

# **SLOVENSKI STANDARD**

## **SIST EN 60601-1-11:2015**

**01-september-2015**

**Nadomešča:**

**SIST EN 60601-1-11:2010**

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**Medicinska električna oprema - 1-11. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Zahteve za medicinsko električno opremo in medicinske električne sisteme, ki se uporabljajo v okolju domače zdravstvene oskrbe**

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

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Medizinische elektrische Geräte - Teil 1-11: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen an medizinische elektrische Geräte und medizinische elektrische Systeme für die medizinische Versorgung in häuslicher Umgebung

Appareils électromédicaux - Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles - Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile

**Ta slovenski standard je istoveten z: EN 60601-1-11:2015**

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**ICS:**

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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**SIST EN 60601-1-11:2015**

**en**

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EUROPEAN STANDARD

**EN 60601-1-11**

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015

ICS 11.040

Supersedes EN 60601-1-11:2010

English Version

**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)**

Appareils électromédicaux - Partie 1-11: Exigences  
générales pour la sécurité de base et les performances  
essentielle - Norme Collatérale: Exigences pour les  
appareils électromédicaux et les systèmes électromédicaux  
utilisés dans l'environnement des soins à domicile  
(IEC 60601-1-11:2015)

Medizinische elektrische Geräte - Teil 1-11: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale - Ergänzungsnorm:  
Anforderungen an medizinische elektrische Geräte und  
medizinische elektrische Systeme für die medizinische  
Versorgung in häuslicher Umgebung  
(IEC 60601-1-11:2015)

## iTeh STANDARD PREVIEW

This European Standard was approved by CENELEC on 2015-04-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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, 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: Avenue Marnix 17, B-1000 Brussels**

## Foreword

The text of document 62A/959/FDIS, future edition 2 of IEC 60601-1-11, 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 60601-1-11:2015.

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) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

This document supersedes EN 60601-1-11:2010.

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.

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 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

## Endorsement notice

The text of the International Standard IEC 60601-1-11:2015 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 60038:2009	NOTE	Harmonized as EN 60038:2011 (modified).
IEC 60065:2014	NOTE	Harmonized as EN 60065:2014 (modified).
IEC 60335-1:2010	NOTE	Harmonized as EN 60335-1:2012 (modified).
IEC 60364	NOTE	Harmonized in HD 384 / HD 60364 series (partly modified).
IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9.
IEC 60721-3-7:1995	NOTE	Harmonized as EN 60721-3-7:1995 (not modified).

IEC 60950-1:2005 + A1:2009 + A2:2013	NOTE	Harmonized as EN 60950-1:2006 (modified) + A1:2010 (modified) + A2:2013 (modified).
IEC 61032:1997	NOTE	Harmonized as EN 61032:1998 (not modified).
ISO 10651-2:2004	NOTE	Harmonized as EN ISO 10651-2:2009 (not modified).

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## 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](http://www.cenelec.eu).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	EN 60068-2-64	2008
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
-	-		+ corrigendum May	1993
+ A1	1999		+ A1	2000
+ A2	2013		+ A2	2013
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
-	-		+ A1/AC	2014
-	-		+ A12	2014
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	2014
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

<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 -	EN 60601-1-8	2007
-	-		+ corrigendum Mar.	2010
+ A1	2012	Collateral Standard: General requirements, tests and guidance for alarm systems in	+ A1	2013
-	-	medical electrical equipment and medical electrical systems	+ A1/AC	2014
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	EN 60601-1-12	2015
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
+ A1	2014		+ A1	2015
CISPR 11 (mod)	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2009
ISO 7000	-	Graphical symbols for use on equipment - Registered symbols	-	-
ISO 7010	2011	Graphical symbols - Safety colours and safety signs - Registered safety signs	EN ISO 7010	2012
+ A1	2012		+ A1	2014
+ A2	2012		+ A2	2014
+ A3	2012		+ A3	2014
+ A4	2013		+ A4	2014
+ A5	2014		+ A5	2015
ISO 15223-1	2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	EN ISO 15223-1	2012

EN 60601-1-11:2015

**Annex ZZ**  
(informative)**Coverage of Essential Requirements of EU Directives**

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

**WARNING:** Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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IEC 60601-1-11

Edition 2.0 2015-01

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**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**

<https://standards.iteh.ai/catalog/standards/sist/cd6d7fd8-8f80-423d-8813-2015a9bd3a/sist-en-60601-1-11-2015>

**Appareils électromédicaux –**  
**Partie 1-11: Exigences générales pour la sécurité de base et les performances**  
**essentielle – Norme Collatérale: Exigences pour les appareils électromédicaux**  
**et les systèmes électromédicaux utilisés dans l'environnement des soins à**  
**domicile**

INTERNATIONAL  
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## CONTENTS

FOREWORD.....	5
INTRODUCTION.....	8
1 Scope, object and related standards.....	9
1.1 * Scope.....	9
1.2 Object.....	9
1.3 Related standards.....	9
1.3.1 IEC 60601-1 .....	9
1.3.2 Particular standards.....	10
2 Normative references .....	10
3 Terms and definitions .....	11
4 General requirements .....	12
4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS.....	12
4.2 * Environmental conditions for ME EQUIPMENT .....	12
4.2.1 General .....	12
4.2.2 * Environmental conditions of transport and storage between uses .....	13
4.2.3 * Environmental operating conditions .....	14
5 * General requirements for testing ME EQUIPMENT.....	16
6 * Classification of ME EQUIPMENT and ME SYSTEMS .....	17
7 ME EQUIPMENT identification, marking and documents .....	17
7.1 * USABILITY of the ACCOMPANYING DOCUMENTS.....	17
7.2 * Additional requirements for marking of IP classification.....	18
7.3 ACCOMPANYING DOCUMENTS.....	18
7.3.1 Contact information .....	18
7.3.2 LAY OPERATOR briefing information .....	18
7.4 Instructions for use .....	19
7.4.1 Additional requirements for warning and safety notices.....	19
7.4.2 * Additional requirements for an electrical power source .....	19
7.4.3 Additional requirements for ME EQUIPMENT description.....	20
7.4.4 Additional requirements for ME EQUIPMENT start-up PROCEDURE .....	20
7.4.5 Additional requirements for operating instructions.....	20
7.4.6 Additional requirements for ME EQUIPMENT messages.....	21
7.4.7 * Additional requirements for cleaning, disinfection and sterilization.....	21
7.4.8 Additional requirements for maintenance .....	21
7.4.9 Additional requirements for environmental protection .....	21
7.4.10 Additional requirements for ME EQUIPMENT and ME SYSTEMS.....	22
7.5 Technical description .....	22
7.5.1 PERMANENTLY INSTALLED CLASS I ME EQUIPMENT .....	22
7.5.2 Additional requirements for professional hygienic maintenance .....	22
8 Protection against excessive temperatures and other HAZARDS .....	22
8.1 * Additional requirements for cleaning, disinfection of ME EQUIPMENT and ME SYSTEMS.....	22
8.2 * Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS.....	23
8.3 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS.....	23
8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT .....	23

8.3.2	* Ingress of water or particulate matter into ME SYSTEMS .....	23
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM .....	23
8.5	Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE .....	24
8.5.1	* Indication of state .....	24
8.5.2	Accessibility of small INTERNAL ELECTRICAL POWER SOURCES .....	25
9	Accuracy of controls and instruments and protection against hazardous outputs .....	25
10	Construction of ME EQUIPMENT .....	25
10.1	* Additional requirements for mechanical strength .....	25
10.1.1	General requirements for mechanical strength .....	25
10.1.2	* Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT .....	27
10.1.3	* Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT .....	28
10.2	Additional requirements for actuating parts of controls of ME EQUIPMENT .....	29
11	* Protection against strangulation or asphyxiation .....	30
12	Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS .....	30
13	Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS .....	30
13.1	* Additional requirement for generation of ALARM SIGNALS .....	30
13.2	* Additional requirement for ALARM SIGNAL volume .....	30
Annex A (informative)	General guidance and rationale .....	31
A.1	General guidance .....	31
A.2	Rationale for particular clauses and subclauses .....	32
Annex B (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS .....	51
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts .....	51
B.2	ACCOMPANYING DOCUMENTS, general .....	51
B.3	ACCOMPANYING DOCUMENTS, instructions for use .....	51
B.4	ACCOMPANYING DOCUMENTS, technical description .....	53
Annex C (informative)	Symbols on marking .....	54
Bibliography	.....	56
Index of defined terms used in this collateral standard	.....	58
Figure 1 – Small finger probe Ø 5,6 .....		17
Figure A.1 – Saturation water vapour pressure as function of temperature .....		36
Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE .....		26
Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE .....		27
Table A.1 – Saturation water vapour pressure as function of temperature .....		37
Table A.2 – Summary by use of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT ENCLOSURE ingress of water and particulate matter requirements .....		46
Table A.3 – Qualitative assessment of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT subjected to shock and vibration .....		47
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts .....		51
Table B.2 – ACCOMPANYING DOCUMENTS, general .....		51
Table B.3 – ACCOMPANYING DOCUMENTS, instructions for use .....		52

Table B.4 – ACCOMPANYING DOCUMENTS, technical description.....	53
Table C.1 – General symbols.....	54

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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**

## FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-1-11 has been prepared by a joint working group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

This second edition constitutes a collateral standard to IEC 60601-1 (third edition, including Amendment 1): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereafter referred to as the general standard.

This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

- correction of test method for relative humidity control at temperatures above 35 °C;
- redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
- harmonizing with the changes to the amendments to the general standard and other collateral standards.

The text of this collateral standard is based on the following documents:

FDIS	Report on voting
62A/959/FDIS	62A/978/RVD

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 17 P-members out of 17 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type*;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this collateral standard, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.3.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (\*).

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this 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 Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC 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.

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