SVENSK STANDARD SS-EN 60601-1-2

Fastställd	Utgåva	Sida	Ansvarig kommitté
2007-09-24	3	1 (1+123)	SEK TK 62

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Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 1-2: Allmänna fordringar beträffande säkerhet och väsentliga prestanda – Tilläggsstandard för elektromagnetisk kompatibilitet

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

Som svensk standard gäller europastandarden EN 60601-1-2:2007. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-2:2007.

Nationellt förord

Europastandarden EN 60601-1-2:2007

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-1-2, Third edition, 2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests**

utarbetad inom International Electrotechnical Commission, IEC.

SS-EN 60601-1-2, utgåva 2, 2001 och SS-EN 60601-1-2/A1, utgåva 1, 2006, fortsätter att gälla tillsammans med de svenska standarder för olika apparatslag som utgör Del 2.

I de fall SS-EN 60601-1-2 tillämpas på apparatslag som ej omfattas av någon Del 2, gäller SS-EN 60601-1-2, utgåva 2, 2001 och SS-EN 60601-1-2/A1, utgåva 1, 2006, inte fr o m 2009-09-12.

Standarden skall användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

ICS 11.040.01; 33.100.10; 33.100.20

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: SEK, Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00. *Telefax*: 08 - 444 14 30
E-post: sek@elstandard.se. *Internet*: www.elstandard.se

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-2

July 2007

ICS 11.040.01; 33.100.10; 33.100.20

Supersedes EN 60601-1-2:2001 + A1:2006

English version

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

(IEC 60601-1-2:2007, modified)

Appareils électromédicaux - Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Compatibilité électromagnétique - Exigences et essais

(CEI 60601-1-2:2007, modifiée)

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

(IEC 60601-1-2:2007, modifiziert)

This European Standard was approved by CENELEC on 2007-04-11. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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

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Ref. No. EN 60601-1-2:2007 E

Foreword

The text of document 62A/560/FDIS, future edition 3 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 2007-04-11.

The following date was 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) 2008-02-01

This European Standard supersedes EN 60601-1-2:2001 and its amendment A1:2006. However, EN 60601-1-2:2001 remains valid until all the parts 2 that are used in conjunction with it have been withdrawn. No date of withdrawal of conflicting national standards (dow) has therefore been fixed. However, when Part 1-2 is used for appliances not covered by a part 2, EN 60601-1-2:2001 is not to be used after 2009-09-12.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

This EN 60601-1-2 was revised to structurally align it with EN 60601-1:2006 and to implement the decision of IEC SC 62A that the clause numbering structure of collateral standards written to EN 60601-1:2006 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in EN 60601-1:2006.

In the 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: in roman type;
- *test specifications: in 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 NOTES: IN SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Table 1 through Table 8, in the tables in Annex C and in statements required to appear in the technical description or instructions for use because they are intended for the OPERATOR or RESPONSIBLE ORGANIZATION, who may not be familiar with the defined terms of EN 60601 standards.

In referring to the structure of this standard, the term

– “clause” means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this 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, items and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-1-2:2007 was approved by CENELEC as a European Standard with agreed common modifications as given below.

COMMON MODIFICATIONS

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 60417	Data base	Graphical symbols for use on equipment	-	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
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	2007
IEC 61000-3-2	- [1)]	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	EN 61000-3-2	2006 [2)]
IEC 61000-3-3	- [1)]	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 + corr. July	1995 [2)] 1997
IEC 61000-4-2	- [1)]	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995 [2)]
IEC 61000-4-3	- [1)]	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006 [2)]

[1)] Undated reference.

[2)] Valid edition at date of issue.

Publication	Year	Title	EN/HD	Year
IEC 61000-4-4	- [1)]	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	2004 [2)]
IEC 61000-4-5	- [1)]	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	2006 [2)]
IEC 61000-4-6 + A1 + A2	2003 2004 2006	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	2007
IEC 61000-4-8	- [1)]	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993 [2)]
IEC 61000-4-11	- [1)]	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	EN 61000-4-11	2004 [2)]
CISPR 11 (mod)	- [1)]	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement	EN 55011	2007 [2)]
CISPR 14-1	- [1)]	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission	EN 55014-1	2006 [2)]
CISPR 15	- [1)]	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment	EN 55015	2006 [2)]
CISPR 16-1-2	- [1)]	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity measuring apparatus - Ancillary equipment - Conducted disturbances	EN 55016-1-2	2004 [2)]
CISPR 22 (mod)	- [1)]	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55022	2006 [2)]

CONTENTS

MEDICAL ELECTRICAL EQUIPMENT –

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

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS.

1.2 Object

The object of this collateral standard is to specify general requirements and tests for ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone;

– "this collateral standard" designates IEC 60601-1-2 alone;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60417, *Graphical symbols for use on equipment*