FibroScan® compact 530

User manual

for the FibroScan® 530 COMPACT

CE

0459

E322M001.5 – Version 5 – 02/2021

(software version 4.0)

en-GB

Người đại diện hợp pháp của cơ sở
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Date: 2022-02-09 16:19:59

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1. PURPOSE OF THE USER MANUAL

The present User Manual has no contractual value whatsoever and under no circumstances may Echosens be held responsible on the basis of the information contained in the present manual.

The present User Manual details, on the one hand, all of the information required for the implementation, use and maintenance of the FibroScan instrument and, on the other hand, the list of information displayed.

After carefully reading the manual, operators shall be able to:

- Connect peripheral elements (mains lead, USB devices, probes) and power up the FibroScan instrument,
- Configure the device,
- Navigate the machine's user interface,
- Perform basic maintenance.

Echosens SA publishes this manual "as is"', without guarantees of any nature, whether explicit or implicit, including, but not limited to, implicit guarantees concerning merchantability or fitness for a particular use, for the purpose of providing simple and accurate information. Consequently, Echosens SA cannot accept any responsibility for any incorrect interpretation of the manual. Though all efforts have been made to offer a manual that is as accurate as possible, the manual may nevertheless contain some technical inaccuracies and/or typographical errors.

Echosens 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 kind. In the event of damages arising from a defect (imperfection) or error contained in the present User Manual, Echosens undertakes to send the physician, as rapidly as possible, a hard copy or electronic document containing all corrections made to the present manual.

This manual is updated on a regular basis. The most recent version of this manual is available from Echosens on simple request. Should any major modifications be made to the manual, however, Echosens undertakes to send the physician, as rapidly as possible, a new copy of the manual in hard copy or electronic format. Note that this does not involve updating the hardware and/or software in your possession.

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

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

Any information or modification requests pertaining to this manual should be sent to: https://support.echosens.com.

1.1. SYMBOLS USED IN THE MANUAL

This symbol means: ATTENTION

Instructions preceded by this symbol may cause injuries or damage the medical device and installation if not correctly followed.

This symbol means: INFORMATION

Additional information with no impact on instrument use.

1.2. PROPERTY AND COPYRIGHT

2. WARNINGS

2.1. ELECTRICAL SAFETY

To avoid the risk of electric shock, this device must be connected to an earthed power supply only.

Multi-socket adapters and extension leads must not be connected to the device.

The power cable socket is intended for use as an isolating device and must be easily accessible to prevent connection problems.

All peripherals connected to signals input/output must be certified according to standard IEC 60950-1.

Any parts not specified in the user manual must not be connected to the system.

Correct grounding operation can only be guaranteed if the system is connected to a socket compliant with safety standards.

Make sure that the vents are not obstructed. If they are, the electronic equipment could overheat, causing irreversible damage.

Do not submerge the device or its probes.

2.2. BATTERY SAFETY

Your battery has been designed for a specific application. Do not use it for any other application. Misusing the battery may cause the battery to overheat, rupture, or ignite and cause serious injury.

Be sure to follow the safety rules listed below:

- Do not place the battery in fire or heat the battery.
- Do not install the battery backwards causing the polarity to be reversed.
- Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object (such as wire).
- Do not store or carry the batteries together with necklaces, hairpins, or other metal objects.
- Do not pierce the battery with nails, strike the battery with a hammer or step on the battery.
- Do not expose the battery to water or salt water, or allow the battery to get wet.
- Do not connect batteries in series or in parallel. Irreversible damage can be done.
- Do not apply pressure that will deform the battery.
- Do not place the battery in a microwave oven, high-pressure containers, or on induction cookware.

Do not disassemble or modify the battery. The battery contains safety and protection devices which, if damaged, may cause the battery to generate heat, rupture or ignite.

Do not place the battery on or near fires, stoves, or other high-temperature locations. Do not place the battery in direct sunshine or use or store the battery inside cars in hot weather. Doing so may cause the battery to generate heat, rupture or ignite. Using the battery in this manner may also result in a loss of performance and shortened life expectancy.

Immediately discontinue use of the battery if, while using, charging or storing the battery, the battery emits an unusual smell, feels hot, changes colour, changes shape, or appears abnormal in any other way. Contact Echosens or its local representative: https://support.echosens.com.

5. In the event that the battery leaks and the fluid gets into your eye, do not rub the eye. Rinse well with water and immediately seek medical care. If left untreated the battery fluid could cause damage to the eye.

Do not plug the battery directly into the power supply. Use the specific external power supply provided with the device to charge the battery, otherwise irreparable damage to the battery could occur.

2.3. ELECTROMAGNETIC SAFETY

The use of accessories not specified in the user guide may cause a non-compliance in terms of electromagnetic compatibility (EMC).

Avoid using the FibroScan device when placed upon or near a machine that generates electromagnetic disturbance.

The FibroScan 530 COMPACT device requires special precautions to be taken regarding to electromagnetic compatibility (EMC). It must be installed and put into service in accordance with the EMC information given in this guide.

2.4. MAGNETIC RESONANCE SAFETY

The FibroScan device is incompatible with magnetic resonance (MR). Under no circumstances should it be taken into a room dedicated to Magnetic Resonance Imaging (MRI).

2.5. USING THE DEVICE

Do not push or lean on the top of the FibroScan unit.

When the device is mounted on the Roll-Stand 530:

The roll-stand shelf must be in its lowest position before moving the device around.

To prevent the FibroScan from tipping over when being moved, move it slowly and grip the shelf firmly to guide it.

To avoid tipping the FibroScan when lowering it down a step, the operator must go in front of the device and guide it on the way down.

In the event of the device mounted on the Roll-Stand 530 falling off, do not use the equipment until after thoroughly inspecting its casing and screen. If you find that it has splintered or cracked, do not use the equipment until it has been repaired by Echosens.

If the housing of the device is chipped or cracked by mechanical impact, do not use the device until it has been repaired by Echosens.

If the device is not sufficiently charged, it may cut out during an examination. This power outage may lead to loss of unsaved data.

2.6. DELETING MEASUREMENTS

All measurements performed before the one chosen for deletion will be eliminated from the examination after confirmation.

2.7. SWITCHING OFF THE UNIT

Never switch the unit off during an examination or whilst in configuration mode. Never switch off the main power supply or disconnect the battery when the unit is switched on. Failure to comply with these instructions could cause a malfunction of the machine and/or loss of data.

2.8. CLEANING AND MAINTENANCE

These maintenance operations must not be performed by a third party other than a technician authorised by Echosens.

The opening or modification of the device by a person other than an authorised Echosens technician is strictly prohibited.

The probe must be calibrated periodically. Beyond the period indicated on the calibration certificate, the manufacturer no longer guarantees the performance characteristics of the probe.

Do not remove/insert the battery when the device is connected to an external power supply.

Following a software update, the battery must be removed for a few seconds and then reinserted.

2.9. CLEANING

To prevent electric shock, switch off the unit before cleaning.

2.10. INTERPRETING THE RESULT

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

3. MISCELLANEOUS INFORMATION

3.1. GUARANTEE

The terms of guarantee are stated in the Echosens terms of sale documents.

For any claims, Echosens is at the disposal of the physician and their assistants and shall, if necessary, pass the aforementioned claim on to the competent local representative.

3.2. LIABILITY

The information displayed on the FibroScan screen is the result of complex calculations performed by the software application built into the FibroScan. These results are then interpreted by the physician in charge. Under no circumstances, and even if Echosens had been notified, can Echosens be held responsible for the incorrect interpretation of these results; Echosens' liability being limited to making the measurements, displaying them and printing them via the FibroScan.

The data from each examination are saved on the machine's hard disk. The user is responsible for saving the data on a regular basis. Echosens cannot under any circumstances be held responsible for the partial or total loss of FibroScan data.

3.3. ESSENTIAL PERFORMANCE CHARACTERISTICS

When a stiffness or CAP (Controlled Attenuation Parameter) value is displayed by FibroScan, this value is considered correct within the range of error specified by Echosens.

Free from the production of unintended or excessive transducer assembly surface temperature.

3.4. PRODUCT LIFE

Echosens guarantees the specification and performance characteristics of the FibroScan device for seven years, provided that all necessary precautions for use and maintenance have been taken in accordance with the recommendations of the user manuals provided.

The battery product life is defined by: 60 % of initial capacity at 500 cycles, with standard charge and discharge at 40 °C (104 °F).

3.5. REVERSE ENGINEERING

The software 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, analysed, modified, incorporated or combined with another software application, with the exception of cases allowed by law.

Resale of the software built into the FibroScan is prohibited.

3.6. REGISTERED TRADEMARKS

Echosens and FibroScan are registered trademarks of Echosens.

Microsoft Excel and Windows Embedded are registered trademarks of Microsoft Corporation in the United States and other countries.

3.7. PATENTED TECHNOLOGY

FibroScan is covered by one or more patents, both in the United States and in other countries.

Patents: www.echosens.com/patents

4. INDICATIONS AND PRECAUTIONS FOR USE

4.1. INTENDED USE

The FibroScan and its probes form an active, non-implantable medical device using ultrasound.

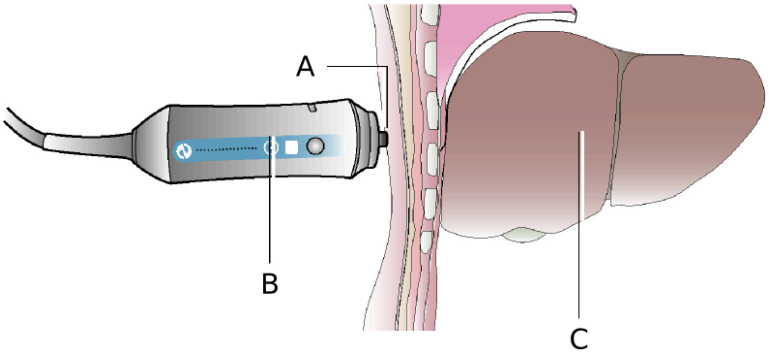
This device is designed to be used in a doctor's office to measure the stiffness and ultrasonic attenuation of the liver in patients with liver disease. It does so in a painless and completely non-invasive manner.

The FibroScan device operates based on the vibration-controlled transient elastography method.

The FibroScan probe comprises a single-element ultrasound transducer mounted on the shaft of an electrodynamic actuator. This transducer generates a transient vibration, which in turn generates an elastic shear wave. This wave propagates through the skin, the subcutaneous tissues, and then the liver. During shear wave propagation, the ultrasound transducer performs a series of ultrasound acquisitions (emission/reception) to measure the speed of shear wave propagation in the liver. Stiffness in kPa of the liver is calculated using this shear wave propagation speed value.

The CAP (Controlled Attenuation Parameter) in dB/m is a measure of the attenuation of ultrasound signals in the tissue. It is taken at the same time as the stiffness measurement, and concerns the same explored volume. This measurement is available on the M^+ and XL^+ probes only.

CAP measurement is not available in all territories.



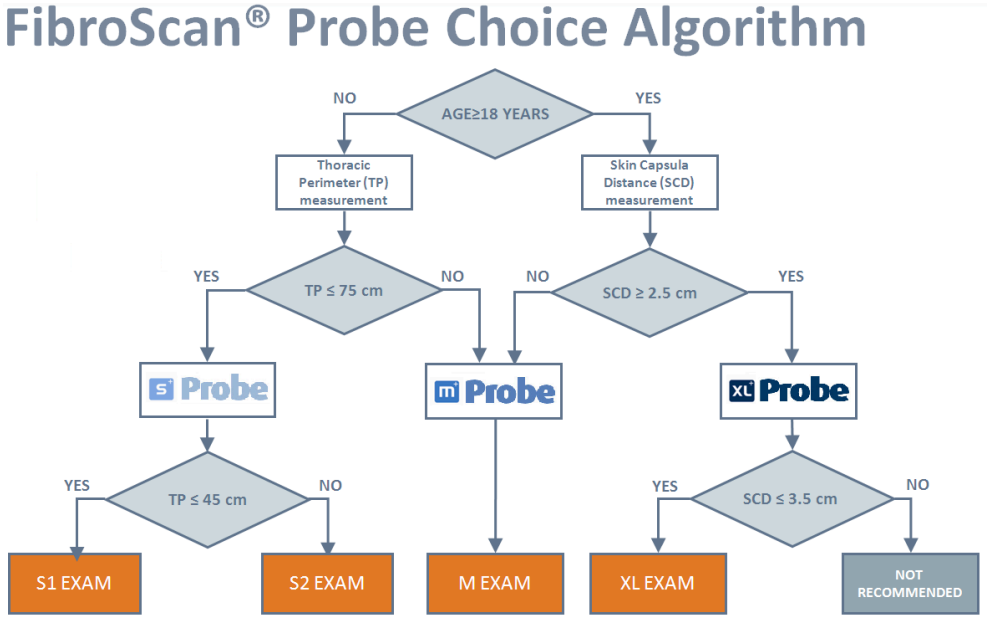
How to use a probe: A: *Ultrasound transducer.* ***B:*** *Electrodynamic actuator.* ***C:*** *Liver.*

4.2. PROBE AND EXAMINATION SELECTION CRITERIA

The recommendations for examination type are defined based on the following data concerning patient morphology:

- TP: Thoracic Perimeter measured at the xiphoid using a tape measure.
- SCD: Skin-to- Capsule Distance measured by ultrasound at the liver stiffness measurement point or using the probe recommendation tool (refer to the chapter on Examination type selection area).

Four types of examination are available: They correspond to specific measurement depths that take into account the liver's depth beneath the skin.



In all cases, Echosens recommends taking 10 valid measurements.

Use of the S^+ probe is not approved for patients over 18 years old, use of the M^+ probe is not approved for patients under 14 years old, and use of the XL^+ probe is not approved for patients under 18 years old.

4.3. PRECAUTIONS FOR USE

The following instructions must be followed in order to ensure patient safety. The FibroScan must not be used in the following situations:

- On an organ other than the liver. The eyes and mucosa must absolutely be avoided.
- On wounds.

Moreover, the presence of ascites between the probe and the liver may prevent measurements from being obtained.

Personnel must follow the user precautions.

4.4. USER TRAINING

Only persons who have received training in the use of the FibroScan unit and who possess a user certificate are authorised to conduct an examination using FibroScan. Training is

essential for correct equipment use and in order to obtain reliable and reproducible measurements.

This manual is not intended to provide user training.

4.5. ELECTRICAL SAFETY

FibroScan is manufactured and tested in accordance with IEC electromagnetic compatibility (EMC) and electrical safety standards. It leaves the factory in full compliance with safety and performance requirements. In order to maintain this compliance and to guarantee the safe use of the medical device, the user must conform to the indications and symbols contained in this manual.

Prior to installation, ensure that the operating and mains voltage values match.

The power lead provided must be connected to the external FibroScan mains connector and to an earthed socket. Correct earthing operation can only be guaranteed if the FibroScan is connected to a power supply network compliant with safety standards.

Refer to the warnings in Chapter 2 concerning electrical safety.

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

- The device is visibly damaged,
- The device is inoperative,
- After prolonged storage in unfavourable conditions,
- After serious damage incurred during transport,
- In the operating theatre.

When the safe use of the FibroScan is no longer possible, the device must be taken out of operation. Steps must be taken to prevent its inadvertent use. The medical device is entrusted to authorised technicians for inspection.

4.6. MAINTENANCE-RELATED SAFETY

For all maintenance operations, the physician and their appointees should contact Echosens, who will send an authorised technician, at: https://support.echosens.com.

For correct and safe use and for all maintenance operations, personnel must conform to the user precautions.

5. EXTERNAL PRESENTATION

5.1. HARDWARE SUPPLIED

When opening the package, ensure the contents match the following list:

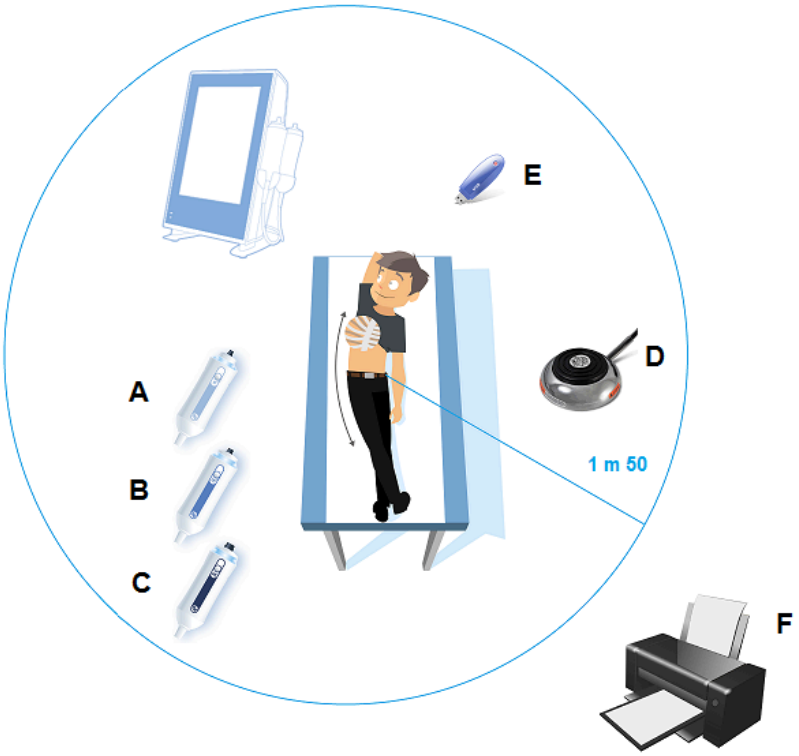
- FibroScan device installed
- Case(s) fitted with probe(s)
- Sealed envelope (Windows EULA license and the present User manual)
- Battery
- External power supply and power cable

5.2. PROBES AND ACCESSORIES

The available probes and accessories are:

- S^+ probe
- M^+ probe
- XL^+ probe
- Roll-Stand 530 (supplied with Quick Start installation guide, 1 screw head concealer cap, 1 Allen key for Torx® TX25 screw, 1 keyboard)
- Control pedal

Set of elements that can be connected to the FibroScan unit:



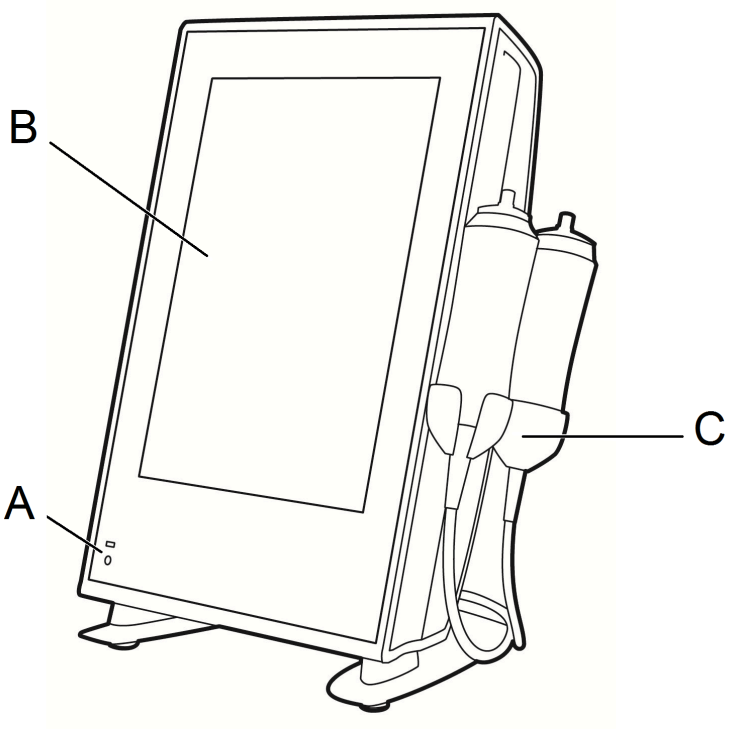
Probes: A: *S+ probe.* ***B:*** *M+ probe.* ***C:*** *XL+ probe.*

Peripherals not included: D: *Control pedal.* ***E:*** *USB storage device.* ***F:*** *Printer.*

5.3. FRONT VIEW

The device contains the electrical power supply, dedicated electronics and a computer. It also serves as support for a monitor and two probe holders.

The following figure presents the instrument's different user-accessible parts.



General arrangement of the FibroScan unit: A: *Standby touch button with battery charge indicator.* ***B:*** *Touch screen.* ***C:*** *Probe holder.*

The standby button

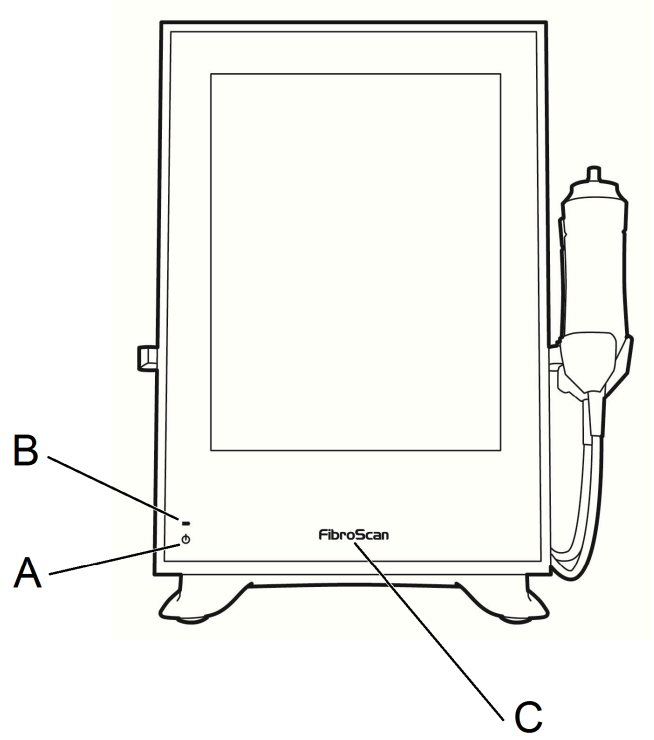
This button is only active if the external power supply is connected to the power network and to the FibroScan, or if it is battery-powered.

To switch the device on or off, press the button until you hear a beep. Release. This button loads the application. After a few seconds, the home window is displayed.

Battery charge indicator

The battery charge indicator may show the following statuses:

- Not lit: Connected to external power source, not battery-powered.
- Flashing green: Connected to external power source, battery charging.
- Steady green: Not connected to external power source and battery charge above 33%.
- Orange: Not connected to external power source and battery charge between 20% and 33%.
- Red: Not connected to external power source and battery charge below 20%.



View of the front panel of the FibroScan unit: A: *Standby touch button.* ***B:*** *Battery charge indicator.* ***C:*** *Power indicator.*

Power indicator

The status of the power indicator is defined as follows:

- Not lit: device off.
- White: the unit is switched on.

The screen and the software

This is a 15-inch colour touch screen.

To protect the screen from any risk of damage, take care not to hang the power cable on the top of the machine.

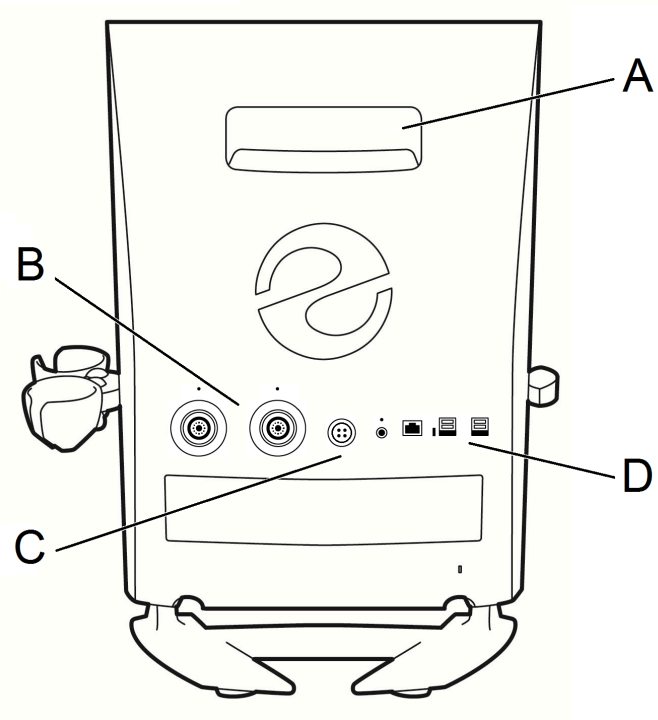
The FibroScan runs on dedicated software.

The software is automatically launched when the FibroScan is switched on. It is used to:

- perform examinations,
- manage examinations saved in archives.

5.4. REAR VIEW

The following figure presents the instrument's different user-accessible parts.



Rear view: A: *Rear handle.* ***B:*** *Probe connectors.* ***C:*** *External power supply connector.* ***D:*** *Computer connectors.*

Moving the device

Do not push or lean on the top of the FibroScan device.

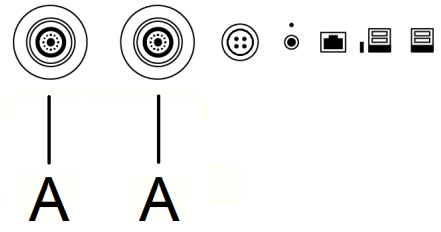
Use the FibroScan's rear handle to move it.

Probe connectors

Before using the FibroScan device, the operator must be able to recognize the Electrostatic discharge (ESD) symbol, and must take the appropriate precautionary measurements as described below:

- Do not touch the pins of connectors marked with the ESD warning symbol,
- Before making any connections, discharge the static electricity from your body, either by touching and remaining in contact with a grounded metal object, or using a properly grounded antistatic bracelet or a potential equalization terminal.

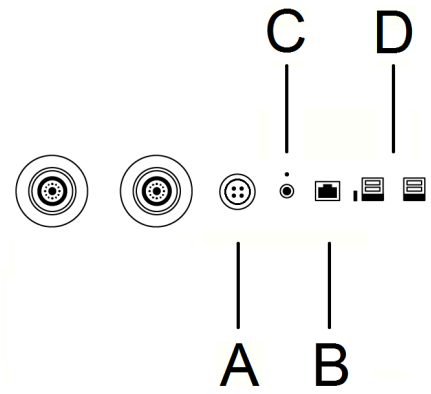
Training in the meaning of the ESD symbol and ESD precautionary procedures is strongly recommended.



Location of probe connectors: A: Probe connectors.

The probe connectors are fragile.

Computer connectors



External power supply and computer connectors: A: *External power supply KPJX-4SS connector.* ***B:*** *RJ45 network connector.* ***C:*** *Auxiliary jack, 5 V.* ***D:*** *USB connectors.*

- Ethernet connector: also used for connectivity. Used by Echosens maintenance staff.
- Four USB 2.0 sockets: to connect an external hard drive for backups, a USB key, or a USB printer.

Echosens recommends using encrypted hard drives or USB keys protected by logon code entered using integrated keypad.

External power supply secondary connector.

The external power supply must be connected to a 100 V or 240 V AC single-phase 50-60 Hz grounded mains socket using the power cord supplied.

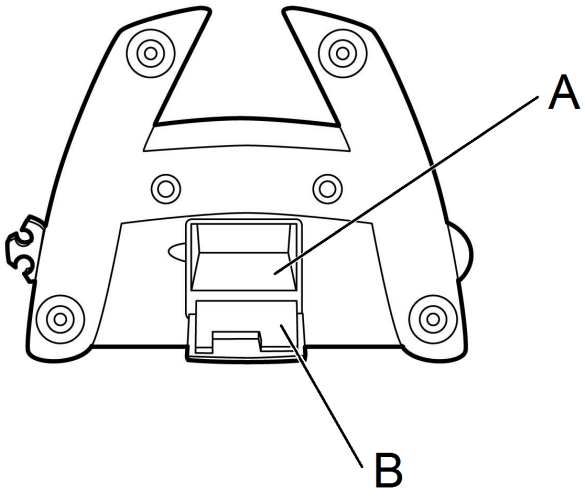
Auxiliary jack, 5 V

This jack enables accessories, such as a control pedal, to be connected.

5.5. VIEW FROM BELOW

The FibroScan is battery-powered.

The following figure presents the access to the battery.



Access to battery: A: *Battery hatch.* ***B:*** *Bolt.*

The battery

If the battery must be replaced, you are strongly advised to use procedure in the Cleaning, maintenance and repairs chapter of this document.

The serial number shown on the battery lead is its unique identification.

Keep the battery clean and dry.

The battery needs to be charged before use. Always use the correct charger and refer to the instructions manual for proper charging instructions.

Do not leave the battery on prolonged charge when not in use.

After extended periods of storage, it may be necessary to charge and discharge battery several times to obtain maximum performance.

Use the battery only in the application for which it was intended.

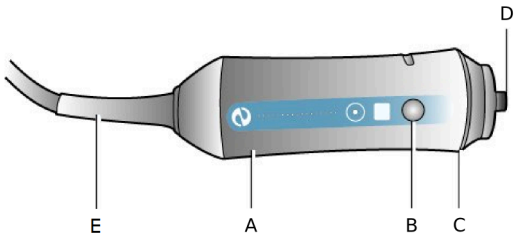
When possible, remove the battery from the device when not in use.

Storage 15% < Capacity < 50% under 30°C.

The cells inside may vent or rupture.

5.6. DESCRIPTION OF PROBES

The probe contains an electrodynamic actuator (vibrator), an ultrasound transducer and a measurement trigger button.



Probe: A: *Electrodynamic actuator.* ***B:*** *Measurement button.* ***C:*** *Light indicator (LED).* ***D:*** *Ultrasonic transducer.* ***E:*** *Probe lead.*

The ultrasound transducer of the probe is a "Type B" applied part, and is the only component of the FibroScan unit in contact with the patient.

Measurement button

As soon as this button is pressed (if sufficient force is placed on the transducer), the electrodynamic transducer generates a shear wave (s-wave) that painlessly impacts the patient's skin. At the same time, the ultrasound transducer performs a series of acquisitions (emission / reception) to measure the propagation speed of this shear wave. Acquisition lasts less than one tenth of a second.

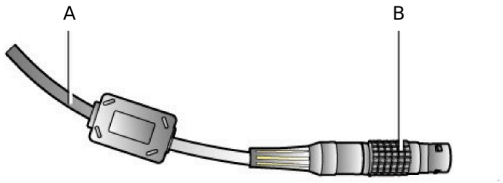
Indicators

The indicator lights (LEDs) display a status as follows:

- Lit up blue during FibroScan start-up and when standing by to launch an examination.
- Flashing blue lights for the probe selected when an examination starts.
- Not lit up during an examination when the operator is not applying correct force on patient’s body.
- Lit up blue during an examination when the operator is applying the correct force to the patient's body. It is however strongly recommended that you view the force exerted by looking at the on-screen force indicator.

If a control pedal is connected, measurement may be launched by using either the pedal or the probe button.

Lead



Probe lead: A: *Connection cable.* ***B:*** *Connector.*

This 1.5 m lead connects the probe to the FibroScan by means of a multi-pin jack with guide pin.

The probe transducer, the probe jack, and the FibroScan connector are fragile elements and must be handled with care.

The probe jack has a red dot that should be aligned with the red dot on the FibroScan socket before insertion.

The serial number marked on the connector identifies the probe uniquely.

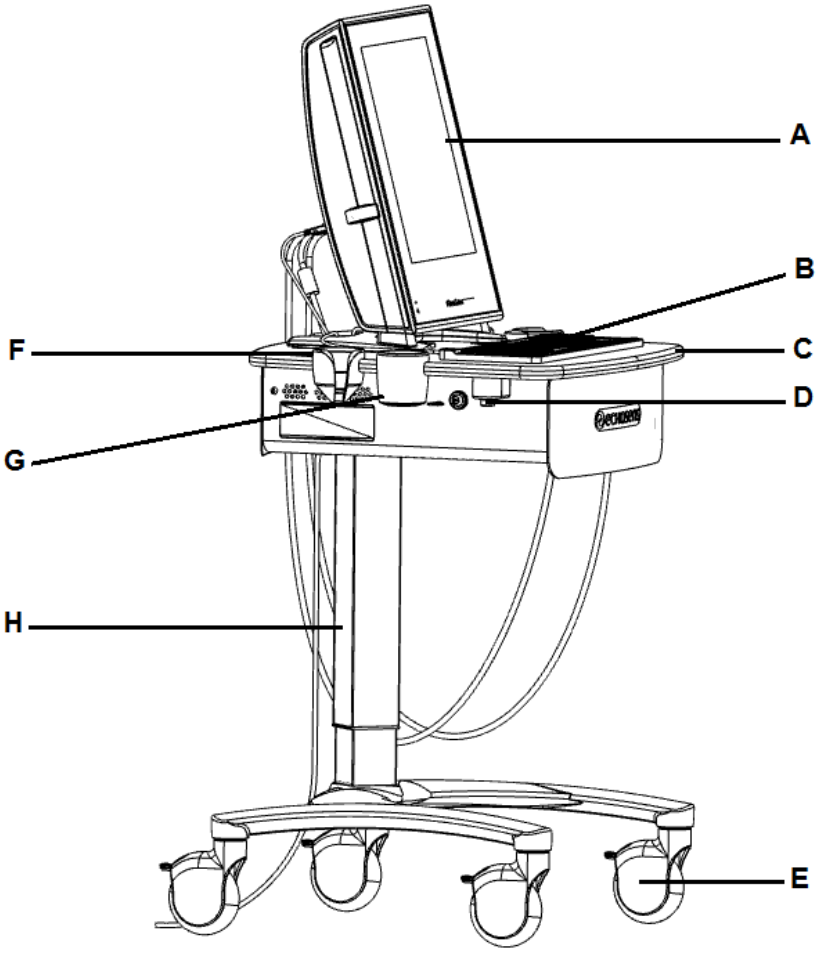
5.7. DESCRIPTION OF CONTROL PEDAL

A control pedal can be connected via the 5 V auxiliary jack. Simply by pressing the central button of the pedal with the foot, it can be used instead of the probe button to take the measurement.

Refer to the warning in Chapter 2 concerning cleaning and maintenance.

5.8. DESCRIPTION OF ROLL-STAND 530

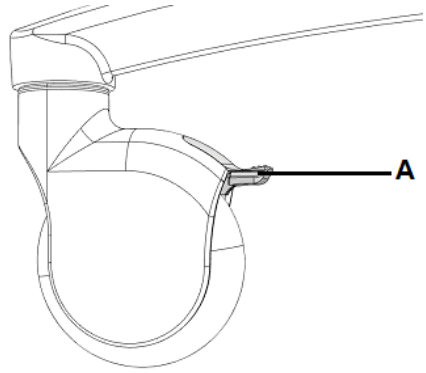
The FibroScan device 530 COMPACT can be mounted on the Roll-Stand 530.



FibroScan on its Roll-Stand 530: A: *FibroScan.* ***B:*** *Keyboard.* ***C:*** *Height-adjustable shelf.* ***D:*** *Column release button.* ***E:*** *Caster with brake.* ***F:*** *Probe holder.* ***G:*** *Gel holder.* ***H:*** *Column.*

Casters and brakes

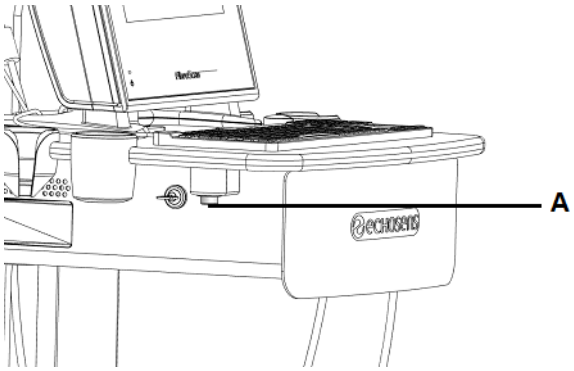
The casters are fitted with a brake. The brake is blocked by pressing the latch. The caster is released by lifting this same latch.



View of a caster with brake: A: *Caster brake.*

Shelf height adjustment

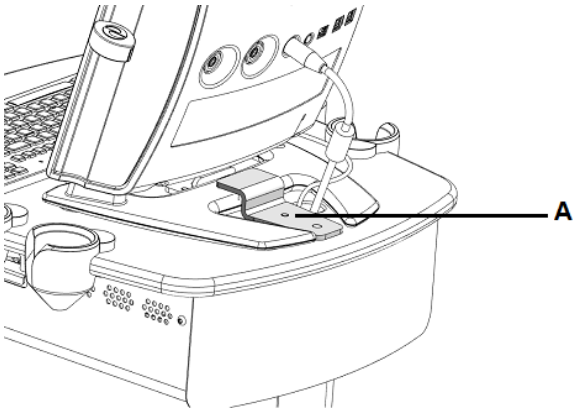
The shelf height can be adjusted. Pressing the shelf height adjustment button releases the column. The shelf can then be slid downwards. Alternatively, it can be slid upwards.



Shelf height adjustment: A: *Column release button.*

FibroScan attachment bracket

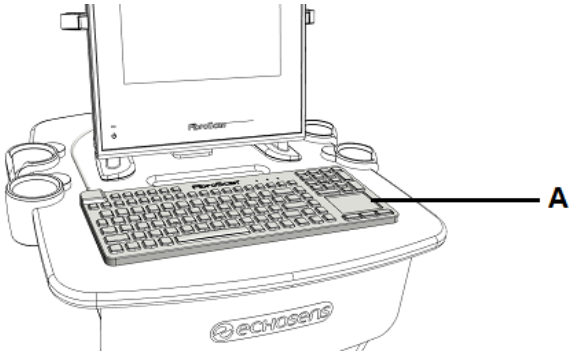
In addition to being positioned in the slots on the shelf, the FibroScan mounted on its roll-stand must be secured using the movable bracket located towards the rear of the shelf.



Securing the FibroScan device: A: *Movable bracket for securing FibroScan device on roll-stand shelf.*

Keyboard

Data can be entered using the keyboard.



Keyboard: A: *Wipe-clean magnetic keyboard.*

Locking the keyboard

If the keyboard needs wiping down, first lock it by pressing and holding the two [CTRL] keys simultaneously for at least 3 seconds. The following key can also be used for this purpose:

Lock the keyboard by pressing and holding the key for at least 3 seconds. Repeat this procedure to unlock the keyboard.

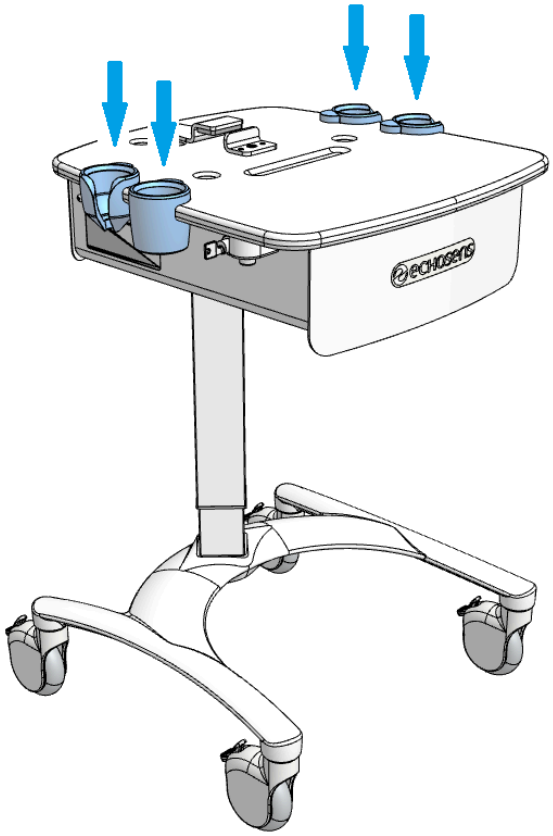
Refer to the manufacturer instructions for use. These instructions are shown on the underside of the keyboard.

5.8.1. Simplified assembly of the device on Roll-Stand 530

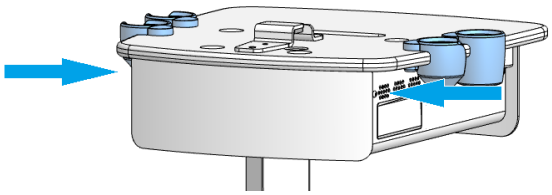
For any activity relating to the Roll-Stand 530, refer to the instructions in the Quick Start - Setup Guide supplied with the roll-stand.

To mount the FibroScan 530 COMPACT on the Roll-Stand 530, follow the steps below:

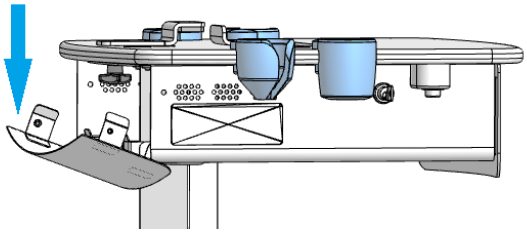
1. Place the probe holder and gel holder cups in their respective housings.



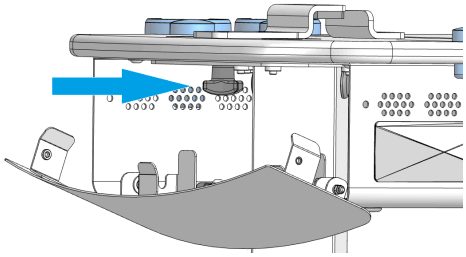
2. Unscrew the rear panel using the Allen key supplied for this purpose.



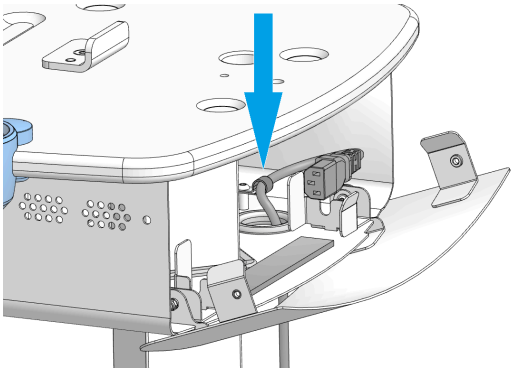
3. Remove the rear panel.



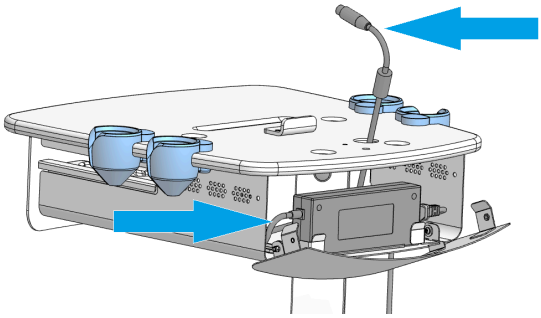
4. Unscrew and remove the black clamping screw from the bracket.



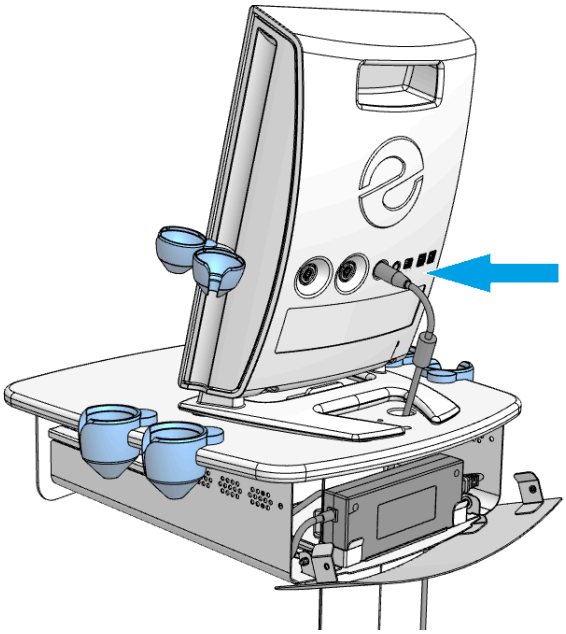
5. Thread the power cable through the cable clip.



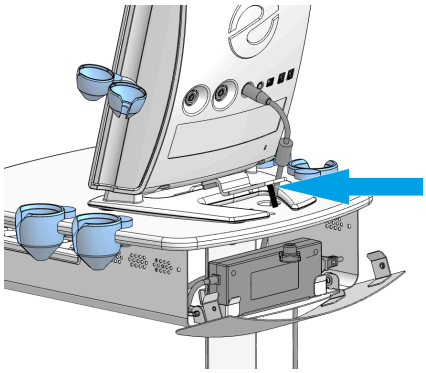
6. Connect the power cable, taking care to pass the plug through the opening in the shelf for this purpose.

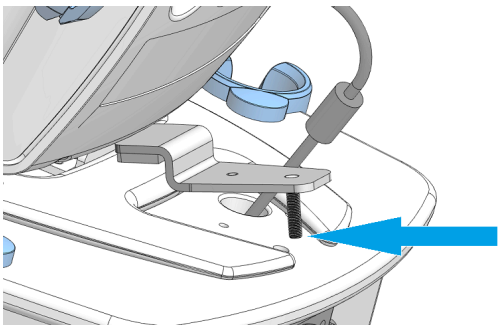


7. Position the FibroScan in the slots on the shelf and connect to the power supply.

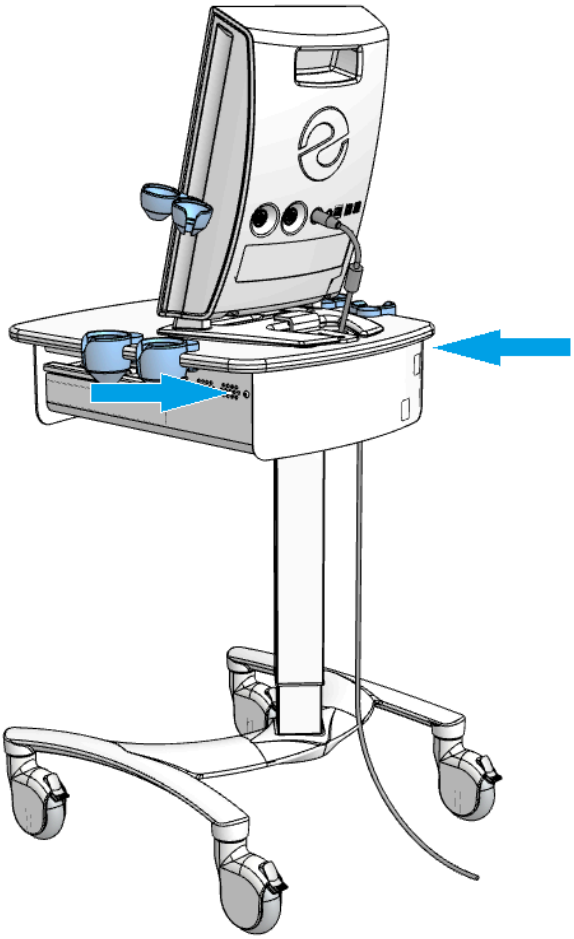


8. Align the FibroScan device with its anchoring bracket and secure by tightening the black anchoring screw. Close the rear panel.





9. Screw the rear panel back in place using the Allen key supplied.

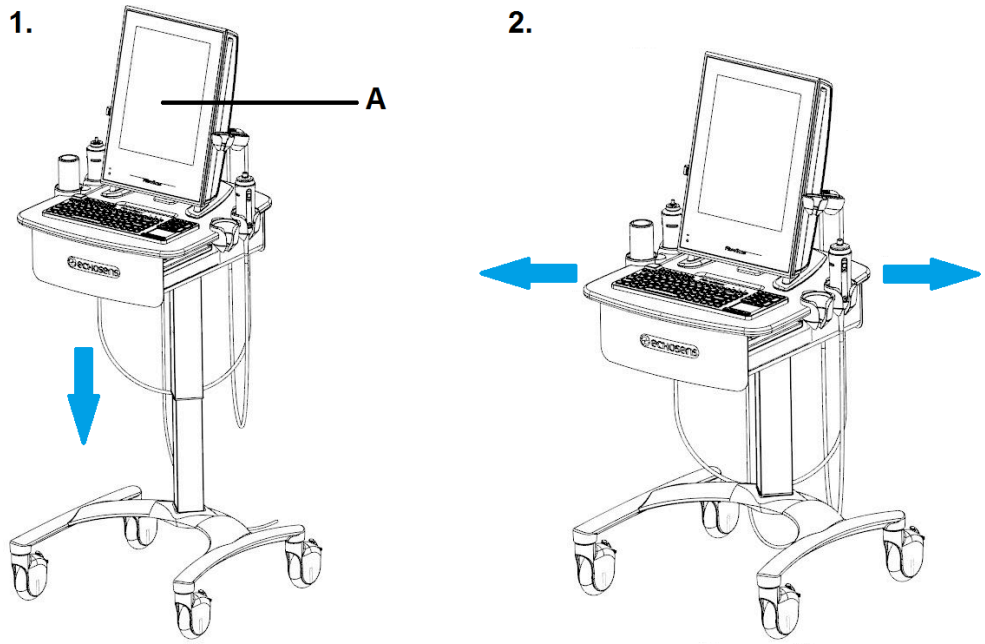


5.8.2. Moving the device around on the Roll-Stand 530

Before moving the roll-stand, make sure the FibroScan device is securely anchored to it.

Do not push or lean on the top of the FibroScan device.

Place the Roll-Stand 530 shelf in its lowest position.



Shelf position prior to moving the device: A: *FibroScan secured to Roll-Stand 530 shelf.* ***1:*** *Shelf slid down to lowest position.* ***2:*** *Moving the device.*

Always release the brakes before moving the device.

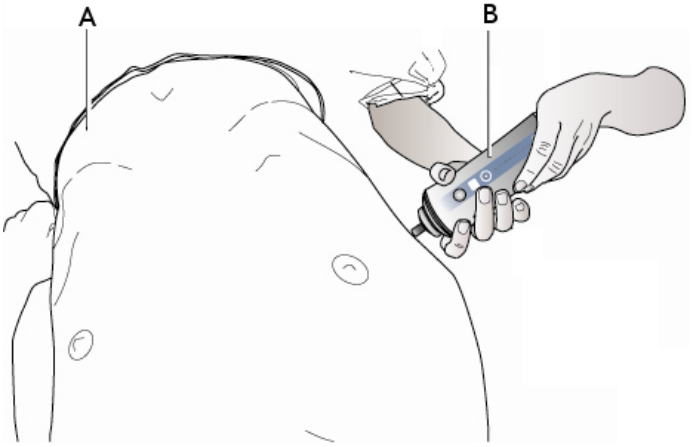
To prevent the FibroScan from tipping over when being moved, move it slowly and grip the shelf firmly to guide it.

To avoid tipping the FibroScan when lowering it down a step, the operator must go in front of the device and guide it on the way down.

6. EXAMINATION PROCEDURE

The examination procedure is completely non-invasive and takes only a few minutes.

Its stages are as follows:



Using the probe: A: *Patient abdomen.* ***B:*** *Probe.*

Once the best zone for measurement has been located, the operator can start taking measurements.

1. In a quiet environment, lie the patient down on their back with their right arm behind their head, fully abducted.
2. Leave the patient to rest for at least 5 minutes so that they are completely relaxed.
3. Position the probe transducer on the patient's skin, between the ribs above the right lobe of the liver.
4. Select the probe and type of examination required for the patient (see Chapter 4).
5. Use the ultrasound localisation tools to locate an area of the liver that meets the FibroScan examination quality criteria: homogeneous tissue with optimum ultrasound signal throughout the entire measurement depth.
6. Take a minimum of 10 valid measurements in each examination, using the same measurement point each time.
7. The final stiffness and CAP (if enabled) values saved are the median of all valid stiffness and CAP (if enabled) measurements performed during the examination.

7. SOFTWARE INTERFACE

The software loaded when the FibroScan unit is started up is used to:

- perform examinations,
- print the results,
- manage the archives,
- export the data in several formats.

If the device is connected to the hospital network, the software also makes it possible to:

- import the lists of patients,
- export the results of the FibroScan examination.

When the device is switched on, access to functions must be authenticated.

Before you reach the authentication page, the following messages may be displayed:

- No probe connected
- Probe out of calibration (see the Probe Calibration section)

7.1. AUTHENTICATION PAGE

If secure session opening has been enabled, all the user accounts are displayed. The login window allows a secured access to the patient data in the device. Otherwise, the application connects automatically to the default **Operator** account.

Restricted user accounts (Manufacturer and Distributor) can be accessed by clicking on the  button.

The enabling of secure session opening and the user accounts are configurable. See the Configuration section.

Beyond a certain idle time, the user is disconnected and the application returns to the login page.

This duration is configurable (see Configuration/General).

7.2. HOME SCREEN

Description of the home menu

 Access to FibroScan configuration. See the Configuration section.

Access to the patient file archives.

Access to the examination.

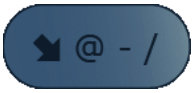
Return to the home screen by clicking the Home button: 

7.3. USING THE KEYPAD

The keypad is displayed whenever an input is required.

Description of keypad:

Shift.

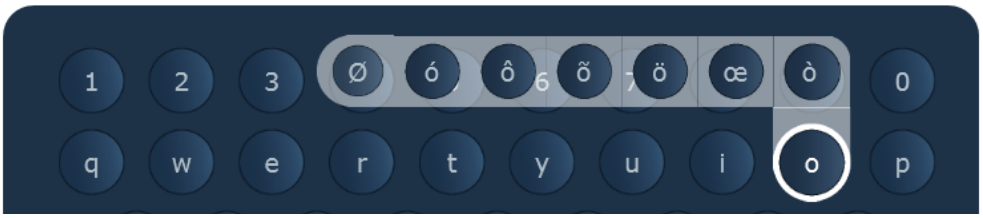


Displaying the special characters keypad.

Delete the character immediately before the cursor.

Tab. To move from one input field to another.

Special characters are accessible by pressing and holding a letter. Example:



7.4. STATUS BAR

Once authenticated, a status bar located at the top of the home screen gives the user information about the device.

Percentage disk space available.

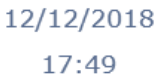
Connectivity status of the device: a symbol is displayed in the event of a connectivity error.

Results of FibroScan examination pending USB or network transfer (see paragraph on Resending failed exports).

Options enabled: CAP, Raw Data, Clinical Research Mode.

Refer to the Configuration chapter to modify these options

Profile types (**Operator** and **Administrator FibroScan**).

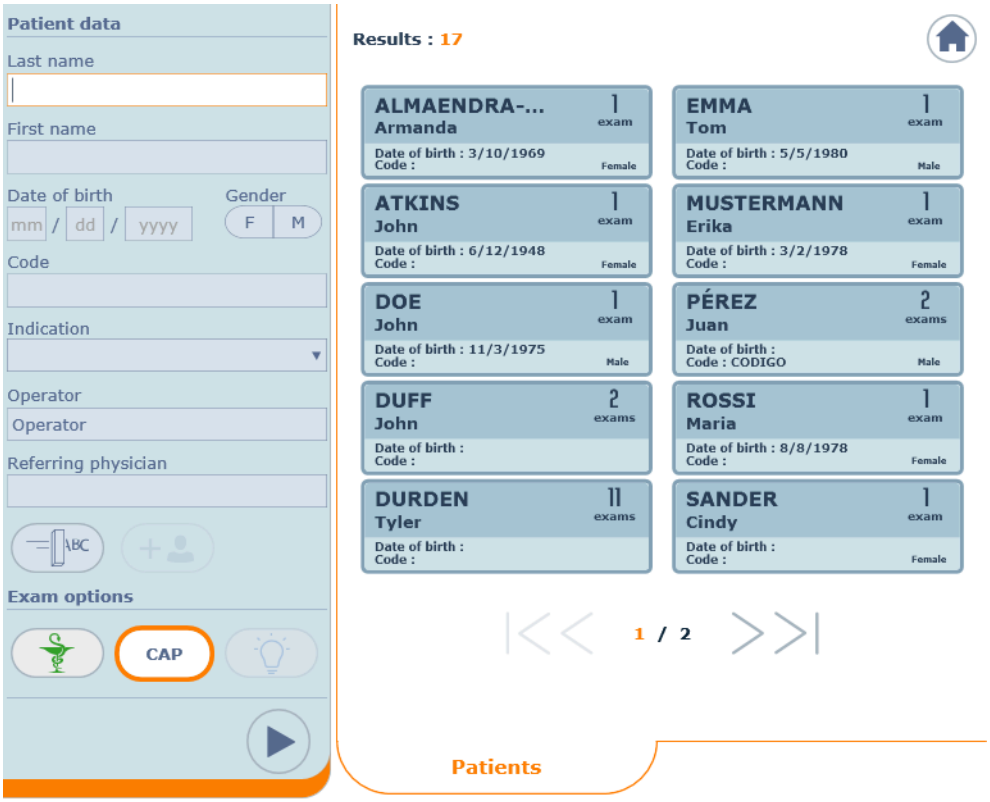


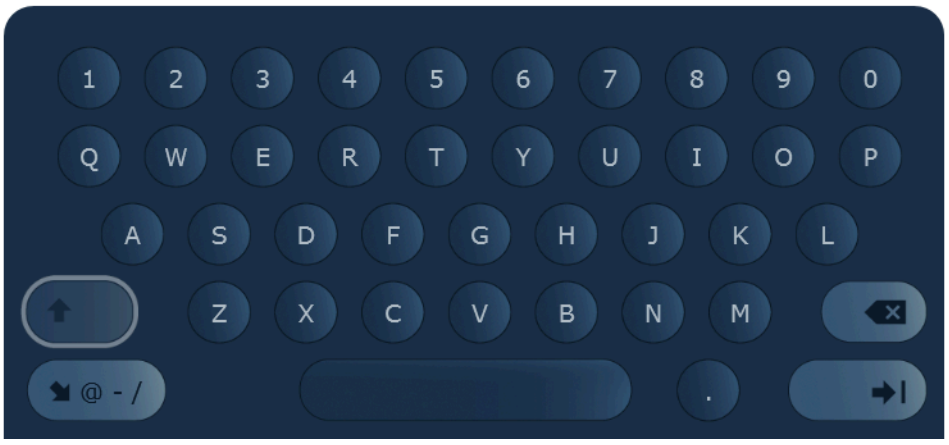
Device date and time.

Battery charge level.

7.5. THE PATIENT RECORD SCREEN

If the patient exists in the patient list, the data will be displayed automatically after the name is entered. Select the patient.





Complete the fields. At least the 'Name' or 'Code' field must be filled in to start the examination.

Enables/disables the CAP option for the examination about to start.

Enables/disables the saving of Raw Data for the examination about to start (available only if RAW Mode was enabled in the Configuration). If the Clinical Research Mode is enabled, RAW Mode is automatically enabled. In this case, the enable/disable button is not displayed.

Enables/disables the Clinical Research mode. If this mode is enabled, Raw Data will be saved for the examination to be performed.

Saving Raw Data can slow the application down considerably.

Adds the selected patient to the patient list. An examination can be performed on this patient later.

Deletes the content of the fields.

Cancels the patient entry.

Starts the examination.

After data input, if the probe is out of calibration the following message appears:

- Probe calibration days overdue: n. Contact your local support team.

Where n is the number of days.

Patient waiting list

A Dicom work list downloads the patient demographic information from the hospital network. If the Dicom option is enabled, this information is then input just once and then sent automatically at every stage concerning the examination.

If a Worklist-type DICOM or FibroView connection (patient waiting list) is enabled (Refer to the Configuration chapter, Connectivity tab), the device automatically queries the network to import the patients waiting for an examination.

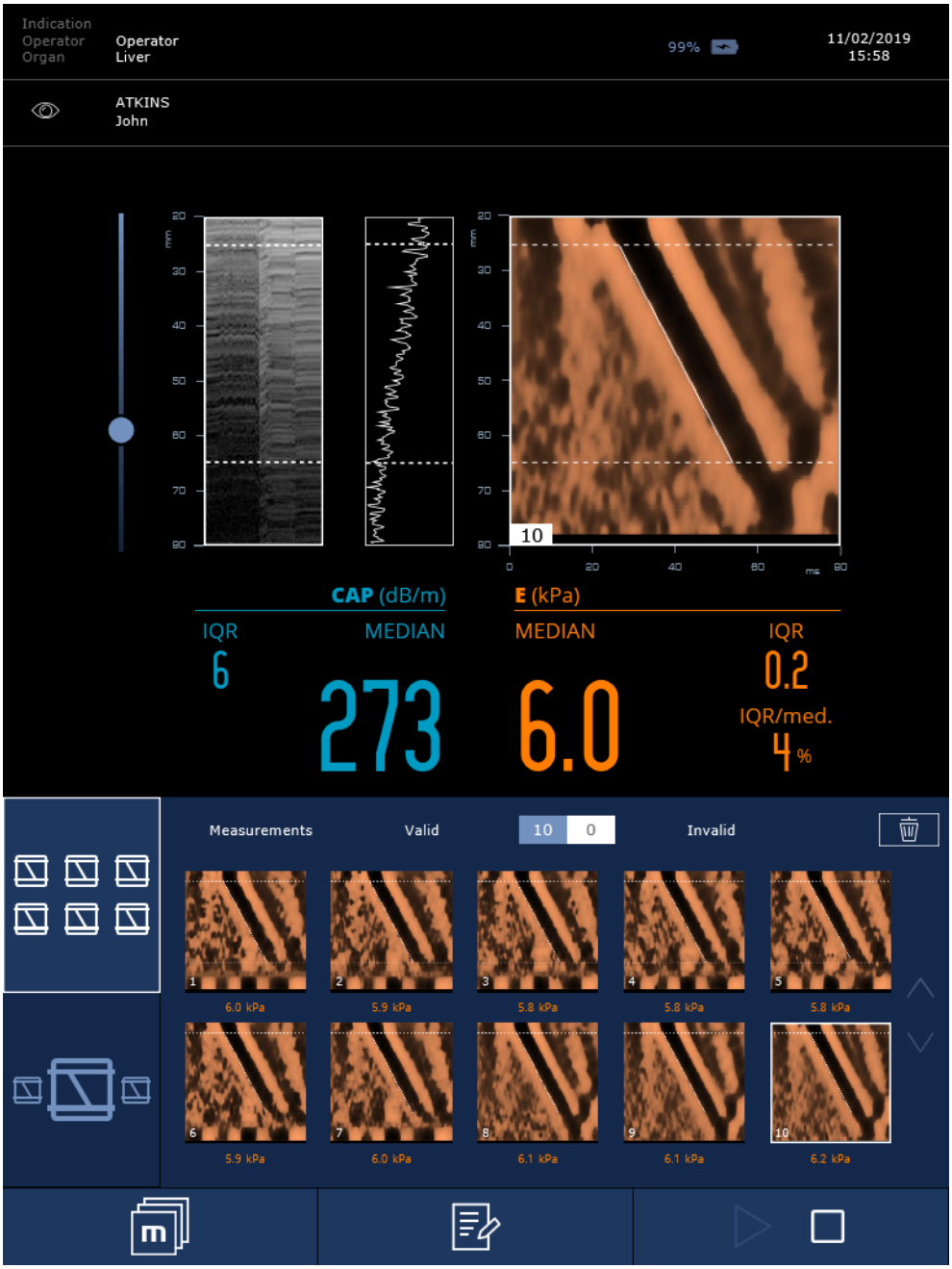
However, to import a patient waiting for an examination in the coming days, a manual patient search must be performed by clicking the magnifying glass button  in the Worklist window.

Deletes the selected patient from the worklist.

A patient file is automatically deleted from the worklist if an examination with at least one valid measurement has been made, or if the patient file has been on the worklist for more than three days.

7.6. ACQUISITION SCREEN

The main data displayed in an acquisition window are presented below.

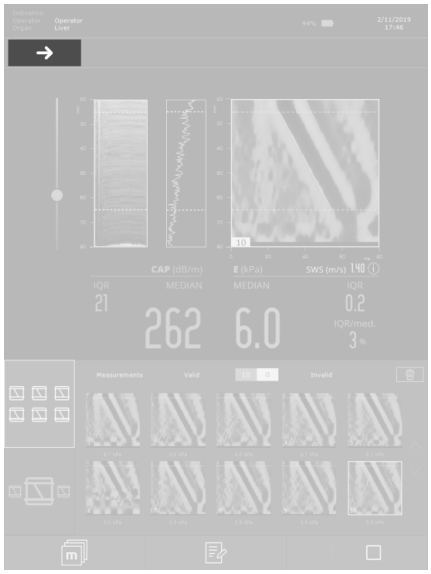


The CAP value (dB/m) is displayed only if the option is installed.

After five minutes of idle time during an acquisition, a message tells 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 is saved and then stopped.

The acquisition window comprises the following elements:

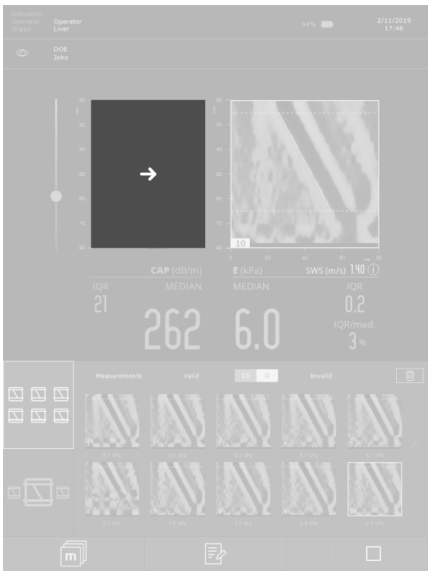
7.6.1. Patient data

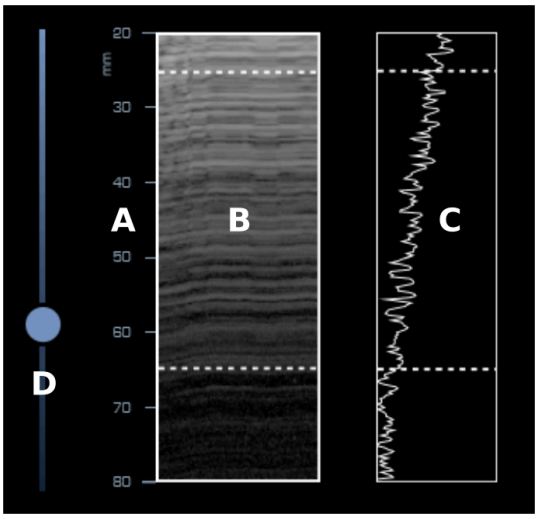


Shows/Hides the patient data.

7.6.2. Ultrasound images

TM and Amplitude Modes





Ultrasound signals in TM (left) and Amplitude (right) modes: A: *Depth explored (mm).* ***B:*** *Ultrasound signal represented in TM (Time-Motion) mode.* ***C:*** *Ultrasound signal represented in A (Amplitude) mode.* ***D:*** *Display gain adjustment.* ***E:*** *Current CAP value.*

Note: The CAP value is displayed only if the option is installed.

As soon as the probe makes contact with the skin, i.e. when a force change is detected, the ultrasound transducer makes ultrasound acquisitions.

The system displays two ultrasound signals used to locate a zone that satisfies the measurement criteria:

- One in Time-Movement (TM) mode, one-dimensional information that shows, in greyscale and according to time, the different elements detected by the ultrasound probe in the course of its scan.
- And the other in A-Mode, one-dimensional information on the amplitude of the ultrasound signal collected by the probe according to depth.

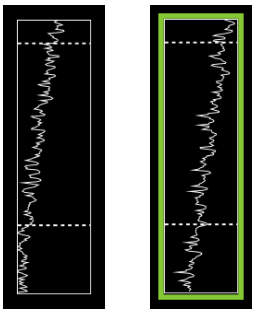
The gain on the display of both modes can be adjusted using the cursor under the ultrasound signals.

These two modes serve to ensure that the probe is correctly positioned to perform a measurement on a sufficiently thick portion of liver, visible throughout the explored depth. They also allow the operator to ensure that the measurement will not be disrupted by the presence of structures not of interest, such as blood vessels.

Ultrasound signal quality indicator

The ultrasound signal quality indicator enables the user to position the probe on an area suitable for stiffness and/or CAP measurement.

As soon as the probe comes into contact with the patient's skin, the ultrasound signal quality indicator shows the quality of the ultrasound signals passing through the liver by means of an indicator light.

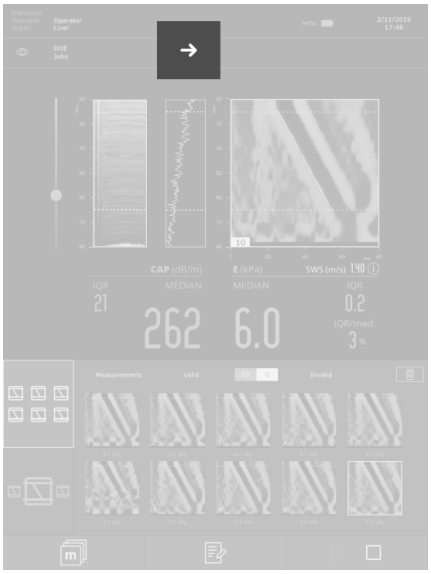


Indicator light: Off: *The quality of the ultrasound signals is low.* ***Green:*** *The quality of the ultrasound signals is high.*

When the indicator light is green, the quality of the ultrasound signals is sufficient to take a measurement.

This tool functions with the M^+ and XL^+ probes only.

7.6.3. Force indicator



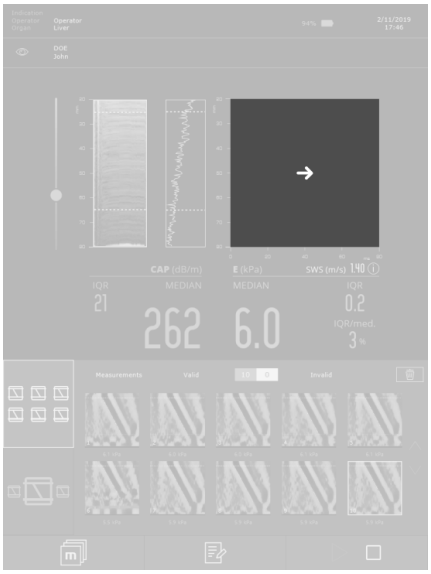
The probe contains a sensor that measures the force applied by the operator to the patient. The force level is given by:

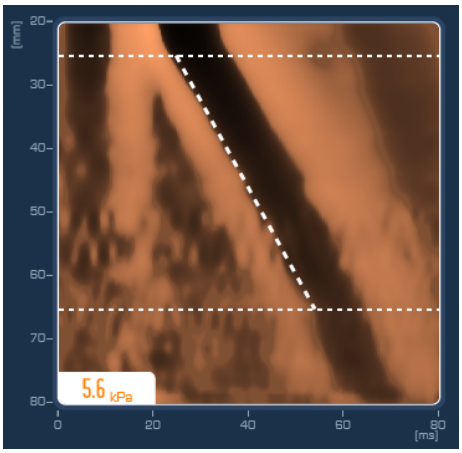
- Software: The force indicator (green/orange/red).
- The probe: blue LEDs.

Measurements may only be made when the force indicator is in the green zone.

		
Force too high (red). *Probe LEDs off.* *Measurement impossible.*	*Force too low (orange).* *Probe LEDs off.* *Measurement impossible.*	*Force correct (green).* *Probe LEDs lit.* *Measurement possible.*

7.6.4. Elastogram



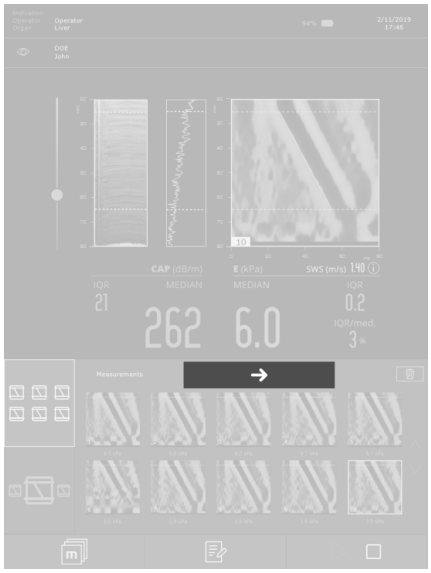


This image is displayed once the measurement is complete. It represents the levels of liver deformation generated by the propagation of the shear wave as a function of time (horizontal axis in milliseconds) and depth (vertical axis in millimetres).

The stiffness value is displayed if the measurement is valid.

The colour scale indicates the sign of the deformations (compression or expansion). Black areas correspond to negative deformation and pale areas to positive deformation. The black strip through the image represents deformations associated with the passage of the shear wave, which penetrates progressively deeper with time.

7.6.5. Counters: Valid and invalid measurements



Valid measurements

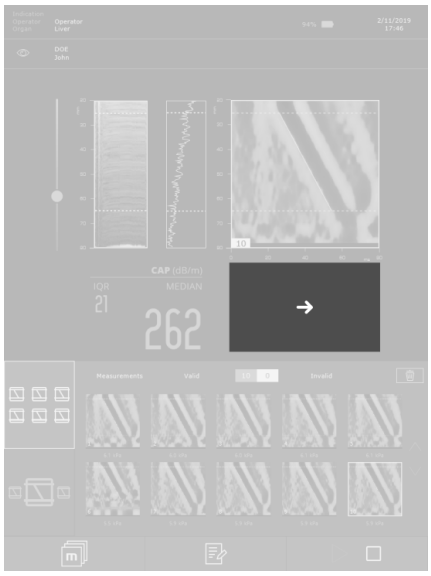
When the number of valid measurements is equal to 1, the IQR and the IQR/median ratio are undefined and therefore are not displayed.

Invalid measures

The measurement is automatically rejected by the machine if the shear wave was not generated under satisfactory conditions, and if the elastograms are not satisfactory.

The message 'INVALID' is then displayed above the elastogram.

7.6.6. Stiffness results area



Median

Stiffness is expressed in kilopascal (kPa). This value is the median of all valid measurements performed during the examination.

If the repeat measurement is invalid, the median is not re-computed. To obtain a reliable and representative liver stiffness measurement, **at least ten valid measurements should be made.**

Refer to the warning in Chapter 2 concerning interpretation of the result.

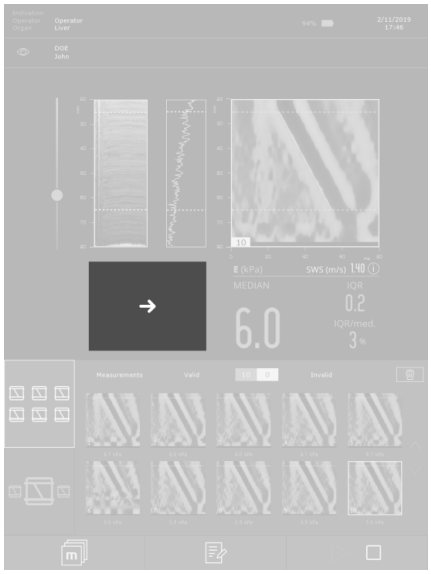
Interquartile range (IQR)

The interquartile range (IQR) is expressed in kilopascal (kPa). It represents the interval around the median within which will fall 50% of all valid measurements. It is re-computed after each new valid measurement.

IQR/Median

This value, expressed as a percentage, is the ratio of the IQR to the median stiffness. It is re-computed after each new valid measurement.

7.6.7. CAP result zone (option)



Note: The CAP value is displayed only if the option is installed.

The CAP is displayed with the M+ and XL+ probes only.

Median

The CAP (Controlled Attenuation Parameter) is expressed in decibels per metre (dB/m). This value is the median of all valid measurements performed during the examination.

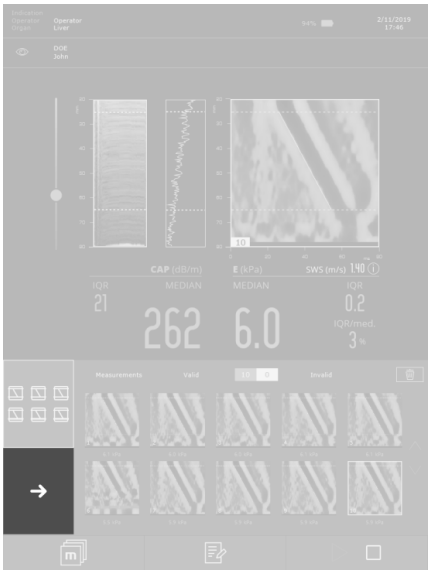
The CAP is calculated when the stiffness measurement is valid.

Refer to the warning in Chapter 2 concerning interpretation of the result.

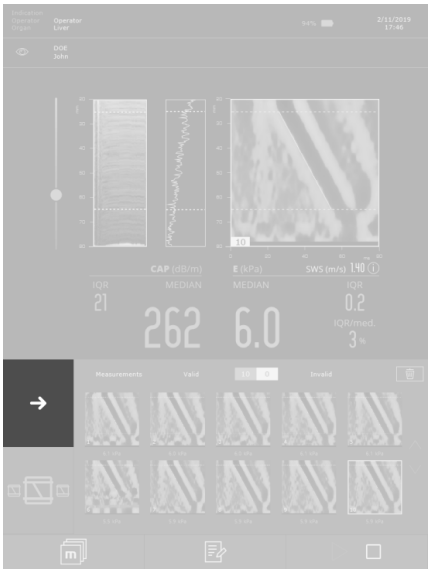
Interquartile range (IQR)

The interquartile range (IQR) is expressed in decibels per metre (dB/m). It represents the interval around the median within which will fall 50% of all valid measurements. It is re-computed after each new valid measurement.

7.6.8. Measurements displayed as image carrousel.

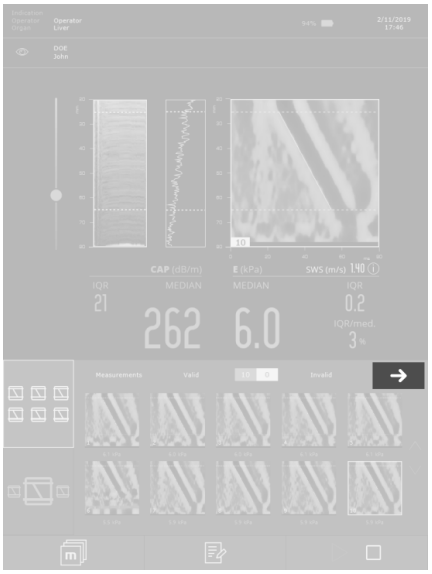


7.6.9. Displays measurements as vignettes



7.6.10. Deleting measurements

Some or all of the measurements in the current examination may be cancelled at any time during the examination.

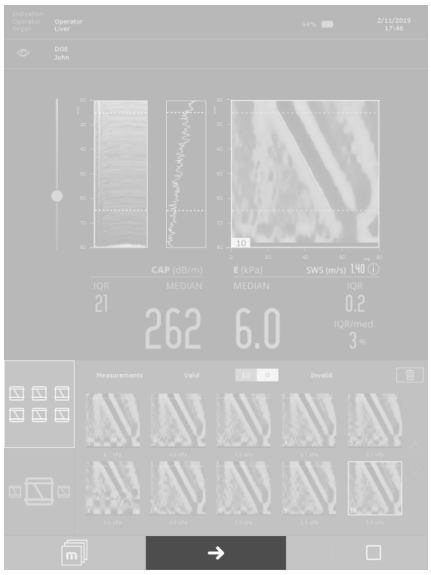


Press the last measurement to be deleted and then the following button:

A confirmation request is displayed and indicates the number of measurements remaining if deletion is confirmed.

Refer to the warning in Chapter 2 concerning deletion of measurements.

7.6.11. Adding a comment



Comments can be added and measurement conditions can be entered during the examination:

- Click on the following button  ,
- Enter comments using the touchpanel.

The entered information will appear on the examination report.

Comments cannot be added to or modified during an examination review.

To display comments or examination conditions during an examination review:

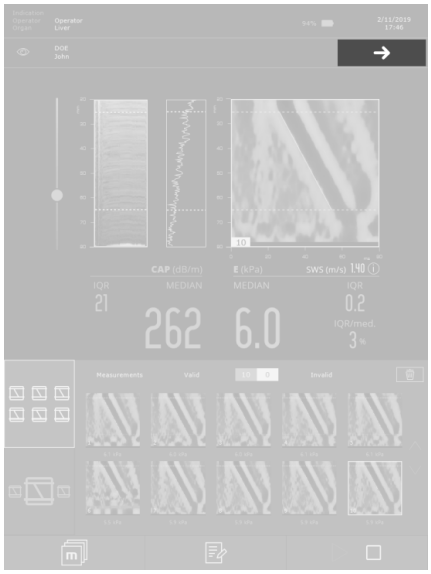
- Click on the following button  ,

of examination performance conditions can be entered during the examination. The following input fields are offered:

- patient weight,
- patient height,
- observance of dietary recommendations,
- patient position,
- Measurement point position,
- narrow intercostal space,
- thick subcutaneous wall,
- presence of vascular structures.

The measurement conditions will appear on the examination result printout.

7.6.12. Message area



The following main messages can be displayed above the elastogram.

Connect the probe.

Replace the probe.

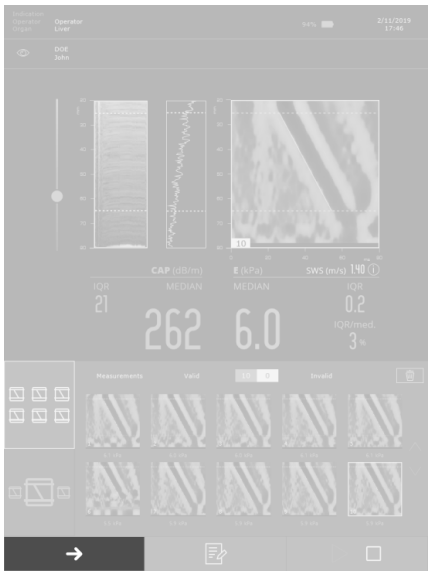
Calibrate the probe.

Electromagnetic disturbances.

Overheat.

7.6.13. Examination type selection area

The examination type selection criteria according to patient morphology are described in the section on 'Criteria for selecting the probe and the type of examination'.



If the S^+ probe is connected, select S1 or S2.

If only the M^+ or XL^+ probe is connected, the corresponding examination type is selected automatically by the machine software.

If several probes are connected, choose the examination type.

Automatic probe recommendation

The automatic probe recommendation tool is based on the SCD (skin-to-capsule distance) measurement using ultrasound signals received by the machine's probe. This feature operates in real time as soon as the probe detects ultrasound signals (probe in contact with patient skin).

This tool functions for the M^+ and XL^+ probes only.

The result of this tool is displayed at the bottom of the screen and may be one of the following three cases:

1. 'Recommended probe: in progress': the tool cannot currently measure the SCD because the probe is not correctly positioned in front of the liver and/or the ultrasound signals are of poor quality.

2. 'Recommended probe: M': The tool measures a SCD that justifies the use of the M+ probe. The box containing the M examination type icon flashes.
3. 'Recommended probe: XL': The tool measures a SCD that justifies the use of the XL+ probe. The box containing the XL examination type icon flashes.

If the tool is able to recommend a probe (case 2 or 3), two situations are possible:

- The probe being used matches the recommendation: the operator continues the examination without changing probes and, if they wish, can confirm the probe choice by pressing the icon of the examination type concerned. The probe recommendation tool is then disabled until the end of the current examination.
- The probe being used does not match the recommendation: the operator replaces the probe as explained in the above paragraph.

Be sure to use enough gel for this tool to function properly.

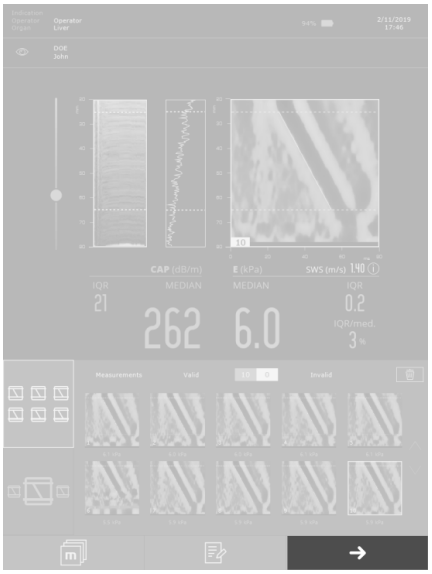
You are strongly advised to use the recommended tool, to guarantee reliable results. The decision whether or not to apply this recommendation, however, rests with the user.

Change of probe during an examination

To change the probe during an Examination:

1. select the new probe type. The following message is displayed:
   - Change of examination type. Changing examination type causes all previous measurements to be definitively erased.
2. Click OK (warning: all measurements taken using the previous probe will be deleted), the following message is displayed:
   - Examination type has changed. Connect the appropriate probe to continue.
3. Connect the appropriate probe if necessary and resume the examination.

7.6.14. View and print the result of the examination



Press the button to end the examination.

The result of the examination is displayed.

Description of contextual buttons:

Back to the home window.

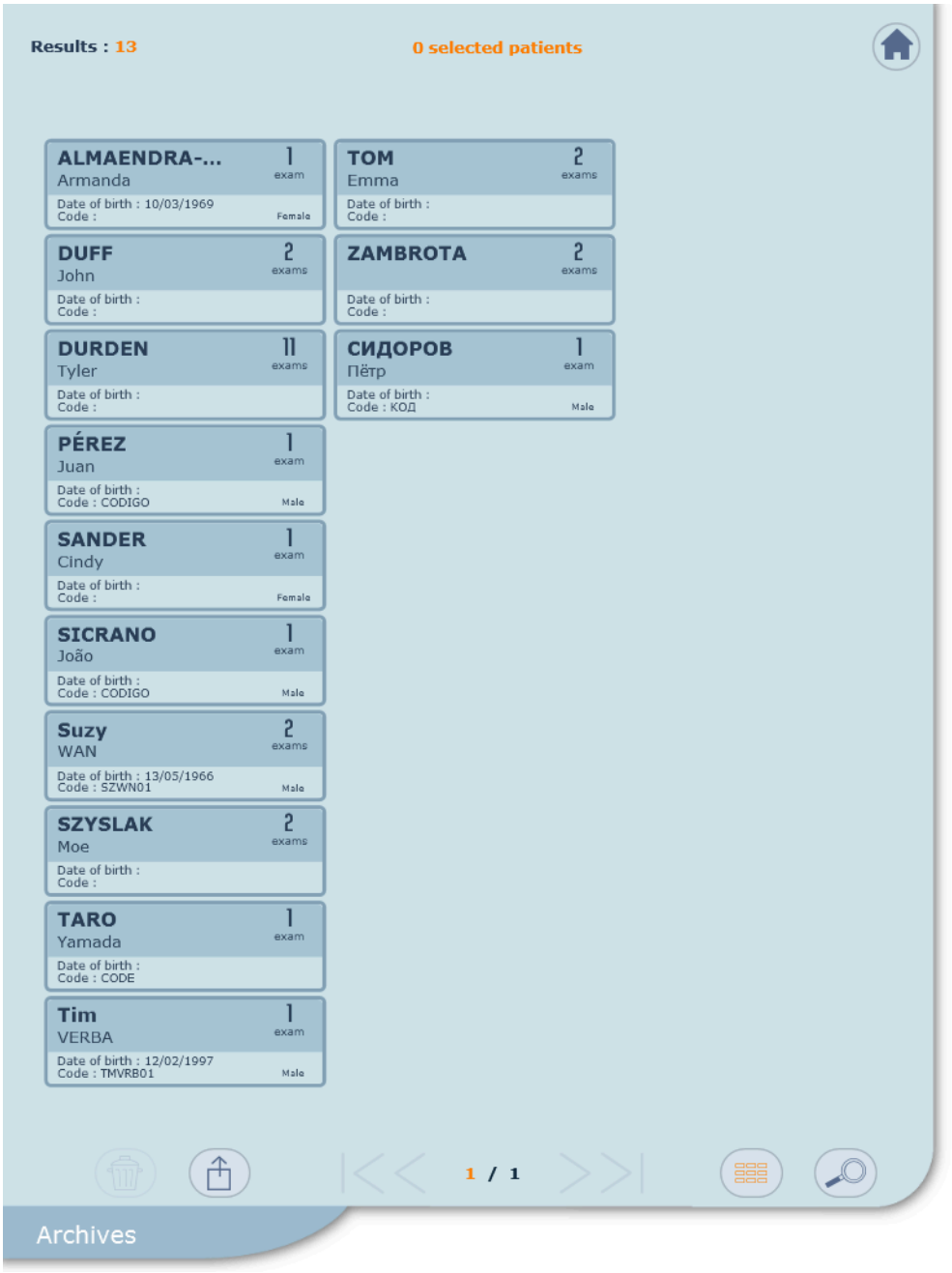
Prints the patient examination result.

Opens the tool for exporting the patient file and examination report.

Starts a new examination.

7.7. MANAGEMENT OF PATIENT FILE ARCHIVES

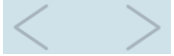
To display the patient file archives, press the  button in the home screen.



File selection when a keyboard is connected: [CTRL]+click to select non-consecutive files, [SHIFT]+click the first and last to select a series of files, and [CTRL]+[A] to select all files.

Deletes the selected files.

Opens the tool for exporting examination files and reports. The list of available export types, and the option for anonymisation by default, are defined in Configuration.



Displays the next / previous page of archives.

Displays the last / first page of archives.

Refines the advanced file search.

Selects all patient files displayed.

Closes the screen and displays the home screen (keyboard shortcut: [Esc] key).

Excel file

The file is generated in the root of the removable USB storage device. The file name contains:

- the serial number of the machine,
- date and time the Excel file was created.

The Excel file comprises two data sheets (Data and Parameters).

7.7.1. Advanced file search

Enter one or more search criteria. The list of matching files is displayed.

Deletes the input.

Closes the advanced search.

Opens the examination of the displayed patient.

7.7.2. Select and view a patient file

To view the examination summary for a patient, click the label and then  .

To view the details of an examination, click the summary of the examination.

7.7.3. Details of the examination

To display the measurements, click a value in the list of valid measurements.

Description of contextual buttons:

Back to the Archives screen.

Deletes the examination.

Prints the result of the examination.

Opens the tool for exporting the patient file and examination report.

Starts a new examination.

7.8. RESENDING FAILED EXPORTS

Export of an examination file or report may fail. The resend option is on the home screen and can be used by clicking on the  button. The superscript number shows the number of queued exports.

A single click lists the connections configured on the device. If at least one of these connections is marked with a green symbol (active connection), a [Retry] button is displayed. Clicking on this button displays the list of all examinations queued for export for each active connection.

The [Send all again] button lets you attempt the export again.

If the export is successful, the following symbol  is displayed next to each exported examination. If it is not, the following symbol  is displayed.

A connection with a problem is indicated by a red symbol. You should restore this connection before attempting to retry export.

You may need to click on the  button to refresh the status of connections.

Lastly, the [Clear list] button lets you clear the list of queued exports.

8. STANDBY AND SHUTTING DOWN THE MACHINE

8.1. BETWEEN SESSIONS

Put the device in standby mode by pressing the standby button in the bottom left-hand corner of the monitor or the shutdown button on the interface.

8.2. AT THE END OF THE DAY

Always shut the machine down by applying the following sequence:

1. Turn the FibroScan off by holding down the standby button in the bottom left-hand corner of the monitor or the shutdown button on the interface.
2. Cut the power supply by disconnecting the external power supply from the electrical network.

Refer to the warning in Chapter 2 concerning switching off the device.

9. CLEANING, MAINTENANCE AND REPAIRS

In the event of malfunction, only the staff of Echosens or its local representative is authorised to work on the FibroScan and its accessories. Any work performed by an unqualified person will terminate the guarantee.

9.1. CLEANING AND DISINFECTION

Apply the following recommendations to clean or disinfect the device, probes, and accessories.

Failure to observe these recommendations may result in damage to the device and the probes, which will then no longer be covered by the guarantee.

Recommendations

- Always wear eye protection and gloves to prevent injury.
- Do not use disinfectant product beyond its expiry date.
- Carefully follow the instructions for use that come with the cleaning or disinfectant product.
- Ensure appropriate concentration of cleaning or disinfection product used and time left in contact with the surface of the device, probes or accessories.
- 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. We also recommend careful reading of the “Guideline for Disinfection and Sterilization in Healthcare Facilities (CDC)”.

9.1.1. Cleaning the surfaces of the device

Refer to the warning in Chapter 2 concerning cleaning.

Whether surfaces are glass, metal or plastic, they must be cleaned strictly in the order described below:

1. clean using a soft cloth soaked in the recommended cleaning product,
2. wipe down with a soft cloth dampened with water,
3. dry carefully with a clean, soft and absorbent cloth.

Precautions

Do not spray any cleaning or disinfectant product directly on the device. Leaks may damage the system, which would then no longer be covered by the guarantee.

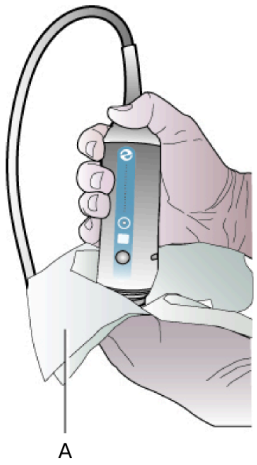
Do not use paper towels or abrasive products for cleaning, as they may scratch the surface of the screen.

9.1.2. Disinfecting the probe (housing, cable and transducer)

It is not necessary to switch off the device before cleaning and disinfecting the probe.

Surfaces of the probe must be cleaned and disinfected strictly in the order described below:

1. Point the probe and transducer downwards.



Cleaning and disinfecting the probe: A: *Wipe.*

2. Remove any remaining traces of gel with a soft cloth
3. Clean surfaces with a soft cloth or wipe dampened with recommended cleaning product.

   Note: if necessary, wipe down the surfaces with a soft cloth dampened with water.
4. Dry the probe with a soft, dry cloth.
5. Wipe the surfaces using a soft cloth or wipe soaked in the recommended disinfectant solution.
6. Dry the probe with a soft, dry cloth.
7. Examine the transducer and probe cable for any damage such as cracks, breakage, or liquid leakage.

If any damage is observed, stop using the probe and contact Echosens or its local representative: https://support.echosens.com.

Precautions

Do not submerge or soak the probe.

Apply the cleaning product and disinfectant solution to the soft cloth, not directly on the surface to be cleaned.

The probe must be cleaned and disinfected between patients. Prior cleaning is necessary in order to ensure effective disinfection.

Do not use surgical brushes or abrasive products to clean the probe, as they may damage it. Even the use of soft brushes could damage the probe.

Take care not to introduce any cleaning product or disinfectant solution into the probe connector.

9.1.3. Recommended cleaning products

Echosens recommends use of the following products:

- Purified water
- Soapy water

- Recommended disinfectant products (see below)

9.1.4. Recommended disinfection products

Recommended products for disinfecting probes are listed on the following website page: http://www.fibroscan.com/en/disinfection.

Quaternary ammonium compounds may generally be used for disinfecting probes.

Users accept sole and full responsibility should they use any disinfectant product not featured in list of products recommended by Echosens.

If you are unsure, contact Echosens or its local representative: https://support.echosens.com.

9.1.5. Prohibited cleaning and disinfection products

Any product not specifically intended for cleaning or disinfecting medical devices **must not be used**.

The products listed below must not be used on the device, probes or accessories:

- **Sodium hydroxide and/or sodium hypochlorite disinfectant products**
- **Hydrogen peroxide disinfectant products**
- Household products, particularly scouring powders or alkaline detergents (pH > 9) containing bleach, caustic soda, potash or ammonia
- Pure or dilute acid solutions of whatever type, including household vinegar
- Hydrocarbon solvents: alkanes, alkenes, benzene, toluene, xylene, gasoline
- Oxygenated solvents: ethanol, methanol (methylated spirits), acetone, MIBK, acetic acid, butyl acetate, ethyl acetate (nail varnish remover), ether, glycol ethers, DMF, DMSO, HMPT
- Halogenated solvents: perchloroethylene, trichlorethylene, dichloromethane, chloroform, tetrachloromethane

If the roll-stand keyboard needs cleaning, refer to manufacturer cleaning instructions. These instructions are shown on the underside of the keyboard.

9.2. CALIBRATING THE FIBROSCAN PROBE

The probe contains mechanical parts that may shift slightly over time.

The probe must therefore be calibrated periodically. Beyond the period indicated on the calibration certificate, the manufacturer no longer guarantees the performance characteristics of the probe.

When an examination is opened, a window displays the expiry of the calibration of your probe. When this is displayed, contact Echosens or its local representative to arrange calibration: https://support.echosens.com

During the examination, the message "Calibrate the probe" is displayed in the message zone.

At the end of an examination, the message "Probe out of calibration" is displayed on the printed examination report.

9.3. REPLACING THE BATTERY

Battery replacement must be performed in precisely the following order and manner:

1. Turn the device around to access the battery hatch, taking care not to damage or scratch the screen,
2. Unscrew the bolt from the hatch using a suitable tool,
3. Pull the strip to lift the battery out,
4. Insert the new battery having first identified the position of the locating pin,
5. Close the hatch and put bolt back in position,
6. Put the device back in position.

To lock the hatch, the bolt must be fully home.

9.4. TROUBLESHOOTING

Events	Solutions
The probe is no longer calibrated.	Contact Echosens or its local representative: https://support.echosens.com
The standby button is inoperative. When pressed, the instrument won't turn on.	Check that the instrument is connected to a correctly powered supply socket (test another electrical device on this same socket). If the device is powered by battery only, make sure that the battery is correctly inserted in its compartment.

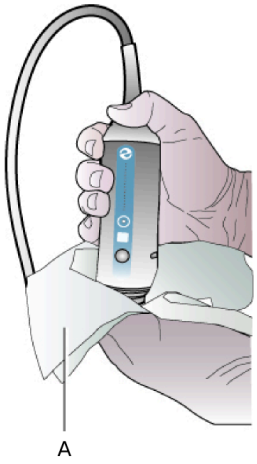
In the event of a failure or malfunction, please contact Echosens or its local representative: https://support.echosens.com.

9.5. PATIENT LEAKAGE CURRENT TESTS: PRECAUTIONS

Refer to the warning in Chapter 2 concerning electrical safety.

If patient leakage current tests are carried out, **take the utmost care not to immerse any part of the probe other than the transducer**.

After drying, return the probe to its resting position with the transducer facing downwards.



Drying the probe: A: Soft dry cloth.

If any damage is observed, stop using the probe and contact Echosens or its local representative: https://support.echosens.com.

10. CONFIGURING THE FIBROSCAN

10.1. ENTERING CONFIGURATION MODE

To enter Configuration mode, press  on the Home screen.

A screen then asks for an identifier and password.

The available passwords and identifiers are in ascending order of the features to which they give access:

Operator Level

User Name: Operator

Password: **0 P 3 R**

FibroScan Administrator Level

User Name: FibroScan Administrator

Password: **5 U P 3 7 4 D M 1 N**

Pay attention to upper/lower case!

In general, click [Apply] to confirm the input and save the new data.

10.2. LOCALISATION TAB

This tab is used to set the date, time, language and user interface.

For an Operator

Language

Select the interface language and examination report from the list.

Date and time

Press [Modify] and then enter the system date and time, and press [Save] to save the data.

For a FibroScan Administrator

Report URL

Gives the address of the examination report accessible by QR Code, according to geographical area.

10.3. INSTITUTION TAB

This tab lets you input the institution contact details.

Information concerning the institution

The information entered will be displayed on the report.

Logo

Press [Modify]. If an image file named *logo_institution.png* is present in the root of the USB storage device connected to the machine, the logo is automatically modified. The logo appears on the examination report.

[Reset] deletes the logo from the examination report.

10.4. PRINTER TAB

This tab lets you configure examination report printing.

For an Operator

Auto-print count

Enter a digit corresponding to the number of reports to automatically print at the end of each examination.

This number is set at 0 by default.

Anonymised auto-print

Activates anonymisation when printing off an examination report.

Printing format

A4 / Letter	Printing format of the examination report. The Letter format matches the American *US Letter* paper format.

The Letter format matches the American paper format.

Printer available

Enables the manual print button displayed during examination review.

For a FibroScan Administrator

Printers

[Update]	Update the list of printers.
[Add printer]	Lets you add a printer. You can add by Port, by IP address or by selecting a shared printer.
[Set as default]	Lets you define a printer as the default printer.
[Delete printer]	Lets you delete a printer. Follow the on-screen instructions.

[Search for printer patch]	Makes it possible to add a printer patch supplied by Echosens.
[Stop any printing in progress]	Lets you cancel current printing operations.

10.5. DATA TAB

This tab lets you manage examination file imports and exports.

For an Operator

Import

Imports examination files in FIBX/.FIBX2 format from a USB storage device.

The files are stored in the root directory of the storage device.

Examination files created with a software version prior to 2.0 cannot be imported into version 4.0.

For a FibroScan Administrator

Export

Launches manual and automatic exports of examination files (FIBX2 format) and examination reports (PDF format) to a USB storage device upon completion of each examination. The files are stored in the root directory of the storage device and can be anonymised if necessary.

10.6. USER TAB

This tab lets you define user accounts and link specific rights to them according to account type: **Operator** or **FibroScan Administrator**.

For an Operator

By selecting their own account, the user can change their password by clicking the button.

For a FibroScan Administrator

Resetting user accounts

Resets all user accounts.

Password control policy

Enables password control. When this mode is enabled, the password for each user account must contain at least two characters, comprising at least one letter and at least one number. The maximum number of characters is 15..

[Add user]	Adds a user account to the list.
[Import]	Imports a list of user accounts created on a FibroScan from a USB storage device.
[Export]	Exports the list of user accounts on the device to a USB storage device.

10.7. CONNECTIVITY TAB

The configuration of network connections is accessible only through the FibroScan Administrator level.

This operation must only be performed by personnel trained in network management.

Network

This tab is used to specify the network parameters of the device. This includes: The Name of the device stated on network (host name), IP address, sub-network mask, gateway, primary and secondary DNS. A host name, IP address and sub-network mask must be entered.

The IP address of the FibroScan can be configured statically or dynamically via the DHCP protocol. To configure the IP address manually, click [Manual] and complete the fields.

Directory

Directory sharing consists of making the contents of a directory available via the network. This tab lets you define a shared directory on the network. To do so, simply specify the absolute access path of the directory (\\computer\name_of_share), as well as the associated login and password.

Once directory sharing has been correctly configured, according to the option chosen (Examination file and/or Examination result), examination results are automatically exported to the shared directory at the end of each examination. Manual export from Archives is also available by clicking on the  button.

The [Check] button lets you test the connection with the shared directory.

DICOM

This tab is used to specify the DICOM connections of the device.

A key is required to enable the DICOM connectivity (to obtain this activation key, contact ECHOSENS or its local representative).

The hospital IT department will provide user support for the configuration of these parameters. If necessary, refer to the FibroScan Device DICOM Conformance Statement.

Worklist	Specify the server through which the device carries out patient searches. To filter the list of available patients on the DICOM server, you can query by element (DICOM tag 0008,0060). It is filtered by AE Title by default. To add patients to the FibroScan Worklist automatically, select the [Automatic] option. Otherwise, you must add patients manually.

Storage	Specify the server through which the device exports the examination reports as a JPG and/or a PDF document.

The parameters Name, IP address, Port and AE Title must be entered for each of the DICOM servers defined. These parameters are generally available from the network administrator.

The AE Title is a unique identifier of the device, and of each of the servers defined. Please note that it is case-sensitive.

The [Check] button lets you test the connection with the selected server.

FibroView

This tab is used to activate the connection with FibroView.

The network address of the FibroView server must be entered, starting with http://. The [Check] button lets you test the connection with FibroView.

To add patients to the FibroScan Worklist automatically, enable the Patient Worklist option. Otherwise, you must add patients manually.

Automatic addition of patients to the Worklist from FibroView is not compatible with automatic addition from a DICOM server. Enabling one disables the other.

10.8. EXAMINATION TAB

This tab lets you enable different examination options.

For an Operator

Clinical Research

Lets you view the studies created for the Clinical Research Mode.

Indications

Lets you fill in, edit, and reset the list of indications.

For a FibroScan Administrator

A key is required to enable the CAP (to obtain this activation key, contact ECHOSENS or its local representative).

Calibration

Lets you enter the name and details of the person at Echosens, or the local representative, to contact when a probe is due for calibration.

Options

Measurement conditions	Automatically displays the form for entering measurement conditions at the end of the examination.

Condition for saving examinations	Minimum number of valid measurements required for an examination to be saved. This number is between 3 and 10. This number is set at 10 by default.

Options

CAP Activates optional CAP display.

Clinical Research

Lets you enable the Clinical Research Mode and then create, edit, delete, and conceal study codes.

10.9. SYSTEM TAB

For an Operator

Information

This tab provides information on the device: Serial numbers (device and connected probes), software version number, firmware versions (AlimEE, FPGA, eSW, Examination Engine), remaining disk space and total disk space, device use time.

Logs

The log file tracks system activity and gives the operator a history of the events that occurred during use of the FibroScan software. This tab lets you view and export the log files.

[Export log files]	Exports log files to a USB storage device.
DICOM log	Exports the log files for DICOM connectivity if a DICOM connection is active.

From all user account types, export log files by clicking on the button [Export log files], having first connected a USB storage device to the device. Log files are shown as compressed files copied to the root directory.

Their name contains:

- The device's serial number,
- The date and time the file was created.

The USB storage device may not be recognised immediately after insertion. In that case, press [Export log files] again if an error message is displayed.

General

Delay before application closing	Period of idle time after which the application logs out. This period may range from 5 to 55 minutes..

For a FibroScan Administrator

Service

This tab lets you access the options required for device maintenance and updates.

[Launch Program]	Execution of an ECHOSENS-certified programme stored on a USB storage device.

A removable USB storage device must be connected.

[Screen Calib.]	Touch screen calibration.
[Upgrade Device]	Update of device software using a USB storage device supplied by Echosens.
Remote access	Allows Echosens to access your device remotely. Once launched, make a note of the TeamViewer identifier so you can pass it on to your Echosens contact person.
[Check Disk]	Hard drive check.
[Probe Memory]	Displays information (serial number, model, date of manufacture, date of last calibration, identifier of calibration operator) on the probes connected to the device.
[Clear Database]	Clears the database. **Note that the examination files remain physically present on the hard drive.**

General

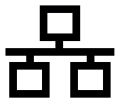
Patient data security	Conceals patient data available in archives or during acquisition. To display the list of patients or information on a particular patient, click on the [Display patients] button.

Anti-malware

Anti-malware software activation	Protects the system from malware. Enabling Anti-malware protection unlocks UpdateMode.
UpdateMode	Allows the system to check for Anti-malware software updates at regular intervals in order to ensure maximum protection against malware attacks.

11. SYMBOLS ON THE DEVICE

11.1. MARKINGS ON THE DEVICE

	Ethernet connector RJ45
	USB connector
	Elastography probe connection
	Connection 5 V
	Warning: Only Echosens-approved maintenance personnel are authorised to open and modify the FibroScan device.
	It is essential to refer to the User Manual to ensure operator and patient safety.
	Manufacturer

	Year of manufacture
	Anti-theft device
	■ When the device is mounted on the Roll-Stand 530: ■ Do not push or lean on the top of the FibroScan unit. ■ To prevent the FibroScan from tipping over when being moved, move it slowly and grip the shelf firmly to guide it. ■ To avoid tipping the FibroScan when lowering it down a step, the operator must go in front of the device and guide it on the way down.
	When the device is mounted on the Roll-Stand 530, the roll-stand shelf must be in its lowest position before moving the stand around.
	Warning: moving the device mounted on the Roll-Stand 530 requires special precautions to be taken to prevent it from tipping over.
	CE marking and notified body identification number Obtained in January 2016.
	Medical Device
	Direct current power supply
	NRTL cBVus mark

+19V	Electrical voltage delivered by the external power supply
5,26A	Electrical power delivered by the external power supply
	**Scrapping the button cell battery** The FibroScan uses a 'button cell' battery. This is a long-life battery and it may never need replacing. In the event of replacement, however, do not discard the old battery with ordinary household waste. Contact your local waste processing department for the address of the nearest battery disposal location. **Scrapping the FibroScan and its probe(s)** To reduce the risk of pollution by electrical and electronic waste, and within the framework of European Directive 2011/65/EC, the FibroScan device and its probe(s) must not be discarded with ordinary household waste. Contact the local electrical and electronic waste processing service for instructions.
	Applied part type B
	Standby/on/off button
	Device incompatible with magnetic resonance (MR). Caution, this symbol does not appear on devices manufactured before 2020.

11.2. MARKINGS ON THE BATTERY

	**Disposing of the battery** The FibroScan uses a Lithium-ion battery. This is a long-life battery and it may never need replacing. In the event of replacement, however, do not discard the old battery with ordinary household waste. Contact your local waste processing department for the address of the nearest battery disposal location.

CE	CE marking
	It is essential to refer to the User Manual to ensure operator and patient safety.

11.3. NOTE

The serial number and Data Matrix marked on the device identify the FibroScan uniquely.

12. TECHNICAL CHARACTERISTICS

12.1. CHARACTERISTICS OF THE DEVICE

Model	FIBROSCAN 530 COMPACT
Medical device classification	Class IIa according to Rule 10 of Appendix IX of Directive 93/42/EC.
Class of protection against electric shock	Class I
Type of part applied	B
Software security class	B
Class and group according to CISPR 11	Group I Class B
IP Code	IPX0: The instrument without probe is not protected against liquids.
Operating mode	Continuous operation
Mechanical Index	MI < 1.0 for all operating modes.
Thermal Index	TI < 1.0 for all operating modes.

12.1.1. Computer characteristics

Operating system	Windows Embedded
Permanent storage system	Hard drive
IT security guaranteed by	Local network security rules (firewall, DMZ, etc.) Windows firewall Anti-malware filter

12.1.2. Metrological performance

NB.: The measured value is stiffness, referred to as "E".

Stiffness	Min.: 2.0 kPa Max.: 75 kPa

		Stiffness E* (kPa)					
		S+		**M+**		**XL+**	
E (kPa)	**Trial number**	**Bias** (in %)**	**Precision** (in %)**	**Bias** (in %)**	**Precision** (in %)**	**Bias** (in %)**	**Precision** (in %)**
Zone 1 3.9	1 2	− 2.1 − 1.5	3.3 3.4	− 5.1 − 5.1	0.0 1.8	− 6.7 − 4.6	1.4 1.1

		Stiffness E* (kPa)					
		S+		M+		XL+	
E (kPa)	Trial number	Bias** (in %)	Precision** (in %)	Bias** (in %)	Precision** (in %)	Bias** (in %)	Precision** (in %)
Zone 2 9.6	1 2	− 17.3 − 17.7	0.6 1.3	− 24.0 − 24.0	0.0 0.0	− 26.5 − 18.5	2.3 0.5
Zone 3 23.3	1 2	− 10.5 − 8.3	2.5 0.9	− 12.9 − 14.1	0.0 0.6	− 12.1 − 12.0	0.9 2.0

* Values obtained with CIRS E-1493-1 phantom

** As defined by ISO 5725-1 1994

CAP	Minimum: 100 dB/m Maximum: 400 dB/m

	Controlled Attenuation Parameter CAP (dB/m)*			
	M+		XL+	
CAP (dB/m)	Bias** (%)	Precision** (%)	Bias** (%)	Precision** (%)
150 (1)	3.7	0.6	2.9	0.9
250 (2)	4.7	1.0	3.9	1.2
350 (3)	− 1.5	1.0	1.4	1.3

* Values obtained with Madsen phantoms Ph^{1}_{150} (1), Ph^{1}_{250} (2) and Ph^{1}_{350} (3)

** As defined by ISO 5725-1 1994

12.1.3. Electrical characteristics

Power supply	100-240 V ~ 50–60 Hz
Apparent power	100 W

12.1.4. Mechanical characteristics

Dimensions	46 cm x 36 cm x 25 cm (Height x Length x Depth)
Weight	10 kg (with accessories)

12.1.5. Environmental characteristics

Operating temperature	+ 10 °C to + 40 °C (+ 50 °F to + 104 °F)
Operating humidity	30 % to 75 % relative humidity, not condensed.
Maximum operating altitude	3000 m
Operating atmospheric pressure	700 hPa to 1060 hPa
Storage and transportation temperature	- 20 °C to + 50 °C (- 4 °F to + 122 °F)
Storage and transportation humidity	10 % to 85 % relative humidity, not condensed.

Maximum altitude for storage and transportation	5000 m
Storage and transportation atmospheric pressure	540 hPa to 1060 hPa

12.1.6. Additional information

Power cables (according to country) - Length < 3 metres	Power cable(s) (according to country)

12.2. BATTERY CHARACTERISTICS

Model	ARTS Energy (ref.4 INR19/66-2) Part number 806957 / M300002

12.2.1. Electrical characteristics

Rated voltage	14.4 V
Capacity	6 A.h

12.2.2. Mechanical characteristics

Dimensions	99 mm x 46 mm x 70 mm (length x width x height)
Weight	475 grams

12.3. EXTERNAL POWER SUPPLY CHARACTERISTICS

Model	XP Power L L C (ref. AHM100PS19-XE1026)

12.3.1. Electrical characteristics

Power supply	100-240 V ~ 1.2 A 50/60 Hz
Output signal	19 V 5.26 A
Apparent power	100 W

12.3.2. Mechanical characteristics

Dimensions	160 mm x 64 mm x 37 mm (length x width x height)
Weight	500 grams

12.4. ROLL-STAND 530 CHARACTERISTICS

12.4.1. Roll-stand mechanical characteristics

Model	E321-10-0001-A04
Dimensions	101 cm x 55 cm x 57 cm (height x length x depth)
Weight	44kg (with FibroScan)

12.4.2. Magnetic keyboard characteristics

Model	Man&Machine Really Cool Touch
Dimensions	381mm x 140mm x 15.3mm (length x width x height)
Weight	780g
Connection type	USB
IP Code	IP68: The keyboard is dust-proof, and waterproof for 30 minutes at depths of less than 1 metre.

12.5. CONTROL PEDAL CHARACTERISTICS

Model	Linemaster GEM SWNO
IP Code	IP68
Mechanical Index	MI < 1.0 for all operating modes.

12.5.1. Mechanical characteristics

Dimensions	97 mm x 33 mm (Diameter x height)
Weight	450 grams
Power cable length	< 3 m

12.6. CONSUMABLES

Not applicable.

13. ELECTROMAGNETIC COMPATIBILITY

Electromagnetic interference (EMI) is a signal or emission, conveyed through open space or through electrical or signal conductors, which may severely disrupt radio navigation or other safety services, or seriously and frequently damage, obstruct or interrupt an authorised radio communication service. These communication services include, but are not limited to, commercial AM/FM radio services, television, cellular telephone services, radio detection, air traffic control, radio paging and GSM systems. These authorised services, along with unintentional sources of disturbance, such as digital equipment, including computer systems, contribute to the electromagnetic environment.

Electromagnetic compatibility is the ability of the elements of an electronic device to interact correctly with the electronic environment. Although this computer system has been designed to conform to the restrictions of the EMI regulatory body, there is no guarantee concerning interference that may occur in a specific installation. Should the device generate interference with radio communication services (this may be determined by turning the device off and on), users are encouraged to attempt to correct this phenomenon by adopting one or all of the following measures:

- Change the orientation of the reception aerial.
- Reposition the computer relative to the receiver.
- Move the computer away from the receiver.
- Connect the computer to a different power socket such that the computer and receiver are on different branch circuits.

The FibroScan 530 COMPACT is designed for use in the electromagnetic environment defined in the following chapter. The customer or the user of the FibroScan 530 COMPACT must ensure that it is used in that type of environment.

The use of cables and/or accessories not specified in the User Manual may damage the device's electromagnetic performance.

The FibroScan device 530 COMPACT complies with standard IEC 60601-1-2:2014.

13.1. CLASSIFICATION

Compliance	Electromagnetic environment
Group 1	The FibroScan 530 COMPACT uses RF energy for its internal functions only. Consequently, its RF emissions are very low and unlikely to cause any interference with nearby electronic equipment.
Class B	The FibroScan530 COMPACT may be used on all premises, including domestic premises and those directly connected to the public low voltage energy grid used to supply domestic buildings.

13.2. IMMUNITY

The FibroScan 530 COMPACT is intended for use in professional healthcare centre environments and in home healthcare environments.

In the following cases, electrostatic charges may be generated:

- By triboelectric effect, by rubbing two different materials together (conductive or insulating), one gains a positive charge and the other a negative charge. The further the two materials are from each other on the triboelectric series, the greater the charge is likely to be.
- by electrostatic effect: Shift of electrostatic charges due to proximity of another charge.

Immunity test	Test level
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiant RF fields and proximity to wireless networks IEC 61000-4-3	10 V/m from 80 MHz to 2.7 GHz 80% in 1 kHz amplitude modulation
Near-field RF emitted by wireless communication equipment IEC 61000-4-3 provisional method	9 V/m at 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz and 5785 MHz 27 V/m at 385 MHz 28 V/m at 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz
Spike / Burst IEC 61000-4-4	± 2 kV for electrical power cables 100 kHz burst frequency
Over-voltages IEC 61000-4-5	Differential mode ± 0.5 kV, ± 1 kV Common mode ± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V from 150 kHz to 80 MHz 6 V in ISM band, from 150 kHz to 80 MHz 80% in 1 kHz amplitude modulation
Magnetic field immunity at supply frequency (50-60 Hz) IEC 61000-4-8	30 A/m
Voltage drops, short interruptions and supply inlet voltage variation IEC 61000-4-11	0 % U_T [1], over 0.5 cycles for 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase shifts. 0 % U_T, over 1 cycle 70 % U_T, over 25 cycles at 50 Hz and 30 cycles at 60 Hz, for a 0° phase shift
Power input voltage interruptions IEC 61000-4-11	0 % U_T over 250 cycles at 50 Hz and 300 cycles at 60 Hz

NOTE: In case of any disturbance in the electromagnetic environment of the FibroScan 530 COMPACT, a message is displayed (see the Message Area chapter) and no measurements can be carried out.

1. U_T: Mains power voltage measured prior to execution of test

13.3. EMISSIONS

The FibroScan 530 COMPACT is intended for use in professional healthcare centre environments and in home healthcare environments.

Test	Emission limits
Conducted emissions	79 dB µV quasi-peak from 150 kHz to 500 kHz
	73 dB µV quasi-peak from 0.5 MHz to 5 MHz
	73 dB µV quasi-peak from 5 MHz to 30 MHz
Radiant emissions	40 µV/m quasi-peak from 30 MHz to 230 MHz
	47 µV/m quasi-peak from 230 MHz to 1 GHz

Portable and mobile RF communications equipment (including peripherals such as aerial cables and external aerials) must not be used at a distance of less than 30 cm (12 inches) from any part of the FibroScan device 530 COMPACT, including cables specified by Echosens. Otherwise, device performance may suffer.

Test	Compliance
Voltage fluctuations/flicker IEC 61000-3-3	Compliant
Harmonic distortion IEC 61000-3-2	Compliant

NOTE: These recommendations may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection caused by structures, objects and individuals.

14. INDEX

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