SLOVENSKI STANDARD

SIST EN 60601-2-27:2006

oktober 2006

Medicinska električna oprema – 2-27. del: Posebne varnostne zahteve, vključno z bistvenimi lastnostmi za elektrokardiografsko nadzorno opremo (IEC 60601-2-27:2005)

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

ICS 11.040.50; 11.040.55

Referenčna številka
SIST EN 60601-2-27:2006(en)

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)

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

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.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-27

Deuxième édition
Second edition
2005-08

Appareils électromédicaux –

Partie 2-27: Exigences particulières de sécurité, incluant les performances essentielles, des appareils de surveillance d'électrocardiographie

Medical electrical equipment –

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

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-27 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994. It constitutes a technical revision that introduces essential performance to electrocardiographic monitoring equipment such as defibrillator protection, performance requirements and alarming.

The text of this Particular Standard is based upon the following documents:

FDIS	Report on Voting
62D/529/FDIS	62D/533/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this Particular 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: smaller type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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.

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

Addition:

2.101
ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT (EQUIPMENT)
device and associated LEAD WIRES and ELECTRODES for the monitoring and/or recording of heart action potentials and displaying the resultant data of one PATIENT

2.102
LEAD WIRE(S)
cable(s) connected between ELECTRODE(S) and the device