EESTI STANDARD EVS-EN 61223-3-4:2002

Evalveerimine ja tavakatsetused meditsiinipiltdiagnostika osakondades. Osa 3-4: Heakskiidukatsetused. Hambaröntgenseadmete pildistuskvaliteedi näitajad

Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 61223-3-4:2002 sisaldab Euroopa standardi EN 61223-3-4:2000 ingliskeelset teksti.	This Estonian standard EVS-EN 61223-3-4:2002 consists of the English text of the European standard EN 61223-3-4:2000.
Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.	This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61223-3-4

September 2000

ICS 11.040.50

English version

Evaluation and routine testing in medical imaging departments
Part 3-4: Acceptance tests
Imaging performance of dental X-ray equipment
(IEC 61223-3-4:2000)

Essais d'évaluation et de routine dans les services d'imagerie médicale
Partie 3-4: Essais d'acceptation
Performance d'imagerie des appareils de radiographie dentaire
(CEI 61223-3-4:2000)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung
Teil 3-4: Abnahmeprüfungen
Leistungsmerkmale zur Bildgebung von zahnärztlichen Röntgeneinrichtungen
(IEC 61223-3-4:2000)

This European Standard was approved by CENELEC on 2000-06-01. 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, Czech Republic, 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

Ref. No. EN 61223-3-4:2000 E

Foreword

The text of document 62B/393/FDIS, future edition 1 of IEC 61223-3-4, 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 61223-3-4 on 2000-06-01.

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) 2001-03-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-06-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes A and ZA are normative and annexes B and C are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-3-4:2000 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 standards indicated:

IEC 60601-2-32 NOTE: Harmonized as EN 60601-2-32:1994 (not modified).

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 60336	1993	X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	1995
IEC 60417-1	1998	Graphical symbols for use on equipment Part 1: Overview and application	EN 60417-1	1999
IEC 60417-2	1998	Part 2: Symbol originals	EN 60417-2	1999
IEC 60522	1999	Determination of the permanent filtration of X-ray tube assemblies	EN 60522	1999
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A13	1990 1994 1996
		NOTE: Amendments A11 and A12 are superseded by EN 60601-1/A2:1995.		
IEC 60601-2-28	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 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 60878	1988	Graphical symbols on electrical equipment in medical practice	-	-
IEC 61223-1	1993	Evaluation and routine testing in medical imaging departments Part 1: General aspects	-	-
IEC 61267	1994	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	1994
ISO 2092	1981	Light metals and their alloys - Code of designation based on chemical symbols	-	-

INTERNATIONAL STANDARD

IEC 61223-3-4

First edition
2000-03

Evaluation and routine testing in medical imaging departments –

Part 3-4:
Acceptance tests –
Imaging performance of dental X-ray equipment

Essais d'évaluation et de routine dans les services d'imagerie médicale –

Partie 3-4:
Essais d'acceptation –
Performance d'imagerie des appareils de radiographie dentaire

Reference number
IEC 61223-3-4:2000(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

INTERNATIONAL STANDARD

IEC 61223-3-4

First edition
2000-03

Evaluation and routine testing in medical imaging departments –

Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

Essais d'évaluation et de routine dans les services d'imagerie médicale –

Partie 3-4: Essais d'acceptation – Performance d'imagerie des appareils de radiographie dentaire

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE V

For price, see current catalogue

CONTENTS

Clause Page

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-4: Acceptance tests – Imaging performance of dental 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 specifications, 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 61223-3-4 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/393/FDIS	62B/402/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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex A forms an integral part of this standard.

Annexes B and C are for information only.

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 60601-1, IN IEC 60788, IN IEC 61223-1 OR IN OTHER IEC PUBLICATIONS REFERENCED IN ANNEX A: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This part of IEC 61223 is part of a series of International Standards which gives methods of acceptance testing and constancy testing for subsystems and systems (for example, diagnostic X-RAY EQUIPMENT) including film processing.

Some provisions or statements in this standard require additional information. Such information is presented in annex B. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of dental X-RAY EQUIPMENT using radiographic imaging systems which influence the image quality and PATIENT dose.

This standard applies to the performance of the ACCEPTANCE TEST on dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR and dental X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR (for example, dental panoramic X-RAY EQUIPMENT or cephalometric X-RAY).

This standard applies to dental film and digital image acquisition and processing.

1.2 Object

This standard defines

a) the essential parameters which describe the performance of the above-mentioned dental X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;

b) methods of testing and whether measured quantities related to those parameters comply with the specified tolerances.

These methods rely mainly on non-invasive measurements, using appropriate test equipment, performed during or after the installation is completed. Signed statements covering steps in the installation procedure may be used as part of the acceptance testing.

The aim is to verify compliance of the installation with specifications affecting the image quality and PATIENT dose, and to detect malfunctions that are not in agreement with those specifications.

This standard does not in itself specify tolerances for the parameters under investigation. Neither is it intended to consider

c) aspects of mechanical and electrical safety;

d) aspects of mechanical, electrical and software performance, unless they are essential to the performance of the tests directly affecting image quality and PATIENT dose.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61223. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 61223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60336:1993, *X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60417-1:1998, *Graphical symbols for use on equipment – Part 1: Overview and application*

IEC 60417-2:1998, *Graphical symbols for use on equipment – Part 2: Symbol originals*

IEC 60522:1999, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60878:1988, *Graphical symbols for electrical equipment in medical practice*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 61267:1994, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*

3 Terminology

3.1 Degree of requirements

In this standard, certain terms which 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.