

DIAGNOLY

GENERAL TERMS AND CONDITIONS

Diagnoly Solution is designed to provide assistance to healthcare professionals in analyzing fetal ultrasound image sequences using artificial intelligence to enhance the quality and efficiency of obstetric ultrasound examination in the prenatal field. Diagnoly Solution is developed and operated by Diagnoly SAS, a French joint stock company having its registered office at Terra Mundi, 2 place de Francfort, 69003 Lyon, France registered with the Lyon register of commerce and companies under number 882 659 360 (referred to as “**Diagnoly**”).

PLEASE READ THESE GENERAL TERMS AND CONDITIONS CAREFULLY BEFORE STARTING TO USE DIAGNOLY SOLUTION. BY USING DIAGNOLY SOLUTION, YOU CONFIRM THAT YOU ACCEPT THESE GENERAL TERMS AND CONDITIONS AND THAT YOU AGREE TO COMPLY WITH THEM. You shall not use nor access Diagnoly Solution if you do not agree with the General Terms and Conditions or if you are unable to be legally bound by the General Terms and Conditions.

The General Terms and Conditions set the framework for a secure and adequate use of Diagnoly Solution by its Clients and their Users, including:

- **Regulatory status.** Diagnoly Solution is:
 - (i) a Class IIa medical device CE marked under Regulation (EU) 2017/745 (MDR), and
 - (ii) an FDA-cleared Class II medical device in the United States.

Its intended use, functionalities and regulatory status may vary depending on the jurisdiction of use. Use of Diagnoly Solution must strictly comply with the regulatory framework applicable in the Territory where it is deployed.

Outside of these jurisdictions, including in any country where such regulatory approvals are not recognized, Diagnoly Solution is provided STRICTLY AND EXCLUSIVELY as a non-medical, educational tool. IN SUCH CASES, THE CLIENT AND USERS EXPRESSLY AGREE THAT:

- Diagnoly Solution SHALL NOT be used in real-time clinical practice;
- Diagnoly Solution SHALL NOT be used in the presence of a patient;
- Diagnoly Solution SHALL NOT be used for diagnosis, screening, monitoring, or any clinical decision-making;
- Diagnoly Solution SHALL ONLY be used retrospectively on previously acquired and fully anonymized data;
- Diagnoly Solution SHALL ONLY be used for training, educational, audit, or internal review purposes.

Any use outside these conditions is strictly prohibited. Client acknowledges and agrees that any misuse may:

- Engage client's sole liability, and
- Immediately terminate the right to use the solution.

- **Diagnoly Solution is an assistant, not a replacement tool:** Client and Users shall be aware that Diagnoly Solution is intended to assist healthcare professionals in their ultrasound examination procedures and enhance their efficiency and accuracy, and not a substitute for their clinical knowledge and expertise. As much as Diagnoly trains its artificial intelligence models to ensure the greatest level of accuracy, they may contain errors.

- **Regulatory scope and restrictions of use:** Diagnoly Solution is CE marked under European Union regulations and does not hold any other regulatory clearance, certification, or market authorization outside of the EU (including but not limited to FDA clearance in the United States or national approvals in non-EU countries). In jurisdictions where CE marking is not recognized, Diagnoly Solution may only be used retrospectively, for research, audit, or educational purposes, and under no circumstances shall it be used for clinical decision-making or patient care.
- **Diagnoly never has access to any Input Data nor Output Data:** Diagnoly Application runs exclusively locally on Client Equipment and does not share any Data with Diagnoly.
- **Trial Use Restrictions.** During any trial period or evaluation phase of Diagnoly Solution, the Client and Users expressly agree that they shall NOT, without the prior written consent of Diagnoly:
 - conduct or initiate any clinical study, research project, or performance evaluation involving the Solution;
 - publish, present, disclose, or communicate any results, feedback, benchmarking, or analysis related to the Solution;
 - compare the Solution with any third-party product or publish comparative assessments;
 - use the Solution for scientific publications, conferences, posters, or public communications of any kind.

Any data, results, observations or feedback generated during the trial period shall be considered Confidential Information of Diagnoly. Any breach of this clause shall constitute a material breach of the Agreement and may result in immediate termination and potential legal action.

- **Diagnoly technical instructions are essential:** Client shall implement the technical instructions included in the Agreement and particularly in the Documentation (including periodic updates) to ensure a secure and continued use of Diagnoly Solution.
- **The Quote complements and supersedes the General Terms and Conditions:** all specific terms between a Client and Diagnoly are set within the Quote (including: Subscription Plan, Licenses, Term...).
- **Modification of Terms.** Diagnoly reserves the right to modify these General Terms and Conditions at any time. The latest version of the General Terms and Conditions is available at: <https://www.diagnoly.com/terms-and-conditions>. Continued access to or use of Diagnoly Solution after such modifications shall constitute full and unconditional acceptance of the updated Terms. It is the Client's responsibility to regularly review the applicable Terms.

BY ACCESSING OR USING DIAGNOLY SOLUTION, YOU ACKNOWLEDGE THAT YOU HAVE READ, UNDERSTOOD, AND AGREED TO THE MOST RECENT VERSION OF THESE TERMS AND CONDITIONS.

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ARTICLE 1. DEFINITIONS

In these General Terms and Conditions, the following terms shall have the meaning hereafter assigned to them:

Agreement	means the Quote, the General Terms and Conditions and the Documentation.
Anomaly	means defect and/or malfunction that is repetitive and reproducible by Client, preventing the normal operation of all or part of a technical solution.
Applicable Laws	means all applicable laws and regulations in France.
Client	means the entity that agrees to enter into the Agreement, in order to use Diagnoly Solution.
Client System	means any hardware device or infrastructure, in particular (i) the ultrasound device, used by the Client for conducting obstetric ultrasound examinations and connected to the Equipment on which is installed Diagnoly Application, in accordance with the specifications provided in the Documentation and (ii) the DICOM server used by the Client to store Examination Reports.
Confidential Information	means any information or documents disclosed by either Party to the other Party in connection with the Agreement, whether in writing or orally, including, without limitation, all written or printed materials, marketing documentation, trade secrets, know-how, data, databases, financial or business records, processes, diagrams, flow charts, source or object codes.
Diagnoly Application or Application	means the application developed, owned and provided by Diagnoly that is accessible to Client via a mobile application store.
Diagnoly Solution or Solution	means Diagnoly Application and Diagnoly Technical Services.
Diagnoly Technical Services or Technical Services	means the technical services provided by Diagnoly to Client, related to the operation of Diagnoly Application.
Documentation	means the technical documentation related to Diagnoly Solution made available to Client by Diagnoly on the Application or on Diagnoly's website accessible at https://www.diagnoly.com/ . The Documentation may be modified by Diagnoly from time to time at its sole discretion by posting the updated Documentation on the Application or on Diagnoly's website.
Equipment	means a hardware device manufactured by a third-party, on which the Diagnoly Application is installed by the Client and which enables the User to use the Diagnoly Solution.
Examination Reports	means the reports generated on demand through the examination report functionality of Diagnoly Application.
Input Data	means any data provided by User when using Diagnoly Application, in particular from Client System.
Intellectual Property Rights	means all intellectual and industrial property rights anywhere in the world, including, without limitation, any patent, copyright, trademark, trade name, design right, database right, know-how, and any other rights of a similar nature (whether or not capable of protection by registration) and the right to apply for any of them.

Organs	means the fetal organs analyzed by Diagnoly Application during an obstetric ultrasound examination.
Output Data	means the data generated and displayed by Diagnoly Application, including Examination Reports.
Party	means Client and Diagnoly, referred to as a “Party” and collectively the “Parties”.
Quote	means the quote provided by Diagnoly and accepted by the Client for the provision of the Diagnoly Solution, which references these General Terms and Conditions.
Subscription Plan	means the price to be paid by Client to Diagnoly in return for the right to use and access Diagnoly Solution under certain conditions determined in such plan, as described in the Quote.
Term	means the term of the Agreement, as specified in the Quote.
Territory	means the place of intended use of Diagnoly Application, as specified in the Quote.
Users	means Client’s employees authorized to access and use Diagnoly Solution.

ARTICLE 2. PURPOSE OF THE AGREEMENT

The purpose of the Agreement is to define the conditions under which Diagnoly undertakes to make Diagnoly Solution available to Client and Client undertakes to use Diagnoly Solution in accordance with the terms of the Agreement.

In the event of a contradiction between the contractual documents, these shall apply in the following order of precedence: (i) the Quote, (ii) the General Terms and Conditions, and (iii) the Documentation.

Client agrees and acknowledges that these General Terms and Conditions may be modified by Diagnoly from time to time at its sole discretion by posting the updated terms on Diagnoly’s website. For each substantial modification of these General Terms and Conditions, Client will be notified by email.

ARTICLE 3. DESCRIPTION OF DIAGNOLY SOLUTION

3.1. PRESENTATION OF DIAGNOLY SOLUTION

Purpose of Diagnoly Solution. Diagnoly Solution is designed to provide assistance in analyzing fetal ultrasound image sequences using artificial intelligence to enhance the quality and efficiency of obstetric ultrasound examination in the prenatal field. DIAGNOLY SOLUTION IS A TOOL INTENDED TO ASSIST HEALTHCARE PROFESSIONALS IN THEIR ULTRASOUND EXAMINATION PROCEDURES AND ENHANCE THEIR EFFICIENCY AND ACCURACY. UNDER NO CIRCUMSTANCES SHOULD DIAGNOLY SOLUTION BE REGARDED AS A SUBSTITUTE FOR THEIR CLINICAL KNOWLEDGE AND EXPERTISE. ALL DIAGNOLY OUTPUT DATA MUST BE REVIEWED AND VALIDATED BY THE HEALTHCARE PROFESSIONAL, WHO SHOULD NOT RELY SOLELY ON DIAGNOLY SOLUTION. AS MUCH AS DIAGNOLY TRAINS ITS MODELS TO ENSURE THE GREATEST LEVEL OF ACCURACY OF DIAGNOLY SOLUTION, THEY MAY CONTAIN ERRORS. DIAGNOLY APPLICATION RUNS EXCLUSIVELY LOCALLY ON CLIENT EQUIPMENT AND DOES NOT SHARE ANY OUTPUT DATA WITH DIAGNOLY.

Description of Diagnoly Application functionalities. Diagnoly Application encompasses a range of functionalities:

- **examination completeness:** Diagnoly Application displays in real-time which Organ views and quality criteria are verified by Diagnoly Application during the examination. The verified Organ views and quality criteria are accessible by Users at any moment of the ultrasound examination, in real-time.
- **biometric quantitative measurement:** Diagnoly Application displays in real-time which Organ measurements are completed by Diagnoly Application during the ultrasound examination and whether these measurements fall within or outside standard references ranges, based on scientific publications. Since Users are solely responsible for the interpretation of measurements, Users are invited to modify these reference ranges at any time, either by selecting standards recognized in their territory or by providing their own internal references. The verified Organ measurements are accessible by Users at any moment during the ultrasound examination.
- **examination illustration:** Diagnoly Application selects an image subset that illustrates:
 - (i) the verified views and qualities criteria. These images can be reviewed by Users to verify the views and criteria's presence. Optionally, Users can display detected quality criteria localization on selected images.
 - (ii) each measurement. For each measurement, the software displays an image with the measurement drawn and the measured value. The normal range for this measurement is also reminded to the User.
- **examination report:** Diagnoly Application enables the User to export on Client System an Examination Report, which contains (i) a summary of measurements and completeness (images) and (ii) measurement illustrations (images) with measurement drawn and value.

3.2. TECHNICAL PREREQUISITES TO DIAGNOLY APPLICATION

Download Diagnoly Application on Client Equipment. Client must download and install Diagnoly Application via application stores on its Equipment. Before installing Diagnoly Application on its Equipment, Client shall verify the compatibility of the Equipment, as well as the operating system, ensuring that they meet the specifications set out in the Documentation.

Enter registration code in the Application. After having signed the Quote, Client shall send an email to Diagnoly at support@diagnoly.com providing Diagnoly with the unique device identifier of the Equipment(s) and any additional information requested by Diagnoly to authenticate Client's use of the Diagnoly Application. Within a reasonable timeframe, Client shall receive a registration code from Diagnoly by email. This code must be entered during the initial activation of Diagnoly Application on the Equipment(s) in order to validate the license(s) and enable access to Diagnoly Application.

Connect Equipment to Client System. In order to use Diagnoly Application, Client shall connect Client System to its Equipment on which Diagnoly Application is installed, in accordance with the Documentation. Client is responsible for the integration of Diagnoly Application with Client System, and for designating a representative with sufficient technical knowledge to complete the Diagnoly Application integration process. If Client is unable to ensure such expertise, Diagnoly may provide onboarding assistance upon request remotely, as described in Article 3.4.2. Client acknowledges that Diagnoly Application has been fully tested with a number of ultrasound systems, as mentioned in the

Documentation, and Diagnoly cannot guarantee optimal Application performance when connected to machines from other manufacturers. By default, the Application does not transmit any data to Client System, ensuring a one-way communication flow from Client System to the Application exclusively. However, the Client has the option to generate an Examination Report at the end of each examination and upload it in the Client System for archiving purposes, as described in the Documentation.

Update regularly Diagnoly Application. Although Internet connectivity is not required for the use of Diagnoly Application, Client is required to connect its Equipment to Internet regularly, at least once per month, to ensure updates of the Application, as described in the Documentation. Failing to do so within the given timeframe, the Diagnoly Application will be automatically deactivated and remain inaccessible until the update is completed.

3.3. CONDITIONS OF USE OF DIAGNOLY APPLICATION

3.3.1. License granted to Client

Client is granted a personal, non-exclusive, non-transferable and non-assignable right to use Diagnoly Application in the Territory, in accordance with the terms of the Agreement. This license is granted throughout the Term of the Agreement. Each license is strictly linked to a specific Equipment and cannot be used on multiple Equipments simultaneously.

3.3.2. Medical Device specificities

Medical device. The examination completeness functionality and examination measurement functionality integrated into Diagnoly Application have passed the conformity assessment procedure with an EU notified body and has received the Class IIa CE mark in accordance with EU Regulation 2017/745. Furthermore, Diagnoly is certified ISO 13485:2016 on Medical devices – Quality management systems.

United States regulatory status. Diagnoly Solution has received clearance from the U.S. Food and Drug Administration (FDA) as a Class II medical device for its intended use. Use within the United States must comply with all applicable federal and state laws and regulations governing medical devices and clinical practice.

Compliance with Applicable Laws. Diagnoly complies with Applicable Laws and more specifically with laws related to medical devices, as above-mentioned. Client acknowledges and agrees that Applicable Laws may vary and that any non-conformity of functionalities of Diagnoly Application due to a change in Applicable Laws may lead to Diagnoly limiting the functionalities of Diagnoly Application.

3.3.3. Client's use of Diagnoly Solution

A Solution dedicated to assisting healthcare professionals. Client acknowledges and agrees that Diagnoly Solution is intended to support and complement the User's existing medical practices in fetal medicine, and must not be used for any other medical or non-medical purpose. UNDER NO CIRCUMSTANCES SHALL DIAGNOLY SOLUTION AND/OR ANY OUTPUT DATA BE CONSIDERED A SUBSTITUTE FOR THE HEALTHCARE PROFESSIONAL'S OWN ANALYSIS AND/OR INTERPRETATION AND/OR CLINICAL JUDGMENT. THE INFORMATION AND DIAGNOSES PROVIDED BY USERS TO THEIR PATIENTS, INCLUDING THOSE BASED IN WHOLE OR IN PART ON OUTPUT DATA, REMAINS USER'S SOLE RESPONSIBILITY AS A HEALTHCARE PROFESSIONAL. THEREFORE, ANY AND ALL OUTPUT DATA MUST BE REVIEWED AND VALIDATED BY THE HEALTHCARE PROFESSIONAL IN CHARGE OF THE EXAMINATION, WHO SHOULD NOT RELY SOLELY ON DIAGNOLY APPLICATION. AS MUCH AS DIAGNOLY

TRAINS ITS MODELS TO ENSURE THE GREATEST LEVEL OF ACCURACY OF DIAGNOLY SOLUTION, THEY MAY CONTAIN ERRORS.

The Client expressly undertakes to ensure that Users comply with the territorial regulatory restrictions defined above. The Client shall be solely responsible for any use of Diagnoly Solution outside its authorized regulatory scope.

User's access. Client is solely and entirely responsible for granting Users access to Diagnoly Application through the Equipment. All access to Diagnoly Application is deemed to have been made by Client and therefore commits Client, and as such Client undertakes to make these General Terms and Conditions binding upon Users. Client warrants that access to Diagnoly Application will be strictly limited to healthcare professionals that are authorized to perform obstetric ultrasound examinations in the prenatal field, according to Applicable Laws.

Incident report. Client shall report to Diagnoly at support@diagnoly.com any incident or risk of incident occurring during the use of Diagnoly Solution without delay. As required under Applicable Law, Diagnoly undertakes to (i) manage the incident in accordance with ISO 13485:2016 on Medical devices and/or (ii) report, when required, to the relevant competent national authority any incident or risk of incident occurring during the use of Diagnoly Solution, including those resulting from misuse of Diagnoly Solution by Client.

User Information and Training Responsibility. The Client acknowledges and agrees that it is solely responsible for ensuring that all Users are duly informed of, understand, and comply with the intended use, instructions for use, limitations, and regulatory status of Diagnoly Solution, as defined in this Agreement and in the Documentation. The Client expressly undertakes to:

- communicate these General Terms and Conditions to all Users prior to granting them access to the Solution;
- ensure that all Users are adequately trained and competent to use Diagnoly Solution in accordance with its intended purpose and applicable regulations;
- inform all Users of the limitations of the Solution, including that it is an assistance tool and not a substitute for clinical judgment;
- inform all Users of the territorial regulatory restrictions applicable to the use of the Solution, including restrictions outside CE-marked and FDA-cleared jurisdictions.

The Client acknowledges that access to the Solution is not personal or nominal and may be shared among authorized Users under its responsibility. Consequently, the Client remains fully liable for any use of the Solution by its Users.

Any failure by the Client to properly inform and supervise Users shall constitute a breach of the Agreement and may engage the Client's sole liability.

3.4. SERVICES ASSOCIATED WITH DIAGNOLY SOLUTION

3.4.1. Diagnoly Technical Services

All Diagnoly Technical Services listed below are included in all Subscription Plans and shall not involve any additional fee.

Support. Diagnoly makes available to Client a support service to (i) declare Anomalies and (ii) obtain assistance regarding the use of Diagnoly Application. The support service is accessible by email at support@diagnoly.com. The support service is available on business days during working hours (from 9:00 am to 5:00 pm CET). Any report of an Anomaly must include a detailed description of the Anomaly

encountered, the conditions for reproducing the Anomaly and a description of the impact on the functioning of the Diagnoly Application. Diagnoly shall make its best efforts to handle support requests in a timely manner.

Maintenance. Diagnoly integrates technical updates on an ongoing basis to Diagnoly Application in order to correct any identified bug and improve the Application. Corrective maintenance is included in all Subscription Plans and performed via regular updates to the Application, notified to Client, through the Application, when its Equipment is connected to the Internet (at least once a month, as described in Article 3.2 and in the Documentation). Whereas upgrades and new features are, at Diagnoly sole discretion, either included or excluded from such Subscription Plans. We will communicate by e-mail to provide supplementary information or to advise on action to be taken in the:

- use of the Device,
- modification of the Device,
- stop of the Device version or
- end-of-life of the Device

3.4.2. Diagnoly additional services

The Parties agree that Diagnoly additional services listed below are not part of the Subscription Plans and will be subject to additional invoicing in accordance with the Agreement.

Onboarding assistance. Client may request onboarding assistance from Diagnoly for the Diagnoly Application, in particular support related to its integration within Client System. The onboarding assistance does not consist, for Diagnoly, in carrying out tasks or examination relating to Client's activity, and is strictly limited to remote support provided to the Client's teams for the integration of the Diagnoly Application. Upon Client's request, Diagnoly shall provide a quote for the requested onboarding assistance.

Trainings. Client may ask Diagnoly to provide trainings on Diagnoly Application, namely support in Client's use and control of Diagnoly Application. The training service does not consist, for Diagnoly, in carrying out tasks or examination relating to Client's activity, and is limited to training its teams on the use of Diagnoly Application. Upon Client's request, Diagnoly shall provide a quote for the requested training services.

Equipment. Diagnoly may provide the Equipment under the conditions set out in the Quote. Client shall install and operate the Diagnoly Product on the Equipment under its sole responsibility. Since Diagnoly is not the manufacturer of the Equipment, Diagnoly makes no warranty nor representation, express or implied, regarding the Equipment provided under this Agreement. In particular, Diagnoly shall not be held liable under the legal warranty for hidden defects (Article 1641 of the French Civil Code) or the warranty against eviction by third parties (Article 1626 of the French Civil Code). In case of any malfunction, defect, or issue related to the Equipment, the Client must directly contact the manufacturer's after-sales service. Diagnoly shall bear no responsibility for the maintenance, repair, or replacement of the Equipment. The Parties agree that the Client becomes the owner of the Equipment upon full payment of the price under the conditions set out in the Quote, and that termination of the Agreement shall not result in the return of the Equipment.

ARTICLE 4 . DATA OWNERSHIP

Input Data. All Input Data are and shall remain the sole property of Client. Since the Application is running on Client's Equipment and does not transmit any data to Diagnoly, Diagnoly never receives

nor stores any Input Data on its servers. This Agreement shall not be interpreted as an assignment and does not transfer to Diagnoly any title or ownership in and to the Input Data. Client is also solely responsible for the lawfulness of the Input Data processed within Diagnoly Application.

Output Data. All Output Data, including Examination Reports, shall remain the sole property of Client. Since the Application is running on Client's Equipment and does not transmit any data to Diagnoly, Diagnoly never receives nor stores any Output Data on its servers. This Agreement shall not be interpreted as an assignment and does not transfer to Diagnoly any title or ownership in and to the Output Data.

No storage of Input Data and Output Data by Diagnoly. DIAGNOLY, THROUGH DIAGNOLY SOLUTION, NEITHER RECEIVES NOR STORES ANY INPUT DATA NOR OUTPUT DATA, INCLUDING EXAMINATION REPORTS. THEREFORE, IT IS THE SOLE RESPONSIBILITY OF CLIENT TO DECIDE TO EXPORT AND SAVE THE EXAMINATION REPORTS TO A SERVER WITHIN CLIENT SYSTEM AFTER EACH EXAMINATION AS DESCRIBED IN THE DOCUMENTATION. FAILING TO DO SO, ALL OUTPUT DATA LINKED TO THE LAST EXAMINATION SHALL BE DELETED AS SOON AS A USER STARTS A NEW EXAMINATION, WITH NO POSSIBILITY OF RECOVERY.

Optional Anonymized Data Sharing. NOTWITHSTANDING THE FOREGOING, CLIENT MAY CHOOSE, AT THEIR SOLE DISCRETION, TO TRANSFER ANONYMIZED OR DE-IDENTIFIED INPUT DATA AND/OR OUTPUT DATA TO DIAGNOLY FOR PURPOSES SUCH AS RESEARCH, ANALYTICS OR IMPROVING DIAGNOLY'S AI TECHNOLOGY. ANY SUCH TRANSFER SHALL BE EXPLICITLY INITIATED BY CLIENT AND SHALL BE ENTIRELY FREE OF CHARGE. CLIENT REMAINS SOLELY RESPONSIBLE FOR ENSURING THAT ANY SHARED DATA COMPLIES WITH APPLICABLE LAWS AND DOES NOT CONTAIN PERSONALLY IDENTIFIABLE INFORMATION OR OTHER SENSITIVE INFORMATION.

ARTICLE 5. DIAGNOLY INTELLECTUAL PROPERTY

Ownership of Diagnoly Application. Subject to any third-party rights, Diagnoly is and remains the exclusive owner of all Intellectual Property Rights over Diagnoly Application. The Agreement cannot under any circumstances be interpreted as an assignment and does not transfer to Client any title or ownership on Diagnoly Application. The only right to Diagnoly Application granted by Diagnoly to Client according to the Agreement is the right to use described in Article 3.3.

In addition, subject to any third-party rights, Diagnoly retains exclusive ownership of all Intellectual Property Rights in and to the software code, algorithms, models, database and infrastructure built by Diagnoly to enable the development and updates of the Application.

Limited use of Diagnoly Application. Except as expressly provided in the Agreement, Client shall not, directly or indirectly: (i) use Diagnoly Application for purposes other than those authorized by the Agreement or for the benefit of any other person or entity not referred to in the Agreement, (ii) reproduce or copy more than the number of authorized licenses, modify, adapt, transcribe, translate, distribute, assign, lease or otherwise transfer Diagnoly Application, in whole or in part, free of charge or not, for any reason whatsoever and (iii) decompile, disassemble, process a reverse engineering of object code or any source code of Diagnoly Application or permit directly or indirectly third parties to do so.

Consequence of Infringement. In the event that Diagnoly Application or part thereof is likely, according to Diagnoly, to be the subject of an infringement action, Diagnoly undertakes, at its sole discretion and expense, to: (i) modify or replace all or part of Diagnoly Application in order to stop the infringement claim, or (ii) obtain the right to use the elements covered by the infringement claim from

the third party owner, without any additional fee to be paid by Client, or (iii) terminate the Agreement under the conditions provided herein.

Indemnification in case of Infringement. Diagnoly shall defend, indemnify and hold Client harmless against any claim incurred as a result of claims, proceedings or legal actions brought against Client by a third party claiming that Client's use of Diagnoly Application infringes any intellectual property rights of such third party. This warranty does not apply and Diagnoly is not responsible for any claim or request arising out of: (i) an allegation that does not specifically indicate that the claim is based on Diagnoly Application; (ii) the use or combination of Diagnoly Application or part thereof with software, hardware or other elements not developed by Diagnoly if the use of Diagnoly Application without this combination would not constitute an infringement, (iii) the modification of Diagnoly Application by a third party, if the use of the unmodified Diagnoly Application would not constitute an infringement, or (iv) an allegation made against Client before the Agreement enters into force or based on actions taken by Client before the entry into force of the Agreement.

Third-party and open-source components. Client recognizes and accepts that Diagnoly Application integrates some open-source components and third-party licensed components. Such components are used by Diagnoly in compliance with their respective licenses, and Client acknowledges that their use may be subject to the terms and conditions of these licenses.

ARTICLE 6 . FINANCIAL CONDITIONS

6.1. PRICING

Subscription Plans. In consideration of the access and use by Client of Diagnoly Solution, Client agrees to subscribe to one of the Subscription Plans under the conditions set forth in the Quote.

Cost of Diagnoly additional services. On a case-by-case basis, and in consideration of any additional services provided by Diagnoly, Client agrees to pay an additional fee under the condition set forth in the Quote or any additional quote and agreed upon by the Parties.

Price revaluation. The cost of the Subscription Plans and Diagnoly additional services, if any, will remain the same throughout the first year of use of Diagnoly Solution and provision of additional services, if any. From the second year onwards, the Subscription Plans and any fees related to additional services may be subject to an annual revaluation at each anniversary date of the Agreement while the Agreement is in force. Such revaluation shall be communicated by Diagnoly to Client at least three (3) months prior to the anniversary date of the Agreement.

All prices are in Euros, exclusive of costs and taxes. Particularly, where applicable, prices are subject to VAT at the rate prevailing at the time of invoicing.

6.2. PAYMENT CONDITIONS

Client agrees to pay the Subscription Plan and fees related to additional services until the Agreement is terminated by either Party under the conditions set forth in the Quote and the relative additional quotes.

If Client does not pay the Subscription Plan or fees related to additional services in due course, and subject to a written notice sent by email to the address provided by Client which remains without effect during eight (8) days, Diagnoly reserves the right to suspend Client's access to Diagnoly Solution until complete payment.

ARTICLE 7. LIABILITY AND INSURANCE

7.1. DIAGNOLY LIABILITY

Exclusion of liability. In no event shall Diagnoly be held liable to (i) Client in case of improper or fraudulent use of Diagnoly Solution by Client or a third party to which Client has deliberately or negligently given access to or (ii) any other third party to the Agreement for any damage whatsoever. UNDER NO CIRCUMSTANCES SHALL DIAGNOLY SOLUTION AND/OR ANY OUTPUT DATA BE CONSIDERED A SUBSTITUTE FOR THE HEALTHCARE PROFESSIONAL'S OWN ANALYSIS AND/OR INTERPRETATION AND/OR CLINICAL JUDGMENT. THE INFORMATION AND DIAGNOSES PROVIDED BY USERS TO PATIENTS, INCLUDING THOSE BASED IN WHOLE OR IN PART ON OUTPUT DATA, REMAINS USER'S SOLE RESPONSIBILITY AS A HEALTHCARE PROFESSIONAL. THEREFORE, ANY OUTPUT DATA MUST BE REVIEWED AND VALIDATED BY THE HEALTHCARE PROFESSIONAL, WHO SHOULD NOT RELY SOLELY ON DIAGNOLY APPLICATION AND OUTPUT DATA. AS MUCH AS DIAGNOLY TRAINS ITS AI MODELS TO ENSURE THE GREATEST LEVEL OF ACCURACY OF DIAGNOLY SOLUTION, THEY MAY CONTAIN ERRORS.

Limitation of liability. Diagnoly's liability shall be limited to direct, personal, and certain damages. The following damages shall be deemed indirect damages and excluded from Diagnoly's liability: loss of profits, loss of sales, loss of goodwill, commercial prejudice, the cost of procuring substitute services, loss consecutive to any failure or interruption of the internet or third-party internet connections or infrastructure as well as any loss caused by a virus or other technologically harmful event outside of Diagnoly's control.

The total liability of Diagnoly, whether in contract, tort (including negligence) or otherwise shall in no circumstances exceed a sum equal to the total fees paid by the Client to Diagnoly in the six (6) months preceding the event giving rise to the liability (VAT excluded).

The exclusions referred to under this article shall apply to the fullest extent permissible by Applicable Laws.

7.2. CLIENT'S LIABILITY

Client shall bear any consequences and undertakes not to seek Diagnoly's liability for any malfunction due to the use of Diagnoly Application by Client and any Users contrary to the Agreement and any instructions for use provided by Diagnoly. Particularly, Client shall connect its Equipment to the internet regularly, at least once per month, to ensure the Application is updated, as described in article 3.2 and in the documentation.

The Client acknowledges and agrees that they shall bear sole responsibility towards their patients in the event of an erroneous medical diagnosis that is based, whether wholly or partially, on the Output Data.

Client undertakes to indemnify Diagnoly against the financial consequences that Diagnoly may have to suffer in the event of actions or claims directed against Diagnoly by a third party, including a patient, resulting from Client's use of Diagnoly Application in breach of the Agreement.

7.3. FORCE MAJEURE

Neither Party will be responsible or have any liability for any delay or failure to perform, to the extent such delay or failure is due to an event of *force majeure*, defined as: unforeseen circumstances or causes beyond its reasonable control, earthquake, fire, flood, sanctions, embargoes, strikes, lockouts or other labor disturbances, civil unrest, riots, terrorist or other malicious or criminal acts, war, pandemics, failure or interruption of the internet or third party internet connections or infrastructure, power failures, acts of civil and military authorities and severe weather.

The affected Party will give the other party prompt written notice (when possible) of the failure to perform and use its reasonable efforts to limit the resulting delay in its performance.

7.4. INSURANCE

Diagnoly and Client have taken out the necessary insurance policies to cover the risks associated with carrying out their activities. They undertake to provide supporting documents upon request.

ARTICLE 8. TERM AND TERMINATION

8.1. TERM OF THE AGREEMENT

The Agreement comes into force on the date of signature of the Quote by the Client and shall remain active for the Term as defined in the Quote or until terminated by either Party, under the conditions described below.

At the end of the initial Term, the Agreement shall then be tacitly renewed, unless terminated by registered letter with acknowledgment of receipt sent by either party at least one (1) month before the end of the initial Term or any additional Term.

8.2. SUSPENSION AND TERMINATION

Suspension. In the event of use of the Diagnoly Solution by Client that is contrary to the conditions set out in the Agreement, particularly any use that is (i) illegal, (ii) in breach of the terms of the Agreement, or (iii) an infringement of the Diagnoly Solution, Diagnoly may immediately suspend access to the Diagnoly Solution by Client. Furthermore, in accordance with Applicable Laws, Diagnoly may be required to withdraw Diagnoly Solution temporarily or permanently from the market, by order of the relevant competent national authority and/or the notifying body, organization or jurisdiction, where appropriate. In such case, Client access to Diagnoly Solution shall be immediately suspended or terminated.

Termination for default. In the event of a breach by either Party of any of its obligations under the Agreement, the other Party may terminate the Agreement where the defaulting Party fails to cure or provide the other Party with a plan for curing said breach within thirty (30) days after receipt of a written notification sent via registered letter with acknowledgment of receipt.

8.3. EFFECTS OF TERMINATION

In the event of termination of the Agreement, for any reason whatsoever:

- Client shall immediately cease using Diagnoly Solution;
- Client shall pay all amounts due to Diagnoly;

Notwithstanding any termination of the Agreement for any reason, the obligations of the Parties under the clauses “Data Ownership”, “Diagnoly Intellectual Property”; “Financial Conditions”, “Liability and Insurance”, “Confidentiality”, “Personal Data” and “Dispute Resolution and Governing Law”, shall remain in full force and effect, as the case may be, in accordance with the terms and conditions specified in said clause.

For the avoidance of doubt, Client is authorized to retain all Examination Reports exported up to the date of termination of the Agreement.

ARTICLE 9 . C O N F I D E N T I A L I T Y

9.1. OBLIGATION OF CONFIDENTIALITY

Throughout the Term of the Agreement and for a period of two (2) years from the end of the Agreement for any reason whatsoever, the Parties agree to (i) guarantee the confidentiality of the other Party’s Confidential Information in the same way as they protect the confidentiality of their own Confidential Information, (ii) only disclose and authorize the internal use of the Confidential Information to their employees, agents and/or representatives (and any authorized subcontractor) who strictly need to know such Confidential Information for the performance of the Agreement and who are bound by a written agreement protecting such Confidential Information under conditions at least equivalent to this Agreement; (iii) not to copy, reproduce, duplicate or use the other Party’s Confidential Information for any reason other than in connection with the performance of the Agreement; (iv) not to disclose the Confidential Information of the other Party to a third party, in any manner whatsoever (including verbally), for any reason whatsoever, without the prior written consent of that other Party, (v) not to use the Confidential Information directly or indirectly to obtain any commercial advantage whatsoever over the other Party in the event of the termination of the Agreement for any reason whatsoever.

It is understood between the Parties that the Confidential Information does not include information in respect of which one Party can demonstrate it is (i) in the public domain, (ii) was known by one Party prior to its disclosure to the other Party, (iii) was independently developed by one Party without breach of any obligation due to the other Party; or (iv) was received from a third party without breach of any obligation due to the other Party or disclosed by mutual agreement between the Parties.

All Confidential Information sent by each of the Parties to the other Party must be destroyed within fifteen (15) days upon request. If a Party is required by law to disclose the other Party’s Confidential Information, it shall inform the other Party in advance (to the extent legally permitted) and undertakes to provide it with reasonable assistance if that Party wishes to challenge such disclosure.

Each Party agrees that any breach of this article may cause damage to the other Party which shall be entitled to obtain compensation from a court of competent jurisdiction.

9.2. COMMERCIAL REFERENCES AND ADVERTISING

By way of exception to the above article 9.1, during the Term of this Agreement and subject to prior written approval, each Party may refer to the other Party as a client or provider and may use the other Party’s name, trade name and main logo (whether registered as a trademark or not) orally and in written commercial materials. The Parties agree that such commercial reference shall be strictly limited to the reproduction of such signs and the information of a commercial relationship between the Parties.

In any case, each Party undertakes not to damage the image, reputation and more generally the rights of the other Party.

ARTICLE 10 . PERSONAL DATA

The Parties undertake to comply with the regulations applicable to the processing of personal data, within the meaning of Section 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Personal Data ("GDPR").

Diagnoly as a data controller. Diagnoly acts as data controller for the sole processing of Personal Data (name, email, phone number) of Client's employees or contractors involved in the negotiation and management of the Agreement. Diagnoly processes such Personal Data for the purpose of managing its contractual relationship with the Client on the legal basis of the pre-contractual relationship and the performance of the Agreement. For more information, see Diagnoly Privacy Policy accessible at <https://www.diagnoly.com/privacy-policy>.

ARTICLE 11 . DISPUTE RESOLUTION AND GOVERNING LAW

The Agreement is governed by French Law. In case of difficulty relating to the interpretation and/or performance of the Agreement, the Parties undertake to cooperate in good faith with a view to finding an amicable solution to their dispute. Any dispute in relation to the Agreement shall be submitted - failing amicable agreement - to the competent courts of Lyon, France.

ARTICLE 12 . GENERAL

Compliance. Each Party shall comply with all applicable laws and regulations regarding the general conduct of business including without limitation all relevant anti-corruption and anti-bribery laws.

Notices. All notifications required by the Agreement shall be made, unless expressly stated otherwise, via email. For Diagnoly, emails shall be sent at support@diagnoly.com.

Entire Agreement. The Agreement constitutes the entire understanding of the Parties and supersedes any prior written or oral agreement, express or implied. It represents the sole will of the Parties.

Subcontracting. Diagnoly reserves the right to subcontract all or part of its obligations under the Agreement to the subcontractor of its choice. Diagnoly remains solely responsible for the performance of the entire Agreement.

Assignment. This Agreement may not be assigned or transferred by a Party to a third party without the prior written consent of the other Party, except in the event of a merger, absorption resulting in the disappearance of Diagnoly or the Client, or in the event of a change of control of Diagnoly or the Client. In this case, the Agreement shall continue for the remaining period between Client or the legal entity that may replace the Client and Diagnoly or the legal entity that may replace Diagnoly. In any of these cases, notification of the other Party is mandatory.

Severability. If any one of the provisions of the Agreement proves to be null and void with regard to a rule of law in force or a court decision which has become final, it shall then be deemed unwritten, without however entailing the invalidity of the Agreement or altering the validity of its other provisions.

No waiver. The fact that a Party does not claim the application of any provision of the Agreement or tolerate its non-performance on a temporary or permanent basis, may under no circumstances be interpreted as a waiver by that Party of exercising the rights it holds hereunder.

Independence of the Parties. No provision of the Agreement can be interpreted as establishing a collaboration between the Parties, and Client must comply with the defined terms and conditions and shall hold Diagnoly harmless against any claim by a third-party concerning damage, losses or costs incurred as a result of Client's failure to comply with the aforementioned obligations.