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Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment (IEC 601-2-27:1994)

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ENGLISH VERSION

Medical electrical equipment
Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
(IEC 601-2-27:1994)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des appareils de surveillance d'électrocardiographie

(CEI 601-2-27:1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Elektrokardiographie-Überwachungsgeräten
(IEC 601-2-27:1994)

This European Standard was approved by CENELEC on 1994-07-05. 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, 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(CO)68, as prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in October 1992.

The reference document was approved by CENELEC as EN 60601-2-27 on 5 July 1994.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1995-07-01
- latest date of withdrawal of conflicting national standards	(dow)	1995-07-01

For products which have complied with the relevant national standard before 1995-07-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-07-01.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-27:1994 was approved by CENELEC as a European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

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Appareils électromédicaux

Partie 2:
Règles particulières de sécurité des appareils de surveillance d'électrocardiographie

Medical electrical equipment

Part 2:
Particular requirements for the safety of electrocardiographic monitoring equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

International Standard IEC 601-2-27 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

DIS	Report on voting
62D(CO)68	62D(CO)77

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

Annex AA is for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type.

– explanations, advice, introductions, general statements, exceptions and references: in smaller type.

– *test specifications: in italic type.*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 601-1: SMALL CAPITALS.

INTRODUCTION

This Particular Standard concerns the safety of electrocardiographic monitoring equipment. It amends and supplements IEC 601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled *"Medical electrical equipment – Part 1: General requirements for safety"*.

A "General guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

It is considered that a 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, this annex 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 the General guidance and rationale section at the end of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety 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 Standard specifies the particular safety requirements for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 2.101 and hereinafter also referred to as EQUIPMENT.

Telemetry monitors, ambulatory ("Holter") monitors and other 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 of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT as defined in 2.101.

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety.*

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

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to 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 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.

3 Terminology and definitions

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

Additional definitions:

2.101 *ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT*

EQUIPMENT and associated ELECTRODES for the monitoring and/or recording of heart action potentials and displaying the resultant data locally and/or transmitting to a central station.

2.102 *LEAD(S) (ECG)*

ELECTRODE combination used for a certain ECG recording.

2.103 *ELECTRODE*

Conductor attached to a specified part of the body to detect heart action voltages in combination with another ELECTRODE or ELECTRODES.

2.104 *LEAD SELECTOR*

System to select LEADS.

2.105 *NEUTRAL ELECTRODE*

Reference point for differential amplifiers and/or interference suppression circuits, not forming part of any ECG LEAD.

2.106 *SENSITIVITY (ECG)*

Ratio of the amplitude of a displayed signal to the amplitude of the signal producing it, expressed in mm/mV.