

Svenska Elektriska Kommissionen, SEK

Fastställt	Utgåva	Sida	Ingår i
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Elektrisk utrustning för medicinskt bruk – Säkerhet –

Del 1-6: Allmänna fordringar –

Tilläggsstandard: Användarvänlighet

Medical electrical equipment –

Part 1-6: General requirements for safety –

Collateral standard: Usability

Som svensk standard gäller europastandarden EN 60601-1-6:2004. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-6:2004.

Nationellt förord

Europastandarden EN 60601-1-6:2004

består av:

- **europastandardens ikraftsättningsdokument**, utarbetad inom CENELEC
- **IEC 60601-1-6, First edition, 2004 - Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, utgåva 1, 1991.

ICS 11.040

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK, som också kan lämna upplysningar om **sakinnehållet** i standarden.

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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

Svenska Elektriska Kommissionen, SEK, 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.

SEK

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English version

Medical electrical equipment
Part 1-6: General requirements for safety –
Collateral standard: Usability
(IEC 60601-1-6:2004)

Appareils électromédicaux
Partie 1-6: Règles générales de sécurité -
Norme collatérale: Aptitude à l'utilisation
(CEI 60601-1-6:2004)

Medizinische elektrische Geräte
Teil 1-6: Allgemeine Festlegungen
für die Sicherheit –
Ergänzungsnorm: Gebrauchstauglichkeit
(IEC 60601-1-6:2004)

This European Standard was approved by CENELEC on 2004-09-01. 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, 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/452/FDIS, future edition 1 of IEC 60601-1-6, 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 60601-1-6 on 2004-09-01.

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) 2005-06-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2007-09-01

This European Standard is a collateral standard to EN 60601-1:1990, hereinafter referred to as the general standard.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to

- a group 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. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this collateral standard corresponds with that of the general standard.

Clauses, subclauses, tables and figures which 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 and definitions: roman type;
- notes, examples, explanations, advice, introductions, general statements and references: smaller roman type;
- *test specifications: italic type*;
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Clauses and subclauses for which a rationale is provided in the informative Annex AAA are marked with an asterisk (*).

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2004 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 standard indicated:

ISO 9000	NOTE	Harmonized as EN ISO 9000:2000 (not modified)
ISO 9001	NOTE	Harmonized as EN ISO 9001:2000 (not modified)
ISO 9241-11	NOTE	Harmonized as EN ISO 9241-11:1998 (not modified)
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified)

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 Where 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 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
A1	1991		+ Corr. Juli	1994
A2	1995		A1	1993
+ corr. June	1995		+ Corr. Juli	1994
			A2	1995
			A13	1996
IEC 60601-1-8	2003	Medical electrical equipment Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2004
ISO 14971	2000	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000
A1	2003		+ corr. February	2002
			A1	2003

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-6: General requirements for safety – Collateral Standard: Usability

SECTION ONE – GENERAL

1 Scope and object

1.201 Scope

This Collateral Standard specifies requirements for a PROCESS to analyse, design, verify and validate the USABILITY, as it relates to SAFETY of MEDICAL ELECTRICAL EQUIPMENT, hereinafter referred to as EQUIPMENT. This standard addresses NORMAL USE and USE ERRORS but excludes ABNORMAL USE.

1.202 Relationship to other standards

1.202.1 IEC 60601-1

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 60601-1-6 alone;
- “this Standard” designates the combination of the General Standard and this Collateral Standard.

1.202.2 Particular Standards

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.202.3 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 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-8:2003, *Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*
Amendment 1 (2003)