

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**





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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

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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