Preventive maintenance instruction

TRINITY®

TRINITY®

CONTACT

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1. AIM OF THE DOCUMENT

This instruction describes all tests to perform during the preventive maintenance visit for TRINITY® system. This visit is made by KOELIS or by an authorised person by KOELIS.

The result of performed test are reported in the maintenance preventive report. Before performing preventive maintenance visit, it's necessary to prepare adequate number of tables corresponding to the number of ultrasound probe installed on site.

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2. TRINITY SYSTEM DESCRITION

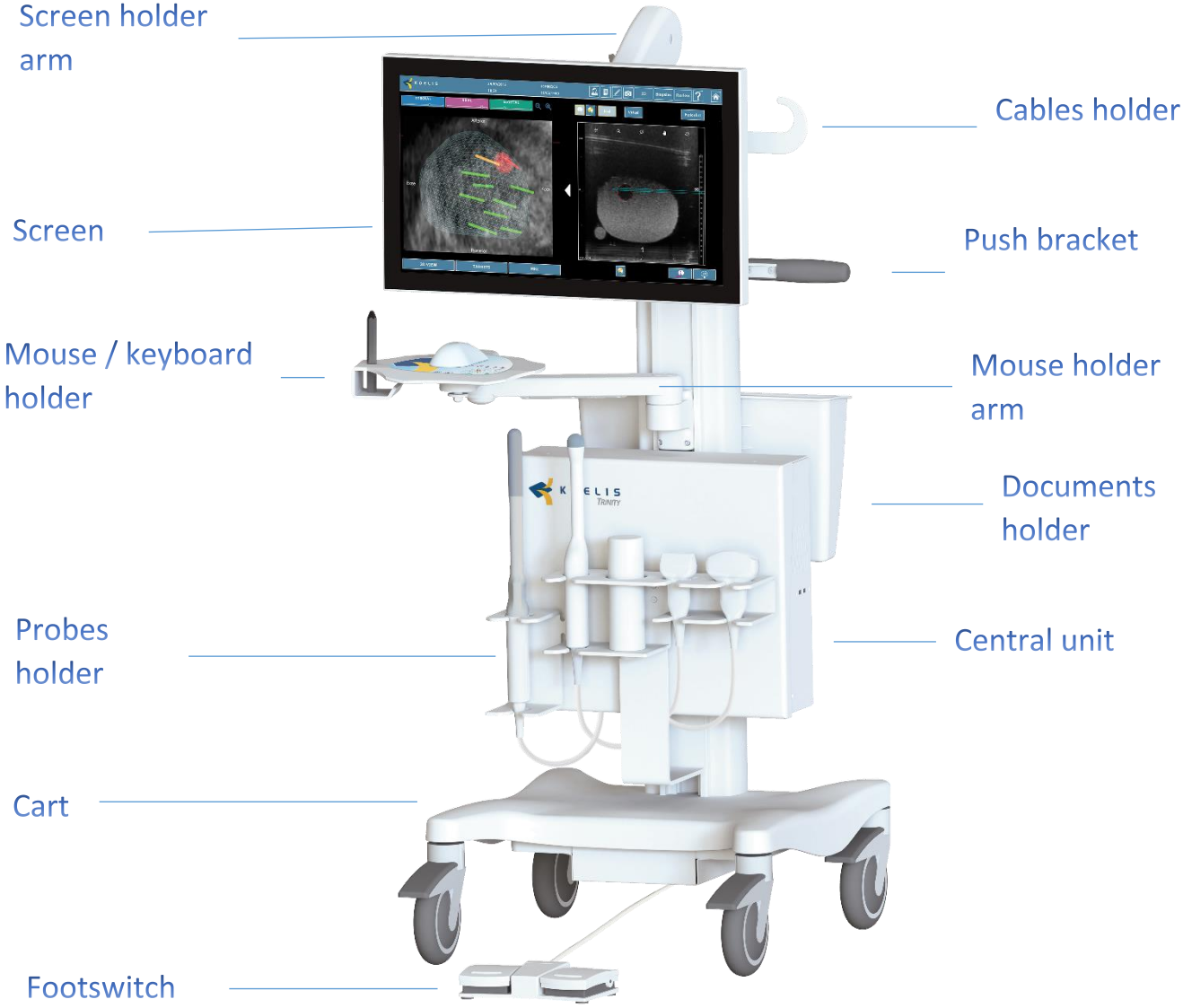


Figure 1 : TRINITY® KURO-3000-2 system description

3. NECESSARY MATERIEL

Materiel	
Phantom ATS 539	
Phantom CIRS 053L	
Allen key set European ISO	Used for: - the screen (key 3 mm) - the cable holder (key 4 mm) - the probe holder (key 2.5 mm)
Allen key set American UNC	Key 1/8 used for: - the screen holder arm, to adjust the weight compensation of the screen holder arm - the push bracket - the mouse holder arm
FOR6720 : Preventive maintenance report for TRINITY®	
Metal rod (diameter 2 mm)	
USB key	

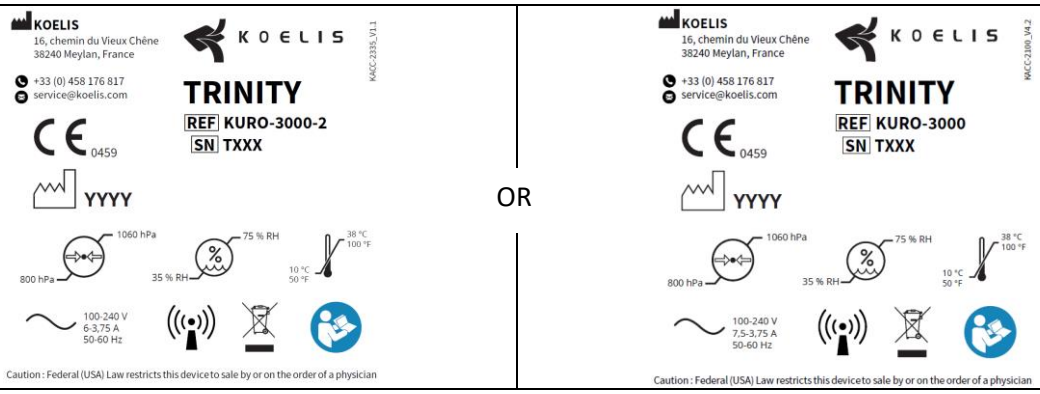
4. VERIFICATION AND TESTS

4.1 CART

4.1.1 BASE AND WHEELS

1- Operate a visual check of the component.

2- Check the presence and the readability of following labels :

<table>
<tr><th>Fuse label</th><th>Warning column label</th></tr>
<tr><td>
<table>
<tr><th colspan="4">2x PRIMARY FUSE</th></tr>
<tr><td>Voltage</td><td>Current</td><td>Operating speed</td><td>Breaking capacity</td></tr>
<tr><td>250 V</td><td>8 A</td><td>fast acting</td><td>1500 A</td></tr>
</table>
</td><td>  </td></tr>
<tr><th colspan="2">Identification label</th></tr>
<tr><td colspan="2">


</td></tr>
</table>

3- Move the cart (forward, backward and rotation).

4- Set up all brakes.

4.1.2 MOUSE HOLDER ARM

1- Operate a visual check of the component.

2- Check the presence and the readability of following labels :

Articulated mouse holder label	Empty label
	

3- Move the articulated mouse holder in extrem positions :

- Extension (figure 2.1),
- Left / right bending (figure 2.2 and 2.3),
- Parking position (figure 2.4 and 2.5).

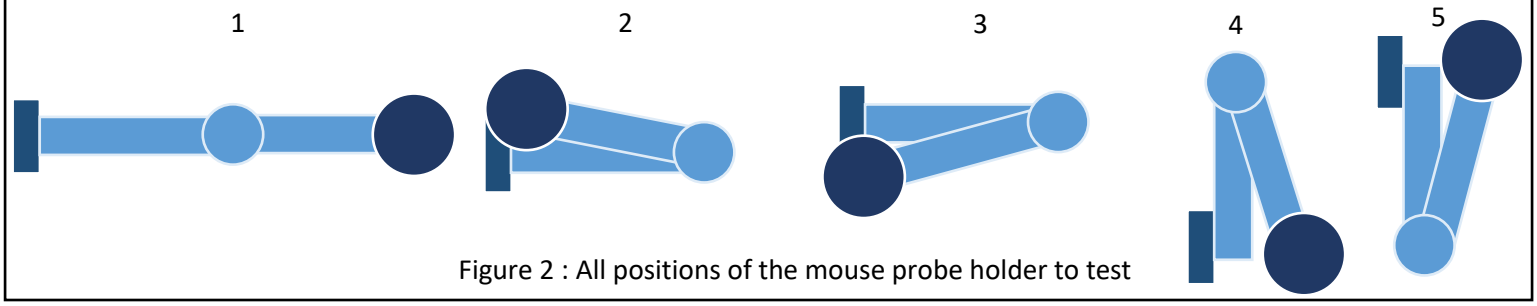


Figure 2 : All positions of the mouse probe holder to test

4- Check that the cable of the mouse is in the cable hider which is under the articulated mouse holder.

4.1.3 SCREEN HOLDER ARM

1- Operate a visual check of the component.

2- Move the screen holder arm in diagonal extrem positions (fig. 3) :

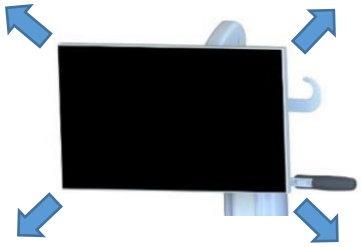


Figure 3 : Movements to test with the TRINITY®

3- Tilt the screen in the following position :

- Up / down,
- Left / right.

4- Check the weight compensation of the screen.

5- Check the cables' stress and check the presence and the state of the ground cable (fig.4).

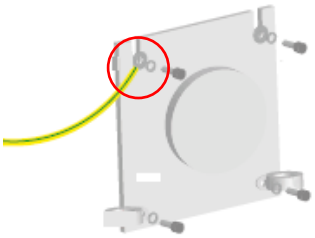


Figure 4 : Back of the screen showing the ground cable

4.1.4 MOUSE / KEYBOARD HOLDER

1- Operate a visual check of the component.

2- Rotating it, move in both extrem positions (fig.5).

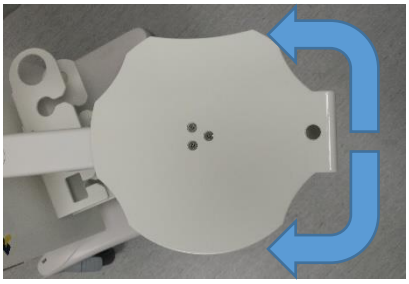


Figure 5 : Moves to test for the mouse holder

3- Check the fixation of the component.

4.1.5 PROBES HOLDER

1- Operate a visual check of the component.

2- Check the presence and the readability of following label :

Probe holder label	< 3 kg / 6.6 lbs

3- Check the fixation of the component.

4.1.6 CABLES HOLDER

1- Operate a visual check of the component.

2- Check the fixation of the component.

4.1.7 PUSH BRACKET

1- Operate a visual check of the component.

2- Check the fixation of the component.

4.1.8 DOCUMENTS CARRIER

1- Operate a visual check of the component.

2- Check the presence and the readability of following label :

Document carrier label	KOELIS REF KIT-3045 < 7 kg / 15.4 lbs

3- Remove the documents carrier sliding it upward and do a visual check of the fastening element of the documents carrier (figure 6).

Figure 6 : Fastening element of the documents carrier

4- Put the documents carrier back.

4.2 ACCESSORY

4.2.1 FOOTSWITCH

1- Operate a visual check of the component.

2- Check the presence and the readability of following labels :

KOELIS label	KOELIS
Green KOELIS label	KOELIS
Pink KOELIS label	KOELIS

3- On PROMAP, select the creation of a patient icon. With the left pedal, cancel the creation of a patient. With the right pedal, validate the creation of the patient.

4.3 COMPUTING COMPONENT

4.3.1 MOUSE

1- Operate a visual check of the component.

2- Check the presence and the readability of following label :

KOELIS label	KOELIS

3- On PROMAP, go to patient list.
Select a patient with:

- Left click,
- Right click,

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- Central bouton of the mouse wheel.

4- Scroll the patient list with up and down button of the mouse wheel.

4.3.2 KEYBOARD

1- Operate a visual check of the component.

2- Check the presence and the readability of following label :

KOELIS label	

3- On PROMAP, open the patient creation window and test all letters and numbers inside it.

4.3.3 SCREEN AND STYLUS

1- Operate a visual check of the components.

2- Check the presence on the screen and the readability of following label :

Ground KOELIS label	

3- Go to user account window of the TRINITY.

4- Test screen function with the rotary selector on the right side of the screen.

5- Go to user account windows. Do a “S” on the screen with the stylus to test touch function.

4.3.4 CENTRAL UNIT

1- Operate a visual check of the components.

2- Check the presence and the readability of following labels:

USB TRINITY® label	Equipotential TRINITY® label (localized on the back of the central unit)
	
Blue TRINITY® label	Yellow TRINITY® label
	

3- Check the security label which prevent the opening of the central unit.

4- Check the cables connection under the central unit.

5- Go to maintenance account, generate the system information report and store it on the USB key.

4.3.5 CONNECTIVITY

1- Create a patient and import to TRINITY® an IRM/PET/CT image from PACS.

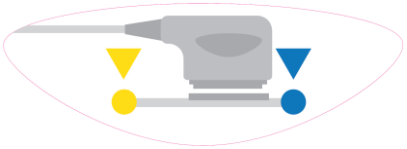
2- Open the patient creation window and import a patient from the WORKLIST.

4.4 ULTRASOUND PROBE

4.4.1 ABDOMINALE AND LINEAR PROBE

1- Operate a visual check of the probe, the cable and the connector.

2- Check the presence and the readability of following labels:

Identification label	Connexion label	Year label (on the identification label)
KOELIS 16, chemin du Vieux Chêne 38240 Meylan, France REF K2DAB00 SN AB00-XXX Rx ONLY 0459 KACC-2145_V4.1 OU KOELIS 16, chemin du Vieux Chêne 38240 Meylan, France REF K2DLN00 SN LN00-XXX Rx ONLY 0459 KACC-2135_V4.1		20xx
Blue probe label		Yellow probe label
		

3- <u>Piezoelectric transducer test (record the test via a cine-loop and export the video on the USB key to send it to KOELIS):</u>

- Connect the ultrasound probe to TRINITY® and open a PROMAP 2D session.

  <u>Necessary ultrasound parameters:</u>

  - *Focus closest to the probe*
  - *Disable all filters (Image averaging:0; Rejection: 0; Contour enhancement: disable; Grain attenuation: disable).*
  - *Power at the maximum*
  - *Inverse harmonic disable*
  - *Exploration angle: 0; Image compounding: 0.*

- Put some drops of water on the probe head.
- Place the metal rod on the probe such that it is orthogonal to the transducer array plane (fig.7).
- Move slowly from transducer element to transducer element. Verify that there is no harsh transition in the ultrasound image when the metal rod is deplaced (example with side-fire probe in figure 8).

Figure 7: Positioning of the metal rod on the probe

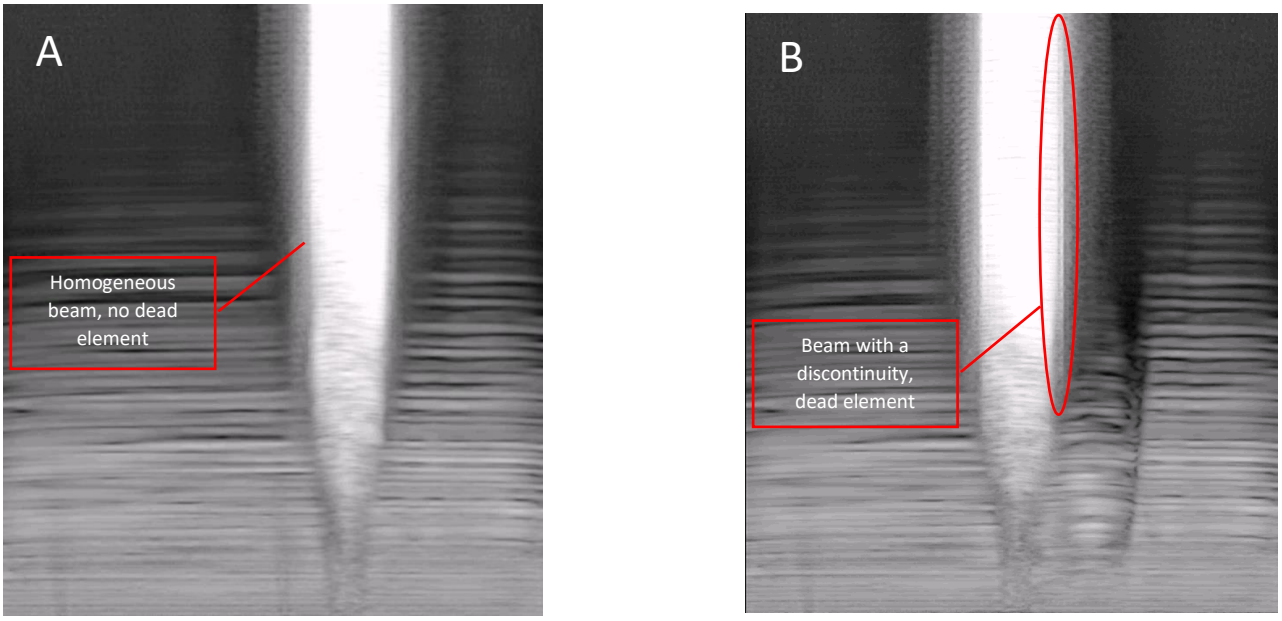


Figure 8: Ultrasound image of the metal rod: A : Beam without discontinuity ;
B : Beam with discontinuity

4- Quality image test : (Perform the test with all available frequency)

- In PROMAP 2D session, add some water into the phantom ATS 539.
- Perform an ultrasound image of the phantom (positioning of the probe described in figure 9) using KOELIS default ultrasound parameters.
- Compare the acquired image with the reference picture with same frequency (appendix 1 or 2 depending of the probe)
- Do a screenshot of the acquired image and export it on USB key to include it on the report.

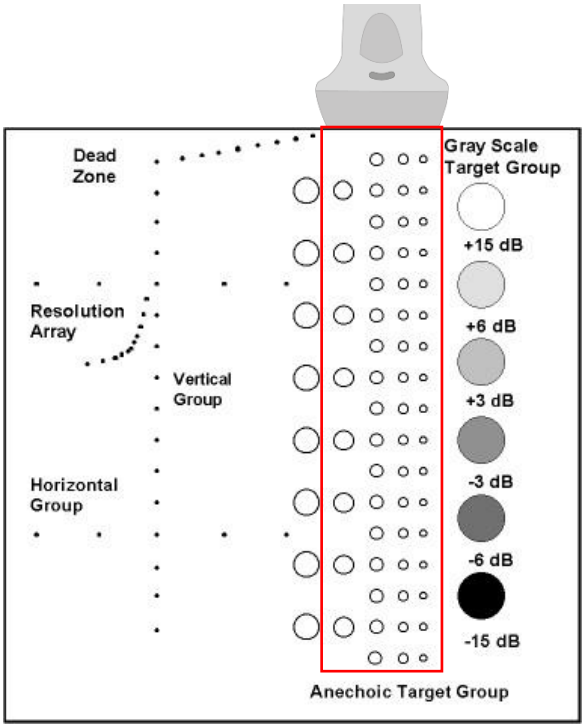
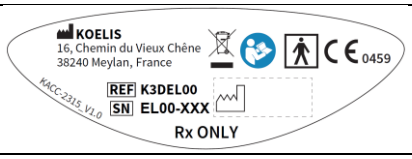


Figure 9 : Positioning of the probe on the phantom ATS 539

4.4.2 SIDE-FIRE PROBE

1- Operate a visual check of the probe, the cable and the connector.

2- Check the presence and the readability of following labels:

Identification label	Connexion label	Year label (on the identification label)
		20xx
Blue probe label	Yellow probe label	
		

3- <u>Piezoelectric transducer test (record the test via a cine-loop and export the video on the USB key to send it to KOELIS):</u>

- Connect the ultrasound probe to TRINITY® and open a PROMAP 2D session.

  <u>Necessary ultrasound parameters:</u>

  - *Focus closest to the probe*
  - *Disable all filters (Image averaging:0; Rejection: 0; Contour enhancement: disable; Grain attenuation: disable).*
  - *Power at the maximum*
  - *Inverse harmonic disable*

- Put some drops of water on the probe head.
- Place the metal rod on the probe such that it is orthogonal to transducer array plane (fig.10)
- Move slowly from transducer element to transducer element. Verify that there is no harsh transition in the ultrasound image when the metal rod is displaced (example in figure 11).

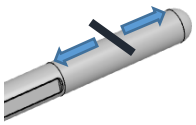


Figure 10: Positioning of the metal rod on the probe

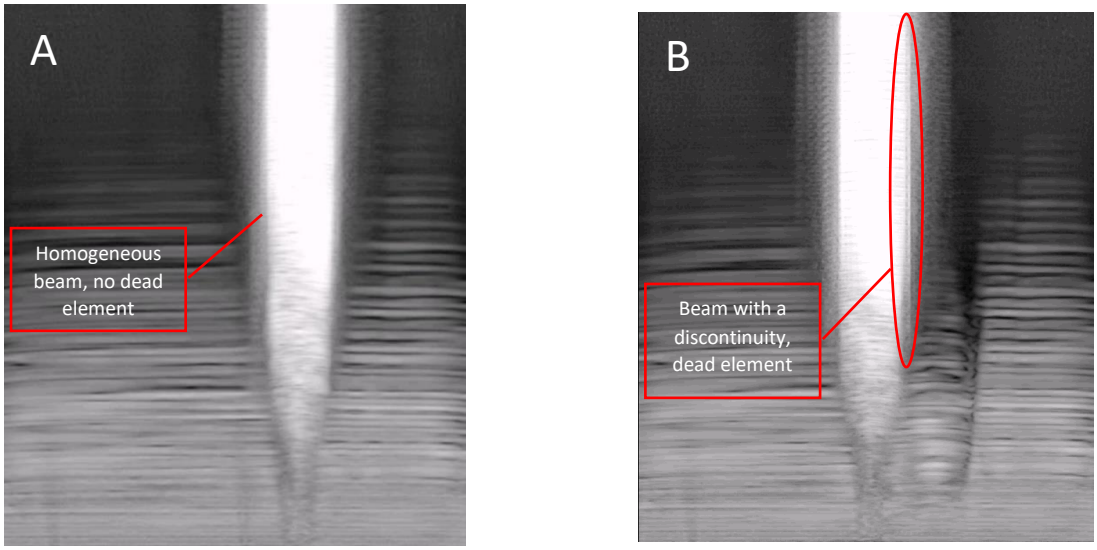


Figure 11: Ultrasound image of the metal rod: A : Beam without discontinuity ;
B : Beam with discontinuity

4- Quality image test : (Perform the test with available frequency)

- In PROMAP 2D session, put some ultrasound transmission gel on the probe and perform an ultrasound image of the phantom CIRS 053L (visualization of the urethra and 1 or 2 lesions) using KOELIS default ultrasound parameters.
- Compare the acquired image with the reference picture with same frequency (appendix 3)
- Do a screenshot of the acquired image and export it on USB key to include it on the report.

5- 3D function test: Into a PROMAP biopsy session, perform a panorama with the ultrasound probe in your hand. Look the probe motor according to the figure 12.

Figure 12 : Positioning to see the motor

6- Motor's position test: Open a PROMAP biopsy session. Fix the needle guide on the probe. Insert a no-twisted needle into the guide and into the farest notches. Perform a panorama into the water where the needle is visible.

Check in axial view that the needle is right (caution: the screen to visualize the panorama disappears after 7 seconds, use the tactile function of the screen to reset the countdown).
A counterexample is given in figure 13.

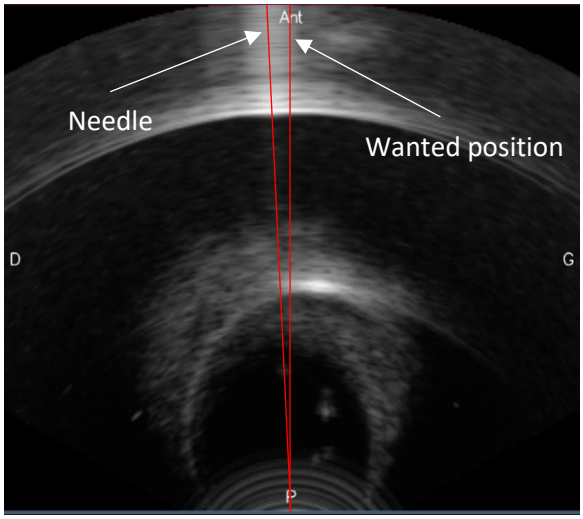
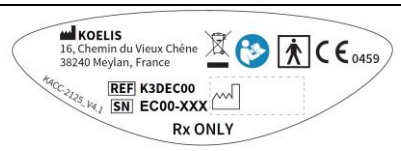
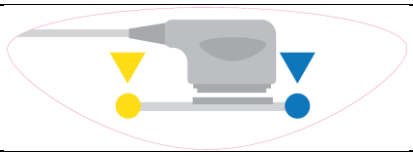
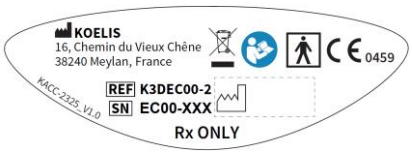


Figure 13: Panorama in axial view showing a non-aligned needle,
the motor is not in position zero

4.4.3 END-FIRE PROBE

1- Operate a visual check of the probe, the cable and the connector.

2- Check the presence and the readability of following labels:

Identification label	Connexion label	Year label (on the identification label)
		20xx
OU	Blue probe label	Yellow probe label
		

If there is no identification label on the probe, note the VERMON number which is inside the connector.

3- <u>Piezoelectric transducer test (record the test via a cine-loop and export the video on the USB key to send it to KOELIS):</u>

- Connect the ultrasound probe to TRINITY® and open a PROMAP 2D session.

  <u>Necessary ultrasound parameters:</u>

  - *Focus closest to the probe*
  - *Disable all filters (Image averaging:0; Rejection: 0; Contour enhancement: disable; Grain attenuation: disable).*
  - *Power at the maximum*
  - *Inverse harmonic disable*

- Put some drops of water on the probe head.
- Place the metal rod on the probe such that it is orthogonal to transducer array plane (fig.14).
- Move slowly from transducer element to transducer element. Verify that there is no harsh transition in the ultrasound image when the metal rod is displaced (example in figure 15).

Figure 14: Positioning of the metal rod on the probe

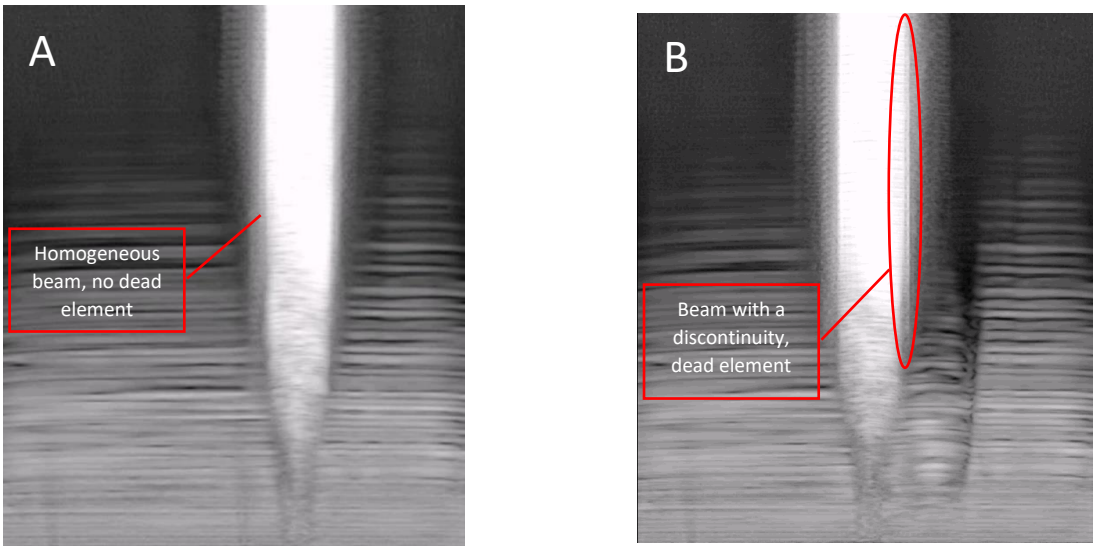


Figure 15: Ultrasound image of the metal rod: A : Beam without discontinuity ;
B : Beam with discontinuity

4- Quality image test : (Perform the test with following frequency: 4 MHz, 7 MHz, 9 MHz)

- In PROMAP 2D session, put some ultrasound transmission gel on the probe and perform an ultrasound image of the phantom CIRS 053L (visualization of the urethra and 1 or 2 lesions) using KOELIS default ultrasound parameters.
- Compare the acquired image with the reference picture with same frequency (appendix 4)
- Do a screenshot of the acquired image and export it on USB key to include it on the report.

5- 3D function test: Into a PROMAP biopsy session, perform a panorama with the ultrasound probe in your hand. Look the probe motor according to the figure 16.

Figure 16 : Positioning to see the motor

6- Motor's position test: Open a PROMAP biopsy session. Fix the needle guide on the probe. Insert a no-twisted needle into the guide. Perform a panorama into the water where the needle is visible.

Check in sagital view that the needle is right (caution: the screen to visualize the panorama disappears after 7 seconds, use the tactile function of the screen to reset the countdown).
A counterexample is given in figure 17.

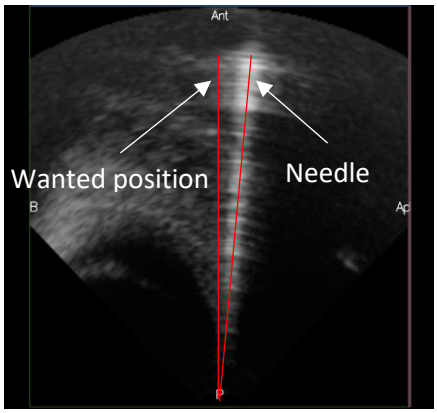
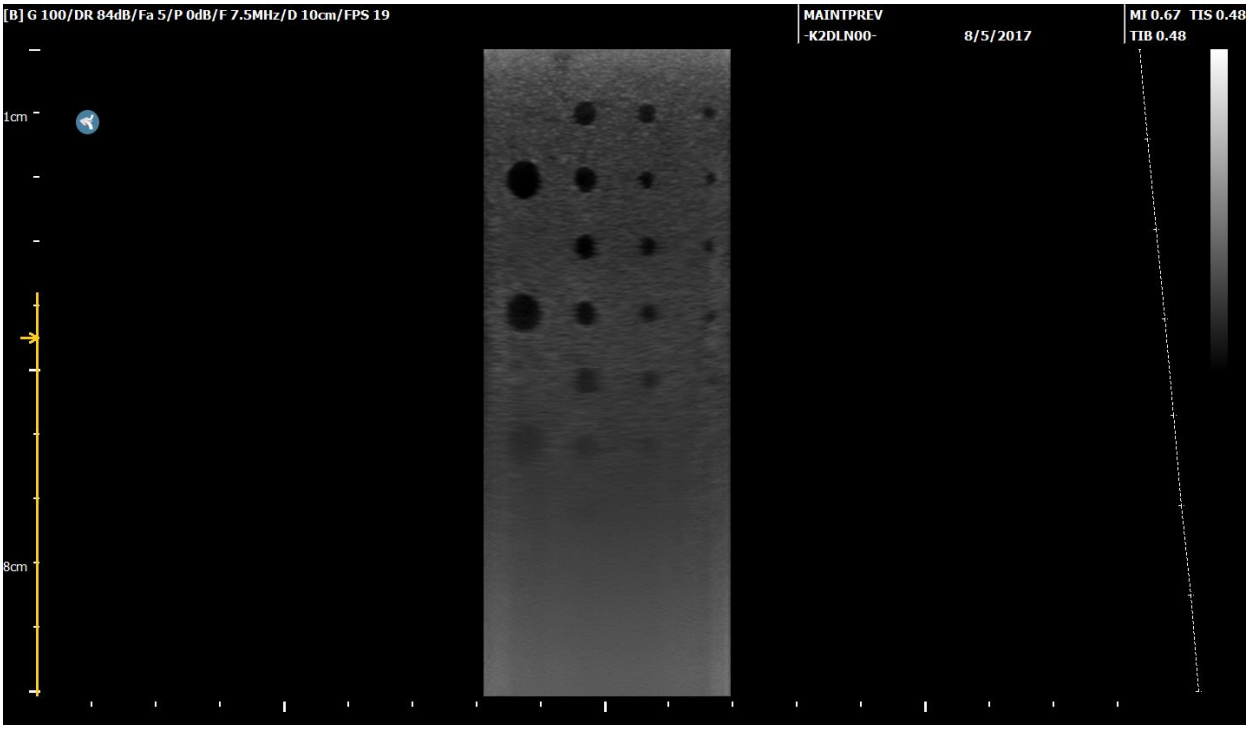


Figure 17 : Panorama in sagital view showing a non-aligned needle, the motor is not in position zero

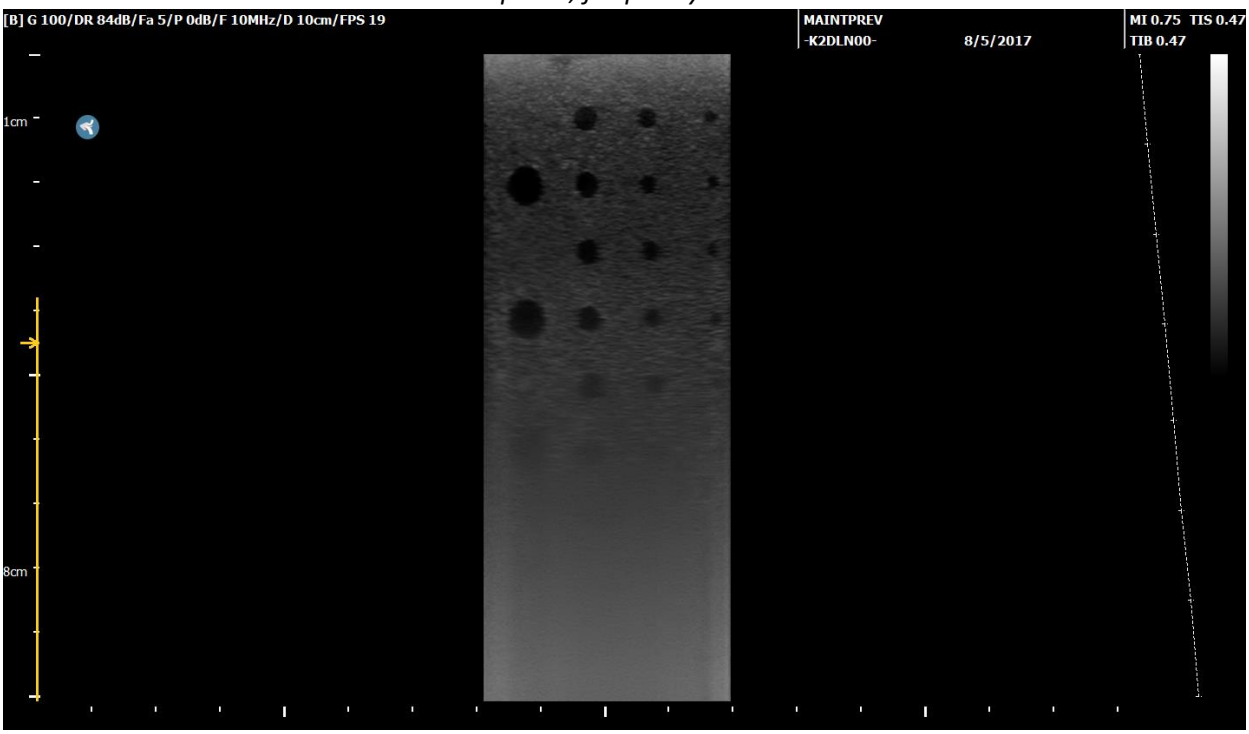
7- Fire line alignement test: In a PROMAP 2D session, add the needle guide on the probe. Insert a no-twisted needle into the guide, put the probe into a bucket of water and display the fire line.

5. APPENDIX

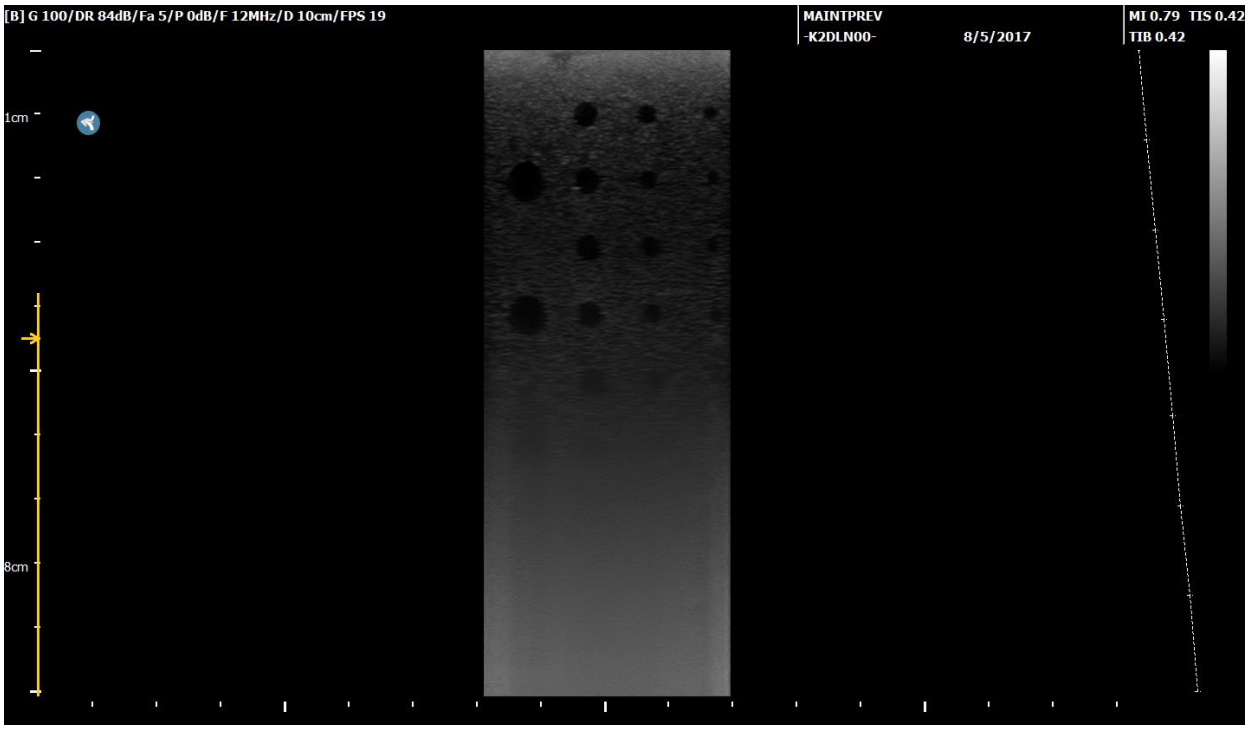
Appendix 1 : Reference picture for linear probe from 7.5MHz to 15MHz



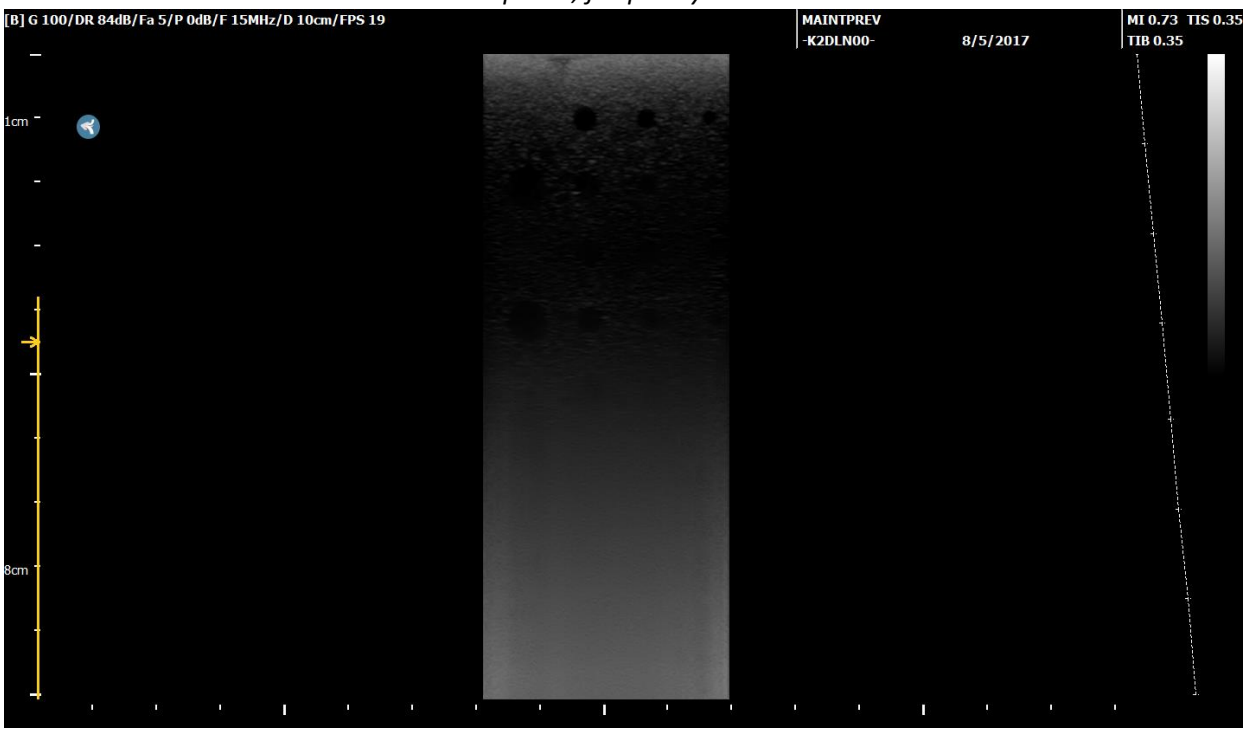
Linear probe, frequency = 7.5 MHz



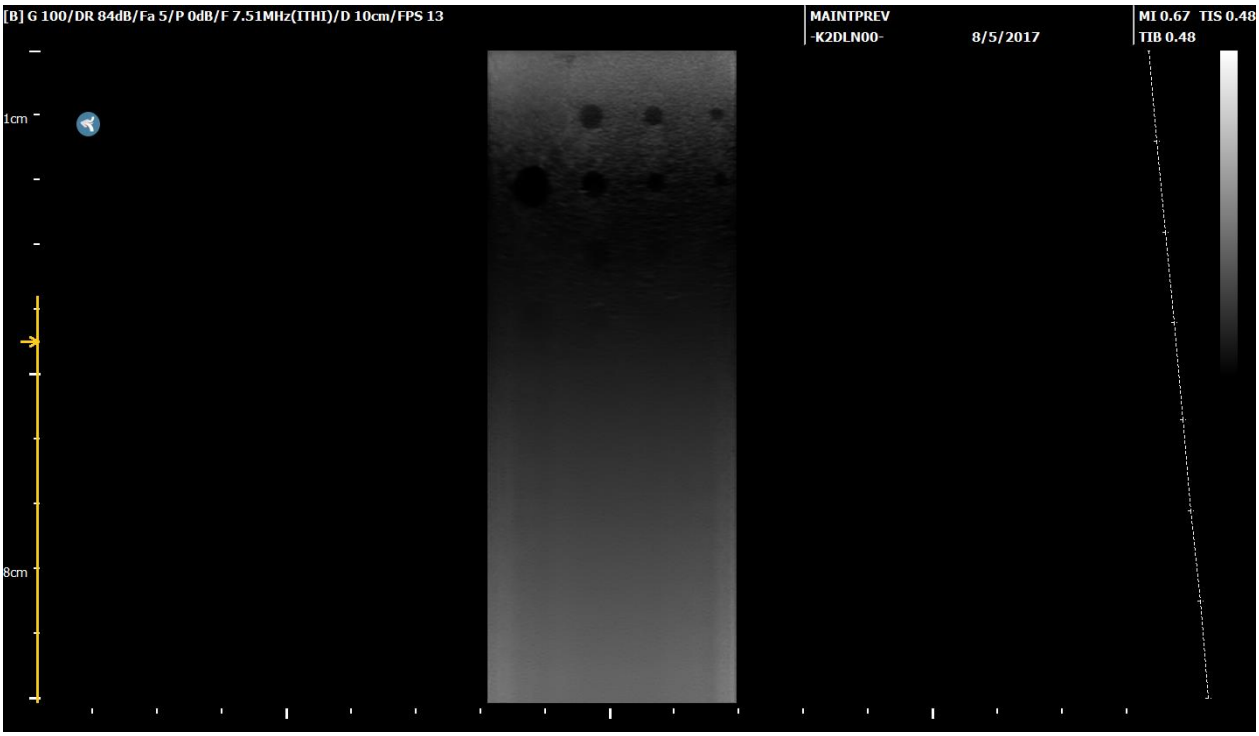
Linear probe, frequency = 10 MHz



Linear probe, frequency = 12 MHz

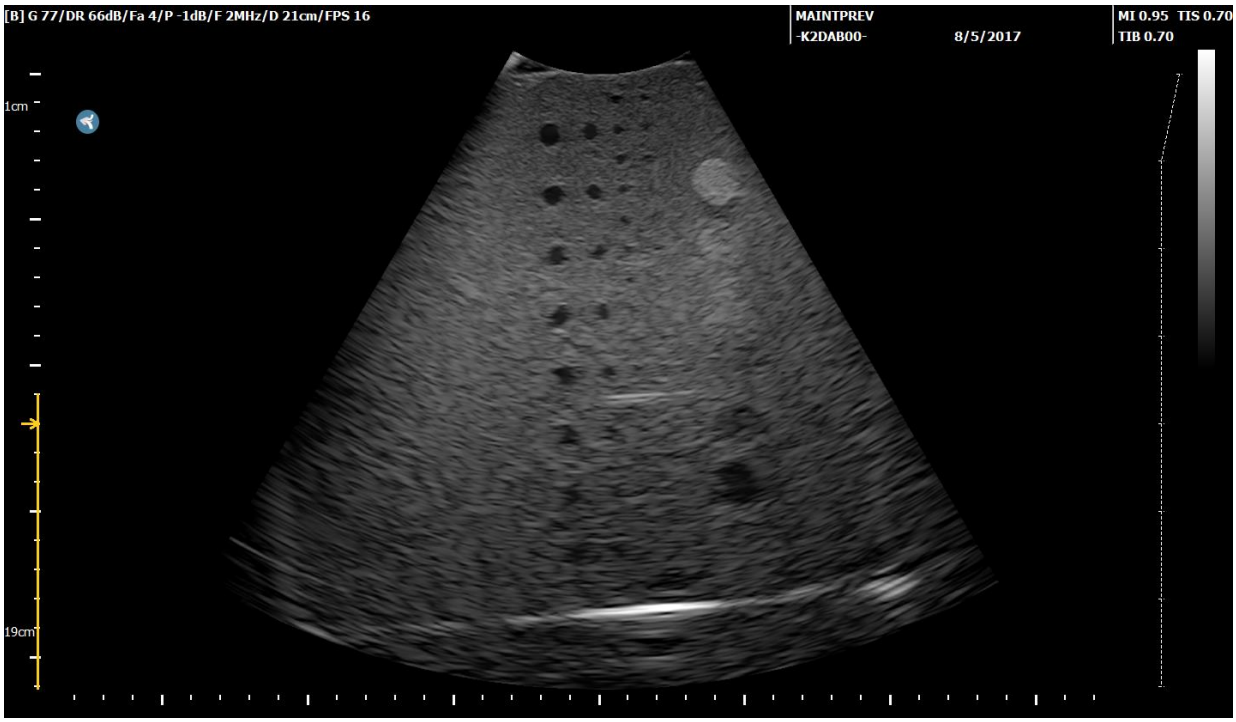


Linear probe, frequency = 15 MHz



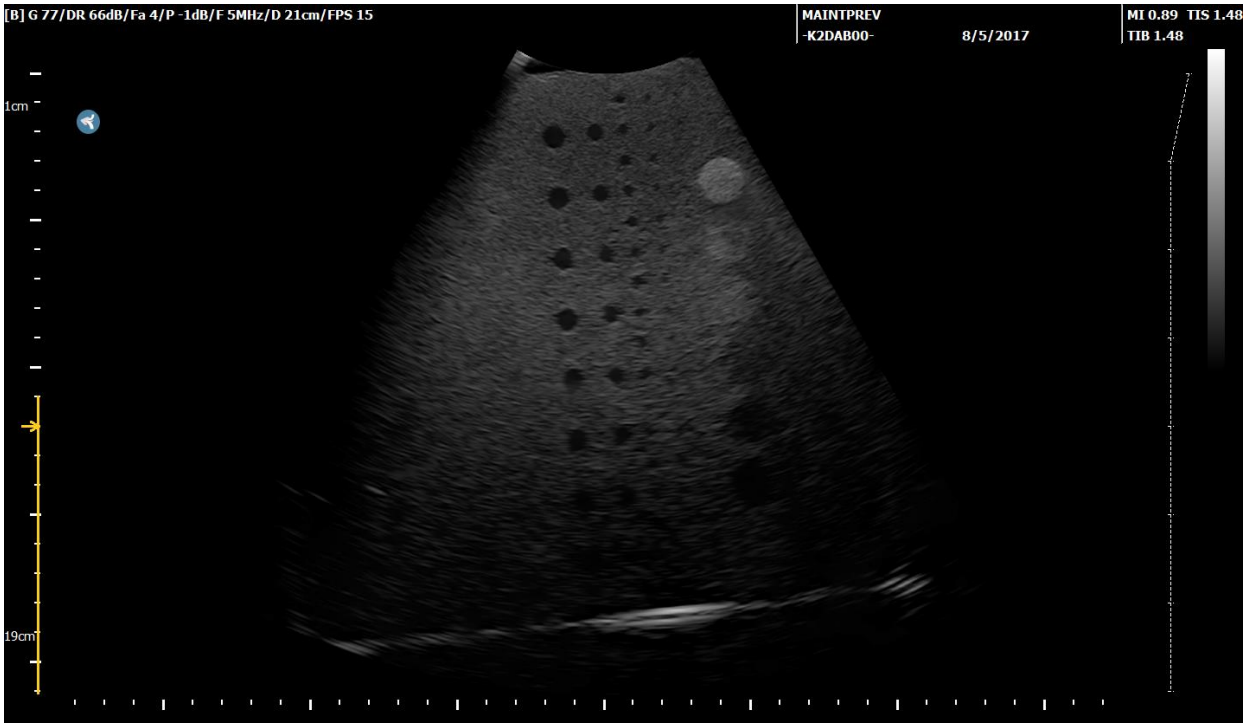
Linear probe, frequency = 7.5 MHz (ITHI)

Appendix 2: Reference picture for convex probe from 2MHz to 5 MHz



Convex probe, frequency = 2 MHz

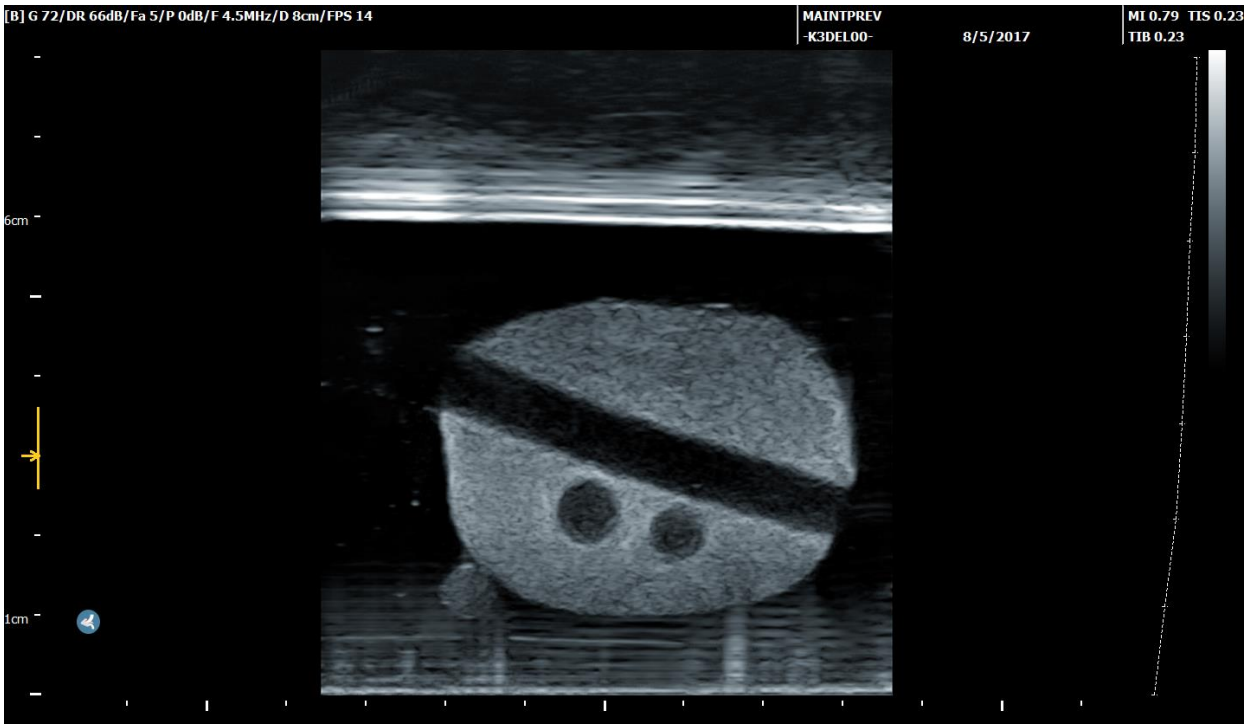
Convex probe, frequency = 3.5 MHz



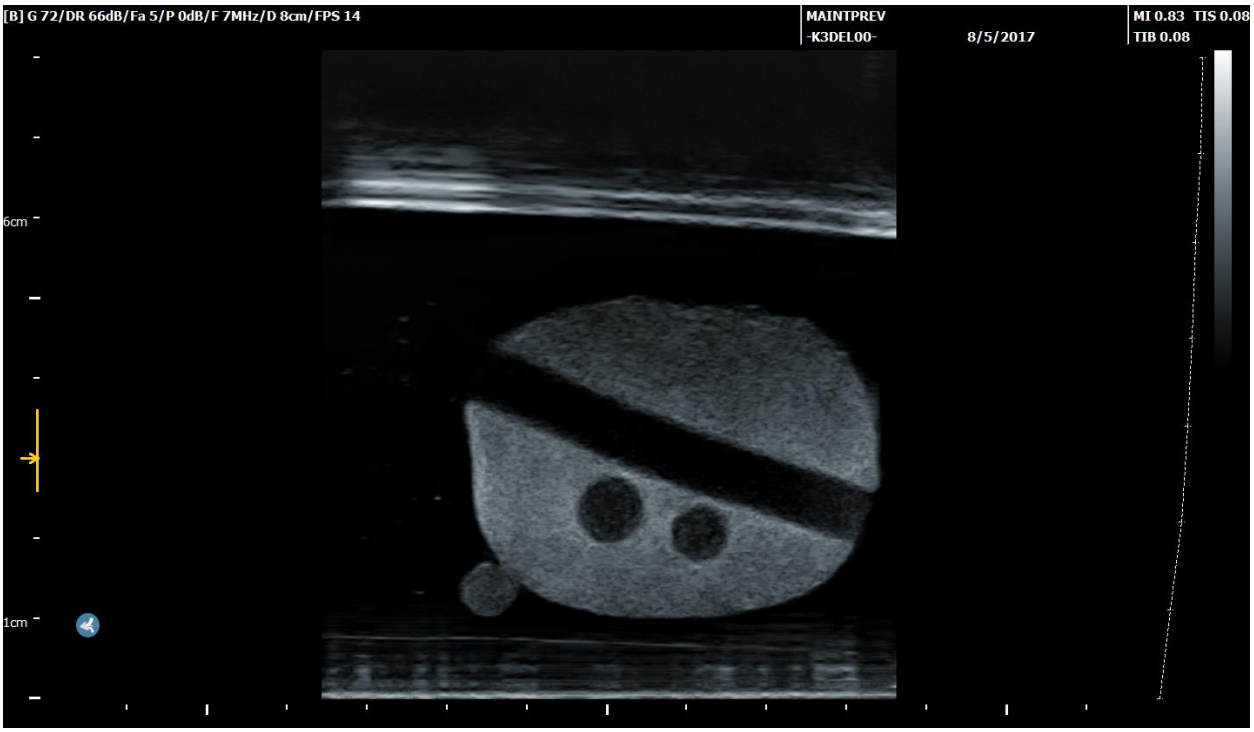
Convex probe, frequency = 5 MHz

Convex probe, frequency = 2 MHz (ITHI)

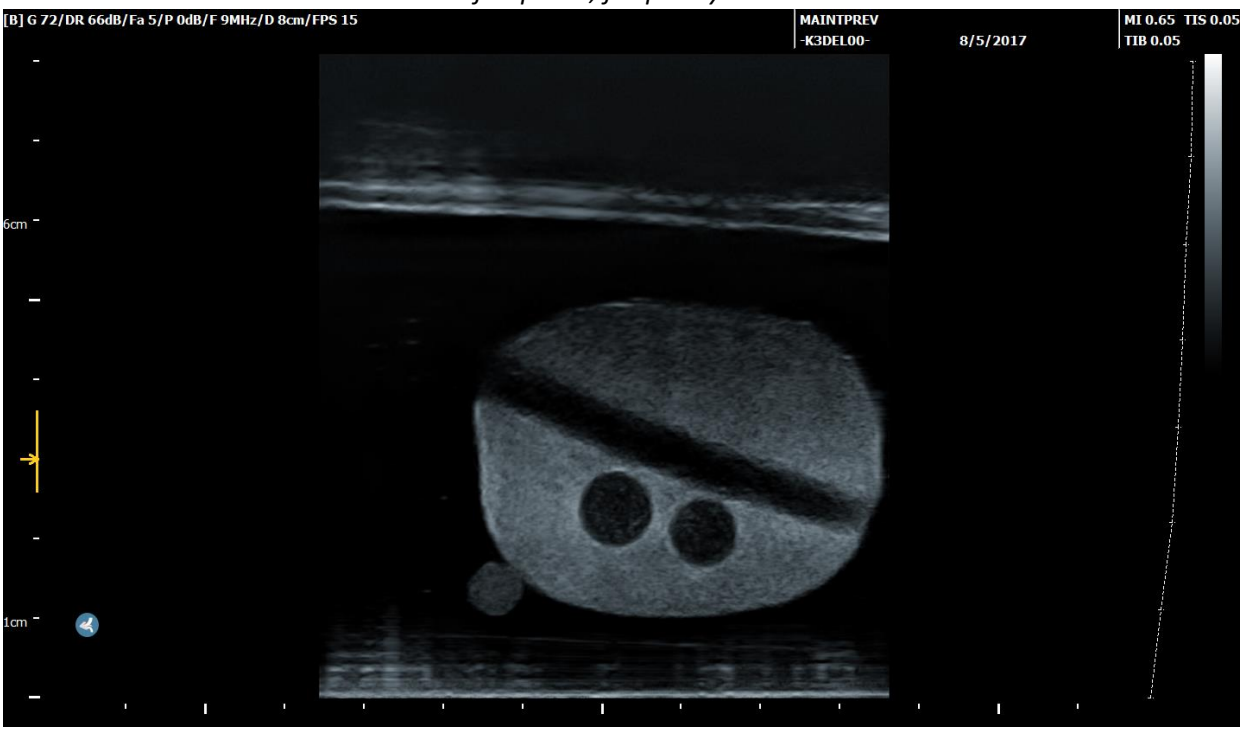
Appendix 3 : Reference pictures for side-fire probe from 4.5MHz to 9MHz



Side-fire probe, frequency = 4.5 MHz



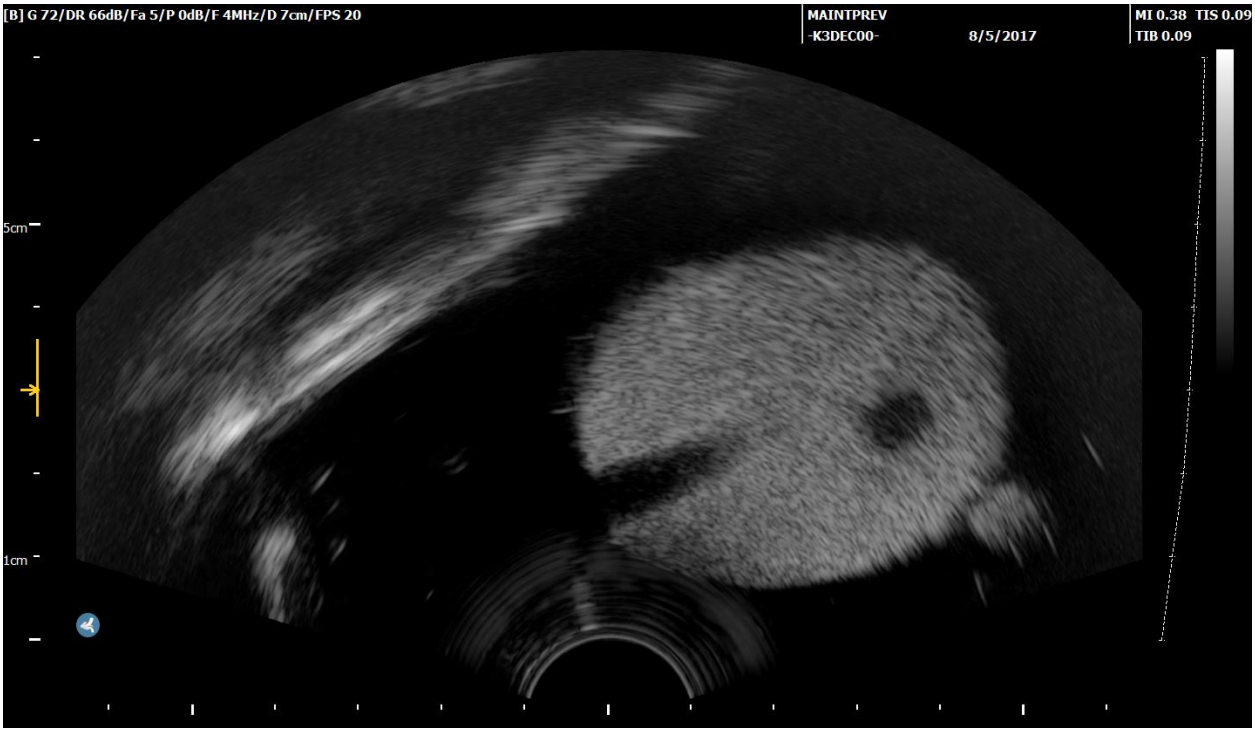
Side-fire probe, frequency = 7 MHz



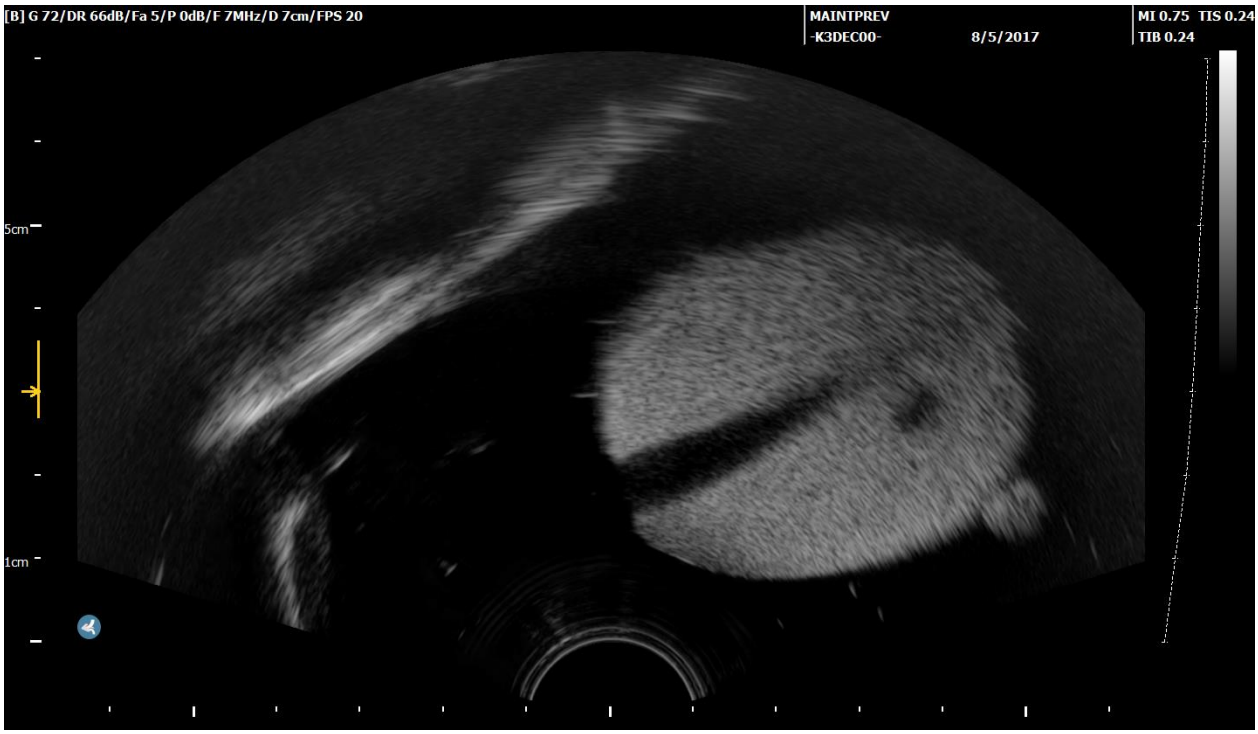
Side-fire probe, frequency = 9 MHz

Side-fire probe, frequency = 4.5 MHz (ITHI)

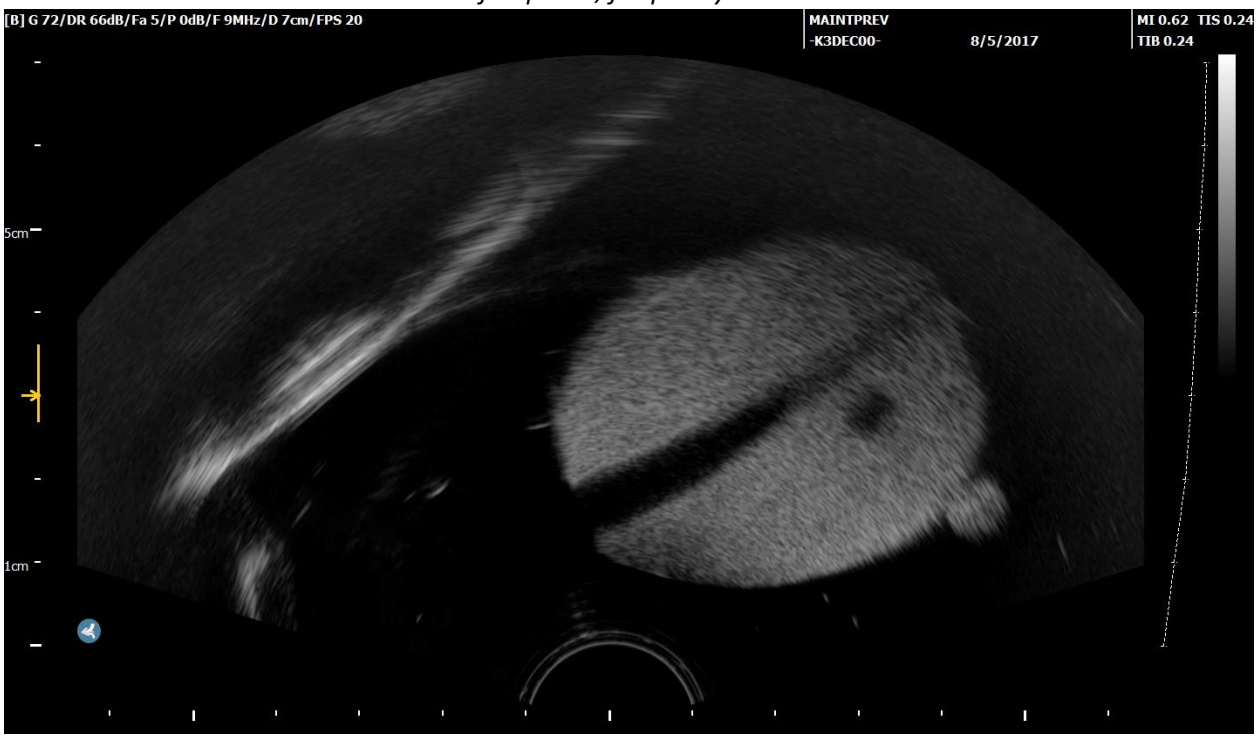
Appendix 4 : Reference pictures for end-fire probe from 4MHz to 9MHz



End-fire probe, frequency = 4 MHz



End-fire probe, frequency = 7 MHz



End-fire probe, frequency = 9 MHz