SLOVENSKI STANDARD
SIST EN 60601-2-44:2009/A1:2014

01-februar-2014

Medicinska električna oprema - 2-44. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za računalniško tomografijo - Dopolnilo A1 (IEC 60601-2-44:2009/A1:2012)

Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

Medizinische elektrische Geräte - Teil 2-44: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für die Computertomographie

Appareils electromédicaux - Partie 2-44: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de tomodensitométrie

Ta slovenski standard je istoveten z: **EN 60601-2-44:2009/A1:2012**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-44:2009/A1:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-44/A1

October 2012

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English version

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/A1:2012)

Appareils electromédicaux -
Partie 2-44: Exigences particulières
pour la sécurité de base
et les performances essentielles
des équipements à rayonnement X
de tomodensitométrie
(CEI 60601-2-44:2009/A1:2012)

Medizinische elektrische Geräte -
Teil 2-44: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Röntgeneinrichtungen
für die Computertomographie
(IEC 60601-2-44:2009/A1:2012)

This amendment A1 modifies the European Standard EN 60601-2-44:2009; it was approved by CENELEC on 2012-10-04. 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.

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

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Foreword

The text of document 62B/869/FDIS, future amendment 1 to edition 3 of IEC 60601-2-44, 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 approved by CENELEC as EN 60601-2-44:2009/A1:2012.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2013-07-04
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-10-04

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Endorsement notice

The text of the International Standard IEC 60601-2-44:2009/A1:2012 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
*In Annex ZA of EN 60601-2-44:2009, **add** under **Replacement** the following new reference:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
*In Annex ZA of EN 60601-2-44:2009, **add** under **Addition** the following new reference:*				
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-

IEC 60601-2-44

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

Appareils électromédicaux –
Partie 2-44: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de tomodensitométrie

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

This amendment has been prepared by subcommittee SC 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/879/FDIS	62B/890/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 this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

NOTE The attention of National Committees 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Introduction to Amendment 1

The main topic addressed in this amendment is an extended concept of CTDI to accommodate CT SCANNERS with very large z-coverage. The other principal subject areas include:

1) a dose-check feature associated with a pre-scanning alert if expected values of dose indices exceed user-configurable DOSE NOTIFICATION VALUES or DOSE ALERT VALUES and
2) requirements covering the use of CT data in radiotherapy treatment planning (RTP).

The CT dose metric in use has been based on the $CTDI_{100}$, i.e. measurement of dose in PHANTOMs and limited integration of scattered radiation, and it is used in many countries' legislation to define "dose reference values" (also called "diagnostic reference levels") for CT examinations. Many people use these indices, $CTDI_{vol}$ and DLP, to derive estimates for effective dose via conversion factors. $CTDI_{100}$ is also part of CT acceptance and constancy testing. The introduction of a new dose index would change all CT SCANNERS' CTDI values. Therefore the intention is to stay with the $CTDI_{100}$, i.e. the integration of primary radiation and scatter over 100 mm, but adapt the way of measuring and reporting the dose index to incorporate large collimations and to rate all collimations the same way, i.e. to reflect approximately the same percentage of $CTDI_{\infty}$ for all collimations.

As defined in the amendment, $CTDI_{100}$ is to be measured only for collimations up to 40 mm with the current equipment, i.e. the PMMA PHANTOMs and a 100-mm chamber, or other suitable methods that use a RADIATION DETECTOR. For these collimations there is no significant change of the ratio $CTDI_{100}$ / $CTDI_{\infty}$ according to published data. For larger collimations at the same CT CONDITIONS OF OPERATION, the z-efficiency may be different and must be evaluated in the dose measurement. This can be accomplished by the measurement of dose 'free air'. Based on these considerations $CTDI_{100}$ and the $CTDI_{free\ air}$ have been refined. Both types of measurement are combined now to determine the CTDI values for larger collimations and they are explained in detail in informative Annexes CC and DD.

Some additional requirements and refinements related to dose have been added: $CTDI_{vol}$ and DLP are defined for a new type of scan mode ('shuttle mode'). In body CT EXAMINATION it is clarified that the $CTDI_{vol}$ and DLP always be reported for the 32-cm diameter PHANTOM. In the amendment it is now required that CT SCANNERS support user-configurable DOSE NOTIFICATION VALUES and DOSE ALERT VALUES.

A new subject area in this Amendment 1 covers requirements for CT SCANNERS providing images for radiotherapy treatment planning. With this amendment begins the implementation of this important CT application into the CT safety standard with a set of requirements that is considered to be safety relevant. It mainly covers scanner hardware adjustments, accuracy of CT image data, and the conversion of HU to electron and mass density.

201.1.1 Scope

Add the following new sentence:

The scope of this International Standard excludes RADIOTHERAPY SIMULATORS and systems where the image is created by a source other than an X-RAY TUBE.

201.1.3 Collateral standards

Replace the existing text of this subclause with the following:

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10[1], IEC 60601-1-11[2] and IEC 60601-1-12[3] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

For collateral standards published after this particular standard, MANUFACTURERS need to determine the applicability in accordance with the RISK MANAGEMENT PROCESS.

201.2 Normative references

Add, under "Replacement", the following new reference:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Add, under "Addition", the following new reference:

IEC 60336 *Medical electric equipment – X-Ray Tube assemblies for medical diagnosis – Characteristics of focal spots*

201.3 Terms and definitions

201.3.202
CT CONDITIONS OF OPERATION

Add a note 3 to this definition:

NOTE 3 CT CONDITIONS OF OPERATION include parameters that are derived by the system from the user-selectable parameters.

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[1] IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

[2] IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

[3] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended to be used in the emergency medical services environment*

201.3.203
COMPUTED TOMOGRAPHY DOSE INDEX 100
***CTDI*$_{100}$**

Replace the existing text of the definition by the following:

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

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

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

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

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 203.108);
$(N \times T)_{Ref}$	is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;
$D_{Ref}(z)$	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 203.108) for $(N \times T)_{Ref}$;
$CTDI_{free\ air,\, N \times T}$	is the $CTDI_{free\ air}$ (201.3.215) for a specific value of $N \times T$;
$CTDI_{free\ air,\, Ref}$	is the $CTDI_{free\ air}$ (201.3.215) for $(N \times T)_{Ref}$;
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 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 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

NOTE 3 A single axial scan is typically a 360° rotation of the X-ray source.

NOTE 4 When the TOMOGRAPHIC SECTIONS overlap, e.g. 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 Typically the z-axis is the axis of rotation.

NOTE 6 The $CTDI_{100}$ is designed to include most of the scattered radiation.

NOTE 7 See Annex CC for explanation.

201.3.204
CT PITCH FACTOR

*Replace, in Note 3, the text "*or $N \times T$ are*" by the word "*is*".*

201.3.212
VOLUME $CTDI_w$
$CTDI_{vol}$
a) for axial scanning

Replace Notes 1 and 2 by the following:

NOTE 1 For the selected CT CONDITIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_w$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration along the z-axis. For axial scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area × Δd.

NOTE 2 For axial scanning with a total table travel much less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area ×Δd.

b) for helical scanning

In Note 1 replace the text "or $N \times T$ are" *by the text* "is".

Replace Notes 2 and 3 by the following:

NOTE 2 For the selected CT CONDITIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_w$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of integration along the z-axis. For helical scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the centre of a 100 mm scan length.

NOTE 3 For helical scanning, when the product of a small number of rotations times the table travel per rotation is much less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the centre of a 100-mm scan length.

Add the following new item:

d) for axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$CTDI_{vol} = n \frac{N \times T}{(N \times T) + R} CTDI_w$$

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;

n is equal to the total number of rotations for the entire scan series;

R is the distance between the two positions;

$CTDI_W$ is the WEIGHTED $CTDI_{100}$.

NOTE 1 Seen Figure 201.102.

NOTE 2 $CTDI_w$ is evaluated as the time weighed $CTDI_w$ reflecting the varying CT CONDITIONS OF OPERATION.