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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 62220-1:2004 sisaldab Euroopa standardi EN 62220-1:2004 ingliskeelset teksti.	This Estonian standard EVS-EN 62220-1:2004 consists of the English text of the European standard EN 62220-1:2004.
Standard on kinnitatud Eesti Standardikeskuse 22.07.2004 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 22.07.2004 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 14.01.2004.	Date of Availability of the European standard text 14.01.2004.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD **EN 62220-1**

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English version

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

(IEC 62220-1:2003)

Appareils électromédicaux - Caractéristiques des appareils d'imagerie à rayonnement X Part 1: Détermination de l'efficacité quantique de détection (CEI 62220-1:2003)

Medizinische elektrische Geräte - Merkmale digitaler Röntgenbildgeräte Teil 1: Bestimmung der detektiven Quanten-Ausbeute (IEC 62220-1:2003)

This European Standard was approved by CENELEC on 2003-12-01. 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.

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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 62220-1:2004 E

Foreword

The text of document 62B/493/FDIS, future edition 1 of IEC 62220-1, 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 was approved by CENELEC as EN 62220-1 on 2003-12-01.

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) 2004-09-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2006-12-01

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.

Annex ZA has been added by CENELEC.

_____

Endorsement notice

The text of the International Standard IEC 62220-1:2003 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	1993	X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	1995
IEC 60601-2-7	- [1)]	Medical electrical equipment Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	EN 60601-2-7	1998 [2)]
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61267	1994	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	1994
ISO 12232	1998	Photography - Electronic still-picture cameras - Determination of ISO speed	-	-

1) Undated reference.

2) Valid edition at date of issue.

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

Reference number
IEC 62220-1:2003(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

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The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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- **IEC Web Site (www.iec.ch)**

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INTERNATIONAL STANDARD

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Partie 1: Détermination de l'efficacité quantique de détection

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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

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 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.

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.

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.

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].

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.

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*