SIST

SLOVENSKI STANDARD
SIST EN 60601-2-43:2010/A1:2018

01-julij-2018

Medicinska električna oprema - 2-43. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za interventne postopke - Dopolnilo A1 (IEC 60601-2-43:2010/A1:2017)

Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-43:2010/A1:2017)

Medizinische elektrische Geräte - Teil 2-43: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für interventionelle Verfahren (IEC 60601-2-43:2010/A1:2017)

Appareils électromédicaux - Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions (IEC 60601-2-43:2010/A1:2017)

Ta slovenski standard je istoveten z: EN 60601-2-43:2010/A1:2018

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-43:2010/A1:2018 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-43:2010/A1

May 2018

ICS 11.040.50; 37.040.25

English Version

Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-43:2010/A1:2017)

Appareils électromédicaux - Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions (IEC 60601-2-43:2010/A1:2017)

Medizinische elektrische Geräte - Teil 2-43: Besondere Festlegungen für die Sicherheit und wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für interventionelle Verfahren (IEC 60601-2-43:2010/A1:2017)

This amendment A1 modifies the European Standard EN 60601-2-43:2010; it was approved by CENELEC on 2017-07-05. 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, Serbia, 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: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-2-43:2010/A1:2018 E

European foreword

The text of document 62B/1012/CDV, future edition 2 of IEC 60601-2-43:2010/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 60601-2-43:2010/A1:2018.

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) 2018-11-18
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2021-05-18

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.

Endorsement notice

The text of the International Standard IEC 60601-2-43:2010/A1:2017 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.

Annex ZA of EN 60601-2-43:2010 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace under "Amendment" the existing references to EN 60601-1-2 and EN 60601-1-3 with the following:				
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 IEC 60601-1-3:2008/AMD1	2008 2013	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 EN 60601-1-3:2008/A1:2013	2008 2013
Publication	Year	Title	EN/HD	Year
Add, under "Addition", the following new references:				
IEC 60601-1 IEC 60601-1:2005/AMD1	2005 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 EN 60601-1:2006/A1	2006 2013
IEC 61910-1	2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy	EN 61910-1	2014
IEC 62220-1-1	2015	Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging	EN 62220-1	2015

Publication	Year	Title	EN/HD	Year
Replace, under "Addition", the existing references to EN 60601-2-54 and to IEC 60788 as follows:				
IEC 60601-2-54 IEC 60601-2-54:2009/AMD1	2009 2015	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	EN 60601-2-54 EN 60601-2-54:2009/AMD1	2009 2015
IEC TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

IEC 60601-2-43

Edition 2.0 2017-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

Appareils électromédicaux –
Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions

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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/1012/CDV	62B/1037/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 purpose of this first amendment to IEC 60601-2-43:2010 is to introduce changes as follows:

– refer to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its applicable collateral standards;
– refer to IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 and consequent subclause adaptations;
– include a requirement to have a maximum time of 10 min to recover all functions after a recoverable failure in 201.4.101;
– include several aspects from IEC 61910-1:2014 and remove the reference to IEC PAS 61910-1:2007 in 201.4.102;
– include an alternative way of testing in 201.11.6.5.103;
– include a clarification for tableside controls in 201.12.4.106.

In addition, a number of technical errors have been corrected.

201.1 Scope, object and related standards

Replace the text of the existing footnote by the following:

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 by the following:

IEC 60601-1-8, IEC 60601-1-10[1)], IEC 60601-1-11[2)] and IEC 60601-1-12[3)] do not apply.

201.2 Normative references

Replace, under "Amendment", *the existing references to IEC 60601-1-2 and to IEC 60601-1-3 as follows:*

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*

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

Add, under "Addition", *the following new references:*

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

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62220-1-1:2015, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*

Replace, under "Addition", *the existing references to IEC 60601-2-54 and to IEC 60788 as follows:*

IEC 60601-2-54:2009, *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/AMD1:2015

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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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 for use in the emergency medical services environment*