



ECHOSENS

TECHNICAL MANUAL

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AUTEUR	Laurent Sandrín	Dir. Technologie	26/06/2013
VERIFICATEUR	Sébastien Vidale	Resp Matériel	26/06/2013
VERIFICATEUR	Karim Chelly	Chargé Qualité	26/06/2013
APPROBATEUR	Clothilde bagé	Dir. Industriel	26/06/2013

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ECHOSENS

FibroScan®

402

TECHNICAL MANUAL



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1 INTRODUCTION

1.1 INTRODUCTION

This document is intended for distributors of Echosens products. It recommends the processes that distributors can implement to repair these products.

It is essential that all operations be performed by technicians who have received appropriate training from an Echosens-approved instructor.

Echosens cannot be held responsible for incorrect or incomplete instructions for operation or maintenance given to end users by distributors or for incidents arising from the actions of persons applying the processes recommended in this document.

Only replacement parts supplied by Echosens must be used.

FibroScan® is an active, non-implantable medical device using ultrasound. It is designed to measure liver stiffness painlessly, immediately, and non-invasively. It is a diagnostic tool.

Fibroscan is based on the pulse elastography technique, and operates according to the following principle. The probe is an ultrasound transducer mounted on the shaft of an electrodynamic transducer (vibrator). The transducer is placed in contact with the skin. The vibrator generates a low-amplitude mechanical pulse. The pulse generates a low-frequency elastic wave, known as a 'shear wave'. The speed of propagation of this elastic wave is directly related to the stiffness of the medium. As the elastic wave passes through the skin, adipose tissue and liver, ultrasound acquisitions are performed. These ultrasonic signals are used to measure the speed of propagation of the elastic wave in the liver in order to determine the liver's stiffness.

Technical support

ECHOSENS
 30 Place d'Italie
 75013 PARIS
 Tel.: +33 1 44 82 78 50
 Fax: +33 1 44 82 78 60
 E-mail: service@echosens.com

2 MISCELLANEOUS INFORMATION

2.1 OWNERSHIP AND COPYRIGHT

All manuals and documents of all types are the property of the company Echosens and are protected by copyright, all rights reserved. Your right to copy this documentation is limited to legal copyright. These manuals cannot be distributed, translated or reproduced, either in whole or in part, in any manner or in any form, without prior written consent from Echosens. Hence, the reproduction, adaptation or translation of the present manual without prior written consent is prohibited, within the limits provided by copyright law.

All rights reserved.
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First edition, September 2010.

2.2 REVERSE ENGINEERING

The software licence 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.

2.3 REGISTERED TRADEMARKS

Echosens® and FibroScan® are registered trademarks of Echosens.

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

3 RECOMMENDATIONS AND SAFETY

3.1 SYMBOLS



This symbol means:

Warning: Read the instructions before using the medical device. Instructions preceded by this symbol may cause injuries or damage the medical device and installation if not correctly followed.



This symbol means:

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



This symbol means:

Additional information with no impact on instrument use.

3.2 ELECTRICAL SAFETY

FibroScan® is manufactured and tested in accordance with IEC electromagnetic compatibility (EMC) and electrical safety standards. It leaves the plant 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 the present manual.

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

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

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

- The device is visibly damaged;
- The medical device is inoperative,
- After prolonged storage in unfavourable conditions,
- After serious damage incurred during transport,
- In the presence of flammable or anaesthetic gases. This may cause an explosion. Do not take the device to 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.

3.3 MAINTENANCE-RELATED SAFETY

For all maintenance operations, the physician and his/her appointees should contact Echosens or his local dealer, which will send an authorised technician. **These maintenance operations must not be performed by a third party other than a technician authorised by Echosens.** For correct and safe use and for all maintenance operations, the personnel must conform to normal safety procedures.

3.4 PATIENT SAFETY

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 patients with active implants such as pacemakers, defibrillators, pumps, etc.
- On wounds.
- On pregnant women.
- On patients with ascites.

The personnel must follow normal safety procedures.

3.5 USER RECOMMENDATIONS

FibroScan® is a diagnostic and monitoring tool. Echosens recommends making 10 measurements per examination in order to obtain a representative stiffness value. Results must only be interpreted by a physician specialising in liver diseases, who is aware of the patient's pathology and clinical context.

3.6 USER TRAINING

Before using the FibroScan®, the user must take the e-learning course given at the following address: www.echosens.com.

On completion of this e-learning course, the user will receive the code to unlock the FibroScan® unit. This code cannot be given until the user has completed the training course and passed the final test with a mark of at least 60%.

This 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 GENERAL PRESENTATION

4.1 INTRODUCTION

The FibroScan® and its probe constitute an active, non-implantable medical device using ultrasound. This device is designed to rapidly measure liver stiffness in a painless and totally non-invasive manner.

The FibroScan® is controlled by a dedicated software application that is automatically launched on power up.

The FibroScan® device operates based on the Controlled pulse vibration elastography technique. The probe has its own specific characteristics and is used for a distinct application.

The FibroScan® probe comprises a single-element ultrasound transducer fixed to the shaft of the electrodynamic transducer. This latter generates a transient vibration, which in turn generates an elastic shear wave. This wave propagates through the skin, subcutaneous tissues, then through the liver. During shear wave propagation, the ultrasound transducer performs a series of ultrasound acquisitions (emission / reception) to measure the speed of s-wave propagation. Liver stiffness is calculated from this s-wave propagation speed value.

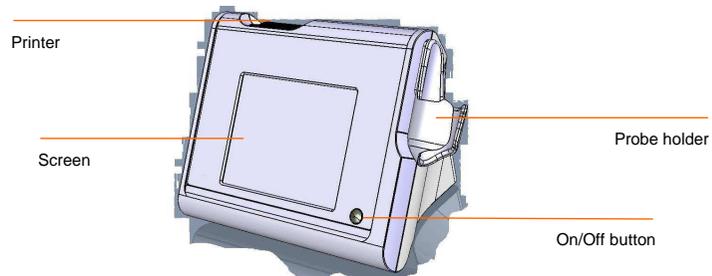
The FibroScan® 402 unit weighs approximately 8 kg and its dimensions are 275 x 434 x 252 mm (height x width x depth). This makes it easily transportable and conveniently compact.

FibroScan® 402 is supplied with the following components:

- Mains lead
- M probe
- A sealed envelope (Windows EULA licence + this FibroScan® User and Configuration Guide + QuickStart Guide + FibroScan® 402 usersupport CD)
- Set of fuses
- Probe carrying case.

4.2 OVERVIEW

4.2.1 Front panel



On/Off button

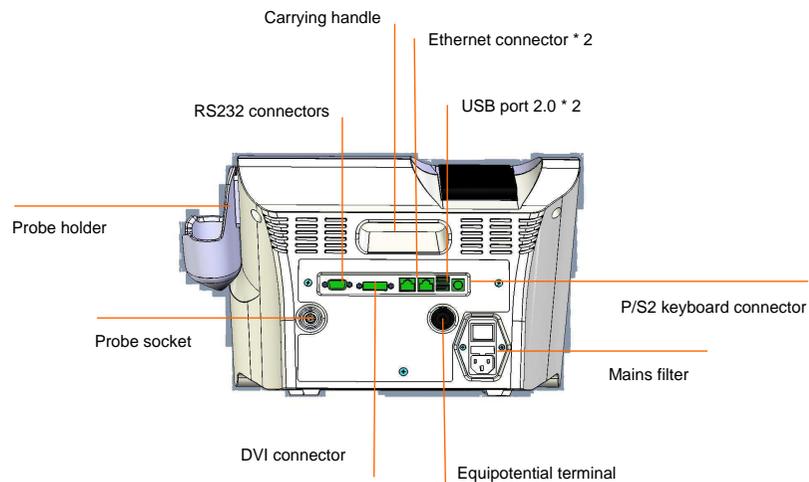


This button is enabled only when the main switch, located at the rear of the device on the mains filter, is set to "I".

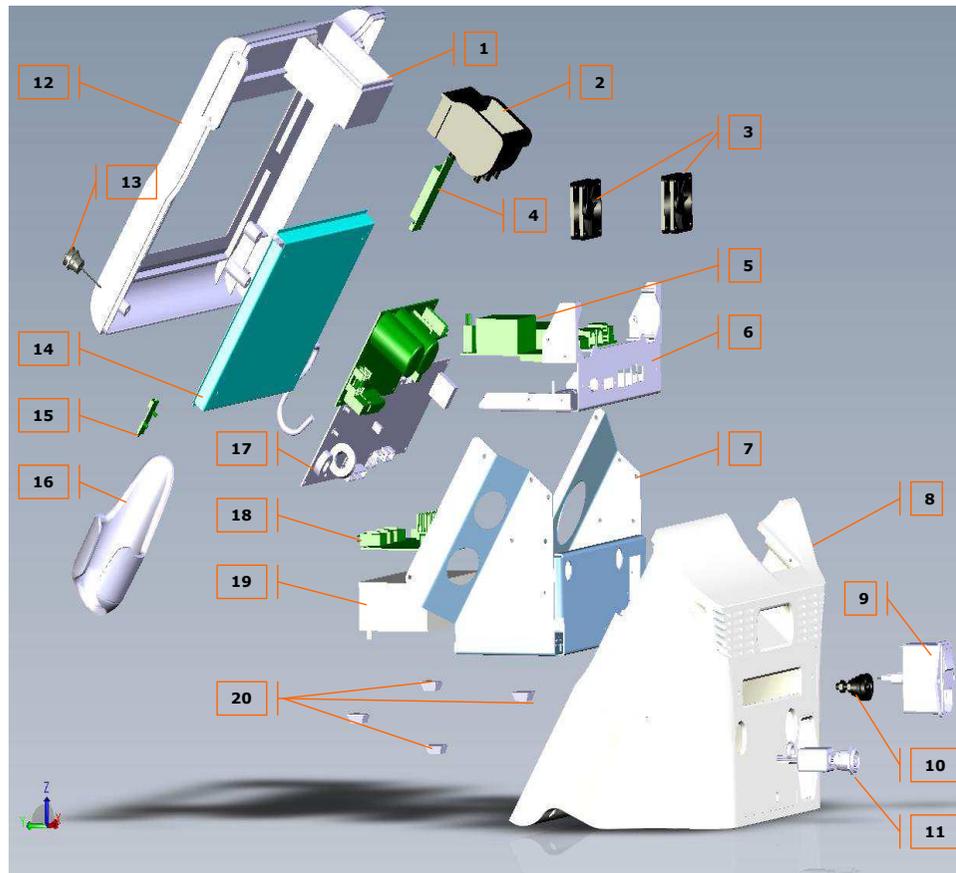
Pressing this button **once** loads the application; the built-in indicator light turns green.

Press this button **again** to close the application. This is the usual position when the FibroScan® will not be in use for a short time (between two patient groups for example). The FibroScan® consumes very little power in this mode.

4.2.2 Rear panel



4.3 EXPLODED VIEW



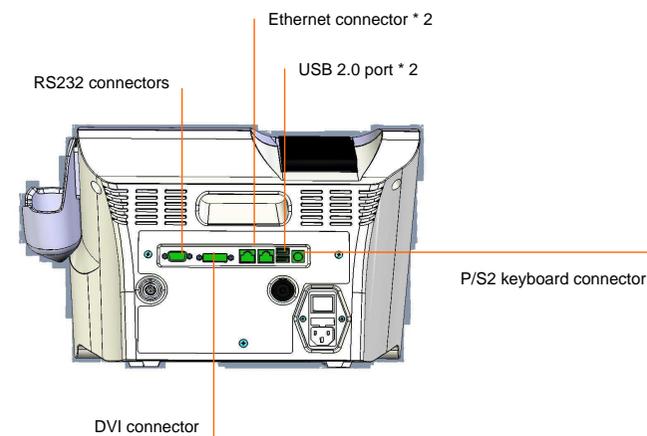
Exploded view

Item	Description
1	Printer location
2	Printer
3	Fans
4	Touchpad controller inverter board
5	Motherboard
6	Motherboard support board
7	Power supply support base
8	Rear panel
9	Mains filter
10	Equipotential terminal
11	Probe socket
12	Front panel
13	On/Off button
14	Screen on its stand
15	Backlight inverter board
16	Probe holder
17	Elastography engine
18	Power supply board
19	Power supply
20	Feet

5 EXTERNAL ELEMENTS

5.1 CONNECTOR INTERFACE

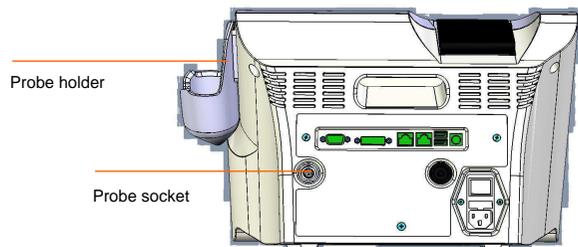
FibroScan® 402 has several types of connector. These are located at the back of the unit. They are described below.



These connectors are used to connect the following devices:

- DVI connector: This is the video output used to connect an additional screen, such as an overhead projector. The maximum distance between the FibroScan® and the additional monitor is approximately 1.80 metres.
- Ethernet connector: to connect the FibroScan® to a local network with a PC or to the hospital network if the connectivity option is selected.
- Two USB 2.0 sockets: to connect an external hard disk for backups, a USB key, USB printer, keyboard, or mouse.
- P/S2 connector: This connector allows a keyboard to be used.

5.2 PROBE AREA



The FibroScan® unit has two dedicated probe locations:

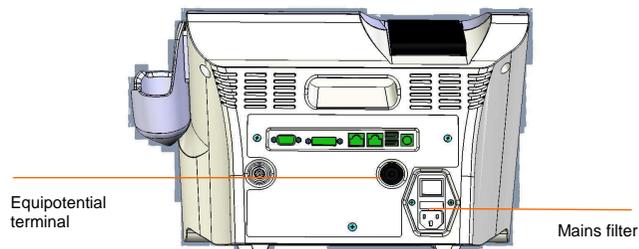
- Probe socket: To use the FibroScan® and the probe, you must connect the probe to this socket.



This connector is fragile.

- Probe holder: this holder provides a place to put the probe down and keep it safe between uses.

5.3 MAINS POWER SUPPLY



- Mains filter: The mains filter includes a power supply connector; an I/O switch to apply power to the unit the fuses.
- Equipotential terminal.



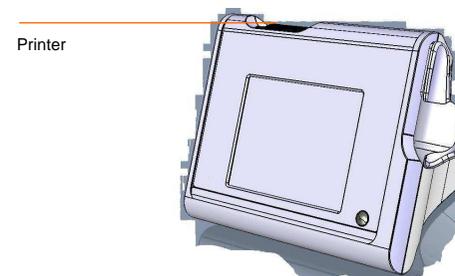
The FibroScan® unit must be connected to a 100 V AC or 230 V AC single-phase 50-60 Hz earthed mains socket using the power cord supplied.



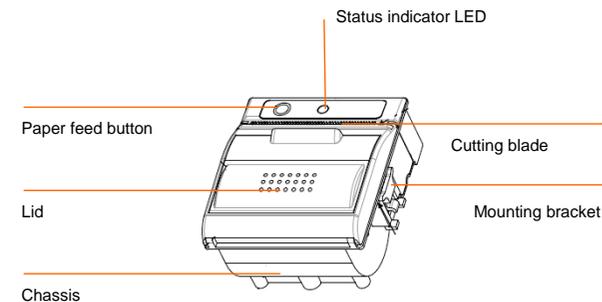
Correct earthing operation can only be guaranteed if the system is connected to a socket compliant with safety standards.

5.4 PRINTER

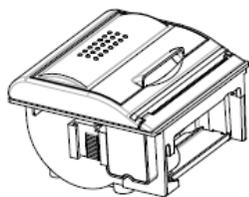
5.4.1 Presentation



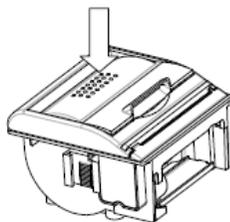
The printer will allow to print report at the end of each examinations, the number of copy can be set on the configuration mode see §7.2. Below are described the maintenance operation. Only paper roll can be changed by anyone, for the other operation a trained technician should do it.



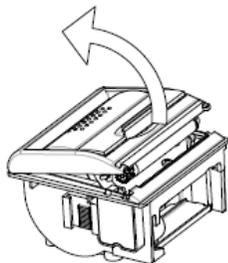
5.4.2 Replacing the paper



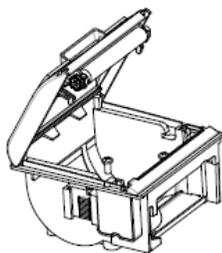
Step 1: lid closed



Step 2: press the lid at the location indicated.



Step 3: Raise the lid.



Step 4: Position the roll of paper, unwind the paper, close the lid. The printer is ready.

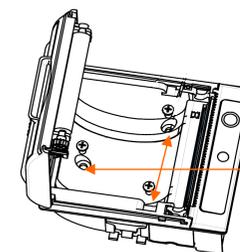
5.4.3 Replacing the printer



The exchanged of the printer should be performed by service engineer certified by Echosens.

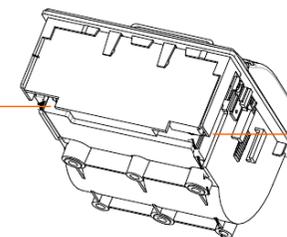
To replace the printer, begin by opening the lid (see the section on replacing the paper). The next steps are as follows:

- Step 1: disconnect the communication cable from the mother board and the power cable from the power board
- Step 2: loosen the three mounting screws



Mounting screws

- Step 2: disconnect cables J1 and J4:



Connector J4: communication

Connector J1: power

- Step 3: to reposition the printer, apply the procedure in reverse.

6 INTERNAL ELEMENTS

6.1 PRESENTATION

The FibroScan® 402 device operates based on the Vibration-Controlled Transient Elastography. This means that a low-frequency wave is generated by the probe, and its propagation in the liver is measured by the system.

FibroScan® 402 therefore comprises the following elements to generate the wave, ultrasound to measure its speed, analyse the signal received, and transmit the results to the user:

- Power supply area: this consists of a power supply and a dedicated board.
- PC area: this area is the interface between the user and the FibroScan® unit.
- Elastography engine area: this area generates the shear wave and the ultrasound, controls the probe, and analyses the signal.
- Monitor area: an extension of the PC area, this area is in direct contact with the user. It is used to manage patient data, configure, and launch examinations.

6.2 OPENING THE FIBROSCAN® 402

Many of the components of the FibroScan® 402 are mounted in a metal structure, and the whole assembly is contained in an external casing.

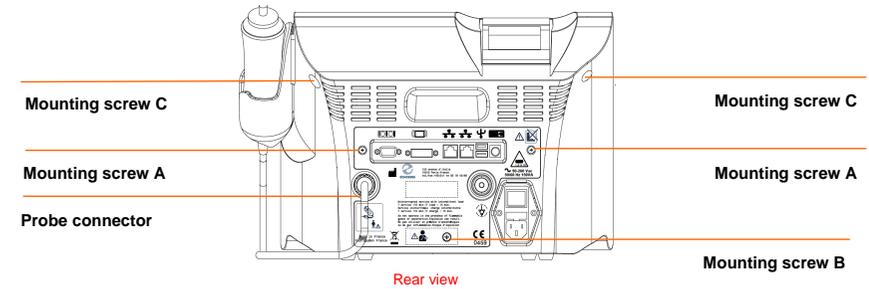
For access to the internal components, this casing must first be removed, and then the structure must be disassembled according to the element to which access is required.

The internal components are interconnected by cables. It is therefore important to apply the steps described below with great care.

6.2.1 Removing the rear casing

For access to the internal components, the first step is to remove the rear casing.

- Step 1: disconnect the probe
- Step 2: loosen mounting screws A, B, and C as indicated on the 'rear view' diagram

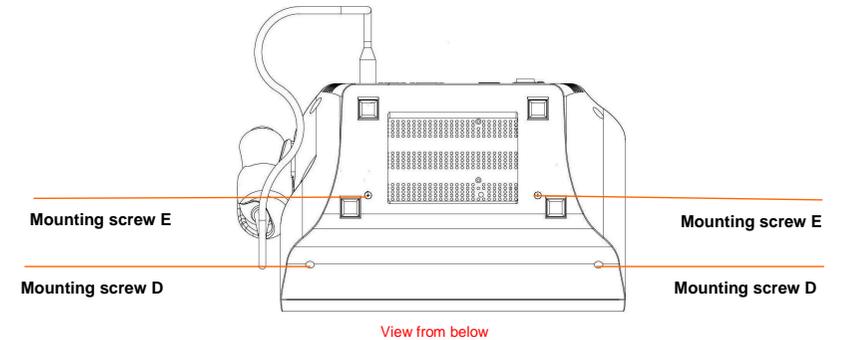


Attention: Disconnect all cables connecting Part A to Part B (cf. §6.2.2).



Mounting screw B is located under a guarantee label. For access to Screw B, remove this label. Remember to affix a new label after servicing.

- Step 3: loosen mounting screws D and E.

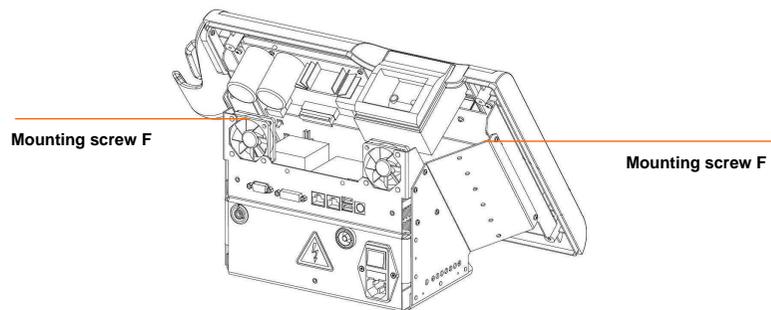


- Step 4: You can now remove the rear casing, and proceed to the next section if necessary.

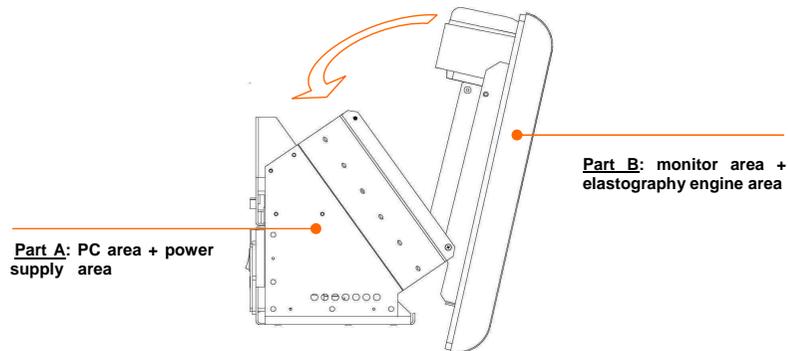
6.2.2 Opening the metal structure

For access to the internal components of FibroScan® 402, the rear casing must first be removed. To do this, refer to the above section, and then remove the metal structure as described.

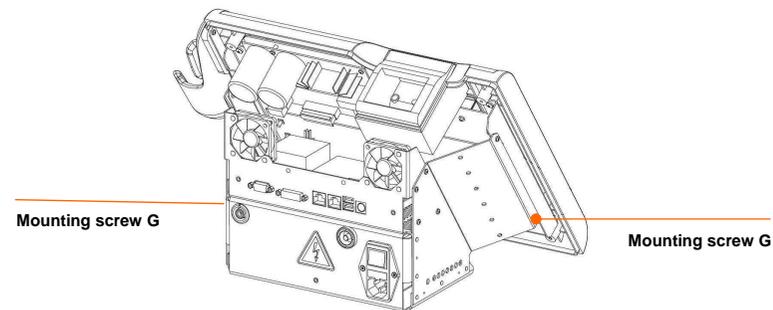
- Step 1: Half-opening the metal structure. It is recommended that you start by loosening mounting screws F only (two screws, one on each side) as indicated below. The elements are on either side of the structure, and so to avoid damaging the cables, screws F must be removed to allow you to partially open the device, and then disconnect the cables if necessary.



Warning: Open the FibroScan® unit carefully to avoid damaging the cables.

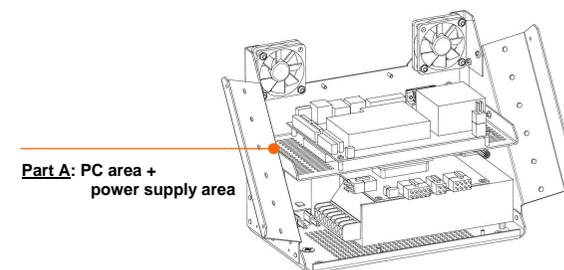


- Step 2: Complete disassembly of the metal structure. To separate the structure into two parts, disconnect all the cables connecting the two parts, and then loosen the mounting screws.

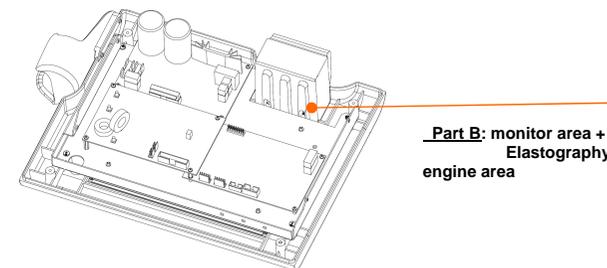


Warning: Disconnect all cables connecting Part A to Part B.

After removal of both mounting screws G, the two parts A and B are separated, as shown below.



The part A is composed by the 2 metal blocks, the power supply, the power board, the mother board, main switch, the probe connector and two fans.

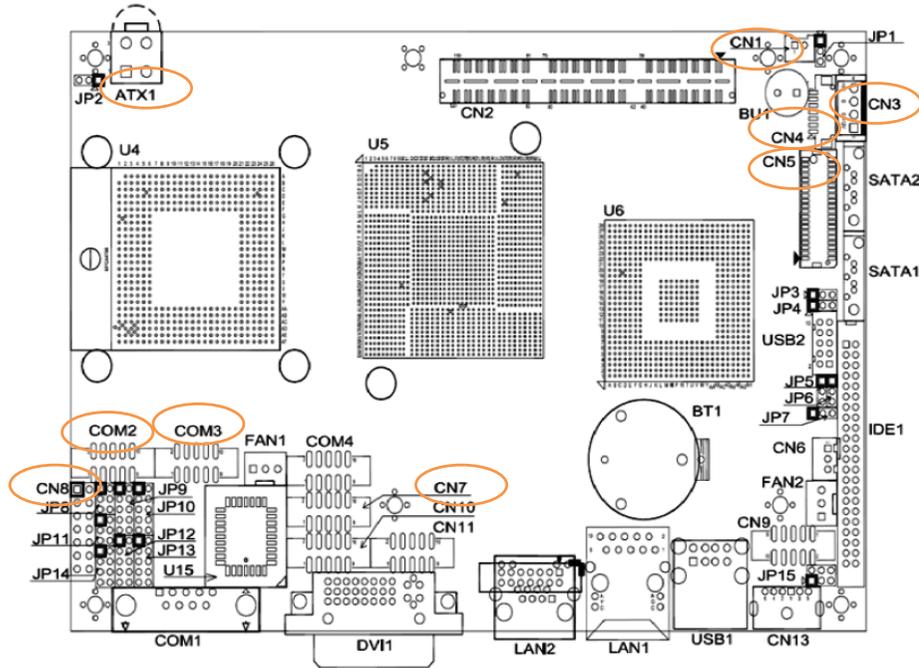


The part B is composed by the Elastography engine, the touch screen, the backlight inverter, touchpad controller inverter board, probe holder and the printer.

6.3 PC AREA

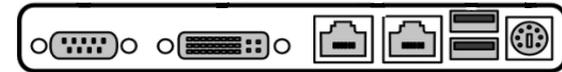
6.3.1 Motherboard EP830 and its connectors

The mother board mounted on the FibroScan® 402 is the model EP830. Below is described the different connections used for FibroScan® 402. Be careful the follow the instruction to not burn it.



Item	Cable #	Description	Item	Cable #	Description
CN1	59	Power supply ATX control	CN8	60	Front panel on/off button
CN3	69	Fan power supply	COM2	61	Printer connection
CN4	56	Backlight inverter board	COM3	58	Touchpad inverter board
CN5	57	Screen connection	ATX	52	Motherboard power supply
CN7	62	Firewire connection (IEEE)			

There is also a connector interface on the motherboard:



Com1 (RS232) DVI 1 LAN1 LAN2 USB CN13(P/S2)

These connectors are used to connect the following devices:

- DVI connector: This is the video output used to connect an additional screen, such as an overhead projector. The maximum distance between the FibroScan® and the additional monitor is approximately 1.80 metres.
- Ethernet connector: to connect the FibroScan® to a local network with a PC or to the hospital network if the connectivity option is selected.
- Two USB 2.0 sockets: to connect an external hard disk for backups, a USB key, USB printer, keyboard, or mouse.
- P/S2 connector: This connector allows a keyboard to be used.
- COM1: not used

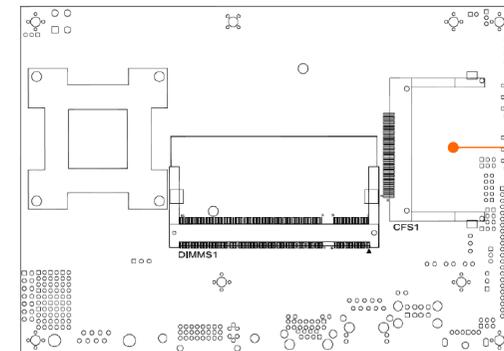
6.3.2 Backup system

The backup and the software are installed on a compact Flash memory like the one shown below:



Warning: Use only compact Flash provided by Echosens. And check the good way before to connect it to the mother board.

This is connected at the back of the motherboard, on the CFS1 connector shown below.



CFS1 connector

6.3.3 Motherboard power supply

The values to be measured are identical: the ATX connector on the motherboard, and Connector J3 on the power supply board. The tolerances for each value are $\pm 5\%$ of the voltage.

Pin	Description
1	GND
2	GND
3	+12V
4	+12V



6.4 POWER SUPPLY AREA

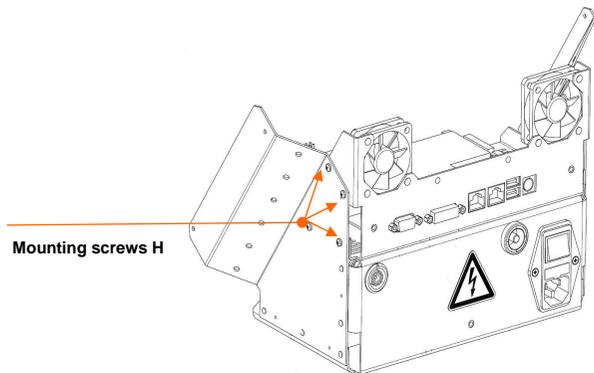
The power supply area is located on Part A, under the PC area. The PC area must therefore be removed to gain access to the power supply area. To have access to the Part A please follow the procedure described on the § 6.2.2.



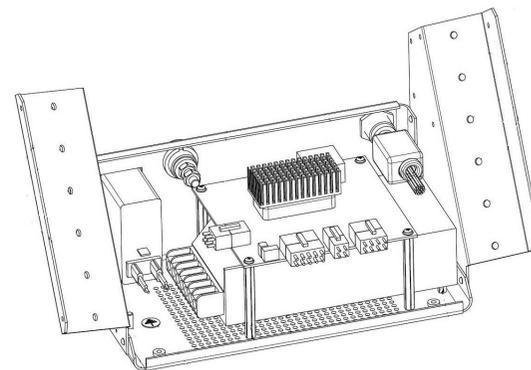
Warning: Take care about cables before to perform any action..

6.4.1 Access to the power supply area

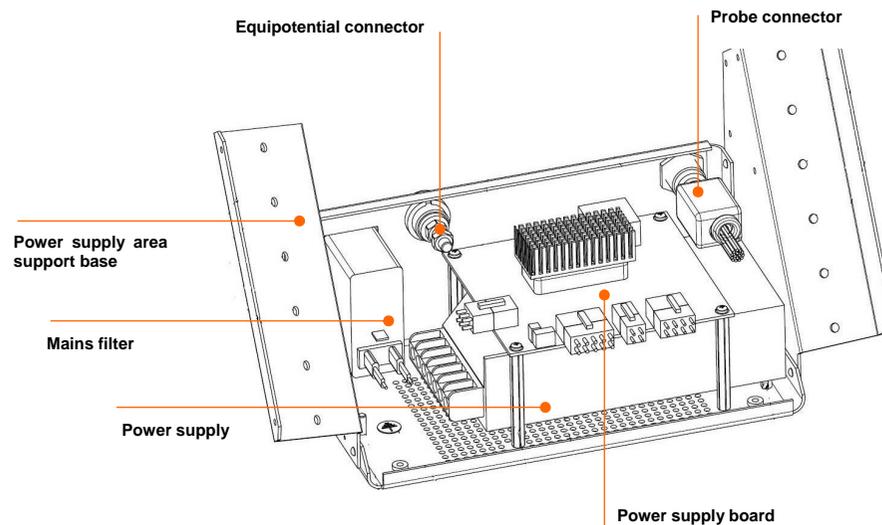
- Step 1: For access to the power supply area, first remove the eight mounting screws H (four screws on each side, as shown below).



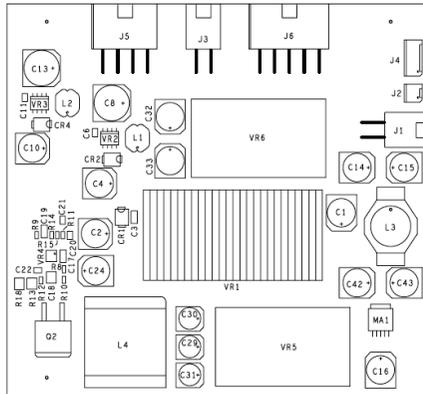
- Step 2: Disconnect the cables connecting the two areas, and then remove the PC area. The following arrangement is then obtained:



6.4.2 Description of the power supply area



6.4.3 Power supply board



- Connector J5 (AMPLI-MOT board JP3). The tolerances for each value are $\pm 5\%$ of the voltage.

J5		Pin	Description
	1	1	Not connected
	2	2	Not connected
	3	3	GND
	4	4	Not connected
	5	5	Not connected
	6	6	+25Vdc
	7	7	Not connected
	8	8	-25Vdc

- Connector J3 (ATX motherboard). The tolerances for each value are $\pm 5\%$ of the voltage.

Pin	Description
1	GND
2	GND
3	+12V
4	+12V



- Connector J4 (printer J1). The tolerances for each value are $\pm 5\%$ of the voltage.

J4		Pin	Description
	1	1	GND
	2	2	GND
	3	3	+7Vdc
	4	4	+7Vdc

- Connector J1. The tolerances for each value are $\pm 5\%$ of the voltage.

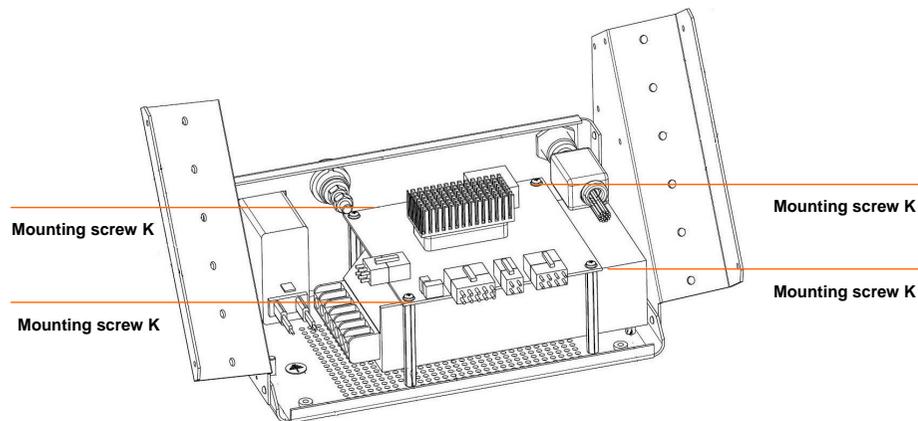
J1		Pin	Description
	1	1	+25 Vdc
	2	2	+25 Vdc
	3	3	GND
	4	4	GND

- Connector J6 (MONO-ACQ board J1). The tolerances for each value are $\pm 5\%$ of the voltage.

J6		Pin	Description
	1	1	+5 Vdc
	2	2	GND
	3	3	Not connected
	4	4	GND
	5	5	+16 VDC
	6	6	+5 Vdc
	7	7	GND
	8	8	Not connected
	9	9	GND
	10	10	-16 Vdc

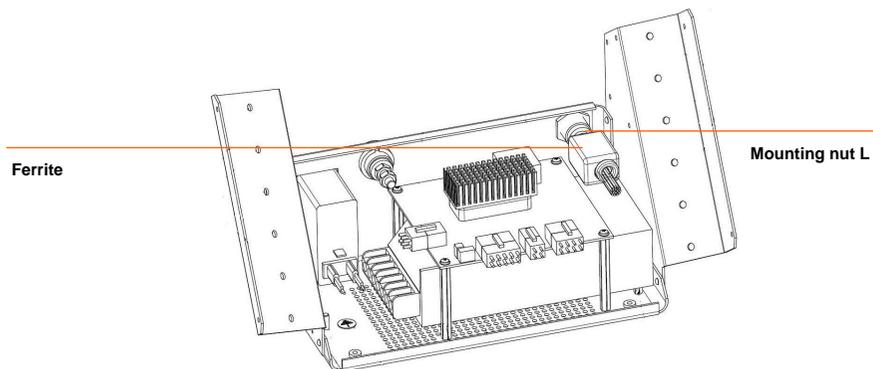
6.4.4 Replacing the power supply board

- Step 1: Open the FibroScan® unit according to the procedure described in the section on 'Opening the FibroScan® 402'.
- Step 2: Disconnect all the cables from the board.
- Step 3: Remove the four mounting screws K.



6.4.5 Replacing the probe connector

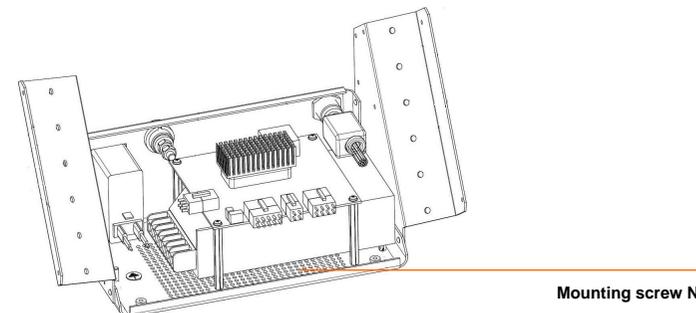
- Step 1: Open the FibroScan® unit according to the procedure described in the section on 'Opening the FibroScan® 402'.
- Step 2: Disconnect all the cables from the probe connector.
- Step 3: Remove the ferrite (special spanner).
- Step 3: Remove mounting nut L.



Warning: When repositioning the connector, ensure that the red dot on the connector is at the top.

6.4.6 Replacing the power supply

- Step 1: Open the FibroScan® unit according to the procedure described in the section on 'Opening the FibroScan® 402'.
- Step 2: Remove the supply board.
- Step 2: Disconnect all the cables from the probe connector.
- Step 3: Remove mounting nut N, located under the Part A support base.

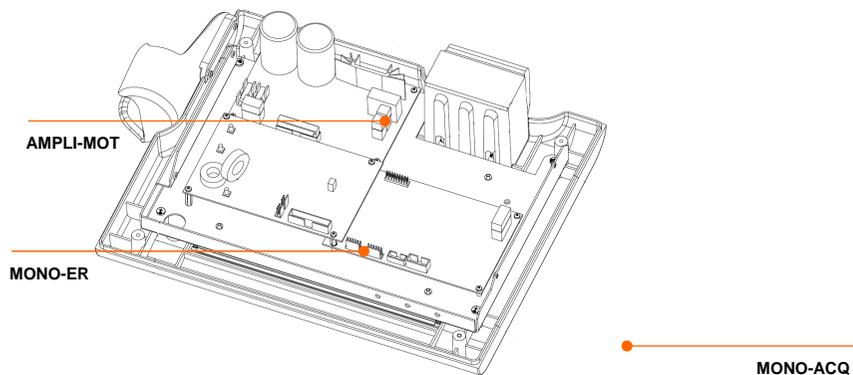


6.5 ELASTOGRAPHY ENGINE AREA

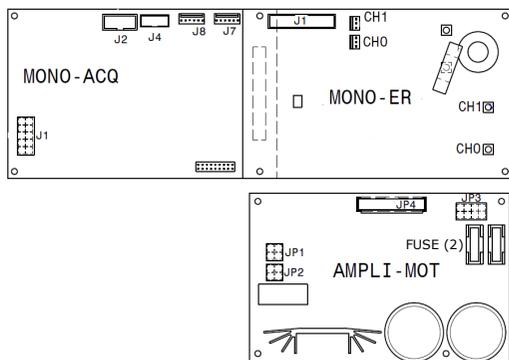
6.5.1 Description of the Elastography engine area

The Elastography engine area is the main part of the FibroScan® unit. It comprises three boards, each with its own function. The assembly is mounted on a metal plate; this assembly is called the 'Elastography engine'. The board assemblies constituting the module are as follows:

- MONO-ACQ Board: The acquisition board handling the analysis of the data sent and received by the MONO-ER board. It also handles communication with the PC area.
- MONO-ER Board: This is the ultrasound signal transmission and reception board, and shapes the signal
- AMPLI-MOT board: This board handles the servo control of the probe. It generates the low-frequency mechanical wave.



6.5.2 Elastography engine area connection



■ MONO-ACQ Board

Item	Cable #	Description
J1	54	MONO-ACQ power supply
J2	62	Firewire connector (IEEE)
J8		Probe socket

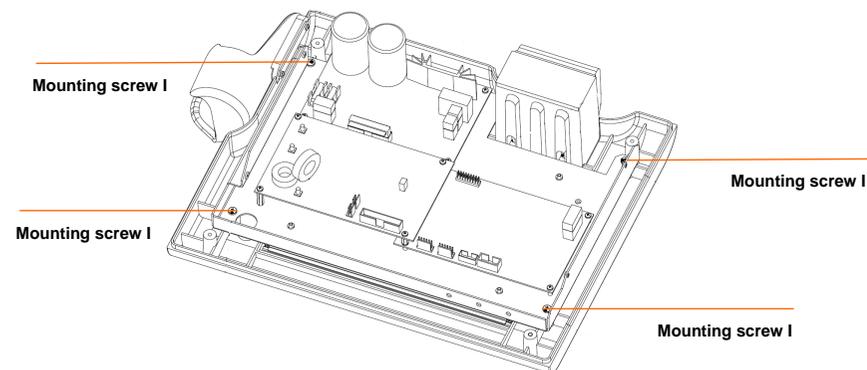
■ MONO-ER Board

Item	Cable #	Description
J1	63	Connected to JP4 on the board AMPLI-MOT (communication)

Item	Cable #	Description
CH1		Probe socket
CH1		Probe socket
■ AMPLI-MOT board		
Item	Cable #	Description
JP2	64	Probe socket
JP3	55	AMPLI-MOT board power supply
JP4	63	Connected to J1 of the MONO-ER board (communication)
FUSE		2 Fuses (5x20 T3.14AH 250V)

6.5.3 Replacing the elastography engine

- Step 1: Open the FibroScan® unit according to the procedure described in the section on 'Opening the FibroScan® 402'.
- Step 2: Disconnect all the cables from the elastography engine.
- Step 3: Remove the four mounting screws I from the module.



- Step 4: Replace the module by applying these steps in reverse.

6.5.4 Elastography engine power supply voltage

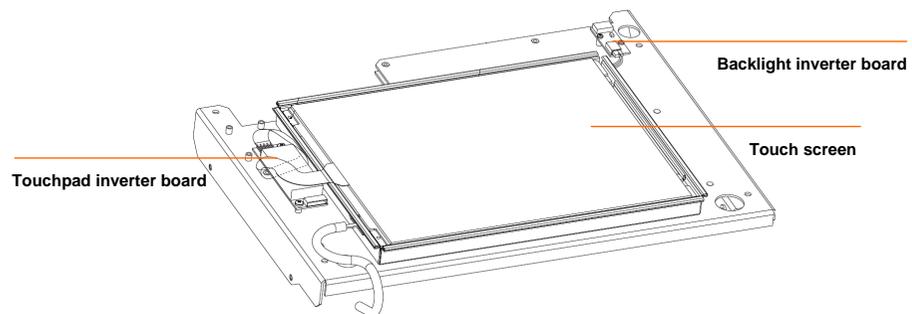
To measure the voltage, refer to Section 6.3.3.

6.6 MONITOR AREA

6.6.1 Description of the monitor area

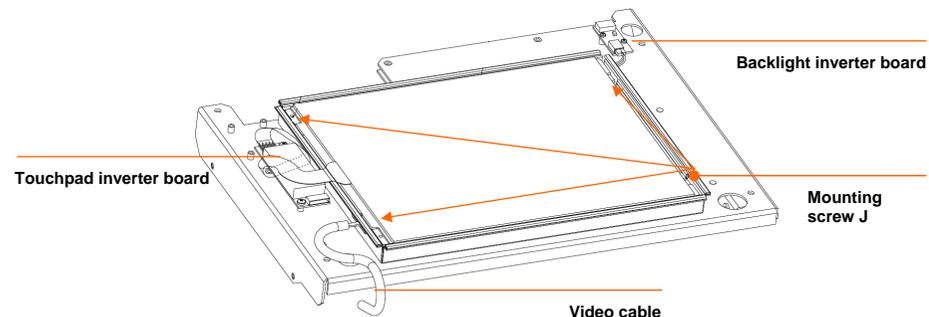
The monitor area comprises three elements:

- The screen with touchpad
- Inverter board for the touchpad
- Inverter board for the backlight.



6.6.2 Replacing the screen

- Step 1: Open the FibroScan® unit according to the procedure described in the section on 'Opening the FibroScan® 402'.
- Step 2: Disconnect the video cable (CN5), the backlight inverter board cable (CN4), and the touchpad inverter board cable (COM3) from the motherboard.
- Step 3: Remove mounting screws I as specified in Section 6.4.3.
- Step 4: Disconnect the backlight inverter board cable and the touchpad inverter board cable, and remove mounting screws J.



- Step 5: Reposition the screen by applying these steps in reverse.

7 SOFTWARE

7.1 SOFTWARE UPDATE

To update the software:

- Plug a keyboard,
- Plug in the installation USB key,
- Switch on the FibroScan® 402,
- Wait approximately 30 seconds to obtain a display indicating that system installation is starting,
- Wait until the display says "The restore has completed successfully" and click enter,
- Switch off the FibroScan® 402,
- Disconnect the USB key.



The installation procedure may take a few minutes.



Warning: Do not use this key in a PC, because if the PC boots on the key, the PC's system partition may be overwritten.

The system is then updated. This update does not delete any data.

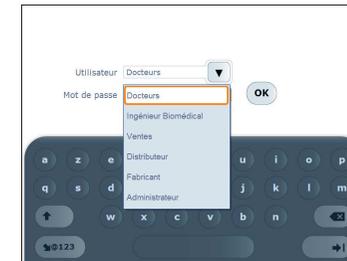
8 CONFIGURATION MODE

8.1 ACCESSING CONFIGURATION MODE



1. Start the FibroScan®.

2. On the home page, press .



3. The window shown opposite gives you the choice of various login options. There are six, of which three are accessible by distributors and two by the customer.

- **Level 1**
Login: Doctors
Password: MD
- **Level 2**
Login: Biomedical engineer
Password: maintenance
- **Level 3**
Login: Distributor
Password: *****

8.3 ACCESSING CONFIGURATION MODE LEVEL 2

The level 2 gives to the user access to 8 tabs: general, logfile, hospital and system. This tabs are describe below.

8.3.1 General tab.



Date / Time
Current date and time : 06 / 15 / 2011 19 : 00 : 25
OK

To set the date and time, just press on button "change".
Set the date and time and click "ok"

English
French

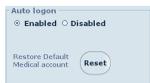
To change the language, press on the arrow and choose on the list

mm_dd_yyyy
dd_mm_yyyy

To change the date format, press on the arrow and choose on the list

Dot
Comma

To change the decimal separator, press on the arrow and choose on the list



The Autologon lets you enable or disable an authentication to start the system. The Auto logon is enable by default.

Enabled :the system will not ask for the password before to launch the Fibrosan application

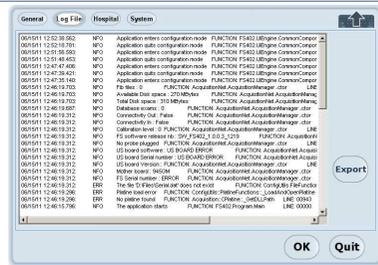
Disabled: the system will ask for the password before to launch the Fibrosan application. When selecting "disabled" you need to enter the new password in the "password" field.

Reset button: it will restore the default setting.



8.3.2 logfile tab.

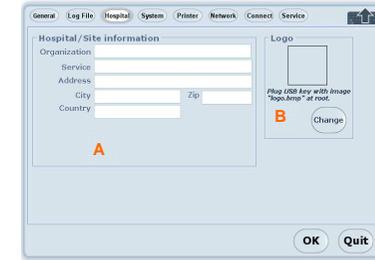
The logfile is the trace of the system activity and gives the operator a histpry of the events that occurred during use of the Fibrosan® software.



To save the log file:

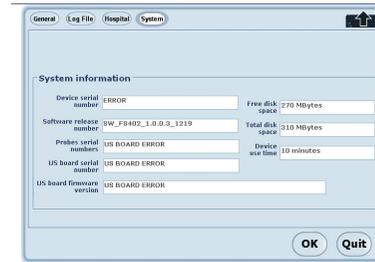
- connect a USB media storage
- press on " export" button
- the file is save under name: "FibrosanSerialNumber_YYYYMMDD_HH MMSS.log"

8.3.3 Hospital tab.



Item	Description
A	This information will be displayed on the PDF export (if the connectivity is enable)
B	Press on "change" and browse for a logo that you would like to appear on the PDF print

8.3.4 System tab.



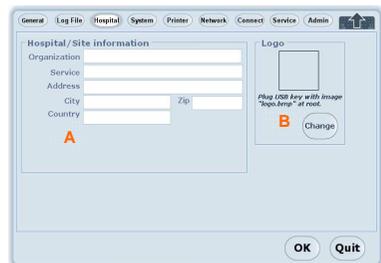
This tab will display all information about the system.

8.3.5 printer tab.



This tab will let you enter the number of tickets printed automatically after the end of the examination.

8.4.3 Hospital tab.



Item	Description
A	This information will be displayed on the PDF export (if the connectivity is enable)
B	Press on "change" and browse for a logo that you would like to appear on the PDF print

8.4.4 System tab.



This tab will display all information about the system.

8.4.5 printer tab.



This tab will let you enter the number of tickets printed automatically after the end of the examination.

8.4.6 Network tab.



Item	Description
Automatic	Dynamic IP configuration
Manual	Static IP configuration
IP Address	IP address field
Mask	Subnet mask field
Gateway	Default gateway field

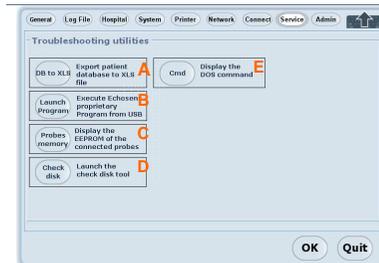
The IP address can be configured statically or dynamically via DHCP. To configure the address statically, complete the "IP Address", "Mask" and "Gateway" fields.

8.4.7 Connect tab.



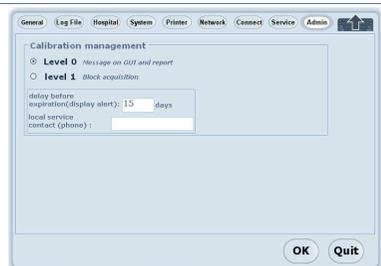
If the connectivity option is not activated the "HL7 Input" and "Output" are not accessible.

8.4.8 Service tab.



Item	Description
A	This is used to export data into Excel file saved on the USB Key. For the sake of confidentiality, the file may be exported in an anonymous or named version. The file saved is named: "FibroscanSerieINunumber_yyyymmdd_hhmmss.xls."
B	This to launch program validated by Echosens from USB memory stick
C	Display the probe memory content.
D	To start a check disk.
E	To start a DOS command

8.4.9 Admin tab.



On this tab you can choose the calibration management. By default it's level 0, the user will have a message on the screen; level 2 the user will be not able to use the probe when calibration is du. It's possible to set the delay the display alert and insert your phone or email that should appears on the message.

8.5 CONNECTIVITY MODE

If connectivity is enabled (see the Configuration section), patient data can be received and sent via the network.

8.5.1 Receiving the list.

To display the list of patients, press the button  in the home screen. In the list, the operator selects the record of the patient to be examined. The examination starts automatically and the patient data are displayed.



8.5.2 Exporting patient data.

Type of export	Description
PDF	All information (including the elastogram)
XML	Information in the form of a table
FIB	Files readable by the FibroScan software only

9 MAINTENANCE

9.1 SPARE PARTS LIST

Zone	Reference	Designation
Probe	AP107_100	M Probe
	AP107_007	Probe S, M, XL Case Foam
	AP107_008	Probe S, M, XL Case
Computer zone		
	AP200_001	FS 402 Mother board set
	E200_002	FS 402 Display set
	E200_003	FS 402 Touchpad inverter board
	E200_004	FS 402 Back Light board
	E200_005	FS 402 Printer and cables
	E200_006	FS 402 FireWire cable
	E200_007	FS 402 On/off button
	E200_008	FS 402 Back Light cable
	E200_009	FS 402 Screen cable
	E200_010	FS 402 Touchpad inverter board cable
	E200_011	FS 402 Mother board power cable
Elastography engine V2 zone	AP40010	FS402 Elastography engine V2
	E200_012	FS 402 Mono_Acq board power cable
	E200_013	FS 402 Ampli_Mot board power cable
	E200_014	FS 402 Probe socket
Power supply zone		
	AP200_006	FS 402 Power supply
	E200_016	FS 402 Power supply board
	AP200_004	FS 402 Main filter

9.2 TROUBLESHOOTING

Hardware error	Communication problem between computer zone and Elastography engine zone	<ul style="list-style-type: none"> - check that the Firewire cable is correctly connected - check the REGANA board voltage values - check with another mother board - check with another Elastography engine 	
	Software	<ul style="list-style-type: none"> - Ensure that the software installed is the correct one - Software compatibility 	
The instrument does not switch on	Mains power	<ul style="list-style-type: none"> - check the wall outlet voltage value 	
	Mains filter	<ul style="list-style-type: none"> - check the filter fuses - check the filter outlet voltage values 	
	Motherboard	<ul style="list-style-type: none"> - check the power supplies - check the power supplies cable 	
	Button on/off in front	<ul style="list-style-type: none"> - check the connector on the mother board - check the connector on the remote control board 	
	Remote control board	<ul style="list-style-type: none"> - check the connection on the remote control board - check with another remote control 	
The instrument turns on, but nothing on-screen	Screen	<ul style="list-style-type: none"> - connect a screen to the front panel VGA connector - if it comes on, check the screen connector on the motherboard - check the inverter board - if still nothing, replace the screen - if the problem persists, replace the motherboard 	
		Software	<ul style="list-style-type: none"> - Reinstall the software
		Hard disk	<ul style="list-style-type: none"> - Hard disk replacement
		Motherboard	<ul style="list-style-type: none"> - motherboard replacement
Fixed image	Touchpad	<ul style="list-style-type: none"> - check with mouse if the software is working 	
	Power supply	<ul style="list-style-type: none"> - check that the power supply cable is connected - check that the printer is switched on 	
No printout	Paper	<ul style="list-style-type: none"> - check the paper tray 	
	COM cable	<ul style="list-style-type: none"> - check or replace the COM cable 	
	Printer	<ul style="list-style-type: none"> - replace the printer 	
Probe not connected error message	Probe	<ul style="list-style-type: none"> - check that the probe is connected - check with another probe if one is available - ensure that the probe's connector pins are not damaged - check the log file for eeprom problems 	
	Elastography engine	<ul style="list-style-type: none"> - check that the probe connector on the Fibrosan is not damaged - check the voltage values - check with another Elastography engine 	
USB Export not possible: Excel or Fib file	Memory stick	<ul style="list-style-type: none"> - check with another memory stick 	
	USB connector	<ul style="list-style-type: none"> - check if USB connector is not broken 	
	Software	<ul style="list-style-type: none"> - Reinstall the software 	
	Motherboard	<ul style="list-style-type: none"> - check the connection on mother board - check with another USB cable - motherboard replacement 	
Not Ultrasound on the TM mode or A mode	probe	<ul style="list-style-type: none"> - check with another probe if one is available - ensure that the probe's connector pins are not damaged - check that the probe connector on the Fibrosan is not damaged - check on the second probe connectors 	
	Elastography engine	<ul style="list-style-type: none"> - check on the second probe connectors - check the voltage values - if the problem persists, replace the elastography engine 	
Virtual memory problem	Software	<ul style="list-style-type: none"> - check if the Patch X1 is installed (cf. ETB007) 	

White screen when turning on	Motherboard	<ul style="list-style-type: none"> - check connection on the mother board - check the video output - exchange the mother board
	The screen	<ul style="list-style-type: none"> - check the screen connector - exchange the screen
The Fibrosan doesn't switch off when the start button is pressed	Motherboard	<ul style="list-style-type: none"> - check the start button connector on motherboard
	Remote control board	<ul style="list-style-type: none"> - check the start button connector on remote control board - replace the remote control board

9.3 CHECK LIST

Product Informations

S/N	Probe S/N	Man. /Dist.
Customer location	Customer name	
Service location	<input type="checkbox"/> Echosens <input type="checkbox"/> Other:..... <input type="checkbox"/> On site	
Service date	Service reference	

SOFTWARE

Check Log files	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Update software	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Check import/export data	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Check of Excel backup	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK

Used instruments

S/N	Model	Manufacturer	Description	Calibration date due

Computer Area

Software Version	Mother board voltage, connector J3		
Connector description	Value obtained	result	
Pin 3 : +12 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Pin 4 : +12 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Check of the connectors	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK		

Power Supply Area

Power supply type			
Main filter	Fuse	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	

Power Supply Area

Board name	Connector description	Value obtained	result
Power supply board			
Connector J5	Pin 6 : + 25 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 8 : - 25 Vdc		
Connector J3	Pin 3 : + 12 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 4 : + 12 Vdc		
Connector J4	Pin 3 : + 7 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 4 : + 7 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Connector J1	Pin 1 : + 25 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 2 : + 25 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Connector J6	Pin 1 : + 5 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 5 : + 16 Vdc		
	Pin 6 : + 5 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 10 : -16 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Main filter	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK		

Product Informations

S/N	Probe S/N	Man. /Dist.
Service date	Service reference	

Elastography engine V2 Area

Board name	Connector description	Value obtained	result
MONO ACQ board voltage	Pin 1 : + 5 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 5 : + 16 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 6 : + 5 Vdc		
	Pin 10 : -16 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Green LED (on=ok)		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
AMPLI MOT board	Red LED (off=ok)		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 6 : + 25 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	Pin 8 : - 25 Vdc		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Mono E/R board	LED of U/S (green)		<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Check of the connectors	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK		

Screen Area

Test on/off button (led on)	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Check the Touchpad	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Test VGA output	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Test USB port	front	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	rear	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Test network output	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK <input type="checkbox"/> N/A	
Test of printer	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK <input type="checkbox"/> N/A	

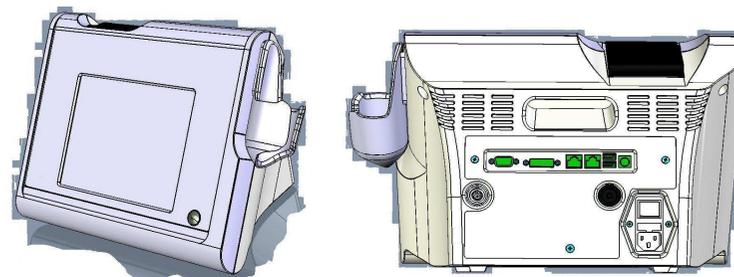
PROBE AREA

Blue LEDS of the probe	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Check the probe on EMPARAMS	Date of next calibration : <input type="checkbox"/> OK <input type="checkbox"/> NOT OK	
Acquisition Test	connector 1	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
	connector 2	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Check the information contact on calibration message	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK	

FRAME

State of device(cf. appendix)	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK
Labeling	<input type="checkbox"/> OK <input type="checkbox"/> NOT OK

FRAME CONTROLE



10 TECHNICAL CHARACTERISTICS

10.1 CHARACTERISTICS OF THE DEVICE



■ Manufacturer	Echosens, SA 153 Avenue d'Italie 75013 Paris – France
■ Model	FibroScan® 402
Computer properties	
■ Operating system	Windows XP Embedded.
Metrological performance	
Note: The measured variable is stiffness, referred to as "S".	
■ Ultrasound transducer	Refer to the specific instructions below.
■ Metrological performance	S min.: 1.5 kPa. S max.: 75 kPa. Accuracy: ± 0.5 kPa.
■ Classification	Class IIa according to directive 93/42/EC
■ Electrical classification	Class I, type B  Group I class A relative to CISPR 11. IPX0: The instrument without probe is not protected against liquids.
■ Operating mode	Uninterrupted service, with intermittent charging. Charge time = Tcharge = 10 min. Rest time = Trest = 15 min.
Electrical characteristics	
■ Power supply	100 - 240 V (+10%/-15%) ~ 50-60 Hz
■ Usable power	150 VA
■ Fuse	2 x 1.6 AT
Mechanical Characteristics	
■ Dimensions	275 x 434 x 252 mm (H x W x D)
■ Weight	8 kg
Environmental characteristics	
■ Operating temperature	+10 to +40°C (+50 to +104 F)
■ Operating humidity	30 to 75% relative humidity, non-condensed.
■ Storage temperature	-20 to +70°C (-4 to +158 F)
■ Storage humidity	10 to 85% relative humidity, non-condensed.
Hardware supplied	
■ Cables provided	1 x CEE22 mains lead (length 2 m) 1 x Probe cable (length 1.5 m)

10.2 PROBE CHARACTERISTICS



■ Manufacturer	Echosens, SA 153 Avenue d'Italie 75013 Paris – France
■ Model	Type M
Metrological performance	
Note: The measured variable is stiffness, referred to as "S".	
Ultrasound transducer	
■ Central frequency	3.5 MHz
■ Measurement depth	25 to 65 mm
■ Metrological performance	S min.: 1.5 kPa. S max.: 75 kPa. Accuracy: ± 0.5 kPa.
General data	
■ Electrical classification	IPX1: The M probe, excluding connectors, is protected from vertically falling drops of water.
■ Operating mode	Uninterrupted service, with intermittent charging. Charge time = Tcharge = 10 min. Rest time = Trest = 15 min.
Electrical characteristics	
■ EMI	See the FibroScan® user manual.
Mechanical Characteristics	
■ Dimensions	158 x 52 mm (L x diameter)
■ Weight	500 grams

Environmental characteristics	
■ Operating temperature	+10 to +40°C (+50 to +104 F)
■ Operating humidity	30 to 75% relative humidity, non-condensed.
■ Storage temperature	-20 to +70°C (-4 to +158 F)
■ Storage humidity	10 to 85% relative humidity, non-condensed.

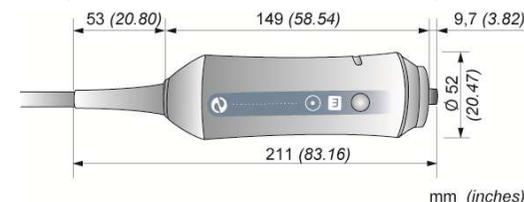


Figure 1: dimension.

11 REGULATIONS

Electromagnetic interference (EMI) is a signal or emission, conveyed through open space or through electrical or signal conductors, which may severely disrupt radionavigation 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, radiodetection, air traffic control, radio paging and GSM systems. These authorised services, along with unintentional disrupters, 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.

11.1 ELECTROMAGNETIC EMISSIONS

The FibroScan® 402 is designed for use in the electromagnetic environment defined below. FibroScan® 402 customers or users must ensure that it is indeed used in such an environment.

Emission test	Compliance	Electromagnetic Environment - Recommendations
RF CISPR11 emissions	Group 1	The FibroScan® 402 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.
RF CISPR11 emissions	Class A	The FibroScan® 402 may be used on all premises other than domestic premises and those directly connected to the public low voltage energy grid used to supply domestic buildings.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/Oscillating emissions EN 61000-3-3	Applicable	

11.2 ELECTROMAGNETIC IMMUNITY (1)

The FibroScan® 402 is designed for use in the electromagnetic environment defined below. FibroScan® 402 customers or users must ensure that it is indeed used in such an environment.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic Environment - Recommendations
Electrostatic Discharge IEC 61000-4-2	±6 kV contact	±6 kV on contact	Floors should be wooden, concrete or ceramic. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
	±8 kV air	±8 kV through air	
Spike/Burst IEC 61000-4-4	±2 kV supply	±2 kV supply	The quality of the electrical network must be that of a typical commercial or hospital environment.
	±1 kV input/output	±1 kV input/output	
Voltage shocks EN 61000-4-5	Differential mode ±1 kV	Differential mode ±1 kV	The quality of the main supply must be that of a typical commercial or hospital environment.
	Common mode ±2 kV	Common mode ±2 kV	
Voltage drops, short interruptions and supply inlet voltage variation IEC 61000-4-11	<5% U_T For 10ms	<5% U_T For 10ms	The quality of the electrical network must be that of a typical commercial or hospital environment. If the FibroScan® 402 user requires continuous operation during mains power cuts, the FibroScan® 402 should be connected to an uninterruptible power supply or battery.
	40% UT For 100ms	40% UT For 100ms	
	70% UT For 500ms	70% UT For 500ms	
	<5% U_T For 5s	<5% U_T For 5s	
Magnetic field immunity at supply frequency (50-60 Hz) IEC 61000-4-8	3A/m	3A/m	Supply frequency magnetic fields must be those of a typical commercial or hospital environment.

NOTE: U_T is the mains supply voltage measured before conducting the test

11.3 ELECTROMAGNETIC IMMUNITY (1)

The FibroScan® 402 is designed for use in the electromagnetic environment defined below. FibroScan® 402 customers or users must ensure that it is indeed used in such an environment.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic Environment - Recommendations
Recommended separation distance			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 196 kHz	3 V	$d=1.17\sqrt{P}$
	0.1 Vrms 196kHz to 8.5MHz	0.1 V	$d=35\sqrt{P}$
	3 Vrms 8.5 MHz to 80 MHz	3V	$d=1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.17\sqrt{P}$ 80 MHz to 800 MHz
			$d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum emitter power in watts (W), as specified by the emitter manufacturer, and d is the recommended separation distance in metres (m).

The EM field force for fixed emitters, as defined by an electromagnetic study A of the site, must be less than the compliance level in each of the frequency bands B.

Interference may occur in the vicinity of devices bearing the following symbol:



NOTE 1: At 80 MHz and 800 MHz, the upper frequency band is applicable

NOTE 2: These recommendations may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection caused by structures, objects and individuals.
A The force of EM fields for fixed emitters such as commercial AM/FM radio broadcasting services, television, cell phone services, radiodetection, air traffic control, radio paging receivers and GSM services cannot be accurately predicted. To assess the EM environment caused by fixed emitters, a site EM study must be conducted. If the force of the fields measured at the location where the FibroScan® 402 is used exceeds the above-mentioned compliance levels, correct operation of the FibroScan® 402 must be checked. If abnormal performance is observed, additional measurements may be required after, for example reorienting or moving the FibroScan® 402.

B Beyond the 150 kHz – 80 MHz band, the force of EM fields must be less than 3V/m

11.4 RECOMMENDED SEPARATION DISTANCES

(between portable or mobile RF communication devices and the FibroScan® 402)

The FibroScan® 402 is designed for use in an electromagnetic environment in which RF disturbance is controlled. FibroScan® 402 customers or users may prevent interference by maintaining a minimum distance between portable or mobile (transmitter) RF communication devices and the FibroScan® 402, as recommended below according to the transmitter's maximum power.

Maximum transmitter emission power (W)	Separation distance according to transmitter frequency (m)				
	150kHz to 196 kHz	196kHz to 8.5MHz	8.5MHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d=1.17 \sqrt{P}$	$d=35 \sqrt{P}$	$d=1.17 \sqrt{P}$	$d=1.17 \sqrt{P}$	$d=2.33 \sqrt{P}$
0.01	0.12	3.50	0.12	0.12	0.23
0.1	0.37	11.01	0.37	0.37	0.74
1	1.17	35.00	1.17	1.17	2.33
10	3.70	110.70	3.70	3.70	7.37
100	11.70	350.00	11.70	11.70	23.30

For emitters whose maximum power is not listed above, the recommended separation distance d can be estimated using the applicable equation at the transmitter's frequency, where P is the maximum transmitter power in watts (W) as specified by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the upper frequency band is applicable.

NOTE 2: These recommendations may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection caused by structures, objects and individuals.



Echosens
 30 Place d'Italie
 75013 PARIS
 Tel : +33 1 44 82 78 50
 Fax : +33 1 44 82 78 60
 Site Web : www.echosens.com
 Email : service@echosens.com