INTERNATIONAL STANDARD

IEC 62220-1

First edition
2003-10

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

Appareils électromédicaux –
Caractéristiques des appareils d'imagerie à rayonnement X –
Partie 1: Détermination de l'efficacité quantique de détection

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 1: Determination of the detective quantum efficiency

FOREWORD

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International Standard IEC 62220-1 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/493/FDIS	62B/506/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.

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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 Annex B. 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.

The committee has decided that the contents of this publication will remain unchanged until 2006-12. At this date, the publication will be

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- withdrawn;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

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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 exposure level, DQE values can also be considered to describe the dose efficiency of a given 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 The standard 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 equipment. 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.

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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.

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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].

The standard will be beneficial for manufacturers, users, distributors and regulatory agencies. It can be regarded as the first of a series describing all 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: Determination of the detective quantum efficiency

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 exposure and of SPATIAL FREQUENCY for the working conditions in the range of the medical application as specified by the MANUFACTURER.

This part of IEC 62220 is applicable to projection DIGITAL X-RAY IMAGING DEVICES producing IMAGES in digital format that are used for medical diagnosis. It is restricted to DIGITAL X-RAY IMAGING DEVICES that are used for radiographic imaging, such as CR systems, selenium-based systems, flat panel detectors, optically coupled CCD detectors, and digital X-RAY IMAGE INTENSIFIERS used for single exposures.

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;
– systems in which the X-ray field is scanned across the patient; 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 general radiography. It is intended to treat some of these techniques in separate standards as has been done for other topics, for instance for speed and contrast, in IEC and ISO standards.

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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 60336:1993, *X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60601-2-7: *Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61267:1994, *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*

3 Terminology and definitions

For the purposes of this part of IEC 62220 the following terms and definitions apply.

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

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

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

NOTE 2 Usually AIR KERMA is substituted for exposure.

NOTE 3 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.

3.4
DETECTOR SURFACE
area which is closest to the IMAGE RECEPTOR PLANE with all protecting parts (including the ANTI-SCATTER GRID and components for AUTOMATIC EXPOSURE CONTROL, if applicable) that can be safely removed out of the RADIATION BEAM without damaging the digital X-ray detector

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

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

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

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

NOTE The LINEARIZED DATA are directly proportional to the exposure.

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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

3.10
NOISE
fluctuations from the expected value of a stochastic process

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.

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

3.13
PHOTON FLUENCE
Q
mean number of photons per unit area

3.14
RAW DATA
pixel values read directly after the analogue-digital-conversion from the DIGITAL X-RAY IMAGING DEVICE without any software corrections

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

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 shall be used (IEC 60601-2-7). The PERCENTAGE RIPPLE shall be equal to, or less than, 4.

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

For the measurement of exposure, calibrated RADIATION METERS shall be used. The uncertainty (coverage factor 2)[2] of the readings 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, 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 (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 According to IEC 61267, 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 2 The additional filtration is the filtration added to the inherent filtration of the X-RAY TUBE.

NOTE 3 The capability of X-RAY GENERATORS to produce low exposure levels may not be sufficient, especially for RQA9. In this case, it is recommended that the distance FOCAL SPOT to DETECTOR SURFACE be increased.

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