ELEKTRILISED MEDITSIINISEADMED. OSA 1-2: ÜLDNÕUDED ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE. KOLLATERAALSTANDARD: ELEKTROMAGNETILINE ÜHILDUVUS. NÕUDED JA KATSETUSED

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-2:2015 sisaldab Euroopa standardi EN 60601-1-2:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-2:2015 consists of the English text of the European standard EN 60601-1-2:2015.
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 18.09.2015.	Date of Availability of the European standard is 18.09.2015.
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 11.040.01, 33.100.10, 33.100.20

EUROPEAN STANDARD

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EN 60601-1-2

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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)

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)

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)

This European Standard was approved by CENELEC on 2014-04-01. 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

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European foreword

The text of document 62A/916/FDIS, future edition 4 of IEC 60601-1-2, 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.

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)	2016-03-18
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-12-31

This document supersedes EN 60601-1-2:2007.

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.

Endorsement notice

The text of the International Standard IEC 60601-1-2:2014 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 60601-1-2:2007	NOTE	Harmonized as EN 60601-1-2:2007 (not modified)
IEC 60601-2-27:2011	NOTE	Harmonized as EN 60601-2-27:2006 (not modified)
IEC 60601-2-44:2009	NOTE	Harmonized as EN 60601-2-44:2009 (not modified)
IEC 61000-3-11:2000	NOTE	Harmonized as EN 61000-3-11:2000 (not modified)
IEC 61000-3-12:2011	NOTE	Harmonized as EN 61000-3-12:2011 (not modified)
IEC 61000-3-12:2011	NOTE	Harmonized as EN 61000-3-12:2011 (not modified)
IEC 60601-6-1:2005	NOTE	Harmonized as EN 60601-6-1:2007 (not modified)
IEC 60601-6-2:2005	NOTE	Harmonized as EN 60601-6-2:2005 (not modified)
IEC 61496-1:2008	NOTE	Harmonized as EN 61496-1:2008 (not modified)
CISPR 16-1-1:2010	NOTE	Harmonized as EN 55016-1-1:2010 (not modified)
CISPR 16-2-3:2010	NOTE	Harmonized as EN 55016-2-3:2010 (not modified)
CISPR 24:2010	NOTE	Harmonized as EN 55024:2010 (not modified)
CISPR 25:2008	NOTE	Harmonized as EN 55025:2008 (not modified)
ISO 17025:2005	NOTE	Harmonized as EN ISO/IEC 17025:2005 (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. However, for any use of this standard “within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60417	Data base	Graphical symbols for use on equipment available from http://www.graphical-symbols.info/equipment	IEC 60417	2004
IEC 60601-1	2005	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
A1	2012		A1	2013
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 + corr. March	2007 2010
A1	2013		A1	2013
IEC 60601-1-11	2010	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	2010
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		
IEC 60601-2-2	2010	Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high		

Publication	Year	Title	EN/HD and IEC/ISO	Year
		frequency surgical equipment and high frequency surgical accessories		
IEC 60601-2-3	2012	Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment		
IEC 61000-3-2	2005	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16 A per phase)	EN 61000-3-2	2006
A1	2008		+A1	2009
A2	2009		+A2	2009
IEC 61000-3-3	2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection	EN 61000-3-3	2013
IEC 61000-4-2	2008	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measuring techniques - Electrostatic discharge immunity test	EN 61000-4-2	2009
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006
A1	2007		+A1	2008
			+IS1	2009
A2	2010		+A2	2010
IEC 61000-4-4	2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	2012
IEC 61000-4-5	2005	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	2006
IEC 61000-4-6	2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields		
IEC 61000-4-8	2009	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	2010
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
CISPR 11	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011 (mod)	2009
A1	2010			
CISPR 14-1	2005	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1	2006
			+A1	2009
			+A2	2011
CISPR 16-1-2	2003	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity	EN 55016-1-2	2004

Publication	Year	Title	EN/HD and IEC/ISO	Year
		measuring apparatus - Ancillary equipment - Conducted disturbances		
A1	2004		+A1	2005
A2	2006		+A2	2006
CISPR 32	2012	Electromagnetic compatibility of multimedia equipment – Emission requirements	EN 55032	2012
ISO 7137	1995	Aircraft – Environmental conditions and test procedures for airborne equipment		
ISO 7637-2	2011	Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only		
ISO 14971	2007	Medical devices – Application of risk management to medical devices	EN ISO 14971	2012

Application of Annexes of the EN 60601 series

The Annex ZZ of EN 60601-1:2006+A1:2013 applies.

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 to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

NOTE 7 According to the scope of this standard the coverage in Table ZZ.1 only applies to protection of ME equipment and ME systems against electromagnetic disturbances. This European Standard lists in Table ZZ.1 only the essential requirements covered.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1: Relationship between Essential Requirements of Directive 93/42/EEC, and Clauses and Subclauses of this standard

No.	Essential Requirements	Coverage EN 60601-1-2
I.	**GENERAL REQUIREMENTS**	
1.	General Guidance notes 1-7 shall be observed	
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:	If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to EMC-aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to clauses 4 to 9 of this collateral standard) without covering the risk benefit balancing.
	- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	Covered in respect to 7.1 Protection of radio services and other equipment, 7.2 Protection of the public mains network, and 8.9 Immunity test levels
2.	General Guidance notes 1-7 shall be observed	
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	1st paragraph: Covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account. 2nd paragraph (including the following 3 bullets): Not covered.
	- eliminate or reduce risks as far as possible (inherently safe design and construction),	
	- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	
	- inform users of the residual risks due to any shortcomings of the protection measures adopted.	
II.	**REQUIREMENTS FOR DESIGN AND CONSTRUCTION**	
General Guidance notes 1-7 shall be observed		
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is	

No.	Essential Requirements	Coverage EN 60601-1-2
	possible:	
	- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	
	- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	Covered in respect to electromagnetic disturbances, see 8.9 Immunity test levels.
	- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment, 7.2 Protection of the public mains network.
	- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	
11	**Protection against radiation**	General Guidance note 1-7 shall be observed
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment.
12	**Requirements for medical devices connected to or equipped with an energy source**	General Guidance notes 1-7 shall be observed
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment.
13	**Information supplied by the manufacturer**	General Guidance notes 1-7 shall be observed
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Covered in respect to aspects related to accessories, components and subassemblies contained in 5.2.1.1 d) and e)

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