National Standards Authority of Ireland
Údarás um Chaighdeáin Náisiúnta na hÉireann

IRISH STANDARD

I.S. EN 62220-1-2:2007

ICS 11.040.50

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 (EQV))

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62220-1-2

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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

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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).

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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.