User Manual

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ES-Series software version v2.1

English

This User Manual is also accessible from E-Scopics website at the following address:

https://www.e-scopics.com/hepatoscope-support

Correspondence & Shipping Address	Headquarter Address
E-Scopics S.A.S. 235 rue Leon Foucault 13100 Aix-en-Provence France	E-Scopics S.A.S. 931 chemin de la Bosque d'Antonelle 13090 Aix-en-Provence France

www.e-scopics.com

support@e-scopics.com

For safe and proper use, follow these instructions.

Keep them for future reference.

1 General information

1.1 Purpose of the User Manual

This User Manual has no contractual value whatsoever and under no circumstances may E-Scopics be held responsible on the basis of the information contained in this Manual.

This User Manual details all the information required for the implementation, use and maintenance of the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems.

After carefully reading this Manual, users shall be able to:

- Power up the Hepatoscope App,
- Configure the Hepatoscope App,
- Navigate the Hepatoscope App user interface,
- Perform basic maintenance.

E-Scopics publishes this manual "as is", without guarantees of any nature, whether explicit or implicit, including, but not limited to implicit guarantees or merchant conditions, or adaptation for specific use in view of providing simple and accurate information. Consequently, E-Scopics cannot accept any responsibility for any incorrect interpretation of the Manual.

Although all efforts have been made to offer a manual that is as accurate as possible, this manual may nevertheless contain some technical inaccuracies and/or typographical errors. E-Scopics cannot, under any circumstances, be held responsible for any loss of profit, loss of business, data loss, business interruption, or for any indirect, specific, accidental or consecutive damages of any type. In the event of damages arising from a defect (imperfection) or error contained in this User Manual, E-Scopics undertakes to send the physician, as rapidly as possible, a hard copy or electronic document containing all corrections made to this manual.

This manual shall be updated on a regular basis and is primarily available in pdf (electronic) format as part of the ES-Series V2 ultrasound diagnostic systems Software.

The most recent version of this manual is available as part of the Hepatoscope App Software and may be obtained from E-Scopics upon request. Should any major modifications be made to the manual, E-Scopics undertakes to send the physician, as rapidly as possible, a new copy of the manual in hard copy or electronic format. Note that this may or not involve updating the hardware and/or software in your possession.

The product owner must keep this manual for as long as the product is used.

This manual contains a chapter for troubleshooting the most commonly encountered problems.

Any information or modification requests pertaining to this manual should be sent to support@e-scopics.com.

1.2 Symbols used in the User Manual

	**INFORMATION FOR SAFETY** Read this information before using the medical device to avoid a potentially hazardous situation, which may result in minor or moderate injury to the user or the patient, or damage to the equipment, or to other property.
	**INFORMATION FOR SAFETY: CAUTION** Read instructions before using the medical device. Instructions preceded by this symbol are indicating a potentially hazardous situation, which, if not avoided, could result in serious injury, although deemed improbable.
	This symbol means: INFORMATION. Information preceded by this symbol indicates additional information with no impact on device use.
	This symbol means: RECOMMENDATION. Instructions preceded by this symbol are indicating a recommendation for optimal use of the device.

1.3 Property and Copyright

1.4 Guarantee

The terms of guarantee are stated in the E-Scopics terms of sale documents.
For any requests, E-Scopics is at the disposal of the physician and their assistants and shall, if necessary, pass the aforementioned request on to the competent local representative.

1.5 Liability

The information provided by the Hepatoscope App is the result of complex calculations performed by the software application. These results are then interpreted by the physician in charge. Under no circumstances, and even if E-Scopics had been notified, could E-Scopics be held responsible for the incorrect interpretation of these results, E-Scopics' liability being limited to making the measurements, displaying them and printing them via the Hepatoscope App.

Exam data are not saved on the Selected Host hard drive disk. The user is responsible for defining the destination of exam reports. E-Scopics cannot under any circumstances be held liable for the partial or total loss of E-Scopics data.

1.6 Essential Performance & Basic Safety characteristics

The Essential Performance of the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems is:

- To provide the user with exam outcome information resulting from operations that shall be free from noise on a waveform, or artefacts, or distortion in an image, or error of a displayed numerical value, which cannot be attributed to a physiological effect, and may alter the diagnosis, and
- To display numerical values associated with the diagnosis to be performed,
- While being free from the production of unintended or excessive ultrasound output, as well as unintended or excessive probe assembly surface temperature.

The Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems has been developed in order to ensure its safe use:

- Electrical safety: ensure the lowest risk possible of electrical shock for the user and the patient
- Thermal safety: ensure the lowest risk possible of skin burn for the user and the patient
- Mechanical safety: ensure the lowest risk possible of physical injury for the user and the patient
- Ultrasonic safety: ensure the lowest risk possible of excessive ultrasound transmission to the patient's body
- Security: ensure the lowest risk possible of exposure of the patient's personal data

In accordance with applicable standards, no residual risks other than negligible have been identified in the development process of the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems.

1.7 Reverse Engineering

The Hepatoscope App License is individual and cannot, under any circumstances, be transferred in any manner to a third party. This software cannot be distributed, reproduced, translated, disassembled,

decompiled, analyzed, modified, incorporated or combined with another software application, with the exception of cases allowed by law.
Resale of the software built into the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems is prohibited.

1.8 Registered Trademarks

E-Scopics and Hepatoscope are registered trademarks of E-Scopics.
Windows is a registered trademark of Microsoft Corporation in the United States and other countries.

1.9 Patented Technology

The Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems is covered by one or more patents, both in the United States and in other countries.

2 Information for Safety

2.1 Electrical Safety

	To avoid the risk of electrical shock, the Selected Host must be powered in compliance with local safety standards.

	Multi-socket adapters and extensions leads must not be used directly or indirectly with the Selected Host.

	All peripherals connected to signal input/output must be certified according to the IEC 60950-1 or IEC 62368-1 standards.

	Any parts, accessories or consumables not specified in the User Manual must not be connected or used with the system.

2.2 Electromagnetic safety

	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

	The use of the Hepatoscope App and the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, not in accordance with this User Manual may cause a non-compliance in terms of electromagnetic compatibility (EMC).

	Avoid using the Selected Host & Hepatoscope App when placed upon or near a machine or equipment that generates electromagnetic disturbances. In the improbable case of perturbation by electromagnetic fields, such as potential RFID sources closer than 15 cm, live B mode image quality, visible in all operating modes, will be degraded as an indication of poor operating conditions to the user.

	The Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, requires special precautions to be taken concerning electromagnetic compatibility (EMC). It must be installed and set up according to the EMC information given in this manual.

2.3 Using the Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems

	The temperature of the probe may become warm. Should this temperature become uncomfortable for the user or the patient, please stop using the probe, unplug it from the host and allow it to come back to room temperature. Please contact technical support at support@e-scopics.com.
	Approved ultrasound transmission gel must be used with the **e.C5-1** Probe and the Hepatoscope App to guarantee optimal acoustic beam transmission and reception.
	The Hepatoscope App using the **e.C5-1** Probe, must be used in a safe environment. Liquid contact should be minimized; liquid contact with the vibrator trap door (see Figure 5, nb 4) must be avoided.
	The **e.C5-1** Probe is IPX1 protection against ingress of water and particulate matter (IEC 60529) up to the vibrator trap door (see Figure 5, nb 4).
	Do not use lotion-based products, mineral oil, or water-based gels that contain mineral oil. Such products may damage the transducer and void the warranty. Do not use hand sanitizing gels.
	The **e.C5-1** Probe should not be left soaking in gel. Remaining gel shall be wiped after the exam is ended.

	Pour ultrasound gel on the patient skin at the location where the **e.C5-1** Probe will be positioned. It is NOT recommended to pour gel on the ultrasound acoustic head of the **e.C5-1** Probe to avoid mechanical shocks between the gel bottle and the acoustic head, which would possibly damage the **e.C5-1** Probe.
	Do not use USB extension cables nor hub to connect the **e.C5-1** Probe to the Selected Host.
	The **e.C5-1** Probe shall remain plugged to the Selected Host during an exam. Ensure a safe environment for the Selected Host to minimize risks of accidental probe unplugging.

2.4 Switching off the system

	Always shut down the application when not in use or when the system is not going to be used immediately after an examination.
	Never switch off the Selected Host or shut down the Hepatoscope App during an examination or whilst using the system.
	Failure to comply with these instructions may cause a malfunction of the system and/or loss of data.

2.5 Maintenance

	Daily maintenance by the user shall consist in visual inspection, cleaning & disinfection of the e.**C5-1** Probe.

2.6 Interpreting the results

	Results must only be interpreted by a physician specialized in liver diseases, who is aware of the patient's pathology and clinical context.

	The measurements of shear wave speed, ultrasound beam attenuation, backscattering coefficient, brightness ratio and speed of sound in the liver may be acquired by healthcare professionals of non-Medical Degree, under the supervision of an experienced physician specialized in liver disease management.

2.7 Reporting of serious incidents

	The user of the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic system, and the patient, shall report any serious incident that has occurred in relation to its use to E-Scopics (support@e-scopics.com) and the relevant Competent Authority.

2.8 Information for security

2.8.1 General

	Follow all security and cybersecurity policies of your institution. If you do not know what these policies are, contact your information technology (IT) department.

	When entering data using the Hepatoscope software, it is your responsibility to protect your security credentials (e.g., passwords) and the personal information of patients (e.g., names).

2.8.2 Network Security

	For information on setting up your wireless network security, refer to your network equipment’s documentation.

	The following actions could introduce new risks to patients, operators, and third parties. It is your organization's responsibility to identify, analyze, evaluate, and control these risks: - Changing network configurations. - Connecting to additional networks or disconnecting from existing networks. - Upgrading to new equipment or updating existing equipment (printer) - Installing/using third party softwares - Using Hepatoscope host to visit websites indicated as unsecure by your firewall or browser

3 Indications and Precautions for Use

3.1 Intended Purpose

The Hepatoscope ultrasound diagnostic system using its accessory probe shall be intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging of the human body and provides measurements of shear wave speed and tissue stiffness, ultrasound tissue brightness parameters such as ultrasound beam attenuation and backscattering coefficient, and estimates of speed of sound, in internal structures of the body.
The device is intended to be used by trained healthcare professionals, in a healthcare environment.

The Hepatoscope App using the e.**C5-1** probe shall be indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen.
In particular, the device is intended to provide:

- Linear distance measurements of anatomical structures,
- Measurement of shear wave speed at selected shear wave frequencies, and estimates of tissue stiffness in the liver and the spleen,
- Estimates of ultrasound tissue brightness parameters in the liver at selected ultrasound frequencies,
- Measurement of brightness ratio between structures and in particular between the liver and the kidney,
- Estimates of speed of sound in the liver.

The shear wave speed measurements, ultrasound tissue brightness parameters, elastic properties estimates, brightness ratio may be used as an aid to the diagnosis, monitoring and clinical management of adult and pediatric patients with liver disease.

3.2 Medical indication

Diagnostic ultrasound for abdominal diseases, including chronic liver disease

3.3 Name of the disease / clinical condition

A multitude of diseases may prompt patient referral to abdominal diagnostic ultrasound, of which chronic liver disease.

3.4 Intended patient population

Pediatric and adult patients referred to diagnostic ultrasound, including those at risk of, or with known chronic liver disease.

3.5 Intended user

Trained healthcare professionals, in a healthcare environment.

3.6 Intended application / Point of contact

Non-invasive external ultrasound imaging device.
External contact with the ultrasound probe via abdomen.

3.7 Duration of use

The Hepatoscope App using the e.C5-1 probe shall be:

- in contact with patient's body for a maximum duration of 5 minutes.
- used for repeat exams in the case of disease severity monitoring, at a pace of 1 exam per 6 months, 1 year, 2 years or more, depending on clinical indication and practice recommendations.

3.8 Invasiveness / Mucosal contact

Not applicable.

3.9 Contraindications

The Hepatoscope App using the **e.C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, should not be used in the following situations:

- On patients with active implants such as pacemakers, defibrillators, pumps, etc
- Wounds or non-intact skin.

	The use of the **e.C5-1** probe is not indicated on wounds or non-intact skin.

3.10 Cautions

	The presence of ascites between the probe and the liver may prevent from obtaining measurements with the system.

	Examinations with the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, shall be performed carefully using the principle of ALARA (As Low As Reasonably Achievable).

3.11 Warnings

Not applicable

3.12 Benefit for the patient

Non-invasive ultrasound diagnostic imaging.
In addition, the shear wave speed measurements, ultrasound beam attenuation, backscattering coefficient, elastic properties estimates, brightness ratio may be used as an aid to the diagnosis, monitoring and clinical management of adult and pediatric patients with liver disease.

3.13 Single use / Reusable

Reusable

3.14 Prescription Device Statement

Caution: United States of America's federal law restricts this system to sale by or on the order of a physician. This statement is reported on the probe and packaging labels with the symbol "USA – Rx only".

4 Description

The Hepatoscope App, using the e.**C5-1** probe, is part of the ES-Series V2 ultrasound diagnostic systems.

4.1 General information

Product or trade name	Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic Systems
Model and type / UDI-DI	ES-Series Basic UDI 37700238590NQ comprising of: - Hepatoscope App: 410-0001 / 3770023859011 - e.C5.1 Probe: 210-0001 / 3770023859004
General description of the device	As part of the ES-Series V2, the Hepatoscope is an ultrasound diagnostic app, developed by E-Scopics and designed to provide a specialized indication for use for abdomen imaging with specific measurements in the liver and the spleen.
List and description of any variants and/or configurations	Not applicable
List of any accessories	Not applicable
Certificate number (if available)	Not yet available
CND code(s)	Z11040103 Portable ultrasound scanners
Class	IIa
Classification rule	10
Expected lifetime	e.C5-1: 2 years Hepatoscope App: 3 years

4.2 System Overview

E-Scopics' Hepatoscope App using the **e.C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, is an ultraportable ultrasound imaging system used to perform non-invasive diagnostic general purpose ultrasound imaging and quantitative imaging studies. The Hepastocope App consists in 1) a Software App running on a consumer off-the-shelf Selected Host and 2) an accessory external curved array transducer, the **e.C5-1** Probe. The system produces images and quantifications, which are displayed on the monitor of the Selected Host. The system is operated from the Selected Host multi-touch screen to perform ultrasound exams quickly and efficiently. The system also allows the user to perform measurements, to save images, and to generate reports sent to a printer.

The Hepatoscope App using the e.**C5-1** probe is designed to perform non-invasive measurements of liver/spleen shear wave speed and to estimate tissue stiffness. The probe, containing a mechanical vibrator, produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver/spleen. Ultrasound is used to track the shear (elastic) wave, measure its speed and provide estimated stiffness. In addition, the Hepatoscope App is designed to measure several quantitative parameters from B Mode imaging: ultrasound attenuation, backscattering coefficient, speed of sound, and compute ultrasound brightness ratio between 2 regions in the image. The results of Hepatoscope App quantitative imaging modalities are displayed on the Selected Host monitor.

4.3 Equipment Supplied

The Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, is shipped in a single Shipping Box.
Labeling on the Shipping Box provides instructions related to the transportation of the e.**C5-1** probe.

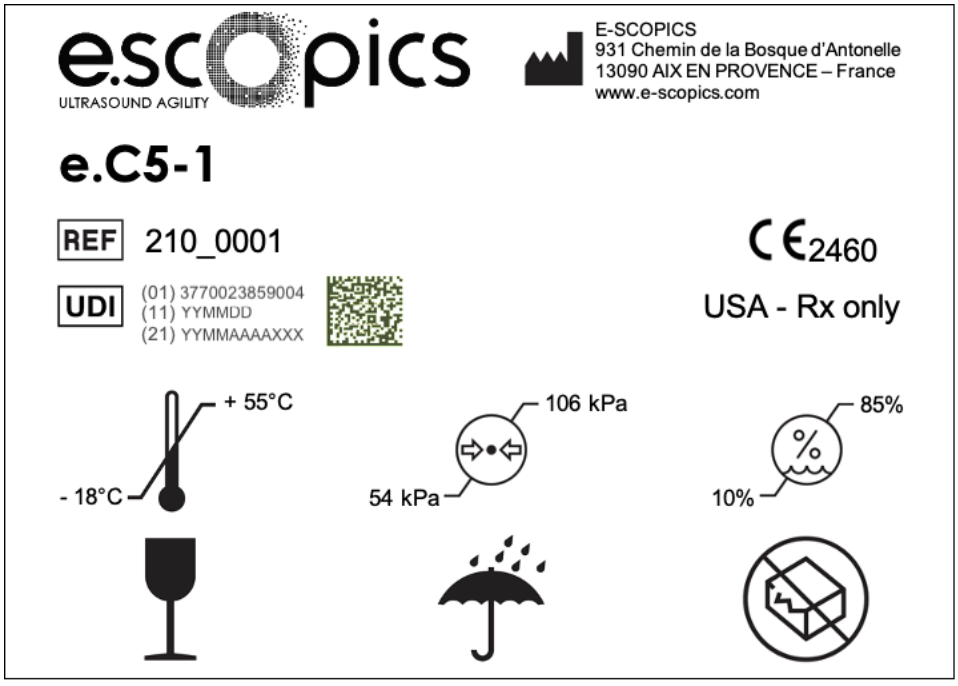


Figure 1. Labeling on the Shipping Box, providing instructions for transportation conditions.

When opening the package, the user shall ensure the content matches the following list of parts:

- The e.**C5-1** Probe in its Carrying Case*
- The Hepatoscope Welcome Flyer

The Shipping Box only contains the e.C5-1 probe Carrying Case and the Hepatoscope Installation Quick Guide. The Selected Host computer, if provided by E-Scopics, is shipped in its original manufacturers packaging.

** The Carrying Case contains space for an ultrasound gel (this may or may not be provided as part of the local sales offer)*

	Only the **e.C5-1** Probe provided by E-Scopics can be used with the Hepatoscope App. No alternative probe shall be used with the Hepatoscope App, nor plugged to the host.

	The Selected Host computer, if provided by E-Scopics, is shipped in its original manufacturers packaging.

Figure 2. Picture of the e.C5-1 probe in its Carrying Case showing the place for a bottle of ultrasound gel.

The labeling on the Carrying Case provides instructions related to the operation of the Hepatoscope App using the e.**C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems.

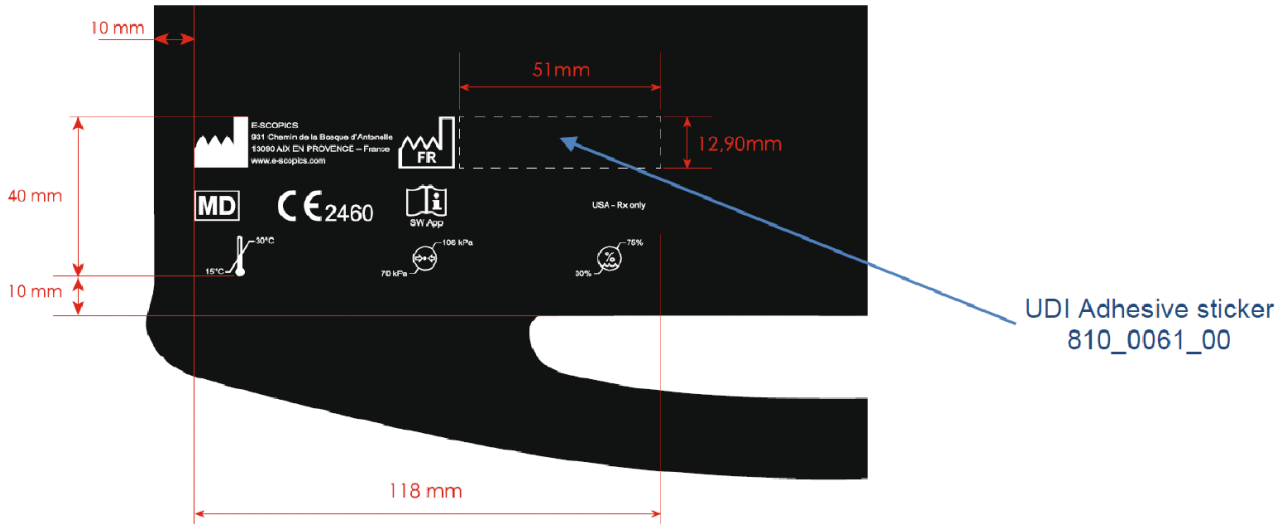


Figure 3. Labeling of the e.C5-1 Probe Carrying Case.

	In the event of the packaging being: 1- Damaged; 2- Unintentionally opened before use; and 3- If the packaging has been exposed to environmental conditions outside of those specified, Do not use the Hepatoscope App using the e.**C5-1** probe, and contact E-Scopics or its local representative: support@e-scopics.com.

4.4 The e.C5-1 Probe

The e.**C5-1** Probe is a curvilinear low-frequency ultrasound imaging probe that connects to the Selected Host via a built-in USB-C lead cable. The e.**C5-1** Probe also comprises an electrodynamic vibrator located at its back, which generates transient vibrations.

Figure 4. Schematics of the e.C5-1 probe and labeling at the back of the probe (right picture).

The **e.C5-1** Probe needs to be connected to the Selected Host via its USB-C socket.

	As it is the case with any USB-C connector, the **e.C5-1** Probe USB-C plug is fragile. It cannot be replaced without changing the whole probe.

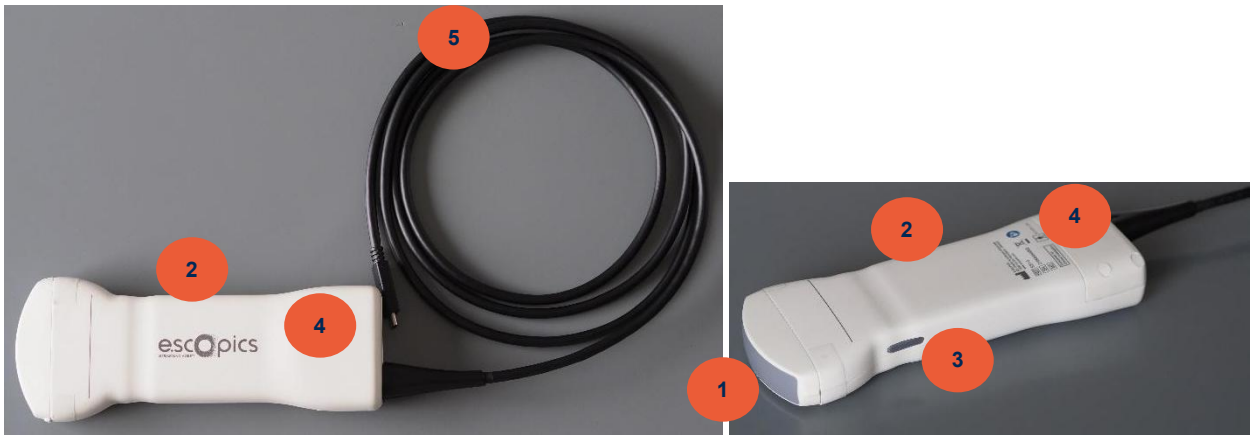


Figure 5. Pictures of the e.C5-1 Probe. 1: acoustic part of the probe. 2: handle of the probe. 3: control button located on the probe. 4: Electrodynamic vibrator is inside this portion of the probe; vibrator trap door on right image. 5. USB-C cable.

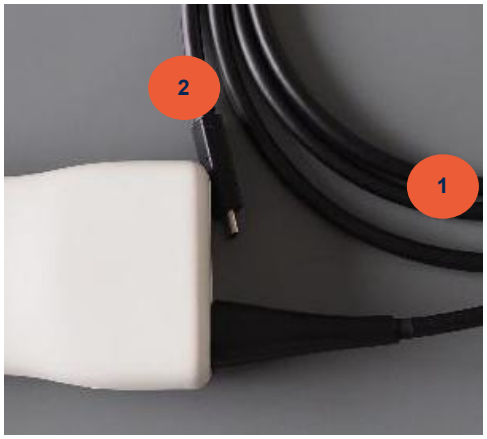


Figure 6. Picture of the probe lead: 1: USB-C connection cable. 2: USB-C connector.

This 1.8-2.0 m lead connects the e.**C5-1** Probe to the Selected Host by means of a USB-C cable.

	The e.**C5-1** probe transducer, the USB-C cable, and the USB-C connector are fragile elements and must be handled with care.

	The serial number marked on the e.**C5-1** probe rear surface identifies the probe uniquely.

	In case probe is dropped on the floor, either during storage or use, the user shall: - immediately check for any external casing and USB-C cable damage, - If no damage can be suspected on the cable and the probe, the user shall connect the probe to the Hepatoscope App and launch it to perform the Probe element check for probe integrity verification, - If the cable and/or the probe are suspected to be damaged, the user shall not use the probe, and shall contact E-Scopics' Technical Support at support@e-scopics.com

	Do not use the probe if it is damaged: This could result in a risk of electric shock.The USB cable shall be unplugged from the host and the user shall contact E-Scopics' Technical Support at support@e-scopics.com.

	In case the **e.C5-1** USB-C probe cable is damaged, the user shall: - immediately check for external jacket and/or connector casing damage, - immediately connect the **e.C5-1** probe to the Hepatoscope App if required and launch it to activate Probe element check to verify probe integrity, - not use probe if there is visible damage. In such a case, the USB cable shall be unplugged from the host, if applicable, and the user shall contact E-Scopics' Technical Support at support@e-scopics.com.

	In case of fumes, the user shall stop immediately using the probe, shall unplug the probe from the host, shall not use the system anymore and contact E-Scopics' Technical Support at support@e-scopics.com.

	The **e.C5-1** Probe shall not be connected to a host that does not match the minimum specifications established by E-Scopics for Selected Hosts (see Chapter 9.3).

	The **e.C5-1** Probe shall not be connected to a software host: - that is suspected by the user to be damaged, and/or - whose power supply block and/or power cord is suspected by the user to be damaged.

4.5 Hepatoscope App Software

The Hepatoscope App using the **e.C5-1** probe, as part of the ES-Series V2 ultrasound diagnostic systems, runs on a proprietary software, the ES-Series V2 ultrasound diagnostic systems.

	The user shall periodically check for available Hepatoscope App updates and upgrades. The user shall ensure the most recent version of the Hepatoscope App is installed.

4.6 The Selected Host

The Selected Host is a commercially available off-the-shelf portable computer, provided in its original package along with its accessories. It shall be connected to the electrical power via its own Power Supply, and powered in compliance with local safety standards.

Only a Selected Host that matches with the minimum specifications established by E-Scopics (recommended computer; see Chapter 9.3) can be used with the e.**C5-1** Probe to run the Hepatoscope App. Refer to the Instructions for Use provided by the manufacturer of the Selected Host to ensure its proper use.

	The e.**C5-1** Probe shall not be connected to a Host that has not been previously established by E-Scopics as a Selected Host.
	The e.**C5-1** Probe shall not be connected to a software host that is suspected by the user to be damaged.
	The e.**C5-1** Probe shall not be connected to a Selected Host whose power supply block and/or power cord is suspected by the user to be damaged.
	Always keep the Selected Host OS / drivers updated.

4.6.1 The screen

The Selected Host monitor is a multi-touch screen that is used to display the exam outcomes, system controls, and as the main system user interface.

When the Selected Host is in open configuration, the position of the screen can be adjusted to ensure optimal visualization conditions.

	To protect the Selected Host screen from any risk of damage, make sure to close-down the Hepatoscope App and the Selected Host-lid when the system is not used. Make sure to unplug the e.**C5-1** Probe from the Selected Host before.

The screen brightness level shall be adjusted by the user from the Selected Host settings, and not in the Hepatoscope App. The Hepatoscope App does not control the Selected Host screen brightness level.

4.6.2 Computer connectors

The Selected Host may have several USB connectors, of which only 1 USB-C socket. If the case, this USB-C socket shall be left available to connect the e.**C5-1** Probe to the Selected Host. Other USB connectors may be used to connect external peripheral devices (hard disk, USB printer, USB key…)

	To protect the computer screen from any risk of damage, make sure to close the Selected Host when the Hepatoscope App is not used.

4.6.3 Operating System updates

The Selected Host Operating System must be kept up to date.

4.7 Accessories & consumables

4.7.1 Accessories supplied directly by E-Scopics

The following accessories may be optionally purchased by a customer and are supplied with the E-Scopics' Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems.

- Probe: The curved probe called e.**C5-1** can be sold separately.

4.7.2 Accessories which are not supplied by E-Scopics

Under some use conditions, additional materials provided by third-party vendors may be used by clinicians performing exams with the Hepatoscope App. The decision to use the product with third-party products is completely at the discretion of the clinician.

4.7.2.1 Probe cleaning and disinfectants

Probes used with the Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, are provided non-sterile and are intended to be reused. Probes are used for all applications listed in the indication

for use of the device. Cleaning and disinfecting are appropriate for use between patients. Instructions for cleaning and disinfecting the probes used with the Hepatoscope App are provided in the User Manual. E-Scopics recommends the use of products which are independently approved for commercialization and recommended for use with conventional ultrasound imaging probes (see Chapter 8.3.2.4).

4.7.2.2 Ultrasound gels

Conventional authorized ultrasound transmission gel must be used with the e.**C5-1** Probe and the Hepatoscope App to guarantee optimal acoustic beam transmission and reception. In countries where applicable, ultrasound transmission gel must be CE-certified. Such ultrasound gel is not provided by E-Scopics. Follow the Instructions for Use provided by the manufacturer of the ultrasound gel used.

4.8 Clinical overview

The Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, uses the accessory e.**C5-1** Probe to provide diagnostic imaging of internal structures of the human body. Diagnostic imaging is presented as a live or frozen two-dimensional grayscale imaging (B Mode).
Measurements can be performed on frozen B Mode images as follows:

- Linear distance measurements between 2 calipers,
- Depth measurement of a given point in the image,
- Ultrasound brightness ratio between 2 regions in the image. This measurement is mainly used to calculate the brightness ratio between the liver and the right kidney cortex, and known as the Hepato-Renal Index (HRI, as displayed in the system UI).

Distance measurements are expressed in centimeters (cm).

In addition, the Hepatoscope App using the e.**C5-1** probe may be used to measure physical parameters of biological tissue, and especially of the liver. Such physical parameters include:

1- Tissue stiffness, under assumptions detailed below,
2- Ultrasound attenuation,
3- Backscattering coefficient,
4- Speed of sound.

4.8.1 Measurements of tissue stiffness

The e.**C5-1** Probe is equipped with a electrodynamic vibrator, located at its back, that generates 50-Hz transient vibrations. When applied to the body surface, these transient mechanical vibrations of the e.**C5-1** Probe create shear waves that propagate from the patient's skin into internal organs. During propagation of the shear waves, the e.**C5-1** probe performs a series of ultrasound acquisitions (transmission/reception) to

track tissue displacement and measure the speed of shear wave propagation (Vs), expressed in meters per second (m/s). Our 2DTE algorithm relies on a particle-displacement based technique to estimate shear wave speed. Prior to shear wave speed estimation, a passband filter between 15 Hz and 90 Hz is applied. As the shear wave excitation is narrow-band and centered around 50 Hz, this filtering has a very limited impact on the shear wave speed measurements.

Assuming the liver is a non-viscous, linear and isotropic elastic incompressible (v = 0,5) medium, the Hepatoscope App, as part of the ES-Series ultrasound diagnostic systems, transforms Vs values into equivalent stiffness values, or Young's Modulus (E), expressed in pressure units of kiloPascals (kPa) using the equation $E = 3 \rho Vs^2$ where ρ is the medium density assumed to be 1000 kg/m^3.

Measurements of tissue stiffness are expressed in both shear wave speed and tissue stiffness values, in units of m/s and kiloPascals (kPa) respectively.

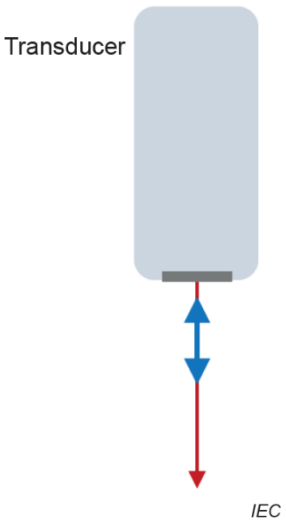


Figure 7. Assumed direction of shear-wave propagation and tissue displacement in relation to the transducer orientation.

4.8.2 Measurements of ultrasound attenuation

Ultrasound attenuation corresponds to the loss of energy as ultrasound propagates in the depth of tissue. The intensity of transmitted ultrasound energy (I0) decreases exponentially with depth (z) according to the following equation: Iz = Io exp (- α(f) z), where Iz is the ultrasound intensity at depth z, f the ultrasound frequency and α(f) the frequency-dependent attenuation coefficient. Ultrasound attenuation mainly depends on the ultrasound frequency and the properties of tissue. It is expressed in decibels per meter (dB/m). The Hepatoscope App using the e.**C5-1** probe assesses the value of α at the frequency of 3.5 MHz.

4.8.3 Measurements of backscattering coefficient

Backscattering coefficient corresponds to the differential scattering cross section per unit volume for a 180° scattering angle. It quantifies the scattering property, i.e. the brightness, of a tissue. It is a fundamental quantity related to the interaction between ultrasound and tissue, like speed of sound and ultrasound attenuation. It mainly depends on the ultrasound frequency and the properties of tissue. It is expressed in decibels per centimeter per steradian (dB/cm-sr). Hepatoscope App using the e.**C5-1** probe assesses the value of the backscatter coefficient at the frequency of 3 MHz.

4.8.4 Measurements of speed of sound

Speed of sound corresponds to the velocity at which ultrasound waves propagate in a tissue. It is a fundamental property of the interaction between ultrasound waves and tissues. It is expressed in meter per second (m/s). Hepatoscope App using the e.**C5-1** probe assesses the value of the local speed of sound within a tissue of interest by exploiting refraction effects of plane waves.

4.8.5 Users training

In order to safely and effectively operate Hepatoscope, the user shall meet the following:

- Training as required by local, state, provincial, and national regulations,
- Additional training as required by the authorizing physician,
- A knowledge and understanding of the material presented in this manual.

5 System Installation

5.1 Prior to Installation

Ensure that the operating and mains voltage values match with the Selected Host. The Selected Host must be powered in compliance with local safety standards. The use of multiple socket-outlets or extension cords is prohibited.

Safe use is no longer guaranteed in the following main, non-exhaustive cases:

- the system is visibly damaged,
- the system is inoperative,
- after prolonged storage in unfavorable conditions,
- after serious damage incurred during transport,
- in the presence of flammable or anesthetic gases. This may cause an explosion. Do not take the system to the operating room.

	Only items that have been specified as part of the ES-Series V2 ultrasound diagnostic systems, or that have been specified as being compatible with them may be connected.

	Multi-socket adapters and extensions leads must not be used directly or indirectly with the Selected Host & the e.**C5-1** probe.

5.2 Installation of the Hepatoscope Application software

The user shall login to the Selected Host using an existing user account.

The Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, needs to be downloaded & installed from www.e-scopics.com/downloads.

	The Hepatoscope App System Administrator shall follow the steps of the First User Connection to the app. These include: - Entering details and credentials for all users. - Configuring the destination of exams reports.

	If a firewall running on the Selected Host prompts any message to control access to the network, the user shall authorize such access.

	If no destination has been configured for the Hepatoscope exam reports (local printer, pdf virtual printer…), they will be lost and cannot be retrieved after the exam has ended.

5.3 Installation of the e.C5-1 Probe

The e.**C5-1** Probe is shipped “ready-for-use” and does not require any installation actions. Probe firmware updates may be required and performed as prompted by the Hepatscope App.

	Do not disconnect the e.**C5-1** probe until the message that the firmware has been updated is displayed.

The integrity of the acoustic part of the probe will be checked automatically at each launch of the Hepatoscope App. In case there is warning message, please refer to chapter 8.5.1.

5.4 Use Environment

5.4.1 General

⚠	The system shall be installed and used in such a way that the Selected Host is outside the defined perimeter of 1.5 meters of the patient zone.

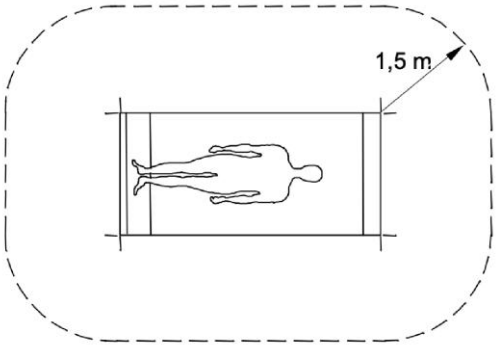


Figure 8. Illustration of the patient perimeter.

⚠	The user shall not touch the Selected Host & patient simultaneously.

5.4.2 Good practices to ensure system & network security

- Use a secure password for login and change it regularly.
- Use a firewall to protect the host from unauthorized access.
- Do not use the Hepatoscope software when connected to a public Wi-Fi network, or use a VPN.
- Use Hepatoscope software only with e.**C5-1** Probe. Usage of e.**C5-1** Probe with other software could lead to user or patient injury.
- Updates of Hepatoscope software are managed by E-Scopics only. Keep an updated version of the host operating system and of Hepatoscope to ensure you have the most up-to-date version.

- Install security software and keep it up to date.

5.4.3 Information confidentiality

Confidentiality of information in Hepatoscope is ensured as follows:

- Private health information is only temporary stored within Hepatoscope app in a ciphered database. Data transferred between Hepatoscope and printing equipment is encrypted.
- The patient report that is printed at the end of a patient examination contains private health information. It is therefore the user's responsibility to print the examination report, and to keep the records of examination in a secure place.

5.5 Hepatoscope App Configuration

5.5.1 System information

This page can be displayed from the “About” menu. Information about the system and the software include: serial numbers (system, probe, etc.), software and firmware version numbers.

5.5.2 Hepatoscope System settings

The following elements can be configured:

- Number of valid measurements in series of quantification of tissue properties
- List of system users, including users profiles and credentials
- Default printer destination of the exam report
- Customization of the Institution Name and Logo to appear on the monitor and in the exams reports

After logged in to the Hepatoscope App, go the App settings by clicking on the icon  .

5.5.2.1 Number of valid measurements per series.

Users can customize the minimum required number of valid measurements that constitutes a series of measurements (from 1 to 20) for:

- Shear wave speed and liver stiffness
- Ultrasound attenuation
- Backscattering coefficient
- Speed of sound

By default, this number is set to 10 for each of the 4 parameters above, and shall lie between 5 and 20.

This setting can be done for each of the 2 exam workflows available on the Hepatoscope, the General Exam and the Liver Exam.

In the Admin Settings, select “Liver Exam” in the left hand-side menu to set the number of valid measurements that constitutes a series of measurements in the “Liver Exam” workflow.
Select “General Exam” in the left hand-side menu to set the number of valid measurements that constitutes a series of measurements in the “General Exam” workflow.

Once the number of valid measurements has been set, click on the “Save” button at the bottom right corner.

5.5.2.2 System users

The administrator(s) of the system can add users for the Hepatoscope who will be required to login with their own confidential ID and password.
In the Admin Settings, select “Users” from the left-hand side menu and follow the steps.

5.5.2.3 Printers setting

A default printer destination must be configured so that exam outcomes are exported and/or printed for records.

To configure exam reports printing options, follow the steps below:

1- In the Admin Settings, select “Printers” in the left hand-side menu
2- If Hepatoscope exam reports are expected to be saved locally as pdf reports, ensure the “Print to file” option is ticked.
3- To select a folder where to save exam reports, browse your local laptop to select the proper folder, by clicking on the icon .
4- Select the proper folder and click on “Select Folder”.
   Note: A file Prefix can be defined that will be added systematically to all pdf reports saved in the folder.
5- To add a hardware printer, select a printer from the list of printing devices connected to the laptop.
6- If a printing device needs to be added to the list, click on the “+” icon. The printer must be connected to the laptop. Then select the printer and click “Add”.
7- Click on “Save” to save these settings, and then on “ Exit Admin Settings ” to exit and go back to system use.

	If the user decides to export exam reports in pdf locally to a folder, it is highly recommended to define an export path that targets a folder accessible to any laptop user profiles. For example, C:\Hepatoscope Reports will be accessible to any laptop user profiles.

5.5.3 Network

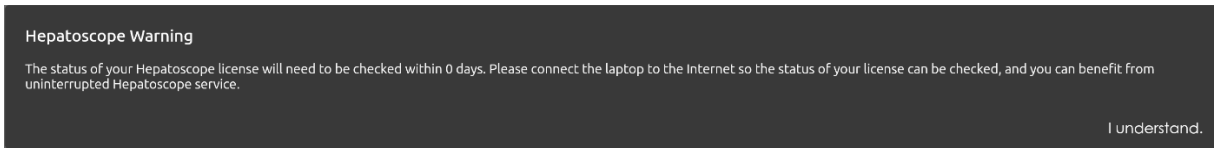
	The Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, does not manage network configuration. Access to network-based resources (printer,…) only depends on the Selected Host network configuration.

	The Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, has no restrictions on other equipment or network/data couplings, to which a signal input/output part may be connected, except for the following ports required for software operations: - 13042 - 13043 - 13051 - 13052

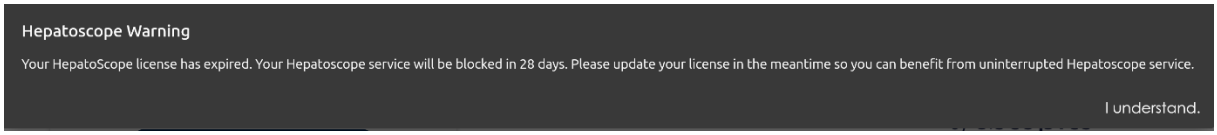
5.6 Hepatoscope App License Management

The Hepatoscope service is activated once the service purchase is processed and confirmed. The service is activated via a software license that is linked to the probe received, and managed by E-Scopics' web-based licenses manager. To check the status of the Hepatoscope service license, the laptop needs to be connected to the Internet at least monthly. In case the system cannot get connected to the Internet, the status of the Hepatoscope service license will not be checked and the service may be interrupted after a certain period of time (grace period). When applicable, this situation may also happen if the monthly payment of the subscription to the Hepatoscope service was not validated and approved.

The Hepatoscope service will inform the operator of any license check planned in the following days. The following message will be displayed by Hepatoscope.

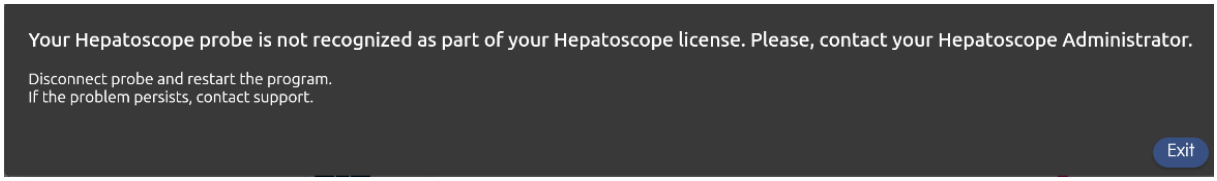


After the Hepatoscope service license has expired or could not be checked, the operator benefits from a 30-day grace period during which the Hepatoscope service will remain available for use. The following message will be displayed by Hepatoscope.



After the grace period has ended and no license check nor any license payment could be confirmed, the Hepatoscope service will be interrupted. The following message will be displayed by Hepatoscope.

If the probe used with the Hepatoscope service does not correspond to the probe that was delivered to the customer, the Hepatoscope service will not be operational. The following message will be displayed.



6 Instructions for use of the Hepatoscope App, using the e.C5-1 probe

	In case of software background tasks running on the Selected Host, possible performance deterioration may occur. The user shall ensure only required software applications are running during an exam session.

6.1 System switch-on

To turn on the Hepatoscope App, the Selected Host must be switched on following Selected Host instructions for use. Once the user has logged in to the Selected Host using his/her credentials, the Hepatoscope App icon on the Selected Host desktop shall be double-clicked to start the Hepatoscope App.

	The Hepatoscope App, can only be used to perform examinations and export exam reports. It cannot be used to store exam data locally.

	To ensure optimal system performances: - The Selected Host shall be plugged to the main power supply during an exam. This ensures optimal computing and data transfer rate performances. - Laptop Power mode should be set to "Best performance" in both plugged and unplugged mode. - Set all laptop "Screen and sleep" options to "Never".

	When the user has forgotten login credentials, contact support@e-scopics.com.

6.2 System standby and shut down

Turn the system off by going to the main menu on the top left-hand side of the screen and select “Exit Hepatoscope”.

When the Hepatoscope App is closed, the e.**C5-1** probe shall be unplugged and stored correctly in the dedicated Carrying Case. The Selected Host can then be switched off using the dedicated command in the operating system menu.

	If the laptop shall be closed to facilitate its transport: 1- Unplug the probe first, 2- Put the laptop in sleep mode, 3- Close the laptop

	Refer to the cautions in Chapter 2 concerning switching off the system.

To ensure secured storage and transfer of clinical data and exam outcome data, the Hepatoscope App will ask for a double confirmation by the user before leaving the App while an exam is ongoing.

6.3 User login and exam start

6.3.1 Login page

When the Hepatoscope App has started, the login page is displayed.

The user shall login to the system with her/his personal credentials. The login page allows the recovery of user-specific system parameters. The software version is displayed at the bottom of the screen.

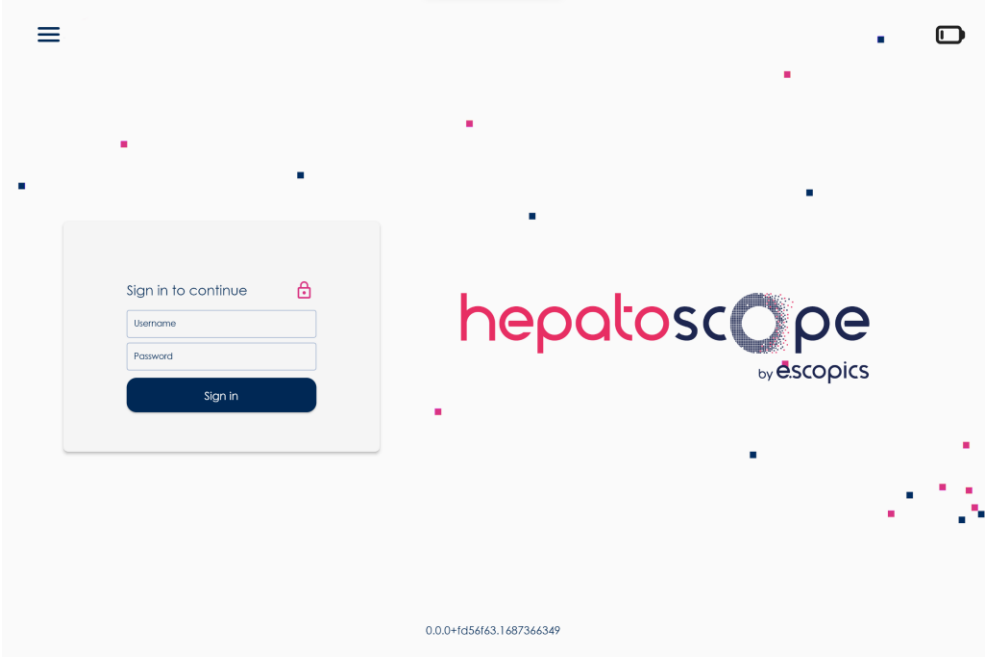


Figure 9. User's login page.

6.3.2 Patient information page

Once the user has logged in to the Hepatoscope App, the patient information page is displayed. Patient's information shall be entered manually on this page. Fields followed by a red asterisk are considered mandatory.

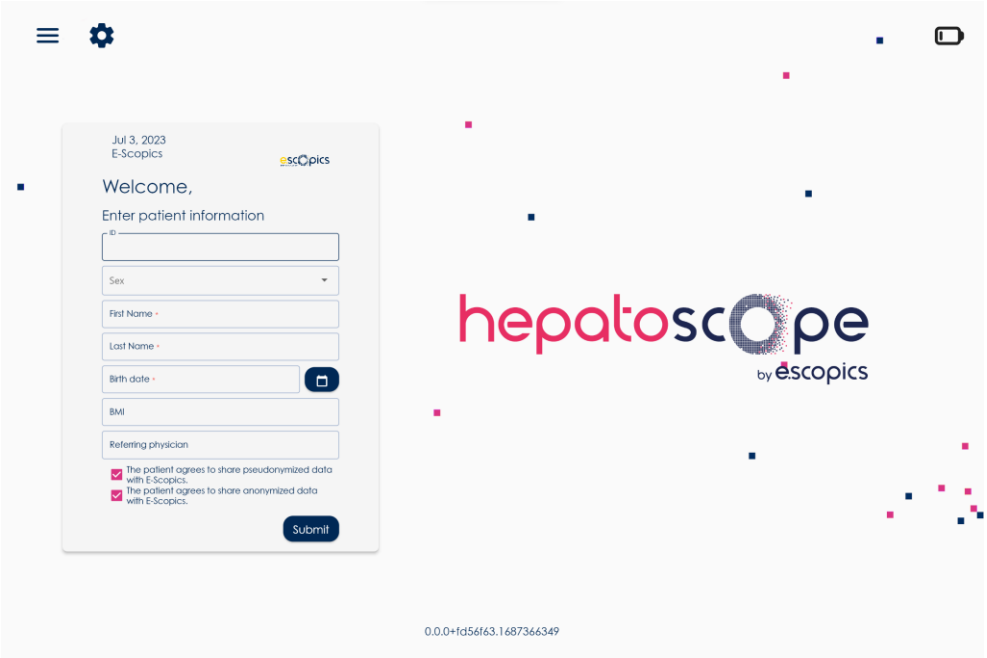


Figure 10. Patient information page.

After entering patient's information, the user shall indicate whether or not the patient agrees that his/her pseudonymized and/or anonymized ultrasound data can be shared with the manufacturer for post-market surveillance and customer support activities.

The remaining number of exams to be exported is indicated in the Hepatoscope App, while exams are ongoing, at the top right corner. The mouse pointer needs to be rolled over the export icon to get the indication of how many exams still need to be exported.

Should exam data be exported, the laptop should be plugged and switched on as long as possible to allow such export.

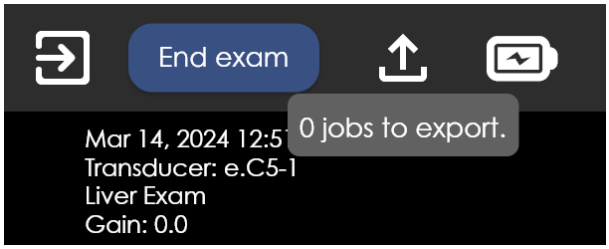


Figure 11. Indicator of the remaining exports of exam data in the Hepatoscope App.

When the Hepatoscope App is closed, the information can be obtained from the Windows applications trail at the bottom right corner of the Windows taskbar.

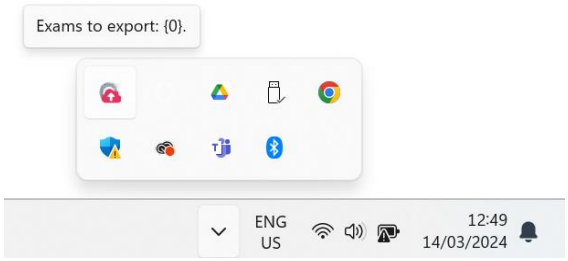


Figure 12. Indicator of the remaining exports of exam data in Windows.

6.4 Exam type selection page

The Exam type selection page allows the user to select the examination workflow that is appropriate. The General Exam provides access to every system modality outside of any particular clinical use workflow. For chronic liver disease assessment, the “Liver Exam” shall be selected.

Figure 13. Exam type selection page.

	Select the “Liver Exam” to benefit from a dedicated software app tailored for the measurement of several liver quantitative physical parameters.

6.5 Ultrasound imaging controls available in all operating modes

- Depth adjustment: the user can adapt the image depth either by pressing on “+” or “-“ in the dedicated area. The user also has the possibility to change image depth by an upward/downward 1 finger sweep over the image area using the touchscreen.
- Overall image gain adjustment: the user can adapt the overall image gain either by pressing on “+” or “-“ in the dedicated area.
- Image Freeze: The ultrasound sequence can be frozen by pressing the snowflake icon located at the bottom left corner of the screen.
- Save image: The user can take a screenshot of the image area using the camera button located at the bottom left corner of the screen.
- The image can be horizontally flipped to inverse the left and right sides of the image, depending on user’s habits, by pressing on the “O” pictogram displayed on the side of the probe line.

The Thermal Indices and the Mechanical Index are 1.0 or less for all device settings. Therefore, these TI and MI indices are not displayed in the user interface.

Figure 14. Screenshot of the user interface in General Exam mode.

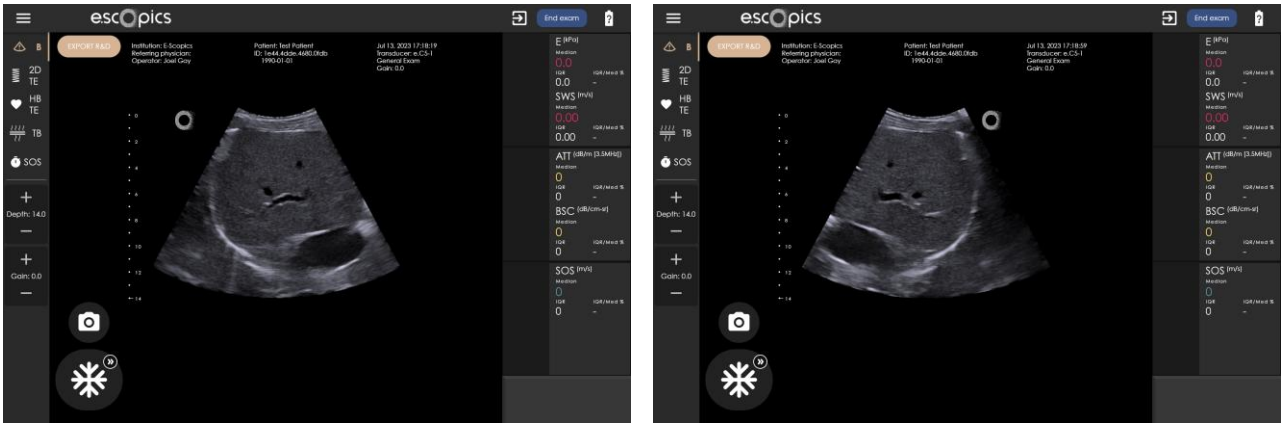


Figure 15. Left: Image left-right orientation by default; the "O" pictogram is on the left side. Right; Flipped image orientation; The "O" pictogram is on the right side.

6.6 System set up

The Selected Host shall be positioned in accordance with working standards so as to avoid muscle strain and eye strain. The operator shall make sure the screen of the Selected Host does not produce too many reflections from the room ambient lighting.

	User shall ensure to safely place the probe next to the Selected Host when no examination is ongoing.

	The e.**C5-1** Probe shall be cleaned and disinfected (see chapter 8.3.2) before every use, between patients and prior to returning to the carrying case. Cleaning is necessary before disinfection in order to ensure effective decontamination.

6.7 Acquisitions in General Exam mode

The main data displayed in an acquisition screen are presented below. Grayscale B Mode images are displayed along with a depth scale.

The grayscale B Mode image is used to ensure the probe is appropriately positioned to acquire diagnostic information and measurements.

	After five minutes of exam time without interactions with the system UI, the image will freeze. Press unfreeze to come back to live imaging.

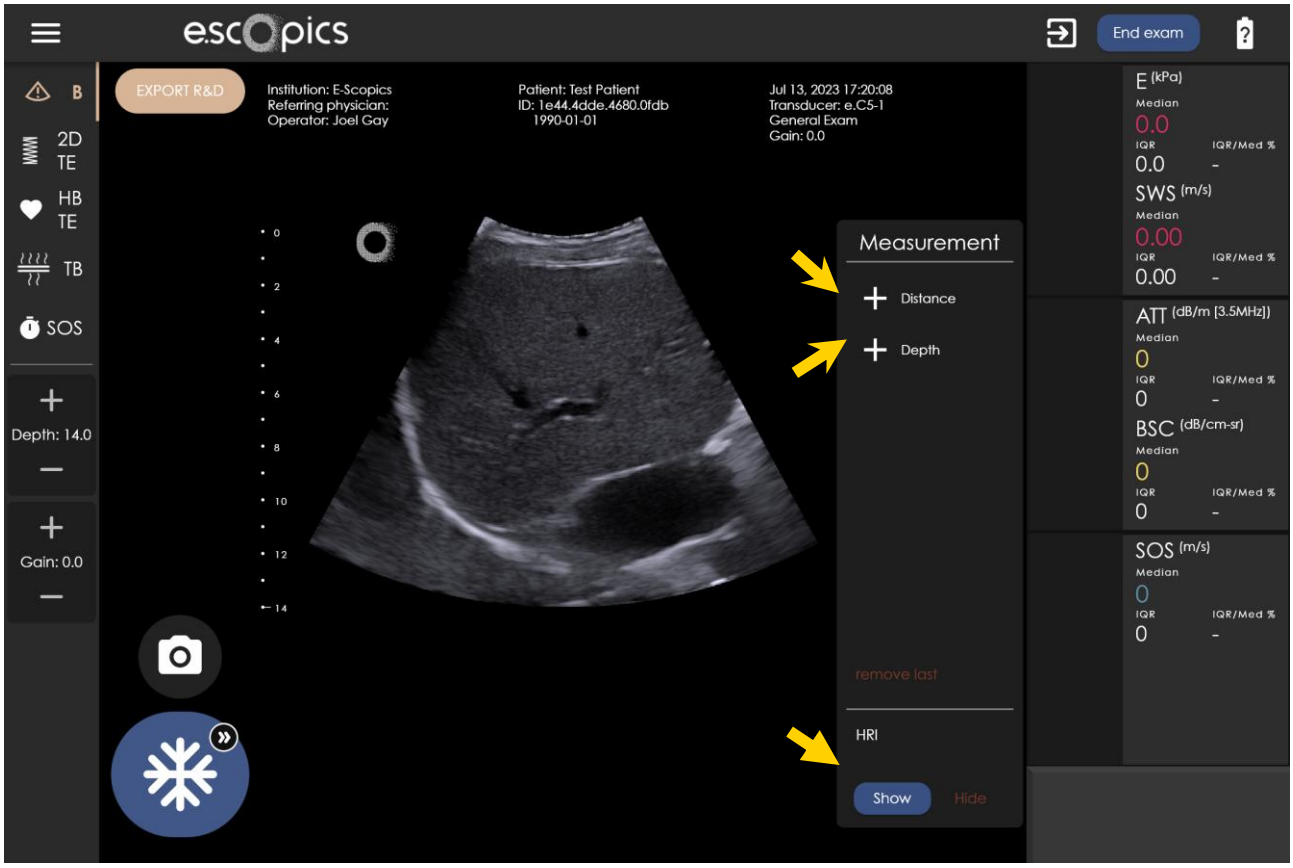


Figure 16. General Exam imaging view in frozen B Mode. Measurement tools are displayed in the dedicated panel, and include Distance measurements ( ), Depth measurements ( ) and Hepato-Renal Index measurement ( ).

6.7.1 B Mode imaging controls

Two imaging controls are available in live B Mode:

- Depth adjustment
- Image Gain adjustment

6.7.2 B Mode linear distance measurements

On B Mode freeze, the user can add a maximum of 10 linear distance measurements on a given image. Linear distance measurements are not saved as autonomous entities and therefore, does not appear in the exam report. The image must be saved if the user wants to keep a record of the linear distance measurements.

When selecting the “Depth” measurement, a circled caliper appears that must be positioned on the structure for which the user wants to measure the depth.

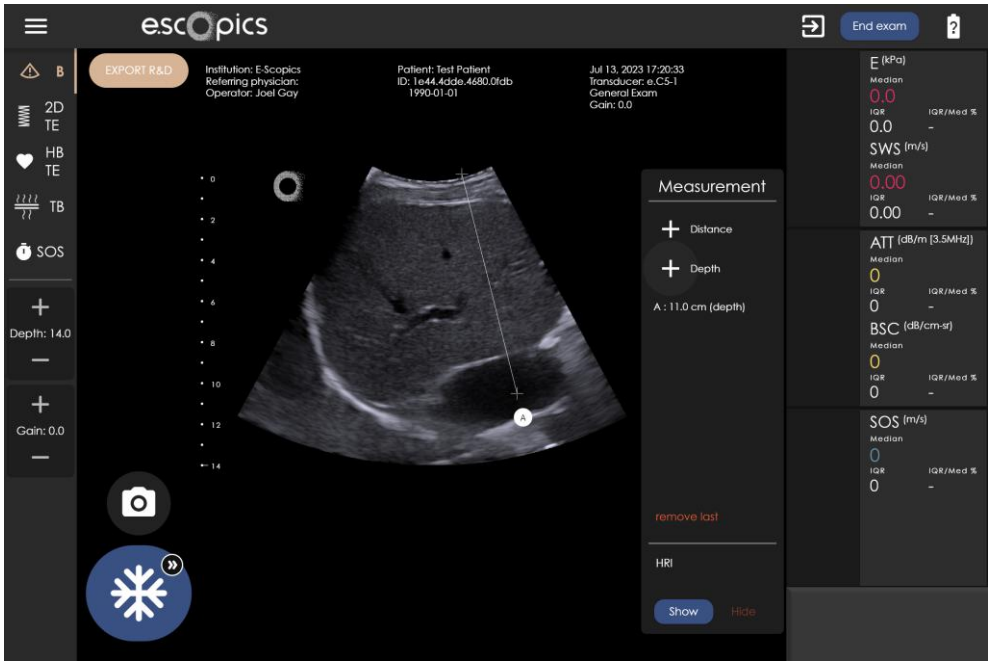


Figure 17. Appearance of the Depth measurement tool on the user interface.

When selecting the “Distance” measurement, 2 squared calipers appear that must be positioned on each point between which the user wants to measure the linear distance.

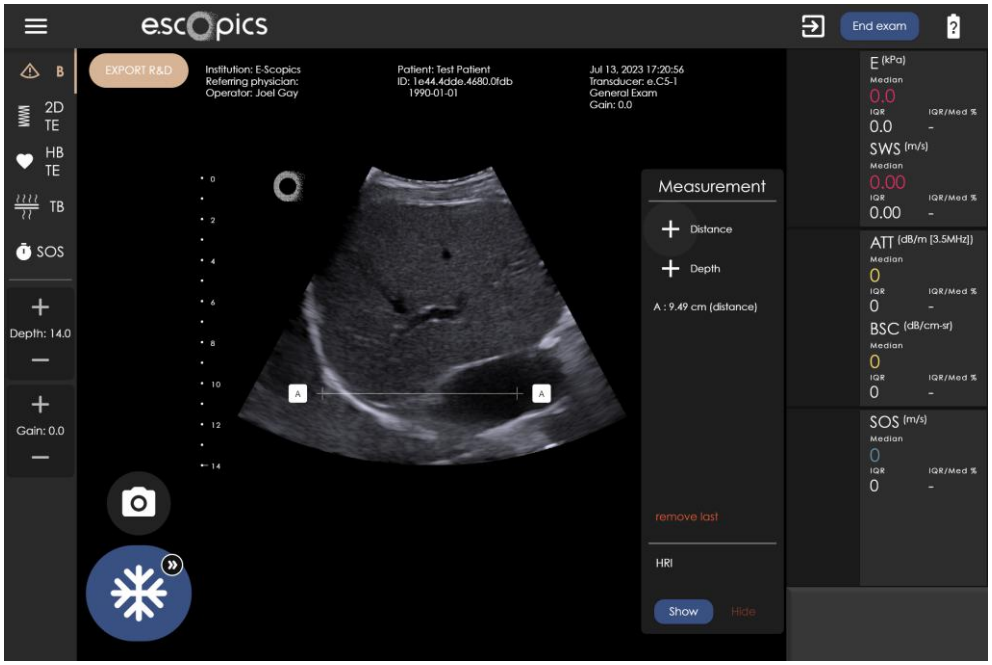


Figure 18. Appearance of the Distance measurement tool on the user interface.

6.7.3 Quantitative imaging modes available in General Exam

The following quantitative imaging modalities are available from the General Exam user interface:

- 2D TE: two-dimensional transient elastography

- HB TE: heart-beat transient elastography
- ATT: ultrasound attenuation
- BSC: backscattering coefficient
- SOS: speed of sound

	The system has been designed to be operated with default regions of interest (ROI) in 2D TE, HB TE, ATT, BSC and SOS modes. Changing the size and/or localization of the ROI in these modes may impact the reliability of measurements performed and the relevance of the Quality Index.

6.8 Acquisitions in Liver Exam mode

6.8.1 Patient and e.C5-1 Probe positioning for proper examination

To ensure optimal examination outcome data, the patient should be fasting for at least 3 hours.
The patient lies down on the examination bed, in supine position, the right arm in maximum abduction, the right hand underneath the neck, the right leg crossed over the left. In case the patient had active physical exercise before the exam, a resting time on the examination bed of at least 15 minutes shall be observed before performing the exam.
The operator shall manually locate the 9th and 10th intercostal spaces by external palpation. Measurements will be retrieved laterally from either of these locations. The operator pours ultrasound transmission gel on the chosen location.

The e.**C5-1** probe is placed intercostal, laterally within the 9th or 10th intercostal space. The user shall use B Mode imaging guidance to monitor the quality of the acoustic window and adjust probe positioning so as to obtain the best image quality and locate areas within the liver parenchyma that are free from major vessels or other abdominal structures such as the gallbladder or focal liver lesions.

The operator shall use the lightest pressure possible on the probe to maximize the contact surface between the e.**C5-1** Probe and the patient's rib cage skin, while not pushing too hard on the ribs. The user shall tilt, rotate, and orient the probe differently to obtain the best image quality possible at a given location, as witnessed on the B Mode image.

The user shall have a good grip on the probe and hold it stably.

6.8.2 Acquisition screen in Liver Exam

The main data displayed in an acquisition screen are presented below. Grayscale B Mode images are displayed along with a depth scale.

2 imaging controls are available:

- Depth adjustment
- Image Gain adjustment

The grayscale B Mode image is used to ensure the probe is appropriately positioned to acquire measurements on the patient's liver. It allows the user to verify that the measurement will not be disrupted by the presence of structures not of interest, such as the gallbladder and large blood vessels.

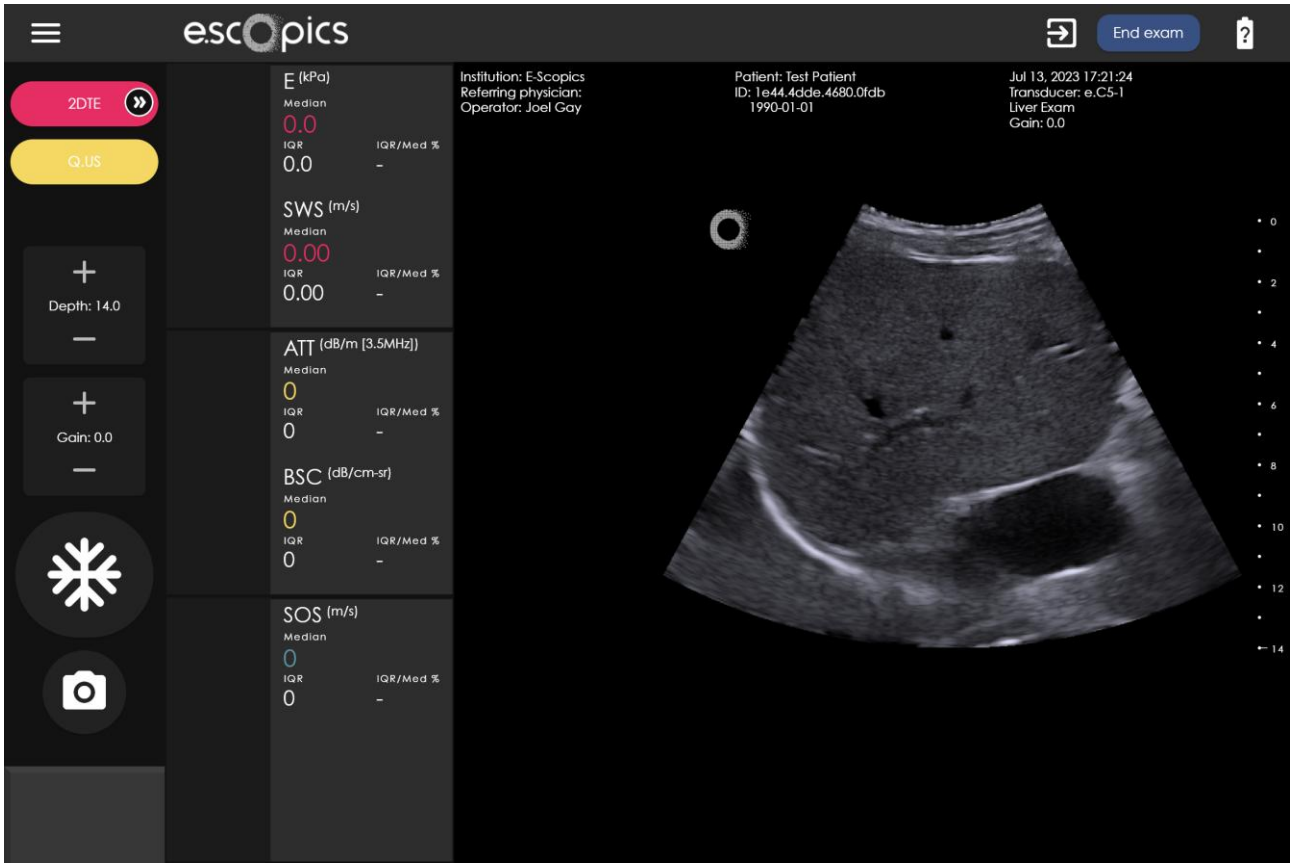


Figure 19. Screen view in the Liver Exam use workflow.

After five minutes of idle time during an acquisition, a message informs the user, who then has five additional minutes before the examination is automatically halted. Beyond this time, if no action has been taken, the examination will be terminated and exam data lost.

6.8.3 Liver assessment tools

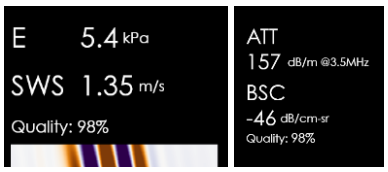
Two types of quantitative liver parameters can be retrieved, using the buttons located on the top left corner of the screen (2DTE and Q.US):

- In 2DTE mode: 1 parameter related to shear wave propagation is measured, namely shear wave speed, also expressed as stiffness (referred to as 2DTE modality and values on the monitor)
- In Q.US mode: 3 parameters related to ultrasound tissue brightness and propagation are measured, namely ultrasound attenuation, backscattering coefficient and speed of sound (referred to as Q.US modality on the monitor, along with ATT, BSC and SOS values)

Measurements performed by the Hepatoscope App are displayed in the user interface with an indication of the level of reliability given by the software algorithms that calculate these measurements.

A measurement that is not considered reliable by the system is displayed in shadowed font; a measurement that is considered reliable by the system is displayed in bright font.

When retrieving measurements of quantitative ultrasound parameters, the system calculates and displays a Quality Index that provides an indication of the level of confidence of such measurement. Measurements that have a Quality Index below the factory preset threshold are not considered trustable, and therefore displayed in shadowed hues and not stored. Measurements that have a Quality Index over the factory preset threshold are considered trustable, and therefore displayed in bright hues and stored. See Quality % on screenshots below for 2DTE (left) and Q.US (right).



The system has been designed to be operated with default regions of interest (ROI) in 2DTE and Q.US modes. Changing the size and/or localization of the ROI in these modes may impact the reliability of measurements performed and the relevance of the Quality Index.

For each of the parameters measured in the liver, pressing on the SAVE button will automatically launch and store a series of 10 consecutive measurements that are considered reliable by the system. Such a number of 10 measurements can be customized by the user in the system preferences. The collection of consecutive measurements can be suspended by the user, by clicking on the Suspend button.

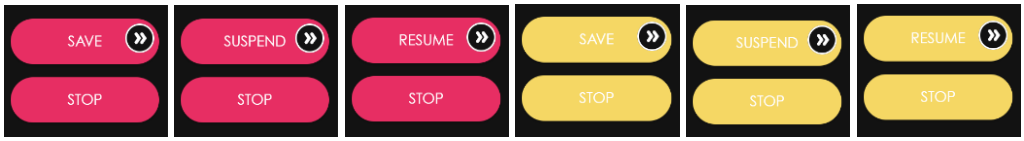


Figure 20. Illustrations of the change in buttons status in both the 2DTE (on the left, in pink color) and Q.US (on the right, in yellow color) modes to collect series of 10 measurements of ultrasound and physical parameters.

The system automatically calculates the Median value and inter-quartile range (IQR) of the 10 measurements performed. The system displays a ratio of IQR/Median in %, that indicates the temporal variability of the 10 measurements stored.

The mode will stop automatically when a series is completed (i.e. up to 10 measurements stored).

In 2DTE mode, a stiffness map overlay is displayed in real-time, which is intended for stiffness visualization and user guidance for the proper positioning of the probe/ROI in the liver. The stiffness map uses color-coding of stiffness values following a fixed color scale displayed on the left-hand side of the image (see Figure 21). The maximum value of this color scale is fixed at 30 kPa such that any value higher than 30 kPa will be color coded in red.
As shown on Figure 21, a “Computational Region”, larger than the stiffness map, is outlined by a pink bold line. This Computational Region aims at localizing the data that are used to compute the stiffness map. The processing indeed uses a fixed kernel size of 7 mm of data points. The user shall refer to this Computational Region to ensure the correct positioning of the stiffness map and make sure this entire Computational Region lies within the liver. In particular, this Computational Region shall be positioned below the liver capsule and avoid anatomical structures other than the liver (as illustrated on Figure 21) being included in the processing.

In 2DTE mode, measurements of tissue stiffness are displayed in units of shear wave speed (m/s) and tissue stiffness (kPa).

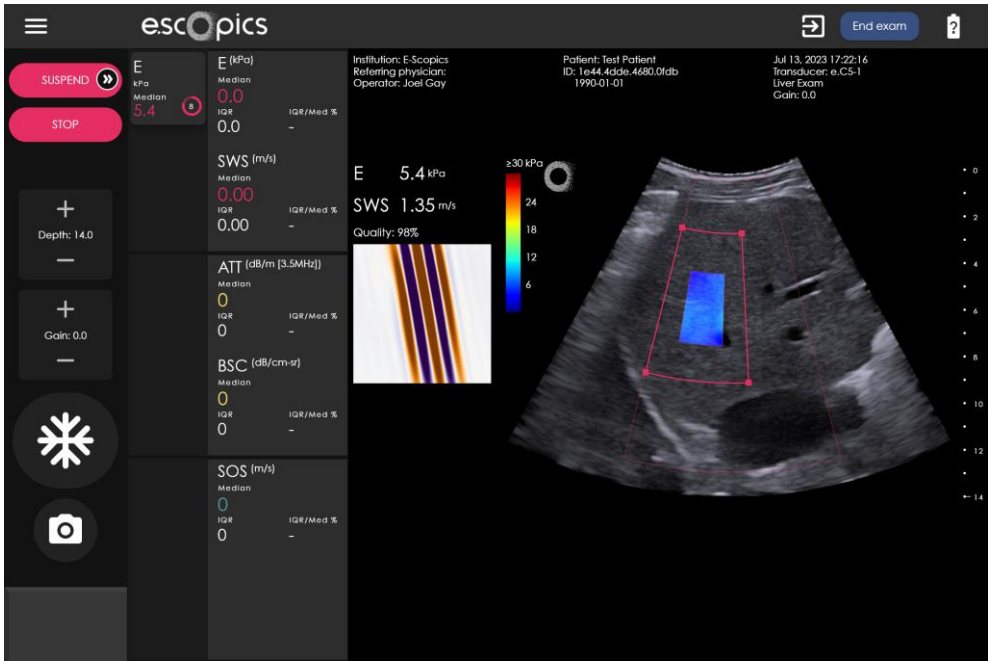


Figure 21. Screen view in the 2DTE measurement mode, in "split screen" display.

In Q.US mode, ultrasound attenuation measurements (ATT) are displayed in units of attenuation coefficient at 3.5 MHz (dB/m), backscattering coefficient measurements (BSC) are displayed in units of dB/m/str at 3.0 MHz and speed of sound measurements (SOS) are displayed in units of m/s.

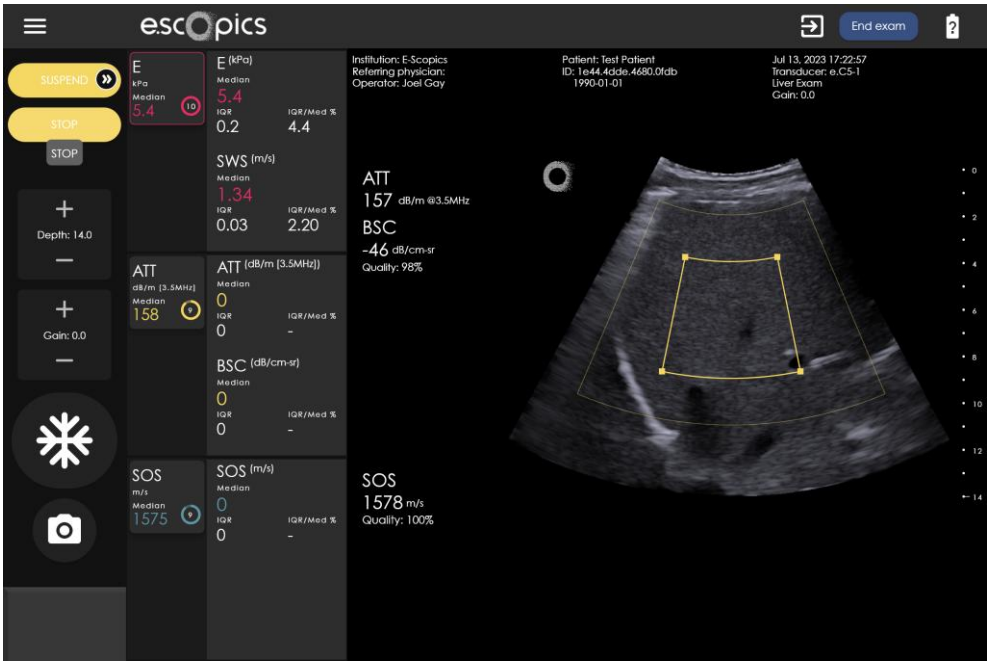


Figure 22. Screen view in the Q.US measurement mode, in "split screen" display.

	The user shall explain to the patient that the probe will vibrate to generate shear waves in the body, so as to track their propagation and measure their speed. The feeling of vibration might be significant.

	When engaging 2DTE, users shall verify the vibration in their hands, prior to application onto the patient. Users should feel or hear the vibrator ticking. If not or in case of doubts about the vibrator integrity, the user shall contact E-Scopics' Technical Support at support@e-scopics.com.

	The maximum number of shear wave speed and liver stiffness measurements to be stored may range from 5 to 20, depending on clinical site practice. This number is defaulted to 10 values, inherited from current practice with other marketed devices using equivalent transient elastography technique to estimate liver stiffness. This number shall be set in the system preferences.

	The IQR/Median percentage (in %) represents the temporal variability of liver stiffness measurements in a given series. This percentage may be used as an indicator of the applicability of liver stiffness assessment for a given exam.

	When the number of valid measurements is less than 5, the IQR is not defined. Therefore, the IQR and IQR/Median are not displayed.

6.8.4 Deleting measurements

The Hepatoscope App does not allow the user to delete series of stored measurements.

The system automatically highlights the less variable series that provided the lowest Median value of quantitative parameters.

6.8.5 End Exam, generate and print exam report

Press the button "End Exam" to end the examination.

The results of the examination are displayed in a paper format report, which is ready for physical and/or virtual print.

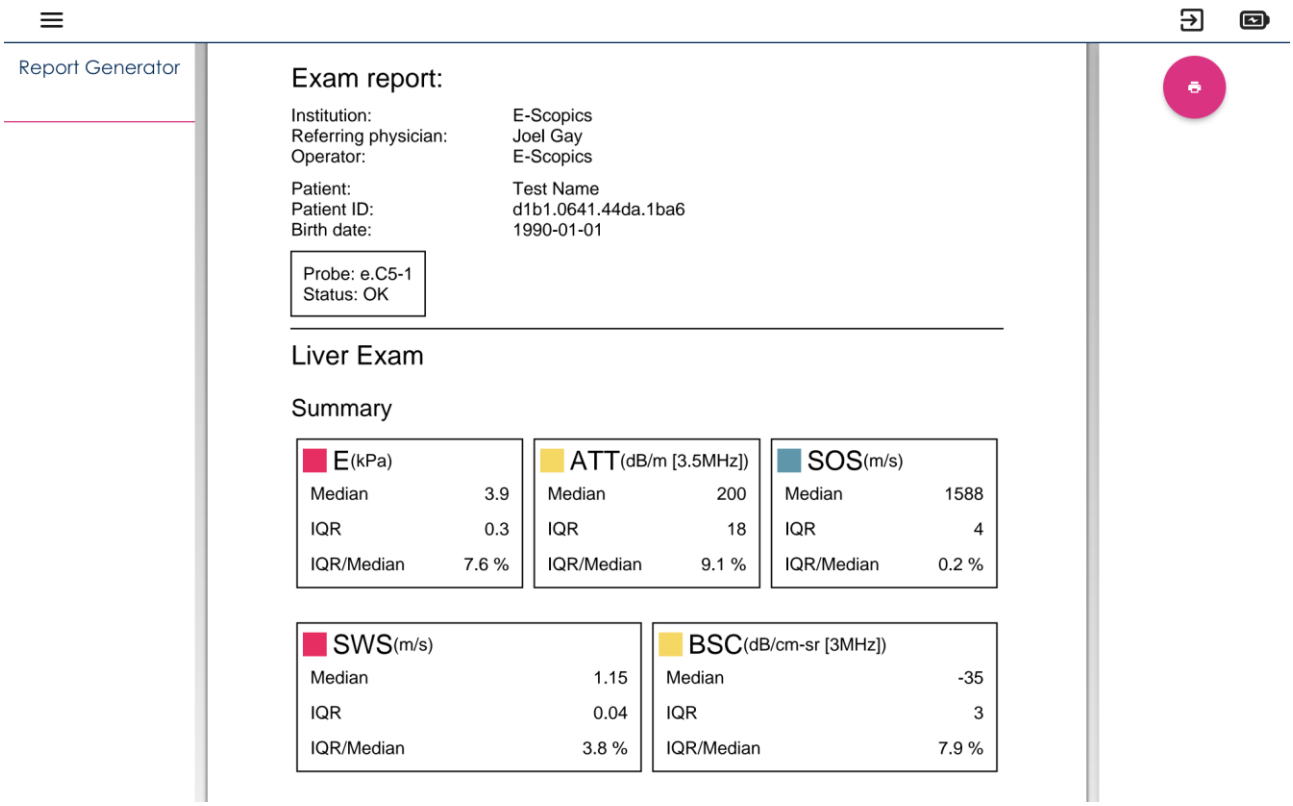


Figure 23. Example of the Report page.

6.8.6 Management of patient file archives

The Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, has not been designed as an archiving device for medical information, records and files. Therefore, archiving of patient files is not allowed with the Hepatoscope App using the e.**C5-1** probe.

7 Research Mode

An ultrasound research mode is available on the Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, in the General Exam application. This research mode named “HB TE" is for use for research only and enables the user to conduct clinical research on heart-beat based transient elastography. The modality is not for clinical use.

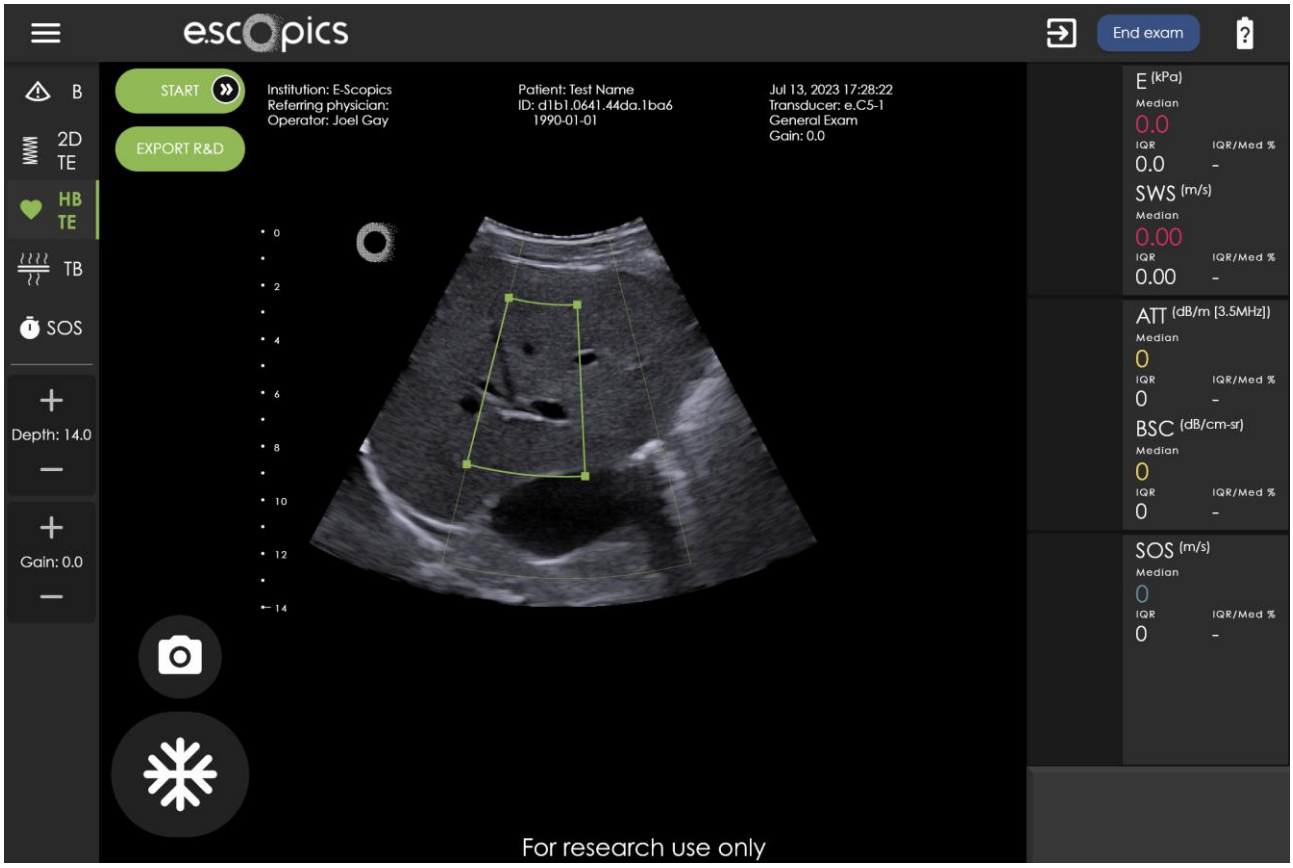


Figure 24. Screen view of the user interface in the General Exam application. The HB TE research mode is available from the menu on the left-hand side of the screen.

8 Instructions for care

In case of a malfunction, only official representatives of E-Scopics are authorized to work on the system and its accessories. Any work performed by an unqualified person will terminate the guarantee.

8.1 Care between uses

The equipment and room supplies need to be checked on a regular basis. Some checks are completed daily, and others need to be completed at the beginning and end of each session or stand. Proceed with visual inspection of the e.**C5-1** probe under adequate lighting conditions before starting any exam. In case of any suspected damage such as corrosion, cracks, breakage, do NOT use the probe and contact E-Scopics' Support Team. Other checks also include preparation of the room and equipment for the session exams, cleaning and disinfection of equipment. Follow the procedures below to ensure that the Hepatoscope App using the e.**C5-1** probe functions properly and remains hygienic throughout the stand. The specific timeframes for equipment QC are as follows: start of stand, start of session, between examinations, end of day, and end of stand.

	Always unplug the **e.C5-1** Probe from the Selected Host, close the Selected Host and unplug it from the mains power supply before moving the system.

8.2 Storage

The Selected Host and Probe shall be safely stored when not used.

- Turn off the system
- Clean and disinfect the **e.C5-1** Probe according to 8.3.2
- Clean the Selected Host
- Ensure the **e.C5-1** probe and host are properly dried before placing them in their dedicated cases.
- Store the **e.C5-1** Probe in the dedicated Carrying Case.
- Secure the storage of the **e.C5-1** Probe and Selected Host in a locked closet/draw.

	The foam used in the **e.C5-1** Probe Carrying Case has been tested for its biocompatibility with the **e.C5-1** Probe materials. Users shall not attempt to replace the foam inside the **e.C5-1** Probe Carrying Case if it becomes damaged. In such a case, contact E-Scopics' Support Team at support@e-scopics.com to order replacement foam, or Carrying Case.

8.3 Cleaning & disinfection

Apply the following recommendations to clean and disinfect the system, probe, and accessories. Failure to observe these recommendations may result in damage to the system and the probe and will terminate the guarantee. Any damage to the system that may result from a failure to observe the manufacturer's recommendations will no longer be covered by the guarantee.

- According to the FDA-modified Spaulding Classification, the **e.C5-1** probe is a non-critical device whose surfaces contact only intact skin and do not penetrate it.
- For non-critical devices, the FDA recommends thorough cleaning, followed by intermediate or low-level disinfection, depending on the nature and extent of contamination.
- The **e.C5-1** probe is a reusable medical device initially supplied as non-sterile to the user, which requires the user to process it (i.e., clean and disinfect) for initial use, as well as to reprocess the device after each use.
- The objectives of cleaning & disinfection are to render the **e.C5-1** probe fit for a subsequent use, after it has been previously used or contaminated.

- To ensure a high degree of protection, cleaning & disinfection shall follow a 2-step process:
  - Thorough cleaning: objective is to remove excess of ultrasound gel
  - Followed by immediate disinfection: objective is to inactivate microorganisms

	The e.**C5-1** probe has been successfully tested for 6,000 cycles of cleaning and disinfection.

	- Observe the expiry dates of cleaning products and decontamination solutions. - Ensure that the contact time and concentration of the cleaning product and decontamination solution are appropriate for the equipment used. Carefully apply the instructions of the manufacturer given on the label of the cleaning product and the decontamination solution. Read cleaning and disinfection products safety datasheets. - Carefully read the recommendations from the Association for Professionals in Infection Control and Epidemiology (APIC) and the Food and Drug Administration (FDA), if applicable in the country.

8.3.1 Cleaning the system

	The Selected Host being not likely to become contaminated with pathogens during use, it must be cleaned following its manufacturer's recommendations, and may not require disinfection. Do NOT apply the cleaning & disinfection recommendations from this User Manual to the Selected Host.

	The e.**C5-1** Probe should not be immersed (or soaked) in liquids for cleaning & disinfection needs. Liquid contact with vibrator trap door must be avoided, (see Figure 5, number 4).

	Only compatible cleaning & disinfectant agents independently approved for commercialization shall be used.

8.3.1.1 Cleaning procedure

Cleaning is defined as the physical removal of excess gel to the extent necessary for further processing; the methods and agents used for cleaning should be designed to remove such excess gel effectively.
The Selected Host is not likely to become contaminated with pathogens during use. It must be cleaned following its manufacturer's recommendations. It may not require disinfection.

8.3.1.2 Precautions

- Do not spray any cleaning or disinfectant product directly on the Selected Host. Leaks may damage the Selected Host, which would then no longer be covered by the guarantee.
- Do not scratch the Selected Host screen.

8.3.2 Cleaning & disinfecting the e.C5-1 Probe

	The **e.C5-1** Probe must be cleaned and disinfected before every use, between patients and prior to returning to its dedicated carrying case. Cleaning is necessary before disinfection in order to ensure effective decontamination.

	Only compatible cleaning & disinfectant agents independently approved for commercialization shall be used.

The **e.C5-1** Probe does not require disassembly before cleaning & disinfection. The **e.C5-1** Probe surfaces must be cleaned & disinfected in strict compliance with the procedure below, and in strict accordance with the instructions for cleaning & disinfection provided by the manufacturers of the cleaning & disinfecting products.

8.3.2.1 Cleaning procedure

1- Disconnect the **e.C5-1** Probe from the Host. Temporarily place the **e.C5-1** Probe where it will not cross-contaminate clean equipment or surfaces.
2- Gently remove the gel from the probe handles and lens by using a soft lint-free cloth or wipe dampened with approved detergent foam or by using an approved pre-impregnated cleaning wipe as referred to in section 8.3.2.4.
3- Change the soft lint-free cloth or dampened wipe as referred to in section 8.3.2.4 and repeat the above step until the probe surfaces are visibly clean.
4- Allow the **e.C5-1** Probe to air dry. You may use a soft, dry lint-free cloth, to dry the transducer.

5- Repeat the previous cleaning steps if it is determined not to be visually clean, or safely dispose of the device if unacceptably deteriorated.
6- Dispose of cleaning materials in accordance with all applicable regulations.
7- Go to step 8.3.2.2 Disinfection procedure.

If any damage is observed, stop using the e.**C5-1** probe and contact E-Scopics or its local representative: support@e-scopics.com.

8.3.2.2 Disinfection procedure

1- Make sure the working environment is adequately cleaned and disinfected.
2- Wipe the surfaces using a soft lint-free cloth or wipe dampened with approved disinfectant foam or by using an approved pre-impregnated cleaning wipe as referred to in section 8.3.2.4.
   Make sure you follow the manufacturer label disinfectant instructions, (temperature, contact time), to achieve the desired activity.
3- Rinse the e.**C5-1** Probe using a soft lint-free cloth or wipe dampened in cold tap water, (or a maximum of 30°C), if the manufacturer disinfectant label instructions require it as referred to in section 8.3.2.4.
4- Allow the e.**C5-1** Probe to air dry. You may use a soft, dry lint-free cloth, to dry the transducer.
5- Once the e.**C5-1** probe is cleaned and disinfected, proceed with its visual inspection under adequate lighting, in search of unacceptable deterioration such as corrosion, cracks, breakage, cracked seals or liquid leakage. Please note that the probe has been successfully tested to withstand a minimum 6000 disinfection cycles. When 6000 disinfection cycles are reached, particular attention shall be paid to identify potential signs of deterioration/degradation. In case the e.**C5-1** Probe is suspected to be damaged, stop using it and contact E-Scopics' Technical Support at support@e-scopics.com.
6- Dispose of disinfection materials in accordance with all applicable regulations.
7- Store the e.**C5-1** Probe in its dedicated carrying case.

8.3.2.3 Precautions

- Do not immerse or soak the e.**C5-1** probe. Liquid contact with vibrator trap door must be avoided, (see Figure 5, number 4).
- Apply the cleaning and disinfecting product solution to the soft lint-free cloth, not directly on the surface to be cleaned.
- The e.**C5-1** probe must be cleaned and disinfected after every use or between patients. Prior cleaning and disinfection is necessary in order to ensure effective decontamination.
- Take care not to introduce any cleaning and disinfecting product solution into the e.**C5-1** probe connector, (see Figure 6, number 2).

Do not use a surgical brush to clean the e.**C5-1** probe.

Even the use of flexible brushes could damage the probe.

Cleaning products which must NOT be used are:

- Abrasive products (such as “Cif’ and scouring powders).
- Alkaline detergents (pH > 9), bleach, etc.
- Sulfuric, acetic, nitric, hydrochloric, and oxalic acid, etc.
- Soda, potash, ammonia, etc.
- Alcohols: Methanol, ethanol, etc.
- Hydrocarbons and solvents: Unleaded petrol, acetone, MED, MIBK, toluene, xylene, benzene, trichloroethylene, diluent, nail varnish solvent, etc.

8.3.2.4 Recommended cleaning and disinfecting solutions and wipes

E-Scopics recommends the use of the cleaning and disinfecting products below. All of them have been independently approved for the cleaning AND the disinfection of ultrasound imaging probes. Please note that the probe has been successfully tested to withstand a minimum of 6000 disinfection cycles. When 6000 disinfection cycles are reached, particular attention shall be paid to identify potential signs of deterioration/degradation, such as corrosion, cracks, breakage, cracked seals or liquid leakage. In case the e.C5-1 Probe is suspected to be damaged, stop using it and contact E-Scopics’ Technical Support at support@e-scopics.com.

Product	Manufacturer	Spray	Wipes	Active compound	Concentration	Cleaning	Disinfection	Rinsing after disinfection
Surfa’Safe *Premium*	Laboratoires Anios	X		Quaternary ammonium	3mg/g	X	X	Required
Wip’Anios Excel	Laboratoires Anios		X	Quaternary ammonium	3mg/g	X	X	Required
Cidalkan	Alkapharm	X	X	Ethanol Dodecylamine	620g/kg 1,5g/kg	X	X	Not required
Super Sani-Cloth	PDI		X	Isopropyl Alcohol Quaternary ammonium	55% 0,50%	X	X	Not required
Kit Duo: Tristel Duo ULT + Tristel Clean + Tristel Duo Wipes	Tristel Solutions Limited	X		Chlorine dioxide	0.1/0.12%	X	X	Not required

8.4 Sterilization

The e.**C5-1** probe must not be sterilized or autoclaved.

8.5 Maintenance & Repair

Once Hepatoscope is installed and activated, it may require software updates that will be available through the ES-Series App Store. To check the status of Hepatoscope updates, the laptop needs to be connected regularly to the Internet.

No preventive maintenance operations are required. Maintenance and Service operations must only be performed by E-Scopics or an authorized representative.
The opening or modification of the Selected Host and the e.**C5-1** Probe, by any person other than E-Scopics or an authorized representative is strictly prohibited.
When required by E-Scopics' Service Team, the user shall return the e.**C5-1** Probe in its original Carrying Case to minimize accidental damage to the probe.

In case of suspicion of damage caused to the system, do not use it and contact E-Scopics or its local representative: support@e-scopics.com.

	Users should not attempt to access the vibrator trap. Removal of the vibrator trap will void all guarantee & warranty conditions. Only authorized representatives of E-Scopics can open and remove the vibrator cover.
	The opening or modification of the e.**C5-1** Probe, by any person other than E-Scopics or an authorized representative will void all guarantee & warranty conditions.
	The USB-C cable of the e.**C5-1** Probe is non-detachable and can only be replaced by E-Scopics or an authorized representative.
	When advised by E-Scopics' support team, the system shall be shipped back to the manufacturer.

8.5.1 e.C5-1 Transducer Element Check

The ES-Series V2 ultrasound diagnostic systems perform an automatic check of the **e.C5-1** Probe transducer elements at the launch of the Hepatoscope App using the **e.C5-1** probe. This check is performed in a transparent manner to the user.

Once the test is done, the System informs the user of the test outcome:

1- When all transducer elements of the Probe are functional, no specific information is provided to the user.

2- When at least 1 transducer element is determined to be NOT functional, the system informs the user with a banner message that disappears automatically after 3 seconds. This message reports:

   a. The number of elements being NOT functional over the total number of probe transducer elements

   b. The list and identification of element(s) being NOT functional

When at least 1 transducer element is determined to be NOT functional, a Probe Icon will be permanently displayed on the top right corner of the Image area, in every modality (GENERAL EXAM and LIVER EXAM) and every exam situation (live and frozen imaging).

On click and hold on this Probe Icon, the “Probe status map” is displayed, that highlights the area(s) within the 2D image that is(are) impacted by the transducer element(s) being NOT functional.

	When at least 1 transducer element is determined to be NOT functional, the user may contact E-Scopics for further support at support@e-scopics.com.

	If there is ultrasound gel or water drops on the acoustic head of the e.C5-1 Probe when the transducer element check is performed, the system may wrongly identify faulty elements and return an error message. Make sure the transducer acoustic head is clean and dry before connecting it to the host and/or launching the Hepatoscope App.

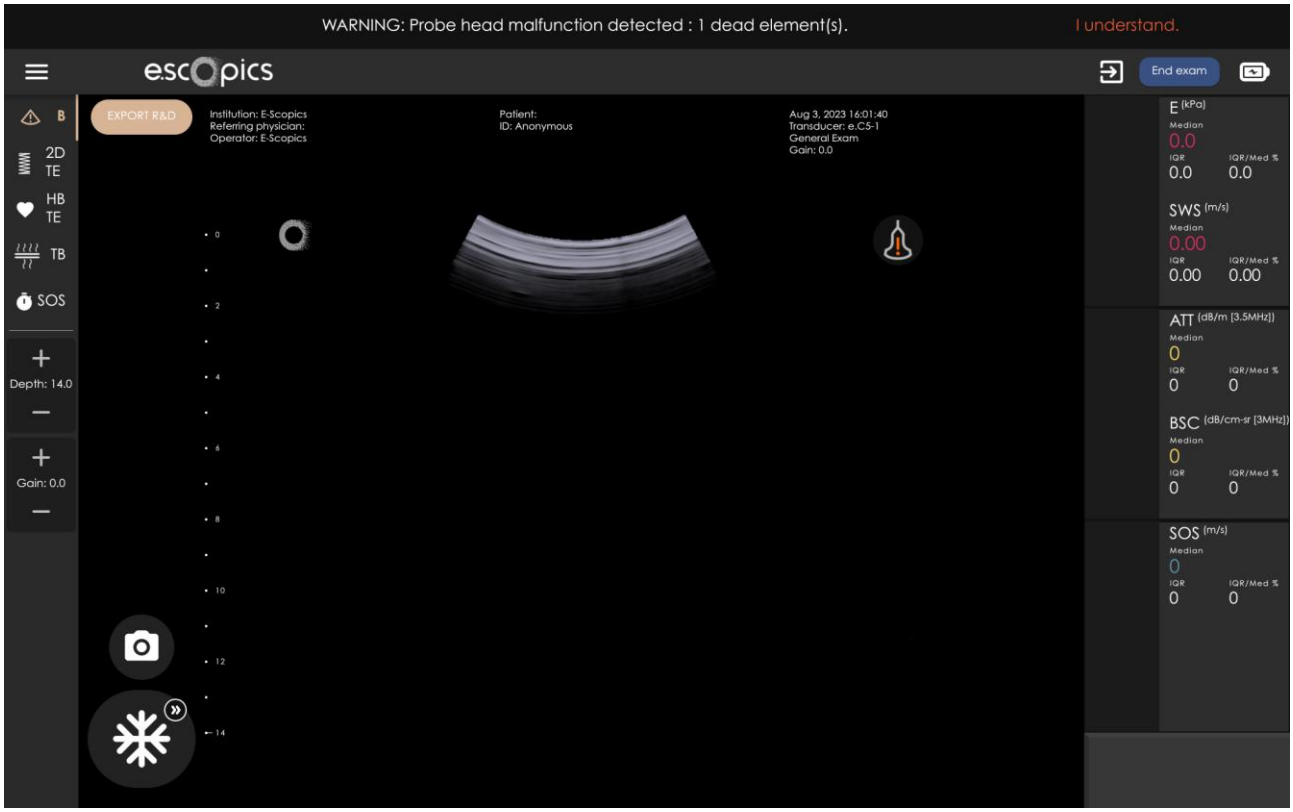


Figure 25. Screenshot showing the warning message at the top of the display with the sentence: "WARNING: Probe head malfunction detected: X dead elements."

8.5.2 Hepatoscope App messages

All messages generated by the system to the user are self-explanatory and propose possible corrective action(s) to be performed by the user.

8.5.3 Troubleshooting

Event	Solution
The Hepatoscope App does not launch after double clicking on its icon.	Contact E-Scopics or its local representative: support@e-scopics.com.
The Hepatoscope App seems to operate slowly, with delay in real-time imaging.	Check that the Selected Host is properly connected to a correctly powered AC supply socket (test another electrical device on this same socket).
The grayscale B Mode image of the acoustic head before using ultrasound gel shows black dot(s) on the probe surface.	Perform automatic tests for acoustic integrity. Exit the Hepatoscope App, plug the probe and launch the Hepatoscope App again. The transducer element check will be performed automatically by the App.

Event	Solution
The Hepatoscope App does not detect the plugged probe	1- Unplug the probe, re-plug the probe 2- Unplug the probe, restart and plug the probe again 3- Unplug the probe, re-plug to another USB-C port if any 4- Contact support@e-scopics.com.
In case of electrical probe malfunction alert	Unplug the probe and restart the system. If the problem persists, please contact support@e-scopics.com.
In case of operating temperature probe malfunction alert	- Unplug the probe - Verify that the system is used in recommended environment conditions. - Restart the system - If the problem persists, please contact support@e-scopics.com.

In the event of a failure or malfunction, please contact E-Scopics or its local representative: support@e-scopics.com.

You can also consult the FAQ online, at the following link:

https://www.e-scopics.com/hepatoscope-support.

8.6 Cybersecurity aspects

8.6.1 Description of detectable cybersecurity events

Here are some situations that could suggest that a cyber-attack has happened on the laptop.

For each situation, refer to the appropriate incident response plan indicated:

Incident detected	Potential cyber event	Incident Response plan
The software does not start anymore	After several unsuccessful attempts, the Hepatoscope does not start. This would suggest that the software executable could have been corrupted/tampered with.	- Disconnect the laptop from the internet - Scan it for malware - Uninstall & reinstall the Hepatoscope Software - Report the incident to the E-Scopics tech support.
user admin is locked out of the application and/or its password is changed without its knowledge	This would suggest that another user successfully logged into the application and edited the user credentials.	- Change your passwords. - Uninstall & reinstall the Hepatoscope Software. - Create new admin account. - Report the incident to the E-Scopics tech support. - Report the incident to your IT department.

Incident detected	Potential cyber event	Incident Response plan
Laptop starts to run slowly	This would suggest that malware was installed.	- Disconnect the laptop from the internet. - Scan it for malware. - Report the incident to the E-Scopics tech support. - Report the incident to your IT department.
Incoherencies are visible in B-Mode Image	This would suggest that the firmware has been tampered with, or that the probe has been damaged.	- Stop using the probe. - Report the incident to the E-Scopics tech support.
Laptop's security software is disabled	This would suggest that another user gained access to the laptop settings.	- Disconnect the laptop from the Internet. - Change your passwords. - Report the incident to the E-Scopics tech support. - Report the incident to your IT department.

If a cyber-attack is suspected, submit the incident as described in Section “How to disclose a vulnerability or an incident”.

8.6.2 Disclosure of a vulnerability or an incident

Any suspected cybersecurity event, vulnerability or incident, shall be disclosed to E-Scopics by sending immediately an email to security@e-scopics.com.

Such disclosure email shall include the following information:

- Sufficient contact information such as your organization and contact name so that E-Scopics can get in touch with you.
- Description as detailed as possible of your discovery (e.g. time & date, product or service name, affected version information, operating system, software configuration of the computer or device configuration at time of discovering the incident) with clear, concise, reproducible steps. If applicable, please provide screenshots and/or videos. These can assist E-Scopics security team in reproducing the issue.
- The impact of the vulnerability; if this bug were exploited, what could happen?
- Recommended solution (optional, but appreciated).

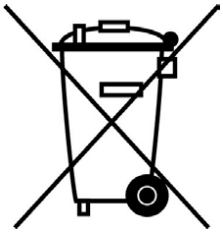
8.7 Product Lifetime

Provided that all necessary precautions for the use and maintenance have been undertaken in accordance with the recommendations of this User Manual, the specifications & performance characteristics of the

e.C5-1 Probe shall be ensured for two years, and three years for the Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems.

8.8 End-of-Life

If the Hepatoscope App using the **e.C5-1** probe can no longer be used safely, the system must be decommissioned. Steps must be taken to prevent its inadvertent use: follow the rules for processing of electrical and electronic devices at the end of their useful life (applicable in the European Union Member States and other European countries operating selective collection systems).



This symbol on a product or its packaging indicates that the product in question must not be processed with household waste. It must be taken to a designated collection point for the recycling of electrical and electronic equipment.
By ensuring that this product is disposed of appropriately, you will help to prevent potential negative effects on the environment and human health.
The recycling of materials will help to preserve natural resources. For additional information on the recycling of this product, contact your town council, waste collection site or store where you purchased the product.
Consumables: All of the disposable consumables must be disposed of by following the procedure implemented for this type of product (Selective sorting, send to the medical waste processing center, etc.).

The system may be shipped back to the manufacturer at end-of-life.

	Any patient data must be deleted from the Selected Host at the product end of life, before the product is decommissioned.

	In case the Carrying Case is damaged at product end of life, contact support@e-scopics.com

9 Technical characteristics

Manufacturer	E-Scopics 931 chemin de la Bosque d'Antonelle 13090 Aix-en-Provence, France
Model	ES-Series V2
MDR Classification	Class IIa, according to Rule 10 of Annex VIII of EU Medical Device Regulation MDR 2017 / 745.
Class of protection against electric shocks	Class II (externally powered)
Type of part applied	Type BF
Protection against harmful ingress of water or particulate matter	IPX1
Software security class	B/Moderate
Class and group according to CISPR 11	A
Operating Mode	Continuous operation
Mechanical Index	MI < 1.0 for all operating modes
Thermal Index	TI < 1.0
FDA Acoustic Level	Track 1 TI and MI are 1.0 or less for all device settings. Therefore these indices are not displayed in the UI.

9.1 Acoustic Table Output

The combined mode of operations reported in Table below are:

- B+2DTE: B-Mode imaging combined with 2D transient elastography
- B+TB: B-Mode imaging combined with tissue brightness estimation
- B+SOS: B-Mode imaging combined with speed of sound estimation
- B+Q.US: B-Mode combined with speed of sound estimation and tissue brightness estimation

Th research mode of operations reported in Table below is B+HBTE which refers to B-Mode combined with heart-beat transient elastography.

		Conventional Mode of operation	Combined Modes of operation				Research Mode of operation
Clinical Application	Global Maximum Output Level (est.)	B	B+2DTE	B+TB	B+SOS	B+Q.US	B + HB TE
Fetal Imaging & Other	max ISPTA.3	2.16	5.70	3.45	3.78	4.05	5.07
	min ISPTA.3	2.16	5.70	3.45	3.78	4.05	5.07
	max MI (or ISPPA.3)	0.47	0.47	0.47	0.47	0.47	0.47
	min MI (or ISPPA.3)	0.47	0.47	0.47	0.47	0.47	0.47
	TIS	0.04	0.08	0.02	0.03	0.03	0.07
	TIB	0.08	0.21	0.08	0.08	0.09	0.18
	TIC	0.14	0.35	0.14	0.14	0.16	0.30
	TI	0.14	0.35	0.14	0.14	0.16	0.30

9.2 Performances

The quantities measured are linear distances, shear wave speed written as “SWS”, stiffness written as “E”, ultrasound attenuation written as “ATT”, backscattering coefficient written as “BSC” and speed of sound written as “SOS”.

Performance testing has been performed in vitro on calibrated phantoms.

9.2.1 Linear distance measurements

Linear distance measurements are performed with the following accuracy:

- Vertical tolerance +/- 1 mm
- Horizontal tolerance +/- 1 mm

9.2.2 Shear wave speed imaging and measurements

9.2.2.1 Shear wave speed/Stiffness imaging

Performance was evaluated using 3 independent measurements performed on a calibrated phantom featuring spherical inclusions of different stiffnesses. The sampling of stiffness values spread from 6 to 47 kPa.

Lateral and axial resolutions were obtained by measuring the transition width of estimated stiffness lateral and axial profiles at the junction between the background region and the inclusion.

Bias of local stiffness estimation were assessed by measuring stiffness values within different calibrated homogeneous regions.

Imaging resolution	Measured Stiffness range (kPa) *	Liver Exam Stiffness Map range (kPa) **	Value (mm)
Lateral resolution	[6 – 47]	]0 – 30]	< 10
Axial resolution	[6 – 47]	]0 – 30]	< 10

Imaging quantification	Measured Stiffness range *	Liver Exam Stiffness Map range **	Bias
SWS (m/s)	[1.4 – 4.0]	]0 - 3.2]	< 0.7
E (kPa)	[6 – 47]	]0 - 30]	< 5

* The Measured Stiffness range corresponds to the range of stiffness values used to assess the performance of the mapping of quantitative stiffness values (requiring off-line processing).

** The Liver Exam Stiffness Map range corresponds to the range of stiffness values available to the user in Liver Exam 2DTE mode. The open bracket “]0” excludes the stiffness value of 0 kPa which has no meaning in the context of the proposed stiffness imaging method. See 6.7.3 for further details.

9.2.2.2 Shear wave speed measurement (SWS)

Performance was evaluated using ten independent series of 10 successive acquisitions performed on four calibrated homogeneous phantoms, of which shear wave speed values spread from approximately 1 to 6 m/s. Bias and Precision of global shear wave speed estimation were assessed by measuring stiffness values within different calibrated homogeneous phantoms. This protocol has been documented as per the RSNA Quantitative Imaging Biomarker Alliance (QIBA) (https://qibawiki.rsna.org/index.php/Ultrasound_SWS_Biomarker_Ctte).

Min value	0.0 m/s
Max value	5.8 m/s
Bias (%)	< 20 %
Precision (%)	< 17 % if 0.9 m/s < SWS ≤ 1.2 m/s < 12 % if 1.2 m/s < SWS ≤ 2.2 m/s < 30 % if 2.2 m/s < SWS

9.2.2.3 Soft tissue stiffness measurement (E)

A similar protocol as in 9.2.2.2 was used with the corresponding calibrated stiffness values, ranging up to 100 kPa.

Min value	0.0 kPa
Max value	100 kPa
Bias (%)	< 45 %
Precision (%)	< 34 % if 2.4 kPa < E ≤ 4.3 kPa < 24 % if 4.3 kPa < E ≤ 14.5 kPa < 59 % if 14.5 kPa < E

9.2.3 Ultrasound attenuation measurements (ATT)

Performance was evaluated using ten independent series of 10 successive acquisitions performed on four calibrated homogeneous phantoms, of which ultrasound attenuation values spread from approximately 105 to 350 dB/m @ 3.5MHz.

Bias and Precision of ultrasound attenuation estimation were assessed by measuring attenuation values within different calibrated homogeneous phantoms.

Min value	105 dB/m @ 3.5 MHz
Max value	350 dB/m @ 3.5 MHz
Bias (%)	< 80 dB/m @ 3.5 MHz
Precision (%)	< 10 %

9.2.4 Backscattering coefficient measurements (BSC)

Performance was evaluated using ten independent series of 10 successive acquisitions performed on four calibrated homogeneous phantoms, of which ultrasound backscattering coefficient values spread from approximately -40 to -20 dB/cm-sr @ 3MHz.

Bias and Precision of ultrasound attenuation estimation were assessed by measuring backscattering coefficient values within different calibrated homogeneous phantoms.

Min value	-40 dB/cm-sr @ 3 MHz
Max value	-20 dB/cm-sr @ 3 MHz
Bias (%)	< 5 dB/cm-sr @ 3 MHz
Precision (%)	< 10 %

9.2.5 Speed of sound measurement (SOS)

Performance was evaluated using ten independent series of 10 successive acquisitions performed on six calibrated homogeneous phantoms, of which speed of sound values spread from approximately 1450 to 1600 m/s.

Bias and Precision of speed of sound estimation were assessed by measuring speed of sound values within different calibrated homogeneous phantoms.

Min value	1450 m/s
Max value	1600 m/s
Bias (%)	< 4 %
Precision (%)	< 1.2 %

9.3 Selected Host minimum specifications

The host shall be an off-the-shelf approved computer.

9.3.1 Computing performances

9.3.1.1 CPU+GPU architectures

CPU	+ GPU	+ Operating System
- Intel® Core™ i7 processor, 10th gen - Or AMD Ryzen 7+ 16 GB of on-board RAM	- NVIDIA® GeForce RTX™ 20 series - Or NVIDIA® GeForce RTX™ 30 series Or NVIDIA® GeForce RTX™ 40 series	64-bit Windows 10 and above

9.3.1.2 Arm64-based architecture

- Snapdragon® X Plus 10 cores + 64-bit Windows 10 and above Operating System + at least 16 GB RAM
- Snapdragon® X Elite 12 cores + 64-bit Windows 10 and above Operating System + at least 16 GB RAM

9.3.2 Hardware features

Display	Power	Data storage
13.5 inches Multi-touch screen 10 points (recommended for optimal use) Resolution: 2736 x 1824 (267 ppi) Image size: 3:2 Contrast ratio: 1600:1 is recommended	USB-C output: 5V 3.0A Power supply: 100-240 V — 50-60 Hz The use of a medical-grade power supply (60601-1 compliant) is recommended	USB-C connector with USB 3 protocol Storage: SSD 260 Go

9.4 e.C5-1 Probe characteristics

Dimensions (mm)	Length: 184.8 Width: 72.8 Thickness: 31
Weight	456 g
Center Frequency	3.0 MHz
Frequency range	Optimum range: 2.44-3.25 MHz Maximum range: 1-5 MHz
Number of transducer elements	128
Radius of curvature	59.46 mm
Electrical	USB-C 5V 3.0A
Data transfer	USB 3.1 Gen 1 (protocol, max throughput of 5 Gbps)
USB-C Cable length	1.8 to 2.0 m

9.5 Environmental characteristics

	Operating conditions	Storage and transportation conditions
Ambient temperature	+ 15 °C to + 30 °C	-20° to + 55°C
Relative humidity (non-condensing)	30 % to 75 %	10% to 85%
Atmospheric pressure	70 kPa to 106 kPa	54 kPa to 106 kPa
Maximum altitude	3000 m	5000 m

10 Regulations

10.1 Electrical Safety & Electromagnetic Compatibility

The e.**C5-1** Probe is manufactured and tested in accordance with IEC electromagnetic compatibility (EMC) and electrical safety standards. To maintain this compliance and to guarantee the safe use, the user must comply with the indications and symbols contained in this manual.

10.2 Electro-Magnetic Conformity specific statements

The Hepatoscope App using the e.**C5-1** probe is intended for use in the electromagnetic environment defined below in a Professional Health Care Facility environment and not intended for use in an MRI environment or where electromagnetic disturbances are considered high.

	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system as degradation of the Essential Performance could result.

	Use of the system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Hepatoscope App using the e.**C5-1** probe and the other equipment should be observed to verify that they are operating normally.

Phenomenon	Basic EMC standard	Professional healthcare facility environment (Group1)	
		Immunity test levels	Hepatoscope App using the e.**C5-1** probe Compliance level
Harmonics current emission **Measurement of voltage fluctuation and flicker** **Conducted emission (measurement)**	IEC 61000-3-2 IEC 6100-3-3	Not applicable.	The test was not performed because the cable length is inferior to 3m and the device is not AC powered.

Measurement of radiated disturbances	CISPR 11: 2015 / AMD1: 2016 / AMD2: 2019 Severity : Group A[1]	30MHz-1GHz	30MHz-1GHz
Electrostatic Discharge (ESD) immunity	IEC 61000-4-2: 2008	± 8 kV contact (indirect / direct) ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact (indirect / direct) ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated, radio-frequency, electromagnetic field immunity	IEC 61000-4-3: 2006 / AMD1: 2007 / AMD2: 2010	80MHz to 2.7GHz	80MHz to 2.7GHz
Electrical fast transient/burst immunity	IEC 61000-4-4	Not applicable.	Does not function on AC power.
Surge immunity	-	-	-
Conducted disturbances induced by radio-frequency fields immunity	Conducted RF 61000-4-6	Not applicable.	The test was not performed because the cable length is inferior to 3m and the device is not AC powered.
Power frequency (50/60Hz) magnetic field immunity	IEC 61000-4-8: 2009	- 50Hz at 30A/m (50Hz) - 60Hz at 30A/m (60Hz)	- 50Hz at 30A/m (50Hz) - 60Hz at 30A/m (60Hz)

[1] The e.**C5-1** Probe uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

FCC STATEMENT: Class A according to CISPR 11:

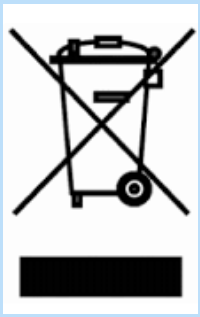
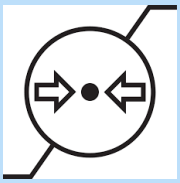
Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in other environments (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

11 Symbols

The table below lists and describes a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. These symbols may be used on the Hepatoscope App, as part of the ES-Series V2 ultrasound diagnostic systems, and on its accessories and packaging. These symbols are compliant with current versions of the listed standards.

Symbol	Standard	Description
	EN ISO 15223-1:2021	Indicates the date when the medical device was manufactured.
	EN ISO 15223-1:2021	Indicates a medical device that can be broken or damaged if not handled carefully.
IPX1	IEC 60529	Ingress Protection rating system showing the degrees of protection from solid objects and liquids. The X indicates insufficient data has been gathered to assign a protection level. The 1 indicates that the system is protected against protection against ingress of water and particulate matter (IEC 60529) up to the trap, and NOT protected against the effects of immersion in water to any depth.
	IEC 60417	Indicates direct current (5V for e.**C5-1** Probe).
	IEC 60601-1 ed3.1:2012 + A2:2020	Indicates isolated patient connection (Type BF applied part).
	EN ISO 15223-1:2021	Indicates a medical device that needs to be protected from moisture.
	EN ISO 15223-1:2021	Indicates the medical device manufacturer, as defined in EU Medical Device Regulation MDR 2017/745.

Symbol	Standard	Description
	EN ISO 7010:2020+A1:2020 Ref M002	To signify that the instruction manual/booklet must be read.
 SW App	ISO 7000: 2019	To indicate the need for the user to consult the instructions for use available in electronic.
	EN ISO 15223-1:2021	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1:2021	Indicates the manufacturer's serial number so that a specific medical device can be identified.
		Indicates in the software the name of the software application service provided by E-Scopics.
		Indicates in the software the version of the ES-Series ultrasound diagnostic systems software provided by E-Scopics.
		Indicates in the software the version build provided by E-Scopics.
	EN ISO 15223-1:2021	Indicates the product is a Medical Device.
	EN ISO 15223-1:2021	Indicates a medical device that needs protection from light sources.

Symbol	Standard	Description
	WEEE Directive 20120/19/EU	Requires a separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by Pb or Hg, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD monitor contain mercury.
	MDR 2017/745	Meets the requirements of the EU Medical Device Regulation MDR 2017/745.
	EN ISO 15223-1:2021	Indicates the Unique Device Identifier of the product.
	EN ISO 15223-1:2021	Do not use if package is damaged and consult instructions for use
	EN ISO 15223-1:2021	Indicates the upper limit of temperature to which the *medical device* can be safely exposed.
	EN ISO 15223-1:2021	Indicates the range of humidity to which the *medical device* can be safely exposed.
	EN ISO 15223-1:2021	Indicates the range of atmospheric pressure to which the *medical device* can be safely exposed.
USA – Rx only	USA 21CFR801.109	Indicates the medical device is for prescription use only. United States Federal law restricts this system to sale by or on the order of a physician.
		Indicates the authorized representative in Switzerland.

12 Abbreviations & Acronyms

2D TE: two-dimensional transient elastography

APIC: Association for Professionals in Infection Control and Epidemiology

ATT: Ultrasound Attenuation

dB: decibels

EMC: Electromagnetic Compatibility

FDA: Food and Drug Administration

HB TE: heart-beat transient elastography

IEC: International Electrotechnical Commission

IQR: Inter Quartile Range

ISO: International Organization for Standardization

kPa: kiloPascals

MHz: MegaHertz

MRI: Magnetic Resonance Imaging

OS: Operating System

QC: Quality Control

Q.US. Quantitative Ultrasound

ROI : Region of Interest

SOS: Speed of Sound

SWS: Shear Wave Speed

UI: User Interface

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CH REP

CMC Medical Devices GmbH
Rigistrasse 3, 6300 Zug, Switzerland
chrep@cmcmedicaldevices.com

Correspondence & Shipping Address	Headquarter Address
E-Scopics S.A.S. 235 rue Leon Foucault 13100 Aix-en-Provence France	E-Scopics S.A.S. 931 chemin de la Bosque d'Antonelle 13090 Aix-en-Provence France

www.e-scopics.com

support@e-scopics.com