SLOVENSKI STANDARD
SIST EN 60601-2-54:2009/A1:2015

01-september-2015

Medicinska električna oprema - 2-54. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za radiografijo in radioskopijo - Dopolnilo A1

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Medizinische elektrische Geräte - Teil 2-54: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für Radiographie und Radioskopie

Appareils électromédicaux -- Partie 2-54: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X utilisés pour la radiographie et la radioscopie

Ta slovenski standard je istoveten z: **EN 60601-2-54:2009/A1:2015**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-54:2009/A1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-54:2009/A1

May 2015

ICS 11.040.50

English Version

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2009/A1:2015)

Appareils électromédicaux - Partie 2-54: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X utilisés pour la radiographie et la radioscopie (IEC 60601-2-54:2009/A1:2015)

Medizinische elektrische Geräte - Teil 2-54: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für Radiographie und Radioskopie (IEC 60601-2-54:2009/A1:2015)

This amendment A1 modifies the European Standard EN 60601-2-54:2009; it was approved by CENELEC on 2015-05-22. 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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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 60601-2-54:2009/A1:2015 E

Foreword

The text of document 62B/929/CDV, future IEC 60601-2-54:2009/A1, 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 60601-2-54:2009/A1:2015.

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) 2016-02-22
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-05-22

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 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-54:2009.

Endorsement notice

The text of the International Standard IEC 60601-2-54:2009/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-54:2009, **replace** notes [1] and [15] by the following notes:

[1]	IEC 60627	NOTE	Harmonized as EN 60627.
[15]	IEC 60601-2-43	NOTE	Harmonized as EN 60601-2-43.

In the Bibliography of EN 60601-2-54:2009, the following notes have to be **added** for the standards indicated:

[16]	IEC 60601-1-11	NOTE	Harmonized as EN 60601-1-11.
[17]	IEC 60601-1-12	NOTE	Harmonized as EN 60601-1-12.

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 60601-2-54:2009, **add** the following new reference:*				
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
-	-		+ A1/AC	2014
-	-		+ A12	2014
*In Annex ZA of EN 60601-2-54:2009, **delete** IEC 60601-1-2:2007:*				
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	2007
*In Annex ZA of EN 60601-2-54:2009, **replace** IEC 60601-1-3 by the following:*				
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 60601-2-54

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Appareils électromédicaux –
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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/929/CDV	62B/956/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 1

The purpose of this first amendment to IEC 60601-2-54:2009 is to introduce changes to reference the first amendment (2012) to IEC 60601-1:2005. As neither IEC 60601-2-54:2009 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed. In addition, a number of technical errors have been corrected.

FOREWORD

Replace, in the existing second paragraph, the phrase "IEC 60601-2-28:1993 (currently under revision)" *with* "parts of IEC 60601-2-28:1993".

201.1 Scope, object and related standards

Amend 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*

201.1.3 Collateral standards

Replace the existing second sentence of the second paragraph with the following:

IEC 60601-1-8, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply.

201.2 Normative references

Add the following new reference:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

Delete the following 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*

Replace the existing reference to IEC 60601-1-3 with the following:

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*
IEC 60601-1-3:2008/AMD1:2013