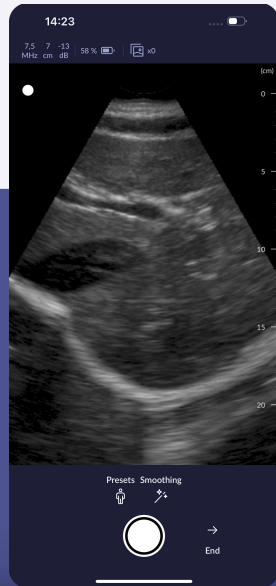


echopen



LAURÉAT 2025

PRIX GALIEN
echOpen O1

Data Sheet

echopen O1

echOpen O1 is a pocket-size Point-Of-Care Ultrasound (POCUS) probe that allows you to visualise the human body's main organs and anatomical structures.

echOpen O1 consists of a single probe head equipped with a triple-frequency transducer. You can adjust the ultrasound frequency depending on the depth of the organ you want to examine. echOpen O1's image quality allows for a high-impact diagnostic assessment and clinical orientation.

The probe connects wirelessly to your Android™ or iPhone™ smartphone and one

single battery charge allows you to perform several examinations throughout the day.

A robust and easy to maintain probe, echOpen O1 is intended to be carried in your pocket and to be used as a natural extension of your stethoscope and other diagnostic tools.

The echOpen On mobile app is your go-to POCUS companion and allows you to adjust your probe's settings. All echOpen O1 solutions are designed and manufactured in France. All data generated by the probe and within the mobile application is stored in Health Data Hosting-certified French servers.



Supported Mobile Platforms

- Android™ smartphones or tablets with OS Android™ 10.0 (or newer).
- iPhones™ or iPad™ with iOS™ 17.0 (or newer).
- The current recommended tested devices and current known incompatible devices are published at :
<https://echopenfactory.com/support/O1/compatibility>.

User Support Tools

- Educational resources are regularly published on the echOpen website, including webinars, thought leadership, video training sessions and information regarding upcoming events.

Operating conditions

Humidity:

- 10-90%

Water resistance:

- IP 54 (probe body), IP 67 (probe head)

Temperature:

- +10° to +40° C (examination mode), -20° to 50° (in storage)

Mobile application

echOpen O1 allows you to start a new POCUS examination in just a few clicks thanks to a user-friendly, minimalistic interface compatible with your Android™ or iPhone™ smartphone.

- Single-hand operable mobile application.
- Quickly pair a new probe by flashing a QR code.
- Automatically connects to the most recently used probe when starting a new examination.
- Simple gesture control of image depth and gain.
- Six presets to choose from to perform optimal examinations of different anatomical areas.
- Automatic archiving of images and video loops via Wifi or 4G.
- Save up to ten probes.
- Save ultrasound images and video loops with one single click.

Standard Configuration

The following items are included in the standard echOpen O1 offering:

- echOpen O1 POCUS probe
- echOpen On mobile application
- EU charger
- “Quick Start” leaflet



Data Security

- The mobile application systematically requires user authentication with every new launch.
- Optional PIN code authentication.
- Health data (image and video-based), user and patient data are stocked in a private smartphone folder that is not accessible by other mobile applications.
- Image data is automatically deleted from the smartphone after 90 days.
- TLS encryption of communications with the cloud-based data platform.
- Automatic blocking of the app after 15 minutes of user inactivity.
- Optional biometric authentication (fingerprint or face ID), depending on available smartphone quick authentication features.
- Encryption of all image and text-based user and patient data (Strong encryption: AES-256-GCM).
- Encryption of all Wifi communications with the probe (WPA2-PSK).
- Protection against malicious probe connection attempts (hidden SSID access point, single-use generated password for each probe).

Safety Conformance

- ISO 13485:2016 compliance
- EU Medical Device Regulations (RDM 2017/745) compliance
- IEC 60601-1 (electrical security) compliance IEC 60601-1-2 (electromagnetic compatibility) compliance IEC 60601-2-37 (ultrasonic emissions) compliance
- HDS-certified Cloud storage
- IEC 62304 (echOpen On) compliance
- Regulation (EU) 2016/679 (General Data Protection Regulation) compliance
- RoHS2 2011/65/EU compliance
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH, regulation 1907/2006) compliance
- CE mark (RDM 2017/745)
- echOpen O1 is a class IIa medical device.

Data Storage

- Patient identification: manual data entry.
- Standard format data storage: .jpeg (image), .mp4 (video)
- All images and videos saved by the user are accessible and viewable for the required length of time (cf. legal notices).



Probe Characteristics

Three ultrasound frequencies:

- 3.5 MHz, 5 MHz, and 7.5 MHz

Dimensions:

- 161 x 99 x 46 mm

Weight:

- ~400 g

Connectivity:

- Point-to-point Wifi that allows for the real-time broadcast of video

Battery:

- Li-ion 7.2 V; 3500 mAh; 25.2 Wh

Recharging:

- USB-C port; 5V@1A

Autonomy:

- ≥ 1 hour in examination mode

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Features

- Measurement accuracy

Axial direction: maximum error of ± 0.1 cm for measurements up to 3.3 cm; above 3.3 cm, maximum error of $\pm 3\%$ of the measured distance.

Lateral direction: maximum error of ± 0.25 cm for measurements up to 5.0 cm; above 5.0 cm, maximum error of $\pm 5\%$ of the measured distance.