SLOVENSKI STANDARD
SIST EN 60601-2-44:2009/A2:2016

01-september-2016

Medicinska električna oprema - 2-44. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za računalniško tomografijo - Dopolnilo A2

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

Ta slovenski standard je istoveten z: **EN 60601-2-44:2009/A2:2016**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-44:2009/A2:2016 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-44:2009/A2

June 2016

ICS 11.040.50

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/A2:2016)

Appareils electromédicaux - Partie 2-44: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de tomodensitométrie
(IEC 60601-2-44:2009/A2:2016)

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/A2:2016)

This amendment A2 modifies the European Standard EN 60601-2-44:2009; it was approved by CENELEC on 2016-05-05. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-2-44:2009/A2:2016 E

European foreword

The text of document 62B/976/CDV, future IEC 60601-2-44:2009/A2, 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/A2:2016.

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) 2017-02-05
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-05-05

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s), see informative Annex ZZ, included in EN 60601-2-44:2009.

Endorsement notice

The text of the International Standard IEC 60601-2-44:2009/A2:2016 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 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 60601-2-44:2009, replace the existing references to the following publications as follows:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ A1/AC	2014

IEC 60601-2-44

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

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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:

CDV	Report on voting
62B/976/CDV	62B/994/RVC

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 website 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.

Introduction to Amendment 2

The main topics addressed in this amendment are editorial corrections and implementation of the last publications of the general and collateral standards as normative references.

Given the degree and significance of the changes to the normative references cited in this amendment, the committee has determined that a 4 year transition period is warranted and appropriate.

201.1 Scope, object and related standards

Replace the footnote to read as follows:

[1)] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

201.2 Normative references

Replace, in the existing reference to IEC 60601-1-2, "2007" by "2014".

Add, under the existing reference to IEC 60601-1-3, "IEC 60601-1-3:2008/AMD1:2013".

Add, under the existing reference to IEC 60601-1:2005, "IEC 60601-1:2005/AMD1:2012".

201.3 Terms and definitions

Replace, in the introductory paragraph, "IEC 60601-1:2005" *by* "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" *and the reference to* "IEC 60601-1-3:2008" *by* "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013".

201.4.5 Equivalent Safety for ME EQUIPMENT or ME SYSTEMS

Replace the title of subclause 201.4.5 by the following new title

201.4.5 *Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Replace the note in this subclause by the following normative text:

Because state of the art technology changes for CT SCANNERS may result in the inability to strictly comply with all clauses of this particular standard, alternate means of addressing risks via risk management are acceptable. Alternate means are acceptable only when the RESIDUAL RISKS resulting from application of the alternative are equal to or less than the RESIDUAL RISKS that would ensue when the particular standards requirements are met.

201.9.8.3.3 Dynamic forces due to LOADING from persons

Replace, in the last paragraph,

"*Any loss of function or structural damage that could result in unacceptable RISK constitutes a failure.*"

by:

"BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained."

201.14 *PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Replace the entire existing text by the following new text:

Clause 14 of the general standard applies, except as follows:

201.14.1 *General

Addition:

NOTE 6 CT SCANNERS have PEMS with functionality necessary for BASIC SAFETY and, in certain cases, could have functionality necessary for ESSENTIAL PERFORMANCE.

202 Electromagnetic compatibility – Requirements and tests

Replace "IEC 60601-1-2:2007" *by* "IEC 60601-1-2:2014".