οδηγίες για ασφαλή λειτουργία με συστήματα τρίτων μέσω Bluetooth (G2, μόνο για Android):

- Ελάχιστες απαιτήσεις δικτύωσης: Bluetooth έκδοση 5 ή μεταγενέστερη.
- Ορίστε έναν ισχυρό κωδικό πρόσβασης στο λογισμικό για την προστασία των εξαγόμενων δεδομένων ασθενούς*.

Οδηγίες για τον ασφαλή έλεγχο πρόσβασης συσκευών (G3):

- Ρυθμίστε μια οθόνη κλειδώματος με ισχυρό κωδικό πρόσβασης*, PIN ή βιομετρικό έλεγχο ταυτότητας.
- Ενεργοποιήστε τις αυτόματες ενημερώσεις για το λειτουργικό σύστημα και για όλες τις εγκατεστημένες εφαρμογές.
- Απενεργοποιήστε τυχόν μη χρησιμοποιούμενες διεπαφές δικτύου (π.χ. NFC, IR).

Οδηγίες για ασφαλή λειτουργία με συστήματα τρίτων μέσω DICOM (G4):

- Βεβαιωθείτε ότι η επικοινωνία πραγματοποιείται μέσω ενός ασφαλούς και τμηματοποιημένου δικτύου, περιορίζοντας την πρόσβαση μέσω ισχυρών διαμορφώσεων τείχους προστασίας και μηχανισμών ελέγχου πρόσβασης.

*Χρησιμοποιήστε ισχυρούς κωδικούς πρόσβασης στο tablet σας και για οποιαδήποτε συσκευή (π.χ. συσκευή τρίτου κατασκευαστή για εξαγωγή FTP) ή διαμόρφωση που συνδέεται με το FETOLY (δηλαδή διαμόρφωση Bluetooth) σύμφωνα με τις συστάσεις της υπηρεσίας κυβερνοάμυνας των ΗΠΑ:

- Μεγάλου μήκους—τουλάχιστον 16 χαρακτήρες (ακόμα μεγαλύτερο μήκος είναι καλύτερο).
- Τυχαίος—όπως μια σειρά από κεφαλαία και πεζά γράμματα, αριθμούς και σύμβολα (η ισχυρότερη επιλογή!) ή μια συνθηματική φράση 5 –7 τυχαίων λέξεων.
- Μοναδικός—χρησιμοποιείται για έναν και μόνο λογαριασμό.

Εάν εντοπιστεί τρωτότητα ή περιστατικό κυβερνοασφάλειας, να το αναφέρετε αμέσως στην ομάδα ασφάλειας ΤΠΕ και στην Diagnoly (support@diagnoly.com). Στο tablet:

- Επαναφορά: Επαναφέρετε τις εργοστασιακές ρυθμίσεις για να διαγράψετε όλα τα δεδομένα και τις διαμορφώσεις.
- Επανεγκατάσταση εφαρμογής: Κατεβάστε την πιο πρόσφατη, ασφαλή έκδοση εφαρμογής από το Google Play Store.
- Εναλλακτική επιλογή: Χρησιμοποιήστε τοπική εξαγωγή σε κάρτα SD εάν έχουν παραβιαστεί οι εξαγωγές που βασίζονται σε δίκτυο.

12.5. Κατάλογος θυρών δικτύου και άλλων διεπαφών

Το λογισμικό FETOLY λαμβάνει δεδομένα ροής εισόδου μέσω ενός καλωδίου που συνδέεται μεταξύ της εξόδου της εξωτερικής οθόνης του συστήματος υπερήχων και της εισόδου USB-C του tablet. Το λογισμικό μπορεί να διαμορφωθεί ώστε να εξάγει αναφορές εξετάσεων σε συσκευή τρίτου κατασκευαστή μέσω TCP/IP, FTPS ή Bluetooth.

Για την εξαγωγή δεδομένων μέσω δικτύου TCP IP/FTPS:

- Πρωτόκολλο: FTPS

- Εισερχόμενες θύρες: Το λογισμικό δεν ανοίγει το ίδιο τις εισερχόμενες θύρες, καθώς λειτουργεί αποκλειστικά ως πελάτης και όχι ως διακομιστής.
- Εξερχόμενες θύρες: Το λογισμικό χρησιμοποιεί μια δυναμικά εκχωρημένη εφήμερη θύρα (εύρος: 1024-65535) για να δημιουργηθεί σύνδεση με τον διακομιστή FTPS σε μια καθορισμένη διεύθυνση IP. Η εισερχόμενη θύρα του διακομιστή FTPS τρίτου κατασκευαστή καθορίζεται από τον χρήστη.
- Κανόνες τείχους προστασίας: Τα τείχη προστασίας τόσο από την πλευρά του πελάτη όσο και από την πλευρά του διακομιστή πρέπει να επιτρέπουν εξερχόμενες συνδέσεις από τον υπολογιστή-πελάτη στη θύρα του διακομιστή.

Για την εξαγωγή δεδομένων μέσω Bluetooth/OBEX (μόνο για Android):

- Κρυπτογράφηση: τα δεδομένα είναι συμπιεσμένα και κρυπτογραφημένα με κωδικό πρόσβασης.

Για την εξαγωγή δεδομένων μέσω DICOM:

- Πρωτόκολλο: DICOM
- Εισερχόμενες θύρες: Το λογισμικό δεν ανοίγει το ίδιο τις εισερχόμενες θύρες, καθώς λειτουργεί αποκλειστικά ως πελάτης και όχι ως διακομιστής.
- Εξερχόμενες θύρες: Το λογισμικό χρησιμοποιεί μια δυναμικά εκχωρημένη εφήμερη θύρα (Android: 32768 έως 60999) για να δημιουργηθεί σύνδεση με το διακομιστή DICOM σε μια καθορισμένη διεύθυνση IP. Η εισερχόμενη θύρα του διακομιστή DICOM τρίτου κατασκευαστή καθορίζεται από τον χρήστη.
- Κανόνες τείχους προστασίας: Τα τείχη προστασίας τόσο από την πλευρά του πελάτη όσο και από την πλευρά του διακομιστή πρέπει να επιτρέπουν εξερχόμενες συνδέσεις από τον υπολογιστή-πελάτη στη θύρα του διακομιστή.

12.6. Απαιτήσεις υποστηρικτικής υποδομής

Ανατρέξτε στην ενότητα 10 για τις απαιτήσεις της υποστηρικτικής υποδομής, συμπεριλαμβανομένης της ελάχιστης διαμόρφωσης του tablet, των συμβατών συστημάτων υπερήχων.

12.7. SBOM

Ένας κατάλογος υλικών λογισμικού (sBoM) είναι διαθέσιμος στους χρήστες για να διαχειρίζονται τα περιουσιακά τους στοιχεία, να κατανοούν τον πιθανό αντίκτυπο των εντοπισμένων τρωτών σημείων και να εφαρμόζουν αντίμετρα για τη διατήρηση της ασφάλειας και της αποτελεσματικότητας της συσκευής. Ο sBoM μπορεί να μεταφορτωθεί στη σελίδα «Πληροφορίες» του λογισμικού, σε μορφή αναγνώσιμη από μηχανή (.csv), κάνοντας κλικ στο «εμφάνιση» μπροστά από την «Ειδοποίηση τρίτου μέρους».

12.8. Οδηγίες ενημέρωσης / ενημέρωσης κώδικα

Ανατρέξτε στην ενότητα 13 «Ενημέρωση λογισμικού και άδειας χρήσης» για οδηγίες ενημέρωσης.

12.9. Περιγραφή του τρόπου απόκρισης της συσκευής όταν εντοπίζονται ανώμαλες συνθήκες

Αυτή η ενότητα περιγράφει τον τρόπο με τον οποίο το λογισμικό ανταποκρίνεται σε συμβάντα ασφαλείας. Όλα τα σφάλματα του λογισμικού εξάγονται μέσω ενός αρχείου καταγραφής σφαλμάτων στο Firebase. Οι ακόλουθες προειδοποιήσεις ενδέχεται να εμφανιστούν κατά τη χρήση του FETOLY:

- Αποτυχία εξαγωγής: ανωμαλία δικτύου που οδηγεί σε αποτυχία εξαγωγής αναφορών μέσω TCP/IP FTPS, DICOM ή Bluetooth.
- Αποτυχία σύνδεσης USB: δεν υπάρχει καλώδιο USB-C συνδεδεμένο στο tablet ή αποτυχία λήψης ροής βίντεο USB-C.
- Αποτυχία επικύρωσης άδειας χρήσης: ο χρήστης επιχειρεί επικύρωση άδειας χρήσης χωρίς σύνδεση στο Διαδίκτυο, ενεργοποίηση αυτόματης ώρας ή έγκυρη άδεια χρήσης.
- Υπερθέρμανση tablet.
- Πρόβλημα συμβατότητας tablet: ρυθμός καρέ ροής βίντεο κάτω από 24 fps.
- Χαμηλή μπαταρία tablet.

12.10. Δημιουργία αντιγράφων ασφαλείας και επαναφορά

Για να επαναφέρετε τις λειτουργίες της συσκευής και την προεπιλεγμένη διαμόρφωση, απεγκαταστήστε και εγκαταστήστε εκ νέου τη το προϊόν μέσω του Google Play/App Store.

12.11. Περιγραφή μεθόδων διατήρησης και ανάκτησης της διαμόρφωσης της συσκευής από εξουσιοδοτημένο χρήστη που έχει υποβληθεί σε έλεγχο ταυτότητας

Οι ρυθμίσεις εξαγωγής, όπως τα διαπιστευτήρια τρίτων, και οι ρυθμίσεις καταγραφής βίντεο, όπως η αναλογία βίντεο εισόδου, διατηρούνται στην προσωρινή μνήμη αποθήκευσης δεδομένων του tablet, απομονωμένες με ασφάλεια από το Android/iOS. Δεδομένου ότι οι προαναφερθείσες διαμορφώσεις ρυθμίζονται γρήγορα, δεν εφαρμόζεται συγκεκριμένη μεθοδολογία ανάκτησης. Ζητείται από τους χρήστες να εισαγάγουν ξανά τις ρυθμίσεις με μη αυτόματο τρόπο κατά την επανεγκατάσταση ή την εγκατάσταση νέου προϊόντος.

12.12. Ασφαλής διαμόρφωση

Αυτή η ενότητα παρέχει οδηγίες για να διασφαλιστεί ότι το λογισμικό FETOLY έχει διαμορφωθεί και συντηρείται με ασφάλεια.

Αρχική ρύθμιση: Κατεβάστε και εγκαταστήστε την πιο πρόσφατη έκδοση από το Google Play/App Store. Βεβαιωθείτε ότι το όνομα και το εικονίδιο της εφαρμογής ταιριάζουν με αυτά που παρέχονται στην ενότητα 13. Εκτελέστε όλα τα βήματα ρύθμισης εξαγωγής μέσω ασφαλούς σύνδεσης δικτύου σύμφωνα με τις οδηγίες G1/2/4 στην ενότητα 12.4. Βεβαιωθείτε ότι η συσκευή που εκτελεί το FETOLY είναι ασφαλής σύμφωνα με την οδηγία G3 στην ενότητα 12.4.

Απόκριση σε περιστατικό: Ενεργοποιήστε τη σύνδεση στο Διαδίκτυο για την καταγραφή σφαλμάτων και ανώμαλων δραστηριοτήτων, όπως περιγράφεται στην ενότητα 12.13. Αναφέρετε οποιαδήποτε τρωτότητα που εντοπίστηκε σύμφωνα με τις οδηγίες στην ενότητα 12.4.

12.13. Συλλογή εγκληματολογικών αποδεικτικών στοιχείων, κατά περίπτωση για το περιβάλλον προβλεπόμενης χρήσης

Ένα σύστημα αναφοράς σφαλμάτων είναι ενσωματωμένο στο λογισμικό. Οι αναφορές σφαλμάτων αποστέλλονται σε περίπτωση σφάλματος εφαρμογής ή ανώμαλου συμβάντος, εάν είναι ενεργοποιημένη μια σύνδεση στο Διαδίκτυο.

12.14. Πληροφορίες για το τέλος του κύκλου ζωής και το τέλος της υποστήριξης για το σύστημα ή τα κατασκευαστικά στοιχεία, εάν είναι γνωστές ή αναμένονται

Το τέλος του κύκλου ζωής και το τέλος της υποστήριξης βασίζονται στην εγκυρότητα της άδειας χρήσης. Η άδεια χρήσης θα ανανεωθεί αυτόματα με σύνδεση στο Διαδίκτυο μόλις η σύμβαση άδειας χρήσης τεθεί ξανά σε ισχύ. Εάν η σύμβαση λήξει ή φτάσει το τέλος του κύκλου ζωής, θα σας ζητηθεί να εισαγάγετε έναν νέο κωδικό εγγραφής.

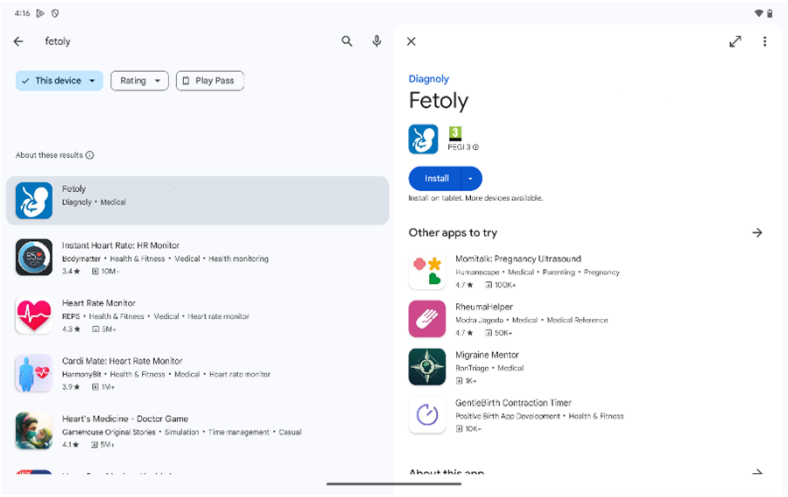
12.15. Ασφαλής παροπλισμός

Για να παροπλίσετε και να απορρίψετε το λογισμικό, απεγκαταστήστε την εφαρμογή μέσω του συστήματος Android/iOS όπως οποιαδήποτε εφαρμογή στο tablet σας, στις παραμέτρους της εφαρμογής, όπως φαίνεται στην ενότητα 13 στην παράγραφο «απεγκατάσταση λογισμικού». Αυτή η απεγκατάσταση θα αφαιρέσει τυχόν δεδομένα που συνδέονται με τη χρήση του FETOLY, συμπεριλαμβανομένης της άδειας, από το tablet σας.

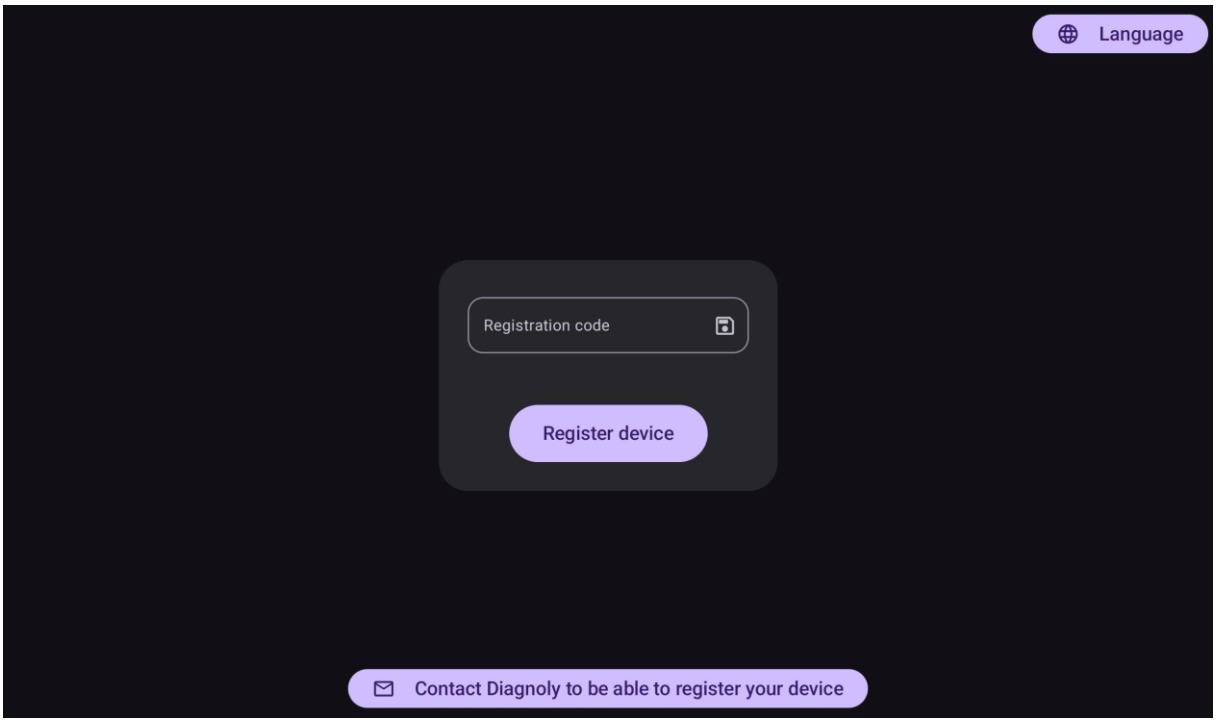
13. Οδηγίες χρήσης

Εγκατάσταση και εκκίνηση λογισμικού

1. Μεταβείτε στο Google Play ή στο App Store, γράψτε FETOLY στη γραμμή αναζήτησης και ξεκινήστε την αυτόματη λήψη και εγκατάσταση



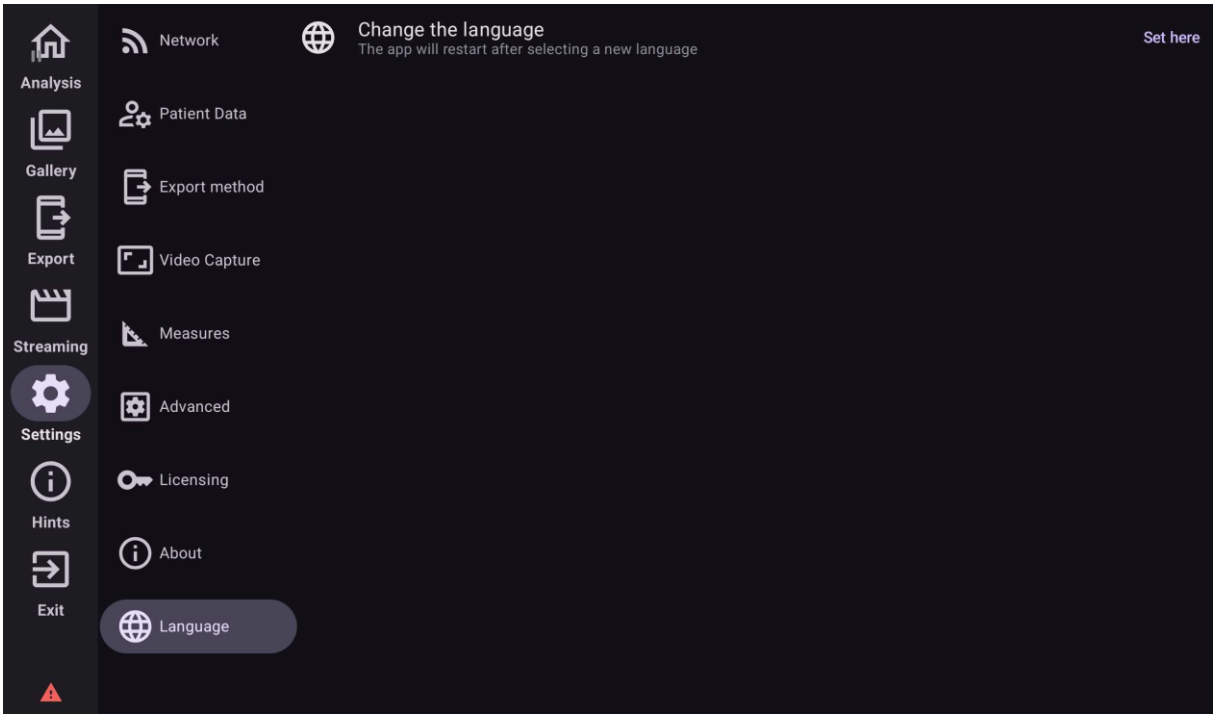
2. Κάντε κλικ στο εικονίδιο του FETOLY στο tablet σας
3. **Επικύρωση άδειας χρήσης**: Εάν απαιτείται, εισαγάγετε τον κωδικό καταχώρησης άδειας όπως φαίνεται παρακάτω. Η Diagnoly είναι υπεύθυνη για την παροχή της άδειας χρήσης. Μπορείτε να επικοινωνήσετε με τη Diagnoly για την έκδοση άδειας χρήσης κάνοντας κλικ απευθείας στο κουμπί που εμφανίζεται στο κάτω μέρος της σελίδας υποδοχής. Η άδεια χρήσης συνδέεται με το αναγνωριστικό της συσκευής σας, το οποίο είναι διαθέσιμο στη σελίδα ρυθμίσεων άδειας χρήσης.

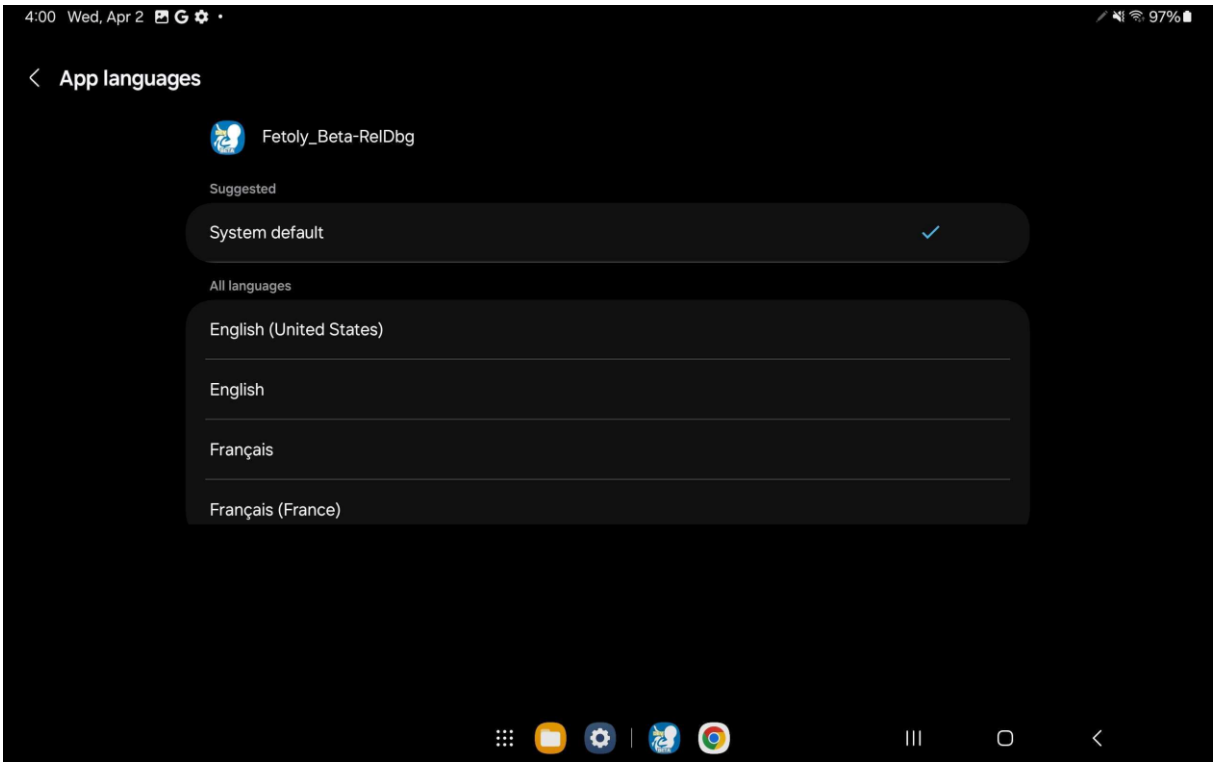


4. **Δημιουργήστε μια σύνδεση Wi-Fi:** Εάν θέλετε να λάβετε τα δεδομένα υπερήχων στον προσωπικό σας υπολογιστή, παρακαλούμε, συνδέστε το tablet στο Wi-Fi hotspot σας.

Ρυθμίσεις γλώσσας

Από προεπιλογή, το λογισμικό έχει ρυθμιστεί στην ίδια γλώσσα με το tablet σας. Ωστόσο, μπορείτε να επιλέξετε τη γλώσσα που χρειάζεστε στις "Ρυθμίσεις" > "Γλώσσα". Αυτό θα σας οδηγήσει στις ρυθμίσεις γλωσσών της εφαρμογής στο Android. Μόλις επιλεγεί η απαιτούμενη γλώσσα, η εφαρμογή θα μεταφραστεί σε αυτήν τη γλώσσα κατά την επανεκκίνηση.



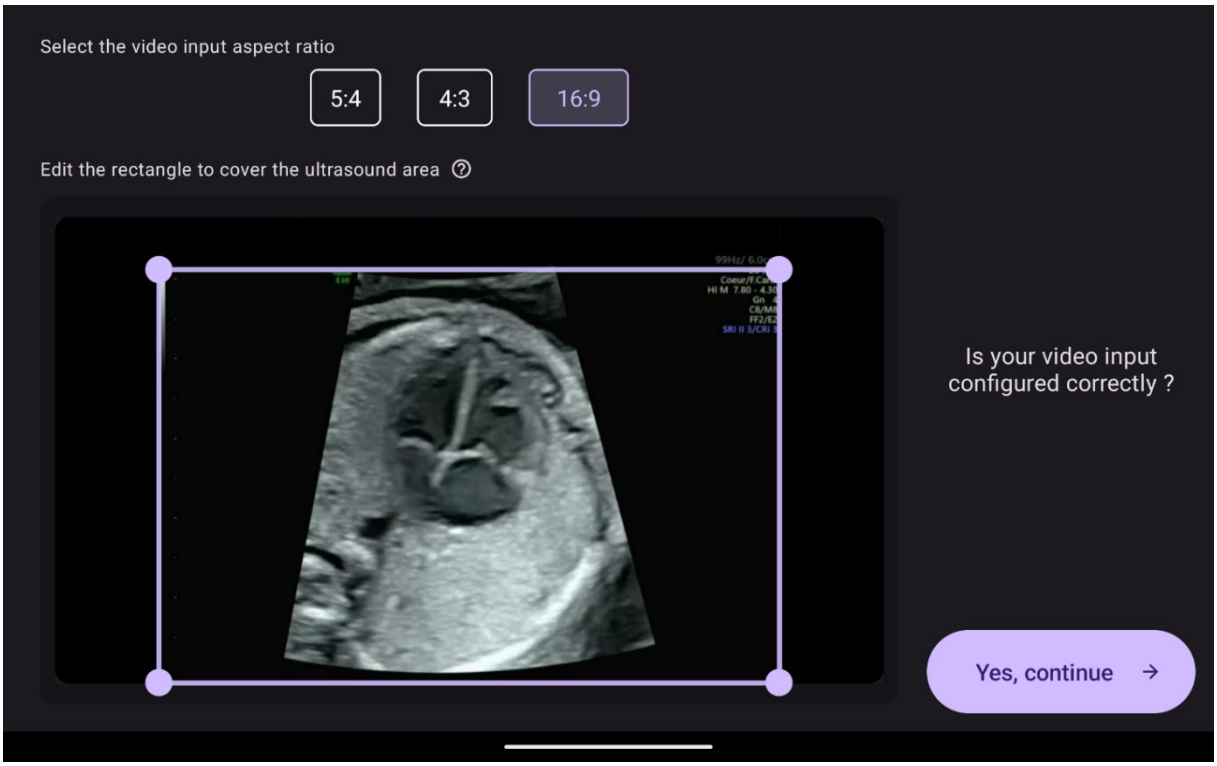


Σύνδεση μηχανήματος υπερηχογραφίας

16. **Ενεργοποιήστε το σύστημα υπερήχων:** Πριν συνδέσετε το tablet σας, βεβαιωθείτε ότι το σύστημα υπερήχων είναι ενεργοποιημένο και σε κατάσταση λειτουργίας.
17. **Συνδέστε το tablet σας στο σύστημα υπερήχων σας:** Για να συνδεθείτε, απλώς συνδέστε το άκρο USB (Τύπος C) ενός προσαρμογέα UVC στο tablet σας και το άκρο HDMI στο μηχάνημα υπερηχογραφίας σας.
18. **Επαλήθευση:** Για να επαληθεύσετε τη σύνδεση μεταξύ του συστήματος υπερήχων και του tablet, ανοίξτε το λογισμικό FETOLY. Εάν έχει συνδεθεί μια νέα πηγή USB, το λογισμικό θα εμφανίσει αυτόματα τη σελίδα διαμόρφωσης ροής βίντεο.

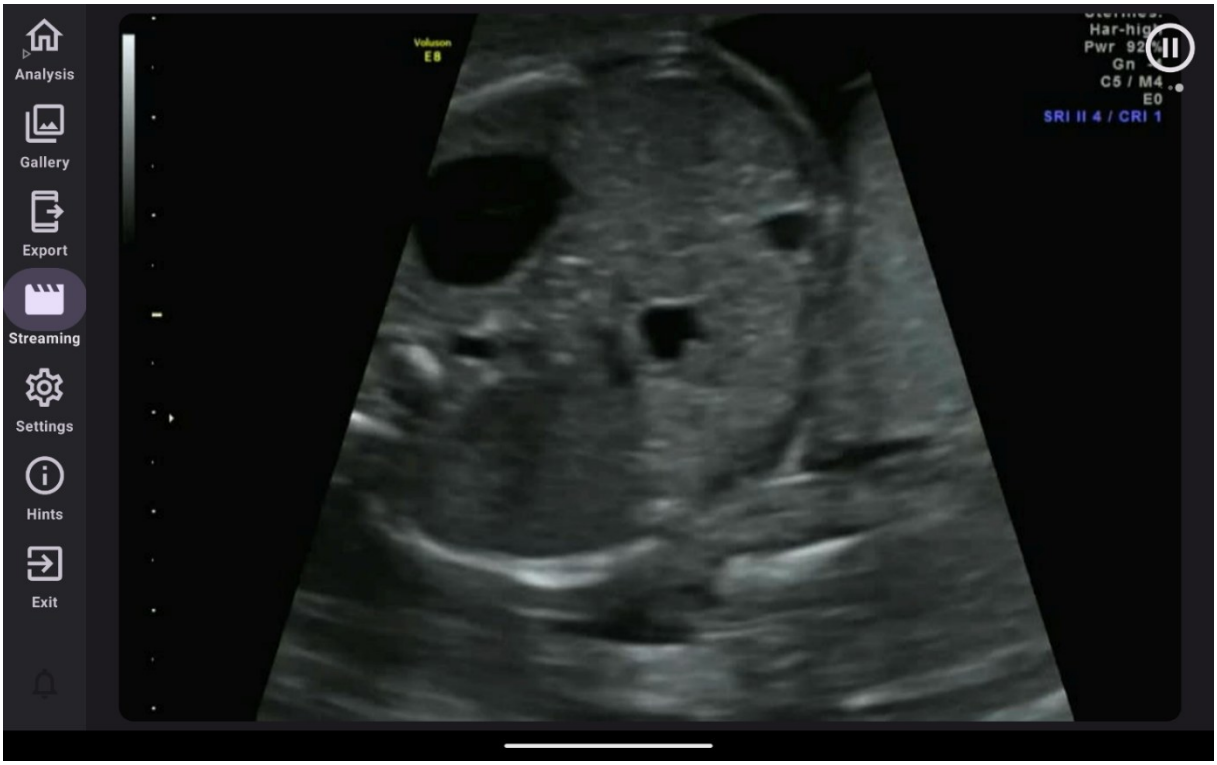
Διαμόρφωση ροής βίντεο

5. Ξεκινήστε τη διαμόρφωση της ροής βίντεο στην εφαρμογή:
    a. Όταν το λογισμικό ανοίξει αυτόματα τη σελίδα διαμόρφωσης βίντεο, επιλέξτε την αναλογία διαστάσεων βίντεο που θα ευθυγραμμιστεί με την αναλογία εξόδου του μηχανήματος υπερηχογραφίας και επιλέξτε την περιοχή του υπερήχου. Σε άλλες περιπτώσεις, μεταβείτε στις «ρυθμίσεις» > «καταγραφή βίντεο» για να διαμορφώσετε τη ροή βίντεο, με την ίδια μεθοδολογία.



l. Η επιλεγμένη περιοχή εμφανίζεται σε πραγματικό χρόνο στη σελίδα ροής. Το κουμπί αναπαραγωγής μπορεί να χρησιμοποιηθεί στη σελίδα ροής για να ξεκινήσει η ανάλυση.

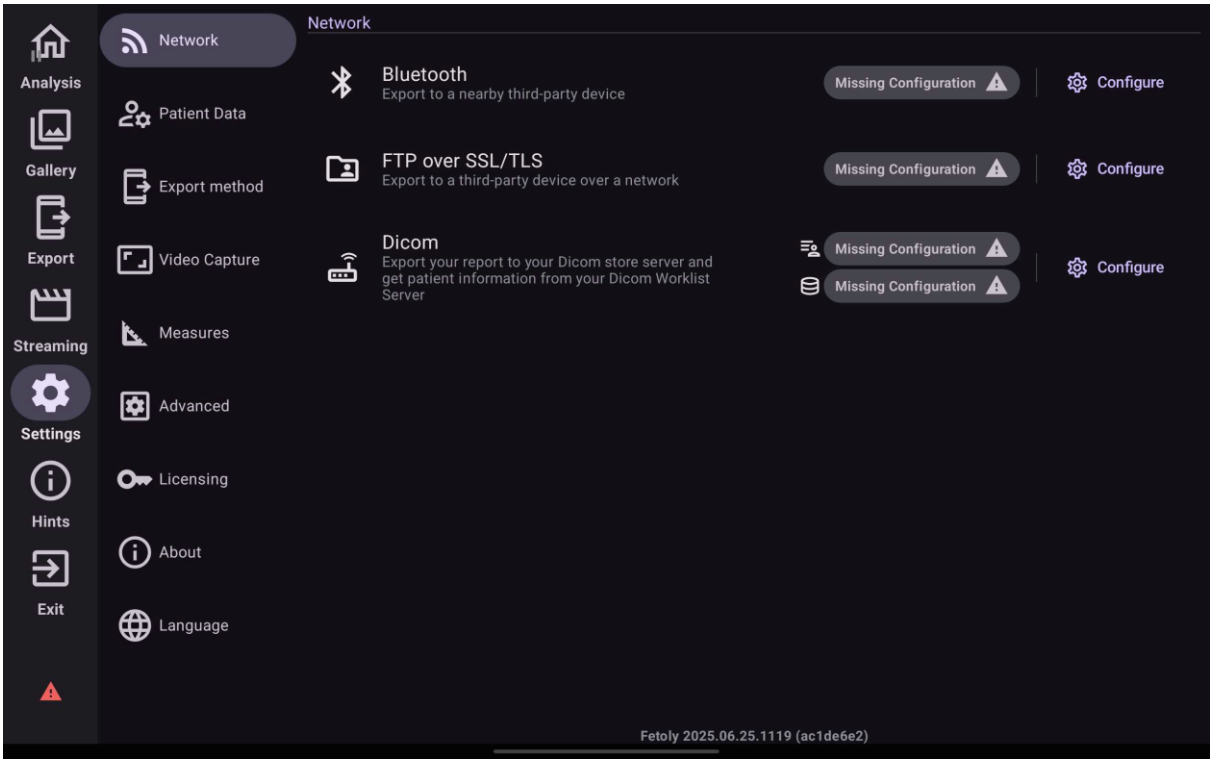
m. Βεβαιωθείτε ότι το μικρόφωνο δεν είναι απενεργοποιημένο στο tablet σας, καθώς κάτι τέτοιο θα οδηγήσει σε αποκλεισμό της εισόδου ροής βίντεο.



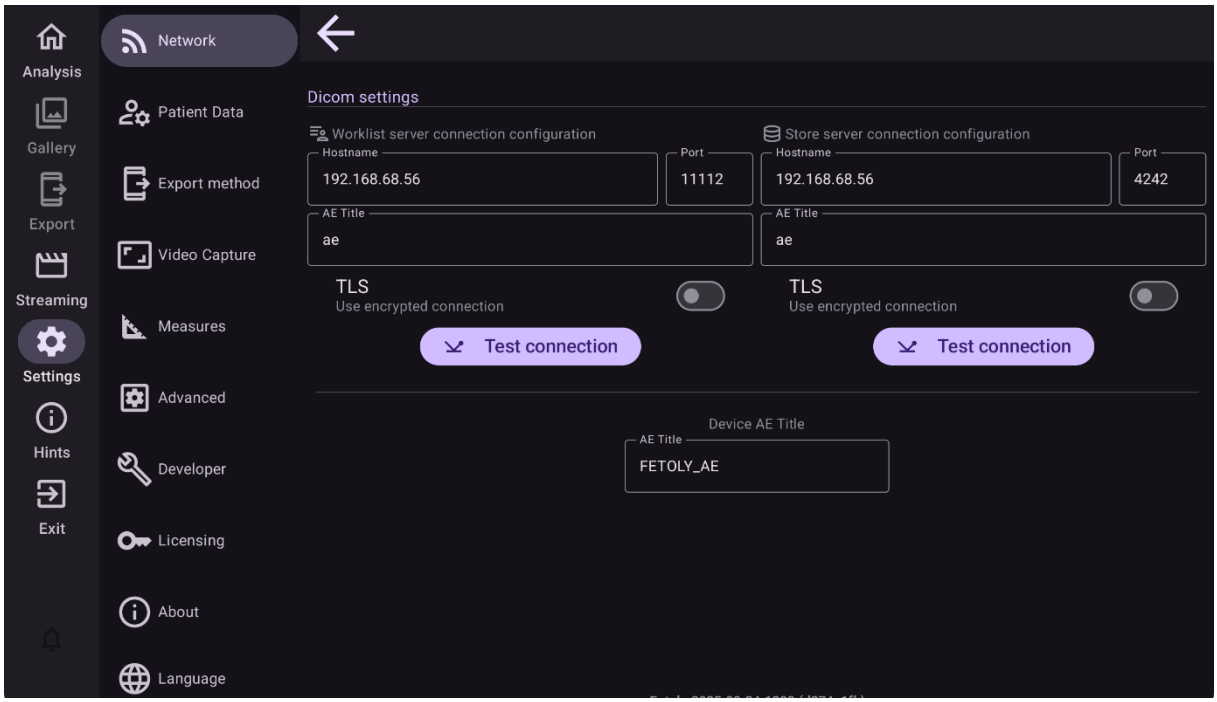
[ΠΡΟΑΙΡΕΤΙΚΟ] Διαμόρφωση του μηχανήματος υπερηχογραφίας

Ορισμένα συστήματα υπερήχων επιτρέπουν τη διαμόρφωση του μεγέθους της περιοχής υπερήχων στην έξοδο βίντεο. Εάν συμβαίνει αυτό, συνιστάται να επιλέξετε τη μεγαλύτερη δυνατή περιοχή.

Διαμόρφωση εξαγωγής

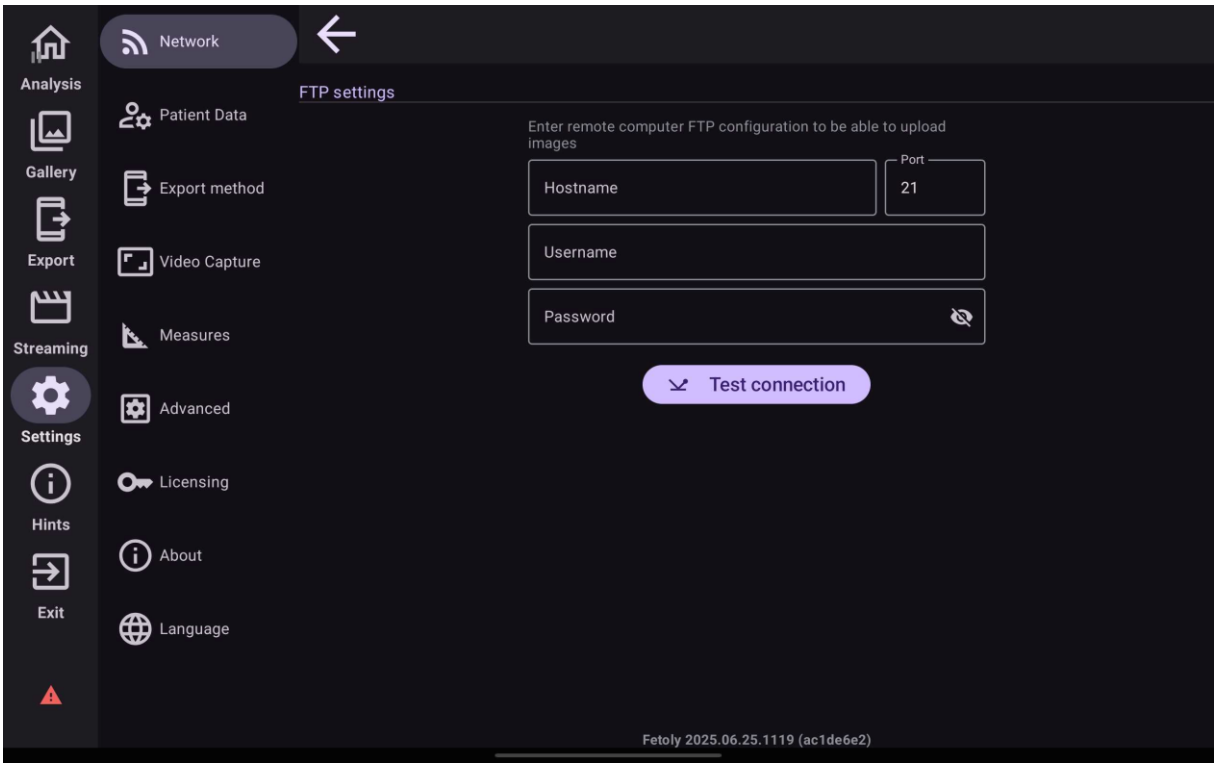


5. Διαμορφώστε τον απομακρυσμένο διακομιστή DICOM για την εξαγωγή εικόνων που καταγράφηκαν από το FETOLY. Λάβετε υπόψη ότι αυτό το βήμα απαιτεί την παρουσία ενός διακομιστή DICOM που εκτελείται σε μια συσκευή συνδεδεμένη στο ίδιο δίκτυο με το tablet που εκτελεί το FETOLY.
    a. Στη συνέχεια, μεταβείτε στις «Ρυθμίσεις» > «Ρυθμίσεις δικτύου», επιλέξτε διαμόρφωση DICOM και εισαγάγετε τις απαιτούμενες πληροφορίες για τον διακομιστή αποθήκευσης DICOM: όνομα κεντρικού υπολογιστή λίστας εργασίας (διεύθυνση IP) και τίτλος οντότητας εφαρμογής (AE), όνομα κεντρικού υπολογιστή DICOM Store (διεύθυνση IP) και τίτλος AE, τίτλος AE συσκευής. Για να επαληθεύσετε τη σύνδεση, κάντε κλικ στο κουμπί «Δοκιμή σύνδεσης» για κάθε διακομιστή DICOM. Αυτό διασφαλίζει ότι η σύνδεση είναι έγκυρη και έτοιμη για την εξαγωγή εικόνων. Μπορείτε επίσης προαιρετικά να ενεργοποιήσετε την επιλογή TLS.



7. Εναλλακτικά, διαμορφώστε τον απομακρυσμένο διακομιστή FTP για την εξαγωγή εικόνων που καταγράφηκαν από το FETOLY. Λάβετε υπόψη ότι αυτό το βήμα απαιτεί την παρουσία ενός διακομιστή FTP που εκτελείται σε μια συσκευή συνδεδεμένη στο ίδιο δίκτυο με το tablet που εκτελεί το FETOLY.

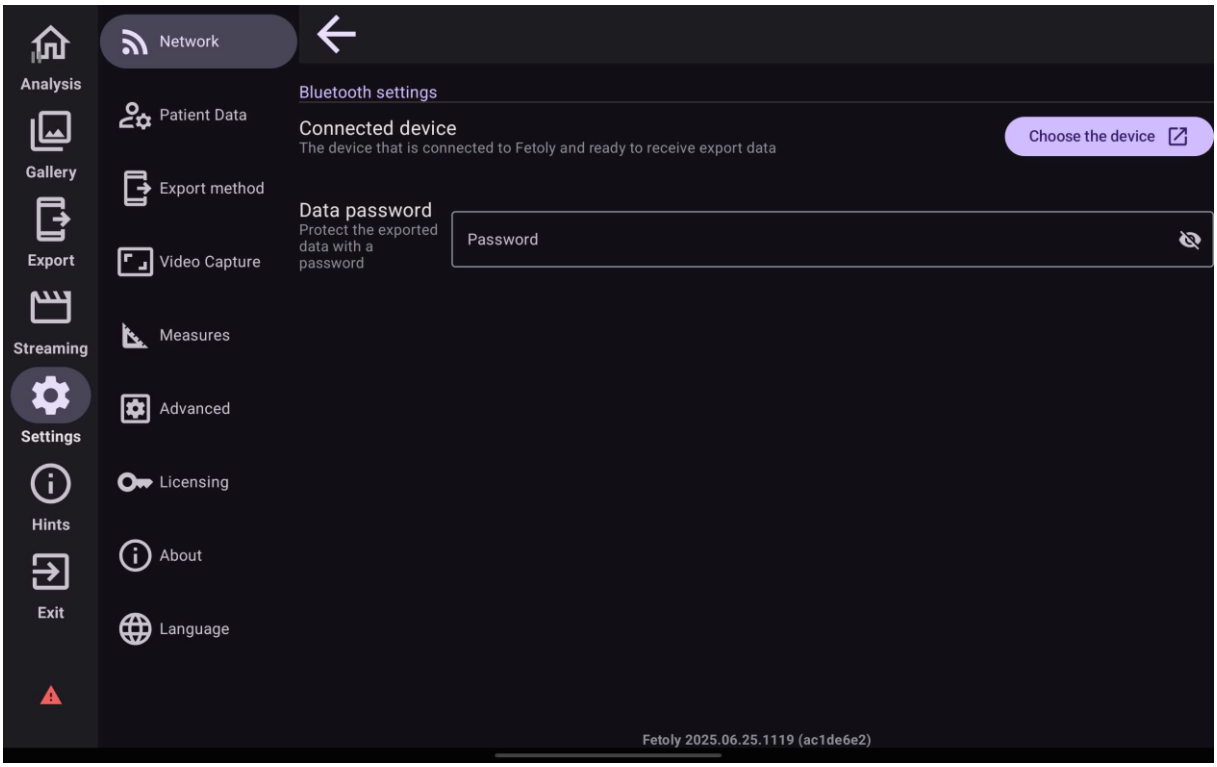
    e. Μεταβείτε στις «Ρυθμίσεις» > «Ρυθμίσεις δικτύου», επιλέξτε διαμόρφωση FTP και εισαγάγετε τις απαιτούμενες πληροφορίες για τον πελάτη FTP: όνομα κεντρικού υπολογιστή (διεύθυνση IP), όνομα χρήστη και κωδικό πρόσβασης. Για να επαληθεύσετε τη σύνδεση, κάντε κλικ στο κουμπί «Δοκιμή σύνδεσης». Αυτό διασφαλίζει ότι η σύνδεση είναι έγκυρη και έτοιμη για την εξαγωγή εικόνων.

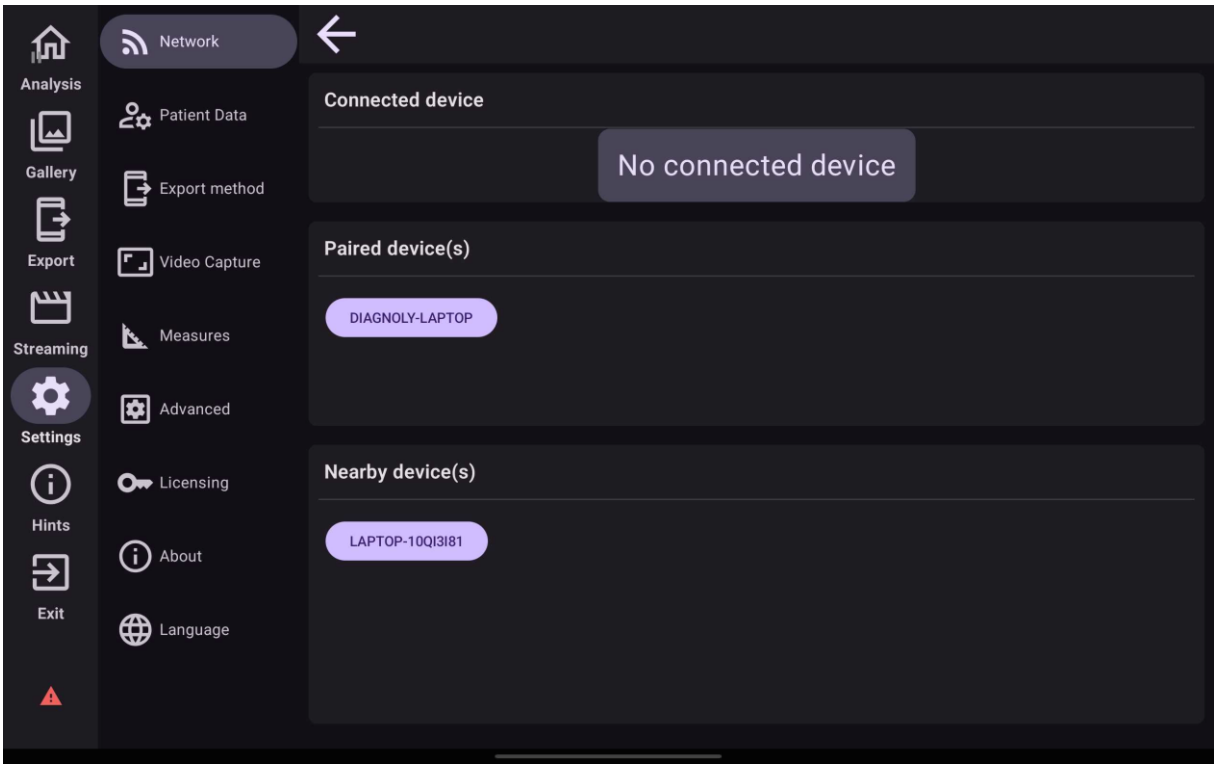


18. Εναλλακτικά, μπορείτε να χρησιμοποιήσετε σύνδεση Bluetooth (μόνο για Android):

    a. «Ρυθμίσεις» > «Ρυθμίσεις δικτύου», επιλέξτε Bluetooth. Για να επιλέξετε τη συσκευή στην οποία θα εξαχθούν τα δεδομένα, πρέπει να αντιστοιχίσετε τη συσκευή επιλέγοντάς την στην ενότητα «κοντινή συσκευή». Στη συνέχεια, επιλέξτε τη συσκευή που θέλετε να συνδέσετε στην ενότητα «συζευγμένη συσκευή». Μόλις επιλεγεί η συσκευή, μπορείτε να δοκιμάσετε τη σύνδεση στην ενότητα «συνδεδεμένη συσκευή». Η σελίδα επιλογής συσκευής είναι προσβάσιμη κάνοντας κλικ στο κουμπί στα δεξιά του «Ρυθμίσεις Bluetooth» > «Συνδεδεμένη συσκευή».

    b. Για την εξαγωγή του αρχείου, πρέπει επιπλέον να ορίσετε έναν κωδικό πρόσβασης. Αυτός ο κωδικός πρόσβασης θα επικολληθεί στο αρχείο .zip που εξάγεται στη συσκευή τρίτου κατασκευαστή

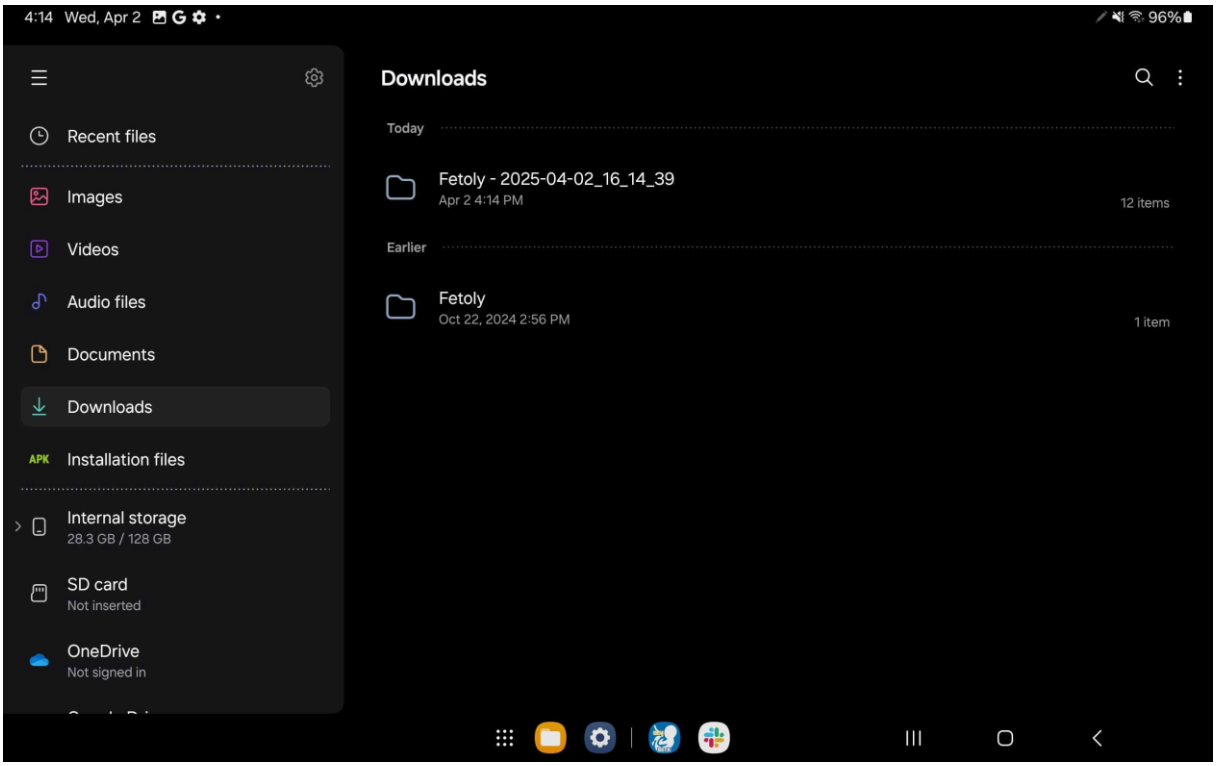




19. Εάν δεν θέλετε να χρησιμοποιήσετε ασύρματη σύνδεση, μπορείτε να εξαγάγετε τα δεδομένα απευθείας στο tablet:

    a. Μεταβείτε στις «Ρυθμίσεις» > «Μέθοδος εξαγωγής», επιλέξτε τοπική. Το αρχείο θα αποθηκευτεί σε μια θέση που έχει ήδη οριστεί από το tablet.

    b. Για να φτάσετε στην καθορισμένη τοποθεσία, μεταβείτε στην επιφάνεια εργασίας του tablet σας, επιλέξτε το εικονίδιο «Αρχεία» και, στη συνέχεια, μεταβείτε στις «Λήψεις» > «Fetoly».

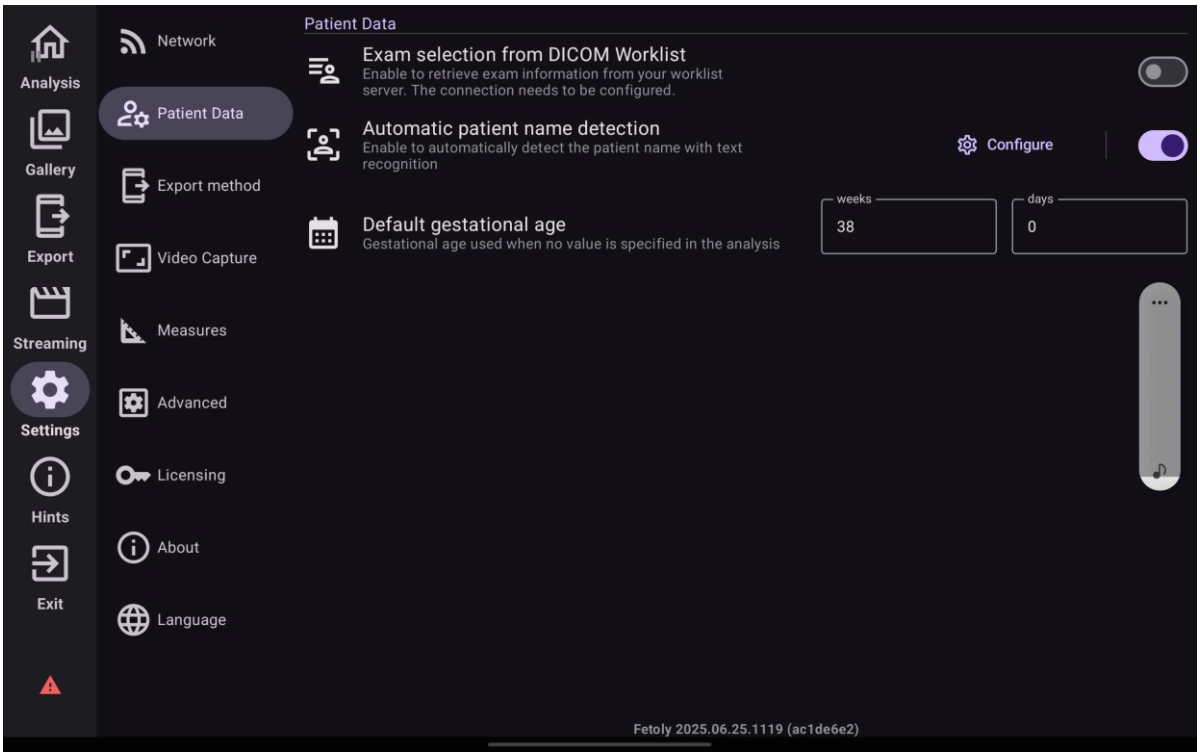


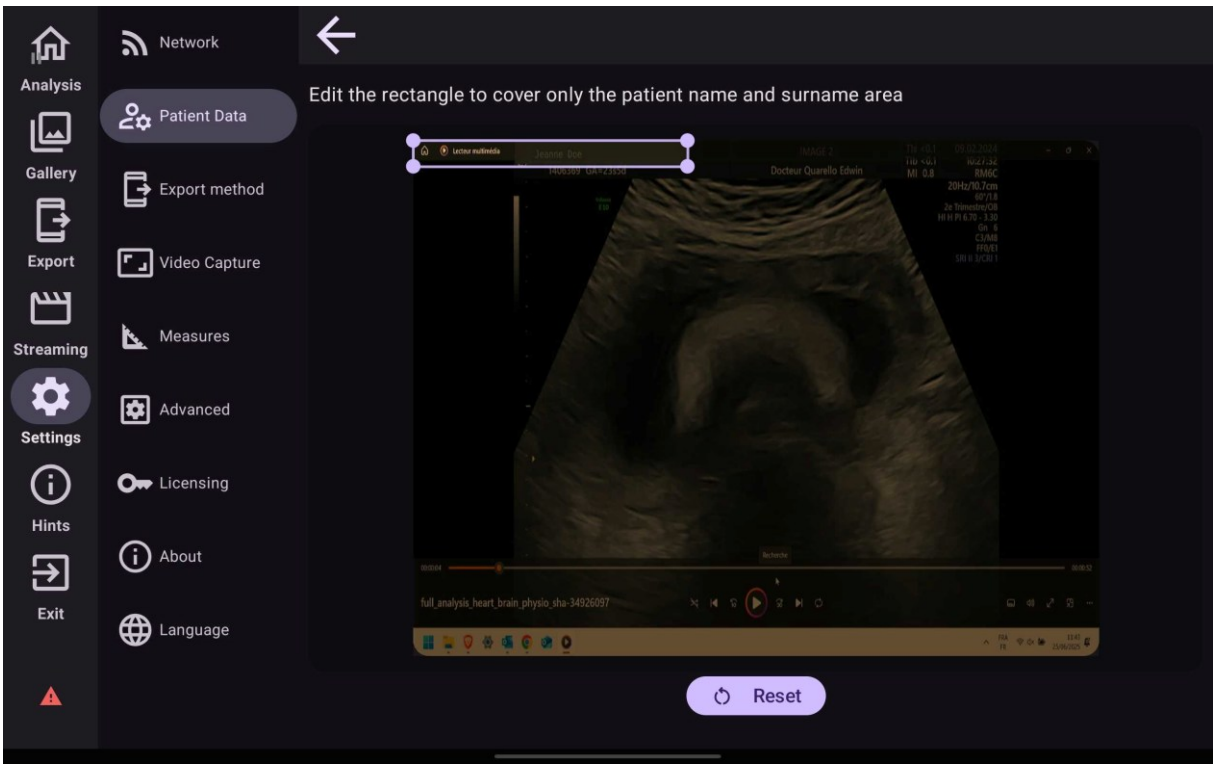
20. Εάν θέλετε να προσθέσετε το όνομα ασθενούς στο όνομα του αρχείου που εξάγεται ή εάν θέλετε να επιλέξετε την εξέταση ασθενούς από τη λίστα εργασιών DICOM:

    a. Συμπληρώστε απευθείας το όνομα ασθενούς με την ηλικία κύησης στη σελίδα ανάλυσης ή

    b. Μεταβείτε στις «ρυθμίσεις» > «Δεδομένα ασθενούς» και ενεργοποιήστε την «επιλογή εξετάσεων από τη λίστα εργασιών DICOM». Σημειώστε ότι αυτή η συνάρτηση λειτουργεί μόνο εάν είστε συνδεδεμένοι σε ένα PACS με διαμορφωμένες παραμέτρους λίστας εργασιών DICOM. Σημειώστε επίσης ότι στη λειτουργία εξαγωγής DICOM, αναγκάζεστε να χρησιμοποιήσετε αυτήν τη ρύθμιση.

    c. Προαιρετικά, μεταβείτε στις «ρυθμίσεις» > «Δεδομένα ασθενούς» και ενεργοποιήστε την «αυτόματη ανίχνευση ονόματος ασθενούς». Στη συνέχεια, μπορείτε να μεταβείτε στη «διαμόρφωση» και να επιλέξετε την περιοχή στη ροή βίντεο υπερήχων όπου εμφανίζεται το όνομα ασθενούς. Στη συνέχεια, το όνομα ασθενούς θα συμπληρωθεί αυτόματα κατά την έναρξη της εξέτασης ή κάνοντας κλικ στο κουμπί ανανέωσης στα δεξιά του ονόματος ασθενούς στη σελίδα ανάλυσης.





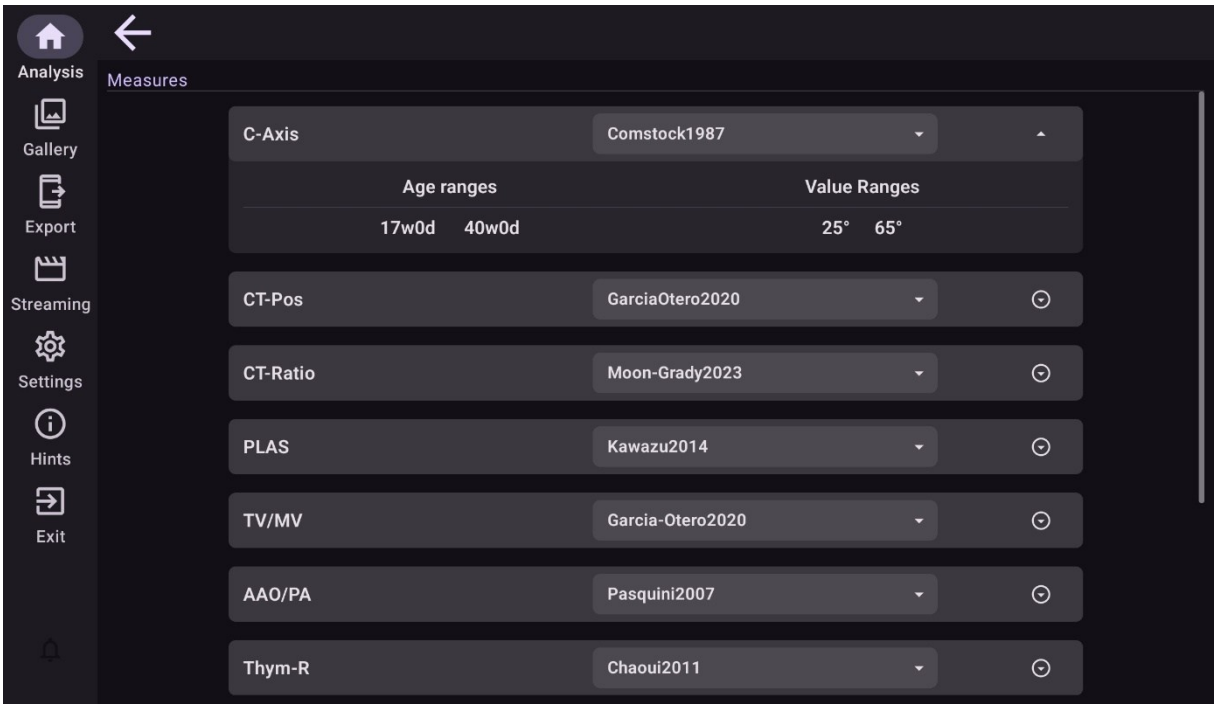
Χρήση

13. Ακολουθήστε αυτά τα βήματα για να πραγματοποιήσετε την πληρότητα της εξέτασης και τις μετρήσεις:

    a. Εισαγάγετε την ηλικία κύησης στη σελίδα ανάλυσης με το όνομα ασθενούς ή επιλέξτε την εξέταση ασθενούς από τη λίστα εργασιών DICOM.

    b. Μπορείτε να διαμορφώσετε την προεπιλεγμένη ηλικία κύησης μεταβαίνοντας στις «Ρυθμίσεις» > «Δεδομένα ασθενούς».

c. Για τη λειτουργία μέτρησης, εάν υπάρχουν πολλές διαθέσιμες πηγές βιβλιογραφίας, επιλέξτε αυτήν που προτιμάτε. Μπορείτε επίσης να ρυθμίσετε μη αυτόματα τα εύρη αναφοράς επιλέγοντας προσαρμοσμένη. Αυτό γίνεται κάνοντας κλικ στο κουμπί νέας καρτέλας στα δεξιά της μέτρησης στη σελίδα ανάλυσης ή μεταβαίνοντας στις «Ρυθμίσεις» > «Ρυθμίσεις μετρήσεων». Αυτό θα σας ανακατευθύνει στη σελίδα ρυθμίσεων μέτρησης.



d. Πατήστε Αναπαραγωγή στη σελίδα ανάλυσης

e. Κάντε την εξέταση ως συνήθως

f. Η εξέταση θεωρείται ολοκληρωμένη όταν επαληθευτούν όλες οι όψεις και τα κριτήρια και όταν γίνουν όλες οι μετρήσεις

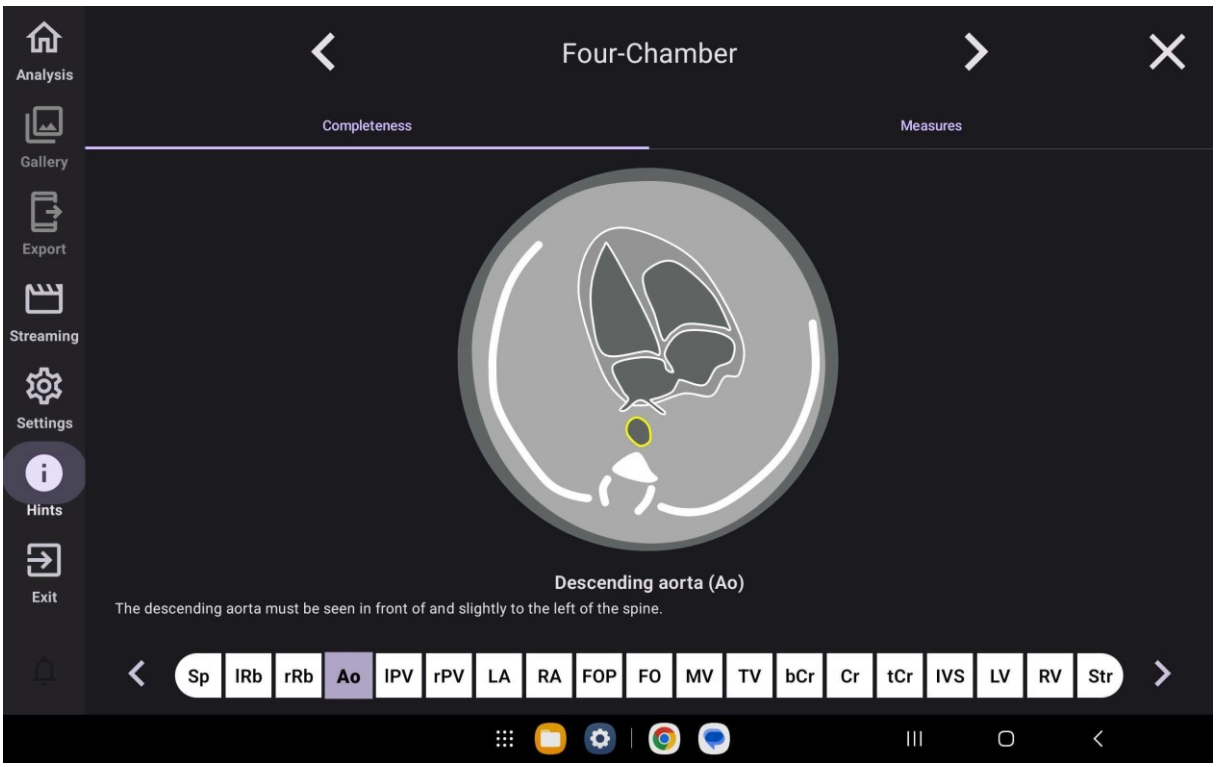
g. Οι μετρήσεις εμφανίζονται ως «εκτός εύρους» εάν βρίσκονται εκτός του καθορισμένου εύρους αναφοράς

h. Όταν ολοκληρωθεί η εξέταση, η σελίδα ανάλυσης το υποδεικνύει και σας επιτρέπει να μεταβείτε απευθείας στη σελίδα της συλλογής για να ελέγξετε τις προτεινόμενες εικόνες

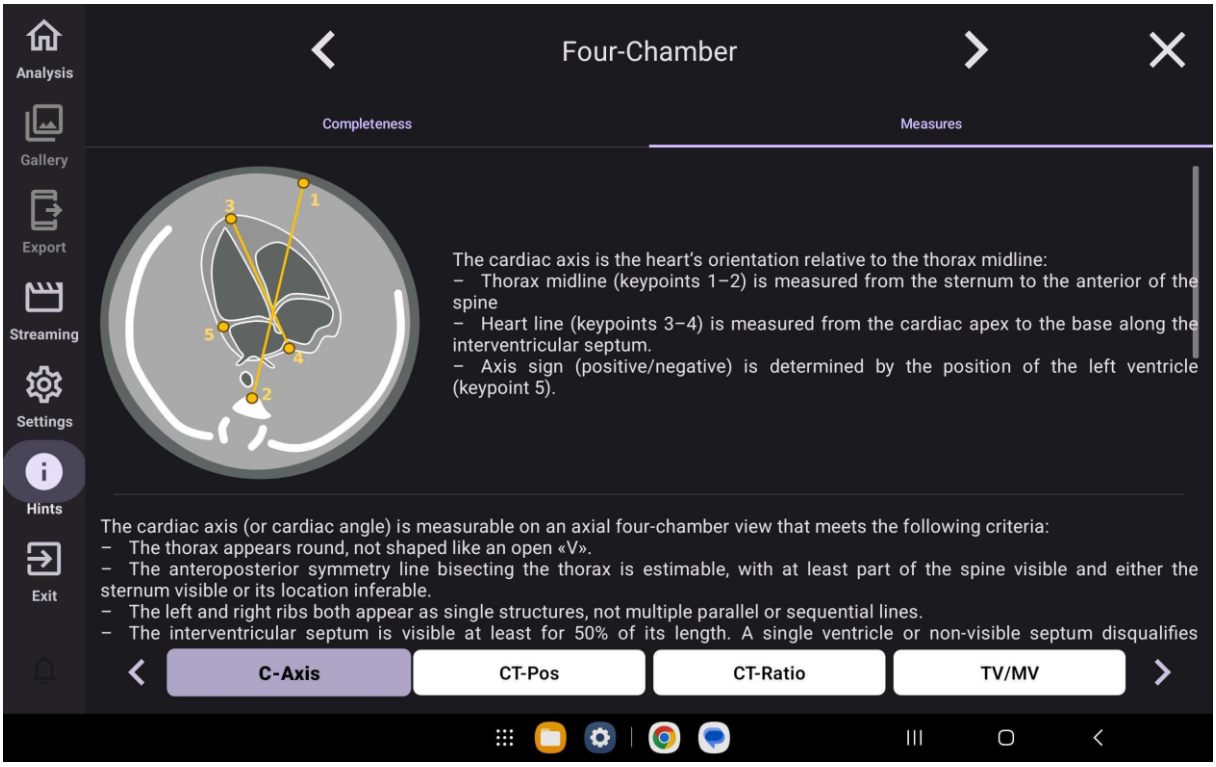


14. Παρακάτω θα βρείτε μια λίστα με συμβουλές για να είστε σίγουροι ότι θα πραγματοποιήσετε εύκολα την πληρότητα της εξέτασης και τις μετρήσεις:

    a. Τα κριτήρια ποιότητας και οι όψεις που εντοπίζονται από το λογισμικό βασίζονται στην κατευθυντήρια οδηγία της ISUOG για καρδιακό και εγκεφαλικό έλεγχο του εμβρύου. Διαβάστε αυτές τις κατευθυντήριες οδηγίες εάν χρειάζεστε υπενθύμιση για τις ορθές πρακτικές καρδιακού/εγκεφαλικού ελέγχου του εμβρύου. Μπορείτε επίσης να μεταβείτε στη σελίδα «Συμβουλές» για να έχετε μια εξήγηση όλων των κριτηρίων ποιότητας



b. Οι βιομετρικές μετρήσεις που γίνονται από το λογισμικό βασίζονται σε διεθνείς κατευθυντήριες οδηγίες και στην καθιερωμένη βιβλιογραφία για τον καρδιακό και εγκεφαλικό έλεγχο του εμβρύου. Διαβάστε τα άρθρα της βιβλιογραφίας που αναφέρονται από το λογισμικό, εάν χρειάζεται, ως υπενθύμιση για τις ορθές πρακτικές καρδιακού/εγκεφαλικού ελέγχου του εμβρύου. Μπορείτε επίσης να μεταβείτε στη σελίδα «Συμβουλές» για να έχετε μια εξήγηση όλων των μετρήσεων που εκτελέστηκαν.



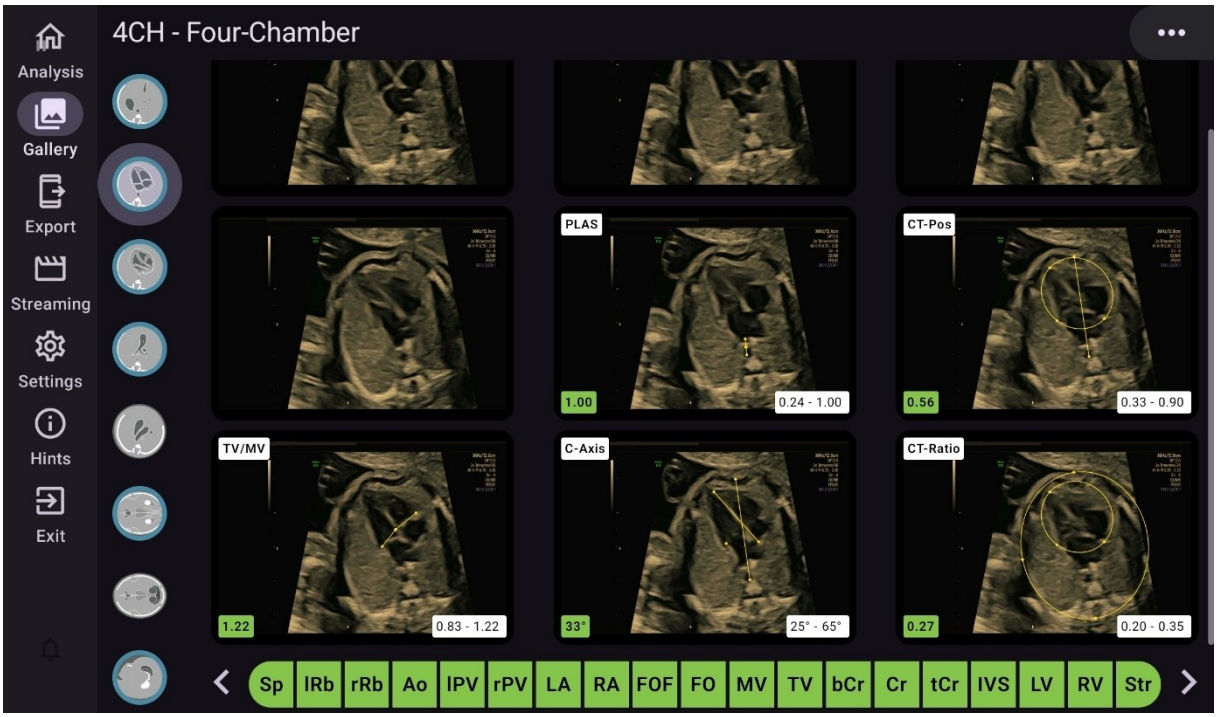
c. Βεβαιωθείτε ότι όλα τα βήματα διαμόρφωσης που εξηγούνται παραπάνω έχουν γίνει σωστά για να αποφύγετε προβλήματα ανίχνευσης.

d. Βεβαιωθείτε ότι χρησιμοποιείτε συμβατό εξοπλισμό σύμφωνα με την ενότητα 10 αυτών των Οδηγιών χρήσης.

e. Υπάρχει μια προειδοποίηση στη σελίδα εξαγωγής εάν τα κριτήρια/μέτρα ποιότητας δεν περιέχονται στο επιλεγμένο σύνολο εικόνων.

f. Μόλις επαληθευτούν όλα τα κριτήρια και γίνουν όλες οι μετρήσεις στη σελίδα ανάλυσης, επαληθεύστε εάν όλα τα αντίστοιχα κριτήρια και μέτρα είναι αναγνωρίσιμα στις εικόνες που έχουν επιλεγεί στη σελίδα «Συλλογή».

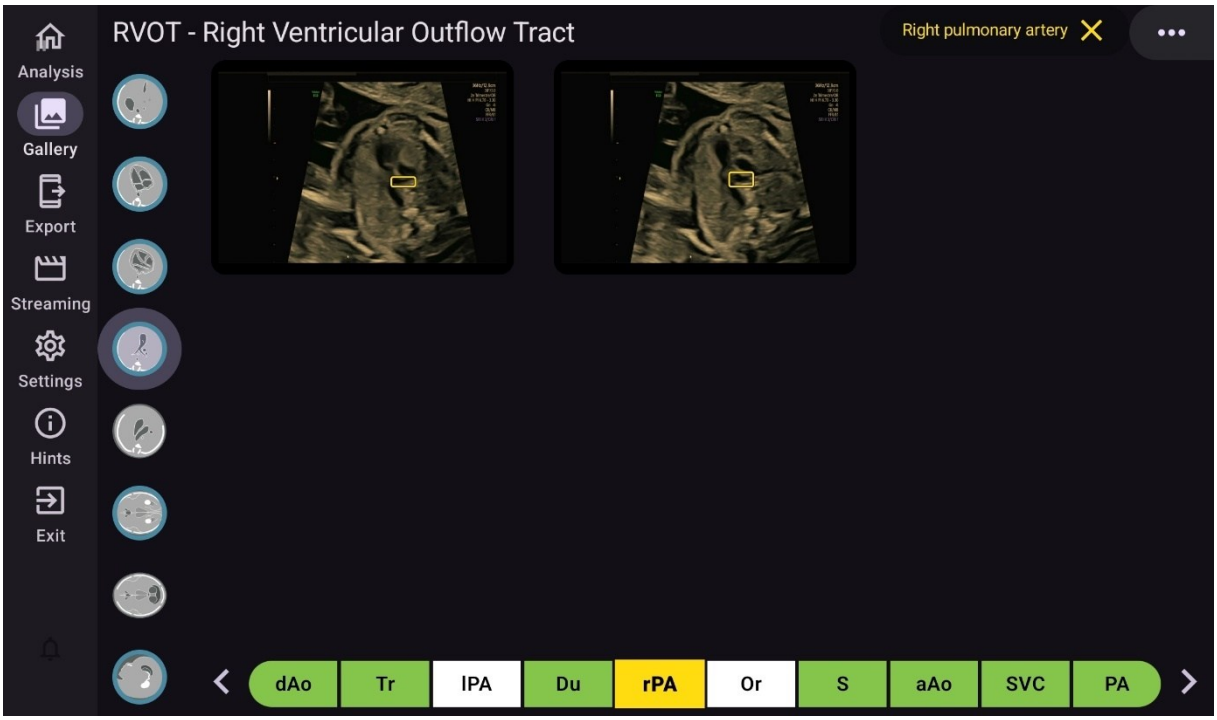
15. Μόλις ολοκληρωθεί η ροή βίντεο, μεταβείτε στην ενότητα «Συλλογή» για να εξερευνήσετε τις επιλεγμένες εικόνες. Για να διευκολυνθεί η πλοήγηση εντός του συνόλου των εικόνων, οι εικόνες κατηγοριοποιούνται ανά επίπεδο.



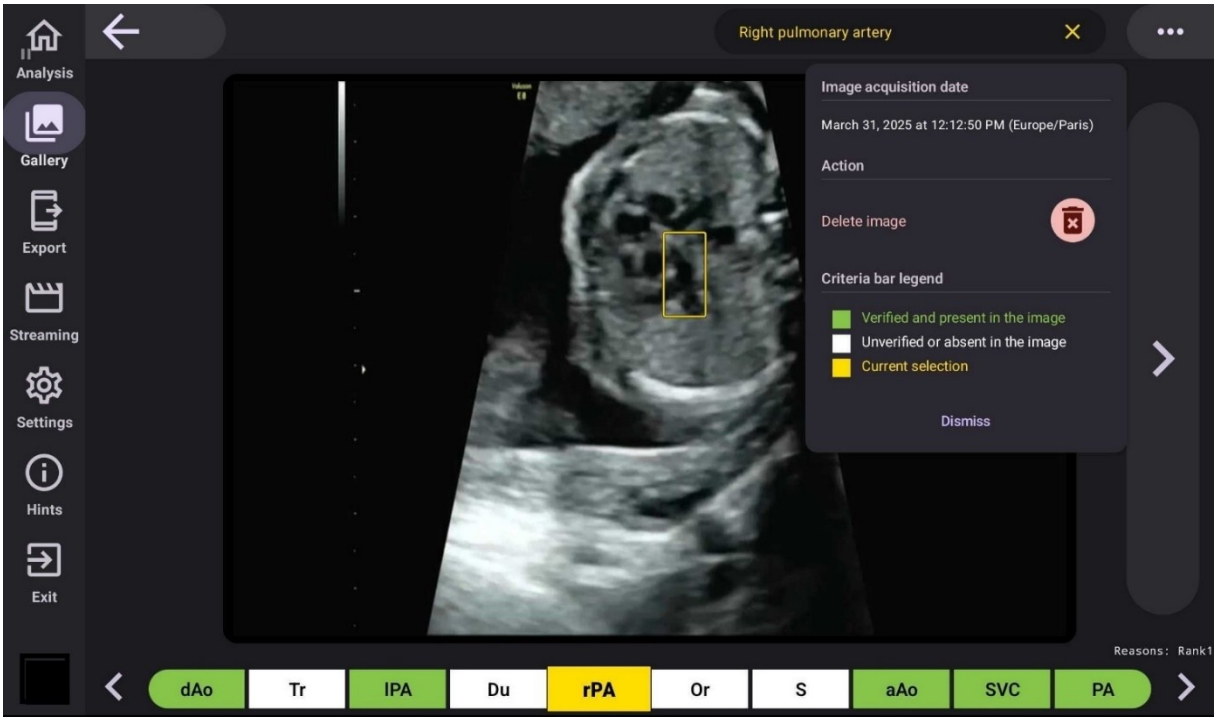
a. Κάντε κλικ σε ένα συγκεκριμένο επίπεδο (αριστερό πλαίσιο) για να δείτε επιλεγμένες εικόνες που σχετίζονται με αυτό το επίπεδο. Τα κριτήρια με πράσινο χρώμα επαληθεύονται και τα κριτήρια με λευκό δεν επαληθεύονται.

b. Οι εικόνες που επιλέγονται για βιομετρικές μετρήσεις περιέχουν τις ακόλουθες πληροφορίες: όνομα μέτρησης, τιμή, εύρος αναφοράς και κατάσταση εκτός εύρους, εάν ισχύει. Τα σημεία-κλειδιά της μέτρησης και τα σχήματα είναι κίτρινα.

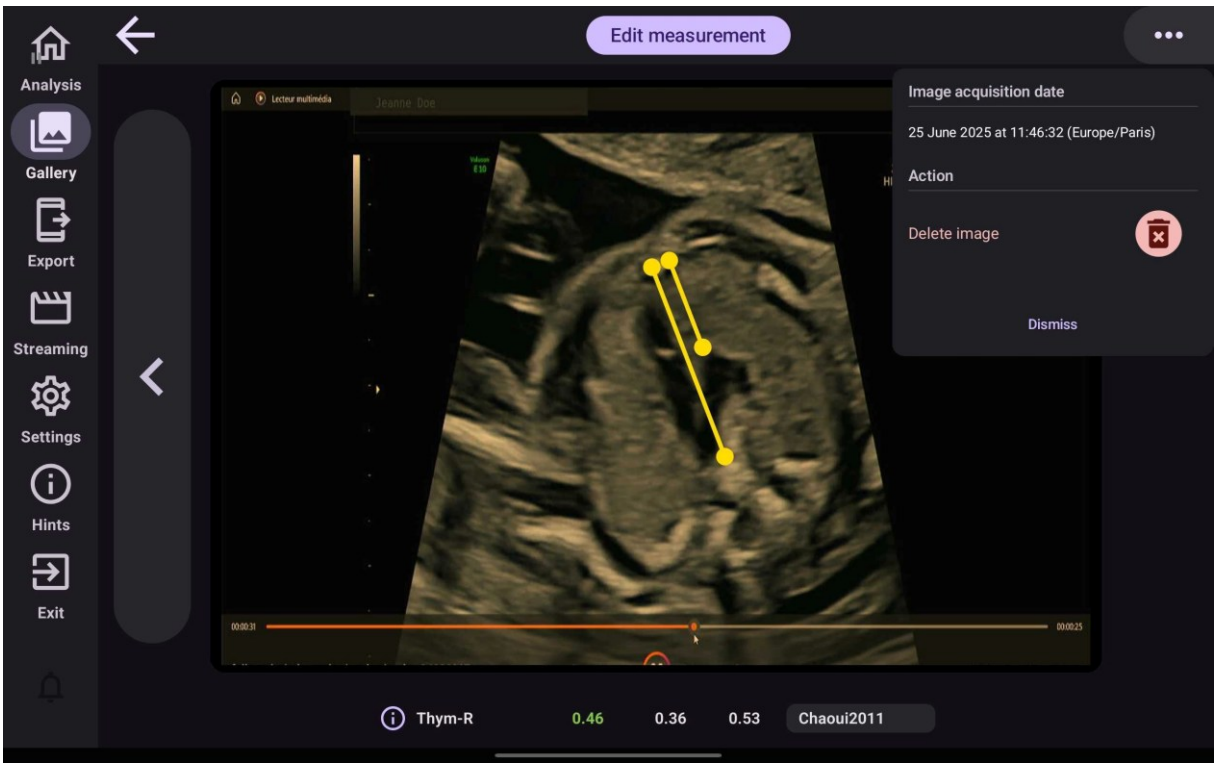
c. Κάντε κλικ σε μια συγκεκριμένη δομή για να δείτε επιλεγμένες εικόνες που περιέχουν αυτήν τη δομή. Το επιλεγμένο κριτήριο ποιότητας είναι κίτρινου χρώματος και το πλαίσιο οριοθέτησης που περιβάλλει το κριτήριο εμφανίζεται στις εικόνες.



d. Κάντε κλικ σε μια εικόνα πληρότητας για μεγέθυνση σε αυτήν. Μπορείτε να κάνετε κλικ σε ένα κριτήριο ποιότητας με πράσινο χρώμα για να εμφανίσετε το πλαίσιο οριοθέτησης που περιβάλλει το κριτήριο ποιότητας. Το κριτήριο ποιότητας που επιλέχθηκε είναι κίτρινου χρώματος. Τα λευκά πλαίσια σημαίνουν ότι τα κριτήρια ποιότητας υπάρχουν σε άλλες εικόνες της συλλογής ή δεν έχουν επαληθευτεί. Κάντε κλικ στο σύμβολο του κάδου απορριμμάτων για να διαγράψετε την εικόνα. Μπορείτε να σύρετε απευθείας στα πλάγια της εικόνας για να μεταβείτε σε άλλες εικόνες της προβολής.



e. Κάντε κλικ σε μια εικόνα μέτρησης για μεγέθυνση σε αυτήν. Τα σημεία-κλειδιά της μέτρησης και τα σχήματα είναι κίτρινα. Σημειώστε ότι τα σημεία-κλειδιά της μέτρησης δεν έχουν σχεδιαστεί για να βρίσκονται στην ακριβή θέση, αλλά για να είναι αρκετά ακριβή ώστε να εμφανίζουν την ορθή τιμή μέτρησης. Εμφανίζονται η τιμή και η κατάσταση «εκτός εύρους», εάν ισχύει, μαζί με το εύρος αναφοράς και τη βιβλιογραφική πηγή που έχουν επιλεγεί. Κάντε κλικ στο σύμβολο του κάδου απορριμμάτων για να διαγράψετε την εικόνα. Μπορείτε να σύρετε απευθείας στα πλάγια της εικόνας για να μεταβείτε σε άλλες εικόνες της προβολής. Μπορείτε να επεξεργαστείτε τα σημεία-κλειδιά για μια μέτρηση σε εικόνες μέτρησης, κάνοντας κλικ στο κουμπί «επεξεργασία μέτρησης». Στη συνέχεια, η τιμή μέτρησης θα ενημερωθεί αναλόγως και το λογισμικό θα αποτρέψει οποιαδήποτε αυτόματη τροποποίηση με εκ νέου σάρωση μετά την έκδοση. Η επεξεργασμένη μέτρηση θα επισημαίνεται με το ακόλουθο σύμβολο: .



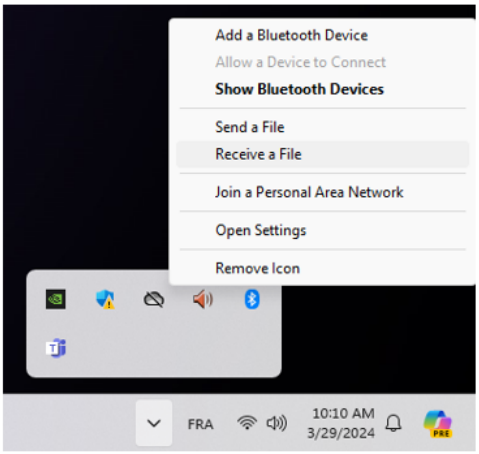


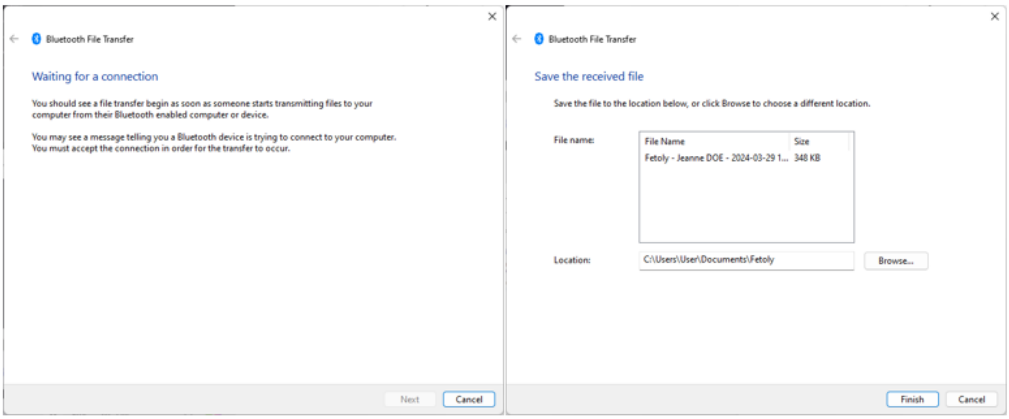
f. Εάν χρειάζεται, μπορείτε να επιστρέψετε στη σελίδα ανάλυσης για να επανεκκινήσετε την ανάλυση και να λάβετε πρόσθετες εικόνες.

Εξαγωγή εικόνων

9. Μεταβείτε στην ενότητα «Μέθοδος εξαγωγής» στις «Ρυθμίσεις» για να επιλέξετε τη λειτουργία εξαγωγής που θέλετε να χρησιμοποιήσετε.
10. Μεταβείτε στην ενότητα «Εξαγωγή» για να εξαγάγετε τις επιλεγμένες εικόνες:

    f. Εάν έχετε επιλέξει σύνδεση Bluetooth (μόνο για Android), μεταβείτε στον υπολογιστή σας και επιλέξτε «λήψη αρχείου» στη διαμόρφωση Bluetooth.





dd. Εάν έχετε επιλέξει σύνδεση DICOM, μπορείτε να επαληθεύσετε εάν η ασθενής που επιλέχθηκε για εξαγωγή η σωστή και να επιλέξετε μια άλλη ασθενή εάν υπάρχει λάθος χρησιμοποιώντας τη λίστα εργασιών DICOM στη σελίδα ανάλυσης.

ee. Η σελίδα εξαγωγής εμφανίζει μια περίληψη της εξέτασης και σας υπενθυμίζει να επαληθεύσετε εάν έχετε όλες τις εικόνες που απαιτούνται για την αποτελεσματική φροντίδα της ασθενούς πριν από την εξαγωγή.

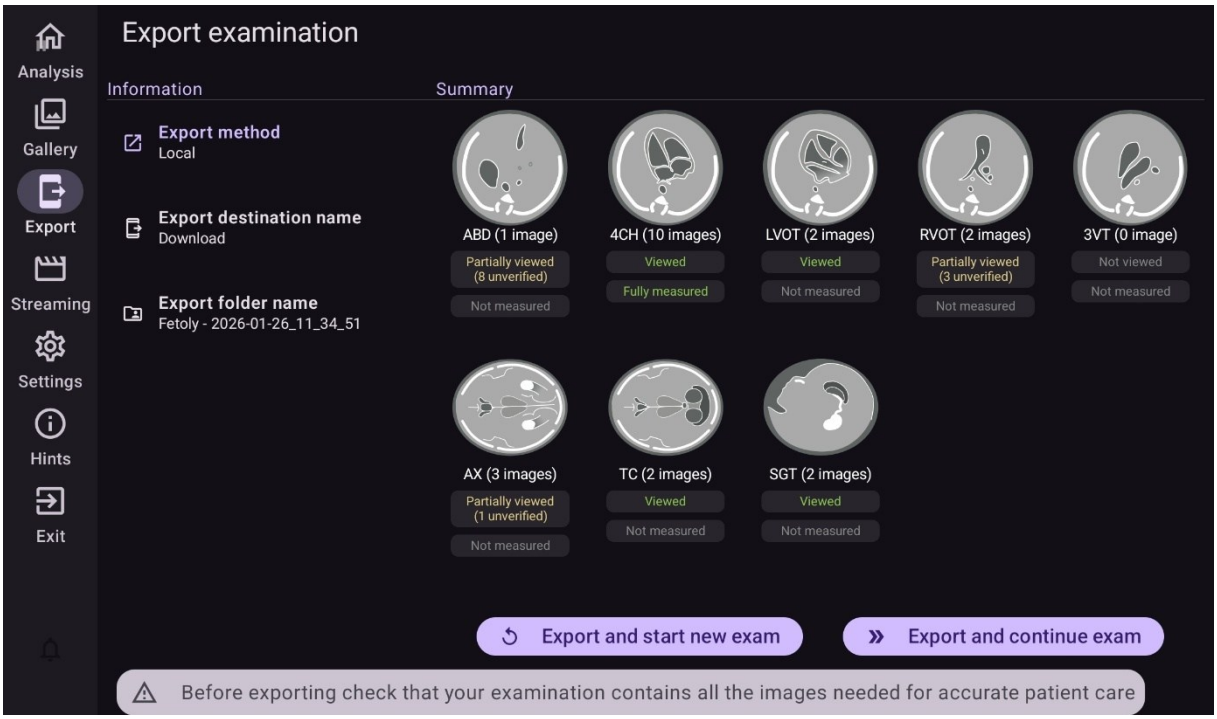
ff. Η σελίδα εξαγωγής εμφανίζει την επιλεγμένη μεθοδολογία εξαγωγής. Εάν θέλετε να αλλάξετε τις ρυθμίσεις, μπορείτε να μεταβείτε απευθείας στη σελίδα ρυθμίσεων εξαγωγής κάνοντας κλικ στη «μέθοδο εξαγωγής».

gg. Η σελίδα εξαγωγής εμφανίζει τη θέση του αρχείου εξαγωγής στην επιλεγμένη συσκευή και το όνομα αρχείου που έχει ρυθμιστεί για τοπική εξαγωγή.

hh. Κάντε κλικ στο κουμπί «Εξαγωγή και έναρξη νέας εξέτασης» για να εξαγάγετε εικόνες και να διαγράψετε την εξέταση πριν ξεκινήσετε μια νέα εξέταση.

ii. Εναλλακτικά, κάντε κλικ στο κουμπί «Εξαγωγή και συνέχεια εξέτασης» για να εξαγάγετε εικόνες χωρίς να διαγράψετε το τρέχον επιλεγμένο σύνολο εικόνων και την ανάλυση πληρότητας.

jj. Το λογισμικό θα σας υποδείξει εάν η εξαγωγή ήταν επιτυχής ή απέτυχε.



Εκ νέου αρχικοποίηση (απαλοιφή)

Εάν δεν χρησιμοποιήσατε τη λειτουργία διαγραφής στη σελίδα εξαγωγής, μεταβείτε στην «Ανάλυση» και κάντε κλικ στο κουμπί «Απαλοιφή» για να αρχικοποιήσετε ξανά το σύνολο των επιλεγμένων εικόνων και την εξέταση.

Ρυθμίσεις για προχωρημένους

Εάν θέλετε να απενεργοποιήσετε τη λειτουργία μέτρησης, μεταβείτε στις «Ρυθμίσεις» > «Για προχωρημένους» και κάντε κλικ στο κουμπί.

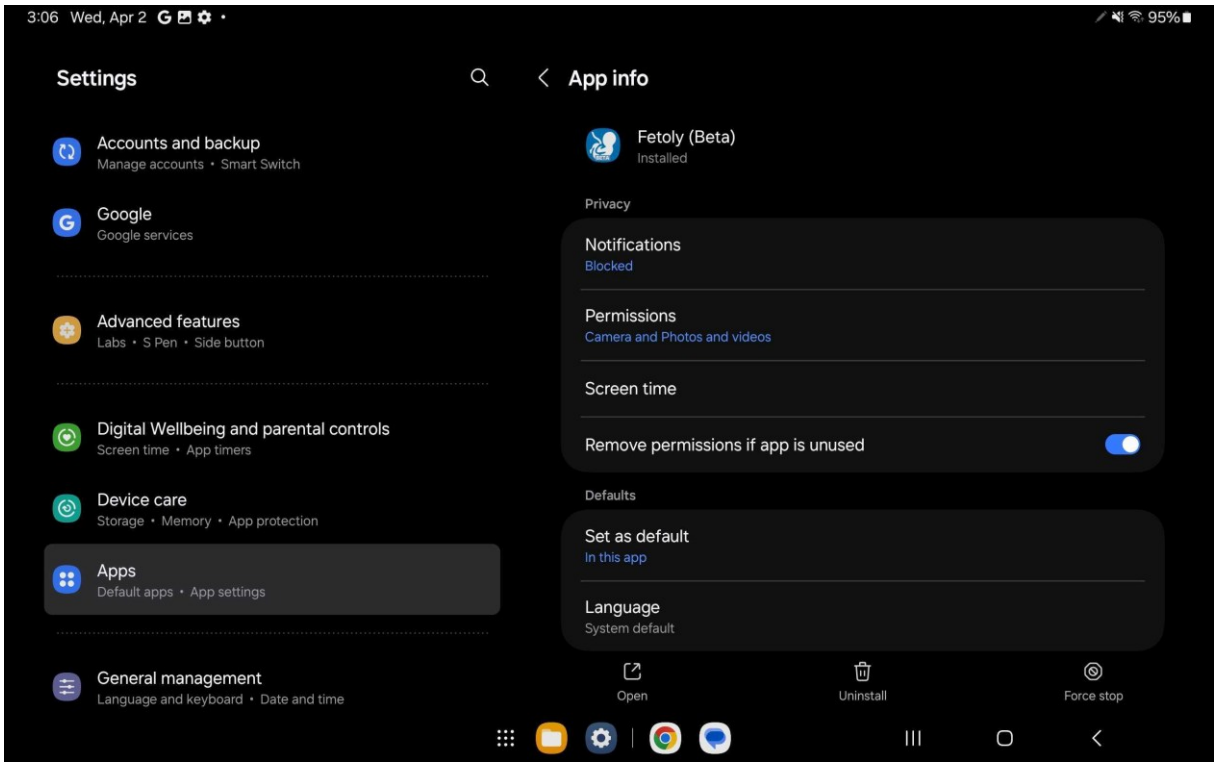
Ενημέρωση λογισμικού και άδειας χρήσης

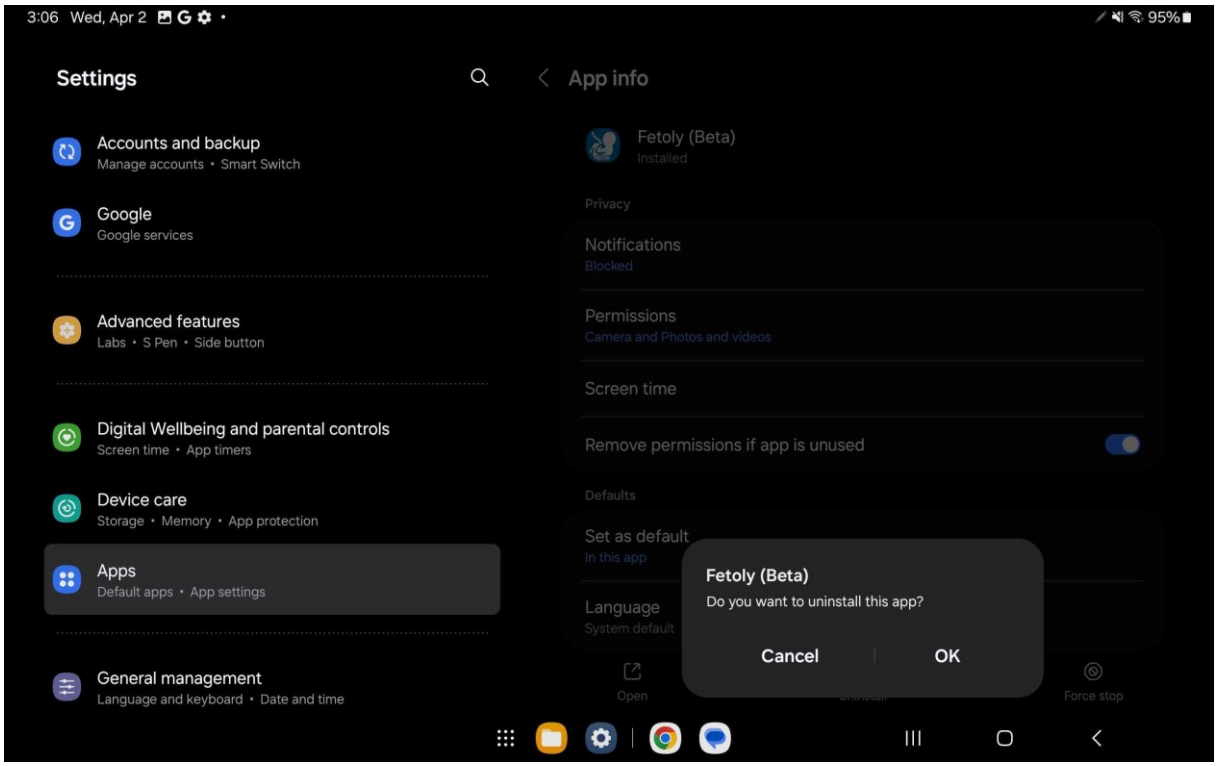
Το λογισμικό ελέγχει περιοδικά για νέες ενημερώσεις της εφαρμογής. Για να διασφαλίσετε την άμεση διαθεσιμότητα νέων ενημερώσεων, ενεργοποιήστε τις ενημερώσεις παρασκηνίου για το FETOLY στις ρυθμίσεις του Google Play/App Store. Όταν είναι διαθέσιμη μια ενημέρωση, το λογισμικό θα εμφανίσει μια σελίδα αποκλεισμού κατά την εκκίνηση, απαιτώντας από τον χρήστη να ενημερώσει και να επανεκκινήσει την εφαρμογή για να συνεχίσει να τη χρησιμοποιεί. Μετά την αποδοχή της ενημέρωσης, το Google Play/App Store χειρίζεται την εγκατάσταση της ενημέρωσης και την επανεκκίνηση της εφαρμογής. Απαιτείται σύνδεση στο διαδίκτυο για τον έλεγχο για ενημερώσεις και την αυτόματη ανανέωση της άδειας χρήσης. Εάν η συσκευή δεν συνδεθεί στο Διαδίκτυο για περίοδο 30 ημερών, το λογισμικό θα αποκλειστεί.

Η άδεια χρήσης σας επαληθεύεται και ανανεώνεται αυτόματα όταν ενεργοποιείται μια σύνδεση στο Διαδίκτυο μέχρι να λήξει η σύμβαση άδειας χρήσης. Η ημερομηνία λήξης της άδειας χρήσης εμφανίζεται στη σελίδα ρυθμίσεων της άδειας χρήσης. Όταν λήξει η σύμβαση άδειας χρήσης, εάν δεν γίνει ανανέωση της σύμβασης, το λογισμικό θα ζητήσει την εισαγωγή νέου κωδικού εγγραφής και θα αποκλείσει τις λειτουργικότητες.

Απεγκατάσταση λογισμικού

Απεγκαταστήστε την εφαρμογή όπως οποιαδήποτε εφαρμογή στο tablet σας, όπως φαίνεται παρακάτω:





14. Συντήρηση, χειρισμός και απόρριψη

- Οι οδηγίες πρέπει να διαβαστούν πριν από τη χρήση.
- Εκκινήστε τις ενημερώσεις όταν σας ζητηθεί από το λογισμικό κατά την εκκίνηση.
- Λάβετε υπόψη ότι, για την αγορά των Ηνωμένων Πολιτειών της Αμερικής, έχει συμπεριληφθεί ένα Σχέδιο Ελέγχου Προκαθορισμένων Αλλαγών (PCCP). Αυτό το PCCP υλοποιείται για το μοντέλο μηχανικής μάθησης που είναι ενσωματωμένο στη συσκευή FETOLY που θα μπορούσε να τροποποιήσει την απόδοση, τις εισόδους ή τη χρήση της συσκευής. Επομένως, συνιστάται ανεπιφύλακτα να είστε τακτικά συνδεδεμένοι στο Διαδίκτυο για να καθίσταται δυνατή η αυτόματη εγκατάσταση ενημερώσεων.
- Εισαγάγετε τον κωδικό εγγραφής όταν σας ζητηθεί από το λογισμικό κατά την εκκίνηση.
- Για να παροπλίσετε και να απορρίψετε το λογισμικό, απεγκαταστήστε την εφαρμογή μέσω του συστήματος Android όπως οποιαδήποτε εφαρμογή στο tablet σας, στις παραμέτρους της εφαρμογής, όπως φαίνεται παραπάνω στην παράγραφο «απεγκατάσταση λογισμικού». Αυτή η απεγκατάσταση θα καταργήσει τυχόν δεδομένα που συνδέονται με τη χρήση του FETOLY, συμπεριλαμβανομένης της άδειας χρήσης, στο tablet σας.

Σύμβολα που χρησιμοποιούνται στην επισήμανση (σελίδα πληροφοριών):

	Κατασκευαστής (σύμβολο εργοστασίου με γεμισμένο περίγραμμα)
	Συσκευή με σήμανση CE
	Μοναδικό αναγνωριστικό συσκευής 01: UDI-DI 11: Ημερομηνία κατασκευής 8012: Έκδοση λογισμικού
	Συμβουλευτείτε τις οδηγίες χρήσης
	Ο ομοσπονδιακός νόμος περιορίζει την πώληση αυτής της συσκευής με ή κατόπιν εντολής γιατρού
	Ιατροτεχνολογικό προϊόν
	Ημερομηνία κατασκευής (σύμβολο εργοστασίου με κενό περίγραμμα)
	Όνομα και διεύθυνση αντιπροσώπου για την Ελβετία