Elektrilised meditsiiniseadmed. Digitaal-röntgenpildiseadmete karakteristikud. Osa 1-3: Tuvastuskvantsaagise määramine. Dünaamilisel kuvamisel kasutatavad detektorid

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 62220-1-3:2008 sisaldab Euroopa standardi EN 62220-1-3:2008 ingliskeelset teksti.	This Estonian standard EVS-EN 62220-1-3:2008 consists of the English text of the European standard EN 62220-1-3:2008.
Standard on kinnitatud Eesti Standardikeskuse 20.10.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 20.10.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 03.09.2008.	Date of Availability of the European standard text 03.09.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.50

EUROPEAN STANDARD

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English version

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

(IEC 62220-1-3:2008)

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 (CEI 62220-1-3:2008)

Medizinische elektrische Geräte - Merkmale digitaler Röntgenbildgeräte - Teil 1-3: Bestimmung der detektiven Quanten-Ausbeute - Bildempfänger für dynamische Bildgebung (IEC 62220-1-3:2008)

This European Standard was approved by CENELEC on 2008-07-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

The text of document 62B/694/FDIS, future edition 1 of IEC 62220-1-3, 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 was approved by CENELEC as EN 62220-1-3 on 2008-07-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2009-04-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2011-07-01

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC/TR 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.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 62220-1-3:2008 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	NOTE	Harmonized as EN 62220-1:2004 (not modified).
IEC 62220-1-2	NOTE	Harmonized as EN 62220-1-2:2007 (not modified).
IEC 61262-5	NOTE	Harmonized as EN 61262-5:1994 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

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

Publication	Year	Title	EN/HD	Year
IEC 60336	-[1)]	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	2005[2)]
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61267	1994	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267[3)]	1994
ISO 12232	1998	Photography - Electronic still-picture cameras - Determination of ISO speed	-	-

[1)] Undated reference.

[2)] Valid edition at date of issue.

[3)] IEC 61267:2005 is harmonised as EN 61267:2006 (not modified).

Annex ZZ
(informative)

Coverage of Essential Requirements of EC 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 as given in Annex I of the EC Directive 93/42/EEC

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 may be applicable to the products falling within the scope of this standard.

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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 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.

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1) Figures in square brackets refer to the bibliography.

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

Part 1-3: 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.)