INTERNATIONAL STANDARD

IEC 60601-2-4

Second edition
2002-08

Medical electrical equipment –

Part 2-4: Particular requirements for the safety of cardiac defibrillators

Appareils électromédicaux –

Partie 2-4: Règles particulières de sécurité pour les défibrillateurs cardiaques

Reference number
IEC 60601-2-4:2002(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Further information on IEC publications

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology. Information relating to this publication, including its validity, is available in the IEC Catalogue of publications (see below) in addition to new editions, amendments and corrigenda. Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is also available from the following:

- **IEC Web Site (www.iec.ch)**

- **Catalogue of IEC publications**

  The on-line catalogue on the IEC web site (http://www.iec.ch/searchpub/cur_fut.htm) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

- **IEC Just Published**

  This summary of recently issued publications (http://www.iec.ch/online_news/justpub/jp_entry.htm) is also available by email. Please contact the Customer Service Centre (see below) for further information.

- **Customer Service Centre**

  If you have any questions regarding this publication or need further assistance, please contact the Customer Service Centre:

  Email: custserv@iec.ch
  Tel: +41 22 919 02 11
  Fax: +41 22 919 03 00

INTERNATIONAL STANDARD

IEC 60601-2-4

Second edition
2002-08

Medical electrical equipment –

Part 2-4: Particular requirements for the safety of cardiac defibrillators

Appareils électromédicaux –

Partie 2-4: Règles particulières de sécurité pour les défibrillateurs cardiaques

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE XA

For price, see current catalogue

CONTENTS

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

SECTION 101 – ADDITIONAL REQUIREMENTS RELATING TO SAFETY

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-4: Particular requirements for the safety of cardiac defibrillators

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 co-operation 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 express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, 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.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any EQUIPMENT declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-4 has been prepared by sub-committee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-4 cancels and replaces the first edition published in 1983 of which it constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/455/FDIS	62D/460/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.

Annexes AA and BB are for information only.

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, headings of subclauses and headings of items: 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 2007-08. At this date, the publication will be

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

The contents of the corrigendum of April 2004 have been included in this copy.

INTRODUCTION

This Particular Standard concerns the safety of CARDIAC DEFIBRILLATORS. It amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, including its amendments 1 (1991) and 2 (1995), hereinafter referred to as the General Standard.

A first edition of this Particular Standard, based on the first edition (1977) of IEC 60601-1 was published in 1983. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above through minor changes to the technical content.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of this Particular 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.

Clauses and subclauses for which a corresponding rationale statement is given in Annex AA are marked with an asterisk * before their number in the text.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of cardiac defibrillators

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 requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand alone CARDIAC MONITORS (which are standardized by IEC 60601-2-27). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which address considerations in waveform selection.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101.

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).

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 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 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.

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

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*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.1.101
CARDIAC 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). May be referred to as DEFIBRILLATOR or EQUIPMENT

NOTE Such EQUIPMENT may also include other monitoring or therapeutic functions.

2.1.102
MONITOR
part of a DEFIBRILLATOR providing a visual display of the electrical activity of the PATIENT's heart

NOTE The term is used within this Particular Standard to distinguish such a MONITOR from one which forms a separate EQUIPMENT in its own right even in cases where the separate stand-alone monitor is able to provide synchronization signals to the DEFIBRILLATOR, used as basis for AED rhythm recognition detection or providing control signals to the DEFIBRILLATOR.

2.1.103
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

2.1.104
DEFIBRILLATOR ELECTRODES
electrodes intended to deliver an electrical pulse to the PATIENT for the purpose of cardiac defibrillation

NOTE DEFIBRILLATOR ELECTRODES may also provide other monitoring (e.g. ECG acquisition) or therapeutic (e.g. transcutaneous pacing) functions and may be disposable or reusable.

2.1.105
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

2.1.106
DISCHARGE CONTROL CIRCUIT
circuit including the manually operated discharge controls and all parts conductively connected to them

2.1.107
INTERNAL DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which discharges the ENERGY STORAGE DEVICE without energizing the DEFIBRILLATOR ELECTRODES

2.1.108
SYNCHRONIZER
device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle

2.1.109
AUTOMATED EXTERNAL DEFIBRILLATOR (AED)
a DEFIBRILLATOR that, once activated by the OPERATOR, analyses the ECG obtained from electrodes placed on the chest surface, identifies shockable cardiac rhythms, and automatically operates the DEFIBRILLATOR when a shockable rhythm is detected, hereinafter referred to as an AED

NOTE AEDs may provide varying levels of automation and be referred to by various terms. See Annex BB.

2.1.110
ENERGY STORAGE DEVICE
the component (for example a capacitor) that is charged with the energy necessary to deliver an electrical defibrillation pulse to the PATIENT

2.1.111
SEPARATE MONITORING ELECTRODES
electrodes applied to the PATIENT for the purpose of monitoring the PATIENT. These electrodes are not used to apply defibrillation pulses to the PATIENT

2.1.112
RHYTHM RECOGNITION DETECTOR (RRD)
a system that analyzes the ECG and identifies whether a cardiac rhythm is shockable. The algorithm in an AED is designed for sensitivity and specificity for the detection of arrythmias for which a defibrillation shock is clinically indicated. May be referred to as RRD

2.12.101
DELIVERED ENERGY
energy which is delivered 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

2.12.104
DUMMY COMPONENT
test replacement for moulded components like transformers, semiconductors etc. The DUMMY COMPONENT has a geometry equal to that of the component it will replace during the test. The moulded volume does not incorporate parts of the original components (ex-semiconductor dye, transformer cores and windings). The DUMMY COMPONENT makes it possible to test creepage, clearance and dielectric strength with the correct geometry without exceeding the internal maximum voltage of the part being replaced

2.12.105
ENERGY METER / DEFIBRILLATOR TESTER
an INSTRUMENT capable of measuring the energy output from a CARDIAC DEFIBRILLATOR while generating a simulated ECG output to the CARDIAC DEFIBRILLATOR

2.12.106
SELECTED ENERGY
energy which the defibrillator is intended to deliver, as determined by the setting of a manual control or by an automatic protocol

2.12.107
FREQUENT USE
term used to describe a DEFIBRILLATOR designed to endure more than 2 500 discharges (see 103)

2.12.108
INFREQUENT USE
term used to describe a DEFIBRILLATOR designed to endure less than 2 500 discharges (see 103)

2.12.109
MANUAL DEFIBRILLATOR
DEFIBRILLATOR capable of being manually operated by the OPERATOR for selection of energy, charging and discharging

4 General requirements for tests

This clause of the General Standard applies except as follows:

*4.5 Ambient temperature, humidity, atmospheric pressure

Additional item:

aa) The test required in 102.2 and 102.3 shall be performed at an ambient temperature of 0 °C ± 2 °C.

4.6 Other conditions

Additional item:

aa) Unless otherwise specified in this Standard all tests apply to all kinds of defibrillator types (manual, AED`s, infrequent use and frequent use defibrillators)

4.11 Sequence

Addition:

The endurance test required in Clause 103 shall be performed after the test for excessive temperatures (see Clause C.20 of the General Standard).

The tests required in Clauses 101, 102, 104, 105 and 106 shall be performed after test C.35 of Appendix C of the General Standard.

*5 Classification

This clause of the General Standard applies except as follows:

5.2 According to the degree of protection against electric shock:

Amendment:

Delete TYPE B APPLIED PART.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of *EQUIPMENT* or *EQUIPMENT* parts

*j) Power input

Replacement (paragraph beginning "If the rating of EQUIPMENT includes ...".*)*:

The RATED power input of mains operated EQUIPMENT shall be the maximum value attained by averaging the power input over any period of 2 s.

Additional items:

*aa) Concise operating instructions

Instructions for defibrillating, and where relevant, monitoring a PATIENT'S ECG, shall be provided by means of either clearly legible markings, or clearly understandable auditory commands.

Compliance shall be checked by either of the following tests:

Markings shall be clearly legible to a person of normal vision from a distance of 1 m in an ambient illumination of 100 lux. The observer shall have a visual acuity of not less than 20/40 or corrected to not less than 20/40 as determined by a standard eye chart or by other appropriate means, such as the Titmus Vision Test Series.

Auditory commands shall be clearly understandable to a person of normal hearing from a distance of 1 m in an ambient white noise (defined as flat ±10 % over the range 100 Hz to 10 kHz) level of 65 dB, as measured with a Type 2 A-weighted sound level meter (see IEC 60651).

*bb) *Internally powered EQUIPMENT*

INTERNALLY POWERED EQUIPMENT 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 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.

cc) Disposable DEFIBRILLATOR electrodes

The labeling accompanying the electrode package shall include, at a minimum, the following information:

1) symbols (in accordance with ISO 15223) or a statement indicating the date the electrodes will expire (e.g., "use before ____") and the lot number or the date of manufacture;

2) appropriate cautions and warnings, including limits on duration of electrode application and a caution that the unit package shall not be opened until immediately prior to use, if applicable;

3) appropriate instructions for use, including procedures for skin preparation;

4) instructions concerning storage requirements, if applicable.

6.3 Marking of controls and INSTRUMENTS

Additional items:

*aa) The DEFIBRILLATOR shall be provided with a control for selection of the SELECTED ENERGY, unless the EQUIPMENT provides an automatic protocol for the SELECTED ENERGY.

The SELECTED ENERGY (including any means for selection in a programming mode/menu) or the relevant indicating means shall be expressed as the nominal DELIVERED ENERGY in joules to a resistive load of 50 Ω.

The DEFIBRILLATOR shall give a clear indication of when the SELECTED ENERGY has been reached.

Compliance shall be checked by inspection.