

American National Standard

ANSI/AAMI DF80:2003/(R)2010



Medical electrical equipment— Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

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Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)

Developed by
Association for the Advancement of Medical Instrumentation

Approved 23 October 2003 and Reaffirmed 20 April 2010 by
American National Standards Institute, Inc.

Abstract: This standard specifies requirements for the safety of 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). This standard does not apply to implantable defibrillators, remote control defibrillators, or separate cardiac monitors.

Keywords: manual defibrillator, automatic external defibrillator, AED, electromedical equipment, cardiac

AAMI Standard

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical

International designation	U.S. designation	Equivalency
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Defibrillator Committee

This standard was developed by the Defibrillator Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Defibrillator Committee** had the following members:

<i>Cochairs:</i>	Richard Kerber, MD Michael Willingham
<i>Members:</i>	John Anderson, University of Ulster Robert William Bain, Prince George's Hospital Center Carole C. Carey, RN, U. S. Food and Drug Administration Hatim M. Carim, PhD, 3M Healthcare Andrew C. Clifford, SGS Medical Devices Regis DeSilva, MD, Harvard Medical School Peter D. Gadsby, Tyco Healthcare/Ludlow Leslie A. Geddes, PhD, Purdue University Janice M. Jenkins, PhD, University of Michigan College of Engineering Gideon Kantor, PhD Richard Kerber, MD, University of Iowa Healthcare Jim Miller, Philips Medical Systems Carl A. Pantiskas, Spacelabs Medical Cameron G. Rouns, Ballard Medical Products David Schlageter, G. E. Marquette Medical Systems William J. Smirles, Heartsine Technologies, Inc. W. A. Tacker, Jr., MD, PhD, Purdue University Kok-Swang Tan, PhD, Medical Devices Bureau Health Michael D. Willingham, Medtronic-Physio Control
<i>Alternates:</i>	Donald Eugene Brodnick, G.E. Medical Systems Fred W. Chapman, PhD, Medtronic Physio-Control Stacy E. Gehman, BS, Philips Medical Systems/Heartstream Shen Luo, PhD, Spacelabs Medical

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background

This standard was developed by the AAMI Defibrillator Committee. The objective of this standard is to specify requirements for the safety of medical electrical equipment intended to defibrillate the heart by an electrical pulse via electrodes applied either to the patient's skin or to the exposed heart.

This is a combined revision of ANSI/AAMI DF2:1996, *Cardiac defibrillator devices* and ANSI/AAMI DF39:1993, *Automatic external defibrillators and remote-control defibrillators*. During the course of putting this document together, the AAMI Defibrillator Committee considered identical adoption of IEC 60601-2-4:2002, *Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillator devices*, which was based in large part on the previous editions of the AAMI standards noted above. In the course of reviewing the IEC standard for U.S. adoption, the committee decided that although the IEC document addressed most of the issues which the committee members felt were important, there were a few areas covered in DF2 and DF39 that had been omitted by IEC. This AAMI standard, therefore, includes all of the requirements from IEC 60601-2-4:2002 as well as some additional requirements and informative text that apply only to the AAMI standard.

The additional requirements and other informative materials that relate only to the American National Standard consist of sections 107 and 108, and informative annexes CC, DD, and EE. The remaining parts of this document are also part of the American National Standard and are identical to IEC 60601-2-4.

IEC 60601-2-4:2002 was developed by IEC Subcommittee (SC) 62D, Electromedical Equipment, which is administered by AAMI on behalf of the International Electrotechnical Commission (IEC), a worldwide organization for standardization. As previously noted, AAMI standards (as well as a previous edition of the IEC document) served as the basis of the international standard. In addition, the AAMI Defibrillator Committee, working as the U.S. Technical Advisory sub-Group for IEC SC 62D/WG2, was responsible for developing U.S. consensus on the international standard and otherwise participated in the drafting of that document.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This background does not contain provisions of the American National Standard *Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)* (ANSI/AAMI DF80:2003), but it does provide important information about the development and intended use of the document.

MEDICAL ELECTRICAL EQUIPMENT—

Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external 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: Electromedical 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.

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 2-4: Particular requirements
for the safety of cardiac defibrillators
(including automated external 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, 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.

This specification defines minimum pad electrode performance. It does not ensure compatibility of a particular pad electrode-defibrillator combination nor does it ensure an acceptable level of performance. While it provides reasonable assurance of safe performance, it does not ensure compatibility of a particular pad electrode-defibrillator combination. As such, the consumer should request compatibility test information from the manufacturer(s).

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 arrhythmias 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 molded components like transformers, semiconductors etc. The DUMMY COMPONENT has a geometry equal to that of the component it will replace during the test. The molded 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 $0\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$.

4.6 Other conditions

Additional item:

aa) Unless otherwise specified in this Standard all tests apply to all kinds of defibrillator types (manual, AEDs, 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 $\pm 10\%$ 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.

6.8 Accompanying documents

6.8.2 Instructions for use

- *** items e), f), g), and h)

Replacement:

e) through h)

- e) full details of the charging procedure for any rechargeable battery;*
- f) advice on the periodic replacement of any primary or rechargeable battery;*

- g) the number of maximum energy discharges (in the case of AEDs, the number of preprogrammed discharges) which are available from a new and fully charged battery at 20 °C ambient temperature;
- h) for EQUIPMENT also capable of connection to the SUPPLY MAINS or to a separate battery charger, information on any limitations of operation when such a connection is made. This information shall include the case of a discharged or missing battery.

Additional item:

aa) *Supplementary instructions for use*

The instructions for use shall additionally contain the following:

- *1) a warning not to touch the PATIENT during defibrillation;
- *2) a description of the correct type and method of handling the DEFIBRILLATOR ELECTRODES in use as well as a prominent warning that DEFIBRILLATOR ELECTRODES shall be kept well clear of other electrodes or metal parts in contact with the PATIENT. The OPERATOR shall be advised that other MEDICAL ELECTRICAL EQUIPMENT which has no DEFIBRILLATION-PROOF applied parts shall be disconnected from the PATIENT during defibrillation;
- 3) advice for the OPERATOR to avoid contact between parts of the PATIENT's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current;
- *4) any environmental limitations regarding storing the EQUIPMENT (e.g., in a car or an ambulance under severe climatic conditions) immediately prior to use;
- 5) where means are provided for monitoring via SEPARATE MONITORING ELECTRODES, instructions for the placement of these electrodes;
- *6) a recommendation calling the OPERATOR's attention to the need for periodic maintenance of the EQUIPMENT irrespective of usage, especially:
 - cleaning of any reusable DEFIBRILLATOR ELECTRODES and the insulating parts of the handles;
 - sterilization procedures for any reusable DEFIBRILLATOR ELECTRODES or handles, including recommended sterilization methods and maximum sterilization cycles, if applicable;
 - cleaning of any reusable monitoring electrodes;
 - inspection of the packaging of any disposable DEFIBRILLATOR ELECTRODES and any disposable monitoring electrodes to ensure integrity of any seals and validity of any expiry date;
 - inspection of cables and electrode handles for possible defects;
 - functional checks;
 - charging of the ENERGY STORAGE DEVICE, if it is of a type requiring periodic charging (e.g., electrolytic or polyvinylidene fluoride (PVDF) capacitors);
- *7) information on the time for charging the fully discharged ENERGY STORAGE DEVICE, when the DEFIBRILLATOR is set to maximum energy,
 - a) with RATED MAINS VOLTAGE and, for an INTERNALLY POWERED DEFIBRILLATOR, with a new fully charged battery;
 - b) as a), but for a MAINS VOLTAGE of 90 % of the RATED value and for an INTERNALLY POWERED DEFIBRILLATOR after 15 maximum energy discharges FOR FREQUENT USE DEFIBRILLATOR or 6 discharges for INFREQUENT USE DEFIBRILLATOR;
 - c) as b) but measured from initially switching power on to charge ready at maximum energy.
- 8) for AEDs, information on the maximum time from the initiation of rhythm analysis to readiness for discharge,

- a) with RATED MAINS VOLTAGE and, for an INTERNALLY POWERED DEFIBRILLATOR, with a new fully charged battery;
 - b) as a), but for a MAINS VOLTAGE of 90 % of the RATED value and for AN INTERNALLY POWERED DEFIBRILLATOR after 15 maximum energy discharges for a FREQUENT USE DEFIBRILLATOR or 6 discharges for an INFREQUENT USE DEFIBRILLATOR.
 - c) as b) but measured from initially switching power on to charge ready at maximum energy;
- 9) for AEDs, information on whether or not the RHYTHM RECOGNITION DETECTOR will continue analyzing the ECG after the RRD has detected a shockable rhythm and the DEFIBRILLATOR is charged and ready to shock and in this case bring the AED into a state where defibrillation is prohibited;
 - 10) a warning that use of a DEFIBRILLATOR in the presence of flammable agents or in an oxygen enriched atmosphere presents an explosion and fire hazard.
 - 11) For EQUIPMENT intended for INFREQUENT USE, the intent shall be clearly stated and the limitations of the EQUIPMENT shall be clearly defined. Recommended or required status tests or preventive maintenance shall also be stated.
 - 12) For EQUIPMENT that delivers energy according to a preset protocol, information regarding the automatic selection of DELIVERED ENERGY and the conditions for resetting of the protocol shall be described in the instructions for use. The instruction for use shall also contain information of how to change the protocol if applicable.

6.8.3 Technical description

Additional item:

*aa) The technical description shall additionally provide:

- 1) essential performance data for defibrillation:
 - a) graphical plots in terms of time and current or voltage of the waveforms of the delivered pulses when the DEFIBRILLATOR is connected in turn to resistive loads of 25 Ω , 50 Ω , 75 Ω , 100 Ω , 125 Ω , 150 Ω , and 175 Ω and set to its maximum output, or according to an automatic protocol for the SELECTED ENERGY if applicable;
 - b) energy accuracy specifications for the DELIVERED ENERGY in a 50 Ω resistor;
 - c) if the DEFIBRILLATOR has a mechanism to inhibit its output when the PATIENT impedance is outside certain limits, disclosure of those limits;
- 2) essential performance data of any SYNCHRONIZER, including:
 - a) the meaning of any displayed synchronization or marker pulse,
 - b) the maximum time delay between the synchronization pulse and delivery of the energy, once the output has been activated, including details of how the time delay was measured, and
 - c) a statement concerning any conditions which will de-select the synchronized mode;
- 3) essential performance data of the RHYTHM RECOGNITION DETECTOR, including:
 - a) ECG Database Test Report

The ECG database for validation of rhythm recognition performance shall include, at a minimum, ventricular fibrillation (VF) rhythms of varying amplitudes, ventricular tachycardia (VT) rhythms of varying rates and QRS width, various sinus rhythms including supraventricular tachycardias, atrial fibrillation, and atrial flutter, sinus rhythm with PVC (premature ventricular contraction), asystole, and pacemaker rhythms. All rhythms shall have been collected using electrode systems and ECG signal processing characteristics similar to the device being tested, and shall be of appropriate length to allow decisions to be made by the detector system.

A test report describing the recording methods, rhythm source, rhythm selection criteria, and annotation methods and criteria shall be available. The results of detector performance shall be reported in terms of specificity, true predictive value, sensitivity, and false positive rates, as follows:

Table 101—Rhythm recognition detector categories

	VF and VT	All other ECG rhythms
Shock	A	B
No shock	C	D

A true positive (A) is a correct classification of a shockable rhythm. A true negative (D) is a correct classification of all rhythms for which a shock is not indicated. A false positive (B) is an organized or perfusing rhythm or asystole that has been incorrectly classified as a shockable rhythm. A false negative (C) is a VF or VT associated with cardiac arrest that has been incorrectly classified as non-shockable.

The sensitivity of the device for shockable rhythms is $A/(A+C)$. The true predictive value is expressed as $A/(A+B)$. The specificity of the device for non-shockable rhythms is $D/(B+D)$. The false positive rate is expressed as $B/(B+D)$.

The report shall clearly summarize the sensitivity for detecting VF, and the sensitivity for detecting VT for those devices designed to treat VT. For those devices designed to treat certain types of ventricular tachycardia (VT) a description of the requirements for indication of VT as a shockable rhythm shall be included. The positive predictive accuracy, the false positive rate, and overall specificity of the device shall also be reported. Reporting the specificity of the device for each non-shockable rhythm group (i.e., normal sinus rhythm, supraventricular rhythms such as atrial fibrillation and atrial flutter, ventricular ectopy, idioventricular rhythms, and asystole) is recommended but not required.

The sensitivity of the device to recognize VF at maximum peak to peak amplitude of 200 μ V or greater shall exceed 90 % in the absence of artifacts (e.g., induced by cardiopulmonary resuscitation). For those devices which detect VT, the sensitivity shall exceed 75 %. The specificity of the detector in correctly differentiating non-shockable rhythms shall exceed 95 % in the absence of artifacts.

- b) If the detector initiates analysis of the rhythm either automatically or following manual initiation by the OPERATOR, this shall be described.
- c) If the DEFIBRILLATOR incorporates a system that detects and analyzes physiological information other than the ECG, in order to increase the sensitivity or specificity of the AED, the technical description shall explain the method of operation of this system and the criteria for recommending shock delivery.

6.8.101 Accompanying documents related to electromagnetic compatibility

In accordance with IEC 60601-1-2, the manufacturer shall include information regarding electromagnetic compatibility of the EQUIPMENT. Specifically, Tables 201, 202, and 203a shall be provided and applicable statements in accordance with 6.8.201.2 shall be included in the instructions for use.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply except as follows:

10 Environmental conditions

This clause of the General Standard applies except as follows:

*10.2 Operation

10.2.1 Environment

Amendment:

- a) Ambient temperature between 0 °C and +40 °C.
- b) Relative humidity between 30 % and 95 %, without condensation.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

14 Requirements related to classification

This clause of the General Standard applies except as follows:

14.6 Types b, bf, and cf applied parts

Addition

- *aa) Any APPLIED PART consisting of SEPARATE MONITORING ELECTRODES for monitoring the ECG shall be TYPE CF.

*17 Separation

This clause of the General Standard applies except as follows:

- *h) first dash

Additional bullet:

- APPLIED PARTS of other PATIENT CIRCUITS;

Amendment:

Delete sixth dash ("the EQUIPMENT shall not be energized;").

Replace second to last paragraph ("Each test is repeated with V_T reversed.") by the following:

Each test is performed both with the EQUIPMENT energized and not energized in turn and is repeated with V_T reversed in each case.

Additional items:

- aa) Arrangements to isolate the DEFIBRILLATOR ELECTRODES from other parts shall be so designed that, during the discharge of the ENERGY STORAGE DEVICE, hazardous electrical energies are excluded from the following:
 - 1) the ENCLOSURE;

- 2) all PATIENT CONNECTIONS belonging to other PATIENT CIRCUITS;
- 3) any SIGNAL INPUT PART and/or any SIGNAL OUTPUT PART;
- 4) a metal foil on which the EQUIPMENT is placed and which has an area at least equal to that of the base of the EQUIPMENT (CLASS II EQUIPMENT or EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE).

Compliance shall be checked by the following test:

The above requirement is met when, after a discharge of the DEFIBRILLATOR connected as shown in Figure 101, the peak voltage between the points Y1 and Y2 does not exceed 1 V. Transients might be imposed on the measurement during the energy discharge. These shall be excluded from the measurement. This voltage corresponds to a charge of 100 μ C from the part under test.

In the case where an active signal output part would effect the measured voltage between Y1 and Y2 the specific signal output port is excluded from the measurement. However the ground reference of such a signal output port shall be measured.

In the case where the connection of the measurement circuit of Figure 101 to an input/output port would create a failure of the device to function properly, the specific input/output port is excluded from measurement. However the ground reference of such an input/output signal shall be measured.

DEFIBRILLATORS requiring an impedance within a certain range to be present at the output of the DISCHARGE CIRCUIT are to be tested connected to a 50 Ω resistive load. In the case of DEFIBRILLATORS requiring the detection of a shockable ECG in order to deliver a shock, an ECG simulator incorporating a 50 Ω resistive load is to be used.

Measurements shall be done at the maximum energy level of the device.

CLASS I EQUIPMENT shall be tested while connected to the protective earth.

CLASS I EQUIPMENT which is capable of operation without a SUPPLY MAINS, e.g., having an internal battery, shall also be tested without the protective earth connection.

Any connection to a FUNCTIONAL EARTH TERMINAL shall be removed.

The test shall be repeated with the earth connection transferred to the other DEFIBRILLATOR ELECTRODE.

- *bb) Any APPLIED PARTS not being DEFIBRILLATOR ELECTRODES shall be DEFIBRILLATION-PROOF APPLIED PARTS unless the manufacturer has taken steps to prevent their use at the same time as performing defibrillation with the same DEFIBRILLATOR.
- *cc) Unintentional charging of the ENERGY STORAGE DEVICE shall not occur when testing the requirements for DEFIBRILLATION-PROOF APPLIED PARTS according to this clause.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

***19.1 General requirements**

Item b), third dash

Addition:

For the measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT the EQUIPMENT shall be operated in turn:

- a) in STAND-BY;
- b) while the ENERGY STORAGE DEVICE is being charged to maximum energy;