FETOLY

Software for fetal ultrasound imaging examination aid

Instructions For Use

IFU-WW-FETOLY-V5 - EN

August 03rd, 2026

INSTRUCTIONS FOR USE (ENGLISH)

1. Device Identification

FETOLY

Software for fetal heart and brain ultrasound imaging examination aid.

Software version linked to this IFU: V2026.08.31

2. Update

FETOLY has been updated as follows for the **V2026.08.31** version:
UI
New interface design
Export
Increased image resolution – HD 1920X1080 pixels
Enhanced keypoint position through improved spatial smoothing.
Report
Improved report: introduced a new design and added image subtitles to highlight the markers visible in each image.
Analysis
Display of live markers on the video stream
Biometric measurements can now be performed on Type 2 images
Implementation of optional Mid-sagittal view
Settings
Automatic ultrasound area and ratio detection — Fetoly now automatically detects the frame ratio of the image and the ultrasound area, reducing manual setup and avoiding inadequate reference range
Automatic gestational age detection via image recognition at each play start
Semi-automatic patient name recognition for iOS
Localisation
Instructions for use translated to German, Danish, Norwegian, Swedish
User interface translated to German, Danish, Norwegian, Swedish

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 international 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.

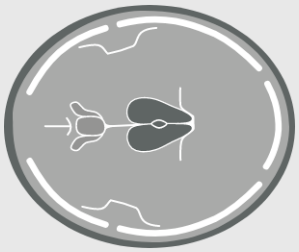
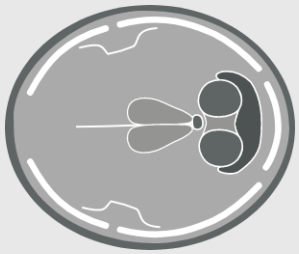
Heart views	***Quality criteria within the views***	
 ***(A) Abdomen*** ***Abdomen view*** ***(n = 8)***	*(A1) Spine*	*Spine*
	(A2) Left rib	*Left rib*
	(A3) Right rib	*Right rib*
	(A4) Desc. Ao	*Descending aorta*
	(A5) IVC	*Inferior vena cava*
	(A6) Stomach	*Stomach*
	(A7) Umbilical vein	*Umbilical vein*
	(A8) Abdomen apex	*Anterior Abdomen*
 ***(B) 4CH*** ***Four chamber view*** ***(n = 19)***	*(B1) Spine*	*Spine*
	(B2) L. rib	*Left rib*
	(B3) R. rib	*Right rib*
	(B4) Ao	*Descending aorta*
	(B5) L. Pulm. vein	*Left pulmonary vein*
	(B6) R. Pulm. vein	*Right pulmonary vein*
	(B7) LA	*Left atrium*
	(B8) RA	*Right atrium*
	(B9) FO flap	*Foramen Ovale Flap*
	(B10) FO	*Foramen Ovale*
	(B11) MV	*Mitral valve*
	(B12) TV	*Tricuspid valve*
	(B13) Septum primum	*Septum primum*
	(B14) Crux	*Crux offset*
	(B15) Inlet IVS	*Inlet Interventricular septum*
	(B16) Muscular IVS	*Muscular Interventricular septum*
	(B17) LV	*Left ventricle*
	(B18) RV	*Right ventricle*
	(B19) Sternum	*Sternum*

 **(C) LVOT** **Left Ventricular Outflow Tract view** **(n = 6)**	*(C1) LA*	*Left atrium*
	(C2) Asc. aorta	*Proximal ascending aorta*
	(C3) Ao valve	*Semilunar valves*
	(C4) LV	*Left ventricle*
	(C5) IVS	*Interventricular septum*
	(C6) RV	*Right ventricle*
 **(D) RVOT** **Right Ventricular Outflow Tract view** **(n = 10)**	*(D1) Desc. ao*	*Descending aorta*
	(D2) Trachea	*Trachea*
	(D3) L. PA	*Left pulmonary artery*
	(D4) Ductus	*Ductus arteriosus*
	(D5) R. PA	*Right pulmonary artery*
	(D6) PA origin	*Origin of pulmonary arteries*
	(D7) PA-AO septum	*Septum between pulmonary artery trunk and ascending aorta*
	(D8) Asc. Ao	*Ascending aorta*
	(D9) SVC	*Superior vena cava*
	(D10) PA trunk	*Pulmonary trunk*
 **(E) 3V** **Three vessels view** **(n = 9)**	*(E1) Spine*	*Spine*
	(E2) Trachea	*Trachea*
	(E3) 4V area	*Fourth vessel assessment area*
	(E4) Ductus (TDA)	*Ductal arch - TDA*
	(E5) Ductus (3VT)	*Ductal arch - 3VT*
	(E6) Asc. Ao	*Ascending aorta*
	(E7) Aortic arch	*Aortic arch*
	(E8) SVC	*Superior vena cava*
	(E9) Thymus / sternum	*Thymus / sternum*

For the fetal brain

Table 2: List of 33 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***	
	(F1) Ant. IHF	*Anterior Interhemispheric Fissure*

 ***(F) Transthalamic*** ***Transthalamic view*** ***(n = 18)***	*(F2) CSP*	*Cavum Septum Pellucidum*
	(F3) Fornix	*Fornix*
	(F4) Dist. Horn	*Distal Anterior Ventricle Horn*
	(F5) Prox. Horn	*Proximal Anterior Ventricle Horn*
	(F6) Amb. Cist	*Ambient Cisterna*
	(F7) Atrium	*Atrium*
	(F8) CP	*Choroid Plexus*
	(F9) P-O Sulcus	*Parieto Occipital Sulcus*
	(F10) Post. IHF	*Posterior Interhemispheric Fissure*
	(F11) Dist. Suture	*Distal Coronal suture*
	(F12) Prox. suture	*Proximal Coronal suture*
	(F13) Sylvian Fiss	*Sylvian Fissure*
	(F14) Skull	*Skull*
	(F15) Thal. Sep.	*Thalami Separation*
	(F16) 3rd Vent.	*3rd Ventricle*
	(F17) Dist. Thal.	*Distal Thalamus*
	(F18) Prox. Thal	*Proximal Thalamus*
 ***(G) Transcerebellar*** ***Transcerebellar view*** ***(n = 8)***	*(G1) Dist. Thal.*	*Distal Thalamus*
	(F18) Prox. Thal	*Proximal Thalamus*
	(G3) 4th Vent.	*4th Ventricle*
	(G4) Vermis	*Vermis*
	(G5) Dist. Hemi	*Distal Cerebellar Hemisphere*
	(G6) Prox. Hemi	*Proximal Cerebellar Hemisphere*
	(G7) CB	*Cerebellar Border*
	(G8) Cist. Magna	*Cisterna Magma*
 ***(I) Mid-sagittal*** ***Mid-Sagittal view*** ***(n = 7)***	*(I1) Up. Vermis*	*Upper Part of Vermis*
	(I2) Low. Vermis	*Lower Part of Vermis*
	(I3) Fastigium	*Fastigium*
	(I4) rgCC	*Rostrum & Genu Corpus Callosum*
	(I5) bCC	*Body Corpus Callosum*
	(I5) sCC	*Splenium Corpus Callosum*
	(I7)CSP	*Cavum Septum Pellicidum*

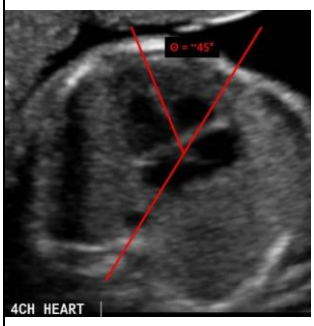
Biometric measurements and reference intervals

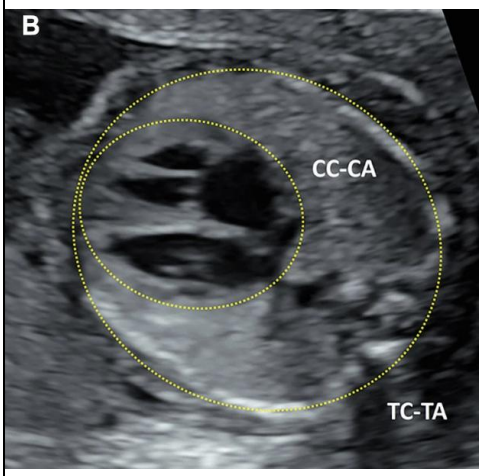
FETOLY provides three types of automated biometric measurements:

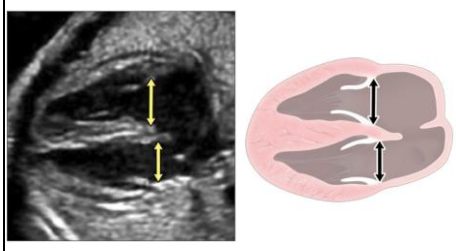
- **Angle measurement** displayed in degrees (°);
- **Ratio measurement** (a distance normalized with another distance, either represented as a ratio or a percentage);
- **Number** of anatomical landmarks detected;

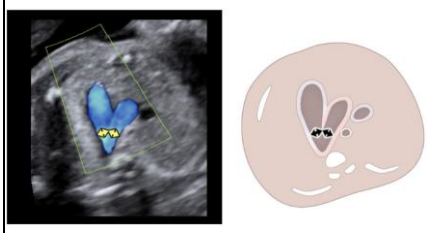
List of measurements and their reference intervals:

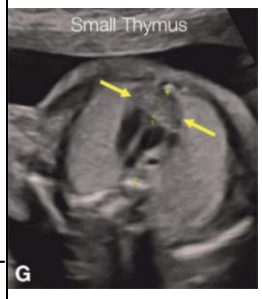
The table below details the biometric measurements provided by FETOLY and their corresponding normal reference intervals based on established literature.

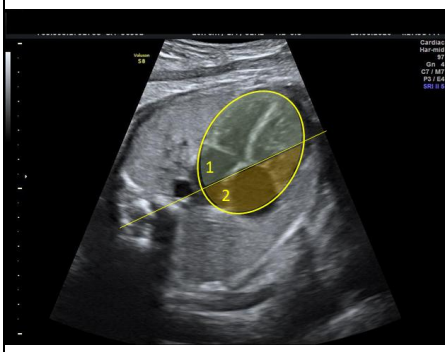
Parameter	*Information accessible in FETOLY (description and sources)*
(M1) Cardiac axis	***What is the cardiac axis (CAx)?***  *(source: https://radiopaedia.org/articles/four-chamber-cardiac-view-fetal)* *The **cardiac axis** (or **cardiac angle**) refers to the orientation of the heart relative to 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)

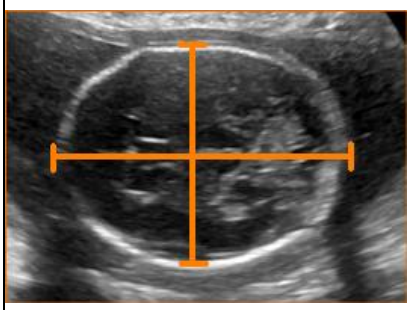
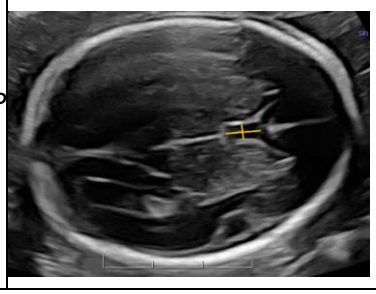
	○ 17-40GA: [25° - 65°]. • **ASE (2023):** (guideline-defined reference range) ○ 17-40GA: [35° - 65°]
(M2) Cardiothoracic area ratio	***What is the cardiothoracic ratio?***  *(source: https://www.onlinejase.com/article/S0894-7317(23)00206-7/fulltext)* *The fetal cardiothoracic area (CTA) ratio is the ratio of the transverse area of the epicardial surface of the heart to the transverse area 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)*

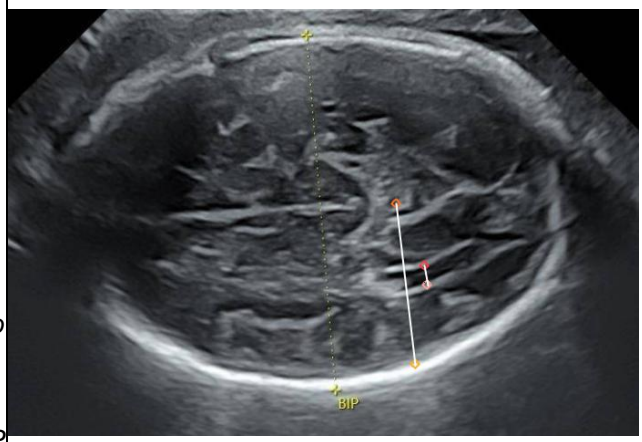
	• *17GA: [0.40 - 0.52]* • *18GA: [0.40 - 0.52]* • *19GA: [0.42 - 0.51]* • *...* • *40GA: [0.46 - 0.56]* • ***Garcia-Otero (2020):*** *(5th and 95th percentiles for area)* • *18GA: [0.16 - 0.25]* • *19GA: [0,16 - 0.26]* • *...* • *40GA: [0.21 - 0.35]* • ***ASE (Moon-Grady2023):*** *(guideline-defined range for optimal fetal score for area)* • *17-40GA: [0.20-0.35]* • ***Sompagdee (2021): (5th and 95th percentiles for area)*** • *17GA: [0.19 - 0.27]* • *18GA: [0,19 - 0.27]* • *...* ○ 37GA: [0.24 - 0.33]
(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?***

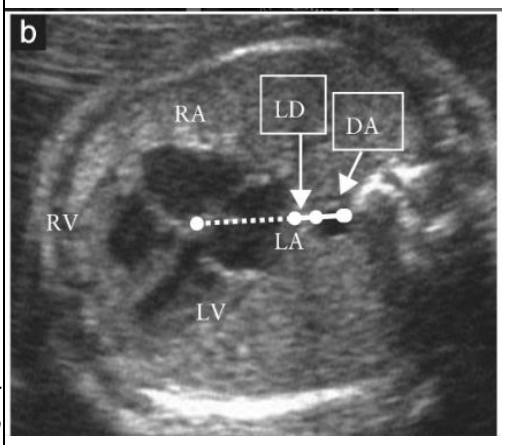
	AIUM guidelines indicate that the comparison of the tricuspid and mitral valve annulus in diastole is a required cardiac biometry ("Tricuspid and mitral valve annulus in diastole ([…] comparison of left- to right-sided valves) is a required cardiac biometry") (AIUM2019). They cite (DeVore2017), (Lee2009), 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.*
Transthalamic 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 Transthalamic 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;
- 3 main foetal brain views and 33 quality criteria, detailed previously, allowing for compliance in brain screening.

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

- A **Start a new exam button** to initiates the analysis of images acquired by the ultrasound system at the beginning of the examination,
- A **play/pause** button allowing to pause and resume the examination during the analysis,
- 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**, it disappears from the remaining markers and its colour changes from white to green in the detailed dashboard page
- 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 status 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 status 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 dashboard pages or the report report 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 dashboard pages or the report 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 is labeled as "Measurements" in the detailed dashboard pages and displays a list of measurements. Clicking the measurement name open detailed information about the measurement.

- **Measurement name – Organ – View - Value and units**: Displays the name or abbreviation of the measurement along with the organ and view related to the measurement and the measurement value. 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 report 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 criterion button in the dashboard pages or within the report page , user can manually define the reference range or update the literature reference if multiples are available.
  Measurement reference can also be accessed within 'Settings' > 'Measurements reference'.
- **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 report 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 3 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 or a computer with an FTP server, 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	*369*	*0.952*	*(0.930,0.973)*	*4840*	*0.984*	*(0.980,0.987)*	*0.62*	*(0.60,0.64)*

trunk and ascending aorta								
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	Continent	n(positive)	Se	Se CI	n(negative)	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_ventricular_ratio	EU	174	0.983	(0.962,1.000)	266	0.906	(0.868,0.936)	0.097	(0.088,0.108)
right-left_ventricular_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.
- Only enable Auto start exam in ‘Settings’ > ‘Networks’ with GE ultrasound systems

- Do not touch the ultrasound system or the patient while simultaneously manipulating the tablet, as simultaneous contact may increase the risk of leakage current exposure.

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.

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.

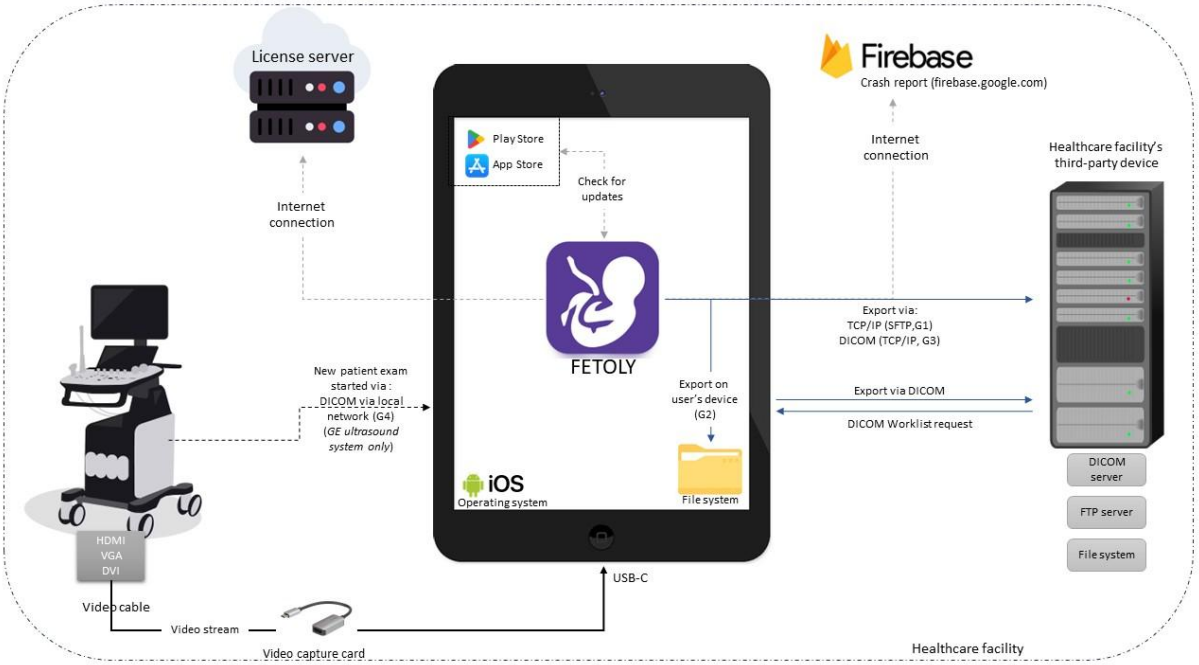
12.2. Inherent cybersecurity risks of the device

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.

12.3. 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 device access control
- G3: Secure operation with third-party systems via DICOM over SSL/TLS
- G4: secure operation with GE Ultrasound systems via DICOM port

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 on secure device access control (G2):

- 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 (G3):

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

Guidelines for secure operation with GE Ultrasound systems via DICOM port (G4):

- Only enable Auto start Exam in 'Settings' > 'Network' with GE ultrasound systems

*Use strong passwords on your tablet and for any device (i.e. third-party device for FTP export) or configuration linked to FETOLY 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 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.

For Automatic start Exam via DICOM with GE Ultrasound systems:

- Protocol: DICOM (TCP)
- Incoming ports: The user can enable or disable Auto start exam (DICOM port) when using Fetoly with GE ultrasound systems.
- Outgoing ports: None (except response to incoming connection).
- Firewall rules: Firewalls must allow (tcp) connections initiated from GE ultrasound system to Fetoly tablet (port configured in the application)

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.

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 or DICOM.
- 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.

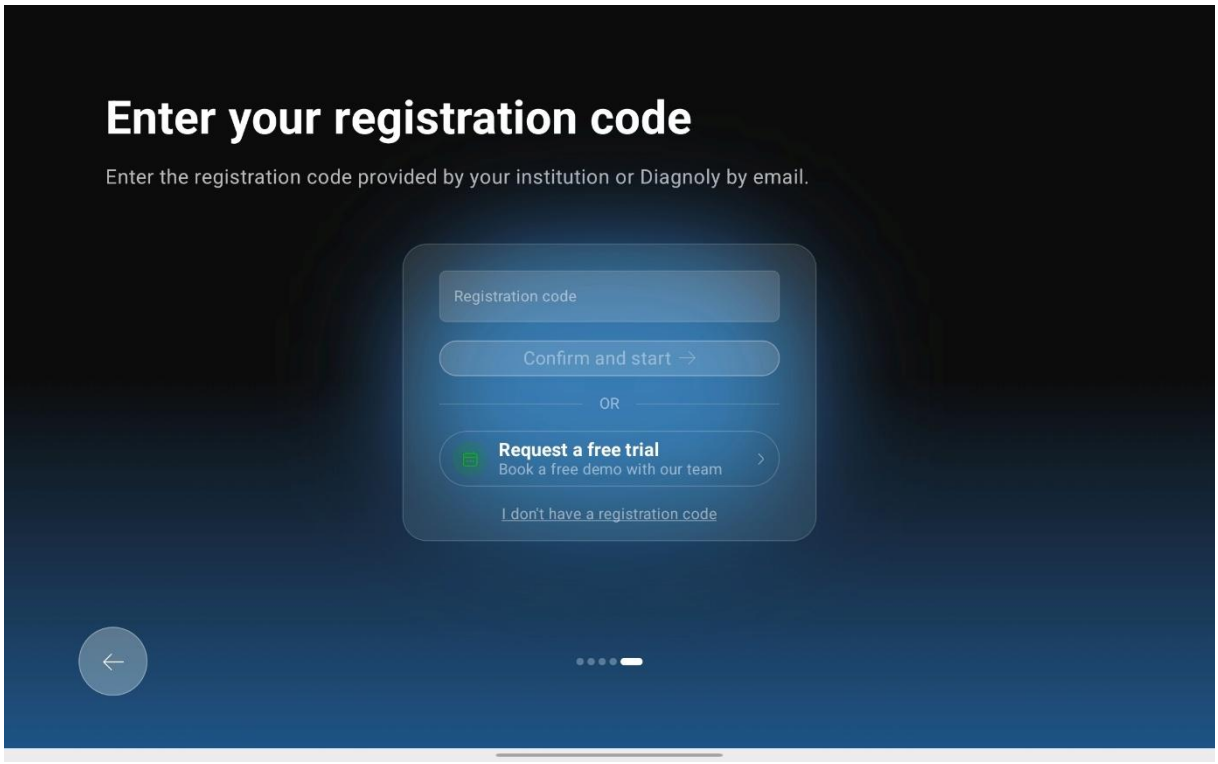
12.15. Secure Decommissioning

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.

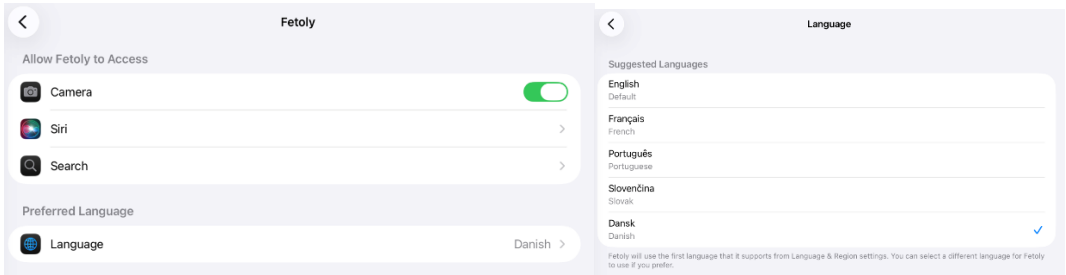


4. **Establish a Wi-Fi connection:** If you want to receive the ultrasound data to your personal computer, please, connect the tablet to your Wi-Fi spot.

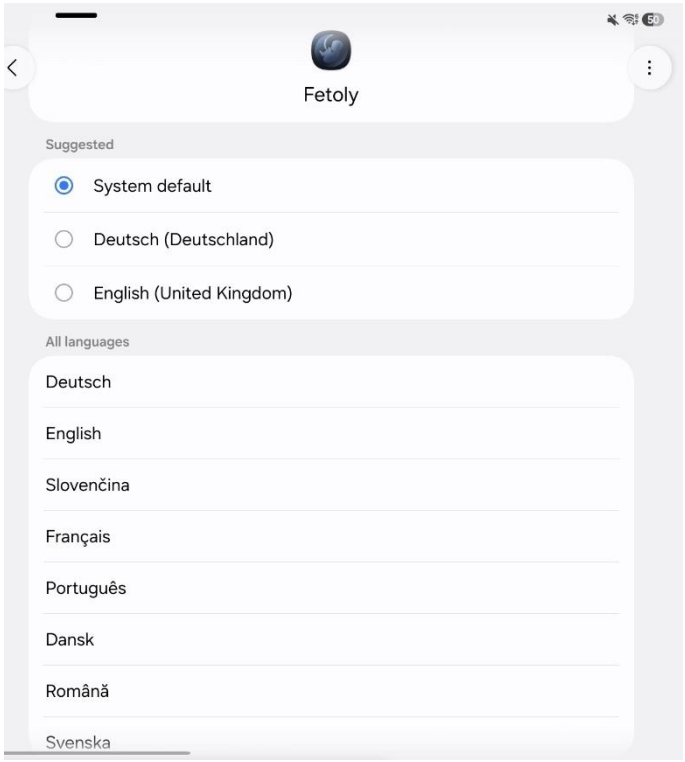
Language settings

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’ > ‘Change Language’. This will lead you to the app languages settings. Once the needed language is selected, the application will be translated in this language at re-launch.

iPAD



Android

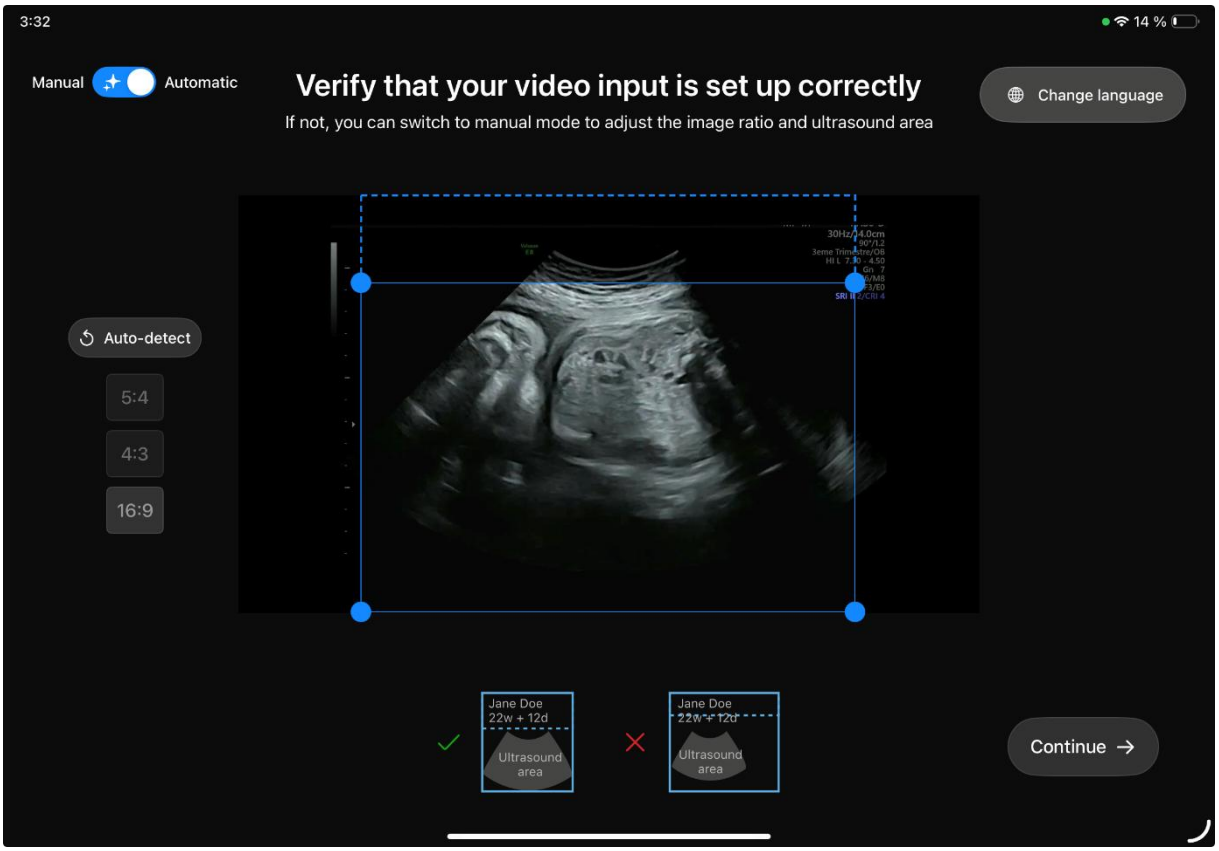


Ultrasound machine connection

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. The software detects automatically the ultrasound area and video input aspect ratio. The automatic detection can be re-launched by clicking on the auto-detect button. A toggle button in ‘settings’ > ‘Ultrasound area’ allows to set these parameters manually, allowing the user to select the video aspect ratio to be aligned with ultrasound machine output ratio and select the region of ultrasound.
2. In other situations, go to ‘settings’ > ‘Ultrasound area’ to configure the video stream, with the same methodology.



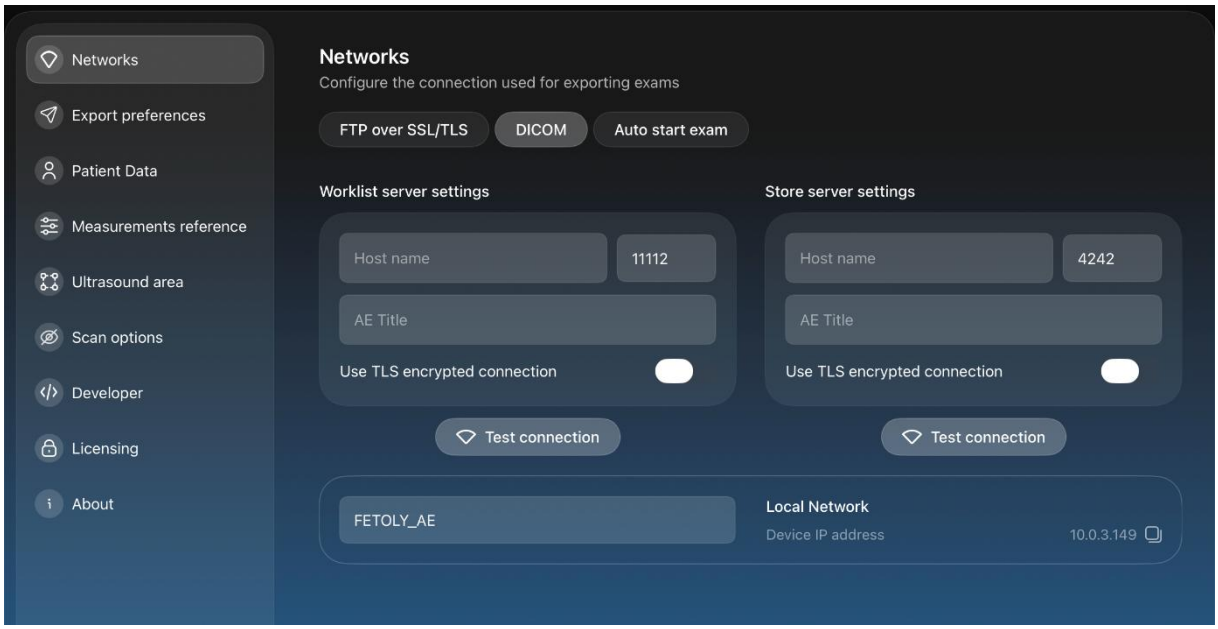
b. The Start new exam button can be used on the dashboard pages to launch the analysis.

c. Verify that the microphone is not deactivated on your tablet as it will lead to video stream input blocking.

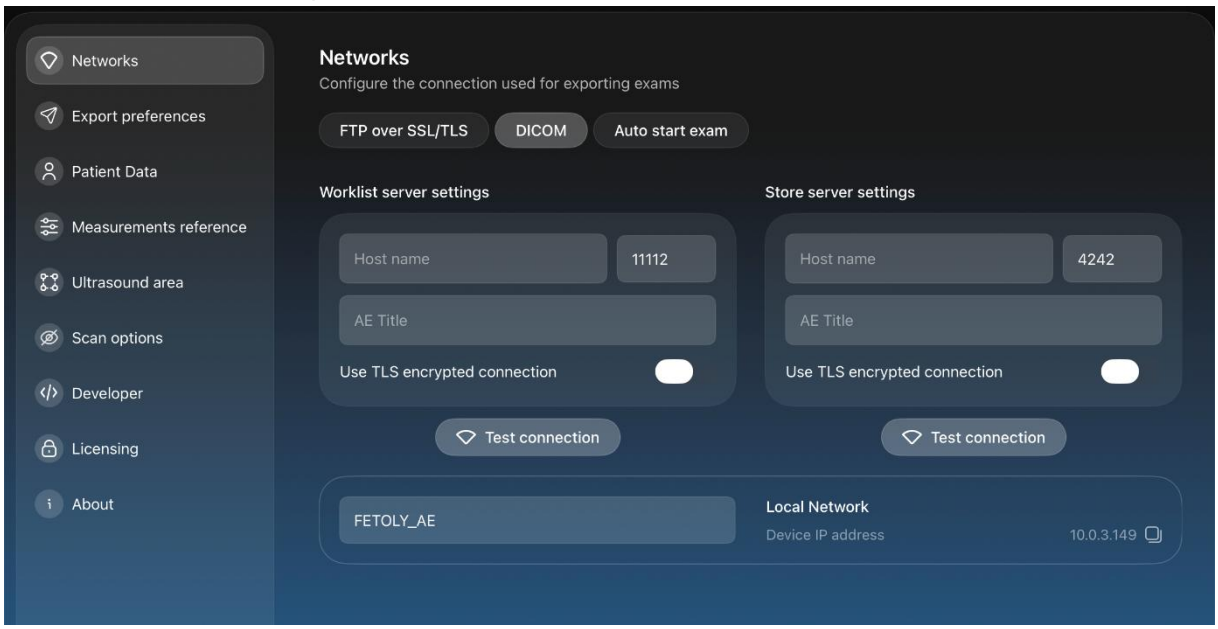
[OPTIONAL] Configuration of the ultrasound machine

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.

Networks

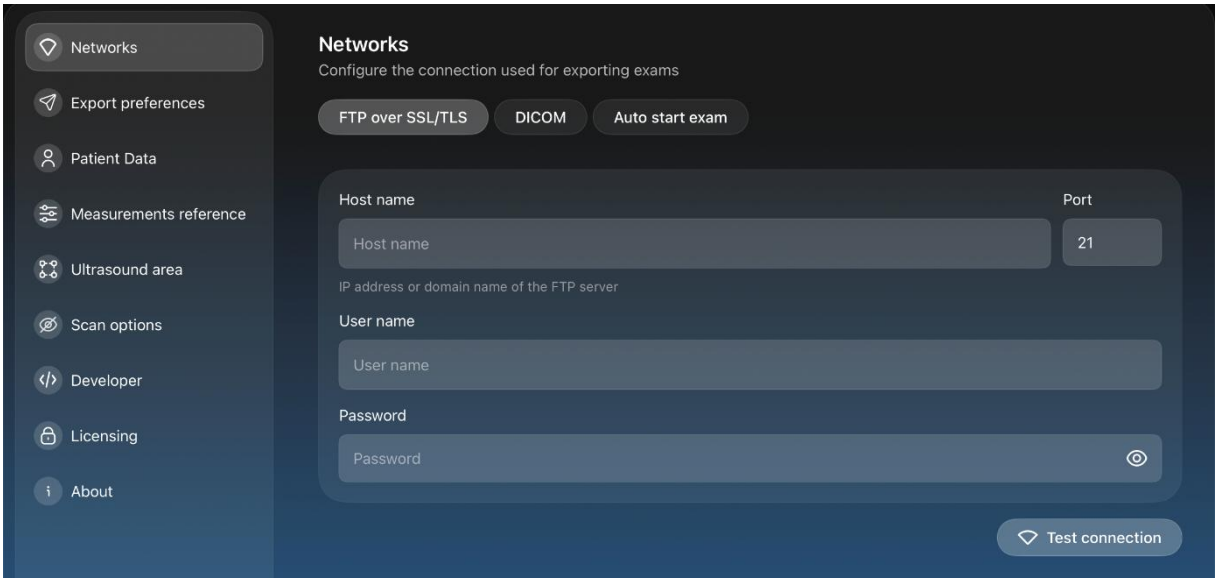


1. Configure the remote DICOM server for exporting images captured by FETOLY. Please note that this step requires the presence of a DICOM server running on a device connected to the same network as the tablet running FETOLY.
    a. Go to Settings' > 'Networks, select DICOM and enter the required information 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.

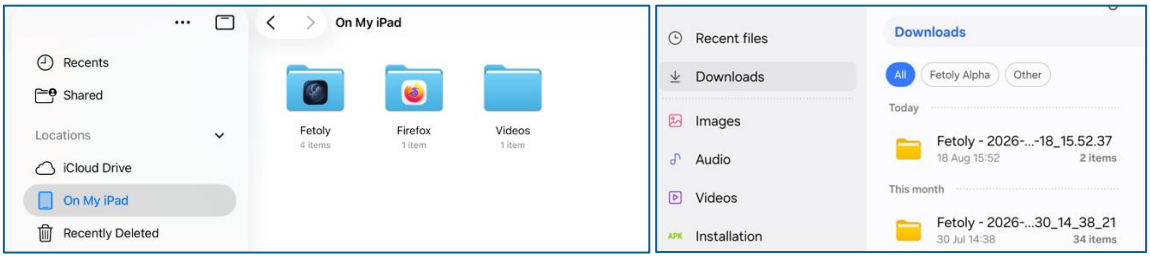
    a. Go to ‘Settings’ > ‘Networks, select FTP and enter the required information for your FTP client: hostname (IP address), username and password. To verify the connection, click the ‘Test connection’ button. This ensures the connection is valid and ready for exporting images.



3. If you don’t want to use a wireless connection, you can export the data directly on the tablet:

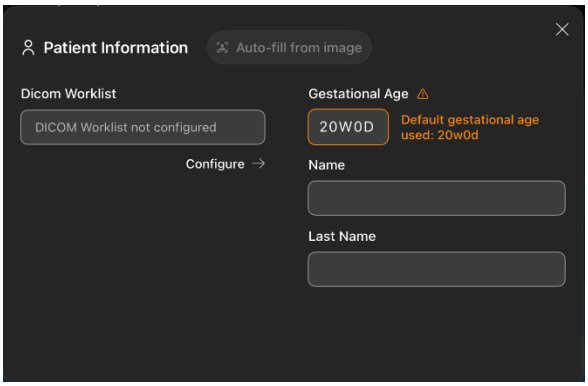
    a. Go to ‘Settings’ > ‘Export preferences”, select local as the export method. The file will be saved on the tablet.

    b. To reach the defined location, go on your tablet desktop, select the ‘Files’ icon, then go to ‘‘On MY iPad’> ‘Fetoly’ for iPad or ‘Downloads’ for Android.

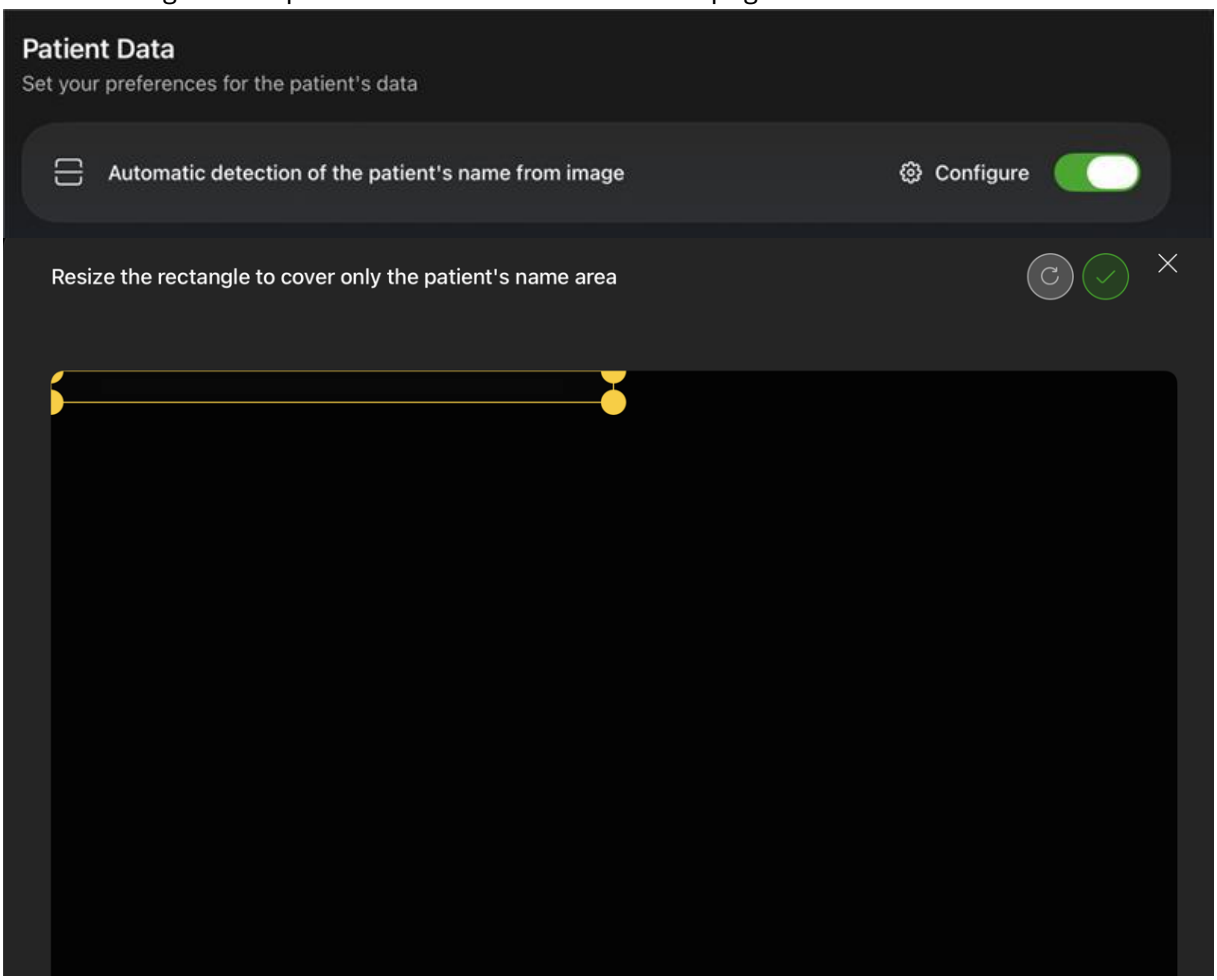


4. If you want to add the name of the patient in the name of the file exported or if you want to select the patient examination from DICOM worklist:

    a. Fill directly the patient’s name with the gestational age on the dashboard pages,



b. 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 dashboard page.

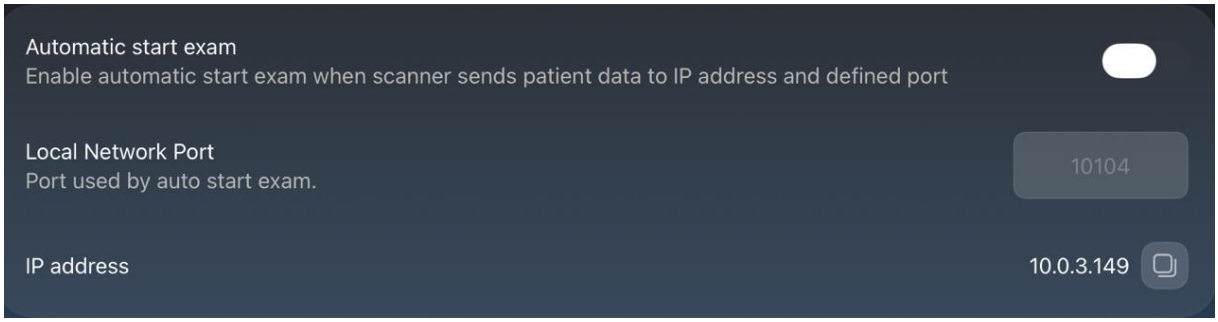


c. Click on ‘Patient’s name’ on the dashboard pages ‘’Export preferences and configure ‘DICOM worklist’. Notice that this function works only if you are connected to a PACS with DICOM worklist parameters configured. Notice also that in DICOM export mode, you are forced to use this setting.

[OPTIONAL] Automatic start of the examination with GE Ultrasound systems

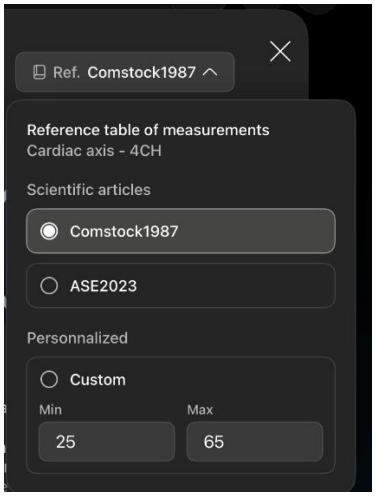
When used with a GE Ultrasound system, go in 'Settings' >'Networks' > "Auto start exam" to enable Auto Start Exam and set up the Local network port and IP address.

FETOLY will then be able to detect automatically the examination start for launching the analysis. When a new examination is detected while there is an ongoing examination (i.e. while there is a new patient), FETOLY will detect it and will reset the ongoing examination to start the new one. If the export has not been done, FETOLY will display a warning allowing to cancel the ongoing examination reset.



USE

1. Follow these steps to realize examination completeness and measurements:
    a. The software automatically detects and displays the gestational age and updates the reference ranges and display the measurement status accordingly.
    b. If the gestational age is not displayed automatically by the software, the user can input manually the gestational age on the dashboard pages.
    c. You can configure the default gestational age by going to 'Settings' > 'Patient data'.
    d. 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 measurement button then on the reference. That will redirect you on the measurement settings.



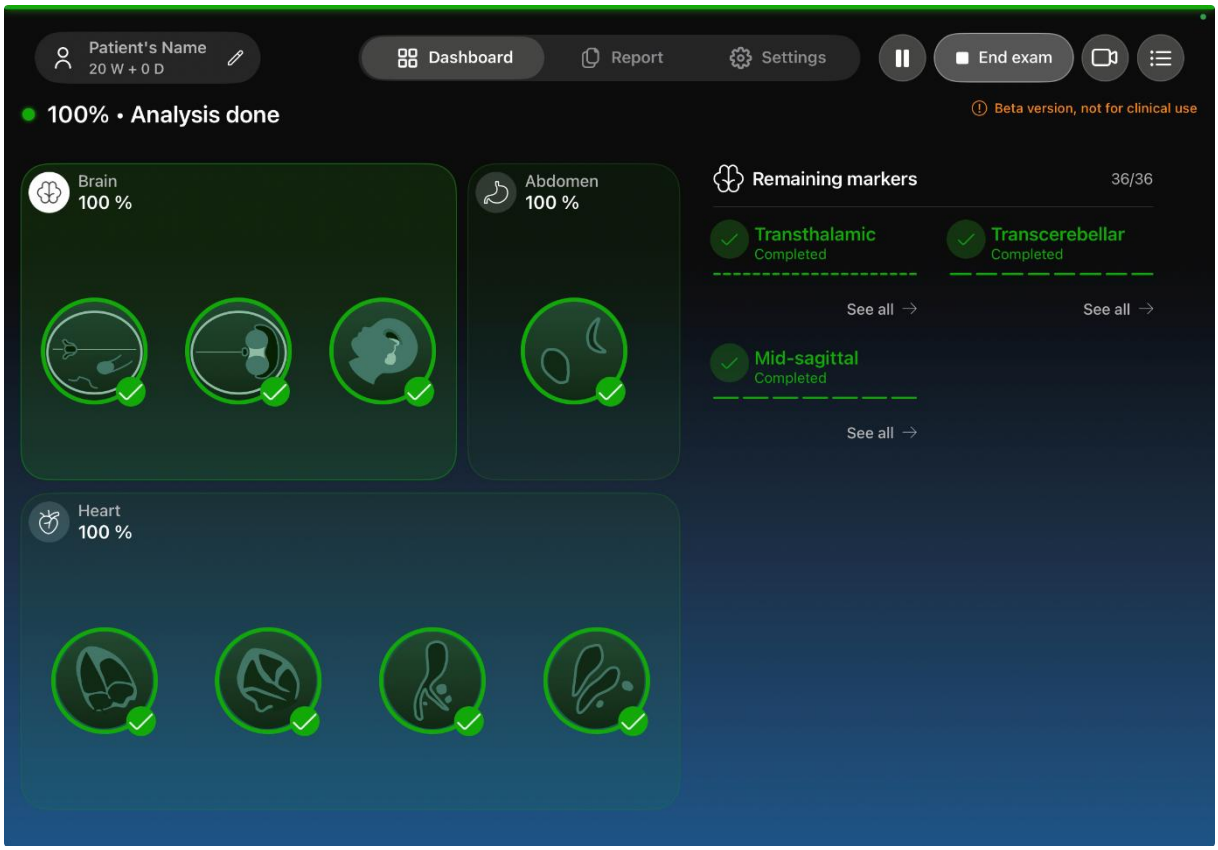
e. Press Start a new exam on the Dashboard pages.

f. Do the examination as usual

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

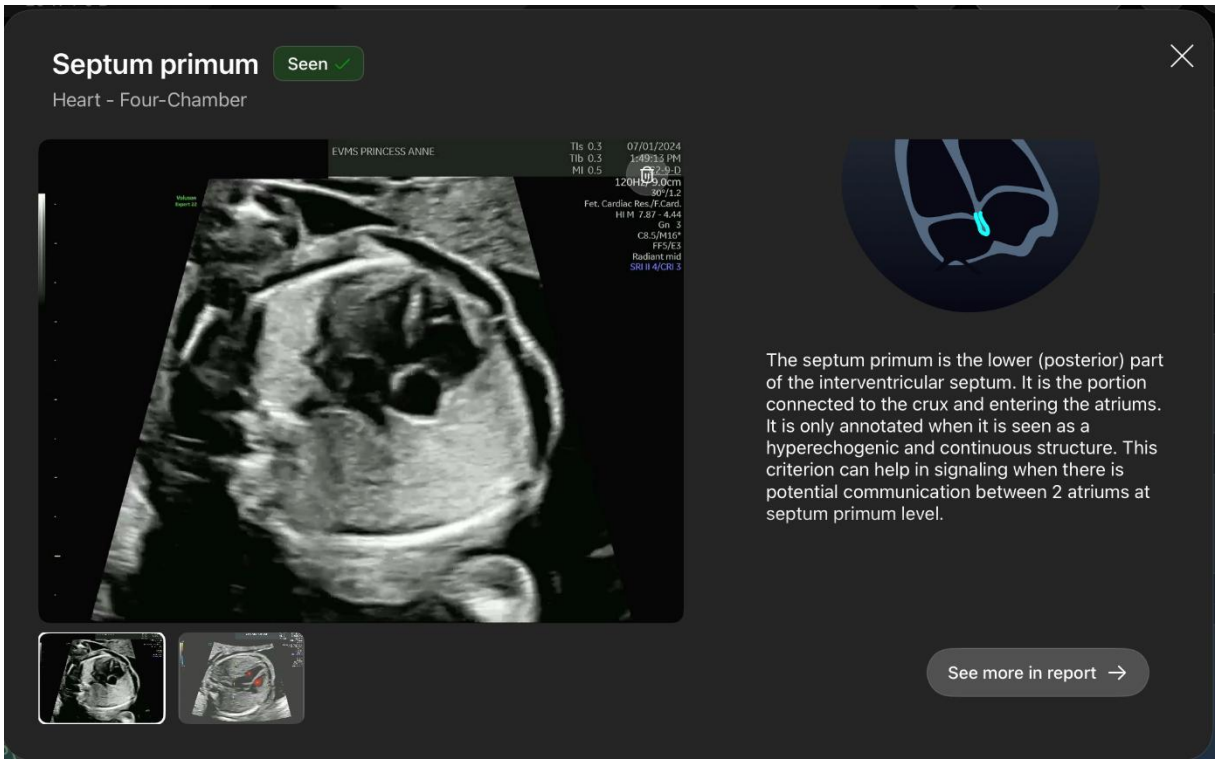
h. The measurements are displayed as “out-of-range” if they are out of the reference range defined

i. When the examination is complete, the dashboard pages indicate it and you can go directly to the report page to check images suggested

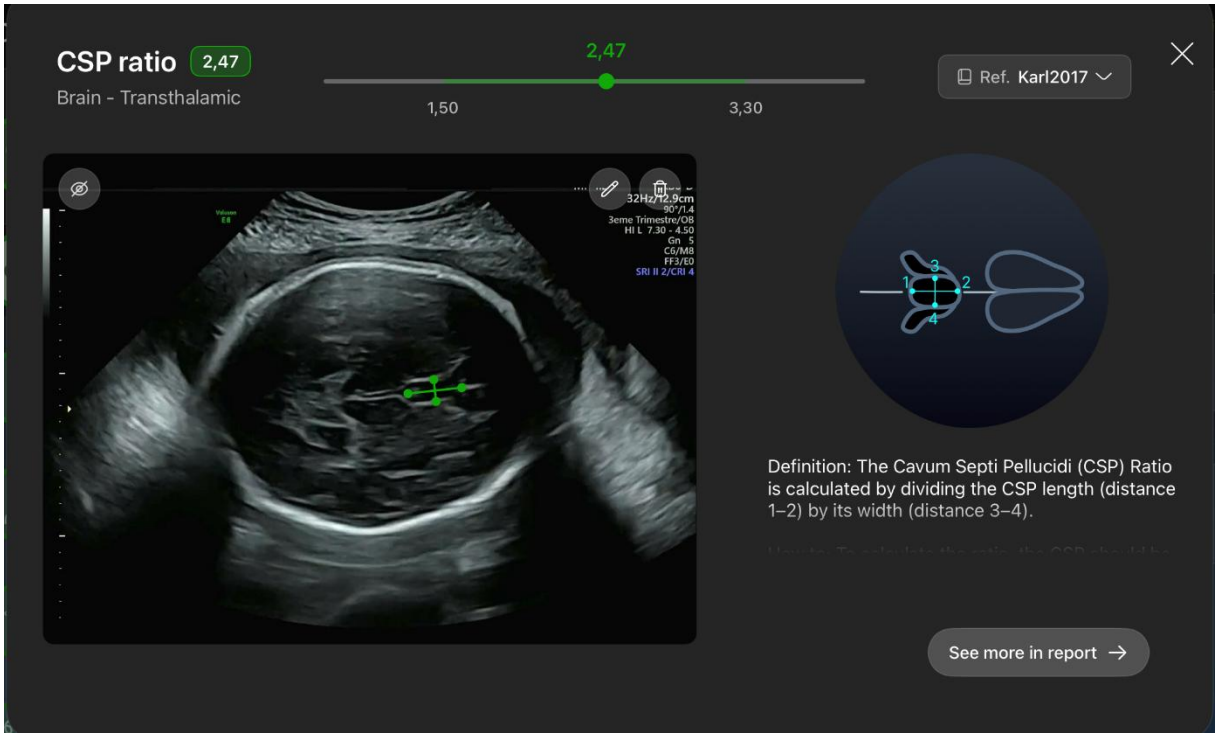


2. Please find hereafter a list of tips to be sure to realize easily the examination completeness and measures:

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 click on a quality criteria 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 click on a measurement to have an explanation of all measurements done.



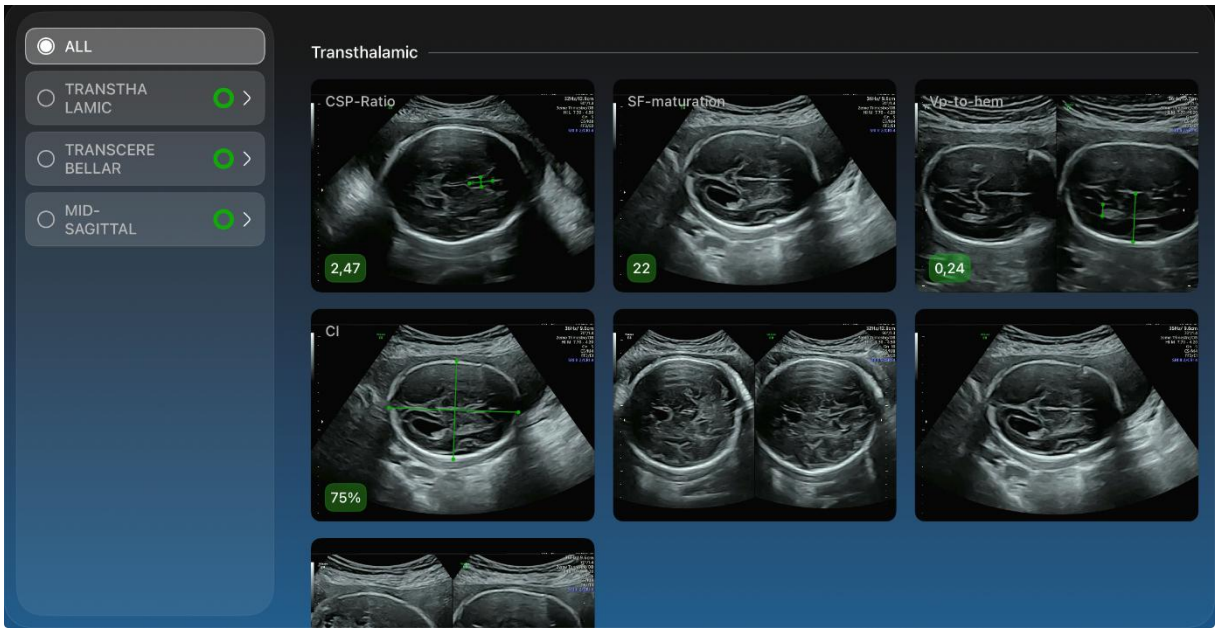
c. Be sure that all the configuration steps explained above are correctly done to avoid detection issues.

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

e. There is a warning on the report 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 dashboard pages, verify if all the corresponding criteria and measures are well identifiable on the images set selected in the report page.

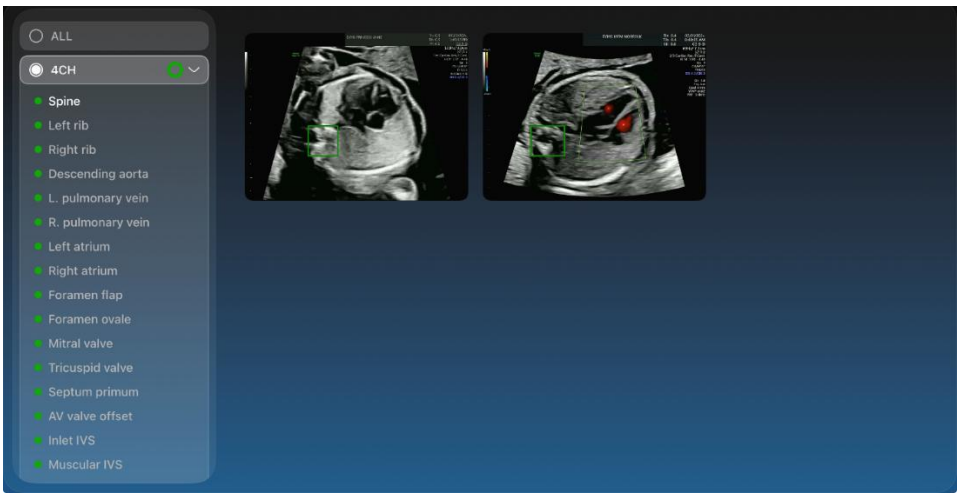
3. Once your video stream is over, go to the 'report section to explore the selected images. To facilitate navigation within the image set, the images are categorized by plane.



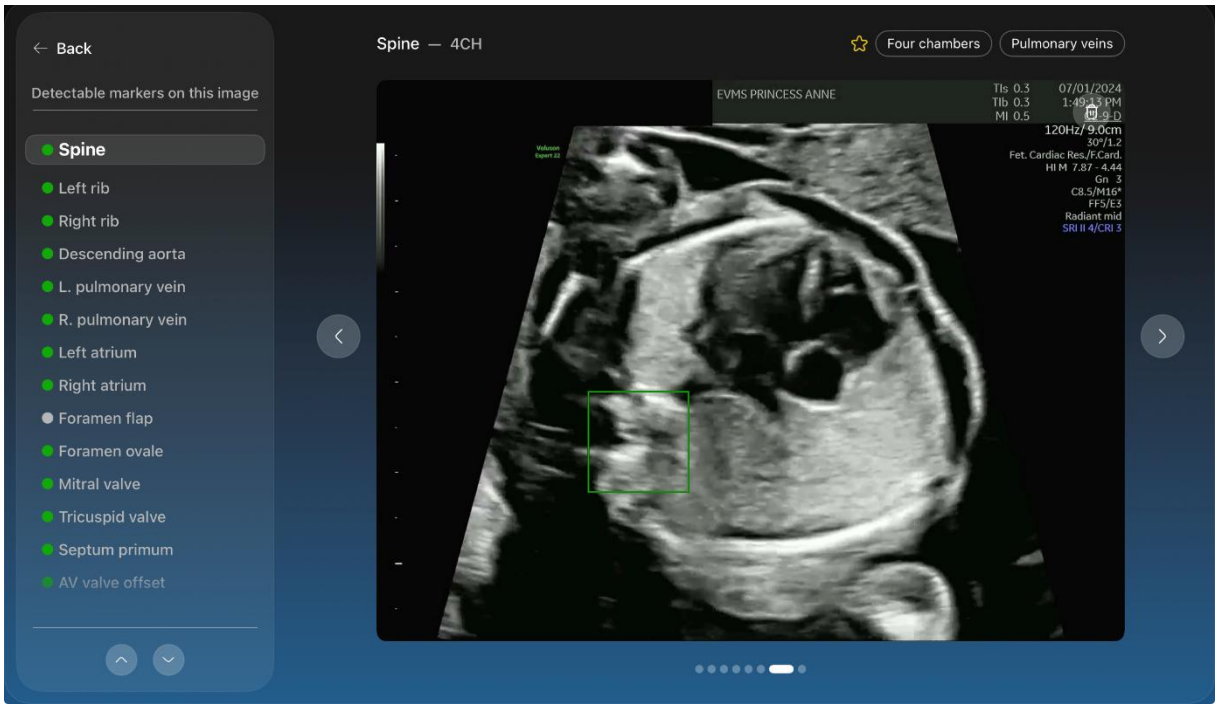
a. Click on a specific plane (left panel) to view selected images related to this plane.

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 green (in-range) or orange (out-of-range).

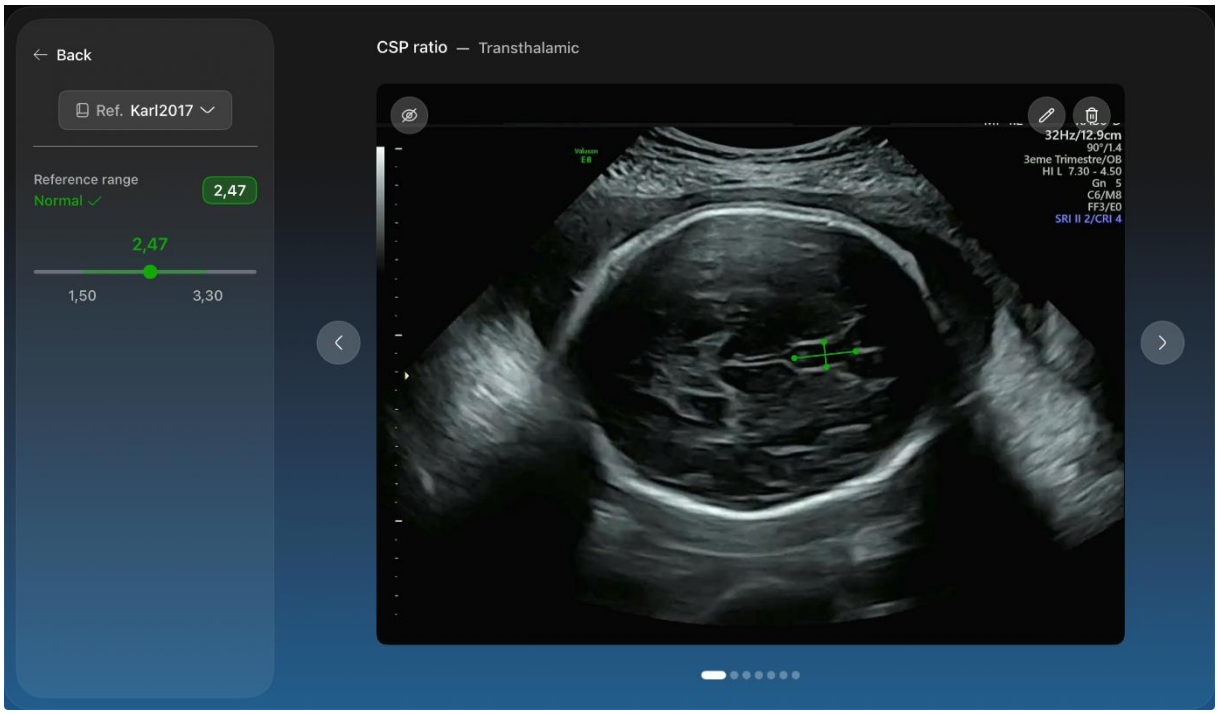
c. Click on a specific structure to view selected images containing this structure. The selected quality criterion is in green and the bounding box surrounding the criterion is displayed on the images.

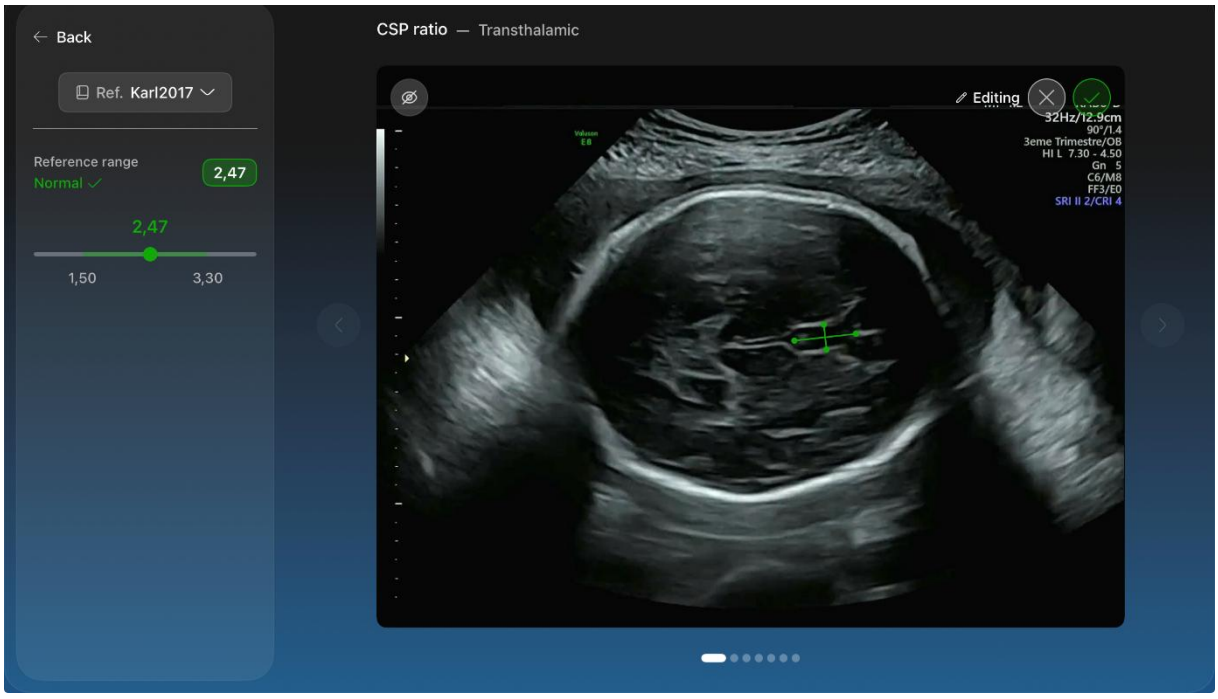


d. Click on a completeness image to zoom on it. You can click on a quality criterion in green to display the bounding box surrounding the quality criterion. The quality criterion chosen is in green. Click on the trash symbol to delete the image. You can directly swipe on the sides of the image to go through other images of the view.



e. Click on a measurement image to zoom on it. The measurement keypoints and shapes are in green (in-range) or orange (out-of-range). 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 dashboard pages to re-launch the analysis and obtain additional images.

Export images

1. Go to the ‘Export preferences section in ‘Settings’ to select the export method that you want to use.
    a. Go to the Report page to export the selected images:
    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 dashboard pages.
    c. The report 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 report page allows to change export preferences by clicking 
    e. Click the ‘Export and finish’ button to export images and clear the examination before beginning a new exam.
    f. Or, click the ‘Export and continue exam’ button to export images without erasing the current selected set of images and completeness analysis.
    g. 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 mid-sagittal view, go to 'Settings' > 'Scan options' and use the toggle button.

Software and licence update

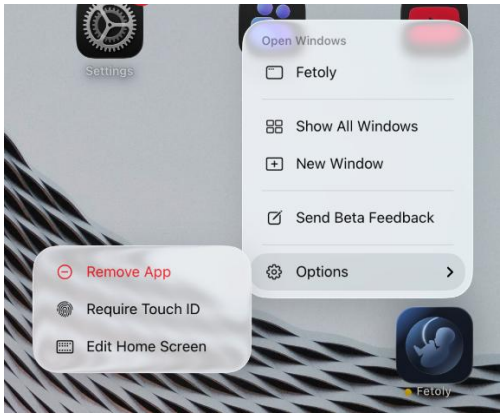
The software checks periodically for new app updates. To ensure immediate availability of new updates, enable background updates for FETOLY in Google Play/App Store settings. When an update is available, the software will display a blocking page at launch, requiring the user to update and restart the 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:

iPad



Android

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
	Medical Device
	Federal law restricts this device to sale on or by the order of a physician
	Manufacturing date (empty factory symbol)
	Swiss representative name and address