ICS 11.040.01, 33.100.10, 33.100.20

SLOVENSKÁ TECHNICKÁ NORMA

Jún 2021

STN	**Zdravotnícke elektrické prístroje Časť 1-2: Všeobecné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti Pridružená norma: Elektromagnetické rušenia Požiadavky a skúšky Zmena A1**	**STN EN 60601-1-2/A1** 36 4800

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/21

STN EN 60601-1-2 z marca 2016 sa bez tejto zmeny A1 môže používať do 19. 3. 2024.

Obsahuje: EN 60601-1-2:2015/A1:2021, IEC 60601-1-2:2014/AMD1:2020

132845

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1-2:2015/A1

March 2021

ICS 11.040.01; 33.100.10; 33.100.20

English Version

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014/A1:2020)

Appareils électromédicaux - Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Perturbations électromagnétiques - Exigences et essais (IEC 60601-1-2:2014/A1:2020)

Medizinische elektrische Geräte - Teil 1-2: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Elektromagnetische Störgrößen - Anforderungen und Prüfungen (IEC 60601-1-2:2014/A1:2020)

This amendment A1 modifies the European Standard EN 60601-1-2:2015; it was approved by CENELEC on 2020-10-06. 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

European foreword

The text of document 62A/1390/FDIS, future IEC 60601-1-2/A1, prepared by SC 62A “Common aspects of electrical equipment used in medical practice” of IEC/TC 62 “Electrical equipment in medical practice” was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-2:2015/A1:2021.

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)	2021–09–19
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2024–03–19

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 60601-1-2:2014/A1:2020 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 61000-1-2:2016	NOTE	Harmonized as EN 61000-1-2:2016 (not modified)
IEC 60601-2 (series)	NOTE	Harmonized as EN 60601-2 (series)
ISO/TR 24971:2020	NOTE	Harmonized as CEN ISO/TR 24971:2020 (not modified)
CISPR 35:2016	NOTE	Harmonized as EN 55035:2017

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.

Replace the existing references to IEC 60601-1, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-1-12, IEC 61000-4-5, IEC 61000-4-11, CISPR 11, CISPR 14-1, CISPR 16-1-2, CISPR 32 and ISO 14971 with the following:

Publication	Year	Title	EN/HD	Year
IEC 60601-1<Tbl_-></Tbl_->	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
-	-		+ A12	2014
+ A2	2020		-	-
IEC 60601-1-8	2006	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	-	-
+ A1	2012		+ A1	2013
-	-		+ AC	2014
+ A2	2020		-	-
IEC 60601-1-11	2015	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	-	-
+ A1	2020		-	-
IEC 60601-1-12	2014	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 used in the emergency medical services environment	-	-
+ A1	2020		+ A1	2020

EN 60601-1-2:2015/A1:2021 (E)

Publication	Year	Title	EN/HD	Year
IEC 61000-4-5	2014	Electromagnetic compatibility (EMC) - Part 4–5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	2014
+ A1	2017		+ A1	2017
IEC 61000-4-11	2004	Electromagnetic compatibility (EMC) - Part 4–11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	2004
+ A1	2017		+ A1	2017
IEC 61000-4-39	2017	Electromagnetic compatibility (EMC) – Part 4–39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test	EN 61000-4-39	2017
CISPR 11 (mod)	2015	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2016
+ A1	2016		+ A1	2017
-	-		+ A11	2020
+ A2	2019		-	-
CISPR 14-1	2016	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1	2017
-	-		+ A11	2020
CISPR 32	2015	Electromagnetic compatibility of multimedia equipment - Emission requirements	EN 55032	2015
-	-		+ A11	2020
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

Delete the reference to ISO 7137.

Add the following normative reference:

Publication	Year	Title	EN/HD	Year
CISPR 16-1-2	2014	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1–2: Radio disturbance and immunity measuring apparatus - Coupling devices for conducted disturbance measurements	EN 55016-1-2	2014
+ A1	2017		+ A1	2018

IEC 60601-1-2

Edition 4.0 2020-09

INTERNATIONAL STANDARD

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AMENDMENT 1

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance –
Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014-02/AMD1:2020-09(en)

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The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

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Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC 60601-1-2

Edition 4.0 2020-09

INTERNATIONAL STANDARD

colour inside

AMENDMENT 1

Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01; 33.100.10; 33.100.20 ISBN 978-2-8322-8630-2

FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, 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
62A/1390/FDIS	62A/1405/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 web site 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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fifth edition of IEC 60601-1-2, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 15 items were presented to the National Committees present. All 15 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

1.3.1 IEC 60601-1

Replace, in the second existing paragraph, the first two existing dashes with the following new dashes:

– "the general standard" designates IEC 60601-1 alone, including any amendments;

– "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;

2 Normative references

Replace the existing references to IEC 60601-1 (including footnote 1), IEC 60601-1-8 (including footnote 2), IEC 60601-1-11, IEC 60601-1-12 (including footnote 3), IEC 61000-4-5, IEC 61000-4-11, CISPR 11 (including footnote 6), CISPR 14-1, CISPR 16-1-2 (including footnote 7), CISPR 32 and ISO 14971 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-8:2006, *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*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-11:2015, *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*
Amendment 1:2020

IEC 60601-1-12:2014, *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*
Amendment 1:2020

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*
Amendment 1:2017

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – Voltage dips, short interruptions and voltage variations immunity tests*
Amendment 1:2017

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
Amendment 1:2016
Amendment 2:2019

CISPR 14-1:2016, *Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission*

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*
Amendment 1:2017

CISPR 32:2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements*

ISO 14971:2019, *Medical devices - Application of risk management to medical devices*

Delete the existing normative reference to ISO 7137.

Add the following normative reference to the existing list:

IEC 61000-4-39:2017, *Electromagnetic compatibility (EMC) – Part 4-39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test*