IEC 62220-1-1

Edition 1.0 2015-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging

**Appareils électromédicaux – Caractéristiques des dispositifs d'imagerie à rayonnement X –
Partie 1-1: Détermination de l'efficacité quantique de détection – Détecteurs utilisés en imagerie radiographique**

IEC 62220-1-1:2015-03(en-fr)

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ICS 11.040.50 ISBN 978-2-8322-2389-5

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International Standard IEC 62220-1-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition of IEC 62220-1-1 cancels and replaces IEC 62220-1:2003. It constitutes a technical revision of IEC 62220-1:2003 and assures a better alignment with the other parts of the IEC 62220 series. The main changes are as follows:

– necessary modifications have been applied as a consequence of taking into account IEC 61267:2005. This influences HVL values and SNR_{in}^2;
– the method for the determination of LAG EFFECTS now considers lag and ghosting compensation;
– as part of the MTF determination, the method of obtaining the final averaged MTF has been restricted (only averaging of the ESF is allowed);

– a description of (optionally) obtaining the diagonal (45°) MTF and NPS has been added.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/968/FDIS	62B/974/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 62220 series, published under the general title *Medical electrical equipment – Characteristics of digital X-ray imaging devices*, can be found on the IEC website.

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60788, in Clause 3 of this standard or in other IEC publications referenced in the Index of defined terms. Where a defined term is used as a qualifier in another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined or recognized as a “derived term without definition”.

NOTE Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower-case letters.

In this standard, certain terms that are not printed in SMALL CAPITALS have particular meanings, as follows:

– "shall" indicates a requirement that is mandatory for compliance;
– "should" indicates a strong recommendation that is not mandatory for compliance;
– "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;
– "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;
– "specified" is used to indicate definitive information stated by the manufacturer in accompanying documents or in other documentation relating to the equipment under consideration, usually concerning its intended purposes, or the parameters or conditions associated with its use or with testing to determine compliance.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

DIGITAL X-RAY IMAGING DEVICES are increasingly used in medical diagnosis and are widely replacing conventional (analogue) imaging devices such as screen-film systems or analogue X-RAY IMAGE INTENSIFIER television systems. It is necessary, therefore, to define parameters that describe the specific imaging properties of these DIGITAL X-RAY IMAGING DEVICES and to standardize the measurement procedures employed.

There is general consensus in the scientific world that the DETECTIVE QUANTUM EFFICIENCY (DQE) is the most suitable parameter for describing the imaging performance of a DIGITAL X-RAY IMAGING DEVICE. The DQE describes the ability of the imaging device to preserve the signal-to-noise ratio from the RADIATION FIELD to the resulting digital image data. Since in X-ray imaging, the NOISE in the RADIATION FIELD is intimately coupled to the AIR KERMA level, DQE values can also be considered to describe the dose efficiency of a given DIGITAL X-RAY IMAGING DEVICE.

NOTE 1 In spite of the fact that the DQE is widely used to describe the performance of imaging devices, the connection between this physical parameter and the decision performance of a human observer is not yet completely understood [1], [3].[1]

NOTE 2 IEC 61262-5 specifies a method to determine the DQE of X-RAY IMAGE INTENSIFIERS at nearly zero SPATIAL FREQUENCY. It focuses only on the electro-optical components of X-RAY IMAGE INTENSIFIERS, not on the imaging properties as this standard does. As a consequence, the output is measured as an optical quantity (luminance), and not as digital data. Moreover, IEC 61262-5 prescribes the use of a RADIATION SOURCE ASSEMBLY, whereas this standard prescribes the use of an X-RAY TUBE. The scope of IEC 61262-5 is limited to X-RAY IMAGE INTENSIFIERS and does not interfere with the scope of this standard.

The DQE is already widely used by manufacturers to describe the performance of their DIGITAL X-RAY IMAGING DEVICE. The specification of the DQE is also required by regulatory agencies (such as the Food and Drug Administration (FDA)) for admission procedures. However, before the publication of the first edition of this standard there was no standard governing either the measurement conditions or the measurement procedure, with the consequence that values from different sources may not be comparable.

This standard has therefore been developed in order to specify the measurement procedure together with the format of the conformance statement for the DETECTIVE QUANTUM EFFICIENCY of DIGITAL X-RAY IMAGING DEVICES.

In the DQE calculations proposed in this standard, it is assumed that system response is measured for objects that attenuate all energies equally (task-independent) [5].

This standard will be beneficial for manufacturers, users, distributors and regulatory agencies.

This first edition of IEC 62220-1-1 forms part of a series of three related standards:

- Part 1-1, which is intended to be used for detectors used in radiographic imaging, excluding MAMMOGRAPHY and RADIOSCOPY;
- Part 1-2, which is intended to be used for detectors used in MAMMOGRAPHY;
- Part 1-3, which is intended to be used for detectors used in dynamic imaging.

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[1] Figures in square brackets refer to the bibliography.

MEDICAL ELECTRICAL EQUIPMENT – CHARACTERISTICS OF DIGITAL X-RAY IMAGING DEVICES –

Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging

1 Scope

This part of IEC 62220 specifies the method for the determination of the DETECTIVE QUANTUM EFFICIENCY (DQE) of DIGITAL X-RAY IMAGING DEVICES as a function of AIR KERMA and of SPATIAL FREQUENCY for the working conditions in the range of the medical application as specified by the MANUFACTURER. The intended users of this part of IEC 62220 are manufacturers and well equipped test laboratories.

NOTE 1 While not recommended, applying this standard to determine the DQE of digital X-ray imaging devices integrated in a clinical system is not excluded as long as the requirements as set in this standard are respected. Points of additional attention could be (for example but not exclusively) the establishment of the required RADIATION QUALITIES, minimizing influences of scattered and back-scattered radiation, accurate AIR KERMA measurements, positioning of the TEST DEVICE, presence of protective covers, removal of ANTI-SCATTER GRID.

This Part 1-1 is restricted to DIGITAL X-RAY IMAGING DEVICES that are used for radiographic imaging such as, but not exclusively, CR systems, direct and indirect flat panel-detector based systems.

It is not recommended to use this part of IEC 62220 for digital X-RAY IMAGE INTENSIFIER-based systems.

NOTE 2 The use of this standard for X-RAY IMAGE INTENSIFER-based systems is discouraged based on the low frequency drop, vignetting and geometrical distortion present in these devices which may put severe limitations on the applicability of the measurement methods described in this standard.

This part of IEC 62220 is not applicable to:

– DIGITAL X-RAY IMAGING DEVICES intended to be used in mammography or in dental radiography;

– slot scanning DIGITAL X-RAY IMAGING DEVICES;

– COMPUTED TOMOGRAPHY;

– devices for dynamic imaging (where series of images are acquired, as in fluoroscopy or cardiac imaging).

NOTE 3 The devices noted above are excluded because they contain many parameters (for instance, beam qualities, geometry, time dependence, etc.) which differ from those important for RADIOGRAPHY. Some of these techniques are treated in other parts of the IEC 62220 standards (IEC 62220-1-2 and IEC 62220-1-3).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60788:2004 and the following apply.

3.1
CALIBRATION CONDITIONS
set of conditions under which calibration is done

3.2
CENTRAL AXIS
line perpendicular to the ENTRANCE PLANE passing through the centre of the ENTRANCE FIELD

3.3
CONVERSION FUNCTION
plot of the large area output level (ORIGINAL DATA) of a DIGITAL X-RAY IMAGING DEVICE versus the number of exposure quanta per unit area (Q) in the DETECTOR SURFACE plane

Note 1 to entry: Q is to be calculated by multiplying the measured AIR KERMA excluding back scatter by the value given in column 2 of Table 3.

3.4
DETECTIVE QUANTUM EFFICIENCY
DQE
DQE(u,v)
ratio of two NOISE POWER SPECTRUM (NPS) functions with the numerator being the NPS of the input signal at the DETECTOR SURFACE of a digital X-ray detector after having gone through the deterministic filter given by the system transfer function, and the denominator being the measured NPS of the output signal (ORIGINAL DATA)

Note 1 to entry: Instead of the two-dimensional DETECTIVE QUANTUM EFFICIENCY, often a cut through the two-dimensional DETECTIVE QUANTUM EFFICIENCY along a specified SPATIAL FREQUENCY axis is published.

Note 2 to entry: The note to entry concerning the origin of the abbreviation "DQE" concerns the French text only.

3.5
DETECTOR SURFACE
accessible area which is closest to the IMAGE RECEPTOR PLANE

Note 1 to entry: After removal of all parts (including the ANTI-SCATTER GRID and components for AUTOMATIC EXPOSURE CONTROL, if applicable) that can be safely removed from the RADIATION BEAM without damaging the digital X-ray detector.

3.6
DIGITAL X-RAY IMAGING DEVICE
device consisting of a digital X-ray detector including the protective layers installed for use in practice, the amplifying and digitizing electronics, and a computer providing the ORIGINAL DATA (DN) of the image

Note 1 to entry: This may include protecting parts, such as ANTI-SCATTER GRIDS and components for AUTOMATIC EXPOSURE CONTROL.

3.7
IMAGE MATRIX
arrangement of matrix elements preferentially in a Cartesian coordinate system

3.8
LAG EFFECT
influence from a previous image on the current one

3.9
LINEARIZED DATA
ORIGINAL DATA to which an inverse CONVERSION FUNCTION has been applied

Note 1 to entry: LINEARIZED DATA are directly proportional to the AIR KERMA under the specific CALIBRATION CONDITIONS used.

Note 2 to entry: This is the data type that best indicates the fundamental performance of the detector and should be the data type used for "physics" testing of systems.

3.10
MODULATION TRANSFER FUNCTION
MTF(u,v)
modulus of the generally complex optical transfer function, expressed as a function of SPATIAL FREQUENCIES u and v

Note 1 to entry: The note to entry concerning the origin of the abbreviation «MTF» concerns the French text only.

3.11
NOISE
fluctuations from the expected value of a stochastic process

3.12
NOISE POWER SPECTRUM
NPS
W(u,v)
modulus of the Fourier transform of the NOISE auto-covariance function; the power of NOISE, contained in a two-dimensional SPATIAL FREQUENCY interval, as a function of the two-dimensional frequency

Note 1 to entry: In the literature, the NOISE POWER SPECTRUM is often named "Wiener spectrum" in honour of the mathematician Norbert Wiener.

Note 2 to entry: The note to entry concerning the origin of the abbreviation «NPS» concerns the French text only.

3.13
ORIGINAL DATA
DN
RAW DATA that has been processed to account for detector and x-ray system limitations as allowed in this standard

Note 1 to entry: The relation of the ORIGINAL DATA to the IMAGE RECEPTOR AIR KERMA may include a non-linear, e.g., logarithmic or square-root characteristic. If so, an inverse CONVERSION FUNCTION should be supplied to produce LINEARIZED DATA.

3.14
PHOTON FLUENCE
Q
mean number of photons per unit area

3.15
PRECISION
closeness of agreement between independent test results obtained under stipulated conditions

[SOURCE: ISO 5725-1:1994, 3.12, modified – the three notes in the original definition have been deleted.]

3.16
RAW DATA
PIXEL values read directly after the analogue-digital-conversion from the DIGITAL X-RAY IMAGING DEVICE or counts from photon counting systems that have not undergone any modification whose intent is to account for detector or x-ray system limitations

Note 1 to entry: Depending on system design, this data may not be accessible.

3.17
SPATIAL FREQUENCY
u* or *v
inverse of the period of a repetitive spatial phenomenon

Note 1 to entry: The dimension of the SPATIAL FREQUENCY is inverse length.

4 Requirements

4.1 Operating conditions

The DIGITAL X-RAY IMAGING DEVICE shall be stored and operated according to the MANUFACTURER'S recommendations. The warm-up time shall be chosen according to the recommendation of the MANUFACTURER. The operating conditions shall be the same as those intended for clinical use and shall be maintained during evaluation as required for the specific tests described herein.

Ambient climatic conditions in the room where the DIGITAL X-RAY IMAGING DEVICE is operated shall be stated together with the results.

4.2 X-RAY EQUIPMENT

For all tests described in the following subclauses, a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR is recommended (IEC 60601-2-54 [36]). The PERCENTAGE RIPPLE shall be equal to, or less than, 4.

The NOMINAL FOCAL SPOT VALUE (IEC 60336) shall be not larger than 1,2.

For the measuring of AIR KERMA, calibrated RADIATION METERS shall be used. The uncertainty (coverage factor 2) [2] of the measurements shall be less than 5 %.

NOTE "Uncertainty" and "coverage factor" are terms defined in the ISO/IEC Guide to the expression of uncertainty in measurement [2].

4.3 RADIATION QUALITY

The RADIATION QUALITIES shall be one or more of four selected RADIATION QUALITIES specified in IEC 61267:2005 (see Table 1). If only a single RADIATION QUALITY is used, RADIATION QUALITY RQA5 should be preferred.

NOTE 1 This first edition of IEC 62220-1-1 (which replaces the first edition of IEC 62220-1:2003) has changed its reference to the second edition of IEC 61267:2005 to establish the RADIATION QUALITIES. As a consequence of these changes in the RADIATION QUALITIES, the values of the input NOISE POWER SPECTRUM have been changed. New values are given in Table 1 and Table 3.

For this standard the RADIATION QUALITIES shall be established by setting a fixed X-RAY TUBE VOLTAGE as defined in Table 1 and adapting the ADDITIONAL FILTRATION (starting with the values as given in Table 1) until the correct HVL is reached with an uncertainty of ±2 %. This procedure is in line with 6.5 of IEC 62167:2005.

While IEC 61267:2005 requires the measurement of X-RAY TUBE VOLTAGE invasively in terms of the practical peak voltage (PPV), this standard allows for non-invasive measurement of

PPV and in cases when the X-RAY GENERATOR is a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR, the use of traditional kVp measurement. These X-RAY TUBE VOLTAGE measurements shall be performed using the RADIATION BEAM without the ADDITIONAL FILTRATION. As given in IEC 61267:2005 the X-RAY TUBE VOLTAGE shall be within an uncertainty of 1,5 kV or 1,5 %, whichever is larger.

NOTE 2 Commercial non-invasive X-RAY TUBE VOLTAGE measuring devices are available that support PPV measurements as well as traditional kVp measurements.

Table 1 – RADIATION QUALITY (IEC 61267:2005) for the determination of DETECTIVE QUANTUM EFFICIENCY and corresponding parameters

RADIATION QUALITY No.	X-RAY TUBE VOLTAGE kV	HALF-VALUE LAYER (HVL) mm Al	Approximate ADDITIONAL FILTRATION mm Al
RQA 3	50	3,8	10,0
RQA 5	70	6,8	21,0
RQA 7	90	9,2	30,0
RQA 9	120	11,6	40,0

NOTE 3 The ADDITIONAL FILTRATION is the filtration added to the inherent filtration of the X-RAY TUBE.

The capability of X-RAY GENERATORS to produce low AIR KERMA levels may not be sufficient, especially for RQA9. In this case, it is recommended that the FOCAL SPOT to DETECTOR SURFACE distance be increased.

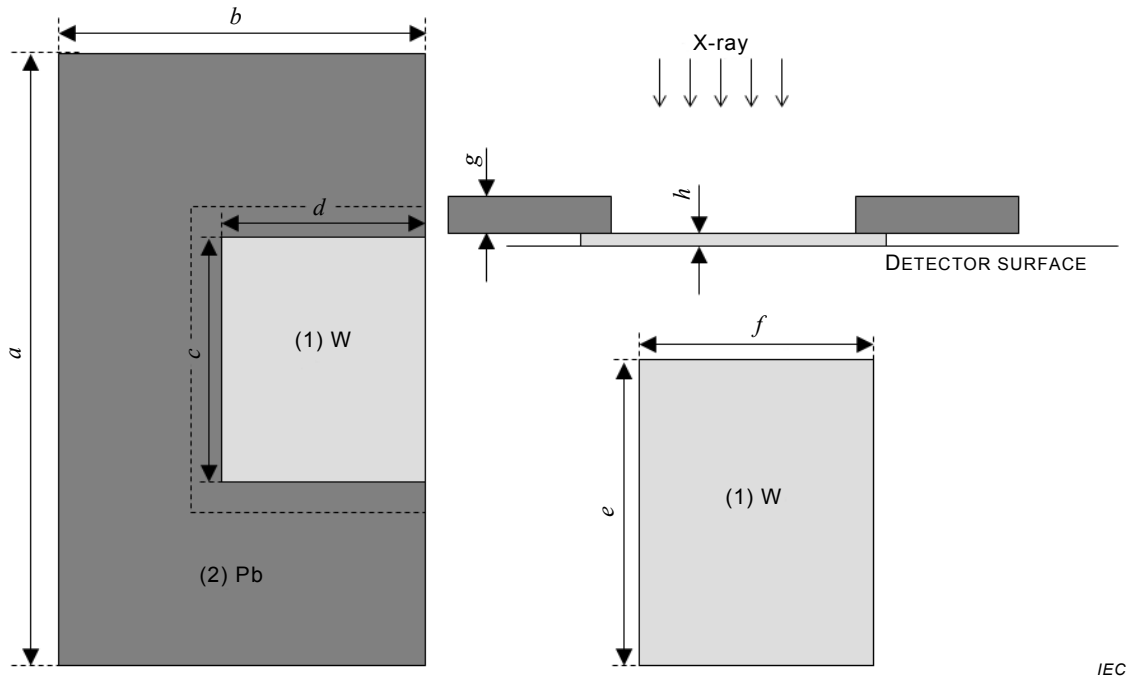
IEC 61267:2005 requires the purity of the aluminium used for the additional filtration to be at least 99,9 %. It has been shown [15] that these kinds of high purity aluminium metals are prone to kinds of non-uniformities which can significantly impact the NPS and hence the DQE determination. It is therefore recommended, contrary to the requirements given in IEC 61267:2005, to use lower purity aluminium filtration (99 % purity, also designated as type-1100).

4.4 TEST DEVICE

The TEST DEVICE for the determination of the MODULATION TRANSFER FUNCTION and the magnitude of LAG EFFECTS shall consist of a 1,0 mm thick tungsten plate (purity higher than 90 %) at least 100 mm long and at least 75 mm wide (see Figure 1). Inadequate purity of tungsten shall be compensated by increased thickness.

The tungsten plate is used as an edge TEST DEVICE. Therefore, the edge which is used for the test IRRADIATION shall be carefully polished straight and at 90° to the plate. If the edge is irradiated by X-rays in contact with a screenless film, the image on the film shall show no ripples on the edge larger than 5 μm.

The tungsten plate shall be fixed on a 3 mm thick lead plate (see Figure 1). This arrangement is suitable to measure the MODULATION TRANSFER FUNCTION of the DIGITAL X-RAY IMAGING DEVICE in one direction.



The TEST DEVICE consists of a tungsten plate (1) fixed on a lead plate (2). Dimension of the lead plate: a: 200 mm, b: 100 mm, c: 90 mm, d: 70 mm, g: 3 mm. Dimension of the tungsten plate: e: 100 mm, f: 75 mm, h: 1 mm.

Figure 1 – TEST DEVICE for the determination of the MODULATION TRANSFER FUNCTION and the magnitude of LAG EFFECTS

4.5 Geometry

The geometrical set-up of the measuring arrangement shall comply with Figure 2. The X-RAY EQUIPMENT is used in that geometric configuration in the same way as it is used for normal diagnostic applications. The distance between the FOCAL SPOT of the X-RAY TUBE and the DETECTOR SURFACE should be not less than 1,50 m. If, for technical reasons, the distance cannot be 1,50 m or more, a smaller distance can be chosen but has to be explicitly declared when reporting results. The REFERENCE AXIS shall be aligned with the CENTRAL AXIS.

This means that the line perpendicular to the ENTRANCE PLANE passing through the centre of the ENTRANCE FIELD shall be aligned with the line in the reference direction through the centre of the RADIATION SOURCE. The TEST DEVICE is placed immediately in front of the DETECTOR SURFACE. The centre of the edge of the TEST DEVICE should be aligned to the REFERENCE AXIS of the X-ray beam. Displacement from the REFERENCE AXIS will lower the measured MTF. The REFERENCE AXIS can be located by maximizing the MTF as a function of TEST DEVICE displacement.

The recommended procedure is that the TEST DEVICE and the X-ray field be centred on the detector. If this is not done, the position of the centre of the X-ray field and of the TEST DEVICE shall be stated.

In the set-up of Figure 2, the DIAPHRAGM B1 and the ADDED FILTER shall be positioned near the FOCAL SPOT of the X-RAY TUBE.

IEC 61267:2005 requires that the ADDED FILTER be placed between 200 mm and 300 mm from the FOCAL SPOT of the X-RAY TUBE. Due to SCATTERED RADIATION from the ADDED FILTER, this is however not the optimal distance for the intended use as given in this standard, as it will lower the measured MTF. Therefore, contrary to the requirement as given in IEC 61267:2005, it is recommended to keep the distance between the ADDED FILTER and the FOCAL SPOT of the X-RAY TUBE as small as possible. The DIAPHRAGMS B2 and B3 may be used to reduce the

effect from SCATTERED RADIATION generated in the ADDED FILTER that will adversely affect the MTF determination. The DIAPHRAGMS B1 and - if applicable - B2 and the ADDED FILTER shall be in a fixed relation to the position of the FOCAL SPOT. The DIAPHRAGM B3 – if applicable – and the DETECTOR SURFACE shall be in a fixed relation at each distance from the FOCAL SPOT. DIAPHRAGM B3 – if applicable – shall be 120 mm in front of the DETECTOR SURFACE and shall be of a size to allow an irradiated field at the DETECTOR SURFACE of at least 160 mm × 160 mm. The RADIATION APERTURE of DIAPHRAGM B2 may be made variable so that the beam remains tightly collimated as the distance is changed. The irradiated field at the DETECTOR SURFACE shall be at least 160 mm × 160 mm. All DIAPHRAGMS shall be square in shape.

The attenuating properties of the DIAPHRAGMS shall be such that their transmission into shielded areas does not contribute to the results of the measurements. The RADIATION APERTURE of the DIAPHRAGM B1 shall be large enough so that the PENUMBRA of the RADIATION BEAM will be outside the sensitive volume of the monitor detector R1 and the RADIATION APERTURE of DIAPHRAGM B2 – if applicable.

A monitor detector should be used to assure the PRECISION of the X-RAY GENERATOR. The monitor detector R1 may be inside the beam that irradiates the DETECTOR SURFACE if it is suitably transparent and free of structure; otherwise, it shall be placed outside of that portion of the beam that passes DIAPHRAGM B3. The PRECISION (standard deviation 1σ) of the monitor detector shall be better than 2 %. The relationship between the monitor reading and the AIR KERMA at the DETECTOR SURFACE shall be calibrated for each RADIATION QUALITY used (see also 4.6.2). In addition, the calibration of the monitor detector may be sensitive to the positioning of the ADDED FILTER and to the adjustment of the shutters built into the X-ray source. Therefore, these items should not be altered without re-calibrating the relationship between the monitor reading and the AIR KERMA at the DETECTOR SURFACE.

This geometry is used without TEST DEVICE to irradiate the DETECTOR SURFACE for the determination of the CONVERSION FUNCTION and the NOISE POWER SPECTRUM (see 4.6.4 and 4.6.5) or to irradiate the DETECTOR SURFACE behind the TEST DEVICE for the determination of the MTF and LAG EFFECTS (see 4.6.3 and 4.6.6).

For all measurements, the same area of the DETECTOR SURFACE shall be irradiated (exception see 4.6.6). The centre of this area, with respect to either the centre or the border of the DIGITAL X-RAY DEVICE, shall be recorded.

All measurements related to one RADIATION QUALITY shall be made using the same geometry. As stated in 4.3, the capability of X-RAY GENERATORS to produce low AIR KERMA levels may not be sufficient, especially for RQA9, and it is recommended that the FOCAL SPOT to DETECTOR SURFACE distance be increased in this case. To comply with the requirement as given above, it is therefore recommended to first determine the correct FOCAL SPOT to DETECTOR SURFACE distance before starting the measurements.