

Evaluation and routine testing in medical imaging departments —

Part 2-6: Constancy tests — Imaging performance of computed tomography X-ray equipment

The European Standard EN 61223-2-6:2007 has the status of a British Standard

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National foreword

This British Standard is the UK implementation of EN 61223-2-6:2007. It is identical to IEC 61223-2-6:2006. It supersedes BS EN 61223-2.6:1995 which is withdrawn.

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.

A list of organizations represented on this committee can be obtained on request to its secretary.

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**Evaluation and routine testing in medical imaging departments -
Part 2-6: Constancy tests -
Imaging performance of computed tomography X-ray equipment
(IEC 61223-2-6:2006)**

Essais d'évaluation et de routine
dans les services d'imagerie médicale -
Partie 2-6: Essais de constance -
Performance d'imagerie des équipements
de tomodensitométrie à rayonnement X
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Bewertung und routinemäßige Prüfung
in Abteilungen
für medizinische Bildgebung -
Teil 2-6: Konstanzprüfungen -
Röntgeneinrichtungen
für die Computertomographie
(IEC 61223-2-6:2006)

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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Foreword

The text of document 62B/629/FDIS, future edition 2 of IEC 61223-2-6, 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 61223-2-6 on 2007-03-01.

This European Standard supersedes EN 61223-2-6:1994.

EN 61223-2-6:2007 is harmonized with the content of EN 60601-2-44:2001 + A1:2003 and with EN 61223-3-5:2004. Instead of harmonizing test procedures for all modalities of X-ray equipment, as intended in EN 61223-2-6:1994, this EN 61223-2-6:2007 comprises part of a set of standards covering all of the particular requirements for CT scanners.

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) | 2007-12-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2010-03-01 |

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, IN EN 60788, IN EN 61223-1 OR IN OTHER PUBLICATIONS REFERENCED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-2-6:2006 was approved by CENELEC as a European Standard without any modification.

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INTRODUCTION

The second edition of this standard is harmonized with the content of

- IEC 60601-2-44:2001, *Particular requirements for the safety of X-ray equipment for computed tomography* and its Amendment 1 (2002), and
- IEC 61223-3-5, *Evaluation and routine testing in medical imaging departments – Part 3-5, Acceptance tests – Imaging performance of computed tomography X-ray equipment*.

In case the CT SCANNER does not offer an integrated, automated evaluation of the test images, attention shall be given to the proper function and setting of the IMAGE DISPLAY DEVICE. It is strongly recommended to assure its proper functioning prior to the constancy testing of the CT SCANNER, applying IEC 61223-2-5 [1] ¹⁾ on IMAGE DISPLAY DEVICES or the related in-house procedure. Some provisions or statements in this standard require additional information, which is presented in the annexes. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

With regard to the measurements, reference is made to methods described in related publications, which for practical reasons should be carried out prior to the application of the methods described in this standard.

This standard forms Part 2-6 of IEC 61223, which includes the following parts of particular interest in the context of this standard:

- Part 1: General aspects [2]
- Part 2-4: Constancy tests – Hard copy cameras [3]
- Part 2-5: Constancy tests – Image display devices

¹⁾ Figures in square brackets refer to the Bibliography.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment

1 Scope and object

This part of IEC 61223 provides assistance in performing CONSTANCY TESTS on a CT SCANNER.

It 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 CT SCANNERS with regard to image quality, PATIENT dose and positioning; the list of parameters to be tested can be found in section 4.5;
- defines the methods of testing the essential parameters;
- provides criteria to be applied in the evaluation of data for compliance with the tolerances of the parameters specified by the ACCOMPANYING DOCUMENTS and with respect to BASELINE VALUES.

These methods rely on non-invasive measurements, using appropriate test equipment, performed 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.

The aim is to verify compliance with specifications affecting the image quality, PATIENT dose and PATIENT positioning.

It is not intended to consider:

- aspects of mechanical and electrical safety nor
- aspects of mechanical, electrical and software performance, unless they are essential for performing the CONSTANCY TESTS and directly affect 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 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61223-3-5:2004, *Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment*

IEC 60601-2-44:2001, *Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography*

Amendment 1 (2002)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60788:2004 and the following apply.

NOTE 1 An index of defined terms used in this standard is given following the annexes

NOTE 2 Attention is drawn to the fact that in cases where the concept addressed is not strongly confined to the definition given in IEC 61223-1 or IEC 60788, a corresponding term is printed in lower case letters.

3.1

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 60601-2-44:2001, definition 2.102]

3.2

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, Amend.1:2002, definition 2.101]

3.3

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 1020.33 [31].

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, Amendment 1:2002, definition 2.106]

3.4

WEIGHTED $CTDI_{100}$

The WEIGHTED $CTDI_{100}$ ($CTDI_w$) is 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 CT DOSIMETRY PHANTOM and

$CTDI_{100(\text{peripheral})}$ is the average value measured in the periphery of the CT DOSIMETRY PHANTOM

3.5

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:

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

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 -1000 (μ_{air} is assumed to be 0).

3.6

COMPUTED TOMOGRAPHY DOSE INDEX FREE IN AIR

$CTDI_{\text{free air}}$

$CTDI_{100}$ measured at isocentre in the absence of a PHANTOM and the PATIENT SUPPORT

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 :

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

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.

[IEC 60601-2-44, Amend.1:2002, definition 2.107]

3.8

DOSE PROFILE

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

[IEC 60601-2-44:2001, definition 2.103]

3.9

MEAN CT NUMBER

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

3.10

NOISE

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

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

3.11

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.

[IEC 60601-2-44, Amend.1:2002, definition 2.110]

3.12

SENSITIVITY PROFILE

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

[IEC 60601-2-44:2001, definition 2.104]

3.13

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.

3.14

TOMOGRAPHIC PLANE

geometric plane perpendicular to the axis of rotation

[IEC 60601-2-44:2001, definition 2.105]

3.15

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.

[IEC 60601-2-44, Amendment 1:2002, definition 2.108]

3.16

TOMOGRAPHIC SECTION THICKNESS

FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE taken at the isocentre of a TOMOGRAPHIC SECTION

[IEC 60601-2-44, Amendment 1:2002, definition 2.109]

3.17

UNIFORMITY

consistency of the CT NUMBERS of the image of a homogeneous material across the scan field

3.18

VOLUME $CTDI_w$

$CTDI_{vol}$

average dose over the total volume scanned for the selected CT CONDITIONS OF OPERATION

The $CTDI_{vol}$ is defined as follows:

a) for axial scanning

$$CTDI_{vol} = \frac{N \cdot T}{\Delta d} \cdot CTDI_w$$

where

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;

Δd is the PATIENT SUPPORT travel in z-direction between consecutive scans.

b) for helical scanning

$$CTDI_{vol} = \frac{CTDI_w}{CT \text{ pitch factor}}$$

c) for scanning without pre-programmed movement of the PATIENT SUPPORT

$$CTDI_{vol} = n \cdot CTDI_w$$

where n is equal to the maximum number of pre-programmed rotations.

NOTE 1 The displayed $CTDI_{vol}$ given by the MANUFACTURER may be a representative figure for that model and not the value measured on the particular CT SCANNER

NOTE 2 The definition of $CTDI_{vol}$ in section c) will likely overestimate the actual dose since the maximum number of pre-programmed rotations is applied, but is used as a conservative estimation of dose to help assure PATIENT protection from skin radiation injury.

NOTE 3 The manual movement of the PATIENT SUPPORT is included under c).

3.19**CT DOSIMETRY PHANTOM**

The dosimetry PHANTOM shall consist of PMMA cylinders of diameter 160 mm for head techniques and 320 mm for body techniques. The length of the PHANTOM shall be at least 140 mm. The PHANTOM shall be longer than the sensitive volume of the RADIATION DETECTOR used for the measurements. The phantom shall contain holes just large enough to accept the RADIATION DETECTOR. These holes shall be parallel to the axis of symmetry of the PHANTOM and the centres of the holes shall be located at the centre and 10 mm below the surface of the PHANTOM at 90° intervals.

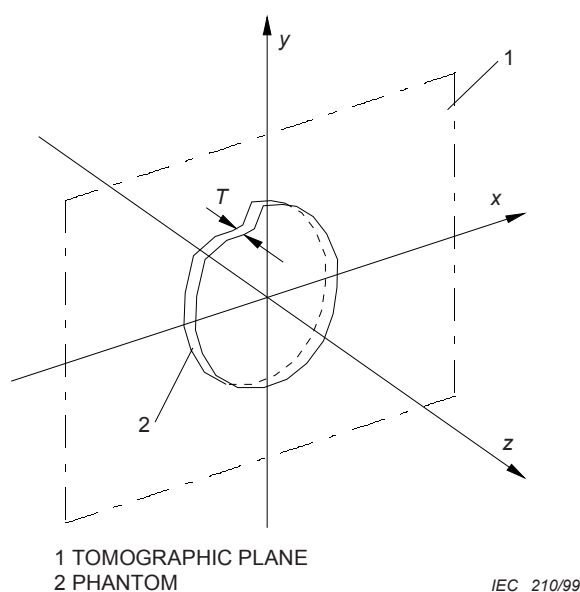


Figure 1 – Coordinate system used for CT SCANNERS

4 General aspects of CONSTANCY TESTS

4.1 Preconditions

For the results of the CONSTANCY TESTS described in this standard to be valid, it is essential to ensure that they are not significantly influenced by anything other than changes in the parameters under test.

All equipment under test or used for testing shall be marked or recorded in order to permit easy identification and to assist in ensuring that the same items are used subsequently in related CONSTANCY TESTS. Prior to testing, the constancy of all equipment that is used for CONSTANCY TESTS shall be checked.

4.2 General conditions affecting test procedures

Careful consideration shall be given to the appropriate choice of the test conditions under which the CT SCANNER is checked, including environmental parameters.

The CONSTANCY TESTS described in this standard have been designed to be robust, that is, their results should be affected only by changes in the parameters under investigation. The range of TEST DEVICES and test equipment has been kept to a minimum and restricted where possible to devices that are passive, inherently simple or reasonably stable.