SLOVENSKI STANDARD
SIST EN 60601-2-43:2010/A2:2020

01-junij-2020

Medicinska električna oprema - 2-43. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za interventne postopke - Dopolnilo A2 (IEC 60601-2-43:2010/A2:2019)

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/A2:2019)

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

Ta slovenski standard je istoveten z: **EN 60601-2-43:2010/A2:2020**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-43:2010/A2:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-43:2010/A2

April 2020

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/A2:2019)

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/A2:2019)

To be completed (IEC 60601-2-43:2010/A2:2019)

This amendment A2 modifies the European Standard EN 60601-2-43:2010; it was approved by CENELEC on 2019-11-20. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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/A2:2020 E

European foreword

The text of document 62B/1137/FDIS, future IEC 60601-2-43/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 60601-2-43:2010/A2:2020.

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) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC 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 60601-2-43:2010.

Endorsement notice

The text of the International Standard IEC 60601-2-43:2010/A2:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8
IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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.

The Annex ZA of EN 60601-1:2006 is applicable, except as follows:

Publication	Year	Title	EN/HD	Year
Amendment				
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
			+EN 60529:1991/corrigendum May 1993	1993
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
			+EN 60601-1-3:2008/corrigendum Mar. 2010	2010
			+A11	2016
Addition				
IEC 60580	2000	Medical electrical equipment - Dose area product meters	EN 60580	2000
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+A12	2014
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011

Publication	Year	Title	EN/HD	Year
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	EN 60601-2-54	2009
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	2003	Medical electrical equipment - Characteristics of digital X-ray imaging devices -- Part 1: Determination of the detective quantum efficiency	EN 62220-1	2004
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 62220-1-1	2015
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms		-

IEC 60601-2-43

Edition 2.0 2019-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 2

AMENDEMENT 2

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

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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:

FDIS	Report on voting
62B/1137/FDIS	62B/1146/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 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.

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 2

The purpose of this second amendment to IEC 60601-2-43:2010 is to introduce changes as follows:

– scope clarification with regards to MOBILE X-ray equipment and applicability of IEC 60601-2-54 subclauses;
– reference to IEC 60601-2-54:2009/AMD2:2018 for common subclauses;
– alignment of 201.7.9.1 with IEC 60601-2-54:2009/AMD2:2018 – 201.7.9.1 is no longer modified;
– inclusion of adapted requirements or recommendations from IEC 60601-2-54:2009/AMD2:2018 for
  - management of radioscopy image storage in 203.6.1.101,
  - display of last image hold (LIH RADIOGRAM) in 203.6.7.101, and
  - graphical indication of the boundaries of the X-RAY FIELD in 203.8.102.2;
– inclusion of a recommendation for protection of gantry enclosures in 201.11.6.5.103;
– inclusion of a requirement for X-RADIATION pulse repetition frequency during radioscopy in 203.6.3.103;

– inclusion of a recommendation for a DOSE MAP in 203.6.4.5 with additional definitions in 201.3;

– inclusion of a requirement for display unit of dose area product in 203.6.4.5;

– addition of a number of technical clarifications.

_____

201.1.1 Scope

Replace the first sentence of the first existing paragraph by the following new sentence:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of both FIXED and MOBILE X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, hereafter referred to as INTERVENTIONAL X-RAY EQUIPMENT.

Replace the third existing note, including the footnote, by the following new note and footnote:

NOTE 3 INTERVENTIONAL X-RAY EQUIPMENT, when used for cone-beam CT mode, is covered by this standard and not by IEC 60601-2-44 [2][2]. No additional requirements for operation in cone-beam CT mode were identified for this standard (see also Note 4 in 203.6.4.5).

_____

2) Figures in square brackets refer to the Bibliography.

Add, after the fourth existing note, the following new paragraph:

The subclauses of this standard supersede IEC 60601-2-54 subclauses. IEC 60601-2-54 applies only with regards to the cited subclauses; non-cited subclauses of IEC 60601-2-54 do not apply.

201.1.3 Collateral standards

Replace, in the second existing paragraph, the second sentence, including its corresponding footnotes, modified by IEC 60601-2-43:2010/AMD1:2017, by the following new sentence and footnotes:

IEC 60601-1-8[6], IEC 60601-1-9[7], IEC 60601-1-10[8], IEC 60601-1-11[9], IEC 60601-1-12[10] do not apply.

_____

6 IEC 60601-1-8, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

7 IEC 60601-1-9, Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design

8 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

9 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

10 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

201.2 Normative references

Add, immediately after the instruction "Amendment", the following new reference:

IEC 60529:1989, Degrees *of protection provided by enclosures* (IP Code)
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

Replace, under "Addition", the existing reference to IEC 60580 and the one to IEC 60601-2-54, modified by IEC 60601-2-43:2010/AMD1:2017, by the following new references:

IEC 60580:2000*, Medical electrical equipment – Dose area product meters*

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 60601-2-54:2009/AMD2:2018

201.3 Terms and definitions

Replace the first existing paragraph, modified by IEC 60601-2-43:2010/AMD1:2017, by the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3/AMD1:2013, IEC 60601-2-54:2009, IEC 60601-2-54:2009/AMD1:2015 and IEC 60601-2-54:2009/AMD2:2018, IEC TR 60788:2004, IEC 61910-1:2014, IEC 62220-1-1:2015 and the following apply.

Add, after the existing definition 201.3.204, added by IEC 60601-2-43:2010/AMD1:2017, the following new terms and definitions:

201.3.205
DOSE MAP
representation of the spatial distribution of a RADIATION dose quantity

201.3.206
SKIN DOSE
estimated ABSORBED DOSE to the skin at a specific point

201.3.207
SKIN DOSE MAP
DOSE MAP of the SKIN DOSE

201.4.102 RADIATION dose documentation

Add, at the end of the paragraph, modified by IEC 60601-2-43:2010/AMD1:2017, but before the compliance statement, the following new paragraph:

The data elements shall be populated with the specified data.

Replace the existing compliance statement by the following new compliance statement:

Compliance is checked by appropriate inspection and functional test.

201.5 General requirements for testing of ME EQUIPMENT

Replace the existing text by the following new text:

Clause 5 of the general standard applies, except as follows:

201.5.7 Humidity preconditioning treatment

Addition:

For INTERVENTIONAL X-RAY EQUIPMENT that is to be used only in controlled environments, as specified in the ACCOMPANYING DOCUMENTS, no humidity preconditioning treatment is required. The ACCOMPANYING DOCUMENTS shall include the time period that the room environmental operating conditions need to be maintained prior to powering the system on.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.2.104 Marking of compliance

Replace, in the second existing paragraph, the reference "IEC 60601-2-43:2010" *by* "IEC 60601-2-43:2010, IEC 60601-2-43:2010/AMD1:2017, IEC 60601-2-43:2010/AMD2:2019".

201.7.2.105 Protection against ingress of liquids

Replace, in the existing paragraph, the reference "IEC 60529" *by* "IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013".

201.7.9.1 General

Replace the existing text by the following new text:

Subclause 201.7.9.1 of IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018 applies.

201.7.9.101 Additional statements in ACCOMPANYING DOCUMENTS

Table 201.102 – Other subclauses requiring statements in ACCOMPANYING DOCUMENTS

Add, after the last row, the following new rows:

201.5.7	Humidity preconditioning treatment
201.11.6.5.103	ENCLOSURES
203.5.2.4.102	EXAMINATION PROTOCOLS
203.6.4.5	Dosimetric indications

Add, after Table 201.102, the following new note:

NOTE While Table 201.C.102 of IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD2:2018 lists the following subclauses "203.6.4.5 Dosimetric indications" and "203.5.2.4.5.101 Dosimetric information for X-RAY EQUIPMENT specified for RADIOSCOPY and/or SERIAL RADIOGRAPHY", the corresponding requirements for statements in ACCOMPANYING DOCUMENTS are located in this standard and not in IEC 60601-2-54:2009 and its amendments.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

*Delete the sentence: "*Clause 8 of the general standard applies, except as follows:*"*