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

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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)

This European Standard was approved by CENELEC on 2005-11-01. 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, 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

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.....	13
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SECTION ONE – GENERAL

1 Scope and object.....	15
2 Terminology and definitions.....	17
4 General requirements for tests	21
5 Classification.....	21
6 Identification, marking and documents.....	23

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

14 Requirements related to classification	29
17 Separation.....	29
20 Dielectric strength	35

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36 Electromagnetic compatibility	37
--	----

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	41
49 Interruption of the power supply	43

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data	45
51 Protection against hazardous output.....	63

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

56 Components and general assembly	77
--	----

Appendix L (normative) References – Publications mentioned in this standard	111
Annex AA (informative) General guidance and rationale	113
Annex BB (informative) Alarm diagrams of Clause 51	131
INDEX OF DEFINED TERMS.....	137
Figure 101 – Alternating QRS complexes and ventricular tachycardia waveforms for testing pattern recognition capability according to 6.8.2 bb) 4) and 6.8.2 bb) 6).....	81
Figure 102 – Set-up for radiated and conducted emission test according to 36.201.1b) 1).....	83
Figure 103 – Set-up for radiated immunity test according to 36.202.3	85
Figure 104 – Test circuit for HF surgery protection according to 36.202.101	87
Figure 105 – Test set-up for HF surgery protection according to 36.202.101	89
Figure 106 – Application of the test voltage to test the energy delivered by the defibrillator (See 17h)101.1)	91
Figure 107 – Test of protection against the effects of defibrillation (differential mode) (See 17h)101.2.....	93
Figure 108 – Test of protection against the effects of defibrillation (common mode) (See 17h)101.3).....	95
Figure 109 – Arrangements of electrodes on sponge (See 17h)101.4)	97
Figure 110 – Test of recovery time from the effects of defibrillation (See 17h)101.4).....	99
Figure 111 – General test circuit	101
Figure 112 – High frequency response (clause 50.102.8 a).....	103
Figure 113 – Test waveforms for T-wave rejection (6.8.2 bb) 2, 50.102.13, 50.102.17)	103
Figure 114 – Test circuit for common mode rejection (See 50.102.10)	105
Figure 115 – Baseline reset (See 50.102.11)	107
Figure 116 – Pacemaker pulse (see 50.102.12)	107
Figure 117 – Normal paced rhythm (see 50.102.13 and Figure 119)	109
Figure 118 – Ineffective pacing (heart rate at 30 1/min, pacemaker pulse at 80 1/min) (see 50.102.13)	109
Figure 119 – Simulated QRS complex (see 50.102.13, 50.102.14 and 50.102.15).....	109
Figure AA.1 – Applied part with multiple patient connections	129
Figure BB.101 – Non-latching alarms w/o silence/reset.....	131
Figure BB.102 – Non-latching alarms with silence/reset.....	131
Figure BB.103 – Latched alarms with silence/reset	133
Figure BB.104 – Two ALARMS with SILENCE/RESET.....	133
Figure BB.105 – INHIBITION of ALARMS	135
Figure BB.106 – SUSPENSION of ALARMS	135

Table 101 – ELECTRODES and NEUTRAL ELECTRODE, their position, identification and colour	23
Table 102 – Protection against the effect of defibrillation (test conditions)	33

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.

