

X. Quality control and Maintenance

Quality Control Procedure		Daily			3 Monthly	
		СТ	PET	NM	СТ	
Peaking	✓					
Background Test	✓					
Uniformity Test	\checkmark					
NM Daily Routine	✓					
CT Daily Routine		\checkmark				
PET Daily Routine			✓			
COR Test				\checkmark		
System Spatial Resolution Test				✓		
System Sensitivity Test				✓		
CT Performance Test				√	\checkmark	
Table Positioning Test				√	√	
Tomographic Plane Accuracy					√	

These are Mediso recommended maintenance tasks and schedules . You may deviate from this according to local laws, rules, regulations and site protocols. Perform peaking prior to the day's first acquisition and prior to acquisitions with a different isotope or acquisitions with another photopeak of a multiple-peak isotope.

1. Cleaning and disinfection

Some cleaning solutions, disinfectants, and other chemicals can be destructive to system components or pose a risk of fire. Mediso is not responsible for damages or injuries that could result from the use of non-authorized chemicals on or near the system.



WARNING



- Do not operate when cleaning the equipment.
- Isolate equipment from facility electrical power before cleaning, disinfection or sterilization to prevent electric shock.
- Do not allow water or other liquids to enter the equipment. These may cause short-circuits and/or corrosion of the scanner's internal components.
- Do not autoclave the equipment.
- Do not use flammable or potentially explosive sprays on this equipment. Vapors from these sprays could ignite and cause personal injury or damage to the equipment.

CAUTION



Do not spray cleaning solution directly onto the equipment. Never use corrosive cleaning agents, solvents, abrasive detergents or polishes. If you are uncertain concerning the properties of a cleaning agent, do not use it.

The use of sprays to disinfect the scanner enclosure is not recommended. Vapors from such sprays can penetrate the equipment and cause electrical short-circuits and/or corrosion of the scanner's internal components.

1.1. Cleaning

The surfaces should be cleaned by wiping with a damp cloth and a mild detergent, and rubbed down with a woolen cloth.

While cleaning the floor or the camera with a liquid, prevent it from entering the inside of device to avoid short-circuit.

Use moderate alkaline agent to clean the gantry and the patient bed if it is necessary.

When cleaning the display, do not apply alcohol and the like, rather use a dry, clean soft-fabric cloth or paper tissue moistened with clear water if necessary. For cleansing the case of display, a soft cloth moistened with neutral liquid cleanser should be used.

If radioactive contamination occurs, use the decontamination agent and method as described in your site protocol to clean the outside of the equipment.

NOTICE

Use of rubber gloves is recommended when cleaning blood or possible infectious materials.



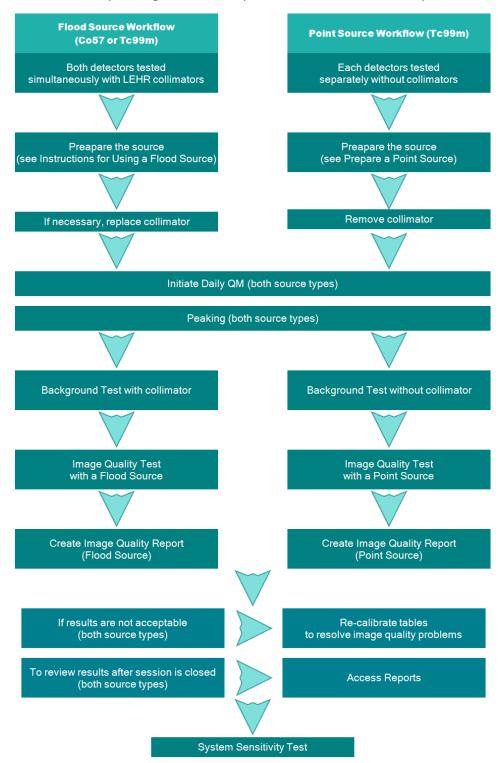
1.2. Disinfection

Moisten a cloth with 70% isopropyl alcohol for use on plastics and enameled metal. Apply to patient contact areas after each contact.



2. Daily NM QC procedure workflow

The workflow differs, depending on whether you use a flood source or a point source.





3. Daily CT QC procedure workflow

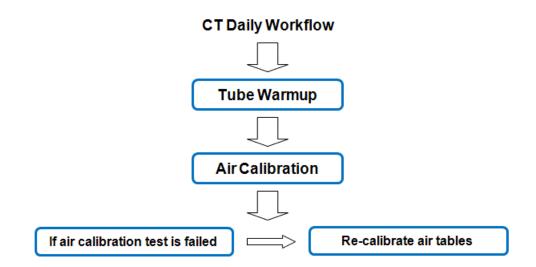


Figure 187. - CT daily QC workflow

4. Sources and activity for NM QC tests

Source	Source Activity		Count Rate	Poguirod	Usage			
	mCi	MBq	cps	Required Collimator	Daily QM and Calibration	COR Test	Uniformity Test	
Tc ^{99m} Point Source (Far)	1-2	30-60	10000- 30000	No collimator	✓	N/A	✓	
Tc ^{99m} Point Source (Close)	~0.16	5-6	10000- 30000	No collimator	√	N/A	✓	
Tc ^{99m} Point Source	~3	120		LEHR	N/A	✓	N/A	
Co ⁵⁷ Flood Source	~8-13	300-500	10000- 30000	LEHR (Base collimator)	√	N/A	✓	
Tc ^{99m} Flood Source	~8 – 13	300-500	10000- 30000	LEHR	N/A	N/A	✓	



4.1. Instructions for Using a Tc^{99m} flood source

The minimal size of the flood source should be 440 mm x 580 mm in order to provide adequate exposure of the entire FOV and to simplify the positioning of the flood source between the detectors.

- 1. Inject the required Tc^{99m} activity inside the flood source over the filling screw.
- 2. Mix the flood source: rotate 10 times.
- 3. With the detector configuration in 180 Degrees mode, and 90 Degrees rotation position, slide in the flood source between the detectors.
- 4. Set the detectors to the minimal radius position.

4.2. Instructions for using a Co57 flood source

The minimal size of the flood source should be 440 mm x 580 mm in order to provide adequate exposure of the entire FOV and to simplify the positioning of the flood source between the detectors.

- 1. With the 180 Degree detector configuration and 0° or 180° gantry angle place the flood holder on the lower detector.
- 2. Set the detectors to the minimal radius position.

4.3. Instructions for Using a Point Source

A point source is prepared in a syringe, as follows:

- 1. Draw the required volume of the source solution into the syringe so that it is located between the plunger and the needle holder.
- 2. After the source has been inserted into the syringe, replace the contaminated needle with a clean needle (capped), membrane adapter or syringe cap.



Figure 188. - Prepared syringe (closed with membrane adapter)

5. Daily quality control

Verify that the detectors will provide acceptable clinical image quality. All values must be within the required specifications. The procedure takes 5-30 minutes, depending on the source activity and the detector setup. The quality maintenance needed flood or point source and collimators, based on Daily NM QC procedure workflow.

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The Quality Control can be accessed from the **Worklist** menu **QC** tab and can be done by the user. Choose **QM Protocols**.

5.1. Peaking

- Start one of SPECT protocol (for example QC->QM Protocols->Uniformity Test protocol). Detector must be exposed with radiation of selected isotope. Press [Auto Peak] button in Spectrum viewer. Program finds the peak positon of spectrum for peak defined in Energy Map Editor (Auto Peak column, checked Energy Range) then stretches the spectrum to match this target position. This operation applies to one detector only. Press [Auto Peak] if this is the first acquisition with a particular isotope, if this isotope has not been imaged for an extended period of time (weeks) or if the spectrum does not appear to align properly with the shaded energy regions.
- Press [Auto Peak All Heads]. This will adjust all detectors' spectrum, does the same as
 [Auto Peak] but for all detectors in the same time. The detectors' spectrum can also
 be auto peaked individually.
- If you have pressed [Auto Peak] or [Auto Peak All Heads] button but you would like to return spectrum to position as it was in the moment you entered to the acquisition protocol, press [Reset All Heads] button.
- When one of [Auto Peak], [Auto Peak All Heads] or [Reset All Heads] button is pressed spectrum is moved in all acquisition steps.

5.2. Background test with collimator

Required Accessories:

- Collimators must be installed on both detectors
- Detectors must not be exposed with radiation

Preparation:

• Set the camera to HOME position

Protocol Selection:

Nucline -> QC -> QM Protocols -> NM Tests -> Background Test Tc-99m LEHR

Steps:

- 1. Press [Move To Initial Position].
- 2. Check the following parameters (*Detector configuration could be 90/102/180 Degree*):



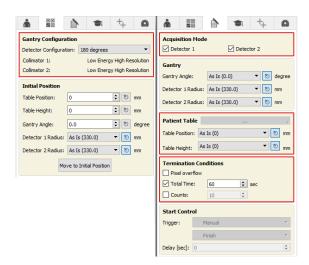


Figure 189. - Extrinsic background protocol parameters

- 3. Press [Prepare].
- 4. Press [Go].
- 5. After the procedure examine the image, the total counts must be less than 2.4 kcounts for each head.

5.3. Background test without collimator

Preparation:

- · Uninstall the collimators
- Set the camera to HOME position
- Detectors must not be exposed with radiation

Protocol Selection:

Nucline -> QC -> QM Protocols -> NM Tests -> Background Test Tc-99m Intrinsic

Steps:

- 1. Check the **Background Activity** is less than 400 cps within the energy window.
- 2. Press [Move To Initial Position].
- 3. Check the following parameters (*Detector configuration could be 90/102/180 Degree*):



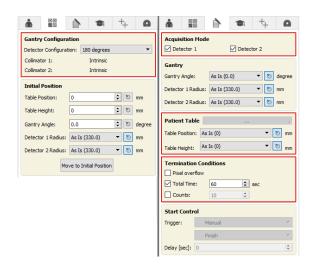


Figure 190. - Intrinsic background test parameters

- 4. Press [Prepare].
- 5. Press [Go].
- 6. After the procedure examine the image, the total counts must be less than 24 kcounts for each image.

5.4. Intrinsic Uniformity Test Tc^{99m}

Required Accessories:

- Tc^{99m} isotope (5-6 MBq activity).
- · Source holder

Preparation:

- · Uninstall the collimators.
- Set the Detector configuration to Degrees.

Protocol Selection:

Nucline -> QC -> QM Protocols -> NM Tests -> Uniformity Test Tc-99m Point Source [Steps:]

- 1. Check the **Background Activity** is less than 400 cps.
- 2. Press [Move To Initial Position].
- 3. Place the prepared Tc^{99m} point in the *Center of Rotation*.
- 4. Check the following parameters:



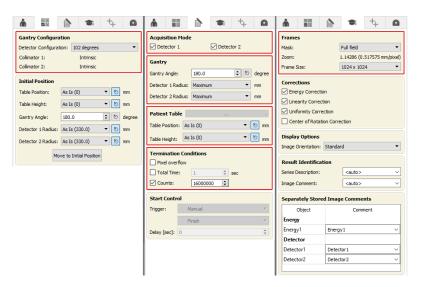


Figure 191. - Intrinsic uniformity test parameters

- 5. Press [Prepare].
- 6. Press [Go].
- 7. After the procedure examine the image in **Mediso Image Quality Center -> Gamma Tests -> Mediso Intrinsic Flood Field Uniformity** with **[Close Correction ON]** and check the results in the specification.

5.5. Extrinsic Uniformity Test Co57

Required Accessories:

- Co-57 flood source
- · Collimator is on the detector

Protocol Selection:

Nucline -> QM -> QM Protocols -> NM Tests -> Uniformity Test Co-57 Flood Source Steps:

- 1. Place the collimator you intend to examine on the detector.
- 2. Set the detector configuration to Degrees.
- 3. Set the detector head in horizontal position.
- 4. Place the flood source on the collimator surface. Make sure it is parallel with the collimator's edges.
- 5. Check the following parameters:



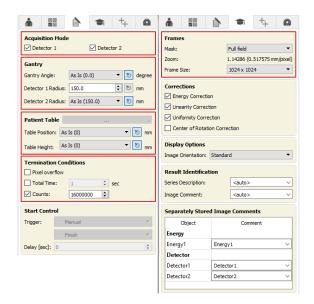


Figure 192. - Extrinsic uniformity test preferences - Detector 1

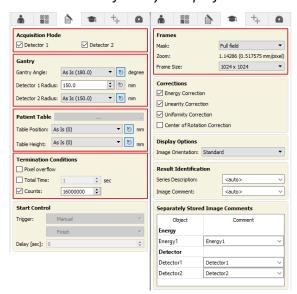


Figure 193. - Extrinsic uniformity test preferences - Detector 2

- 6. Set the **Energy Map** to **Co-57** in the **Energies** menu.
- 7. Press [Prepare].
- 8. Press [**Go**].
- After the procedure examine the image in Mediso Image Quality Center -> Gamma
 Tests -> Mediso Extrinsic Flood Field Uniformity with [Close Correction Off] and
 check the results in the specification.





Figure 194. - Gantry and Isotope position

5.6. Extrinsic Uniformity Test Tc^{99m}

Required Accessories:

- Water flood phantom
- Collimator (LE*) is on the detector

Protocol Selection:

Nucline -> QM -> QM Protocols -> NM Tests -> Uniformity Test Tc-99m Flood Source Steps:

- 1. Fill up the water phantom with 600-700 MBq Tc^{99m} isotope, and mix it.
- 2. Place the collimator you intend to examine (LE*) on the detector.
- 3. Set the detector configuration to 180 Degrees
- 4. Set the detector heads in vertical position.
- 5. Place the water flood source between the detectors.
- 6. Move the detector heads close to the flood source.
- 7. Check the following parameters:

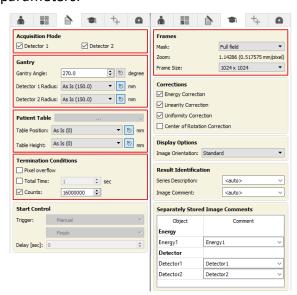


Figure 195. - Extrinsic uniformity test parameters

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- 8. Set the **Energy Map** to **Tc^{99m}** in **Energies** menu.
- 9. Press [Prepare].
- 10. Press [Go].
- 11. After the procedure examine the image in **Mediso Image Quality Center -> Gamma Tests -> Mediso Extrinsic Flood Field Uniformity** and check the results in the specification.



Figure 196. - Gantry and Isotope position

5.7. Re-calibrate Energy and Uniformity Correction

An energy and uniformity calibration must be performed semi-annually or in accordance with quantification performance. This calibration consists of a high-count point-source measurement (flood). Calibration procedures must be performed by Mediso sevice personnel.

5.8. NM daily routine

Based on clinical practice Mediso recommends the following daily QC procedures.

Description	Intrinsic test	Extrinsic test		
Isotopes	Tc ^{99m} point source	Co ⁵⁷ flood source (600x460 mm, 10/20 mCi)		
Collimator	N/A	LEHR or any LE*		
Backgroun test [kcps]	<2.5	<0.5		
Energy peak [keV]	140.5±1.5	122±1.5		
Energy resolution [keV]	<10.5	<10.5		
Integral Unif UFOV/CFOV @ 6 Mcts	<4.5	<4.5		

Table 8. - Mediso recommended daily NM procedures



Please note:

- These are not solely based on NEMA performance tests, but practical aspects, too.
- The camera room and the corridors next to it must be free of any radioactive material, except the ones used in the test.

5.9. CT daily routine

Press Worklist icon . On appearing screen press [QC] button. Choose one of the first three protocols of the tree view Factory / QM Protocols / CT QC. Select the Daily Routine protocol on a new workday (this protocol contains the Warm Up and Air Calibration protocols). All parameters of the loaded protocol are factory preset and do not need to change.



Figure 197. - CT daily routine worklist

Perform the **Daily Routine** protocol. Follow the instructions on the screen.

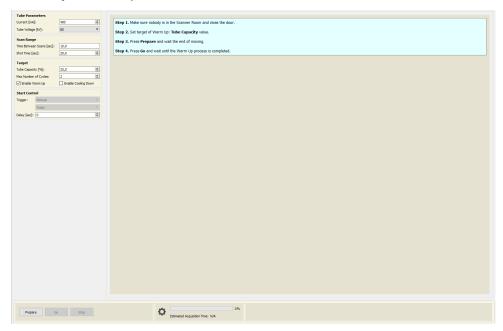


Figure 198. - Tube Warm Up protocol step



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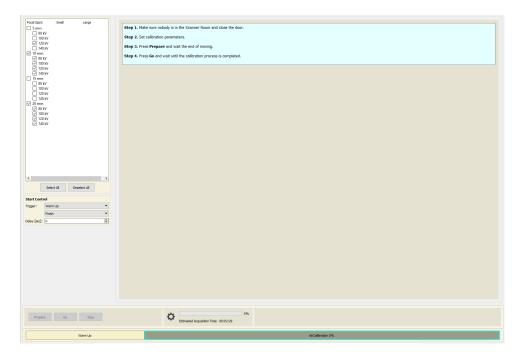


Figure 199. - Air Calibration protocol step

The process includes test for every sub step. In case of any failed test each of their check boxes remain marked for the easy repeat of the calibration. If the calibration cannot be performed after several attempts, contact the Mediso Service.



5.10. PET Daily routine

Required Accessories:

- 15-40 MBq FDG source (high concentration) in 3 ml syringe
- Mediso Daily Phantom
- HUPET Syringe Holder (part of HUPET Phantom Kit)

Protocol Selection:

QC -> QM Protocols -> Factory -> QM Protocols -> CT + PET QC -> CT+PET Daily QC Steps:

 Mount the Mediso Daily QC phantom on the patient table according to the markings done by Mediso Service. Make sure the whole phantom hangs over the edge of the table.



Figure 200. - Positioning the phantom

- 2. Screw the HUPET Syringe Holder into the middle of the phantom.
- 3. Place the prepared FDG point source into the HUPET Syringe Holder.
- 4. Acquire the **Localizer**. Verify the entire point source is visible on the image.
- 5. Start **PET Source Positioning** protocol.
- 6. **Table Height** and **Table Translate** alignments done automatically, but rest have to be done manually.
- 7. Select the **PET Daily QC Acquisition** protocol.
- 8. In the **Patient** tab add the radionuclide information

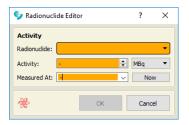


Figure 201. - Radionuclide editor

9. Check the following parameters:



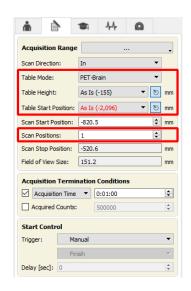


Figure 202. - PET daily routine preferences

- 10. Press [Prepare] and [Go].
- 11. After PET Daily QC Acquisition the PET Daily QC Calculation automatically starts.
- 12. Results are automatically evaluated as OK or Failed. If failed call Mediso Service.

6. 3 monthly quality control

6.1. COR test

Required Accessories:

- Tc^{99m} Isotope
- · Collimator is on the detector

Protocol Selection:

Nucline -> QC -> QM Protocols -> NM Tests -> COR Test

Steps:

- 1. Set the **Detector Configuration** 90/102/180 Degrees.
- 2. Set **Detector Radius** on the **Prepare** tab depending on the detector configuration:

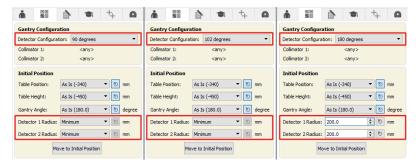


Figure 203. - Detector Radius settings for 90/102/180 detector configuration.



- 3. Fill up a 2 ml syringe with 0.5 ml Isotope. Take care there is no air bubble in the syringe.
- 4. Change the needle or pump up air the needle (only to the needle).
- 5. Completely pull out the special source holder from the Lift 3.
- 6. Insert the prepared syringe to the holder.
- 7. Check the following parameters:

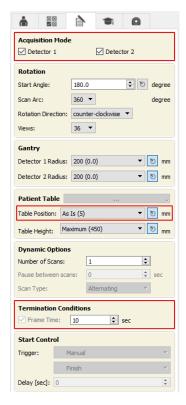


Figure 204. - COR test parameters (Frame Time: 50 kcnts / actual kcnts [sec], min 10 sec)

- 8. Press [Prepare].
- 9. Press [Go].
- After the procedure examine the image in Mediso Image Quality Center -> Gamma
 Tests -> Mediso System Alignment (1 Source) and check the results in the
 specification.



Figure 205. - Gantry and Isotope position



6.2. System whole body spatial resolution test

Required Accessories:

- Tc^{99m} Isotope ~1000MBq/ml
- Capillary tubes, stuffing material
- · Collimator is on the detector

Protocol Selection:

Nucline -> QC -> Service Protocols -> NM Whole Body System Spatial Resolution Test Steps:

- 1. Install the collimator you intend to examine on the detector.
- 2. Set the detector configuration to 180 Degrees.
- 3. Set the Detector 1 in an upper horizontal position.
- 4. Fill the capillaries with Tc^{99m}, plug their ends and put in to the holder.
- 5. Place the capillaries on the end of the table pallet, 50 mm apart and parallel to each other.
- 6. Align the capillaries parallel to the sides of Assistant Square.
- 7. Move the pallet to 100 mm from the touch plate and to the most inner positions where the acquired signal just over the edge of the screen.
- 8. Check the following parameters:

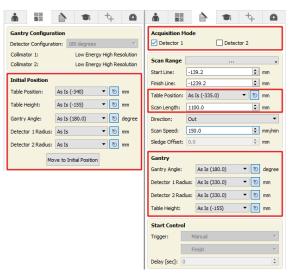


Figure 206. - System spatial resolution test preferences

- 9. Press [Prepare].
- 10. Press [Go].
- 11. Rotate the capillaries with 90° and proceed to next procedure step.
- 12. Repeat step 1-11 for Detector 2.
- 13. After the procedure examine Mediso Image Quality Center -> Gamma Tests -> Whole-Body System Spatial Resolution Without Scatter or Mediso Image Quality Center -> Gamma Tests -> Mediso Whole-Body System Spatial Resolution and check the results in the specification.





Figure 207. - Gantry and Isotope position

6.3. System sensitivity test

Required Accessories:

- Tc^{99m} Isotope
- Ø150mm petri dish source holder
- The collimator is on the detector

Protocol Selection:

Nucline -> Local Worklist -> New -> Scheduled Procedure -> Clinical Protocols -> Base Procedures -> SPECT Base Procedures -> Static Planar

Steps:

- 1. Measure the exact activity of the source and register it.
- 2. Install the collimator on the detector.
- 3. Place a plastic sheet to the collimator to avoid the contamination.
- 4. Place the source above the geometrical center of the collimator on the paper sheet.
- 5. Check the following parameters:

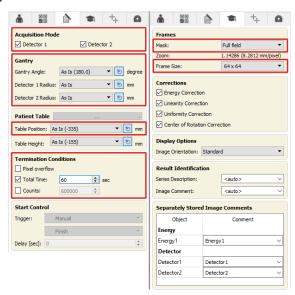


Figure 208. - System sensitivity test preferences

6. Press [Prepare].



- 7. Press [Go].
- 8. Repeat these steps for the second detector.
- After the procedure examine the image in Mediso Image Quality Center -> Gamma
 Tests -> Mediso System Sensitivity and check the results in the specification.



Figure 209. - Gantry and Isotope position

6.4. CT performance test

- 1. Make sure **Nucline** is running.
- 2. Select the QM Protocols/CT QC/Daily QC protocol and press the [Open] button.
- 3. Select the **Prepare** tab.
- 4. Click on **Move** to initial position.

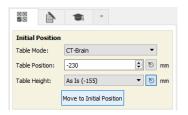


Figure 210. - CT performance test

5. Mount the Mediso Daily QC phantom on the patient table according to the markings done by Mediso Service. Make sure the whole phantom hangs over the edge of the table.



Figure 211. - Mediso Daily QC phantom on the patient table

- 6. Verify that the phantom is in the isocenter of the scanner using the lasers (by adjusting the table height if necessary).
- 7. Acquire the **Localizer**. Verify that the entire phantom is visible on the image.



- 8. Move the selection to **10mm Axial** step. Verify that the scan region covers the whole phantom, adjust if necessary.
- 9. Perform the scan. When the bottom of the window turns green press [GO].
- 10. After all the procedure steps are finished close the **Study**.
- 11. Remove the phantom.
- 12. Start Mediso Image Quality Center from the Desktop and click on [CT Tests], [Mediso Quality Check].
- In the Study Browser select DICOM / Local DICOM and the recently created QM / 10mm Axial Series. Click [Load].
- 14. The program tries to find automatically the correct slices, if necessary adjust the slices manually with the sliders above.
- 15. Press the **[Calculate]**. If the results meet the specification a ⑤ is indicated. In case it's out of specifications (indicated by ⑥) you need to adjust the slices corresponding to the red results with the slider above them. The three slices correspond to the following values:
 - Water: a slice where the phantom contains only water. Corresponds to Noise, Uniformity, Water, MTF (50%), MTF (10%) and MTF (2%) results.
 - Material: a slice where the phantom contains all of the six material inserts but nothing else. Corresponds to Polystyrene, Teflon, Ldpe, Ertalon, Delrin and Acrylic results.
 - Wire: a slice where the wire inside the phantom is visible. Corresponds to Slice
 Thickness result.
- 16. Press the **[Calculate]** button. If the result is still out of specification after multiple adjustments, please inform Mediso service about the problem.

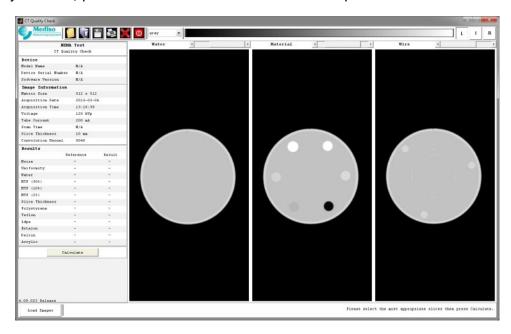


Figure 212. - Mediso Quality Check



6.5. Table positioning test

 Mount the Mediso Daily QC phantom on the patient table according to the markings done by Mediso Service. Make sure the whole phantom hangs over the edge of the table.



Figure 213. - Positioning the phantom

2. Press the [Table Test] button on the gantry monitor.



Figure 214. - Table test

3. Position the phantom manually in the isocenter of the scanner using the lasers, so they overlap the cuts and the white crosshair on the phantom.

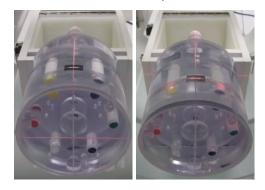


Figure 215. - Vertical and horizontal alignment of the phantom

- 4. Press the **[Start]** button to initiate the preprogrammed motion. The table moves 30 cm forward, then backward to the initial position.
- 5. Make sure the laser crosses the white range of the crosshair.





Figure 216. - Acceptable range

NOTICE

If there is no Table test button on the gantry monitor, skip point 3. After the positioning (point 4) record the **Table Translate** position. Move the table 30 cm forward, and then back to the recorded position with the handcontroller. Continue with point 6.

6.6. Tomographic plane accuracy test

- 1. In Table Mode select [CT-Brain].
- 2. Mount the Mediso Daily QC phantom on the patient table according to the markings done by Mediso Service. Make sure the whole phantom hangs over the edge of the table.



Figure 217. - Positioning the phantom

3. Position the phantom manually in the isocenter of the scanner using the lasers, so they overlap the cuts and the white crosshair on the phantom.

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Figure 218. - Vertical and horizontal alignment of the phantom

- 4. Select the Service Protocols / CT / Tomographic Plane Accuracy protocol.
- 5. Select **Axial CT**, check **Star Line** is set to **As Is**, if necessary set, than press [**Prepare**], [**Go**].

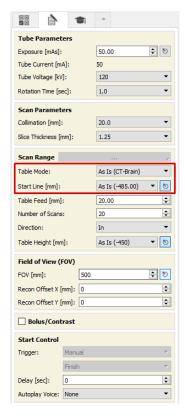


Figure 219. - Tomographic plane accuracy test preferences

6. When the scan is finished, on the **Scan** tab select \square **Layout4** .



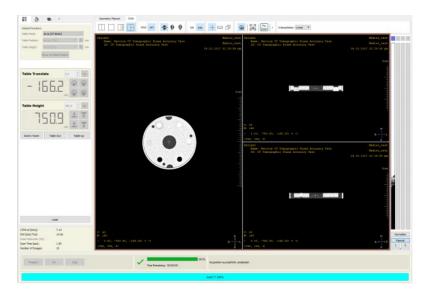


Figure 220. - Axial CT result

7. On the **Axial** view zoom in and find the phantom's cut. You can aid this by adjust aliasing the **Interpolation** (hotkey "i"). When you found it, place a marker at the bottom of the cut.

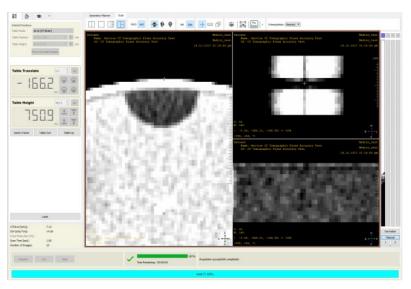


Figure 221. - Phantom cut with marker

8. On the **Coronal** view zoom in and with the **Ruler** tool measure the distance between the middle and the edge of the cut. You can find the middle easier with the **Cross Hair** (hotkey "c"). Note the measurement (0.63mm in the example below).

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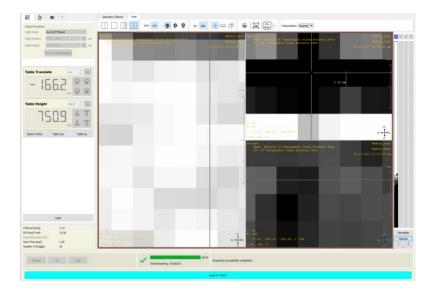


Figure 222. - Measuring the distance

9. Switch to **Tomographic Plane Accuracy** protocol step. According to the instructions enter the measured distance and than press **[Save]**.



Figure 223. - Saving the measured distance