

ELEKTRILISED MEDITSIINISEADMED. OSA 1-12:
ÜLDISED NÕUDED ESMASELE OHUTUSELE JA
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KOLLATERAALSTANDARD: NÕUDED
KIIRABITEENUSTES KASUTATAVATELE
ELEKTRILISTELE MEDITSIINISEADMETELE JA
-SÜSTEEMIDELE

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-12:2015 sisaldab Euroopa standardi EN 60601-1-12:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-12:2015 consists of the English text of the European standard EN 60601-1-12:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.05.2015.	Date of Availability of the European standard is 22.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

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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)**

Appareils électromédicaux - Partie 1-12: Exigences
générales pour la sécurité de base et les performances
essentielles - 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)

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)

This European Standard was approved by CENELEC on 2014-07-24. 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.

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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/932/FDIS, future edition 1 of IEC 60601-1-12, 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.

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) 2015-11-22
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

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 Directives 93/42/EEC and 90/385/EEC, see informative Annexes ZZA and ZZB, which are integral parts of this document.

Endorsement notice

The text of the International Standard IEC 60601-1-12:2014 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	NOTE	Harmonized as EN 60065.
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 60721-3-7:1995 + A1:1996	NOTE	Harmonized as EN 60721-3-7:1995 (not modified) + A1:1997 (not modified).
IEC 60950-1:2005	NOTE	Harmonized as EN 60950-1:2006 (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).

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.

<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
IEC 60601-1	2005	Medical electrical equipment -	EN 60601-1	2006
-	-	Part 1: General requirements for basic	+ corrigendum Mar.	2010
+ A1	2012	safety and essential performance	+ A1	2013
-	-		+ A1/AC	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 -	EN 60601-1-6	2010
+ A1	2013	Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	+ A1	2015
IEC 60601-1-8	2006	Medical electrical equipment -	EN 60601-1-8	2007
-	-	Part 1-8: General requirements for basic	+ corrigendum Mar.	2010
+ A1	2012	safety and essential performance -	+ A1	2013
-	-	Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	+ A1/AC	2014

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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
CISPR 11 (mod)	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2009
ISO 7000	2014	Graphical symbols for use on equipment - Registered symbols	-	-
ISO 7010	2011	Graphical symbols - Safety colours and	EN ISO 7010	2012
+ A1	2012	safety signs - Registered safety signs	+ 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

Annex ZZA

(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.

Annex ZZB
(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 1 of EU Directive 90/385/EEC of 20 June 1990 relating to active implantable 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.

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
1 Scope, object and related standards.....	8
1.1 * Scope.....	8
1.2 * Object	8
1.3 Related standards.....	9
1.3.1 IEC 60601-1	9
1.3.2 Particular standards.....	9
2 Normative references	9
3 Terms and definitions	10
4 General requirements	11
4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	11
4.2 * Environmental conditions for ME EQUIPMENT	11
4.2.1 * Environmental conditions of transport and storage between uses	12
4.2.2 * Environmental operating conditions	13
5 * Classification of ME EQUIPMENT and ME SYSTEMS	15
6 ME EQUIPMENT identification, marking and documents	16
6.1 * Additional requirements for legibility of markings	16
6.2 * Additional requirements for marking of IP classification	16
6.3 * Instructions for use	16
6.3.1 Additional general requirements	16
6.3.2 * Additional requirements for an electrical power source	17
6.3.3 Additional requirements for ME EQUIPMENT start-up PROCEDURE	17
6.3.4 * Additional requirements for operating instructions	18
6.3.5 Additional requirements for ME EQUIPMENT messages.....	18
6.4 Technical description – FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT	18
7 * Protection against electrical HAZARDS from ME EQUIPMENT	18
8 Protection against excessive temperatures and other HAZARDS	19
8.1 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS	19
8.1.1 * Ingress of water or particulate matter into ME EQUIPMENT.....	19
8.1.2 * Ingress of water or particulate matter into ME SYSTEMS	19
8.2 Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM.....	19
8.3 * Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT	20
9 * Accuracy of controls and instruments and protection against hazardous outputs	21
10 Construction of ME EQUIPMENT.....	21
10.1 * Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT.....	21
10.1.1 General requirements for mechanical strength	21
10.1.2 * Requirements for mechanical strength for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT intended for use in a road ambulance	22
10.1.3 * Requirements for mechanical strength for TRANSPORTABLE ME EQUIPMENT	23

10.1.4	* Requirements for mechanical strength for ME EQUIPMENT intended for airborne use	24
10.2	Requirements for mounting of ME EQUIPMENT.....	25
11	Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	25
Annex A (informative)	General guidance and rationale.....	26
A.1	General guidance.....	26
A.2	Rationale for particular clauses and subclauses.....	28
Annex B (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	42
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	42
B.2	ACCOMPANYING DOCUMENTS, instructions for use.....	42
B.3	ACCOMPANYING DOCUMENTS, technical description.....	43
Annex C (informative)	Symbols on marking.....	44
Bibliography	46
Index of defined terms used in this collateral standard		48
Figure A.1 – Saturation water vapour pressure as function of temperature		31
Table 1 – Mechanical strength test applicability		22
Table A.1 – Saturation water vapour pressure as function of temperature		32
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts		42
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use		42
Table B.3 – ACCOMPANYING DOCUMENTS, technical description.....		43
Table C.1 – General symbols		44