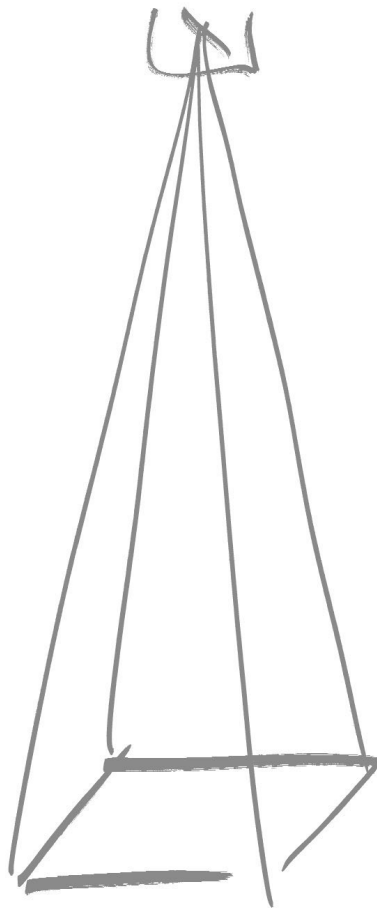


Easy Quality Control with PTW and QRM Equipment

Code of Practice | Quality Control of kV X-ray Equipment

Revised edition | October 2025



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Introduction

The quality of X-ray images is influenced by a number of parameters. To maintain the consistent performance of X-ray installations, quality checks have to be conducted regularly.

Regular quality controls:

- ensure proper functioning of medical X-ray devices
- reduce patient exposure
- avoid unnecessary double exposures
- reduce X-ray department costs

The various components of the imaging chain are ideally tested independently to identify malfunctions and easily eliminate them.

PTW Freiburg offers a variety of test tools for different X-ray equipment. The PTW Freiburg product line-up includes devices and phantoms for acceptance and constancy testing in kV energy ranges according to different standards such as international (AAPM, IEC, EFOMP etc.) and national (DIN, DIN EN etc.) standards for direct as well as for indirect radiography, for digital mammography, for digital subtraction angiography, for computer tomography, and CBCTs including IGRT.

This code of practice defines in an easy and compact way how to perform quality assurance measurements on different X-ray installations in kV energy ranges. The necessary equipment for measuring the main parameters as well as the acceptable limits are mentioned accordingly. In case the acceptable limits differ from the basic values, action has to be taken to reestablish the basic situation.

This guideline was prepared conscientiously based on the actual status of standardization up to the time of publication. This guideline is not exhaustive. For a detailed and all-embracing performance of the checks, the relevant version of the AAPM, DIN, DIN EN or IEC standard and the appropriate manual of the test equipment have to be used.

PTW Freiburg, October 2025

FAQ

Why to perform an acceptance test?

An acceptance test has to be conducted after a new X-ray installation has been installed or major modifications have been made to existing X-ray equipment to facilitate verification of applicable safety and performance standards, regulations, and contractual specifications, which influence the image quality, patient dose, or positioning.

An acceptance test is therefore normally performed by a technician from the manufacturing company of the X-ray installation. Acceptance tests ensure that the required image quality is reached with the lowest amount of X-ray exposure to the patient.

During an acceptance test, the reference or basic values for the constancy checks are defined with the same equipment, which will be used later on for constancy checks. The results of an acceptance test have to be documented and archived together with the analogue or digital X-ray image.

Why to perform a constancy check?

To avoid creeping deficiencies that result in worse X-ray images, constancy checks have to be performed regularly and within the defined frequency (monthly, semi-annually, or annually) as specified in the standards dependent on the tests. Without mechanical or electrical interferences, a constancy check enables the operator to check the image quality as well as the X-ray exposure in accordance with the standards defined during the acceptance test.

When new X-ray equipment is brought into use or any component of the X-ray equipment, accessories or test equipment is changed with the potential to cause a variation in the test result, an initial constancy check must be conducted immediately after an acceptance test has indicated that performance is satisfactory. The purpose of the initial constancy check is to establish new baseline values for the parameters tested.

The methods for testing the constancy are designed to enable the operator to detect changes in image quality of images produced by the X-ray equipment. For the results of the constancy check, it is essential to ensure that they are not significantly influenced by anything other than changes in the parameters under test. All equipment under test and the test equipment have to be identified during the initial constancy check to ensure that the same items are used in subsequent constancy checks.

Constancy checks are normally performed with loading factors which are the same as those used most frequently in clinical practice. It is important to record and reproduce all significant settings of the X-ray equipment and accessories each time a test is conducted and to check that the same equipment, components, and accessories are used. The test instrumentation has to be checked regularly and particularly when any significant variation in the X-ray equipment is suspected.

Why to use phantoms during quality control measurements?

Phantoms for constancy checks include various important structures to simulate important image details, which are characteristic of the image quality. Therefore using a phantom during constancy checks enables the operator to check whether a good X-ray image can be acquired with low X-ray exposure.

How often do quality control measurements normally have to be performed?

Quality control measurements have to be performed whenever malfunction is suspected e.g., after maintenance work that could affect the parameters under test. Constancy checks should be conducted according to the corresponding standard.

Why to use a Diamentor RS-KSK as a part of the quality checks?

DIAMENTOR RS-KSK is primarily a measuring device for patient dosimetry, on the other hand, IEC 61223-3-8-2024 provides an informative Annex G as "Guidance for Manufacturer supplied Quality Control manual. In the part of "Example of Quality Control manual for a dose-area product verification", it is stated that the DAP value can either be measured with DIAMENTOR or calculated from the real-time settings of the system as a part of the quality checks. Therefore, the verification of the dose-area product (air kerma- area product P_{KA}) value has been deliberately included in this COP.

Have all the sections in this code of practice been written by taking into account international / national (AAPM, IEC, EFOMP, DIN, DIN EN etc.) standards?

Even though all currently available standards have been reviewed in the preparation of this document, it should be noted that some sections of this CoP, such as 5.3.2, also include company recommendations. Therefore, it should be taken into account that this document does not replace any of the existing standards and is only intended to assist the technicians/physicist. It is strongly recommended to follow existing international/national standards or those recommended by the manufacturer.

Quality assurance equipment for different X-ray installations

QA tests according to	Scope of testing?	PTW products	Ordering information?	Page
Analogue and Digital Fluoroscopy and Radiography acc. to DIN 6868-4, DIN EN IEC 61223-3-8, and DIN 6868-150	• resolution, contrast, dynamic range, artifacts, coincidence of the radiation/ light field, pixel value • Incident air kerma, Ki, Incident air kerma rate, Ki rate, irradiation time, dose per pulse, pulses, kVp, total filtration, and HVL • Dose-area product (air kerma- area product P_{KA})	NORMI RAD/FLU NOMEX Multimeter DIAMENTOR RS-KDK	L981302 L981309 L981301 L981473 L981606 L981415	Page 10
Digital Subtraction Angiography acc. to DIN 6868-4, DIN EN IEC 61223-3-8, and DIN 6868-150	• resolution, contrast resolution, dynamic range, artifacts, coincidence of the radiation/ light field logarithmic error • Incident air kerma, Ki, Incident air kerma rate, Ki rate, irradiation time, dose per pulse, pulses, kVp, total filtration, and HVL • Dose-area product (air kerma- area product P_{KA})	X-Check DSA NORMI RAD/FLU NOMEX Multimeter DIAMENTOR RS-KDK	T42003 L981302 L981309 L981301 L981606 L981415	Page 18
Digital Radiography acc. to DIN 6868-13	• coincidence of the radiation/ light field, resolution, contrast, artifacts, pixel value • Incident air kerma, Ki, Incident air kerma rate, Ki rate, irradiation time, dose per pulse, pulses, kVp, total filtration, and HVL • Dose-area product (air kerma- area product P_{KA})	NORMI 13 NOMEX Multimeter DIAMENTOR RS-KDK	L981246 L981247 L981473 L981606 L981415	Page 22
Digital Mammography acc. to DIN 6868-14 and DIN 6868-162	• radiation field, Image limitation on the thoracic wall, AEC, SDNR, dynamic range, irradiation time, mean parenchymal dose, decay • kV, dose output, and HVL	NORMI MAM digital 14/162 NOMEX Multimeter	T42040 L981613 T40046	Page 27
Computed Tomography acc. to DIN EN IEC 61223-3-5:2024-07	• $CTDI_{100}$ • $CTDI_w$ • Incident air kerma, Ki, Incident air kerma rate, Ki rate, irradiation time, dose per pulse, pulses, kVp, total filtration, and HVL	CT head phantom or CT body phantom or CT head/body phantom or Pediatric Head Phantom UNIDOS CT ion chamber, 100 mm long CT ion chamber, 300 mm long Wire Phantom, air or Wire Phantom, D100 Cone-Beam Phantom, Basic or Cone-Beam Phantom, Expert	T40017 T40016 T40027 T40073 L981629-34 30009 30017 QRM-10138 QRM-10105 QRM-10120 QRM-10103	Page 35
Digital Volume Tomography acc. to DIN 6868-4 and DIN EN IEC 61223-3-8	• resolution, low-contrast resolution, artifacts • Dose-area product (air kerma- area product P_{KA})	NORMI 3D NOMEX Multimeter DIAMENTOR RS-KDK	T42038 L981606 L981415	Page 41
Cone Beam Computed Tomography incl.IGRT acc.to DIN EN IEC 61223-3-8, AAPM TG-179 and EFOMP-ESTRO-IAEA PROTOCOL	• Uniformity, geometric accuracy, linearity, voxel density values, noise, low-contrast resolution, spatial resolution, • Cumulative air kerma, CTDI metrics, cumulative dose-area product, air kerma at entrance plane	Cone-Beam Phantom, Basic or Cone-Beam Phantom, Expert NOMEX Multimeter DIAMENTOR RS-KDK	QRM-10120 QRM-10103 L981606 L981415	Page 44

I. EQUIPMENT FOR ANALOGUE & DIGITAL FLUOROSCOPY AND RADIOGRAPHY ACC. TO DIN 6868-4:2021-03, IEC 61223-3-8:2024-3 and DIN 6868-150:2022-01

Hint: **DIN 6868-4:2021-03** and **DIN EN IEC 61223-3-8:2024-03** allows fluoroscopy tests on analogue and digital units using dynamic flat panels as well as tests by film exposure from the image intensifier screen.

1.1 Test parameters

- Dose indicator
- Lp/mm resolution
- Contrast resolution
 - Dynamic Range
 - Low-contrast resolution
- Inhomogeneity and Artifacts
- Coincidence of the radiation field with the light field
- Characteristic pixel value
- Incident Air kerma, K_i
- Air kerma- area product P_{KA} (Dose-area product)

1.2 Test equipment

- NOMEX Multimeter
- NORMI RAD/FLU phantom
- DIAMENTOR RS-KDK

1.3 Test adjustment

1.3.1 Put the NORMI RAD/FLU phantom as close as possible to the image receptor of the fluoroscopic equipment while the structure plate is faced to the focus. Use the additional supports if necessary. Centre the phantom, the image receptor, and the front shutter under fluoroscopy control.

1.3.2 Adjust the field size in the same way as during the initial state. The concentric rings and the mesh on the NORMI RAD/FLU structure plate can be used for the adjustment and also allow evaluation of the field size and the image scale [picture 1].

Hint: If the fluoroscopic equipment is applied with scattering grids, always use the same grid.



Picture 1: Adjustment of the NORMI RAD/FLU phantom at a digital fluoroscopy unit using a dynamic flat panel

Hint: The focus to image receptor distance as well as the focus to phantom distance should be consistent with the one used in the initial constancy check, while the geometric enlargement should not exceed 1.3.

1.4 Test procedure

Hint: It should be noted that all parameters could be taken in one set-up if the X-ray system is not a fully digital system. Otherwise, two different set-ups are required to avoid misreading.

1.4.1 NORMI RAD/FLU phantom

1.4.1.1 Set up the loading factors identical to those used in the initial constancy check and start the fluoroscopy.

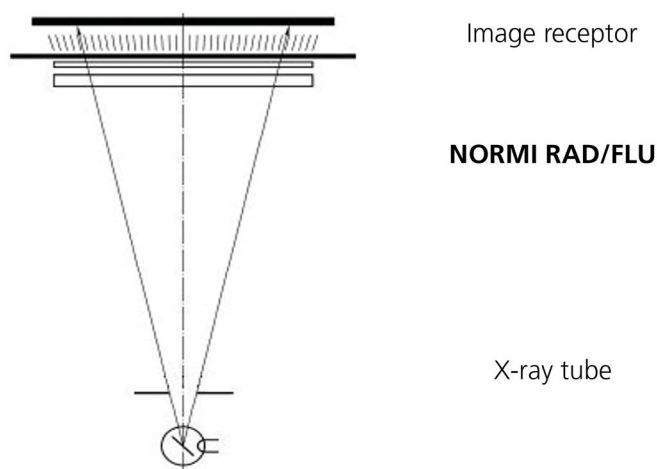
- Fluoroscopy mode with manual adjustment:

The test is performed with manually selected fluoroscopy values at a tube voltage of $75 \text{ kV} \pm 7 \text{ kV}$ and the tube current determined during the initial constancy check.

- Fluoroscopy mode with automatic dose rate control:

Use the same automatic dose rate control settings as during the acceptance test.

1.4.1.2 Evaluate the image.



Picture 2: NORMI RAD/FLU schematic adjustment

Picture 3: NORMI RAD/FLU applicatory adjustment

1.4.2 NOMEX Multimeter

1.4.2.1 Position the NOMEX Multimeter on the bucky table (Picture 4), or vertically positioned on the wall bucky stand with the necessary holders. As NOMEX Multimeter is rotation-independent, it is sufficient to position it in the central beam, no further alignment is required.

Hint:

- For dose rate measurements, the dose has to be measured during an interval of 20 seconds. In case of exposing an image, the dose per image has to be detected.
- The dose value under test is the average value out of three tests normally.

1.4.2.2 Note the dose value displayed on the screen connected to the NOMEX Multimeter (Picture 5 & 6).



Picture 4: Positioning the NOMEX Multimeter within the radiation field in digital radiography



Picture 5: NOMEX Multimeter measurements in digital radiography



Picture 6: Positioning and measurements of NOMEX Multimeter with c-arm systems

1.5 Data evaluation

Document and file the protocol with the results of the constancy check. Also note the parameters kV and mAs. The protocol formats can be found at the end of this document.

Hint: If the system fails to meet the criteria in comparison with the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

1.5.1 Dose indicator

For digital projection radiography:

The maximum deviation of the dose indicator is determined and documented by the manufacturer. Therefore, the tolerances of the dose indicator are to be taken from the manufacturer data.

Criteria to be applied: (under free exposure / manual control and under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The dose indicator deviation from the reference value for the dose indicators acc. to DIN EN 62494-1 must not exceed a deviation corresponding to $\pm 25\%$ of the image receptor dose. For the other dose indicators, manufacturer specifications are applied.

Hint: If the test leads to non-constant values, the manufacturer's specifications can be used.

1.5.2 Lp/mm resolution

Visually examine the resolution test pattern using the same image used for the test of low contrast resolution, dynamic range and dose indicator and note the maximum spatial frequencies and the smallest differentiable line structure. Compare the values with the established baseline values.

Criteria to be applied: (under AEC) (defined reference format 30 x 30 cm)

The resolution has to be a maximum of 1 lp/mm less than the baseline values.

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

1.5.3 Contrast resolution

1.5.3.1 Low-contrast resolution

Visually count and document the number of different visible steps and the visible low-contrast objects.

Criteria to be applied: (under AEC) (defined reference format 30 x 30 cm)

The following criteria have to be applied in comparison to the baseline values:

- The number of visible low-contrast objects has to be a maximum of 1 low-contrast object less than the baseline values determined in the initial test.

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

1.5.3.2 Dynamic range

The dynamic range can be checked with the dynamic steps. Testing one format is sufficient, whereby the diameter of the format is at least set to 25 cm in order to capture the dynamic levels as completely as possible. Start the measurement.

Criteria to be applied: (defined reference format 30 x 30 cm)

The following criteria have to be applied in comparison to the baseline values:

- For digital fluoroscopy (the "normal" and "high level" modes): The number of distinguishable dynamic steps has to be a maximum of 1 dynamic step less than the baseline values.
- For digital radiography, cine, and continuous mode (under automatic exposure control): The number of distinguishable dynamic steps has to be a maximum of 1 dynamic step less than the baseline values.

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

1.5.4 Inhomogeneity and artifacts

The test image has to be checked for artifacts visually which may influence the diagnosis.

Criteria to be applied: (under free exposure (manual control) and under AEC)

The following criteria have to be applied in comparison to the baseline values:

The X-ray image must be free of any artifacts, e.g. no ghost images or pixel deficiencies are allowed. The image has to be identical in comparison to the baseline values. Any new artifacts must be evaluated and documented for their impact on the diagnosis.

1.5.5 Coincidence of the radiation field with the light field

For projection radiography:

From the test image, any variation between the light field (shown in the picture 7 as 1) and the radiation field (shown on picture 7 as 2) must be determined. To measure the image geometry, the lengths of the outer lines at the top, bottom, left and right, the two middle lines of height and width are measured and recorded. Check whether the lines and shapes of the NORMI RAD/FLU are straight within themselves without any visible distortions.

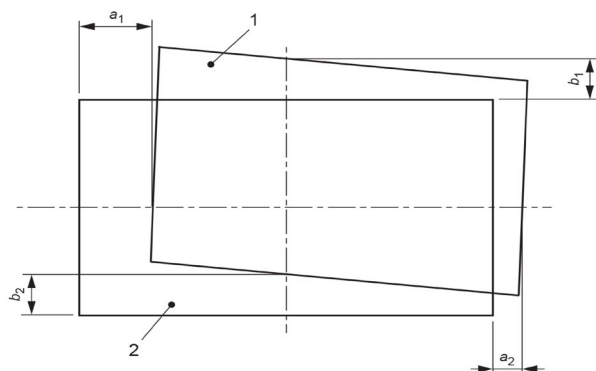
Criteria to be applied: (under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The sum of the deviations between radiation field and the light field for each axis at the image sensor level must not exceed 2 % of the focal spot to image receptor distance (FBA) (shown on picture 7 as):

$$|a_1| + |a_2| \leq 0,02 \times \text{FBA}$$

$$|b_1| + |b_2| \leq 0,02 \times \text{FBA}$$



Picture 7: NORMI RAD/FLU Deviation between the radiation field and the light field

For fluoroscopy, cine, and continuous mode:

Align the NORMI RAD/FLU centrally using FOV and fade into one of the markings on NORMI RAD/FLU by using the given beam field indicators.

If the system has a light visor, the above specified test for projection radiography can be performed.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- The sum of the deviations from baseline values (x and y) for each axis ($a_1 + a_2$ or $b_1 + b_2$) must not exceed 1 cm (equals 1 scale division in NORMI RAD/FLU)

$$|a_1| + |a_2| \leq x$$

$$|b_1| + |b_2| \leq y$$

Hint:

- Use the measurement tools of the program installed at the workplace. Only in exceptional situations should rulers

be used for measurements.

- Defined reference format for fluoroscopy is 30 x 30 cm.

1.5.6 Characteristic pixel value

For digital projection radiography:

Position the measuring field (place ROI), which is slightly smaller than the middle step (P9), in the center of the middle step (P9).

Use the below formula to calculate the characteristic pixel value for P9 using dynamic steps in NORMI RAD/FLU

$$\Delta P = \left| \frac{P_8 - P_{10}}{2} \right|$$

Criteria to be applied: (under free exposure (manual control) and under AEC)

- The characteristic pixel value P9 has to be identical in comparison to the baseline values.

1.5.7 Incident Air kerma, Ki

Compare the measured values for Incident Air kerma, Ki or Incident Air kerma, Ki rate with the established baseline values.

Criteria to be applied: The following criteria have to be applied in comparison to the baseline values of measured dose in mGy or measured dose rate in mGy/s.

- | | |
|--|--------|
| • Digital fluoroscopy, cine, and continuous mode | ± 25 % |
| • Digital projection radiography at 75 kV ± 7 kV | |
| under free exposure (manual control): | ± 25 % |
| under automatic exposure control: | ± 25 % |

Hint:

- For continuous mode, dose should be measured for each image.
- Defined reference format for fluoroscopy is app. 30 cm x 30 cm for image intensifier (smallest image receiver format)

1.5.8 Dose-area product (air kerma- area product P_{KA})

Compare the measured values for air kerma- area product P_{KA} (dose-area product) with the established baseline values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values of air kerma- area product P_{KA} (dose-area product) in μGym^2

- | | |
|---------------------------------------|--------|
| • For fluoroscopy | ± 15 % |
| • For digital projection radiography: | |
| under free exposure (manual control): | ± 25 % |
| under automatic exposure control: | ± 25 % |

Hint: If the system has an option to adjust all exposure parameters including aperture position and focus-image receptor distance, the criteria for fluoroscopy, cine, and continuous mode could be taken into account.

Table 1: NORMI RAD/FLU Limit Values (minimum requirements) (source: DIN 6868-150: 2022-01 [6])

Image intensifier-TV als image receptor (normal mode), format-dose rate	Flat detector (normal mode), format-dose rate
For Fluoroscopy	
25 cm – 0.60 µGy/s	25 cm – 0.60 µGy/s
30 cm – 0.42 µGy/s	20 cm – 0.60 µGy/s
36 cm – 0.29 µGy/s	30 cm – 0.50 µGy/s
38 cm – 0.26 µGy/s	40 cm – 0.38 µGy/s
For Cine Mode	
25 cm – 0,20 µGy/ Image	25 cm – 0,20 µGy/ Image
30 cm – 0,14 µGy/ Image	20 cm – 0,20 µGy/ Image
36 cm – 0,10 µGy/ Image	30 cm – 0,17 µGy/ Image
38 cm – 0,09 µGy/ Image	40 cm – 0,13 µGy/ Image
For Continuous Mode	
25 cm – 2.0 µGy/ Image	25 cm – 2.0 µGy/ Image
30 cm – 1.4 µGy/ Image	20 cm – 2.0 µGy/ Image
36 cm – 0.96 µGy/ Image	30 cm – 1.7 µGy/ Image
38 cm – 0.87 µGy/ Image	40 cm – 1.3 µGy/ Image
For DSA	
25 cm – 5.0 µGy/ Image	25 cm – 5.0 µGy/ Image
30 cm – 3.5 µGy/ Image	20 cm – 5.0 µGy/ Image
36 cm – 2.4 µGy/ Image	30 cm – 4.2 µGy/ Image
38 cm – 2.2 µGy/ Image	40 cm – 3.1 µGy/ Image

Table 2: NORMI RAD/FLU Scope and frequency of constancy checks (source: DIN 6868-4:2021-03 [1])

	Digital Radiography with AEC	Digital Radiography free exposure (manual control)	Fluoroscopy	Cine Mode	Continuous Mode (1 bis 10 B/s)	DSA / Subtraction Function	Digital Volume Tomography (DVT)
Visual and functional test	Always before all other test points						
Coincidence of the radiation field with light field	x	o	o(x)	o	o	oo	
Air-kerma area product P_{KA} (Dose-area product)	x	o	o	o	x	oo	xx
Dose indicator	o (x)	o (x)					
Inhomogeneity and artifacts	x	x	x	x	x	xx	xx
lp/cm resolution	x	o	x	x	x		
Low-contrast resolution	x	o	x	x	x		
Dynamic range	x	o	x	x	x		
Low-contrast resolution (DSA / Subtraction function)						xx	
Dynamic range (DSA / Subtraction function)						xx	
Spatial resolution DVT							xx
Incident Air kerma, K_i	x	x				xx ^{a,b}	
Incident Air kerma, K_i rate			x	x		xx ^{a,b}	
Incident Air kerma, K_i / image					x	xx ^a	
Characteristic pixel value	o (x)	o (x)					

x: Monthly

xx: Annually

o: Not applicable if already tested on this application device

oo: As previous point "o", annually

a: It should be performed in the test setup as defined at page 9 (1.4.2) on this document

b: Measurement of the dose rate is an alternative if the DSA operating mode is performed at > 1 image/s (for example c-arm)

II. EQUIPMENT FOR DIGITAL SUBTRACTION ANGIOGRAPHY ACC. TO DIN 6868-4:2021-03, IEC 61223-3-8:2024-3 and DIN 6868-150:2022-01

Hint: The following constancy check is carried out normally after the constancy check acc. to DIN 6868-4:2021-03 and DIN EN IEC 61223-3-8:2024-03

2.1 Test parameters

- Lp/mm resolution
- Contrast resolution
 - Dynamic range (DSA mode)
 - Dynamic range (Subtraction function)
 - Low-contrast resolution (DSA mode and Subtraction function)
- Inhomogeneity and Artifacts
- Logarithmic Error
- Coincidence of the radiation field with the light field
- Logarithmic error
- Incident air kerma, K_i
- Air kerma- area product P_{KA} (Dose-area product)

2.2 Test equipment

- NOMEX Multimeter
- X-Check DSA phantom
- NORMI RAD/FLU phantom
- DIAMENTOR RS-KDK

2.3 Test adjustment

2.3.1 Put the X-Check DSA on table and move it until the step wedge is horizontally orientated within the image [picture 8], so that the dynamic steps appear horizontally in the image.

2.3.2 Make sure that the X-Check DSA cannot shift during the movement and the center of the X-Check DSA is in the middle of the radiation beam.

2.3.3 Adjust the minimal distance between the X-Check DSA and the image intensifier [picture 9].

2.3.4 Check whether the irradiation field is smaller than the X-Check DSA. Make sure that the image intensifier is not irradiated directly.

2.3.5 Perform image acquisition [picture 10].

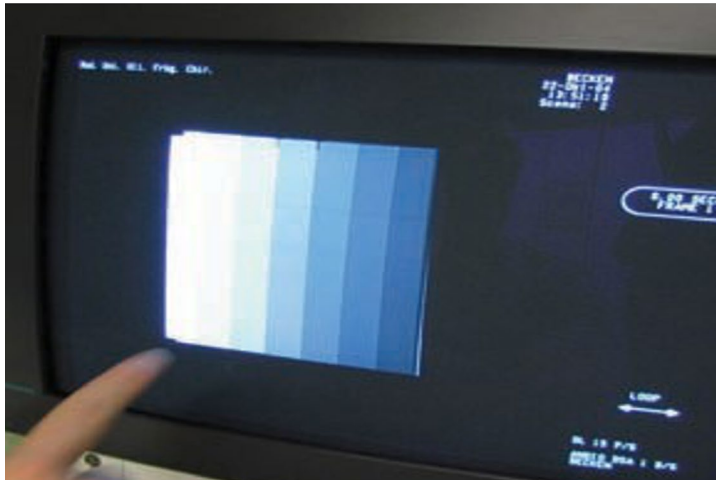
Hint: It is sufficient to make only one DSA picture and one basic picture.



Picture 8: Adjust the X-Check DSA



Picture 9: Choose the minimal distance- X-Check DSA



Picture 10: Centre the X-Check DSA

2.4 Test procedure

2.4.1 Using the automatic exposure control (if available) or the automatic dose rate control sets up the loading factors identical to those used in the initial constancy check (for the acceptance tests: 70 kV and for the constancy checks: $75 \text{ kV} \pm 7 \text{ kV}$). The image frequencies should be the same as those used clinically. Normally, the measuring time should be at least 20 seconds [s] at a picture frequency of at least 1 s^{-1} .

2.4.2 Start the measurement and shift the pneumatic X-Check DSA slider after approx. five seconds.

2.4.3 Evaluate and document the results.

Hint:

- Note that for AEC, the irradiation time and focus size should be adjusted to achieve the desired voltage of $75 \text{ kV} \pm 7 \text{ kV}$. For this purpose, low atomic number attenuation materials can be placed in the beam close to the focus.
- It should also be noted that acceptance tests should be carried out at the same dose level as used for image-receiving dose measurement.

2.5 Data evaluation

Document and file the measured values in the protocol of the constancy check.

Hint: If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

2.5.1 Lp/mm resolution

The resolution has to be determined with the NORMI RAD/FLU for one selected image intensifier format. Visually examine the resolution test pattern and note the maximum spatial frequencies and the smallest differentiable line structure. Compare the values with the established baseline values.

Criteria to be applied:

- The resolution (lp/mm) has to be a maximum of 1 lp/mm less than the baseline values

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

2.5.2 Contrast resolution

2.5.2.1 Dynamic range (DSA mode)

The dynamic range can be checked with the step wedge using X-Check DSA. The DSA installation should at least provide a dynamic range of 1 to 15. Start the measurement and shift the slider after 5 seconds.

Observe the determinations. Low movement artifacts which appear through dark or light cut-off points can be ignored.

Criteria to be applied:

The following criteria has to be applied in comparison to the baseline values:

- On the subtracted image, the 0.4 mm vessel simulation representing the thickest test object must be visible with all copper steps, and the strips of the DSA image should be homogeneous.

2.5.2.2 Dynamic range (subtraction function)

Criteria to be applied:

The following criteria has to be applied in comparison to the baseline values:

- At the 0.8 mm Cu level the 0.2 mm vessel simulation line should still be visible. (as indicated by the arrows on the phantom).

Hint:

- It should be noted that if the system has a DSA mode and the test specified in section 2.5.2.1 has been successfully carried out, then this test is no longer necessary.
- The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

2.5.2.3 Low-contrast resolution (DSA mode and subtraction function)

The low-contrast resolution has to be determined using X-Check DSA. The low-contrast resolution test shows, whether the DSA system is able to recognize vessels with very low contrast.

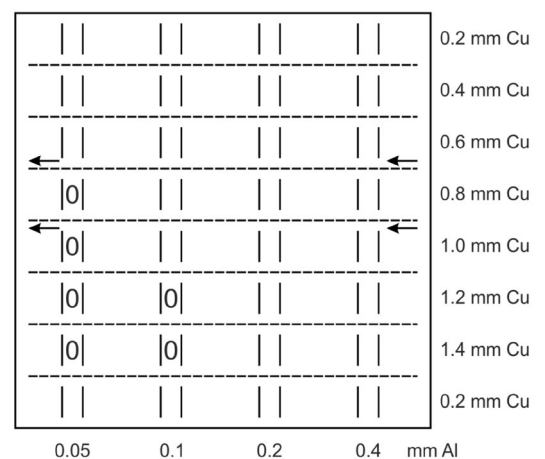
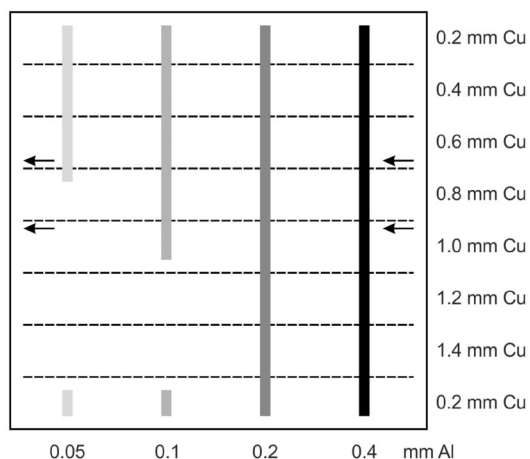
Criteria to be applied:

The following criteria have to be applied in comparison to the baseline value:

- The thinnest vessel simulation (0.05 mm Al) should be exactly recognizable in the area of the 0.8 mm Cu step if a dose of approx. 5 μ Gy per image is used.

Hint:

If the test element is not visible, you should also consider the exposure dose in the evaluation.



Picture 11: X-Check DSA example of detectable structures in the subtracted image

Picture 12: X-Check DSA evaluation matrix for the above example of detectable structures (O = location where no structures can be detected)

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

2.5.3 Inhomogeneity and artifacts

There are four reasons for artifacts, which should be examined if they occur:

- two pictures do not refer to the same coordinate system
- the beam quality was drifting during the runs
- the measuring values are not correctly digitized
- influences of the beam geometry occurred

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- Any visible deterioration across the image not presented before is not allowed and should lead to further action.

2.5.4 Logarithmic error (only for the equipment with analog logarithmic amplifiers)

The attenuation of X-rays is not proportional to the object thickness or to the object density. To compensate for this effect, a DSA unit works with logarithmic amplifiers. If these amplifiers are not working well, logarithmic errors occur. These errors can be checked by observing the step wedge using X-Check DSA. Use the low-contrast resolution images for the analysis.

Criteria to be applied:

- If the DSA image shows a difference in gray values between the 1.4 copper step and the 0.2 copper step, a logarithmic error has caused this failure and has to be eliminated.

2.5.5 Coincidence of the radiation field with the light field

Align the NORMI RAD/FLU centrally using FOV and fad into one of the markings on NORMI RAD/FLU by using the given beam field indicators.

If the system has a light visor, the test specified for projection radiography at section 1.5.6 can be performed.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- The sum of the deviations from baseline values (x and y) for each axis ($a_1 + a_2$ or $b_1 + b_2$) must not exceed 1 cm (equals 1 scale division in NORMI RAD/FLU)

$$|a_1| + |a_2| \leq x$$

$$|b_1| + |b_2| \leq y$$

2.5.6 Incident Air Kerma, K_i

This measurement is carried out according to DIN 6868-4:2021-03 using NOMEX Multimeter [refer to page 10]. Compare the measured values for Incident Air kerma, K_i or Incident Air kerma, K_i rate with the established baseline values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values of measured dose in mGy or measured dose rate in mGy/s.

- For DSA and Subtraction functions: $\pm 25 \%$

2.5.7 Dose-area product (Air kerma- area product P_{KA})

Compare the measured values for air kerma- area product P_{KA} (dose-area product) with the established baseline values:

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values of air kerma- area product P_{KA} (dose-area product) in μGym^2

- For DSA and Subtraction functions: $\pm 15 \%$

III. EQUIPMENT FOR DIGITAL RADIOGRAPHY ACC. TO DIN 6868-13:2012-03 (*) and DIN EN IEC 61223-3-8:2024-03

***Even if the above standard has been withdrawn, it is stated in the currently valid standard, DIN 6868-4:2021-03, that the test object specified in DIN 6868-13:2012-03 could be used for constancy checks. For this purpose, this section was deliberately included in the PTW Code of Practice. Please note that DIN 6868-4:2021-03 should be taken into account for the tolerances.**

Hint:

The following section describes the constancy check of equipment for digital projection radiography. This standard applies to equipment that utilize imaging plates or semiconductor image detectors, which use film on an image viewer or image display device for diagnosis (monitor diagnosis).

3.1 Test parameters

- Dose indicator
- Lp/mm resolution
- Contrast resolution
- Inhomogeneity and artifacts
- Coincidence of the radiation field with the light field
- Characteristic pixel value
- Incident Air kerma, K_i
- Air kerma- area product P_{KA} (Dose-area product)

3.2 Test equipment

- NOMEX Multimeter
- NORMI 13 phantom
- DIAMENTOR RS-KDK

3.3 Test adjustment

3.3.1 Adjust the NORMI 13 phantom on the couch and put the image plate including the film into the position for exposure. Always use the same marked image plate [picture 14].

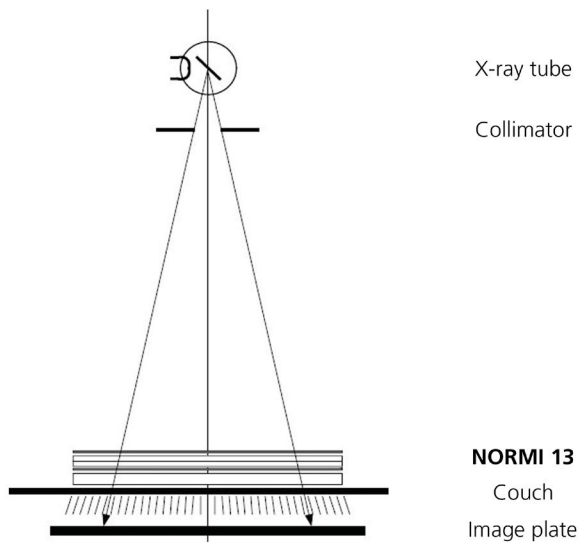
- For over couch tubes, the indication "focus" on the NORMI 13 structure plate has to face the X-ray focus above.
- For under couch measurements, the NORMI 13 is assembled by using the additional supports. In this case the NORMI 13 structure plate with the indication "focus" faces down in direction to the tube.
- The NORMI 13 can also be used in combination with the NORMI 13 wall mount [L981473].

3.3.2 Always adjust the NORMI 13 phantom in the same way, as defined in the initial constancy check. Therefore, use the light field of the X-ray installation. Adjust the light field beginning with the adjustment to the mid-marks and then to the edge-marks of the NORMI 13 structure plate [picture 16].

Hint:

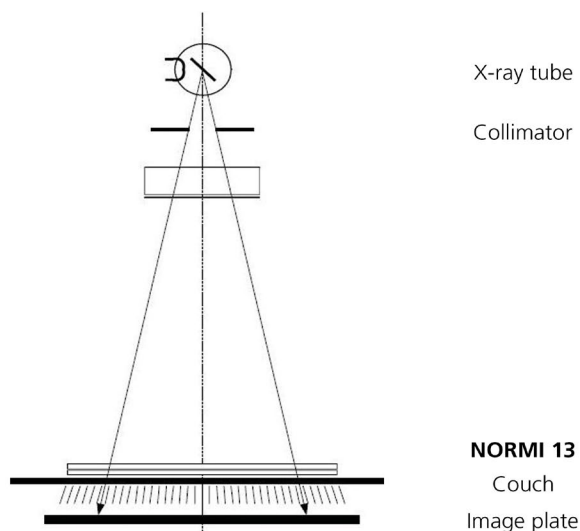
- If there is no light field, use the fluoroscopy control to center the NORMI 13 to the image display device.
- Always use the same imaging plate with the same foil.
- Always use the same scattering grid adjusted in the same spatial orientation and same distance.

Hint: The measurement adjustment should be reproducible within ± 1 % of the focus to image-receiver distance used in the initial constancy check.



Picture 13: Schematic adjustment of NORMI 13 with a PMMA attenuator

Picture 14: Applicatory adjustment of NORMI 13



Picture 15: Schematic adjustment of NORMI 13 with an Al attenuator

Picture 16: Applicatory adjustment of NORMI 13

3.4 Test procedure

Carry out exposures under both manual exposure control and automatic exposure control if both are used in clinical routine:

Hint: It should be noted that all parameters could be taken in one set-up if the x-ray system is not a fully digital system (under automatic exposure control). Otherwise, two different set-ups are required to avoid misreading.

3.4.1 NORMI 13 phantom

3.4.1.1 Set up the loading factors identical to those used in the initial constancy check and make an exposure.

3.4.1.2 Evaluate the image.

3.4.2 NOMEX Multimeter

3.4.2.1 Place the NOMEX Multimeter on the bucky table, or vertically position it on the wall bucky stand with the necessary holders. As NOMEX Multimeter is rotation-independent, it is sufficient to position it in the central beam, no further alignment is required. (Picture 17)

3.4.2.2 Note the dose value displayed on the screen connected to the NOMEX Multimeter

Hint: For measurements at 100 kV, an additional copper plate can be used to attain sufficient switching time.



Picture 17: NOMEX Multimeter under the tube and within the radiation field

3.5 Test evaluation

Document and file the measured values in the protocol of the constancy check.

Hint: If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

3.5.1 Dose indicator

The maximum deviation of the dose indicator is determined and documented by the manufacturer. Therefore, the tolerances of the dose indicator are to be taken from the manufacturer data.

Criteria to be applied: (under free exposure (manual control) and under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The dose indicator deviation from the reference value for the dose indicators acc. to DIN EN 62494-1 must not exceed a deviation corresponding to $\pm 25\%$ of the image receptor dose. For the other dose indicators, manufacturer specifications are applied.

Hint: If the test leads to non-constant values, the manufacturer's specifications can be used.

3.5.2 Lp/mm resolution

The spatial resolution is determined using the lead foil test pattern of the NORMI 13. The image of the lead foil can be evaluated visually using a 4 to 8 magnifying glass. The parameter is the number of line pairs per millimeter (Lp/mm) in the line group which can be distinguished at the resolution. Compare the values with the established baseline values.

Criteria to be applied: (under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The resolution (Lp/mm) has to be a maximum of 1 Lp/mm less than the baseline values

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

3.5.3 Contrast resolution

Inspect the dynamic steps and observe the low contrast objects visually. Enter them into the test report.

Criteria to be applied: (under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The number of visible low-contrast objects has to be a maximum of one low-contrast object less than the baseline values determined in the initial test.

Hint: The tolerance tables (Source: DIN 6868-150: 2022-01 [6]) for the acceptance tests can be found in the appendix to this document.

3.5.4 Inhomogeneity and artifacts

The test image has to be checked for artifacts visually which may influence the diagnosis.

Criteria to be applied: (under free exposure (manual control) and under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The X-ray image must be free of any artifacts.

3.5.5 Coincidence of the radiation field with the light field

From the test image any variation between the light field (shown in the picture 18 as 1) and the radiation field (shown in the picture 18 as 2) must be determined. To measure the image geometry, the lengths of the outer lines at the top, bottom, left and right, the two middle lines of height and width are measured and recorded. Check whether the lines and shapes of the NORMI 13 are straight within themselves without any visible distortions.

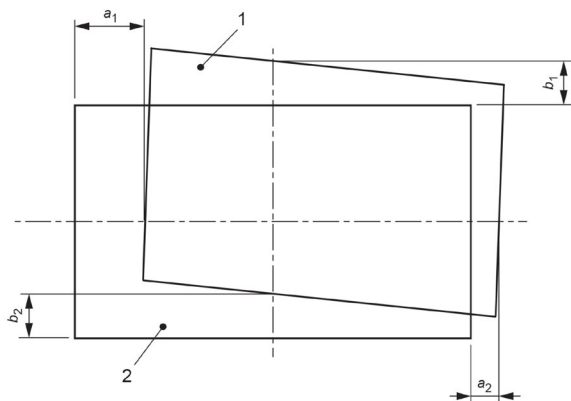
Criteria to be applied: (under AEC)

The following criteria have to be applied in comparison to the baseline values:

- The sum of the deviations between radiation field and the light field for each axis at the image sensor level must not exceed 2 % of the focal spot to image receptor distance (FBA) (shown in the picture 18 as):

$$|a1| + |a2| \leq 0,02 \times \text{FBA}$$

$$|b1| + |b2| \leq 0,02 \times \text{FBA}$$



Picture 18: NORMI 13 Deviation between the radiation field and the light field

Hint: Use the measurement tools of the program installed at the workplace. Only in exceptional situations should rulers be used for measurements

3.5.6 Characteristic pixel value

Centrally position the measuring field (place ROI), which is slightly smaller than the middle step (P9), on the middle step (P9).

Use the below formula to calculate the characteristic pixel value for P9 using dynamic steps in NORMI 13

$$\Delta P = \left| \frac{P_8 - P_{10}}{2} \right|$$

Criteria to be applied: (under free exposure (manual control) and under AEC)

- The characteristic pixel value P9 has to be identical in comparison to the baseline values.

3.5.7 Incident air kerma, Ki

Compare the measured values for Incident Air kerma, Ki or Incident Air kerma, Ki rate with the established baseline values.

Criteria to be applied: (under free exposure (manual control) and under AEC)

The following criteria have to be applied in comparison to the baseline values of measured dose in mGy or measured dose rate in mGy/s.

- Under free exposure (manual control): $\pm 25 \%$ (at 75 kV ± 7 kV)
- Under automatic exposure control: $\pm 25 \%$ (at 75 kV ± 7 kV)

3.5.8 Air kerma- area product P_{KA}

Compare the measured values for air kerma- area product P_{KA} (dose-area product) with the established baseline values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values of air kerma- area product P_{KA} (dose-area product) in μGym^2

- Under free exposure (manual control): $\pm 25 \%$
- Under automatic exposure control: $\pm 25 \%$

IV. EQUIPMENT FOR DIGITAL MAMMOGRAPHY ACC. TO DIN 6868-14:2022-01 and DIN 6868-162:2022-01

4.1 Test parameter

- X-ray tube voltage
- Half-value layer
- Dose output
- Radiation field
- Image limitation on the thoracic wall side
- Automatic exposure control (AEC)
 - SDNR (signal difference to noise ratio)
 - Reproducibility of the applied dose
 - Irradiation time
- Interfering structures
- Mean parenchymal dose
- Dynamic range
- Decay
- Compression force

4.2 Test equipment

- NOMEX Multimeter
- NORMI MAM digital 162/14 phantom

4.3 Test adjustment

- 4.3.1 Adjust the NORMI MAM digital phantom on the patient support (configuration with 40 mm PMMA attenuator and 6 mm structure plate).
- 4.3.2 Choose the minimum distance adjustable at the given mammography unit and put the cassette into the position for exposure.
- 4.3.3 Align the NORMI MAM digital phantom to ensure that the chest wall boundary surface and the patient support wall boundary are on the same plane.
- 4.3.4 Ensure that the long side of the NORMI MAM digital phantom on the thoracic wall side is flush with the long side of the patient support on the thoracic wall side (use the stops on the base plate).



Picture 19: NORMI MAM digital with test element SDNR

4.4 Test procedure

- Set up the loading factors identical to those used in the initial test and start the measurement.
- Evaluate the NORMI MAM digital phantom images.
- Then place the NOMEX Multimeter on the patient support. Use the settings of the X-ray tube voltage identical to those used in the initial constancy check and start the measurement.
- Take one image of all different combinations available (different patient supports, anode filter combinations, focal spot sizes intended by the manufacturer).
- Note down the dose values displayed on the screen connected to the NOMEX Multimeter for each exposure (Picture 20).



Picture 20: NOMEX Multimeter setup

The following performance characteristics can be determined with the NOMEX Multimeter for constancy checks on an annual basis, and the following criteria have to be applied:

- **X-ray tube voltage:** At least three X-ray voltage (25 kV, 28 kV, and 30 kV) for largest and smallest optical focal spot should be performed. One filter combination is sufficient.

Criteria to be applied:

The differences between the measured value and the displayed value on the system shouldn't be more than 1.0 kV.

Hint: This test should be performed annually.

- **Half-value layer:** In order to measure HVL, the compression plate must be positioned in the radiation beam. The measurement should be carried out at the greatest possible distance between NOMEX Multimeter and compression plate. It is essential that the vertical projection of the measurement location is positioned 6 cm away from the edge of the thoracic wall and centered laterally on the patient support.

Criteria to be applied:

- The measured HVL must not fall below the values given in Table 3 by more than 0.06 mm Al.

Table 3: The measured HVL values (source: DIN 6868-162:2022-01 [7])

Target and Filter	HVL (mm Al @ 25 kV)	HVL (mm Al @ 28 kV)	HVL (mm Al @ 31 kV)	HVL (mm Al @ 34 kV)
Mo + 30 µm Mo	0.32	0.36	0.38	0.41
Mo + 25 µm Rh	0.38	0.41	0.44	0.46
Rh + 25 µm Rh	0.36	0.42	0.47	0.50
W + 50 µm Rh	0.49	0.52	0.55	0.58
W + 50 µm Ag	0.49	0.56	0.61	0.64
W + 60 µm Mo	0.37	0.38	0.40	0.42
W + 0,5 mm Al	0.36	0.42	0.48	0.53

Hint: It should be noted that the table contains only the most frequently used target-filter combinations of the manufacturers. In such cases, the measured HVL must not fall below the 1% of the X-ray voltage (kV).

Hint: This test should be performed annually.

- **Dose Output (mGy/mAs):** In order to test the linearity and the short and long-term reproducibility of the dose output, NORMI MAM digital phantom can be used to simulate the filter effect of the patient. The dose output must be at least 30 $\mu\text{Gy/mAs}$ at 28 kV X-ray voltage, at 30- μm molybdenum filter and at 100 cm distance from the focal spot. If 28 kV X-ray voltage is not available, the evaluation factors given below (Table 4) should be taken into account for 30 kV and for the various filter combinations. The largest adjustable optical focal spot must be determined for all adjustable target-filter combinations.

Criteria to be applied:

- The coefficient of variation, which characterizes the reproducibility of the delivered dose, must not be greater than 0.02.

Hint: This test should be performed annually.

Table 4: NORMI MAM digital evaluation factors for different filters (source: DIN 6868-162:2022-01 [7])

Target/Filter	Mo / 30 μm Mo	Mo / 25 μm Rh	W/ 60 μm Mo	W/ 50 μm Rh	Rh + 25 μm Rh
Evaluation factor @ 28 kV	1.0	0.87	0.42	0.38	0.58
Evaluation factor @ 30 kV	1.22	1.07	0.48	0.44	0.71

4.5 Data evaluation

Document and file the measured values in the constancy check protocol for each image.

Hint: If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

4.5.1 Radiation field

Make exposures with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm.
- One exposure with each combination of photography table, patient support, anode target, and focal spot as intended by the manufacturer.
- For each row of steel balls in the NORMI MAM digital phantom, determine the number of balls that appear completely or in halves on the film.
- For all four edges, determine the radiation beyond the image receptor.

Criteria to be applied:

- The following criteria have to be applied
- Radiation exceeding image receptor:
- The radiation field may exceed the edge on the thoracic wall side by not more than 2 mm.
- The radiation must not exceed the other three edges of the film by more than 2 % of the direct focal spot-to-image receptor distance.

Hint: This test should be performed annually.

4.5.2 Image limitation on the thoracic wall side

Make exposures with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm.
- One exposure with each combination of photography table, patient support, anode target, and focal spot as intended by the manufacturer.

- For each row of steel balls in the NORMI MAM digital phantom, determine the number of balls that are displayed completely or in halves.
- For all four edges, determine the radiation beyond the image receptor.
- Criteria to be applied:
 - The following criteria have to be applied in comparison to the baseline values
 - The width of the area not shown in the plane of the patient support and in the plane 40 mm above the patient support must not exceed 5 mm (this is equivalent to the full visibility of 2.5 of the 5 steel balls per row in the test object).

Hint: This test should be performed monthly and annually.

4.5.3 Automatic exposure control

Make an exposure with the following settings:

- Place a large-format absorber with a rectangular contour in the radiation field in a position where it blocks all direct beams to the X-ray image receptor.
- Same automatic exposure control setting as for routine use

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values

The displayed mAs value may not deviate from the reference value by more than 15 %.

Hint: This test should be performed on a daily basis.

4.5.3.1 SDNR (Signal difference to noise ratio)

Make an exposure with the following settings for constancy checks:

- Measurements with the same automatic exposure control setting as for routine use
- The entire effective measurement field must be located under the absorber.
- Make three exposures, using absorbers with structure plate and SDNR test element with thicknesses of 26 mm, 46 mm, and 66 mm.

Hint: With 46 mm PMMA, the irradiation time must be less than 2 seconds.

Determination of SDNR:

Within the markings of the SDNR test element, define two areas with axial symmetry and comprising approx. 40,000 pixels each. For both areas, determine the mean pixel values m_{AL} and m_{BG} as well as the standard deviations σ_{AL} and σ_{BG} (AL = values referred to the area covered with Al foil and BG = compare values).

Calculate SDNR using below formula.

$$SDNR = \frac{|m_{BG} - m_{AL}|}{\sqrt{\frac{(\sigma_{BG}^2 - \sigma_{AL}^2)}{2}}}$$

Criteria to be applied:

The following criteria have to be applied:

For monthly tests:

- The displayed mAs values and the calculated SDNR values may not deviate from the baseline value by more than 15 %.

For annual tests:

- The SDNR may not deviate from the reference values determined during the acceptance test by more than 15 %.
- The SDNR must decrease monotonically starting from an object thickness of 20 mm with the defined variation of absorber thicknesses.

- The SDNR of an absorber thickness may exceed the SDNR of the next smaller absorber thickness by not more than 5 %.
- The SDNR at an absorber thickness of 70 mm must be greater than 65 % of the SDNR at an absorber thickness of 46 mm.

4.5.3.2 Reproducibility of the applied dose

Make an exposure with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm
- Choose a position of the NOMEX Multimeter that does not interfere with the automatic exposure control function.
- Measure the applied dose as air kerma with five different X-ray loads and with a constant tube voltage.
- Then, calculate the variation coefficient as the quotient of the standard deviation and the average of the five air kerma values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values

- The variation coefficient must not be greater than 0.02.

Hint: This test should be performed annually.

4.5.3.3 Irradiation time

Make an exposure with the following settings:

- Settings as for SDNR
- Measure the required irradiation time for an absorber with a thickness of 46 mm.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values

- Irradiation time < 2 s

Hint: This test should be performed on an annual basis.

4.5.4 Interfering structures

For the test, use the X-ray image created for AEC and check the image visually. The conditions and accessories should be the same as in routine use.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values

- The X-ray image must be free from interfering structures that may lead to an inaccurate medical diagnosis.

Hint: This test should be performed on a daily basis.

4.5.5 Mean parenchymal dose

Make exposures as for SDNR but with manual exposure setting.

- Place the NOMEX Multimeter on the absorber. The NOMEX Multimeter must be in contact with the bottom of the compression paddle.
- Measure the air kerma values at the entrance surface of the absorbers and determine the half-value layers. Scattered radiation from the absorbers must not affect the measurement results.
- Calculate the mean parenchymal dose using the conversion factors from the tables below.

Criteria to be applied:

The following criteria have to be applied:

Table 5: Upper limits of the mean parenchymal dose (mGy)(source: DIN 6868-162:2022-01 [7])

Absorber thickness (mm)	Equivalent breast thickness (mm)	Upper limit value of the mean parenchymal dose (mGy)
-------------------------	----------------------------------	--

20	21	1.0
30	32	1.5
40	45	2.0
45	53	2.5
50	60	3.0
60	75	4.5
70	90	6.5

Conversion tables:

Table 6: g-factors for breast simulation with PMMA (source: DIN 6868-162:2022-01 [7])

PMMA thickness (mm)	Equivalent breast thickness (mm)	Granularity of the equivalent breast thickness	g-factors (mGy/mGy)							
			HVL (mm Al)							
			0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60
20	21	97	0.329	0.378	0.421	0.460	0.496	0.529	0.559	0.585
30	32	67	0.222	0.261	0.294	0.326	0.357	0.388	0.419	0.448
40	45	41	0.155	0.183	0.208	0.232	0.258	0.285	0.311	0.339
45	53	29	0.130	0.155	0.177	0.198	0.220	0.245	0.272	0.295
50	60	20	0.112	0.135	0.154	0.172	0.192	0.214	0.236	0.261
60	75	9	0.088	0.106	0.121	0.136	0.152	0.166	0.189	0.210
70	90	4	-	0.086	0.098	0.111	0.123	0.136	0.154	0.172
80	103	3	-	0.074	0.085	0.096	0.106	0.117	0.133	0.149

Table 7: c-factors for breast simulation with PMMA (age group between 50-64 years old) (source: DIN 6868-162:2022-01 [7])

PMMA thickness (mm)	Equivalent breast thickness (mm)	Granularity of the equivalent breast thickness	g-factors (mGy/mGy)						
			HVL (mm Al)						
			0.30	0.35	0.40	0.45	0.50	0.55	0.60
20	21	97	0.889	0.895	0.903	0.908	0.912	0.917	0.921
30	32	67	0.940	0.943	0.945	0.946	0.949	0.952	0.953
40	45	41	1.043	1.041	1.040	1.039	1.037	1.035	1.034
45	53	29	1.109	1.105	1.102	1.099	1.096	1.091	1.088
50	60	20	1.164	1.160	1.151	1.150	1.144	1.139	1.134
60	75	9	1.254	1.245	1.235	1.231	1.225	1.217	1.207
70	90	4	1.299	1.292	1.282	1.275	1.270	1.260	1.249
80	103	3	1.307	1.299	1.292	1.287	1.283	1.273	1.262

Table 8: s-factors for clinically used target-filter combinations (source: DIN 6868-162:2022-01[7])

Target-Filter Combination	s-Factors
Mo/Mo	1.000
Mo/Rh	1.017
Rh/Rh	1.061
Rh/Al	1.044
W/Rh	1.042

Table 9: s-factors for system with W/AI combination (0.5 mm Al filtered) (source: DIN 6868-162:2022-01 [7])

PMMA Thickness	s Factors
20	1.075
30	1.104
40	1.134
45	1.149
50	1.160
60	1.181
70	1.198
80	1.208

4.5.6 Dynamic range

Make an exposure with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm (equivalent to 53 mm breast thickness) with dynamic steps and PMMA test element
- All other settings as for SDNR
- Determine the mean pixel values in the individual fields of the steps.
- Determine the offset at the lead step of the steps. Step 0 (unattenuated primary radiation) must yield the maximum mean pixel value, the other steps the appropriate mean pixel values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values

- Display of the entire aluminum steps
- Continuity of the mean pixel values and aluminum thickness

Hint: It is recommended to perform the test on the uncorrected raw image.

4.5.7 Decay

a. Make an initial exposure with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm and PMMA test element
- Manual setting: same settings as with automatic exposure control and 46 mm test object configuration
- Take picture according to manufacturer's recommendations
- Between exposures, operate the digital X-ray image system according to manufacturer's recommendations

b. Make a second exposure with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm and HK test element
- Manual setting: same settings as with automatic exposure control and 70 mm PMMA
- Take picture according to manufacturer's recommendations
- Between exposures, operate the digital X-ray image system according to manufacturer's recommendations

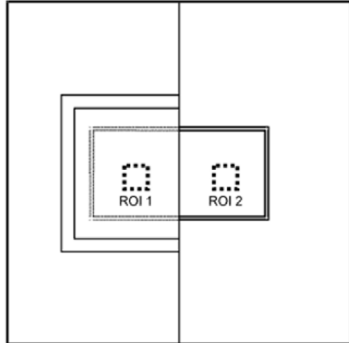
c. Make a third exposure with the following settings:

- NORMI MAM digital phantom with an overall thickness of 46 mm and PMMA test element. Imaging settings as for the first image
- Take picture according to manufacturer's recommendations
- Between exposures, operate the digital X-ray image system according to manufacturer's recommendations

d. Measure the following mean values (refer to Picture 21):

- Test images 1 and 3: from rectangular region minimum of 1000 pixels, ROI 1 within the high contrast object; values: $F1_{ROI1}$ and $F3_{ROI1}$
- Test images 1 and 3: average of the linearized data from the rectangular region of a minimum of 1000 pixels, next to ROI 2, but not overlapping; values: $F1_{ROI2}$ and $F3_{ROI2}$

Determine the measuring quantity M:



Picture 21: NORMI MAM digital definition of ROI

$$M = \frac{(F1_{ROI1} - F1_{ROI2}) - (F3_{ROI1} - F3_{ROI2})}{\frac{(F1_{ROI2} + F3_{ROI2})}{2}}$$

Criteria to be applied:

The following criteria have to be applied:

- The determined measuring quantity M must be less than 0.01

V. EQUIPMENT FOR COMPUTED TOMOGRAPHY ACC. TO DIN EN 61223-3-5:2024-07

5.1 Test parameters

- Computed tomography dose index [CTDI_{100}]
- Weighted CTDI_{100} [CTDI_w]
- Spatial Resolution
- Low-contrast resolution
- Mean CT Number and Homogeneity
- Noise

5.2 Test equipment

- CT head & body phantom or CT body phantom or CT head phantom or pediatric CT head phantom
- UNIDOS electrometer with CT chamber and CT adapter
- NOMEX Multimeter
- QRM Cone-Beam Phantom, Basic or Expert

5.3 Test adjustment

5.3.1 CT Phantoms and Ion Chambers

5.3.1.1. Connect the CT chamber to the CT adapter and then to the UNIDOS.

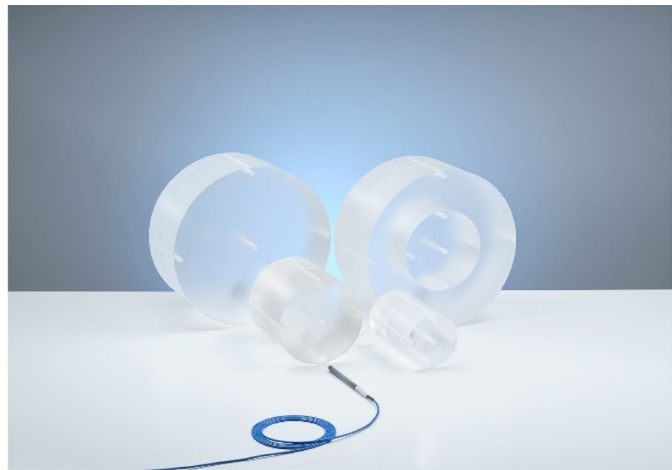
5.3.1.2. Adjust the head or body phantom in that way that one of the outer holes is on the top, in the so-called 12 o'clock position.

5.3.1.3. Insert the CT chamber into the 12 o'clock hole and close the other holes with plugs [picture 22].

5.3.1.4. Align the phantom with respect to the CT plane and rotational axis using the crosshair of the CT phantom. Switch on the UNIDOS.



Picture 22: Adjust the CT body phantom and insert the CT chamber



Picture 23: Overview of CT Phantoms

5.3.2 NOMEX Multimeter for reference dosimetry and quality control measurements (recommendation for the so-called topogram or service mode)

Hint:

- This section (5.3.2) is not based on international and/or national guidelines. It is a company recommendation only for the case where there is no rotating radiation, and deliberately included to emphasize the available measurements that could be performed by the NOMEX Multimeter: Dose rate, dose (incident air kerma), kV, irradiation time, HVL, total filtration, kV waveform, and dose rate waveform.

- It should be noted that the X-ray tube should be operated in the so-called topogram or service mode and be positioned vertically above the NOMEX Multimeter, and if the rotation of the CT tube and the treatment table cannot be deactivated (service mode), the NOMEX Multimeter cannot be used to perform these measurements (Picture 24).

5.3.2.1 Positioned NOMEX Multimeter within the central beam independently of any consideration of the tube axis alignment. (Picture 24)

5.3.2.2 NOMEX Multimeter sets up itself automatically and measurements start and stop automatically after detection of radiation. The scans should be performed under topogram mode without the rotation of the gantry.

5.3.2.3 After an exposure, the results will be displayed and listed in a data set chart for further analysis or for data tracking, e.g. within software. Note down the displayed values on the screen connected to the NOMEX Multimeter for each exposure.



Picture 24: NOMEX Multimeter setup with CT



Picture 25: NOMEX Multimeter with PC connection

5.4 Test procedure for CTDI measurement

- Set up the CT for the scan. Set up the loading factors identical to those used in the initial constancy check.
- Perform a CT scan and start the measurement of the DLP. Read out and note down the measured data from the UNIDOS.
- Change the chamber position by inserting the CT chamber into the center hole of the CT phantom and close the unused hole with the plug.

Hint: Change the chamber and plugs carefully. If the phantom moves, the alignment has to be repeated.

- For the determination of the weighted computed dose index, the DLP has to be measured as described above.
- Evaluate the CT scan.

5.5 Evaluation data

Document and file the measured values with the protocol of the constancy check.

Hint: If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!

5.5.1 CTDI₁₀₀

Determine the CTDI₁₀₀ from the measured DLP and compare it with the base line value.

Hint: Calculate the CTDI₁₀₀ with the following formula if N * T is smaller than or equal to 40 mm:

$$\text{CTDI}_{100} = \int_{-50 \text{ mm}}^{+50 \text{ mm}} \frac{D(z)}{N * T} dz$$

with

D(z): Dose profile along the line z perpendicular to the tomography plane

N: Number of tomography sections produced in a single axial scan

T: Nominal tomography section thickness

Criteria to be applied:

The following criteria has to be applied in comparison to the baseline value:

- Please refer to the table 10 and 11 in this document for tolerance levels for both acceptance and constancy checks.

(Source: DIN EN IEC 61223-3-5:2024-07[3])

Hint: Direct measurement of the $CTDI_{100}$ for $N \times T > 40$ mm is not possible. If the $N \times T$ is greater than 40 mm, the following formula should be used and it should be calculated from the $CTDI_{free-air}$ for this $N \times T$ together with the $CTDI_{100}$ and $CTDI_{free-air}$ for a reference collimation of 20 mm or the largest available value of $N \times T$, which must not be greater than 20 mm.

$$CTDI_{100} = \int_{-50}^{+50} \frac{D_{ref}(z)}{(N \times T)_{Ref}} dz \times \frac{CTDI_{free-air, N \times T}}{CTDI_{free-air, Ref}}$$

- $D_{ref}(z)$: Dose profile along the line z perpendicular to the tomography plane for $(N \times T)_{ref}$
- $(N \times T)_{ref}$: a specific value for $N \times T$ of 20 mm or the largest available value of $N \times T$, which must not be greater than 20 mm
- $CTDI_{free-air, N \times T}$: a CTDI free-air value for a specific value of $N \times T$
- $CTDI_{free-air, Ref}$: a CTDI free-air value for a specific value of $(N \times T)_{ref}$

5.5.2 $CTDI_w$

Determine the $CTDI_w$ from the measured DLP and compare it with the base line value.

Hint:

Calculate the $CTDI_w$ with the following formula:

$$CTDI_w = \frac{1}{3} CTDI_{100(centre)} + \frac{2}{3} CTDI_{100(peripheral)}$$

with

$CTDI_{100(centre)}$: CT value measured in the center of the CT phantom

$CTDI_{100(peripheral)}$: Average CT value measured in the outer or peripheral holes of the CT phantom

Criteria to be applied:

The following criteria has to be applied in comparison to the baseline value:

$CTDI_w$: $\pm 20\%$

Hint: The dose values for spiral scans can be determined from axial dose measurements ($CTDI_w$) using the $CTDI_{vol}$ definition. It is recommended that $CTDI_w$ values used to determine the dose of spiral scans be determined at the same or as similar an insertion site as possible to the axial CT operating conditions.

5.5.3 Spatial resolution

It should be described by the MTF (Modulation Transfer Function), which is obtained from the Fourier transformation of the line spread function (LSF) or, point spread function (PSF), or edge spread function (ESF).

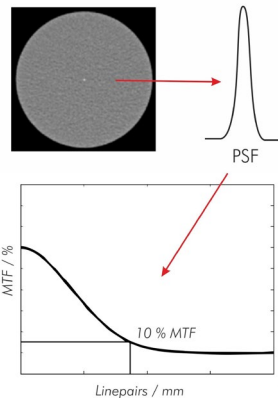
- Position the phantom on the gantry and ensure that the phantom is aligned parallel to the z-axis of the system and 30 mm $\pm$ 10 mm outside the center of rotation.
- Select the FOV small enough not to limit the scan to pixel values.
- Measure the 50% and 10% points of the MTF.
- The ESF or PSF should be measured by using an appropriate QRM Phantom (Cone-Beam Phantom or Wire Phantom)
- Calculate the MTF of the imaging system.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- The value must not exceed the baseline values. Please refer to table 10 for tolerance levels for acceptance tests or

constancy checks. (Source: DIN EN IEC 61223-3-5:2024-07[3])



Picture 26: QRM Wire Phantom MTF analysis

Hint: Reconstruction techniques such as filter back projection or manufacturer's instructions can be followed/used.

5.5.4 Low-contrast resolution

In accordance with DIN EC IEC 61223-3-5:2024-07, acceptance and stability checking for low contrast resolution is not mandatory. Consequently, no information is provided in this document. Should the manufacturer request regular checking, the tests described in the manufacturer's documentation must be followed.

5.5.5 Mean CT number and homogeneity

Place four evenly distributed peripheral ROIs at the outer edge of the uniform area of the QRM Cone-Beam Phantom and determine the mean CT number in a central ROI in the image of the phantom. Uniformity is the determination of the difference in the mean CT numbers in one central and four peripheral ROIs in the image of cylindrical water phantoms. The recommended distance is 1 cm, and the positions must be selected at reproducible positions (e.g., 3, 6, 9 and 12 o'clock). The diameter of the ROIs must be approximately equivalent to a circular area equal to 10% of the diameter of the QRM Cone-Beam Phantom. Just for children's protocols, it should be 20% of the diameter of the phantom. A 20 cm head and pediatric body phantom, and a 30 cm adult body phantom should be used for acceptance tests. 20 cm phantom is sufficient for all constancy checks.

Criteria to be applied:

The following criteria have to be applied:

- Please refer to the table 11 for tolerance levels for both acceptance and constancy checks. (Source: DIN EN IEC 61223-3-5:2024-07[3])

Hint: For axial scans, each image should be evaluated. For helical scans, the evaluation of an image near the center of the phantom is sufficient.

5.5.6 Noise

Place one central ROI in the image of the QRM Cone-Beam Phantom. The diameter of ROI should be approximately equal to a circular area of 40% of the QRM Cone-Beam Phantom. A 20 cm head and pediatric body phantom, and a 30 cm adult body phantom should be used for acceptance tests. 20 cm phantom is sufficient for all constancy checks.

Criteria to be applied:

The following criteria have to be applied:

Please refer to the table 11 for tolerance levels for both acceptance and constancy checks.

(Source: DIN EN IEC 61223-3-5:2024-07[3])

Table 10: Scope and frequency of quality controls in computed tomography (source: DIN EN IEC 61223-3-5:2024-07[3])

SCOPE OF QUALITY CONTROLS	FREQUENCY OF CONSTANCY TEST	TOLERANCE LEVELS FOR ACCEPTANCE TEST	TOLERANCE LEVELS FOR CONSTANCY TEST
Positioning of the couch	Yearly	$\leq \pm 1$ mm	Same as acceptance test
Axial patient positioning accuracy	Yearly	$\leq \pm 2$ mm	Same as acceptance test
Accuracy of the sagittal & coronal patient-light visor	Yearly	According to the accompanying documents	Sagittal & Coronal: According to the accompanying documents
Reconstructed slice thickness	For axial mode Yearly For helical mode According to the accompanying documents, if performed	Axial: ± 0.5 mm for slice thickness < 1 mm ± 50 % for slice thickness from 1 mm to 2 mm ± 1 mm for slice thickness > 2 mm Helical: not required According to the accompanying documents, if performed	Axial: Same as acceptance test Helical: not required According to the accompanying documents, if performed
Incident Air kerma, K_i	Yearly or after important maintenance	In comparison to display values: $CTDI_{W}$, $CTDI_{FREE-AIR}$: According to the accompanying documents For $CTDI_{VOL}$: In comparison to display values and the accompanying papers $\rightarrow \pm 20\%$ or ± 1 mGy (whichever is greater) for typical examination protocol Adult body Adult head Pediatric body Pediatric head For other test situations: According to the accompanying documents	For $CTDI_{W}$ and $CTDI_{FREE-AIR}$: In comparison to display values $\rightarrow \pm 20\%$ or ± 1 mGy (whichever is greater) for typical examination protocol Adult body Adult head Pediatric body Pediatric head $CTDI_{VOL}$: In comparison to display values and the accompanying papers $\rightarrow \pm 20\%$ or ± 1 mGy (whichever is greater) for typical examination protocol Adult body Adult head Pediatric body Pediatric head In addition, acceptance test criteria are applied.
Inhomogeneity and	Yearly	Visual inspection of all images by qualified	Same as acceptance test
Mean CT Number	Yearly for all Monthly for Adult head	Please refer to Table 11	Please refer to Table 11
Noise	Yearly for all Monthly for Adult head	Please refer to Table 11	Please refer to Table 11
Uniformity	Yearly	Please refer to Table 11	Please refer to Table 11
Spatial Resolution (High-contrast)	Yearly	According to the accompanying documents	The 10 % MTF and 50 % MTF shall be ± 0.75 lp/cm or ± 15 %, whichever is greater, from the reference values. In addition, the acceptance test criteria must be applied if the test is carried out with CT operating conditions and a test specimen in accordance with the specifications in the accompanying documents.
Automatic Exposure Control (AEC)	1) Not required	1) Not required	1) Not required
Low-contrast	1) Not required	1) Not required	1) Not required

In addition to above given-frequencies, the constancy checks should be repeated if any of the following parameters occur:

- after a major maintenance or update that could affect the performance of the CT-systems.
- due to suspicion of a malfunction.
- if the constancy checks do not match with the predefined baseline values.

Table 11: The tolerances of Mean CT Number/ Noise/ Homogeneity for Acceptance and Constancy test tolerances
 (source: DIN EN IEC 61223-3-5:2024-07[3])

	Mean CT Number		Noise		Uniformity	
	Acceptance test	Constancy test	Acceptance test	Constancy test	Acceptance test	Constancy test
Adult head	nominal value ± 4 HU (w/ small phantom)	reference value ± 5 HU (w/small phantom)	nominal value $\pm \max(15\%; 0.75 \text{ HU})$ (w/small phantom)	reference value $\pm \max(10\%; 0.5 \text{ HU})$ (w/small phantom)	≤ 4 HU (small phantom)	≤ 4 HU (small phantom)
Adult body	nominal value ± 6 HU (w/ large phantom)	reference value ± 7 HU (w/small or large phantom)	nominal value $\pm \max(15\%; 0.75 \text{ HU})$ (w/large phantom)	reference value $\pm \max(10\%; 0.5 \text{ HU})$ (w/small or large phantom)	≤ 8 HU (large phantom)	≤ 4 HU (small phantom) or ≤ 8 HU (large phantom)
Pediatric Head	nominal value ± 4 HU (w/ small phantom)	reference value ± 5 HU (w/small phantom)	nominal value $\pm \max(15\%; 0.75 \text{ HU})$ (w/small phantom)	reference value $\pm \max(10\%; 0.5 \text{ HU})$ (w/small phantom)	≤ 4 HU (small phantom)	≤ 4 HU (small phantom)
Pediatric Body	nominal value ± 4 HU (w/ small phantom)	reference value ± 5 HU (w/small phantom)	nominal value $\pm \max(15\%; 0.75 \text{ HU})$ (w/small phantom)	reference value $\pm \max(10\%; 0.5 \text{ HU})$ (w/small phantom)	≤ 4 HU (small phantom)	≤ 4 HU (small phantom)
Adult body with changes in the X-ray voltage	nominal value ± 6 HU (w/ small or large phantom)	reference value ± 7 HU (w/small or large phantom)	nominal value $\pm \max(15\%; 0.75 \text{ HU})$ (w/small or large phantom)	Not required	≤ 8 HU (small or large phantom)	Not required
Pediatric Body with changes in the X-ray voltage	nominal value ± 6 HU (w/ small phantom)	reference value ± 7 HU (w/small phantom)	nominal value $\pm \max(15\%; 0.75 \text{ HU})$ (w/small phantom)	Not required	≤ 8 HU (small phantom)	Not required

VI. EQUIPMENT FOR DIGITAL VOLUME TOMOGRAPHY ACC.TO DIN 6868-4:2021-03 AND EN IEC 61223-3-8:2024-03

6.1 Test parameters

- Spatial Resolution
- Low-contrast resolution
- Inhomogeneity and artifacts
- Air kerma- area product P_{KA} (Dose-area product)

6.2 Test equipment

- NORMI 3D
- DIAMENTOR RS-KDK

6.3 Test adjustment

6.3.1 Positioned NORMI 3D on the couch or with other supports in the isocenter.

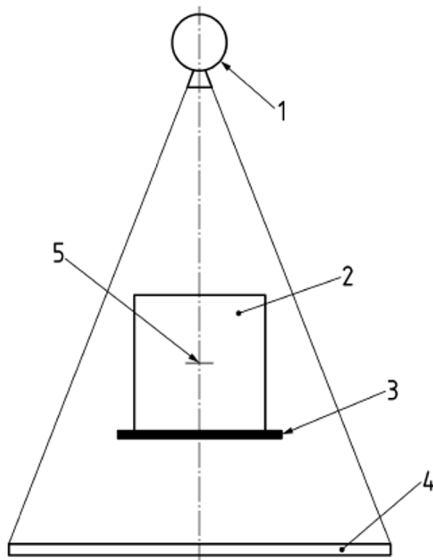
6.3.2 The z-axis of the NORMI 3D shall be aligned parallel to the rotation axis of the system (Picture 27).

6.3.3 For the systems with AEC, it is essential to ensure that the NORMI 3D covers the measuring area for dose control, and that the operational parameters align with the specified reference value.

6.3.4 For this purpose, select the largest available format used for the 3D operating mode.

6.3.5 Scan NORMI 3D at an X-ray tube voltage of $75\text{kV} \pm 7\text{kV}$ without the use of an additional filters when using the automatic exposure function (if available)

Hint: The device settings used here (e.g. dose level, number of projections, exposure geometry) must correspond to the settings used for dose measurement.



Picture 27: NORMI 3D Schematic adjustment | 1. X-Ray Tube, 2. NORMI 3D, 3. Couch or other holder, 4. Image receptor, 5. Axis of rotation

6.4 Test procedure

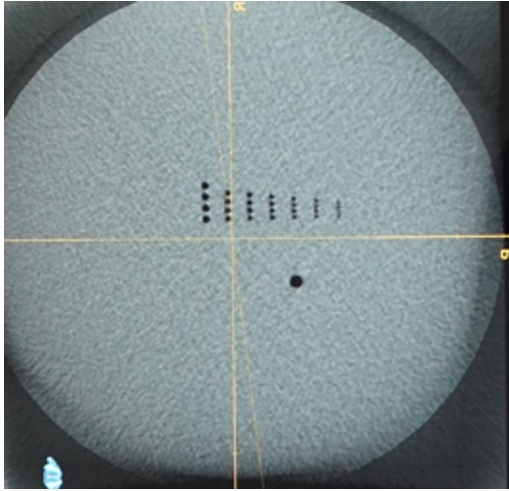
- 6.4.1 Set up the loading factors identical to those used in the initial constancy check.
- 6.4.2 Start the scan.

6.5 Data evaluation

Visually evaluate the image or use the system software as shown (Picture 28)

Document and file the protocol with the results of the constancy check.

Hint: If the system fails to meet the criteria in comparison to the initial state, steps have to be taken to restore the initial state and the baseline values of the X-ray equipment!



Picture 28: NORMI 3D X-Ray Image showing the detailed object

6.5.1 Spatial resolution

Examine the resolution test pattern visible and note the maximum spatial frequencies. Compare the values with the established baseline values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- The number of the visible resolution test pattern has to be a maximum of 1 test pattern less than the baseline values determined in the initial test.

Hint: Determination of baseline values in the initial test – depending on the X-ray installation used, at least the bore hole diameters according to Table 12 have to be visible in the image.

Table 12: Criteria to be applied for the spatial resolution in DVT (source: DIN 6868-150: 2022-01 [6])

Device group ^{a)}	Operation mode	Adjusted format ^{b)}	Visible bore hole diameter
DVT installations in otolaryngology	3D-high contrast mode	< 20 cm	0.6 mm
Fluoroscopic installations ^{d)}	3D-low contrast mode	< 20 cm	0.6 mm
		≥ 20 cm	0.9 mm
	3D-high contrast mode	Irrespective of the format	1.3 mm

a) The classification of the device groups is carried out according to the clinical application and not according to the technical realization or construction.

b) The indicated format refers to the format used during DVD.

c) X-ray installations that are only used in otolaryngology.

d) X-ray installations that are not limited to an application in otolaryngology.

6.5.2 Low-contrast resolution

Count and document the number of different visible low contrast objects.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- The number of low contrast objects visible should not differ from the reference number determined in the initial test.

6.5.3 Inhomogeneity and artifacts

The test image has to be checked for artifacts visually which may influence the diagnosis.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values:

- The X-ray image must be free of any artifacts.

6.5.4 Dose-area product (air kerma-area product P_{KA})

Compare the measured values for air kerma-area product P_{KA} (dose-area product) with the established baseline values.

Criteria to be applied:

The following criteria have to be applied in comparison to the baseline values of air kerma- area product P_{KA} (dose-area product) in μGym^2

- Air kerma- area product P_{KA} (Dose-area product) $\pm 25 \%$

VII. EQUIPMENT FOR QUALITY CONTROL IN CBCT ACC.TO IEC 61223-3-8:2024-3 AAPM TG-179 AND EFOMP-ESTRO-IAEA PROTOCOL*

There are different types of cone beam CT modes for different applications such as interventional radiology, dental applications or radiation therapy (IGRT). At the time of preparation of this document, there is no consensus and no written quality control documents for all these modes, except for the recommendations of EFOMP-ESTRO-IAEA PROTOCOL, IEC 61223-3-8:2024-3, and AAPM TG-179. It should therefore be noted that when performing quality control in CBCT, it is advisable to follow the manufacturer's user manual / recommendations and/or relevant guidelines, if applicable.

7.1 Test parameters

- Uniformity
- Geometric accuracy and linearity
- Voxel density values
- Noise
- Low-contrast resolution
- Spatial resolution
- CTDI Metrics (**)
- Cumulative dose-area product (**)
- Air kerma at the entrance plane of the image receptor (**)
- Cumulative Air kerma (**)

7.2 Test equipment

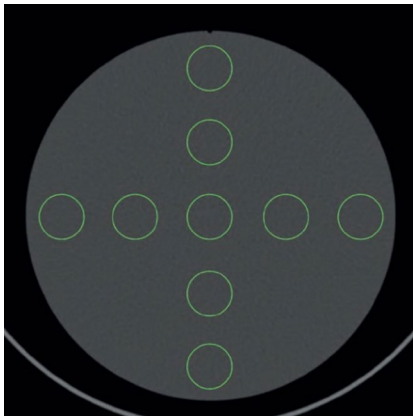
- QRM Cone-Beam Phantom, Basic or Expert
- NOMEX Multimeter
- DIAMENTOR RS-KDK

7.3 Test procedure

Depending on the intended application, either the NORMI RAD/Flu or the QRM Cone-Beam Phantom should be placed. For NORMI RAD/Flu, follow the instructions provided in Section 1.4; for the QRM Cone-Beam Phantom, proceed with the steps outlined below. The corresponding evaluation criteria for each application are defined under the respective test procedures.

7.3.1 Uniformity

- Place the QRM Cone-Beam Phantom on couch and align it centrally at the isocenter.
- Select the maximum available pixel size and tube current. In addition, the most clinically frequently used tube voltage should be selected.
- Acquire an image for 2 mm and 5 mm slice thicknesses.
- Place 5 circular ROI over all images. The diameter of the ROIs must be approximately equivalent to a circular area equal to 20% of the diameter of the QRM Cone-Beam Phantom.
- Ensure that the peripheral ROIs are not placed too close to the phantom edge.
- Evaluate the percentage of difference (maximum deviation) between the greyscale value in the central ROI and the greyscale value in the four outer ROIs.



Picture 29: QRM Cone-Beam Phantom X-ray image -homogeneity analysis by placing ROIs

Criteria to be applied:

The following criteria has to be applied:

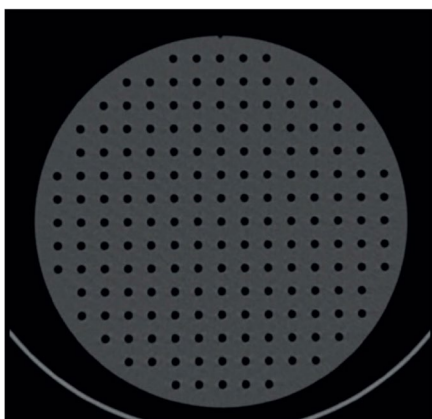
- For IGRT: The deviation should not exceed ± 10 HU
- For interventional radiology: <10 % (air / water-equivalent material differences), or follow the manufacturer's guidelines

Hint: Annual check is sufficient for dental and interventional radiology. Monthly checks are recommended for IGRT.

7.3.2 Geometric accuracy and linearity

The purpose of this test is to check the geometrical accuracy, linearity, and spatial stability (for IGRT) of the CBCT systems.

- Place the QRM Cone-Beam Phantom on couch and align it centrally at the isocenter.
- Use thin slices (approx. 1 mm thickness) and suitable reconstruction kernel, e.g. a regularly/frequently used scan protocol and high-resolution kernel.
- Measure the dimensions of the holes at each position using a ruler or equivalent tool of your DICOM Viewer to determine a distortion of the hole matrix. An overestimation of hole size depends on scanner settings and beam hardening in the image. The holes may appear larger than they are. Measure the positions of the holes within the regular hole grid to uncover a distortion of the hole matrix in the periphery.



Picture 30: QRM Cone-Beam Phantom X-ray image - geometric accuracy analysis

Hint:

- Monthly checks are recommended for IGRT, but daily checks for spatial stability may be necessary to avoid errors that may occur between the treatment and imaging isocenters for CBCTs. For interventional radiography and dental, annual tests are sufficient unless no upgrade or important maintenance has occurred.

Criteria to be applied:

The following criteria has to be applied:

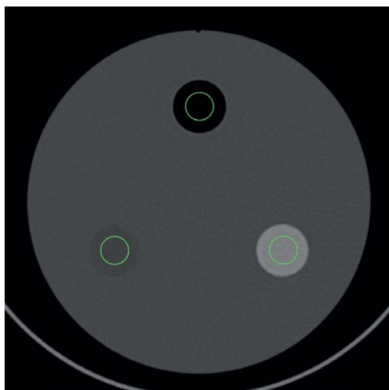
- For IGRT: >2 mm for conventional treatments,
>1 mm for SBRT and SRS,
- For interventional radiology: >2 mm
- For dental applications: >1 mm

7.3.3 Voxel density values

- Place the QRM Cone-Beam Phantom on couch and align it centrally at the isocenter.
- Ensure that the phantom is positioned in precisely the same manner during the constancy checks.
- Draw circular ROIs of appropriate size and place them in the scaling inserts
- ROI measurements are carried out using the exact same axial slices that were used to determine the baseline values.
- Read out mean CT values within the ROIs and compare them to data acquired in prior quality assurance checks/measurements.

$$CT\ Value = \left(\frac{\mu_{material} - \mu_{water}}{\mu_{water}} \right) \times 1000$$

μ = CT linear attenuation coefficient



Picture 31: QRM Cone-Beam Phantom X-ray image - voxel density value analysis

Criteria to be applied:

The following criteria have to be applied:

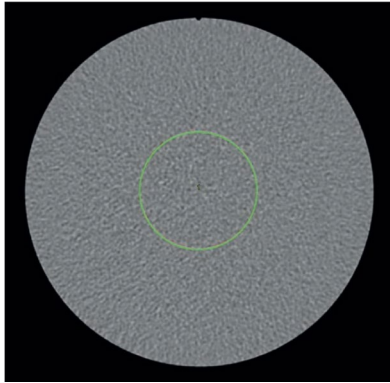
- For IGRT and interventional radiology: > 50 HU
- For dental applications: > 25 HU (air-/ water equivalent material differences)
or follow the manufacturer's guidelines.

Hint: Annually check is sufficient for dental and interventional radiology. Monthly checks are recommended for IGRT. It should be note that this test should be performed after any major maintenance including software upgrades.

7.3.4 Noise

- Place the QRM Cone-Beam Phantom on couch and align the homogeneous section centrally at the isocenter.
- Scan the phantom with the axial scan protocol for which the noise should be evaluated using a slice thickness of at least 2 mm.
- Draw a circular ROI of sufficient size (e.g. 30 % of the phantom diameter) in the center of the phantom and examine the mean CT value and the noise level (standard deviation of CT values within the ROI).

Hint: It is advisable to measure noise in several consecutive axial slices. Should the difference between consecutive slices be less than 20%, it is sufficient to check the noise during constancy checks in a single slice.



Picture 32: QRM Cone-Beam Phantom X-ray image - noise analysis

Criteria to be applied:

The following criteria has to be applied in comparison to the baseline value:

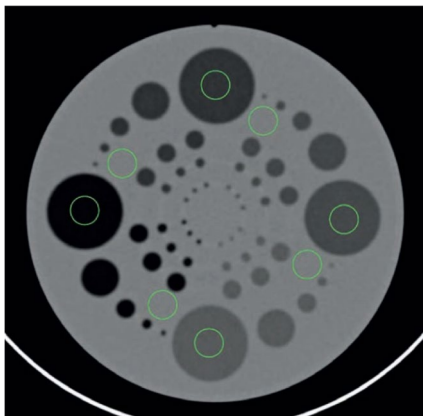
- For IGRT, interventional radiology and dental: > 20 %

Hint: Annual check for dental, interventional radiology and monthly check for IGRT.

7.3.5 Low-contrast resolution

- Place the QRM Cone-Beam Phantom on couch and align the homogeneous section centrally at the isocenter.
- Use only the largest inserts for the assessment of the CNRs (seen as circles/disks). Smaller inserts should only be evaluated according to their visibility.
- Draw circular ROIs of appropriate size and place them within the large inserts.
- For reference, place similar ROIs in the proximity of the inserts, but at some distance from the phantom edge.
- Read out mean CT values within the ROIs and the signal noise (standard deviation of the fluctuating CT values) of the background and calculate the CNR.

$$CNR = \left| \frac{CT^{\#}_{contrast\ insert} - CT^{\#}_{bg}}{\sigma_{bg}} \right|$$



Picture 33: QRM Cone-Beam Phantom contrast resolution analysis

Criteria to be applied:

The following criteria has to be applied in comparison to the baseline value:

- For IGRT, interventional radiology and dental: > 40 %

Hint: Annually check for dental, interventional radiology and monthly check for IGRT.

7.3.6 Spatial resolution

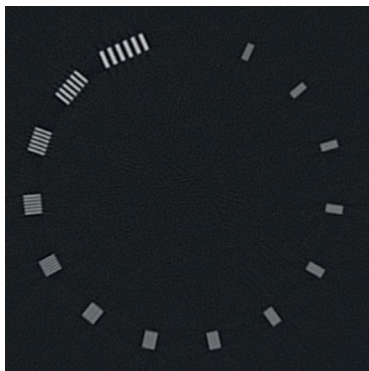
As it is affected by the performance of the image receptor and the focal size, it should be checked regularly. There are two different methods for evaluating spatial resolution.

Subjective method: (Visual spatial resolution evaluation)

- Position the QRM Cone-Beam Phantom on the gantry and ensure that the phantom is aligned parallel to the z-axis of the system
- Ensure that the phantom is positioned in precisely the same manner during the constancy checks.
- Prefer high kV and mA values to limit the noise at minimum
- Use thin slices (approx. 1 mm slice thickness) and a suitable kernel, e.g. 'standard' for regular scan protocols and 'hi-res' for high-resolution scan protocols.
- Several line patterns shall be seen with distinguishable bright bars and dark spacing between the bars. Read out the corresponding spatial resolution (in lp/cm) of the smallest resolvable structure from the phantom datasheet.
- The smallest visible pattern determines the highest in-plane spatial resolution.

Example:

30 lp/cm corresponds to ≈ 0.016 cm



Picture 34: QRM Cone-Beam Phantom spatial resolution analysis

A quantitative objective method

It should be described by the MTF (Modulation Transfer Function), which is obtained from the Fourier transformation of the line spread function (LSF), point spread function (PSF) or edge spread function (ESF).

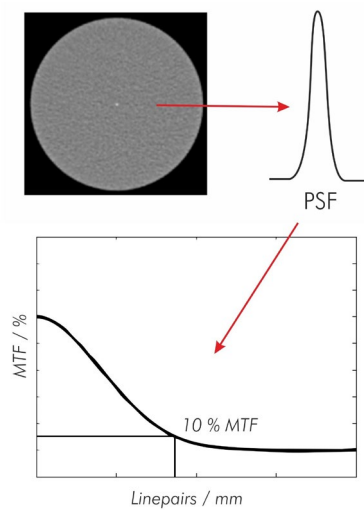
- Position the appropriate QRM Phantom (QRM Cone-Beam Phantom or QRM Wire Phantom) on the gantry and ensure that the phantom is aligned parallel to the z-axis of the system
- Ensure that the phantom is positioned in precisely the same manner during the constancy checks.
- Prefer high kV and mA values to limit the noise at minimum
- Check MTF for two different protocols such as 'standard' for regular scan protocols and 'hi-res' for high-resolution scan protocols. Use thin slices (approx. 1 mm slice thickness), a suitable kernel, FOV and maximum number of projection view e.g.
- Select the FOV small enough for high-resolution protocols not to limit the scan to pixel values
- Measure the F50 (50%) and F10 (10%) MTF values

Criteria to be applied: (%10 MTF)

The following criteria have to be applied in comparison to the baseline values

- For dental and interventional radiology: < 10 lp/cm (high res mode)
- For IGRT: < 5 lp/cm

Hint: Annual check for dental, interventional radiology and IGRT.



Picture 35: QRM Wire Phantom MTF analysis

7.3.7 CTDI Metrics

Suitable CT Phantoms (Adult body or head, or Pediatric body or head) should be used for the measurement as explained at the section 5.5. $CTDI_w$ ($CBDI_w$) can be calculated by using the following formulas.

$$CTDI_{100} = \int_{-50 \text{ mm}}^{+50 \text{ mm}} \frac{D(z)}{N * T} dz$$

$$CTDI_w = \frac{1}{3} CTDI_{100(\text{centre})} + \frac{2}{3} CTDI_{100(\text{peripheral})}$$

Criteria to be applied:

- Manufacturer's guidelines must be followed.

7.3.8 Cumulative dose-area product

It could be measured directly during rotational mode by DIAMENTOR either in free-air or with a phantom set-up. The outcome is not a direct indication of reference air kerma. Therefore, the manufacturer's guidelines must be followed for the assessment criteria, the acceptable tolerance values and, if applicable, the test setup.

7.3.9 Air kerma at the entrance plane of the X-ray image receptor

It could be measured during rotational mode by NOMEX Multimeter. If the AEC is available on the system, the NOMEX Multimeter should be placed outside the sensitive area of image intensifier. The outcome is not a direct indication of reference air kerma. Therefore, the manufacturer's guidelines must be followed for the assessment criteria, the acceptable tolerance values and, if applicable, the test setup.

7.3.10 Cumulative air kerma

It could be measured during rotational mode with a dosimeter attached to the X-ray tube. If the AEC is available on the system, the phantom specified by the manufacturer should be used for this assessment. The manufacturer's guidelines must be followed for the assessment criteria, the acceptable tolerance values and, if applicable, the test setup.

Hint: The procedures described in sections 7.3.7, 7.3.8, 7.3.9, and 7.3.10 of this CoP have been prepared in accordance with IEC 61223-3-8:2024-3 and EFOMP-ESTRO-IAEA, and it is stated that it is not mandatory to perform all of these tests for quality control purposes. It is advisable to follow the manufacturer's user manual/recommendations and/or relevant guidelines, if applicable.

Table 13: Scope and frequency of quality controls in CBCT (source: EFOMP-ESTRO-ASTRO Protocol[9])

SCOPE OF QUALITY CONTROLS	FREQUENCY OF CONSTANCY TEST
Uniformity	Yearly
Geometric accuracy and linearity	Yearly (monthly for IGRT)
Voxel density values	Yearly
Noise	Yearly
Low-contrast resolution	Yearly
Spatial resolution	Yearly
Cumulative dose-area product	Yearly
CTDI Metrics	Yearly
Air kerma at the entrance plane of the X-ray image receptor	Yearly
Cumulative air kerma	Yearly

Hint: Even though the frequencies are defined annually in these reports, strict general test frequencies and action levels may be required for some specific CBCT techniques such as IGRT (Image-guided Radiotherapy) which have a direct impact on the patient treatment. Please refer to the relevant standards.

Table 14: Tolerances and frequencies for IGRT (source: APPM TG-179 [8])

Geometric Accuracy	± 1 mm	monthly
Uniformity	Baseline	monthly
High contrast spatial resolution	≤ 2 mm (or 5 lp/cm)	monthly
Low contrast detectability	Baseline	monthly
CT number accuracy and stability	Baseline	monthly
Imaging dose	Baseline	annually
X-ray generator performance (kV systems only): tube potential, mA, ms accuracy, and linearity	Baseline	annually

Table 15: Example of Quality Control Report (source: EFOMP-ESTRO-IAEA protocol [9])

USER DATA		PHANTOM DATA					
Name:		Manufacturer:					
Facility:		Model:					
Telephone number/email:		S/N:					
DEVICE DATA		GEOMETRIC DATA					
Type:		Distance from the focal spot to the isocentre:					
Manufacturer:		Distance from the detector to the focal spot:					
Model:		Horizontal diameter of scanned volume:					
S/N:		Horizontal diameter of radiation field at the detector:					
Effective area of the detector:							
SCAN DATA		ANALYSIS SOFTWARE DATA					
Maximum scan time:		Name:					
kVp/mAs:		Manufacturer:					
Mode:		Website:					
Conventional tests							
Section	Parameter	Pass/Fail					
2	Radiation output: tube potential, leakage, filtration, repeatability, reproducibility						
2	Beam collimation						
2	Image display (monitor)						
2	Artefacts						
2	Operator protection (report from radiation protection expert is provided)						
Image quality tests							
Parameter	Result	Baseline	Dif. from baseline	Action level	Pass/Fail		
Uniformity (DIN procedure)							
Geometrical evaluation [mm]							
Voxel density values [HU]							
Noise [HU]							
CNR							
Acceptance indicator							
Frequency at 10% MTF [lp/mm]							
Frequency at 10% MTFz [lp/mm]							
Tests of radiation output							
Parameter	M1	M2	M3	Result	Max Dev	Action level	Pass/Fail
Air kerma at the detector [mGy]							
Dose to the field of view [mGy]							

Date and Signature:

VIII. QRM Phantoms

In order to find out the detailed specifications of the available phantoms including the specific Code of Practice, please visit our website qrm.de

Image Quality Phantoms	Phantoms for estimating image quality in X-ray imaging are manufactured with the highest precision. Different types of IQ phantoms are available to test spatial resolution, high contrast, low contrast, geometrical setups, and other IQ criteria. These phantoms are based on soft tissue-, bone- and water-equivalent materials, solid resins or PMMA.	• Multi-Energy QA Phantom • Dual Energy CT Phantoms, • Spectral CT Phantom • Breast CT QA Phantom • Cone-Beam Phantoms • Low Contrast Phantoms • Medium Contrast Phantom • Spatial Resolution Phantom • Slice Sensitivity Phantom • Wire Phantom • Beam Stop Phantom • Dental CBCT QA Phantom Basic • Water Tank Phantom • Calcium Scoring Phantom • Coronary Artery Stenosis Phantoms • High Contrast Resolution Phantom, D100 • MAM Phantoms
Anthropomorphic Phantoms	All semi-anthropomorphic phantoms for X-ray imaging purposes and associated procedures are manufactured with the highest precision. These phantoms simulate the human body as thorax, abdomen, head, or other body parts under X-ray attenuation. The shape of the phantoms is geometrically optimized and based on soft tissue, bone and water equivalent materials, solid resins or PMMA.	• Thorax Phantom • Abdomen Phantom • Oval Body Phantom • Extension Rings • Liver Nodule Phantom • Pediatric Thorax & Abdomen Phantoms • Cranial CT Phantom • Lung Nodule Phantom • D100 Insert Phantoms
Dosimetry Phantoms	High precision phantoms for dosimetry purposes in X-ray imaging. Different types of dosimetry phantoms are available to measure dose in accordance with national and international CT standards. These phantoms are made of tissue- or water-equivalent materials or solid resins.	• CTDI CTWater Phantom • Thorax & Abdomen Dosimetry Phantoms • Pediatric Thorax & Abdomen Phantoms • Extension Rings
Bone Densitometry Phantoms	Whether in clinical routine or in osteoporosis research, the BMD phantoms are the first choice to determinate bone density or perform quality assurance in CT and DXA. All BMD phantoms are made with Ca-hydroxy-apatite, the material of the highest interest in bone mineral densitometry. The phantoms are calibrated, analyzed, and tested according to the highest BMD standards.	• European Spine Phantom • European Forearm Phantom • Bone Density Calibration Phantoms • Forearm Phantom • DXA Spine QA Phantom, • HIP Calibration Phantom • DXA Femur Phantom • JIS Forearm Phantom • JIS Heel Phantom

Bibliography

[1] DIN 6868-4:2021-03	Image quality assurance in diagnostic X-ray departments - Part 4: Constancy checking of medical X-ray equipment for projection radiography with digital image receptor systems and fluoroscopy
[2] DIN 6868-14:2022-01	Image quality assurance in diagnostic X-ray departments - Part 14: Constancy checking of X-ray installations for digital mammography
[3] DIN EN IEC 61223-3-5:2024-07	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests and constancy checks - Imaging performance of computed tomography X-ray equipment (IEC 61223-3-5:2019 + Cor. 1:2022); German version EN IEC 61223-3-5:2019 + AC:2022
[4] DIN 6868-13:2012-03	Image quality assurance in diagnostic X-ray departments - Part 13: R _ö V constancy check of projection radiography systems with digital image receptors
[5] DIN EN IEC 61223-3-8:2024-03	Evaluation and routine testing in medical imaging departments – Part 3-8: Acceptance and constancy checks – Imaging performance of X-ray equipment for radiography and radioscopy
[6] DIN 6868-150:2022-01	Image quality assurance in diagnostic X-ray departments - Part 150: Acceptance test of medical radiographic and fluoroscopic X-ray equipment
[7] DIN 6868-162:2022-01	Image quality assurance in diagnostic X-ray departments - Part 162: Acceptance test of digital mammography installations
[8] AAPM TG-179	Quality assurance for image-guided radiation therapy utilizing CT-based technologies: A report of the AAPM TG-179
[9] EFOMP-ESTRO-IAEA PROTOCOL	Quality control in cone-beam computed tomography (CBCT)
[10] EFOMP PROTOCOL	Quality control of dynamic x-ray imaging systems version 01.2024

List of Abbreviations

Al	Aluminium
AEC	Automatic exposure control
CT	Computer tomography
CTDI	Computed tomography dose index
Cu	Copper
DIN	Deutsches Institut für Normung corresponds to "German institute for standardization"
DSA	Digital subtraction angiography
EN	Europäische Norm corresponds to "European standard"
FAQ	Frequently asked questions
HK	High contrast
IEC	International Electrotechnical Commission
KRV	Contrast-to-noise ratio
kV	Kilo Volt
Lp/mm	Line pairs per mm
mA	Milli ampere
mAs	Milli ampere per second
MAM	Mammography
mGy; nGy	Milli; nano gray
Mo	Molybdenum
Rh	Rhodium
W	Tungsten
Ag	Silver
Al	Aluminum
PMMA	Polymethylmethacrylat
PTW	Physikalisch-Technische Werkstätten Dr. Pchlau GmbH
QRM	Quality Assurance in Radiology and Medicine
QA	Quality Assurance
ROI	Region of interest
s	Second
SRV	Signal-to noise ratio

Ordering Information

Ordering information	Product	Scope of delivery
L981301	NORMI RAD/FLU Set PMMA, (300 x 300) mm	test object for analogue and digital fluoroscopic X-ray installations, size (300 x 300) mm. Includes a 1 mm copper absorber, a 30 mm PMMA absorber, 4x 35 cm long distance supports for use with under-couch tubes and a carrying case
L981302	NORMI RAD/FLU Set Al, (300 x 300) mm	test object for analogue and digital fluoroscopic X-ray installations, size (300 x 300) mm. Includes a 25 mm thick aluminum absorber for fixation next to the focus, a fluoroscopic measuring stand and a carrying case
L981309	NORMI RAD/FLU Set Al, (200 x 200) mm	test object for analogue and digital fluoroscopic X-ray installations, size (200 x 200) mm. Includes a 25 mm thick aluminum absorber for fixation next to the focus, a fluoroscopic measuring stand and a carrying case
L981473	NORMI holder for bucky wall stand	for fixation of the test object NORMI 13 or NORMI RAD/FLU on a bucky wall stand. Includes bucky mounting device T20005 and accessory T20018
L981247	NORMI 13 Set PMMA	set for quality control of digital X-ray installations acc. DIN 6868 part 13, version 2012. Includes structure plate, PMMA absorber, bucky mounting device, Velcro tape and a carrying case
L981246	NORMI 13 Set Al	set for quality control of X-ray installations acc. DIN 6868-13, version 2012. Includes a structure plate, bucky mounting device, an Al absorber (to be fixed directly to the collimator), velcro tape and a carrying case
T42003	X-Check DSA Test Object	test object for constancy and acceptance tests on DSA installations according to IEC 61223-3-3 and DIN 6868-4 / -150. Includes pneumatic control and carrying case
T42003.1.006	X-Check DSA frame	for use with under-couch tubes, (300 x 300) mm frame with four 260 mm long distance supports
T42038	NORMI 3D DVT Test Object	test object for quality control and acceptance tests of digital volume tomography X-ray units acc. to DIN 6868-150. Includes cylindrical cavities (each 4x with 1.3/1/0.9/0.8/0.7/0.6/0.5 mm) for testing the spatial resolution
T40016	CT body phantom	15 cm long acrylic cylinder, 32 cm in diameter. Features hole in the center and four holes off-center for accommodation of CT ionization chamber 30009. Includes 4 blind plugs. For dose measurements in accordance with IEC 61223-2-6
T40017	CT head phantom	15 cm long acrylic cylinder, 16 cm in diameter. Features hole in the center and four holes off-center for accommodation of CT ionization chamber 30009. Includes 4 blind plugs. For dose measurements in accordance with IEC 61223-2-6
T40027	CT head & body phantom	two 15 cm long acrylic cylinders, 16 and 32 cm in diameter. The big cylinder can accommodate the small one. Both cylinders feature four holes off-center and one central hole for CT chamber 30009. For dose measurements in accordance with IEC 61223-2-6
T40073	Pediatric CT Head Phantom	15 cm long acrylic cylinder, 10 cm in diameter. Features hole in the centre and four holes off-centre for accommodation of CT ionization chamber 30009. Includes 4 blind plugs. For dose measurements in accordance with DIN EN IEC 61223-3-5:2024-07
Tx30009	CT ion chamber 3.14 cm ³ , 100 mm long	cylindrical ion chamber for dose-length product (DLP) measurements in CT. Length of measuring volume 100 mm, cable length 2.5 m, connecting system Lemo

Tx30017	CT ion chamber 9.3 cm ³ , 300 mm long	cylindrical ionization chamber with 9.3 cm ³ for dose-length product measurements in CT. Length of measuring volume 300 mm, cable length 2.5 m, connecting system BNT. CT chamber holder [T77336/U20] optional available
T42040	NORMI MAM digital 14 / 162	for constancy and acceptance tests of digital mammography modalities acc. to DIN 6868-14 and -162. Incl. basic plate with Al step, structure plate, test elements, absorbers, and a transport case
L981611	NOMEX Multimeter R/F	for radiography and fluoroscopy (R/F). Incl. NOMEX Multimeter, NOMEX Software, 2 m USB cable, 5 m active extension cable and a transport case/box. Requires connection to a PC
L981613	NOMEX Multimeter MAM	for mammography. Incl. NOMEX Multimeter, NOMEX Software, 2 m USB cable, 5 m active extension cable and a transport case/box. Requires connection to a PC
L981617	NOMEX Multimeter CT	for computed tomography. Incl. NOMEX Multimeter, NOMEX Software, 2 m USB cable, 5 m active extension cable and a transport case/box. Requires connection to a PC
L981415	Set DIAMENTOR RS-KDK, wireless	incl. DIAMENTOR RS-KDK, BT interface, RS connector box, network cables 3 m, 2 m and a power supply cable, 3m. Requires connection to a power supply (12...32) VDC, 60601-1 compliant, max. 15 W
L981629	UNIDOS Tango Electrometer with M connector	UNIDOS Tango reference class electrometer for dose meas. in radiation therapy, diagnostic radiology and brachytherapy with WLAN module and 2D code scanner. Set consists of power cable, network cable, inclined stand.
L981630	UNIDOS Tango Electrometer with BNT connector	UNIDOS Tango reference class electrometer for dose meas. in radiation therapy, diagnostic radiology and brachytherapy with WLAN module and 2D code scanner. Set consists of power cable, network cable, inclined stand. Connecting system BNT
L981631	UNIDOS Tango Electrometer with TNC connector	UNIDOS Tango reference class electrometer for dose meas. in radiation therapy, diagnostic radiology and brachytherapy with WLAN module and 2D code scanner. Set consists of power cable, network cable, inclined stand. Connecting system TNC
QRM-10120	Cone-Beam Phantom, Basic	for testing the imaging performance in diagnostic CT and Cone-Beam CT. Contains 8 sections including advanced low contrast resolution test section. Transport case and protocol included
QRM-10103	Cone-Beam Phantom, Expert	for testing the imaging performance in diagnostic CT and Cone-Beam CT. Contains 9 sections including advanced low contrast resolution test sections. Transport case and protocol included
QRM-10105	Wire Phantom, D100	evaluation of PSF (Point Spread Function) & MTF (Modulation Transfer Function). Diameter 100 mm. Wire 50 micron embedded in soft tissue-equiv. material. Ideal in combination with Thorax/Abdomen Phantom. D100 compatible. Delivered in a plastic rotary pack
QRM-10138	Wire Phantom, air	stand-alone wire phantom (diameter 45 mm) to evaluate PSF (Point Spread Function) & MTF (Modulation Transfer Function). 50 micron wire mounted in plastic housing (surrounded by air). Delivered in a plastic rotary pack

ACCEPTANCE TEST TOLERANCES for lp/cm resolution, low-contrast resolution, and dynamic range (source: DIN 6868-150:2022-01[6])

Table 16.1: Limit values for line pair resolution – equipment with image intensifier television chain as image receptor

Operation mode	Limit values for line pair resolution			
	Reference format 25 cm	Format 30 cm	Format 36 cm	Format 38 cm
Fluoroscopy				
D1: Normal mode ^{a)}	1.0 mm ⁻¹	0.8 mm ⁻¹	0.7 mm ⁻¹	0.7 mm ⁻¹
Exposure (series technology)				
S1: Cine ^{b)}	1.0 mm ⁻¹	0.8 mm ⁻¹	0.7 mm ⁻¹	0.7 mm ⁻¹
S2: Image series ^{c)} (rate ≤ 10 images/s)	1.2 mm ⁻¹	1.0 mm ⁻¹	0.8 mm ⁻¹	0.8 mm ⁻¹
S3: DSA ^{d)}	1.2 mm ⁻¹	1.0 mm ⁻¹	0.8 mm ⁻¹	0.8 mm ⁻¹

a) Test in normal mode is sufficient

b) Cine mode is normally used in coronary angiography for the documentation of rapid dynamic sequences.

c) In the image series mode (formerly image intensifier radiography), single images can be taken if necessary. The requirements for the image quality, however, are less stringent than for the single image mode.

d) The limit values are valid for the unsubtracted representation. If approved by the manufacturer, the limit values of the image series mode can be applied.

Table 16.2: Limit values for line pair resolution – equipment with flat panel detector as image receptor

Operation mode	Limit value reference format 25 cm	Limit value formats
Fluoroscopy		
D1: Normal mode ^{a)}	1.0 mm ⁻¹	1.0 mm ⁻¹
Exposure (series technology)		
S1: Cine ^{b)}	1.0 mm ⁻¹	1.0 mm ⁻¹
S2: Image series ^{c)} (rate ≤ 10 images/s)	1.2 mm ⁻¹	1.2 mm ⁻¹
S3: DSA ^{d)}	1.2 mm ⁻¹	1.2 mm ⁻¹

a) Test in normal mode is sufficient

b) Cine mode is normally used in coronary angiography for the documentation of rapid dynamic sequences.

c) In the image series mode (formerly image intensifier radiography), single images can be taken if necessary. The requirements for the image quality, however, are less stringent than for the single image mode.

d) The limit values are valid for the unsubtracted representation. If approved by the manufacturer, the limit values of the image series mode can be applied.

Table 16.3: Limit values for line pair resolution – single image

Operation mode	Dose level ^{a), d)} μGy	Limit value formats ^{d)} mm ⁻¹
Single image		
E1: Digital Radiography ^{a)}	≤ 10	2.8
	≤ 5.0	2.4
E2: Film-screen systems ^{b)}	10	3.4
	5.0	2.8
	2.5	2.4
	1.25	2.0

a) The limit values in the digital radiography mode do not depend on the format.

b) The requirements were adopted from DIN 6868-50.1990-06: higher dose levels with KS > 10 μGy are not included because they are not widely used.

c) In the context of digital radiography, the dose level refers to the image receptor dose KB, in the context of film-screen systems, to the required dose KS as indicated by the manufacturer.

d) Intermediate values for the required dose can be determined from K_s=1000 μGy / S and intermediate values for the line pair resolution limits can be determined by interpolation.

Table 16.4: Limit values for low-contrast resolution and dynamic range – equipment with image intensifier television chain as image receptor

Operation mode	Set format ^{a)}	Number of steps	Number of details
Fluoroscopy			
D1: Normal mode	25 cm	12	3
D2: High-level mode		12	4
Exposure (series technology)			
S1: Cine	25 cm	12	5
S2: Image series (rate ≤ 10 images/s)		12	5

a) Diameter covering the dynamic steps as completely as possible

Table 16.5: Limit values for low-contrast resolution and dynamic range – equipment with flat panel detector as image receptor

Operation mode	Set format ^{a)}	Number of steps	Number of details
Fluoroscopy			
D1: Normal mode	30 cm x 30 cm	14	3
D2: High-level mode		14	4
Exposure (series technology)			
S1: Cine	30 cm x 30 cm	14	5
S2: Image series (rate ≤ 10 images/s)		14	5

a) Format (height x width) covering the dynamic steps as completely as possible

Table 16.6: Limit values for low-contrast resolution and dynamic range – equipment with flat panel detector as image receptor

Operation mode	Set format ^{a)}	Number of steps	Number of details
Single image			
E1: Digital Radiography ^{a)}	30 cm x 30 cm	16	5
E2: Film-screen systems ^{b)}	No test ^{c)}		

a) Format (height x width) covering the dynamic steps as completely as possible

b) The test method described here deviates from the former method according to DIN V 6868-58:2001-01 because it uses a different test object design. However, the requirements for low-contrast resolution and dynamic range are equivalent.

c) The test cannot be used with film-screen systems.

PROTOCOLS (SOURCE: DIN 6868-4:2021-03[1])

Table 17.1: Test report sample for the digital radiography operating mode

Table 17.1.a: Determining the reference value

Test Report							
Digital Projection Radiography							
Determination of the reference values for the constancy test according to DIN 6868-4							
Operator/Customer				Customer No			
Street				Equipment No			
Location				Room			
WORKPLACE/APPLICATION DEVICE							
Manufacturer							
Name			Serial No				
Source type			Serial No				
IMAGE PROCESSING (Digital system)							
Manufacturer			Installation location				
Name			Serial No				
TEST CONDITIONS							
Test specimen (type/no.)			Serial No				
Dosimeter (type/no.)			Serial No				
Attenuation body			Dose measurement unit				
Tools			Additional filter				
Image detector format			Field size light				
APPLICATION DEVICE, Adjustment Values							
Name AWG:							
Distance focus-PK (cm)			Distance focus-BE (cm)				
Anti-scatter grid			f _o (cm)				
Orientation of test specimen							
Special features							
GENERATOR, Adjustment Values			Reference values			Tolerances	
						from	to
Automatic Exposure			Dose		25%		
			Char. Pixel value P9			$\Delta P = \left \frac{P_8 - P_{10}}{2} \right $	
Voltage [kV]			Pixel value P8				
Focal Spot			Pixel value P10				
Dose Level			Dose Indicator		25%		
Measuring field			High contrast levels			– 1 level	
Exposure level			Low contrast levels			– 1 level	
mAs			Resolution		Lp/mm	– 1 group	
mA, ms			Faults			None	
Reading — Mode			Dose-area product		25%		
Free exposure			Dose		25%		

Digital Projection Radiography

Determination of the reference values for the constancy test according to DIN 6868-4						
Free exposure		Dose		25 %		
		Char. Pixel value P9			$\Delta P = \left \frac{P_8 - P_{10}}{2} \right $	
Voltage [kV]		Pixel value P8				
Focal Spot		Pixel value P10				
mAs		Dose Indikator		25 %		
mA, ms		High contrast levels			– 1 level	
Reading — Mode		Low contrast levels			– 1 level	
		Resolution		Lp/mm	– 1 group	
		Faults			None	
		Dose-area product		25 %		
Matching of visible and effective beam field		Deviation a + b		SKT	max. 2	
		Deviation c + d		SKT	max. 2	
		1 SKT = 1 cm in object plane				
Remark:						
Name of the examiner:						
Signature:				Date:		

Table 17.1.b: Updating the constancy check

Operator:				Measurements for Constancy Testing Digital Radiography (DIN 6868-4)																									
Room:				Date:																									
Device		Reference value	Tolerance		Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.			
			from	to																									
kV	Dose																												
Auto- matic expo- sure	Char. pixel value P9																												
	Dose indicator																												
	High contrast levels		– 1 level																										
	Low contrast levels		– 1 level																										
	Resolution (Lp/mm)		– 1 group																										
	Artefacts		None																										
	Dose-area product																												
kV	Dose																												
Free expo- sure	Char. pixel value P9																												
	Dose indicator																												
	High contrast levels		– 1 level																										
	Low contrast levels		– 1 level																										
	Resolution (Lp/mm)		– 1 group																										
	Artefacts		None																										
	Dose-area product																												
Distance focus-BE (cm)																													
Matching of visible and useful beam fields:																													
Deviation a + b (right + left)			max. 2																										
Deviation c + d (above + below)			max. 2																										
OK (tolerances met)?					Yes / No																								
Name sign:																													
Remarks:																													

For setting data, see reference value definition

Table 17.2 Test report sample for the fluoroscopy, cine, continuous and DSA/Subtraction function

Table 17.2.a: Determining the reference value

Test Report							
Fluoroscopy Technology							
Determination of the reference values for the constancy test according to DIN 6868-4							
Operator/Customer				Customer No			
Street				Equipment No			
Location				Room			
WORKPLACE/APPLICATION DEVICE							
Manufacturer							
Name		Serial No					
Source type		Serial No					
Anti-scatter grid		f ₀ (cm)					
IMAGE PROCESSING (Digital system)							
Manufacturer		Installation location					
Name		Serial No					
TEST CONDITIONS							
Test specimen (type/no.)		Serial No					
Dosimeter (type/no.)		Serial No					
Attenuation body		Dose measurement unit					
Tools		Additional filter					
APPLICATION DEVICE, Adjustment Values							
Distance focus-PK (cm)		Distance focus-BE (cm)					
Orientation of test specimen							
Special features							
Fluoroscopy parameters							
Program name		Verified reference formats					
DL mode		Image processing					
DL Level		Contrast evaluation					
		Place of assessment					
System, setting values		Reference values				Tolerances	
REFERENCE FORMAT (1)		cm	Dose		25%		
Programm			Dynamic levels			– 1 level	
DL mode			Low contrast levels			– 1 level	
Measuring time for dose		s	Resolution		Lp/mm	– 1 group	
			Radiation field size				
Voltage		kV	right — left X		SKT	– 1	1
Current		mA	top — bottom Y		SKT	– 1	1
			Faults			like reference	
			Dose-area product		15 %		

Fluoroscopy Technology

Determination of the reference values for the constancy test according to DIN 6868-4							
Optional Format (2)		cm	Dose		25 %		
Program			Dynamic levels			– 1 level	
DL mode			Low contrast levels			– 1 level	
Measuring time for dose		s	Resolution		Lp/mm	– 1 group	
			Radiation field size				
Voltage		kV	right — left X		SKT	– 1	1
Current		mA	top — bottom Y		SKT	– 1	1
			Faults			like reference	
			Dose-area product		15 %		
Remark:				Note: 1 SKT = 1 cm in test specimen plane			
Name of the Examiner:					Date:		
Signature:							

Table 17.2.b: Updating the constancy check

Operator:				Measurements for Constancy Testing Digital Radiography (DIN 6868-4)																							
Room:																											
Date:		Equi.-No:																									
Device:		Reference value	Tolerance		Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	Meas. value	ok.	
			from	to																							
Format (1) cm	Dose 1 ()																										
	Dynamic levels																										
	Low control levels																										
	Resolution (Lp/mm)																										
	Radiation field X (SKT.)																										
	Radiation field Y (SKT.)																										
	Voltage (kV)																										
	Current (mA)																										
DFP ()																											
Format (2) cm	Dose 1 ()																										
	Dynamic levels																										
	Low control levels																										
	Resolution (Lp/mm)																										
	Radiation field X (SKT.)																										
	Radiation field Y (SKT.)																										
	Voltage (kV)																										
	Current (mA)																										
DFP ()																											
Defects — testing for all formats			Yes / No																								
Tolerances maintained?			Yes / No																								
Name sign:																											
Remarks:				Note: 1 SKT = 1 cm in test specimen plane										For setting data, see reference value specification													