SVENSK STANDARD SS-EN 60601-2-27

Fastställd	Utgåva	Sida	Ingår i
2006-05-29	2	1 (1+70)	SEK Område 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-27: Särskilda fordringar på utrustning för EKG-övervakning

Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

Som svensk standard gäller europastandarden EN 60601-2-27:2006. Den svenska standarden innehållller den officiella engelska språkversionen av EN 60601-2-27:2006.

Nationellt förord

Europastandarden EN 60601-2-27:2006

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
- **IEC 60601-2-27, Second edition, 2005 - Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment**

  utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60601-2-27, utgåva 1, 1995, gäller ej fr o m 2008-11-01.

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 11.040.50

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.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-27

April 2006

ICS 11.040.50

Supersedes EN 60601-2-27:1994

English version

Medical electrical equipment
Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
(IEC 60601-2-27:2005)

Appareils électromédicaux
Partie 2-27: Exigences particulières de sécurité, incluant les performances essentielles, des appareils de surveillance d'électrocardiographie
(CEI 60601-2-27:2005)

Medizinische elektrische Geräte
Teil 2-27: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektrokardiographie-Überwachungsgeräten
(IEC 60601-2-27:2005)

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 60601-2-27:2006 E

Foreword

The text of document 62D/529/FDIS, future edition 2 of IEC 60601-2-27, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-27 on 2005-11-01.

This European Standard supersedes EN 60601-2-27:1994.

It introduces essential performance to electrocardiographic monitoring equipment such as defibrillator protection, performance requirements and alarming.

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)	2006-11-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2008-11-01

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 makes reference to International Standards. Where the International Standard referred to has been endorsed as a European Standard or a home-grown European Standard exists, this European Standard shall be applied instead. Pertinent information can be found on the CENELEC web site.

In this standard, the following print types are used:

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

Endorsement notice

The text of the International Standard IEC 60601-2-27:2005 was approved by CENELEC as a European Standard without any modification.

CONTENTS

INTRODUCTION

This Particular Standard concerns the safety of electrocardiographic monitoring equipment including essential performance. It amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety*) and its Amendment 1 (1991) and Amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

A “General guidance and rationale” for the requirements of this Particular Standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in Annex AA.

At the time of publication of this Particular Standard work was in progress to create a joint ISO/IEC collateral standard addressing “General requirements and guidelines for the application of alarms in medical electrical equipment”. It is intended to harmonize this standard with the above-mentioned collateral standard following its publication.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

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 the particular safety requirements, including essential performance, for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 2.101 and hereinafter also referred to as EQUIPMENT. This standard is applicable to EQUIPMENT used in a hospital environment.

If the EQUIPMENT is used outside the hospital environment, such as in ambulances and air transport, the EQUIPMENT shall comply with this standard.

NOTE Additional standards apply to the EQUIPMENT covering specifically use outside the hospital environment.

This standard is not applicable to electrocardiographic monitors for home use. However, manufacturers should consider using relevant clauses of this standard as appropriate for their intended use.

ECG telemetry systems, ambulatory ("Holter") monitors and other ECG recording devices are outside the scope of this Particular Standard.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular requirements for the safety, including essential performance, of EQUIPMENT as defined in 2.101.

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). The General Standard takes into account IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems,* IEC 60601-1-2:2001, *Medical electrical*

equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests and IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electric medical systems* and its Amendment 1 (1999).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-1, IEC 60601-1-2 and IEC 60601-1-4 as the “Collateral Standards”.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses, tables or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and Collateral Standard mentioned above.