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

IEC 61223-3-5:2019-09(en-fr)

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FOREWORD

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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.

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- withdrawn,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

Note 1 to entry: Examples of such conditions include 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.

Note 2 to entry: Some CT CONDITIONS OF OPERATION may vary during the exposure.

Note 3 to entry: CT CONDITIONS OF OPERATION include parameters that are derived by the system from the user-selectable parameters.

[SOURCE: IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.202]

3.4
CT DOSE INDEX 100
$CTDI_{100}$
integral of the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE divided by N x T according to the following:

for $N \times T$ less than or equal to 40 mm

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

for $N \times T$ greater than 40 mm (all CT CONDITIONS OF OPERATION except collimation are kept the same for these measurements)

$$CTDI_{100} = \int_{-50\,\mathrm{mm}}^{+50\,\mathrm{mm}} \frac{D_{\mathrm{Ref}}(z)}{(N \times T)_{\mathrm{Ref}}}\, dz \times \frac{CTDI_{\mathrm{free\ air},\, N \times T}}{CTDI_{\mathrm{free\ air,\ Ref}}}$$

where

$D(z)$ is the DOSE PROFILE representative of a single axial scan along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 203.108);

$(N \times T)_{\mathrm{Ref}}$ is a SPECIFIC $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;

$D_{\mathrm{Ref}}(z)$ is the DOSE PROFILE representative of a single axial scan along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 203.108) for $(N \times T)_{\mathrm{Ref}}$;

$CTDI_{\mathrm{free\ air},\, N \times T}$ is the $CTDI_{\mathrm{free\ air}}$ (IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.215) for a SPECIFIC value of $N \times T$;

$CTDI_{\mathrm{free\ air,\ Ref}}$ is the $CTDI_{\mathrm{free\ air}}$ (IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.215) for $(N \times T)_{\mathrm{Ref}}$;

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 to entry: The dose is reported as ABSORBED DOSE to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.

Note 2 to entry: This definition assumes that the DOSE PROFILE is centred on $z = 0$.

Note 3 to entry: A single axial scan is typically a 360° rotation of the X-ray source.

Note 4 to entry: When the TOMOGRAPHIC SECTIONS overlap, for example in CT SCANNERS with a "z-flying FOCAL SPOT", the denominator of the integral needs to be replaced by the total nominal width along z of overlapping

TOMOGRAPHIC SECTIONS. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by 0,5 × N × T.

Note 5 to entry: Typically the z-axis is the axis of rotation.

Note 6 to entry: See Annex CC of IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012 for explanation.

[SOURCE: IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.203, modified – In the term, "computed tomography" has been replaced by "CT". Note 6 has been deleted, and Note 7 renumbered Note 6.]

3.5
CT DOSE INDEX MEASURED FREE-IN-AIR
$CTDI_{\text{free air}}$
integral of the DOSE PROFILE representative of a single axial scan along a line through the ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

$$CTDI_{\text{free air}} = \int_{-L/2}^{+L/2} \frac{D(z)}{N \times T} dz$$

where

$D(z)$ is the DOSE PROFILE representative of a single axial scan along a line z through ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

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;

L is at least ($N \times T$) +40 mm, but not less than 100 mm

Note 1 to entry: This definition assumes that the DOSE PROFILE is centred on z = 0.

Note 2 to entry: When the TOMOGRAPHIC SECTIONS overlap, for example in CT SCANNERS with a "z-flying FOCAL SPOT", the denominator of the integral needs to be replaced by the total nominal width along z of overlapping TOMOGRAPHIC SECTIONS. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by 0,5 × N × T.

Note 3 to entry: Typically, a RADIATION DETECTOR of length L or longer is used. Annex DD of IEC 60601-2-44:2009, IEC 60601-2-44:2009/AMD1:2016 and IEC 60601-2-44:2009/AMD2:2016 provides an example for alternate measurements.

[SOURCE: IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.215, modified – In the term, "computed tomography" has been replaced by "CT".]

3.6
CT NUMBER
number used to represent the mean X-ray ATTENUATION associated with each elemental area of the COMPUTED TOMOGRAPHY image

Note 1 to entry: The CT NUMBER is normally expressed in Hounsfield units. MEASURED VALUES of the linear ATTENUATION coefficients are transformed into CT NUMBERS using the international Hounsfield scale, using the expression:

$$\text{CT NUMBER} = \frac{\mu_{\text{material}} - \mu_{\text{water}}}{\mu_{\text{water}}} \times 1\,000$$

where

μ is the linear ATTENUATION coefficient.

Note 2 to entry: The CT NUMBER scale is defined so that water has a value of 0 and air a value of –1 000 (μ_{air} is assumed to be 0).

3.7
CT PITCH FACTOR
in helical scanning the ratio of the PATIENT SUPPORT travel Δd along the z direction per rotation of the X-ray source divided by the product of the NOMINAL TOMOGRAPHIC SECTION THICKNESS T and the number of TOMOGRAPHIC SECTIONS N:

$$CT\ pitch\ factor = \frac{\Delta d}{N \times T}$$

where

Δd is the PATIENT SUPPORT travel along the z-direction per rotation of the X-RAY SOURCE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-RAY SOURCE.

Note 1 to entry: Although the CT PITCH FACTOR is associated with helical scanning, its definition refers to parameters T and N that are defined only for axial scanning. This definition of CT PITCH FACTOR presumes that these axial-scanning parameters T and N correspond to the same collimation and active-detector configuration as that of the helical scanning for which the CT PITCH FACTOR is being evaluated.

Note 2 to entry: When the TOMOGRAPHIC SECTIONS overlap, for example in CT SCANNERS with a "z-flying FOCAL SPOT", the denominator of the integral needs to be replaced by the total nominal width along z of overlapping TOMOGRAPHIC SECTIONS. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by $0{,}5 \times N \times T$.

Note 3 to entry: CT PITCH FACTOR will be a function of time when Δd is variable during the exposure.

Note 4 to entry: The terms "helical" is used in this document as a synonym for the term "spiral".

[SOURCE: IEC 60601-2-44:2009 and IEC 60601-2-44:2009/AMD1:2012, 201.3.204, modified – Note 2 has been replaced by a new note.]

3.8
CT SCANNER
X-RAY EQUIPMENT intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data obtained at different angles, which may include signal analysis and display equipment, PATIENT SUPPORT, support parts and ACCESSORIES

Note 1 to entry: The scope of IEC 60601-2-44:2009 is limited to CT SCANNERS intended to be used for both head and body imaging, characterized by an ENCLOSURE of the X-ray source(s) and imaging detector(s) in a common protective cover in the shape of a toroid.

Note 2 to entry: Secondary imaging processing is not included in the scope of IEC 60601-2-44:2009.

[SOURCE: IEC 60601-2-44:2009, 201.3.201]

3.9
DOSE PROFILE
representation of the dose as a function of position along a line

[SOURCE: IEC 60601-2-44:2009, 201.3.205]

3.10
FULL WIDTH AT HALF-MAXIMUM
FWHM
interval parallel to the abscissa between the points on a curve with the value of one-half of the maximum of the curve

3.11
IMAGE DISPLAY DEVICE
device capable of displaying images from an input signal provided by an imaging system

3.12
LOW CONTRAST RESOLUTION
smallest size that can be individually resolved at a given level of contrast and for a SPECIFIED shape from a uniform background

3.13
MAJOR SERVICE ACTION
service action that may significantly affect RADIATION OUTPUT, image quality, or PATIENT positioning, and requires an ACCEPTANCE TEST as described in the ACCOMPANYING DOCUMENTS

3.14
MEAN CT NUMBER
mean value of the CT NUMBERS of all pixels within a certain defined REGION OF INTEREST

3.15
NOISE
variation of CT NUMBERS from a mean value in a defined area in the image of a uniform substance

Note 1 to entry: The magnitude of NOISE is indicated by the standard deviation of the CT NUMBERS of a uniform substance in the REGION OF INTEREST.

3.16
NOMINAL TOMOGRAPHIC SECTION THICKNESS
in CT SCANNERS, the TOMOGRAPHIC SECTION THICKNESS which is selected and indicated on the CONTROL PANEL

Note 1 to entry: The RECONSTRUCTED SECTION THICKNESS might or might not be equal to the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

[SOURCE: IEC 60601-2-44:2009, 201.3.206, modified – Note 1 to entry has been rephrased.]

3.17
RECONSTRUCTED SECTION THICKNESS
FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE of a reconstructed image

3.18
REGION OF INTEREST
ROI
localized part of an image, of defined shape and dimension, which is of particular interest at a given time

Note 1 to entry: This note applies to the French language only.

3.19
SENSITIVITY PROFILE
relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

[SOURCE: IEC 60601-2-44:2009, 201.3.207]

3.20
SPATIAL RESOLUTION
<CT SCANNERS> ability to resolve spatially adjacent objects in the image, when the difference in ATTENUATION between the objects and the background is large compared to NOISE

Note 1 to entry: Normally, a difference in ATTENUATION coefficient between the object and the background resulting in a difference of the respective CT NUMBERS of several hundred Hounsfield units is regarded as large enough.