

Svenska Elektriska Kommissionen, SEK

Fastställt	Utgåva	Sida	Ingår i
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Elektrisk utrustning för medicinskt bruk – Del 2-4: Särskilda säkerhetsfordringar på defibrillatorer

*Medical electrical equipment –**Part 2-4: Particular requirements for the safety of cardiac defibrillators*

Som svensk standard gäller europastandarden EN 60601-2-4:2003. Den svenska standarden innehåller den officiella språkversionen av EN 60601-2-4:2003.

Nationellt förord

Europastandarden EN 60601-2-4:2003

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-4, Second edition, 2002 - Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare utgiven svensk standard SS-IEC 601-2-4, utgåva 1, 1986, gäller ej fr o m 2005-10-01.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

- en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
- särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskild behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.10

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.

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Stora delar av arbetet sker internationellt

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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.

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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.

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EUROPEAN STANDARD

EN 60601-2-4

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2003

ICS 11.040.10

Supersedes HD 395.2.4 S1:1988

English version

Medical electrical equipment
Part 2-4: Particular requirements for the safety of cardiac defibrillators
(IEC 60601-2-4:2002)

Appareils électromédicaux
Partie 2-4: Règles particulières de
sécurité pour les défibrillateurs cardiaques
(CEI 60601-2-4:2002)

Medizinische elektrische Geräte
Teil 2-4: Besondere Festlegungen für die
Sicherheit von Defibrillatoren
(IEC 60601-2-4:2002)

This European Standard was approved by CENELEC on 2002-10-01. 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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, 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 62D/455/FDIS, future edition 2 of IEC 60601-2-4, prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-4 on 2002-10-01.

This European Standard supersedes HD 395.2.4 S1:1988.

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) 2003-08-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2005-10-01

In this standard, the following print types are used:

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

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 AA, BB and ZB are informative.

Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-4:2002 was approved by CENELEC as a European Standard without any modification.

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 60300-3-9	- ¹⁾	Dependability management Part 3: Application guide – Section 9: Risk analysis of technological systems	-	-
IEC 60651	- ¹⁾	Sound level meters	EN 60651	1994 ²⁾
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⁾	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2002 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⁾

¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

Annex ZB
(informative)

**Other international publications mentioned in this standard
with the references of the European publications**

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-2-27	- 1)	Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment	EN 60601-2-27	1994 2)

1) Undated reference.

2) Valid edition at date of issue.

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MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of cardiac defibrillators

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand alone CARDIAC MONITORS (which are standardized by IEC 60601-2-27). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which address considerations in waveform selection.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.