SLOVENSKI STANDARD
SIST EN 62220-1-2:2007

01-november-2007

Električna medicinska oprema – Karakteristike digitalnih rentgenskih naprav – 1-2. del: Določanje kvantnega izkoristka zaznavanja – mamografski detektor (IEC 62220 -1-2:2007)

Medical electrical equipment - Characteristics of digital X-ray imaging devices -- Part 1-2: Determination of the detective quantum efficiency - Mammography detectors (IEC 62220 -1-2:2007)

Medizinische elektrische Geräte - Merkmale digitaler Röntgenbildgeräte - Teil 1-2: Bestimmung der detektiven Quanten-Ausbeute - Bildempfänger für Mammographieeinrichtungen (IEC 62220-1-2:2007)

Appareils électromédicaux - Caractéristiques des dispositifs d'imagerie numérique a rayonnement X -- Partie 1-2: Détermination de l'efficacité quantique de détection - Détecteurs utilisés en mammographie (IEC 62220-1-2:2007)

Ta slovenski standard je istoveten z: **EN 62220-1-2:2007**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 62220-1-2:2007 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62220-1-2

September 2007

ICS 11.040.50

English version

Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography

(IEC 62220-1-2:2007)

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 (CEI 62220-1-2:2007)

Medizinische elektrische Geräte - Merkmale digitaler Röntgenbildgeräte - Teil 1-2: Bestimmung der detektiven Quanten-Ausbeute - Bildempfänger für Mammographieeinrichtungen (IEC 62220-1-2:2007)

This European Standard was approved by CENELEC on 2007-09-01. 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

Ref. No. EN 62220-1-2:2007 E

Foreword

The text of document 62B/649/FDIS, future edition 1 of IEC 62220-1-2, 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 62220-1-2 on 2007-09-01.

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)	2008-06-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-09-01

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

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 62220-1-2:2007 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

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 60601-2-45	-[1)]	Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices	EN 60601-2-45	2001[2)]
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC 62220-1	2003	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency	EN 62220-1	2004
ISO 12232	1998	Photography - Electronic still-picture cameras - Determination of ISO speed	-	-

[1)] Undated reference.

[2)] Valid edition at date of issue.

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.

INTERNATIONAL STANDARD

NORME INTERNATIONALE

IEC
CEI
62220-1-2

First edition
Première édition
2007-06

**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**

Commission Electrotechnique Internationale
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For price, see current catalogue
Pour prix, voir catalogue en vigueur

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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

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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

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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”.

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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*