SLOVENSKI STANDARD

SIST EN 61223-3-5:2005

januar 2005

Ovrednotenje in rutinsko preskušanje v medicinskih oddelkih za slikanje – 3-5. del: Preskusi sprejemljivosti – Slikovni učinek rentgenske opreme za računalniško podprto tomografijo

(istoveten EN 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

ICS 11.040.50

Referenčna številka
SIST EN 61223-3-5:2005(en)

EUROPEAN STANDARD **EN 61223-3-5**

NORME EUROPÉENNE

EUROPÄISCHE NORM September 2004

ICS 11.040.50

English version

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

Essais d'évaluation et de routine dans les services d'imagerie médicale Partie 3-5: Essais d'acceptation – Performance d'imagerie des équipements de tomodensitométrie à rayonnement X (CEI 61223-3-5:2004)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung Teil 3-5: Abnahmeprüfungen – Leistungsmerkmale zur Bildgebung von Röntgeneinrichtungen für Computertomographie (IEC 61223-3-5:2004)

This European Standard was approved by CENELEC on 2004-09-01. 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, 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 61223-3-5:2004 E

Foreword

The text of document 62B/525/FDIS, future edition 1 of IEC 61223-3-5, 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 61223-3-5 on 2004-09-01.

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)	2005-06-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2007-09-01

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, EN 60788, EN 61223-1 OR IN OTHER STANDARDS REFERENCED IN ANNEX A: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-3-5:2004 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 61223-2-4	NOTE	Harmonized as EN 61223-2-4:1994 (not modified).
IEC 61223-2-6	NOTE	Harmonized as EN 61223-2-6:1994 (not modified).
IEC 60336	NOTE	Harmonized as EN 60336:1995 (not modified).
IEC 60522	NOTE	Harmonized as EN 60522:1999 (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 61267:1994 (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 Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	- [1)]	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990 [2)]
IEC 60601-2-44	2001	Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography	EN 60601-2-44	2001
A1	2002		A1	2003
IEC/TR 60788	- [1)]	Medical electrical equipment - Glossary of defined terms	-	-

1) Undated reference.

2) Valid edition at date of issue.

NORME INTERNATIONALE

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CEI
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61223-3-5

Première édition
First edition
2004-08

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

Partie 3-5: Essais d'acceptation – Performance d'imagerie des équipements de tomodensitométrie à rayonnement X

Evaluation and routine testing in medical imaging departments –

Part 3-5: Acceptance 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 3-5: Acceptance 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 61223-3-5 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 of voting
62B/525/FDIS	62B/544/RVD

Full information on the voting for the approval of this standard can be found in the report of voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

IEC 61223-3 includes the following parts, under the general title *Evaluation and routine testing in medical imaging departments – Part 3: Acceptance tests:*

Part 3-1: Imaging performance of X-ray equipment for radiographic and radioscopic systems

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

Part 3-3: Imaging performance of X-ray equipment for digital subtraction angiography (DSA)

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

Part 3-5: Imaging performance of computed tomography X-ray equipment

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, IEC 60788, 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 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

This International Standard forms part of the IEC 61223 series, which gives methods of acceptance testing and constancy testing for medical diagnostic X-RAY EQUIPMENT.

The ACCEPTANCE TEST is carried out after new EQUIPMENT has been installed, or major modifications have been made to existing EQUIPMENT, in order to facilitate verification of applicable safety and performance standards, regulations, and contractual specifications which influence the image quality, PATIENT dose and positioning.

To maintain the homogeneity of this IEC standard with the other two IEC standards addressing CT SCANNERS, the measuring methods and the terminology are taken as applicable from

– the CT safety standard IEC 60601-2-44, and

– the CT constancy testing standard IEC 61223-2-6 [3][1)]

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

1) Figures in square brackets refer to the bibliography.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment

1 Scope and object

This part of IEC 61223 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 the CT SCANNERS with regard to image quality, PATIENT dose and positioning; the list of parameters to be tested can be found in section 4.4.
- defines the methods of testing the essential parameters;
- evaluates compliance with the tolerances of the parameters specified by the ACCOMPANYING DOCUMENTS.

These methods rely mainly on non-invasive measurements, using appropriate test EQUIPMENT, performed during the installation or after it has been completed. Signed statements covering steps in the installation procedure may be used as part of the ACCEPTANCE TEST report.

This part of IEC 61223 is intended to assist in performing the ACCEPTANCE TESTS on a CT SCANNER The aim is to verify compliance of the installation with specifications affecting the image quality, PATIENT dose and positioning.

It is not intended to consider:

- aspects of mechanical and electrical safety;
- aspects of mechanical, electrical and software performance, unless they are essential for performing the ACCEPTANCE TESTS and are directly affecting 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 60601-1, *Medical electrical equipment – Part 1: General requirements for safety*[2)]

IEC 60601-2-44:2001, *Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography* [3)]
Amendment 1 (2002)

IEC 60788, *Medical electrical equipment – Glossary of defined terms*

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2) The new edition of IEC 60601-1 (to be published) will be entitled: *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

3) There exists a consolidated edition 2.1 (2002) including Edition 2 (2001) and its Amendment 1 (2002)