SLOVENSKI STANDARD
SIST EN 61223-3-2:1998

01-september-1998

Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment (IEC 61223-3-2:1996)

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

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung -- Teil 3-2: Abnahmeprüfungen - Abbildungsleistung von Röntgen-Einrichtungen für Mammographie

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

Ta slovenski standard je istoveten z: **EN 61223-3-2:1996**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 61223-3-2:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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December 1996

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

English version

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.

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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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	-	-

NORME INTERNATIONALE

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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

Evaluation and routine testing in medical imaging departments –

Part 3-2:
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 1223-3-2 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/287/FDIS	62B/300/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.

Annex A forms an integral part of this standard.

The French version of this standard has not been voted upon.

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;
- *Test specifications: italic type;*
- TERMS DEFINED IN IEC 788 OR IN IEC 1223: SMALL CAPITALS (SEE ANNEX A).

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (such as diagnostic X-RAY EQUIPMENT), including film processing, used in medical imaging departments.