

Svenska Elektriska Kommissionen, SEK

Fastställt	Utgåva	Sida	Ingår i
2004-08-23	1	1 (1+70)	SEK Område 62

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## Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 1-8: Allmänna fordringar – Tilläggsstandard för larmsystem

*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*

Som svensk standard gäller europastandarden EN 60601-1-8:2004. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-8:2004.

### Nationellt förord

Europastandarden EN 60601-1-8:2004

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-1-8, First edition, 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**

utarbetad inom International Electrotechnical Commission, IEC.

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

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ICS 11.040.01

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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.

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

Appareils électromédicaux  
Partie 1-8: Règles générales de sécurité -  
Norme collatérale: Règles générales,  
essais et guides pour les systèmes  
d'alarme dans l'équipement  
électromédical et les systèmes  
électromédicaux  
(CEI 60601-1-8:2003)

Medizinische elektrische Geräte  
Teil 1-8: Allgemeine Festlegungen  
für die Sicherheit -  
Ergänzungsnorm: Alarmsysteme -  
Allgemeine Festlegungen, Prüfungen  
und Richtlinien für Alarmsysteme  
in medizinischen elektrischen Geräten  
und in medizinischen Systemen  
(IEC 60601-1-8:2003)

This European Standard was approved by CENELEC on 2003-12-02. 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, 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/424/FDIS, future edition 1 of IEC 60601-1-8, prepared by a Joint Working Group of SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, and SC3, Lung ventilators and related devices, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-8 on 2003-12-02.

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) 2004-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2006-12-01

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. alarm systems).

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 and guidance in Annex AAA: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: 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.

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## Endorsement notice

The text of the International Standard IEC 60601-1-8:2003 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 14971      NOTE      Harmonized as EN ISO 14971:2000 (not modified).

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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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60417	database	Graphical symbols for use on equipment	-	-
IEC 60601-1	1988	Medical electrical equipment	EN 60601-1	1990
A1	1991	Part 1: General requirements for safety	+ corr. July A1	1994 1993
A2	1995		+ corr. July A2	1994 1995
+ corr. June	1995		A13	1996
IEC 60601-1-1	2000	Medical electrical equipment Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	2001
IEC 60601-1-6	- <sup>1)</sup>	Part 1-6: General requirements for safety - Collateral standard: Usability	-	-
IEC 60651	1979	Sound level meters	EN 60651	1994
A1	1993		A1	1994
A2	2000		A2	2001
ISO 3744	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane	EN ISO 3744	1999
ISO 7000	1989	Graphical symbols for use on equipment - Index and synopsis	-	-

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<sup>1)</sup> To be published.



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**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**

**SECTION ONE – GENERAL**

**1 \* Scope and object**

**1.201 Scope**

This collateral standard specifies requirements for ALARM SYSTEMS and ALARM SIGNALS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.

It also provides guidance for the application of ALARM SYSTEMS.

**1.202 Object**

The object of this collateral standard is to specify basic safety and essential performance requirements and tests for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent ALARM SIGNALS and consistent control states and their marking for all ALARM SYSTEMS.

NOTE See IEC 60513:1994 [4] for a description of basic safety and essential performance.

This collateral standard does not specify:

- whether any particular MEDICAL ELECTRICAL EQUIPMENT OR MEDICAL ELECTRICAL SYSTEM is required to be provided with ALARM SYSTEMS;
- the particular circumstances which initiate an ALARM CONDITION;
- the allocation of priorities to a particular ALARM CONDITION; or
- the means of generating ALARM SIGNALS.

**1.203 Relationship to other standards**

**1.203.1 IEC 60601-1**

For MEDICAL ELECTRICAL EQUIPMENT, 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 60601-1-8 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

**1.203.2 Particular standards**

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