TECHNICAL MANUAL

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1 INTRODUCTION

1.1 INTRODUCTION

This document is intended for ECHOSENS product distributors. It provides recommendations for those processes that distributors may implement when repairing these products.

All operations must be performed by technicians with appropriate training, dispensed by an ECHOSENS-qualified instructor.

ECHOSENS cannot be held responsible for any erroneous or incomplete instructions for use that may be communicated by the distributor to end users, nor of any incidents caused by anyone implementing the processes recommended in this document.

Use only those spare parts provided by ECHOSENS.

Technical support

ECHOSENS
5 rue Jean Lemoine
94000 CRETEIL
Tél: +33 1 49 81 89 29
Email: service@echosens.com

2 MISCELLANEOUS INFORMATION

2.1 PROPERTY AND COPYRIGHT

3 RECOMMENDATIONS AND SAFETY

3.1 SYMBOLS

This symbol means:
Warning: see the instructions before using the **FibroScan.**
Instructions preceded by this symbol may cause injuries or damage the **FibroScan** 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

The FibroScan is manufactured and tested in accordance with IECelectromagnetic compatibility (EMCand 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 usage 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 doesn't work;
- After prolonged storage under unfavourable conditions;
- After serious damage incurred during transport.
- In the presence of flammable or anaesthetic gasses. 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 avoid its

inadvertent use. The medical device is entrusted to authorised technicians for inspection.

4 DISASSEMBLY

4.1 ELECTROSTATIC DISCHARGE

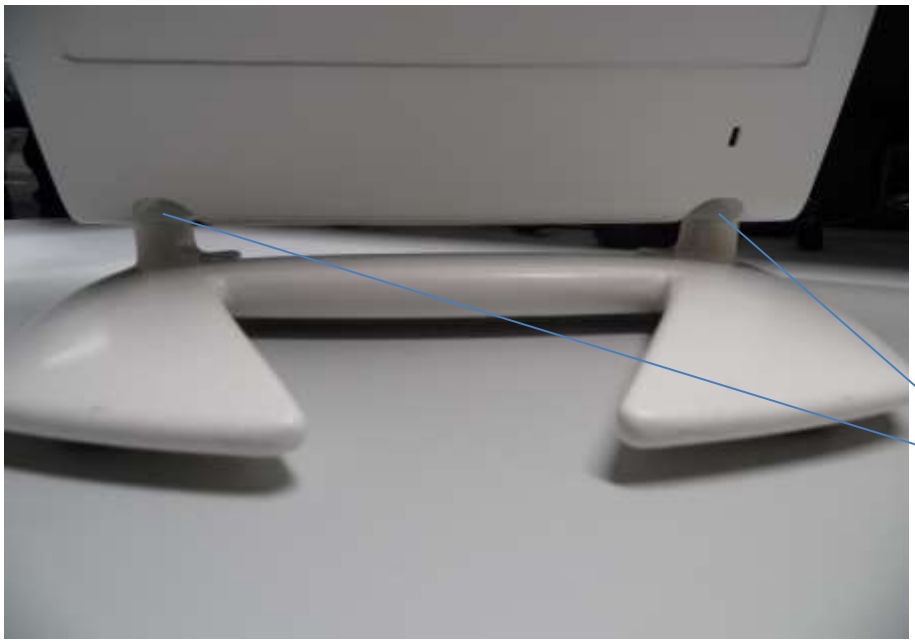
Many of the materials in our common environment generate by friction of the electric loads which, if they are not diverted in the earth, accumulate in the time. They so build up to themselves potential with regard to the earth which can reach several thousand volts, those are the discharges electrostatics (ESD: ElectroStatic Discharge). These potential are not in themselves dangerous for compounds or electronic components. It is the abrupt variations of potential that present a risk. It is thus advisable to protect itself against the effects of this phenomenon during manipulation of the component or tired compound which are used.
It is thus necessary during every visit of maintenance or repair to use an ESD portable maintenance kit (see picture below) bracelet or quite other means to be connected in the earth. In addition any spare part should be carried in an ESD bag.
Example:

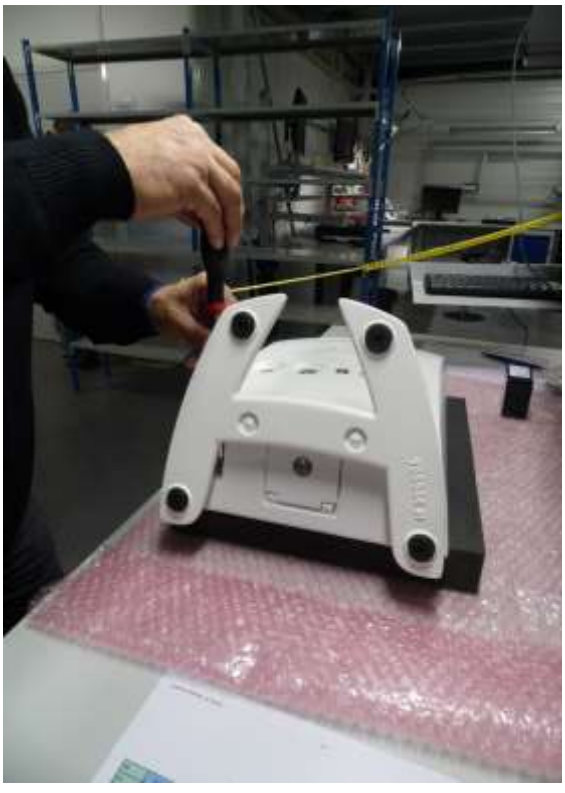
4.2 OPENING THE DEVICE

You will need M5 Allen key

Before any manipulation on the device remove the battery (see chapter 8.3 of "Guide530_C2 0EUROPE" for details).

In order to access the inside of the device one should unscrew the 2 bottom outer screw (the warranty seal has to be broken first).

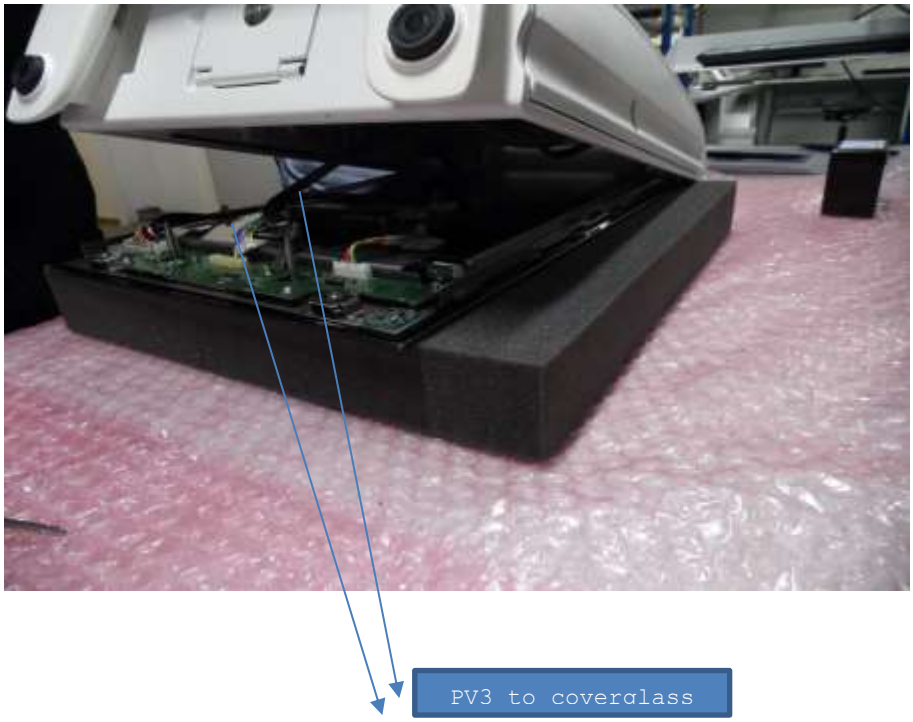




The LCD screen should always lie on a mellow surface (foam, manila paper)

4.3 ACCESSING COVERGLASS

Gently lift up the back cover to remove M300021 (cable from PV3 to cover glass) and ground. Remember to press the white nipple on the plastic connector locker to lift it up.



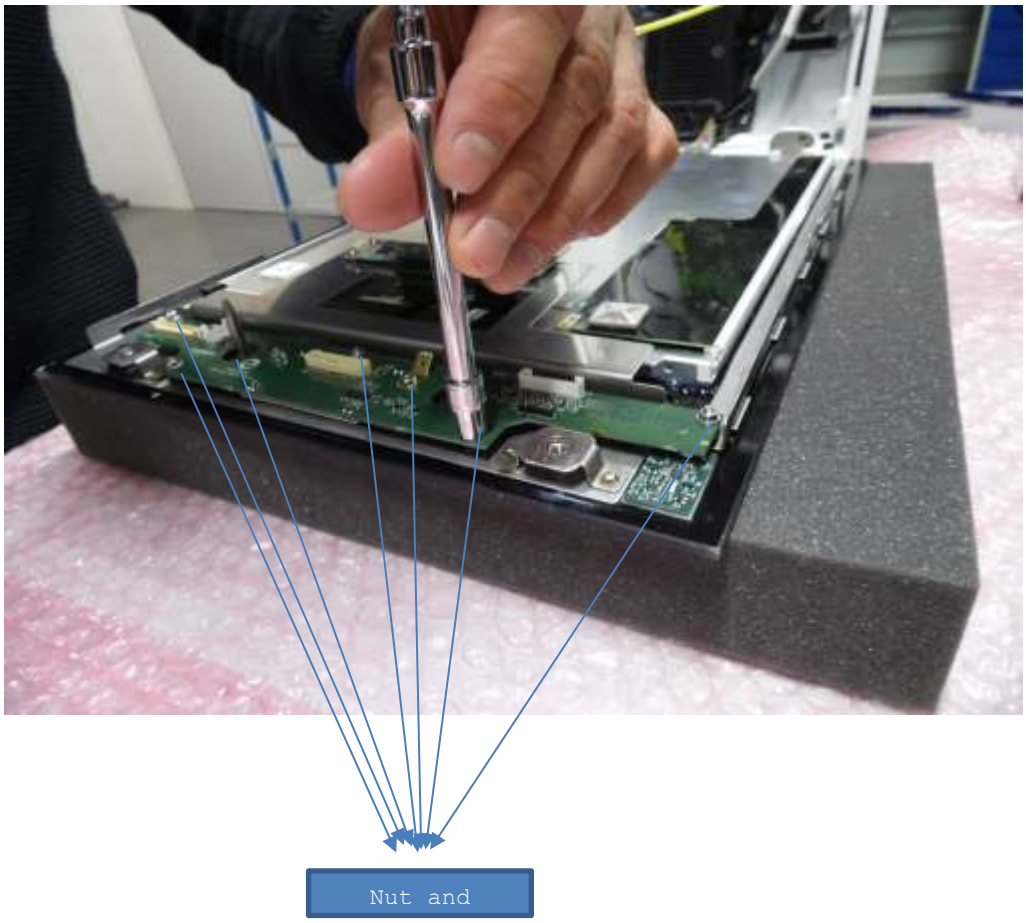
In order to exchange the following cables just cut the strip and disconnect both sides of the cable

- M300005 LVDS to cover glass
- M300019 backlight to cover glass
- M300020 USB touchscreen to cover glass

Use tweezers in order not to damage the connector.

In order to remove HDMI printed Circuit Board, remove the 7 nuts and washers.

You will need M3 nut driver for HM3.

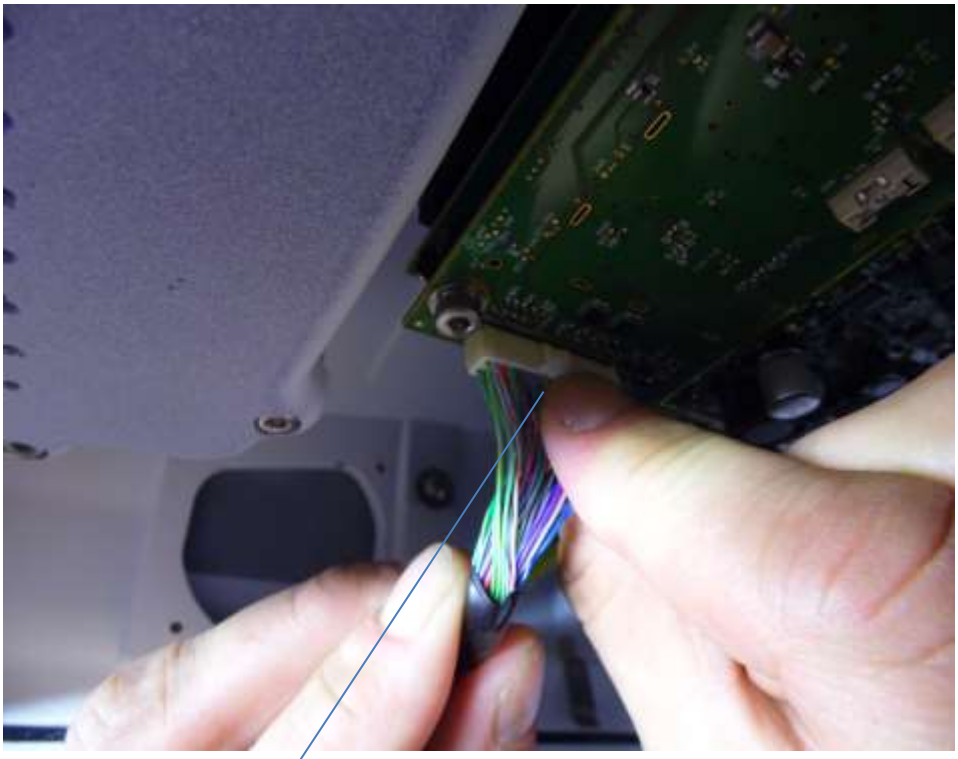


In order to disassemble the ON button PCB, gently lift it up with the help of a flat screwdriver to remove the double sided tape

4.4 Accessing PV3

In order to exchange the following cables disconnect both connectors (be careful with the nipple designed to unlock the connector)

- M300021 coverglass to PV3 and grounding
- M300019 data connectics
- M300018 power connectics
- M300010 battery connectics



White nipple to

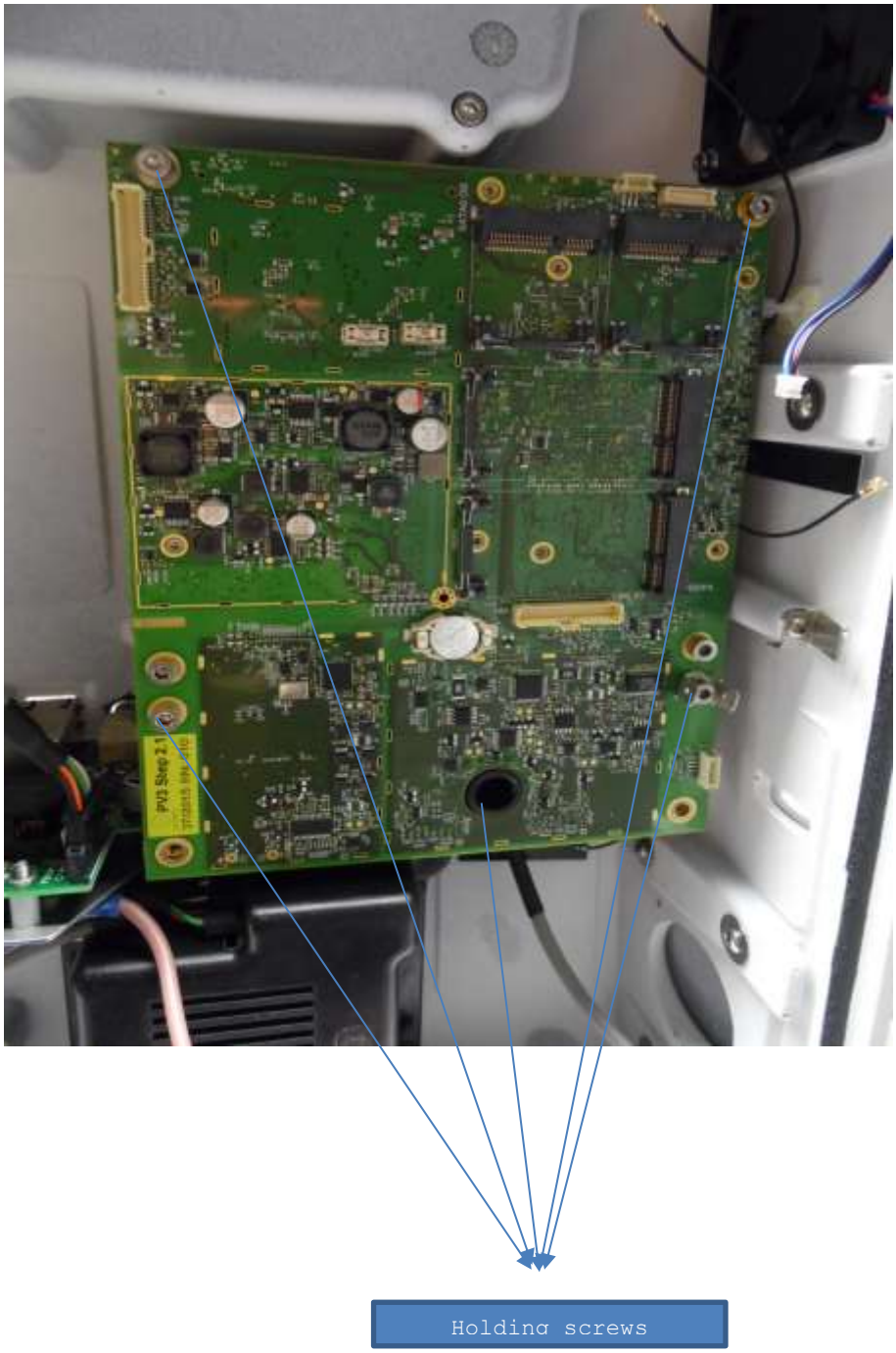
In order to remove the WIFI/Bluetooth PCB with the help of a clamp disconnect both antennas and bend the spring to lift up and slide out the PCB.

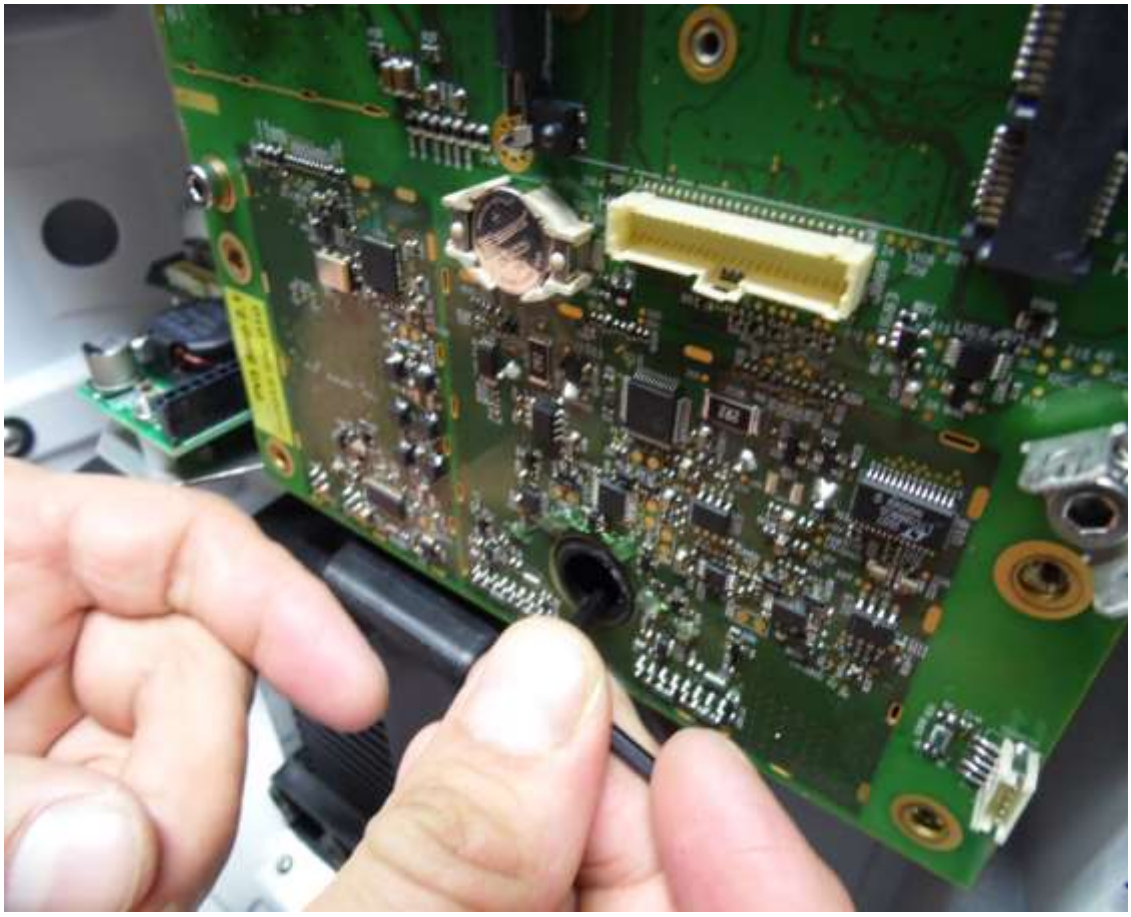
HDD 1&2 are swapped in the same manner.

Wifi/bluetooth

In order to remove PV3 module, unscrew the 5 screws holding it to the chassis (including the screw deep in the black plastic hole)

You will need M4 Allen key for M4*8mm screws.

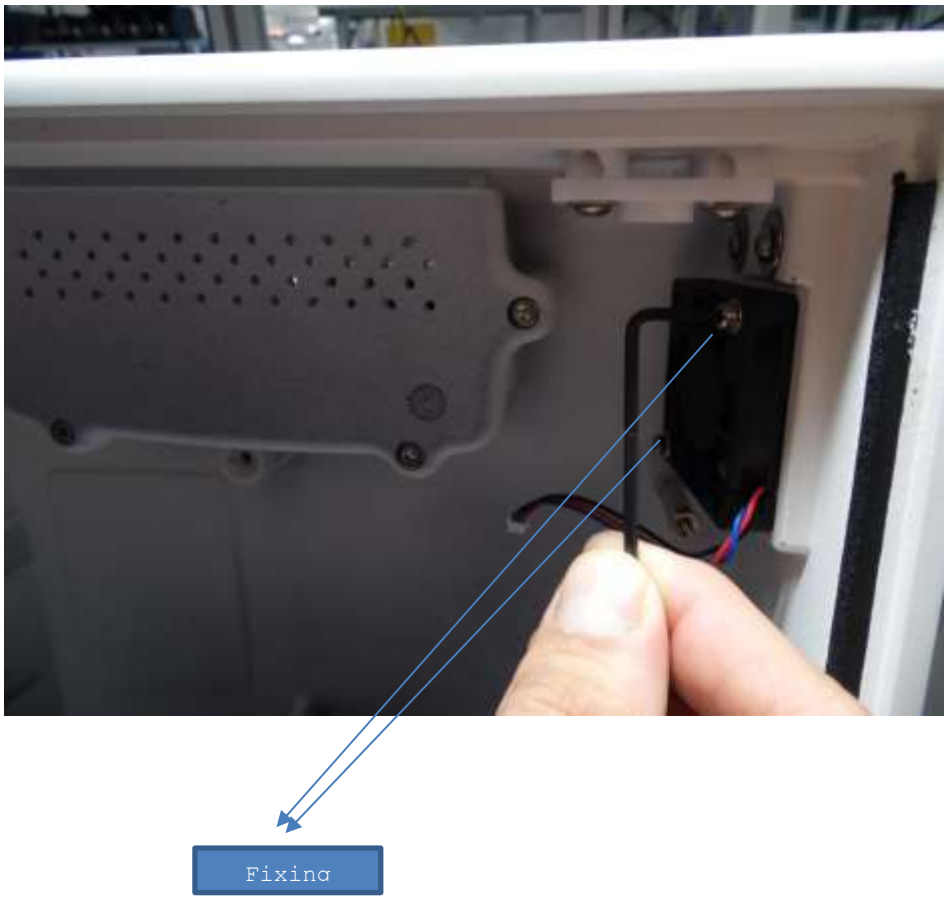




4.5 ACCESSING FAN AND ANTENNAS

In order to remove the fan, untighten the 2 holding screws (please note upon reassembly that the white sticker is on the chassis side)

You will need M3 Allen key for CHC M3*16mm.

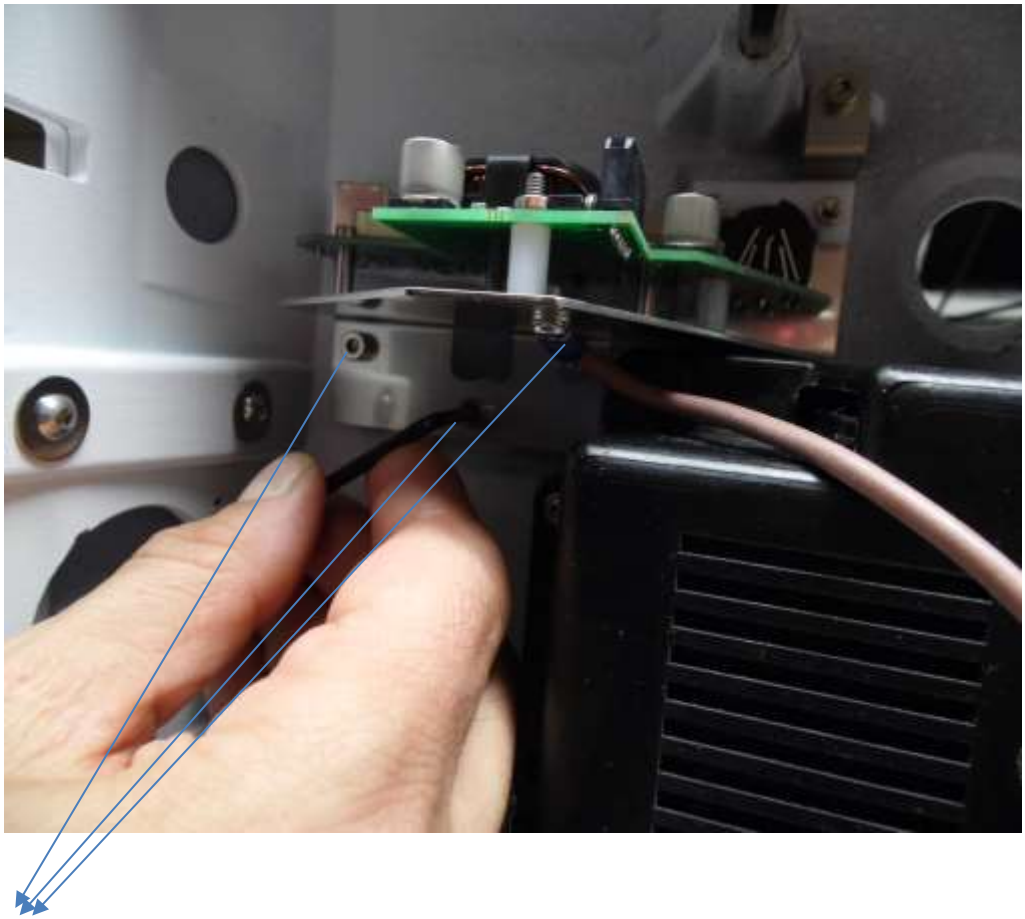


In order to remove the 2 antennas, gently lift up the double sided tape (use a flat screwdriver)

4.6 ACCESSING DATA CONNECTICS AND POWER CONNECTICS BOARDS

In order to remove the 2 upper mentioned boards, detach from chassis the metal bracket (3 screws), you can after that separate each PCB from the bracket.

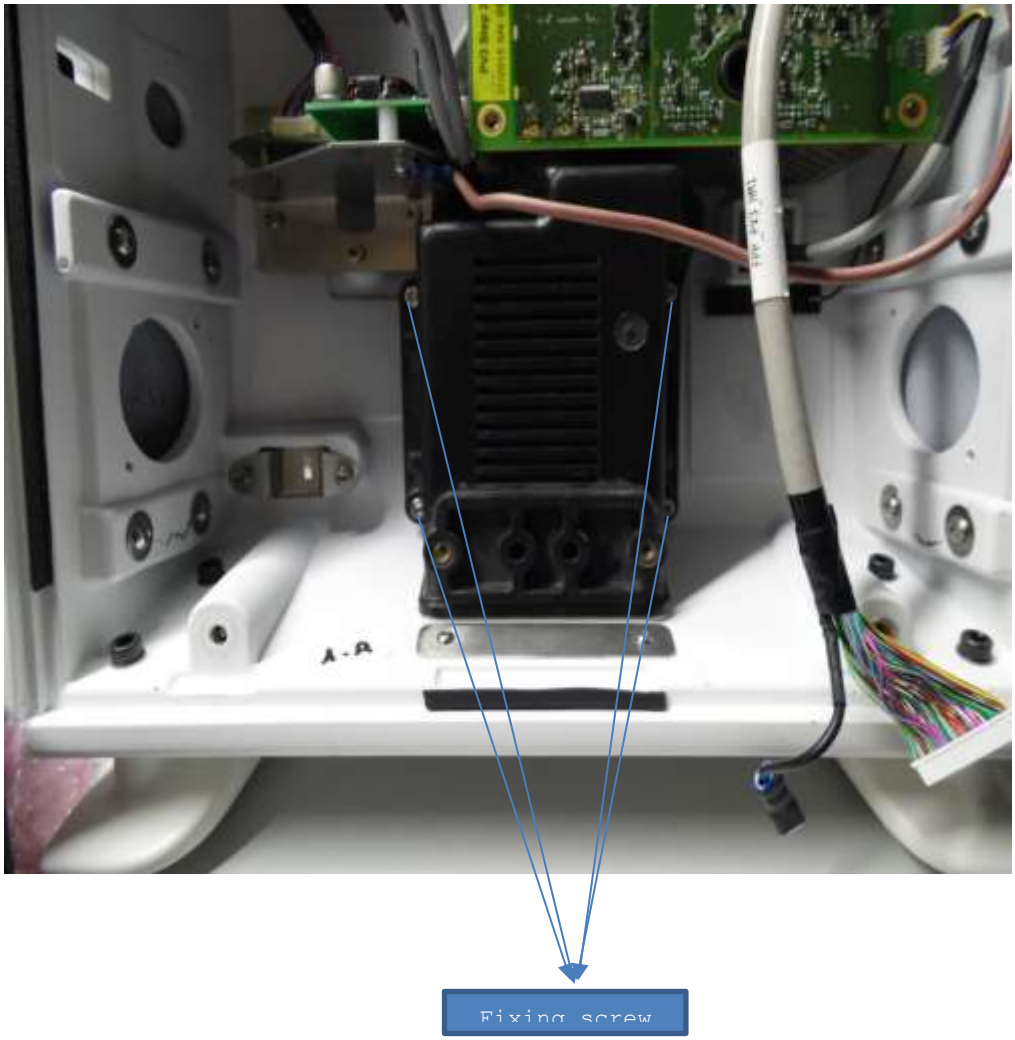
You will need M4 Allen key for CHC M4*8mm



Fixing

In order to remove the battery box untighten the 4 screws from the chassis, you can then remove the battery PCB from the black plastic housing (remove locking screw and washer)

You will need M3&M4 Allen key to remove BHC M3*6mm and M4*8mm



Locking screw and

5 FORMATTING AND RELOADING THE OPERATING SYSTEM IN M SATA

5.1 MAKE A USB STICK BOOTABLE

In order to launch software in the FS530 you will have to use a bootable memory stick, hereafter the procedure to create one:

Connect a USB memory stick with a capacity superior to 4G0 to a computer.

Open diskpart by clicking on the windows logo and typing in the searchbar "diskpart"

Run the following commands

```
DISKPART > list disk
```

Will list the available disks so that you find the ID of the memory stick, pay attention not to select the computer C : drive

```
DISKPART > select disk <id>
```

Replace <id> by the ID found on the previous step

```
DISKPART > clean
```

Delete all partitions on the USB key

```
DISKPART > create partition primary
```

Create primary partition

```
DISKPART> format fs=ntfs quick
```

Format as NTFS the partition

```
DISKPART > active
```

Makes the partition bootable.

5.2 DELETE MSATA & INSTALL OPERATING SYSTEM

In case the upgrade of software is not feasible or you feel the MSATA needs to be cleaned up one can erase the MSATA content

To do so, download the needed software from ECHOSENS, copy it on the bootable memory stick, boot on the USB key then on the DOS command window type (you will need a USB keyboard).

- cleanAllSata.bat
- wpeutil shutdown

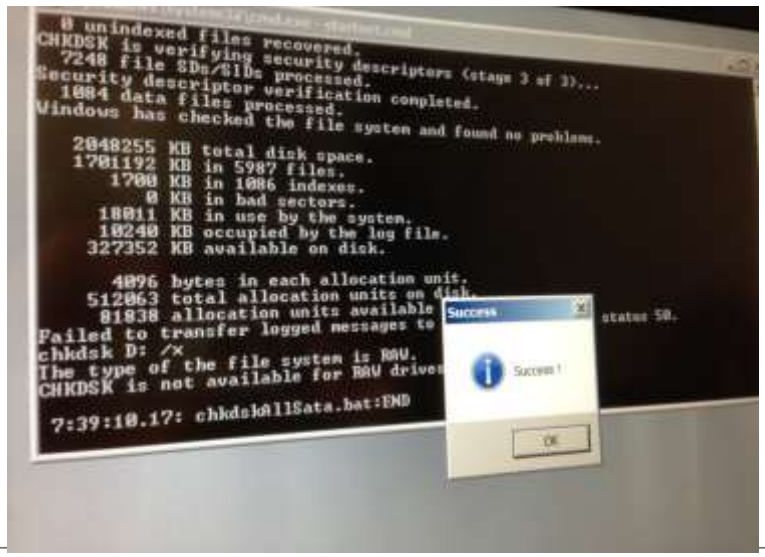
Once this is done you can reinstall software, in order to do so just copy the Operating System software you will get from ECHOSENS, copy it on USB memory stick and boot the FS530 with the USB key inserted, just wait for the end of the process.

5.3 USING MAGIC FIX

Magic fix is a software that can be provided on demand by ECHOSENS service which can fix and check faulty Msatas (CHKDSK)

In order to run it, one should copy the software on a bootable USB stick (7.1) then boot on the machine.

Let the script run without interaction and make sure the result is "success"



6 CONFIGURATION MENU

In order to access the configuration menus :

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 four, of which one is accessible by distributors and one by the customer (Admin will not be mentioned in this documentation).

- ***Level 1***
  Login: Operator
  Password: no password requested
- ***Level 2***
  Login: FibrosScan Admin (ECHOSENS only)
- ***Level 3***
  Login: Service
  Password: *********
- ***Level 4***
  Login: Manufacturer (ECHOSENS only)
  Password: *********

In the following chapter we will review all configuration menus from a "Manufacturer" perspective as this profile has full access to all of them, find underneath the authorisation for the other profiles:

	Operator	Service	Manufacturer
Localisation			
Language	FULL ACCESS	FULL ACCESS	FULL ACCESS
Date and time	FULL ACCESS	FULL ACCESS	FULL ACCESS
Institution			
logo	FULL ACCESS	FULL ACCESS	FULL ACCESS
institution detail	FULL ACCESS	FULL ACCESS	FULL ACCESS
Printer			
auto print count	FULL ACCESS	FULL ACCESS	FULL ACCESS

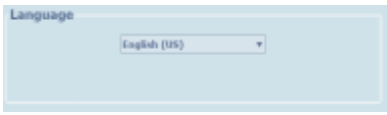
refresh/add/delete/set as default	NO ACCESS	FULL ACCESS	FULL ACCESS
Data			
Archive	FULL ACCESS	FULL ACCESS	FULL ACCESS
Export			
Transfer of exams	NO ACCESS	FULL ACCESS	FULL ACCESS
File anonymisation	NO ACCESS	FULL ACCESS	FULL ACCESS
Import	FULL ACCESS	FULL ACCESS	FULL ACCESS
User			
login mode	READ ONLY	FULL ACCESS	FULL ACCESS
Operator auto logon	READ ONLY	FULL ACCESS	FULL ACCESS
Connectivity			
Network			
Auto/manuel	NO ACCESS	FULL ACCESS	FULL ACCESS
Directory			
shared directory	NO ACCESS	FULL ACCESS	FULL ACCESS
Dicom			
Enable Dicom	NO ACCESS	FULL ACCESS	FULL ACCESS
Add licence	NO ACCESS	FULL ACCESS	FULL ACCESS
Add PACS	NO ACCESS	FULL ACCESS	FULL ACCESS
	operator	service	manufacturer
Exam			
Calibration			
service contact	NO ACCESS	FULL ACCESS	FULL ACCESS
Day before expiration	NO ACCESS	FULL ACCESS	FULL ACCESS
options			
SWS	NO ACCESS	FULL ACCESS	FULL ACCESS
Measurement condition	NO ACCESS	FULL ACCESS	FULL ACCESS
CAP	FULL ACCESS	FULL ACCESS	FULL ACCESS
Pay per use	NO ACCESS	NO ACCESS	FULL ACCESS
Special mode			
Phantom mode	NO ACCESS	FULL ACCESS	FULL ACCESS
Clinical mode	NO ACCESS	FULL ACCESS	FULL ACCESS
test mode	NO ACCESS	NO ACCESS	FULL ACCESS
system			

information			
S/N	READ ONLY	READ ONLY	FULL ACCESS
logs			
export	NO ACCESS	FULL ACCESS	FULL ACCESS
clear	NO ACCESS	FULL ACCESS	FULL ACCESS
service			
launch program	NO ACCESS	FULL ACCESS	FULL ACCESS
test and maintenance	NO ACCESS	FULL ACCESS	FULL ACCESS
disk mgt	NO ACCESS	NO ACCESS	FULL ACCESS
control panel	NO ACCESS	NO ACCESS	FULL ACCESS
eject disk	FULL ACCESS	FULL ACCESS	FULL ACCESS
screen calib	NO ACCESS	FULL ACCESS	FULL ACCESS
cmd	NO ACCESS	NO ACCESS	FULL ACCESS
hardware mgt	NO ACCESS	NO ACCESS	FULL ACCESS
probes memory	NO ACCESS	FULL ACCESS	FULL ACCESS
check disk	NO ACCESS	FULL ACCESS	FULL ACCESS
explorer	NO ACCESS	NO ACCESS	FULL ACCESS
auto test	NO ACCESS	FULL ACCESS	FULL ACCESS
general			
day before application lock	FULL ACCESS	FULL ACCESS	FULL ACCESS

The following menues will be found in the configuration pages

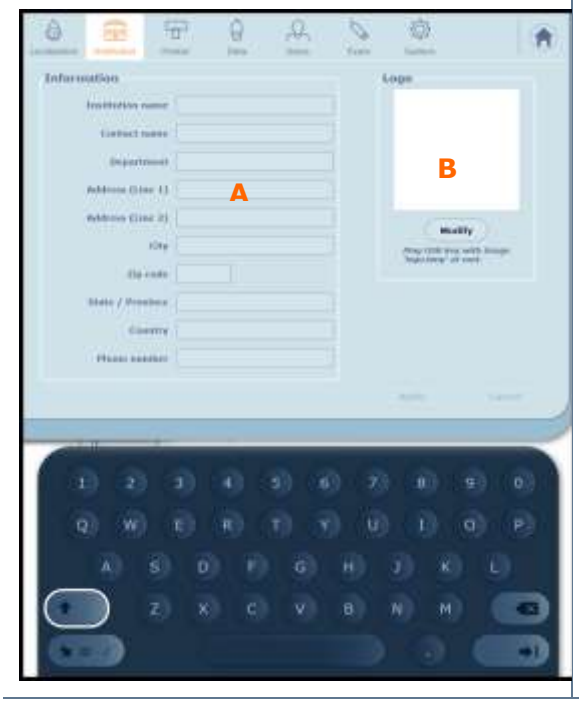
Localization tab.

To set the date and time, just press on button "Modify".
Set the date and time and click "Save"



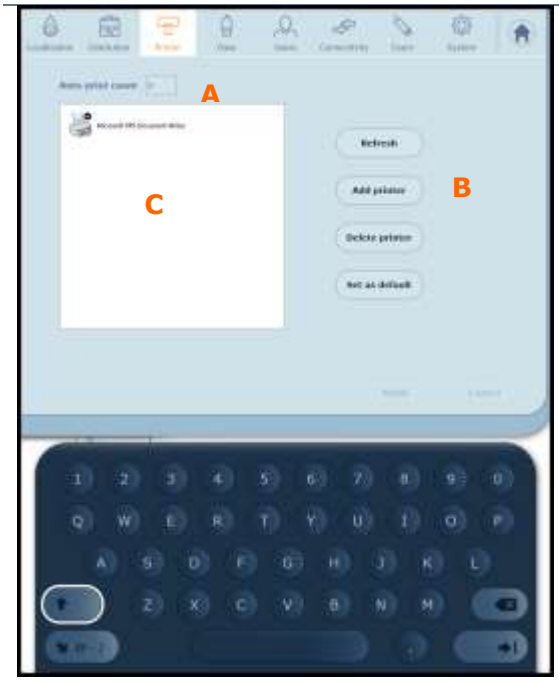
To change the language, press on the arrow and choose on the list

Institution tab



Item	Description
A	This information will be displayed on the print and report.
B	Plug USB key with an image 'logo.bmp' at root and press on "Modify".

Printer tab.



Item	Description
A	You can set the auto print and the number of copy you need.
B	To add printer
C	Display the printers installed.

Data tab – Archive/Export/Import

Archive/Import exams files:
It's possible to save on USB media storage and delete exams for a period by selecting the date "from" "to", it is also possible to import from a USB amovible media storage exams previously saved.

Automatic USB export:
It's possible to save automatically and manually the exams files on media storage after each patient.

Users tab

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

Enabled :the system will ask for the password before launching the Fibroscan application

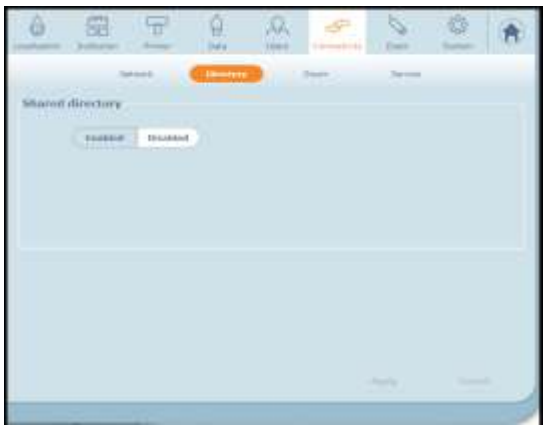
Disabled: the system will not ask for the password before launching the Fibroscan application. When selecting "disabled" you need to enter the new password in the "password" field.

Customized lets you add/import/export different Users Accounts.

Connectivity tab – Network

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

Connectivity tab – Directory



This tab will allow you to connect a Fibroscan to a windows domain network in order to see it as a shared folder and retrieve the fibx remotely:

Connectivity tab – Dicom

- The FibroScan can now join a DICOM network.
- Storage and worklist servers details must be set , a licence shall be purchased
- Patient data's retrieved directly from server from faster use
- Automatic upload of exams to the server

In case of network traffic interruption, non-transmitted exams to DICOM are visible on home screen

Exam tab – calibration

Calibration management:
Service centre details can pop up automatically a few days before probe calibration is required (default 15 days).

Exam tab – options

A: SWS Mode:
Shear Wave Special mode selection (only US) display shear wave speed (m/s)

B: CAP activation :
The CAP option can be activated but an activation key will be requested.

C: Measurement conditions:
Measurements conditions of the patient can be added at the end of the exam (weight, height, patient positioning …)

D: Pay per Use activation:
Pay per use activation (licence can be entered from the home screen)

System tab – information

This tab will display all information
about the system:

- Serial number of the Fibroscan.
- Software version
- Probe serial number
- ElastographyEngine serial number board
- ElastographyEngine firmware version
- Free HDD space
- HDD size
- Total time of using device

System tab – logs

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

To save the log file:

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

System tab – service

Item	Description
A	This to launch program validated by Echosens from USB memory stick.
B	To eject the CD.
C	Display the probe memory content.
D	To start a "tests and maintenance" programme see §!7.3.8.
E	To calibrate the touch screen.
F	To start a check disk
G	Create or modify partitions on HDD
H	Display the DOS command
I	Display the windows explorer
J	Display the windows control panel
K	Display the US board information
L	Launch the FibroScan resistance test

System tab – general

Allow you to deactivate the FibroScan after a laps of time

7 TECHNICAL CHARACTERISTICS

7.1 CHARACTERISTICS OF THE DEVICE

Manufacturer	Echosens 30 Place d'Italie 75013 Paris - France
Model	FIBROSCAN 530 COMPACT
Classification	Class IIa according to Rule 10 of Appendix IX of Directive 93/42/EC.
Electrical classification	Group I class A relative to CISPR 11
IP Code	IPX0: The instrument without probe is not protected against liquids.
Operating mode	Continuous operation
Mechanical Index	MI < 1.0 for all operating modes.
Thermal Index	TI < 1.0 for all operating modes.

Computer properties

Operating system	Windows Embedded
Permanent storage system	Hard drive
IT security guaranteed by	Local network security rules (firewall, DMZ, etc.) Windows firewall Wi-Fi system protected by advanced encryption modes (e.g.: WPA2)

Metrological performance

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

Stiffness	Min.: 2.0 kPa Max.: 75 kPa

		Stiffness S (kPa)*			
		M+		XL+	
S (kPa)	Trial number	Bias** (%)	Accuracy** (%)	Bias** (%)	Accuracy** (%)
Zone 1 3.9	1 2	− 5,1 − 5,1	0.0 1.8	− 6,7 − 4,6	1.4 1.1
Zone 2 9.6	1 2	− 24,0 − 24,0	0.0 0.0	− 26,5 − 18,5	2.3 0.5
Zone 3	1	− 12,9	0.0	− 12,1	0.

		Stiffness S (kPa)*			
		M+		XL+	
S (kPa)	Trial number	Bias** (%)	Accuracy** (%)	Bias** (%)	Accuracy** (%)
23.3	2	− 14,1	0.6	− 12,0	2.0

* Values obtained with CIRS E-1493-1 phantom

** As defined by ISO 5725-1 1994

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

	Control Attenuation Parameter CAP (dB/m)*			
	M+		XL+	
CAP (dB/m)	Bias** (%)	Accuracy** (%)	Bias** (%)	Accuracy** (%)
150 (1)	3.7	0.6	2.9	0.9
250 (2)	4.7	1.0	3.9	1.2
350 (3)	− 1,5	1.0	1.4	1.3

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

** As defined by ISO 5725-1 1994

Electrical characteristics

Power supply	100-240 V ~ 50–60 Hz
Apparent power	150 W

Mechanical characteristics

Dimensions	480 mm x 360 mm x 360 mm (H x W x D)
Weight	10 kg (with accessories)

Environmental characteristics

Operating temperature	+10°C to +40°C (+50°F to +104°F)
Operating humidity	30% to 75% relative humidity, not condensed.
Maximum operating altitude	3000 m
Operating atmospheric pressure	700 hPa to 1060 hPa
Storage and transportation temperature	-20°C to +50°C (-4°F to +122°F)
Storage and transportation humidity	10% to 85% relative humidity, not condensed.
Maximum altitude for storage and transportation	5000 m

Storage and transportation atmospheric pressure	540 hPa to 1060 hPa

Additional information

Power cables (according to country) - Length < 3 meters	1 x Australia power cable 1 x Brazil power cable 1 x China power cable 1 x Switzerland power cable 1 x EU power cable 1 x UK power cable 1 US/CA Hospital Grade power cable

7.2 BATTERY CHARACTERISTICS

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

Electrical characteristics

Rated voltage	14.4 V
Capacity	6 Ah.

Mechanical characteristics

Dimensions	97 mm x 33 mm (L x Diameter)
Weight	450 grams

7.3 EXTERNAL POWER SUPPLY CHARACTERISTICS

Model	XP Power L L C (ref. AHM150PS19-XE0931)

Electrical characteristics Power supply

	100-240 V ~ 1.8 A 50/60 Hz
Output signal	19 V 7.89 A
Apparent power	150 W

Mechanical characteristics

Dimensions	200 mm x 80 mm (L x W)
Weight	600 grams

7.4 WI-FI BLUETOOTH MODULE CHARACTERISTICS

Model	Intel® Dual Band Wireless-AC 3160 HWM
Standard Wi-Fi	802.11ac 1x1

Number of antennae	2
Wi-Fi TX/RX chains	1x1 chain
Antenna allocation	a. Wi-Fi only b. BT only
Wi-Fi TX/RX rate	433 MB/s
Bluetooth core	Bluetooth 4.0
Intel® WiDi support	Intel® WiDi 4
Single/dual chip	Single
Windows OS AOAC	Intel® Smart Connect Technology

7.5 CONTROL PEDAL CHARACTERISTICS

Model	Linemaster Gem-V2
IP Code	IP68
Mechanical Index	MI < 1.0 for all operating modes.

11.5.1. Mechanical characteristics

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

7.6 CONSUMABLES

Not applicable.

8 REGULATIONS

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

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

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

7.8 ELECTROMAGNETIC EMISSIONS

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

Emissions testing	Compliance	Electromagnetic Environment - Directives
RF CISPR 11 emissions	Group 1	The FibroScan COMPACT 530 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 CISPR 11 emissions	Class B	The FibroScan COMPACT 530 may be used on all premises, including domestic premises and those directly connected to the public low voltage energy grid used to supply domestic buildings.
Harmonic emissions CEI 61000-3-2	Class A	
Voltage fluctuations/flicker CEI 61000-3-3	Compliant	

NOTE: The use of cables and/or accessories not specified in the user guide may increase the device's emissions.

7.9 ELECTROMAGNETIC IMMUNITY (1)

In the following cases, electrostatic charges may be generated:

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

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

Immunity test	IEC 60601 test level	Compliance	Electromagnetic Environment - Recommendations
Electrostatic Discharge IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV through air	Floors should be wooden, concrete or ceramic. If the floor is covered with a synthetic material, the relative humidity must be at least 30 %.
Spike/Burst IEC 61000-4-4	+ 2 kV supply ± 1 kV input/output	+ 2 kV supply ± 1 kV input/output	The quality of the electrical network must be that of a typical commercial or hospital environment.
Voltage shocks EN 61000-4-5	Differential mode ± 1 kV Common mode ± 2 kV	Differential mode ± 1 kV Common mode ± 2 kV	The quality of the main supply must be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and supply inlet voltage variation IEC 61000-4-11	< 5 % $_{U}T$ [1] for 10 ms. 40 % U_T, for 100 ms. 70 % U_T, for 500 ms. < 5 % U_T, for 5 s.	< 5 % U_T, for 10 ms. 40 % U_T, for 100 ms. 70 % U_T, for 500 ms. < 5 % U_T, for 5 s.	The quality of the electrical network must be that of a typical commercial or hospital environment. If the user of the FibroScan unit COMPACT 530 requires uninterrupted operation during electrical power cuts, it is recommended that the FibroScan unit COMPACT 530 be powered by an uninterruptible power supply or battery.
Magnetic field immunity at supply frequency (50-60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Supply frequency magnetic fields must be those of a typical commercial or hospital environment.

1. U_T: network power supply voltage measured before the test

7.10 ELECTROMAGNETIC IMMUNITY (2)

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

Immunity test	IEC 60601 test level	Compliance	Electromagnetic Environment - Directives
			Portable and mobile RF communication equipment must be kept far away from the FibroScan unit COMPACT 530 (including its cables), at a distance greater than the recommended distance calculated using the equation applicable to the emitter frequency.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1.17 \sqrt{P}$
	3 Vrms	3 V	$d = 1.17 \sqrt{P}$
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 meters (m). The strength of EM fields for fixed emitters, as determined by a study [2]electromagnetic of the site must be less than the compliance level in each of the frequency bands. [3] Interference may occur in the vicinity of devices bearing the following symbol: 

NB 1: at 80 MHz and 800 MHz, the upper frequency band is applicable

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

NB 3: The use of cables and/or accessories not specified in the user guide may reduce the device's immunity.

2. The strength of EM fields for fixed emitters such as commercial AM/FM radio broadcasting services, television, cell phone services, radio detection, 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 field strength measured at the location where the FibroScan unit COMPACT 530 is used exceeds the compliance levels mentioned above, correct operation of the FibroScan unit COMPACT 530 must be checked. If abnormal performance is observed, additional measurements may be required after, for example reorienting or moving the FibroScan COMPACT 530.

3. In the frequency range 150 kHz - 80 MHz, field intensity should ideally be less than 3 V/m.

NB 4: In case of any disturbance in the electromagnetic environment of the FibroScan, COMPACT 530, a message is displayed (see the Message Area chapter) and no measurements can be carried out.

7.11 RECOMMENDED SEPARATION DISTANCES

(Between portable or mobile RF communication devices and the FibroScan) COMPACT 530)

The FibroScan COMPACT 530 is designed for use in an electromagnetic environment in which RF disturbance is controlled. The customer or the user of the FibroScan COMPACT 530 can take precautions against interference by maintaining a minimal distance between the portable or mobile RF communication equipment (transmitters) and the FibroScan COMPACT 530 as recommended below according to the maximum power of the communicative device.

Maximum transmitter output power (W)	**Separation distance according to transmitter frequency (m)**		
	150 kHz to 80 MHz **d = 3.5/3**	**80 MHz to 800 MHz** **d = 3.5/3**	**800 MHz to 2.5 GHz** **d = 7/3**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For emitters whose maximum power is not listed above, the recommended separation distance in meters (m) 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.

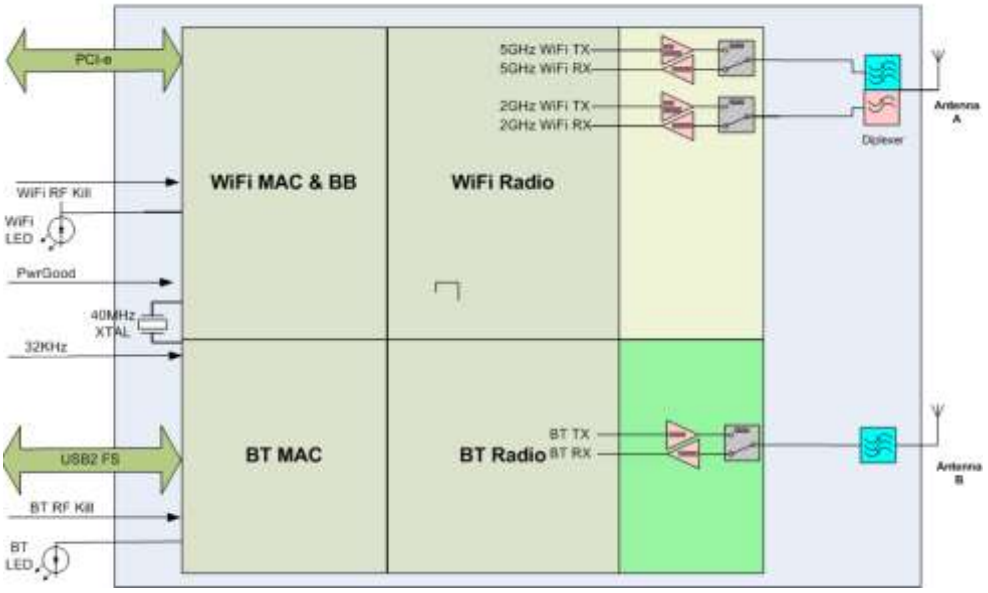
NB 1: At 80 MHz and 800 MHz, the upper frequency band is applicable for the separation distance.

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

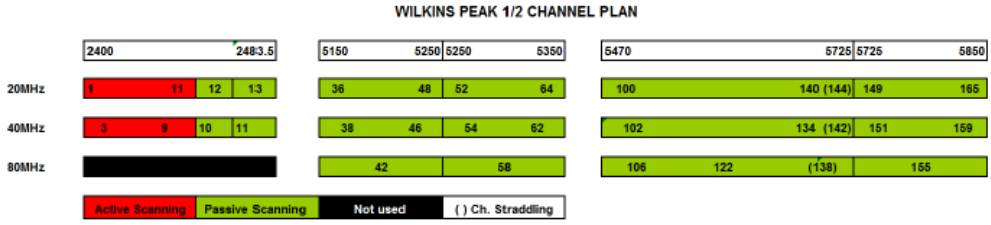
7.12 WIFI/BLUETOOTH CONNECTIVITY

The Intel® Dual Band Wireless-AC 3160 HWM is a Wi-Fi 1x1 and Bluetooth combination single chip solution. AC 3160 HWM use Intel's 1st generation 802.11ac Wi-Fi solution and shall support both 2.4, and 5.2 GHz bands. On 5.2 GHz band, it shall operate on an 80 MHz wide channel reaching PHY rates of up to 433 Mbps. AC 3160 HWM use a Bluetooth core that support Bluetooth 4.0 standard including Bluetooth 3.0 High Speed and Bluetooth 4.0 Low Energy (BLE). AC 3160 HWM have 2 antenna ports: one shall be dedicated to Wi-Fi and the other to Bluetooth.

System architecture diagram



Channel configuration table



Maximum transmitter emission power:

- Bluetooth: 9.9 dBm
- Wi-Fi 2.4 GHz: 19.8 dBm
- Wi-Fi 5.2 GHz: 22.1 dBm
- Wi-Fi 5.6 GHz: 21.6 dB

8 PARE PART LIST

FibroScan® COMPACT 530	FS530 External Power	M300005
	FS530 Probe support	M300038
	FS530 Coverglass	M300001
	FS530 Battery	M300002
	FS530 Carte HMI	M300017
	FS530 Carte battery	M300024
	FS530 Carte Power connectic	M300027
	FS530 Elastometry module V3	M300009
	FS530 Antenne WIFI	M300007
	FS530 Module WIFI	M300006
	FS530 Antenne BT	M300008
	FS530 Fan	M300031
	FS530 CableDataConnectics	M300029
	FS530 CablePowerConnectics	M300028
	FS530 CableLVDS_CoverGlass	M300018
	FS530 CableBackLight_CoverGlass	M300019
	FS530 CableUSBTouchscreen_CoverGlass	M300020
	FS530 CableCoverGlass PV3	M300021
	FS530 CablebatteryConnectics	M300025
	FS503 Interventional Kit Including: M300005 / M300015 + M300016 / M300001 / M300002 / M300017 / M300024 / M300027 / M300009 / M300007 / M300006 / M300008 / M300031 / M300029 / M300028 / M300018 / M300019 / M300020 / M300021 / M300025	KSP0530

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