

Using Guide of Sonolith i-sys with option Visio Track

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1. DESCRIPTION SONOLITH I-SYS VISIO TRACK

The Sonolith® i-sys with option Visio Track have exactly the same function than standard version. We have added a new localization system by ultrasound.



Figure 1 : Sonolith i-sys description

The system uses an infrared camera (1), watching continuously different tools named « 3D sensors » (2) (3) (4). It allows the localization and the follow up by ultrasound. The Sonolith® adds an arm with a brake to give the good direction to the camera.



Figure 2 : Visio track's probe

The ultrasound probe allows searching the stone, probe in hand, inside the patient. For using of this probe, follow the chapter 3.1.2.



Warning

**The 3D sensors must not be touched.
To ensure correct device spatial localization, the reflective spheres on the locating devices should be replaced regularly.**

2. PRECAUTIONS FOR USE

2.1 Physical impact the Visio Track arm.

During movement of the generator to Parking/Treatment or Treatment/Parking, the operator must ensure that this latter does not bang his/her head on the Visio track arm.

2.2 Physical impact between table tool and generator.

There is a high risk of shocks between the ultrasound probe support and the generator, when the ultrasound probe is in contact with the patient, and the operator move up the generator to 50° position.

3. SONOLITH I-SYS WITH VISIO TRACK PROCEDURE

3.1 Visio Track

The "Visio Track" system is an automatic ultrasound localization device. It is comprised of the following elements:

- Ultrasound probe.
- Infrared video camera.
- Localization tools

This system is extremely simple to set up and use.

3.1.1 Daily check

When starting the Sonolith® i-move equipped with the Visio Track system, a calibration check is requested. Place the generator's ultrasound probe at this location.



Figure 3: Calibration check of the Visio Track

The following message is displayed

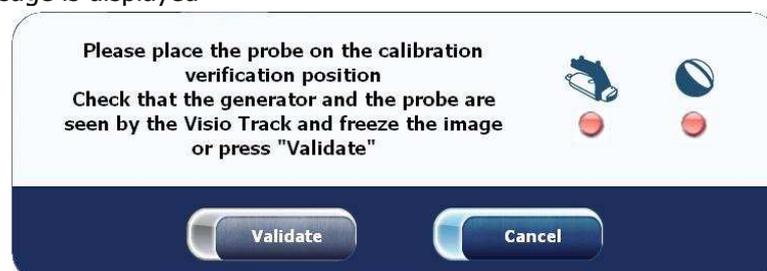


Figure 4 : Visio Track calibration check

Check that both red indicator lights turn green, then freeze the image by pressing the button on the ultrasound probe, or press the "Confirm" button.

Warning

To ensure correct device spatial localization, the reflective spheres on the locating devices should be replaced regularly.

If the test fails after several attempts, we recommend changing the spheres on the locating devices.

3.1.2 Procedure

1. From the main window, press ESWL.



Figure 5 : Main Window

2. Enter the patient's data into the database and initiate the treatment (see fluoroscopy localization).
3. Accessing the main ESWL treatment window.



Figure 6 : Treatment window



Information

For installing and positioning the patient, see Section 5 (TMS 229 976), Chapter 1.5 "Installing and positioning the patient" in the "Sonolith® i-sys procedures" section.



Information

When you put the towels on the table, be sure that the localization tools are not hidden.

4. Take position in the operator zone (see Section 4 (TMS 229 975), Chapter 2.1.1).
5. From the main window of the navigation platform, select the patient's position.



Figure 7: Choice of patient's position on the table.



Information

The ultrasound image settings can be modified. For this, in the treatment window, on the "Localization" or "Imaging settings" tab, click on the "U/S +" button. The following window is displayed:

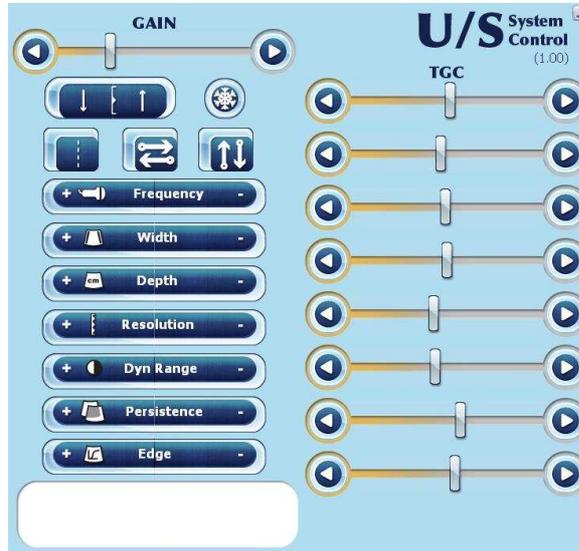


Figure 8: Ultrasound image quality settings window

6. Place the generator in the Treatment position, with ultrasound gel on the membrane.
7. Take hold of the ultrasound probe fitted with the "3D sensor".
8. Apply gel to the probe.
9. Search for the stone using the ultrasound probe. Once the stone has been located, freeze the image by pressing the button on the probe, or click on "Stone position".

Warning

It's very important to immobilize the right arm of your patient, when you treat the right kidney or ureter. Use an Broad strap (See Section 7 (TMS 229 978), Chapter 4 "List of accessories").

10. Using your finger, target the stone position on the right-hand screen. Two lines are displayed

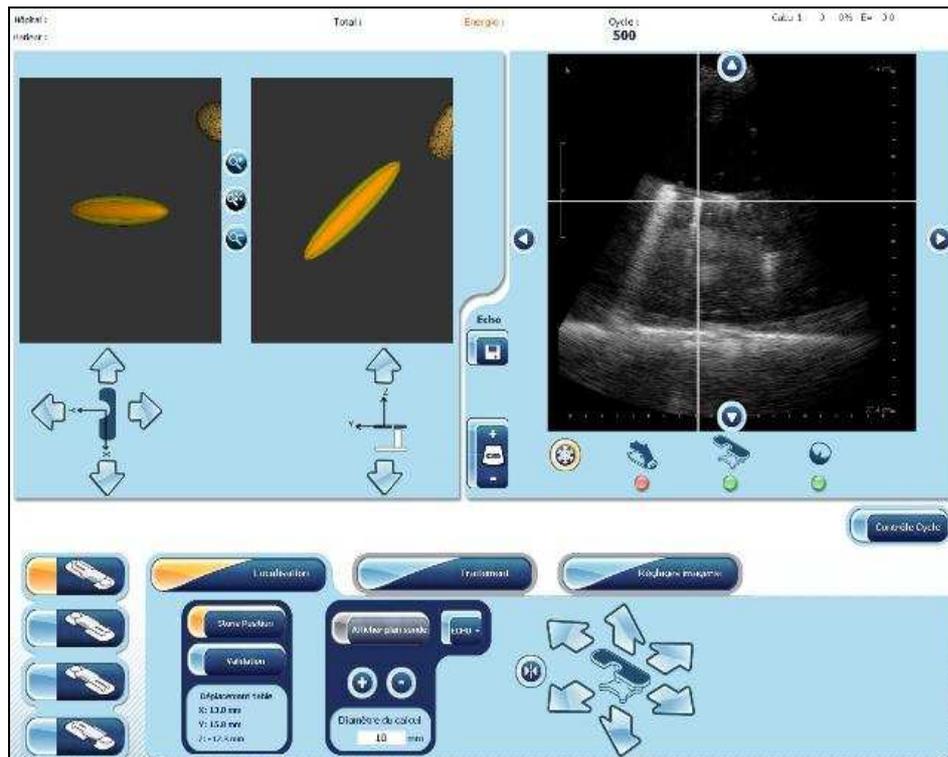


Figure 9: Localization window

11. The stone position targeting process can be improved. For this, use the 4 arrows displayed around the ultrasound image.



Information

The two "virtual" views that appear on the left-hand side of the window represent the XY and YZ sections through the plane of the table and centered on the F2 focal point.

12. Once the stone has been correctly targeted, the software displays the movement to be made by the table to bring the stone to the generator's focal point.
 - a. If the located stone is within the table's movement limits, the table movement arrows are displayed (in the two circles) in the two "virtual" views and the "Confirmation" button is enabled.

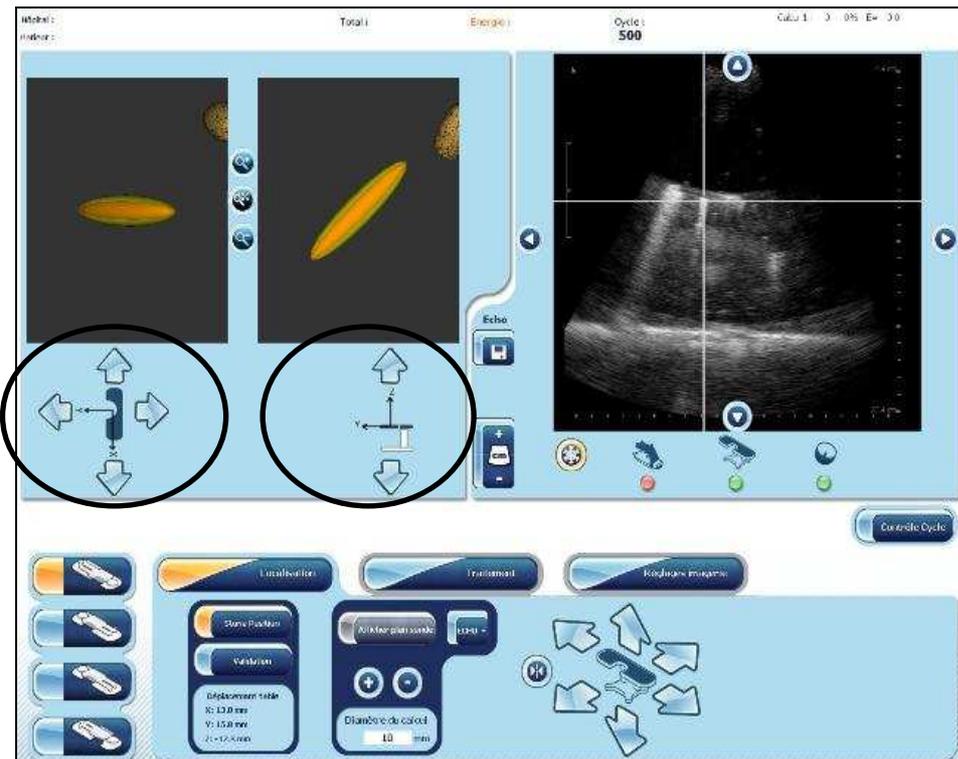


Figure 10: Ultrasound localization

The user then has two options:

- Either press the "Confirmation" button, the table automatically brings the patient's stone to the focal point.
 - Or press the arrows to manually bring the stone to the focal point.
- b. If the located stone is beyond the table's movement limits, a message is displayed asking the user to move the patient according to the diagram shown on-screen (see circle).



Figure 11: Patient movement

Move the patient as indicated and repeat the ultrasound-assisted stone localization, then repeat the procedure from step 12.

13. Immobilize the probe support using the articulated arm mounted on the table and unfreeze the ultrasound image; the stone should be on the cross shown on-screen.

⇒ **The stone now is localized.**



Important

Do not fit the probe onto the articulated arm until the stone has been correctly targeted and the table has finished moving (risk of collision between probe and generator).

Always confirm that the stone has been correctly located by means of a second ultrasound search: the cross should be on the stone in the ultrasound image.

If the generator is not in the 0° position, it is also possible to perform an X-ray-assisted check.

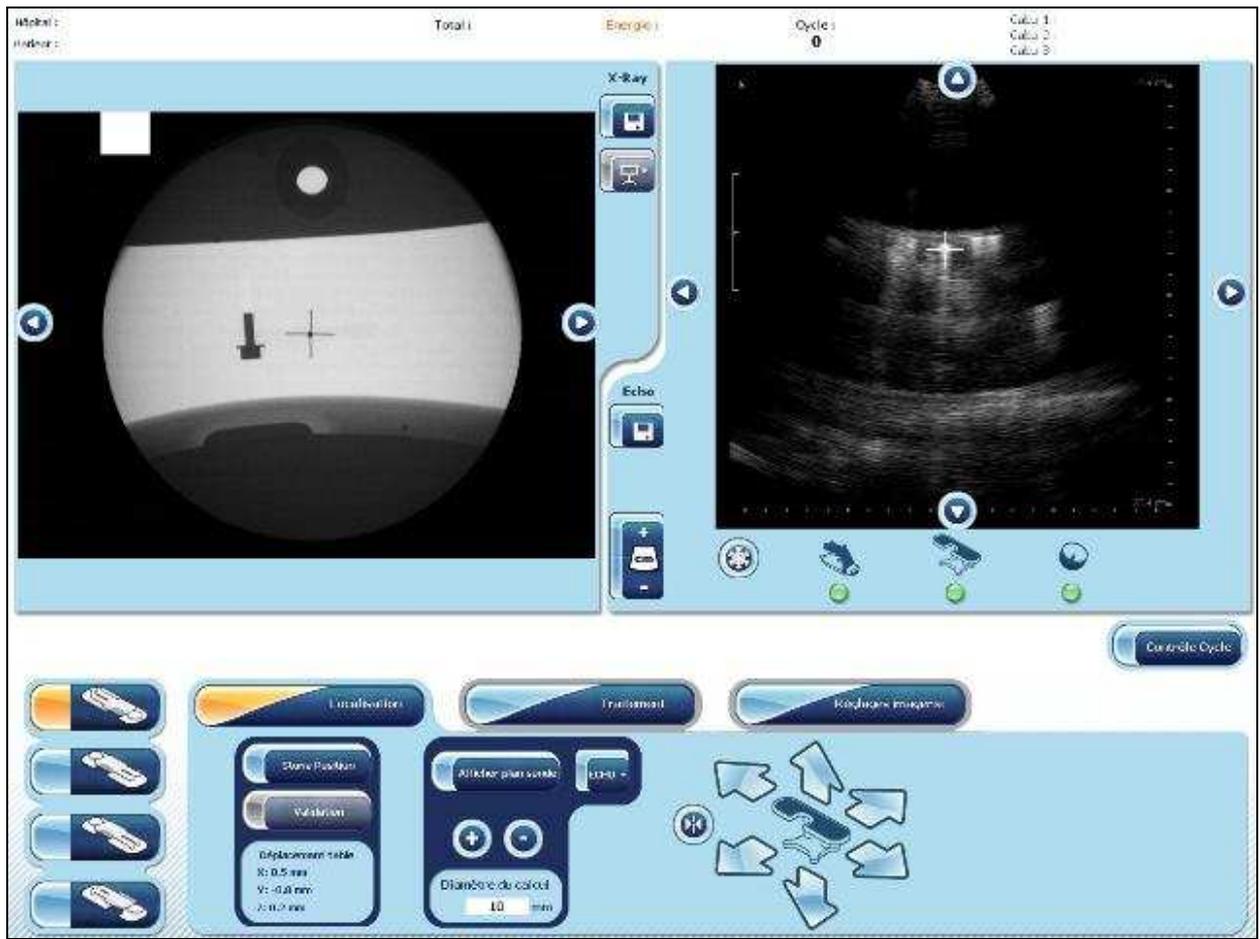


Figure 12: Stone monitoring

14. From the "Localization" tab, select the "Display probe plane". The ultrasound probe's section plane is displayed on the left-hand screen, along with the focal point; this allows the stone position to be corrected, if necessary, relative to the focal point.
 - a. Locate the stone using the ultrasound probe. Immobilize the ultrasound probe using the locking system.
 - b. If the cross on the ultrasound image is not directly over the stone, either raise or lower the table in order to display the cross on the right-hand image.
 - c. Move the table transversally or longitudinally to bring the stone to the focal point (represented by a cross).

15. Select the "Treatment" tab. To start the treatment, adjust the following settings:
 - a. Desired power: 25%
 - b. Shot frequency: 2 Hz.
 You can then start the firing process. For this, press and hold the firing button on the remote control.

16. Leave the ultrasound probe in contact with the patient throughout the treatment, thanks to the ultrasound probe support arm and check that the stone remains on the cross.

 **Information**

Once the plane of the probe is perfectly positioned on the focal spot (to within $\pm 6\text{mm}$), a cross is displayed to indicate that the stone is correctly positioned. Then up to 10mm, the focal spot is represented by two lines. Beyond this, no marks are displayed.

 **Information**

It is important to inform the patient that treatment is about to begin to avoid any involuntary movements. If appropriate, you can invite him/her to wear safety earmuffs (See Section 7 (TMS 229 978), Chapter 6 "List of Accessories").

See Section 5 (TMS 229 975), Chapter 1.4 "Beginning treatment" for treatment management.

4. DAILY CHECKS

4.1 X-Ray calibration checking

4.1.1 Tool for checking



Figure 13 : F2 calibration tool with membrane



Figure 14 : F2 simulator tool

4.1.2 X-Ray C-Arm calibration

Start the Sonolith® i-sys (See Section 5 (TMS 229 976), chapter 1.1)
Put the F2 calibration tool with membrane on the generator.
The generator must at 50° position



Figure 15 : F2 calibration tool in position for X-ray calibration

With the C-arm, make X-ray image. The sphere must touch both side of the cross

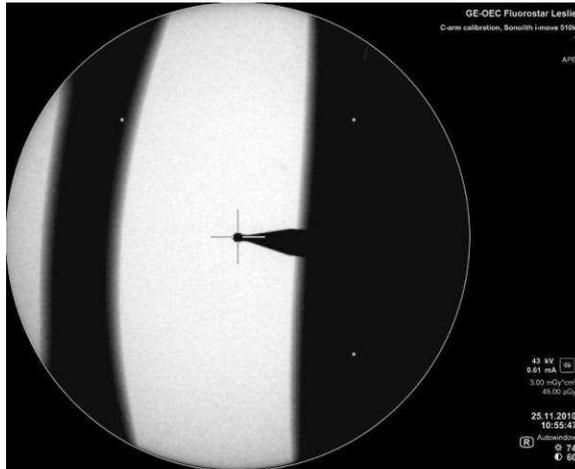


Figure 16 : X-Ray calibration checking (0°)

Move the C-arm to +25°, make X-ray image. The sphere must touch both side of the cross

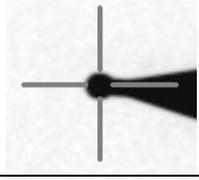
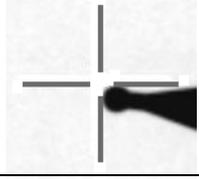
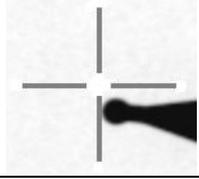


Figure 17 : X-Ray calibration checking (+25°)

Move the C-arm to -25°, make X-ray image. The sphere must touch side of the cross.



Figure 18 : X-ray calibration checking (-25°)

Status	Image example	Conclusion
The sphere is to centered inside the X-ray cross		Calibration is fine
The periphery of the sphere is in contact with at least 2 lines of the X-ray cross		Calibration is not fine but remains acceptable
The periphery of the sphere is in contact with only 1 line of the X-ray cross		Calibration is NOT acceptable

Remove the F2 calibration tool with membrane.

4.1.3 X-Ray localization accuracy test

The accuracy of the X-ray localization is checked by the "needle-needle" test.

1. F2 simulator tool is fixed in the generator in parking position and the X-ray/U-S Localization tool is placed on the table with the X-ray needle option mounted.
2. The table is set to the central position.

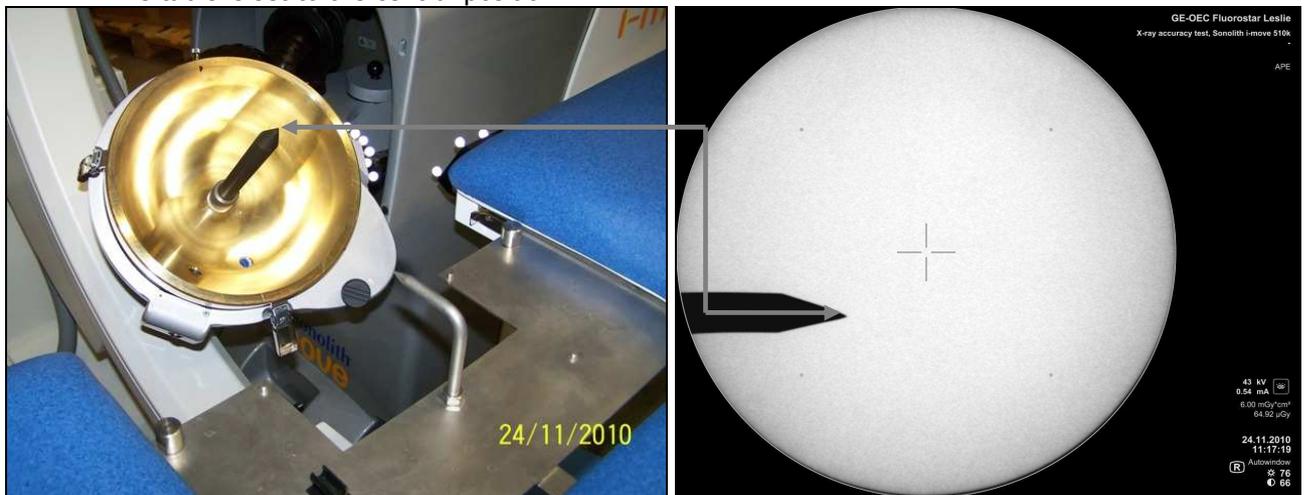


Figure 19 : Localization tool with X-ray localization

3. X-ray localization is performed following the localization procedure described Section 4, chapter 3.6 Fluoroscopy stone localization.

- Put the generator in treatment position and the distances between the 2 needles' tips are measured with a mechanical ruler along X, Y and Z axis. X-ray images are recorded for the 3 C-arm's angulations 0°, +25° and -25°.

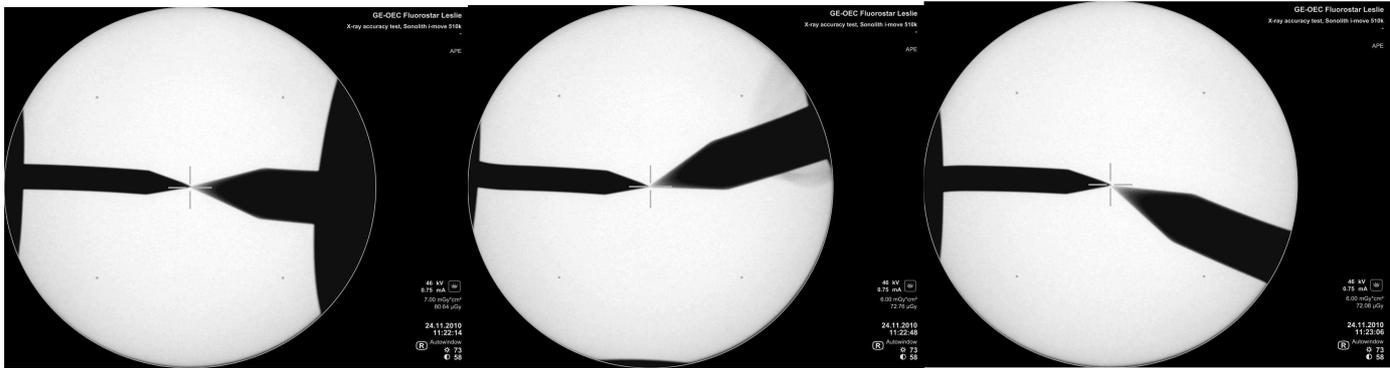


Figure 20 : X-Ray checking

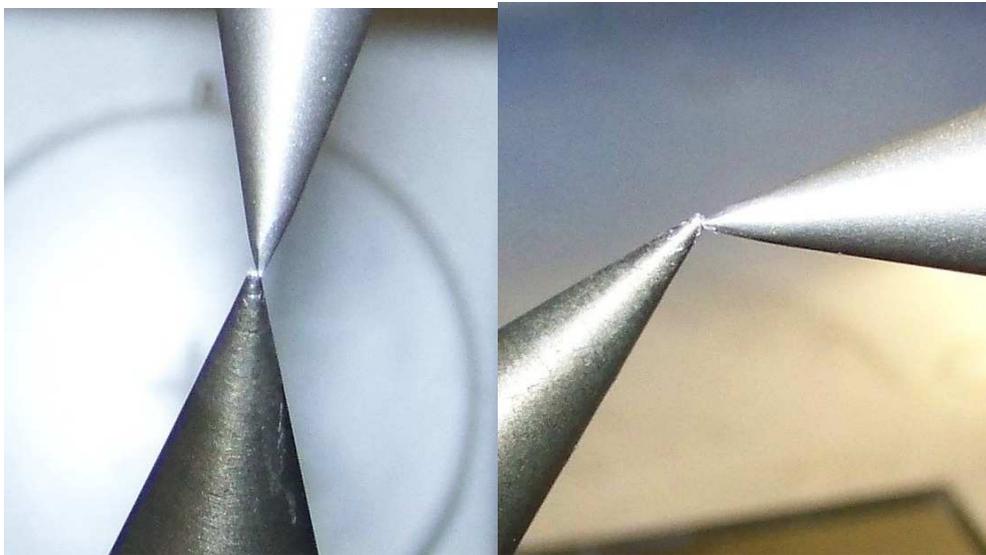


Figure 21 : X, Y axis and Z axis Visual checking

- Check with a ruler the distance between the F2 simulator tool and X-ray/U-S Localization tool. The maximal distance between the two tools is 2 mm.

4.2 Accuracy of ultrasound calibration with Visio Track:

4.2.1 Description of the daily integration test of Visio Track

A daily compulsory integration test is requested when Sonolith i-move is switched on. The Visio Track system is switched on and relative positions of the U/S probe markers with the ESWL generator markers (for the 50° and 0° positions) are compared. If the test's recorded space coordinates (X, Y, and Z) are greater than 1mm relative to the memorized positions, the test is declared as failed and the Visio Track localization feature is inhibited and unusable.

4.2.2 Visio Track test tool

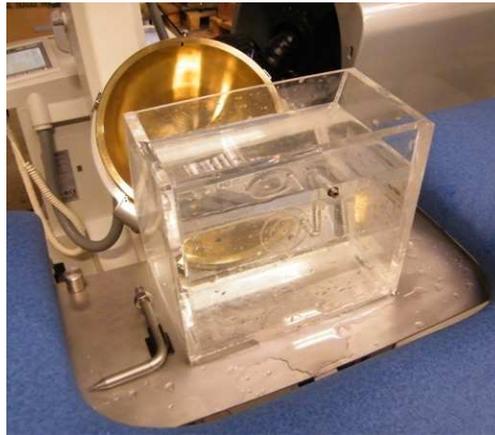


Figure 22 : Test tank

4.3.3 Description of overall localization accuracy test:

1. X-ray localization of the fishing ball is performed using the standard procedure :

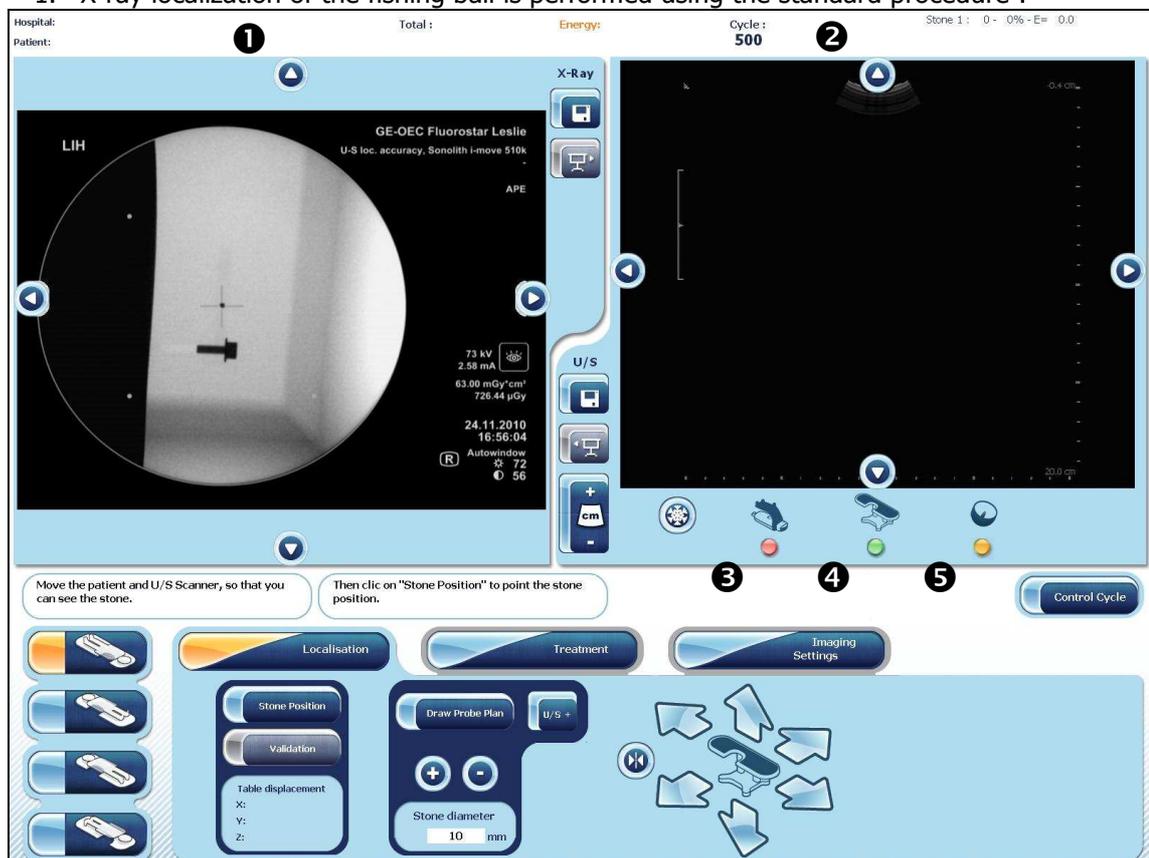


Figure 23 : Treatment window

- 1 X-ray image: Ball is targeted after X-ray localization procedure.
 - 2 U/S image: Live image – Visio Track U/S probe not in contact with the localization tool.
 - 3 Visio Track U/S probe indicator: Red means the probe is not visible in the Visio track field.
 - 4 Visio Track Patient's table indicator: Green means the probe is visible in the Visio track field.
 - 5 Visio Track ESWL generator indicator: Orange means ESWL generator is in parking position.
2. Ultrasound gel is applied to the tip of the U/S probe and the probe is brought in contact with the tool.



Figure 24 : Test tank

- The U/S probe is moved by the operator until the ball is clearly visible on the U/S image (Draw plan function can be used for a quicker localization). Because the ball has been previously precisely targeted with X-ray (left image), the Visio Track F2 cross is automatically appearing on the ball (right image).

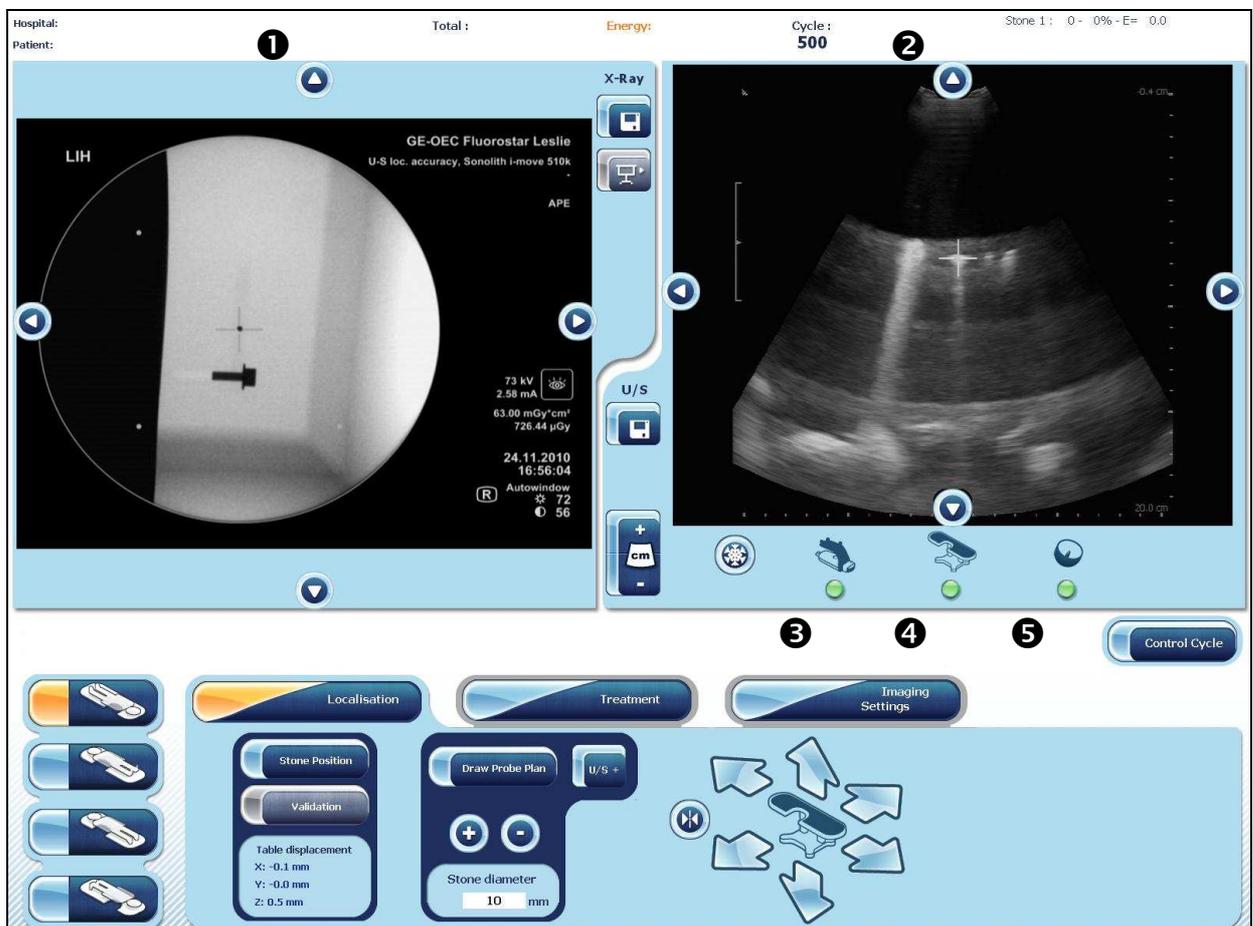


Figure 25 : Treatment window

- X-ray image: Ball is still targeted after X-ray localization procedure*
 - U/S image: Live image – Visio Track U/S probe is pointing the ball with F2 cross on it*
 - Visio Track U/S probe indicator: Green means the probe is visible in the Visio track field*
 - Visio Track Patient's table indicator: Green means the probe is visible in the Visio track field*
 - Visio Track ESWL generator indicator: Green means ESWL generator is in Treatment position*
- The position of the ball is checked on the U/S imaging regarding the position of the F2 cross.
 - The measure distance function of the U/S scanner is used to measure the distance between the F2 cross center and the center of the ball

6. The maximum error must be ± 2 mm.



IMPORTANT

If the result is good, you can continue the checking.

If the result is not correct, try to do again the calibration of X-Ray system. If it is not correct again, don't use the Visio Track for treat. Call the local technical service.

5. ERROR MESSAGES

5.1 Visio track errors

Code	Text	Possible cause(s)	Actions to undertake
1800	Cannot open the Visio Track COM port.	Ensure that the system is turned on.	Retry. Else, try to restart. If the problem persists, Ignore, but you will no longer be able to use Visio Track-assisted ultrasound localization.
1801	Cannot determine the type of Visio Track system	Visio Track to PC USB link problem.	Ignore, but you will no longer be able to use Visio Track-assisted ultrasound localization.
1802	Cannot initialize the Visio Track system	Visio Track to PC USB link problem.	Ignore, but you will no longer be able to use Visio Track-assisted ultrasound localization.
1803	Cannot activate the NDI ports. Check ROM file configuration. Ensure that the system is on and has initialized.	Visio Track to PC USB link problem.	Ignore, but you will no longer be able to use Visio Track-assisted ultrasound localization.
1804	Cannot communicate with the Visio Track	Visio Track to PC USB link problem.	Retry. Else, try to restart. If the problem persists, Ignore, but you will no longer be able to use Visio Track-assisted ultrasound localization.
1805	Visio Track temperature error	Visio Track to PC USB link problem.	Retry. Else, try to restart. If the problem persists, Ignore, but you will no longer be able to use Visio Track-assisted ultrasound localization.

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