This document is linked with the Check List I-Sys TMS 509673E

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 or hardware update).

Copy starting point to another file, update required fields (date, service reports numbers etc…).

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

Always use "**administrateur**" windows login, "**T.M.S.**" hospital' "**admin**" user and "**Level 1**" usage level to perform any test.

PREREQUISITS

Requested tools:

- Set of metric Allen wrench.
- Set of screwdrivers.
- Graduated metric steel ruler.
- Painter tape.
- Regular maintenance kit.
- New electrode.
- Digital Multi-Meter (report metrology information in dedicated filed on the bottom of checklist page 1.
- Report presence of tool delivered with system in dedicated filed on the bottom of checklist page 1.

Electrical safety test:

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

0. SYSTEM IDENTIFICATION

The Identification must be complete during the Installation. If the Identification has never been done before, complete it.

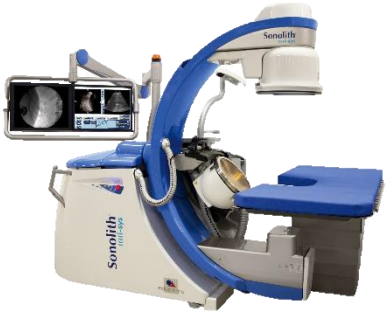
Report identification information from installation or first regular maintenance to all following maintenances.

0.1 Module

- Identify and report module type among the three available types as shown below:

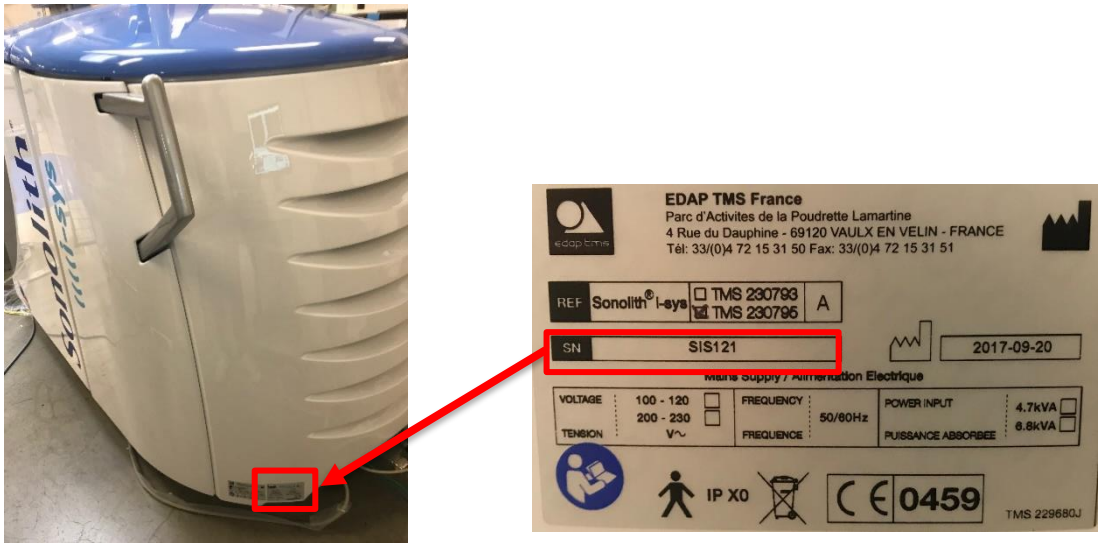
STANDARD

AUPS



VISIOTRACK

- Report firing module serial number indicated on the identification plate located on the rear cover of the module as shown below:



- Report presence of remote console by ticking IHMD box

0.2 Table

- Identify and report module type and serial number (label indicated by red arrow):

I-SYS Table

KARBON F Table

KARBON S Table

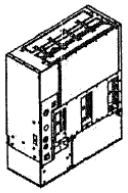
0.3 Image intensifier size

12” or 32cm

9” or 21cm

0.4 U/S Scanner

- If present, report if U/S scanner is internal or external.
- Report model among all compatible U/S scanners.



Internal:

Profocus/UV EB2300

External:

Profocus/UV Flexfocus EB3000

- Report serial number from identification plate.

0.5 Probe

- If available, identify the U/S probe associated with the system. Among all compatible U/S probes, most common are B&K 8823 and 8830 type. If another U/S probe type is associated, report type into dedicated field
- In addition, report the Serial number of the probe

0.6 U/S Com. Cable

If present, identify and report communication type:

- If U/S scanner cable harness includes DB9 connector, tick “**RS232**”
- If U/S scanner cable harness includes RJ45 connector, tick “**TCP/IP**”

0.7 Operating system

- Start system normally.
- Choose “**Cancel**” at hospital identification.
- Choose “**Close current session and login on another name**”.
- Login “**administrateur**” windows user with password provided during training.
- Right click on “**My Computer**” icon and select “**Properties**”.
- Report operating system version and close all windows.

0.8 VisioTrack reflectors version

Identify and report version of the VisioTrack Spheres. (The NDI spheres are no longer supported)

Pre-requirements for software identification:

- Start database interface software
- Log as "**T.M.S.**" hospital with password given during technical training.
- Let system software initialize perform necessary action if requested.
- Perform Visio-Track daily test if necessary.
- If possible a connect keyboard to system or use remote console.

0.9 ESWL

- On the touch screen, report the software version indicated at the top left corner of the interface.

0.10 BDD

- Go in "**Treatment**" tab and press "**ESWL**"
- If an "**1200**" error pop up press "**Ignore**"

For Windows 7 operating system only:

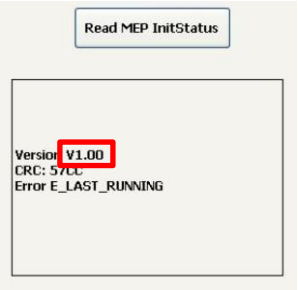
- Report software version indicated in top right corner, as displayed on the right.

For Windows XP operating system only:

- Press "Parameters" on the lower left corner of patient list.
- Report software version indicated on the lower left corner of parameters windows, as displayed on the right.

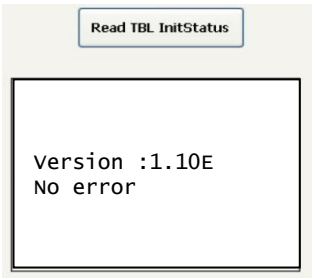
For all Systems, go back to main menu.

0.11 MEP



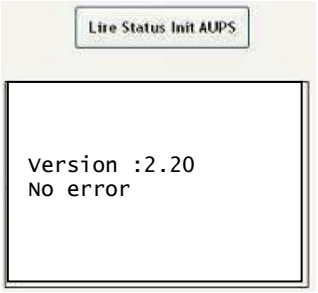
- If not done yet, go in "**Settings**" tab
- Press on "**Usage Level**".
- Enter maintenance password given during technical training.
- Check that "**Level 1**" appears on the top left corner of the screen.
- Press on "**Maintenance**".
- Go in "**EEPROM**" tab and press "**Read MEP InitStatus**"
- Report MEP version displayed after "**Version**" char as displayed on the right.

0.12 Table



- Press "**Read TBL InitStatus**"
- Report Table version displayed after "**Version**" as displayed on the right.

0.13 AUPS



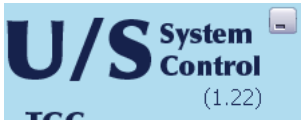
<u>For systems with AUPS only</u>, if not report "N/A".

- Press "**Read AUPS InitStatus**" .
- Report Table version displayed after "**Version**" as displayed on the right.

0.14 U/S Scanner interface

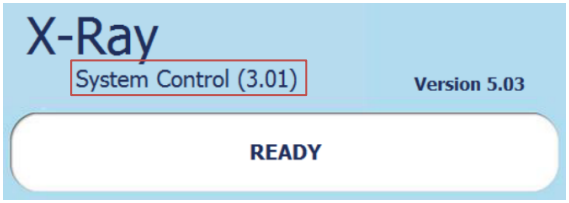
- Press "**Quit**" to close maintenance interface.
- Press "**Technical Files**" then go in "**Imaging**" tab.

<u>For system with no U/S scanner</u>, report "N/A".
<u>For "AUPS" and "Visio-Track" system</u>:



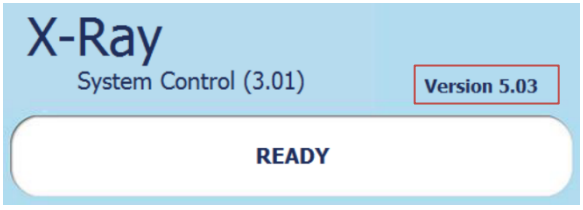
- Press "**Calibrate Ultrasound Scanner Imaging**" .
- On the windows that appears press on "**U/S+**".
- Report software version indicated in top right corner, as displayed on the right.
- Press on "**U/S+**" to discard interface.
- Press "**Cancel**" to quit U/S imaging calibration page.

0.15 X RAY DUNLEE



- If not done yet, press "**Technical Files**" then go in "**Imaging**" tab.
- Press "**Calibrate X-Ray Imaging**"
- On the windows that appears press on "**X-ray+**"
- In "**RX Dunlee**" interface appear, report the software version of "**RX Dunlee**" is located under the title "**X-Ray**" as displayed on the right

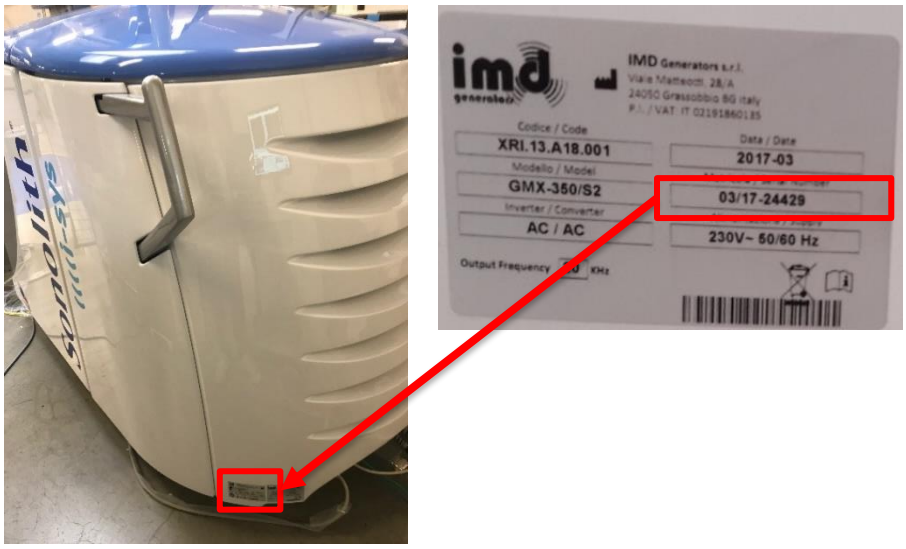
0.16 X RAY PLC



- Report the software version of PLC controller is located under on the right of the screen

0.17 X-Ray rack serial number

- Report X-Ray rack serial number



0.18 X-Ray monoblock number

- Report X-Ray monoblock serial number

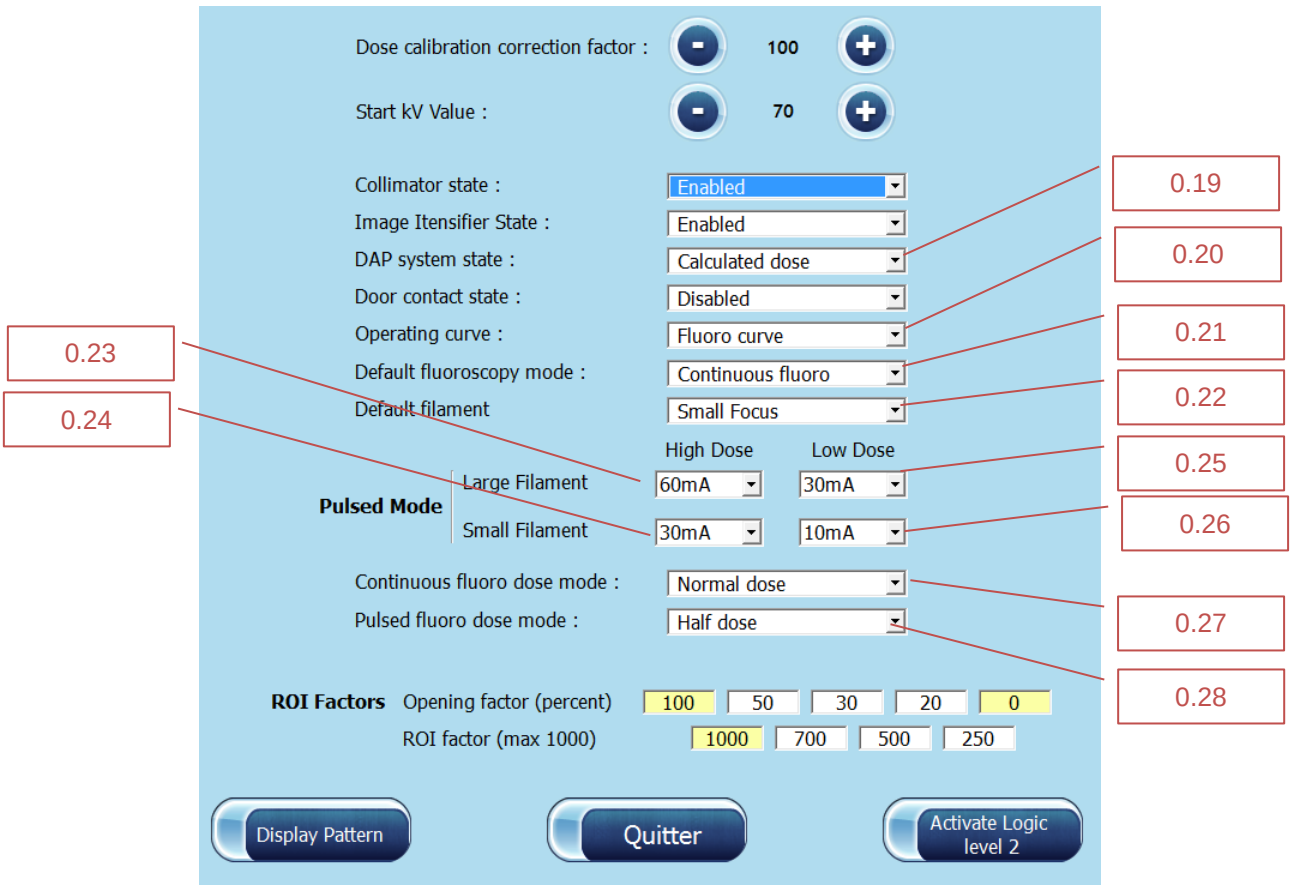
Pre-requirements for X RAY identification:

For all Windows XP version and windows 7 up to B version:

- Press on "**Service**" button to display default settings.
- Report in the checklist table the values requested as see below.

For windows 7 C version and above:

- Press "**X-ray+**" to discard "**RX Dunlee**" interface.
- Press "**Cancel**" twice to quit "**Technical File**" page.
- Press on "**Quit**" to close applicative interface
- Double-click on "**RX Dunlee**" desktop shortcut. (1)
- "**RX Dunlee**" start in standalone mode.
- Click on "**Service**". (2)
- On the Service menu, report in the checklist table the values requested as see below.



s

1. CONTROL TOOLS

1.1 Digital Multi-Meter

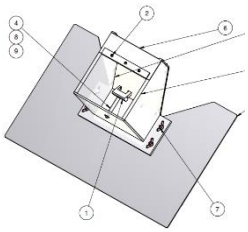
If local regulation requires it, report digital multi-meter serial number and validity period from metrology follow-up.
If regulation doesn't require it, report digital multi-meter serial number only.

1.2 X-Ray KV Meter

If local regulation requires it, report KV meter serial number and validity period from metrology follow-up.
If regulation doesn't require it, report KV meter serial number only.

1.3 X-Ray Dose Meter

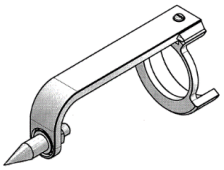
If local regulation requires it, report dose meter serial number and validity period from metrology follow-up.
If regulation doesn't require it, report dose meter serial number only.



1.4 U/S accuracy and fragmentation test tool

- For Visio-Track or latest systems.
- Report presence of **TMS233020** accuracy and fragmentation test tool

1.5 AUPS peak tool TMS230290

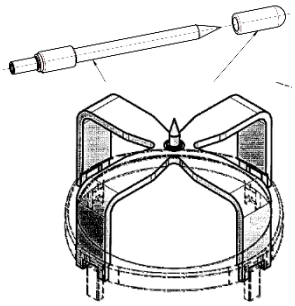


- For system equipped with AUPS localization, check that AUPS peak tool is present and in good condition.
- Report inspection result.

1.6 USB Peripherals

- Check that USB keyboard is present, in good condition and functional.
- Check that USB mouse is present, in good condition and functional.
- Report inspection result.

1.7 F2 simulators:

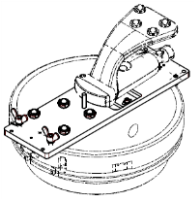


- Check that F2 simulator peak **TMS238187** with its protection is present and in good condition.
- Check that F2 peak simulator **TMS236466** for use with membrane is present and in good condition.
- Report inspection result.

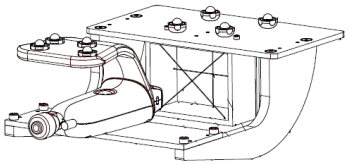
1.8 Visio-track calibration tool(s)

For I-sys Visio-Track only:

- Check that Visio track calibration plate **TMS238255** is present and in good condition.
- Check that Visio track V2 calibration tool **TMS237415** is present and in good condition
- Report inspection result.



TMS238255

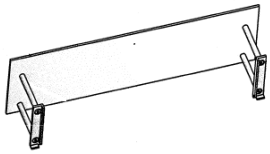


TMS237415

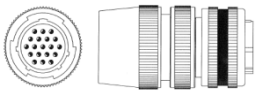
1.9 Table accessories

For I-sys with KARBON table only:

- Check that calibration plate **TMS237284** is present and in good condition.
- Check that table plug **TMS230961** is present and in good condition.

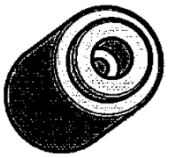


TMS230847



TMS230961

1.10 X-Ray tank alignment tool



- Check that monoblock centering tool **TMS229030** is present and in good condition.

1.11 Fragmentation test tool

For systems with AUPS only

- Check that fragmentation test tool **TMS229799** is present and in good condition.

2. REMOTE CONTROLLERS

If not done yet, start system normally. At hospital prompt, press "**Cancel**". In power management interface choose "**Close current session…**" and log in as "**administrateur**" windows user with password.
Start treatment interface in standalone mode. In "**Settings**" tab, press "**Usage Level**" button and enter maintenance password.

2.1 Module control panel buttons

- Check all buttons on module control functions correctly (mind that U/S scanner display is deactivated at button release on system with external U/S scanner).
- Report inspection result.

2.2 Module remote controller buttons

- Go in "**Settings**" tab then press "**Maintenance**" button.
- Go in "**MEP digital I/O**" tab and press "**Continuous read**" in the right side of the screen.
- Press all remote button one by one and check in "**XP13**" box that functions associated with button is correctly displayed.
- Report inspection result.
- Press "**Stop Continuous**" button

2.3 Table remote controller buttons

- Go in "**TBL I/O**" tab and press "**Continuous read**" on lower right corner of the screen.
- Press all remote button one by one and check in "**XP13**" box that functions changed (action displayed might not be correctly displayed).
- Report inspection result.
- Press "**Stop Continuous**" button

2.4 Cables

- Check that all cables of remote controllers are in good condition
- Report inspection result

2.5 Leds and backlights

- Check that remote backlights work properly when room light is dimmed.
- Set generator in parking 0° position.
- Go in "**TBL Movement**" tab, in mode box select "**Maintenance(5)**".
- Check that all green LEDs are blinking.
- In mode box select "**Litho7(1)**" and move table on any axis to its limit.
- Check that red LEDs is blinking.
- Report inspection result.
- Set generator in parking 50° position.

3. PARTS TO REPLACE (NOT FOR INSTALLATION)

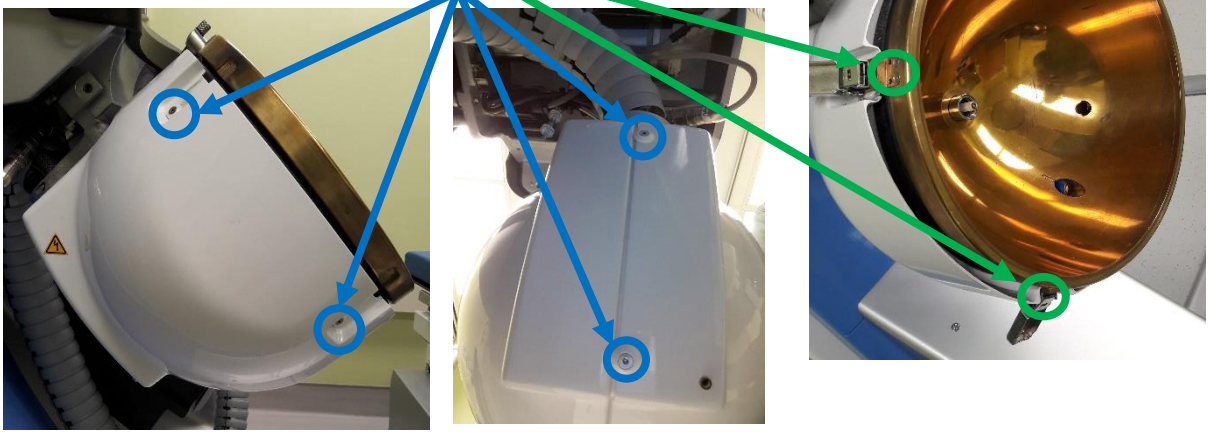
Make sure that generator is empty. If not select "**REMOVE ELECTRODE**" in electrode menu.
Open water treatment door, place hose end in an empty 20 liters tank.
Go in "**MAINTENANCE**" then select "**DRAIN TANK**". Draining process will stop automatically when module tank is empty.
After draining, turn off firing module and disconnect main supply.

3.1 Electrode socket

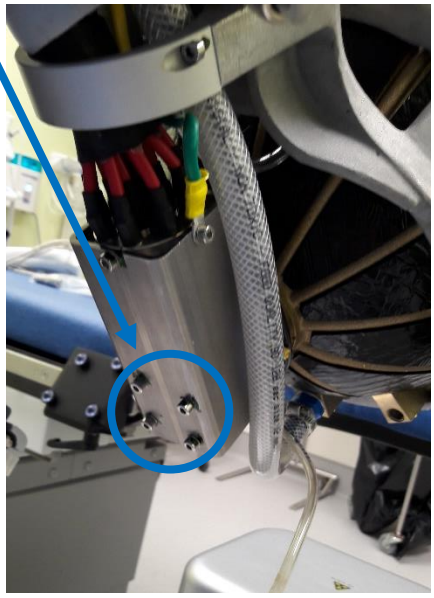
- If not done yet remove membrane holder

On each side:

- Remove generator clip holders.
- Remove generator covers screws:



- If present, remove electrode.
- Remove the 4 screws on the base part of the electrode socket and extract base part of electrode socket.
- Remove the upper part of the electrode socket.



Perform the test of section "4 INSPECTIONS" before installing new electrode socket

- Transfers water pipe, electrode detector or cap from current socket to new socket.

- Insert the new electrode socket (Lubricate O-ring with water if necessary)
- Rotate electrode socket to set water pipe in lower position.
- Insert an electrode and check that its indexing is correct.
- Remove electrode

Threads in generator are made of brass, tight fit screws.
Overtightening can damage thread and screw heads.

- Install lower part of electrode socket and screws.
- Report electrode socket base part replacement.
- Install generator cover. (Mind to pass electrode socket drain tube through cover if dedicated hole is present).

3.2 Membrane holder clip kit

Threads in generator are made of brass and screw heads are small, tight fit screws.
Overtightening can damage thread and screw heads.

- Remove clips from clips holder.
- Discard genuine clips and screws.
- Install new clip on clip holder with new screws.
- Install clip holder on generator with new screws.
- Remove clip hooks on membrane holder.
- Discard genuine clip hooks and screws.
- Install new clip hooks on membrane holder.
- Report replacement.

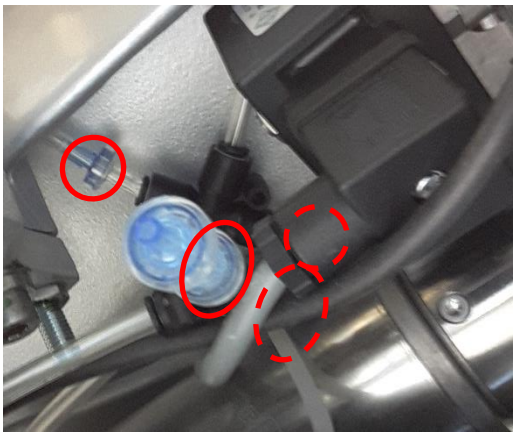
3.3 Membrane.

- Punch out membrane installed.
- Install new membrane.
- Make sure that membrane edge is correctly inserted into membrane holder groove.
- The membrane must be correctly positioned (without bead) to ensure optimal sealing.

3.4 Purge valve O-Ring.

- Remove the screw holding the O-Ring
- Replace the O-Ring
- Make sure that the screw is correctly tightened on the generator.

3.5 One way valve



- Replace 4 one-way valves (2 before electro valve, 2 after) some of them can be hidden behind cable or motor.
- If system is equipped with a set of 2 one-way valve as see below, replace only inner one-way valve. (Blue part of the one way valve must face the air entrance).

4. INSPECTION

Perform this inspection during previous item to avoid unnecessary manipulations.

4.1 Crimping of the high voltage harness

- After removal of four screws fixing HV cable to electrode socket base.
- Check that 15 cables are present.
- Check according to version:
- Screws holding hot point contacts are tight and no cable are loose
- Contacts are locked in position by circlip
- If one or two cables are loose, you must remove it completely and replace complete High voltage beam in best delay.
- Verify that the harness has no ashes, no amercing or burn marks.
- Report inspection result.

4.2 Insulation and contact of the electrode socket base

- Inspect electrode socket base:
- White insulation tubing is in good condition (no cracking or missing chunk).
- Hot point contact is clean and bright (no ashes or oxidation as shown on the left).
- Report inspection result.

5. WATER TREATMENT

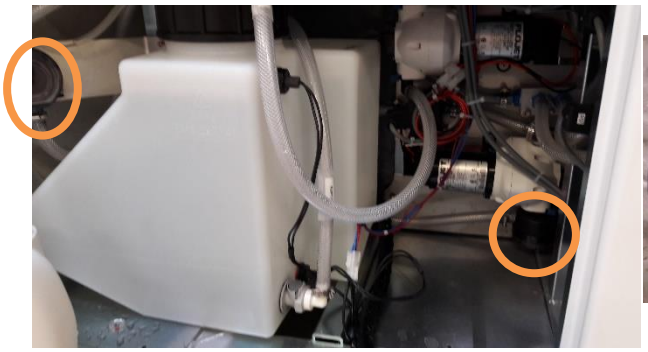
5.1 Tank cleaned and rinsed.

- Disconnect all pipes and connectors from tank and remove it. (mind some water connector might not be equipped with self-closing sockets).
- Remove water tank from the frame.
- Open water tank cap, clean, rinse and wipe any deposit.

5.2 Water filters cleaning

The first one is at the top left of the hydraulic circuit. The second filter is located at the bottom right of the hydraulic circuit under one pump.

- Unscrew both water filter covers,
- Remove and clean each metallic grid.
- Install grid back in filter and screw water filter manually (over tightening can cause air intake or leakage).Make sure to installed the filters back with input arrow in the right way.
- Report action completion or NA for installation.



- Install water tank into the frame.
- Connect all pipe.
- Connect water level sensor.
- Report action completion or NA for installation.
- Install generator covers and clip holders.

5.3 Tank Filling

- If not done yet, start system normally. At hospital prompt, press "**Cancel**". In power management interface choose "**Close current session…**" and log in as "**administrateur**" windows user with password.
- Start "**ESWL_L7.exe**" treatment interface. In "**Settings**" tab, press "**Usage Level**" button and enter maintenance password.
- Place the hose into a 18 liters canister of clean demineralized water.
- In "**MAINTENANCE**" and select "**FILL TANK**" (no password necessary).
- Inspect water system for leakage during tank filling.
- Wait for tank filling automatic process.
- Report action completion.

5.4 Air bubbles

- If available, install last used electrode in generator.
- If not, open a new electrode and install it.
- In main menu, go in "**Electrode**" tab.
- Select "**INSTALL ELECTRODE**" then "**SAME ELECTRODE**" and press "**FILL**".
- Inspect water circuit for leakage during generator filling.
- Check during generator filling that no large air bubble arrive in generator. (micro-bubble can be caused by tank filling in previous step).
- Report inspection result.

5.5 Flat membrane

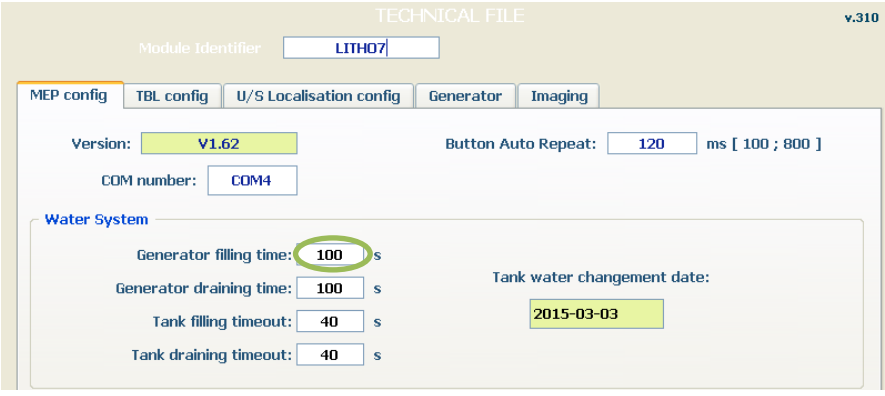
- Go in "**Electrode**" menu, select "**REMOVE ELECTRODE**"
- Check during generator draining that membrane is, maximum, in contact with electrode tip.
- Report inspection result.

5.6 Leakage

- Report that no leakage has been observed during all water treatments items of maintenance.

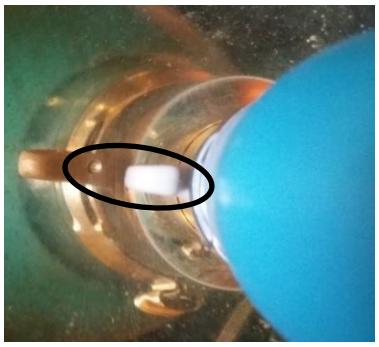
5.7 Generator filling time.

- From main menu go to "**Settings**" tab and press on "**TECHNICAL FILES**".
- Report "**Generator filling Time**" value.



6. ELECTRODE RUNNING IN

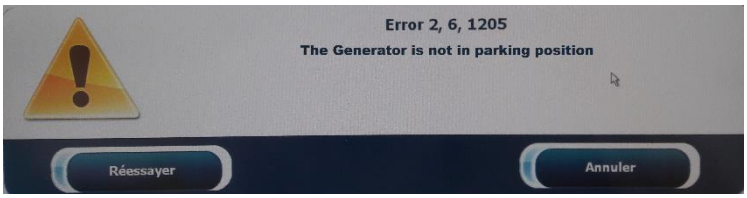
6.1 Electrode insertion



- If an electrode has been used previously, remove membrane holder, remove electrode and discard it. Install new electrode for maintenance.
- If the new electrode has been used previously, remove membrane holder.
- Check that electrode inserts properly into socket.
- Check that electrode wing is aligned with dot in generator when electrode is tight screw.
- Report inspection result.

6.2 Treatment position detection

- If not done yet, move generator to treatment position.
- In "**Electrode**" menu, select "**INSTALL ELECTRODE**" then "**NEW ELECTRODE**". Confirm all validation screens.
- Wait for generator filling completion.
- After tank filling the alarm message displayed above appears.
- Report error appearance.

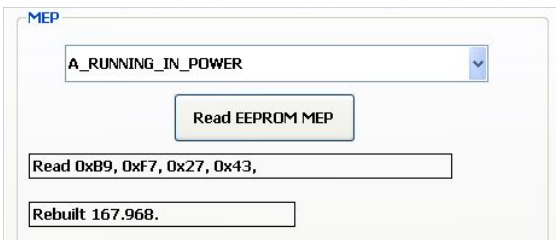


6.3 Electrode running in

- Move generator to parking position and press "**Retry**" button.
- Running in process should start (110 shocks).
- Wait for running in process completion.
- Check that no alarm message appears until the end of a running in test.
- Report running in test has passed.

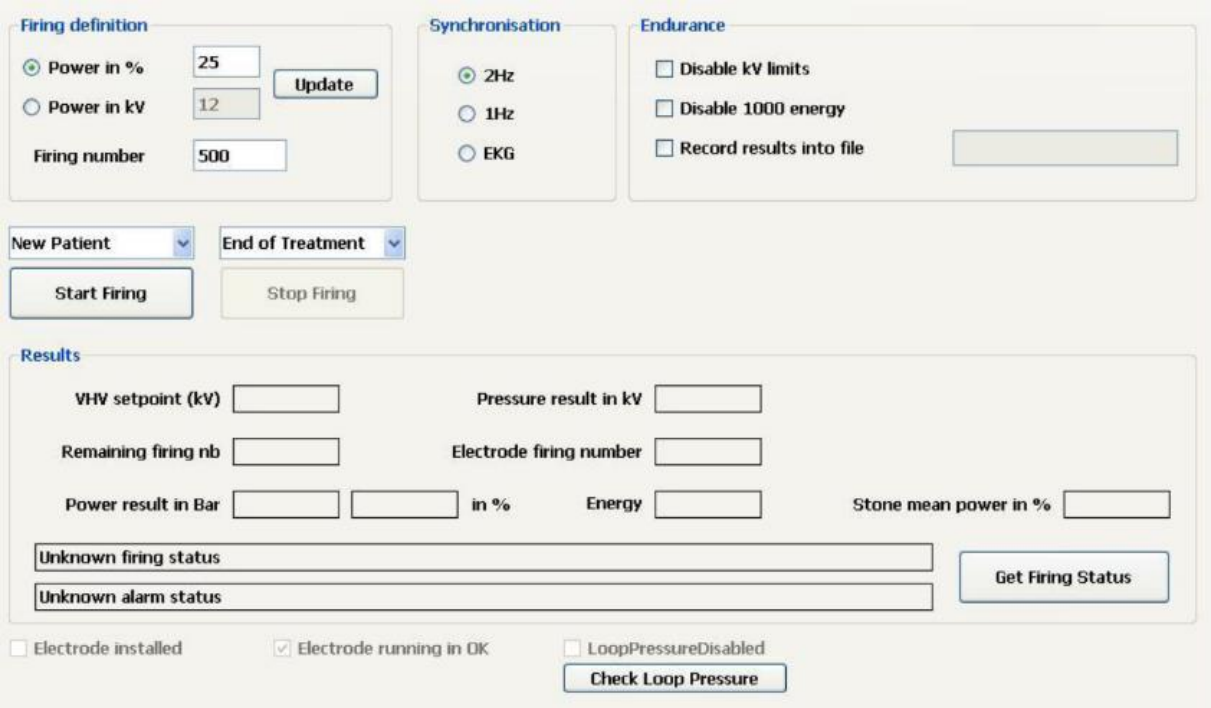
6.4 Running in value

- From main menu, go in "**Settings**" tab press "**Maintenance**" then "**EEPROM**" tab.
- Select "**A_RUNNING_IN_POWER**" and press "**Read EEPROM MEP**"
- Value in the field "**Rebuilt**" is updated
- Report running in value.(Value expected between 55% and 85%)



6.5 KV Stability

- If not done yet, set generator to treatment position.
- Go in the "**Generator**" tab.
- Enter "**100%**" in the "**Power in %**" field
- Enter "**200**" in "**Firing number**" field.
- Click on "**Start Firing**" button
- Press and hold firing button until shocks stop automatically.
- During firing, check that the value shown in "**Pressure result in kV**" is 15.5kV ±1.5kV when regulation is settled.
- Report "**VHV setpoint (kV)**".



6.6 Electrode presence

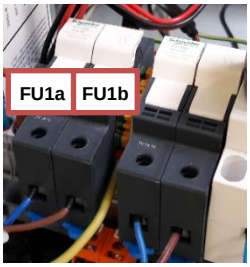
For system equipped with electrode detector only:

- Open the "**Maintenance**" menu.
- Select the "**MEP digital I/O tab**".
- Press "**Continuous read**" button
- Check that "**(Ex4) Electrode in detector**" is ticked
- Report inspection result

7. CONNECTIONS

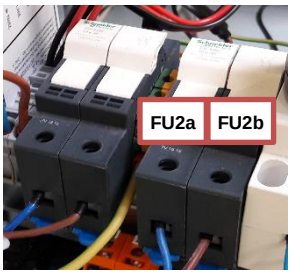
If not done yet remove electronic cover and rear cover.

7.1 Transformer primary voltage



- Measure AC voltage between FU1a and FU1b.
- Measured voltage must match local main voltage ± 10%.
- Report voltage value and inspection result.

7.2 Transformer secondary voltage



- Measure AC voltage between FU2a and FU2b.
- Measured voltage must be 230Vac ± 10%.
- Report voltage value and inspection result.

7.3 Module emergency stop

- Start treatment simulation.
- Press the emergency stop button of the main module.
- You should hear a relay contact noise inside the main module.
- Check that error message appear “5020, 24V is not present” or any message related to X-Ray failure.
- Release the emergency stop button.
- Press “Restart” to clear the error message.
- Let X-ray system restart.
- Report test result.

7.4 Remote console emergency stop

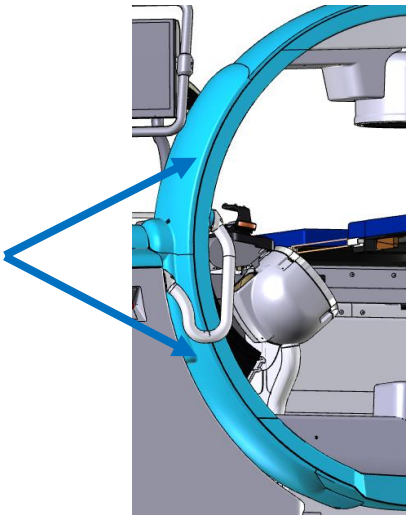
- If present, press the emergency stop button of the main module.
- You should hear a relay contact noise inside the main module.
- Check that error message appear “5020, 24V is not present” or any message related to X-Ray failure.
- Release the emergency stop button.
- Press “Restart” to clear the error message.
- Let X-ray system restart.
- Report test result.

7.5 Table emergency stop

- Press the emergency button of the table.
- Check that an error message is displayed in dialogue bar of treatment interface.
- Check that missing 24V LED code is displayed on table remote (according to table type)
- Release the emergency button.
- Report test result.

8. MECHANICAL STRUCTURE

8.1 C-Arm bearings.



- Remove C-Arm covers as indicated on the right.

- Activate orbital rotation from maximum to minimum position repetitively.
- Check for each of the 4 groups of bearing the 4 bearing

spinning during the whole displacement.
- Install previously removed C-arm covers
- Report inspection result.

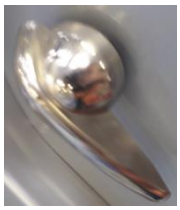
8.2 Generator bearings.

- Activate generator rotation from maximum to minimum position repetitively.
- Check that all bearing spinning during the whole displacement
- Report inspection result.

8.3 Carriage movements

- Make sure that the generator' carriage is moving form parking to treatment position easily.
- Report inspection result.

8.4 Carriage unlocking lever



- Check that unlocking lever is easy to activate for treatment and parking position.
- Check that carriage move slightly backward when unlocked in both positions.
- Check that carriage is locked and the lever goes down when carriage reach both positions
- Report inspection result.

8.5 2 Video monitor screens movement.

- Check that monitor position is steady and don't move further from its wanted position when released.
- Report inspection result.

8.6 2 Video monitor screens screws.

For system with individual screen arm only

- Check that all screws on the monitor arm are correctly tightened.
- Report inspection result.

8.7 Wheel wedges are firmly in place.

For mobile unit indicate NA

- Check that all wheel wedges are in place and correctly placed.
- Report inspection result.

8.8 Generator is clean

- Check that the generator is clean and bright.
- Necessary use Ouator polish.
- Report inspection result.

8.9 Generator chain

- Check that generator' rotation chain is tighten.
- If necessary adjust lower screw.
- Report inspection result.

8.10 Generator rotation

- Install any F2 simulator on generator

For system with i-sys table, if necessary,perform patient loading to initialize table.

- Press and hold table centering position until “litho7” mode is lit continously.
- Use articulated arm or any available support to align a sharp object point to point with the F2 point
- Activate generator rotation from maximum to minimum position repetitively.
- Stop movement when gap between object and F2 is the biggest
- Measure and report maximum distance between F2 and object (tolerance 2mm).
- Remove object and F2 simulator.

9. TABLE

9.1 Origin position

- If necessary perform C-arm and generator centering.
- For system with i-sys table, if necessary perform patient loading to initialize table.
- Press and hold table centering position until “litho7” mode is lit continously.

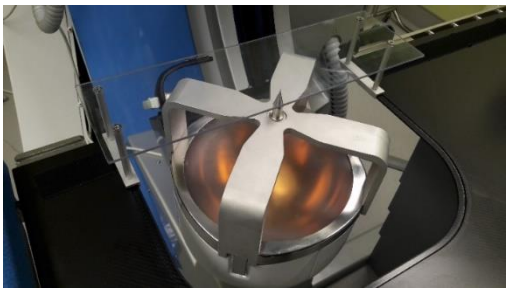
9.2 Cushions

- Check that all cushions of the table are not scratched nor damaged.
- Check that the cushions are not marked with spots of paint or blood.
- Report inspection result.

9.3 Table centering

For Karbon table with tool **TMS230847** available only:

- Set generator to treatment then 0° position.
- Remove table main cushion and install **TMS230847** tool.
- Check that F2 point is centered on dot as see below. (tolerance 1mm).
- Report inspection result.



For all other :

- Perform table-centering, check that distance between table and treatment head is the same on left and right side.
- Report inspection result.

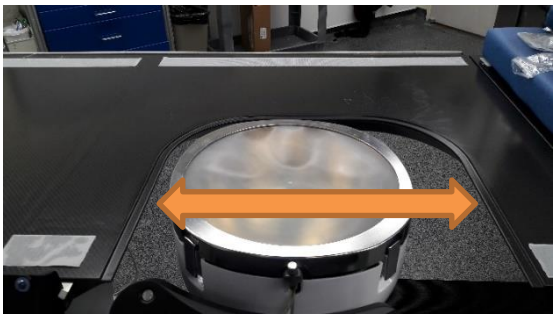
9.4 Movement's software.

- Test that all movements from all movement interface (IHM and remote) are functional.
- Report inspection result.

9.5 Table collision

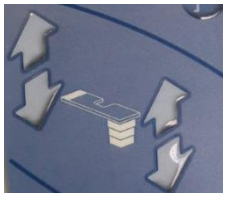
For this test monitor carefully table movement, if collision occurs, don't let movement pry or damage system.

- If not done yet set generator to treatment 0° position.
- Move table to center position, then move it down to minimum position
- Move table toward generator until it reach its limits.
- Move table sideway from limit to limit.



- Report that during whole process table did not collide with generator.
- Move table to center position and set generator to parking 0° position.

9.6 Trendelenburg movement



- If not done yet, necessary go in "**Maintenance**" page, "**TBL Movements**" tab then activate "**Maintenance(5)" Mode**".
- Check that all "Trendelenburg" movements are working properly.
- Report inspection result.
- Select "**Litho7(1)**" mode.

9.7 Steel rails

- Check that all screws of the steel rails of the table are correctly tightened.
- Report inspection result.

9.8 Torx screws

<u>For I-Sys table only</u>

- Check that all torx screws of the table plate are correctly tightened
- Report inspection result

9.9 Table clamping

<u>For I-Sys mobile only</u>

- Check that main module clamping system functionning correctly: table is locked or free according handle position.
- Report inspection result.

10.TABLE MOVEMENT ACCURACY

- If not done yet, go in “Maintenance” page, “TBL Movements”, then center Center table.
- Press “**Read X,Y,Z position**” and report values in “**Movements X,Y,Z**” boxes.

10.1 Movement X axis

- Change value in box next to “**Goto X**” to add 25 to current value and press “**Goto X,Y,Z position**”.
- Stick painter tape band and mark plate position using steel ruler as see below.
- Change value in box next to “**Goto X**” to subtract 50 to current value and press “**Goto X,Y,Z position”.**
- Mark plate position using steel ruler as see below
- Measure and report real table movement.
- Report test success if value is 50mm ±2mm.

10.2 Movement Y axis

- Change value in box next to “**Goto Y**” to add 20 to current value and press “**Goto X,Y,Z position**”.
- Stick painter tape band and mark plate position using steel ruler as see below.
- Change value in box next to “**Goto Y**” to subtract 40 to current value and press “**Goto X,Y,Z position**”.
- Mark plate position using steel ruler as see below.
- Measure and report real table movement Y axis.
- Report test success if value is 40mm ±2mm.

10.3 Movement Z axis

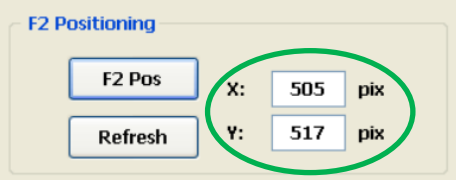
- Change value in box next to “**Goto Z**” to subtract 50 to current value and press “**Goto X,Y,Z position**”.
- Mesure distance between rail and ground
- Change value in box next to “**Goto Z**” to addt 100 to current value and press “**Goto X,Y,Z position**”.
- Mesure distance between rail and ground and substract previous measured value to get table movement. Report result value
- Report test success if value is 100mm ±2mm.

11.X-RAY LOCALIZATION SYSTEM

CHECK THAT ELECTRODE IS INSTALLED AND SHOCK GENERATOR IS FULL OF WATER.

Always wear protective gear when emitting X-ray. Respect local regulation recommendation.
If not done yet, quit completely treatment interface, restart database interface and log in "**T.M.S**." hospital.

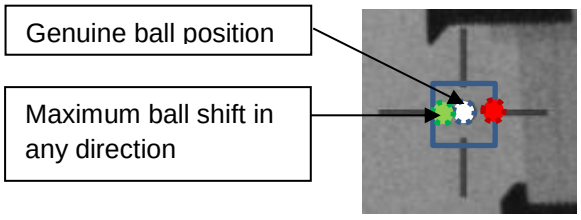
11.1 Computer cross centration



- Press "**Quit**" to close maintenance interface.
- Press "**Technical Files**" then go in "**Imaging**" tab.
- Press "**Calibrate X-Ray Imaging**".
- Report F2 X and Y position (tolerance 512 ±12 pix) and test result.
- Press "**Cancel**" twice to quit "**Technical File**" page.
- Set generator in treatment 50° position.
- In main page go in "**Treatment**" tab and press on "**ESWL**" to start treatment simulation.
- Install **TMS233020** accuracy and fragmentation test tool. (do not fill with water yet).
- Install lead ball target tool into test tank.
- On treatment interface localize stone and place it in center of X-Ray cross on 3 axis. (X and Y movements with X-ray C-arm in 0° position, then Z movement with a 15° cranio-caudal rotation).

11.2 Isocenter orbital rotation stability

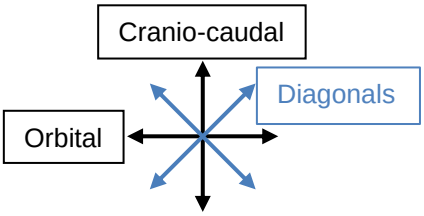
- If not done yet, zero C-arm movement.
- Rotate C-arm on orbital axis to minimum, as long as lead ball stay visible.
- Check that lead ball stay in the gap between overlay cross' bar, if possible make a screenshot or save X-ray picture.
- Rotate C-arm on orbital axis to maximum, as long as lead ball stay visible.
- Check that lead ball stay in the gap between overlay cross' bar, if possible make a screenshot or save X-ray picture.
- Report test success if ball does not move more than its diameter (2mm)cross as see below.



11.3 Isocenter cranio-caudal rotation stability

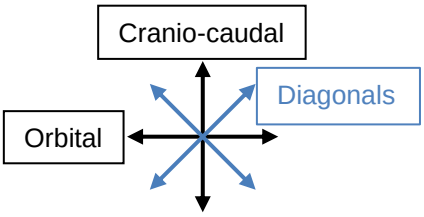
- Rotate C-arm on cranio-caudal axis to minimum, as long as lead ball stay visible.
- Check that lead ball stay in the gap between overlay cross' bar, if possible make a screenshot or save X-ray picture.
- Rotate C-arm on cranio-caudal axis to maximum, as long as lead ball stay visible.
- Check that lead ball stay in the gap between overlay cross' bar, if possible make a screenshot or save X-ray picture.
- Report test success if ball stay inside the square defined by inner arms of X-ray cross.

11.4 Isocenter combined rotation stability

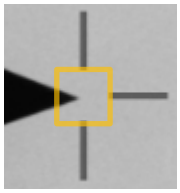


- Rotate C-arm with both cranio-caudal and orbital axis to a diagonal position, as long as lead ball stay visible.
- Check that lead ball stay in the gap between overlay cross' bar, if possible make a screenshot or save X-ray picture.
- Repeat previous steps with 3 other diagonal positions.
- Report test success if ball stay inside the square defined by inner arms of X-ray cross.

11.5 F2 point alignment

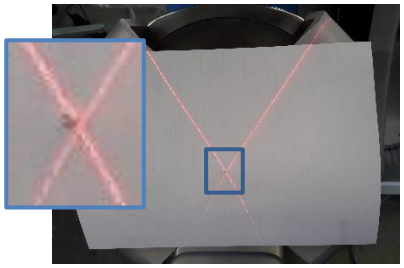


- Remove **TMS233020** accuracy and fragmentation test tool.
- Install **TMS236466** F2 simulator with membrane tool.
- Center C-arm to 0° position in all axis.
- Check that F2 point is in the center of the cross.
- Save picture or make a screenshot.
- Rotate C-arm in any axis to its maximum, as long as F2 simulator is visible.



- Check that F2 point is in the center of the cross.
- Save picture or make a screenshot.
- Repeat rotation and checking for all other axis.
- Report test success if F2 simulator stay inside the square defined by inner arms of X-ray cross.

11.6 Laser cross alignment



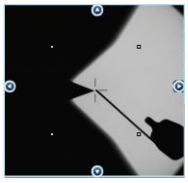
- Activate I.I. laser cross.
- Check that laser cross is aligned on F2. (tolerance 5mm)
- Report test result.

11.7 Laser lines intersection

- Check that laser cross is visible from 20cm to 55cm for I.I. entry.
- Report test result.

11.8 Localization accuracy

- Set generator carriage to parking position and set table in center position.
- Place a sharp tool as target in a steady position (f.e. small Allen wrench strap to articulated arm) near F2 point.
- Localize tip of the tool and use table movement in X and Y-axis to place it in center of X-ray cross with C-arm in 0° position.
- Localize tip of the tool and use table movement in Z-axis to place it in center of X-ray cross with C-arm in any angulation.
- Set carefully generator carriage to treatment position.
- Measure distance between tool tip and F2 point. (tolerance 2mm)
- If possible, save pictures with C-arm on 0° position and with any angulation.

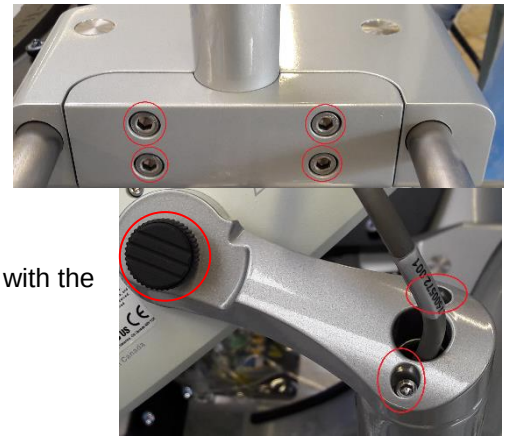


12. VISIO TRACK LOCALIZATION SYSTEM

If not done yet remove any tool from system.

For system equipped with Visio-track only

12.1 Camera support



- Check that the 4 screws at the bottom of the VisioTrack mast are correctly tighten
- Verify that the 2 screws at the top of the VisioTrack mast are correctly tighten.
- Report inspection result
- Verify that the camera is correctly secured on the mast with the screw.
- Report inspection result

12.2 Radix sphere cleaning

- Use a moist soft tissue to clean radix sphere on Visio-track tool.
- Report action completion.

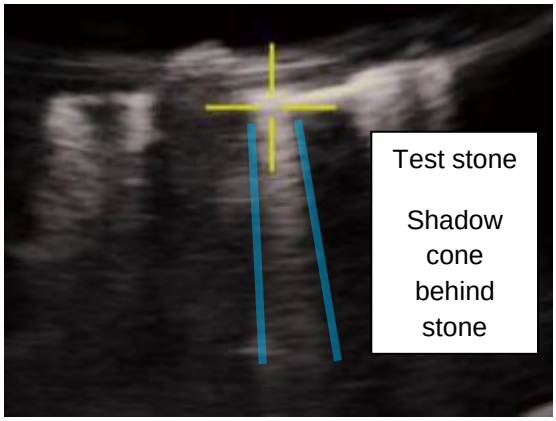
If some NDI sphere are installed, replace them with radix sphere according to service bulletin MAR201316.

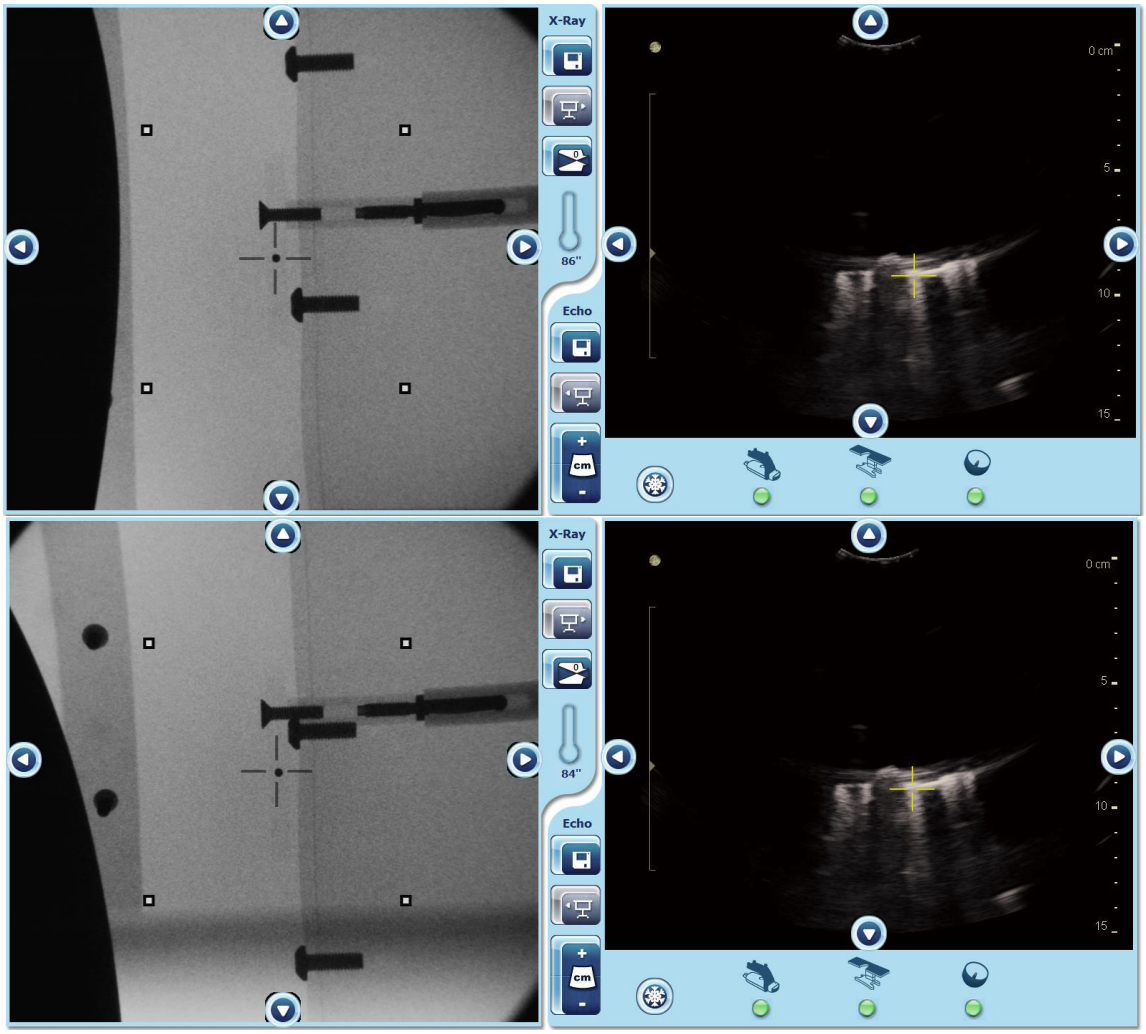
12.3 Visio-Track calibration

- Perform full Visio-track calibration as described in the service manual.
- Report action completion.

12.4 X-ray cross and Visio-track cross superposition

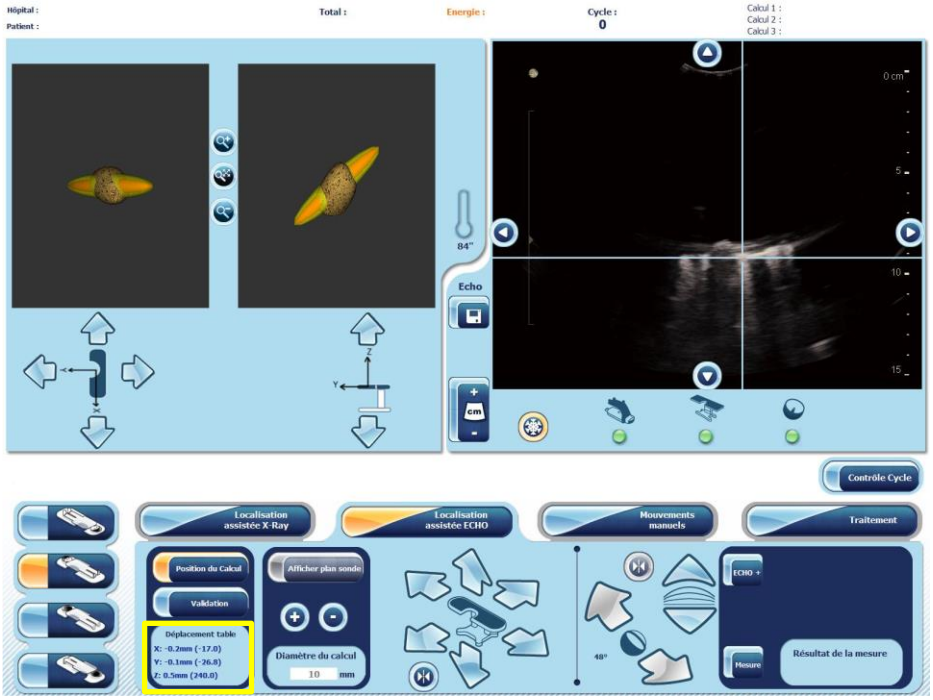
- If not done yet start a treatment simulation.
- Install **TMS233020** accuracy and fragmentation test tool.
- Install lead ball target tool into test tank.
- Fill test tank with water.
- Localize lead ball and use table movement in X and Y axis to place it in center of X-ray cross with C-arm in 0° position.
- Localize lead ball and use table movement in Z axis to place it in center of X-ray cross with C-arm in any angulation.
- Attach probe holder to articulated arm.
- Apply U/S gel on probe tip.
- Scan test tank to find lead ball (yellow cross should appear on it).
- Secure articulated arm with its handle to have a steady picture of test stone with the widest shadow cone.
- Make a screenshot of treatment screen with both x-ray and image for C-arm at 0°.
- Make a screenshot of treatment screen with both x-ray and image for C-arm with angulation.
- Report action completion.





12.5 VisioTrack localization accuracy

- Go into "**U/S stone locking system**" tab."
- Click on stone position and point stone, if necessary perform position fine tuning with arrows.
- Record "**Table displacement**" values (tolerance 2mm)
- If possible, make a screenshot.
- Report test result.



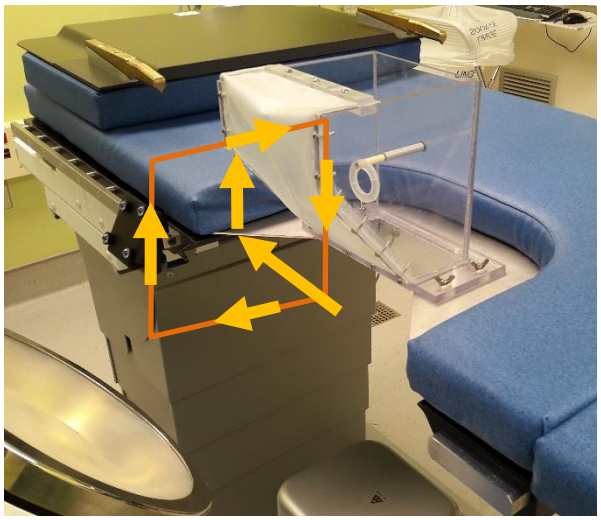
- Remove **TMS233020** accuracy and fragmentation test tool form the table to a safe place.
- Clean U/S imaging probe tip.

12.6 Locating pins and holes

- Check that probe tool socket is clean.
- Check that probe support generator is in good condition (no corrosion, no dried U/s gel…).
- For system with pins install probe holder in test position and check that mechanical free-play is
- Report inspection result.

12.7 Table tool spheres visibility

- Quit totally treatment interface.
- Start the NDI software “**Tracker**” tool.
- Check that table tool is correctly attach to the rail (1cm from rail end maximum).
- Check that loaded tool are “**TMS232722 probe tool**”, “**TMS232764 generator tool**” and “**TMS232862 table tool**”).
- On the lower right part of screen, select “**TMS232862 table tool**”.
- During the following movement, check that all reflectors “marker” are green .
- Move table to its longitudinal limit.
- Move table to describe a square of lateral and vertical limit (as see below).
- Report test result and set table to its centered position.



1) Move table to its farthest longitudinal limt.
2) Move table to its upper limit.
3) Start checking continuously marker status.
4) Move table to its farthest lateral limit.
5) Move table to its lower limit.
6) Move table to its closest lateral limit.
7) Move table to its upper limit.
8) Move table to its farthest lateral limit.
9) During steps 4) to 8) all markers should have stay green.

Adjust NDI mast position if necessary.

12.8 Generator tool spheres visiblity

- On the lower right part of screen, select “**TMS232764 generator tool**”.
- During the following movement, check that all reflectors “marker” are green.
- Generator from upper to lower position.
- Report test result and set table to its centered position.
- Close the NDI software “**Tracker**”.

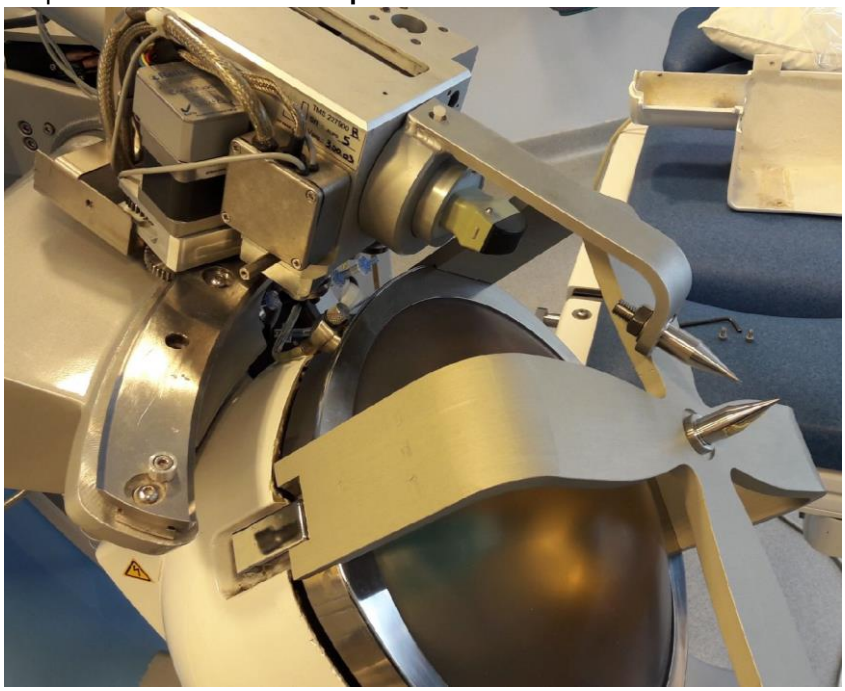
13. AUPS LOCALIZATION SYSTEM

For system equipped with AUPS only

- If not done yet, start treatment simulation

13.1 AUPS alignment

- Install "**F2 simulator**" tool.
- Extend AUPS probe holder 3 cm approximatively.
- Install **TMS230290** "**AUPS peak tool**" and secure with its screw.
- Extend AUPS probe holder until "**AUPS peak tool**" almost touch "**F2 simulator**".



- Check that peak of tools matches whatever probe holder position
- Report inspection result.
- Remove **TMS230290** "**AUPS peak tool**".

13.2 AUPS fixation

- Check that all screw are correctly tighten.
- Check that probe holder is correctly secured (no mechanical play).
- Report inspection result.

13.3 AUPS movements

- Check that all AUPS movements function correctly.
- Report inspection result.

13.4 DF2 Check

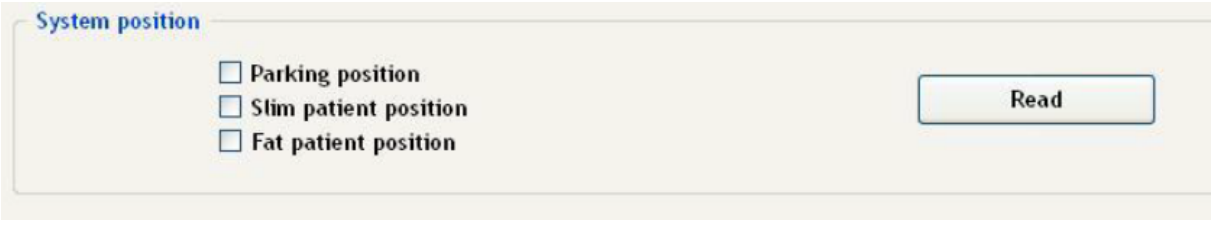
- If not done yet, install F2 simulator.
- In treatment interface, go on "**U/S Stone Locking System**" tab.
- Set probe holder to most retracted position.
- Measure distance between probe tip and F2 point.
- Distance should match with DF2 value on lower right corner of the screen.
- Set probe holder to extended position.
- Measure distance between probe tip and F2 point.
- Distance should match with DF2 value on lower right corner of the screen.
- Report test result.

13.5 U/S localization accuracy

- Install accuracy test tank.
- Fill test tank with water.
- Localize lead ball and use table movement in X and Y-axis to place it in center of X-ray cross with C-arm in 0° position.
- Localize lead ball and use table movement in Z-axis to place it in center of X-ray cross with C-arm in any angulation.
- Apply U/S gel on probe tip.
- Extend probe holder until probe is in contact with test tank.
- On U/S image, check that lead ball appear on dotted vertical line with yellow bars on each side.
- Check that lead ball stay with different AUPS positions
- Make a screenshot of treatment screen with both x-ray and image for C-arm at 0°.
- Make a screenshot of treatment screen with both x-ray and image for C-arm with angulation.
- Report inspection result.

13.6 Patient size position detection

- Quit treatment interface and go back to main page.
- Set AUPS to "**Slim patient position**" as indicated in user manual.
- Go in "**Settings**" tab and press "**Maintenance**".
- Go in "**AUPS**" tab



- Press read once and check that "**Slim patient position**" is ticked.
- Set AUPS to "**Fat patient position**".
- Press read once and check that "**Slim patient position**" is ticked.
- Report test success if position detected match mechanical position.
- Quit maintenance interface and go back to main menu.

14. X-RAY SYSTEM (EVERY 6 MONTHS)

Always wear protective gear when emitting X-ray. Respect local regulation recommendation.

- If not done yet, start treatment simulation.

14.1 Seasoning

- If the system has not been use for 3 months, perform X-ray monoblock seasoning as described in service manual.
- Report action completion or NA.

14.2 4 Squares X-Ray image

- Set table to its center position and check that 4 square showing approximate table limits are displayed.
- Report inspection result.

14.3 X-Ray emisson warning

- Activate X-ray.
- Check that beeping sound is emitted and warning blinking.
- If present, check external warning light function properly.
- Report inspection result.

14.4 Image intensifier safety device

- Activate image intensifier' patient collision detector safety device.
- Check that a warning sign appear on treatment interface.
- Check that C-arm and table movement are in step by step mode.
- Deactivate image intensifier' patient collision detector safety device.
- Check that message disappear and movements are in normal mode.
- Report inspection result.

14.5 Iris collimator

- Set generator in parking position.
- If not done yet open completely iris collimator.
- For all magnification level, make a short x-ray exposure.
- Check that iris collimator is visible on the edge of picture on imaging screen..
- Open "**X-ray+**" interface.
- Check that iris collimator is functional.
- Report inspection result.

14.6 Blade collimator

- Use "**X-ray+**" interface to close and rotate blade collimator.
- Check that blade collimator is functional.
- Report inspection result.

14.7 PSM05 Voltage TP2

- Connect DVM to TP2 of PSM05 board (use TP5 for ground).
- Set "**X-ray+**" interface to fixed 90kV and place 3mm of copper plate on monoblock output.
- Activate X-ray emission.
- Let DVM value stabilize.
- Report value.
- Report test success if $Reported\ value = mA\ value\ (on\ XR+) \pm 10\%$.

14.8 PSM05 Voltage TP3

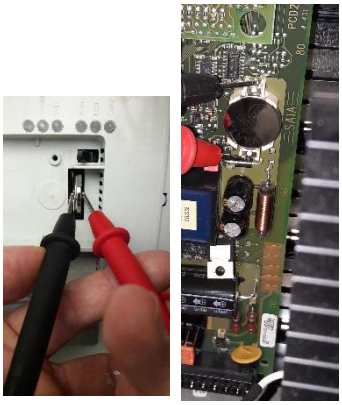
- Connect DVM to TP3 of PSM05 board (use TP5 for ground).
- Activate X-ray emission.
- Let DVM value stabilize.
- Report value.
- Report test success if $Reported\ value = 4{,}5Vdc \pm 0{,}2Vdc$.

14.9 Autodose (ABC)

  - Set "**X-ray+**interface to automatic kV and place 1mm of copper plate on monoblock output.
  - Activate X-ray emission.
  - Let kV value stabilize.
  - Report kV value from "**X-ray+**" interface.
  - Report test success (tolerance ±4kV).
- Repeat process with 2 and 3mm of copper plate.
- Remove copper plate from monoblock output.

14.10 PLC back-up battery

- Activate Emergency stop switch.
- Open X-ray rack.
- Remove PLC cover (disconnect serial communication if necessary).
- Use DVM to measure backup battery.
- Replace backup battery (CR2032) if voltage <2,91Vdc or battery is more than 3 year old (check last replacement date).
- Report backup battery voltage and replacement date as comment.
- Report test result.
- If necessary report battery replacement in comment.
- Install PLC cover (connect serial communication if necessary).
- Close X-ray rack.
- Deactivate Emergency stop switch.



14.11 X-ray footswitch

- Check local X-ray footswitch activation for both footswitches.
- If present, check remote X-ray footswitch activation for both footswitches.
- Report test result

14.12 Spatial resolution

- Install X-ray spatial resolution tool (line pair test pattern f.e. TOR 18FG test tool) on I.I. (line pairs must be oriented with a 45° angle from horizontal).
- Install 1mm Copper plate on monoblock output.
- Activate X-ray emission.
- Let kV value stabilize.
- Deactivate X-ray emission.
- On **Imaging screen**, read and report spatial resolution value according test tool datasheet.
- Report test success if result is >1.6 lp/mm for a 23 cm I.I. or >1.25lp/mm for a 32 cm I.I.
- Remove test pattern.

14.13 Timer and DAP

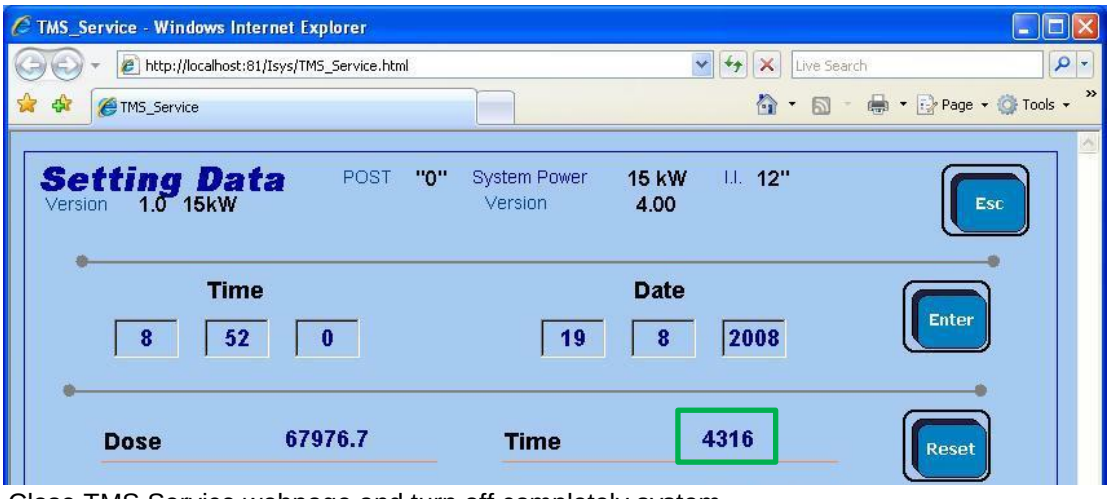
- Activate X-ray emission.
- Check that timer and DAP value grow during exposure.
- Deactivate X-ray emission.
- Check that timer and DAP value remain steady during exposure.
- Reset timer and dose.
- Check that timer and DAP are reset.
- Activate X-ray emission; if necessary validate the reset message.
- Deactivate X-ray emission.
- Quit treatment interface.

14.14 X-ray parameters

- Use process described in “X-ray Identification” at the beginning of the instruction.
- Check that default settings match with previous default settings from reported (except if a change has been asked by local staff)
- Report inspection result.
- Quit treatment interface.

14.15 Operating Hours

- Start SBC.net or Swebconnect.
- Start internet explorer and browse to TMS service web page.
- Go in “**Service**” then “**Setting Data**”, report operating hours.



- Close TMS Service webpage and turn off completely system.

15.X-RAY SYSTEM (YEARLY TEST)

X-ray yearly test are based on French regulatory test. Adapt values and periodicity according most demanding regulation (local regulation or test below).

Some test require to know user most used exposure mode (continuous or pulsed).

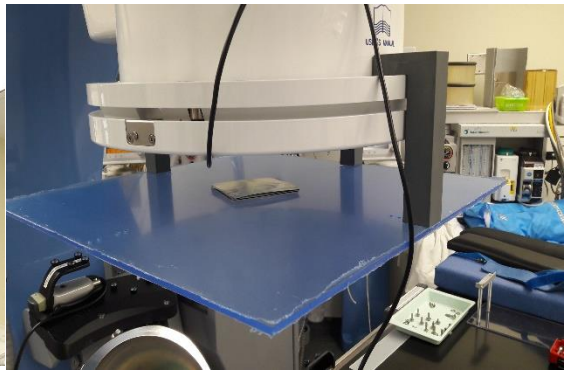
- If not done yet, turn on system.
- Log as "**administrateur**" windows user. Start treatment interface. Go in "**Level 1**" usage.
- Start treatment simulation.

15.1 KV Accuracy

- Install kV meter on mono block output
- Make several short exposure to check that sensor is fully displayed on X-ray image.
- Display "**X-ray+**" interface set manual kV mode.
  - Set system to 60 kV.
  - Activate X-ray emission.
  - Let kV reading value stabilize.
  - Report kV value.
  - Report test result (tolerance 10%).
- Repeat measurement for 70, 90 and 110kV.

15.2 Halving Layer Dose Value

- Place dose meter at I.I. entrance
- Set system to 70kV, place HDLV test spacer on I.I.
- Measure dose rate at naked fire. Divide naked fire value by 2 to get the target value
- Top-up aluminum sheets between spacer and dosimeter until the measured dose rate is just below the target value.
- Report Aluminum plate thickness (minimum value 2,5 mm Al)



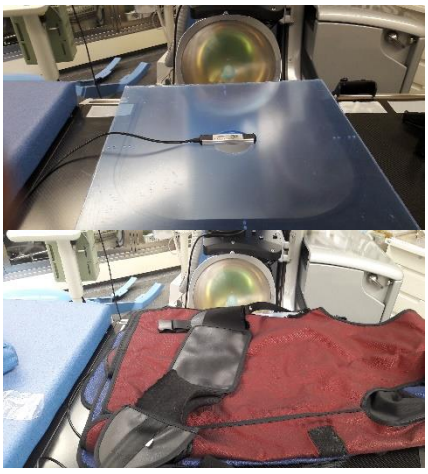
15.3 Continuous fluoroscopy timer accuracy

- Place dose meter in field of view.
- Set system to manual kV and 40kV continuous fluoroscopy.
- Reset i-sys timer.
- Activate X-ray for 1-minute using timer of dose meter.
- Compare measured and indicated times on the ISYS interface. Tolerance 3s.
- Quit treatment and go back to main menu

15.4 DAP Accuracy

- Use DAP calculation excel sheet if available.
- Install field of view measurement tool at I.I. entrance. Report field of view radius for all three Zoom mode in table in checklist.
- Calculate and report irradiated surface for all fields of view $(Area = Radius^2 * \pi)$
- Remove field of view measurement tool and place dose meter at I.I. entrance.
- Set X-ray to manual 70kV and continuous fluoroscopy.
- Repeat the procedure below for each field of view:
  - Reset counter.
  - Make a 30s exposure.
  - Report i-sys DAP in table.
  - Report measured dose in table.
  - Calculate and report Real DAP $(Real\ DAP = Dose * \pi * Radius^2)$
  - Calculate and report error $(Error = 100 * \frac{Isys\ DAP - Real\ DAP}{Isys\ DAP})$
  - Report test success if error is lower than 25% and local regulation.
- If test fail, perform DAP calibration according to service manual instructions.

15.5 Max Dose Rate in normal mode



- Set table to centering position.
- Install dose meter at patient level (use HVLD tool or articulated arm), use laser cross to align with I.I. center.
- Set table to minimum position in Z axis
- Place 2 or 3 leaded apron flat on table to protect I.I.
- Set X-ray system to the most used exposure mode.
- Set continuous fluoroscopy at 120kV.
- Activate X-ray emission at short time and check that image is not over-exposed (is so add an extra leaded apron).
  - Activate X-ray emission.
  - Let dose meter reading stabilize.
  - Deactivate X-ray emission.
  - Report dose rate in mGy/min $(dose\ rate\ (mGy/\min) = dose\ rate\ (mGy/s) * 60)$.
  - Report test success if dose rate <100 mGy/min.
- Repeat test for all 3 different field of view.

15.6 Max Dose Rate in double mA mode

- Set continuous fluoroscopy at 120kV with double mA button  activated.
- Activate X-ray emission at short time and check that image is not over-exposed (is so add an extra leaded apron).
  - Activate X-ray emission with double mA button activated.
  - Let dose meter reading stabilize.
  - Deactivate X-ray emission.
  - Report dose rate in mGy/min $(dose\ rate\ (mGy/\min) = dose\ rate\ (mGy/s) * 60)$.
  - Report test success if dose rate <200 mGy/min.
- Repeat test for all 3 different field of view.

Image quality test 15.7 to 15.9 must be perform

15.7 Low Contrast Resolution

- Install low contrast resolution tool at I.I. entrance.
  - Place 1mm Cu plate on monoblock output.
  - Select manual kV mode.
  - Activate X-ray emission.
  - Adjust kV to hardly view 2 circles in the two squares.
  - Deactivate X-ray emission.
  - If kV value is not 60,65,70,75 or 80kV change copper plate thickness (1mm, 1.5mm or 2mm Cu plate).
  - Count number of fully visible outer circles.
  - Check in table associated with the test phantom low contrast resolution.
  - If necessary by 100 to obtain a percentage and report values.
  - Report test success if value is lower than 4.5%.
- Repeat process for all field of view.

15.8 Spatial Resolution normal mode

For system with remote console, indicate spatial resolution of remote console screen (imaging if present or GUI).

- Measure visible diameter or use measurements from DAP accuracy $(\text{raduis} * 2)$.
- Report visible diameter for each field of view in table below.
- Place resolution tool at I.I. entrance. Line pair must be display with 45° angle from horizontal.
- Place 1mm Cu plate on monoblock output.
- Set system to automatic kV in the most used mode (indicate fps for pulsed fluoroscopy mode).
  - Activate X-ray emission.
  - Make exposure and let kV stabilize.
  - Deactivate X-ray emission.
  - On imaging screen, select smallest line pairs where black and white lines can be tell apart.
  - Report special resolution according test tool datasheet.
  - Report test success according table below.

Visible diameter	Minimum spatial resolution
28-33 cm	1.4 lp/mm
20-25 cm	1.6 lp/mm
15-18 cm	2 lp/mm
11-13 cm	2.24 lp/mm

- Repeat process for all field of view.

15.9 Spatial Resolution double mA mode

For system with remote console, indicate spatial resolution of remote console screen (imaging if present or GUI).

- If not done yet, measure visible diameter or use measurement from any previous test.
- If not done yet, report visible diameter for each field of view in table below.
- If not done yet, place resolution tool at I.I. entrance. Line pair must be display with 45° angle from horizontal.
- If not done yet, place 1mm Cu plate on monoblock output.
- Set system to automatic kV in the most used mode (indicate fps for pulsed fluoroscopy mode).
  - Activate X-ray emission in double mA  mode.
  - Make exposure and let kV stabilize.
  - Deactivate X-ray emission.
  - On imaging screen, select smallest line pairs where black and white lines can be tell appart.
  - Report special resolution according test tool datasheet.
  - Report test success according table below.

Visible diameter	Minimum spatial resolution
28-33 cm	1.4 lp/mm
20-25 cm	1.6 lp/mm
15-18 cm	2 lp/mm
11-13 cm	2.24 lp/mm

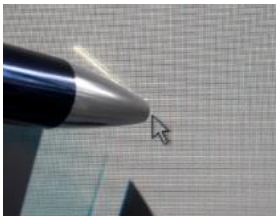
- Repeat process for all field of view.
- Remove test tool and copper plates.

16. COMPUTER

16.1 PC screen image

- Check that screen image is correctly centered and scaled.
- Report inspection result.

16.2 Touch screen accuracy



- Check that touch screen follow the user input. (Calibrate touchscreen if necessary).
- Report inspection result.

16.3 Printer

If a printer is installed only if not report NA.

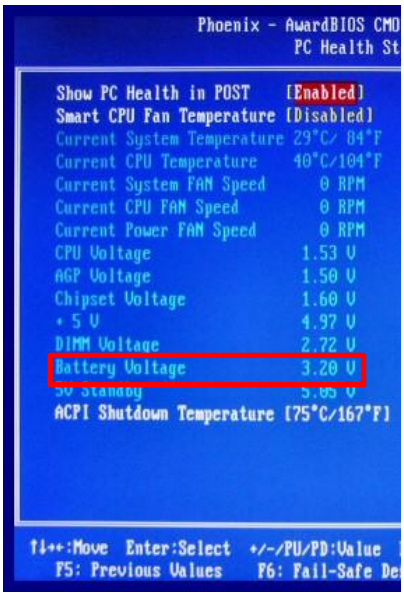
- Go in “**Settings**” tab and press “**Technical File**”.
- Press “**Print Tech File**”.
- Check that technical files data is correctly printed.
- Report inspection result and save printed document for sub reporting.

16.4 Ink cartridge

For system with printer where ink cartridge supply is not managed by hospital.

- Check that spare ink cartridges are available.
- Report inspection result.

16.5 Motherboard battery



For Windows XP device only.

- If not done yet connect USB keyboard or use remote console keyboard.
- Quit treatment interface.
- On power off interface select “**Restart computer…**” and press “**OK**”.
- On keybord press repetitively “**Del**” or “**F12**” during computer booting.
- Browse through BIOS interface to “Hardware health monitor”.
- Check that the motherboard battery (Vbat or battery voltage) is above 3.0Vdc (replace battery if test fail).
- Report battery voltage and inspection result.
- Quit BIOS without saving any change.
- Let computer restart and log as “**administrateur**” windows user.

16.6 Hospital name

- Start database interface.
- Check that all hospital names are correctly entered (in the connection page or on the top left of the BDD page.
- Report inspection result.

16.7 Automatic data base back up

- Login "**T.M.S.**" hospital with "**admin**" user.
- In "Treatment" tab, press "**ESWL**".
- Press "**Ignore**" if an "**1200 Electrode not installed…**" appear.
- In patient list, press "Parameter" or gear button.
- In "Parameters" tab, report "Frequency" value.
- Report inspection success if
  - Value is 1 for Windows XP computer.
  - Value is 0 for Windows 7 computer.
- For Windows XP computer only, press "**Backup now**".
- Close treatment interface and go back to windows desktop.

16.8 MDB backup of the data base

For I-sys with Windows XP computer only.

- Perform a "**Backup an access MDB database**" as described in Service Manual.
- Report action completion or NA for Window 7 computer.
- Close OraScriptUni interface

16.9 Database files backup

- Use windows explorer to copy files listed below in D: hard drive according to maintenance habits (f.e. D:\Backup\YYYYMMDD Maintenance\).

For I-sys Windows XP computer only:

- Back up the "**exp_ISYS.dmp**" file in D: drive. (usually in **C:\Litho\BDD_LITHO**).
- Back up the "**ISYS_V2.mdb**" file in D: drive. (usually in **C:\Program Files\OraScriptUni**).
- Report each action completion or NA for Window 7 computer.

For I-sys Windows 7 computer:

- Back up the "**BDD_LITHO.sqlite**" file in D: drive. (usually in **D:\BASE_SQLITE\DATA\BDD_LITHO**).
- Report each action completion or NA for Window XP computer.

16.10 Free space on hard drive

- If not done yet, open a windows explorer and clic on "Computer"
- Report available space for D: drive.
- Report available space for C: drive.

16.11 Defragmentation

- Start windows disk defragmentation tool.
- Perform disk analysis on both drive.
- Perform disk defragmentation if necessary
- Report action completion or NA if defragmentation was not necessary.

16.12 Dust filter

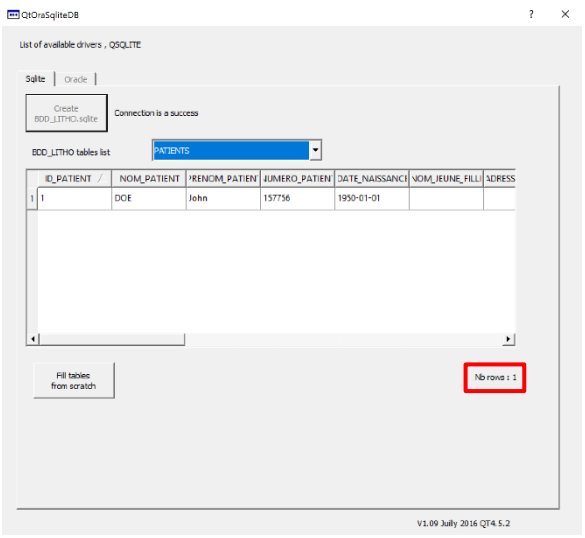
- Open large cover on operator side (mind control panel cable length).
- Open the filter' flap (on the front cover of the PC)
- Remove and clean the dust filter.
- Install back filter, close the flap and re-install large cover.
- Report action completion.

17.SUBREPORTING DATA

17.1 Number of treatment

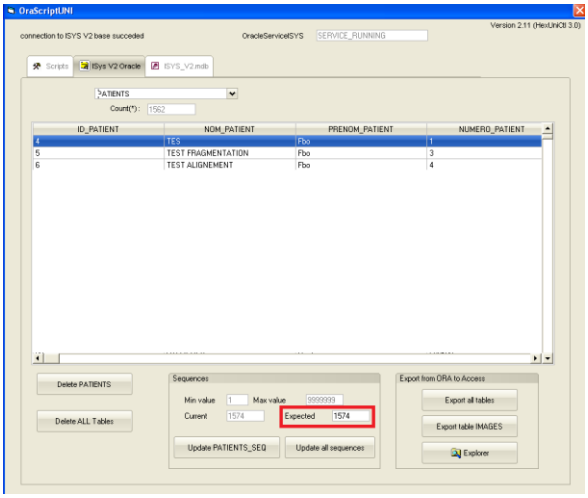
For Windows 7 computer only:

- Start "**QtOraSqliteDB**" software.
- Select "**Traitements**" in dropdown box.
- Report the value after "**Nb rows**".



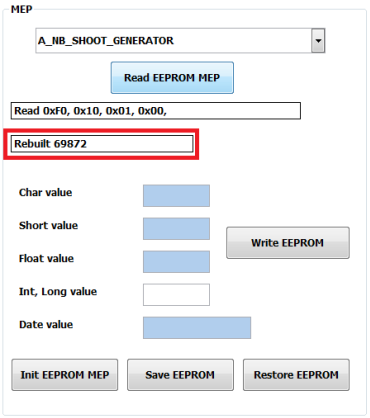
For Windows XP computer only:

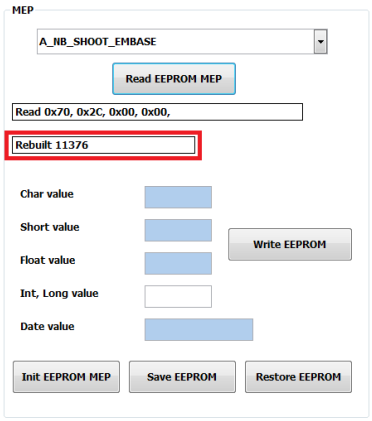
- Start "**OraScriptUni**" software.
- Go in "**ISYS V2 Oracle**" tab.
- Select in the list "**TRAITEMENTS**".
- Report in the field the value in "**Expected**" box.

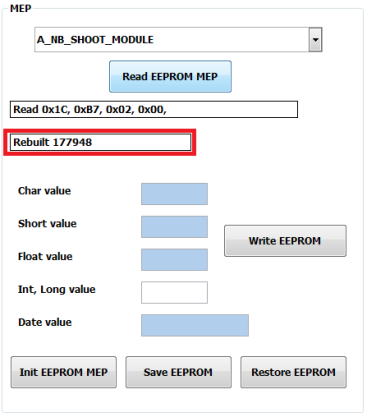


17.2 Counters report

- If any counter has been reset, report counter before reset and mention counter reset as comment.
- Start treatment interface in standalone mode.
- Go in the "**Maintenance**" menu.
- Select the "**EEPROM**" tab
  - On the left side of the screen, select "**A_NB_SHOOT_GENERATOR**".
  - Press on "**Read EEPROM MEP**"
  - Report the number of shots from "**Rebuilt**" box.
- Repeat process for "**A_NB_SHOOT_EMBASE**" and "**A_NB_SHOOT_MODULE**".







- If button present press "**Save EEPROM**".
- Quit treatment interface.

17.3 Files backup

- Use windows explorer to copy files listed below in D: hard drive according to maintenance habits (f.e. D:\Backup\YYYYMMDD Maintenance\).
- Backup "**C:\Litho7**" folder for i-sys with AUPS and Windows XP computer.
- Backup "**C:\Litho7_VT**" folder for i-sys with Visio-track and Windows XP computer.
- Backup "**C:\isysVT_x..**" folder for i-sys with Windows 7 computer.
- Backup "**C:\webpages**" folder
- Report action completion.

17.4 Check logs

- Inspect "**Error.log**" and check that occurrence of technical error message are low.
- Inspect "**FollowUp.log**" and check lifetime of electrode is steady. If available, check that "**running in**" result of the electrodes are steady.
- Inspect "**VisioTrackFollowUp.log**" and check that the daily test pass at every utilization.
- Report inspection result.
- If not done yet, install back all covers of systems.

18. TREATMENT SIMULATION

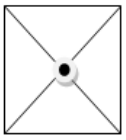
18.1 Fragmentation test with TMS229799 tool

For system with **TMS229799** tool only.

- Install fragmentation tool in place of membrane holder.
- Fill the test tool 1cm above the top of the mesh basket.
- Install test cylinder in mesh basket.
- Start treatment simulation with database interface.
- Set power to 100%
- Start delivering shocks.
- Perform **18.3** to **18.5** inspection during shocks delivery.
- Stop shocks when test stone is completely disintegrated.
- Report in the field how many shocks has been made to disintegrate the test stone.
- Report test result if number of shock is approximatively the same as previous maintenances.

18.2 Fragmentation test with TMS233020 tool

For system with **TMS233020** tool only.



- Trace diagonals on the test stone (**PM0916**). Put a lead ball (**PM1144**) in the middle of the test stone.
- Install **TMS233020** tool on table.
- Install prepared test stone in place of target lead ball.
- Start treatment simulation with database interface.
- Localize lead ball and use table movement in X and Y-axis to place it in center of X-ray cross with C-arm in 0° position.
- Localize lead ball and use table movement in Z-axis to place it in center of X-ray cross with C-arm in any angulation.
- Spread U/S gel on membrane.
- Inflate membrane to have an optimal contact with **TMS233020** test tank membrane.
- Set power to 100%
- Start delivering shocks.
- Perform **18.3** to **18.5** inspections during shocks delivery.
- Stop shocks when shock counter reach **400**.
- Report inspection result or NA.

18.3 Touchscreen interference (X-Rays side)

- Check that shock delivery does not make interferences on reported X-Ray image.
- Report inspection result.

18.4 Touchscreen interference (U/S side)

- Check that shock delivery does not make interferences on reported U/S image.
- Report inspection result.

18.5 Power feed back

- Check that power feedback is between 90% and 110%.
- Report inspection result.

18.6 Report details

- Before finish treatment write down few treatments parameters (exposure time, DAP, energy…).
- Finish treatment
- In report page, check that parameters noted previously match with parameters display.
- Report inspection result.
- In report page, display report printing preview.
- Check that parameters noted previously match with parameters display on preview.
- Report inspection result.
- Go back to main menu.

18.7 Test stone inspection

For system with **TMS233020** tool only.

- Remove test stone from tank.
- Check that impact are focused.
- Report inspection result.
- Take a picture of test stone.
- Report action completion.

19. ECG

For system associated with ECG monitor only.

19.1 ECG synchronization.

- Install the ECG system.
- Connect the ECG cable on the main module
- Start a treatment simulation and use the ECG synchronization.
- Verify that all shoots are synchronized with the R wave of the ECG complex.
- Report inspection result.

19.2 Cables.

- Check if all cables of the ECG system (Power cord, 4 cable for the heart) are in good condition.
- Report inspection result.

20. APPEARANCE

20.1 Panels condition

- Inspect all covers. Make sure they are properly fitted and in good condition.
- Report inspection result for
  - I-sys treatment module.
  - I.I covers (no visible cable).
  - AUPS panels (if present).
  - Remote console.

20.2 Cables condition

- Inspect all cable. Make sure they are in good condition (not damaged nor frayed).
- Report inspection result for
  - 16A cable of I-sys treatment module.
  - 32A cable of I-sys X-ray system.
  - Cables of treatment table (supply, communication and grounding).
  - Cables of remote console (i**f present**, RJ45 for KVM and Harting cable for signals).
  - X-ray footswitch cable (local and remote if present).
  - DICOM cable (if present).
  - U/S cable harness. (for system with external U/S scanner only)

20.3 Labels

- Check that all labels of the system are visible and in good condition (not cracked or missing).
- Report inspection result

20.4 Panels and screen clean

- Check that all panels and screens for all devices are clean and free of dust, organic fluids or ultrasound gel.
- Report inspection result.

20.5 PM Stickers

For France only.

- Put the sticker on the white hood of the I-sys.
- Write the date of the next expected PM
- Report action completion.

21.ELECTRODE STORAGE UNIT

21.1 Blue LED

- Verify that when you put the power button to ON position the blue LED above the button turns ON.
- Report inspection result.

21.2 Pressure drops below -0.95

- Make sure that the pressure drops below -0.95 bar and doesn't stop before.
- Report inspection result.

21.3 Time to achieve vacuum pressure

- Record the time to reach the -0.95 bar (it must be under one minutes)
- Report inspection result.

21.4 OFF button

- Make sure that when you put the power button on the off position, it stops the vacuum and put the pressure to 0 bar.
- Report inspection result.

21.5 Electric cord is not frayed or damaged

- Make sure that the power cord is in good condition.
- Report inspection result.

21.6 Electrobox

<u>If an Electrobox is available only</u>

- Check that electro box is in good condition, not pierced nor broken.

22. ELECTRICAL SAFETY TEST

If IEC 62353 electrical safety tests are required by local regulation only:

Perform i-sys module electrical safety test according **TMS511958** Electrical safety test instruction.
Report results in **TMS511950** Maintenance checklist EST.

Perform table electrical safety test according **TMS511958** Electrical safety test instruction.
Report results in **TMS511950** 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.

23. SYSTEM READY

- Empty and clean test tank(s) mind not throwing the lead ball is the drain.
- Store all tools in its intended place.
- Remove electrode using treatment interface.
- Store the least used electrode in its storage bench and discard the other one.
- Wipe dry membrane and generator.

For systems with Windows 7 computer, global version D or higher:

- Log as "**isys**" window user.

For all system:

- Turn off system.
- If not done yet install table cushions.

24. REPORTING

- Send filled checklist to EDAP TMS personal in charge of technical followup.
- Send logs inspected at item 17.6
- Arrange all pictures and screenshots with test item number for each in a unique document and send it.