SVENSK STANDARD SS-EN 61223-3-2

Fastställd	Utgåva	Sida	Ansvarig kommitté
2008-12-15	2	1 (1+64)	SEK TK 62BC

Utvärdering och rutinprovning i avdelningar för medicinsk bildframställning – Del 3-2: Leveransprovning – Bildkvalitet hos röntgenutrustning för mammografi

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

Som svensk standard gäller europastandarden EN 61223-3-2:2008. Den svenska standarden innehåller den officiella engelska språkversionen av EN 61223-3-2:2008.

Nationellt förord

Europastandarden EN 61223-3-2:2008

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

– **IEC 61223-3-2, Second edition, 2007 - Evaluation and routine testing in medical imaging departments - Part-3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 61223-3-2, utgåva 1, 1998, gäller ej fr o m 2011-06-01.

ICS 11.040.50

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

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Stora delar av arbetet sker internationellt

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Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61223-3-2

July 2008

ICS 11.040.50

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

SEK Svensk Elstandard

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.

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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.

CONTENTS

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for diagnostic X-RAY EQUIPMENT.

This second edition of the particular standard for the ACCEPTANCE TEST of mammographic X-RAY EQUIPMENT describes test methods for EQUIPMENT using RADIOGRAPHIC FILMS, EQUIPMENT using storage phosphor plates, EQUIPMENT using integrated digital X-RAY IMAGE RECEPTORS, and MAMMOGRAPHIC STEREOTACTIC DEVICES.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

1 Scope

This part of IEC 61223 applies to the effectiveness of mammographic X-RAY EQUIPMENT, with respect to image quality and dose, in combination with aspects of EQUIPMENT safety.

This standard applies to mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES.

The tests described in this standard require the quality and performance of the X-RAY IMAGE RECEPTORS to be assured prior to the acceptance testing when they are not an integral part of the mammographic X-RAY EQUIPMENT. This includes RADIOGRAPHIC FILMS, INTENSIFYING SCREENS, RADIOGRAPHIC CASSETTES, storage phosphor plates and ASSOCIATED EQUIPMENT such as film processors or storage phosphor plate readers, IMAGE DISPLAY DEVICES and HARD COPY CAMERAS.

For testing RADIOGRAPHIC CASSETTES and INTENSIFYING SCREENS, this standard makes reference to ISO 4090. Sensitivity and contrast for the screen-film image receptors are considered to be stated according to ISO 9236-3.

NOTE Currently there exists no IEC standard for acceptance testing of HARD COPY CAMERAS or IMAGE DISPLAY DEVICES.

By the measurements described in this standard, data for AVERAGE GLANDULAR DOSE calculation can be determined.

When the results of the ACCEPTANCE TEST are in compliance with the expected values, the baseline values for the subsequent CONSTANCY TESTS are established.

This part of IEC 61223 defines

a) the essential parameters which describe the performance of the above-mentioned mammographic X-RAY EQUIPMENT with regard to image quality and dose; and
b) the methods of testing whether measured quantities related to those parameters comply with specified tolerances.

These methods mainly rely on non-invasive measurements that use appropriate test EQUIPMENT and are performed during or after the installation. Signed statements covering steps in the installation procedure can be used as part of the ACCEPTANCE TEST. Tests required by a higher level of compliance take precedence over similar tests with a lower level of compliance. This concept is described in 4.1.

This standard does not in itself specify limiting values or tolerances for the parameters under investigation.

A difficulty may arise with regard to the responsibility for acceptance testing when the film/screen combination, film processing chemistry or computed radiography system is changed. This arises from a combination of causes. Firstly, the image receptor MANUFACTURER and the X-RAY EQUIPMENT MANUFACTURER may be different. Secondly a change in image receptor or film processing chemistry may alter the system performance. When system integration such as the above occurs, it is important that acceptance testing is performed. When a change occurs which could alter system performance, it is essential that the system integrator (i.e. whoever is responsible for this change) discusses the implication of their change with the X-RAY EQUIPMENT MANUFACTURER so that the latter can adjust the imaging system if necessary.

ACCEPTANCE TESTING of mammographic X-RAY EQUIPMENT requires average skill in medical physics. However, the decision concerning who performs the test is determined by local rules (e.g. contract, regulation, law).

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 60336:2005, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60601 (all parts), *Medical electrical equipment*

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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 61223-2-1, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

IEC 61674, *Medical electrical equipment – Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

ISO 4090, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

ISO 9236-3, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*