SLOVENSKI STANDARD

SIST EN 60601-1-2:2002

01-junij-2002

Nadomešča:

SIST EN 60601-1-2:1995

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

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

Medizinische elektrische Geräte -- Teil 1-2: Allgemeine Festlegungen für die Sicherheit - Ergänzungsnorm: Elektromagnetische Verträglichkeit - Anforderungen und Prüfungen

Appareils électromédicaux -- Partie 1-2: Règles générales de sécurité - Norme collatérale: Compatibilité électromagnétique - Exigences et essais

Ta slovenski standard je istoveten z: EN 60601-1-2:2001

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

SIST EN 60601-1-2:2002 **en**

EUROPEAN STANDARD **EN 60601-1-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM November 2001

ICS 11.040.01;33.100.10;33.100.20 Supersedes EN 60601-1-2:1993

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

Ref. No. EN 60601-1-2:2001 E

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.

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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.

Publication	Year	Title	EN/HD	Year
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
			+ corr. July	1994
A1	1991		A1	1993
			+ corr. July	1994
A2	1995			
+ 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	1995 [2)]
			+ corr. July	1997

[1)] Undated reference.

[2)] Valid edition at time of issue.

Publication	Year	Title	EN/HD	Year
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

IEC 60601-1-2

Second edition
2001-09

Medical electrical equipment –

Part 1-2:
General requirements for safety –

Collateral standard:
Electromagnetic compatibility –
Requirements and tests

Appareils électromédicaux –

Partie 1-2:
Règles générales de sécurité –
Norme collatérale:
Compatibilité électromagnétique –
Prescriptions et essais

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE X

For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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 second edition of IEC 60601-1-2 cancels and replaces the first edition published in 1993 and constitutes a technical revision.

This second edition constitutes a Collateral Standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

The text of this Collateral Standard is based on the following documents:

FDIS	Report on voting
62A/336/FDIS	62A/341/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.

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

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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 and the Bibliography are for information only.

The committee has decided that the contents of this publication will remain unchanged until 2005. 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

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[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 second edition allows a risk analysis to be used to determine the ESSENTIAL PERFORMANCE and safety of MEDICAL ELECTRICAL EQUIPMENT that must be examined during IMMUNITY testing and whether testing according to this standard is required for non-medical electrical equipment that is combined with MEDICAL ELECTRICAL EQUIPMENT to form a SYSTEM.

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.