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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-3: Determination of the detective quantum efficiency – Detectors used in dynamic imaging

**Appareils électromédicaux – Caractéristiques des dispositifs d'imagerie numérique à rayonnement X –
Partie 1-3: Détermination de l'efficacité quantique de détection – Détecteurs utilisés en imagerie dynamique**

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FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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International Standard IEC 62220-1-3 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/694/FDIS	62B/702/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 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 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, 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 third document out of a series of three related standards:

- Part 1, which is intended to be used in RADIOGRAPHY, excluding MAMMOGRAPHY and RADIOSCOPY.
- Part 1-2, which is intended to be used for MAMMOGRAPHY.
- the present 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 IEC 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 1-3: Determination of the detective quantum efficiency – Detectors used in dynamic 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.

This Part 1-3 is restricted to DIGITAL X-RAY IMAGING DEVICES that are used for dynamic imaging such as, but not exclusively, 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 1 This negative recommendation is 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;
- COMPUTED TOMOGRAPHY; and
- systems in which the X-ray field is scanned across the patient.

NOTE 2 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 dynamic imaging. Some of these techniques are treated in separate standards (IEC 62220-1 and IEC 62220-1-2).

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 61267:1994,[2] *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

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

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[2] Although a second edition (2005) of IEC 61267 exists, reference to the first edition (IEC 61267:1994) is expressly retained throughout this standard for reasons of harmonization within the IEC62220 family. (See 4.3, Note 1.)

3 Terms and definitions

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

3.1
CENTRAL AXIS
line perpendicular to the ENTRANCE PLANE passing through the centre of the entrance field

[IEC 62220-1:2003, definition 3.1]

3.2
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

[IEC 62220-1:2003, definition 3.2]

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

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

3.3
DETECTIVE QUANTUM EFFICIENCY
$DQE(u,v)$
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 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.

[IEC 62220-1:2003, definition 3.3]

3.4
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]

3.5
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]

3.6
IMAGE MATRIX
arrangement of matrix elements preferentially in a Cartesian coordinate system

[IEC 62220-1:2003, definition 3.6]

3.7
LAG EFFECT
influence from a previous image on the current one

[IEC 62220-1:2003, definition 3.7]

3.8
LINEARIZED DATA
ORIGINAL DATA to which the inverse CONVERSION FUNCTION has been applied

[IEC 62220-1:2003, definition 3.8]

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

3.9
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]

3.10
NOISE
fluctuations from the expected value of a stochastic process

[IEC 62220-1:2003, definition 3.10]

3.11
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]

3.12
ORIGINAL DATA
DN
RAW DATA to which the corrections allowed in this standard have been applied

[IEC 62220-1:2003, definition 3.12]

3.13
PHOTON FLUENCE
Q
mean number of photons per unit area

[IEC 62220-1:2003, definition 3.13]

3.14
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]

3.15
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 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 including the frame rate 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 60601-2-7). 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 1 "Uncertainty" and "coverage factor" are terms defined in the ISO/IEC Guide to the expression of uncertainty in measurement [2].

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

4.3 RADIATION QUALITY

The RADIATION QUALITIES shall be one or more out of four selected RADIATION QUALITIES specified in IEC 61267:1994 (see Table 1). If only a single RADIATION QUALITY is used, RADIATION QUALITY RQA5 should be preferred.

For the application of the RADIATION QUALITIES, refer to IEC 61267:1994.

NOTE 1 Although a more recent edition of IEC 61267 is available, this standard will keep its reference to IEC 61267:1994 for reasons of harmonization within the IEC 62220 family. In addition, IEC 61267:2005 puts severe requirements on the practical realization of the RADIATION QUALITIES. These requirements are not necessary for the intended use in this standard.

NOTE 2 According to IEC 61267:1994, RADIATION QUALITIES are defined by a fixed ADDITIONAL FILTRATION and a HALF-VALUE LAYER that is realized with this filtration by a suitable adaptation of the X-RAY TUBE VOLTAGE, starting from the approximate X-RAY TUBE VOLTAGE (Table 1).

Table 1 – RADIATION QUALITY (IEC 61267:1994) for the determination of DETECTIVE QUANTUM EFFICIENCY and corresponding parameters

RADIATION QUALITY No.	Approximate X-RAY TUBE VOLTAGE kV	HALF-VALUE LAYER (HVL) mm Al	ADDITIONAL FILTRATION mm Al
RQA 3	50	4,0	10,0
RQA 5	70	7,1	21,0
RQA 7	90	9,1	30,0
RQA 9	120	11,5	40,0

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

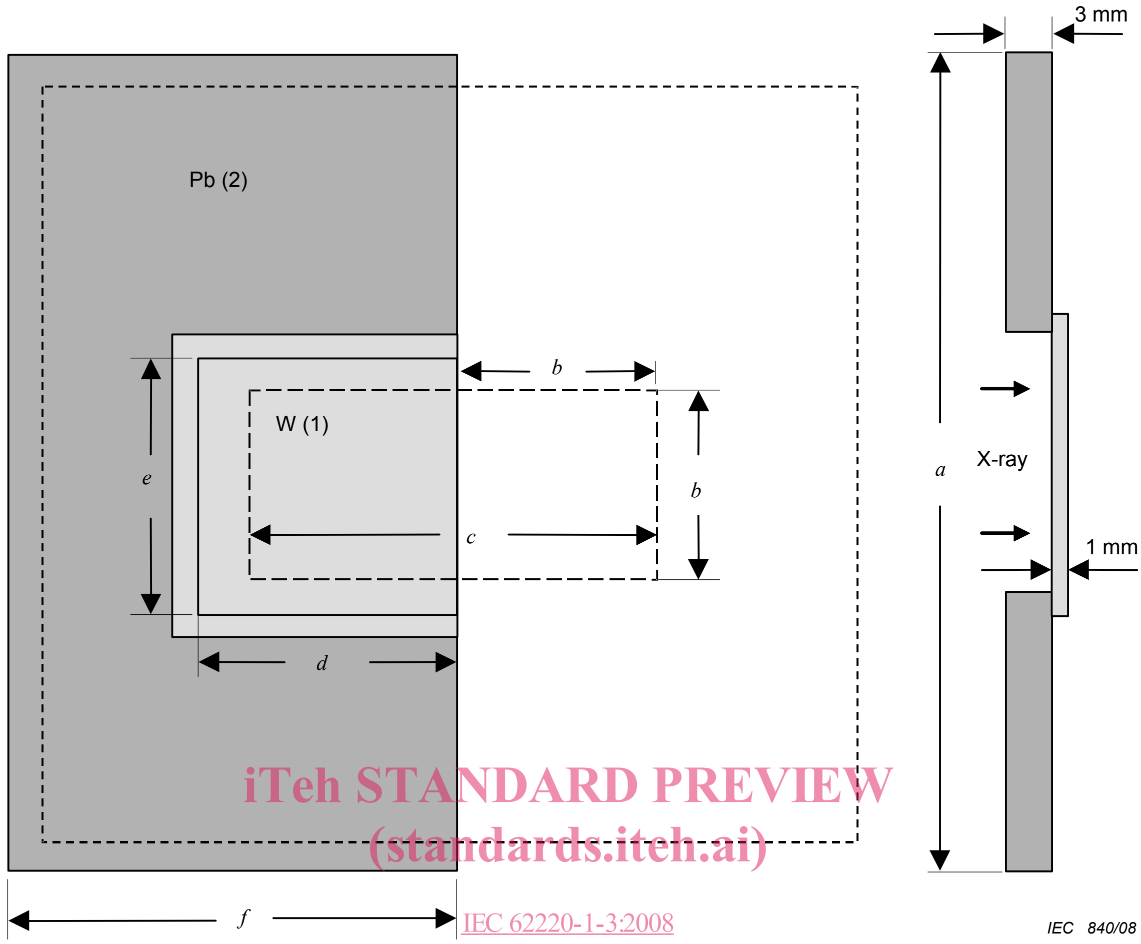
NOTE 4 The capability of X-RAY GENERATORS to produce low AIR KERMA levels may not be sufficient, especially for RQA9. In this case, it is recommended that the distance FOCAL SPOT to DETECTOR SURFACE be increased.

4.4 TEST DEVICE

The TEST DEVICE for the determination of the MODULATION TRANSFER FUNCTION shall consist of a 1,0 mm thick tungsten plate (purity higher than 90 %) 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.



NOTE The TEST DEVICE consists of a 1,0 mm thick tungsten plate (1) fixed on a 3 mm thick lead plate (2).

Dimension of the lead plate: *a:* 200 mm, *d:* 70 mm, *e:* 90 mm, *f:* 100 mm.

Dimension of the tungsten plate: 100 mm × 75 mm.

The region of interest (ROI) used for the determination of the MTF is defined by $b \times c$, 50 mm × 100 mm (inner long dashed line).

The irradiated field on the detector (outer dashed line) is at least 160 mm × 160 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 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.

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 needs to 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. The diaphragms B2 and B3 should be used, but may be omitted if it is proven that this does not change the result of the measurements. 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. The square 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.

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 aperture 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). To minimize the effect of back-scatter from layers behind the detector, a minimum distance of 500 mm to other objects should be provided.

NOTE 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-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. The centre of this area, with respect to either the centre or the border of the digital X-ray detector, shall be recorded.

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.