USER MANUAL

RaySafe Pro-CT 600

RaySafe™

1. PRODUCT FEATURES

The product meets the requirements of:

- IEC 61223-3-5:2019
- AAPM guidelines
- ACR guidelines (Designed to meet the requirements but does not hold an accreditation)

The Manual provides detailed guidelines for carrying out each test, results assessment and registration.

2. PRODUCT DESCRIPTION

The Pro-CT 600 phantom is designed for comprehensive evaluation of imaging parameters in computed tomography (CT) systems. The phantom enables the measurement of absolute values for calibration purposes while being optimized for routine daily quality assurance.

The Pro-CT 600 supports acceptance, constancy, and performance testing of CT scanners in accordance with IEC 61223-3-5 and AAPM (American Association of Physicists in Medicine) guidelines.

The phantom comprises multiple integrated test modules housed within a cylindrical enclosure. It can be mounted directly on the CT table holder or placed on an adjustable stand, allowing precise alignment for both on-table and off-table measurements. Clearly visible positioning markings and built-in leveling aids facilitate accurate and reproducible setup.

3. TECHNICAL DATA AND CONTENTS OF THE PACKAGE

- Main module contains PMMA section with array of holes 2mm in diameter, 10mm deep placed in 10mm intervals
- Outside diameter: 200 mm
- Length: 230 mm
- Positioning stand for on and off table measurements
- Carrying case

Low contrast module

- Diameter: 184 mm
- Thickness: 30 mm
- Made of PMMA

Contains:

- Three groups of low-contrast objects: in each group, there are rods of the same density, 20 mm in height and with a diameter ranging from 1 to 15 mm. Contrast difference between groups and surrounding material is 0.3 (#1), 0.6 (#2) and 1% (#3)
- Subslice targets having a nominal 1.0% (#3) contrast and z-axis lengths of 3, 5, and 7 mm. For each of these lengths, there are objects of 2, 3, 5, 7 and 9 mm in diameter

Sensitometric / contrast module

- Diameter: 184 mm
- Thickness: 30 mm

Contains: 9 sensitometric samples shaped like rods (ø25 mm): PTFE, LDPE, POM-C, ABS, PA-6, PET, air, plastic water equivalent and PMMA – modules body

Geometry module

- Diameter: 184 mm
- Thickness: 30 mm
- Contains two pairs of aluminium wire ramps whose slope angle tangent is equal to 0.5.
- Middles of ramps intersect on the same plane allowing very precise evaluation of the slice location.
- Contains four air rods (ø5 mm) placed in vertexes of a square (sides 100 mm long). The rods are placed on the vertical and horizontal axes of the module. This makes it possible to precisely evaluate the correctness of shape and geometry imaging.
- Contains 4 rods with a diameter of 5mm and 4 rods with a diameter of 3mm from the air in the vertices of the regular octagon close to the outer perimeter of the phantom for evaluating symmetry and circular geometry.
- Contains a 0.05 mm disc at the modules center, designed for evaluating z-axis Slice Sensitivity Profile (SSP).
- Nine spheres to evaluate the scanner's imaging of subslice spherical volumes, diameters: 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm
- Linear Spread Function (LSF) PTFE / PMMA interface
- Point Spread Function (PSF) - 0.25 mm stainless steel wire in air

Resolution

- Diameter: 184 mm
- Thickness: 30 mm
- Contains 22 concentrically placed high contrast elements for spatial resolution evaluation from 1 to 22 LP/cm.
- Two tungsten carbide beads ø0.18 mm and ø0.28 mm for PSF and SSP calculation

Homogeneous module made of Pro-Water water-equivalent

- Diameter: 184 mm
- Thickness: 55 mm
- Mimics true water within 1% accuracy (120 kVp)

4. WORKING, TRANSPORT AND STORAGE CONDITIONS

MODE	TEMPERATURE AND HUMIDITY
WORK	15 – 25°C ; max 75 % (RH) non-condensing
STORAGE CONDITIONS	15 – 25°C ; max 75 % (RH) non-condensing
TRANSPORT	5– 35°C ; max 75 % (RH) non-condensing

5. INDICATIONS FOR USE

The phantom can be used to do the following tests:

- Geometric distortion
- CT number (HU) measurement
- Noise / Uniformity
- Artefacts
- MTF
- SSP, LSF, PSF
- CNR
- Spatial resolution
- Contrast resolution
- Low contrast resolution
- Slice profile
- Alignment
- Linearity
- Beamwidth
- Spatial resolution in Z dimension

6. SECURITY MEASURES

The product or its accessories cannot be used in the patient environment (It must be further than 1.5m away from the patient examination area).

The product serves only as evaluation of the physical parameters of the diagnostic equipment using ionizing radiation. The device cannot be used to control radiographic, radio therapeutic or similar devices.

7. RECOMMENDATIONS FOR WASHING AND STORING PHANTOMS

- Washing the phantom should be should be performed in rooms specially designed for that purpose.
- Phantoms should be washed with water of up to 25°C, using soft cloth or antistatic fluid designed for plastics.
- Do not use powders, rough cloths, scrapers, etc.
- Protect from scratching.
- Do not wash with agents containing alcohol, which destroy the phantom's structure resulting in cracks and micro cracks.
- Ozonation method or cleaning with non-alcohol detergents (e.g. soap, dishwashing liquid) can be used to disinfect all phantoms.
- Do not leave or store in aggressive environments like solvents, alcohols, etc.
- When the washing is over, dry with a soft cloth.
- Protect from falling. A fall can result in damage to the product and injury to people.
- Phantoms must not be washed in dishwashers, warmed up in microwaves, heaters or similar devices.
- Store in room temperature.
- Protect from solar radiation.
- Use the products only as intended, in accordance with the manual provided.

8. GENERAL INFORMATION

- This user manual is an integral part of the product and should always be kept near the device. Taking notice of the manual is a prerequisite for proper performance and correct operation of the device.
- Operator safety, specific measuring accuracy and interference-free operation is guaranteed only if original parts and accessories are used.
- Dispose of packaging material according to the applicable waste disposal regulations.
- The product should be kept out of reach of children.
- Before using the device, the operator must ascertain that it is in correct working order and that working conditions are adequate. The product does not require any special installation.
- All necessary information is contained in the operating instructions supplied with the products, on the website www.raysafe.com.
- RaySafe cannot be held liable for any damage resulting from using accessories from other manufacturers.
- The warranty period is 1 (one) year. See www.raysafe.com for more warranty information.
- This technical documentation is in agreement with the device specifications and all safety standards (if applicable) valid on the day of printing.
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9. WASTE MANAGEMENT

When a service cycle of the product is over, waste handling in each case should be in accordance with the requirements of environment protection and legislation connected with waste management, as well as with the requirements of the local authorities.

Whenever in doubt, the method of waste handling should be agreed with the local Environment Protection Inspectorate centre.

Recommended waste classification

Depending on the product's constituents:

20 01 39	Plastics
17 04 02	Aluminium
17 04 01	Copper
20 02 03	Other non-biodegradable waste

10. TEST PROCEDURES

PROCEDURES FOR CARRYING OUT TESTS WITH THE PRO-CT 600

Counterweight Requirement (Annuli/beam hardening rings Configuration)

When using annuli, a counterweight of approximately 10–14 kg shall be placed on the stand before mounting the phantom.

The phantom housing weighs approximately 4 kg.

Adding additional weight—for example, two 5-liter water containers placed inside the housing—provides sufficient counterbalance and ensures stable positioning during scanning.

BASIC SETUP OF THE PHANTOM FOR CT TESTING

1. Place the phantom on the CT table using either the adjustable stand or a vendor-specific mounting adapter compatible with the CT system.
2. Level the phantom using the positioning screws and integrated bubble level located on the phantom housing.
3. Verify that the CT system lasers (sagittal, coronal, and transverse) are visible and aligned with the white reference lines marked on the phantom modules.
4. Move the table to position the Geometry module at the CT isocenter. Ensure that the built-in alignment markers within the module coincide with the point where the lasers intersect.
5. Acquire a scan covering the entire length of the phantom, ensuring that all test modules are included.
6. Perform image evaluation for each module according to the applicable test procedures.
7. Example test results are shown below.

All measurements and evaluations must be performed in accordance with local regulations and applicable standards.

Reference Values

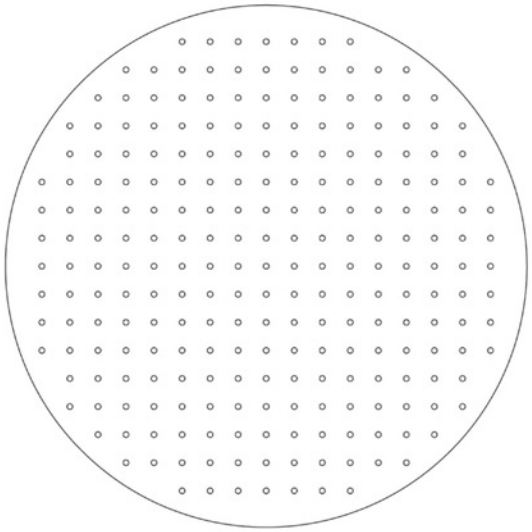
Reference values shall be established during acceptance testing of a fully functional CT system using the specified scan and reconstruction parameters.

Unless otherwise stated, reference values shall be determined from a series of approximately five repeated measurements and recorded as baseline data.

Reference values shall be re-established after major system modifications, software upgrades, or hardware repairs that may affect image quality or system performance.

The tests shown in this manual are an example. Be sure to comply with your local regulations.

Geometry distortion module / Lid



Evaluation

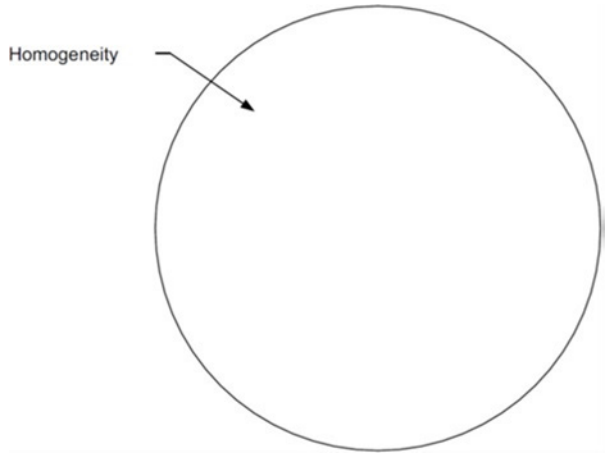
- Using the images acquired during the scan of the zeroed phantom, identify the image series containing the lid hole array.
- Select the image slice in which the holes are most clearly visible (typically the slice intersecting the center of the hole depth).
- Verify that all holes in the array are clearly visible and uniformly distributed.
- Measure the center-to-center distance between adjacent holes along the X and Y directions using the measurement tools available on the CT console or workstation.
- Compare the measured distances to the nominal physical spacing of 10 mm.
- Optionally, count the number of pixels between hole centers and calculate the pixel size using the known physical distance.

Acceptance Criteria

- The measured center-to-center distance between adjacent holes shall not deviate by more than ±1 mm from the nominal 10 mm spacing.
- Calculated pixel size shall be consistent with the nominal pixel size defined by the scan protocol and reconstruction matrix.
- No systematic scaling difference between the X and Y directions shall be observed.

Check with local regulations.

Homogeneity module



1. Artefacts (Visual Image Quality)

Evaluation

- Perform a visual inspection of the reconstructed image of the homogeneous module.

Acceptance Criteria

- No significant artefacts, distortions, streaks, or non-uniform structures shall be visible.

2. Noise (Image Noise)

Evaluation

- Measure the standard deviation of CT numbers (HU) within a 50 mm^2 ROI placed at the center of the module image.

Acceptance Criteria

- The measured noise shall not deviate by more than ±20% from the reference value.

3. Homogeneity (Uniformity)

Evaluation

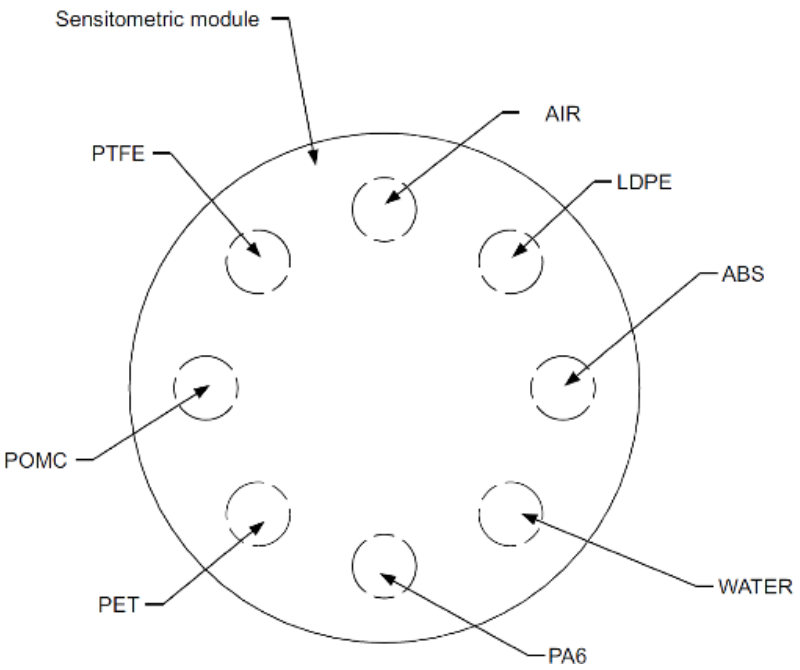
- Measure the mean CT number (HU) within ROIs.
- The ROI diameters should be about 10% of the phantom's diameter and their spacing should correspond to the 12, 3, 6 and 9 o'clock positions on a clock's face and about 1 cm from the perimeter.

Acceptance Criteria

- The HU difference between the center and peripheral ROIs shall remain stable over time and shall not deviate by more than ±4 HU from the reference values.

Check with local regulations.

Sensitometric module / Linearity



Evaluation

- Measure the mean CT number (HU) within ROIs placed at the center of each sensitometric insert and within the module body.
- Use consistent ROI size and positioning for all measurements.

Acceptance Criteria

- Deviations from the corresponding reference values shall not exceed ±4 HU for water, ±10 HU for other materials.

Check with local regulations.

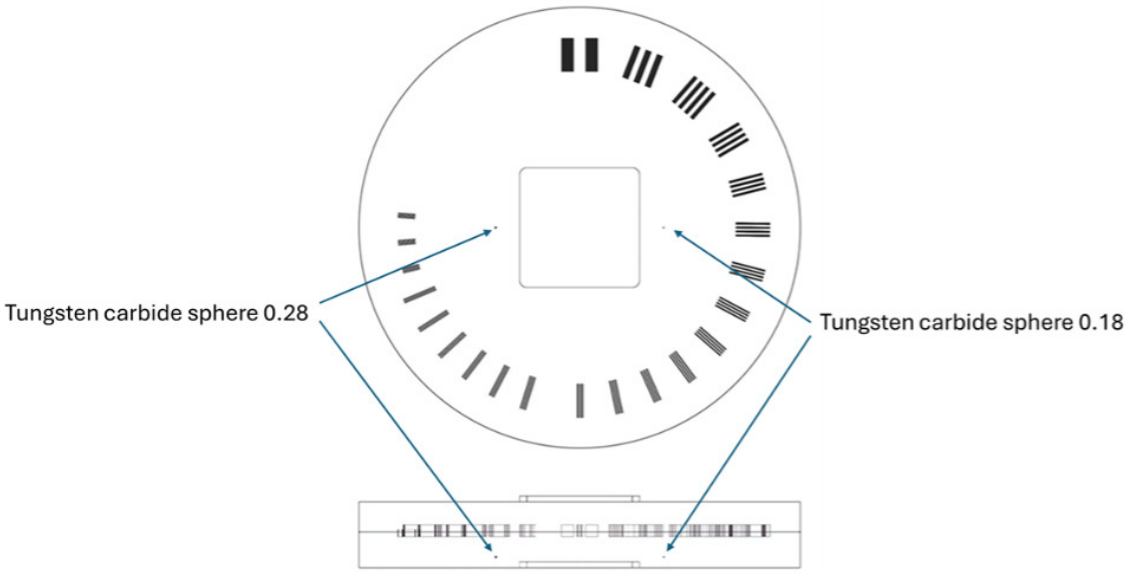
PRO-CT 600 MATERIALS

(Nominal Material Properties — Informative)

MATERIAL	GRAVITY	SAMPLE HU	ELECTRON DENSIT [10^23e/CM^3] Y	RELATIVE ELECTRON DENSITY
Air	0.00	-1020	0.004	0.001
Water	1.00	-5	3.343	1.0
PTFE	2.16	941	6.243	1.868
LDPE	0.93	-87	3.247	0.945
POM-C	1.41	320	4.557	1.363
ABS	1.05	-39	3.400	1.017
PA-6	1.13	61	3.730	1.116
PET	1.36	247	4.387	1.40
PMMA	1.18	106	3.833	1.147

Resolution Module

High-Contrast Spatial Resolution (Bar Patterns)



Evaluation

- Visually assess the bar patterns in the reconstructed image.
- Determine the highest spatial frequency (line pairs per centimeter, LP/cm) at which individual bars can be clearly distinguished without merging or ambiguity.

Acceptance Criteria

- Visually assess the bar patterns in the reconstructed image.
- The visually resolved spatial frequency shall remain stable relative to reference values.
- Any noticeable degradation in resolvable line pairs shall be investigated.

Spatial Resolution Using Tungsten Carbide Spheres (MTF)

Evaluation

- Identify the tungsten carbide sphere in the resolution module image.
- Use the image data surrounding the sphere to derive the point spread function (PSF) of the CT system.
- From the PSF, derive the line spread function (LSF) and calculate the modulation transfer function (MTF) using appropriate analysis software.

Acceptance Criteria

- Spatial resolution characteristics derived from the MTF shall remain stable relative to reference values
- Significant deviations from reference MTF curves shall be investigated.

Check with local regulations.

Notes

Automated MTF analysis tools provided by the CT system manufacturer or third-party software may be used.

The small size of the tungsten carbide spheres allows them to be treated as point sources for practical resolution analysis.

Optional Use of Tungsten Carbide Sphere for Slice Sensitivity Profile (SSP)

Evaluation

- The tungsten carbide sphere may be used to assess the slice sensitivity profile by analyzing its signal extent along the z-axis in reconstructed images.
- The full width at half maximum (FWHM) of the signal distribution along the z-axis represents the effective slice thickness.

Acceptance Criteria

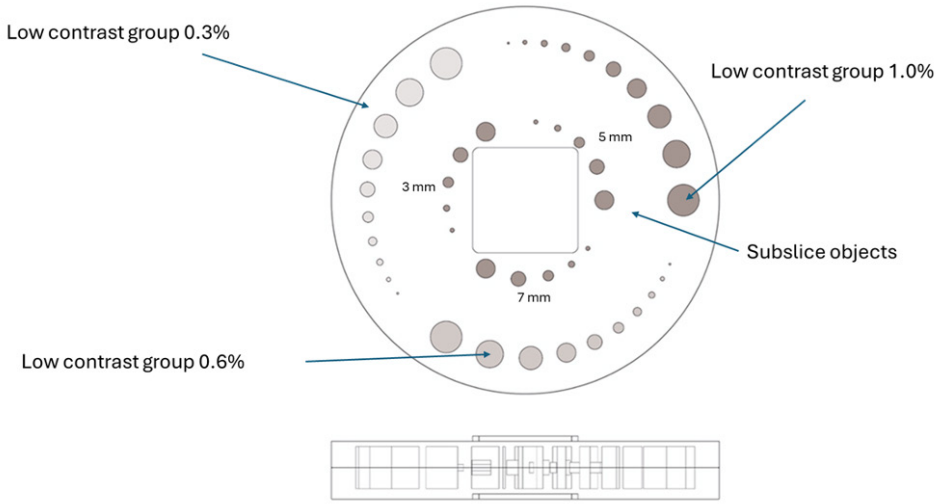
- Measured slice sensitivity characteristics shall remain stable relative to reference values

Low contrast module

The purpose of this test is to assess the ability of the CT system to detect objects with small contrast differences and to verify the stability of low-contrast performance over time. Some quality assurance guidelines do not consider this test mandatory, as system performance changes are often detected through other image quality tests.

The module contains:

- Three groups of low-contrast objects: in each group, there are rods of the same density, 20 mm in height and with a diameter ranging from 1 to 15 mm. Contrast difference between groups and surrounding material is 0.3, 0.6 and 1%
- Subslice targets having a nominal 1.0% contrast and z-axis lengths of 3, 5, and 7 mm. For each of these lengths, there are objects of 2, 3, 5, 7 and 9 mm in diameter



Evaluation

- Visually assess the low-contrast objects in the reconstructed image using the specified clinical protocol.
- Determine the smallest low-contrast object that can be reliably distinguished from the background.
- Perform the evaluation under consistent viewing conditions and display settings.

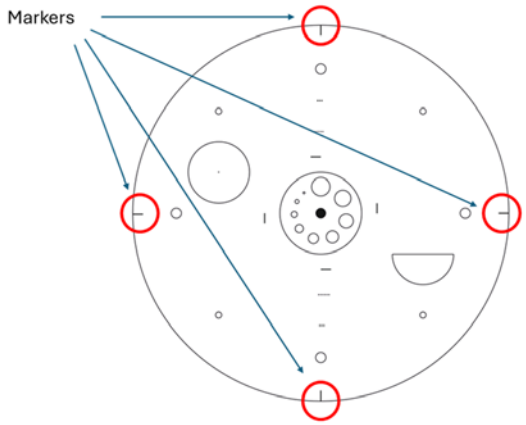
Acceptance Criteria

- Low-contrast detectability shall remain stable relative to reference values.
- Any noticeable degradation in the visibility of low-contrast objects shall be investigated.

Note

Quantitative evaluation using dedicated image analysis software may be applied where available.

Geometry module



Positioning Laser Accuracy (Image-Based Marker Method)

This test provides a quick verification of positioning laser accuracy using image data acquired from a zeroed phantom.

All phantom positioning and zeroing shall be performed according to the **Basic Setup of the Phantom**.

Evaluation

- Using the images acquired during the scan of the zeroed phantom, identify the image series containing the housing markers.
- Note the slice position at which the reference markers have the highest HU value.
- Verify that all reference markers are visible on the images.
- Determine the offset of the marker positions along the scan axis by counting the number of image slices between the expected and actual marker locations.
- Convert the slice offset to a positional deviation using the nominal slice thickness.

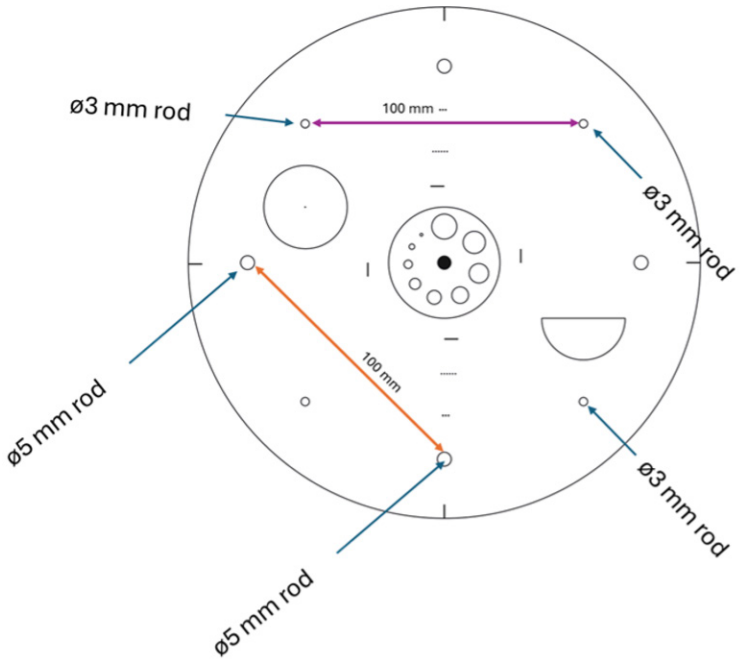
Acceptance Criteria

- The calculated positional deviation shall not exceed ±2 mm.

Notes

- This method provides a fast, image-based assessment of positioning accuracy and is suitable for routine constancy checks.
- A more accurate evaluation of positioning and slice geometry can be performed using ramp-based geometry tests, which are considered more precise and should be used for acceptance testing or detailed investigations.

Image Geometry (Distance Accuracy)



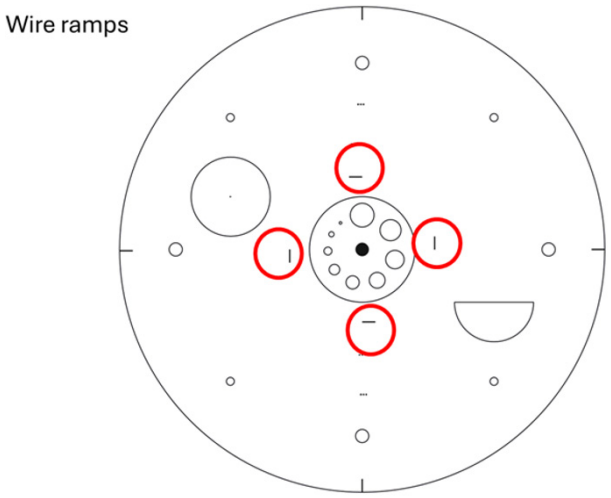
Evaluation

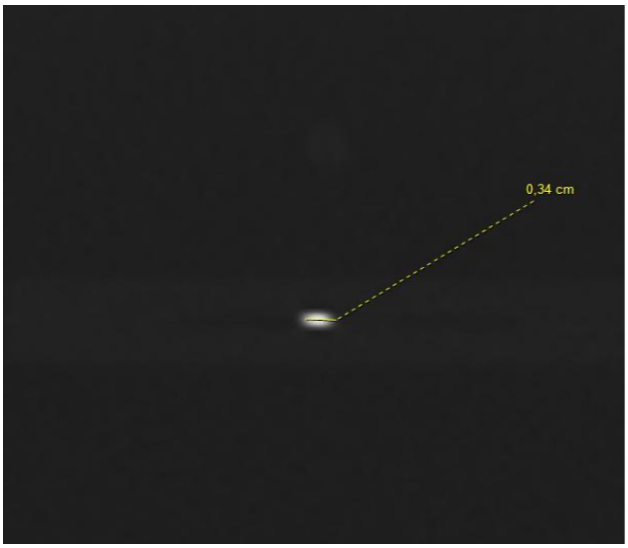
- Measure the distances between the rods in horizontal, vertical, and diagonal directions.
- The module contains four rods with a diameter of 3 mm located at the vertices of a 10 × 10 cm square.
- The module also contains four rods with a diameter of 5 mm located at the vertices of a 10 × 10 cm square rotated by 45°.

Acceptance Criteria

- Measured distances shall not differ from the nominal values by more than ±1 mm.

Slice Thickness





Evaluation

- Measure the length of the ramp images using the full width at half maximum (FWHM) method.
- Calculate the slice thickness as half of the measured ramp length.

Acceptance Criteria

- The measured slice thickness shall not differ from the nominal slice thickness by more than ±20%.

FWHM measurement (Geometry module)

To calculate FWHM (Full Width at Half Maximum) for wire ramps maximal HU values for background and ramps must be evaluated. To find the ramp maximum restrict the window to 1 or lowest selectable value. Move the window centre to the point when ramp image almost disappears. This level value is maximum for the ramp. Background can be evaluated using ROI tool – mean value of HU near ramps.

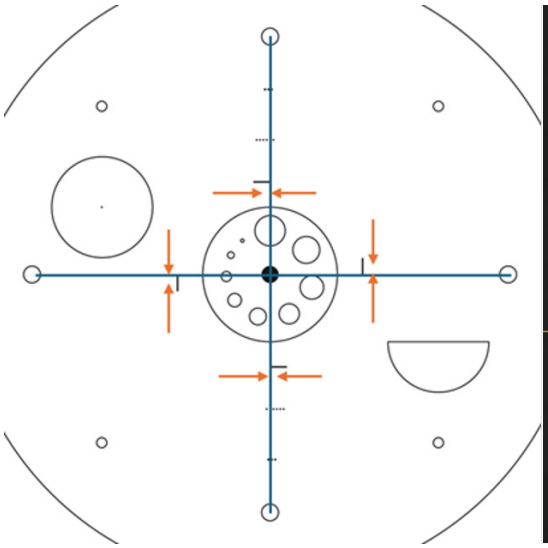
Net HU peak = maximal HU value for ramps – background

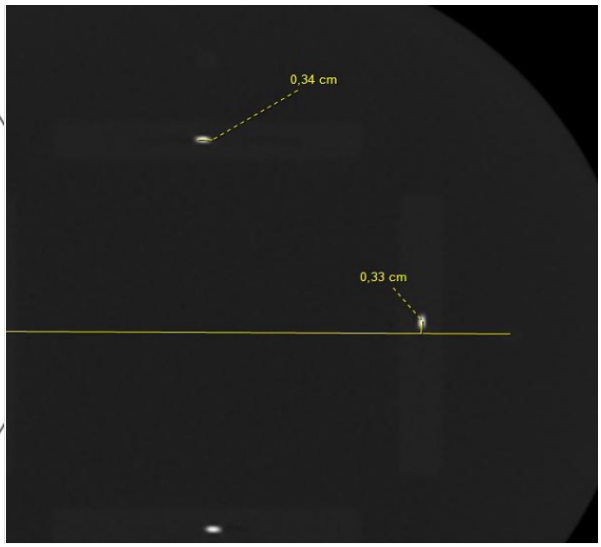
Half peak net = Net HU peak / 2

HU Value at half maximum = Half peak net + background

1. Set window centre to calculated HU value and window width to 1
2. Measure ramp length to get FWHM

Alignment (Position Accuracy)





Evaluation

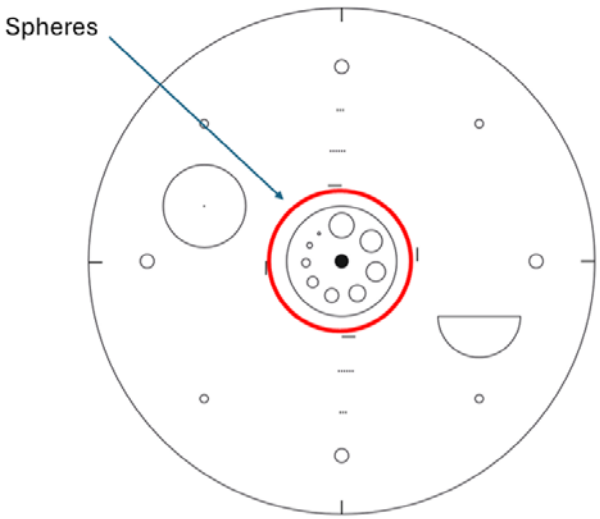
- Define the main horizontal and vertical axes of the module by drawing lines through the centers of the four central rods.
- Measure the distance between the centers of the wire ramp images and the defined module axes.
- The module contains two opposing ramp pairs, whose centers coincide with the true module axes.

Acceptance Criteria

- The measured offset shall not exceed 2 mm.

Subslice Spherical Volume Imaging

The module contains nine spherical targets with diameters of 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0 mm.



All measurements shall be performed using the previously defined Basic Setup of the Phantom.

Evaluation

- Identify the spherical targets in the reconstructed images.
- Visually assess the visibility and shape of each sphere, starting from the largest diameter and proceeding to the smallest.
- Determine the smallest sphere that can be reliably distinguished from the surrounding material.
- Verify that the spheres appear circular and centered without elongation or distortion along the z-axis.

Optional quantitative evaluation:

- Measure the mean CT number of each sphere and of the surrounding background using appropriately sized ROIs.
- Evaluate contrast or contrast-to-noise ratio (CNR) as a function of sphere diameter.

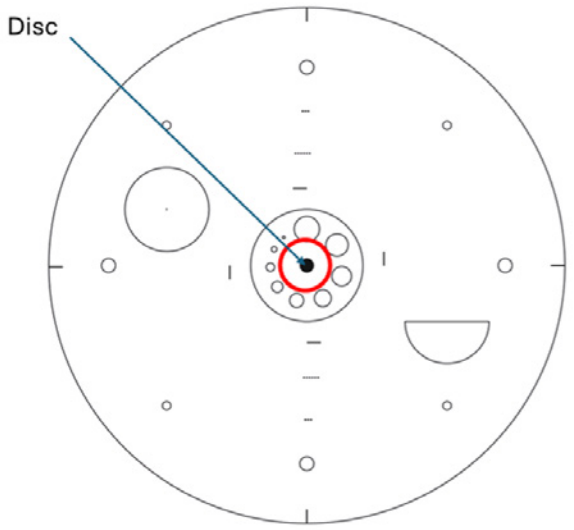
Acceptance Criteria

- The smallest reliably visible sphere size shall remain stable relative to reference values.
- Significant changes in sphere visibility, shape, or apparent size shall be investigated.

Notes

- This test is sensitive to slice thickness, reconstruction interval, and partial volume effects.
- It is particularly useful for assessing subslice performance and volumetric imaging consistency.
- Some quality assurance guidelines consider this test informative rather than mandatory, as related performance changes may also be detected using other image quality tests.

Slice thickness – helical (Slice Sensitivity Profile)



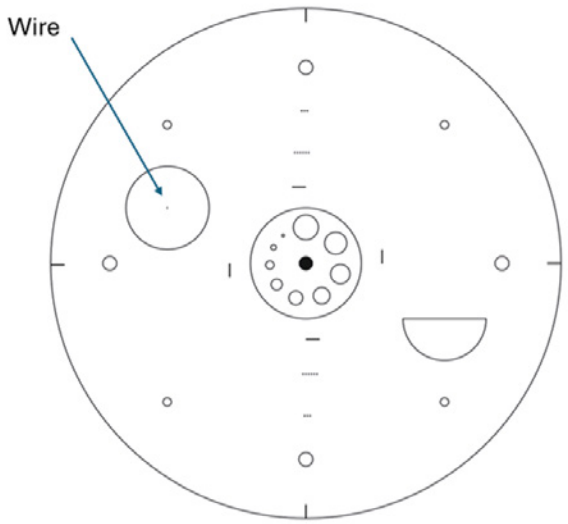
Evaluation

1. Start the scan with a set CT conditions of operation typical of helical scanning.
2. Reconstruct the images at small Z position increments/gap/interval (10 % or less of the slice thickness).
3. The mean CT number of the disc (or bead from Resolution module) material is measured over the set of images using a suitable ROI (the same placement and size for all images.
4. Record the mean CT number as a function of Z position (slice sensitivity profile - SSP).
5. Compute the width as the full width at half-maximum of the sensitivity profile.

Acceptance Criteria

- Measured slice thickness should not differ more than ±20% form nominal value.

Spatial Resolution Using Tungsten Wire (MTF)



Evaluation

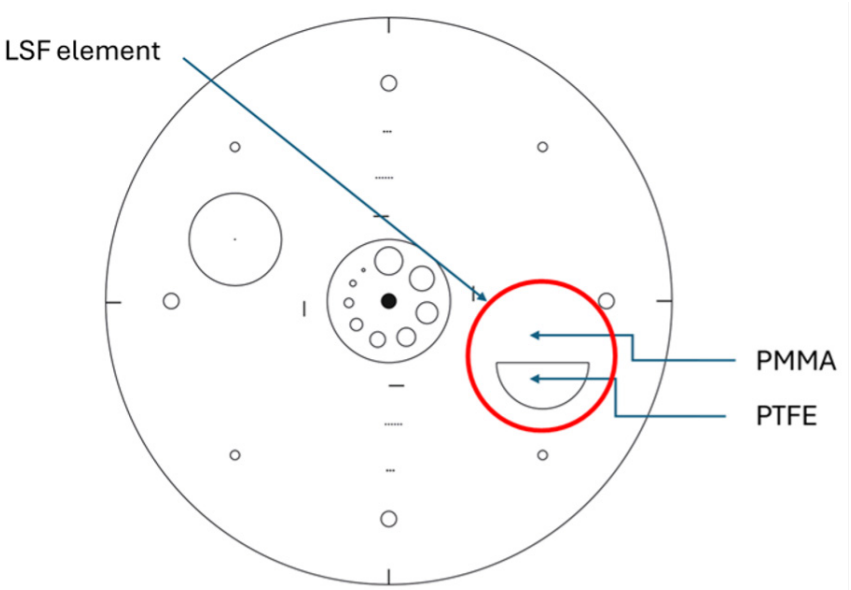
- Identify the tungsten wire element in the geometry module image.
- Use the image data surrounding the wire to derive the point spread function (PSF) of the CT system.
- From the PSF, derive the line spread function (LSF) and calculate the modulation transfer function (MTF) using appropriate analysis software.

Acceptance Criteria

- Spatial resolution characteristics derived from the MTF shall remain stable relative to reference values.
- Significant deviations from reference MTF curves shall be investigated.

Check with local regulations.

Line Spread Function (LSF)



Evaluation

- Identify the LSF element in the geometry module image.
- Extract a one-dimensional CT number profile perpendicular to the PTFE–PMMA boundary at the straight portion of the semi-circular edge.
- Differentiate the edge spread function (ESF) to obtain the line spread function (LSF).
- If required, use the LSF to calculate the modulation transfer function (MTF) using appropriate analysis software.

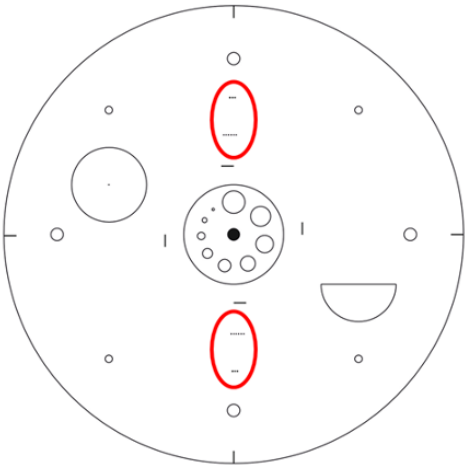
Acceptance Criteria

- The shape and width of the LSF, or the derived MTF characteristics, shall remain stable relative to reference values.
- Significant deviations from reference data shall be investigated.

Check with local regulations.

Slice Thickness Using Bead Ramps

Tungsten bead ramps



The geometry module contains two opposing bead ramp pairs for slice thickness evaluation.

One bead ramp has a 1.0 mm spacing between beads along the z-axis, and the second bead ramp has a 0.25 mm spacing.

These ramps allow slice thickness to be determined by counting the number of visible beads within the reconstructed slice.

All measurements shall be performed using the previously defined Basic Setup of the Phantom.

Evaluation

- Reconstruct an axial image through the bead ramp region using the selected slice thickness.
- Identify the bead ramp in the reconstructed image.
- Count the number of beads that are visibly included within the slice profile.
- Multiply the number of visible beads by the known bead spacing (1.0 mm or 0.25 mm) to estimate the effective slice thickness.
- Use the bead ramp with finer spacing (0.25 mm) for thin slices and higher accuracy.

Acceptance Criteria

- The measured slice thickness shall not differ from the nominal slice thickness by more than ±20%.

Example

If the bead ramp with 1.0 mm spacing is used and 4 beads are visible within the slice profile:

Effective slice thickness = 4 × 1.0 mm = 4.0 mm

If the bead ramp with 0.25 mm spacing is used and 10 beads are visible:

Effective slice thickness = 10 × 0.25 mm = 2.5 mm

The measured value is then compared with the nominal slice thickness set on the CT system.

Notes

- Accuracy depends on correct phantom positioning and consistent reconstruction parameters.
- For detailed analysis, slice thickness may also be evaluated using ramp FWHM or slice sensitivity profile (SSP) methods.

Check with local regulations.

11. TECHNICAL SERVICE

In case of questions concerning product handling or service issues, please contact us at:

RaySafe.com

12. EXPLANATIONS OF THE SYMBOLS USED

SYMBOL	MEANING
	Product number
	Series number
	Warning
	Compliance with European standards
	Manufacturer
	Date of manufacturing
	Read the instructions for use

13. TEST RESULTS

HOMOGENOUS MODULE

Unit:_____

X-Ray device: _____

REFERENCE VALUES					
HU standard deviation in centre ROI					
1	2	3	4	5	**Mean**
Mean difference between centre and side ROIs					
1	2	3	4	5	**Mean**

TEST RESULTS						
Date						
Artefacts visible [Yes / No] **No**						
Mean value in centre ROI [HU]						
Difference from the reference [%] **≤ 20%**						
Mean difference between centre and side ROIs [HU]						
Difference from the reference [HU] **≤ 4 HU**						

SENSITOMETRIC MODULE

Unit:_____

X-Ray device: _____

REFERENCE VALUES					
Mean HU value in sample I					
1	2	3	4	5	**Mean**
Mean HU value in sample II					
1	2	3	4	5	**Mean**
Mean HU value in sample III					
1	2	3	4	5	**Mean**
Mean HU value in sample IV					
1	2	3	4	5	**Mean**
Mean HU value in sample V					
1	2	3	4	5	**Mean**
Mean HU value in sample VI					
1	2	3	4	5	**Mean**
Mean HU value in sample VII					
1	2	3	4	5	**Mean**
Mean HU value in sample VIII					
1	2	3	4	5	**Mean**
Mean HU value in module's body IX					
1	2	3	4	5	**Mean**

TEST RESULTS							
Date							
Difference from reference values [|HU|] **≤ 4 HU**	I						
	II						
	III						
	IV						
	V						
	VI						
	VII						
	VIII						
	IX						

LOW CONTRAST MODULE

Unit:_____

X-Ray device: _____

REFERENCE VALUES					
Number of low contrast objects (group I)					
1	2	3	4	5	**Mean**
Number of low contrast objects (group II)					
1	2	3	4	5	**Mean**
Number of low contrast objects (group III)					
1	2	3	4	5	**Mean**

TEST RESULTS							
Date							
Number of low contrast objects **≥ reference value**	**I**						
	II						
	III						

SPATIAL RESOLUTION MODULE

Unit:_____

X-Ray device: _____

REFERENCE VALUES					
Number of distinguishable high contrast patterns					
1	2	3	4	5	**Mean**

TEST RESULTS						
Date						
Number of high contrast patterns						
≥ reference value						

GEOMETRY MODULE

Unit:_____

X-Ray device: _____

TEST RESULTS							
Date							
Distance between rods [mm]	I						
	II						
	III						
	IV						
Rod diameter [mm]	I						
	II						
	III						
	IV						
Mean ramp length **(D) [mm]**							
Mean ramp thickness **(S) [mm]**							
Slice thickness **(D - S) * 0.5**							
Difference between set-up and measured value [%] **≤ 20%**							
Mean distance of ramp middles from module axes **(Sd)** [mm] **≤ ±2mm**							