

 edap tms Bringing New Horizons to Therapy	INSTRUCTION	Réf : Version :	INS-367 E
Focal One	PREVENTIVE MAINTENANCE		

This document is linked with the Preventive Maintenance Checklist FMU-431 and the Probe Installation Checklist FMU-231

Tip for documentation use:

Fill the first page information for one equipment and save it to a dedicated file. That file will be used as starting point for next intervention or regular maintenance.

Update starting point file when required (software and/or hardware update).

All ticked NA must be justified by comment. Text in **Red** is instruction to report in the checklist and text in **blue** is instruction to be done.

Password are only provided to trained field service engineer, during first training or knowledge update with EDAP TMS service engineer.

0 PREREQUISITES

Requested tools:

- Set of metric Allen wrench
- Set of screwdrivers
- USB Stick (upper than 1GB)
- Digital Volt meter (report metrology information in dedicated section of checklist)
- Report presence of control tool (in dedicated section of checklist)

Dedicated tools:

- Test tank
- 3D test tool
- Test focal pack
- Load bench

Electrical safety test:

- Homologated test device according IEC 62353 specifications or any other local regulation that apply.

1 PREVENTIVE MAINTENANCE INFORMATION

Report:

- **Call number linked with the preventive maintenance**
- **Date of preventive maintenance**
- **Name of engineer who operates the preventive maintenance**
- **Distributor information if applicable**
- **Customer Information if the machine is no mobile**

2 FOCAL ONE® IDENTIFICATION

Report the Serial number of the Focal One

You can find it on the blue panel of the patient side.

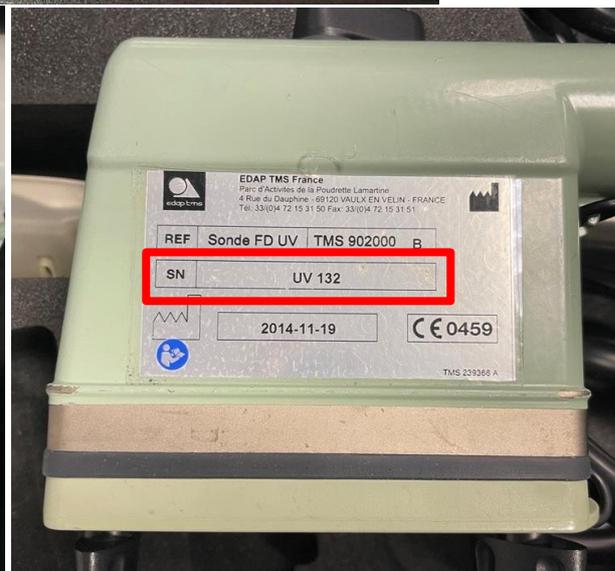
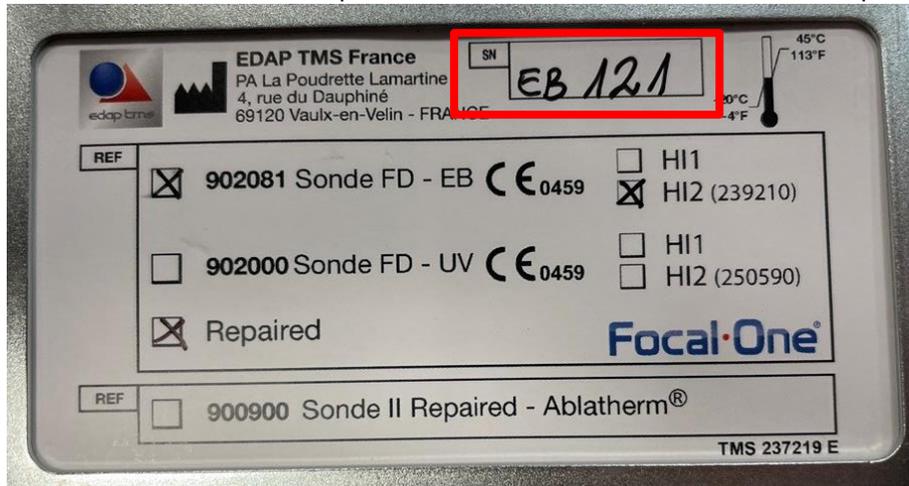
	EDAP TMS France Parc d'Activités de la Poudrette Lamartine 4, Rue du Dauphiné - 69120 VALULX EN VELIN - FRANCE Tél: 33(0)4 72 15 31 50 Fax: 33(0)4 72 15 31 51				
REF	Focal One® TMS 239320		Made in France		
SN	<input type="text"/>				
Mains Supply / Alimentation Electrique					
VOLTAGE VOLTAGE TENSION	100-120 V~	FREQUENCY FREQUENCY	50/60Hz	POWER INPUT PUISSANCE ABSORBEE	2 KVA
Amplifier/ Amplificateur	MAX. POWER PUISSANCE MAX.	320 W	FREQUENCY FREQUENCE	3 MHz	
		IP XXB		TMS 239316 A	

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If it is installation, report Installation date.

Report serial number of probe 1 and 2 (tick NA if there is no second probe).

You can find the serial number on the box of the probe or on the ultrasound connector of the probe.

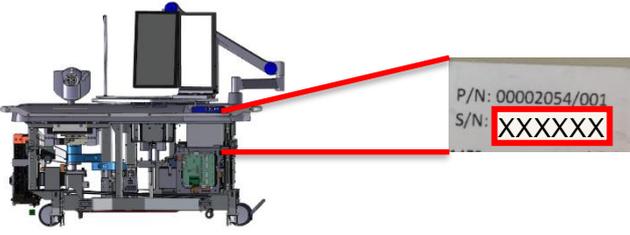
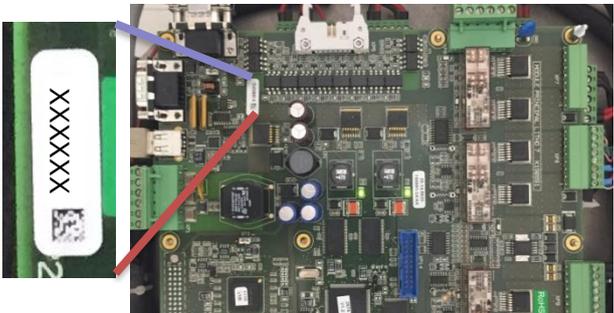
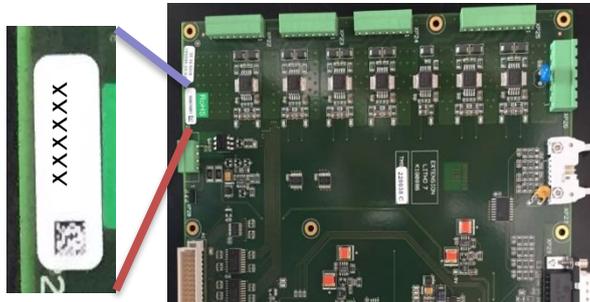
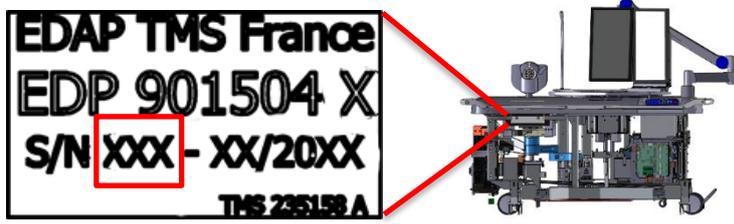
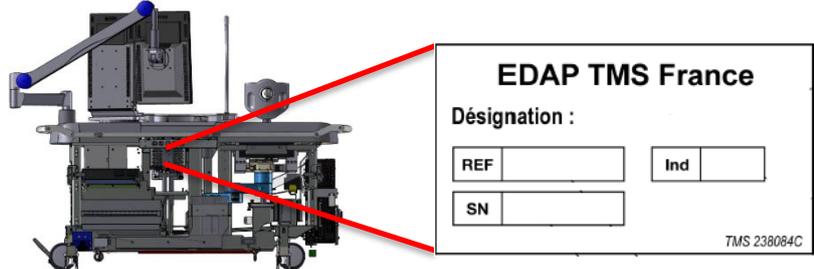


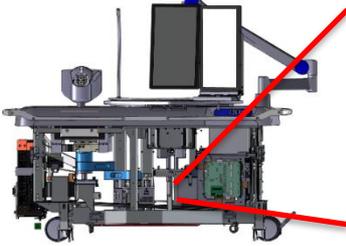
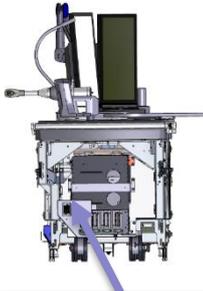
2.1 Subassemblies serial numbers and versions

Remove all panels

Report serial number of each subassembly.

You can find them according the table below:

Serial number	
Computer	
MEP board	
Extension board	
MOT probe Motorisation	
Cooling	

Amplifier		<div style="border: 1px solid black; padding: 5px;"> <p>EDAP TMS France Générateur RF 16 Voies TMS 233360 SN : AF-XXX TMS 235503A</p> </div>
US scanner	Ultraview SN	EB2300 SN + Windows version (label if Windows 10, if no label it's Windows 8)
	From operator side behind TSRL. 	Label is above USB connections (visible looking upward)  

You can fill versions after switch on the focal one (part 7).

Switch on the machine, go in “Administrator” session, open “Setup”, “Maintenance”, “Version” tab.
Report version for each subassembly.

Maintenance			
Id Machine		00021	
		Com OK	
MEP Digital I/O MEP Analog I/O Probe-Holder Arm Cooling Firings and Power Video Versions			
	Current Version	Expected Version	Status
Global			
Global Version	1.60	G5	OK
Technical File		1.60	OK
Software			
<i>Main</i>			
FOneTherapy	3.7.6.0	3.7.6.0	OK
FOneSetup	4.5.2.0	4.5.2.0	OK
SessionManager	2.4.9.0	2.4.9.0	OK
<i>Modules</i>			
MEP_FOne	V 1.13.00	V 1.13.00	OK
MOT Probe Motorisation	MOT 2.0.1	MOT 2.0.1	OK
Cooling	GF 1.12.02	GF 1.12.02	OK
Probe	unavailable	V 2.11.0	Not same version
Ampli	V 1.11.00	V 1.11.00	OK
<i>USScanner</i>			
USScanner_BK	1.22.1.0	1.22.1.0	OK
USScanner_SSI	unavailable	1.30.0.0	Not same version
<i>Options</i>			
HIFusion	5.4.3.0	5.4.3.0	OK

	INSTRUCTION	Réf : Version :	INS-367 E
Focal·One	PREVENTIVE MAINTENANCE		

3	CONTROL TOOLS IDENTIFICATION
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Report serial numbers and validity period from metrology follow-up of control tools.

Validity period is optional according to local regulation. EDAP TMS strongly recommend a metrology follow up.

- **Voltmeter:** You need Voltmeter only to measure 12V DC, 24V DC and 230V AC.
- **Thermometer:** You need Thermometer with a small sensor to go (with the cooling pouch) inside the cooling system. The range needed is from 40°C to 0°C with a sensitivity of 0.1°C.
- **Inclinometer:** You need an inclinometer with a zero calibration function. The sensitivity must be 0.1°.
- **Current clamp:** You must have an ampere meter type clamp. The minimum range needed is 40A DC.
- **Load bench:** For the 3D Ultrasound imaging test you need the tool ref TMS235330. It's a simulation tools for the power and the communication of the treatment probe.

4	SITE INSTALLATION
To be done only if it's an installation (if not tick NA)	

4.1 Installation recommendations

Verify that the room is conform to the instruction recommended by EDAP TMS.
Refer to technical specifications **SPE-089**.

Report results.

4.2 UPS

Report presence of UPS (Uninterrupted Power Supply), line regulator or any similar device. Ask to the personal of the hospital in charge of the room where the Focal One will be located if a back-up supply or a regulator is available.

4.3 Circuit breaker (Type D or slow trip)

If access to breakers and competent hospital personal are available. Power off system asks competent personal to test earth leakage circuit break.

Report presence.

4.4 Earth leakage circuit breaker

If ACE accessible report the value of the circuit breaker.

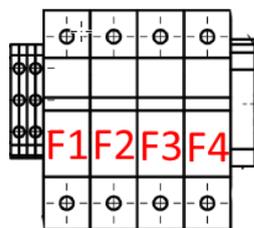
4.5 Fuses

4.5.1 For main power supply 100/120VAC

Verify visually:

- F1 and F2 = **20 A gG** (transformer primary)
- F3 and F4 = **8 A gG** (transformer secondary)
- F13 = **6.33 A cG** (cooling system alimentation)

Report conformity or tick NA if 200/230VAC.

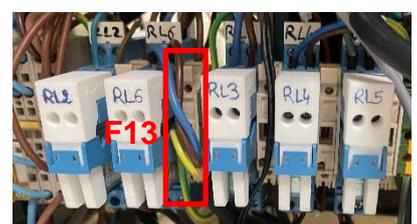
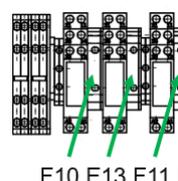


4.5.2 For main power supply 200/230VAC

Verify visually:

- F1 and F2 = **20 A gG** (transformer primary)
- F3 and F4 = **8 A gG** (transformer secondary)
- F13 = **3.15 A cG** (cooling system alimentation)

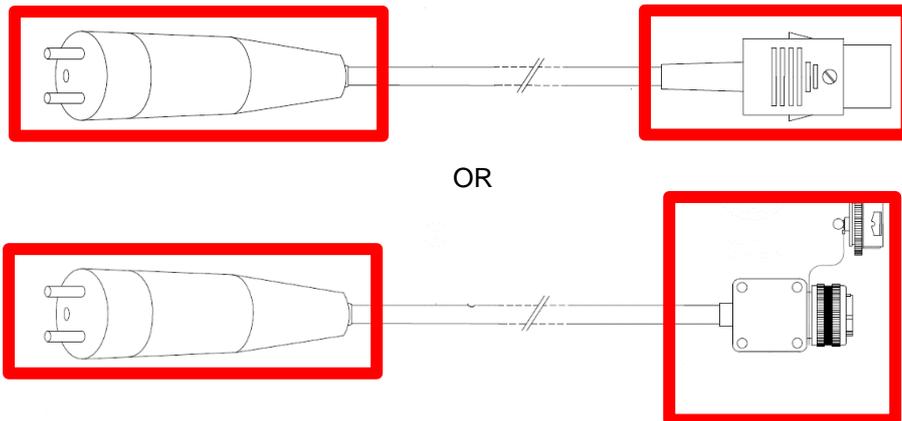
Report conformity or tick NA if 100/120VAC.



5.1 Main power cable

Check the good condition of the main power cable, connectors and contacts.

Report the results.



5.2 Main screen movement

Try to move the first screen, when you release it doesn't have to move itself and doesn't make noise.

Report results.

5.3 Secondary screen movement

Put your inclinometer at the back of the screen and test the last hold position. Check that the screen doesn't make noise when moving.

The screen can support 70° angles without falling.

Report results.

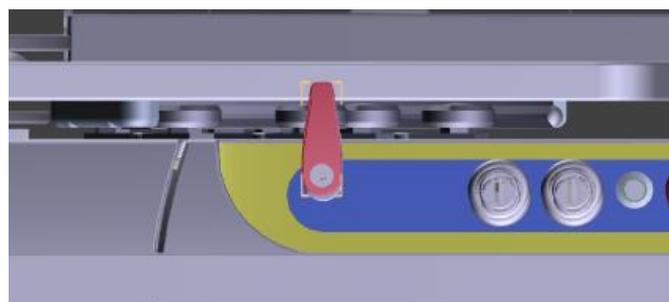
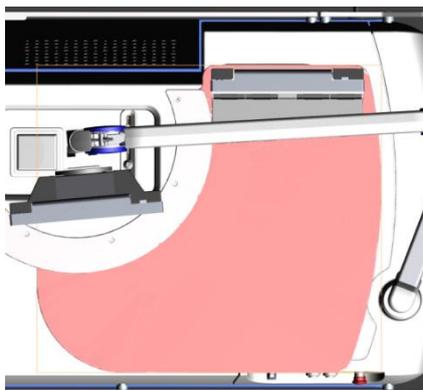
5.4 Tablet displacement and locking system

Move the tablet.

No excessive noise during tablet displacement.

Check if tablet's locking system, in release or retracted position, is possible.

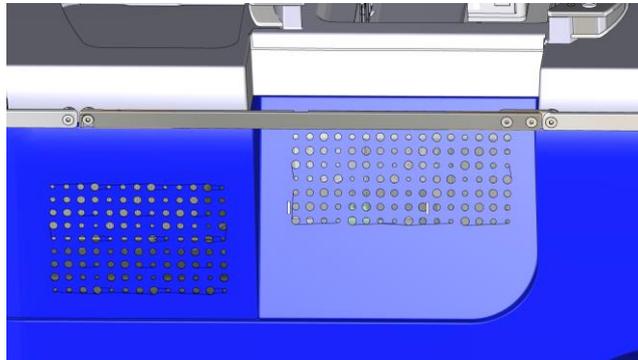
Report results.



5.5 Ablasonic holder

Check if the Ablasonic holder tight correctly (stay in place at the vertical)

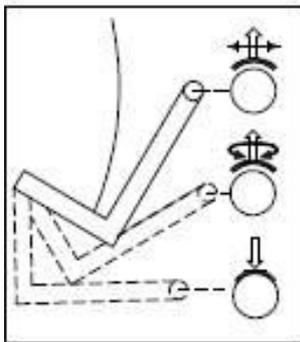
Report results.



5.6 Positions of breaking pedal

Check if it's possible to action the three positions of wheels.

Report results.

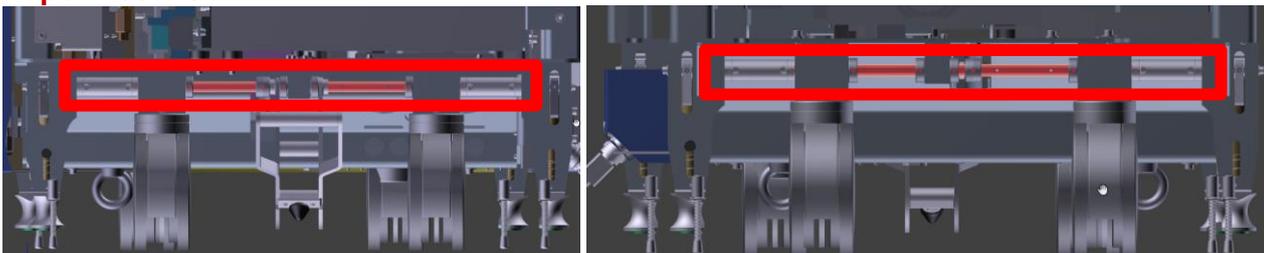


		Wheels	
		Brake side	Opposite side
Brake pedal position	High	Free in steering	Blocked in steering
	Midpoint	Free in steering	
	Low	Wheels braked and pads lowered	

5.7 Hexagon's socket set screws

Check that hexagon's socket set screws on both sides are tightened.

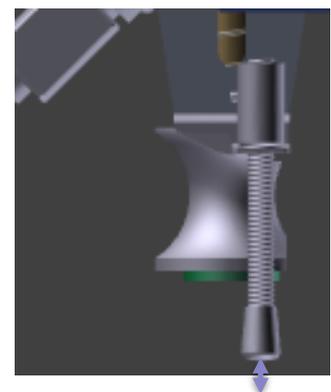
Report results.



5.8 Cable wipers

Check if cable wipers are in good condition, correctly set and lock. Set them at 4mm from the ground.

Report results or tick NA if it's mobile machine.



5.9 Labels

Inspect all Labels (Company logos, identification labels, push bar, probe support).

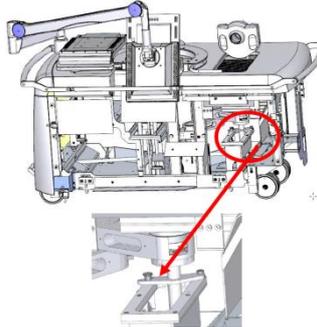
Make sure they are properly fitted (aligned) clean and in good condition.

Report inspection results.

5.10 Mönninghoff arm's locking system

If present, check that Mönninghoff arm's parking locking system is correctly set and there is no free play.

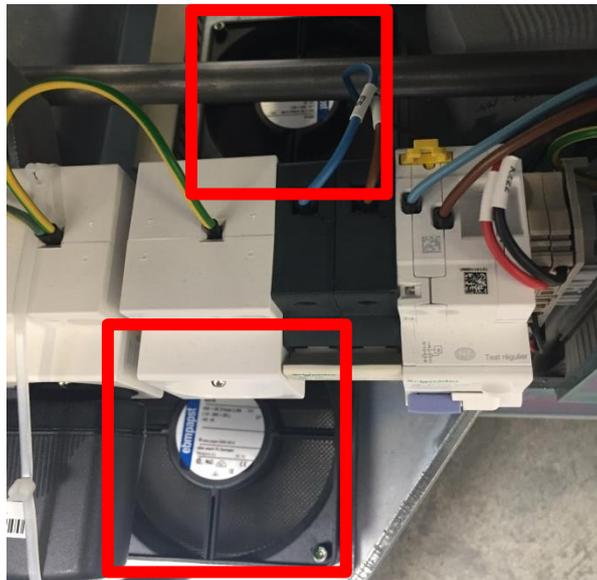
Report results.



5.11 Chassis Fans

Turn manually the 2 fans on frame. They must not make noise.

Report results.



5.12 Accessories

- **Leg holder:**
Test the leg holder on the focal one rails. Be sure that there is a minimum of 3 screws. This screws are in good conditions. The lever of the feet works well and the fixing plate is in good condition.
- **Transport carriage:**
Check that transport carriage and this cover is clean and in good condition.
- **Covers :**
Check that machine cover is clean and in good condition, that screens covers are clean and in good condition and that probe holder cover is clean and in good condition.



Report results of accessories inspections or tick NA if accessory is not present.

5.13 Maintenance sticker

Fill the sticker and put it on the device.

Report action or tick NA if isn't applied in your country.


6

FOCAL ONE® SWITCH ON

6.1 Blue LEDs

Connect the machine to hospital power supply.
 Connect the probe.

Check that 2 blue LEDs "Power On" are lit when power cable is connected on hospital power supply (mains supply is present).

Reports results.



6.2 Switch ON Focal One®

Switch ON Focal One® pressing "ON/OFF" button during more than 2s.

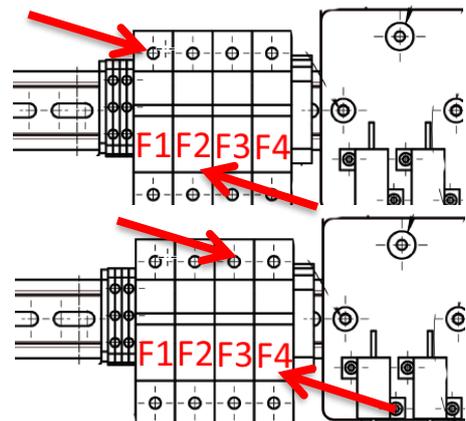
Version F	Version G and H
<p>Check that:</p> <ul style="list-style-type: none"> ○ Focal One® switches ON and button light is ON. ○ "SessionManager" software is launch on main screen. ○ "FOneTherapy" software launch automatically. ○ Connect on hospital "EDAP" : <ul style="list-style-type: none"> ○ No troubles. ○ Keyboard works 	<p>Check that:</p> <ul style="list-style-type: none"> ○ Focal One® switches ON and button light is ON. ○ "SessionManager" software is launch on main screen. ○ Connect on hospital "EDAP" : <ul style="list-style-type: none"> ○ No troubles. ○ Keyboard works ○ Only "TherapyUro" software is available.

Report results.

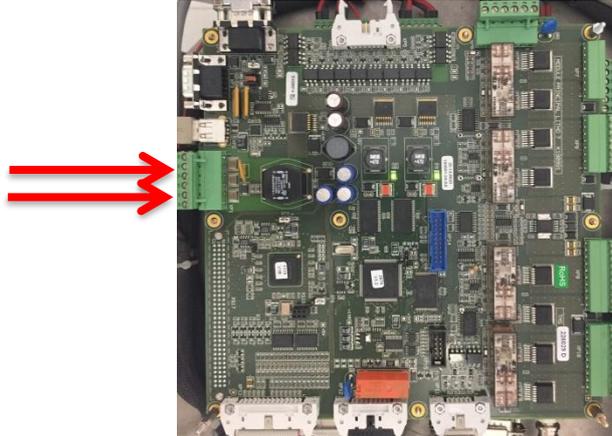
6.3 Powers supplies

Thanks to the voltmeter, check power supplies:

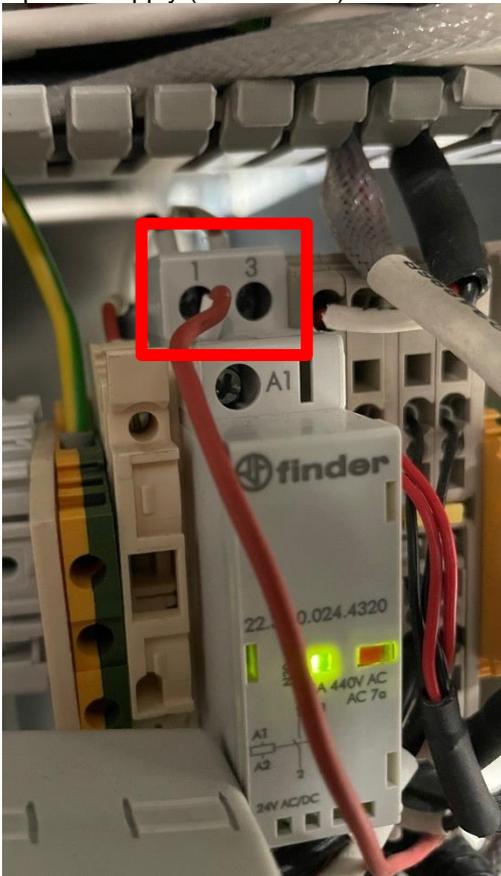
- Before F1 and after F2: Main power $\pm 10\%$ (alternative tension)
- Before F3 and after F4: 217V-253V (alternative tension)



- MEP power supply (MEP XP1 2-5): 22.8V – 25.2V (continuous tension)



- 12V power supply (RL8 / 21-14): 11.4V – 12.6V (continuous tension)



Report values.

6.4 LED tape

Check functioning of LED tape.

LED tape colors change and all parts are lit. You can see that between the top panel and the tablet.

Report results.

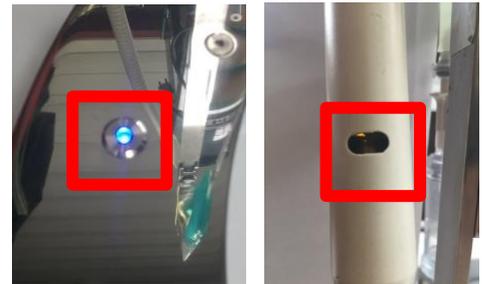


6.5 Patient movement detector

Put a reflector in front of patient movement detector.

Check that blue light indicator is lit on flange.
 Check that orange light indicator is lit on detector head.

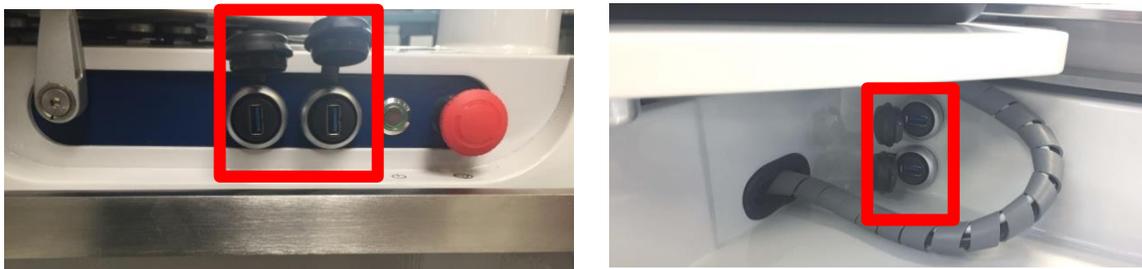
Check that if you release the detector, it stays in same position.
Report results.



6.6 External USB connectors

Connect peripheral (mouse for example) on each of 4 USB connectors.

Report peripheral working properly on each connector.



6.7 Touch screen

Touch the 2 screens. Check that the mouse moves.

Report results.

6.8 “Get Init Status”

Close “TherapyUro” application log out.

Log in “Administrator” session, launch “Setup”, then go to “Maintenance” menu.

After initialization, browse in all tabs and check if all sub-assemblies communicate (press “Get Init Status” and “OK” should appear on “Status”).

- MEP Digital I/O
- MEP Analog I/O
- Probe-Holder Arm
- Cooling
- Firings and Power



6.9 MEP Analog inputs

Go to “MEP Analog I/O” and tick inputs below and click on “Read inputs once”:

- “In7 - 3.3 Volts Power Supply” is between 3.13V and 3.47V.
- “In8 - 24 Volts Power Supply” is between 22.8V and 25.2V.

Report “Get in Status” and values.

Close “Maintenance” menu .

Open windows explorer and create a backup folder on:

D:/Saves/”AAAAMMDD_ KindOfIntervention_ TrigramOfEngineer”.

If it’s an installation, create “Saves” folder.

Go to “Technical File” menu and save technical file in PDF into the backup folder

Close “Setup”.

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Focal·One	PREVENTIVE MAINTENANCE		

6.10 “Error” file

If F3 version: **Open the file in C:\FocalOne\ErrorFOXXX.txt.**

If G or more version: **Open the file named “ErrorFOXXX.txt” in D:\log\FOneTherapy (XXX is the serial number of the Focal One)**

Check all errors that happened since last pm.

Report results and put in comments what are the recurrent technical errors if existing.

6.11 Emergency stop functions

Press emergency stop button.

Check that:

- Computer, ultrasound and screens are on.
- Manuals movements are unlocked
- Probe support keypad buttons are off.
- Amplifier is off.

Release emergency stop button.

Check that Manuals movements are locked.

Report inspection results.

Switch off completely Focal One®, disconnect main power cable and wait 1 minute before switch on.

7	COMPUTER
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7.1 Image display

Log in “Administrator” session, check that screens image is correctly centred and scaled.

Report inspection result.

7.2 Free space on HDD

Open a windows explorer and click on “Computer”.

Report available space for D: drive.

Report available space for C: drive.

7.3 Number of patients treated since last maintenance activity

Check the number of treatments since last preventive maintenance date by counting treatment folders in D:\FocalOne\img\“hospital name” if version F or D:\Clinical\FocalOne\img\“hospital name” if version G or above.

Report results or N/A for installation or mobile unit.

7.4 Date of last maintenance

Open a windows explorer, go on D drive D:\Saves\ and check the last backup folder.

Report results or N/A for installation.

7.5 Defrag analysis

Start windows disk defragmentation tool (Open windows explorer, go on “Computer”, right click on the disk and click on “Properties”, go in “Tools” tab, click on “Optimize”).

Perform disk analysis on both drive If 10% are fragmented, run defragment disk.

Report action completion or NA if defragmentation was not necessary.

7.6 Date and time

Check the date and time of the computer (Windows) is similar to the local one.

Report results.

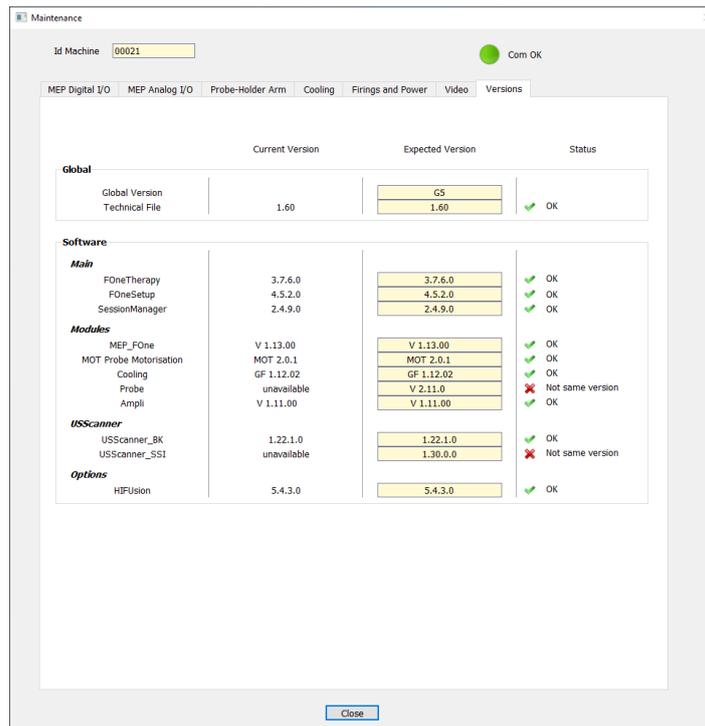
7.7 Software versions

Open “Setup” and go to “Maintenance” menu, “Versions” tab.

Check if expected versions are the same as current versions

Probe version and USScanner_SSI can be different.

Report results.



	Current Version	Expected Version	Status
Global			
Global Version	1.60	GS	OK
Technical File		1.60	OK
Software			
<i>Main</i>			
FOneTherapy	3.7.6.0	3.7.6.0	OK
FOneSetup	4.5.2.0	4.5.2.0	OK
SessionManager	2.4.9.0	2.4.9.0	OK
<i>Modules</i>			
MEP_FOne	V 1.13.00	V 1.13.00	OK
MOT Probe Motorisation	MOT 2.0.1	MOT 2.0.1	OK
Cooling	GF 1.12.02	GF 1.12.02	OK
Probe	unavailable	V 2.11.0	Not same version
Ampli	V 1.11.00	V 1.11.00	OK
<i>USScanner</i>			
USScanner_BK	1.22.1.0	1.22.1.0	OK
USScanner_SSI	unavailable	1.30.0.0	Not same version
<i>Options</i>			
HFUsion	5.4.3.0	5.4.3.0	OK

7.8 Back up battery.

For Ecrin computer only, connect USB keyboard directly on the computer (next to the power on button of the machine).

Press emergency button.

On SessionManager, select “Restart computer...” and press “OK”.

On keyboard press repetitively “Del” or “F12” during computer booting.

Browse through BIOS interface to “Advanced”, “H/W Monitor”.

Check that the motherboard battery (Vbat or battery voltage) is above 2.8Vdc (replace battery if test fail).

Report results or N/A if IPO computer.

Quit BIOS without saving any change.

7.9 Computer dust filter.

Open the filter’ flap (on the front cover of the PC)

Remove and clean the dust filter.

Install back filter, close the flap.

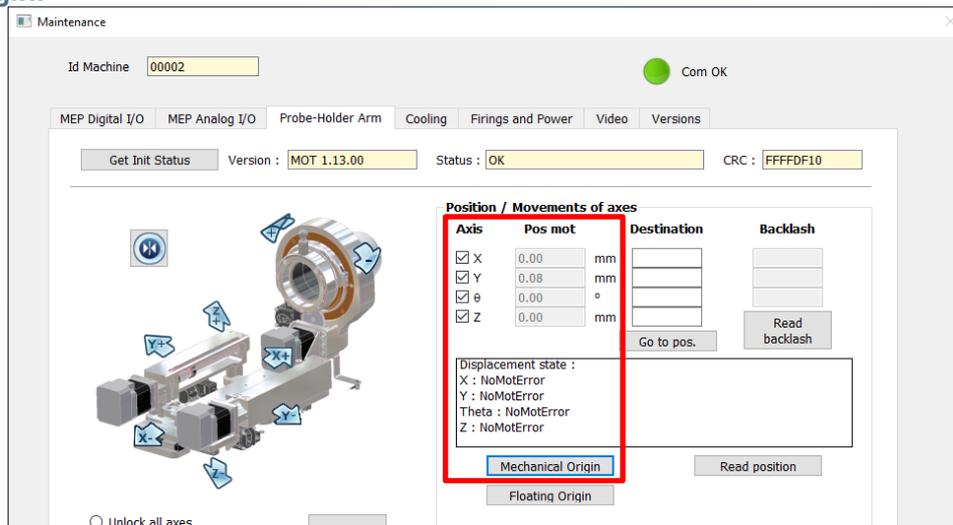
Report action completion.



8.1 All AXIS

If not done yet Start Focal One. If version F, Close “FOneTherapy” application. Then in the SessionManager window, select the option “Close current session...”, then click on “Execute option”. Log in “Administrator” session and launch “Setup”.

Go in “Maintenance” menu, “Probe Holder Arm” tab, tick 4 motorized axes and launch 2 times the mechanical origin.



8.1.1 Status after centering

At the end of the mechanical origin, 4 motors status are “NoMotError” and movement’s buttons are blue into software screen.

Report results.

8.1.2 Values of “Pos Mot”

Value are 0mm ± 0.2mm for X, Y et Z and 0 ° ± 1° for θ.

Report values.

8.1.3 Keypad buttons

Test all 4 buttons to be sure they work. Check that each button activates its dedicated function. Test if Keypad of manual movements is in good condition and all LEDs work.

Report results.



8.1.4 Theta fan

Check that theta fan is working. You can put sheet of paper to see airflow.

Report results.



8.2 X AXIS (LONGITUDINAL)

Request a destination of -50mm.

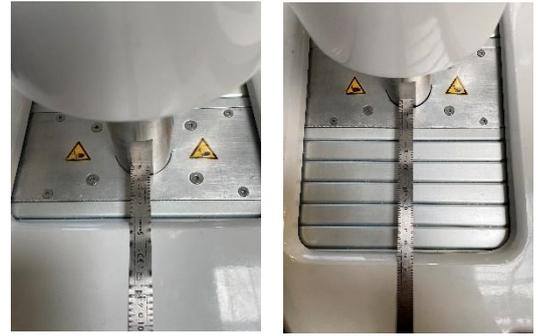
Define referent point and measure thanks to a ruler the distance between this point and probe holder.

Report measured value (2) and software value (1).

Request a destination of +50mm.

Measure thanks to a ruler the distance between the referent point and probe holder (must be same point on each measurement).

Report measured value (4) and software value (3).



Calculate software displacement : absolute value of 1 + value 3. **Report value.**

Calculate measured displacement : value 4 - value 2. **Report value.**

Both value must be $100\text{mm} \pm 2\text{mm}$.

Launch a mechanical origin.

8.3 Y AXIS (TRANSVERSAL)

Request a destination of -25mm.

Define referent point and measure thanks to a ruler the distance between this point and probe holder.

Report measured value (2) and software value (1).

Request a destination of +25mm.

Measure thanks to a ruler the distance between the referent point and probe holder (must be same point on each measurement).

Report measured value (4) and software value (3).



Calculate software displacement : absolute value of 1 + value 3. **Report value.**

Calculate measured displacement : value 2 - value 4. **Report value.**

Both value must be $50\text{mm} \pm 2\text{mm}$.

Launch a mechanical origin.

8.4 Z AXIS (ACTUATOR)

Request a destination of -40mm.

Define referent point and measure thanks to a ruler the distance between this point and probe holder.

***Report measured value (2) and software value (1).**

Request a destination of +40mm.

Measure thanks to a ruler the distance between the referent point and probe holder (must be same point on each measurement).

Report measured value (4) and software value (3).



Calculate software displacement : absolute value of 1 + value 3. **Report value.**

Calculate measured displacement : value 4 - value 2. **Report value.**

Both value must be $80\text{mm} \pm 2\text{mm}$.

Launch a mechanical origin.

8.5 Θ AXIS (THETA)

If not done yet, remove probe.

Use the tools ref 236937 (refer to the TN-2016-27) and the inclinometer.

Calibrate the inclinometer on the floor.

Place tool and inclinometer on the tool.

Request a destination of -70° .

Report software value (1) and measured value (2) by inclinometer.

Request a destination of $+70^{\circ}$.

Report software value (3) and measured value (4) by inclinometer.

Calculate software displacement : absolute value of 1 + value 3. Report value.

Calculate measured displacement : value 4 + value 2. Report value.

Both value must be $140^{\circ} \pm 2^{\circ}$.

Launch a mechanical origin, clear destination values and remove tool.



8.6 Manual movements and top panel collision check

8.6.1 Probe holder levelled

Thanks to the inclinometer, check:

- On X axis:

Place the inclinometer as shown on the picture.

The probe holder must be levelled at $0^{\circ} \pm 2^{\circ}$ to the floor.

Report value.

- On Y axis:

Place the inclinometer as shown on the picture.

The probe holder must be levelled at $0^{\circ} \pm 2^{\circ}$ to the floor.

Report value.

Remove inclinometer.



8.6.2 Manual displacements

Move manually probe holder in all directions.

Verify that there is not hard point during displacement.

Report results.

8.6.3 Panels collision check

- Displacement front right:

Request destinations of **+50mm on X, -25mm on Y and +38.5 mm on Z.**

Unlock all manual movements.

Move the probe holder to front right.

Verify that there is no interferences between motors board cables, frame, shutter and panels. Check that there is no friction with top panel.

Report results.

- Displacement front left:

Request destinations of **+50mm on X, +25mm on Y and +38.5 mm on Z.**

Unlock all manual movements.

Move the probe holder to back right.

Verify that there is no interferences between motors board cables, frame, shutter and panels. Check that there is no friction with top panel.

Report results.

- Displacement back left:

Request destinations of **-50mm on X, +25mm on Y and +38.5 mm on Z.**

Unlock all manual movements.

Move the probe holder to back right.

Verify that there is no interferences between motors board cables, frame, shutter and panels. Check that there is no friction with top panel.

Report results.

- Displacement back right:

Request destinations of **-50mm on X, -25mm on Y and +38.5 mm on Z.**

Unlock all manual movements.

Move the probe holder to back right.

Verify that there is no interferences between motors board cables, frame, shutter and panels. Check that there is no friction with top panel.

Report results.

8.7 Random movements

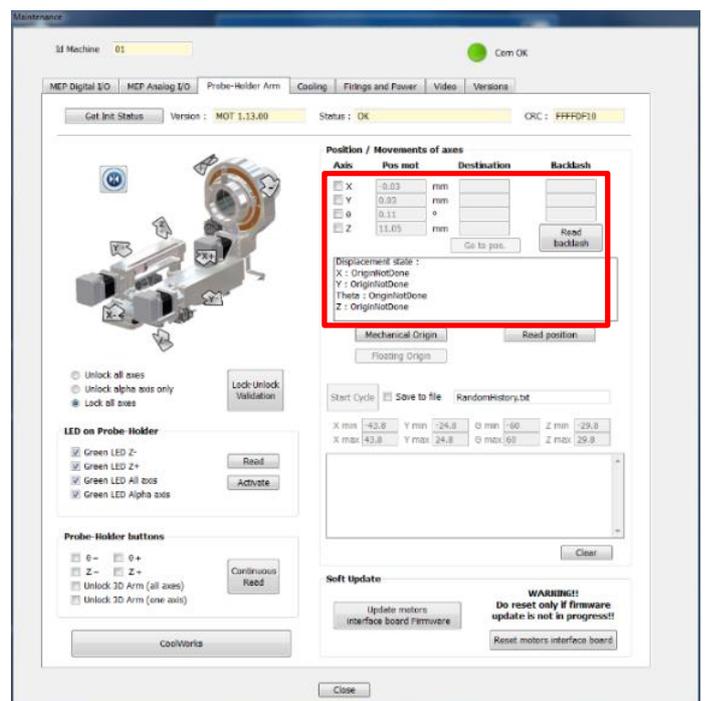
8.7.1 Mechanical origin

Launch mechanical origin on 4 axis twice.

Verify that no motor error occur after mechanical origin.

Report results and backlash values for X, Y and Θ .

Tolerance for backlash values are : maximum 0.3mm for X and Y and maximum 0.6° for Θ .



8.7.2 Time and movements

On random window part, tick “Save to file”.

Rename file “RandomHistory.txt” by “RandomHistory”DateOfTheMaintenance”.txt”

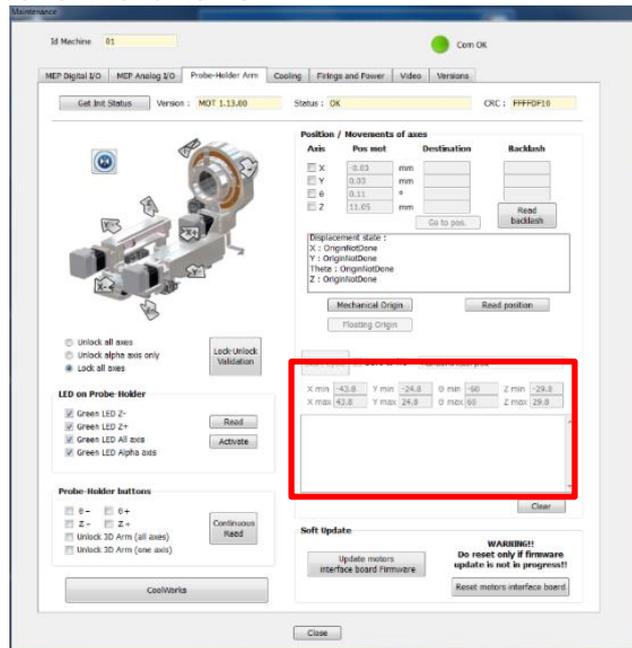
Click on “Start cycle” to launch random movements.

Record time start.

Wait 40min minimum with random movements on.

Click on “Stop cycle”.to stop random movements.

Record time stop and number of movements.



8.7.3 Analyze Random file

Open Windows explorer and go to:

- If Version F: C:\FocalOne\Maintenance\
- If Version G and more: D:\Config\Maintenance

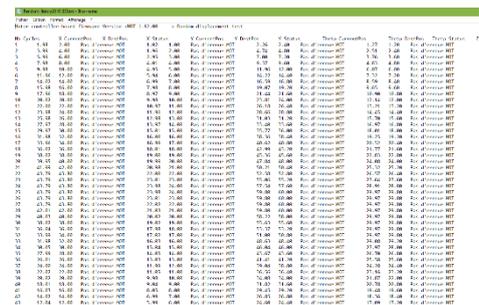
Then cut and paste file:

“RandomHistoryMaintenance*DateOfTheMaintenance*.txt”

on save folder.

Open file and check if there is no error during displacement.

Report results.



8.7.4 Mechanical origin

Launch mechanical origin 2 times.

No motor errors occur after mechanical origin.

Report inspection result.

8.7.5 Backlash values

Report backlash value for X, Y and θ.

Report difference between before and after random

The difference between before and after random must be less than X = (<0.3mm) / Y = (<0.3mm) / T = (<0.6°).

9.1 Peltier consumption during regulation.

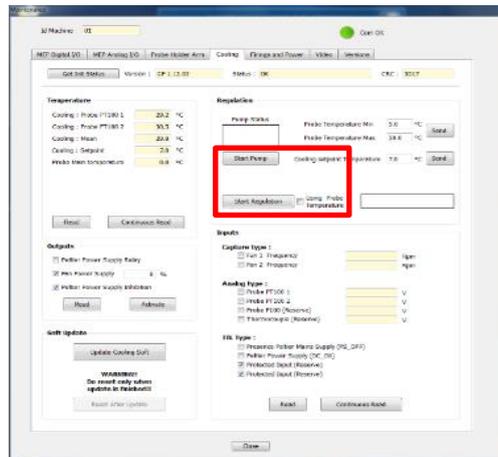
If not done yet Start Focal One. If version F, Close “FOneTherapy” application. Then in the SessionManager window, select the option “Close current session...”, then click on “Execute option”. Log in “Administrator” session and launch “Setup”.

Connect both connectors of probe. Go in “Maintenance” menu, “Cooling” tab.

Switch ON a Clamp meter and connect it on white Peltier wires to measure current (A).

Connect a test FocalPak with balloon

Tick on “Use probe temperature”, then click on “Start regulation” and “Start pump”.

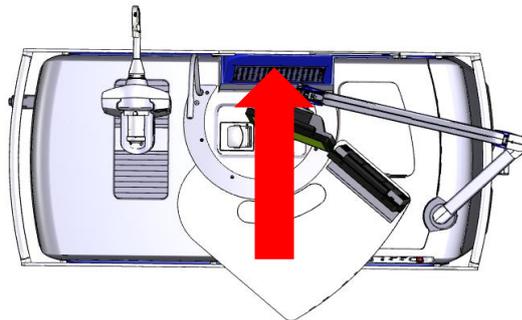


Report, Peltier consumption during regulation

The consumption must be between 27A and 38A and it decreases progressively.

9.2 Fans

Check that fans operate without noise and that air flow is from user to patient.



 edap tms Bringing New Horizons to Therapy	INSTRUCTION	Réf : Version :	INS-367 E
Focal·One	PREVENTIVE MAINTENANCE		

9.3 Pump

Check that pump turns in clockwise, no make too much noise and pumps Ablasonic efficiently.
Check that there is no backlash on the opening part of the pump.

Report results.

9.4 Regulation

Check that values of PT100 1 and 2 decreases during regulation and after 10 minutes, measured temperature (Mean) is closed to setpoint and regulation is working.

Report results.

9.5 Peltier consumption between regulation

After setpoint is reached make sure the Peltier turn off and consumption is less than 0.2A.

Report results.

Remove Clamp meter.

9.6 Difference between the two PT100

Report the difference between the two PT100. It must be less than 2°C.

9.7 Difference between thermometer and mean value

Place thermocouple inside the Peltier module (Focalpak location, see picture below) and wait the stabilization of the thermometer.

Report the difference between thermometer and Mean value on the screen. It must be less than 4.5°C.



Stop pump and regulation and close “Maintenance” menu.

10.1 BK checklist

If not done yet Start Focal One. If version F, Close “FOneTherapy” application. Then in the SessionManager window, select the option “Close current session...”, then click on “Execute option”. Log in “Administrator” session and launch “Setup”. Go to “Technical File” menu, “US imaging” tab.

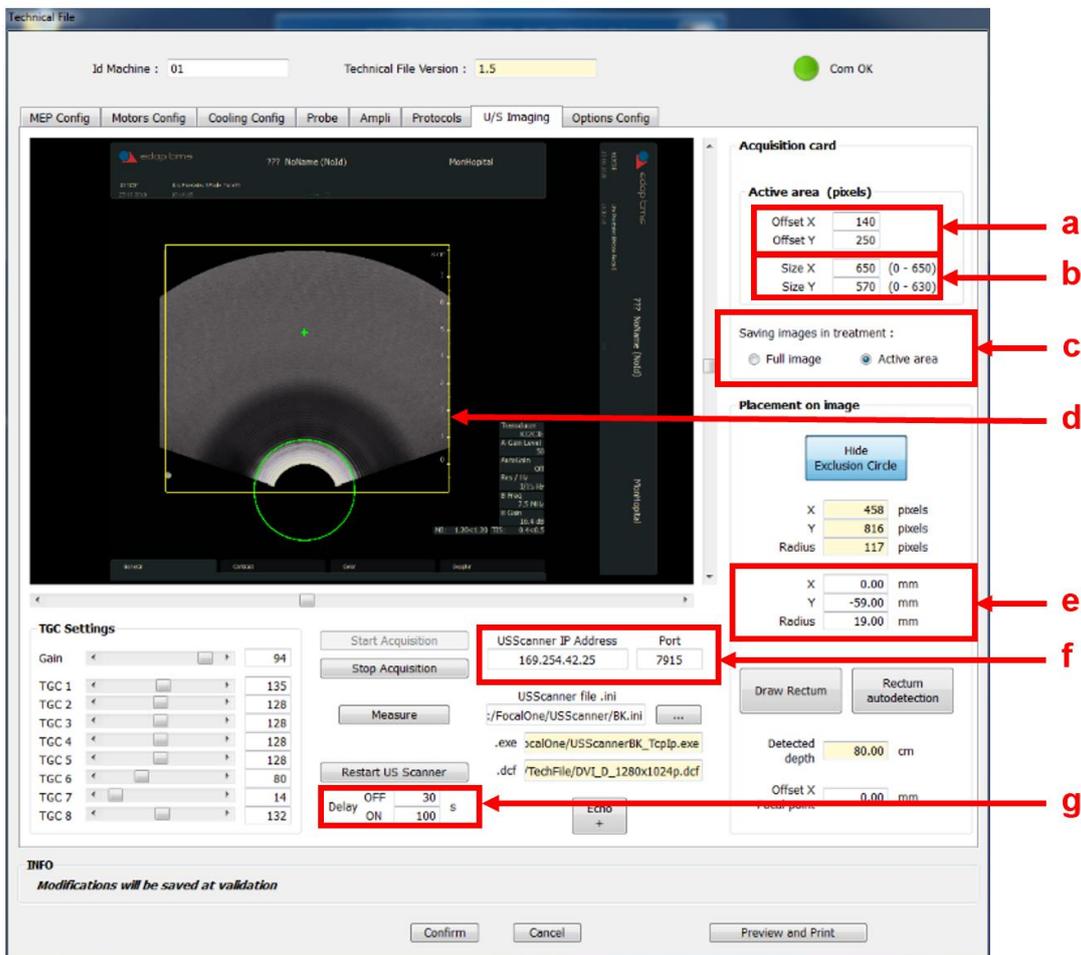
Perform U/S scanner preventive maintenance according manufacturer instructions. See specific table in the checklist.

Report only results for step with empty cells.

10.2 Parameters in Technical File

Report :

- a. Offset
- b. Size
- c. Active area
- d. Yellow box
- e. Exclusion circle coordinates
- f. IP address and Port number
- g. Delay



The screenshot shows the 'Technical File' software interface with the 'U/S Imaging' tab selected. The interface includes a central ultrasound image, various configuration panels, and a 'Restart US Scanner' dialog box. Red boxes and arrows highlight specific parameters:

- a. Offset:** Offset X (140) and Offset Y (250) in the 'Active area (pixels)' section.
- b. Size:** Size X (650 (0 - 650)) and Size Y (570 (0 - 630)) in the 'Active area (pixels)' section.
- c. Active area:** The 'Active area' radio button is selected under 'Saving images in treatment'.
- d. Yellow box:** A yellow box highlights the 'Placement on image' section, which includes the 'Hide Exclusion Circle' button.
- e. Exclusion circle coordinates:** X (0.00 mm), Y (-59.00 mm), and Radius (19.00 mm) in the 'Placement on image' section.
- f. IP address and Port number:** USScanner IP Address (169.254.42.25) and Port (7915) in the 'Restart US Scanner' dialog box.
- g. Delay:** Delay (OFF 30, ON 100 s) in the 'Restart US Scanner' dialog box.

Close “Setup” software.

10.3 Scanner parameters

Open Windows Explorer.

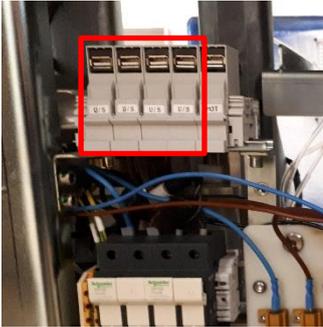
In Version F, go on C:\Focalone\Techfile

In Version G and more, go on D:\Config\Techfiles

Select the good .dcf file:

- Profocus ultraview orion.dcf for Ultraview
- DVI_D_1280x1024p.dcf for EB2300

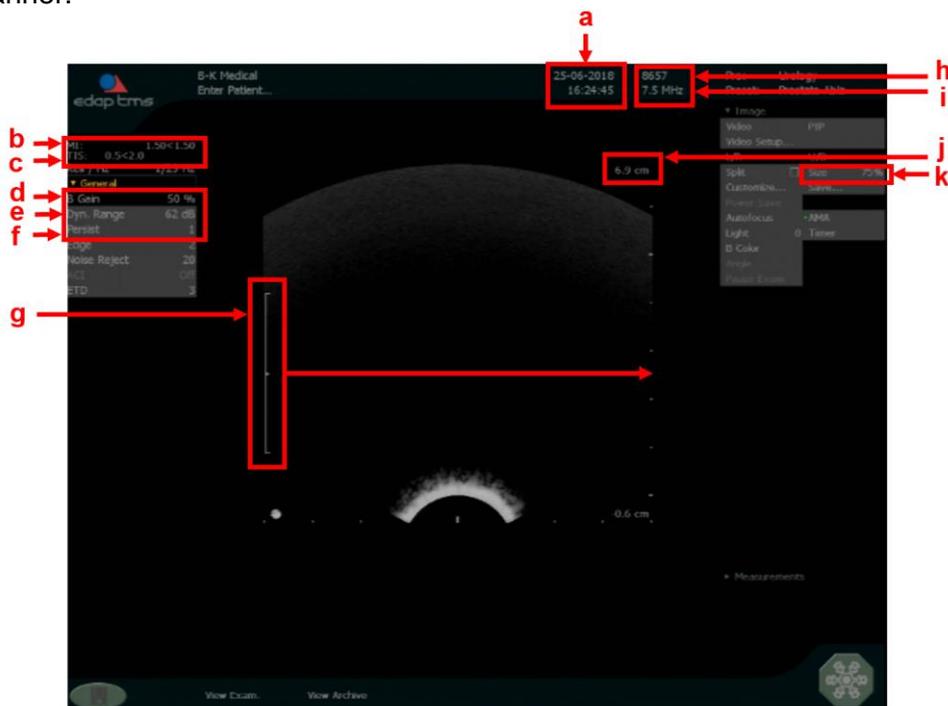
Connect an USB mouse on USB dock corresponding to ultrasound.



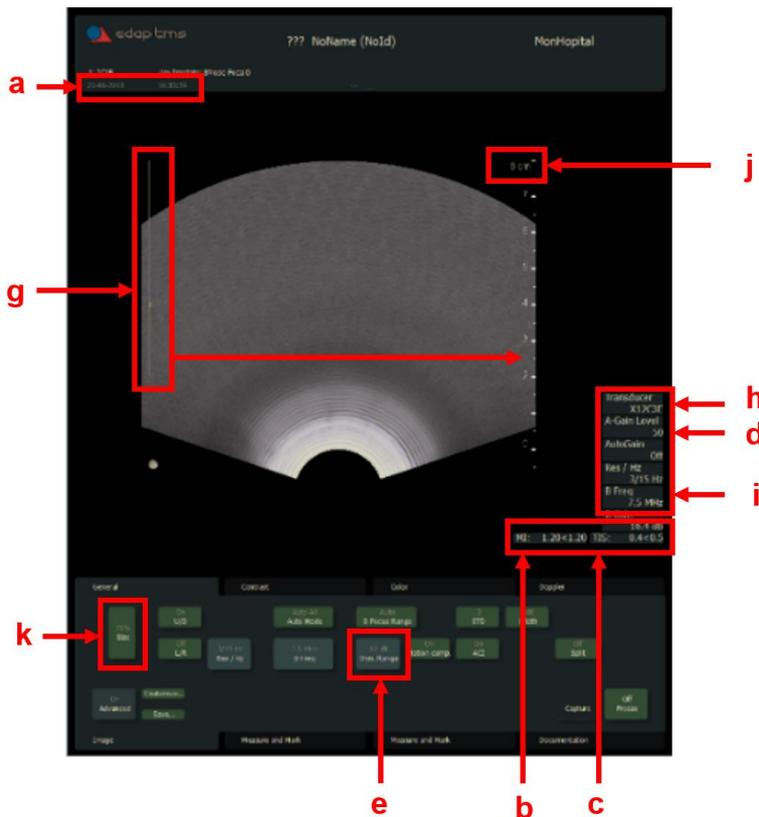
Report:

- a. Date and time
- b. Mi (Ultraview: 1.39/1.50 / EB2300 : 1.2/1.2)
- c. TIS (0.3/4.0Hz)
- d. Gain (50%)
- e. Dyn Range (62dB)
- f. Pers (Ultraview: 1 / EB2300: NA)
- g. Resolution (only 1 focal point at 25mm)
- h. Imaging cell (Ultraview: 6030 / EB2300: X12C3E)
- i. Frequency (7.5MHz)
- j. Depth (7,8cm or 8cm)
- k. Size (75% for version F – 100% for version G)

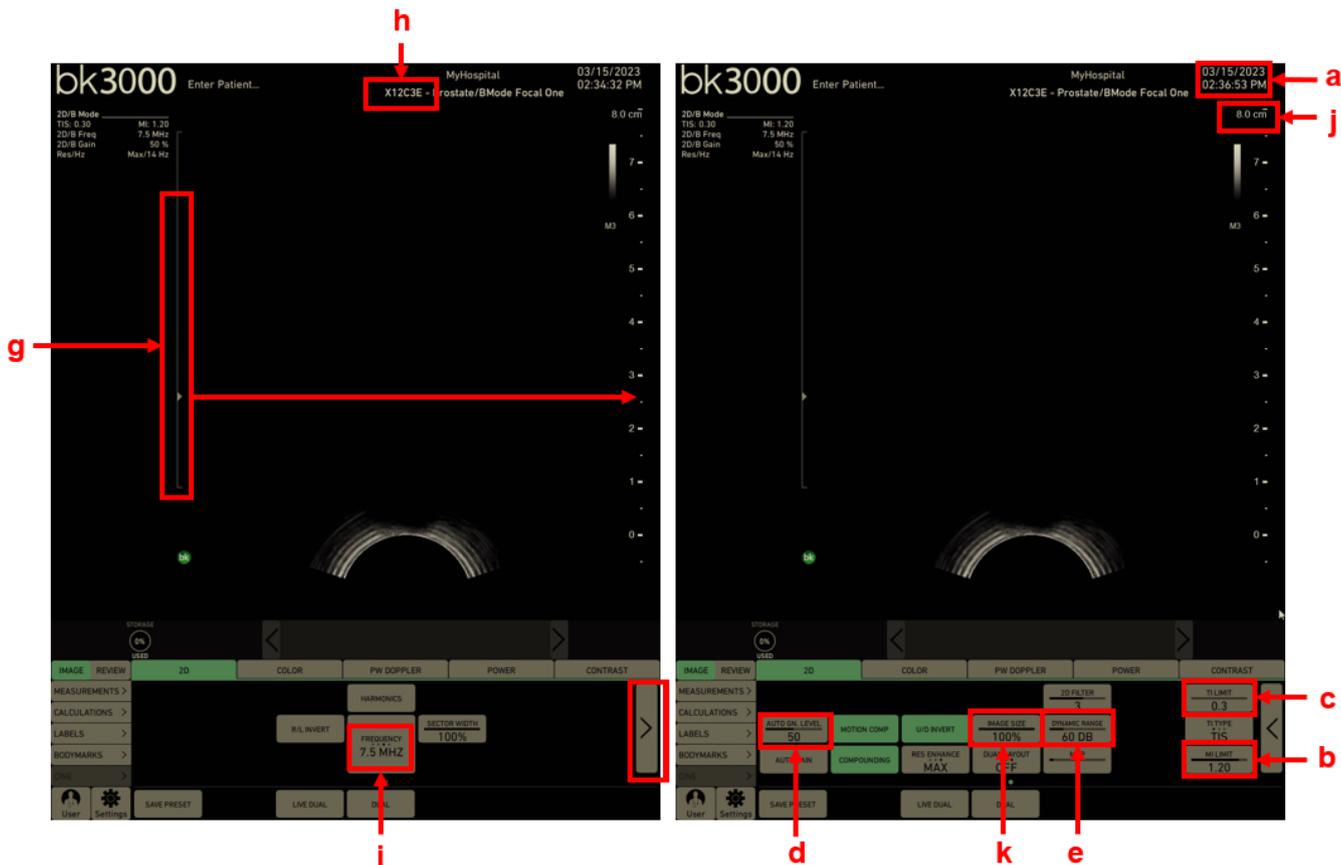
For Ultraview scanner:



For EB2300 W8 scanner:



For EB2300 W10 scanner:

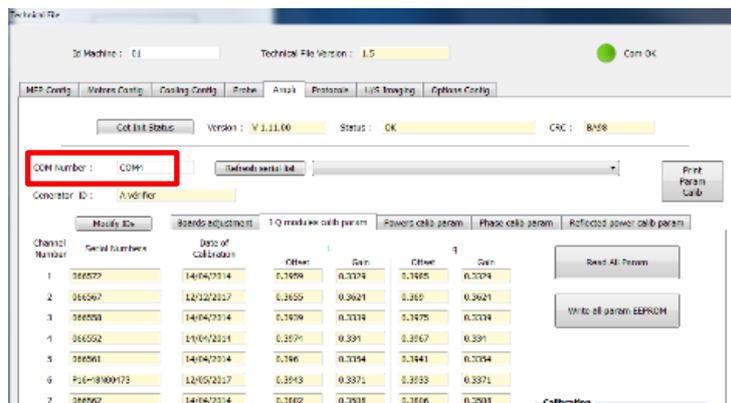


Close software.

11.1 Serial number and COM

If not done yet Start Focal One. If version F, Close “FOneTherapy” application. Then in the SessionManager window, select the option “Close current session...”, then click on “Execute option”. Log in “Administrator” session and launch “Setup”. Go to “Technical File” menu, “Ampli” tab.

Record Serial number and COM number.



Close “Technical File”.

11.2 Wires

Check the amplifier wiring. Verify that they are correctly connected.

Report results.



Replace all panels.

12

PROBE

This part must be done for each probe.
If there is not second probe, tick NA to the part.

WARNING

- Treatment probe has to be controlled 6 months after its first use (first treatment)
- If probe has not been changed, inform user.
- Probe power and imaging connectors are in position.

12.1 Probe serial number

Report probe the serial number from the box of the probe Or on the ultrasound connector of the probe. If the 2nd probe isn't available tick N/A.

12.2 Power connector VPC

Check that it inserts easily in the control panel socket, no pin are bent or loose, the lock is smooth and easy.

Report results.



12.3 Ultrasound connector

Check that it inserts easily in the control panel socket, no pin are bent or loose, the lock is smooth and easy.

Report results.



OR

12.4 Probe adaptation

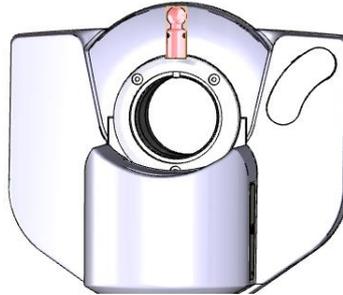
Check that probe adapts correctly without forcing onto its support.

Report results.

12.5 Holding pin

Check that holding pin correctly locks the probe each time the probe is fitted to the machine.

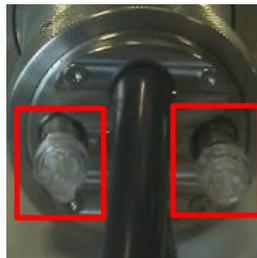
Report results.



12.6 Luer connections

Check that Luer connections are in good conditions on probe and FocalPak connectors are easy to connect.

Report results.



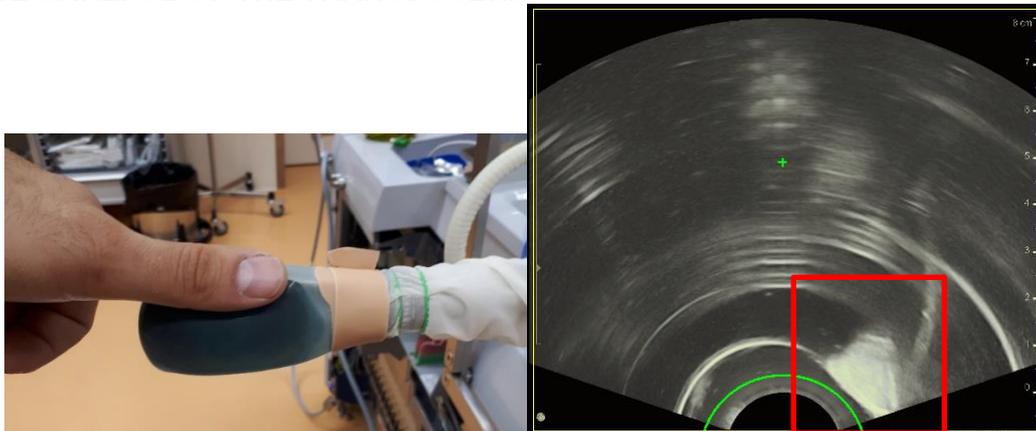
12.7 Image orientation

If not done yet Start Focal One. If version F, Close “FOneTherapy” application. Then in the SessionManager window, select the option “Close current session...”, then click on “Execute option”. Log in “Administrator” session and launch “Setup”.

Go to “Technical File” menu, “US imaging” tab.

Place finger on the upper parts of the cell and verify that shadow is on the right side of the image.

WARNING: BE CAREFUL OF THE TRANSDUCER.



12.8 Correspondence between software and data sheet

If not done yet Start Focal One. If version F, Close “FOneTherapy” application. Then in the SessionManager window, select the option “Close current session...”, then click on “Execute option”. Log in “Administrator” session and launch “Setup”. Go to “Technical File” and “Probe” tab. Check the correspondence between software and data sheet:

- Probe Serial Number
- Transducer Serial Number
- Imaging cell Serial Number
- Natural focal value
- Power for each Focal point (9 focal length)

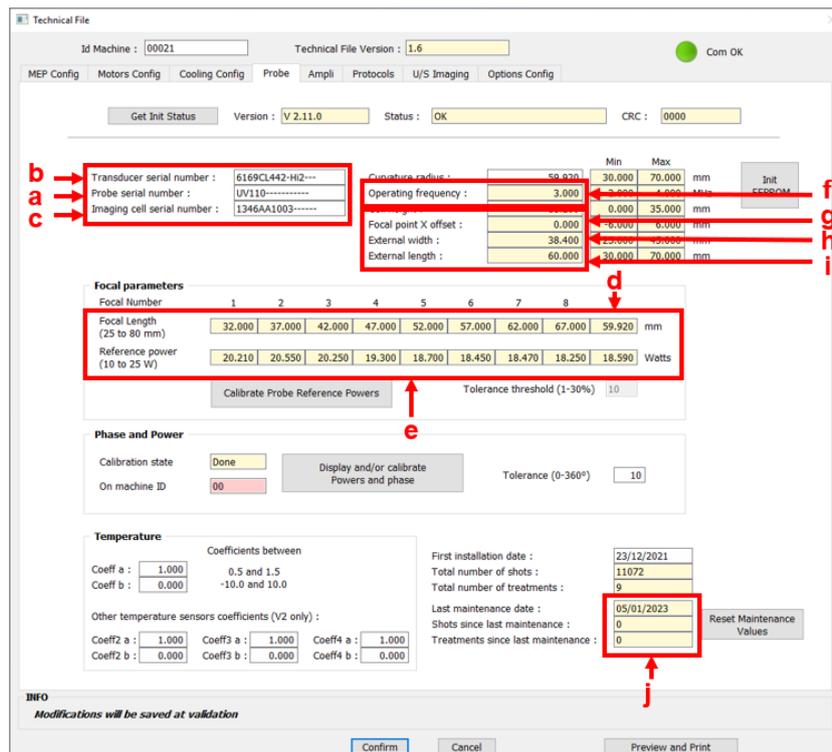
Check also in “Technical File”:

- Operating frequency = 3MHz
- Focal point X offset = 0
- External width = 38,4mm
- External length = 60mm

Report results.

- Record “last maintenance date” and “number of treatments since last maintenance”.

N° série Sonde UDI (Probe serial number)	UV 110	a
N° série transducteur (transducer identification)	6169CL442-HI2	b
Itération de contrôle (control iteration)	442-1-B	d
Focale naturelle (natural focal length)	59.92	c
Référence cellule échographique (ultrasound cell ref.)	1346AA1003	c
Puissance de référence (reference power)		
Focale naturelle (natural focal length)	18.59 W	
Focale 32 (Focal 32)	20.21 W	
Focale 37 (Focal 37)	20.55 W	
Focale 42 (Focal 42)	20.25 W	
Focale 47 (Focal 47)	19.30 W	e
Focale 52 (Focal 52)	18.70 W	
Focale 57 (Focal 57)	18.45 W	
Focale 62 (Focal 62)	18.47 W	
Focale 67 (Focal 67)	18.25 W	
Calibré le (calibrated on) JJ/MM/AAAA :	13-déc-22	
La sonde doit être renvoyée à Edap-TMS six mois après la date de la 1ère utilisation (premier traitement) suivant cette calibration. The Treatment Probe has to be changed and returned to Edap-TMS every 6 months after first treatment after this calibration		



Technical File

Id Machine : 00021 Technical File Version : 1.6 Com OK

MEP Config Motors Config Cooling Config Probe Ampli Protocols U/S Imaging Options Config

Get Init Status Version : V 2.11.0 Status : OK CRC : 0000

a → Transducer serial number : 6169CL442-HI2---
 b → Probe serial number : UV110-----
 c → Imaging cell serial number : 1346AA1003-----

Curvature radius : 59.920 Min 30.000 Max 70.000 mm
 Operating frequency : 3.000 Min 3.000 Max 4.000 MHz
 Focal point X offset : 0.000 Min -6.000 Max 6.000 mm
 External width : 38.400 Min 38.000 Max 38.800 mm
 External length : 60.000 Min 30.000 Max 70.000 mm

d → Focal parameters table:
 Focal Number: 1, 2, 3, 4, 5, 6, 7, 8
 Focal Length (25 to 80 mm): 32.000, 37.000, 42.000, 47.000, 52.000, 57.000, 62.000, 67.000, 59.920 mm
 Reference power (10 to 25 W): 20.210, 20.550, 20.250, 19.300, 18.700, 18.450, 18.470, 18.250, 18.590 Watts

e → Calibrate Probe Reference Powers Tolerance threshold (1-30%) 10

Phase and Power
 Calibration state: Done Display and/or calibrate Powers and phase Tolerance (0-360°) 10
 On machine ID: 00

Temperature
 Coefficients between: Coeff a: 1.000, Coeff b: 0.000 0.5 and 1.5, -10.0 and 10.0
 Other temperature sensors coefficients (V2 only): Coeff2 a: 1.000, Coeff2 b: 0.000, Coeff3 a: 1.000, Coeff3 b: 0.000, Coeff4 a: 1.000, Coeff4 b: 0.000

First installation date : 23/12/2021
 Total number of shots : 11072
 Total number of treatments : 9
 Last maintenance date : 05/01/2023
 Shots since last maintenance : 0
 Treatments since last maintenance : 0 Reset Maintenance Values

INFO
Modifications will be saved at validation

Confirm Cancel Preview and Print

13
CALIBRATION

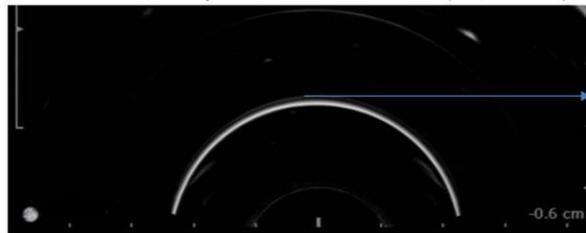
This part must be done for each probe.
 If there is not second probe, tick NA to the part.

If not done yet, connect DF probe to Focal One and insert it into its support

If not done yet connect to Administrator Windows session. Connect to “EDAP” hospital and open “Setup”.

If probe support is in parking position, click on “Maintenance”, go in “Probe-holder arm” tab, select the 4 axis and perform “mechanical origin”.

Install test tank and its support on Focal One rail. Deflate balloon and put the probe into the test tank. Go in “Video” tab, click on “Start Framegrabbing”, inflate or deflate balloon until its top matches a 12mm distance to imaging transducer (Use the tool “Measure”).



Go in “Cooling tab”, click on “Start pump”, tick “Using Probe Temperature” and then click on “Start Regulation”.

Remove bubbles in balloon.

Fill the test tank with cold water (or temper) until, around, 20mm to the top of tank.

Remove air bubble on the balloon surface and tank surfaces.

Close “Maintenance” menu.

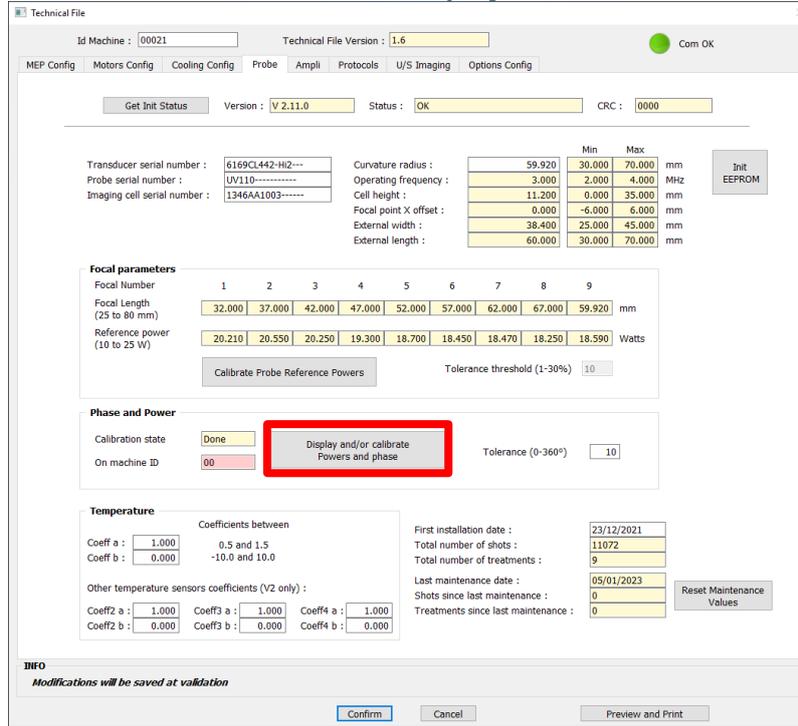
WARNING

- Probe power and imaging connectors are in position.
- Probe should be fully immersed into water, as cold as possible in the test tank.
- No other object is in the test tank.
- All panels need to be in position
- Transducer has to be moved away 10cm from test tank edge on transversal axis and in the middle of the tank on longitudinal axis.
- Probe should not be aligned with the tank but with a slight angle to avoid any reflection back to the transducer.
- Cooling has to be started with a complete FocalPak and balloon in good conditions.
- No bubbles are present into and onto the balloon and into test tank.

Be careful during this process because if one of these recommendations is not respected, transducer can be destroyed by reflected acoustics wave and cause irreversible damages

13.1 Probe calibration

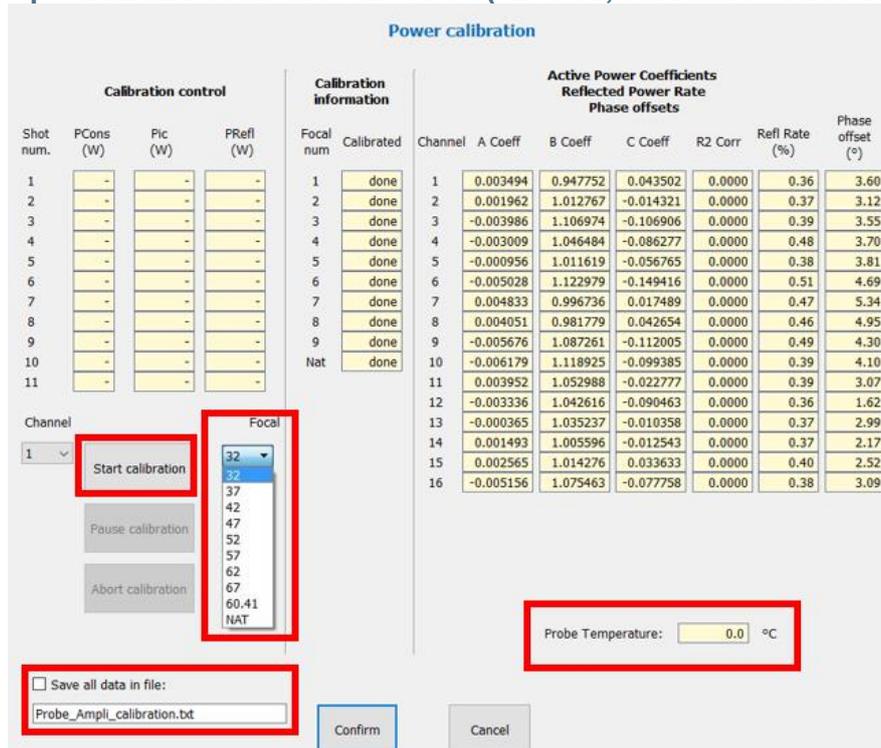
Go in “Technical Files”, in “Probe” tab, click on “Display and/or calibrate Power and Phase”.



Cooling system and pump should have started.

Check the box “Save all data in file:”. This will create one .txt file for each focal point under the maintenance folder on the D drive.

Wait for the probe temperature displayed in the lower right corner to stabilize between 12° and 14°C. Select first focal (32) and click on “Start calibration”, check as prompted that the probe is properly immersed without bubbles as requested and click on “Yes”. Wait for the calibration process to finish. Repeat previous steps until all Focals are calibrated (32 to 67, curvature radius value and NATural).



On “Trajectory Parameters”, Select 10 shoots in “Nb of firing in trajectory”.

On the left open a trajectory from file “.rpm” (C:\FocalOne\Maintenance if version F or D:\Config\Maintenance if version G or more) if existing. If not, enter values for each firing (refer to procedure described in the service manual MAN-049):

Shoot 1 = Focal 32 =: 1W per channel, Total = 16W

Shoot 2 = Focal 37: 2W per channel, Total = 32W

Shoot 3 = Focal 42: 3W per channel, Total = 48W

Shoot 4 = Focal 47: 4W per channel, Total = 64W

Shoot 5 = Focal 52: 5W per channel, Total = 80W

Shoot 6 = Focal 57: 6W per channel, Total = 96W

Shoot 7 = Focal 62: 7W per channel, Total = 112W

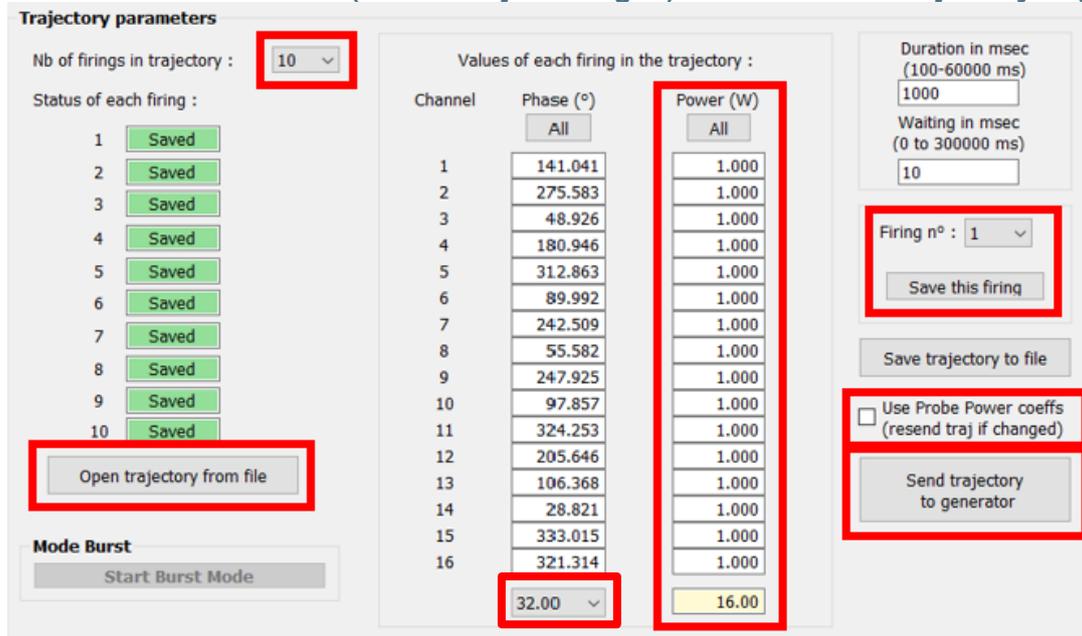
Shoot 8 = Focal 67: 8W per channel, Total = 128W

Shoot 9 = Focal 72: 9W per channel, Total = 144W

Shoot 10 = Natural focal: 10W per channel, Total = 160W

(don't forget to click on “Save this firing” after each modification to validate it)

Then tick “Use Probe Power coeffs (resend traj if changed)” and on “Send trajectory to generator”.



Trajectory parameters

Nb of firings in trajectory : 10

Status of each firing :

1	Saved
2	Saved
3	Saved
4	Saved
5	Saved
6	Saved
7	Saved
8	Saved
9	Saved
10	Saved

Open trajectory from file

Mode Burst
Start Burst Mode

Values of each firing in the trajectory :

Channel	Phase (°)	Power (W)
1	141.041	1.000
2	275.583	1.000
3	48.926	1.000
4	180.946	1.000
5	312.863	1.000
6	89.992	1.000
7	242.509	1.000
8	55.582	1.000
9	247.925	1.000
10	97.857	1.000
11	324.253	1.000
12	205.646	1.000
13	106.368	1.000
14	28.821	1.000
15	333.015	1.000
16	321.314	1.000
Total	32.00	16.00

Duration in msec (100-60000 ms): 1000
Waiting in msec (0 to 300000 ms): 10

Firing n° : 1

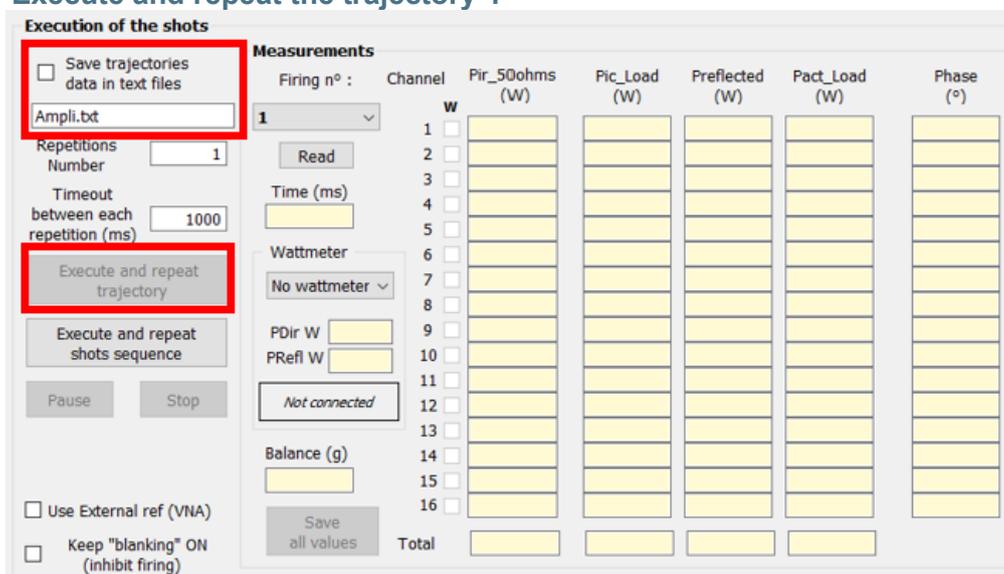
Save this firing

Save trajectory to file

Use Probe Power coeffs (resend traj if changed)

Send trajectory to generator

At the bottom of the windows on “Execution of the shots”, tick “Save trajectories data in text files” and add date and probe number to the name of the file. Check that the temperature is in tolerance and click on “Execute and repeat the trajectory”.



Execution of the shots

Save trajectories data in text files
Ampli.bt

Repetitions Number: 1
Timeout between each repetition (ms): 1000

Execute and repeat trajectory

Execute and repeat shots sequence

Pause Stop

Use External ref (VNA)
 Keep "blanking" ON (inhibit firing)

Measurements

Firing n° : 1

Channel	Pir_50ohms (W)	Pic_Load (W)	Preflected (W)	Pact_Load (W)	Phase (°)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
Total					

Wattmeter: No wattmeter

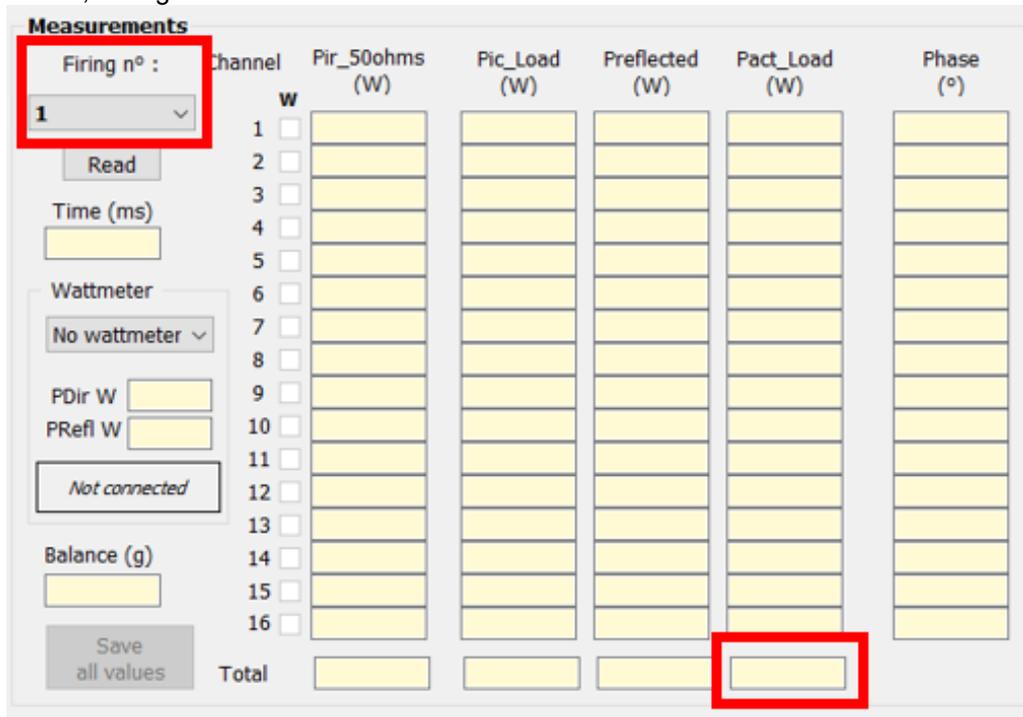
PDir W:
PRef W:
Not connected

Balance (g):
Save all values

14.1 Power results

On **“Execution of the shot”** report value **Total of Watts** into **“Pact_Load (W)”** for each shot.

Under **“Measurement”**, change the shot number to retrieve values.



Measurements

Firing n° : **1**

Read

Time (ms)

Wattmeter

No wattmeter

PDir W

PRef1 W

Not connected

Balance (g)

Save all values

Channel	Pir_50ohms (W)	Pic_Load (W)	Preflected (W)	Pact_Load (W)	Phase (°)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
Total					

14.2 Shoots into tolerances

At the end of the trajectory check that all values for all shoots are into tolerances.

Report results.

If there is red values, perform a calibration of the probe and restart this test.

Close **“Setup”**.

15

FUNCTIONAL TESTS

This part must be done for each probe.
 If there is not second probe, tick NA to the part.

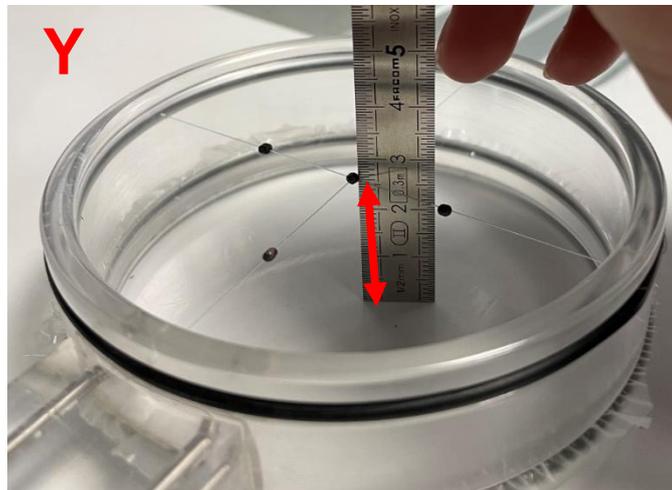
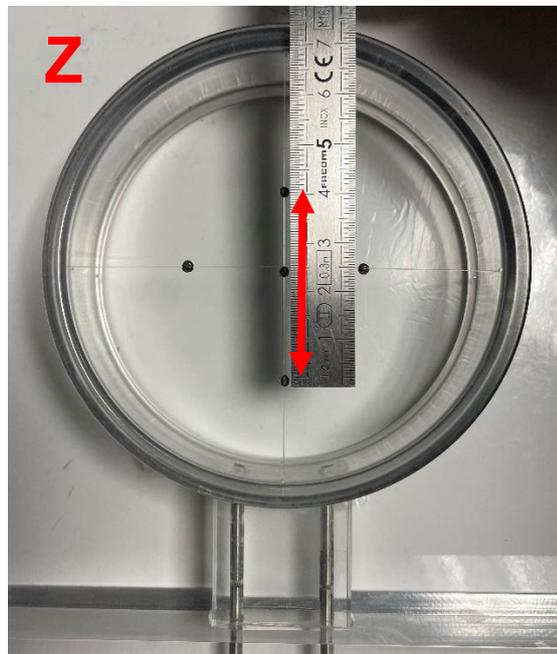
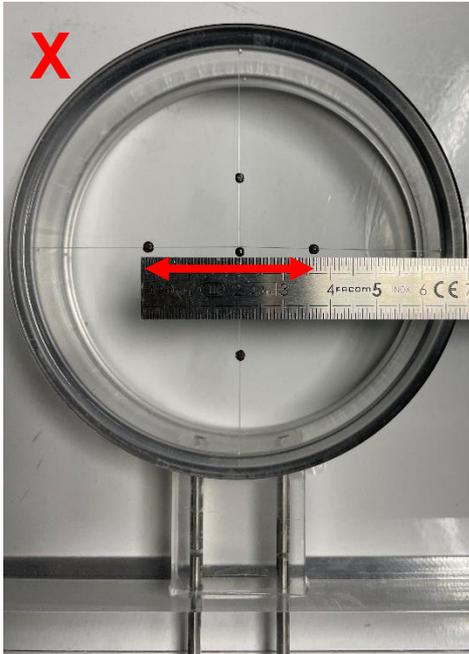
WARNING

- Probe imaging connector is in position.
- Probe power connector is NOT connected.
- Dummy Load is connected to VPC connector.

15.1 3D Measurements

Use test target tool for 3d measurement

Measure the real distance on the three direction: For X and Z take reference in the middle of balls, for Y take reference above the ball.



Report X, Z and Y measured values in 15.1.1, 15.1.2 and 15.1.3 parts.

Put target into the tank with the lead balls on the probe side.



 edap tms <small>Bringing New Horizons to Therapy</small>	INSTRUCTION	Réf : Version :	INS-367 E
Focal·One	PREVENTIVE MAINTENANCE		

Connect to “EDAP” hospital and change the level to 1.

Start “TherapyUro” software.

Inquire patient data in this format:

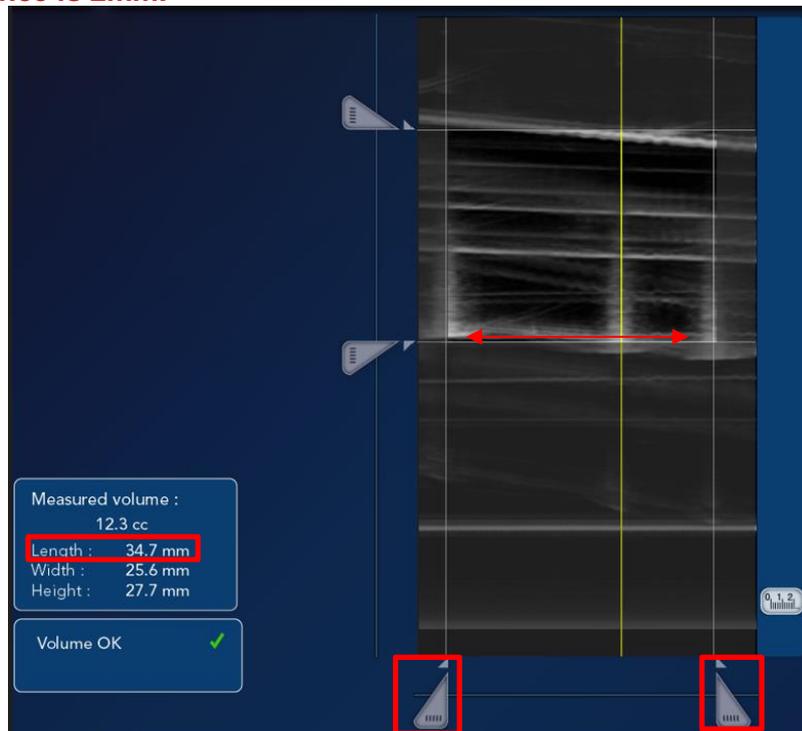
- Name: Probe XXX (serial number of the probe)
- First name: 3D test
- Case ID: FOXXX(serial number of machine)+trigram of engineer
- Date of birth: today’s date -100 years
- FocalPak number
- Treatment protocol: “93.Test no temp”
- (Version G5 and H only) Treatment strategy: “Other”
- (Version G5 and H only) Type of anaesthesia: “Other”

Go to the next step “Probe Insertion” and then “Acquisition”.

15.1.1 Measurement of X (longitudinal) axis

Thanks to the vertical cursors, measure longitudinal (length on the application, Apex-Base direction for patient), into “Volume” windows. Place the cursors at the middle of both balls.

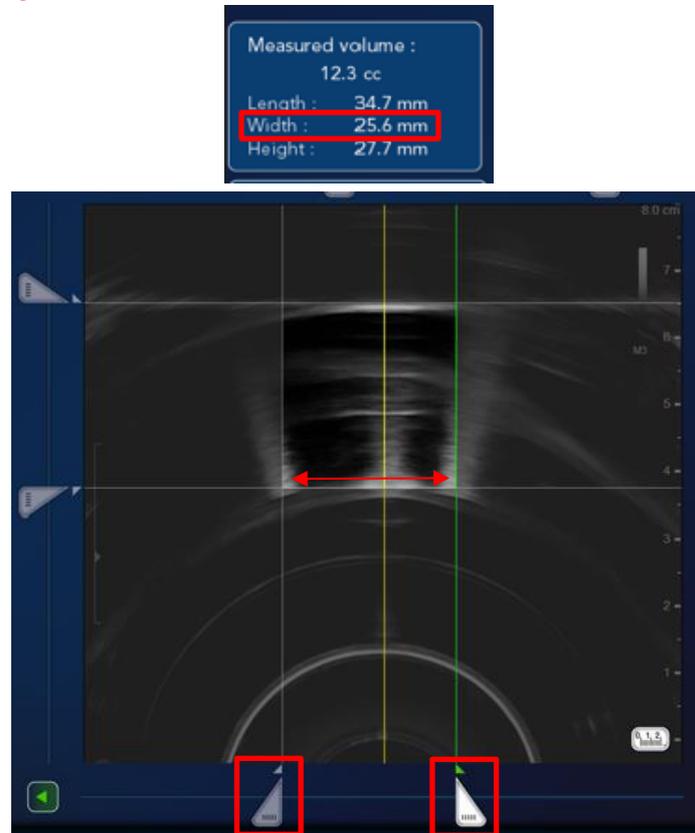
Report result. Tolerance is 2mm.



15.1.2 Measurement of Z (vertical) axis

Thanks to the vertical cursors, measure vertical (width on the application, left-right direction for patient), into "Volume" windows. Place the cursors at the middle of both balls.

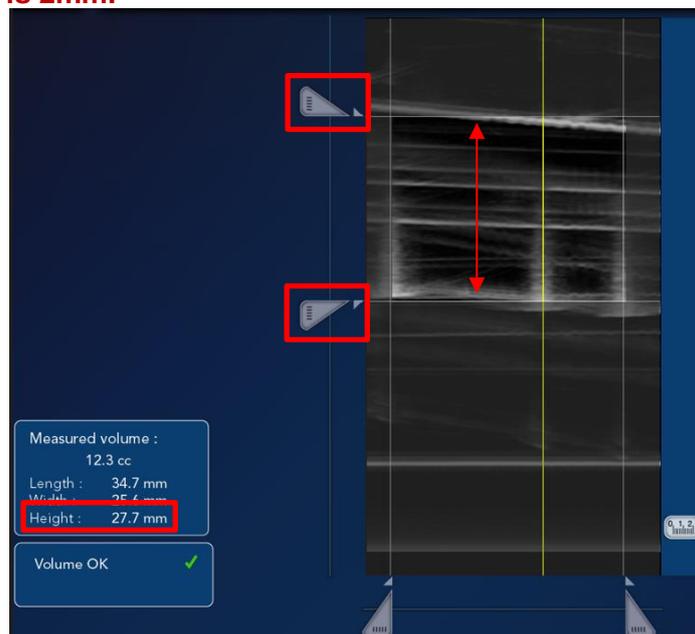
Report result. Tolerance is 2mm.



15.1.3 Measurement of Y (depth) axis

Thanks to horizontal cursors, measure depth (height on the application, antero-posterior direction for patient), into "Volume" windows. Place one cursors on the membrane and the other on the front of the ball.

Report result. Tolerance is 2mm.

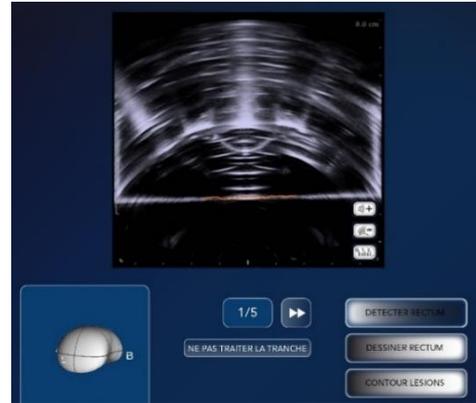


Go to next step "Treatment area".

15.2 Rectum detection functions

15.2.1 Detection

In longitudinal imaging, define 1 block. Then, go to next step “Lesions Repartition”. Reverse test target tool (with the membrane on the probe side). Use tool like rectum wall with deflated probe balloon. Then click on “Rectum detection”.



Check that rectum is automatically detected on the membrane (orange line appears).
Report result.

15.2.2 Transverse corrections

Define trajectories and start treatment.
 Move the rectal wall between 1 and 4mm from original position.
 Check that the probe moves automatically to follow the rectal wall displacement.
 Rectal wall is detected and treatment doesn't stop after correction.
Report results.

15.2.3 Error message

Move the rectal wall more than 4mm from original position and check that error appears.
Report result.
 Cancel treatment and close “TherapyUro” software. Remove dummy load and connect main probe power connector.

 edap tms <small>Bringing New Horizons to Therapy</small>	INSTRUCTION	Réf : Version :	INS-367 E
Focal·One	PREVENTIVE MAINTENANCE		

16	TREATMENT SIMULATION
<p>This part must be done for each probe. If there is not second probe, tick NA to the part.</p>	

WARNING

- Probe power and imaging connectors are in position.
- Probe should be fully immersed into water, as cold as possible in the test tank.
- No other object is in the test tank.
- All panels need to be in position
- Transducer has to be moved away 10cm from test tank edge on transversal axis and in the middle of the tank on longitudinal axis.
- Probe should not be aligned with the tank but with a slight angle to avoid any reflection back to the transducer.
- Cooling has to be started with a complete FocalPak and balloon in good conditions.
- No bubbles are present into and onto the balloon and into test tank.

Be careful during this process because if one of these recommendations is not respected, transducer can be destroyed by reflected acoustics wave and cause irreversible damages

16.1 Initialization

Connect to Focal One Windows user session, connect to “EDAP”, start “TherapyUro” software, activate level 1 and click on “Start Treatment”.

Check that no error message occur and motors centring is done.

Report results.

Then go to next window.

Inquire patient data in this format:

- Name: Probe XXX (serial number of the probe)
- First name: PM test
- Case ID: FOXXX (serial number of machine) + trigram of engineer
- Date of birth: today's date -100 years
- FocalPak number
- Treatment protocol: “**92.Test no rect**”
- (Version G5 and H only) Treatment strategy: “Other”
- (Version G5 and H only) Type of anesthesia: “Other”

Go to the next step of treatment.

Fill balloon to the orange line from imaging cell.

Move manually probe close to the border of the test tank.

Select 50mm between bladder side and apex side.

After volume measurement, go to the next step, right click on the prostate representation and select left hemiablation.

Select area of treatment to compose 4 blocks and 20 slices (33mm).

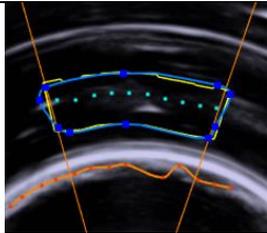
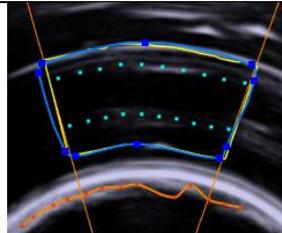
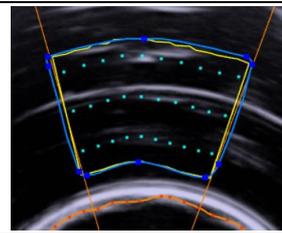
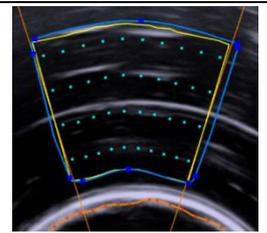
Go to the next step.

16.2 Firing test

For preventive maintenance apply the entire procedure described below.
 For probe installation, see the dedicated procedure described at the end of this part.

On Treatment Area step select right hemiablation. Draw balloon wall as a rectum (click on detect rectum).

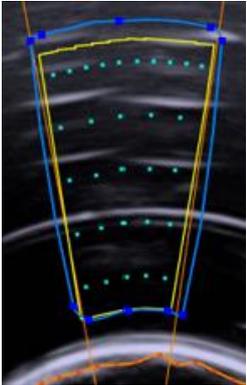
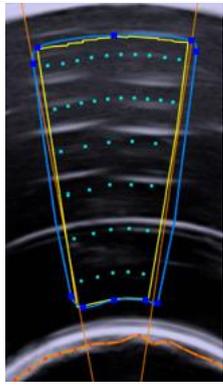
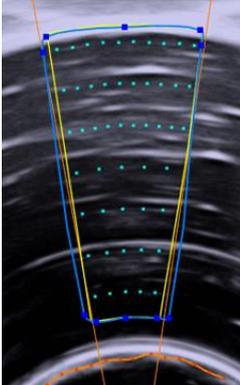
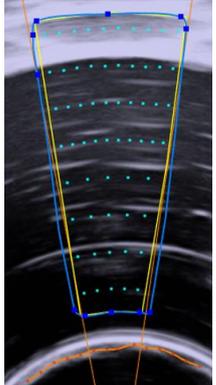
For the 4 first blocks: Click on “Lesion contour” and draw 10 lesions as shown in the table below:

LESION CONTOUR				
Block N°	1	2	3	4
Slices	5	5	5	5
Focal	32	32, 37	32, 37, 42	32, 37, 42, 47
Contouring lesions				
Instructions	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.

Click on “New Area”.

Move manually probe close to the border of the test tank. Select 50mm between bladder side and apex side. After volume measurement, go to the next step, right click on the prostate representation and select left hemiablation. Select area of treatment to compose 4 blocks and 20 slices (33mm). Go to the next step.

For the 4 last blocks: Click on “Lesion contour” and draw 10 lesions for the top line as shown in the table below:

LESION CONTOUR				
Block N°	1	2	3	4
Slices	5	5	5	5
Focal	32, 37, 42, 47, 52	32, 37, 42, 47, 52, 57	32, 37, 42, 47, 52, 57, 62	32, 37, 42, 47, 52, 57, 62, 67
Contouring lesions				
Instructions	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.

For each area, block and slice, check and report that:

- Treatment area is correctly defined.
- Lesions are correctly displayed.
- Endo-rectal probe moves to the next slice.
- Localization process is successfully completed.
- Endo-rectal probe moves from lesion to lesion.
- Treatment area is successfully completed.
- Treatment duration

At the end of the treatment, open report and save it the report in the “save” folder in PDF.

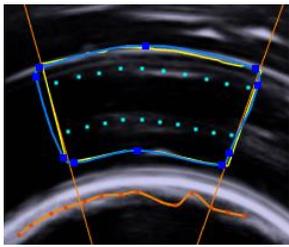
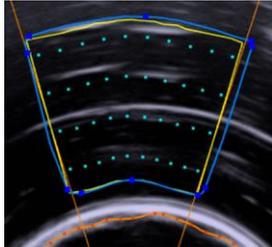
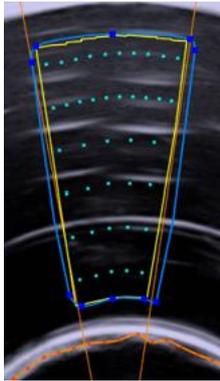
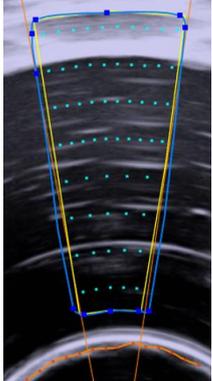
For probe installation only (FMU-231):

On Treatment Area step select Total ablation

Draw balloon wall as a rectum (click on detect rectum).

For the 4 blocks:

Click on “Lesion contour” and draw 10 lesions as shown in the table below:

Block N°	1	2	3	4
Slices	5	5	5	5
Focal	32, 37	32, 37, 42, 47	32, 37, 42, 47, 52, 57	32, 37, 42, 47, 52, 57, 62, 67
Contouring lesions				
Instructions	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.	Click on “Start firing” and wait end of 5 slices treatment.

For each area, block and slice, check and report that:

- Treatment area is correctly defined.
- Lesions are correctly displayed.
- Endo-rectal probe moves to the next slice.
- Localization process is successfully completed.
- Endo-rectal probe moves from lesion to lesion.
- Treatment area is successfully completed.
- Treatment duration

At the end of the treatment, open report and save it the report in the “save” folder in PDF.

17.1 Printer test

If printer is present, print report and verify that there is ink cartridge available.

Report result.

17.2 Files backup and retrieve

Step to be done only at the end of the preventive maintenance.

- If there is two probe: Do it after the second probe and tick NA for the first probe
- If there is only one probe: Do it for the first probe.

Go in administrator session.

Copy files detailed in the table below and according to the checklist in the backup folder "D:/Saves/XXX" created previously.

Files	PM (FMU-431)	Probe installation (FMU-231)	Path on F version	Path on G and H versions
DICOM.ini	X	-	C:\FocalOne\DICOM	D:\Config\Ini\DicomGateway
BK.ini	X	-	C:\FocalOne\USScanner	D:\Config\Ini\USScannerBK
ErrorFOXXX.txt	X	-	C:\FocalOne	D:\Logs\FOneTherapy.exe
HiFusionConfigFile.ini	X	-	C:\FocalOne	D:\Config\Ini\HiFusion
HospitalData.dat	X	-	C:\FocalOne	D:\Clinical
SessionManager.ini	X	-	C:\SessionManager	D:\Config\Ini\SessionManager\BK
FocalPak.txt	X	-	C:\FocalOne	D:\Config\FocalPak
Simulation treatment folder (total of minimum 4 last folders, two for 3d test and two for treatment simulation)	X	X	D:\FocalOne\Img\EDAP\EDAPXXXX (were the XXXX have to be replace by the number of treatment)	D:\Clinical\TreatmentData\EDAP
Calibration files of two probes	X	X	C:\FocalOne\Maintenance	D:\Config\Maintenance
Random	X	-	C:\FocalOne\Maintenance	D:\Config\Maintenance

Copy "D:\Saves\XXX" folder with all files copied to an external USB stick.

Report action completion.

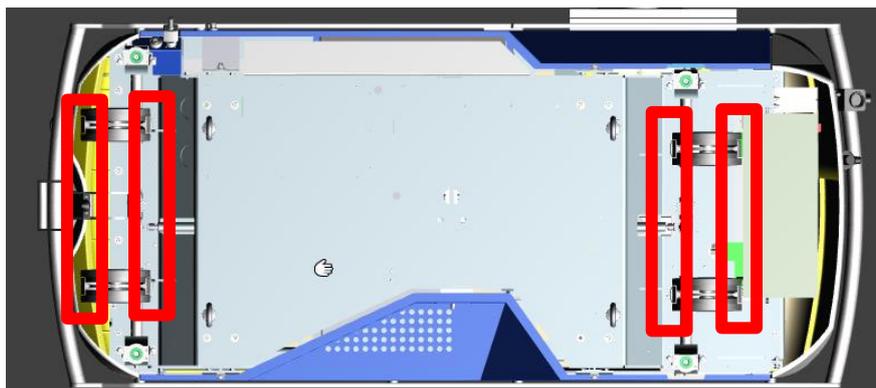
On SessionManager restart and log as "Focal One" windows session twice.

Shut down the machine.

17.3 Wheels

Check if during displacement, wheels don't touch panels or chassis in each side.

Report results.



 edap tms <small>Bringing New Horizons to Therapy</small>	INSTRUCTION	Réf : Version :	INS-367 E
Focal·One	PREVENTIVE MAINTENANCE		

17.4 Panels

Inspect all panels.

Make sure they are properly fitted (aligned) clean and in good condition.

Check that you can open and close easily the two long panels (with the special opening tools).

Report results.

17.5 Panels ground cables

Check that ground cables are firmly attached to long panels.

Report results or tick NA if there are plastic panels.

18	ELECTRICAL SAFETY TEST
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If IEC 62353 electrical safety tests are required by local regulation only:

Perform Focal One electrical safety test according **INS-360** Electrical safety test instruction.

Report results in **FMU-224** Maintenance checklist EST.

If local regulation requests other test, perform test accordingly and fill test report.

Report test completion and join check-list or test report.

If no regulation applies, tick the NA box.

19	COMMENTS / DOCUMENTS
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If existing, list other documents completed linked with this preventive maintenance (for example the electrical safety test checklist). Complete "Title" and "Description".

If necessary, summarize and/or add comments in the section dedicated.

20	REPORTING / APPROVALS
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Send by mail all documents completed and files saved (ZIP format) to your **local referent technical engineer** and to **ccc@edap-tms.com**