SLOVENSKI STANDARD
SIST EN 60601-2-44:2002/A1:2003

01-april-2003

Medicinska električna oprema - 2-44. del: Posebne varnostne zahteve za rentgensko opremo za računalniško podprto tomografijo (IEC 60601-2-44:2001/A1:2002)

Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography (IEC 60601-2-44:2001/A1:2002)

Medizinische elektrische Geräte - Teil 2-44: Besondere Festlegungen für die Sicherheit von Röntgeneinrichtungen für die Computer-Tomographie (IEC 60601-2-44:2001/A1:2002)

Appareils électromédicaux - Partie 2-44: Règles particulières de sécurité pour les équipements à rayonnement X de tomodensitométrie (CEI 60601-2-44:2001/A1:2002)

Ta slovenski standard je istoveten z: **EN 60601-2-44:2001/A1:2003**

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11.040.50 Radiografska oprema Radiographic equipment

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EUROPEAN STANDARD

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English version

Medical electrical equipment
Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography
(IEC 60601-2-44:2001/A1:2002)

Appareils électromédicaux
Partie 2-44: Règles particulières
de sécurité pour les équipements
à rayonnement X de tomodensitométrie
(CEI 60601-2-44:2001/A1:2002)

Medizinische elektrische Geräte
Teil 2-44: Besondere Festlegungen für
die Sicherheit von Röntgeneinrichtungen
für die Computer-Tomographie
(IEC 60601-2-44:2001/A1:2002)

This amendment A1 modifies the European Standard EN 60601-2-44:2001; it was approved by CENELEC on 2002-12-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 Central Secretariat or to any CENELEC member.

This amendment 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 Central Secretariat has the same status as the official versions.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-44:2001/A1:2003 E

Foreword

The text of document 62B/472/FDIS, future amendment 1 to IEC 60601-2-44:2001, 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 amendment A1 to EN 60601-2-44:2001 on 2002-12-01.

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2003-09-01
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2005-12-01

Endorsement notice

The text of amendment 1:2002 to the International Standard IEC 60601-2-44:2001 was approved by CENELEC as an amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

IEC 60601-2-44

2001

AMENDMENT 1
2002-09

Amendment 1

Medical electrical equipment –

Part 2-44:
Particular requirements for the safety of X-ray equipment for computed tomography

Amendement 1

Appareils électromédicaux –

Partie 2-44:
Règles particulières de sécurité pour les équipements à rayonnement X de tomodensitométrie

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For price, see current catalogue

FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/472/FDIS	62B/478/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until 2004-06. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of April 2006 have been included in this copy.

INTRODUCTION

In the second edition of this Particular Standard six definitions were changed compared with the first edition. These changes, however, were not in line with the definitions used in international scientific publications. This amendment to the Particular Standard mainly corrects those definitions and adds more detailed definitions of the dose values to be displayed.

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2 Terminology and definitions

Replace the existing definitions 2.101 and 2.106 to 2.110 by the following:

2.101
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.

2.106
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:*

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

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 –7T to +7T as defined by the FDA in 21 CFR 1020.33 [1].

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.

2.107
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:*

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

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.

2.108
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.

2.109
TOMOGRAPHIC SECTION THICKNESS

FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE taken at the iso-centre of a TOMOGRAPHIC SECTION

2.110
NOMINAL TOMOGRAPHIC SECTION THICKNESS

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

[1] See bibliography

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.

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6.8.101 Reference to ACCOMPANYING DOCUMENTS

Delete the following lines:

Frequency of SUPPLY MAINS ..... 6.1 h)

Power input ..... 6.1 j)

Add the following line:

Protection against STRAY RADIATION 29.208

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29.1.101.2 Limitation of RADIATION output

Replace the second paragraph of item a) as follows:

During IRRADIATION, the OPERATOR shall be able to terminate the LOADINGS at any time, but means may be provided to acquire up to one additional rotation of the X-RAY SOURCE.

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29.1.101.3 Connection of external INTERLOCKS

Replace the existing text of the second paragraph as follows:

The diagnostic and interventional methods performed on a CT-SCANNER will in practically all cases expose the PATIENT as well as the OPERATOR to a significantly higher dose when external INTERLOCKS are activated, as the radiological examination may have to be repeated. Also the interruption of an interventional procedure may cause an additional risk to the PATIENT. Such INTERLOCKS should therefore only be applied when unavoidable, e.g. when required by other regulations.

29.1.102.1 Dose statements

Replace the existing text of item a) by the following:

a) The $CTDI_{100}$ and the corresponding CT CONDITIONS OF OPERATION at the following locations in the dosimetry PHANTOM specified in 29.1.102.2:

   1) Along the axis of rotation of the PHANTOM ($CTDI_{100(centre)}$).

   2) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM, with the PHANTOM positioned so that the $CTDI_{100}$ is the maximum obtainable at this depth.

3) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM at positions 90°, 180° and 270° from the position in item a) 2) of this subclause. The CT CONDITIONS OF OPERATION shall be the typical values suggested by the MANUFACTURER. The location of the position where the $CTDI_{100}$ is maximum as specified in item a) 2) of this subclause shall be given by the MANUFACTURER with respect to the housing of the scanning mechanism or other readily identifiable part of the CT SCANNER in such a manner as to permit placement of the dosimetry PHANTOM in this orientation.

4) $CTDI_{100\ (peripheral)}$ is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery according to 29.1.102.1 a) 2) and 3).

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29.1.103.3 Weighted $CTDI_{100}$

Replace the entire existing text of the subclause as follows:

The weighted $CTDI_{100}$ ($CTDI_w$) is defined as

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

see 29.1.102.1 a), items 1) and 4).

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Add the following new subclause:

29.1.103.4 Volume $CTDI_w$ ($CTDI_{vol}$)

The volume $CTDI_w$ ($CTDI_{vol}$) describes the 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

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

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

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