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Medical electrical equipment – Characteristics of digital X-ray imaging devices –

Part 1-2: Determination of the detective quantum efficiency – Detectors used in mammography

Appareils électromédicaux – Caractéristiques des dispositifs d'imagerie numérique à rayonnement X –

Partie 1-2: Détermination de l'efficacité quantique de détection – Détecteurs utilisés en mammographie

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 1-2: Determination of the detective quantum efficiency – Detectors used in mammography

FOREWORD

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International Standard IEC 62220-1-2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/649/FDIS	62B/656/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 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 maintenance result 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 will widely replace conventional (analogue) imaging devices such as screen-film systems or analogue X-RAY IMAGE INTENSIFIER television systems in the future. 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 growing consensus in the scientific world that the DETECTIVE QUANTUM EFFICIENCY (DQE) is the most suitable parameter for describing the imaging performance of an 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 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)]

The DQE is already widely used by manufacturers to describe the performance of their DIGITAL X-RAY IMAGING DEVICES. The specification of the DQE is also required by regulatory agencies (such as the Food and Drug Administration (FDA)) for admission procedures. However, there is presently 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. It is the second document out of a series of three related standards:

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

These standards can be regarded as the first part of the family of 62220 standards describing the relevant parameters of DIGITAL X-RAY IMAGING DEVICES.

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

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

Part 1-2: Determination of the detective quantum efficiency – Detectors used in mammography

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.

This Part 1-2 is restricted to DIGITAL X-RAY IMAGING DEVICES that are used for mammographic imaging such as but not exclusively, CR systems, direct and indirect flat panel detector based systems, scanning systems (CCD based or photon-counting). This part of IEC 62220 is not applicable to

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

– computed tomography;

and

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

NOTE 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 mammography. Some of these techniques are treated in separate standards (IEC 62220-1 and IEC 62220-1-3) as has been done for other topics, for instance for speed and contrast, in IEC and ISO standards.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 60601-2-45, *Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices*

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

IEC 62220-1:2003, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*

ISO 12232:1998, *Photography – Electronic still-picture cameras – Determination of ISO speed*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC 60788 which are listed in the Index of defined terms and the following apply.

3.1
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 Q is to be calculated by multiplying the measured AIR KERMA excluding back scatter by the value given in column 4 of Table 2.

NOTE 2 Many calibration laboratories, such as national metrology institutes, calibrate RADIATION METERS to measure AIR KERMA.

[IEC 62220-1:2003, definition 3.2, modified]

3.2
DETECTIVE QUANTUM EFFICIENCY
DQE(u,v)
ratio of two 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 Instead of the two-dimensional DETECTIVE QUANTUM EFFICIENCY, often a cut through the two-dimensional DETECTIVE QUANTUM EFFICIENCY along a specified line in the frequency plane is published.

[IEC 62220-1:2003, definition 3.3, modified]

3.3
DETECTOR SURFACE
accessible area which is closest to the IMAGE RECEPTOR PLANE

NOTE 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.

[IEC 62220-1:2003, definition 3.4, modified]

3.4
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

[IEC 62220-1:2003, definition 3.5]

3.5
IMAGE MATRIX
arrangement of MATRIX ELEMENTS preferentially in a Cartesian coordinate system

[IEC 62220-1:2003, definition 3.6, modified]

3.6
LAG EFFECT
influence from a previous image on a current one

[IEC 62220-1:2003, definition 3.7]

3.7
LINEARIZED DATA
ORIGINAL DATA to which the inverse CONVERSION FUNCTION has been applied

NOTE The LINEARIZED DATA are directly proportional to the AIR KERMA.

[IEC 62220-1:2003, definition 3.8]

3.8
MODULATION TRANSFER FUNCTION
MTF(u,v)
modulus of the generally complex optical transfer function, expressed as a function of SPATIAL FREQUENCIES u and v

[IEC 62220-1:2003, definition 3.9]

3.9
NOISE
fluctuations from the expected value of a stochastic process

[IEC 62220-1:2003, definition 3.10]

3.10
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 In literature, the NOISE POWER SPECTRUM is often named “Wiener spectrum” in honour of the mathematician Norbert Wiener.

[IEC 62220-1:2003, definition 3.11]

3.11
ORIGINAL DATA
DN
RAW DATA to which the corrections allowed in this standard have been applied

[IEC 62220-1:2003, definition 3.12]

3.12
PHOTON FLUENCE
Q
mean number of photons per unit area

[IEC 62220-1:2003, definition 3.13]

3.13
RAW DATA
PIXEL values read directly after the analogue-digital-conversion from the DIGITAL X-RAY IMAGING DEVICE or counts from photon counting systems without any software corrections

[IEC 62220-1:2003, definition 3.14, modified]

3.14
SPATIAL FREQUENCY
u* or *v
inverse of the period of a repetitive spatial phenomenon. The dimension of the SPATIAL FREQUENCY is inverse length

[IEC 62220-1:2003, definition 3.15]

4 Requirements

4.1 Operating conditions

The DIGITAL X-RAY IMAGING DEVICE shall be stored and operated according to the MANUFACTURERS' 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 shall be used (IEC 60601-2-45). The PERCENTAGE RIPPLE shall be equal to, or less than, 4.

The NOMINAL FOCAL SPOT VALUE (IEC 60336) shall be not larger than 0,4.

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

NOTE 1 "Uncertainty" and "coverage factor" are terms defined in the ISO Guide to the expression of uncertainty in measurement [2].

NOTE 2 RADIATION METERS to read AIR KERMA are calibrated by many national metrology institutes.

4.3 RADIATION QUALITY

The RADIATION QUALITY shall be RQA-M 2 as specified in IEC 61267, if relevant for the clinical use for that detector. Optionally other RADIATION QUALITIES may be used that are applied clinically with the DIGITAL X-RAY IMAGING DEVICE, such as RQA-M 1, RQA-M 3, and RQA-M 4 or RADIATION QUALITIES based on anode materials other than Molybdenum (see Table 1).

For the application of the RADIATION QUALITIES, refer to IEC 61267:2005-11.

NOTE According to IEC 61267 RADIATION QUALITIES RQA-M are defined by emitting TARGET of molybdenum, TOTAL FILTRATION of 0,032 mm ± 0,002 mm molybdenum in the radiation source assembly, ADDED FILTER of 2 mm aluminium (Table 1).

Table 1 – RADIATION QUALITY for the determination of DETECTIVE QUANTUM EFFICIENCY and corresponding parameters

Standard RADIATION QUALITY characterization (IEC 61267)	Filter thickness mm	Nominal X-RAY TUBE VOLTAGE kV	NOMINAL FIRST HALF-VALUE LAYER (HVL) mm Al	ADDED FILTER mm aluminium
Mo/Mo (RQA-M 1)	0,032	25	0,56	2
Mo/Mo (RQA-M 2)	0,032	28	0,60	2
Mo/Mo (RQA-M 3)	0,032	30	0,62	2
Mo/Mo (RQA-M 4)	0,032	35	0,68	2
Mo/Rh	0,025	28	0,65	2
Rh/Rh	0,025	28	0,74	2
W/Rh	0,050	28	0,75	2
W/Al	0,500	28	0,83	2

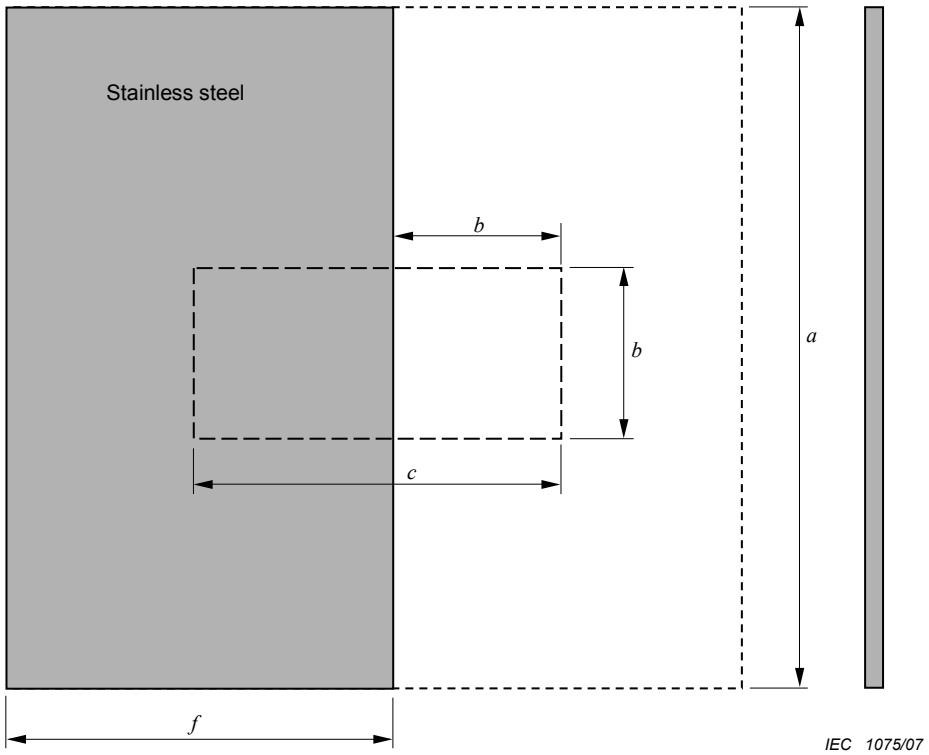
It is noted that several mammograhy systems do not use molybdenum target and filter but other target and/or filter materials such as but not exclusively, rhodium target with rhodium filtration or tungsten target with aluminium filtration (Table 1). In the case that a RADIATION QUALITY other than those mentioned in Table 1 is used it shall be explicitly stated in the conformance statement including target material, filter material and thickness, X-RAY TUBE VOLTAGE, HALF-VALUE LAYER (HVL) in mm Al and the used value for SNR_{in}^2 (see also 6.2).

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 stainless steel plate (type 304 stainless steel) with minimum dimensions: 0,8 mm thick, 120 mm long and 60 mm wide, covering half the irradiated field (see Figure 1).

The stainless steel 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.

As an alterative, it is also allowed to use the TEST DEVICE as specified in IEC 62220-1.



NOTE The TEST DEVICE consists of a 0,8 mm (minimum) thick stainless steel plate

Minimum dimensions of the plate: *a*: 120 mm, *f*: 60 mm.

The region of interest (ROI) used for the determination of the MTF is defined by $b \times c$, 25 mm × 50 mm (inner dotted line).

The irradiated field on the detector (outer dotted line) is at least 100 mm × 100 mm

Figure 1 – TEST DEVICE

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 between 600 mm and 700 mm. If, for technical reasons, a distance within this range cannot be achieved, a different distance can be chosen but has to be explicitly declared when reporting results.

The TEST DEVICE is placed immediately in front of the DETECTOR SURFACE. The centre of the edge of the TEST DEVICE is placed 60 mm from the centre of the chest wall side of the detector. The irradiated area of the DETECTOR SURFACE shall be 100 mm by 100 mm, with the centre of this area 60 mm from the centre of the chest wall side of the detector.

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. The DIAPHRAGM B2 should be used, but may be omitted if it is proven that this does not change the result of the measurements.

A monitor detector should be used to assure the precision of the X-RAY GENERATOR. The monitor detector R1 shall be placed outside of that portion of the beam that passes DIAPHRAGM B2. 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. When calibrating this relationship, care shall be taken that the reading of the RADIATION METER is not influenced by radiation back-scattered from any equipment behind the RADIATION METER. In any case, it shall

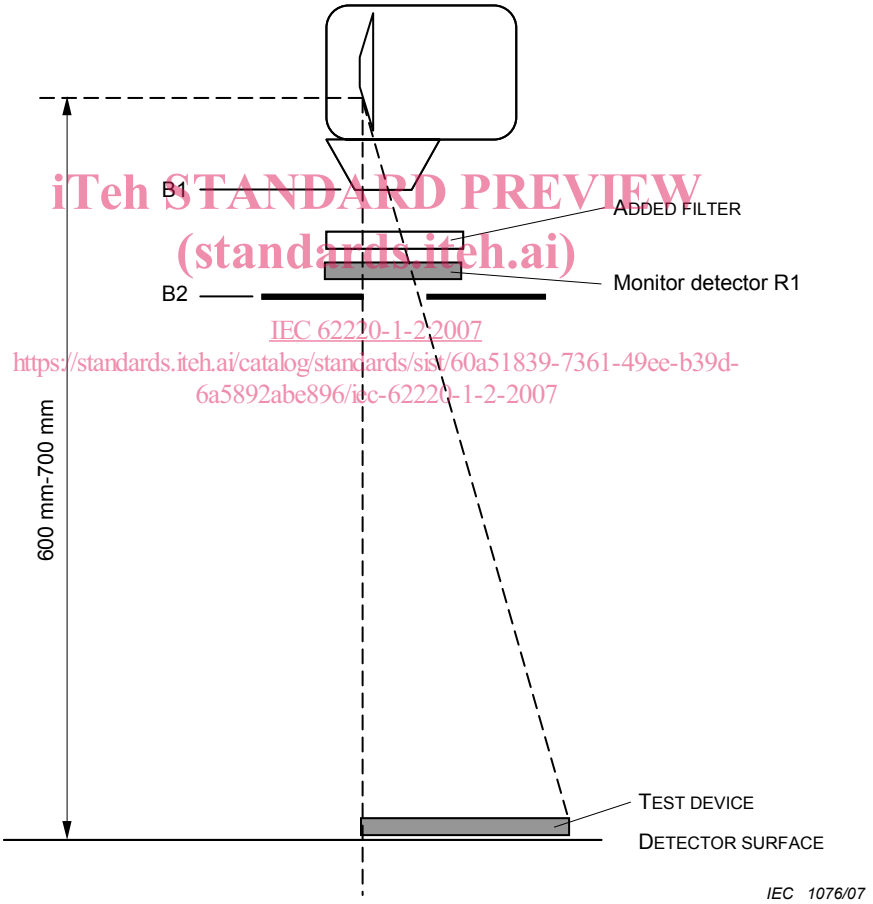
be checked that the monitor detector does not influence the measurement of the CONVERSION FUNCTION, of the MTF, or of the NOISE POWER SPECTRUM. To minimize the effect of back-scatter from layers behind the detector, a minimum distance of 250 mm to other objects should be provided.

NOTE The calibration procedure 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-measuring the calibration of the monitor detector.

This geometry is used either to irradiate the DETECTOR SURFACE uniformly for the determination of the CONVERSION FUNCTION and the NOISE POWER SPECTRUM or to irradiate the DETECTOR SURFACE behind a TEST DEVICE (see 4.6.6). For all measurements, the same area of the DETECTOR SURFACE shall be irradiated.

All measurements shall be made using the same geometry.

For the determination of the NOISE POWER SPECTRUM and the CONVERSION FUNCTION, the TEST DEVICE shall be moved out of the beam.



NOTE The TEST DEVICE is not used for the measurement of the CONVERSION FUNCTION and the NOISE POWER SPECTRUM.

Figure 2 – Geometry for exposing the DIGITAL X-RAY IMAGING DEVICE in order to determine the CONVERSION FUNCTION, the NOISE POWER SPECTRUM or the MODULATION TRANSFER FUNCTION behind the TEST DEVICE

4.6 IRRADIATION conditions

4.6.1 General conditions

The calibration of the digital X-ray detector shall be carried out prior to any testing, i.e., all operations necessary for corrections according to Clause 5 shall be effected. The whole

series of measurements shall be done without re-calibration. Offset calibrations are excluded from this requirement. They can be performed as in normal clinical use.

The exposure level shall be chosen as that used when the digital X-ray detector is operated for the intended use in clinical practice. This is called the “reference“ level and shall be specified by the MANUFACTURER. At least two additional exposure levels shall be chosen, one 2 times the “reference“ level and one at 1/2 of the “reference“ level. No change of system settings (such as gain etc.) shall be allowed when changing exposure levels.

To cover the range of various clinical examinations, additional levels may be chosen. For these additional levels other system settings may be chosen and kept constant during the test procedure.

The variation of AIR KERMA shall be carried out by variation of the X-RAY TUBE CURRENT or the IRRADIATION TIME or both. The IRRADIATION TIME shall be similar to the conditions for clinical application of the digital X-ray detector. LAG EFFECTS shall be avoided (see 4.6.3).

The IRRADIATION conditions shall be stated together with the results (see Clause 7).

4.6.2 AIR KERMA measurement

The AIR KERMA at the DETECTOR SURFACE is measured with an appropriate RADIATION METER. For this purpose, the digital X-ray detector is removed from the beam and the RADIATION DETECTOR of the RADIATION METER is placed in the DETECTOR SURFACE plane. Care shall be taken to minimize the back-SCATTERED RADIATION. The correlation between the readings of the RADIATION METER and the monitoring detector, if used, shall be noted and shall be used for the AIR KERMA calculation at the DETECTOR SURFACE when irradiating the DETECTOR SURFACE to determine the CONVERSION FUNCTION, the NOISE POWER SPECTRUM and the MTF. It is recommended that about five exposures be monitored and that the average be used for the correct AIR KERMA.

For scanning devices with pre-patient collimator the AIR KERMA shall be measured after this beam limiting device.

If it is not possible to remove the digital X-ray detector out of the beam, the AIR KERMA at the DETECTOR SURFACE may be calculated via the inverse square distance law. For that purpose, the AIR KERMA is measured at different distances from the FOCAL SPOT in front of the DETECTOR SURFACE. For this measurement, radiation, back-scattered from the DETECTOR SURFACE, shall be avoided. Therefore, a distance between the DETECTOR SURFACE and the RADIATION DETECTOR of 100 mm to 200 mm is recommended.

NOTE 1 Air attenuation must be taken into account.

NOTE 2 If the pre-patient collimator is a multi-slit collimator, the exposure must be integrated during a scan. Multi-slit collimators will result in an inhomogeneous radiation field to the RADIATION DETECTOR; therefore a longer scan over the RADIATION DETECTOR is needed to get the correct reading.

If a monitoring detector is used, the following equation shall be plotted as a function of the distance d between the FOCAL SPOT and the RADIATION DETECTOR:

$$f(d) = \sqrt{\frac{\text{monitor detector reading}}{\text{radiation detector reading}}}$$

By extrapolating this approximately linear curve up to the distance between the FOCAL SPOT and the DETECTOR SURFACE r_{SID}, the ratio of the readings at r_{SID} can be obtained and the AIR KERMA at the DETECTOR SURFACE for any monitoring detector reading can be calculated.