

STN	Zdravotnícke elektrické prístroje Časť 1-12: Všeobecné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti Pridružená norma: Požiadavky na zdravotnícke elektrické prístroje a zdravotnícke elektrické systémy určené na používanie v prostredí záchranej zdravotníckej služby Zmena A1	STN EN 60601-1-12/A1 36 4800
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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

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. 11/20

STN EN 60601-1-12 z októbra 2015 sa bez tejto zmeny A1 môže používať do 26. 8. 2023.

Obsahuje: EN 60601-1-12:2015/A1:2020, IEC 60601-1-12:2014/AMD1:2020

132016

EUROPEAN STANDARD

EN 60601-1-12:2015/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2020

ICS 11.040

English Version

**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
(IEC 60601-1-12:2014/A1:2020)**

Appareils électromédicaux - Partie 1-12: Exigences
générales pour la sécurité de base et les performances
essentielle - Norme collatérale: Exigences pour les
appareils électromédicaux et les systèmes électromédicaux
destinés à être utilisés dans l'environnement des services
médicaux d'urgence
(IEC 60601-1-12:2014/A1:2020)

Medizinische elektrische Geräte - Teil 1-12: Allgemeine
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale - Ergänzungsnorm:
Anforderungen an medizinische elektrische Geräte und
medizinische elektrische Systeme in der Umgebung für den
Notfalleinsatz
(IEC 60601-1-12:2014/A1:2020)

This amendment A1 modifies the European Standard EN 60601-1-12:2015; it was approved by CENELEC on 2020-08-26. 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: Rue de la Science 23, B-1040 Brussels

EN 60601-1-12:2015/A1:2020 (E)**European foreword**

The text of document 62A/1396/FDIS, future IEC 60601-1-12/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 60601-1-12:2015/A1:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2021-05-26 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2023-08-26 document have to be withdrawn

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 60601-1-12:2014/A1:2020 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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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
-	-		+ A12	2014
+ A2	2020		+A2	— ¹
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
+ A1	2020		+A1	— ²
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015
+ A2	2020		+A2	— ³

¹ Under preparation. Stage at time of publication: EN 60601-1:2006/FprA2:2020.

² Under preparation. Stage at time of publication: EN 60601-1-2:2015/FprA1:2020.

³ Under preparation. Stage at time of publication: EN 60601-1-6:2010/FprA2:2020.

EN 60601-1-12:2015/A1:2020 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	EN 60601-1-8	2007
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
+ A2	2020		+A2	— ⁴
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	EN 60601-1-11	2015
+ A1	2020		+A1	— ⁵
ISO 7010	2019	Graphical symbols - Safety colours and safety signs - Registered safety signs	-	-

⁴ Under preparation. Stage at time of publication: EN 60601-1-8:2007/FprA2:2020.

⁵ Under preparation. Stage at time of publication: EN 60601-1-11:2015/FprA2:2020.



IEC 60601-1-12

Edition 1.0 2020-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1 AMENDEMENT 1

**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**

**Appareils électromédicaux –
Partie 1-12: Exigences générales pour la sécurité de base et les performances
essentiels – Norme collatérale: Exigences pour les appareils électromédicaux
et les systèmes électromédicaux destinés à être utilisés dans l'environnement
des services médicaux d'urgence**



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IEC 60601-1-12

Edition 1.0 2020-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**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**

**Appareils électromédicaux –
Partie 1-12: Exigences générales pour la sécurité de base et les performances
essentiels – Norme collatérale: Exigences pour les appareils électromédicaux
et les systèmes électromédicaux destinés à être utilisés dans l'environnement
des services médicaux d'urgence**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8625-8

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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, and ISO subcommittee 3: Respiratory devices and related equipment used for patient care of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

The text of this amendment is based on the following documents of IEC:

FDIS	Report on voting
62A/1396/FDIS	62A/1411/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. In ISO, the amendment has been approved by 16 P members out of 16 having cast a vote.

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.

INTRODUCTION TO AMENDMENT 1

The first edition of IEC 60601-1-12 was published in 2014. Since the publication of IEC 60601-1-12:2014, 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 second edition of IEC 60601-1-12, which is presently targeted for publication sometime after 2024.

As directed in item 1 of Kobe Resolution 1, the IEC/SC 62A Chairman Advisory Group (CAG) considered the 27 issues collected by the SC/62A Secretariat for IEC 60601-1-12:2014 and determined that none met the selection criteria stated in Kobe Resolution 1.

However, an amendment is needed to update the references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. In London in 2018, SC 62A approved the development of an administrative amendment to IEC 60601-1-12:2014.

Because this is an amendment to IEC 60601-1-12:2014, the style in force at the time of publication of IEC 60601-1-12 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

Delete, in the existing first paragraph, the words "hereafter referred to as the general standard".

Add, in the first two dashes of the existing second paragraph, the words ", including any amendments".

2 Normative references

Replace the existing references to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and ISO 7010 with 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 60601-1:2005/AMD2:2020

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 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-6:2010/AMD2:2020

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*

IEC 60601-1-8:2006/AMD1:2012

IEC 60601-1-8:2006/AMD1:2020

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*

IEC 60601-1-11:2015/AMD1:2020

ISO 7010:2019, *Graphical symbols – Safety colours and safety signs – Registered safety*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN