

Evaluation and routine testing in medical imaging departments —

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

The European Standard EN 61223-3-5:2004 has the status of a British Standard

ICS 11.040.50

National foreword

This British Standard is the official English language version of EN 61223-3-5:2004. It is identical with IEC 61223-3-5:2004.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/2, Diagnostic imaging equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 33 and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 12 November 2004

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ISBN 0 580 44750 2

**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)

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CENELEC

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

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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).

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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*

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)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE 1 In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard or in IEC 60788.

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 An index of defined terms used in this standard is given in Annex A.

NOTE 4 Associated conditions qualifying the usage of certain terms are given below.

3.1

ACCEPTANCE TEST

test carried out after new EQUIPMENT has been installed, or major modifications have been made to existing EQUIPMENT, in order to verify compliance with contractual specifications

[IEC 61223-1:1993, definition 3.2.4] [1]

3.2

CONSTANCY TEST

each of a series of tests carried out to ensure that the functional performance of EQUIPMENT meets established criteria; or to enable the early recognition of changes in the properties of components of the EQUIPMENT

[IEC 61223-1:1993, definition 3.2.6]

3.3

CT CONDITIONS OF OPERATION

all selectable parameters governing the operation of a CT SCANNER, for example 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

[IEC 60601-2-44, definition 2.102]

3.4

CT SCANNER

X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT)

diagnostic X-ray system intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data obtained at different angles. This generic type of device may include signal analysis and display EQUIPMENT, PATIENT SUPPORT, support parts and ACCESSORIES

NOTE Secondary imaging processing is not included in the scope of this standard.

[IEC 60601-2-44, definition 2.101]

3.5

COMPUTED TOMOGRAPHY DOSE INDEX 100

CTDI ₁₀₀

integral of the DOSE PROFILE produced in a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE from -50 mm to +50 mm, divided by the product of the number of TOMOGRAPHIC SECTIONS N and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T

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

where

$D(z)$ is the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as absorbed dose to air;

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 The term $CTDI_{100}$ has been introduced as a more representative value for dose than the traditional $CTDI$ integrated from $-7 T$ to $+7 T$ as defined by the FDA in 21 CFR 1020.33⁴⁾.

NOTE 2 The dose is reported as absorbed dose to air. This is required in order to avoid present confusion, as some MANUFACTURERS of CT SCANNERS express dose values calculated as absorbed dose to air and others as absorbed dose to polymethyl-methacrylate (PMMA).

Although $CTDI_{100}$ refers to absorbed dose to air, for practical purposes the evaluation of absorbed dose to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the air kerma with an ionization chamber in the PHANTOM.

NOTE 3 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

NOTE 4 A single axial scan is typically a 360° rotation of the X-ray source.

[IEC 60601-2-44, definition 2.106]

3.6

WEIGHTED $CTDI_{100}$

weighted $CTDI$ ($CTDI_w$) defined as

$$CTDI_w = \frac{1}{3} CTDI_{100(\text{centre})} + \frac{2}{3} CTDI_{100(\text{peripheral})}$$

where

$CTDI_{100(\text{centre})}$ is the value measured in the centre of the test object, and

$CTDI_{100(\text{peripheral})}$ is the average value measured in the periphery of the test object.

3.7

COMPUTED TOMOGRAPHY NUMBER

CT NUMBER

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

NOTE 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:

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

where

μ is the linear ATTENUATION coefficient.

The CT NUMBER scale is defined so that water has a value of 0 and air a value of 1 000.

[IEC 61223-2-6:1994, definition 3.3.2] [3]

4) U.S.Code of Federal Regulations, Title 21, Chapter 1: Food and Drug Administration (FDA), Part 1020 – Performance standards for ionizing radiation emitting products: Section 1020.33: Computed tomography (CT) equipment

3.8

DOSE PROFILE

representation of the dose as a function of position along a line

[60601-2-44, definition 2.103]

3.9

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

[IEC 61223-2-6:1994, definition 3.3.4]

3.10

IMAGE DISPLAY DEVICE

device capable of displaying images from an input signal provided by an imaging system

3.11

LOW CONTRAST RESOLUTION

lowest contrast detail of an object of a SPECIFIED shape and area that can be resolved from a uniform background

3.12

MEAN CT NUMBER

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

[IEC 61223-2-6:1994, definition 3.3.6]

3.13

NOISE

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

The magnitude of NOISE is indicated by the standard deviation of the CT NUMBERS of a uniform substance in the REGION OF INTEREST

[IEC 61223-2-6:1994, definition 3.3.7]

3.14

NOMINAL TOMOGRAPHIC SECTION THICKNESS

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

NOTE In helical scanning the thickness of a reconstructed image depends on the helical reconstruction algorithm and pitch, and hence this thickness may not equal the NOMINAL TOMOGRAPHIC SECTION THICKNESS. The thickness of the reconstructed image may be indicated or selected prior to the helical scan.

[60601-2-44, definition 2.110]

3.15

REGION OF INTEREST

ROI

localised part of an image, which is of particular interest at a given time

[IEC 61223-2-6:1994, definition 3.3.9]

3.16

SENSITIVITY PROFILE

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

[source 60601-2-44, definition 2.104]

3.17

SPATIAL RESOLUTION

in EQUIPMENT for COMPUTED TOMOGRAPHY, the ability to resolve different objects in the displayed image, when the difference in ATTENUATION between the objects and the background is large compared to NOISE

NOTE 1 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.

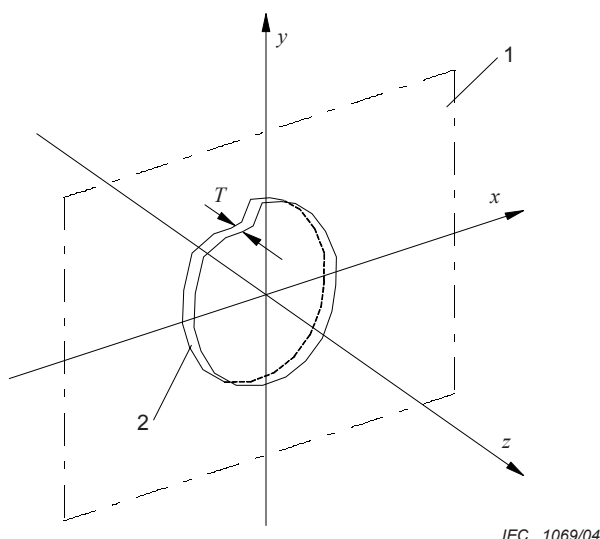
NOTE 2 high-contrast resolution is an alternative name for SPATIAL RESOLUTION.

[IEC 61223-2-6:1994, definition 3.3.12]

3.18

TOMOGRAPHIC PLANE

geometric plane perpendicular to the axis of rotation (see Figure 1)



IEC 1069/04

Key

- 1 TOMOGRAPHIC PLANE
- 2 PHANTOM

Figure 1 – Coordinate system

3.19

TOMOGRAPHIC SECTION

volume over which TRANSMISSION data of X-RADIATION are collected in a single axial scan

NOTE In a CT SCANNER with multiple detector elements along the z-axis, it is the volume over which data are collected by a single acquisition channel (selected grouping of elements) and not the total volume irradiated.

[source 60601-2-44, definition 2.108]