# **GENERAL TERMS AND CONDITIONS OF SALE**

# FOR ECHOPEN O1® AND ACCESS TO ECHOPEN ON® AND MYECHOPEN

#### **VERSION 6**

Please read these General Terms and Conditions of Sale for the echOpen O1® ultrasound imaging probe, the subscription to the echOpen On® application, and the MyEchOpen platform carefully. By purchasing these products, you acknowledge and agree that these GTCS and the General Terms of Use (as defined in Article 2 below) constitute a legally binding agreement that you undertake to comply with in all respects.

#### 1 PURPOSE

- 1.1 These General Terms and Conditions of Sale ("GTCS") set out the terms governing the sale of the echOpen O1® probe by echOpen Factory, a French société par actions simplifiée 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 ("echOpen", "we", "us" and "our"), to its customers, who are exclusively healthcare professionals meeting the conditions set out in Article 3.1 below ("Client", "you" and "your").
- 1.2 echOpen has developed echOpen O1®, a tri-frequency portable ultrasound imaging probe (the "Probe"), which connects to the customer's/practitioner's smartphone and, via the echOpen On® application, enables improved diagnostic conditions and, where applicable, storage of images collected with the Probe. The Probe and the echOpen On® application (excluding storage of images collected with the Probe) each constitute medical devices (the "Devices") whose CE marking certifies compliance with the requirements of Regulation (EU) 2017/745. MyEchOpen is a secure web platform providing access to images/videos stored via echOpen On®, training content, and user account management.
- 1.3 The GTCS and the General Terms of Use (as defined in Article 2 below), including the Personal Data Protection Policy appended thereto and accessible at this link echopen.com/protectiondesdonnées, constitute the agreement governing the sale of the Devices by echOpen to the Client and, where applicable, access to the additional and optional echOpen On® features for storing images collected with the Probe and to MyEchOpen (the "Digital Services") (the "Agreement").
- 1.4 These GTCS have been provided and made available to the Client in accordance with Article L. 441-1 of the French Commercial Code. Any order for the Devices and, where applicable, access to the Digital Services placed by the Client with echOpen and their use implies the Client's unreserved acceptance of the Agreement.
- 1.5 In the event of any inconsistency between the General Terms of Use and the GTCS, the provisions of the GTCS shall prevail.
- 1.6 The fact that echOpen does not invoke, at a given time or for a specific matter, any provision of the GTCS may not under any circumstances be interpreted as a waiver of its right to invoke it subsequently.

1.7 echOpen reserves the right to periodically update the GTCS and/or the General Terms of Use as well as the Personal Data Protection Policy, subject to prior notice to users of the Devices and Digital Services, who will be asked to confirm their agreement to such changes.

#### 2 DEFINITIONS

- 2.1 "echOpen On®" means the echOpen On® application designed, operated and updated by echOpen, downloadable from mobile app stores, activated by an individual access code, and required to use the Probe.
- 2.2 "MyEchOpen" means the web platform designed, operated and updated by echOpen, accessible via a browser (computer, smartphone, tablet), providing a portal to access images and videos stored via echOpen On®, training content, and administrative account management functions (logins, passwords, profile).
- 2.3 "Competent Authority" means any supervisory authority responsible for public health and safety and for overseeing your professional practice, including the French National Agency for Medicines and Health Products Safety (ANSM), the French National Medical Council (CNOM), and the Regional Health Agencies (ARS), or the equivalent authority in the country where you practise.
- 2.4 "General Terms of Use" means the terms governing access to and use of the Devices and, where applicable, the Digital Services by the Client, accessible at this link echopen.com/cqu.
- 2.5 "Agreement" means the GTCS and the General Terms of Use, including all of their appendices and any updates.
- 2.6 "Quotation" means the quotation issued by echOpen to the Client and signed electronically or manually by the Client upon acceptance, in accordance with the procedure described in Article 3.2 below.
- 2.7 "Devices" means the echOpen O1® Probe and the echOpen On® application (excluding its features for storing images collected with the Probe).
- 2.8 "Intellectual Property Rights" means all patents, patent applications, copyrights, know-how, trademarks, designs and models, software, databases, data, specifications, inventions, processes, improvements and developments, whether registered or not, together with all related registrations and applications.
- 2.9 "Confidential Information" means all information disclosed or provided by one party to the other under the Agreement (research, development, data, results, products, trade secrets, processes, designs, formulas, patents, licences, business, marketing, sales, strategies, costs, prices, suppliers, customers, market data, staff), including pre-existing Intellectual Property Rights.
- 2.10 "Applicable Laws" means all laws, regulations, policies, ethical rules, codes, guidelines and any other applicable rules in force at the time you access and use the Devices and Digital Services, including the GDPR, provisions of the French Public Health Code and/or the professional and regulatory rules applicable in the country where you practise.

- 2.11 "Subscription Period" means the period during which you are authorised to access and use the Digital Services in consideration of payment of the Subscription Price and subject to compliance with the terms of the Agreement. The Subscription Period is one (1) year from the date the Client is provided access to the Digital Services and is tacitly renewed for successive periods of one (1) year unless terminated in writing by the Client at least one month prior to renewal. At any time, at the Client's request or at echOpen's proposal, the parties may agree to a multi-year recommitment; the duration and financial scope of such commitment are set by mutual agreement in an amendment or a new Quotation.
- 2.12 "Subscription Price" means the price you must pay to echOpen pursuant to Article 4 of these GTCS to access and use the Digital Services during the Subscription Period.
- 2.13 "Purchase Price" means the sales price of the Devices you must pay to echOpen pursuant to Article 4 of these GTCS.
- 2.14 "Price" means the Purchase Price and the Subscription Price.
- 2.15 "RPPS" means the Shared Register of Healthcare Professionals (applicable in France).
- 2.16 "Digital Services" means the echOpen On® features for storing images collected with the Probe as well as the services and content accessible via MyEchOpen.
- 2.17 "Probe" means the tri-frequency portable ultrasound imaging probe echOpen O1® developed and manufactured by echOpen, connected to your smartphone via echOpen On®.

# **3 ORDERING**

- 3.1 The Devices and Digital Services may be used only by a healthcare professional authorised to perform ultrasound examinations in the country where they practise, duly registered and authorised for this purpose with the local Competent Authorities, as well as by students pursuing studies to become healthcare professionals and authorised, in that context, to perform ultrasound examinations, where applicable under the supervision of the aforementioned healthcare professional. (In France, this authorisation notably includes registration with the RPPS.)
- 3.2 At the Client's request, and where applicable after echOpen analyses its needs, echOpen sends the Client a Quotation containing instructions on how to place an order and the applicable pricing terms, including the Price. If the Client accepts the Price and the applicable terms, the Client signs the Quotation electronically or manually and returns it to echOpen.
- 3.3 Any order by the Client must be expressly accepted in writing by echOpen, evidenced by shipment of the Probe and activation of the Client's personal access code to the echOpen On® application and the Digital Services, or by any other order validation process used by echOpen.
- 3.4 From the time it is accepted by echOpen, any order is deemed firm and final and binding on the Client. Consequently, the order may not be cancelled or modified by the Client after echOpen's acceptance, except with echOpen's prior written consent or as provided in these GTCS.

## **4 PRICE**

- 4.1 The Price is the price in effect on the order date, as set out in the Quotation.
- 4.2 The Price is payable in euros, non-cancellable and non-refundable, excluding VAT, which will be added to echOpen's invoices at the applicable rate on the order date.
- 4.3 The Subscription Price may be unilaterally modified by echOpen upon prior notice to the Client. The modified Subscription Price automatically applies from renewal of the Subscription Period.

# 4.4 Functional scope and new features

The functional scope of the Digital Services included in the Subscription is determined on the date of delivery of the Probe and activation of the Services. Updates necessary to maintain regulatory compliance, security and proper operation of the Digital Services are included in the Subscription Price throughout the commitment term and upon renewals. echOpen retains the exclusive right to develop new features distinct from the initial scope: they may be included at no additional cost or offered as paid options, at echOpen's sole discretion. The Client will be informed of the price and access terms for optional features.

#### 4.5 User accounts

The credentials provided by echOpen are strictly personal and may not be shared by multiple individuals. Any sharing of credentials constitutes a material breach of the GTCS/GTU. Additional user accesses may be opened at the Client's request; subject to echOpen's approval, such accesses are billed at a negotiated rate applicable to clients who already hold a Probe and an active Subscription.

## **5 PAYMENT TERMS**

- 5.1 Unless otherwise expressly agreed between the parties, the Price is paid by direct debit from the bank account specified in the SEPA direct debit mandate provided by the Client when signing the Quotation, within the timeframe stipulated in the Quotation.
- 5.2 Any payment owed by the Client to echOpen may not be suspended or be the subject of any reduction or set-off by the Client.
- 5.3 In the event of late payment of the Purchase Price or the Subscription Price, echOpen may suspend the Client's access to the Digital Services and, where applicable, terminate the Agreement under the conditions set out in Article 5.7 of these GTCS, without prejudice to any other remedies, and the Client shall pay echOpen a late-payment penalty equal to three (3) times the interest rate applied by the European Central Bank to its most recent refinancing operation, increased by 10 percentage points, applicable on the date of the payment incident.
- 5.4 The late-payment penalties provided for in Article 5.4 are calculated on the gross amount (including VAT) of the outstanding sum and accrue from the day following the due date of the Price. Late-payment penalties are due without reminder from echOpen.

5.5 In addition to late-payment penalties, the Client shall automatically owe echOpen a fixed recovery indemnity of forty (40) euros per invoice, pursuant to Article D. 441-5 of the French Commercial Code.

5.6 If the Subscription Price is not paid when due, echOpen may suspend the Client's access to the Digital Services, and terminate the Agreement as of right seven (7) days after a formal notice remains without effect, without prejudice to any damages that echOpen may claim.

5.7 Title to the Probe remains with echOpen until the Purchase Price has been paid in full by the Client under the conditions set out in this Article 5. This clause does not preclude the transfer of risks associated with use of the Probe as from its delivery. If the Purchase Price is not paid when due, echOpen may terminate the Agreement as of right seven (7) days after a formal notice remains without effect, without prejudice to any damages that echOpen may claim. In the event of early termination of the Agreement by echOpen pursuant to this Article 5.8, the Client shall return the Probe to echOpen at its own expense and in accordance with echOpen's instructions. The Client shall be liable for any damage to the Probe thus returned.

#### **6 WARRANTY**

- 6.1 echOpen warrants that the Devices and Digital Services are free from any material defect under the conditions set out in Articles 1641 to 1648 of the French Civil Code. If, in accordance with these provisions, a material defect is notified to echOpen in writing and such defect does not result from the Client's breach of any of its obligations set out in Article 3 of the General Terms of Use, the Client may, as applicable, (i) request replacement or repair of the defective Probe and/or application, (ii) return the Probe to echOpen and request a refund of the Purchase Price, or (iii) request termination of its access to the Digital Services and a refund of the Subscription Price pro rata the period of the Subscription Period during which the Client was unable to use the Digital Services.
- 6.2 The Client is solely responsible for selecting the Devices for its professional use and acknowledges that the Devices were not developed to meet its specific needs.
- 6.3 Except in the cases specifically provided for in Article 6.1, echOpen gives no other warranty, express or implied, regarding the Devices, the Digital Services, or any other equipment, supplies or services provided by echOpen under the Agreement. echOpen assumes no liability in the event of unauthorised use, disposal or sale of the Devices by the Client, particularly outside the use for which they were designed and certified.

# **7 LIMITATION OF LIABILITY**

7.1 The Client agrees to defend, indemnify and hold harmless echOpen, its directors, officers, employees and agents from and against any loss, liability, damage, claim, demand or proceeding, and related costs and expenses incurred (including reasonable legal fees and attorneys' fees) arising from or resulting from any third-party claim, to the extent such claims result from or are caused, directly or indirectly, by (i) the Client's breach of the Agreement, (ii) the negligence or misconduct of the Client or its employees or agents, or (iii) the Client's breach of any Applicable Law.

7.2 echOpen shall not be liable for:

- i. any loss of profits, sales, business or revenue;
- ii. any business interruption;
- iii. any loss of anticipated savings;
- iv. any loss of business opportunity, goodwill or reputation; or
- v. any indirect loss or damage, or any cost, charge or expense of any kind, including additional interest or financing costs, arising out of or in connection with the temporary unavailability of access to the Devices or the Digital Services.
- 7.3 echOpen shall not be liable for any loss or damage caused by a virus, cyberattack or any other technologically harmful incident that could compromise the Client's equipment, computer programs, data or other material due to its use of the Devices or the Digital Services, unless such loss or damage is due to echOpen's failure to comply with its obligations under the Agreement.
- 7.4 Subject to the requirements of the Agreement and Applicable Laws, echOpen's aggregate liability to the Client for any contractual, tortious or other claim arising out of performance of the Agreement shall be limited to the amount of the Price paid during the twelve (12) months immediately preceding the date the claim arose.

#### **8 TERM OF THE AGREEMENT AND TERMINATION**

- 8.1 The Agreement takes effect on the date the Client's order is accepted by echOpen pursuant to Article 3.3 of the GTCS and remains in force for as long as the Client uses the Devices and/or the Digital Services, unless terminated in accordance with Article 8.2 of these GTCS.
- 8.2 The Agreement may be terminated in any of the following cases:
- 8.2.1 With respect to the Digital Services, echOpen may terminate the Agreement at its discretion at any time, with or without cause, without compensation to the Client, subject to fifteen (15) days' prior notice.
- 8.2.2 echOpen may terminate the Agreement immediately in the event of the Client's breach of any of its obligations set out in Article 3 of the General Terms of Use, without compensation.
- 8.2.3 Either Party may terminate the Agreement immediately by giving written notice to the other party if the latter breaches the Agreement and fails to remedy such breach within thirty (30) days of receiving notice.
- 8.2.4 The Client may terminate the Agreement in the event of a material defect in the Devices and/or the Digital Services under the conditions set out in Article 6.1 of the GTCS.
- 8.2.5 Each party may terminate the Agreement in the event of Force Majeure in accordance with Article 9.3 of the GTCS.

8.2.6 The Client may terminate the Agreement, with respect to the Digital Services, by expressly notifying echOpen in writing at least one month before renewal of the Subscription Period.

# 8.3 Multi-year recommitment

Without waiting for the expiry of the current Subscription Period, the Client may recommit for a multi-year term upon simple request (or upon echOpen's proposal). The duration and financial scope of such commitment are agreed by amendment or new Quotation. This commitment replaces the current period and may be tacitly renewed for an equivalent duration, unless otherwise provided.

#### 8.4 Access in the event of non-renewal

If the Subscription is not renewed, the Client retains restricted access to echOpen On® and/or MyEchOpen, limited to a reduced functional scope determined at echOpen's sole discretion. Certain advanced features, including storage, image capture and sharing, presets or advanced filters, may no longer be accessible.

8.5 In the event of termination of the Agreement for any reason, the Client must (i) pay the Price due under the Agreement up to the effective date of such termination, and (ii) return or destroy the Confidential Information in accordance with Article 11.5 of the GTCS.

# 9 FORCE MAJEURE

- 9.1 Neither party shall be liable to the other under the Agreement if it is prevented or delayed in performing its obligations under the Agreement, or in carrying on its business, by an event constituting force majeure under the Applicable Laws for the duration of such event. Force majeure is any event beyond the debtor's control, which could not reasonably be foreseen at the time the Agreement was concluded, the effects of which cannot be avoided by appropriate measures, and which prevents performance of its obligation by the debtor. Events considered as force majeure include, in particular, strikes, lock-outs or other labour disputes, failure of a public service or of a transport or telecommunications network, war, riots, civil commotion, malicious acts, accidents, collapse of plant or machinery, fire, flood or storm ("Force Majeure Event"). The party prevented from performing its obligation under the Agreement must notify the other party of the occurrence of the Force Majeure Event and its anticipated duration within three (3) days of the time it knew or should reasonably have known of the event. The prevented party must use its best efforts to mitigate the effects of the Force Majeure Event.
- 9.2 Following such notification, the affected party shall be excused from performing those obligations that are prevented, limited or hindered due to the occurrence of a Force Majeure Event. Such party shall not be deemed to have breached its obligations under this Agreement and shall not be subject to any liability or damages due to its inability to perform such obligations as a result of the Force Majeure Event. A Force Majeure Event affecting one of a party's contractors or subcontractors shall be deemed to be a Force Majeure Event affecting that party. The period during which a party must perform its obligations under this Agreement shall be extended by the duration of the Force Majeure Event. For the sake of clarity, both parties are fully aware of the COVID-19 epidemic and have taken it into account

when entering into this Agreement. This epidemic shall not serve as a justification for any delay, unless a lockdown constitutes a Force Majeure Event.

- 9.3 If a Force Majeure Event continues for more than two (2) months, each party may terminate this Agreement by giving thirty (30) days' notice to the other party, or continue the Agreement despite the Force Majeure Event.
- 9.4 If either party chooses to terminate the Agreement due to a Force Majeure Event, neither party shall be entitled to claim damages in relation to such termination and non-performance and, from the date of termination, the parties shall be released from any further obligations under this Agreement, except where the termination concerns a Force Majeure Event affecting you, in which case you shall remain liable for the Price owed to echOpen prior to the start date of the Force Majeure Event.

#### 10 INTELLECTUAL PROPERTY

- 10.1 echOpen exclusively owns all Intellectual Property Rights in the Probe, echOpen On® and MyEchOpen, and in any additional module or new version thereof. The Client acknowledges that it has no rights in the Devices and the Digital Services, other than ownership of the Probe and the right to use echOpen On®, MyEchOpen and the Digital Services in accordance with the terms and limitations of the Agreement.
- 10.2 echOpen warrants that it holds and will continue to hold throughout the term of the Agreement all rights necessary for the use of the Devices and the Digital Services and for the performance of its obligations under the Agreement.

## 11 CONFIDENTIAL INFORMATION

- 11.1 Except as expressly permitted by the Agreement or by the disclosing party in writing, or as required by Applicable Laws, the receiving party undertakes to keep the Confidential Information confidential and not to disclose it to any third party or use it for any purpose other than those provided for in the Agreement throughout the term of the Agreement and for ten (10) years from its expiry or termination.
- 11.2 The receiving party may use the Confidential Information only to the extent necessary to perform its obligations under the Agreement and may not use it for any other purpose. The receiving party may disclose Confidential Information only to personnel who need such information to perform the Agreement, provided they are subject to confidentiality obligations at least as stringent as those set out in this Article 11.
- 11.3 The confidentiality obligations set out in Article 11 do not apply where the receiving party can demonstrate that the information:
- 11.3.1 is in or has entered the public domain without fault of the receiving party;
- 11.3.2 was provided to the receiving party by a third party lawfully in possession of such information and not subject to any confidentiality obligation with respect to it;
- 11.3.3 was already known to the receiving party at the time of receiving such Confidential Information, as evidenced by the receiving party's written records existing at the time of disclosure; or

- 11.3.4 was 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.
- 11.4 Notwithstanding this Article 11, the receiving party may disclose certain Confidential Information to the extent such disclosure is required by Applicable Laws or a Competent Authority or pursuant to a valid court order, provided that the receiving party informs the disclosing party of such disclosure in writing within a reasonable time and, at the disclosing party's request, provides all reasonably necessary assistance to obtain a protective order or confidential treatment preventing or limiting disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the Applicable Laws or a Competent Authority require it or for which the order was issued.
- 11.5 Upon termination or expiry of the Agreement, or upon the disclosing party's written request, the receiving party shall promptly return or destroy all documents, notes and other tangible materials containing Confidential Information, as well as all copies thereof, provided that the receiving party may retain one copy where applicable in accordance with its archiving obligations.

#### 12 PERSONAL DATA PROTECTION

- 12.1 In performing the Agreement, the parties must comply with all Applicable Laws on the protection of personal data. The Client acknowledges that it is the data controller in accordance with Applicable Laws and that echOpen is a processor with respect to the processing of patient personal data generated when using the echOpen On® application, under the conditions set out in Articles 8.1 and 8.2 and Appendix 1 of the General Terms of Use.
- 12.2 Notwithstanding the foregoing, in the context of research or for the purpose of improving our services, products or algorithms, echOpen may reuse certain patient personal data for its own purposes. echOpen will then act as a data controller and will comply with applicable laws and regulations. Appendix 2 of the General Terms of Use describes the framework for the reuse of certain data, which will be carried out in compliance with the MR-004 reference methodology (Deliberation No. 2018-155 of 3 May 2018). Your acceptance of the General Terms of Use implies your full agreement to cooperate in accordance with their Appendix 2 so that echOpen can meet the obligations arising therefrom.
- 12.3 You are reminded that you must never share patient personal data in public or unsecured spaces and, more generally, outside the channels and safeguards provided for in the General Terms of Use and their Appendices (notably via echOpen On® and MyEchOpen). Failing this, you may incur liability towards echOpen and your patients.
- 12.4 echOpen collects and processes the Client's personal data for the management of our commercial relationship and acts for this sole purpose as data controller, under the conditions set out in Appendix 3 of the General Terms of Use.

## **13 MISCELLANEOUS**

- 13.1 The General Terms of Use and the GTCS constitute the entire Agreement between the parties with respect to the subject matter hereof and supersede any prior oral or written agreement or arrangement.
- 13.2 Any amendment to the Agreement must, in order to be binding on the parties, be the subject of a written addendum signed by both parties.
- 13.3 Nothing in 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 is solely that of seller and buyer, and of licensor and licensee. Neither party is a partner, agent, joint venturer or representative of the other party.
- 13.4 If one or more provisions of this Agreement are held to be invalid, illegal or unenforceable, in whole or in part, for any reason, all other provisions of the Agreement shall remain valid and enforceable.
- 13.5 Each party undertakes, at its own expense, to take out and maintain appropriate insurance in a sufficient amount to cover its liability under the Agreement. Upon request by one party, the other party undertakes to promptly provide written proof of such insurance.
- 13.6 The Agreement is concluded *intuitu personae* and the Client may not assign it, in whole or in part, to any third party without echOpen's prior written consent.
- 13.7 Any dispute, controversy or claim arising out of or in connection with the Agreement, including concerning the validity and interpretation of the Agreement and non-contractual disputes and claims, shall be governed by and construed in accordance with French law.