

# FibroScan® 402

# **TECHNICAL MANUAL**



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# **1 INTRODUCTION**

#### <u>1.1</u> 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

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# **2 MISCELLANEOUS INFORMATION**

#### 2.1 **OWNERSHIP AND COPYRIGHT**

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#### 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:

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: <u>www.echosens.com</u>.

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<sup>®</sup> 402 unit weighs approximately 8 kg and its dimensions are  $275 \times 434 \times 252$  mm (height x width x depth). This makes it easily transportable and conveniently compact.

FibroScan<sup>®</sup> 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

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ltem	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<sup>®</sup> 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<sup>®</sup> 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.



The FibroScan<sup>®</sup> unit has two dedicated probe locations:

Probe socket: To use the FibroScan<sup>®</sup> and the probe, you must connect the probe to this socket.



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



- 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 singlephase 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 allows 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.

	Status indicator LED		
Paper food button			
Paper leed bullon		Cutting blade	
Lid		Mounting bracket	
Chassis			

### 5.4.2 Replacing the paper



# 5.4.3 Replacing the printer



He 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



Step 2: disconnect cables J1 and J4:



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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 402

Many of the components of the FibroScan<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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.

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



The part A is composer by the 2 metals blocs, 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<sup>®</sup> 402 is the model EP830. Below is described the different connections used for FibroScan<sup>®</sup> 402. Be carefull the foolow the instruction to not burn it.



Item	Cable #	Description	ltem	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:



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<sup>®</sup> 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:

There is 2 compact Flash memory capacity :

• 2Gb supporting CLPC B1.0 and B2.0



• 8Gb supporting CLPC B2.1





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



Warning: Do not install CLPC B2.1 on a 2Gb Compact Flash. That software version requires 8Gb memory size





#### 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 4
3	+12V	1 2
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:





**Probe connector Equipotential connector** ECHOSENS IS REGISTERED TRADEMARKS © COPYRIGHT ECHOSENS ALL RIGUTS RESERVED



6.4.3 Power supply board



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

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

Connector J3 (ATX motherboard). The tolerances for each value are ±5% of the voltage.

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

Connector J4 (printer J1). The tolerances for each value are ±5% of the voltage.



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

Connector J1. The tolerances for each value are ±5% of the voltage.

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

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

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

#### 6.4.4 Replacing the power supply board

- Step 1: Open the FibroScan<sup>®</sup> unit according to the procedure described in the section on 'Opening the FibroScan<sup>®</sup> 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<sup>®</sup> unit according to the procedure described in the section on 'Opening the FibroScan<sup>®</sup> 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<sup>®</sup> unit according to the procedure described in the section on 'Opening the FibroScan<sup>®</sup> 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.



Mounting screw N

#### 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<sup>®</sup> 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



ltem	Cable #	Description	
J1	54	MONO-ACQ power supply	
J2	62	Firewire connector (IEEE)	
J8		Probe socket	
■ MO	NO-ER Board		
ltem	Cable #	Description	
J1	63	Connected to JP4 on the board AMPLI-MOT (communication)	
CH1		Probe socket	
CH1	CH1 Probe socket		
AMI	PLI-MOT board		
ltem	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)	

#### MONO-ACQ Board

# 6.5.3 Replacing the elastography engine

- Step 1: Open the FibroScan<sup>®</sup> unit according to the procedure described in the section on 'Opening the FibroScan<sup>®</sup> 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<sup>®</sup> unit according to the procedure described in the section on 'Opening the FibroScan<sup>®</sup> 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.



# Warning: Do not install CLPC B2.1 on a 2Gb Compact Flash. That software version requires 8Gb memory size

The upgrade to CLPC B2.1 must be done by Echosens service. This special upgrade requires changing the compact flash memory.

That change requires to save the configuration before upgrading and to reinstall the configuration afterwards.

# 8 CONFIGURATION MODE

8.1 ACCESSING CONFIGURATION MODE			
	1. Start the FibroScan®.		
FibroScan <sup>®</sup> 402	2. On the home page, press		
eformation sur www.echosens.com			
Utilisateur Docteurs Mot de passe Docteurs Ingénieur Biomédical	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.		
z e Distributeur u i o p Fabricant j k l m	Level1 Login: Doctors Password: MD		
Administrateur w x c v b n X water water	<ul> <li>Level 2 Login: Biomedical engineer Password: maintenance</li> </ul>		
	Level 3 Login: Distributor Password: ********		

E200M006.5

#### 8.2 ACCESSING CONFIGURATION MODE LEVEL 1

The level 1 gives to the user access to 4 tabs: general, logfile, hospital and system. This tabs are describe below.

#### 8.2.1 General tab.



#### 8.2.2 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 Fibroscan® software.

Der 6411 12423 8 652 0007511 12241 0781 0007511 12251 65 653 0007511 1251 64 45 0007511 1251 44 45 0007511 1251 44 45 0007511 1247 59 4421 0007511 1247 59 4421 0007511 1246 19 1020 0007511 1246 19 1020 000751 10075 000751 10075 000755 0007	FO FO FO FO FO FO FO FO FO FO FO FO FO F	Application set or comparison one PLACTION FSGULPEGRE Connectionary Application set of comparison one PLACTION FSGULPEGRE Connectionary Application set or comparison one PLACTION FSGULPEGRE Connectionary Application set one Comparison one PLACTION FSGULPEGRE Connectionary Application set one Comparison one PLACTION FSGULPEGRE Connectionary Application set one Comparison one PLACTION FSGULPEGRE Connectionary PLACENT FSGULPEGRE Connectionary Connectivity II: Fisse PLACENT AcquisitorManager. dot Use one otherwise ISS PLACENT FSGULPEGRE Connectionary PLACENT FSGULPEGRE Connectionary Connectivity II: Fisse PLACENT AcquisitorManager. dot Use one otherwise ISS PLACENT AcquisitorManager. dot Use one otherwise ISS PLACENT AcquisitorManager. dot Use one otherwise ISS PLACENT AcquisitorManager. dot PLACENT AcquisitorMana	Export	To save the log file: - connect a USB media storage - press on " export" button - the file is save under name: "FibroscanSerialNumber_YYYYMMDD_HHM MSS.log"
--	---	---	--------	--

# 8.2.3 Hospital tab.

General Log File Mospital System Printer Network Connect Service	Item	Description
Hospital/Site information     Logo       Organization	A	This information will be displayed on the PDF export (if the connectivity is enable)
A B Change	В	Press on "change" and browse for a logo that you would like to appear on the PDF print
OK Quit		

# 8.2.4 System tab.

System information     EROR       Device serial number     EROR       Software releases     SW_FS402_1.0.0.3_1219       Probes serial number     US BOARD ERROR       US board serial US BOARD ERROR     US BOARD ERROR       US board firmware version     US BOARD ERROR	Free disk space Total disk Jacobie Use time Device Use time Devic	This tab will display all information about the system.

### 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.

General Log File Hospital System Printer Network Date / Time Current date and time : Wednesday, June 13 12 : 53 : 20	Connect Service	Date / Time Current date and time : To set the date butto Set the date a	ок ок and time, just press on on "change". nd time and click "ok"
Auto logon     Interna     Enabled O Disabled     Applicat     Engli     Restore Default     Medical account     Reset	tionalization ion language sh v ion date format d voor	English French	To change the language, press on the arrow and choose on the list
Decimal	separator	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
Auto logon ☉ Enabled ○ Disabled	The Autologon lets ye the system. The Auto	ou enable or disable logon is enable by o	an authentication to start default.
Restore Default Medical account (Reset)	Enabled :the system the Fibroscan application	will not ask for the p ation	assword before to launch
Auto logon     ⊙ Enabled     Oisabled  Restore Default Medical account	n will ask for the pas ation. When selecting ord in the "password estore the default se	sword before to launch g "disabled" you need to " field. tting.	

### 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 Fibroscan® software.

004551122230402 00551122231402 00551112231402 005511122515628 005511122515628 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 0055111247354 005511124753 00551124753 00551124753 00551124753 00551124555 00551124555 00551124555 00551124555 00551124555 0055112455555 0055112455555 00551124555 005	#F0 #F0 #F0 #F0 #F0 #F0 #F0 #F0 #F0 #F0	Appleiden seins configuration most FUNCTION F302 UBright CosmonOmer Appleiden seins configuration most FUNCTION F302 UBright CosmonOmer Appleiden auf configuration most FUNCTION Cospatiston F4 Advantation Memory automatication automatication automatication F300 Biol	Export	ר - - אין אין	To save the log file: - connect a USB media storage - press on " export" button - the file is save under name: 'FibroscanSerialNumber_YYYYMMDD_HH MMSS.log"
--	--	--	--------	---------------------------	--

# 8.3.3 Hospital tab.

General Log File Hospital System Printer Network Connect Service	Item	Description
Hospital/Site information     Logo       Organization	A	This information will be displayed on the PDF export (if the connectivity is enable)
A	В	Press on "change" and browse for a logo that you would like to appear on the PDF print
OK Quit		

### 8.3.4 System tab.



#### 8.3.5 printer tab.



# 8.3.6 Network tab.

General Log File (Hospital System) Printer Retwork Connect Service)         Network Configuration         Image: System Printer Retwork Connect Service)         Image: System Printer Retwork Connect Service)	O Automatic ⊙ Manual IP Address Mask Gateway · · · ·
OK Quit	The IP address can be configured statically or dynamically via DHCP. To configure the address statically, complete the" IP Adress", "Mask" and "Gateway" fields.

### 8.3.7 Connect tab.

General Log File Hospital System Printer Network Connect Service Connectivity - HL7 Input © Enabled © Disabled Connectivity - Output © Enabled © Disabled OK Quit	If the connectivity option is not activated the "HL7 Input" and "Output" are not accessible.

#### 8.3.8 Service tab.



### 8.4 ACCESSING CONFIGURATION MODE LEVEL 3

The level 3 gives to the user access to 9 tabs: general, logfile, hospital and system. This tabs are describe below.

### 8.4.1 General tab.

General Log File (lospita) System (Printer Retwork Date / Time Current date and time : Wednesday, June 12 : 53 : 2	15, 2011 Change	Date / Time Current date and time : To set the date butt Set the date a	ок e and time, just press on on "change". and time and click "ok"
Auto logon © Enabled O Disabled Restore Default Medical account Reset	ationalization ation language lish ation date format	English French	To change the language, press on the arrow and choose on the list
Decim		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
Auto logon ☉ Enabled ☉ Disabled	The Autologon lets yo the system. The Auto	ou enable or disable logon is enable by	an authentication to start default.
Restore Default Medical account (Reset	<b>Enabled</b> :the system the Fibroscan application	will not ask for the p tion	bassword before to launch
Auto logon     O Enabled     Constant     Restore Default     Medical account     (Reset)	<b>Disabled</b> : the system the Fibroscan applicat enter the new passwo	will not ask for the tion. When selecting ord in the "password	password before to launch g "disabled" you need to " field.
	Reset button: it will re	estore the default se	tting.

### 8.4.2 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 Fibroscan® software.

General         Log File           Denfort         12:22:19.28: 006701 (12:22:19.28: 006701 (12:22:19.28: 006701 (12:24:19.28: 006701 (12:47:39.28: 006701 (12:47:39.28: 006701 (12:47:39.28: 006701 (12:47:39.28: 006701 (12:47:39.28: 006701 (12:46:19.28: 006701 (12:46:19.28: 0067	Hospi NFO NFO NFO NFO NFO NFO NFO NFO NFO NFO	Internet         Perinter         Network         Connect         Service         Admin           Apploiden artise configuration mode Apploiden artise configuration and and and and apploiden artise Apploiden artise configuration and and and and and and apploident artise configuration and Apploiden artis apploiden artise configuration and apploiden artise Apploiden a	Export Clear Quit	To save the log file: - connect a USB media storage - press on " export" button - the file is save under name: "FibroscanSerialNumber_YYYYMMDD_HHM MSS.log" To clear the log file press on the buttor "clear"
---	---	--	-------------------------	--

# 8.4.3 Hospital tab.

General Log File Hospital System Printer Network Connect Service Admin		Item	Description
Hospital/Site information Organization Service Address City Country Co		A	This information will be displayed on the PDF export (if the connectivity is enable)
		В	Press on "change" and browse for a logo that you would like to appear on the PDF print
OK Qui	t		

# 8.4.4 System tab.

General (Log Fili Hospital System Printer) (Network Connect Service Admin The system information         Device cerial number         Berker Status         Software release Swy_FS402_1.0.0.3_1219         Total disk system         Probes serial US BOARD ERROR         US board cerial         US board cerial         US board cerial         US board cerial	This tab will display all information about the system.
US board firmware version OK Quit	

### 8.4.5 printer tab.



# 8.4.6 Network tab.

General Leg File Hospital System Printer Network Connect Service         Network Configuration         Image: A state of the service         Imag	O Automatic ⊙ Manual IP Address · · · · Mask · · · · · Gateway · · · ·
OK Quit	The IP address can be configured statically or dynamically via DHCP. To configure the address statically, complete the" IP Adress", "Mask" and "Gateway" fields.

### 8.4.7 Connect tab.



# 8.4.8 Service tab.

General Log File (Hospital System Printer Network Connect Service Admin	Item	Description
Troubleshooting utilities       DB to XLB     Export patient database to XLB     Cmd     Display the DOS command       Launch (Program)     Export patient proprietary Program from UBB       Photos: (Photos: (Check)     Display the Commeted probes       Check     Launch the check disk tool	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: "FibroscanSerielNunumber_y yyymmdd_hhmmss.xls.
OK Quit	В	This to launch program validated by Echosens from USB memory stick
	С	Display the probe memory content.
	D	To start a check disk.
	Е	To start a DOS command

### 8.4.9 Admin tab.

### 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  $\checkmark$  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	
Description	Reference
FS 402 Display set	M200132
FS 402 Touchpad inverter board	M200136
FS 402 Printer and cables	M200137
FS 402 Power supply board	M200138
FS 402 Mother board module	M200147
FS 402 Elastometry module V2	M200149
FS 402 FireWire cable	M200150
FS 402 cable mother board to printer	M200151
FS 402 cable Alim mother board to printer	M200152
FS 402 Ampli_Mot board cable	M200153
FS 402 Back Light board	M200154
FS Compact flash 2Go (until CLPC B2.0)	M200155
FS 402 Cable powersupply	M200156
FS 402 Main filter	M200157
FS 402 Mono_Acq power cable	M200158
FS 402 Mother Board power cable	M200159
FS 402 Mother Board set	M200160
FS 402 On/off button	M200161
FS 402 Power supply	M200162
FS 402 Probe socket	M200163
FS 402 Screen cable	M200164
FS 402 inverter board cable	M200165
FS 402 Printer plate	M200167
FS 402 Front cover	M200168
FS 402 Back cover	M200169
FS 402 Front lexan	M200170
FS 402 Back Light cable	M200196
FS 402 Power Cable button	M200224
FS 402 Fan	M200228
FS 402 Probe support	M200229
FS Compact flash 8 Go (from CLPCB2.1)	M200245
FS 402 Fan cable	M200247
FS 402 Over Packaging kit	M200248

	9.2	TROUBLESHOOTING	
Hardware error		Communication	- check that the Firewire cable is correctly connected
		problem between	- check the REGANA board voltage values
		computer zone and	- check with another mother board
		Elastography	- chack with another Elastography engine
		engine zone	
	Software	Software	- Ensure that the software installed is the correct one
		compationity	
The instrument		Mains power	- check the wall outlet voltage value
does not switch		Mains filter	- check the filter fuses
on			<ul> <li>check the filter outlet voltage values</li> </ul>
		Motherboard	- check the power supplies
			- check the power supplies cable
		Button on/off in front	- check the connector on the mother board
		Domoto control	- check the connector on the remote control board
		heard	- check the connection on the remote control board
		board	
The instrument		Screen	- connect a screen to the front panel VGA connector
turns on, but			- if it comes on, check the screen connector on the motherboard
nothing on-screen			- check the inverter board
			- if still nothing, replace the screen
			- if the problem persists, replace the motherboard
Fixed image		Software	- Reinstall the software
r ixou imago		Hard disk	- Hard disk replacement
		Motherboard	- motherboard replacement
		Touchpad	- check with mouse if the software is working
No printout		Power supply	- check that the power supply cable is connected
			- check that the printer is switched on
		<u>Paper</u>	- check the paper tray
		Printer	- replace the printer
Probe not		Probe	- check that the probe is connected
connected error			- check with another probe if one is available
message			- ensure that the probe's connector pins are not damaged
			- check the log file for eeprom problems
		Elastography	- check that the probe connector on the Fibroscan is not damaged
		engine	- check the voltage values
USB Export not		Memory stick	- check with another memory stick
possible: Excel or		USB connector	<ul> <li>check if USB connector is not broken</li> </ul>
Fib file		Software	- Reinstall the software
		Motherboard	- check the connection on mother board
			- check with another USB cable
			- motherboard replacement
Not Ultrasound on		probe	- check with another probe if one is available
the TM mode or A		1	- ensure that the probe's connector pins are not damaged
mode			- check that the probe connector on the Fibroscan is not damaged
			- check on the second probe connectors
		Elastography	- check on the second probe connectors
		engine	- check the voltage values
			- if the problem persists, replace the elastography engine
Virtual memory		Software	- check if the Patch X1 is installed (cf. ETB007) $\rightarrow$ only for CI PC
problem		20111010	B2.0
•			

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White screen	Motherboard	- Check connection on the mother board		
when turning on		- check the video output		
		- exchange the mother board		
	The screen	- check the screen connector		
		- exchange the screen		
The Fibroscan	Motherboard	<ul> <li>check the start button connector on motherboard</li> </ul>		
doesn't switch off	Remote control	<ul> <li>check the start button connector on remote control board</li> </ul>		
when the start	board	- replace the remote control board		
button is pressed				

# 9.3 CHECK LIST

Product Informations						
S/N			Probe S/N		Man. /Dist.	
Custon	ner locatio	ו ו		Customer name		
Service	location	□ Echose	ens D Other:		□ On site .	
Service	date			Service reference		

SOFTWARE				
Check Log files				
Update software				
Check import/export data				
Check of Excel backup				

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		□ OK □NOT OK		
Pin 4 : +12 Vdc				
Check of the connectors		I NOT OK		

Power Supply Area				
Power supply type				
Main filter	Fuse	D OK I	I NOT OK	

Power Supply Area						
Board name	Connector description	Value obtained	result d			
Power supply board						
Connector J5	Pin 6 : + 25 Vdc		□ OK □NOT OK			
	Pin 8 : - 25 Vdc					
Connector J3	Pin 3 : + 12 Vdc		□ OK □NOT OK			
	Pin 4 : + 12 Vdc					
Connector J4	Pin 3 : + 7 Vdc					
	Pin 4 : + 7 Vdc					
Connector J1	Pin 1 : + 25 Vdc					
	Pin 2 : + 25 Vdc					
Connector J6	Pin 1 : + 5 Vdc					
	Pin 5 : + 16 Vdc					
	Pin 6 : + 5 Vdc					
	Pin 10 : -16 Vdc					
Main filter			K			

# *<b>Cechosens*

Product Informations			
S/N	Probe S/N	Man. /Dist.	

Service date

Service reference

Elastography engine V2 Area						
Board name Connector description Value result						
		obtained				
MONO ACQ board voltage	Pin 1 : + 5 Vdc		□ OK	DNOT OK		
	Pin 5 : + 16 Vdc		□ OK	DNOT OK		
	Pin 6 : + 5 Vdc					
	Pin 10 : -16 Vdc		D OK	□NOT OK		
	Green LED (on=ok)		D OK	□NOT OK		
	Red LED (off=ok)		□ OK	INOT OK		
AMPLI MOT board	Pin 6 : + 25 Vdc		□ OK	INOT OK		
	Pin 8 : - 25 Vdc		□ OK	INOT OK		
Mono E/R board	LED of U/S (green)		D OK	<b>DNOT OK</b>		
Check of the connectors		OK DNOT OK				

Screen Area			
Test on/off button (led on)			
Check the Touchpad			
Test VGA output			
Test USB port	front		
	rear		
Test network output			
Test of printer			

PROBE AREA				
Blue LEDS of the probe				
Check the probe on EMPARAMS	Date of next calibration :			NOT OK
Acquisition Test	connector 1		I NOT OK	
	connector 2		I NOT OK	
Check the information contact on calibration message				

	FRAME
State of device(cf. appendix)	
Labeling	

# FRAME CONTROLE





# **10TECHNICAL CHARACTERISTICS**

	<b>C E</b> 0459
Manufacturer	Echosens, SA 30 Place d'Italie 75013 Paris – France
Model	FibroScan <sup>®</sup> 402
Computer properties <ul> <li>Operating system</li> </ul>	Windows XP Embedded.
<ul> <li>Metrological performance</li> <li>Note: The measured variable is stiffness,</li> <li>Ultrasound transducer</li> <li>Metrological performance</li> </ul>	referred to as "S". Refer to the specific instructions below. S min.: 1.5 kPa. S max.: 75 kPa. Accuracy: ± 0.5 kPa.
<ul> <li>Classification</li> <li>Electrical classification</li> </ul>	Class IIa according to directive 93/42/EC Class I, type B <b>A</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 <ul> <li>Power supply</li> <li>Usable power</li> <li>Fuse</li> </ul>	100 - 240 V (+10%/-15%) ~ 50–60 Hz 150 VA 2 x 1.6 AT
Mechanical Characteristics Dimensions Weight	275 x 434 x 252 mm (H x W x D) 8 kg
<ul> <li>Environmental characteristics</li> <li>Operating temperature</li> <li>Operating humidity</li> <li>Storage temperature</li> <li>Storage humidity</li> </ul>	+10 to +40°C (+50 to +104 F) 30 to 75% relative humidity, non-condensed. -20 to +70°C (-4 to +158 F) 10 to 85% relative humidity, non-condensed.
<ul><li>Hardware supplied</li><li>Cables provided</li></ul>	1 x CEE22 mains lead (length 2 m) 1 x Probe cable (length 1.5 m)

# 10.1 CHARACTERISTICS OF THE DEVICE

E200M006.5

# 10.2 PROBE CHARACTERISTICS

Manufacturer	Echosens SA
	30 Place d'Italie
	75013 Paris – France
Model	Туре М
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	DV4. The Manual a successful in a successful in
Electrical classification	IPX1: The M probe, excluding connectors, is
Operating mode	protected from vertically failing drops of water.
	Charge time Teherge 10 min
	$\frac{\text{Charge time} = \text{Tcharge} = 10 \text{ min.}}{\text{Post time} = \text{Treat} = 15 \text{ min}}$
	Rest unite = Trest = TSTrurt.
Electrical characteristics	
FMI	See the FibroScan® user manual
Mechanical Characteristics	
Dimensions	158 x 52 mm (L x diameter)
Weight	500 grams
<u> </u>	~
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.
53 (20.80)	149 (58.54) 9,7 (3.82)
	12 22
0	
	<u>ت</u>

mm (inches)

Figure 1: dimension.

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# **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<sup>®</sup> 402 is designed for use in the electromagnetic environment defined below. FibroScan<sup>®</sup> 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 <sup>®</sup> 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	
Harmonic emissions EN 61000-3-2	Class A	The FibroScan® 402 may be used on all premises other than domestic premises and those directly
Voltage fluctuations/Oscillating		connected to the public low voltage energy grid used
emissions	Applicable	to supply domestic buildings.
EN 61000-3-3		

# **11.2** ELECTROMAGNETIC IMMUNITY (1)

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

las as constant a st		O a man li a m a a	Electronic en etie Environment		
Immunity test	IEC 60601 test level	Compliance	Electromagnetic Environment -		
			Recommendations		
Electrostatic Discharge	±6 kV contact	±6 kV on contact	Floors should be wooden, concrete		
IEC 61000-4-2			or ceramic. If the floor is covered		
	±8 kV air	±8 kV through air	with a synthetic material, the relative		
			humidity must be at least 30%.		
Spike/Burst	±2 kV supply	±2 kV supply	The quality of the electrical network		
IEC 61000-4-4			must be that of a typical commercial		
	±1 kV input/output	±1 kV input/output	or hospital environment.		
Voltage shocks	Differential mode	Differential mode	The quality of the main supply must		
EN 61000-4-5	±1 kV	±1 kV	be that of a typical commercial or		
			hospital environment.		
	Common mode	Common mode			
	±2 kV	±2 kV			
Voltage drops, short	<5% UT		The quality of the electrical network		
interruptions and supply	For 10ms	<5% UT	must be that of a typical commercial		
inlet voltage variation		For 10ms	or hospital environment. If the		
IFC 61000-4-11	40% UT		FibroScan <sup>®</sup> 402 user requires		
	For 100ms	40% UT	continuous operation during mains		
		For 100ms	power cuts the FibroScan <sup>®</sup> 402		
	70% LIT		should be connected to an		
	For 500ms	70% LIT	uninterruntible power supply or		
	1 01 000113	For 500ms	hattery		
	<5% Hz	1 01 000113	ballery.		
	For 5s	<5% Hz			
	10103	5070 07 For 5s			
		10100			
Magnetic field immunity	3A/m	3A/m	Supply frequency magnetic fields		
at supply frequency (50-	57 VIII	87 VIII	must be those of a typical		
60 Hz)			commercial or hospital environment		
IEC 61000-4-8			commercial of hospital environment.		
NOTE: Using the major supply voltage measured before conducting the test					
NOTE. 07 is the mains supply voltage measured before conducting the test					

#### 11.3 ELECTROMAGNETIC IMMUNITY (1

The FibroScan<sup>®</sup> 402 is designed for use in the electromagnetic environment defined below. FibroScan<sup>®</sup> 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
			Portable and mobile RF communication devices must be kept away from the FibroScan <sup>®</sup> 402 (including its cables), at a greater distance that the recommended value calculated from the equation applicable to the emitter frequency.
			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 <i>d</i> 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<sup>®</sup> 402 is used exceeds the above-mentioned compliance levels, correct operation of the FibroScan<sup>®</sup> 402 must be checked. If abnormal performance is observed, additional measurements may be required after, for example reorienting or moving the FibroScan<sup>®</sup> 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	Se	paration distance a	according to trans	mitter frequency (I	m)
transmitter	150kHz to	196kHz to	8.5MHz to	80MHz to	800MHz to
emission power	196 kHz	8.5MHz	80MHz	800MHz	2.5GHz
(W)	$d=1.17\sqrt{P}$	$d=35\sqrt{P}$	$d=1.17\sqrt{P}$	$d=1.17\sqrt{P}$	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.



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