

X. Quality control and Maintenance

Quality Control Procedure	Daily	3 Monthly
Peaking	\checkmark	
Background Test	✓	
Uniformity Test	✓	
NM Daily Routine	✓	
COR Test		✓
System Spatial Resolution Test		✓
System Sensitivity Test		✓

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.

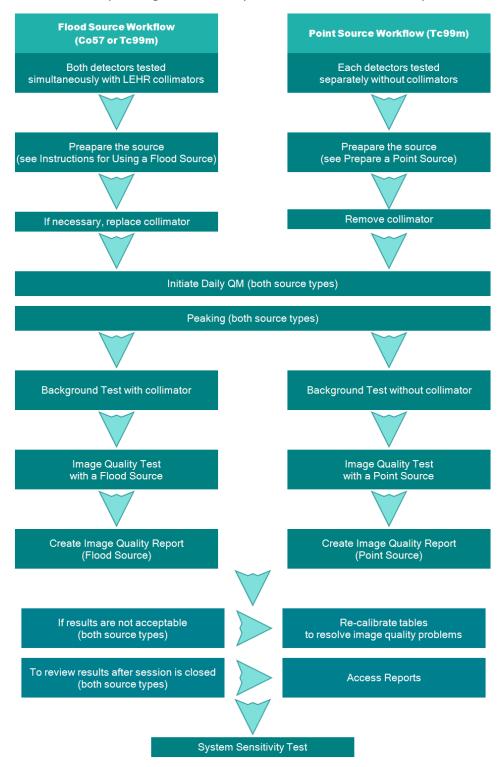
1.2. Disinfection

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. Sources and activity for NM QC tests

Source	Source Activity		Count Rate	Dogwinod	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	✓

3.1. 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.

3.2. 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.



3.3. 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 158. - Prepared syringe (closed with membrane adapter)

4. 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.

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

4.1. 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.



4.2. 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):

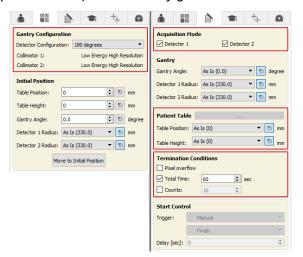


Figure 159. - Extrinsic background protocol parameters

- 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.

4.3. 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):

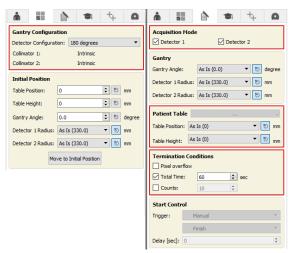


Figure 160. - Intrinsic background test parameters

- 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.

4.4. Intrinsic Uniformity Test Tc^{99m}

Required Accessories:

- Tc^{99m} isotope (5-6 MBg 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:



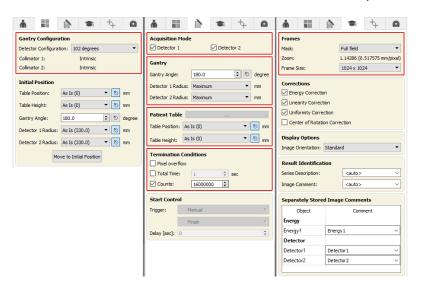


Figure 161. - Intrinsic uniformity test parameters

- 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.

4.5. 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:



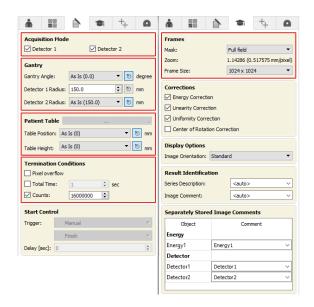


Figure 162. - Extrinsic uniformity test preferences - Detector 1

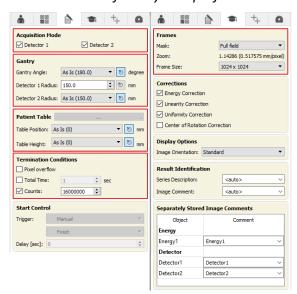


Figure 163. - Extrinsic uniformity test preferences - Detector 2

- 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 164. - Gantry and Isotope position

4.6. 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:

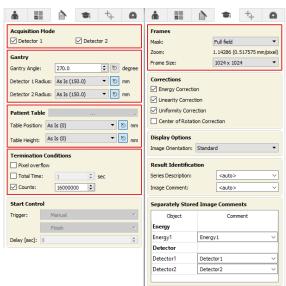


Figure 165. - Extrinsic uniformity test parameters



- 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 166. - Gantry and Isotope position

4.7. 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.

4.8. 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 7. - 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. 3 monthly quality control

5.1. 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:

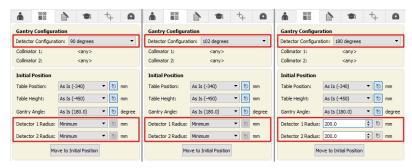


Figure 167. - Detector Radius settings for 90/102/180 detector configuration.

- 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:



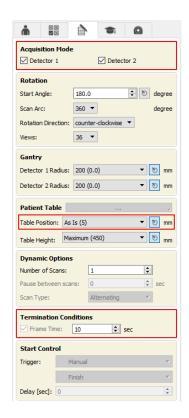


Figure 168. - COR test parameters (Frame Time: 50 kcnts / actual kcnts [sec], min 10 sec)

- 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 169. - Gantry and Isotope position

5.2. 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:

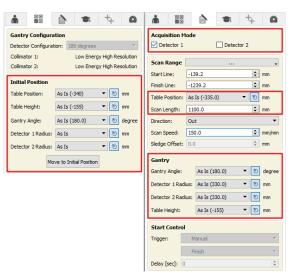


Figure 170. - System spatial resolution test preferences

- 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 171. - Gantry and Isotope position

5.3. 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:

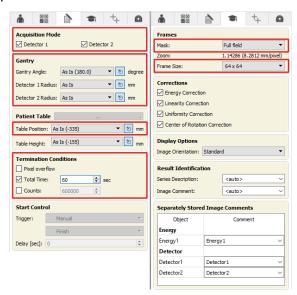


Figure 172. - System sensitivity test preferences

6. Press [Prepare].



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



Figure 173. - Gantry and Isotope position