

**Elektrilised meditsiiniseadmed. Osa 1:
Üldised ohutusnõuded 2.
kollateraalsandard: Elektromagnetiline
ühilduvus. Nõuded ja testid**

Medical electrical equipment - Part 1-2: General
requirements for safety - Collateral Standard:
Electromagnetic compatibility - Requirements and
tests

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-1-2:2002 sisaldab Euroopa standardi EN 60601-1-2:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 60601-1-2:2002 consists of the English text of the European standard EN 60601-1-2:2001. This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.
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Käsitlusala: Käesolev standard rakendub elektrilistele meditsiiniseadmetele, elektrilistele meditsiinisüsteemidele, elektrilistes meditsiinisüsteemides kasutatavatele infotehnoloogiaseadmetele ning kõigile teistele seadmetele, mis moodustavad osa elektrilisest meditsiinisüsteemist	Scope:
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ICS 11.040.01, 33.100.10, 33.100.20

Võtmesõnad:

English version

Medical electrical equipment
Part 1-2: General requirements for safety -
Collateral standard: Electromagnetic compatibility -
Requirements and tests
(IEC 60601-1-2:2001)

Appareils électromédicaux
Partie 1-2: Règles générales de sécurité -
Norme collatérale:
Compatibilité électromagnétique -
Prescriptions et essais
(CEI 60601-1-2:2001)

Medizinische elektrische Geräte
Teil 1-2: Allgemeine Festlegungen
für die Sicherheit -
Ergänzungsnorm:
Elektromagnetische Verträglichkeit -
Anforderungen und Prüfungen
(IEC 60601-1-2:2001)

This European Standard was approved by CENELEC on 2001-11-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A/336/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-1-2 on 2001-11-01.

This European Standard supersedes EN 60601-1-2:1993.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2002-08-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2004-11-01

This European Standard is a Collateral Standard to EN 60601-1:1990, hereinafter referred to as the General Standard.

In the EN 60601 series of publications, Collateral Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. ELECTROMAGNETIC COMPATIBILITY).

In addition, EN 60601-1-1 has expanded the scope of the general standard to include MEDICAL ELECTRICAL SYSTEMS. In recognition of that expanded scope, this edition of the EMC Collateral Standard takes into account the fact that the general standard now applies to MEDICAL ELECTRICAL SYSTEMS as well as MEDICAL ELECTRICAL EQUIPMENT and includes EMC requirements that are, in most cases, applicable to all parts of the SYSTEM.

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc.

In this Collateral Standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Tables 201-208, in the tables in Annex BBB and in statements required to appear in the ACCOMPANYING DOCUMENTS or instructions for use because they are intended for the customer or user, who may not be familiar with the defined terms of IEC 60601 standards.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) in the left margin of a clause or subclause indicates the presence of additional information in Annex AAA.

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annex ZA is normative and annexes AAA, BBB, CCC, DDD and EEE are informative. Annex ZA replaces annex FFF of IEC 60601-1-2:2001.

Endorsement notice

The text of the International Standard IEC 60601-1-2:2001 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:

CISPR 24	NOTE Harmonized as EN 55024 (modified).
IEC 60601-1-4:1996 + A1:1999	NOTE Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 61000-4-1:2000	NOTE Harmonized as EN 61000-4-1:2000 (not modified).
IEC 61000-4-2:1995 + A1:1998 + A2:2000	NOTE Harmonized as EN 61000-4-2:1995 + A1:1998 + A2:2001 (modified).
IEC 61000-4-3:1995 + A1:1998 + A2:2000	NOTE Harmonized as EN 61000-4-2:1996 + A1:1998 + A2:2001 (modified).
IEC 61000-4-6 + A1:2000	NOTE Harmonized as EN 61000-4-6 + A1:2001 (not modified).
ISO 14971:2000	NOTE Harmonized as EN ISO 14971:2000 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60050-161	1990	International Electrotechnical	-	-
A1	1997	Vocabulary (IEV) -	-	-
A2	1998	Chapter 161: Electromagnetic compatibility	-	-
IEC 60417-2	1998	Graphical symbols for use on equipment Part 2: Symbol originals	EN 60417-2	1999
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
A1	1991		+ corr. July A1	1994 1993
A2	1995		+ corr. July	1994
+ corr. June	1995		A2	1995
			A13	1996
IEC 60601-1-1	2000	Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	2001
IEC 61000-3-2 (mod)	- ¹⁾	Electromagnetic compatibility (EMC) Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)	EN 61000-3-2	2000 ²⁾
IEC 61000-3-3	- ¹⁾	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 + corr. July	1995 ²⁾ 1997

¹⁾ Undated reference.

²⁾ Valid edition at time of issue.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61000-4-2	- ¹⁾	Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995 ²⁾
IEC 61000-4-3 (mod)	- ¹⁾	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996 ²⁾
IEC 61000-4-4	- ¹⁾	Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	1995 ²⁾
IEC 61000-4-5	- ¹⁾	Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	1995 ²⁾
IEC 61000-4-6	- ¹⁾	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996 ²⁾
IEC 61000-4-8	- ¹⁾	Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993 ²⁾
IEC 61000-4-11	- ¹⁾	Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	1994 ²⁾
CISPR 11 (mod)	- ¹⁾	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011	1998 ²⁾
CISPR 14-1	- ¹⁾	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus Part 1: Emission	EN 55014-1	2000 ²⁾
CISPR 15	- ¹⁾	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	EN 55015	2000 ²⁾
CISPR 16-1	- ¹⁾	Specification for radio disturbance and immunity measuring apparatus and methods Part 1: Radio disturbance and immunity measuring apparatus	-	-
CISPR 22 (mod)	- ¹⁾	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55022 + corr. July	1998 ²⁾ 2001

INTERNATIONAL STANDARD

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60601-1-2

Edition 2.1

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Medical electrical equipment –

**Part 1-2:
General requirements for safety –**

**Collateral standard:
Electromagnetic compatibility –
Requirements and tests**



Reference number
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Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

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INTERNATIONAL STANDARD

IEC
60601-1-2

Edition 2.1

2004-11

Edition 2:2001 consolidated with amendment 1:2004

Medical electrical equipment –

**Part 1-2:
General requirements for safety –**

**Collateral standard:
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International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

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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International Standard IEC 60601-1-2 has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This consolidated version of IEC 60601-1-2 is based on the second edition (2001) [documents 62A/336/FDIS and 62A/341/RVD] and its amendment 1 (2004) [documents 62A/462/FDIS and 62A/469/RVD].

It bears the edition number 2.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

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

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. ELECTROMAGNETIC COMPATIBILITY).

In addition, IEC 60601-1-1 has expanded the scope of the general standard to include MEDICAL ELECTRICAL SYSTEMS. In recognition of that expanded scope, this edition of the EMC Collateral Standard takes into account the fact that the general standard now applies to MEDICAL ELECTRICAL SYSTEMS as well as MEDICAL ELECTRICAL EQUIPMENT and includes EMC requirements that are, in most cases, applicable to all parts of the SYSTEM.

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this Collateral Standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Tables 201-208, in the tables in Annex BBB and in statements required to appear in the ACCOMPANYING DOCUMENTS or instructions for use because they are intended for the customer or user, who may not be familiar with the defined terms of IEC 60601 standards.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) in the left margin of a clause or subclause indicates the presence of additional information in Annex AAA.

Annex FFF forms an integral part of this standard.

Annexes AAA, BBB, CCC, DDD, EEE, GGG, HHH and the Bibliography are for information only.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the maintenance result 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.

INTRODUCTION

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS (referred to as EQUIPMENT and SYSTEMS, respectively, in this Collateral Standard) is well recognized.

In particular, the existence of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

- safety services;
- other EQUIPMENT and SYSTEMS;
- non-medical electrical equipment (e.g. computers);
- telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the existence of ELECTROMAGNETIC IMMUNITY standards is essential to assure safety of EQUIPMENT and SYSTEMS. ELECTROMAGNETIC COMPATIBILITY (see definition 2.204) differs from other aspects of safety covered by IEC 60601-1 because the electromagnetic phenomena exist, with varying degrees of severity, in the normal use environment of all EQUIPMENT and SYSTEMS and by definition the equipment must “perform satisfactorily” within its intended environment in order to establish ELECTROMAGNETIC COMPATIBILITY. This means that the conventional single fault approach to safety is not appropriate for application to ELECTROMAGNETIC COMPATIBILITY standards. The ELECTROMAGNETIC DISTURBANCE environment can be compared to ambient temperature, humidity and atmospheric pressure. EQUIPMENT and SYSTEMS may experience environmental conditions within the expected range at any time, and for extended periods of time. As with atmospheric pressure and humidity, the user of the EQUIPMENT or SYSTEM ¹ may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the EQUIPMENT or SYSTEM would also be expected to be normal.

IEC 60513 states that the distinction between safety and performance standards is often unclear. EQUIPMENT and SYSTEMS are used in the practice of medicine because they provide needed FUNCTIONS. If an EQUIPMENT or SYSTEM does not provide its needed FUNCTION, because of a lack of IMMUNITY to events expected in the normal use environment, this interferes with the practice of medicine and cannot be considered an acceptable situation. Therefore, this second edition of IEC 60601-1-2 departs from the first edition by establishing a minimum baseline of performance in the presence of expected levels of ELECTROMAGNETIC DISTURBANCE.

This second edition recognizes that there is a shared responsibility between manufacturers, customers and users to ensure that EQUIPMENT and SYSTEMS are designed and operated as intended. The EQUIPMENT or SYSTEM manufacturer's responsibility is to design and manufacture to meet the requirements of this standard and to disclose information to the customer or user so that a compatible ELECTROMAGNETIC ENVIRONMENT can be maintained in order that the EQUIPMENT or SYSTEM will perform as intended.

Because the practice of medicine involves many specialities, there will by necessity be EQUIPMENT and SYSTEMS that are designed to perform a variety of FUNCTIONS. Some FUNCTIONS involve, for example, measurement of signals from a PATIENT that are of very low levels when compared to ELECTROMAGNETIC NOISE levels that can be coupled into EQUIPMENT and SYSTEMS during the ELECTROMAGNETIC IMMUNITY testing specified in this standard. Because of the proven benefits of many such EQUIPMENT and SYSTEMS, this standard allows the IMMUNITY TEST LEVELS to be lowered, provided there is sufficient justification based on physical, technological or physiological limitations. In this case, the manufacturer is required

¹ In this standard, “or” should be understood to include “and”.

to disclose the levels at which the EQUIPMENT or SYSTEM meets the performance requirements of this standard and to specify the characteristics of the ELECTROMAGNETIC use environment and how this environment is established, in which the EQUIPMENT or SYSTEM will perform as intended.

This standard also recognizes that for certain environments, higher IMMUNITY LEVELS may be required. Research necessary to determine how to identify the environments that may require higher IMMUNITY LEVELS, as well as what the levels should be, is in progress.

Finally, this standard recognizes that for LIFE-SUPPORTING EQUIPMENT and SYSTEMS, higher levels of IMMUNITY are necessary in order to establish a broader safety margin, even for use in the general medical use environment. Therefore, this standard specifies additional requirements for LIFE-SUPPORTING EQUIPMENT and SYSTEMS.

This standard is based on existing IEC standards prepared by SC 62A, TC 77 (Electromagnetic compatibility between electrical equipment including networks) and CISPR (International special committee on radio interference).

The ELECTROMAGNETIC COMPATIBILITY requirements specified by this standard are generally applicable to EQUIPMENT and SYSTEMS as described in 1.201. For certain types of EQUIPMENT and SYSTEMS, these requirements may need to be modified by the special requirements of a Particular Standard. Writers of Particular Standards are encouraged to refer to Annex DDD for guidance in the application of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

SECTION ONE – GENERAL

1 Scope and object

*1.201 Scope

This standard applies to ELECTROMAGNETIC COMPATIBILITY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereinafter referred to as EQUIPMENT and SYSTEMS, respectively.

1.202 Object

This standard specifies requirements and tests for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS and serves as the basis of ELECTROMAGNETIC COMPATIBILITY requirements and tests in Particular Standards.

2 Terminology and definitions

For the purposes of this Collateral Standard, the terms and definitions given in IEC 60601-1:1988, IEC 60601-1-1:2000, IEC 60601-1-8:2003 and ISO 14971:2000 and the following apply:

2.201

(IMMUNITY) COMPLIANCE LEVEL

level less than or equal to the IMMUNITY LEVEL for which the EQUIPMENT or SYSTEM meets the requirements of the applicable subclause of 36.202

NOTE Additional requirements for COMPLIANCE LEVELS are specified in 6.8.3.201.

*2.202

DEGRADATION (of performance)

undesired departure in the operational performance of an EQUIPMENT or SYSTEM from its intended performance

NOTE The term "DEGRADATION" can apply to temporary or permanent failure.

[IEV 161-01-19, modified]

*2.203

EFFECTIVE RADIATED POWER (ERP)

power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

NOTE As used by the ITU and as used in Chapter 712 of the IECV, the term "effective radiated power" appears without qualification only when the reference antenna is a half-wave dipole.

[IEV 161-04-16, modified]

*2.204

ELECTROMAGNETIC COMPATIBILITY (EMC)

ability of an EQUIPMENT or SYSTEM to function satisfactorily in its ELECTROMAGNETIC ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment

[IEV 161-01-07, modified]