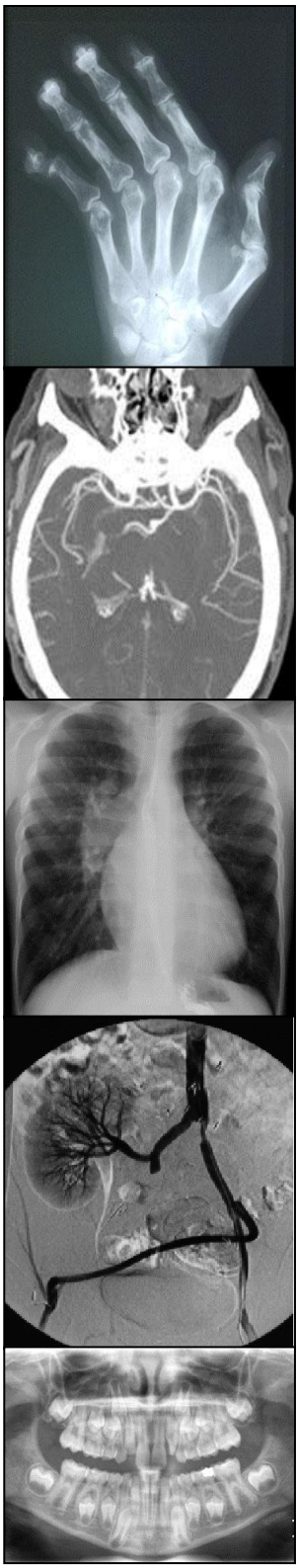
Belgian Protocol for Annual Quality control of X-Ray Equipment : Fluoroscopic Devices



Belgian Hospital Physicist Association

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Contents

1. Introduction

This protocol addresses fluoroscopy systems as used in diagnostic and interventional radiology, cardiology and vascular surgery, for 2D projection imaging. Three dimensional applications and tomosynthesis are not covered in the present text.

Fluoroscopic systems are used for many applications. The systems can be simple, for limited purposes, but can also be used for complex angiography examinations or cardiac catheterization procedures. Interventional radiology and cardiology procedures are so sophisticated or ambitious that they are often associated with long exposure times and large numbers of acquired images and this increases the chance of deterministic radiation effects at the level of the skin, especially in obese patients. Recently, there has been increased focus on operator eye lens dose because more radiation effects were seen than previously assumed (ref 0). Dedicated systems should be used and these systems should be included in a dedicated Quality Assurance program by the medical physics expert.

Current systems are very sophisticated, with a great deal of flexibility designed in, and as such the choices made by the operator are very influential. Effectively, the operator can be considered a 'component of the system' (private communication S. Balter) and advice to the operator on the correct set up of the system is an important part of the QC process. Justification of practices implies that not only the system as a whole but also the automatic dose rate control (ADRC) of the device meets the standards. An excellent reference to situate our tasks is the NCRP168 report (ref 1).

Each fluoroscopy system needs to be tested for its intended use. An essential step in the QC process is establishing a good relationship with the staff in the examination rooms. They should indicate the applications performed with the system and which preprogrammed settings are most commonly used. The **list of clinical programs** to be evaluated using the protocol shall be established in consultation with the staff. A well-defined geometry, as used clinically, is required for relevant and reproducible measurements. Include in your reports a list of the most frequently used and tested adult clinical programs and pediatric programs if applicable. Ask the personnel in the room for verification whether the selected programs are common choices for their common applications.

Fluoroscopy devices can be classified according to function and geometry:

- **According to function**
    1. Combined Radiography & Fluoroscopy systems with movable table for barium studies, iodine contrast studies and classical X-ray exams in which positioning is done using fluoroscopy.
    2. Mobile image intensifier or flat panel image receptors with C-arm used for example during orthopedic procedures in the operating room/surgery
    3. C-arm for vascular diagnostic and therapeutic studies, often equipped with DSA
    4. C-arm for cardiac applications
    5. Systems for specific applications, such as lithotripsy, urology, etc.

• **According to geometry**
    1. C-arm (configuration depending on application)
    2. Under couch configuration (X-ray tube below table, detector above).
    3. Over couch configuration (X-ray tube above table, detector below).

• **According to technology**
- X-ray intensifiers converting the low intensity x-ray flux exiting the patient into a high fluence of visible photons, using different conversion layers. This process is largely analogue in nature.
- Flat panel detectors converting X-rays to light (indirect conversion) or charge (direct conversion) which is then read out using thin film transistors (TFT array) to create a digital signal.

The intention of this document is to be a standalone text that can be applied to compare a fluoroscopy system with the applicable acceptability criteria. This text is not a manual for optimizing a system. Although this is a very important task of a medical physics expert (MPE) and it will be a future annual obligation to run optimization studies, this goes beyond the scope of present document. Physicists performing QA tests should report on conditions in need for optimization.

Hints when using present protocol:
- Some systems do not permit manual changes of beam quality or dose level at the image receptor. Some specific steps are therefore required in order to be able to image certain test objects with the beam qualities suggested in the protocol.
- The tests in this protocol can, where possible and appropriate, be performed in radiography mode (ex. the accuracy of the tube voltage).
- A typical set-up for the measurement of the beam quality is the lateral direction: with this configuration there is no table in the radiation beam while the table can be used to mount the test objects.
- If there is no fixed table, tests can be performed without table. The test objects can then be put on the detector housing.
- In case of biplane systems, each tube-detector combination should be tested.

A system for fluoroscopy must at least comply with the following requirements:
- The system must include either an image intensifier, a flat panel or any other digital detector. Direct fluoroscopy is prohibited.
- Each system must have a patient dose indicator in accordance with the FANC decree of September 28, 2011.
- Each system must produce an acoustic signal every 5 minutes of fluoroscopy.
- Each system must have an automatic dose rate control, except for systems in use for very specific applications.
- Systems manufactured after 2020 should have Last Image Hold.
- Systems manufactured after 2020 should be provided with virtual collimation: it must be possible to collimate on the Last Image Hold.
- Systems manufactured after 2020 must implement the latest DICOM standards of structured dose reports. Radiation Dose Structured Reports (RDSR) should be automatically pushed forward to external electronic devices (PACS, dose registration

system, ...) for all new systems purchased from 2020 in order to make the dose data retrievable for further processing or surveys.
- Systems for interventional procedures, manufactured after 2020, must have the XR27 option.

Depending on the type of applications, the following aspects have to be considered too:
- The systems should have removable grid in case of pediatric applications.
- Additional filtration such as copper filters are an obligation for angiography / cardiac examinations.
- Systems should have different pulse rates and dose levels.
- Application specific pre-programming should be possible.

We urge the manufacturers to provide the "user quality control mode", in accordance with the proposals of MITA (XR-27) (ref 3). This mode provides the possibility of manually selecting the exposure settings, the access to raw ('for processing') data, and auditing, storing and finding changes to the imaging protocols programmed on the system and the opportunity to save a calibration factor for dosimetric applications. We recommend all physicists to explain the purchasing service to include this option in the tenders.

A lot of valuable information on the system is available in the manual of the system (this is recommended reading!) or by contacting the service engineer. Companies may have good reasons to deviate from classical ADRC modes for magnification, pulsed imaging, imaging as a function of patient thickness, … In the future, 'constant Air Kerma at the image receptor' will be replaced by other principles (like contrast to noise ratio constant), and we should therefore not impose old schemes, yet test how the system is performing for these different settings. If applications are pre-programmed with continuous fluoroscopy, the use of this potentially high dose mode has to be characterized and justified.

In Belgium, procedure specific air kerma area product (KAP) levels that correspond to 2 Gy peak skin dose (PSD) have been published (ref 2) and are summarized in Table 1. We encourage the MPE to use them during investigations and to inform the medical team of the existence of these data. In a recent report, the NCRP has stressed the importance of trigger levels too. We urge manufacturers to generate alarms or warnings when any of these trigger levels are exceeded.

The MPE needs different measuring devices and test objects in order to perform the tests. The necessary equipment includes a dose meter which can measure **incident dose** (without backscatter), **entrance surface Air Kerma (ESAK)** (measurements including backscatter or a dosimeter to evaluate the back scatter factors) and **Incident Air Kerma** (IAK) on the image receptor. The dose meter for IAKR measurements should be able to measure very low exposure rates with Cu filter (ref 4).

Table 1. Copied from: Struelens L et al., Establishment of trigger levels to steer the follow-up of radiation effects in patients undergoing fluoroscopically-guided interventional procedures in Belgium, Physica Medica (2014),

Trigger levels in terms of total KAP, corresponding to a peak skin dose of 2 Gy, for several interventional procedures in Belgian hospitals.

Trigger levels		KAP Gy cm^2
TIPSS & chemo embolisations of the liver		330
Cerebral embolisations	Mono-plane	175
	Bi-plane	240
RF ablations		180
Biliary drainages	Conventional	160
	PTC	180
Embolisations vena spermatica		270
ERCP		295
CA & PTCA [16]		125

Table 2: Copied from NCRP report 168, Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures. July 2010

Summary of Radiation Monitoring Dose Notification Thresholds

Parameter	First Notification	Subsequent Notifications
Peak skin dose (PSD)	2,000 mGy	500 mGy
Reference point air kerma ($K_{a,r}$)	3,000 mGy	1,000 mGy
Kerma-area-product (P_{KA})	300 Gy · cm^{2*}	100 Gy · cm^{2*}
Fluoroscopy time (FT)	30 min	15 min

* Assuming a 100-cm^2 field at the patient's skin. The value should be adjusted to the actual procedural field size.

The routine practice of using line pair tests on image intensifiers has a limited significance for flat panel detectors as line pair tests basically assess pixel size, while high contrast spatial resolution is not necessarily limited by pixel size. However, images with smaller FOV are magnified on the screen (with obvious impact on line pair reading results) and higher field sizes may use binning (where the line pair resolution drops). These arguments, next to knowing at which level a system is performing, do justify a classical line pair resolution test. We propose however to add contrast detail analysis as a more complete performance test that includes next to contrast assessment also sharpness. Human reading is the current standard for contrast-detail studies in fluoroscopy/acquisition. Assessment of MTF and/or model observer analysis of contrast-detail curves requires access to (for processing) images.

An important aspect not tested at this point is the influence of motion on image sharpness. The only assessment of the dynamics in this text is the pulse width tracking as part of the characteristic curve evaluation. We recommend that pulse width for cardiological applications should be in the region of 3 ms to 10 ms, depending on patient/test object thickness. Values above 10 ms should be investigated/questioned. A final aspect that is important but not included in any of the tests is image processing. More research is needed to define relevant test proposals.

We welcome any comments that can further strengthen our protocol. We aim for active participation in achieving 'good clinical practice' in the most critical x-ray rooms of our hospitals.

May 24, 2019

Prof. Hilde Bosmans,
on behalf of the working group Radiology of the BHPA

Comments to this text should be sent to prof. Hilde Bosmans, hilde.bosmans@uzleuven.be, stating "BHPA protocol for fluorosocopic devices”

2. Definitions and measurement conditions

Fluoroscopically-guided interventional procedures comprise procedures guiding therapeutic and diagnostic interventions, by percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site or treatment site, to monitor the procedure, and to control and document therapy (ref 1)

Reference point and standard set-up

When testing systems with adjustable tube – image receptor distance, the distance between focal spot and image receptor (SID) should be as close as possible to 1.15m.

The Belgian QA **Reference Point** (RP) is situated 25 cm above the table (for tele-operated over-couch systems) or at 30 cm distance from the image receptor housing (C-arm configuration, often under couch). For mini C-arm the reference point is situated 5cm from the image receptor housing. In this document, distances from or to the 'image receptor' mean from or to the 'receptor housing'.

The **interventional reference point (IRP)** is a point defined by IEC: it is 15cm away from the iso-center in the direction of the tube.

The **iso-center** is the point in space about which a C-arm fluoroscope rotates. An object placed in the isocenter remains in the center of the FOV at any gantry angle.

Standard setup = a condition without table in the beam or with the fixed table in the beam; the ADRC is used; the geometry (over or under couch and focal spot image receptor distances, SID) is documented; the SID is as close as possible to 1.15m; the grid remains in place; PMMA test slabs are as close as possible to the image receptor. ESAK is recalculated to the Belgian QA RP.

Entrance surface air kerma (ESAK) includes backscatter. A backscatter factor 1.4 can be used to obtain the entrance surface dose from incident dose measurements. For more details use Table 3.

We define some basic **categories** of systems depending on their function, along with a diagonal field size, in order to apply limiting values. Currently, these are systems for:

- positioning (diagonal 42 cm)
- Ba-exams (diagonal 42 cm),
- orthopedic surgery in the OR (diagonal 25 cm)
- angiography with DSA function (diagonal 42 cm)
- cardio-angiography (diagonal 25 cm).

Clinical conditions

When a C-arm configuration for angiographic or cardiac catheterization applications is tested, the most frequently used configuration should be used for the tests (usually under couch configuration, table in the beam). Other C-arms, used in combination with different types of tables, for example in the operating theater, can be tested without table between the x-ray tube

and the image receptor. The report of the measurements shall always indicate the presence or absence of the table in the measurement set-up.

For mini C-arms, with a smaller focus-image receptor distance than usual, the test and the limiting values should be adjusted to the specific situation.

In addition to fluoroscopy modes, most systems also have an ‘acquisition’ mode, with acquisition meaning ‘a mode of operation during which a series of images are recorded for later review, typically using a higher dose per frame than fluoroscopy’. This mode is also termed ‘ciné radiography’ or cardioangiography and typically operates at lower image receptor incident Air Kerma/frame than acquisition mode on vascular angiography systems, but with higher frame rates (ranging between 7.5 frames/s and 15 frames/s) (ref 4). Digital Subtraction Angiography (DSA) is another commonly used series acquisition mode. At least one fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category should be tested. If our text mentions that a test should be performed in fluoroscopy and acquisition while only one mode is available, it should be tested in that mode (only).

Viewing conditions in the room

Test objects that are read out in the room use routine clinical conditions. This is especially the case at the level of the monitor. If read-out conditions are not acceptable, this should be discussed with the staff. A protocol on monitors, light boxes and ambient light will be developed later.

3. Tube Voltage

i) Accuracy

1. Purpose

Verification whether the measured tube voltage corresponds to the value indicated on the control panel. This allows accurate calculation of contrast threshold values and effective dose of the patient. Deviating tube voltages may explain anomalously high patient skin dose effects.

2. Material, methods, acceptability criteria

Material	kVp meter.
Methods	The kVp meter is positioned according to the manufacturer's instructions.
Acceptability criteria	Deviation ≤ 10 %.

3. Methods

- The kVp meter is placed centrally in the beam. Light field or fluoroscopy can be used for correct positioning. The tube voltage is measured without a table between focus and measuring device, if such a configuration can be realized.
- At least three tube voltages are tested, or one setting if voltage accuracy has been tested in radiography mode. The test is preferably repeated for all tube voltages in increments of 10 kV between 60 kV and 120 kV. If the tube voltage cannot be adjusted manually, a kV variation is obtained by placing attenuation (e.g. PMMA plates, copper sheets or lead) in the X-ray beam between the kVp meter and the image receptor.

4. Calculations

The deviation expressed in percentage should be less than 10 %:

$$\text{Deviation (\%)} = \left| \frac{\text{Measured Tube Voltage (kV)} - \text{Set Tube Voltage (kV)}}{\text{Set Tube Voltage (kV)}} \right|$$

ii) Reproducibility

1 Purpose

Verification whether the tube voltage and therefore beam quality is reproducible.

2. Material, methods, acceptability criteria

Material	kVp meter.
Methods	The kVp meter is placed according to the manufacturer's instructions.
Acceptability criteria	Deviation ≤ 5 %.

3. Methods

- The kVp meter is placed centrally in the beam. Light field or fluoroscopy can be used for correct positioning. It is acceptable to perform this test for the radiography mode only.
- The tube voltage is set to a specific, clinically used voltage and at least four measurements are performed.

4. Calculations

For all four measurements, the deviation is calculated using the following formula:

$$\text{Deviation (\%)} = \left| \frac{\text{Measured Tube Voltage (kV)} - \text{Mean Measured Tube Voltage (kV)}}{\text{Mean Measured Tube Voltage (kV)}} \right|$$

The maximum deviation is calculated, and should be smaller than 5 %.

4. Half Value Layer (HVL) and total filtration

1. Purpose

Characterization of the X-ray beam quality by means of the half value layer for a setting as close as possible to 80kV.
The available filters are listed and their use in frequently used programs is documented. If the filters are not pre-programmed where they should be programmed according to good clinical practice (personal judgement), this will be noted as action point in the report.

2. Material, methods, acceptability criteria

Material	Dose meter Al sheets of 1 mm thickness with a measuring stand or validated automatic filtration determination.
Methods	Create a set-up so that a tube voltage as close as possible to 80 kV is obtained and this with minimal filtration (eg without copper filter and, if possible, without a table between the tube and the dose meter).
Acceptability criteria	The total filtration must be greater than 2.5 mm Al equivalent.

3. Methods

- Set up the equipment so that Al sheets can be put easily between focus and dose meter while the exposure settings stay fixed. Consecutive measurements are made with increasing Al in the beam (between focus and dose meter). Be aware that solid state dosimeters with a lead backed scatter protector can influence the ADRC, with effect on tube voltage selection. The test can be performed in radiography/acquisition mode, although the system pre-filtration of the x-ray beam can be different between fluoroscopy and acquisition modes.
- Automatic measurement of HVL and total filtration is permitted provided the automatic method has been shown to be accurate.

4. Calculations

The half-value layer and total filtration are calculated.
The total filtration must be greater than 2.5mm Al equivalent.

5. Remark

Note that the anode angle correction is especially relevant for cardiovascular systems. The effect of anode angle on beam quality and HVL can be taken into account. There are tools available on the web, such as 'spekcalc', http://spekcalc.weebly.com/ or from IPEM 78, http://linux.fjfi.cvut.cz/~madlenka/medphys.htm

For some dosimeters it is important to use narrow beam conditions.

5. Timer

1. Purpose

The user must be notified in case of prolonged exposure of patients. It has to be verified whether an audible signal goes on automatically at a cumulative 'foot on the pedal time' of maximum 5 minutes. After an additional 5 minutes there should be a second audible signal.

2. Material, methods, acceptability criteria

Material	No additional material.
Methods	Perform a series of fluoroscopy exposures and verify whether there is an acoustic signal.
Acceptability criteria	After 5 minutes, there must be an acoustic signal that is well audible in the examination room and that has to be reset manually. At acceptance it is verified whether there is a second acoustic signal after 10 minutes. The timer should correct for the time period in between pulses.

3. Methods

- Perform a series of fluoroscopy exposures and verify whether there is an acoustic signal after 5 minutes of foot on the pedal time. At acceptance verify whether there is a second acoustic signal after 10 minutes of foot on the pedal time.

6. Imaged field size versus radiation field size and virtual collimators

1. Purpose

Verification whether
(1) the imaged area corresponds to the area of the X-ray field for all available magnification strengths.
The RP162 requires that the ratio between X-ray field and imaged area < 1.25. For square collimators and a round image receptor, which is still frequently used in conventional radiology, we recognize that this value may not be achieved. The minimal ratio of a square area that fits around a circular area is 1.27.
(2) the virtual collimation system performs conform its intended use. It is considered good practice when collimators are visible in the image.

2. Material, methods, acceptability criteria

Material	Equipment to measure the X-ray field. Equipment that allows to calibrate the visualized sizes of the irradiated test slab (example: lead rulers)
Methods	Irradiate the X-ray field meter for different magnifications. Verify whether the virtual collimator functions according to its intended use (example: show the borders of the radiation field, show the center of the radiation field, ..)
Acceptability criteria	In case of image intensifiers with square collimators in combination with a round image receptor, the ratio of the surface of the irradiated field to the surface of the visualized test slab should be < 1.27. In case of image intensifiers with non-square collimators and a round image receptor, the ratio of the surface of the irradiated field to the surface of the visualized test slab should be: < 1.15 for field sizes with inner diameter > 24 cm; < 1.20 for field sizes with inner diameters between 18 and 24 cm; < 1.25 for field sizes with inner diameter < 18 cm. In case of flat panels with rectangular collimators and a rectangular image receptor, the ratio of the surface of the irradiated field to the surface of the visualized test slab is < 1.15. A target value is < 1.10. The virtual collimation system should conform with its intended use, i.e. positioning lines in the Last Image Hold should correspond to their real position. The deviation between position of the virtual collimator and the irradiation field should not be larger than 1% of the distance between focus and image receptor housing.

3. Methods

- This test involves the measurement of the surface of the radiation field and the imaged area for all possible magnifications.
- Use an irradiation field indicator (example gafchromic films or CR plates) and perform exposures with all magnifications.
- Measure the areas of the irradiation fields
- For the same acquisitions, the area of the field shown on the monitor is determined.
- Put a ruler on the image receptor, perform fluoroscopy, collimate with your virtual collimator (without the use of fluoroscopy) to a fixed position of the ruler, perform fluoroscopy again and verify on the monitor for the correspondence between the imaged part of the ruler and the position of the virtual collimator on the ruler.

4. Calculations

Calculate the ratios between irradiation field and imaged area. The ratios must comply with the limits.
Calculate the deviations between the position of the virtual collimator and the irradiation field.

5. Remark

If there is a light field indicator, verify its deviations or calibrate it for all sides of the irradiation fields. Correspondence between irradiation field and imaged test slab can then be verified by means of the light field indicator.

7. Orthogonality

1. Purpose

Verification of the beam geometry: Is the X-ray beam perpendicular to the image receptor?

2. Material, methods, acceptability criteria

Material	Test object with two marker points at different distances from the x-ray tube. The marker points result, in case of correct geometry of the x-ray beam, in a coincidence.
Methods	Tube at 1m distance from the test object or according to the manual of the test object.
Acceptability criteria	The angle between the central axis of the x-ray beam and the image plane should be 90 ° ± 1.5 °.

3. Methods

The tube is placed perpendicular to the test object with the marker points in the center of the X-ray field (or according to the manual of the test object). Make an exposure according to the instructions in the manual of the test object.

4. Calculations

Compare the position of both mark projections according to the manual of the test object and compare with the standards.

5. Remarks

The position of the X-ray tube and image receptor will in general be vertical, but may differ from this set-up.

8. Patient entrance surface air kerma rate (ESAKR) in fluoroscopy mode and acquisition mode for frequently used clinical programs

1. Purpose

Verification of patient entrance ESAKR levels (basic safety).

- For a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category (including the average dose rates of a complete DSA run), register the ESAKR for 20 cm PMMA. The acceptability criteria apply, except if these programs are flagged as 'high dose or boost mode' with audible signal.
- For the selected fluoroscopy and acquisition programs, the effects of different pulse rates, different dose levels and different field sizes are verified.
- Verification whether preprogrammed names are logical in terms of dose. Example: we expect with "lower pulse rates" to find lower ESAKR.

2. Material, methods, acceptability criteria

Material	Dose meter, 20 cm of PMMA, typically 20cm x 20cm. For mini-C arms, 5 cm of PMMA is used.
Methods	Standard set-up.
Acceptability criteria	For field sizes as specified in Tables A1 to A8, - For fluoroscopy, ESAKR at the RP should be ≤ 30 mGy/min. An expected value for pulsed fluoroscopy is ≤ 15 mGy/min. An expected value for continuous fluoroscopy is ≤ 25 mGy/min. - For barium-type series acquisition, the ESAKR should be ≤ 1 mGy/frame and typical values are 0.4 mGy/frame and ≤ 100 mGy/min. - For cardiac acquisition, ESAKR should be ≤ 0.2 mGy/frame at 15 frames/s and an expected value is ≤ 250 mGy/min. - For DSA, ESAKR should be ≤ 2 mGy/frame and an expected value is ≤ 150 mGy/min. - Guidelines for neuro-angiography will be established later - With mini C-arms, where the focus to image receptor distance is less than 45 cm, the ESAKR should be ≤ 5

	mGy/min. An expected value for these systems is ≤ 2 mGy/min. - ESAKR changes of 25% compared to the previous tests have to be investigated and/or remediated.

3. Methods

- Use 20 cm of PMMA.
- Consecutive annual testing should be done with the same set-up.
- Measure the PMMA ESAKR for 1 to 5 clinical programs and recalculate these values to the dose in the RP.
- For a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category, measure the ESAKR for at least the following conditions:
  • all dose modes (low, medium and high)
  • a variety of pulse rates (at acceptance test)
  • all fields of view (FOVs)

4. Calculations

- Doses are scaled to the RP
- If IAKR is being measured (rather than ESAKR), apply a backscatter factor of 1.4, or see Table 3 if more precision is needed, to obtain an estimate of ESAKR.
- Report the ESAKR per frame and per minute.
- Report added Cu filtration
- Compare to the acceptability criteria
- Verify whether the dose levels are logically programmed
- Compare with the values from the previous tests and report discrepancies.

5. Remarks

- The back scatter factors of Table 3 can be used.

Table 3: Backscatter factors according to the ICRU (ref 4)

		fieldsize	100 mm x 100 mm			200 mm x 200 mm			250 mm x 250 mm		
kV	**filter**	**HVL**	**Water**	**ICRU tissue**	**PMMA**	**Water**	**ICRU tissue**	**PMMA**	**Water**	**ICRU tissue**	**PMMA**
50	2.5 mm Al	1.74	1.24	1.25	1.33	1.26	1.27	1.36	1.26	1.28	1.36
60	2.5 mm Al	2.08	1.28	1.28	1.36	1.31	1.32	1.41	1.31	1.32	1.42
70	2.5 mm Al	2.41	1.3	1.31	1.39	1.34	1.36	1.45	1.35	1.36	1.46
70	3 mm Al	2.64	1.32	1.32	1.4	1.36	1.37	1.47	1.36	1.38	1.48
70	3 mm Al + 0.1 mm Cu	3.96	1.38	1.39	1.48	1.45	1.47	1.58	1.46	1.47	1.59
80	2.5 mm Al	2.78	1.32	1.33	1.41	1.37	1.39	1.47	1.38	1.39	1.5
80	3 mm Al	3.04	1.34	1.34	1.42	1.39	1.4	1.51	1.4	1.41	1.52
80	3 mm Al + 0.1 mm Cu	4.55	1.4	1.4	1.49	1.48	1.5	1.61	1.49	1.51	1.63
90	2.5 mm Al	3.17	1.34	1.34	1.43	1.4	1.41	1.51	1.41	1.42	1.53
90	3 mm Al	3.45	1.35	1.36	1.44	1.42	1.43	1.53	1.42	1.44	1.55
90	3 mm Al + 0.1 mm Cu	5.12	1.41	1.41	1.5	1.5	1.51	1.62	1.51	1.53	1.65
100	2.5 mm Al	3.24	1.34	1.34	1.42	1.4	1.41	1.51	1.41	1.42	1.53
100	3 mm Al	3.88	1.36	1.37	1.45	1.44	1.45	1.55	1.45	1.46	1.57
100	3 mm Al + 0.1 mm Cu	5.65	1.41	1.42	1.5	1.51	1.53	1.64	1.53	1.55	1.66
110	2.5 mm Al	3.59	1.35	1.35	1.43	1.42	1.43	1.53	1.43	1.44	1.55
120	3 mm Al	4.73	1.37	1.38	1.46	1.46	1.48	1.58	1.48	1.49	1.6
120	3 mm Al + 0.1 mm Cu	6.62	1.41	1.42	1.5	1.53	1.54	1.64	1.54	1.56	1.67
130	2.5 mm Al	4.32	1.36	1.36	1.44	1.44	1.45	1.55	1.45	1.47	1.57
150	2.5 mm Al	4.79	1.36	1.36	1.44	1.45	1.46	1.55	1.46	1.48	1.58
150	3 mm Al	6.8	1.39	1.39	1.47	1.5	1.51	1.61	1.52	1.53	1.63
150	3 mm Al + 0.1 mm Cu	8.5	1.4	1.41	1.48	1.53	1.54	1.64	1.55	1.57	1.67

9. Maximum patient incident air kerma rate in fluoroscopy

1. Purpose

Verification whether the maximum incident air kerma rate for fluoroscopy (not to be applied for acquisition mode) is complying with the acceptability criteria.

2. Material, methods, acceptability criteria

Material	Dose meter. Lead patches/flaps, PMMA and eventually any other material until the dose is maximal, defined as the situation in which doses do not further increase upon addition of extra attenuation. With mini C-arms, 5 cm PMMA and some lead patches are sufficient.
Methods	Standard setup.
Acceptability criteria	The test is performed at acceptance and when changes in IAKR are noticed. The IAKR in the RP (without backscatter) should be less than 88 mGy/min. This value assumes no table between tube and PMMA but it can also be applied in an under couch configuration. This limiting value can be exceeded provided that there is a continuous audible warning, and that this program requires manual activation e.g. in a 'boost' mode. For all cases the IAKR should not be greater than 176 mGy/min.

3. Methods

- A stack of PMMA is put on the table and a frequently used clinical program selected. An increasing amount of attenuating material is added (lead patches/flaps and eventually any other material) until the ESAK reaches a maximum i.e. no further increase upon addition of extra attenuation.
  Consecutive annual tests should be done with the same setup.
- The measured IAKR should be less than 88 mGy/min.
- For high dose modes with warning (continuous sound and manual activation) the measured IAKR should be less than 176 mGy/min.

4. Calculations

- The measured dose rate is recalculated to the dose rate at the RP. This value is compared with the limit.

10. Incident Air Kerma Rate (IAKR) at the image receptor

1. Purpose

Verification whether the Incident Air Kerma Rate at the image receptor (IAKR) is acceptable for a selection of routine programs, for fluoroscopy and acquisitions. At acceptance, the measurements are also compared with the displayed values.

2. Material, methods, acceptability criteria

Material	Dose meter. The dose meter needs to be appropriate for measurement in a low dose domain and with Cu filtration. 2 mm Cu is attached to the tube (for attenuation and beam hardening) so that there is minimal scatter radiation at the image receptor. For mini C-arms, 5cm PMMA equivalent material is used (eg. 6mm of Al). Note the position of the grid and use grid correction factors when needed.
Methods	Position the dose meter according to the manual.
Acceptability criteria	For field sizes as specified in Tables A1 to A8, - For fluoroscopy, IAKR should be ≤ 1.5 µGy/s. Expected values will range between 0.2 and 0.6 µGy/s - For barium acquisition, IAKR should be ≤ 2 µGy/frame. - For cardiac acquisition, IAKR should be ≤ 1 µGy/frame. - For DSA, IAKR should be ≤ 4 µGy/frame. Expected values will range from 0.5 µGy/frame to 2 µGy - With mini C-arms IAKR should be ≤ 2 µGy/s. If IAKRs are higher than these limiting values, the exposure settings (ADRC) have to be investigated, taking into account the patient dose and/or the philosophy behind these settings. Dose changes of 25% compared to the previous tests have to be investigated and/or remediated. Displayed IAKR values should not deviate more than 25% from measured IAKR.

3. Methods

- A Cu filter of 2 mm is placed on the tube exit.
- The dose meter is positioned so that the ADRC sensing regions are not affected, if possible.
- Measure the IAKR for 1 to 5 clinical programs.

- For a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category, measure the IAKR for at least the following conditions:
  • all dose modes (low, medium and high)
  • a variety of pulse rates (at acceptance test)
  • all fields of view (FOVs)

4. Calculations

- Record the doses and compare with the limits. Compare with the values of previous tests and report discrepancies
- At acceptance: compare measured IAKR values and displayed dose values. In case of discrepancies, verify whether the measurement conditions are in accordance with the manufacturer's specifications. If needed, discuss with the manufacturer.

11. Verification of the integrated dose indicator calibration

1. Purpose

Verification of the accuracy of the 'dose' indications displayed on the system: KAP, (incident) air kerma in the interventional reference point (IRP, defined by the manufacturer), KAP in the DICOM header, etc. The accuracy of all dose indications that could be used by the medical practitioner, the radiographer, the medical physicist or a dose tracking system must be verified.
The dose indications have to be verified for a selection of beam qualities that are routinely applied or for beam qualities defined by the manufacturer for particular dose indicators (example: RQA qualities)
Measure correction factors between the specified and measured values if large deviations are observed.

2. Material, methods, acceptability criteria

Material	For verification of the KAP meter calibration: Dose meter and system for measuring the size of the irradiated surface. Alternative: a separately calibrated KAP meter (ref 6) . For other dose indicators: the set-up depends on the definition of the dose indicator (see manual of the system)
Methods	For the KAP: position the dose meter and the device to measure the radiation field. For other dose indicators, follow the instructions of the manufacturer. Measure the dose at the different tube voltages, typical 60 to 100 kV at intervals of ± 10kV. For air kerma at the interventional reference point (IRP): position the dose meter and the device to measure the incident air kerma in a chosen point at measured distance from the tube. Recalculate the air kerma to the IRP defined by the manufacturer.

	Verify indicated dose rate during exposure by measuring with the dosemeter.
Acceptability criteria	Each dose indicator should be within 20 % of the measured values (acceptable level). The achievable limit is 10%.

3. Methods

(1) KAP

The verification of the calibration of the KAP meter is performed without the table in the beam for over couch systems. For systems that can be used in both over couch and under couch geometries, the KAP calibration is verified for both geometries. The geometry has to be stated in the report.

Calculate the product of the measured IAK at a point in the beam and the irradiated surface through the same point and perpendicular to the beam. The measurement of IAK or area can also be performed at a different distance and has then to be recalculated to the foreseen position. The product of IAK and area is compared with the indication on the KAP meter.

The dose measurements are repeated at different tube voltages.

(2) other dose indications:

See instructions regarding their meaning or definition. The correct meaning of the dose indicator is retrieved from the manual of the system and a set-up is made to allow verification of measured and displayed dose indicator.

4. Calculations

Calculate the correction factor:

$$Correction\ Factor\ = \frac{measured\ value}{indicated\ value}$$

Indicate in the report whether any correction factors have to be applied.

12. Characteristic curve

1. Purpose

Verify whether the preprogrammed "focus-kV-Cu filter-mA-pulse width – pulse rate" settings are appropriate, i.e. consistent with the intended program modes for different thicknesses of PMMA or generally acceptable.

This test will provide insight in the ADRC of the system and contains a lot of information with direct clinical relevance. The measurements are crucial to find preprogrammed ADRC curves with inappropriate settings. Characteristic curves can be used to illustrate when improved pre-programming of the system is needed.

2. Material, methods, acceptability criteria

Material	Dose meter A total thickness of 25 cm PMMA (sufficiently large and covering the ADRC), and up to 40 cm for cardiac systems
Methods	For a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category: PMMA plates are placed on the table in increments of 5 cm. For mini C-arms a total thickness of 10 cm PMMA is stacked in increments of 2 cm PMMA.
Acceptability criteria	Every tested program must have a logical choice of beam qualities (kV and added filtration if possible), dose level, dose rate and pulse width (if indicated, and if not indicated, aim for a measurement). Compare with the values of previous tests and report discrepancies.

3. Methods

- The plates are placed in steps of 5cm on the table.
- Consecutive annual tests should be done with the same set-up.
- Measure the ESAKR and pulse width in fluoroscopy and acquisition mode for different PMMA thicknesses ranging from 5 cm to 25 cm (and possibly higher) in steps of 5 cm. For mini-C-arms, the maximum thickness is adjusted to the system under study.
- Note the focus, kV, mA, Cu filtration, entrance dose rate, possibly pulse width and pulse rate, for different thicknesses and programs.

4. Calculations

The focus - kV- Cu filter – mA - pulse width – pulse rate combinations must be logical, with doses and beam quality increasing if thickness increases, and consistent with the clinical task for which the program is named/used. For example, pulse width evaluation is essential for cardiac series acquisitions, with the requirement of short pulses for the range of relevant patient thicknesses (20 cm to 40 cm PMMA).

13. Low (optional) and high contrast resolution of the system

1. Purpose

Low and high contrast limiting resolution of the entire system (including an implicit assessment of focal spot size, beam quality, scattered radiation, geometry) are evaluated for a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category. This test estimates low and high contrast on the basis of a test object which contains low and high contrast inserts (eg. TOR 18FG) on top of PMMA (at the side of the tube). Use 20 cm of PMMA.

Possible causes for a poor low contrast resolution, apparent in the system test and not in the image receptor test, are the absence of a grid or a poorly performing grid, and for the high contrast resolution, a large focal spot.

In exceptional cases, lower image quality can be accepted, if the fluoroscopy option is only used for patient positioning for non-dynamic X-ray exams and if the lower image quality is not the reason for prolonged fluoroscopy times. In any case, such exceptions have to be communicated to the medical team and marked on the device.

2. Material, methods, acceptability criteria

Material	Test object with low and high contrast inserts, 20 cm PMMA for general fluoroscopy systems and 5 cm PMMA for mini C-arm
Methods	The measurement set-up is as follows: tube - test object - PMMA - image receptor. The test pattern for high resolution (lead line pairs) is placed at an angle of 45 ° to the pixel rows and grid. The test is performed for a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category. The high contrast resolution test is performed for all field sizes.
Acceptability criteria	For fluoroscopy, nominal contrast should be ≤ 3.3%. For all systems: Resolution ≥ 1.0 lp/mm for > 30 cm field sizes. Resolution ≥ 1.4 lp/mm for field sizes > 24 and ≤ 30 cm Resolution ≥ 1.6 lp/mm for field sizes > 18 and ≤ 24 cm Resolution ≥ 1.8 lp/mm for field sizes > 15 and ≤ 18 cm Resolution ≥ 2 lp/mm for ≤ 15 cm field sizes. Report when binning occurs and the resolution is lower. With mini C-arms system resolution should ≥ 2.6 lp/mm. In acquisition mode, nominal contrast should ≤ 2.7%. System resolution should ≥ 1.6 lp/mm. The high and low contrast resolution are compared to the image receptor resolution (paragraph 14) for further interpretation.

3. Methods

- Make the following measurement setup: tube - test object - PMMA - image receptor.
- Use the clinical modes as defined in the list

- Measure the low and high contrast resolution. Calculate the nominal contrast at 70kV and 1 mmCu using the manual of the test object.

. 4. Calculations

- Compare high and low contrast resolution with the acceptability criteria
- For high and low contrast resolution, the results are compared with the results of the image receptor resolution. Differences between the system test and the image receptor test of more than 0.4 lp/mm should be subject to an investigation.

5. Remarks

- Binning can occur for larger field sizes. This is common for field sizes larger than 42 cm, combined with small pixel sizes.
- The occurrence of binning can be checked with the pixel size in the DICOM header or in the manual of the system.

14. Large area threshold contrast resolution of the image receptor (optional)

1. Purpose

Verification of the large area threshold contrast resolution (also called 'low contrast resolution') of the image receptor under standardized, scatter free conditions.

2. Material, methods, acceptability criteria

Material	Cu filtration according to the manual of the test object. TOR 18FG test object or equivalent. For mini C-arms, 5cm PMMA equivalent material is used (eg. 6mm of Al).
Methods	The test is performed for a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category. The manual of the test object is applied. As an example for the TOR 18FG, the tube voltage should be as near as possible to 70kVp. The test object is placed on the image receptor; the Cu filtration is attached to the tube (approx. scatter free conditions at the level of the image receptor). Acquire images in fluoroscopy and acquisition mode under ADRC control of the commonly used clinical program.
Acceptability criteria	Image receptor large area threshold contrast should be $\leq$ 3.3% for all systems when fluoroscopy is used. In acquisition mode, image receptor threshold contrast should be $\leq 2.7\%$. These values assume no table between tube and image receptor, but will also be applicable in a tube under fixed table configuration.

3. Methods

- The test object is placed on the image receptor; the Cu-filtration is attached to the tube (scatter free conditions at the level of the image receptor). The test is preferably done without a table in the beam. Consecutive annual tests should be done with the same set-up.
- The tube voltage should (if possible) be as near as possible to 70 kVp (or according to the manual of the test object). If this is not possible, the test can be done with another tube voltage, but the threshold contrast might differ from the calculations in the manual of the test object.

4. Calculations

- Compare with the limiting values.

15. High contrast resolution of the image receptor

1. Purpose of the measurement

Verification of the intrinsic spatial resolution of the image receptor at a central point. In case of doubt, also in peripheral points.
Optionally, an exposure is made with a mesh phantom to detect localized blur.

2. Material, methods, acceptability criteria

Material	TOR 18FG or Huttner line pair test object or other test object with similar patterns
Methods	The test object is placed on the image receptor according to the manual. The test pattern is placed at an angle of 45 ° to the pixel rows and grid. The test is performed for a selected acquisition program and, where acquisition is not available, for a selected fluoroscopy program, if possible the one most commonly used.
Acceptability criteria	For all systems: Resolution ≥ 1.0 lp/mm for > 30 cm field sizes. Resolution ≥ 1.4 lp/mm for field sizes > 2 and ≤ 30 cm Resolution ≥ 1.6 lp/mm for field sizes > 18 and ≤ 24 cm Resolution ≥ 1.8 lp/mm for field sizes > 15 and ≤ 18 cm Resolution ≥ 2 lp/mm for ≤ 15 cm field sizes. If binning occurs this should be reported and if suspicious, investigated. For mini C-arms the resolution ≥ 2.6 lp/mm. If the systems fails, check if the failure is due to the Nyquist criterion (professional judgment). Perform the alternative contrast-detail test.

3. Methods

- The test object is placed on the image receptor; there is no other material in the beam except if the image would not be readable or be saturated, in which case Cu can be added. Consecutive annual tests should be done with the same set-up.
- Position the test object as specified in the manual. Take images with the different magnifications.
- Study the viewing conditions at the level of the monitor where the read-out occurs. Read out in clinical circumstances. Determine the spatial resolution.

4. Calculations

- Compare the spatial resolution with the limits

16. System image quality test with a contrast-detail test object

1. Purpose

Quantification of image quality in terms of the minimally detectable contrasts of objects with different sizes. This test is sensitive to unsharpness, noise and applied recursive temporal filtering. This test gives an overall evaluation of system imaging performance. Note that this evaluation is currently made with static test objects.

Possible causes for a poor low contrast resolution, apparent in the system test and not in the image receptor test, are the absence of a grid or a poorly performing grid, and for poor small detail detectability, a large focal spot.

2. Material, methods, acceptability criteria

Material	Homogeneous plates, contrast detail test object TO12
Methods	Position the test object on the x-ray beam entrance side of a 20 cm PMMA phantom. For a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category with the magnification following the tables in appendix A.1 and A.2. This test is not applicable to mini C-arms
Acceptability criteria	Contrast detail curves are calculated and compared to typical curves with and without normalization for dose. Contrast thresholds on or outside the remedial level require investigation (= 50% deviation from the typical curve shown in Appendix A). The number of visible discs should not differ from previous result by more than one disc. Limiting values are preliminary.

3. Methods

- Set up the 20 cm PMMA phantom as for the ESAKR test (section 8)
- Position the test object on the x-ray beam entrance side of the phantom.
- Acquire the selected fluoroscopy and acquisition program and read out the test images from the clinically used monitor. The c-d reading should be made from the 'live' fluoroscopy or if a function like 'store fluoro series' is available, the test object can be scored from a playback loop of the run. For cardiac acquisition, acquire a series run of at least 5 s and then score this as a dynamically replayed loop. Use a variable viewing distance: larger distances for large discs and close up the for smaller discs. Scores of half a disc are allowed – these are given for a disc that seems to appear and disappear regularly, at a position where a disc is expected. At acceptance, the curve should, if possible, be read by more than one reader.
- Calculate the contrast detail curves and compare to typical curves and remedial curves

4. Calculations

- Calculate the threshold contrast for a nominal 70 kV and 1 mm Cu beam quality (the true contrasts are not known for the beam conditions).
- (appendix A.3) and compare to the corresponding typical curve and remedial level in appendix A.1.
- Correct the measured c-d curve fit data (C_m) to the reference ESAKR as follows to give a dose corrected c-d curve (C_c):

$$C_c = C_m \cdot \sqrt{\frac{measured\ ESAKR}{reference\ ESAKR}}$$

- Compare the dose corrected curve fit (C_c) with the corresponding typical curve and remedial level in appendix A.1.

5. Remarks

- For DSA imaging modes, subtracted images (and not the mask image) should be read. To acquire these images, attach a ~30 cm piece tape to the test object to enable safe manipulation of the test object. Set the DSA mode to be tested, start the acquisition and a few seconds into the run, pull the test object into the centre of the image field. When the test object is centred, do not move the test object anymore so that a number of stable subtracted images of the test object are acquired. Select a good (subtracted) image for scoring and read the image with a variable viewing distance on the clinically used monitor.

17. Detector Image quality test with a contrast-detail test object

1. Purpose

Quantification of image quality in terms of the minimally detectable contrasts of objects with different sizes of the image receptor under standardized, scatter free conditions. This evaluation is currently made with static test objects.

2. Material, methods, acceptability criteria

Material	Cu filter, contrast detail test object TO12
Methods	Position the test object on the image receptor and 2 mm Cu filtration at the tube. For a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category with the magnification following the tables in appendix A.1 and A.2. This test is not applicable to mini C-arms
Acceptability criteria	The test is performed for a selected fluoroscopy and acquisition program, if possible the one most commonly used and if feasible one of each category with the magnification following the tables in app. A.1 and A.2. Contrast detail curves are calculated and compared to typical curves with and without dose correction. Contrast thresholds at remedial level require investigation. The readings should not differ from previous results by more than one detail over the range of sizes. Limiting values are preliminary.

3. Methods

- Position the test object on the image receptor with Cu filtration attached to the tube (low scatter condition at the level of the image receptor).
- The tube voltage should lie between 65 kVp and 80 kVp so that the contrasts can be corrected using data in the TO12 manual. If the tube voltage lies outside this range then reduce the Cu filter to 1 mm or 1.5 mm Cu. If still outside this range then the contrasts cannot be corrected for this fluoroscopy program (this could happen for some Ba programs).
- Acquire the clinical fluoroscopy and acquisition mode and read out the test images from the clinically used monitor. The c-d reading should be made from the 'live' fluoroscopy or if a function like 'store fluoro series' is available, the test object can be scored from a playback loop of the run. For cardiac acquisition, acquire a series run of at 5 s and then score this as a dynamically replayed loop. Use a variable viewing distance: larger distances for large discs and close up the for smaller discs. Scores of half a disc are allowed – these are given for a disc that seems to appear and disappear regularly, at a position where a disc is expected. At acceptance, the curve should, if possible, be read by more than one reader.
- Calculate the contrast detail curves and compare to typical curves and remedial curves

4. Calculations

- Calculate the threshold contrasts for the used kV and 2 mm Cu.
- Apply a 2nd order polynomial curve fit to the log of the c-d data (appendix A.3) and compare to the corresponding typical curve and remedial level in appendix A.2.
- Correct the measured c-d curve fit data (C_m) to the reference dose as follows to give a dose corrected c-d curve (C_c):

$$C_c = C_m \cdot \sqrt{\frac{measured\ dose}{reference\ dose}}$$

- Compare the dose rate corrected curve fit (C_c) with the corresponding typical curve and remedial level in appendix A.1.

5. Remarks

- For DSA imaging modes, subtracted images (and not the mask image) should be read. To acquire these images, attach two pieces of paper tape to the test object to enable safe manipulation of the test object. Set the DSA mode to be tested, start the acquisition and a few seconds into the run, hold/insert the test object at image receptor, at the centre of the image field. When the test object is centred, do not move the test object anymore so that a number of stable subtracted images of the test object are acquired. Select a good (subtracted) image for scoring and read the image with a variable viewing distance on the clinically used monitor.
- A correction for extra added filtration can be done (appendix A.5).

18. Artifact and distortion evaluation

1. Purpose

Verification of image quality, by means of an inspection for artifacts, distortion, non-uniformities (ghost), etc.

2. Material, methods, acceptability criteria

Material	Homogeneous plates, test object for evaluation of distortion.
Methods	Position the test object according to the manual of the test object. Make an exposure with a clinically used program.
Acceptability criteria	Visual inspection.

3. Methods
- Position the test object as specified in the manual. Take an image with a clinically used program and do a visual inspection.
- Interpret and report the severity of observed artifacts.

19. Response function, MTF and noise power spectrum (NPS) of the digital image receptor (optional)

1. Purpose

Verification of the overall quality of the digital image receptor: image receptor response, MTF and noise power spectrum (NPS).
Manufacturers are encouraged to implement the 'physics mode' (as defined by MITA) or to give access to raw (for processing) data. This is recommended as soon as XR27 is available.

2. Material, methods, acceptability criteria

Material	Homogeneous plates and edge test object. Access to "for processing" (raw) images is required.
Methods	Make a setup in accordance (as close as possible) with the IEC standard but adapted to the clinical situation (non-invasive test).
Acceptability criteria	Record of parameters and observe variations in time. Changes larger than 10% have to be investigated.

3. Methods
- Use a fixed beam quality of 70 kV and 1 mm Cu filter placed at the x-ray tube.
- Select a commonly used field size (e.g. close to 42 cm or 25 cm, depending on system type)
- Acquire at least 5 series (fluoroscopy and acquisition where available) as a function of mA(s). Measure the DAK for the different exposures. Measure the pixel value and the variance in an ROI centrally positioned in the image. Determine the pixel value offset (if any) and fit the PV data as a function of DAK/image using a linear or other relevant monotonic relationship provided by the manufacturer. Linearize the images.
- Make an exposure with an edge test object for the MTF calculation. The edge should be positioned at or close to the image receptor input plane, at the centre of the field of view. The NPS should be calculated from one of the (homogeneous) image series used for response function. Use a series acquired close the clinical DAKR or DAK/image for fluoroscopy and acquisition modes.

4. Calculations
- Calculations of MTF and NPS are made according to IEC standards, or close to this standard given the constraints of the QC/clinical situation.
- The frequency where the MTF reaches 0.5 and 0.10 are recorded and followed over time.

20. Image Receptor lag (optional)

1. Purpose

Quantification of image receptor lag, and ghosting if relevant
Lag = signal transmission from a previous image in the current image.
Ghosting = reduction of the sensitivity of the image receptor due to preceding exposures.

Manufacturers are encouraged to make raw (for processing) data available or to implement the MITA working group documents (XR-27). This is recommended as soon as XR27 is available.

The test must be carried out if problems are suspected.
A rotating spoke phantom can be used to study and visualize problems with lag (cardiac applications)

2. Material, methods, acceptability criteria

Material	Lead test object to completely stop the X-ray beam and a thin test object.
Methods	Access to "for processing" (raw) data is necessary.
Acceptability criteria	Record of parameters and follow up in time.

3. Methods

- Select a program with a low frame rate.
- Set manual mode, 70 kV and 1 mm Cu at the x-ray tube, and mA(s) to get a clinically relevant DAKR or DAK/image.
- Select a commonly used field size (e.g. close to 42 cm or 25 cm, depending on system type)
- Start fluoroscopy and after a few images have been acquired, block the exposure of subsequent images with a radio-opaque sheet.
- Store the images and measure the linearized PV with a 5 x 5 mm ROI at the center of the image. Compare the linearized PV in the first image (I_0) with that in successive images (I_n).

4. Calculations

- Calculate:

$$L_n = \left(\frac{I_n - I_0}{I_0}\right)$$

where
L_n is defined as the "lag" in the n-th image
I_n is the pixel value in the n-th image,
I_0 is the pixel value in the first image.

- Compare with basic values or with data of similar devices.

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Appendix A.1 Tables of typical curves and remedial curves for system contrast detail analysis

Table A.1: Typical and remedial curves for **system** contrast detail analysis for each category and corresponding field size for **fluoroscopy** examination.

Treshold contrasts [%]		**Positioning**		**Orthopedics**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		25		42		25	
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	2.59	3.88	1.49	2.23	1.42	2.14	2.80	4.19
B	7.90	3.07	4.60	1.72	2.58	1.77	2.65	2.71	4.07
C	5.60	3.78	5.67	2.08	3.11	2.30	3.45	2.85	4.27
D	4.00	4.79	7.18	2.58	3.87	3.08	4.62	3.21	4.82
E	2.80	6.37	9.56	3.37	5.06	4.33	6.49	3.92	5.88
F	2.00	8.62	12.94	4.48	6.73	6.12	9.17	5.06	7.59
G	1.40	12.29	18.44	6.28	9.41	9.06	13.59	7.09	10.64
H	1.00	17.73	26.60	8.90	13.35	13.44	20.16	10.40	15.60
J	0.70	27.04	40.56	13.33	19.99	21.01	31.52	16.71	25.06
K	0.50	41.57	62.35	20.16	30.24	33.07	49.60	27.92	41.89
L	0.35	67.84	101.76	32.42	48.63	55.72	83.57	51.83	77.74
M	0.25	111.27	166.90	52.62	78.92	95.61	143.42	100.05	150.07

Table A.2: Typical and remedial **ESAKR corrected (at the reference point)** curves for **system** contrast detail analysis for each category and corresponding field size for **fluoroscopy** examination.

Treshold contrasts [%]		**Positioning**		**Orthopedics**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		25		42		25	
Ref. ESAKR [mGy/min]		4		20		10		7.5	
Group	Disc size [mm]	typical curve	remedial level	typical curve	remedial level	typical curve	remedial level	typical curve	remedial level
A	11.10	2.81	4.21	1.25	1.87	1.41	2.12	2.76	4.14
B	7.90	3.30	4.95	1.45	2.17	1.70	2.55	2.63	3.95
C	5.60	4.03	6.04	1.75	2.62	2.15	3.23	2.72	4.09
D	4.00	5.05	7.57	2.17	3.26	2.83	4.24	3.03	4.55
E	2.80	6.65	9.98	2.84	4.25	3.93	5.89	3.67	5.50
F	2.00	8.91	13.36	3.77	5.65	5.52	8.29	4.70	7.06
G	1.40	12.57	18.86	5.27	7.91	8.19	12.29	6.58	9.87
H	1.00	17.97	26.95	7.47	11.20	12.26	18.38	9.66	14.50
J	0.70	27.15	40.73	11.17	16.76	19.46	29.20	15.62	23.42
K	0.50	41.40	62.10	16.89	25.33	31.29	46.94	26.34	39.51
L	0.35	67.05	100.57	27.12	40.68	54.29	81.44	49.56	74.34
M	0.25	109.21	163.81	43.96	65.94	96.24	144.37	97.21	145.81

Table A.3: Typical and remedial curves for **system** contrast detail analysis for each category and corresponding field size for **acquisition** (cinegraphic examination).

Treshold contrasts [%]		**Ba-exams**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		42		25	
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	1.69	2.53	0.55	0.82	1.36	2.04
B	7.90	1.91	2.87	0.58	0.87	1.45	2.18
C	5.60	2.27	3.40	0.64	0.97	1.64	2.46
D	4.00	2.79	4.18	0.74	1.11	1.96	2.94
E	2.80	3.61	5.42	0.90	1.35	2.50	3.75
F	2.00	4.80	7.21	1.12	1.68	3.32	4.98
G	1.40	6.78	10.17	1.47	2.21	4.75	7.12
H	1.00	9.76	14.64	1.99	2.98	7.02	10.52
J	0.70	14.98	22.47	2.85	4.28	11.24	16.86
K	0.50	23.38	35.08	4.17	6.25	18.51	27.77
L	0.35	39.17	58.75	6.51	9.76	33.36	50.03
M	0.25	66.47	99.70	10.30	15.46	61.61	92.41

Table A.4: Typical and remedial **ESAKR or ESAK/pulse corrected** curves for **system** contrast detail analysis for each category and corresponding field size for **acquisition** (cinegraphic examination).

Treshold contrasts [%]		**Ba-exams**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		42		25	
Ref. ESAKR [mGy/min]						68	
Ref. ESAK/frame [µGy/pulse]		255		530			
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	1.53	2.29	0.62	0.93	1.11	1.66
B	7.90	1.71	2.56	0.66	0.99	1.16	1.73
C	5.60	2.00	3.00	0.73	1.10	1.29	1.93
D	4.00	2.43	3.65	0.84	1.26	1.52	2.28
E	2.80	3.12	4.69	1.02	1.52	1.92	2.88
F	2.00	4.12	6.18	1.26	1.90	2.55	3.82
G	1.40	5.77	8.66	1.67	2.50	3.65	5.48
H	1.00	8.26	12.39	2.25	3.37	5.43	8.15
J	0.70	12.62	18.93	3.23	4.84	8.80	13.21
K	0.50	19.61	29.42	4.72	7.09	14.74	22.11
L	0.35	32.72	49.08	7.38	11.07	27.16	40.74
M	0.25	55.35	83.03	11.72	17.57	51.58	77.37

Appendix A.2 Tables of typical curves and remedial curves for detector contrast detail analysis

Table A.5: Typical and remedial curves for **detector** contrast detail analysis for each category and corresponding field size for **fluoroscopy** examination (contrasts corrected for beam quality using the TO12 manual)

Treshold contrasts [%]		**Positioning**		**Orthopedics**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		25		42		25	
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	2.38	3.57	1.28	1.92	1.54	2.30	2.30	3.44
B	7.90	2.87	4.31	1.50	2.26	1.81	2.71	2.28	3.42
C	5.60	3.58	5.37	1.84	2.77	2.20	3.31	2.44	3.65
D	4.00	4.58	6.87	2.33	3.50	2.77	4.15	2.78	4.17
E	2.80	6.13	9.19	3.11	4.67	3.65	5.47	3.43	5.14
F	2.00	8.31	12.47	4.24	6.36	4.89	7.34	4.45	6.67
G	1.40	11.85	17.77	6.11	9.16	6.94	10.40	6.26	9.39
H	1.00	17.05	25.58	8.93	13.39	9.99	14.98	9.20	13.79
J	0.70	25.90	38.85	13.88	20.81	15.29	22.94	14.75	22.12
K	0.50	39.61	59.41	21.81	32.72	23.77	35.66	24.51	36.77
L	0.35	64.23	96.34	36.66	54.99	39.66	59.50	44.99	67.49
M	0.25	104.63	156.94	62.19	93.29	67.21	100.82	85.37	128.05

Table A.6: Typical and remedial detector **IAKR corrected** curves for **detector** contrast detail analysis for each category and corresponding field size for **fluoroscopy** examination (contrasts corrected for beam quality using the TO12 manual)

Treshold contrasts [%]		**Positioning**		**Orthopedics**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		25		42		25	
Ref. detector IAKR [µGy/sec]		0.30		0.35		0.47		0.35	
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	1.61	2.41	1.14	1.71	1.52	2.28	2.06	3.09
B	7.90	1.94	2.91	1.37	2.06	1.78	2.67	2.03	3.05
C	5.60	2.42	3.62	1.71	2.56	2.17	3.26	2.15	3.23
D	4.00	3.09	4.63	2.17	3.26	2.72	4.09	2.44	3.67
E	2.80	4.13	6.20	2.90	4.34	3.59	5.39	3.00	4.49
F	2.00	5.60	8.40	3.91	5.87	4.83	7.25	3.87	5.81
G	1.40	7.97	11.96	5.54	8.32	6.86	10.30	5.45	8.17
H	1.00	11.46	17.20	7.94	11.90	9.92	14.87	7.99	11.99
J	0.70	17.39	26.08	11.97	17.95	15.25	22.87	12.85	19.27
K	0.50	26.55	39.82	18.17	27.26	23.82	35.73	21.44	32.15
L	0.35	42.96	64.44	29.23	43.84	39.98	59.97	39.56	59.33
M	0.25	69.85	104.78	47.22	70.84	68.18	102.27	75.48	113.22

Table A.7: Typical and remedial curves for **detector** contrast detail analysis for each category and corresponding field size for **acquisition** (cinegraphic examination) (contrasts corrected for beam quality using the TO12 manual)

Treshold contrasts [%]		**Ba-exams**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		42		25	
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	1.17	1.75	0.43	0.64	1.20	1.81
B	7.90	1.24	1.87	0.52	0.78	1.30	1.95
C	5.60	1.39	2.09	0.64	0.96	1.49	2.23
D	4.00	1.63	2.45	0.80	1.20	1.80	2.70
E	2.80	2.03	3.05	1.05	1.57	2.35	3.52
F	2.00	2.61	3.92	1.38	2.07	3.18	4.77
G	1.40	3.58	5.37	1.90	2.85	4.66	6.99
H	1.00	5.04	7.57	2.62	3.93	7.06	10.60
J	0.70	7.60	11.40	3.78	5.68	11.63	17.45
K	0.50	11.71	17.56	5.49	8.23	19.68	29.52
L	0.35	19.41	29.12	8.36	12.53	36.47	54.70
M	0.25	32.76	49.15	12.75	19.12	69.10	103.65

Table A.8: Typical and remedial **detector IAKR** or **IAK/pulse dose corrected** curves for **detector** contrast detail analysis for each category and corresponding field size for **acquisition** (cinegraphic examination) (contrasts corrected for beam quality using the TO12 manual)

Treshold contrasts [%]		**Ba-exams**		**Angio/DSA**		**Cardiac**	
Field size diagonal, displayed [cm]		42		42		25	
Ref. detector IAKR [µGy/sec]						1.8	
Ref. detector IAK/frame [µGy/pulse]		1		1.3			
Group	*Disc size [mm]*	*typical curve*	*remedial level*	*typical curve*	*remedial level*	*typical curve*	*remedial level*
A	11.10	1.17	1.75	0.48	0.73	1.07	1.61
B	7.90	1.24	1.86	0.58	0.87	1.13	1.70
C	5.60	1.39	2.09	0.72	1.08	1.28	1.92
D	4.00	1.63	2.45	0.90	1.36	1.53	2.30
E	2.80	2.03	3.05	1.18	1.77	1.97	2.96
F	2.00	2.61	3.92	1.56	2.34	2.66	3.98
G	1.40	3.58	5.38	2.14	3.21	3.88	5.82
H	1.00	5.05	7.58	2.97	4.45	5.88	8.81
J	0.70	7.62	11.43	4.30	6.45	9.71	14.57
K	0.50	11.74	17.62	6.26	9.39	16.55	24.82
L	0.35	19.50	29.25	9.57	14.35	31.00	46.50
M	0.25	32.95	49.43	14.66	22.00	59.51	89.26

Appendix A.3 Calculation of contrast detail curves

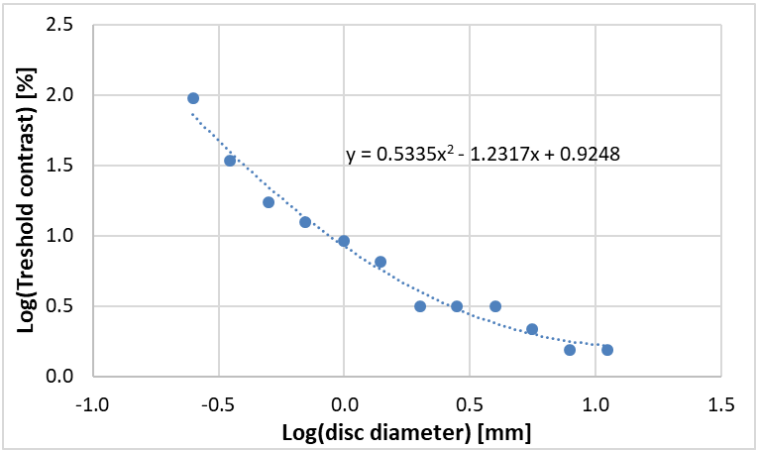
1. Use the manual of the manufacturer to calculate the contrast thresholds (C%) from the disc number with a given kV and added filtration. For system image quality use 70 kV and 1 mm Cu (the true contrasts are not known for the beam qualities). For detector image quality use the used kV and 2 mm Cu.

   Tabel A.9. Example of calculation from the disc number to contrast thresholds using the manual of Leeds testobject TO12 for system image quality using 70 kV and 1 mm Cu.

Group	*Disc diameter (d) [mm]*	*# discs*	*C%*
A	11.10	5.0	1.55
B	7.90	5.0	1.55
C	5.60	4.0	2.15
D	4.00	5.0	3.22
E	2.80	5.0	3.22
F	2.00	5.0	3.22
G	1.40	5.0	6.74
H	1.00	4.0	8.76
J	0.70	3.0	12.80
K	0.50	6.0	16.70
L	0.35	4.0	36.00
M	0.25	1.0	95.40

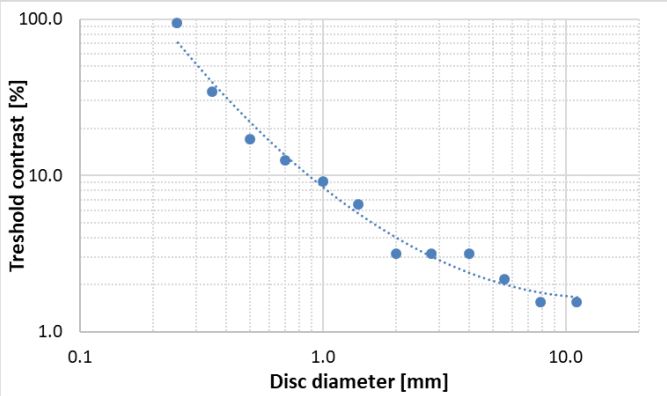
2. Apply a 2nd order polynomial curve fit to the log of the c-d data.

   $Log(C\%) = a.Log(d)^2 + b.Log(d) + c$



Log(d) [mm]	*Log(C%)*
1.05	0.19
0.90	0.19
0.75	0.33
0.60	0.51
0.45	0.51
0.30	0.51
0.15	0.83
0.00	0.94
-0.15	1.11
-0.30	1.22
-0.46	1.56
-0.60	1.98

3. Plot the curve fit on a logarithmic scale to visualize the c-d curve.



Appendix A.4 Determination of typical curves and remedial levels for contrast detail

Data was collected from contrast detail readings using TO12 for systems used for positioning, Ba-exams, orthopedics, angio and cardio. For each category a typical curve was calculated from the average curves of systems that showed typical performance.

To calculate the typical curve for dose corrected curves the contrast detail readings were calculated by choosing one of the readings as a reference for dose correction. After dose correction of each system, the average of the dose corrected curves was calculated and used as a typical curve. Dose correction is done with dose rate for categories where the pulse rate or frame rate is typically higher than 7.5 pulses per sec (for all fluoroscopic exams and cine cardio). Dose correction is done with dose/frame where the frame rates gets smaller than 7.5 frames per sec (for Ba-exams and cine angio).

The remedial levels were determined to be 150% of the typical curves, which means in practice that one can read one disc less than a typical performing system over the whole range of disc sizes. There is a factor of 2 difference in dose in order to see one disc more (or less).