Evalveerimine ja tavakatsetused meditsiinipiltdiagnostika osakondades. Osa 3-2: Heakskiidukatsetused. Mammograafiliste röntgenseadmete pildistuskvaliteedi näitajad

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 61223-3-2:2008 sisaldab Euroopa standardi EN 61223-3-2:2008 ingliskeelset teksti.	This Estonian standard EVS-EN 61223-3-2:2008 consists of the English text of the European standard EN 61223-3-2:2008.
Standard on kinnitatud Eesti Standardikeskuse 19.08.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 19.08.2008 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 25.07.2008.	Date of Availability of the European standard text 25.07.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.50

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Descriptors: Medical electrical equipment, medical imaging, mammography, acceptance tests, performance

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Evaluation and routine testing in medical imaging departments Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment (IEC 1223-3-2:1996)

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 1223-3-2:1996)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung Teil 3-2: Abnahmeprüfungen Abbildungsqualität von Röntgen-Einrichtungen für die Mammographie (IEC 1223-3-2:1996)

This European Standard was approved by CENELEC on 1996-10-01. 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.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62B/287/FDIS, future edition 1 of IEC 1223-3-2, 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 1996-10-01.

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) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-07-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annexes A and ZA are normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 1223-3-2:1996 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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 336	1993	X-ray tube assemblies for medical diagnosis Characteristics of focal spots	EN 60336	1995
IEC 417N	1995[1)]	Graphical symbols for use on equipment - Index, survey and compilation of the single sheets	-	-
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
			+ corr. July	1994
A1	1991		A1	1993
			+ corr. July	1994
A2	1995		A2[2)]	1995
			A13	1996
IEC 601-1-3	1994	Medical electrical equipment Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994
IEC 601-2-7	1987	Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	HD 395.2.7 S1	1989
IEC 601-2-28	1993	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	EN 60601-2-28	1993
IEC 601-2-32	1994	Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	EN 60601-2-32	1994
IEC 788	1984	Medical radiology - Terminology	HD 501 S1	1988

1) IEC 417:1973 and its supplements A:1974 to M:1994 are harmonized as HD 243 S12:1995.

2) A2 includes corrigendum June 1995 to IEC 601-1:1988/A2.

Publication	Year	Title	EN/HD	Year
IEC 878	1988	Graphical symbols on electrical equipment in medical practice	-	-
IEC 1223-1	1993	Evaluation and routine testing in medical imaging departments Part 1: General aspects	-	-
IEC 1223-2-1	1993	Part 2: Constancy tests - Film processors	-	-
IEC 1223-2-2	1993	Part 2: Constancy tests - Radiographic cassettes and film changers - Film screen contact and relative sensitivity	-	-
IEC 1223-2-3	1993	Part 2: Constancy tests - Darkroom conditions	-	-
ISO 2092	1981	Light metals and their alloys - Code of designation based on chemical symbols	-	-

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*