Irish Standard
I.S. EN 61223-3-2:2008

Evaluation and routine testing in medical imaging departments -- Part 3 -2: Acceptance tests - Imaging performance of mammographic X-ray equipment (IEC 61223-3-2:2007 (EQV))

I.S. EN 61223-3-2:2008

Incorporating amendments/corrigenda issued since publication:

This standard replaces:	*This standard is based on:*	*Published:*
I.S. EN 61223-3-2:1999	EN 61223-3-2:2008 EN 61223-3-2:1996	25 July, 2008 26 February, 1999

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EUROPEAN STANDARD

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EN 61223-3-2

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Supersedes EN 61223-3-2:1996

English version

Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment

(IEC 61223-3-2:2007)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-2: Essais d'acceptation - Performance d'imagerie des appareils de mammographie à rayonnement X (CEI 61223-3-2:2007)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-2: Abnahmeprüfungen - Leistungsmerkmale zur Bildgebung von Röntgen-Einrichtungen für die Mammographie (IEC 61223-3-2:2007)

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 61223-3-2:2008 E

Foreword

The text of document 62B/651/FDIS, future edition 2 of IEC 61223-3-2, 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 61223-3-2 on 2008-06-01.

This European Standard supersedes EN 61223-3-2:1996.

EN 61223-3-2:2008 has been expanded by including tests of equipment properties depending on X-RAY IMAGE RECEPTORS, by putting emphasis on the aspect of image quality and dose and through harmonization, where possible, with other recognized standards. Annex L compares the specific content of EN 61223-3-2:1996 and EN 61223-3-2:2008.

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)	2009-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2011-06-01

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: smaller type;

– TERMS DEFINED IN IEC/TR 60788, EN 60601-1 OR IN CLAUSE 3 OF THIS STANDARD: SMALL CAPITALS (see index of defined terms).

NOTE 1 Where a defined term is used as a qualifier with 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 a definition.

NOTE 2 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 61223-3-2:2007 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 60601-1-3	NOTE	Harmonized as EN 60601-1-3:2008 (not modified).
IEC 60601-2-28	NOTE	Harmonized as EN 60601-2-28:1993 (not modified).
IEC 60627	NOTE	Harmonized as EN 60627:2001 (not modified).
IEC 61223-2-4	NOTE	Harmonized as EN 61223-2-4:1994 (not modified).
IEC 61223-2-5	NOTE	Harmonized as EN 61223-2-5:1994 (not modified).
IEC 61223-3-1	NOTE	Harmonized as EN 61223-3-1:1999 (not modified).
IEC 61223-3-3	NOTE	Harmonized as EN 61223-3-3:1996 (not modified).
IEC 61223-3-4	NOTE	Harmonized as EN 61223-3-4:2000 (not modified).
IEC 62220-1-2	NOTE	Harmonized as EN 62220-1-2:2007 (not modified).
ISO 3386-1	NOTE	Harmonized as EN ISO 3386-1:1997 (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	2005	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	2005
IEC 60601	Series	Medical electrical equipment	EN 60601	Series
IEC 60601-1	-[1)]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006[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/TS 61223-2-1	-[1)]	Evaluation and routing testing in medical imaging departments - Part 2-1: Constancy tests - Film processors	-	-
IEC 61674	-[1)]	Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging	EN 61674	1997[2)]
IEC 61676	2002	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN 61676	2002
ISO 4090	-[1)]	Photography - Medical radiographic cassettes/screens/films and hard-copy imaging films - Dimensions and specifications	-	-
ISO 9236-3	-[1)]	Photography - Sensitometry of screen/film systems for medical radiography - Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography	-	-

[1)] Undated reference.

[2)] Valid edition at date of issue.