SLOVENSKI STANDARD
SIST EN IEC 61223-3-5:2020

01-januar-2020

Nadomešča:
SIST EN 61223-2-6:2010
SIST EN 61223-3-5:2005

Ovrednotenje in rutinsko preskušanje v medicinskih oddelkih za slikanje - 3-5. del: Preskusi sprejemljivosti in konstantnosti - Slikovni učinek rentgenske opreme za računalniško podprto tomografijo (IEC 61223-3-5:2019)

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)

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)

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)

Ta slovenski standard je istoveten z: **EN IEC 61223-3-5:2019**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN IEC 61223-3-5:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61223-3-5

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 and constancy tests - Imaging performance of computed tomography X-ray equipment (IEC 61223-3-5:2019)

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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

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.

Publication	Year	Title	EN/HD	Year
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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-7280-0

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

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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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 60788, IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2012 and IEC 60601-2-44:2009/AMD2:2016 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 Terms printed in SMALL CAPITALS are used in accordance with their definitions in the documents referred to in the Index of defined terms at the end of this document.

NOTE 2 Attention is drawn to the fact that in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

NOTE 3 Associated conditions qualifying the usage of certain terms are given below.

3.1
ACCEPTANCE TEST
test performed after new equipment has been installed, or MAJOR SERVICE ACTIONS have been made to existing equipment, in order to verify that the functional performance of equipment meets ESTABLISHED CRITERIA from the MANUFACTURER, contractual specifications, and/or requirements of this document

Note 1 to entry: The ESTABLISHED CRITERIA verified are specifications affecting the image quality, RADIATION OUTPUT and PATIENT positioning. Additionally, during or immediately after the ACCEPTANCE TEST, the BASELINE VALUES for CONSTANCY TEST are established.

3.2
CONSTANCY TEST
test performed to verify 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

Note 1 to entry: The test verifies conformance with specifications affecting the image quality, radiation output and PATIENT positioning.

3.3
CT CONDITIONS OF OPERATION
selectable parameters governing the operation of a CT SCANNER