SLOVENSKI STANDARD
SIST EN 61223-2-6:2010

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Vrednotenje in rutinsko preskušanje v oddelkih za medicinsko slikanje - 2-6. del: Preskus konstantnosti - Rentgenska oprema za računalniško tomografijo (IEC 61223-2-6:2006)

Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment (IEC 61223-2-6:2006)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 2-6: Konstanzprüfungen - Röntgeneinrichtungen für die Computertomographie (IEC 61223-2-6:2006)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 2-6: Essais de constance - Performance d'imagerie des équipements de tomodensitométrie à rayonnement X (CEI 61223-2-6:2006)

Ta slovenski standard je istoveten z: **EN 61223-2-6:2007**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN 61223-2-6:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61223-2-6

May 2007

ICS 11.040.50

Supersedes EN 61223-2-6:1994

English version

Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment

(IEC 61223-2-6:2006)

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This European Standard was approved by CENELEC on 2007-03-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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 61223-2-6:2007 E

Foreword

The text of document 62B/629/FDIS, future edition 2 of IEC 61223-2-6, 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 61223-2-6 on 2007-03-01.

This European Standard supersedes EN 61223-2-6:1994.

EN 61223-2-6:2007 is harmonized with the content of EN 60601-2-44:2001 + A1:2003 and with EN 61223-3-5:2004. Instead of harmonizing test procedures for all modalities of X-ray equipment, as intended in EN 61223-2-6:1994, this EN 61223-2-6:2007 comprises part of a set of standards covering all of the particular requirements for CT scanners.

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)	2007-12-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-03-01

In this standard, the following print types are used:

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

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

– *test specifications: in italic type*;

– TERMS DEFINED IN EN 60601-1, IN EN 60788, IN EN 61223-1 OR IN OTHER PUBLICATIONS REFERENCED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-2-6:2006 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 61223-2-5	NOTE	Harmonized as EN 61223-2-5:1994 (not modified).
IEC 61223-2-4	NOTE	Harmonized as EN 61223-2-4:1994 (not modified).
IEC 60336	NOTE	Harmonized as EN 60336:2005 (not modified).
IEC 60522	NOTE	Harmonized as EN 60522:1999 (not modified).
IEC 60601-1	NOTE	Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-2-28	NOTE	Harmonized as EN 60601-2-28:1993 (not modified).
IEC 60601-2-32	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
IEC 61267	NOTE	Harmonized as EN 61267:2006 (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 60601-2-44 A1	2001 2002	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography	EN 60601-2-44 A1	2001 2003
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment	EN 61223-3-5	2004

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
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61223-2-6

Deuxième édition
Second edition
2006-11

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

Partie 2-6: Essais de constance – Performance d'imagerie des équipements de tomodensitométrie à rayonnement X

Evaluation and routine testing in medical imaging departments –

Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 61223-2-6 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994. It constitutes a technical revision. This second edition is harmonized with the content of IEC 60601-2-44:2001 and its Amendment 1 (2002) and with IEC 61223-3-5. Instead of harmonizing test procedures for all modalities of X-ray equipment, as intended in the first edition, this second edition comprises part of a set of standards covering all of the particular requirements for CT scanners.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/629/FDIS	62B/639/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 2.

A list of all parts of the IEC 61223 series, published under the general title *Evaluation and routine testing in medical imaging departments,* can be found on the IEC website.

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– explanations, advice, notes, general statements, exceptions and references: in smaller type;
– *test specifications and headings of subclauses: in italic type*;
– TERMS DEFINED IN IEC 60601-1, IN IEC 60788, IN IEC 61223-1 OR IN OTHER IEC PUBLICATIONS REFERENCED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

The second edition of this standard is harmonized with the content of

– IEC 60601-2-44:2001, *Particular requirements for the safety of X-ray equipment for computed tomography* and its Amendment 1 (2002), and

– IEC 61223-3-5, *Evaluation and routine testing in medical imaging departments – Part 3-5, Acceptance tests – Imaging performance of computed tomography X-ray equipment*.

In case the CT SCANNER does not offer an integrated, automated evaluation of the test images, attention shall be given to the proper function and setting of the IMAGE DISPLAY DEVICE. It is strongly recommended to assure its proper functioning prior to the constancy testing of the CT SCANNER, applying IEC 61223-2-5 [1] [1)] on IMAGE DISPLAY DEVICES or the related in-house procedure. Some provisions or statements in this standard require additional information, which is presented in the annexes. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

With regard to the measurements, reference is made to methods described in related publications, which for practical reasons should be carried out prior to the application of the methods described in this standard.

This standard forms Part 2-6 of IEC 61223, which includes the following parts of particular interest in the context of this standard:

Part 1: General aspects [2]

Part 2-4: Constancy tests – Hard copy cameras [3]

Part 2-5: Constancy tests – Image display devices

1) Figures in square brackets refer to the Bibliography.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment

1 Scope and object

This part of IEC 61223 provides assistance in performing CONSTANCY TESTS on a CT SCANNER.

It applies to those components of CT SCANNERS which influence the image quality, PATIENT dose and positioning.

This standard

– defines the essential parameters which describe the performance of CT SCANNERS with regard to image quality, PATIENT dose and positioning; the list of parameters to be tested can be found in section 4.5;

– defines the methods of testing the essential parameters;

– provides criteria to be applied in the evaluation of data for compliance with the tolerances of the parameters specified by the ACCOMPANYING DOCUMENTS and with respect to BASELINE VALUES.

These methods rely on non-invasive measurements, using appropriate test equipment, performed to ensure that the functional performance of EQUIPMENT meets ESTABLISHED CRITERIA or to enable the early recognition of changes in the properties of components of the EQUIPMENT.

The aim is to verify compliance with specifications affecting the image quality, PATIENT dose and PATIENT positioning.

It is not intended to consider:

– aspects of mechanical and electrical safety nor

– aspects of mechanical, electrical and software performance, unless they are essential for performing the CONSTANCY TESTS and directly affect image quality, PATIENT dose and positioning.

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 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61223-3-5:2004, *Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment*

IEC 60601-2-44:2001, *Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography*

Amendment 1 (2002)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60788:2004 and the following apply.

NOTE 1 An index of defined terms used in this standard is given following the annexes

NOTE 2 Attention is drawn to the fact that in cases where the concept addressed is not strongly confined to the definition given in IEC 61223-1 or IEC 60788, a corresponding term is printed in lower case letters.

3.1
CT CONDITIONS OF OPERATION
all selectable parameters governing the operation of a CT SCANNER, for example NOMINAL TOMOGRAPHIC SECTION THICKNESS, CT PITCH FACTOR, FILTRATION, peak X-RAY TUBE VOLTAGE and either X-RAY TUBE CURRENT and LOADING TIME or CURRENT TIME PRODUCT

[IEC 60601-2-44:2001, definition 2.102]

3.2
CT SCANNER
X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT)
diagnostic X-ray system intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data obtained at different angles. This generic type of device may include signal analysis and display equipment, PATIENT SUPPORT, support parts and accessories

NOTE Secondary imaging processing is not included in the scope of this standard.

[IEC 60601-2-44, Amend.1:2002, definition 2.101]

3.3
COMPUTED TOMOGRAPHY DOSE INDEX 100
***CTDI*$_{100}$**
integral of the DOSE PROFILE produced in a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE from – 50 mm to + 50 mm, divided by the product of the number of TOMOGRAPHIC SECTIONS N and the NOMINAL TOMOGRAPHIC SECTION THICKNESS *T*

$$CTDI_{100} = \int_{-50\,\mathrm{mm}}^{+50\,\mathrm{mm}} \frac{D(z)}{N \cdot T}\, dz$$

where

D(z) is the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE to air;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

NOTE 1 The term $CTDI_{100}$ has been introduced as a more representative value for dose than the traditional CTDI integrated from – 7 T to + 7 T as defined by the FDA in 21 CFR 1020.33 [31].

NOTE 2 The dose is reported as ABSORBED DOSE to air. This is required in order to avoid present confusion, as some MANUFACTURERS of CT SCANNERS express dose values calculated as ABSORBED DOSE to air and others as ABSORBED DOSE to polymethyl-methacrylate (PMMA).