TERMS AND CONDITIONS OF USE

Prior to any use of echOpen Factory's products and services, all Users must carefully read these Terms and Conditions of Use.

1. PREAMBLE

1.1 echOpen Factory is a simplified joint-stock company (*Société par Actions Simplifiée*) incorporated under French law, with its registered office at 1 place du Parvis de Notre-Dame, 75004 Paris, France, registered with the Paris Trade and Companies Register under number 882 017 346 (hereinafter "echOpen"), specializing in the manufacture and commercialization of portable ultrasound imaging medical devices and digital services.

1.2 echOpen has developed a Probe connected to an application, echOpen On®, enabling Users to benefit from the Associated Digital Services and, in the case of a Subscription, from Additional Digital Services.

1.3 The User, whether an echOpen Customer or a person duly authorized by an echOpen Customer, and acting in their capacity as a healthcare professional authorized to perform ultrasound examinations in the territory in which they practice, wishes to use echOpen Medical Devices and, where applicable, the Additional Digital Services.

2. PURPOSE

2.1 These Terms and Conditions of Use (hereinafter the "Terms") govern Users' access to and use of the Probe and echOpen On®, including the Associated Digital Services and, where applicable, the Additional Digital Services.

3. DEFINITIONS

3.1 "**Competent Authority**" means any supervisory authority responsible for public health and safety and for overseeing professional medical practices, including in particular the French National Agency for the Safety of Medicines and Health Products (*ANSM*), the French National Council of the Order of Physicians (*CNOM*), and the Regional Health Agencies (*ARS*), or any equivalent authority in the territory or country in which the Devices or Digital Services, as defined below, are used.

3.2 "**GTC**" means the General Terms and Conditions of sale applicable to the Medical Devices and Digital Services as defined below, available at the following link: https://assets.echopen.com/support/o1/tos/en.

3.3 "**Customer**" means any natural or legal person, organization, or healthcare professional acquiring an echOpen O1® Probe.

3.4 "**Agreement**" means the Quotation and the GTC, together with all appendices and any amendments thereto.

3.5 "**Order**" means the Customer's acceptance of a Quotation.

3.6 "**Quotation**" means any written offer issued by echOpen enabling an Order to be placed.

3.7 "**Medical Devices**" means the echOpen O1® Probe, and any subsequent version thereof, as well as the echOpen On® application, both certified as medical devices within the meaning of Regulation (EU) 2017/745 on medical devices ("MDR") and bearing the CE marking.

3.8 "**Intellectual Property Rights**" means all intellectual property rights, whether registered or unregistered, including (i) patents and patent applications, (ii) copyrights and related rights in works of authorship (including copyright in software and copyright in databases, including copyright in the original structure and the sui generis right of database producers), (iii) trademarks, trade names, and other distinctive signs, (iv) designs and models and applications for their registration, (v) trade secrets and know-how, whether protectable or not, and all other intellectual property rights recognized under applicable laws and regulations, as well as all registrations and applications for registration of the aforementioned rights.

3.9 "**echOpen On®**" means the echOpen On® application, in its current version and any subsequent version, designed, operated, and updated by echOpen, downloadable from mobile application stores, activated by an access code, and strictly necessary and mandatory for use of the Probe. It constitutes a Class IIa medical device intended to control and display the output information of the Probe.

3.10 "**FAQ**" means the drop-down menu providing instructions and answers to frequently asked questions identified by echOpen regarding access to and use of all echOpen Products and Services, available on the echOpen website.

3.11 "**Confidential Information**" means all information, of whatever nature and in whatever form (whether written, oral, digital, or otherwise) disclosed by one party (the "Disclosing Party") to the other party (the "Receiving Party") under this Agreement, as well as during any prior negotiations, marked as confidential or whose nature implies confidentiality. This includes, without limitation, know-how and trade secrets, data, documents, inventions, strategies including marketing strategies, software, and each party's pre-existing Intellectual Property Rights. The following shall not be considered Confidential Information under this definition: information (i) generated through the use of the Medical Devices and Associated Digital Services or, where applicable, Additional Digital Services, (ii) that is in the public domain or falls into the public domain through no fault of the Receiving Party, (iii) provided to the Receiving Party by a third party lawfully in possession of such information and not bound by any confidentiality obligation toward the Receiving Party, (iv) already known to the Receiving Party at the time of disclosure, as evidenced by the Receiving Party's written records existing at the time of disclosure, or (v) independently developed by the Receiving Party without access to the Confidential Information, as evidenced by the Receiving Party's written records existing at the time of disclosure.

3.12 "**Applicable Regulations**" means all laws and regulations applicable at the time the Customer accesses and uses the Medical Devices and Digital Services, including in particular the General Data Protection Regulation ("GDPR"), the MDR, the provisions of the French Public Health Code, and/or the ethical and regulatory rules applicable in the territory or country where the Customer resides.

3.13 "**Subscription Period**" or "**Subscription**" means the period during which the Customer is authorized to access and use the Additional Digital Services in consideration for payment of the Subscription Price. The initial duration of the Subscription Period is defined in the Quotation. Unless otherwise provided, the Subscription Term shall automatically renew upon expiration of the initial Subscription Term or any renewal term for successive periods of the same duration as the initial Subscription Term or the immediately preceding renewal term, unless terminated by either Party in accordance with the terms set forth herein. Each Subscription is entered into for a minimum term of one (1) year.

3.14 "**Price**" means the purchase price of the Medical Device and the Associated Digital Services and, where applicable, the Subscription Price for the Additional Digital Services.

3.15 "**Subscription Price**" means the price payable by the Customer to echOpen to access and use the Additional Digital Services during the Subscription Period.

3.16 "**Products and Services**" means the Medical Devices, the Associated Digital Services, and the Additional Digital Services.

3.17 "**RPPS**" means the Shared Directory of Healthcare Professionals (*Répertoire Partagé des Professionnels de Santé*).

3.18 "**Digital Services**" collectively means the Associated Digital Services and the Additional Digital Services.

3.19 "**Associated Digital Services**" means the functionality available to any User of an echOpen O1® Probe enabling real-time display of images delivered by the Probe on a mobile device (e.g., smartphone, tablet) through echOpen On®, and management of the User account through the MyEchOpen interface (as defined below).

3.20 "**Additional Digital Services**" means optional services provided as part of a Subscription taken out by the Customer in a Quotation and made available to the User through the echOpen On® application and MyEchOpen, including in particular features for storing images collected with the Probe and accessing content via MyEchOpen. The MyEchOpen interface is a secure web platform, in its current version and any subsequent version, designed, operated, and updated by echOpen, accessible through a web browser on any computing device (including computers, smartphones, and tablets), and serving as the access portal to (i) User account management, (ii) images/videos stored via echOpen On®, and (iii) various content, including training materials (hereinafter "MyEchOpen").

3.21 "**Probe**" means the portable tri-frequency echOpen O1® ultrasound imaging probe, or any subsequent version, developed and manufactured by echOpen. This probe constitutes a Class IIa medical device intended for point-of-care ultrasound (POCUS) imaging of adult patients to enable ultrasound imaging of organs and tissues of the human body. The Probe is supplied with its instructions for use within the meaning of the MDR.

3.22 "**User**" means any natural person having rights to use the Probe and echOpen On®, including the Associated Digital Services and, optionally, the Additional Digital Services.

4. CONTRACTUAL DOCUMENTS

4.1 Any use of the Products and Services by a User constitutes full and unconditional acceptance of these Terms and Conditions of Use.

4.2 The Terms and Conditions of Use form an appendix to the GTC, which apply to any Order placed by a Customer following receipt of a Quotation from echOpen. The Terms and Conditions of Use form an integral part of the Agreement concluded between echOpen and its Customer.

4.3 The User may be the Customer who placed the Order, or any person duly authorized by the Customer to whom these Terms and Conditions of Use have been made enforceable.

4.4 For the avoidance of doubt, the contractual documents binding the Customer and echOpen shall prevail in the following order of priority:

- the GTC and their appendices, including these Terms and Conditions of Use;
- the Quotation, which becomes an Order upon acceptance and signature by the Customer.

4.5 If one or more provisions of the Agreement are held, in whole or in part, to be invalid, illegal, or unenforceable for any reason whatsoever, all other provisions of the Agreement shall remain valid and enforceable.

5. TERM

5.1 These Terms and Conditions of Use apply for the entire duration of the User's use of the Products and Services.

6. USER WARRANTIES

6.1 As a prerequisite for accessing and using the Products and Services, the User represents and warrants:

6.1.1 that they are (a) a healthcare professional authorized to perform ultrasound examinations in the country in which they practice, duly registered and authorized for such purpose with the relevant Competent Authorities (in France, such authorization notably includes registration in the RPPS); or (b) a student pursuing studies to become a healthcare professional and, in that capacity, authorized to perform ultrasound examinations, where applicable under the supervision of the aforementioned healthcare professional; and

6.1.2 that they comply with all requirements arising from Applicable Laws, including the obligation to maintain professional civil liability insurance covering the professional activities for which they use the echOpen Products and Services.

7. USER ACCOUNT MANAGEMENT

7.1 Provision of a license key per Medical Device

7.1.1 echOpen Factory creates one license per Medical Device enabling the Customer to activate their account, which allows access to echOpen On® and, where applicable, to MyEchOpen. Where the Customer is also the User of the Digital Services, the Customer/User may activate their account directly.

7.1.2 Where the Customer is not the User of the Digital Services, echOpen creates one license per Medical Device so that one or more Users may activate their account to access echOpen On® and, where applicable, MyEchOpen. Where the Customer has subscribed to a Subscription authorizing the creation of multiple User accounts, the license key provided by echOpen Factory enables activation of the number of accounts, and therefore Users, defined in the Agreement.

7.2 Activation of the User account using the license key

7.2.1 The license key is made available to each User under the conditions set out in the preceding article. Once the access code has been used, the User account is created and the User is prompted to set a password.

7.2.2 The password chosen by the User, under their responsibility at the time of account activation using the license key, must comply with the recommendations of the French Data Protection Authority (CNIL): it must contain at least twelve characters, include the four character types (uppercase letters, lowercase letters, numbers, and special characters), and must not be related to the account holder (such as name or date of birth).

7.3 Password Management

7.3.1 The User is solely responsible for safeguarding and maintaining the confidentiality of their username and password, as well as for all activities resulting from the use of such username and password. The User undertakes to take all appropriate measures to ensure such confidentiality, including logging out after each session.

7.3.2 Any use of the username and/or password shall be deemed to have been carried out on behalf of the User.

7.3.3 The User undertakes to change their password without delay in the event of theft, loss, forgetfulness, or voluntary or involuntary disclosure of their password to third parties. Such change shall be carried out directly in the User account settings.

7.3.4 If the User forgets their password, they may request an email by clicking on the "Forgot password?" tab, containing a link allowing them to reset their password using their username.

7.3.5 echOpen shall not be held liable under any circumstances for fraudulent or improper use resulting from voluntary or involuntary disclosure of the User's username and/or password to any person.

8. USER OBLIGATIONS RELATING TO ACCESS TO AND USE OF THE PRODUCTS AND SERVICES

8.1 The User shall use the Medical Devices in accordance with their intended purpose as described in their instructions for use. It is the User's responsibility to ensure that their use of the Products and Services complies with such instructions for use, the Applicable Regulations and, where applicable, echOpen's FAQ and the Agreement.

8.2 The Products and Services are intended to improve the User's diagnostic conditions; however, medical diagnosis remains under the User's sole responsibility. The User acknowledges that the Products and Services do not under any circumstances replace the medical diagnosis they provide to their patients.

8.3 The acts listed below constitute serious breaches of these Terms and Conditions of Use. In particular, the User agrees not to:

(i) sublicense, assign, transfer, or otherwise share, in whole or in part, the benefit of the licenses granted hereunder (including by sharing the strictly personal credentials used to access the Products and Services);
(ii) reproduce, by any means whatsoever, in whole or in part, the Products and Services;
(iii) decompile, disassemble, reverse engineer the object code or any source code of echOpen On® or MyEchOpen, or directly or indirectly allow any third party to do so;
(iv) correct, directly or indirectly, any malfunction of the Products and Services without echOpen's prior written consent;
(v) lend, rent, sell, or provide access, directly or indirectly, to the Products and Services to any third party by any means whatsoever, except under the conditions set out in the Agreement;
(vi) distribute or sell the Probe, whether free of charge or not, or use it to train third parties without echOpen's prior written consent;
(vii) adapt, modify, convert, or enhance the Products and Services in whole or in part;
(viii) use the Products and Services in any manner for the purpose of designing, producing, distributing, or marketing a similar, equivalent, or substitute product;
(ix) use the Products and Services in any manner likely to harm echOpen's reputation, brand image, or any other rights associated with the Products and Services;
(x) use the Products and Services in any manner likely to harm patients;
(xi) make unlawful use of the Digital Services by knowingly introducing viruses, trojans, worms, logic bombs, or any other malicious or technologically harmful material;
(xii) attempt to gain unauthorized access to the Digital Services, the server on which the Digital Services are stored, or any server, computer, or database connected to the Digital Services.

8.4 In the event of a breach of any of the prohibitions set out in this Article, the User's right to use the Products and Services may be immediately suspended, and echOpen shall be entitled to terminate the Agreement immediately in accordance with the article of the GTC relating to termination of the Agreement.

9. TECHNICAL CONDITIONS FOR ACCESS TO THE DIGITAL SERVICES

9.1 Prerequisites for access to the Digital Services:

- To access echOpen On® from a mobile device, the User must have a smartphone or tablet meeting the criteria set out in the list available at the following link: https://assets.echopen.com/support/o1/compatibility
- Where applicable, to access MyEchOpen via an internet browser, the User must use a mainstream browser that is kept up to date by its publisher.

9.2 Access to the Digital Services is reserved for Users with internet access.

9.3 All costs relating to access, including hardware, software, or internet access costs, shall be borne exclusively by the User. The User is solely responsible for the proper functioning of their internet access.

9.4 The User is solely responsible for any problem, delay, failure, or other loss or damage resulting from their own network connection and/or information systems.

10. AVAILABILITY AND MAINTENANCE OF THE DIGITAL SERVICES

10.1 The Digital Services accessible via echOpen On® are available 24 hours a day, 7 days a week, subject in particular to internet network contingencies and periods of suspension, including for maintenance purposes. echOpen shall use its best efforts to provide the User with continuous access to the Digital Services for events within its control.

10.2 In the case of scheduled maintenance, any maintenance or update of the Digital Services that may affect their operation shall be notified in advance by echOpen. echOpen shall use its best efforts to minimize any interruption in the use of echOpen On® and the Digital Services during such period.

In the event of a service interruption other than scheduled maintenance, echOpen Factory shall use its best efforts to provide all relevant information reasonably necessary to understand the situation, the expected downtime of the affected Digital Services, and the implementation of any alternative or recovery measures.

10.3 In the event of an interruption or inability to use the Digital Services, the User may submit a request to the following address: support@echopen.com.

11. CONTROLS AND AUDITS

11.1 At the request of the Customer or the User, or at the request of any Competent Authority, echOpen shall provide the Customer or the User, as well as their auditors, with such information, documents, or records relating to the Products and Services as may reasonably be requested for inspection purposes by any Competent Authority.

11.2 The Customer and/or the User must immediately inform echOpen of any audit, inspection, or investigation concerning the Products and Services conducted by a Competent Authority of which they become aware. Any response to a Competent Authority regarding the Products and Services must be prepared in accordance with echOpen's instructions and submitted for echOpen's prior written approval (including by email). The Customer and/or the User undertakes to cooperate with any Competent Authority and to implement all measures required to comply with the Competent Authority's findings and to remedy any non-compliance identified by it.

12. INTELLECTUAL PROPERTY

12.1 As stated in the GTC, echOpen exclusively owns all Intellectual Property Rights in the Probe, echOpen On®, and MyEchOpen (including their source code), in all its Products and Services, and in any new versions thereof.

12.2 The provision of a personal access code to the User enabling access to and use of the Digital Services does not transfer to the User any Intellectual Property Rights relating to such Digital Services.

12.3 The User acknowledges that they hold no Intellectual Property Rights in the Products and Services other than a license to use the Digital Services accessible via echOpen On®, subject to the terms and limitations of the Agreement.

12.4 The User is granted, for the entire duration of the Agreement, a limited, revocable, personal, non-transferable, and non-exclusive license to access and use the Digital Services, subject to compliance with the terms of the Agreement and the Applicable Regulations.

12.5 echOpen warrants that, as of the date of these Terms and Conditions of Use, it holds all rights necessary for the use of the Products and Services and shall use its best efforts to maintain such rights in the performance of the Agreement.

13. PERSONAL DATA PROTECTION

13.1 For the purposes of this Article, the terms "Recipient," "Personal Data," "Purpose," "Data Subject," "Controller," "Processor," "Processing," and "Personal Data Breach" shall have the meanings given to them in the General Data Protection Regulation ("**GDPR**") and in French Data Protection Act No. 78-17 as amended (together, the "**Applicable Personal Data Protection Regulations**").

13.2 Processing of Personal Data for the purpose of providing the Products and Services:

13.2.1 Where the User is not echOpen's direct Customer, meaning a healthcare professional affiliated with an entity that is itself an echOpen Customer, echOpen acts as a Processor on behalf of the Customer, who acts as Controller, with respect to the processing of (i) patients' Personal Data generated through the healthcare professional User's use of the Products and Services, and (ii) the Personal Data of such healthcare professional User, under the conditions defined in Appendix I of the GTC.

13.2.2 Where the User is echOpen's direct Customer, meaning a self-employed healthcare professional:

13.2.3 echOpen acts as Controller for the Processing of the Personal Data of the self-employed healthcare professional User in the context of providing the echOpen Products and Services. Such processing is carried out in accordance with the Privacy Policy applicable to self-employed healthcare professional Users, available at the following link: https://assets.echopen.com/support/o1/user_privacy/en.

13.2.4 echOpen acts as a Processor for the Processing of patients' Personal Data generated through the User's use of the Products and Services, on behalf of the healthcare professional User acting as Controller, under the conditions defined in Appendix 2 of the GTC.

13.2.5 The procedures for exercising the right to erasure of Data and for requesting the deletion of Personal Data are set out in the Privacy Policy for Customers and the Privacy Policy for Self-Employed Healthcare Professionals.

14. INDEPENDENCE

No provision of the Agreement shall be construed as creating an employment relationship, a joint venture, or a partnership between the parties. The relationship between echOpen and the Customer or the User is solely that of seller and purchaser or seller and user, and licensor and licensee. Neither party is a partner, agent, joint venturer, or representative of the other party.

15. NO WAIVER

echOpen's failure at any time, or with respect to any specific matter, to rely on any provision of the Terms and Conditions of Use shall not be construed as a waiver of its right to rely on such provision at a later time.

16. GOVERNING LAW

16.1 In the event of any translation of these Terms and Conditions of Use, in case of discrepancy between the translated version and the French version, the original version, i.e., the French version, shall prevail.

16.2 The Agreement is governed by French law. This applies to both substantive and procedural rules, notwithstanding the place of performance of the principal or ancillary obligations.

17. JURISDICTION

In the event of a dispute, following an attempt at amicable settlement between the parties, express jurisdiction is granted to the courts within the jurisdiction of the Paris Court of Appeal.