

| | | |
|------------|---|--|
| STN | Hodnotenie a prevádzkové skúšky v oddeleniach určených na lekárske zobrazovanie Časť 3-5: Preberacie skúšky a skúšky stálosti Zobrazovacie vlastnosti röntgenových zariadení na výpočtovú tomografiu | STN EN IEC 61223-3-5 85 4012 |
|------------|---|--|

Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests and and constancy tests - Imaging performance of computed tomography X-ray equipment

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/20

Obsahuje: EN IEC 61223-3-5:2019, IEC 61223-3-5:2019

Oznámením tejto normy sa od 21.10.2022 ruší
STN EN 61223-3-5 (85 4012) z novembra 2005

131205

EUROPEAN STANDARD

EN IEC 61223-3-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2019

ICS 11.040.50

Supersedes EN 61223-3-5:2004 and all of its
amendments and corrigenda (if any)

English Version

**Evaluation and routine testing in medical imaging departments -
Part 3-5: Acceptance tests and constancy tests - Imaging
performance of computed tomography X-ray equipment
(IEC 61223-3-5:2019)**

Essais d'évaluation et de routine dans les services
d'imagerie médicale - Partie 3-5: Essais d'acceptation et de
constance - Performance d'imagerie des équipements de
tomodensitométrie à rayonnement X
(IEC 61223-3-5:2019)

Bewertung und routinemäßige Prüfung in Abteilungen für
medizinische Bildgebung - Teil 3-5: Abnahmeprüfungen -
Leistungsmerkmale zur Bildgebung von
Röntgeneinrichtungen für Computertomographie
(IEC 61223-3-5:2019)

This European Standard was approved by CENELEC on 2019-10-21. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 61223-3-5:2019 (E)**European foreword**

The text of document 62B/1134/FDIS, future edition 2 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 approved by CENELEC as EN IEC 61223-3-5:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-07-21
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-10-21

This document supersedes EN 61223-3-5:2004 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 61223-3-5:2019 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 standard indicated:

IEC 61674:2012 NOTE Harmonized as EN 61674:2013 (not modified)

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|---|---------------|-------------|
| IEC 60601-1 | 2005 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | EN 60601-1 | 2006 |
| + A1 | 2012 | | + A1 | 2013 |
| - | - | | + A12 | 2014 |
| IEC 60601-2-44 | 2009 | Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography | EN 60601-2-44 | 2009 |
| - | - | | + A11 | 2011 |
| + A1 | 2012 | | + A1 | 2012 |
| + A2 | 2016 | | + A2 | 2016 |
| IEC/TR 60788 | 2004 | Medical electrical equipment - Glossary of defined terms | | - |



IEC 61223-3-5

Edition 2.0 2019-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

**Essais d'évaluation et de routine dans les services d'imagerie médicale –
Partie 3-5: Essais d'acceptation et de constance – Performance d'imagerie des
équipements de tomodensitométrie à rayonnement X**



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2019 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.



IEC 61223-3-5

Edition 2.0 2019-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

**Essais d'évaluation et de routine dans les services d'imagerie médicale –
Partie 3-5: Essais d'acceptation et de constance – Performance d'imagerie des
équipements de tomodensitométrie à rayonnement X**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-7280-0

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

CONTENTS

| | |
|--|----|
| FOREWORD..... | 5 |
| INTRODUCTION..... | 7 |
| 1 Scope and object..... | 8 |
| 2 Normative references | 9 |
| 3 Terms and definitions | 9 |
| 4 General aspects of ACCEPTANCE TESTS and CONSTANCY TESTS | 17 |
| 4.1 General conditions to be considered in test procedures | 17 |
| 4.1.1 General | 17 |
| 4.1.2 Preconditions..... | 18 |
| 4.1.3 BASELINE VALUES | 18 |
| 4.1.4 Identification and recording of equipment, instrumentation, and test conditions | 18 |
| 4.1.5 TEST DEVICES | 18 |
| 4.2 Documents and data for the tests in the ACCOMPANYING DOCUMENTS | 19 |
| 4.3 Scope of tests | 20 |
| 4.4 Considerations for selection of ACCEPTANCE and CONSTANCY TESTS | 20 |
| 4.5 Measuring equipment..... | 21 |
| 4.6 Actions to be taken after a MAJOR SERVICE ACTION | 21 |
| 4.7 Establishment of BASELINE VALUES | 21 |
| 4.8 Frequency of CONSTANCY TESTS..... | 22 |
| 5 Test methods for CT SCANNERS | 22 |
| 5.1 Positioning of the PATIENT SUPPORT | 22 |
| 5.1.1 Summary | 22 |
| 5.1.2 Test equipment..... | 22 |
| 5.1.3 Test procedure | 22 |
| 5.1.4 Data evaluation | 23 |
| 5.1.5 Criteria to be applied | 23 |
| 5.1.6 Constancy testing | 23 |
| 5.2 PATIENT positioning accuracy | 24 |
| 5.2.1 Axial PATIENT positioning accuracy | 24 |
| 5.2.2 Sagittal and coronal PATIENT positioning light accuracy (if available)..... | 25 |
| 5.2.3 Constancy testing – Axial, sagittal, and coronal positioning light accuracy | 25 |
| 5.3 RECONSTRUCTED SECTION THICKNESS..... | 26 |
| 5.3.1 General | 26 |
| 5.3.2 RECONSTRUCTED SECTION THICKNESS for axial scanning | 26 |
| 5.3.3 RECONSTRUCTED SECTION THICKNESS for helical scanning | 28 |
| 5.4 Dose | 28 |
| 5.4.1 Summary | 28 |
| 5.4.2 Test equipment..... | 28 |
| 5.4.3 Test procedure | 28 |
| 5.4.4 Data evaluation | 29 |
| 5.4.5 Criteria to be applied | 30 |
| 5.4.6 Constancy testing | 30 |
| 5.5 MEAN CT NUMBER, magnitude of NOISE, and UNIFORMITY | 31 |
| 5.5.1 Summary | 31 |
| 5.5.2 Test equipment..... | 32 |

| | | |
|---|---|----|
| 5.5.3 | Test procedure | 32 |
| 5.5.4 | Scan conditions | 32 |
| 5.5.5 | Criteria to be applied for ACCEPTANCE TEST | 35 |
| 5.5.6 | Criteria to be applied for CONSTANCY TESTS | 36 |
| 5.6 | SPATIAL RESOLUTION (high contrast)..... | 38 |
| 5.6.1 | Summary | 38 |
| 5.6.2 | Information to be supplied in the ACCOMPANYING DOCUMENTS..... | 38 |
| 5.6.3 | Test equipment..... | 38 |
| 5.6.4 | Test procedure | 38 |
| 5.6.5 | Data evaluation | 39 |
| 5.6.6 | Criteria to be applied | 39 |
| 5.6.7 | Constancy testing | 39 |
| 5.7 | Automatic exposure control (AEC) | 39 |
| 5.8 | LOW CONTRAST RESOLUTION and LOW CONTRAST DETECTABILITY | 40 |
| Annex A (informative) Visual method for LOW CONTRAST RESOLUTION | | 41 |
| Annex B (informative) DOSE PROFILE | | 42 |
| B.1 | Summary | 42 |
| B.2 | Methods..... | 42 |
| B.2.1 | Point dosimeter method | 42 |
| B.2.2 | Film method..... | 42 |
| B.2.3 | Criteria to be applied | 42 |
| Annex C (informative) Accuracy of the gantry tilt..... | | 43 |
| C.1 | Summary | 43 |
| C.2 | Method A | 43 |
| C.2.1 | Test equipment..... | 43 |
| C.2.2 | Test procedure | 43 |
| C.2.3 | Data evaluation | 43 |
| C.2.4 | Criteria to be applied | 43 |
| C.3 | Method B | 44 |
| C.3.1 | Test equipment..... | 44 |
| C.3.2 | Test procedure | 44 |
| C.3.3 | Data evaluation | 44 |
| C.4 | Criteria to be applied..... | 44 |
| Annex D (informative) Characterization of z-axis SPATIAL RESOLUTION | | 45 |
| Annex E (informative) Helical RECONSTRUCTED SECTION THICKNESS | | 46 |
| E.1 | Summary | 46 |
| E.2 | Test equipment | 46 |
| E.3 | Test procedure..... | 46 |
| E.4 | Data evaluation..... | 46 |
| Annex F (informative) Guidance on action to be taken | | 47 |
| F.1 | Failing the ESTABLISHED CRITERIA at first measurement | 47 |
| F.2 | Failing the ESTABLISHED CRITERIA after repeated measurement | 47 |
| F.3 | Marginally failing the ESTABLISHED CRITERIA | 47 |
| F.4 | Substantially failing the ESTABLISHED CRITERIA | 47 |
| F.5 | History of repeatedly failing the ESTABLISHED CRITERIA | 48 |
| F.6 | Failing the established CONSTANCY CRITERIA but passing the established ACCEPTANCE CRITERIA | 48 |
| F.7 | Cases not covered by Clauses F.1 to F.5..... | 48 |

| | |
|---|----|
| Annex G (informative) Automated exposure control (AEC) | 49 |
| G.1 Overview..... | 49 |
| G.2 Test equipment | 49 |
| G.3 Test procedure..... | 49 |
| G.4 Size-dependent modulation evaluation | 49 |
| G.4.1 Size-dependent modulation evaluation for Adult Body PROTOCOL ELEMENTS..... | 49 |
| G.4.2 Size-dependent modulation evaluation for Paediatric Body PROTOCOL ELEMENTS..... | 50 |
| G.5 Longitudinal modulation evaluation | 50 |
| G.6 Data evaluation..... | 51 |
| G.6.1 Size-dependent modulation evaluation | 51 |
| G.6.2 Longitudinal modulation evaluation | 51 |
| G.7 Criteria to be applied..... | 51 |
| G.7.1 Size-dependent modulation evaluation | 51 |
| G.7.2 Longitudinal modulation evaluation | 51 |
| Annex H (informative) Mapping of IEC requirements to regulations | 52 |
| Annex I (informative) Overview of criteria for acceptance and constancy testing for 5.5 | 54 |
| Annex J (informative) Overview of criteria and frequency for all acceptance and constancy testing..... | 55 |
| Bibliography..... | 59 |
| Index of defined terms | 60 |
| | |
| Figure 1 – Coordinate system | 14 |
| Figure 2 – Illustration of $N \times T$, R and $(N \times T) + R$ | 16 |
| Figure G.1 – TEST DEVICE aligned | 50 |
| | |
| Table 1 – Test pattern for $CTDI_{free\ air}$ for Adult Body PROTOCOL ELEMENTS | 29 |
| Table 2 – Combination of PROTOCOL ELEMENTS and PHANTOMS used for ACCEPTANCE TEST scans..... | 33 |
| Table 3 – Combination of PROTOCOL ELEMENTS and PHANTOMS used for CONSTANCY TEST scans..... | 33 |
| Table H.1 – Mapping of IEC requirements to regulations..... | 52 |
| Table I.1 – Overview of criteria for ACCEPTANCE and CONSTANCY TESTING for 5.5 | 54 |
| Table J.1 –Overview of criteria and frequency..... | 55 |

INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-5: Acceptance and 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.
- 2) The formal decisions or agreements of 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 IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

This second edition cancels and replaces the first edition published in 2004, and the second edition of IEC 61223-2-6 published in 2006. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition and to IEC 61223-2-6:

- a) modification of the RADIATION protection and control;
- b) modification of the acceptance testing;
- c) introduction of constancy testing.

The text of this International Standard is based on the following documents:

| FDIS | Report on voting |
|---------------|------------------|
| 62B/1134/FDIS | 62B/1145/RVD |

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

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

In this document, 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 USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of the users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

This part of IEC 61223 gives methods for acceptance testing and constancy testing for medical diagnostic CT equipment.

The complete set of ACCEPTANCE TESTS is to be carried out after new equipment has been installed, or a subset of the tests is to be carried out after each MAJOR SERVICE ACTION that is made to existing equipment. This is done in order to facilitate verification of applicable safety and performance standards, regulations, and published and/or contractual specifications that influence the image quality, RADIATION OUTPUT and PATIENT positioning.

To maintain the homogeneity of this document with the other IEC standards addressing CT SCANNERS, the measuring methods and the terminology are taken as applicable from the CT safety standard IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016.

Some provisions or statements in this document require additional information, which is presented in the annexes.

IEC 61223-3-5 is referenced by IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012 using an undated reference. This can suggest the reference to change from IEC 61223-3-5:2004 to IEC 61223-3-5:2019 with the date of its publication. However, the IEC technical subcommittee 62B who prepared both standards does not intend this immediate change of reference. The IEC technical subcommittee 62B clearly recommends in the foreword of both standards the necessity for MANUFACTURERS and testing organizations for a transitional period to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. Therefore, the reference in IEC 60601-2-44 has to be seen as a dated reference towards IEC 61223-3-5:2004, for a transitional period of not less than 3 years from the date of publication of this document. The IEC technical subcommittee 62B intends to clarify this undated reference with the preparation of a new version 4 of IEC 60601-2-44.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

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

1 Scope and object

This part of IEC 61223 applies to CT SCANNERS that conform to IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016.

IEC 60601-2-44 and this document

- defines the essential parameters which describe the performance of CT SCANNERS with regard to image quality, RADIATION OUTPUT and PATIENT positioning; the list of parameters to be tested can be found in 4.3,
- defines the methods of testing the essential parameters, and
- evaluates compliance with the tolerances of the parameters SPECIFIED by the ACCOMPANYING DOCUMENTS.

The methods defined in IEC 60601-2-44 and this document rely on non-invasive measurements, using appropriate test equipment, performed during or after installation. Signed statements covering steps in the installation procedure can be used as part of the ACCEPTANCE TEST report.

This document applies to ACCEPTANCE TESTS and CONSTANCY TESTS on a CT SCANNER. The aim of the ACCEPTANCE TESTS is to verify compliance of the installation or MAJOR SERVICE ACTION with specifications affecting the image quality, RADIATION OUTPUT and PATIENT positioning. The CONSTANCY TESTS are performed to ensure that the functional performance of EQUIPMENT meets ESTABLISHED CRITERIA and to enable the early recognition of changes in the properties of components of the EQUIPMENT, and to verify compliance with specifications affecting the image quality, RADIATION OUTPUT and PATIENT positioning.

This document also contains requirements associated with ACCEPTANCE TEST and CONSTANCY TEST for the ACCOMPANYING DOCUMENTS of the CT SCANNER.

This document does not apply to

- aspects of mechanical and electrical safety, and
- aspects of mechanical, electrical and software performance, unless they are essential for performing the ACCEPTANCE TESTS and CONSTANCY TESTS, and are directly affecting image quality, RADIATION OUTPUT and PATIENT positioning.

NOTE 1 If a user of this document wishes to apply this document to CT SCANNERS that were designed to comply with editions of IEC 60601-2-44:2009 and earlier, understanding and adjustment for the different definitions that have been used for $CTDI_{vol}$ is critical. Additionally, the ACCOMPANYING DOCUMENTS for CT scanners that were designed and manufactured to these older editions can be referenced to obtain applicable specifications.

NOTE 2 It is possible the accompanying documents that were compiled in accordance with IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012 or IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016 do not include all the needed content and specifications identified in this document prior to the completion of the transition period to this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-44:2009, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*
IEC 60601-2-44:2009/AMD1:2012
IEC 60601-2-44:2009/AMD2:2016

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN