



## GENERAL TERMS AND CONDITIONS OF SALE

### 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 associated digital services.
- 1.2 echOpen has developed a Probe connected to an application, echOpen On<sup>®</sup>, enabling Users to benefit from the Associated Digital Services and, in the case of a Subscription, Additional Digital Services.
- 1.3 The parties expressly acknowledge that all information necessary for the conclusion of this Agreement and essential to their consent has been exchanged. In particular, the Customer acknowledges having received all information relating to the Medical Devices.
- 1.4 The Customer is solely responsible for selecting the Product and the Digital Services for its professional use and acknowledges that they were not developed to meet its specific needs.
- 1.5 The Customer, in its capacity as a healthcare institution or healthcare professional, wishes to benefit from the medical devices.

### 2. PURPOSE

- 2.1 The purpose of these provisions is to define the general terms and conditions of sale (hereinafter the “GTC”) applicable between the Parties to any Order placed by a Customer.
- 2.2 echOpen reserves the right to update them periodically; however, only the GTC in force at the time of the Order shall apply between the Parties.

### 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 are used.
- 3.2 “**Customer**” means any natural or legal person, organization, or healthcare professional acquiring an echOpen O1<sup>®</sup> Probe.
- 3.3 “**Terms and Conditions of Use**” or “**Terms**” means echOpen’s terms and conditions governing Users’ access to and use of the Probe and echOpen On<sup>®</sup>, including the Associated Digital Services and, where applicable, the Additional Digital Services, available at the following link: <https://assets.echopen.com/support/o1/tou/en>.
- 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<sup>®</sup> Probe and the Associated Digital Services available through the echOpen On<sup>®</sup> application, in their current versions and any subsequent versions, 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<sup>®</sup>**” means the echOpen On<sup>®</sup> 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 “**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.
- 3.11 “**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.
- 3.12 “**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. If this duration is less than five (5) years and unless otherwise stipulated, the Subscription Period shall be automatically renewed for a successive period equivalent to the initial Subscription Period, unless terminated by either Party under the conditions set out herein.
- 3.13 “**Subscription Price**” means the price payable by the Customer to echOpen to access and use the Additional Digital Services during the Subscription Period.
- 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 “**Products and Services**” means the Medical Devices, the Associated Digital Services, and the Additional Digital Services.
- 3.16 “**RPPS**” means the Shared Directory of Healthcare Professionals (applicable in France).
- 3.17 “**Digital Services**” collectively means the Associated Digital Services and the Additional Digital Services.
- 3.18 “**Associated Digital Services**” means the functionalities available to a User of a Customer of an echOpen O1® Probe, in particular 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).
- 3.19 “**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 the functionalities described in Appendix V. 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 and user account administration (hereinafter “MyEchOpen”).
- 3.20 “**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.
- 3.21 “**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 The GTC apply to any Order placed by a Customer following receipt of a Quotation from echOpen.
- 4.2 The contractual documents forming the Agreement between the Parties are therefore, in the following order of priority:
- the GTC and their appendices;
  - the Quotation, which becomes an Order upon acceptance and signature by the Customer.

- 4.3 The Customer's general terms and conditions (including, in particular, purchasing terms) shall not be enforceable against echOpen, unless otherwise provided in a contractual document signed by the Parties.
- 4.4 The Agreement prevails over any prior oral or written agreement or arrangement between the Parties.
- 4.5 Any amendment to the Agreement shall, to be binding on the Parties, be made in a written addendum signed by both Parties.
- 4.6 If one or more provisions of this 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. QUOTATION AND ORDER**

- 5.1 At the Customer's request, echOpen shall provide the Customer with a Quotation, valid for a period of two (2) months, specifying the subscribed Products and Services, the price, and the payment terms.
- 5.2 If the Customer accepts the Quotation, the Customer shall sign it electronically in accordance with Article 1367 of the French Civil Code, or manually in two original copies, and return it to echOpen, thereby placing an Order.

## **6. TERM OF THE AGREEMENT**

- 6.1 The Agreement takes effect on the date the Customer places the Order, for an initial term of the Additional Digital Services corresponding to the Subscription Period defined in the Order.
- 6.2 The start date of the Subscription Period for the Additional Digital Services shall be the earlier of the following dates: the date of activation of a User account, or fifteen (15) calendar days from delivery of the Order to the Customer.
- 6.3 Upon expiry of the Subscription Period for the Additional Digital Services, the Subscription shall be automatically renewed for successive one-year periods from the anniversary date of the Order, unless terminated by registered letter with acknowledgment of receipt, subject to one (1) month's notice prior to the end of the current period.

In the event of termination of the Subscription Period, the Customer shall retain, on the one hand, the Probe, and on the other hand, the Associated Digital Services for a period of up to five (5) years from the date of the Order, but shall no longer benefit from the Additional Digital Services.

Images recorded prior to the end of the Agreement or termination of the Subscription shall remain accessible and downloadable for three (3) months following such end or termination. At echOpen's discretion, they shall thereafter be made available to the Customer in one or more of the following ways: (i) direct download by the User, (ii) dedicated transmission of the images by echOpen to the User, or (iii) a download link valid for three months from the date it is provided to the Customer by any means.

The functionalities of the Additional Digital Services as defined in Appendix V shall no longer be available upon expiry of the Subscription Period or after termination of the Subscription.

However, the Associated Digital Services shall remain available until the end of the Agreement.

## **7. TERMINATION**

- 7.1 Termination of the Subscription:

With respect to the Additional Digital Services, echOpen reserves the right to terminate the Subscription for convenience subject to fifteen (15) days' prior notice. In such case, echOpen shall refund the Customer any sums paid in advance, on a pro rata basis corresponding to the Subscription period remaining after the effective date of termination.

- 7.2 Termination of the Contract

- i. echOpen may terminate the Contract automatically and with immediate effect in the event of a serious breach by the Client, meaning a breach of its payment obligations, the User authorization requirements, the conditions of use set out in the Terms of Use, or any violation of the intellectual property provisions defined herein.
- ii. In the event that either party breaches any of its obligations under the Contract, the other party may terminate the Contract automatically after a period of thirty (30) days following receipt by the defaulting party of written notice requesting that the breach be remedied, if such notice remains without effect.
- iii. Either party may terminate the Contract in the event of Force Majeure in accordance with the "Force Majeure" article.

## **8. ACTIVATION OF ACCESS AND USER MANAGEMENT**

- 8.1 echOpen's Terms and Conditions of Use, attached hereto, govern Users' use of the Probe, echOpen On<sup>®</sup> and the Associated Digital Services and, where applicable, the Additional Digital Services (also accessible at: [echopen.com/cgu](http://echopen.com/cgu)). Any use of the Products and Services constitutes full and unconditional acceptance of the Terms and Conditions of Use by both the Client and the Users, the Client undertaking vis-à-vis echOpen to ensure that its Users comply with them.
- 8.2 The Client undertakes to echOpen that each User meets the following conditions:
- 8.3 The User is (a) a healthcare professional authorized to perform ultrasound examinations in the country in which they practice, duly registered and authorized for this purpose with the relevant Competent Authorities (in France, such authorization notably includes registration with the RPPS); or (b) a student pursuing studies to become a healthcare professional and, in that capacity, authorized to perform ultrasound examinations under the supervision of a healthcare professional; and
- 8.4 The User complies with all requirements arising from the applicable Regulations, including the obligation to be covered by professional civil liability insurance for the activities in connection with which they use the echOpen Products and Services.
- 8.5 Following the Client's Order, echOpen activates the personal access code to echOpen On<sup>®</sup>, or enables the Client to authorize its Users to access echOpen On<sup>®</sup>, including, where applicable, the Additional Digital Services.

## **9. PRICE**

- 9.1 The Quote defines the price of the Probe and the Associated Digital Services and, where applicable, the Subscription Price.
- 9.2 The Price is defined in the Order (stated in Euros excluding taxes, to which shall be added Value Added Tax (VAT) at the rate applicable on the date of the Order), as well as delivery costs.
- 9.3 In the event of renewal of a Subscription Period, the Subscription Price may be modified by echOpen subject to forty-five (45) days' prior notice given by any means before application of the new Subscription Price. The modified Subscription Price shall automatically apply as of the renewal of the Subscription Period, unless terminated by the Client.
- 9.4 Prices may be adjusted annually in accordance with the Syntec index in force, starting from January 2026, under the following conditions:  
example:  $P(t) = P(t-1) \times [S(t) / S(t-1)]$ , where:
- P(t-1) is the base price or the price corresponding to the last revision;
  - P(t) is the revised price;
  - S(t-1) is the latest Syntec index published on the signature date;
  - S(t) is the latest Syntec index published on the revision date.
- In the event the revision index ceases to exist and failing agreement on a replacement index, express jurisdiction is granted to the President of the Paris Commercial Court to define an index to be incorporated into the revision formula. This index shall be selected so as to be as close as possible to the discontinued index and to reflect the spirit intended by the Parties when drafting this revision clause.
- 9.5 The functional scope of the Additional Digital Services included in the Subscription is determined on the date of the Order. Updates necessary to maintain regulatory compliance, security, and proper functioning of the Additional Digital Services are included in the Subscription Price throughout the commitment period and any renewals.
- 9.6 echOpen reserves the right to develop new features, which may be integrated at no additional cost or offered as paid options, at echOpen's sole discretion.

## **10. TERMS AND CONDITIONS OF PAYMENT**

- 10.1 Unless otherwise agreed between echOpen and the Client as part of the Order, all invoices are payable by the Client on the date indicated on the invoice, by automatic bank debit, possibly via credit card, for the upcoming term.
- 10.2 echOpen may, at its discretion, use the services of a payment institution authorized by the competent authority to process automatic debit payments. Information on how that institution processes your Personal Data and your rights regarding Personal Data protection, including your right to object, is available on the relevant institution's website.
- 10.3 Any invoice not disputed within thirty (30) days of its issue date is deemed accepted by the Client. The Client may not rely on set-off or deduction mechanisms, nor withhold any sums owed to echOpen under the Contract. The Client shall be liable for any bank transaction fees associated with payment, where applicable.

- 10.4 In the absence of payment of all or part of an invoice within the specified timeframe, echOpen may automatically apply late payment interest equal to three times the legal interest rate, as well as a fixed recovery fee of €40. Late payment interest is calculated on the total amount due including taxes and is payable without prior notice.
- 10.5 Any payment due by the Client to echOpen may not under any circumstances be suspended or subject to any reduction or set-off by the Client, except where provided by law.
- 10.6 Failure by the Client to fulfill any payment obligation entitles echOpen to demand the immediate return of the delivered Probe at the Client's sole cost, risk, and expense, without prejudice to any damages echOpen may claim. In the event of early termination of the Contract by echOpen Factory, the Client must return the Probe to echOpen at its own expense and in accordance with echOpen's instructions. The Client shall be responsible for any damage to the returned Probe.

## **11. RETENTION OF TITLE AND TRANSFERT OF RISK**

- 11.1 The transfer of risk to the Client takes place upon delivery of the Probe.
- 11.2 The delivered Probe remains the full property of echOpen until complete payment of the sale price, interest, ancillary costs, taxes and any related charges. Failure to pay any installment may result in echOpen reclaiming the Probe. This clause does not prevent the transfer of risks associated with the use of the Probe as soon as it is made available.
- 11.3 Notwithstanding the retention of title, during the period between delivery and transfer of ownership, the risks of loss or deterioration of the sold Probe, theft or destruction, as well as any damage the Probe may cause, remain the exclusive responsibility of the Client.

## **12. PRODUCT WARRANTY**

- 12.1 echOpen warrants that the Probe (i) complies with its specifications, (ii) meets the legal and regulatory requirements applicable on the delivery date, and (iii) is free from manufacturing and workmanship defects under normal use and proper operation (the "Warranty") for the following periods:
  - New Probe and standard exchange: twelve (12) months
  - Spare parts: twelve (12) months (including as part of a repair)
  - Used Probe or used part: six (6) months
  - Repair of a new Probe: three (3) months for labor and twelve (12) months for new spare parts
  - Repair of a used Probe: three (3) months for labor and six (6) months for new spare partsstarting from delivery of the Probe to the Client (the "Warranty Period").

In the event of repair of a new or used Probe during the Warranty Period, the new applicable warranty period may not be shorter than the remaining duration of the original warranty prior to the failure. However, it may not exceed a period of twelve (12) months from delivery of the replacement Probe.
- 12.2 In any event, the contractual warranty may never extend beyond eighteen (18) months from the delivery date.
- 12.3 EchOpen provides no warranty other than the one set out above. The Client must notify echOpen in writing, failing which any related claim will be forfeited, of the existence of defects within ten (10) days of their discovery.
- 12.4 If the Warranty is invoked, the Client may only claim, at echOpen's sole discretion, repair or replacement of the Probe, and may not request cancellation of the sale, a price reduction, or any other compensation.
- 12.5 No replacement or repair under Warranty may be carried out before the Probe concerned has been examined by echOpen.
- 12.6 The Warranty provided under this article does not apply in the event of non-payment of the Probe by the Client.
- 12.7 The Warranty is also excluded in the following cases:
  - (i) undeclared apparent defects,
  - (ii) defects and damage caused by normal wear and tear or by an accident,
  - (iii) improper use of the Probe,
  - (iv) failure by the Client and/or a User to comply with the user manual and/or any instructions provided by echOpen,
  - (v) lack of supervision, storage, or maintenance by the Client and/or the User,
  - (vi) repair, modification, alteration, or any other handling carried out on the Probe without echOpen's approval,
  - (vii) accident or negligence by any person or entity other than echOpen,
  - (viii) repair performed outside echOpen's technical services,
  - (ix) damage caused, in whole or in part, by the use of parts, accessories, or other products not supplied by echOpen,
  - (x) Probes distributed but not manufactured by echOpen (in which case the manufacturer's warranty applies).

- 12.8 It is expressly reminded in these Terms and Conditions that the Probes, regardless of model, are particularly fragile items and must be handled with great care in accordance with the instructions set out in the user manual. EchOpen Probes are not covered by the contractual warranty in the event of breakage or destruction resulting from improper handling or any other non-compliant use causing damage of any kind, including breakage or corrosion of the Probe.
- 12.9 Given the sensitive and fragile components used in EchOpen Probes, in the event of a return it is the Client's responsibility to use protective packaging capable of preserving the integrity of the equipment throughout transport until receipt by echOpen or the distributor. EchOpen draws the Client's attention to this obligation: if equipment is returned without sufficiently protective packaging for any reason whatsoever, echOpen or the distributor reserves the right to invoice any additional repair costs resulting from damage caused by insufficient or defective packaging.

### **13. LIMITATION OF LIABILITY**

- 13.1 echOpen is subject to a best-efforts obligation in providing the Digital Services. By mutual agreement, the Parties expressly agree that echOpen's liability may only be incurred by the Client in the event of proven fault.
- 13.2 The Digital Services are used by the Users under the Client's exclusive responsibility. In any event, the Services shall in no way replace the medical diagnosis, which remains under the sole responsibility of the Users. In this respect, the Client undertakes to inform the Users, prior to any use of the Digital Services, of their exclusive responsibility regarding medical diagnosis.
- 13.3 By mutual agreement, the Parties agree that echOpen shall only be liable for the consequences of direct damages resulting from contractual breaches, and compensation for indirect damages is excluded. Indirect damages include, in particular, loss of data, loss of time, damage to image or reputation, failure to achieve expected results, any loss of profits, business or revenue, business interruption, loss of savings, loss of customers or goodwill, and third-party claims, even if echOpen was duly informed of the risk of such damages occurring.
- 13.4 echOpen's liability is, by mutual agreement, limited to the amounts actually paid by the Client for the Products and Services during the year in which the damage occurred.

### **14. MEDICAL DEVICE VIGILANCE FOR ECHOPEN FACTORY DEVICES**

- 14.1 Pursuant to the Applicable medical device regulations (including Regulation (EU) 2017/745 and Articles L.5211-1 et seq. of the French Public Health Code), and insofar as the Probe and echOpen On<sup>®</sup> constitute such Medical Devices for which echOpen is the Manufacturer, any Client or User who becomes aware of an incident or a risk of an incident involving a Medical Device that has caused or may cause death or serious deterioration in the health of a patient, a User, or a third party must:
- imperatively and immediately notify echOpen in writing of any incident falling within the scope of the medical device vigilance reporting obligation applicable to an echOpen Medical Device;
  - report it without delay to the relevant Competent Authority, namely, in France, the ANSM, including via that Competent Authority's website.
- 14.2 The Client must comply with this obligation personally and, where applicable, must expressly inform in writing its end Customers or User(s) of an echOpen Medical Device of this specific obligation so that, together with echOpen, they can effectively comply with it.

### **15. INTELLECTUAL PROPERTY**

- 15.1 echOpen exclusively owns all Intellectual Property Rights in the echOpen O1<sup>®</sup> Probe, echOpen On<sup>®</sup> and the MyEchOpen interface, and in all its Products and Services, including any present or future versions thereof.
- 15.2 The placement of an Order by a Client and the delivery of Products and Services by echOpen do not transfer to the Client any Intellectual Property Rights relating to any of these echOpen Products and Services.
- 15.3 The Client acknowledges that it holds no Intellectual Property Rights in the Products and Services other than a license to use the Digital Services.
- echOpen warrants to the Client that, as of the date of the Contract, it holds all Intellectual Property Rights necessary for the use of the Medical Devices and Associated Digital Services and, where applicable, Additional Digital Services, and for the performance of its obligations under the Contract, and will use its best efforts to maintain such rights for the duration of the Contract.

- 15.4 As part of the provision of the Digital Services, echOpen grants the Client, for the entire duration of the Contract, a limited, revocable, personal, non-transferable and non-exclusive license allowing it, when it acts as a User, or the Users it designates in accordance with the User authorization conditions set out herein, to access and use the Digital Services, subject to compliance with the terms of the Contract and applicable regulations.
- 15.5 The Client and any authorized User shall access and use the Digital Services in compliance with the obligations set out in the Terms of Use. Any use not expressly authorized by echOpen under these terms and under the Terms of Use is unlawful, in accordance with Article L.122-6 of the French Intellectual Property Code.

## **16. CONFIDENTIAL INFORMATION**

- 16.1 Unless expressly authorized to disclose by the disclosing Party, or where disclosure is required by applicable regulations, the receiving Party undertakes to preserve the confidentiality of the Confidential Information and not to disclose it to any third party or use it for any purpose other than those provided for in the Contract, for the entire duration of the Contract and for ten (10) years following its expiration or termination.
- 16.2 The receiving Party may use the Confidential Information only to the extent necessary for the performance of its obligations under the Contract and may not use it for any other purpose. The receiving Party may disclose the Confidential Information only to personnel who need such information to perform the Contract, provided that such personnel are subject to confidentiality obligations at least as strict as those set out in this Article 16, and that the Confidential Information is strictly necessary for the performance of their professional duties.
- 16.3 Notwithstanding the provisions of this Article, the receiving Party may disclose certain Confidential Information to the extent such disclosure is required by applicable regulations, a Competent Authority, or pursuant to a valid order of a court of competent jurisdiction. In such a case, the receiving Party shall: (i) inform the disclosing Party of the disclosure in writing within a reasonable time, and (ii) provide the disclosing Party, upon request, with any reasonable assistance necessary to obtain a protective order or confidential treatment preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used solely for the purposes required by applicable regulations, a Competent Authority, or the relevant court order.

Upon termination or expiration of the Contract, the receiving Party must promptly return or destroy all documents, notes, and other tangible materials containing Confidential Information, as well as all copies thereof, provided however that the receiving Party may retain one copy where necessary to comply with its record-keeping obligations.

## **17. FORCE MAJEURE**

- 17.1 Neither Party shall be held liable to the other under the Contract if it is prevented or delayed in performing its obligations under the Contract, or in carrying out its activities, by an event constituting force majeure under the Applicable Regulations for the duration of such event. A force majeure event means any event beyond the control of the obligor, which could not reasonably have been foreseen at the time the Contract was concluded, whose effects cannot be avoided by appropriate measures, and which prevents the performance of its obligation by the obligor. Events considered as force majeure include, in particular, strikes, lockouts or other labor disputes, failure of a public service or of a transport or telecommunications network, war, riots, civil unrest, malicious acts, accidents, collapse of facilities or machinery breakdown, fires, floods, or storms ("**Force Majeure Event**"). The Party prevented from performing its obligation under the Contract must notify the other Party of the occurrence of the Force Majeure Event and its anticipated duration within three (3) days from the date it became aware, or should reasonably have become aware, of the event. The affected Party must use its best efforts to mitigate the effects of the Force Majeure Event.
- 17.2 Following such notification, the affected Party shall be excused from performing the obligations that are prevented, restricted, or hindered due to the occurrence of a Force Majeure Event. That Party shall not be deemed to be in breach of its obligations under the Contract and shall not incur any liability or damages as a result of its inability to perform said obligations due to the Force Majeure Event. A Force Majeure Event affecting a contractor or subcontractor of a Party shall be deemed to be a Force Majeure Event affecting that Party. The period during which a Party must perform its obligations under the Contract shall be extended by the duration of the Force Majeure Event. For the sake of clarity, the Parties expressly acknowledge that they are fully aware of the COVID-19 epidemic and have taken it into account when entering into the Contract. This epidemic shall not justify any delay, except where a lockdown constitutes a Force Majeure Event.
- 17.3 If a Force Majeure Event continues for more than two (2) months, either Party may terminate the Contract by giving thirty (30) days' notice to the other Party, or elect to continue the Contract despite the occurrence of the Force Majeure Event.

- 17.4 If either Party chooses to terminate the Contract due to a Force Majeure Event, neither Party shall be entitled to claim damages in connection with such termination or non-performance, and from the date of termination the Parties shall be released from any further obligations under the Contract, except where the termination relates to a Force Majeure Event affecting you, in which case you shall remain liable for payment of the Price due to echOpen prior to the start date of the Force Majeure Event.

## **18. PERSONAL DATA PROTECTION**

- 18.1 For the purposes of this Article and Appendices II and III, the terms “Recipient,” “Personal Data,” “Purpose,” “Data Subject,” “Controller,” “Processor,” “Processing,” and “Personal Data Breach” shall have the meanings given to them under the General Data Protection Regulation (“GDPR”) and the French Data Protection Act No. 78-17 as amended (together the “Applicable Personal Data Protection Regulations”).
- 18.2 Processing of Personal Data for the purposes of managing the commercial relationship.
- 18.2.1 For the purposes of performing and monitoring the Contract, each party processes, as Data Controller, the Personal Data of the other party’s contact personnel.
- 18.2.2 Each party undertakes to process the Personal Data of the other party’s contact personnel in accordance with the applicable personal data protection regulations, and to provide its contact personnel with the other Party’s privacy policy containing information relating to the processing of personal data of its Clients’ contact personnel. For this purpose, echOpen provides its Clients with the Privacy Policy for echOpen Clients, accessible on echOpen’s website via the following link: [https://assets.echopen.com/support/o1/customer\\_privacy/en](https://assets.echopen.com/support/o1/customer_privacy/en).
- 18.3 Processing of Personal Data for the purpose of providing echOpen Products and Services:
- 18.3.1 Where the Client is a legal entity (for example a healthcare institution), echOpen is authorized to process personal data, in its capacity as Processor, on behalf of the Client acting as Controller.:
- personal data of patients generated during the use of the Products and Services by the healthcare professional User, and
  - personal data of such healthcare professional User.
- These processing activities are carried out in accordance with the provisions of Annex II (“**Data Processing Agreement with Clients – Entities**”).
- 18.3.2 Where the Client is a self-employed healthcare professional:
- echOpen is authorized to process, in its capacity as Processor, on behalf of the Client acting as Controller, personal data of patients generated during the use of the Products and Services by the healthcare professional User.  
These processing activities are carried out in accordance with the provisions of Annex III (“Data Processing Agreement with Clients – Self-employed Healthcare Professionals”).
  - However, and in accordance with the Terms of Use, echOpen acts as Controller for the processing of personal data of the self-employed healthcare professional User in the context of the provision of echOpen Products and Services. These processing activities are carried out in accordance with the Privacy Policy intended for self-employed healthcare professional Users, accessible via the following link: [https://assets.echopen.com/support/o1/user\\_privacy/en](https://assets.echopen.com/support/o1/user_privacy/en).
- 18.4 Authorization to Anonymize Personal Data
- 18.4.1 The Client expressly authorizes echOpen to carry out a subsequent anonymization processing of patients’ Personal Data, and where applicable, of Users’ data, which it processes as a Processor on behalf of the Client, for the purpose of improving echOpen Products and Services, as well as its algorithms, provided that the anonymization techniques implemented by echOpen effectively prevent any risk of correlation, inference, or individualization, so that the Data Subjects are no longer identifiable.
- 18.4.2 The Client expressly undertakes to inform its patients of the subsequent anonymization processing implemented by echOpen.

## **19. SECURITY**

EchOpen undertakes to use its best efforts to provide Digital Services that meet the security and interoperability requirements applicable to digital health services.

## **20. SUPPORT**

Support and maintenance provided by echOpen include:

- telephone assistance from Monday to Friday, excluding French public holidays, between 10:00 a.m. and 5:00 p.m.;
- a guaranteed response within a maximum of five (5) business days, excluding French public holidays;
- in the context of the provision of the Digital Services by echOpen under normal operating and usage conditions, the implementation, where possible, of a temporary workaround solution in the event of a blocking malfunction of the Digital Services, it being specified that a workaround consists of providing an alternative way to use the Digital Service(s) while properly achieving the intended purpose;
- an indicative timeframe regarding the availability of a fix;
- updates to the Digital Service(s), decided unilaterally and installed by the Provider as they become available and at no additional cost. Such updates are intended in particular to improve algorithm performance, enhance the User experience, and implement any modifications required due to legal and regulatory developments.

## **21. HEALTH DATA HOSTING**

- 21.1 The hosting of patients' personal data is carried out by OVH, certified as a Health Data Hosting Provider in accordance with Article L. 1111-8 of the French Public Health Code and under the conditions set out in Annex IV "Health Data Hosting".
- 21.2 A copy of the certificate shall be provided to the Client upon first request.

## **22. 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 Client 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.

## **23. INSURANCE**

Each Party undertakes, at its own expense, to obtain and maintain appropriate insurance coverage in an amount sufficient to cover its liability under the Agreement. Upon request by one Party, the other Party shall promptly provide written evidence of such insurance.

## **24. ASSIGNMENT**

- 24.1 Neither Party may assign or transfer, in any manner whatsoever, all or part of its rights and obligations under this Agreement without the prior written consent of the other Party, which shall not be unreasonably withheld. Any assignment or transfer, in whole or in part, made without the Parties' consent shall be null and void.
- 24.2 By way of exception to the foregoing, echOpen may freely, and without the Client's consent, assign or transfer all or part of its rights and obligations to any third party in connection with a merger, acquisition, asset sale, change of control of echOpen, or to any financial institution as part of a refinancing transaction. As a condition of validity, any assignment or transfer shall be subject to the authorized assignee agreeing in writing to comply with all provisions of this Agreement.

## **25. NO WAIVER**

The fact that echOpen does not rely, at a given time or in relation to a specific matter, on any provision of the Terms and Conditions shall not be construed as a waiver of its right to rely on such provision at a later time.

## **26. GOVERNING LAW**

- 26.1 In the event of any discrepancy between a translated version of these Terms and Conditions and the French version, the original version, namely the French version, shall prevail.
- 26.2 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.

## **27. JURISDICTION**

In the event of a dispute, following an amicable conciliation phase between the Parties, exclusive jurisdiction is granted to the courts within the jurisdiction of the Paris Court of Appeal.

## **28. ANNEXES**

- Annex I: Terms and Conditions of Use
- Annex II: Data Processing Agreement with Clients – Entities
- Annex III: Data Processing Agreement with Clients – Self-employed Healthcare Professionals
- Annex IV: Health Data Hosting
- Annex V: Content of the Additional Digital Services

## **ANNEX I – 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<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> Probe, and any subsequent version thereof, as well as the echOpen On<sup>®</sup> 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<sup>®</sup>**" means the echOpen On<sup>®</sup> 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 stipulated, the Subscription Period shall be automatically renewed for successive one-year periods following the initial Subscription Period or any renewal period, unless terminated by either Party under the conditions set forth herein.
- 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>, 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](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.

## **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.

## **ANNEX II – DATA PROCESSING AGREEMENT WITH CLIENTS - ENTITIES**

### **1. PURPOSE**

- 1.1 The purpose of this Annex is to define the conditions under which echOpen (hereinafter the “**Processor**”) undertakes to carry out, on behalf of the Client (hereinafter the “**Controller**”), the personal data processing operations defined below.
- 1.2 In the context of their relationship, the Parties undertake to comply with the regulations applicable to the protection of personal data.

### **2. DESCRIPTION OF THE PROCESSING SUBJECT TO PROCESSING BY THE PROCESSOR**

- 2.1 The characteristics of the processing operations carried out by the Processor on behalf of the Controller are as follows:

<b>Purpose of the Processing</b>	Provision of the Products and Services covered by the Agreement
<b>Nature of the Processing</b>	The processing operations carried out include, in particular, collection, recording, consultation, organization, structuring, and storage.
<b>Purpose(s) of the Processing</b>	The purposes of the Processing are: <ul style="list-style-type: none"><li>- the provision of echOpen Products and Services, in particular the use of and access to echOpen On®;</li><li>- the hosting of personal data;</li><li>- support for the echOpen On® application.</li></ul>
<b>Type of Personal Data</b>	The personal data collected are: <ul style="list-style-type: none"><li>- Healthcare professionals:<ul style="list-style-type: none"><li>– Identification data: title, last name, first name, professional email address;</li><li>– Personal data: UID (technical identifier assigned upon creation of the echOpen On® account), email identifier, password;</li><li>– Professional data: RPPS number, specialty, qualifications, postal address, professional telephone number, serial number of the medical device used by the User.</li></ul></li><li>- Patients:<ul style="list-style-type: none"><li>– Identification data: last name, first name, date of birth, personal identification number (or NIP);</li><li>– Health data: ultrasound results in the form of images and/or videos (ultrasound loops or sequences);</li><li>– Other data: metadata including technical configuration data, as well as the device number used and the date of data collection.</li></ul></li></ul>
<b>Categories of Data Subjects</b>	The Data Subjects are: <ul style="list-style-type: none"><li>- healthcare professionals using the echOpen On® application;</li><li>- patients.</li></ul>
<b>Duration of the Processing</b>	The Processor processes the Personal Data for the duration of the Agreement.

### **3. OBLIGATIONS OF THE PROCESSOR TOWARDS THE CONTROLLER**

- 3.1 The Processor undertakes to:
- (i) process the data only for the purposes subject to the processing arrangement;
  - (ii) process the Personal Data in accordance with the documented instructions of the Controller;
  - (iii) immediately inform the Controller if, in its opinion, an instruction infringes the regulations applicable to the protection of personal data.
  - (iv) where it is required to transfer Personal Data to a third country or an international organization under Union law or the law of a Member State to which it is subject, inform the Controller of that legal requirement before processing, unless the relevant law prohibits such information on important grounds of public interest;
  - (v) ensure the confidentiality of the Personal Data processed under this Agreement;
  - (vi) ensure that persons authorized to process Personal Data under this Agreement:
    - have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;

- receive appropriate training in the protection of Personal Data.
- (vii) implement, within its tools, products, the echOpen On® application and Digital Services, the principles of data protection by design and by default.
- 3.2 The Processor is authorized by the Controller to engage Lecpac Consulting and OVH, certified health data hosting providers, for the storage of health data (each hereinafter referred to as a “**Sub-processor**”).
- 3.3 The Processor shall obtain the Controller’s prior, specific written authorization before engaging any other sub-processor.
- 3.4 The Sub-processor shall be required to comply with the obligations of this Annex on behalf of and in accordance with the instructions of the Controller. It is the responsibility of the initial Processor to ensure that the Sub-processor provides sufficient guarantees to implement appropriate technical and organizational measures so that the processing meets the requirements of the regulations applicable to the protection of personal data. Where the Sub-processor fails to fulfill its data protection obligations, the initial Processor shall remain fully liable to the Controller for the performance of the Sub-processor’s obligations.
- 3.5 The Controller is responsible for providing information to the Data Subjects regarding the processing operations at the time the data are collected.
- 3.6 To the extent possible, the Processor shall assist the Controller in fulfilling its obligation to respond to requests for the exercise of Data Subjects’ rights.
- 3.7 The Processor shall notify the Controller of any Personal Data Breach within 24 hours of becoming aware of it by sending an email. This notification shall be accompanied by all relevant documentation to enable the Controller, where necessary, to notify the competent supervisory authority.
- 3.8 Where necessary, the Processor may assist the Controller in carrying out a data protection impact assessment and, where applicable, prior consultation with the supervisory authority.
- 3.9 The Processor undertakes to implement measures ensuring a level of security appropriate to the risk, including secure authentication and encryption of data on smartphones and in communications. More generally, the Processor shall implement measures to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services, as well as measures enabling the restoration of the availability of and access to Personal Data within appropriate timeframes in the event of a physical or technical incident, and a procedure for regularly testing, assessing and evaluating the effectiveness of the technical and organizational measures to ensure the security of the Processing.
- 3.10 Upon completion of the services relating to the processing of such data, or at the latest within three months following termination of the Agreement in accordance with the article relating to the term and termination of the Agreement in the Terms and Conditions, the Processor undertakes to destroy all Personal Data and to confirm such destruction in writing. Any return of data must be accompanied by the destruction of all existing copies in the Processor’s information systems, unless Union law or the law of a Member State requires retention of the Personal Data. Once destruction has been completed, the Processor shall provide written confirmation thereof.
- 3.11 The Processor’s Data Protection Officer (“DPO”) may be contacted at the following email address: [dpo@echopen.com](mailto:dpo@echopen.com).
- 3.12 The Processor declares that it maintains a written record of all categories of processing activities carried out on behalf of the Controller, in accordance with Article 30 of the GDPR, including:
  - the name and contact details of the Controller on whose behalf it acts, of any sub-processors and, where applicable, of the Data Protection Officer;
  - the categories of processing carried out on behalf of the Controller;
  - where applicable, transfers of Personal Data to a third country or an international organization, including identification of that third country or international organization and, in the case of transfers referred to in Article 49(1), second subparagraph of the GDPR, documentation of appropriate safeguards; and
  - where possible, a general description of the technical and organizational security measures.
- 3.13 The Processor shall make available to the Controller all documentation necessary to demonstrate compliance with its obligations and to allow for audits, including inspections, conducted by the Controller or another auditor mandated by the Controller, and shall contribute to such audits.

#### **4. OBLIGATIONS OF THE CONTROLLER TOWARDS THE PROCESSOR**

- 4.1 The Controller undertakes to:
  - 4.1.1 document in writing any instructions concerning the processing of data by the Processor;
  - 4.1.2 ensure, prior to and throughout the duration of the Processing, compliance by the Processor with the obligations laid down in the regulations applicable to the protection of personal data;
  - 4.1.3 supervise the Processing, including carrying out audits and inspections of the Processor.

## **ANNEX III – DATA PROCESSING AGREEMENT WITH SELF-EMPLOYED HEALTHCARE PROFESSIONAL CLIENTS**

### **1. PURPOSE**

- 1.1 The purpose of this Annex is to define the conditions under which echOpen (hereinafter the “**Processor**”) undertakes to carry out, on behalf of the Client (hereinafter the “**Controller**”), the personal data processing operations defined below.
- 1.2 In the context of their relationship, the Parties undertake to comply with the regulations applicable to the protection of personal data.

### **2. DESCRIPTION OF THE PROCESSING SUBJECT TO PROCESSING BY THE PROCESSOR**

- 2.1 The characteristics of the processing operations carried out by the Processor on behalf of the Controller are as follows:

<b>Purpose of the Processing</b>	Provision of the Products and Services covered by the Agreement
<b>Nature of the Processing</b>	The processing operations carried out include, in particular, collection, recording, consultation, organization, structuring, and storage.
<b>Purpose(s) of the Processing</b>	The purposes of the Processing are: <ul style="list-style-type: none"><li>– provision of echOpen Products and Services, in particular the use of and access to the echOpen On<sup>®</sup> application;</li><li>– – hosting of personal data;</li><li>– – resolution of any technical issues encountered when using the echOpen On<sup>®</sup> application.</li></ul>
<b>Type of Personal Data</b>	The personal data of patients collected are: <ul style="list-style-type: none"><li>– identification data: last name, first name, date of birth, personal identification number (or NIP);</li><li>– health data: ultrasound results in the form of images and/or videos (ultrasound loops or sequences);</li><li>– other data: metadata including technical configuration data, as well as the device number used and the date of data collection.</li></ul>
<b>Categories of Data Subjects</b>	The Data Subjects are the Client’s patients.
<b>Duration of the Processing</b>	The Processor processes the Personal Data for the duration of the Agreement.

### **3. OBLIGATIONS OF THE PROCESSOR TOWARDS THE CONTROLLER**

- 3.1 The Processor undertakes to:
- (i) process the data only for the purposes subject to the processing arrangement;
  - (ii) process the Personal Data in accordance with the documented instructions of the Controller;
  - (iii) immediately inform the Controller if, in its opinion, an instruction infringes the regulations applicable to the protection of personal data;
  - (iv) where it is required to transfer Personal Data to a third country or an international organization under Union law or the law of a Member State to which it is subject, inform the Controller of that legal requirement before processing, unless the relevant law prohibits such information on important grounds of public interest;
  - (v) ensure the confidentiality of the Personal Data processed under this Agreement;
  - (vi) ensure that persons authorized to process Personal Data under this Agreement:
    - have committed themselves to confidentiality or are subject to an appropriate statutory obligation of confidentiality;
    - receive appropriate training in the protection of Personal Data.
  - (vii) implement, within its tools, products, the echOpen On<sup>®</sup> application and services, the principles of data protection by design and by default.
- 3.2 The Processor is authorized by the Controller to engage Lecpac Consulting and OVH, certified health data hosting providers, for the storage of health data (each hereinafter referred to as a “**Sub-processor**”).
- 3.3 The Processor shall obtain the Controller’s prior, specific written authorization before engaging any other sub-processor.

- 3.4 The Sub-processor shall be required to comply with the obligations of this Annex on behalf of and in accordance with the instructions of the Controller. It is the responsibility of the initial Processor to ensure that the Sub-processor provides sufficient guarantees to implement appropriate technical and organizational measures so that the processing meets the requirements of the regulations applicable to the protection of personal data. Where the Sub-processor fails to fulfill its data protection obligations, the initial Processor shall remain fully liable to the Controller for the performance of the Sub-processor's obligations.
- 3.5 The Controller is responsible for providing information to the Data Subjects regarding the processing operations at the time the data are collected.
- 3.6 To the extent possible, the Processor shall assist the Controller in fulfilling its obligation to respond to requests for the exercise of Data Subjects' rights.
- 3.7 The Processor shall notify the Controller of any Personal Data Breach within 24 hours of becoming aware of it by sending an email. This notification shall be accompanied by all relevant documentation to enable the Controller, where necessary, to notify the competent supervisory authority.
- 3.8 Where necessary, the Processor may assist the Controller in carrying out a data protection impact assessment and, where applicable, prior consultation with the supervisory authority.
- 3.9 The Processor undertakes to implement measures ensuring a level of security appropriate to the risk, including secure authentication and encryption of data on smartphones and in communications. More generally, the Processor shall implement measures to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services, as well as measures enabling the restoration of the availability of and access to Personal Data within appropriate timeframes in the event of a physical or technical incident, and a procedure for regularly testing, assessing and evaluating the effectiveness of the technical and organizational measures to ensure the security of the Processing.
- 3.10 Upon completion of the services relating to the processing of such data, or at the latest within three months following termination of the Agreement in accordance with the article relating to the term and termination of the Agreement in the Terms and Conditions, the Processor undertakes to destroy all Personal Data and to confirm such destruction in writing. Any return of data must be accompanied by the destruction of all existing copies in the Processor's information systems, unless Union law or the law of a Member State requires retention of the Personal Data. Once destruction has been completed, the Processor shall provide written confirmation thereof.
- 3.11 The Processor's Data Protection Officer ("DPO") may be contacted at the following email address: [dpo@echopen.com](mailto:dpo@echopen.com).
- 3.12 The Processor declares that it maintains a written record of all categories of processing activities carried out on behalf of the Controller, in accordance with Article 30 of the GDPR, including:
- the name and contact details of the Controller on whose behalf it acts, of any sub-processors and, where applicable, of the Data Protection Officer;
  - the categories of processing carried out on behalf of the Controller;
  - where applicable, transfers of Personal Data to a third country or an international organization, including identification of that third country or international organization and, in the case of transfers referred to in Article 49(1), second subparagraph of the GDPR, documentation of appropriate safeguards; and
  - where possible, a general description of the technical and organizational security measures.
- 3.13 The Processor shall make available to the Controller all documentation necessary to demonstrate compliance with its obligations and to enable audits, including inspections, to be carried out by the Controller or an auditor mandated by the Controller, and shall contribute to such audits.

#### **4. OBLIGATIONS OF THE CONTROLLER TOWARDS THE PROCESSOR**

- 4.1 The Controller undertakes to:
- 4.1.1 document in writing any instructions concerning the processing of data by the Processor;
- 4.1.2 ensure, prior to and throughout the duration of the Processing, compliance by the Processor with the obligations laid down in the regulations applicable to the protection of personal data;
- 4.1.3 supervise the Processing, including carrying out audits and inspections of the Processor.

## **ANNEX IV – HEALTH DATA HOSTING**

### **1. PURPOSE AND MANDATORY INFORMATION PURSUANT TO ARTICLE R1111-11 OF THE FRENCH PUBLIC HEALTH CODE**

This Annex, relating to the hosting of health data, is intended to define, in accordance with Article R.1111-11, II of the French Public Health Code, the clauses of the agreement concluded between echOpen and the managed services provider responsible in particular for hosting health data (hereinafter the “Host”), whose details are as follows: LecPac-Consulting, having its registered office at 9 Rue Danielle Casanova – 91170 Viry-Châtillon (France), and using the hosting infrastructure of OVH – 2 rue Kellermann – BP 80157 – 59053 Roubaix Cedex 1 (France).

- certified health data hosting provider for personal health data, for activities 1 to 6 as defined in Article R.1111-9 of the French Public Health Code;
- date of issuance and, where applicable, renewal of the certificate: certificate renewed on 15/07/2025 and valid until 23/06/2028.

### **2. DESCRIPTION OF THE SERVICES PROVIDED**

The services provided by the certified Host correspond to activities 1 to 6 as defined in Article R.1111-9 of the French Public Health Code.

### **3. HOSTING LOCATIONS**

The certified Host’s infrastructure is located at the following sites: Strasbourg, Gravelines and Roubaix:  
<https://www.ovhcloud.com/fr/public-cloud/regions-availability/>

### **4. ECHOPEN CONTRACTUAL CONTACT FOR THE HANDLING OF INCIDENTS IMPACTING HOSTED HEALTH DATA**

echOpen’s contractual contact is Olivier de Fresnoye, co-Chief Executive Officer, reachable at the following address: olivier.defresnoye@echopenfactory.com, to be contacted for the handling of incidents impacting hosted health data.

### **5. QUALITY AND PERFORMANCE INDICATORS**

The quality and performance indicators enabling verification of the announced service level, the guaranteed level and the frequency of their measurement are as follows:

- monthly availability greater than 99.5% ;

The Host undertakes to perform all services without interruption during the service availability periods detailed in the contractual documents and in accordance with the performance targets, quality indicators, service levels and results defined in the Service Agreement between the Host and the company.

Service credits resulting from penalties are granted to the company in accordance with the terms set out in the agreement concluded with the Host. Such penalties are without prejudice to any damages that echOpen may claim as a result of the breaches referred to in the agreement with the provider.

### **6. MEASURES IMPLEMENTED TO ENSURE COMPLIANCE WITH THE RIGHTS OF DATA SUBJECT REGARDING HEALTH DATA**

The Host undertakes to implement the necessary measures to ensure compliance with the rights of data subjects whose health data are hosted. In this respect:

- In the event of receiving a request from a data subject whose health data are hosted, the Host shall promptly forward it to echOpen;
- The Host shall facilitate the exercise of the right to data portability, in particular by ensuring that the data are made available in a structured, commonly used and machine-readable format;
- The Host shall implement internal procedures enabling it to promptly notify echOpen of any Personal Data Breach of which it becomes aware;
- The Host shall authorize and facilitate audits conducted by echOpen’s Data Protection Officer (DPO), in accordance with the contractually defined arrangements, in order to verify that hosting operations comply with applicable legal and regulatory requirements.

## **7. SUBPROCESSING**

The conditions governing the use of external technical service providers and the Host's commitments to ensure a level of protection equivalent to that imposed by its own obligations are as follows:

- the Host shall ensure, through a written agreement, that its own sub-processor accesses and uses the hosted data only to the extent necessary for the performance of the obligations subcontracted to it by the Host, and that the requirements arising from Article 28 of the GDPR are imposed on it;
- the Host remains responsible for all obligations it subcontracts, and for all acts or omissions of its sub-processors.

## **8. ACCESS TO DATA**

The arrangements put in place to govern access to hosted personal health data include in particular the following:

- access strictly limited to authorized personnel to production environments hosting/processing client platforms;
- controlled authentication;
- authorization and rights management: management of access rights according to a specific model, with traceability of connections and actions;
- account lifecycle management: creation according to defined rules, deactivation/deletion upon departure, review of access rights in the event of a change of position, and audit of changes in authentication directories;
- separation/limitation of privileged accounts;
- password vault;
- secure network access and administration;
- traceability and logging.

## **9. SEGREGATION: SEPARATE AND SEGMENTED AUTHENTICATION FRAMEWORKS AND ENVIRONMENT ISOLATION MEASURES. OBLIGATIONS IN THE EVENT OF MODIFICATIONS OR TECHNICAL CHANGES INTRODUCED BY THE HOST OR REQUIRED BY APPLICABLE LEGAL FRAMEWORK**

The Host shall ensure continuity of the hosting services during major changes and shall obtain echOpen's prior approval where such modifications or changes introduced by the Host do not comply with the required and guaranteed service levels.

## **10. WARRANTIES**

The guarantees and procedures implemented by the Host to cover any potential failure on its part include in particular the following:

- support/continuity framework: services performed during the guaranteed service window, 7 days a week;
- intervention and recovery timeframes;
- regular encrypted backups;
- monitoring and recovery in the event of backup failure;
- restoration procedures and testing;
- supervision/monitoring and incident management;
- management of security incidents;
- technical measures to limit failures;
- notification, breach management and client information;
- controls/audits and action plan in the event of failure;
- reversibility: reversibility plan to organize a smooth and secure transfer.

## **11. PROHIBITION ON THE HOST USING HEALTH DATA FOR PURPOSES OTHER THAN THE PERFORMANCE OF THE HOSTING ACTIVITY**

The Host shall use the hosted health data solely for the purpose of performing the health data hosting activity.

## **12. LOSS OR WITHDRAWAL OF CERTIFICATION**

In the event of termination of the hosting services, for any reason whatsoever, in particular in the event of loss or withdrawal of the certification required under Article L.1111-8 of the French Public Health Code, the Host undertakes to:

- promptly inform echOpen of the occurrence of any event affecting the certification;
- maintain the hosting services in conditions of security and compliance until full implementation of the reversibility process;

- make available to echOpen, in a structured, commonly used and machine-readable format, all hosted health data as well as the associated metadata, within the contractually agreed timeframes;
- fully cooperate with echOpen and/or any new host designated by it to ensure the secure, complete and confidential transfer of the data;
- provide full technical documentation enabling the recovery of the data and associated services;
- guarantee the definitive deletion of the data from the Host's information systems once the reversibility process has been completed, unless otherwise required by law or regulation.

### **13. REVERSIBILITY AND HANDLING OF HEALTH DATA**

The Host shall return the health data in accordance with the defined reversibility conditions and shall destroy all copies thereof.

## **ANNEX V – CONTENT OF THE ADDITIONAL DIGITAL SERVICES**

The Additional Digital Services enable a User to benefit in particular from the following features; this list being provided for information purposes as of the date of the Terms and Conditions:

- image recording;
- screenshot capture;
- cloud services and storage of new images;
- sharing of images between Users and within a User Group;
- image freeze function and image or video capture function;
- image post-processing, including in particular registration, segmentation or analysis;
- presets relating in particular to certain anatomical regions, organ systems or organs;
- advanced filters enabling optimization of image display;
- access to modules or training sessions of any kind;
- access to any new functionality made available within the Digital Services;
- any additional User account per Medical Device.