

TERMS AND CONDITIONS OF USE

FOR THE APPLICATION “myFibroScan®” of ECHOSENS

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Echosens, a French limited liability company (*société anonyme*) registered with the Trade Registry under the number 438 209 157 RCS Paris, headquartered at 6 rue Ferrus, 75014 Paris France, duly represented by its CEO M. Dominique Legros (hereinafter “Echosens”) is offering to you as an individual or the legal entity you represent (the “User”) the Echosens’ **myFibroScan® application** and every supplementary feature (“myFibroScan®” or the “**Product**”) subject to User’s acceptance of all of the terms and conditions contained herein.

The present Terms and Conditions of Use (the “Conditions”) must be read before using myFibroScan®, to understand the contraindications, warnings and precautions associated with its use and interactions with other products. By using myFibroScan®, the User acknowledges and agrees that it is bound by the Conditions.

myFibroScan® is a mobile application intended **TO BE USED ONLY BY HEALTHCARE PROFESSIONALS EXPERIENCED IN DEALING WITH LIVER DISEASES acting for medical purposes** to give them access to medical device tools based on FibroScan® results (E for measurements of the liver stiffness and CAP for the measurement of liver ultrasound attenuation).

myFibroScan® is intended to be used as an aid to collect, interpret and manage medical data.

myFibroScan® also provides a proven source of information including scientific publications, related to liver, guidelines and FibroScan® best practices.

1. CONDITIONS AND INTENDED USE

myFibroScan® is a mobile application provided by Echosens to User, for User’s internal medical business purposes only, for the duration specified in Section 5 below and subject to the other terms of the present Conditions.

myFibroScan® is a mobile application intended to be used together with software as medical devices or software as in vitro diagnostic medical devices hosted in a cloud server.

myFibroScan is intended to enter input data used by these devices, display results and generate reports.

Prior first installation, the User must have an Internet access which costs remain at his own expenses.

The User further acknowledges that he/she has checked that his smartphone / tablet does not contain any virus or content that could threaten the security of the application. The User shall:

- install the mobile application on a smartphone or a tablet, operating on iOS or Android in conformity with the technical conditions described on application stores on which the application is available ;
- retrieve liver stiffness and liver CAP information either by scanning a QR code or by manually entering the values ;
- get access to score computation ;
- generate a report from available scores and interpretation guide.

2. RESTRICTIONS

2.1 User acknowledges and agrees that:

- (i) the values obtained from FibroScan® exams and/or from any Echosens’ medical device(s) must be interpreted by a physician experienced in dealing with liver disease, taking into account the complete medical record of the patient;
- (ii) According to the Federal Food, Drug, and Cosmetic Act (21 CFR 880.6310) the Product is a non-device CDS. And a Class I accessory of MD according to European directive 93/42/EEC and accessory of IVD according to European directive 98/79/EC.

- (iii) User accepts sole and entire responsibility for any decision made or action taken or not in accordance with myFibroScan®. The User remains sole responsible for any data manually provided in the App.

User acknowledges and agrees that he/she is responsible for the diagnosis, care and treatment of the User's patients. User agrees that he/she shall indemnify, hold harmless and defend Echosens from any and all claims relating to the diagnosis, care and treatment of the User's patients, notwithstanding that such claim may involve the use of myFibroScan®.

2.2. User shall not and shall not cause any third party to:

- (i) use or reproduce any portion of myFibroScan® in source code format;
- (ii) translate, reverse engineer, decompile, or disassemble myFibroScan®, except to the extent the foregoing restriction is expressly prohibited by applicable law;
- (iii) remove or modify any copyright, confidential or proprietary markings, legends, intellectual property rights or restrictions that are in myFibroScan® originally supplied to User, or
- (iv) violate any obligations with respect to Confidential Information as defined below.

2.3 User acknowledges that any use of myFibroScan® in connection with any product, system, application or other material than the products intended to be connected as expressly authorized by Echosens, is prohibited.

2.4 User agrees not to download, publish, send by e-mail, transmit any information or contents through myFibroScan® which could be the infringement or violation of the intellectual property, brand, license or other exclusive rights of another party, except if the relevant owner gives you its prior written express authorization and subject to the requirements of applicable law. In addition, any such action, where made possible in application of the foregoing sentence, shall be subject to strict compliance with other rules of applicable law, including on the protection of health or other personal data.

3. OWNERSHIP & INTELLECTUAL PROPERTY

User hereby acknowledges and agrees that Echosens owns the entire right, title and interest in and to the Product as well as in and to any and all associated manuals, drawings, technical information and documentation (the "Documentation") including, without limitation, all patent, copyright, trademark, trade secret, other intellectual property, know-how or other proprietary rights ("Intellectual Property Rights") in and to all components and elements thereof, all of which shall remain the sole and exclusive property of Echosens.

Echosens and FibroScan® among others are trademarks and/or service mark of Echosens Group and are registered in the U.S. and/or other countries.

4. CONFIDENTIALITY

User agrees that the Product and its Documentation, and all components and elements thereof, including, without limitation, the specific design and structure of individual programs, constitute confidential information and trade secrets of Echosens (the "Confidential Information").

User agrees not to disclose, provide or otherwise make available such Confidential Information, including without limitation, any trade secrets or copyrighted material, in any form to any third party. User will keep the Confidential Information confidential and protect such Confidential Information in the same manner as User maintains User's own highly confidential information, and in no event with less than a reasonable degree of care.

This obligation of confidentiality shall survive the termination of the Conditions, for whatever reason, for a period of five (5) years, except for Echosens' know-how which shall survive for the duration of its own confidentiality without the User being able to breach it.

5. DURATION AND TERMINATION

The Conditions come into force for the User at the day of creation of his/her User account and acceptance of the Conditions of Use. They remain in full force and effect for the duration of the User's continued registration to the services provided by myFibroScan®. The termination of registration takes effect either on the day of the User's request to unsubscribe or on the day of termination of his/her registration by Echosens, in conformity with the conditions described in these general conditions.

The authorization provided to the User shall terminate automatically without prior notice from Echosens if the User fails to comply with any of the terms of the Conditions. This termination shall occur when notified by an email addressed to the User by Echosens. The User may also terminate the Conditions by notifying this decision to Echosens by email at any time.

Upon termination, Echosens will close the User's account and myFibroScan® will no longer be made accessible to the User.

The limitation of warranties and liability set out below shall continue in force even after any termination whether from Echosens or from the User, for the duration or statute barring applying to the rights and obligations deriving from the provisions in question.

6. LIMITATION OF WARRANTIES AND LIABILITY

6.1 The Product shall operate in compliance with the documentation and the requirements of applicable law. In his/her capacity as a professional, more especially a healthcare professional, user assumes all responsibility and risk for the activities, including medical activities. User assumes all responsibility and risk for the activities that he/she shall perform while using this product and/or for the use of any third-party system, content, equipment or solution, including any website.

Echosens may additionally not be found liable for any damage, defect, malfunction or non-conformity resulting from a breach by user of any rules of applicable law or professional standards or guidelines or all or part of this Conditions, the documentation or Echosens' instructions for the use of the Product.

The foregoing limitation of liability shall apply only to the extent permitted by applicable law and may not apply in a number of liability cases that cannot be limited or excluded as per the public policy rules of applicable law.

Liability for defective products as per Art. 1245 & seq, of the French Civil code may also not be excluded unless as expressly permitted by the relevant rules of applicable law.

6.2 Echosens may temporarily limit some functionalities of myFibroScan® if this is necessary for reasons related to capacity, security or server or data integrity limitations or enhancements or in order to take technical measures, and if it is for the purpose of providing correct or improved services (in particular in the event of maintenance work). In this case, Echosens shall take into account the legitimate interests of its Users, for example by providing them with prior information subject to its availability.

7. DATA PROTECTION

7.1 Responsibility of Echosens regarding the User's personal data

In the performance of the Conditions, Echosens may, in its capacity as data controller, collect and further process personal data relating to the User (ie. identification and contact data). Processing of this collected data is necessary for using myFibroScan®.

Echosens commits itself to process this data according to the rules provided for by Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data (the "GDPR") and, on a subsidiary basis, by the amended French Data Protection Act no. 78-17 of 6 January 2018 (the "Data Protection Laws").

For the purpose of the foregoing, the following terms shall have the same meaning as in the GDPR: "personal data", "data subject", "data controller", "personal data", "health personal data", "processing" and "supervisory authority".

The User's data is processed exclusively for the performance of these Conditions, customer-relationship management, commercial solicitations, studies and surveys, operation and maintenance of myFibroScan® as well as requests from User as a data subject to exercise his or her individual rights and according to the authorizations given by the User when he/she registered in the Echosens Cloud system. Such processing shall be based, as the case may be, on the performance of the contract to which the User is a party, on the legitimate interests pursued by Echosens or on compliance with applicable legal obligations binding on Echosens.

The User must provide accurate, current and complete information when registering his/her account. Without prejudice to any other obligation hereunder, provision of a false identity or false professional status information while trying to access myFibroScan® is expressly prohibited. Echosens reserves the right at any time to request proof of the User's identity and/or status as a healthcare professional and to suspend or terminate without notice, this user agreement, should the User not provide adequate proof of the same.

Only the employees responsible for the performance of the Conditions, the operation and maintenance of myFibroScan® or in charge of conducting administrative tasks within Echosens can access User's data. It may also be communicated to Echosens' authorized services providers involved in the performance of the Conditions or in the implementation of the aforementioned purposes.

The User's data will be stored for the duration of the Conditions, except for data necessary to comply with legal obligations or to prove the existence or scope or conditions of enforcement of a right or contract, which may be archived by Echosens in accordance with applicable law.

Subject to the conditions set out in Data Protection Laws, the User shall have, in particular, a right to access, correct or erase his/her personal data, a right to limit his/her processing and a right to object to his/her processing as well as the right to direct how his/her personal data should be used after his/her death. These rights can be exercised by e-mail to the following address: dpo@echosens.com.

The User also has the possibility to lodge a complaint with the competent data protection supervisory authority (CNIL in France).

7.2 Responsibility regarding personal data collected or otherwise processed by or on behalf of the User through the use of myFibroScan®

THESE CONDITIONS AND THE SERVICES PROVIDED BY ECHOSENS DO NOT CONCERN THE PROCESSING OF PERSONAL DATA BY OR ON BEHALF OF THE USER.

The User is the sole data controller regarding the processing of his/her patient's personal data, including health personal data, or any other data that the User shall enter in myFibroScan® and engages himself/herself to comply with Data Protection Laws in this respect.

The User's device is considered to be personal. Personal data of User's patients will remain locally stored on the User's mobile device under the sole control and liability of User in his/her capacity as the data controller.

It is the User's sole responsibility to comply with all applicable obligations in his/her capacity as data controller. Without limitation, the User shall implement all appropriate technical and organizational measures and ensure personal data's security (including their confidentiality, availability and integrity) the minimization of their processing, the required limited duration or certified conditions of their storage, their valid transfers outside the European Union as the case may be. It is also up to the User to comply with the rights and freedoms of data subjects whose personal data are processed (including information, transparency, consent, access, limitation, objection, portability, erasure, control of data post-mortem and remedies to the extent those rights apply).

ECHOSENS HAS NO ACCESS TO THE PATIENT DATA AND CANNOT BE HELD RESPONSIBLE FOR THEIR PROCESSING.

IN PARTICULAR, ECHOSENS MAY NOT BE HELD RESPONSIBLE FOR ANY COMMUNICATION OF PATIENT DATA, LOSS OF ANY DATA AND/OR BREACH OF CONFIDENTIALITY AS A RESULT OF USER'S ACTION OR OMISSION.

7.3 Security

The User must not disclose his/her ID and password to anyone. He/she must take all appropriate steps to keep his/her information secure, and by keeping it confidential. If the User knows or suspects that anyone other than himself/herself knows his/her password or any other information relating to the User, the User should promptly notify Echosens as required below regarding Security Incidents. The User is entirely responsible for all activities occurring through the use of his/her password. Echosens is not responsible for any losses or liabilities arising out of, or in connection with, any unauthorized use of myFibroScan®.

The parties will notify each other promptly upon discovery of any incident which a party reasonably believes to be a security incident ("Security Incident") of which a party becomes aware. If a party (or any of its affiliates, subcontractors, staff or representatives) causes or originates the security incident, or is otherwise so obligated under Data Protection Laws, at the originating party's expense, the originating party must promptly take all necessary and appropriate corrective actions if and as required by Data Protection Laws, including, without limitation, for the User in his/her capacity as the data controller, to provide notification to those individuals whose personal data may have been affected by his/her use of myFibroScan®. The parties agree that upon any Security Incident under this clause, they will work together in good faith to respond to the Security Incident in a time and manner as agreed by the Parties and in accordance with Data Protection Laws. For purposes of this clause, "Security Incident" means, solely with respect to personal data processed by or through myFibroScan®, the successful unauthorized access, use, disclosure, modification, or destruction of such personal data or interference with system operations in myFibroScan®, of which a party has knowledge or should, with the exercise of reasonable diligence, have knowledge, excluding any situations which would not be deemed a security incident by Data Protection Laws.

7.4 Hosting

Data collected via myFibroScan® that do not contain any individual patient health information, are housed in public cloud infrastructure of Amazon Web Services.

Amazon Web Services EMEA SARL 38 avenue John F.KennedyL-1855 Luxembourg

<http://aws.amazon.com>

8. GENERAL

The Conditions are the entire agreement between Echosens and the User and substitute for any other agreement or discussion, oral or written, in relation to the subject matter hereof and may not be changed except by a written amendment hereto or revised version hereof duly accepted by the parties.

If the Product is used from a device owned by a corporation or other legal entity, then the Conditions are formed by and between Echosens and such entity. The individual agreeing to the terms of the Conditions represents and warrants to Echosens that he/she has the authority to bind such entity the Conditions.

User agrees to defend, indemnify and hold Echosens, its employees, directors, affiliates, agents, licensors, distributors, resellers, and subcontractors harmless against any and all claims, losses, liabilities, damages, costs and expenses, including reasonable attorney's fees and court costs, which such indemnitees may incur in connection with a breach of the Conditions of Use by User or User's unauthorized use of the Product.

User shall not have the right to assign, transfer, or sublicense any obligations or benefits under the Conditions (including by operation of law) without Echosens' prior express written consent on a case by case basis.

The Conditions shall be interpreted and enforced in accordance with the laws of France. In case of litigation, the courts of Paris jurisdictions are declared solely competent unless otherwise provided by law.

If any provision of the Conditions is declared by a court of competent jurisdiction to be invalid, illegal, or unenforceable, such a provision shall be severed from the Conditions and all other provisions shall remain in full force and effect.