SLOVENSKI STANDARD
SIST EN 60601-2-63:2015/A1:2019

01-december-2019

Medicinska električna oprema - 2-63. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za ekstraoralni zobni rentgen - Dopolnilo A1 (IEC 60601-2-63:2012/A1:2017)

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment (IEC 60601-2-63:2012/A1:2017)

Medizinische elektrische Geräte - Teil 2-63: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von extraoralen zahnärztlichen Röntgeneinrichtungen (IEC 60601-2-63:2012/A1:2017)

Appareils électromédicaux - Partie 2-63: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires extra-oraux (IEC 60601-2-63:2012/A1:2017)

Ta slovenski standard je istoveten z: **EN 60601-2-63:2015/A1:2019**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.060.20	Zobotehnična oprema	Dental equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-63:2015/A1:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-63:2015/A1

October 2019

ICS 11.040.50

English Version

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment (IEC 60601-2-63:2012/A1:2017)

Appareils électromédicaux - Partie 2-63: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires extra-oraux
(IEC 60601-2-63:2012/A1:2017)

Medizinische elektrische Geräte - Teil 2-63: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von extraoralen zahnärztlichen Röntgeneinrichtungen
(IEC 60601-2-63:2012/A1:2017)

This amendment A1 modifies the European Standard EN 60601-2-63:2015; it was approved by CENELEC on 2019-08-07. 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 60601-2-63:2015/A1:2019 E

European foreword

The text of document 62B/1049/FDIS, future IEC 60601-2-63/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 60601-2-63:2015/A1:2019.

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)	2020-04-11
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2022-10-11

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.

Endorsement notice

The text of the International Standard IEC 60601-2-63:2012/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 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
Addition				
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-
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
IEC 60601-2-29	2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	EN 60601-2-29	2008
			+A11	2011
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/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC/PAS 61910-1	2007	Medical electrical equipment - Radiation dose documentation -- Part 1: Equipment for radiography and radioscopy	-	-
Replacement				
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

IEC 60601-2-63

Edition 1.0 2017-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

Appareils électromédicaux –
Partie 2-63: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires extra-oraux

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-4454-8

Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

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/1049/FDIS	62B/1058/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.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-63:2012 is to introduce changes to reference the Amendment 1 (2012) to IEC 60601-1:2005. As neither IEC 60601-2-63:2012 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.

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

Delete, under "Replacement", the existing reference to IEC 60601-1-2:2007.

Replace, under "Replacement", the existing reference to 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*
IEC 60601-1-3:2008/AMD1:2013

Add, under "Addition", 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

201.3 Terminology and definitions

Replace, under "Amendment", "IEC 60601-1:2005" *by* "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012".

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Replace the existing title of this subclause by the following:

201.4.3.101 Additional potential ESSENTIAL PERFORMANCE requirements

202 Electromagnetic compatibility – Requirements and tests

Replace the first sentence of this subclause by the following:

IEC 60601-1-2 applies, except as follows.

202.101 Immunity testing of ESSENTIAL PERFORMANCE

Replace the existing first paragraph by the following new paragraph:

The MANUFACTURER may minimize the test requirements of the additional potential ESSENTIAL PERFORMANCE requirements listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

Replace the last paragraph by the following new paragraphs:

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by the inspection of RISK MANAGEMENT FILE.

203 Radiation protection in diagnostic X-ray equipment

Replace, in the first sentence, "IEC 60601-1-3:2008 applies" *by* "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 apply".

---

[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*