SLOVENSKI STANDARD
SIST EN 60601-2-8:2015/A1:2016

01-marec-2016

Medicinska električna oprema - 2-8. del: Posebne zahteve za osnovno varnost in bistvene lastnosti terapevtske rentgenske opreme, ki deluje v območju od 10 kV do 1 MV - Dopolnilo A1 (IEC 60601-2-8:2010/A1:2015)

Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV (IEC 60601-2-8:2010/A1:2015)

Medizinische elektrische Geräte - Teil 2-8: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Therapie-Röntgeneinrichtungen im Bereich von 10 kV bis 1 MV

Appareils électromédicaux - Partie 2-8: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV

Ta slovenski standard je istoveten z: EN 60601-2-8:2015/A1:2016

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-8:2015/A1:2016 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-8:2015/A1

January 2016

ICS 11.040.50

English Version

Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV (IEC 60601-2-8:2010/A1:2015)

Appareils électromédicaux - Partie 2-8: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV (IEC 60601-2-8:2010/A1:2015)

Medizinische elektrische Geräte - Teil 2-8: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Therapie-Röntgeneinrichtungen im Bereich von 10 kV bis 1 MV (IEC 60601-2-8:2010/A1:2015)

This amendment A1 modifies the European Standard EN 60601-2-8:2015; it was approved by CENELEC on 2015-11-03. 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.

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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 60601-2-8:2015/A1:2016 E

European foreword

The text of document 62C/593/CDV, future IEC 60601-2-8:2010/A1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-8:2015/A1:2016.

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) 2016-08-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-11-03

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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 60601-2-8:2015.

Endorsement notice

The text of the International Standard IEC 60601-2-8:2010/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-8:2015, replace the existing reference to IEC 60601-2-17 by the following:

IEC 60601-2-17:2013	NOTE	Harmonized as EN 60601-2-17:2015 (not modified).

IEC 60601-2-8

Edition 2.0 2015-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

Appareils électromédicaux –
Partie 2-8: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV

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FOREWORD

This amendment has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, 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
62C/593/CDV	62C/619/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 THE AMENDMENT

The second edition of IEC 60601-2-8 was published in 2010. Since that publication, an amendment to the parent standard, IEC 60601-1:2005, has been published (IEC 60601-1:2005/AMD1:2012). This Amendment 1 to IEC 60601-2-8:2010 addresses technical and editorial changes resulting from the amended general standard IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its collateral standards.

In addition, requirements regarding the original language of the ACCOMPANYING DOCUMENTS have been deleted.

201.1 Scope, object and related standards

Replace existing footnote 1) with the following text:

[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*

201.3 Terms and definitions

*Replace, in the opening paragraph, the reference to "*IEC 60601-1:2005*" with "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012"

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Delete, in the Addition, the existing second paragraph and the NOTE.

201.13 HAZARDOUS SITUATIONS and fault conditions

Replace the existing header with the following header:

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Bibliography

Replace the existing reference to IEC 60601-2-17 with the following:

IEC 60601-2-17:2013, *Medical electrical equipment – Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*

Delete footnote 3.

Index of defined terms used in this particular standard

Replace the following terms:

HAZARD ..... IEC 60601-1:2005/AMD1:2012, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005/AMD1:2012, 3.40
MAINS PART ..... IEC 60601-1:2005/AMD1:2012, 3.49
MANUFACTURER ..... IEC 60601-1:2005/AMD1:2012, 3.55
NORMAL USE ..... IEC 60601-1:2005/AMD1:2012, 3.71
PATIENT ..... IEC 60601-1:2005/AMD1:2012, 3.76
SINGLE FAULT CONDITION ..... IEC 60601-1:2005/AMD1:2012, 3.116