BS EN 62220-1-1:2015

BSI Standards Publication

Medical electrical equipment — Characteristics of digital x-ray imaging devices

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

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National foreword

This British Standard is the UK implementation of EN 62220-1-1:2015. It is identical to IEC 62220-1-1:2015. It supersedes BS EN 62220-1:2004, which will be withdrawn on 16 April 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging (IEC 62220-1-1:2015)

Appareils électromédicaux - Caractéristiques des appareils d'imagerie à rayonnements x - Partie 1-1: Détermination de l'efficacité quantique de détection - Détecteurs utilisés en imagerie radiographique (IEC 62220-1-1:2015)

Medizinische elektrische Geräte - Merkmale digitaler Röntgenbildgeräte - Teil 1-1: Bestimmung der detektiven Quanten-Ausbeute - Bildempfänger für Röntgenbildgebung (IEC 62220-1-1:2015)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62B/968/FDIS, future edition 2 of IEC 62220-1-1, prepared by SC 62B, "Diagnostic imaging equipment", of IEC TC 62, "Electrical equipment in medical practice " was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62220-1-1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-16
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-16

This document supersedes EN 62220-1:2004.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 62220-1-1:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 62220-1-3:2008	NOTE	Harmonized as EN 62220-1-3:2008.
IEC 62220-1-2:2007	NOTE	Harmonized as EN 62220-1-2:2007.
IEC 61262-5:1994	NOTE	Harmonized as EN 61262-5:1994.
IEC 60601-2-54	NOTE	Harmonized as EN 60601-2-54.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-
IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EC Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives can be applied to the products falling within the scope of this standard.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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

FOREWORD

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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*