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Medical electrical equipment - Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors (IEC 60601-2-4:1983)

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MEDICAL ELECTRICAL EQUIPMENT. PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CARDIAC DEFIBRILLATORS AND CARDIAC DEFIBRILLATOR-MONITORS

Appareils électromédicaux
Deuxième partie: Règles
particulières de sécurité pour
défibrillateurs cardiaques
et moniteurs-défibrillateurs
cardiaques

Medizinische elektrische
Geräte
Teil 2: Besondere Festlegungen
für die Sicherheit von
Defibrillatoren mit und ohne
Monitor

BODY OF THE HD

The Harmonization Document consists of:

- **IEC 601-2-4 (1983) ed 1; IEC/SC 62D, not appended**

This Harmonization Document was approved by CENELEC on 1988-09-13.

The English and French versions of this Harmonization Document are provided by the text of the IEC publication and the German version is the official translation of the IEC text.

According to the CENELEC Internal Regulations the CENELEC member National Committees are bound:

to announce the existence of this Harmonization Document at national level **by or before 1989-01-01**

to publish their new harmonized national standard **by or before 1989-07-01**

to withdraw all conflicting national standards **by or before 1989-07-01.**

Harmonized national standards are listed on the HD information sheet, which is available from the CENELEC National Committees or from the CENELEC Central Secretariat.

The CENELEC National Committees are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

NORME DE LA CEI

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Appareils électromédicaux

Deuxième partie: Règles particulières de sécurité pour défibrillateurs cardiaques et moniteurs-défibrillateurs cardiaques

Medical electrical equipment

Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors

Bureau Central de la Commission Electrotechnique Internationale

3 rue de Varembé

Genève Suisse

Prix Price Frs 85.–

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors

FOREWORD

1) 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.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This standard has been prepared by Sub-Committee 62D: Electromedical Equipment, of IEC Technical Committee No. 62: Electrical Equipment in Medical Practice.

Drafts were discussed at the meetings held in Moscow in 1977 and in Washington in 1979. As a result of these meetings, a draft, Document 62D(Central Office)8, was submitted to the National Committees for approval under the Six Months' Rule in May 1980.

Amendments, Document 62D(Central Office)20, were submitted to the National Committees for approval under the Two Months' Procedure in March 1982.

The National Committees of the following countries voted explicitly in favour of publication:

Australia
Belgium
China
Finland
France
Germany
Ireland
Israel
Italy
Japan
Norway
Romania
South Africa (Republic of)
Spain
Sweden
Switzerland
Turkey
Union of Soviet Socialist Republics
United Kingdom

This Particular Standard amends and supplements IEC Publication 601-1 (first edition 1977): Safety of Medical Electrical Equipment. Part 1: General Requirements, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard. The title of the General Standard will be changed in the next edition to read:

Medical electrical equipment: Part 1: General requirements for safety

This change is anticipated in the title of this Particular Standard.

The numbering of sections, clauses and sub-clauses of this Particular Standard corresponds with that of the General Standard.

Sections, clauses, sub-clauses or figures which are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc., and additional items *aa)*, *bb)*, etc.

In this 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 DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by Sub-Committee 62D at the meeting in Washington in 1979, a rationale for the more important requirements is given in Appendix 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 practices or as a result of developments in technology. However this appendix does not form part of the requirements of this Standard.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors

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SECTION ONE — GENERAL

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 and CARDIAC DEFIBRILLATOR-MONITORS as defined in Sub-clauses 2.1.101 and 2.1.102, hereinafter referred to as EQUIPMENT, incorporating a capacitive energy storage device.

This Standard does not apply to a CARDIAC MONITOR which is not part of a DEFIBRILLATOR-MONITOR.

In combined EQUIPMENT in which the ECG monitoring signal cannot be derived via the DEFIBRILLATOR ELECTRODES, this Standard applies to the DEFIBRILLATOR part only.

1.4 *Environmental conditions*

Item b) Operation

1) *Environment*

Amendment:

a) Ambient temperature between 0 °C and +40 °C.

b) Relative humidity between 30% and 95%, without condensation.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Addition:

For the EQUIPMENT, the APPLIED PART includes the DEFIBRILLATOR ELECTRODES and any separate monitoring electrodes and all parts conductively connected to any of these electrodes.

Additional definitions:

2.1.101 *CARDIAC DEFIBRILLATOR (DEFIBRILLATOR)*

MEDICAL ELECTRICAL EQUIPMENT intended to defibrillate the heart by an electrical pulse via electrodes applied either to the PATIENT's skin (external electrodes), or to the exposed heart (internal electrodes).

2.1.102 *CARDIAC DEFIBRILLATOR-MONITOR (DEFIBRILLATOR-MONITOR)*

Combination of DEFIBRILLATOR and CARDIAC MONITOR where the ECG monitoring signal can be derived via the external DEFIBRILLATOR ELECTRODES.

Additionally separate monitoring electrodes may be provided.

2.1.103 *CARDIAC MONITOR (MONITOR)*

Part of a DEFIBRILLATOR-MONITOR providing a visible display of the electrical activity of the PATIENT's heart.

2.1.104 *CHARGING CIRCUIT*

Circuit within the DEFIBRILLATOR intended for charging the energy storage device. This circuit includes all parts conductively connected to the energy storage device during the charging period.

2.1.105 *DEFIBRILLATOR ELECTRODES*

Electrodes intended to deliver an electrical pulse to the PATIENT for the purpose of cardiac defibrillation.

2.1.106 *DISCHARGE CIRCUIT*

Circuit within the DEFIBRILLATOR which connects the energy storage device to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES.

2.1.107 *DISCHARGE CONTROL CIRCUIT*

Circuit including the manually operated discharge controls and all parts conductively connected to them.

2.1.108 *INTERNAL DISCHARGE CIRCUIT*

Circuit within the DEFIBRILLATOR which discharges the energy storage device without activating the DEFIBRILLATOR ELECTRODES.

2.1.109 *SYNCHRONIZER*

Device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle.

2.12.101 *DELIVERED ENERGY*

Energy which is passed through the DEFIBRILLATOR ELECTRODES and dissipated in the PATIENT or in a resistance of specified value.

2.12.102 *STAND-BY*

Mode of operation in which the EQUIPMENT is operational except that the energy storage device is not yet charged.

2.12.103 *STORED ENERGY*

Energy which is stored in the DEFIBRILLATOR energy storage device.

3. General requirements

This clause of the General Standard applies.

4. General requirements for tests

This clause of the General Standard applies except as follows:

4.1 *Type tests and routine tests*

Addition to Item b):

Additional routine tests: see Appendix B.

4.5 *Ambient temperature, humidity, atmospheric pressure*

d) Replacement:

The test required in Sub-clause 102.2 shall be performed at an ambient temperature of 0 ± 2 °C.

4.11 *Sequence*

Amendment:

The endurance test required in Clause 103 shall be performed after the test for excessive temperatures (Clause C20 of Appendix C of the General Standard).

Addition:

The tests required in Clauses 101, 102, 104, 105 and 106 shall be performed after test C35 of Appendix C of the General Standard.

5. Classification

This clause of the General Standard applies except as follows:

5.1 *Amendment:*

Delete CLASS III EQUIPMENT.

5.2 *Amendment:*

Delete TYPE B EQUIPMENT.

6. Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside*

j) Power input

Replacement: Lines 39 to 41.

The RATED power input of MAINS OPERATED EQUIPMENT shall be the maximum power input averaged over any period of 2 s.

See also Sub-clause 7.101 of this Standard.

l) Classification

Addition:

For DEFIBRILLATOR-MONITORS providing for the connection of separate ECG, monitoring electrodes shall also be marked as incorporating DEFIBRILLATOR protection. See Figure 101, page 52.

Additional items:

aa) Concise operating instructions

The EQUIPMENT shall be permanently marked in a prominent place with short instructions for defibrillating and, where relevant, monitoring a PATIENT. This marking shall be in a language recognized where the EQUIPMENT is intended to be used and shall be clearly legible to a person having normal vision from a distance of at least 1 m.

bb) Battery powered EQUIPMENT

EQUIPMENT incorporating a primary or a rechargeable battery and any separate battery charger shall be marked with brief instructions for, as appropriate, the re-charging or replacement of the battery.

In the case of such EQUIPMENT also capable of connection to the SUPPLY MAINS or to a separate battery charger, the EQUIPMENT and such charger shall be marked to indicate any limitations of operation when the EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. Such instructions shall include the case of a discharged or missing battery.

6.3 *Marking of controls*

Additional item:

aa) The control for selecting the output energy or the relevant indicating means shall be calibrated in terms of DELIVERED ENERGY in joules to a resistive load of 50 Ω.

6.8 *ACCOMPANYING DOCUMENTS*

6.8.2 *Instructions for use*

e), f), g) Replacement:

EQUIPMENT incorporating a battery

The instructions for use shall contain additionally:

— Full details of the charging procedure for any rechargeable battery.