

echOpen

FACTORY

echOpen O1, handheld ultrasound imaging device and
echOpen ON, dedicated software application

User Manual



Manufacturer's contact information

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The product names mentioned in this manual may be trademarks of their respective licensees.

Disclaimer

The information contained in this manual may be changed without notice.

Some of the features described in this manual may not be available to all users based on local regulations and subscribed services.

The names and data used for the examples in this manual are fictitious.

Mention to the user

Any serious incident related to the echOpen O1 device must be notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

Please contact support@echopenfactory.com.

Security Conventions



Warning: Warnings highlight vital and unsafe information that could jeopardize the safety of the patient, operator and anyone else in the vicinity.



Caution: Cautions highlight practices that can result in minor injury, device degradation or data loss.

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1. About echOpen O1

1.1. Overview

This manual provides information allowing users with appropriate training to use the echOpen O1 device and dedicated application echOpen ON safely and effectively. It is important to read and understand this entire manual before using the device and to pay particular attention to the warnings given throughout the manual. This manual needs to be kept for the whole duration of use of the echOpen O1 device.

1.2. Intended Use

echOpen O1 is a handheld ultrasound imaging device intended for point of care ultrasound (POCUS) of patients of all ages to allow ultrasound imaging of organs and tissues of the human body. echOpen O1 includes a tri-frequency ultrasound probe to be used with a dedicated software application on a connected mobile device (smartphone, tablet). The device is to be used by trained healthcare professionals. echOpen O1 is intended to complement the standard clinical examination by providing ultrasound imaging findings and also to locate organs prior to catheterization.

echOpen ON is an accessory software application intended to control and present output information from a dedicated ultrasound probe in order to fulfill its intended purpose.

Intended use environment

The echOpen O1 device is intended to be used in the following environments:

- Hospital environment (Emergency ward and other wards)
- General care environment (Private practice facilities, public care facilities, remote area facilities, nursing homes)



The echOpen O1 device is not intended for use as a self-sufficient diagnosis tool, interpretation of the obtained images must be made in a specific clinical situation. (It is contraindicated to consider only the information of the ultrasound examination without taking into consideration the clinical context of the patient as a whole).

The echOpen O1 device is not intended for use for measurement or monitoring purposes, although size estimates may be appreciated.

The echOpen O1 device should not be used for intra-vaginal examinations or other invasive gestures.

The echOpen O1 device is not intended for use on mucous membranes or damaged areas of the skin.

The echOpen O1 device is not intended for use on the following environments: emergency vehicles and private homes.

1.3. Indications

The echOpen O1 device is indicated for Point-Of-Care Ultrasound (POCUS) which complements the standard clinical examination by providing ultrasound imaging findings. The following targets and the related clinical conditions are examples of what can be visualized:

ANATOMICAL AREAS	ORGANS	CLINICAL CONDITIONS
Thorax (Adult)	Lung	Pleural effusion
	Heart	Pericardial effusion
Abdominal & Pelvis (Adult)	Peritoneum	Abdominal effusion
	Vessels	Abdominal aorta aneurysm
Protocols (Adult)	FAST, eFAST	Pleural effusion
		Abdominal effusion
		Pericardial effusion
Location prior to catheterization (Adult)	Big vessels	Internal jugular
		Common femoral
		Subclavian
	Peripheral access	Basilic Vein

1.4. Contraindications

Due to a lack of clinical data, and acoustic or intrinsic limitations, the echOpen O1 device is not intended to be used in the following population or conditions:

- For the diagnostic ultrasound of the fetus, neonates, and infants and pediatric;
- For the guidance of a needle-guided biopsy and needle-guided catheterization;

- For an ultrasound scan of the face or skull;
- For ophthalmologic ultrasound;
- For osteoarticular ultrasonography;
- For either thoracic or abdominal diagnostic ultrasound in obese patients (Body Mass Index >35 kg/m²);
- Any time that the patient's life is at stake and requires emergent medical care.

Indeed, no data is available yet on its performance in scanning fetus or its use in guiding biopsies. Plus acoustic impedance varying between tissues ultrasound cannot properly penetrate bones (skulls), joint/cartilage, and large fatty tissues. Lastly, the lack of Doppler and reduced resolution for analyzing very thin anatomical elements/tissues (e.g. thin wall, heart valves, or their respective pillars) prevents its use in cardiac ultrasound as well.

1.5. Training

The intended users of echOpen O1 and echOpen ON are Health Care Professionals (HCPs) trained and qualified in using ultrasound technology according to national law/guidelines and/or local requirements.

1.6. Benefits and risks of the device

Benefits

- echOpen O1 improves and secures catheterizations by providing images that enable the user to locate blood vessels.
- The use of echOpen O1 enhances the standard clinical examination (Inspection, palpation, percussion, and auscultation) by providing ultrasound imaging findings.
- echOpen O1 is handheld and allows clinical examination at the point of care

Risks

The risk of ultrasound is low due to a non-ionizing radiation technology, mastered in medicine for several decades. Prolonged exposure to ultrasonic waves may result in slight warming of human tissues.

Always apply the ALARA principle (As Low As Reasonably Achievable) to limit ultrasound exposure. Exposure time and acoustic power should be kept as low as reasonably possible, while allowing for the collection of acceptable diagnostic images for medical purposes. Sonographers must respect the ALARA principle during POCUS clinical examinations, taking particular caution for the surface of the lung for thin patients and patients treated with specific drugs.

Essential performances

Essential performances of the echOpen O1 device are compliant with standard EN 60601-2-37:2008, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

2. Safety guidelines

2.1. Introduction

The following instructions apply to the echOpen O1 probe and its dedicated mobile application echOpen ON. Please read all this information before using the echOpen O1 device.

2.2. Basic security of the echOpen O1 device and accessories



Do not use the echOpen O1 device without being properly trained.

Always use clinical judgment when interpreting images obtained using the echOpen O1 device.

Do not use the echOpen O1 device until you have read and understood this manual in its entirety.

Do not use the echOpen O1 device for purposes other than those specified in this manual.

Failure to follow the safety instructions specified in this manual can result in serious injury or even death.

Do not use the echOpen O1 device if the package is opened or damaged.

Always inspect the probe before and after each cleaning, disinfection or use to detect any signs of degradation (cracks, abrasions, leaks...). Do not use the probe if it shows signs of deterioration.

Only use accessories provided by echOpen Factory. The use of accessories (cables, chargers, etc.) other than those specified or supplied by the manufacturer can lead to malfunctions of the device.

Do not use the echOpen ON application (echOpen ON app) on a mobile device that does not meet the minimum requirements specified in this manual otherwise performance and quality of the image may be affected (see 10.1. Mobile device requirements). The list of compatible mobile devices is available online: www.echopenfactory.com/support/O1/compatibility.



Using third-party applications on the same mobile device as echOpen ON app can affect the performance of the application. If so, it is recommended to install the echOpen ON application on a dedicated mobile device.

In case of malfunction of the mobile device, the user must follow a suitable medical examination protocol without ultrasound examination.

The echOpen O1 device is not compatible with magnetic resonance. It may cause unacceptable risks to the patient, medical staff or anyone else present in the magnetic resonance environment.



The echOpen O1 device usage is alternating periods of 2 minutes with probe ON followed by periods of 15 minutes with probe OFF.

Only the probe nose and the usual ultrasound gel should come into direct contact with the patient's intact skin (see 3.1. Components of the device).

Do not leave the probe in contact with the patient's skin outside of the ultrasound examination.

Stop using the probe in the event of leakage, overheating, smelling or smoke. Contact the manufacturer and set aside the probe using adequate equipment pending the intervention of qualified personnel for inspection, testing and replacement of the device if necessary.

Do not allow any liquid to enter the probe. Any entering of liquid into the device can damage it and cause a risk of fire or electric shock.

Do not attempt to open the probe or manipulate the internal components of the device, including the battery, this may cause injury to the patient or user.

The use of damaged equipment or accessories may cause the device to malfunction and/or cause injury to the patient or user. Entrust maintenance to qualified staff.

No changes are allowed. Do not modify cables, cases, batteries, probes, chargers or specified accessories to be used with the echOpen O1 device. Any changes to the equipment may cause the system to malfunction or cause injury to the patient or operator.

2.3. Use environment safety



Do not use the probe in the presence of flammable gases or anesthetics or near a source of heat or fire.



Portable and mobile radio frequency (RF) communication devices can affect medical electro devices. Do not use RF communication devices within 30 cm of any part of the echOpen O1 device, including accessories provided by the manufacturer to avoid device degradation.

2.4. Electrical safety



Do not use the device if the charger is connected to it. The use of the probe connected to its charger can cause electric shock.

The probe nose only can be immersed (see 6.1. Cleaning and disinfection, figure 12). Do not submerge or spray the entire probe. Immersion or sprinkling can cause electric shock.

Always inspect the probe before and after each cleaning, disinfection or use to detect any signs of deterioration (cracks, abrasions, leaks...). To avoid the risk of electrical hazards, do not use the probe if it shows signs of deterioration.

Always inspect the charger before use. Do not use in case of signs of degradation. The use of a damaged charger can cause electrical shock.

The operation of the echOpen O1 device implies the presence of high voltages. No parts should be repaired by the user. Do not attempt to open the probe case. Do not handle the probe if the case is broken. Contact the manufacturer and set aside the probe using adequate equipment pending the intervention of qualified personnel for inspection, testing and replacement of the device if necessary.



The use of accessories (cables, chargers, etc.) other than those specified or supplied by the manufacturer may lead to an increase in electromagnetic emissions or a decrease in electromagnetic immunity of the equipment and cause the device to malfunction.

2.5. Security in case of defibrillation



Remove all items in contact with the patient before applying a high voltage defibrillation pulse.

Single-use probe protection does not protect against defibrillation.

2.6. Equipment protection



The probe must be cleaned and disinfected **IN BETWEEN** each use with the appropriate detergent according to the maintenance procedures specified in this manual (see 6.1. Cleaning and disinfection).

Immediately stop using the echOpen O1 device in the event of a fall. Inspect the probe for signs of deterioration and visually check for sharp edges.

Do not use the probe if it shows signs of deterioration.

Do not use the probe outside of the environmental operating conditions specified in this manual (see 10.4. Environmental operating and storage conditions).



Between each use, store the probe safe from danger, **contamination** and damage for example:

- In a space dedicated to storage
- In the user's pocket or bag

Do not store the probe in full sunlight, in places that are too hot or too cold.

Do not store the probe outside the environmental storage conditions specified in this manual (see 10.4. Environmental operating and storage conditions).

To avoid any risk of loss and deterioration, it is recommended to store the charger safely and close to the probe.

2.7. Biological safety



Always apply the ALARA principle (As Low As Reasonably Achievable) for ultrasound exposure on each examination although the echOpen O1 probes do not at any time deliver dangerous ultrasound levels in normal use (see 1.6. Benefits and risks of the device).

Always inspect the probe before and after each cleaning, disinfection or use to detect any signs of degradation (cracks, abrasions, leaks...). Do not use the probe if it shows signs of deterioration.

Only the probe nose and the usual ultrasound gel should come into direct contact with the patient's intact skin (see 3.1. Components of the device, Figure 1).

Do not leave the probe in contact with the patient's skin outside of the ultrasound examination.

The probe is not intended for use in a sterile environment or in contact with non-intact skin or mucous membranes. Following information is given for informational purpose only.

Protect the probe with an adapted single-use protection such as KRYSTAL COVER™ - SUPERFICIAL PROBES PROTECTION (ref. PE1830) or Scanning Cover Varay Laborix (ref. PDS5080) if the device is susceptible to be in contact with non-intact skin or mucous membranes.

If the echOpen O1 device is used in a sterile environment, it is recommended to use single-use ultrasound gel. Follow the protocol of the user's institution and/or the instructions provided with the gel.

2.8. Operator safety



The user must follow the procedures in place in his institution regarding Personal Protection Equipment (PPE) and infection prevention.



In particular, it is recommended to wear gloves when using the echOpen O1 device to avoid contamination.

The user must follow the hand cleaning recommendations in place in his institution **between** each use of the echOpen O1 device.

Prolonged use of the device in a non-ergonomic position can cause fatigue and tension in the user's hands, arms and neck.

2.9. Patient data protection



The user of the echOpen O1 device has the duty to inform the patient and to ensure patient consent before any use of the echOpen O1 device resulting in recording of patient data.

The user of the echOpen O1 device is the only one held responsible in case of data sharing. It is recommended that the user refer to the regulations in force in his country. For European Union country members, refer to Regulation (EU) 2016/679 (General Data Protection Regulation).

It is recommended that you protect patient data by encrypting your personal mobile device thanks to a password or passcode.

echOpen ON application itself is equipped with ID, password or PIN authentication. To ensure strong authentication, your password must contain a minimum of 12 characters, including at least one uppercase, one lowercase, and one digit.

To ensure better protection of patient data, the echOpen ON application disconnects after 15 minutes of inactivity, so it is necessary to enter your PIN again to access it.

3. Introducing the echOpen O1 device and accessories

3.1. Components

The echOpen O1 device is a handheld ultrasound imaging device intended for point of care ultrasound. It consists of several elements:

- The echOpen O1 ultrasound probe;
- The echOpen ON app;
- The battery charger.

The use of echOpen O1 device requires a mobile device (typically a smartphone).

The probe and charger are supplied with the echOpen O1 device. Before any use, be sure to identify each element of the device and verify that all the elements are present.

Probe

The echOpen O1 device includes a three-frequency probe to be used with the dedicated echOpen ON application.

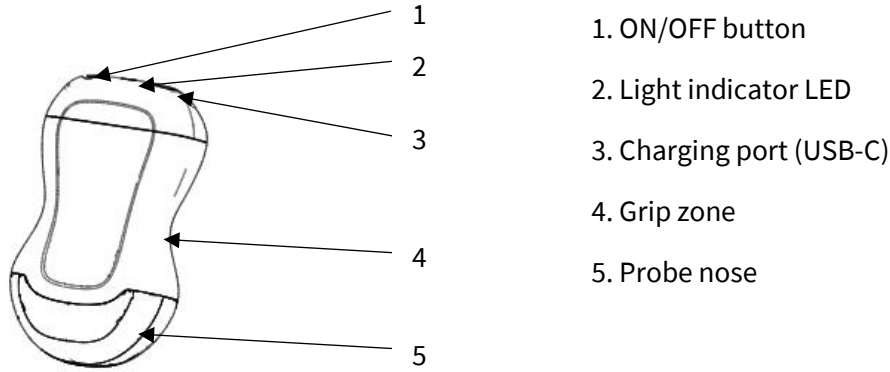


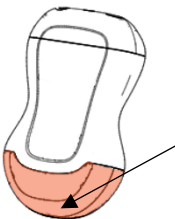
Figure 1 : echOpen O1 probe

Applied parts

Applied parts refer to the parts of the echOpen O1 device which come into physical contact with the patient in order for the device to carry out its intended functions. These are applied parts of type BF (isolated patient connection).



Only the probe nose and the usual ultrasound gel should come into direct contact with the patient's intact skin.



Probe nose: direct contact with patient's skin

Mobile device

The mobile device (typically a smartphone) is used to display images acquired by the probe. A Wi-Fi connection, generated by the echOpen O1 probe, is used for communication between the mobile device and the probe.



Using third-party applications on the same mobile device can affect the performance of the echOpen ON app. If so, it is recommended to install the echOpen ON application on a dedicated mobile device.

In the event of malfunction of the mobile device, the user must resort to a suitable medical examination without ultrasound examination.



You can place your mobile device on a stand for better grip during the exam.

If you answer a phone call on your mobile device during a consultation, your consultation ends and your media are saved.

echOpen ON application

The echOpen ON application allows you to control your consultations and visualize organs and tissues of the human body.

The echOpen ON app is downloadable from Google Play store and Apple App store or any other controlled broadcasting system used by your organization. It is necessary to create a personal echOpen account to be able to connect to the application.



Do not use the echOpen ON app on a mobile device that does not meet the minimum requirements specified in this manual or risk affecting the performance and quality of the image (see 10.1. Mobile device requirements). The list of compatible mobile devices is available online: www.echopenfactory.com/support/O1/compatibility.

Probe battery charger

The battery charger is used to charge the probe's battery.

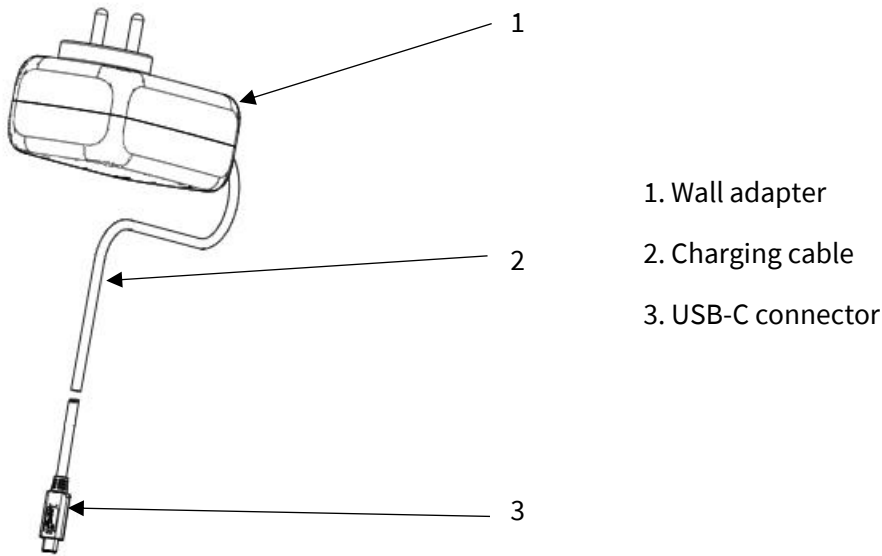


Figure 2 : Probe battery charger



Always inspect the charger before use. Do not use in case of signs of degradation. The use of a damaged charger can cause electrical shock.

Use only the charger supplied with the probe by the manufacturer.

3.2. Internet connectivity

No internet connection is required during the consultation.



Once the echOpen ON app is connected to the probe, your mobile device disconnects from WiFi network or mobile data because the connection between the probe and the device use a Wi-Fi connection generated by the probe.

If your facility uses WiFi-connected devices for emergency communications, it is recommended not to use this device for the echOpen ON application. When the probe is connected to the mobile device no emergency communication connected to the WiFi network can be received.



An Internet connection is required to download the echOpen ON app and install updates.

It is necessary to connect the application to the Internet at least every 90 days to ensure that it has the latest security updates.

4. Start and set up of the echOpen OI device

4.1. Charging the probe



It is imperative to unplug the probe from its charger before any use. The use of the probe connected to its charger can cause electric shock.

Use only accessories provided by echOpen. The use of accessories (cables, chargers, etc.) other than those specified or supplied by the manufacturer can lead to malfunctions.

Always inspect the probe before recharging to detect any signs of degradation (cracks, abrasions, leaks...). Do not recharge the probe if it shows signs of deterioration.



In order to keep the probe sufficiently charged, it is recommended to recharge it at the end of each day of use.

To recharge the probe:

1. Connect the provided charger to the probe's USB C port.
2. Plug the wall adaptor at the other end of the charger into a power outlet.
3. The probe's LED light turns orange to indicate that the probe is charging. Charge the probe until the light turns green.

4.2. Checking the probe's battery level

To check the probe's battery level while charging:

When the probe is connected to the charger, the color of the probe's light indicates if the battery is charged.

Loading level	Color of the LED light	Profile of the light indicator
Battery is charging (0-99%)	Orange	Continuous
Battery is charged (99-100%)	Green	Continuous

To check the probe's battery level using the echOpen ON app:

Once the probe is connected to the echOpen ON app, its battery level appears on the home screen in the **My Probe** section as shown on Figure 3.a.

During the consultation, the probe's battery level is displayed at the top left of the screen (Figure 3.b).

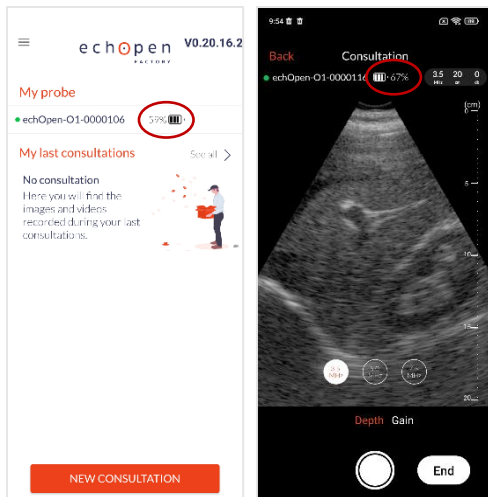


Figure 3.a (on the left): Battery level - Home screen

Figure 3.b (on the right): Battery level - While scanning



If the battery level is too low, it is sometimes necessary to recharge the probe before starting a new consultation.

If the probe's battery level is below 2%, the probe automatically shuts down.

4.3. Creating an echOpen account

Before using the echOpen O1 device it is necessary to create your personal echOpen account by going to the following address www.echopenfactory.com/account. Your account ID and password will allow you to access all echOpen services. You can change your password anytime by clicking on "Forgot password" on the screen.

4.4. echOpen ON app download and installation

The echOpen ON app can be downloaded from the Apple App Store or Google Play Store from your mobile device. To do this go to the store compatible with your device and enter «echOpen ON» in the search field to download and install the application.

4.5. First connection



Please make sure to fully charge your probe before the first use.

It is necessary to pair your probe with your echOpen ON app when you first log in. This step is required only once per probe. The application remembers the already paired probes for future uses.

1. Open the echOpen ON app
2. Login using your echOpen account's login and password (see 4.3. Creating an echOpen account)
3. Set up your PIN and/or biometric authentication

- Set your mobile device's luminosity. The calibration screen is displayed at your first connection, adjust the screen brightness from your mobile device settings to best distinguish the 16 different shades of gray (Figure 4).



Figure 4: Grey level calibration

- Turn on the probe after you've charged it by pressing the ON/OFF button
- Pair the probe and echOpen ON app by scanning the probe's flash code on the label (Figure 5). If you can't match your probe by scanning the flash code, you can pair it manually (see 4.7. Manage my probes). Geolocation must be enabled at pairing to allow Wi-Fi connection between the probe and the app. Make sure geolocation is turned on.

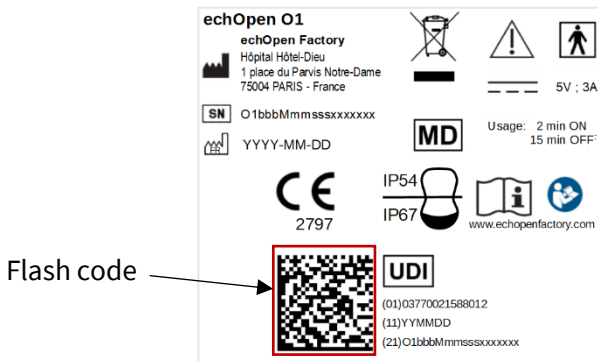


Figure 5: Label



Make sure you can visualize the 16 grey levels on the calibration screen before starting your consultation. Do not use echOpen O1 device if this is not the case.

Poor grayscale calibration can affect the performance of the device. If you have any doubts about the rendering quality of your screen, you can find the calibration screen in the app **Settings**.

4.6. Change your PIN - My Account

You can change your PIN from the **My Account** tab on the main menu.

The **My Account** tab also shows your echOpen account information.

4.7. Manage my probes

For more information on the probes you've already used, press the **My Probes** tab.

If a probe is connected to the echOpen ON app you will be able to view its battery level, the state of the WiFi connection and access its identifying SSID by clicking on the information icon.

The **My Probes** menu also allows you to view the list of probes already paired with your app.

Delete a probe from the list

To delete a probe from the list of probes already paired with your app, click on the information icon of the corresponding probe in the **My probes** menu.

Click **FORGET THE PROBE**.

Manual pairing

If you can't pair your probe to the app by scanning the slash code, click the **MANUAL ENTRY** button at the bottom of the pairing screen.

Enter your probe's UDI displayed at the back of your probe (next to the flash code on the right) and click **PAIR**.

4.8. Changing the language

To change the language of the app, select the **Language** tab. There you can choose your preferred language from the list.

4.9. Disconnect from echOpen ON application

To log out of the app, click the **DISCONNECT** button. The app then logs out of your echOpen account and you'll need to re-enter your login and password at your next connection.

4.10. Managing updates to the echOpen ON app



The echOpen ON app needs to be updated on a regular basis. An internet connection is required to install the latest update of the echOpen ON app.

To ensure optimal and secure use of the echOpen ON app, you are responsible of updating the mobile device's OS on a regular basis, at least once a month.

Updates to the echOpen ON app are available from the Apple App Store or Google Play Store.

You can set up automatic or manual updates to the echOpen ON app from your mobile device settings.

If your mobile device is configured to automatically update its apps, the echOpen ON app will update automatically each time a new update becomes available.

If you've chosen manual updates, you'll need to regularly install new updates to the app from Apple's App Store or Google Play Store.

5. Use of the echOpen O1 device

5.1. Precautions before use

For every use, make sure:

- That your probe is charged
- That your mobile device is charged, if your mobile device's battery is too low, it may shut down during the exam
- Of the presence of ultrasound gel

5.2. New consultation

1. Turn on the probe
2. Open echOpen ON app and connect
3. If it's the first connection with your probe, pair the probe and echOpen ON app (see 4.5. First connection).
4. Click on the NEW CONSULTATION button at the bottom of the home screen to start the ultrasound examination (Figure 6).
5. The exam starts automatically with a set of default settings that you can change during the consultation.



Figure 6 : Home screen

5.3. Settings



At the beginning of the consultation, always start the ultrasound examination by identifying a recognizable anatomical structure to ensure the quality of the image displayed. If no anatomical structure can be recognized, stop the examination.

Depth



Figure 7: Depth setting

To set the depth you can change your probe frequency and adjust the depth of the displayed image.

Select the **Depth** setting at the bottom of the screen:

1. Select the frequency of your choice (3,5 MHz ; 5 MHz ; 7,5 MHz). Depth is inversely proportional to the probe's frequency
2. Adjust the display depth by sliding vertically on the screen. The entire screen surface can be used to adjust the depth of the displayed image.

Gain



Figure 8: Gain setting

You can also adjust the gain. Select the Gain setting at the bottom of the screen, a lateral slider appears on the screen. You can adjust the gain by sliding vertically on the screen. The entire screen surface can be used to adjust the gain.

5.4. Creating images and video loops

Images

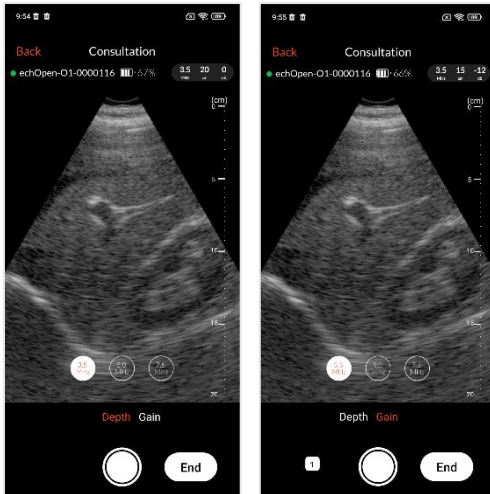



Figure 9: Image

Press the button  once to save an image. A sticker appears at the left bottom of the screen to display the number of saved media during the consultation.

Video loops

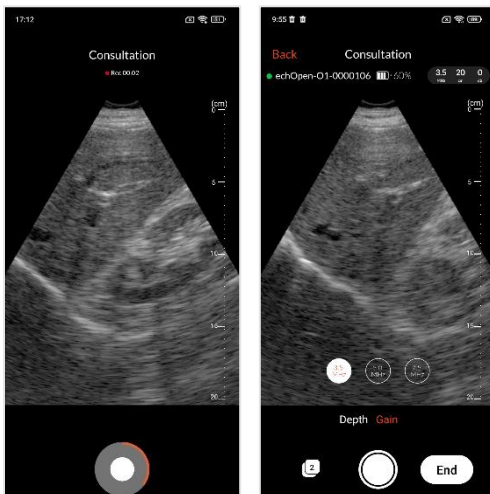


Figure 10: Video Loop

Hold the button  to record a 5 sec video loop.

5.5. End the consultation

Press the **END** button at the bottom right of the screen to end the consultation.

If you saved any media during the consultation you will be able preview all recorded media and enter patient information before ending the consultation. You can also delete a media by clicking once on the delete button at the right upper corner of the image.

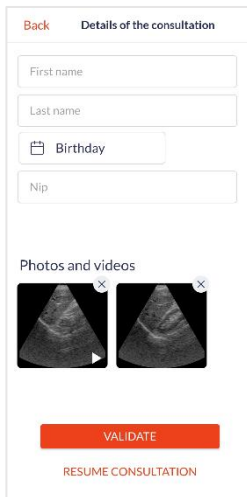


Figure 11: End of consultation

Patient information are not required to save the consultation.

If you didn't save any media you will be directly redirected to the home screen.



Your probe automatically disconnects from the application at the end of the consultation to allow the synchronization of your media with the echOpen platform. The synchronization stops automatically when you start a new consultation and resume next time you open the app while connected to internet.

An internet connection is required for synchronization, you can choose your backup preferences (Wifi, Mobile Data) in the **Settings** of the application. If you don't have access to an internet connection at the time of the consultation, synchronization will automatically start the next time you open the app while connected to internet.

Don't forget to turn off the probe after each use.

5.6. Adding information



Adding information to your consultations in echOpen ON app is no substitute for the patient follow-up protocol in your facility.

You can also add patient information later when selecting the consultation in your gallery.

To add information from your gallery:

Go to the **Gallery** tab. Once in the gallery, you can select the consultation in question and click on **MODIFY**. You'll then have access to the same features as at the **End Of Consultation** screen (5.5. End the consultation).

5.7. View my consultations

To view your previous consultations, go to the **Gallery** tab from the main menu. You can also access your latest consultations directly from the home screen.

All personal and medical recorded information in the echOpen ON app is encrypted and only viewable by the user using his personal password-protected account.

Gallery

Once in your gallery, you can choose to display your media by **FILES** or by **PHOTOS**.

The **FILES** view will give you access to your images and videos grouped by consultation. You will also be able to access and edit the added information. The consultations are sorted from the most recent to the oldest.

The **PHOTOS** view lets you view all your images and videos sorted by date.

Your images and videos remain available for 90 days in the echOpen ON app. Beyond this retention period the media are deleted from the application. Be sure to sync your media with the echOpen platform before it is deleted.

The synchronization is automatic at the end of the consultation if you have an internet connection. You can choose your backup preferences (Wifi, Mobile Data) in the App **Settings**. If you don't have access to an internet connection at the time of the consultation, synchronization will automatically start the next time you open the app while connected to internet.

6. Maintenance of the echOpen O1 device

6.1. Cleaning and disinfection



It is your responsibility to appropriately clean and disinfect your mobile device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.

It is essential to disinfect the probe echOpen O1 **IN BETWEEN** each use.

The probe nose only can be immersed (see figure 12 below). Do not submerge or spray or clean/disinfect the entire probe or charger. Immersion or sprinkling can cause electric shock.

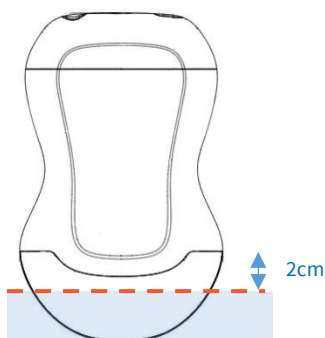


Figure 12 : Immersion limit of echOpen O1 probe

The cleaning and disinfection classification depends on the type of tissue the echOpen O1 probe comes into contact with according to the Spaulding classification. Refer to Table 1 to determine the appropriate [cleaning and disinfection level](#).

Table 1 : Spaulding classification

Class	Usage	Cleaning and disinfection
Non-critical class	In contact with intact skin	Followed Intermediate-Level Disinfection (ILD)

Cleaning of the probe

It is essential to remove any traces of ultrasound gel or other particles before proceeding with the disinfection of the probe.

1. Make sure the probe is turned off and disconnected from the charger before you start cleaning.
2. Remove the gel using lint-free cloth.
3. Clean the probe nose with soapy water until the probe is visibly clean and rinse with water.
4. Dry the probe with a lint-free cloth.
5. Visually inspect the probe to ensure all surfaces are clean, Repeat the operation if necessary.

Intermediate Level Disinfection

It is recommended that you use Super Sani-Cloth® Wipes by the sponsor.

1. Clean the probe nose with soapy water and rinse abundantly with water.
2. Dry the probe with a lint-free cloth.
3. Clean the probe with disinfecting wipes (Super Sani-Cloth® Wipes) and leave it on for 2 minutes.
4. Dry at room temperature.
5. Rinse carefully with a water-soaked lint-free cloth then rinse abundantly with water.
6. Dry the probe with a lint-free cloth.

6.2. Device Storage

Between each use, store the probe and charger safe from danger, [contamination](#) and damage for example:

- In a space dedicated to storage.
- In the user's pocket or bag.



Do not store the probe in full sun or in places that are too hot or too cold or too humid.

Do not store the probe outside the environmental storage conditions specified in this manual (see 10.4. Environmental operating and storage conditions).

To avoid any risk of loss, it is recommended to store the charger near the probe.

7. Recycling and disposal

The echOpen O1 device is part of the 2002/96/EEC Directive on Electrical and Electronic Equipment Waste (EEE) and national legislation.



At the end of its life, the echOpen O1 device should be disposed in specifically authorized processing facilities and should not be disposed as unsorted municipal waste.



The echOpen O1 device complies with the RoHS Directive 2011/65/EU on limiting the use of certain hazardous substances in electrical and electronic equipment and the EU REACH regulation to protect human health and environment from chemical risks.

8. Troubleshooting



Stop using the probe in case of leakage, overheating, selling, irregular noise or smoke.

Do not use the probe if it shows signs of deterioration. The use of damaged equipment or accessories can cause the malfunction of the device and/or cause injury to the patient or user.

Do not attempt to open the probe or manipulate the internal components of the device, including the battery, otherwise the patient or the operator may be injured.

No parts should be repaired by the user. Do not attempt to open the probe case. Entrust maintenance to qualified staff. Do not handle the probe if the case is broken.

Table 2 lists the most common problems and their resolution. If you can't solve the problem, contact our support (see 9. echOpen support).

Table 2 : Troubleshooting

Frequent problems	Cause	Solution
First use		
The app refuses to install on my mobile device	Your mobile device or your version of Android/iOS is incompatible with the app	See the device compatibility list online: www.echopenfactory.com/support/O1/compatibility and section 10.1. Mobile device requirements or contact support
The app asks for an ID and password. I don't know	To use the app, you need to have created an echOpen account	Go to www.echopenfactory.com/account to create your account
		If you forgot your password, you can create a new one. Click on "Forgot password" when login in the application.
The app starts and stops immediately	There is an incompatibility between your mobile device and the app	Contact support
	A third-party app affects how the echOpen ON app works	Close all other open apps on your mobile device
My mobile device fails to read the flash code	Unreadable flash code	Pair the probe manually (see 4.6. Manage my probes)
	Faulty photo module	Make sure the photo module lens is clean. If this persists, pair the probe manually (see 4.6. Manage my probes)
App start		
I can no longer start the app, either with my PIN or with my echOpen ID/password	Your IDs have not been validated for too long	Turn on your internet connection and restart the app
Starting and connecting the probe		
The probe does not start	Battery discharged	Recharge the probe before starting it again
The probe's light indicator flashes red	Overheated probe	Stop the probe and place it in a cool place to let it cool down for a few minutes
	Internal error	- Turn off the probe for a few moments - Restart the probe - Contact support if the outage continues
	Wi-Fi is disabled	Turn on Wi-Fi on your mobile device and try again

The app fails to connect to the probe	Location is disabled	Geolocation must be enabled to allow Wi-Fi connection between the probe and the app. Make sure geolocation is turned on.
	The probe shut down because it took you too long to connect	Restart the probe and try again
The app had connected successfully but the probe just disconnected and shut down	The probe shut down because it remained inactive for too long	Restart the probe and the app should reconnect after a few seconds
During the exam		
The probe has stopped during examination or the probe refuses to launch a new examination	Insufficient battery	Recharge the probe before starting a new exam
	The temperature of the probe nose is too high	Stop the probe and place it in a cool place to let it cool down for a few minutes
The probe shuts down	Empty battery	Recharge the probe before restarting it
The image quality is poor and has random vertical stripes	There's a Wi-Fi communication problem	Bring the probe closer to the mobile device
		Move to a place less prone to electromagnetic disturbance
The image quality is poor and you have difficulty perceiving the organs	There may be poor contact between the probe nose and the patient's skin.	Add ultrasound gel or use appropriate ultrasound gel
	Manual settings are incorrect	Adjust the manual settings
The image suddenly shifted sideways	There has been a shift in the internal mechanism, possibly due to a shock on the probe.	Stop the consultation or restart the probe completely before launching a new consultation, the image should then be centered. If the problem persists, contact support
Media management		
I can't find the recorded media	The mobile device could not save them due to a lack of space	Free up storage space on your mobile device
	For data protection reasons, the app must remove stored media after a certain time	Your synchronized media are stored on the echOpen platform

I can't transfer my media to the echOpen platform	You need to be connected to the internet when the app is launched so that your media is automatically transferred to the platform	<ul style="list-style-type: none"> - Check that the probe is disconnected - Check your internet connection, syncing should start automatically
Recharging		
The probe's luminous indicator remains orange and never goes green	Damaged battery	Contact support
The probe heats up abnormally	Damaged battery	Unplug the charger and place the probe on a cold, non-combustible surface such as tile. Contact the support.
The probe does not start	For safety reasons, it is not possible to use the probe while charging	<ul style="list-style-type: none"> - Wait for the charging to finish - Unplug the probe - Turn on the probe
Other alerts and messages from the app		
Probe error Probe encounters an error. Please restart the probe and start a new consultation.	The probe encounters a technical issue	Stop the probe for a few minutes before turning it back on and starting a new consultation. If the error persists, please contact support.
The probe has experience abnormal heating. Please turn it off and wait few minutes before starting a new consultation.	Probe's temperature is too high OR Chip's temperature is too high	Stop the probe and place it in a cool place to let it cool down for a few minutes
Probe connection is not optimal Please ensure your mobile device is not too far.	Poor communication quality between the probe and the echOpen ON app	Bring the probe closer to the mobile device
		Move to a place less prone to electromagnetic disturbance
Probe cannot be found Make sure that your probe is turned on and paired to your mobile app	Communication between the probe and the echOpen ON app is lost	Bring the probe closer to the mobile device
		Move to a place less prone to electromagnetic disturbance
Low battery	Probe battery status goes below	The probe might stop during consultation. Recharge the probe before starting it again.

Please recharge your probe.	2% during a consultation	
Low battery Please recharge your probe before starting a new consultation.	Probe battery status goes below 2%	Probe battery status is too low to start a new consultation. Recharge the probe before starting it again.
Cannot start a consultation, probe is charging	The charger is connected to the probe	For safety reasons, it is not possible to use the probe during charging. Unplug the charger before starting a new consultation or wait until charging is complete.
Impossible operation, the probe is charging	The consultation stops automatically because the charger is plugged in during the consultation	For safety reasons, it is not possible to use the probe during charging. Unplug the charger before starting a new consultation or wait until charging is complete.
Media retention period is expiring Please ensure internet connection to synchronize your media	Media haven't been transferred to the platform	- Check that the probe is disconnected - Check your internet connection, syncing should start automatically
Disk full? Your disk is full, we could not record this media. Please free some space on your smartphone	There is not enough space in the storage space of your mobile device to record your consultation.	If you want to save your consultation, free up space on your mobile device.
Deletion of media during backup? Deletion of media not allowed while backup is in progress.	You are deleting media while synchronization is in progress.	Wait for the synchronization to complete before deleting the media.
Location Please enable and grant location permission to connect to the probe.	Location is disabled	Geolocation must be enabled to allow Wi-Fi connection between the probe and the app. Make sure geolocation is turned on.
Enable Wifi Please activate your mobile device's WiFi.	Wi-Fi is disabled	Turn on Wi-Fi on your mobile device and try again
Downloaded	The user manual has been	You can now consult the user manual at any time from the Downloads file of your mobile device.

User manual has been successfully downloaded in Downloads file	downloaded to your mobile device	
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9. echOpen support

Get assistance by contacting our echOpen support service:

Email address: support@echopenfactory.com

Get support from the echOpen ON app:

Go to the **Help** tab of the echOpen ON app:

- If you have a problem or a question, click on the **FAQ** tab.
- If you can't find the solution to your problem, send us a message by clicking on the **Report an issue** tab.

10. Technical features of the echOpen O1 device and accessories

10.1. Mobile device requirements



Do not use the echOpen ON application on a mobile device that does not meet the minimum requirements specified below or risk affecting the performance and quality of the image.

Registered media being viewed are temporarily stored in your app. Make sure you keep enough space in the storage space of your personal mobile device.

The echOpen ON application works on a large number of Android and iOS devices:

- Devices running iOS must run iOS 12.0 or a higher version;
- Android devices must run the Android 9.0 version or a higher version.

The list of compatible mobile devices is updated on our website www.echopenfactory.com/support/O1/compatibility.

10.2. Technical features of the echOpen O1 device and echOpen ON application

Table 3 : Technical features of echOpen O1 device

echOpen O1 probe characteristics	
Probe Dimensions	Approx. 161x99x47 mm
Probe Weight	Approx. 400g
Power supply	Li-ion battery (rechargeable)
Battery characteristics	7.2 V / 3200 mAh ; 23.04 Wh

Battery life	≥ 1 hour in scan mode; ≥ 8 hours without acquisition
Recharge	Port USB-C ; 5V@1A
Transducers / Frequencies	3 transducers (3.5 MHz, 5 MHz, 7.5MHz)
Expected life-time	Each echOpen O1 device has an expected life-time of five (5) years. Expected life-time is based on a use frequency of 210 days/year and 30 scan cycles per day.
echOpen ON app characteristics	
Languages	French, English
Maximum display depth	
3.5 MHz	250 mm
5 MHz	130 mm
7.5 MHz	60 mm
Operating system	Devices running iOS must run iOS 12.0 or a higher version Android devices must run the Android 9.0 version or a higher version

10.3. Probe battery charger

Table 4 : Technical feature of the charger

Technical characteristics	
Manufacturer	CINCON ELECTRONICS CO,LTD
Model	TR18RDM050
Input voltage	80 - 264VAC
Output voltage	5V / 3A
Output interface	USB-C
Efficiency	81.84%
Protection	Surge protection; Protection from continuous short-circuiting
Dimensions	80.40 x 43.00 X 36.90 mm
Cable length	≥ 1800 mm
Weight	115g

10.4. Environmental operating and storage conditions

Table 5 : Environnemental operating and storage conditions

	Operating limits	Transportation and storage limits
Temperature	+10°C to +40°C	-20°C to +50°C
Humidity	30% to 90%	30% to 90%
Atmospheric pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Immersion*	75 mm	75 mm
* Only the probe nose can be immersed as shown on the figure 12 (see 6.1. Cleaning and disinfection).		

10.5. Electromagnetic compatibility (ECM)

The echOpen O1 device should be used in the electromagnetic environments specified in the tables below. The use of the device in an environment that does not meet these conditions can degrade the performance of the device.



The use of accessories (cables, chargers, etc.) other than those specified or supplied by the manufacturer can lead to an increase in electromagnetic emissions or a decrease in the electromagnetic immunity of the equipment and cause malfunction of the device.

Table 6 : Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment
Radio frequency emissions, CISPR11 EN55011	Group 1	The system uses RF energy for its internal function and for wireless communication in the ISM bands. Therefore, its RF emissions outside the ISM bands are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency emissions, CISPR11 EN55011	Class B	The echOpen O1 device can be used in all establishments, including domestic ones and ones directly connected to the public low-voltage power grid that powers residential buildings.
Harmonic Emissions, IEC 61000-3-2	Non applicable (no limit for P<75W)	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Non applicable (not likely to produce significant voltage fluctuation and flicker, therefore it is compliant without measurement)	

Table 7 : Electromagnetic immunity

Immunity test	Test Level IEC 60601-1-2	Compliance level
Electrostatic discharge EN/IEC 61000-4 -2	+/- 8kV contact +/- 2kV, +/- 4kV, +/- 8kV, +/- 15kV air	+/- 8kV contact +/- 2kV, +/- 4kV, +/- 8kV, +/- 15kV air
Radiated RF IEC 61000-4-3	3V/m 80MHz - 2.7GHz 9 à 28V/m 80MHz - 6GHz	3V/m 80MHz - 1GHz 9 à 28V/m 80MHz - 1GHz
Transitional Electrical rapid salvos EN/IEC 61000-4-4	2kV Freq 5kHz 2kV Freq 100kHz	2kV Freq 5kHz 2kV Freq 100kHz
Conducted RF 61000-4-6	3Veff 150kHz à 80MHz	3Veff 150kHz à 80MHz
Network frequency Magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m@50Hz	30 A/m@50Hz
Tension hollows/interruptions in charging mode EN/IEC 61000-4-11	0% 10ms 0% 20ms 70% 500ms 0% 5s	0% 10ms 0% 20ms 70% 500ms 0% 5s

10.6. Separation distances



Portable and mobile radio frequency (RF) communication devices can affect medical electro devices. The echOpen O1 device must be used in an electromagnetic environment where radiated RF disturbances are controlled.

Respect the recommended separation distance when you use portable and mobile radio frequency (RF) communication devices. Check that the field intensities of fixed RF transmitters, as determined by an electromagnetic site study, are below the compliance level in each frequency range, as shown in table 8.

The table below shows the recommended separation distances for the echOpen O1 device to be kept away from any radio frequency-transmitting equipment.

Table 8 : Recommended Separation Distances by Emission Frequency

Maximum rated transmitter output (W)	150 kHz to 80 MHz	80 to 800 MHz	800 MHz to 2.5 GHz
0,01	0.35 m	0.12 m	0.23 m
0,1	1.1 m	0.38 m	0.73 m
1	3.5 m	1.2 m	2.3 m
10	11 m	3.8 m	7.3 m
100	35 m	12 m	23 m

Ultrasound scanners can be sensitive to RF interference in the probe bandwidth.

10.7. Acoustic emissions

Thermal and mechanical indexes are under 1.0 for all device settings.

Table 9 : Frequency 3.5MHz, Mode Bmode, 280V

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.58	0.33		0.69		0.69
Index component value				0.33	0.33	0.69	0.33	
Associated acoustic parameters	pr	(MPa)	1.04					
	W0	(mW)		53.4		53.4		53.4
	W1x1	(mW)		21.4		21.4		
	zs	(cm)			2.4			
	zb	(cm)					3.8	
	ZMI	(cm)	5.62					
	Zpii,a	(cm)	5.62					
	fawf	(MHz)	3.25	3.25		3.25		3.25
Other information	pr	(Hz)	1280(a)					
	srr	(Hz)	10					
	npps		1					
	lpa,a à Zpii,a	(W/cm ²)	887.6					
	lspta,a à Zpii,a	(mW/cm ²)	0.71					
	lspta,a à Zpii	(mW/cm ²)	2.56					
	Pr à Zpii	(MPa)	1.96					
b) The PRR value reported correspond to the product of the frame rate and the number of lines per frame, which is the maximum number of pulses fired per second in all directions								

Table 10 : Frequency 5MHz, Mode Bmode, 280V











Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.72	0.26		0.45		0.45
Index component value				0.26	0.26	0.45	0.26	
Associated acoustic parameters	pr	(MPa)	1.38					
	W0	(mW)		27.6		27.6		27.6
	W1x1	(mW)		10.9		10.9		
	zs	(cm)			1.52			
	zb	(cm)					2.76	
	ZMI	(cm)	3					
	Zpii,a	(cm)	3					
	fawf	(MHz)	4.95	4.59		4.59		4.59
Other information	pr	(Hz)	1280 ^(a)					
	srr	(Hz)	10					
	npps		1					
	lpa,a à Zpii,a	(W/cm ²)	1453					
	lspta,a à Zpii,a	(mW/cm ²)	0.81					
	lspta,a à Zpii	(mW/cm ²)	2.32					
	Pr à Zpii	(MPa)	2.59					
	b) The PRR value reported correspond to the product of the frame rate and the number of lines per frame, which is the maximum number of pulses fired per second in all directions							








Table 11 : Frequency 7,5MHz, Mode Bmode, 280V

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.72	0.22		0.24		0.24
Index component value				0.22	0.22	0.24	0.22	
Associated acoustic parameters	pr	(MPa)	1.99					
	W0	(mW)		16.6		16.6		16.6
	W1x1	(mW)		6.5		6.5		
	zs	(cm)			1.4			
	zb	(cm)					1.84	
	ZMI	(cm)	1.85					
	Zpii,a	(cm)	1.85					
	fawf	(MHz)	6.95	6.95		6.95		6.95
Other information	pr	(Hz)	1280 ^(a)					
	srr	(Hz)	10					
	npps		1					
	lpa,a à Zpii,a	(W/cm ²)	2070					
	lspta,a à Zpii,a	(mW/cm ²)	0.77					
	lspta,a à Zpii	(mW/cm ²)	1.93					
	Pr à Zpii	(MPa)	3.04					
	(a) The PRR value reported correspond to the product of the frame rate and the number of lines per frame, which is the maximum number of pulses fired per second in all directions							

11. Pictograms

Table 12 : Pictograms

Pictogram	Référence	Nom	Description
	ISO 7000 no. 3082	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 7000 no. 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 7000 no. 2498	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223 no. 5.7.10	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information This symbol shall be placed adjacent to the Unique Device Identifier carrier.
	ISO 7000 no. 2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 7000 no. 0434A	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000 no. 5031	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	ISO 7000 no. 5333	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	ISO 7000 no. 6414	WEEE; waste electrical and electronic equipment	To indicate that separate collection for waste electric and electronic equipment (WEEE) is required
	ISO 7010 no. M002	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read

	ISO 15223 no.5.4.3	Consult electronic instruction for use	Indicates the need for the user to consult the instructions for use online at www.echopenfactory.com
	ISO 15223 no. 5.7.7	Medical device	Indicates the item is a medical device
	EU 2017/745	European conformity	Meets the requirements of the European Regulation for Medical Devices.
	ASTM F2503-1	MR Unsafe	Indicates an object that poses an unacceptable risk to the patient, medical personnel, or any other person present in the magnetic resonance environment.
	ISO 15223 no.5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223 no.5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223 no.5.3.9	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.