List of Titles

American National Standard

ANSI/AAMI DF80:2003

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

AAMI Association for the Advancement of Medical Instrumentation

# 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.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

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.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

## INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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American National Standard

ANSI/AAMI DF80:2003
(Combined revision of ANSI/AAMI DF2:1996
and ANSI/AAMI DF39:1993)

# 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 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

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## AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

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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:

| | |
|---|---|
| *Cochairs:* | Richard Kerber, MD |
| | Michael Willingham |
| *Members:* | 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 |
| *Alternates:* | 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.

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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.

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# 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.

**American National Standard** **ANSI/AAMI DF80:2003**

# 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 °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, 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 ± 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 μV 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 $\mu$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 $\Omega$ 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 $\Omega$ 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;

c) while the ENERGY STORAGE DEVICE is maintained at maximum energy until internal energy discharge is automatically performed, or for 1 min;

d) for 1 min, starting 1 s after the commencement of the output pulse into a 50 Ω load (the period of discharge being excluded).

Item e)

*Addition:*

For the DEFIBRILLATOR ELECTRODES the requirements of the General Standard are replaced by the following:

The PATIENT LEAKAGE CURRENT shall be measured with the DEFIBRILLATOR ELECTRODES connected to a 50 Ω load, The measurement shall be made from either DEFIBRILLATOR ELECTRODE to earth, the following parts being connected together and to earth:

a) conductive ACCESSIBLE PARTS;

b) metal foil on which the EQUIPMENT is positioned and which has an area at least equal to that of the base of the EQUIPMENT;

c) any SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS which may be connected to earth in NORMAL USE.

### 19.2 Single fault conditions

Item b) second dash

*Addition:*

For the DEFIBRILLATOR ELECTRODES, this requirement of the General Standard is replaced by the following:

– a voltage equal to 110 % of the highest RATED MAINS VOLTAGE applied between earth and, in turn, the external DEFIBRILLATOR ELECTRODES connected together and any internal DEFIBRILLATOR ELECTRODES connected together, metal foil being wrapped around, and in intimate contact with, the electrode handles and connected to earth and to the parts of 19.1 e) of this Particular Standard.

### * 19.3 Allowable values

*Additional item:*

*aa) For TYPE CF DEFIBRILLATOR APPLIED PARTS, the allowable value of the PATIENT LEAKAGE CURRENT for the SINGLE FAULT CONDITION of MAINS VOLTAGE on the DEFIBRILLATOR ELECTRODES is 0.1 mA.

## * 20 Dielectric strength

This clause of the General Standard applies except as follows:

### 20.2 Requirements for EQUIPMENT with an APPLIED PART

and

### 20.3 Values of test voltages

*Amendment:*

For the DEFIBRILLATOR high-voltage circuit (for example DEFIBRILLATOR ELECTRODES, CHARGING CIRCUIT and switching devices) the following requirements and tests shall apply in addition to those of the General Standard for insulation category B-a and shall replace those of the General Standard for insulation categories B-b, B-c, B-d and B-e.

The insulation of the above circuit shall withstand a DC test voltage of 1.5 times the highest peak voltage *U* occurring between the parts concerned during discharging in any mode of normal operation. The insulation resistance of the above insulation shall not be less than 500 MΩ.

*Compliance shall be checked by the following combined dielectric strength and insulation resistance test:*

*The external DC test voltage is applied:*

*Test 1: With the switching devices of the DISCHARGE CIRCUIT activated between each pair of DEFIBRILLATOR ELECTRODES connected together and all of the following parts connected together:*

*a) conductive ACCESSIBLE PARTS,*

*b) the PROTECTIVE EARTH TERMINAL in the case of CLASS I EQUIPMENT or metal foil on which the EQUIPMENT rests in the case of CLASS II EQUIPMENT or EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE,*

*c) metal foil in intimate contact with non-conductive parts liable to be handled in NORMAL USE, and*

*d) any isolated DISCHARGE CONTROL CIRCUIT and any isolated SIGNAL INPUT or SIGNAL OUTPUT PART.*

*If the CHARGING CIRCUIT is floating and is isolated from the DEFIBRILLATOR ELECTRODES during discharging it shall be connected to them during this test.*

*Any resistors forming the isolating means between the DEFIBRILLATOR and other PATIENT CIRCUITS shall be replaced by a DUMMY COMPONENT.*

*Any other PATIENT CONNECTIONS, their cables and associated connectors shall be disconnected from the equipment during this test.*

*Any switching arrangements used to isolate the high-voltage circuit of the DEFIBRILLATOR from the other PATIENT circuits, other than those activated in NORMAL USE by the connection of their respective cables and PATIENT CONNECTIONS, shall be held in the open-circuit position.*

*Any resistors bridging the insulation under test (e.g., components of a metering circuit) shall be replaced by a DUMMY component during this test provided that their effective value in the test configuration is not less than 5 MΩ. Any components which are known not to withstand the test voltage of 1.5 U, but which have been demonstrated to be safe by the test at the end of this subclause, shall be accepted as meeting the requirements of this subclause.*

NOTE "Pair" here refers to any two DEFIBRILLATOR ELECTRODES used together in NORMAL USE.

*Newer circuit topologies for DEFIBRILLATORS may make it difficult to carry out the test outlined above. Components which are not rated at 1.5 U, or which are known to fail at less than 1.5 U, are acceptable if they pass the following test. The highest peak voltage U is determined by circuit analysis, making allowances for circuit component tolerances. The distribution of breakdown voltages for the component under test is obtained from the supplier, or is determined by testing to breakdown a sample of sufficient size, to yield 90 % confidence that the probability of failure of the component at U is less than 0.0001. In addition, manufacturers shall through fault mode and effect analysis (see IEC 60300-3-9) demonstrate that the implemented circuit topology does not create a SAFETY HAZARD in SINGLE FAULT CONDITION and that the OPERATOR is made aware of such a failure.*

*Test 2: Between the defibrillator electrodes of each pair—external and internal in turn—while:*

*a) the ENERGY STORAGE DEVICE is disconnected,*

*b) THE switching devices of the DISCHARGE CIRCUIT are activated,*

*c) any switching arrangements used to isolate the high-voltage circuit of the DEFIBRILLATOR FROM other PATIENT CIRCUITS are held in the open-circuit position, and*

*d) any COMPONENTS which would provide a conductive pathway between the DEFIBRILLATOR ELECTRODES during this test are disconnected.*

*Newer circuit topologies for DEFIBRILLATORS may make it difficult to carry out the test outlined above. Components which are not rated at 1.5 U, or which are known to fail at less than 1.5 U, are acceptable if they pass the following test. The highest peak voltage U is determined by circuit analysis, making allowances for circuit component tolerances. The distribution of breakdown voltages for the component under test is obtained from the supplier, or is determined by testing to breakdown a sample of sufficient size, to yield 90 % confidence that the probability of failure of the component at U is less than 0.0001. In addition, manufacturers shall, through fault mode and effect analysis (see IEC 60300-3-9), demonstrate that the implemented circuit topology do not create a SAFETY HAZARD in SINGLE FAULT CONDITION and that the OPERATOR is made aware of such a failure.*

*Test 3: Across each switching device in the DISCHARGE CIRCUIT and in the CHARGING CIRCUIT.*

*In the case of switches in the DISCHARGE CIRCUIT intended to operate in series as a single functional group, the following tests shall be performed.*

*a) Place the test voltage across each functional group in the polarity consistent with that of the ENERGY STORAGE DEVICE and verify DC withstand per the provisions of the section.*

*b) Disconnect the ENERGY STORAGE DEVICE and substitute with a test voltage source set per the CALCULATIONS above, with polarity consistent with the ENERGY STORAGE DEVICE.*

*By shorting functional groups, simulate cascade-failures of each series functional switching group in turn. Demonstrate that, under simulated cascade failure conditions, energy discharge to the PATIENT connection does not occur.*

*Test 4: Between the mains part and the DEFIBRILLATOR electrodes connected together while the switching devices of the discharge circuit are activated.*

NOTE It may not be possible to activate the switching means for extended periods of time. In such cases the switching procedure may be simulated for this test.

*This test shall not be performed if the mains part and the applied part containing the DEFIBRILLATOR electrodes are effectively separated by a protectively earthed shield or a protectively earthed intermediate circuit.*

*Where the effectiveness of the separation is in doubt (e.g. the protective shielding is incomplete) the shield shall be disconnected and the dielectric strength test performed.*

*The test voltage is initially set at U and the current is measured. The voltage is raised to 1.5 U in a time of not less than 10 s and then maintained constant for a period of 1 min during which no breakdown or flashover shall occur.*

*The current shall be proportional to the applied test voltage within ± 20 %. Any transient increase in the current due to non-linearity of the increase of the test voltage shall be ignored. The insulation resistance shall be calculated from the maximum voltage and the steady-state current.*

*During the tests specified in the General Standard for insulation category B-a, that portion of the test voltage appearing across any switching device in the charging circuit or in the discharge circuit shall be restricted so as not to exceed a peak value equal to the DC test voltage specified above.*

### 20.4 Tests

*Item a), first dash*

*Amendment:*

*Change "warming up to operating temperature" to read "attaining the steady-state temperature reached by the EQUIPMENT operating in STAND-BY."*

## SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply.

## SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the Collateral Standard IEC 60601-1-2, 2001 apply except as follows:

### *36 Electromagnetic compatibility (EMC)

*Replacement:*

#### 36.201 Emissions

These requirements are waived during a DEFIBRILLATOR charge/discharge cycle.

#### 36.201.1 Protection of radio services

a) Requirements

The DEFIBRILLATOR shall comply with the requirements of CISPR 11, group 1, in all configurations and operating modes. DEFIBRILLATORs are classified as Class B *EQUIPMENT* for determining applicable CISPR 11 requirements. Emission levels measured 10 m from the INSTRUMENT shall not exceed 30 dB µV from 30 MHz to 230 MHz and shall not exceed 37 dB µV from 230 MHz to 1,000 MHz.

*b) Tests:*

*Compliance shall be checked in accordance with CISPR test methods.*

*Replacement:*

### 36.202.2 Electrostatic discharge (ESD)

a) Requirements

For open air discharges up to 4 kV and direct contact discharges up to 2 kV, the OPERATOR shall not notice any change in EQUIPMENT operation. The EQUIPMENT shall operate within normal limits of its specifications. No degradation of system performance or loss of functionality is allowed. However, ECG spikes, pacemaker pulse detection, display glitches, or momentary light-emitting diode (LED) flashes are acceptable during an ESD discharge.

For open air discharges up to 8 kV or direct contact discharges up to 6 kV, the EQUIPMENT may exhibit momentary loss of functionality but shall recover within 2 s without OPERATOR intervention. There shall be no unintended energy delivery, unsafe failure mode, or loss of stored data.

b) *Tests*

*The test methods and INSTRUMENTS specified in IEC 61000-4-2 apply with the following addition:*

*The EQUIPMENT is exposed, at any point on its surface accessible to the OPERATOR or PATIENT, to open air discharges up to 8 kV or direct contact discharges up to 6 kV, both positive and negative.*

### 36.202.3 Radiated RF electromagnetic fields

a) Requirements

The EQUIPMENT is exposed to a modulated RF field with the following characteristics:

- field strength: 10 V/m;
- carrier frequency range: 80 MHz to 2.5 GHz;
- AM modulation, 80 % index, at 5 Hz.

*b) Tests*

*The test methods and INSTRUMENTS specified in IEC 61000-4-3, apply with the following modifications:*

*Compliance shall be checked by the following test:*

*The DEFIBRILLATOR ELECTRODES are terminated in a simulated PATIENT load (1 kΩ resistor in parallel with a 1 µF capacitor). The INSTRUMENT is tested with all its faces sequentially exposed to the RF field. When exposed to a field strength of 10 V/m, no inadvertent discharge or other unintended change of state shall occur. No inadvertent activation of the RRD (false positive) shall be allowed. When exposed to a field strength of 20 V/m, no inadvertent energy delivery is allowed.*

*Certain PATIENT cable configurations may cause failure to meet these immunity requirements. In such a case, the manufacturer shall disclose the reduced immunity levels which are met.*

### 36.202.4 Electrical fast transients and bursts

a) Requirements

Mains connectable INSTRUMENTS shall test using level 3 at the mains plug. Only transient loss of functionality is allowed. No inadvertent energy delivery or other unintentional change of state is allowed. The device shall revert to its condition just prior to the burst without OPERATOR intervention.

*b) Tests*

*The test methods and INSTRUMENTS specified in IEC 61000-4-4 apply.*

### 36.202.5 Surges

a) Requirements

Mains connectable EQUIPMENT shall be tested according to installation Clause 3. Compliance criteria: no inadvertent energy delivery or other unintentional change of state is allowed. The device shall revert to its prior condition without OPERATOR intervention.

*b) Tests*

*The test methods and INSTRUMENTS specified in IEC 61000-4-5 apply.*

### 36.202.6 Conducted disturbances, induced by RF fields

a) Requirements

No inadvertent discharge or other unintentional change of state shall occur during this period. No loss of functionality is allowed.

*b) Tests*

*The test methods and INSTRUMENTS specified in IEC 61000-4-6 apply with the following modifications:*

*When a DEFIBRILLATOR can be operated from line power as well as a battery, an RF voltage with the following characteristics is injected into the input power cord (not in the signal input):*

- *RF voltage amplitude: 3 V r.m.s.;*
- *carrier frequency: 150 kHz to 80 MHz;*
- *AM modulation, 80 % index, at 5 Hz.*

### 36.202.8 Magnetic fields

a) Requirements

No inadvertent discharge or other unintentional change of state shall occur during this test. Some display jitter is allowed, however the displayed information shall be readable and stored data shall not be lost or corrupted.

*b) Test*

*The test methods and INSTRUMENTS specified in IEC 61000-4-8 are applied as follows:*

*The EQUIPMENT is exposed on all axes. The ECG leads and electrodes are short-circuited at the instrument.*

## SECTION SIX– PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

# SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

## * 42 Excessive temperatures

This clause of the General Standard applies except as follows:

**42.3**

Item 3) *DUTY CYCLE*

*Replacement:*

*The EQUIPMENT is operated in STAND-BY until temperature equilibrium is attained. For MANUAL DEFIBRILLATORS, the DEFIBRILLATOR is alternately charged and discharged with its maximum energy 15 times at the rate of three per minute into a resistive load of 50 Ω. For AEDs the number and rate of discharges shall be the maximum specified by the manufacturer for normal operation.*

## 44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection, and compatibility

This clause of the General Standard applies except as follows:

### * 44.6 Ingress of liquids

*Replacement:*

The EQUIPMENT shall be so constructed that, in the event of spillage of liquids (accidental wetting), no SAFETY HAZARD shall result.

*Compliance shall be checked by the following test:*

*One sample of the EQUIPMENT is placed in the least favorable position of NORMAL USE with the DEFIBRILLATOR ELECTRODES in the stored position. The EQUIPMENT is then subjected for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0.5 m above the top of the EQUIPMENT. The EQUIPMENT shall not be energized during the test. PATIENT cables, mains cables etc., shall be placed in the least favorable position during the test.*

*A test apparatus is shown in Figure 3 of IEC 60529.*

*An intercepting device may be used to determine the duration of the test.*

*Immediately after the 30 second exposure, visible moisture on the ENCLOSURE is removed. Immediately after the above test, the DEFIBRILLATOR is alternately charged and discharged with its maximum energy 15 times at the rate of three per minute into a resistive load of 50 Ω. For AEDs, the maximum number of discharges and rate of discharge may be limited to the manufacturer's specifications for normal operation.*

*It shall be verified that any water which may have entered the EQUIPMENT cannot result in a SAFETY HAZARD. In particular the EQUIPMENT shall be capable of meeting the dielectric strength tests A-$a_1$, A-$a_2$. For APPLIED PARTS which are not DEFIBRILLATOR ELECTRODES the EQUIPMENT shall be capable of meeting the dielectric strength tests B-a and B-d specified in 20.1 to 20.3 in the General Standard.*

After the test the DEFIBRILLATOR is disassembled to inspect for water ingress. The EQUIPMENT shall show no signs of wetting of electrical insulation, which is liable to be adversely affected by such liquid. There shall be no sign of water in the high-voltage circuitry.

The EQUIPMENT shall function normally.

*** 44.7 Cleaning, sterilization and disinfection**

*Addition:*

Internal DEFIBRILLATOR ELECTRODES including handles, any incorporated controls or indicators, and associated cables shall be sterilizable. See 6.8.2 aa) 6) for requirements for instructions for use.

## 46 Human errors

This clause of the General Standard applies except as follows:

*Replacement:*

## 46 Human errors

***46.101 ELECTRODE energizing controls**

a) The EQUIPMENT shall be so designed as to prevent the external and internal DEFIBRILLATOR ELECTRODES being energized simultaneously.

*Compliance shall be checked by inspection and functional test.*

b) The means for triggering the DEFIBRILLATOR DISCHARGE CIRCUIT shall be so designed as to minimize the possibility of inadvertent operation.

Acceptable arrangements are:

1) for anterior-anterior DEFIBRILLATOR ELECTRODES, two momentary switches, one located on each DEFIBRILLATOR ELECTRODE handle;
2) for anterior-posterior DEFIBRILLATOR ELECTRODES, a single momentary switch located on the anterior electrode handle;
3) for internal DEFIBRILLATOR ELECTRODES, a single momentary switch located on one of the electrode handles or one or two single momentary switches on the panel only;
4) for external self-adhesive DEFIBRILLATOR ELECTRODES, one or two single momentary switches located on the panel only.

Foot-operated switches shall not be used to trigger the defibrillation pulse.

Compliance shall be checked by inspection and functional test.

**46.102 Display of signals**

The DEFIBRILLATOR shall not display signals from more than one input simultaneously unless the origin of the signals is labeled unambiguously.

*Compliance shall be checked by inspection.*

*** 46.103 Audible warnings prior to energy delivery**

Audible warnings to the OPERATOR shall be provided prior to energy delivery by the DEFIBRILLATOR. As a minimum requirement, voice or audible tones shall be provided at the following times (warnings may be continuous or intermittent):

a) for AEDs, when the RHYTHM RECOGNITION DETECTOR has reached a determination that a shockable rhythm is detected;

b) in the case of DEFIBRILLATORS with OPERATOR activated discharge control, when the device is ready to be discharged by the OPERATOR.

c) in the case of AEDs with automatic discharge control, at least 5 s prior to energy delivery.

## SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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

### *50 Accuracy of operating data

This clause of the General Standard applies except as follows:

#### *50.1 Marking of controls and INSTRUMENTS

*Replacement:*

If the DEFIBRILLATOR is provided with means for the selection, continuously or in steps, of the SELECTED ENERGY then an indication of the SELECTED ENERGY in joules shall be incorporated, expressed as the nominal DELIVERED ENERGY in joules to a resistive load of 50 Ω.

Alternatively, the DEFIBRILLATOR may deliver a single preset energy, or a sequence of energies according to a preset protocol described in the instructions for use. If the DEFIBRILLATOR is designed to supply a single energy, or a programmed sequence of energies, no means for energy selection is required.

*Compliance shall be checked by inspection*

#### * 50.2 Accuracy of controls and INSTRUMENTS

*Replacement:*

The rated DELIVERED ENERGY (according to EQUIPMENT SETTINGS) into loads of 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω, and 175 Ω shall be specified. The measured DELIVERED ENERGY into these load resistances shall not vary from the DELIVERED ENERGY for that impedance by more than ± 3 J or ± 15 %, whichever is greater, at any energy level.

*Compliance shall be checked by measurement of DELIVERED ENERGY in load resistances of 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω, and 175 Ω at energy levels as above or by measurement of the internal resistance of the DEFIBRILLATOR output circuit and hence calculation of the DELIVERED ENERGY.*

### 51 Protection against hazardous output

This clause of the General Standard applies except as follows:

#### * 51.1 Intentional exceeding of safety limits

*Addition:*

Output control range

a) The SELECTED ENERGY shall not exceed 360 J.

b) For internal DEFIBRILLATOR ELECTRODES the SELECTED ENERGY shall not exceed 50 J.

*Compliance shall be checked by inspection and functional test.*

*Addition:*

***51.101** The output voltage of the DEFIBRILLATOR across a 175 Ω load resistance shall not exceed 5 kV.

*Compliance shall be checked by measurement.*

*** 51.102** The *EQUIPMENT* shall be so designed that in the event of a power failure (either of the supply mains or of the internal electrical power source) or when the *EQUIPMENT* is switched off, no unintentional energy shall be available at the DEFIBRILLATOR electrodes.

*Compliance shall be checked by functional test.*

*** 51.103** A DEFIBRILLATOR shall be provided with an internal discharge circuit whereby STORED ENERGY that for some reason is not to be delivered through the DEFIBRILLATOR electrodes can be dissipated without energizing the DEFIBRILLATOR electrodes.

This INTERNAL DISCHARGE CIRCUIT may be combined with that required by 51.102.

*Compliance shall be checked by functional test.*

## SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

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

### 52 Abnormal operation and fault conditions

*Addition:*

***52.4.101** Inadvertent charging or discharging of the energy storage device.

## SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

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

### * 56 Components and general assembly

This clause of the General Standard applies except as follows:

*Addition:*

*** 56.101 DEFIBRILLATOR electrodes and their cables**

a) Any DEFIBRILLATOR ELECTRODE handles shall have no conductive ACCESSIBLE PARTS.

This requirement does not apply to small metal parts such as screws in or through insulating material which cannot become live under single fault conditions.

*Compliance shall be checked by inspection and the dielectric strength test (see Test 1, 20.2).*

*b) DEFIBRILLATOR ELECTRODE cables and their anchorages shall be capable of satisfactorily passing the following tests. Additionally the anchorages for reusable DEFIBRILLATOR ELECTRODES shall comply with the requirements for POWER SUPPLY CORDS as described in dashes 1 – 4 of item a) of 57.4 of the General Standard. For single use cables or cable/electrode assemblies the number of cycles of flexing in Test 2 shall be divided by 100. Each cable to EQUIPMENT/DEFIBRILLATOR ELECTRODE and each cable to EQUIPMENT/DEFIBRILLATOR ELECTRODE connector, where relevant, in turn shall be subjected to the tests as for DEFIBRILLATOR ELECTRODES, unless two or more connectors have identical construction, in which case only one of these shall be tested. Where a connector is fitted with two or more cables these shall be tested together, the total tension on the connector being the sum of the tensions appropriate to each cable individually. (See Annex AA and Figure 108 for guidance on identification of anchorages that require testing).

*Compliance shall be checked by inspection and by the following tests:*

*Test 1: For rewirable cable, the conductors are introduced in the terminals in the DEFIBRILLATOR ELECTRODES, any terminal screws being tightened just sufficiently to prevent easy displacement of the conductors. The cord anchorage is then tightened in the normal way. For all cables, to measure the longitudinal displacement a mark is made on the cable at a distance of approximately 2 cm from the cord anchorage.*

*Immediately afterwards the cable shall be subjected to a pull of 30 N, or the maximum force that can be applied to the anchorage before the connector becomes disconnected, or the electrode is pulled off the PATIENT, where applicable, for 1 min, whichever is the least. At the end of this period the cable shall not have been displaced longitudinally by more than 2 mm. For rewirable cables the conductors shall not have moved by more than 1 mm in the terminals nor shall there be appreciable strain on the conductors while the pull is still being applied. For non-rewirable cables not more than 10 % of the total number of conductor strands in each wire of the cable may have been broken.*

*Test 2: One DEFIBRILLATOR ELECTRODE is fixed in an apparatus similar to that shown in Figure 102, so that when the oscillating member of the apparatus is at the middle of its travel, the axis of the cable, where it leaves the electrode or electrode handle, is vertical and passes through the axis of oscillation. Tension is applied to the cable as follows:*

*i) for extensible cables a tension equal to that necessary to extend the cable to three times its natural (unextended) length, or to the weight of one DEFIBRILLATOR ELECTRODE, whichever is the greater, is applied and the cable is clamped at a distance of 300 mm from the axis of oscillation;*

*ii) for non-extensible cables, the cable is passed through an aperture 300 mm from the axis of oscillation and a weight equal to the weight of one DEFIBRILLATOR ELECTRODE, or 5 N, whichever is the greater, is fixed to the cable below this aperture.*

*The oscillating member is rotated through an angle of*

*– 180° (90° on each side of the vertical) for internal electrodes;*

*– 90° (45° on each side of the vertical) for external electrodes.*

*The number of cycles shall be 10,000 at the rate of 30 cycles per minute. After 5,000 cycles the DEFIBRILLATOR ELECTRODE is turned through 90° about the center line of the cable entry point and the remaining 5,000 cycles are completed in this plane.*

*After the test, the cable shall not have worked loose and neither the cord anchorage nor the cable shall show any damage, except that not more than 10 % of the total number of conductor strands in each wire of the cable may have been broken.*

*c) Minimum DEFIBRILLATOR ELECTRODE area*

*The minimum area of each of the DEFIBRILLATOR ELECTRODES shall be:*

- *50 $cm^2$ for adult external use;*
- *32 $cm^2$ for adult internal use;*
- *15 $cm^2$ for pediatric external use;*
- *9 $cm^2$ for pediatric internal use.*

## 57 MAINS PARTS, components, and layout

This clause of the General Standard applies except as follows:

### 57.10 CREEPAGE DISTANCES and AIR CLEARANCES

*Additional items:*

*aa) Between the LIVE parts of a DEFIBRILLATOR ELECTRODE and parts of any associated handle and any switches or controls likely to be touched in NORMAL USE there shall be a CREEPAGE DISTANCE of at least 50 mm and an AIR CLEARANCE of at least 25 mm.

*bb) Except for components where the adequacy of ratings can be demonstrated (e.g., by component manufacturers' ratings or by the dielectric strength tests of Clause 20) the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the high-voltage circuit and other parts, and between different parts of the high-voltage circuit, shall be at least 3 mm/kV.

This requirement shall also apply to the isolating means between the high-voltage circuit of the DEFIBRILLATOR and other PATIENT CIRCUITS.

*Compliance shall be checked by measurement.*

*cc) Non-reusable DEFIBRILLATOR ELECTRODES are not required to comply with the creepage and clearance requirements of bb) above and are not required to comply with the dielectric strength requirements of 20.

*dd) The cable connecting the DEFIBRILLATOR to the DEFIBRILLATOR ELECTRODES shall have double insulation (two separately molded insulation layers). For a non-reusable cable included as part of non-reusable DEFIBRILLATOR ELECTRODES, where the non-reusable cable has a length of less than 2 m, there is no requirement of double isolation. The insulation resistance of the cable shall not be less than 500 MΩ. The dielectric strength of the cable shall be tested using a voltage of 1.5 times the highest voltage occurring between the DEFIBRILLATOR ELECTRODES in any normal mode of operation, as described below:

A length of 100 mm of the outside of the cable is wrapped with conductive foil. The test voltage is applied between the high voltage conductor and the outside conductive wrapping. The voltage is raised to 1.5 U in a time of not less than 10 s and then maintained constant for a period of 1 min during which no breakdown or flashover shall occur. The leakage current between the high voltage conductor and the wrapping shall demonstrate an insulation resistance of more than 500 MΩ.

# SECTION 101 – ADDITIONAL REQUIREMENTS RELATING TO SAFETY

## * 101 Charging time

### * 101.1 Requirements for frequent use, manual defibrillators

a) The time for charging a completely discharged ENERGY STORAGE DEVICE to maximum energy shall not exceed 15 s under the following conditions:

- when the DEFIBRILLATOR is operated on 90 % of the rated mains voltage;
- with batteries depleted by the delivery of 15 discharges at maximum energy.

b) The time from initially switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 25 s. This requirement shall apply to charging a completely discharged ENERGY STORAGE DEVICE to maximum energy under the following conditions:

- when the DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE,
- with batteries depleted by the delivery of 15 discharges at maximum energy.

Compliance with 101.1 a) and b) shall be checked by measurement. In the case of INTERNALLY POWERED EQUIPMENT, the test shall start with a new and fully charged battery. In the case of such EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is checked when the EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 6.1 bb).

In case of a DEFIBRILLATOR with non-rechargeable batteries, the test shall start with a battery depleted by the delivery of the number of charge/discharge cycles specified by the manufacturer, or when the EQUIPMENT indicates that the battery needs replacement, whichever comes first.

***101.2 Requirements for infrequent use, manual defibrillators**

a) The following charge time requirements apply.

- When the DEFIBRILLATOR is operated on 90 % of the rated mains voltage, the time for charging a completely discharged energy storage device to maximum energy shall not exceed 20 s.
- With batteries depleted by the delivery of 6 discharges at maximum energy, the time for charging a completely discharged ENERGY STORAGE DEVICE to maximum energy shall not exceed 20 s.
- With batteries depleted by the delivery of 15 discharges at maximum energy, the time for charging a completely discharged ENERGY STORAGE DEVICE to maximum energy shall not exceed 25 s.

b) For the time from initially switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy the following applies.

- When the DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE, the time from switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 30 s.
- With batteries depleted by the delivery of 6 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 30 s.
- With batteries depleted by the delivery of 15 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 35 s

*Compliance with 101.2 a) and b) shall be checked by measurement. In the case of INTERNALLY POWERED EQUIPMENT, the test shall start with a new and fully charged battery. In the case of such EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is also checked when the EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 6.1 bb).*

*In case of a DEFIBRILLATOR with non-rechargeable batteries, the test shall start with a battery depleted by the delivery of the number of charge/discharge cycles specified by the manufacturer, or when the EQUIPMENT indicates that the battery needs replacement, whichever comes first.*

***101.3 Requirements for frequent use, automated external defibrillators**

a) The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to the DEFIBRILLATOR being ready for discharge at maximum energy, shall not exceed 30 s under the following conditions:

- when the AED is operated on 90 % of the RATED MAINS VOLTAGE;
- with batteries depleted by the delivery of 15 discharges at maximum energy.

*b) The time from initially switching power on, or from within any OPERATOR programming mode, to the DEFIBRILLATOR being ready at maximum energy shall not exceed 40 s. This requirement shall apply to charging a completely discharged ENERGY STORAGE DEVICE to maximum energy under the following conditions:

- when the AED is operated on 90 % of the RATED MAINS VOLTAGE;
- with batteries depleted by the delivery of 15 discharges at maximum energy.

***101.4 Requirements for infrequent use, automated external defibrillators**

a) The following charge time requirements for INFREQUENT USE AUTOMATED EXTERNAL DEFIBRILLATORS apply.

- The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to ready for discharge at maximum energy, shall not exceed 35 s when the AED is operated on 90 % of the RATED MAINS VOLTAGE
- The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to ready for discharge at maximum energy, shall not exceed 35 s with batteries depleted by the delivery of 6 discharges at maximum energy
- The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to ready for discharge at maximum energy, shall not exceed 40 s with batteries depleted by the delivery of 15 discharges at maximum energy

b) For the time from initially switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy the following applies.

- When the AED is operated on 90 % of the RATED MAINS VOLTAGE, the time from switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 45 s.
- With batteries depleted by the delivery of 6 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 45 s.
- With batteries depleted by the delivery of 15 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to charge ready at maximum energy shall not exceed 50 s.

*Compliance with 101.3 a) and b) and 101.4 a) and b) shall be checked by the following test:*

*A shockable simulated PATIENT rhythm signal as defined by the manufacturer, is applied to the SEPARATE MONITORING ELECTRODES or the DEFIBRILLATOR ELECTRODES. The visual or audible instructions given by the DEFIBRILLATOR are followed. The charge time is measured from RRD activation (for 101.3 a) and 101.4 a)) or initial power on (for 101.3 b) and 101.4 b)) to ready for discharge.*

*In the case of INTERNALLY POWERED EQUIPMENT, the test shall start with a new and fully charged battery. In the case of such EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is checked when the EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 6.1 bb).*

*In case of a DEFIBRILLATOR with non-rechargeable batteries, the test shall start with a battery depleted by the delivery of the number of charge/discharge cycles specified by the manufacturer, or when the EQUIPMENT indicates that the battery needs replacement, whichever comes first.*

*For EQUIPMENT with a pre-programmed energy setting sequence, not changeable by the OPERATOR or USER, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the pre-programmed energy setting sequence. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or USER, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the worst case energy setting sequence selectable.*

## 102 Internal electrical power source

### 102.1 General

The requirements of this clause apply whether or not the EQUIPMENT can also be operated from a supply mains.

### *102.2 Requirements for MANUAL DEFIBRILLATORS

The capacity of a new and fully charged battery shall be such that at 0 °C the EQUIPMENT can provide at least 20 defibrillation discharges having each the maximum DELIVERED ENERGY of the EQUIPMENT, performed in cycles, each of which comprising three discharges in 1 min and 1 min rest. For INFREQUENT USE MANUAL DEFIBRILLATORs, each cycle shall consist of three discharges in 90 s with 1 min rest.

Where EQUIPMENT contains the possibility to insert more than one battery which can be selected randomly by the OPERATOR, the requirement of 20 discharges is the total amount of discharges available when the DEFIBRILLATOR is equipped with the maximum amount of batteries.

If the standby battery is not actually mounted in the DEFIBRILLATOR, the standby battery shall not be included in the test.

*Compliance shall be checked by a functional test at 0 °C ± 2 °C, the EQUIPMENT having first been prepared as follows:*

a) *The battery shall be fully charged in accordance with the manufacturer's instructions (or until the EQUIPMENT indicates that the battery is fully charged) at an ambient temperature of 20 °C ± 2 °C, or according to environmental operating conditions as specified by the manufacturer according to 10.2, whichever constitutes the most severe conditions.*

b) *The EQUIPMENT including the battery is cooled to 0 °C ± 2 °C until it reaches thermal equilibrium.*

### *102.3 Requirements for automated external defibrillators

**102.3.1** For a FREQUENT USE AED, the capacity of a new and fully charged battery shall be such that at 0 °C the EQUIPMENT can provide at least 20 defibrillation discharges at the maximum DELIVERED ENERGY of the AED performed in cycles, each comprising three discharges in 105 s and 1 min rest.

Where a FREQUENT USE AED contains the possibility to insert more than one battery at the same time which can be selected randomly by the OPERATOR, the requirement of 20 discharges is the total amount of discharges available when the DEFIBRILLATOR is equipped with the maximum amount of batteries.

If the standby battery is not actually mounted in the DEFIBRILLATOR the standby battery shall not be included in the test.

For an AED with a pre-programmed energy setting sequence, not changeable by the OPERATOR or USER, the AED shall be able to deliver 20 defibrillation discharges at the pre-programmed setting. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or USER the AED shall be able to deliver 20 defibrillation discharges at the maximum energy setting sequence selectable.

**102.3.2** For an INFREQUENT USE AED, a new and fully charged battery shall be capable of providing at least 20 maximum energy discharges at the maximum DELIVERED ENERGY of the EQUIPMENT performed in cycles, each comprising three discharges in 135 s and 1 min rest.

For an INFREQUENT USE AED with a pre-programmed energy setting sequence, not changeable by the OPERATOR or USER, the AED shall be able to deliver 20 defibrillation discharges at the pre-programmed setting. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or USER the AED shall be able to deliver 20 defibrillation discharges at the maximum energy setting sequence selectable.

*Compliance with 102.3.1 and 102.3.2 shall be checked by a functional test at 0 °C ± 2 °C, the EQUIPMENT having first been prepared as follows:*

*a) The battery shall be fully charged in accordance with manufacturer's instructions (or until the EQUIPMENT indicates that the battery is fully charged) at an ambient temperature of 0 °C ± 2 °C , 20 °C ± 2 °C, and 40 °C ± 2 °C, or according to environmental operating conditions as specified by the manufacturer according to 10.2, whichever are the most severe conditions.*

*b) The EQUIPMENT including the battery is cooled to 0 °C ± 2 °C until it reaches thermal equilibrium.*

*A shockable cardiac rhythm signal is applied to the SEPARATE MONITORING ELECTRODES or the DEFIBRILLATOR ELECTRODES. The visual or audible instructions given by the DEFIBRILLATOR are followed ensuring that DEFIBRILLATOR discharges is performed in cycles as specified above.*

*Where EQUIPMENT contains the possibility to insert more than one battery at the same time which can be selected randomly by the OPERATOR, the requirement of 20 discharges is the total amount of discharges available when the DEFIBRILLATOR is equipped with the maximum amount of batteries.*

*If the standby battery is not actually mounted in the DEFIBRILLATOR the standby battery shall not be included in the test.*

***102.4** Means shall be provided to indicate clearly when non-rechargeable batteries require replacement or rechargeable batteries require recharging. These means shall not make the EQUIPMENT inoperative, and the EQUIPMENT shall be capable of delivering three maximum energy discharges once the indication is given.

For EQUIPMENT with a pre-programmed energy setting sequence, not changeable by the OPERATOR or USER, the AED shall be able to deliver 3 defibrillation discharges at the pre-programmed settings once the indication is given. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or USER the AED shall be able to deliver 3 defibrillation discharges at the maximum energy setting sequence selectable.

*Compliance shall be checked by inspection and functional test at 20 °C ± 2 °C.*

**102.5** Means shall be provided to indicate clearly when any rechargeable battery is being charged.

*Compliance shall be checked by inspection and functional test.*

***102.6** Any rechargeable new battery shall enable the EQUIPMENT to pass the following test:

*a) Test requirements for MANUAL DEFIBRILLATOR*

*After fully charging the battery, the EQUIPMENT is stored while switched off for 168 h (7 days) at a temperature of 20 °C ± 5 °C and at a relative humidity of 65 % ± 10 %. The EQUIPMENT is then charged and discharged with the maximum DELIVERED ENERGY of the EQUIPMENT, 14 times into a 50 Ω load at the rate of one charge-discharge per minute. The charging time for the 15th charge shall not exceed 15 s (25 s for INFREQUENT USE MANUAL DEFIBRILLATOR).*

*If the DEFIBRILLATOR contains the possibility to perform a wake-up self-test that is automatically started with pre-selectable intervals when the DEFIBRILLATOR is powered off, the test shall be performed with the wake-up self-test enabled with the shortest possible interval.*

*b) Test requirements for automated external defibrillators*

*After fully charging the battery, the EQUIPMENT is stored while switched off for 168 h (7 days) at a temperature of 20 °C ± 5 °C and at a relative humidity of 65 % ± 10 %. The EQUIPMENT is then charged and discharged, with the maximum DELIVERED ENERGY of the EQUIPMENT, 14 times into a 50 Ω load at the rate of one charge-discharge per minute. The time measured from application of the shockable cardiac rhythm to the DEFIBRILLATOR is ready for discharge number 15 shall not exceed*

– *30 s for FREQUENT USE AEDS;*

– *40 s for INFREQUENT USE AEDS*

*For EQUIPMENT with a pre-programmed energy setting sequence, not changeable by the OPERATOR or USER, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the pre-programmed energy setting sequence. In a case of the pre-programmed energy setting sequence being changeable by the OPERATOR or USER, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the maximum energy setting sequence selectable.*

*If the DEFIBRILLATOR contains the possibility to perform a wake-up self-test that is automatically started with pre-selectable intervals when the DEFIBRILLATOR is powered off, the test shall be performed with the wake-up self-test enabled with the shortest possible interval.*

### *103 Endurance

The EQUIPMENT shall be capable of meeting the following endurance test which shall be carried out after the test for excessive temperatures as specified in Clause 42 of this Standard:

a) *A FREQUENT USE DEFIBRILLATOR shall be charged and discharged 2 500 times into a 50 Ω load at maximum energy or according to a programmed energy protocol. DEFIBRILLATORS intended for INFREQUENT USE shall be charged and discharged 100 times into a 50 Ω load at maximum energy or according to a programmed energy protocol. During this test forced cooling of the EQUIPMENT and the load is permitted. The accelerated test procedure shall not be allowed to produce temperatures in excess of those obtained in the test of Clause 42. INTERNALLY POWERED EQUIPMENT may be supplied from an external power source during this test.*

b) *The DEFIBRILLATOR is charged and discharged ten times at maximum energy or according to an internal protocol, with the DEFIBRILLATOR ELECTRODES short-circuited. The intervals between consecutive discharges shall not exceed 3 min.*

   *Where short-circuited discharge is not possible, this test does not apply.*

c) *The DEFIBRILLATOR is then charged and discharged five times at maximum energy with the DEFIBRILLATOR ELECTRODES open-circuited, but with one electrode and any conductive ENCLOSURE connected to earth. The test is then repeated with the other electrode and this ENCLOSURE connected to earth. In the case of a non-conductive ENCLOSURE each electrode in turn is connected to earthed metal on which the EQUIPMENT is positioned as in NORMAL USE. The earthed metal shall have an area at least equal to that of the base of the EQUIPMENT.*

   *The intervals between consecutive discharges shall not exceed 3 min.*

   *Where open-circuited discharge is not possible, this test does not apply.*

d) *For FREQUENT USE DEFIBRILLATORS, each INTERNAL DISCHARGE CIRCUIT is tested 500 times at the maximum STORED ENERGY. The INTERNAL DISCHARGE CIRCUIT used in INFREQUENT USE DEFIBRILLATORS shall be tested 20 times at the maximum STORED ENERGY. During this test forced cooling of the EQUIPMENT and the load is permitted. The accelerated test procedure shall not be allowed to produce temperatures in excess of those obtained in the test of Clause 42. INTERNALLY POWERED EQUIPMENT may be supplied from an external power source during this test.*

   *After completion of these tests, the EQUIPMENT shall comply with all other requirements of this Standard.*

### *104 SYNCHRONIZER

Where a SYNCHRONIZER is provided, the following requirements shall be met:

a) There shall be a clear indication by a visible and optionally audible signal when the DEFIBRILLATOR is in the synchronized mode.

b) A defibrillation pulse shall occur only if a synchronization pulse occurs while the discharge control(s) is/are operated.

c) The maximum time delay from the peak of the QRS or the onset of an external triggering pulse to the peak of the DEFIBRILLATOR output waveform shall be:

   1) 60 ms where the ECG is derived via an APPLIED PART or a SIGNAL INPUT PART of the DEFIBRILLATOR, or

   2) 25 ms where the synchronizing triggering signal (not being an ECG) is derived via a SIGNAL INPUT PART.

d) The DEFIBRILLATOR shall not default to synchronization mode on power up or on selection of defibrillation mode from any other mode.

## *105 Recovery of the MONITOR/ECG INPUT after defibrillation

### 105.1 ECG signal derived via DEFIBRILLATOR ELECTRODES

When the DEFIBRILLATOR is tested as described below, after a maximum period of 10 s following the DEFIBRILLATOR pulse the test signal shall be visible on the MONITOR display (if applicable) and the peak-to-valley amplitude of the displayed signal shall not deviate from the original amplitude by more than 50 %.

In addition to the above requirement, the RHYTHM RECOGNITION DETECTOR, if present, shall be able to detect a shockable rhythm 20 s after the defibrillation pulse. In this case, the signal applied to the DEFIBRILLATOR ELECTRODES shall be a signal recognizable by the DEFIBRILLATOR as shockable.

*Compliance shall be checked by a test using the following apparatus, as shown in Figure 103. Self-adhesive electrodes are attached to the metal plates. Paddle surfaces, with conductive gel as supplied by the manufacturer if relevant, are pressed onto the metal plates with an appropriate force.*

*Any USER selectable sensitivity control is set so that the MONITOR sensitivity is adjusted to 10 mm/mV. Any control affecting the MONITOR frequency response is set to the widest frequency response.*

*With $S_1$ closed, the signal generator output is adjusted to give a displayed signal of 10 mm peak-to-valley on the MONITOR display (if applicable). For a DEFIBRILLATOR with a RHYTHM RECOGNITION DETECTOR, the amplitude of the applied shockable rhythm signal shall be adjusted to enable the DEFIBRILLATOR to detect a shockable rhythm.*

*With $S_1$ opened, a maximum energy pulse is delivered into the apparatus. $S_1$ is immediately closed and the MONITOR display is observed. The period of 10 s specified above is measured from this closure of $S_1$. In addition the ECG RHYTHM RECOGNITION DETECTOR, if relevant, shall have detected a shockable rhythm within 20 s after closure of $S_1$.*

### 105.2 ECG signal derived via any SEPARATE MONITORING ELECTRODES

The test of 105.1 is performed with the SEPARATE MONITORING ELECTRODES attached to the metal plate using electrodes specified by the manufacturers. The same compliance criteria apply.

### 105.3 ECG signal derived via non-reusable DEFIBRILLATOR ELECTRODES

When the DEFIBRILLATOR is tested as described below, after a maximum period of 10 s following the defibrillation pulses the ECG shall be visible on the MONITOR display and the peak-to-peak amplitude of the displayed signal shall not deviate from the original amplitude by more than 50 %. For a DEFIBRILLATOR not incorporating a MONITOR, but where the ECG input is used for the ECG RHYTHM RECOGNITION DETECTOR, the ECG shall be correctly interpreted by the ECG RHYTHM RECOGNITION DETECTOR 20 s following the defibrillation pulse.

*Compliance shall be checked by the test described below:*

*A pair of non-reusable DEFIBRILLATOR ELECTRODES of the type(s) recommended by the manufacturer are connected back-to-back (conductive surface against conductive surface). The ELECTRODES are connected to the DEFIBRILLATOR in series with an ENERGY METER/ DEFIBRILLATOR TESTER incorporating an ECG simulator. The ECG simulator is set to Ventricular Fibrillation. Ten energy pulses are delivered at the highest energy output of the device, or according to a fixed protocol if such is incorporated in the device. The energy pulses are delivered at the highest rate obtainable with the device.*

### *106 Disturbance to the MONITOR from charging or internal discharging

NOTE This clause does not apply to DEFIBRILLATORS which do not incorporate a MONITOR.

During charging or internal discharging of the ENERGY STORAGE DEVICE, with the MONITOR display sensitivity set to 10 mm/mV ± 20 %:

a) any interference visible on the MONITOR display shall not exceed 0.2 mV peak-to-valley, and

b) the displayed amplitude of a 10 Hz sine wave input of 1 mV peak-to-valley shall not change by more than 20 %.

Any disturbances having a total duration of less than 1 s shall be ignored. A baseline shift shall be ignored provided that the entire signal remains visible on the display.

The above requirement shall be met with the MONITOR input derived as shown in Figure 105:

a) from any SEPARATE MONITORING ELECTRODES;

b) from the DEFIBRILLATOR ELECTRODES, any SEPARATE MONITORING ELECTRODES being disconnected;

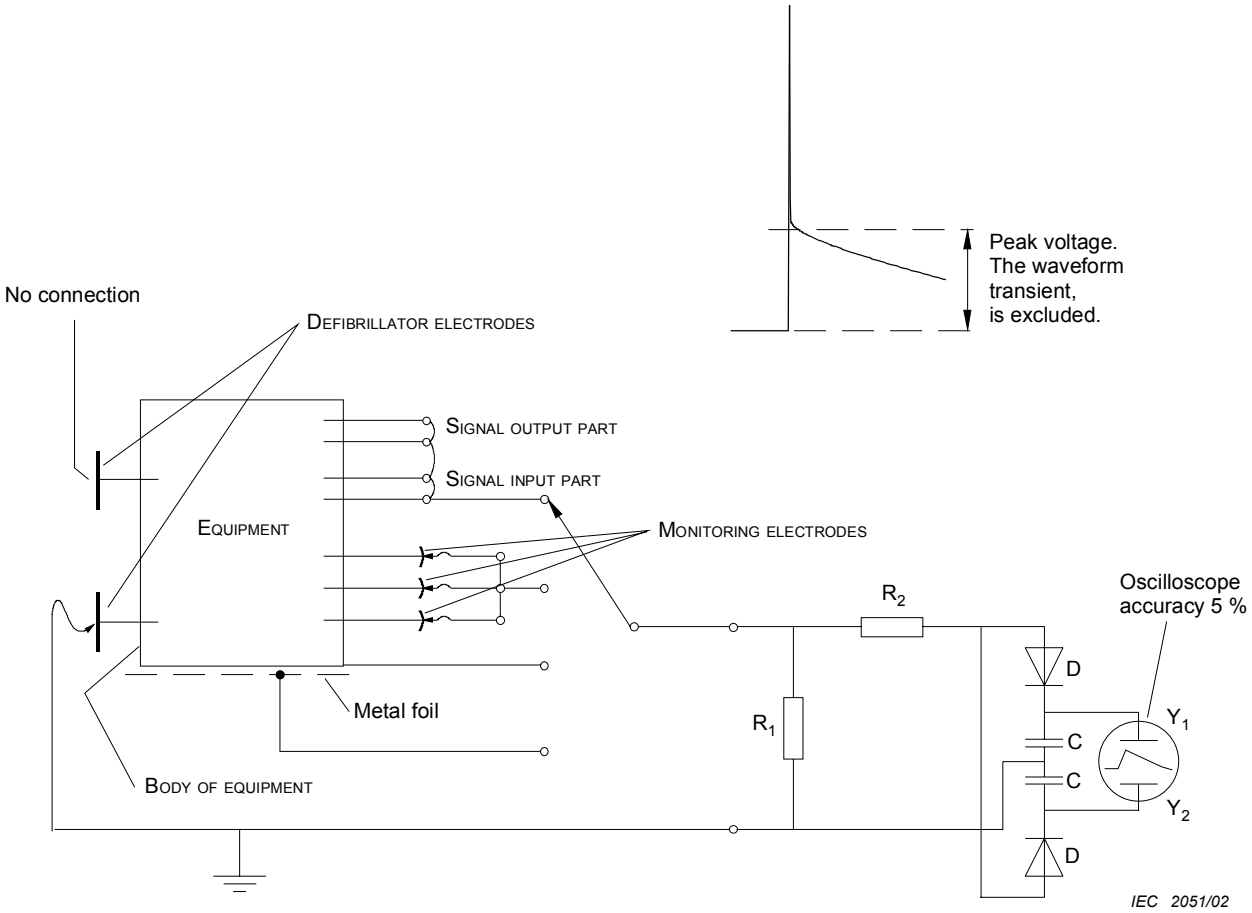
c) from the DEFIBRILLATOR ELECTRODES, the SEPARATE MONITORING ELECTRODES being connected to the EQUIPMENT, if applicable.

*Compliance shall be checked by measurement.*

"Additional U.S. requirements, figures, and annexes" begin after Annex BB.

### 107 Defibrillator electrodes (U.S.) – See page 50

### 108 External pacing (U.S.) – See page 52




$R_1$ = 1 kΩ ± 2 % (≥ 2 kV)
$R_2$ = 100 kΩ ± 2 % (≥ 2 kV)
C = 1 μF ± 5 %
D : Small signal silicon diodes

**Figure 101—Dynamic test for limitation of energy from different parts of the EQUIPMENT (see item aa) of Clause 17)**

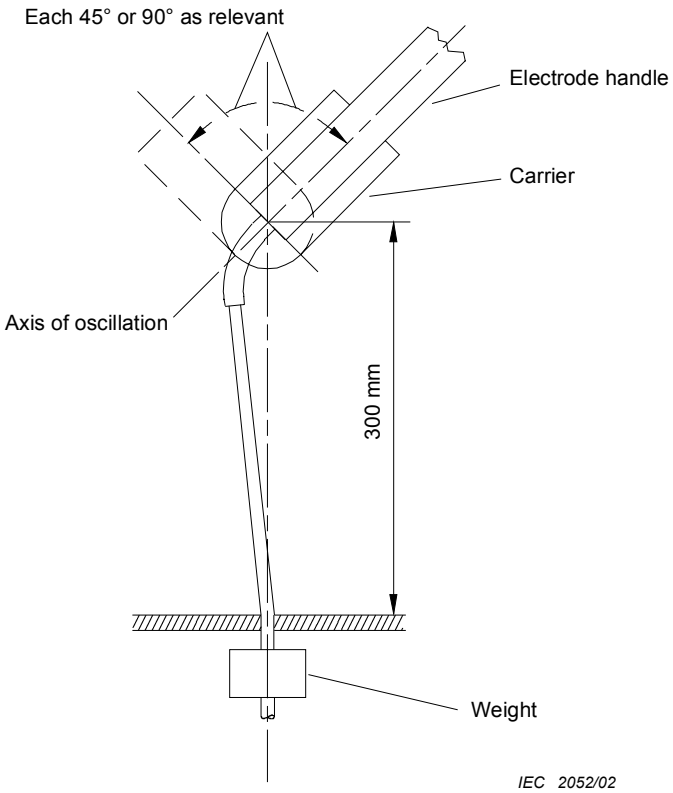



**Figure 102—Test apparatus for flexible cords and their anchorages (see Test 2 of item b) of 56.101)**

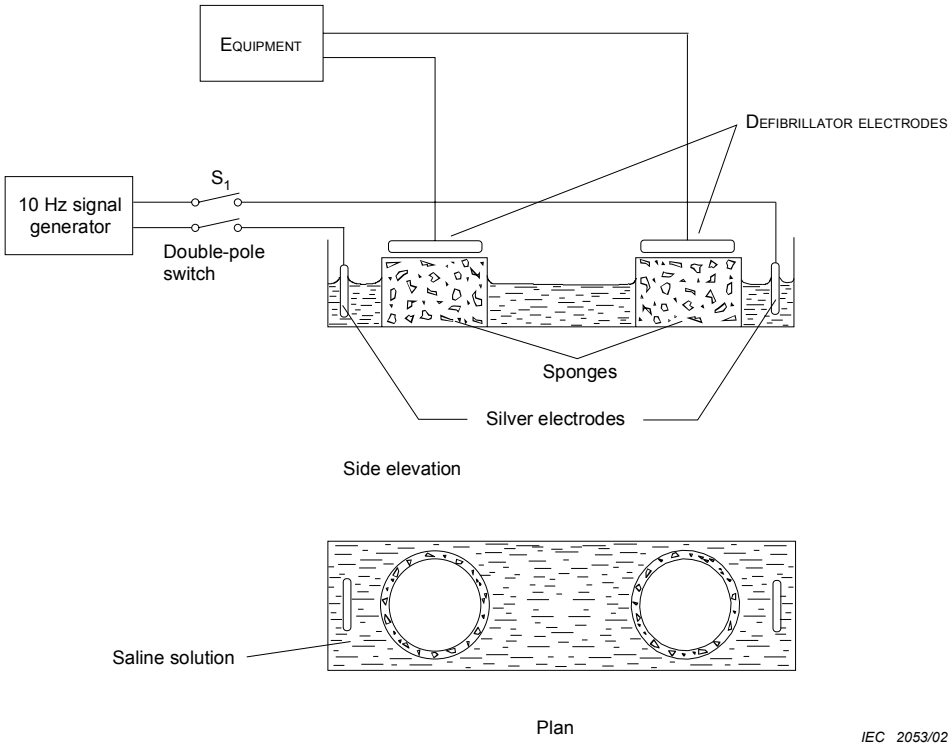



**Figure 103—Arrangement for test of recovery after defibrillation (see 105.1)**

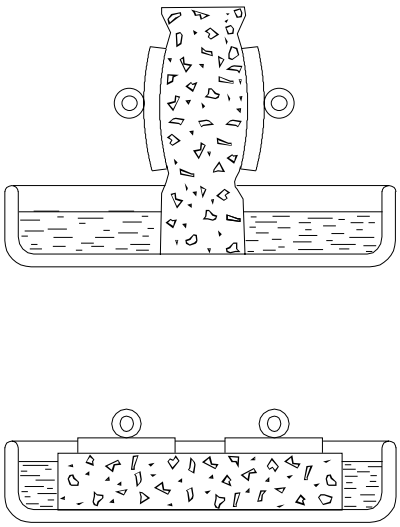


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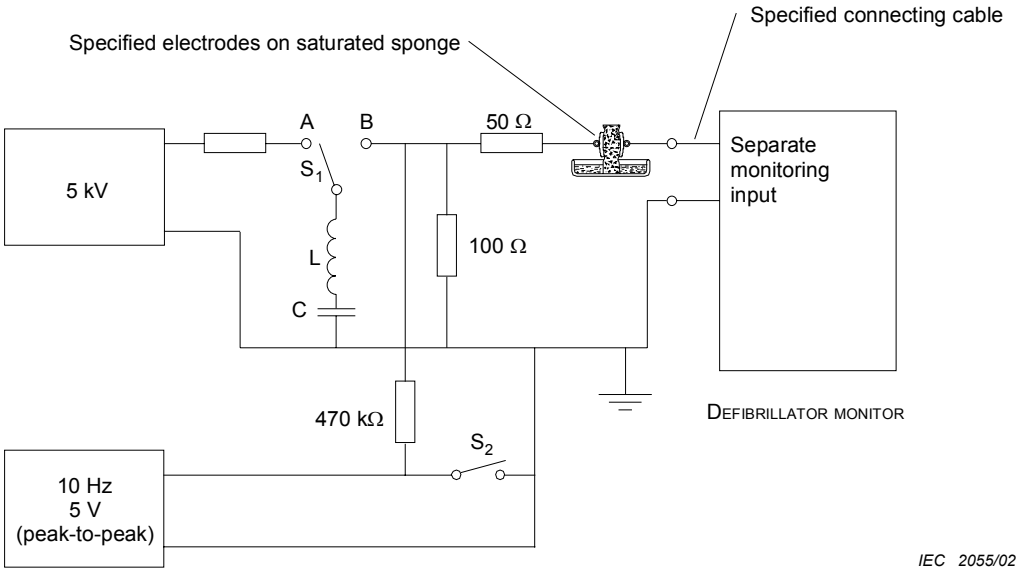
**Figure 104—Arrangement of monitoring electrodes on sponge (see 105.2)**




L = 500 μH
$R_L \leq 10\ \Omega$
C = 32 μF

**Figure 105—Arrangement for recovery test after defibrillation (see 105.2)**

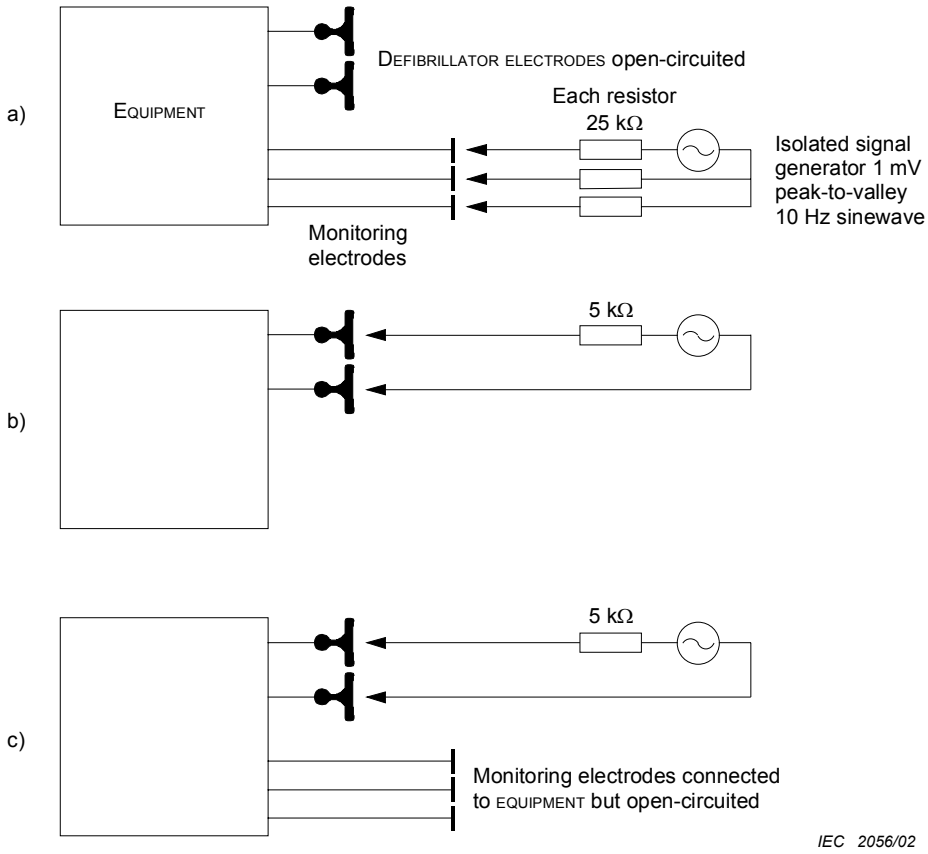



**Figure 106—Arrangement for test of disturbance from charging and internal discharging (see Clause 106)**

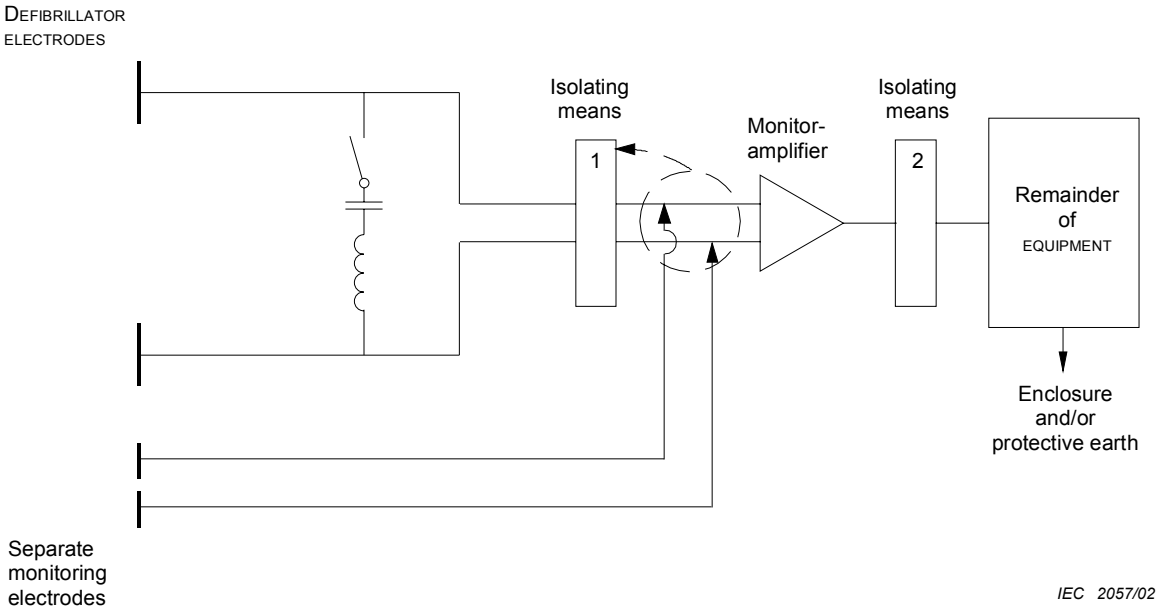
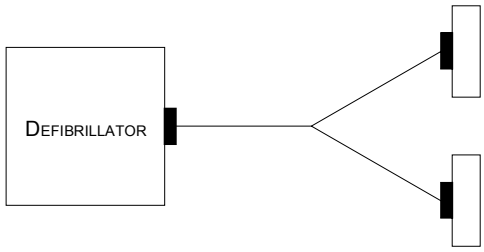


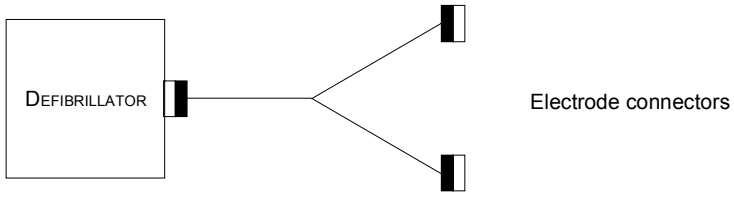

**Figure 107—Isolation of DEFIBRILLATOR circuit from separate monitoring electrodes (see Annex AA, rationale on Clause 20)**

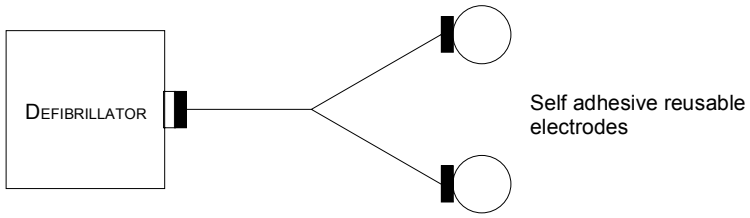
Reusable cable and electrodes:



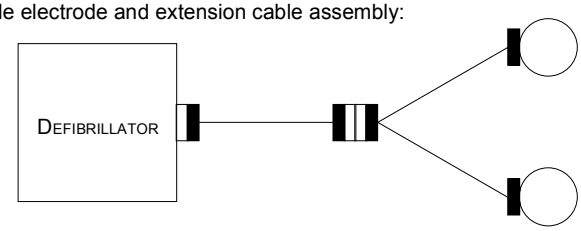

Reusable cable and single use electrodes:




Single use cable and electrode:




Reusable cable with single electrode and extension cable assembly:




Cable anchorage requiring testing

Connector to defibrillator or electrode where relevant

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**Figure 108—Examples of cord anchorages that require testing**

List of Titles

### Annexes

The appendices of the General Standard apply except as follows:

## Appendix L

## References—Publications mentioned in this Standard

This appendix of the General Standard applies except as follows:

*Addition:*

IEC 60300-3-9, *Dependability management—Part 3: Application guide—Section 9: Risk analysis of technological systems*

IEC 60601-2-27, *Medical electrical equipment—Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment*

IEC 60651, *Sound level meters*

IEC 61000-4-2, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 2: Electrostatic discharge immunity test. Basic EMC Publication*

IEC 61000-4-3, *Electromagnetic compatibility (EMC)—Part 4-3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 4: Electrical fast transient/burst immunity test. Basic EMC Publication*

IEC 61000-4-5, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 5: Surge immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 6: Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 8: Power frequency magnetic field immunity test*

# Annex AA
(informative)

# General guidance and rationale

This annex provides a concise rationale for the important requirements of this Standard and is intended for those who are familiar with the subject of the Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the Standard. Furthermore as clinical practice and technology change it is believed that a rationale for the present requirements will facilitate any revision of the Standard necessitated by these developments.

From the standpoint of safety, CARDIAC DEFIBRILLATORS pose special problems not only because of the possible shock hazard to the OPERATOR, but because the DEFIBRILLATOR has to deliver the selected output even after a long period of disuse, otherwise the PATIENT's safety may be at risk. Thus CARDIAC DEFIBRILLATORS require a high order of reliability.

The minimum safety and reliability requirements as specified in this Standard are considered to provide for an acceptable level of safety in operation and reliability in use.

## 1.1 Scope

The requirements of this Standard are specified for the commonly used DEFIBRILLATOR with or without an incorporated MONITOR, that is, an EQUIPMENT containing a capacitor as an ENERGY STORAGE DEVICE. This capacitor is charged to a HIGH VOLTAGE and connected to the output electrodes either directly or via a series inductor or resistor.

The first edition of this Standard made a distinction between a DEFIBRILLATOR and a DEFIBRILLATOR-monitor. This was due to development of a draft specification for the latter being developed in parallel with that for DEFIBRILLATORS and the two specifications being combined in a later draft. This distinction is no longer necessary and has been eliminated in this edition.

This Particular Standard does not address requirements for implantable DEFIBRILLATORS since they are considered to have sufficient differences to merit separate treatment.

Since publication of the first edition of this Standard, AUTOMATED EXTERNAL DEFIBRILLATORS (AEDs) have come into widespread use. Several requirements of this Standard have been revised or created to standardize these devices.

A variety of therapeutic waveforms have been used to terminate cardiac fibrillation including damped sine, biphasic, and truncated exponential. DEFIBRILLATOR designers, USERS and evaluators should take into consideration that clinical studies have demonstrated that fibrillator termination efficacy varies widely with waveshape as well as other parameters including voltage amplitude, DELIVERED ENERGY, tilt, and total duration. Waveform technology is evolving rapidly. This precludes stating specific safety requirements in this Standard. However, due to the efficacy sensitivity to variations in these parameters, adequate clinical validation should be considered essential. Particular validation attention should be given to the efficacy of waveforms with insufficient current or protracted duration, and the safety of waveforms with excessive peak current. .

## 4.5 Ambient temperature, humidity, atmospheric pressure

In accordance with the environmental conditions (see 10.2), battery powered EQUIPMENT also has to be type-tested at 0 °C to reveal any temperature-dependent characteristics which may adversely affect safety.

 

If EQUIPMENT for an extended range of environmental temperatures is needed (for example in ambulances or helicopters) this requires special agreement between the manufacturer and the OPERATOR.

## 5 Classification

Reference to TYPE B APPLIED PARTS is deleted, as the output circuit has to be isolated from earth to avoid unwanted current paths if the PATIENT has another earth connection. An isolated output circuit is also essential for the safety of the OPERATOR.

### 6.1 j) Power input

A large surge of current may be drawn from the SUPPLY MAINS during charging of the DEFIBRILLATOR. The OPERATOR should operate the EQUIPMENT on a suitably RATED mains circuit. This is particularly a problem with a DC SUPPLY MAINS.

### 6.1 aa) Concise operating instructions

As a DEFIBRILLATOR is frequently needed in an emergency situation, the essential operating information has to be available without recourse to the instructions for use.

### 6.1 bb) Internally powered EQUIPMENT

Here the same rationale as in 6.1 aa) applies. Additionally, the marking should indicate whether the DEFIBRILLATOR with a discharged or missing battery can be used effectively from a built-in or separate battery charger.

### 6.3 aa)

Values for the PATIENT resistance reported in the literature vary over a range from 25 Ω to 175 Ω in clinical situations. A significant portion of the STORED ENERGY is dissipated in the resistance of the DISCHARGE CIRCUIT or may remain in the storage capacitor. The value of 50 Ω used here represents a suitable reference value rather than a normal or typical value.

In order not to restrict design unnecessarily no stricter requirements regarding numbers of steps are specified. For easy and safe use, all EQUIPMENT is required to be calibrated in joules of DELIVERED ENERGY. However, it is recognized that many newer DEFIBRILLATORS are incorporating sophisticated techniques for optimizing defibrillation output by waveform adjustments based on PATIENT impedance measurements. It is widely recognized that many parameters of defibrillation waveforms, not just total energy, can affect efficacy.

It is an essential safety feature that the OPERATOR can clearly see or hear the charge ready indication from normal distance from PATIENT to device or in typical noise ambient levels. Devices with both audible and visual indicators are preferred.

### 6.8.2 e), f), g), h)

A rechargeable battery has a limited lifetime and should be replaced periodically.

### 6.8.2 aa) Supplementary instructions for use

1) and 2) This information is necessary for the protection of OPERATOR and PATIENT as well as of other MEDICAL ELECTRICAL EQUIPMENT. Many AEDs include features to allow defibrillation only if the impedance load falls within a predetermined range, as a safety technique to prevent inappropriate shocks.

4) Adverse environmental conditions immediately prior to use may affect the reliable operation of the EQUIPMENT.

6) As the reliable function of a DEFIBRILLATOR is essential for the PATIENT's safety, this maintenance is considered important. Inspection of the packaging of disposable electrodes is necessary because the stated conditions could lead to an increase in electrode impedance which may result in degradation in performance of the DEFIBRILLATOR.

7) Knowledge of the charging time under best and worst conditions is considered to be essential.

**6.8.3 aa)**

1) As the PATIENT resistance is subject to variation, details of the waveform and the effect of changes in load resistance should be made available to the OPERATOR.

2) The data listed for SYNCHRONISER performance is based on problems which have arisen in practice.

3) The essential performance of RHYTHM RECOGNITION DETECTORS has been the object of considerable clinical/industry collaboration recently, and has resulted in useful, insightful, and statistically meaningful methods of specifying the performance of such system. The standard should simply adopt the results of these efforts:

   *Automatic External DEFIBRILLATORS for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety*, A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy.

**10.2 Operation**

Extended ranges of temperature and humidity are required since mains-powered as well as INTERNALLY POWERED DEFIBRILLATORS may be used outside medically used rooms. The requirements specified here are intended to cover the majority of environmental conditions likely to be encountered in practical use. However, for special applications, EQUIPMENT having a wider temperature range may be necessary.

**14.6 aa)**

TYPE CF requirements are necessary, because a DEFIBRILLATOR providing for the connection of SEPARATE MONITORING ELECTRODES may be used for intracardiac monitoring.

**17 h)**

It is also necessary for the requirement of item bb) of Clause 17 to apply if other PATIENT CIRCUITS of a DEFIBRILLATOR are used and the PATIENT is treated with another DEFIBRILLATOR. The requirements for DEFIBRILLATION-PROOF APPLIED PARTS given in the General Standard generally provide adequate protection for other PATIENT CIRCUITS which have been specifically included in the DEFIBRILLATOR. The amendments given here take account of other APPLIED PARTS which may be connected to the EQUIPMENT but not connected to the PATIENT, in addition to testing with the power off they are tested with power on, which is the normal operating condition.

**17 bb)**

The severity of electric shock a person receives when touching ACCESSIBLE PARTS during defibrillation is limited to a value which can be felt and which may be unpleasant, but which is not dangerous. SIGNAL INPUT and OUTPUT PARTS are included, as signal lines to remote recording and other EQUIPMENT could otherwise carry voltage surges which could cause hazardous shocks from such EQUIPMENT.

 

**17 cc)**

Where the manufacturer has made use of an APPLIED PART at the same time as performing defibrillation impossible, such an APPLIED PART need not be a DEFIBRILLATION-PROOF APPLIED PART.

### 19.1 General requirements

Due to capacitive coupling between the DEFIBRILLATOR APPLIED PART and other (possibly earthed) parts a certain amount of LEAKAGE CURRENT is unavoidable. During discharge, LEAKAGE CURRENTS may be higher, but will be much smaller than the intended defibrillating pulse current and will not present a SAFETY HAZARD to the PATIENT or the OPERATOR. The period of 1 s for this exemption was chosen in order to include all possible waveforms and to allow any mechanical contactor to reset.

### 19.3 Allowable values

The lower limit specified in the General Standard is valid for small-area contacts with the myocardium whereas the internal DEFIBRILLATOR ELECTRODES have a relatively large area. Furthermore the SINGLE FAULT CONDITION, i.e. MAINS VOLTAGE on the PATIENT for which this value applies, is unlikely to occur during open-chest surgery.

## 20 Dielectric strength

Voltage spikes on the SUPPLY MAINS will not appreciably affect the voltage on the energy storage capacitor; therefore a moderate test voltage was considered to be sufficient. In the General Standard earthing of the PATIENT is not considered to be a fault condition; consequently, the situation where one side of the APPLIED PART is connected to earth had to be included.

A high insulation resistance together with the other insulation requirements prevents the appearance of dangerous voltages on conductive ACCESSIBLE PARTS. In most insulating materials a breakdown is preceded by a non-linear increase of the current.

Resistors bridging this insulation should have a value high enough not to conflict with the principle of an isolated DEFIBRILLATOR APPLIED PART.

The purpose of Test 1 is to investigate the insulation between the high-voltage circuit of the DEFIBRILLATOR and other ACCESSIBLE PARTS.

The purpose of Test 2 is to investigate the isolation between the basic wiring and conductive parts of the high-voltage circuit of the DEFIBRILLATOR.

The purpose of Test 3 is to investigate if the isolation across components in the CHARGING CIRCUIT and the DISCHARGE CIRCUIT safely can handle the voltage levels present in the DEFIBRILLATOR.

The high voltage switching elements in a DEFIBRILLATOR provide a barrier between the energy storage element and the PATIENT, and this section is specifically designed to assure the integrity of those switching elements. The essential need is to assure that PATIENT safety is not compromised due to inadvertent energy discharge.

In many traditional DEFIBRILLATOR designs, the switch under test is simply a relay, which either passes the high-voltage test or not. However, newer DEFIBRILLATOR designs may include more complex switching methods. These methods permit for example, the generation of new defibrillation waveforms and provide improved ability to monitor the integrity of the internal systems.

Series-connected switching devices offer useful design advantages in these newer systems, but care must be taken to assure that faults in any one switching element do not lead to compromise of safety. Accordingly, the intent of this requirement is to subject the DEFIBRILLATOR switching system to over-voltage stresses in conjunction with single-fault conditions. The manufacturer must demonstrate that,

while gaining the versatility of newer switching techniques, PATIENT safety is not compromised in the event of failure.

### 36 Electromagnetic compatibility (EMC) requirements

DEFIBRILLATORS are life-saving EQUIPMENT and are often used in the field, or in ambulances, where the electromagnetic environment may be particularly severe. This makes it necessary to expand upon the general requirements of IEC 60601-1-2 in order to provide a reasonable assurance that DEFIBRILLATORS will perform well and safely in all of their intended uses.

Immunity to radiated RF fields is generally insured by requiring that the EQUIPMENT meets all its specifications when exposed to a field strength of 3 $Vm^{-1}$ which is seldom exceeded in hospitals. However, DEFIBRILLATORS used in transport or ambulances are likely to be used in the vicinity of powerful RF sources (mobile radio transmitters, cellular phones,...) where the field strength may reach or exceed 10 $Vm^{-1}$. An 8 W GSM transmitter, for instance, produces a field of 20 $Vm^{-1}$ at a distance of 1 m. State of the art technology does not ensure that DEFIBRILLATORS meet all specifications in the presence of a modulated 10 $Vm^{-1}$ RF field but a minimum safety requirement is that such intense fields should not result in a SAFETY HAZARD.

Examples of SAFETY HAZARDS include failures involving changes in operating state (e.g., unintended charge or discharge), irrecoverable loss or change of stored data, or clinically serious errors in control software (e.g., unintended change in discharge energy level).

### 42 Excessive temperatures

The operating conditions specified in 42.3 are considered to represent the most severe operating conditions liable to occur in practical use.

### 44.6 Ingress of liquids

The EQUIPMENT is likely to be carried and used outside medically used rooms and therefore a certain degree of protection against rainfall and spillage was deemed to be necessary. During the functionality test of the DEFIBRILLATOR it is allowed that secondary functionality (e.g., a recorder) does not operate after the test, as long as this does not adversely affect the DEFIBRILLATOR functionality.

Especially for AEDs it is required that voice prompts (if applicable) are still functional after the test.

For some EQUIPMENT there may be more than one position of NORMAL USE.

### 44.7 Cleaning, sterilization and disinfection

This requirement was deemed to be essential as the internal DEFIBRILLATOR ELECTRODES are used during open-chest surgery.

### 46.101 a)

The simultaneous energizing of two pairs of electrodes would create a SAFETY HAZARD.

### 46.101 b)

This safety requirement may be fulfilled by a design employing a recessed push-button or by similar means. In view of the difficulty of producing a sterilizable internal electrode containing a momentary switch in the electrode handle, a push-button on the panel was deemed to be satisfactory. Furthermore, it may be operated by an assistant during open-chest surgery. The risk of accidental operation of a foot switch is considered unacceptable. Example 4) addresses the advent of self-adhesive DEFIBRILLATOR

ELECTRODES since the first edition of this Particular Standard and presents the same degree of safety as Example 2).

**46.103**

Adequate OPERATOR warning prior to discharge is important. However, it is possible to charge safely even though discharge may not be imminent. Because charging may be an internal "background" function of the device, it is more important to the OPERATOR to be warned of impending external events, such as energy delivery. Of more relevance to the OPERATOR are:

a) The DEFIBRILLATOR senses a "shockable" rhythm and reaches a "shock" decision. This decision needs to be announced by voice or other audible or visual warning to the OPERATOR. This announcement allows the OPERATOR and any bystanders to prepare for the shock.

b) If the DEFIBRILLATOR is of the "advisory" type, further audible warnings are needed when the DEFIBRILLATOR becomes fully armed and ready to shock.

c) If the DEFIBRILLATOR is fully automatic, voice or warning sound warnings at least 5 s prior to discharge are needed to allow time to cease touching the PATIENT.)

## 50 Accuracy of operating data

Many quite different waveforms are currently used for the treatment of cardiac dysrhythmias. The energy levels used with these different waveforms also vary widely and there is at present no general agreement in the medical profession on an optimum form of electrical output for a CARDIAC DEFIBRILLATOR. This Standard therefore does not specify output parameters in any detail.

### 50.1 Marking of controls and INSTRUMENTS

Some standby DEFIBRILLATORs are simple, single energy devices. As long as the accuracy of the device is within the provisions of this Standard, no advantages are available to the OPERATOR from a quantitative DELIVERED ENERGY indication.) Also, most AEDs have a programmed sequence of energy settings, precluding the OPERATOR from energy selection during PATIENT use. Therefore, a SELECTED ENERGY control is not appropriate.

### 50.2 Accuracy of controls and INSTRUMENTS

The specified accuracy is considered adequate and is practical with existing technology. It was noted that the accuracy tolerance is quite broad for lower energy selections (e.g., < 10 J) It is important that an increase (or decrease) in SELECTED ENERGY produce a corresponding increase (or decrease) in DELIVERED ENERGY. The absolute accuracy of the DELIVERED ENERGY is somewhat less important. DEFIBRILLATORS should meet the output accuracy requirements even when the USER waits for a while before deciding to deliver a shock.

When the standard was first written, most defibrillators used a damped sinusoidal waveform. Consequently the DELIVERED ENERGY (for a given STORED ENERGY) increased with PATIENT impedance which may range from 25 to 175 Ω. For example, with a DEFIBRILLATOR internal impedance of 10 Ω and a DELIVERED ENERGY into 50 Ω equal to $ED_{50}$, the DELIVERED ENERGY into 25 Ω is 0.86 $ED_{50}$, into 100 Ω is 1.09 $ED_{50}$, and into 175 Ω is 1.135 $ED_{50}$. If the DEFIBRILLATOR interval impedance were 15 Ω, the range would be 0.81 $ED_{50}$ to 1.20 $ED_{50}$, i.e., ± 20 % of $ED_{50}$. This variation is systematic, reproducible and easily calculated and verified. Hence in the previous standard the required energy accuracy was ± 15 % at 50 Ω, and ± 30 % over the whole range of impedance, not because the DEFIBRILLATOR was less accurate but to accommodate the known variation of DELIVERED ENERGY with impedance.

The present standard takes a more logical approach. It requires that the dependence of DELIVERED ENERGY on impedance be disclosed for the entire range of PATIENT impedances, 25 Ω to 175 Ω, and that the accuracy requirement be ± 3 J or ± 15 %, whichever is greater, for any impedance; i.e., the actual DELIVERED ENERGY at any impedance must be within ± 15 % of the expected (nominal) DELIVERED ENERGY

for that impedance. As an example, if the DELIVERED ENERGY is 200 J (in a 50 Ω PATIENT) and the PATIENT has a very low impedance of 25 Ω, we know that the DELIVERED ENERGY should be 172 J, and we require that the actual DELIVERED ENERGY must be within ± 15 %, i.e., ± 26 J, of 172 J.

### 51.1 Intentional exceeding of safety limits

As very high output current or voltage may cause irreversible damage to the myocardium, its inadvertent application should be avoided by additional safety precautions. The problem of the dosage level necessary for defibrillation versus that which may damage the heart is currently the subject of study and discussion in medical literature.

#### 51.101

It has been considered necessary to impose an upper limit on the peak output voltage in order to reduce the risk of damage to other MEDICAL ELECTRICAL EQUIPMENT which may be connected to the PATIENT when the DEFIBRILLATOR is used.

#### 51.102

This requirement is necessary in order to prevent the unexpected availability of energy when the SUPPLY MAINS is restored or the EQUIPMENT is switched on again.

#### 51.103

The INTERNAL DISCHARGE CIRCUIT is needed, for example, when the DELIVERED ENERGY selected has to be reduced after charging the storage capacitor.

#### 52.4.101

Inadvertent discharge can be accepted if the likelihood of the fault condition to occur is negligible. An example where the DEFIBRILLATOR will discharge inadvertently is in a case where the means for triggering the discharge circuit described in 46.101 4) short circuit during the ready period with self-adhesive electrodes attached to the PATIENT. The likelihood of this occurring is considered to be negligible and therefore the risk must be accepted.

### 56 Components and general assembly

Any connector for DEFIBRILLATOR ELECTRODES should withstand the pulling forces expected in NORMAL USE.

### 56.101 DEFIBRILLATOR electrodes and their cables

External DEFIBRILLATOR ELECTRODE handles should be so designed as to minimize the possibility of contact between the electrodes and the OPERATOR in NORMAL USE. The use of electrode jelly should be taken into account. Controls should be so constructed and positioned that inadvertent operation is unlikely.

#### 56.101 b)

These requirements are specified because in practice the cables and their anchorages are subject to considerable stress. The cables of external paddles have several lines; therefore, if required to meet the test for internal cables, they would become thick and loose flexibility.

 

**57.10 aa)**

Relatively large distances are specified to allow for the probable spread of conductive jelly.

**57.10 bb)**

Voltage spikes on the MAINS VOLTAGE will not significantly influence the voltage on the storage capacitor; therefore relatively small distances are considered to provide enough safety.

**57.10 cc)**

Non-reusable DEFIBRILLATOR ELECTRODES are not required to comply with the creepage and clearance requirements of bb above and are not required to comply with the dielectric strength requirements of 20.

**57.10 dd)**

Double insulation for reusable cables that may become worn with time and rough handling provides a margin of safety for the OPERATOR to protect from high voltage exposure. For single use cables of moderate length, this risk is remote and the requirement is relaxed.

**101 Charging time**

A delay in delivery of shock is undesirable: even under unfavorable conditions, an excessively long charging time is not acceptable. The time from power-on to having this energy ready becomes a significant problem where self-diagnostics on power-on take more time and check more facilities, particularly when they are repeated if the system re-boots. From within any USER programming mode (once starting to adjust filter settings for instance), if the software were to require completion of a lengthy procedure before returning to normal mode this could lead to further delays.

**101.1 – 101.4**

When EQUIPMENT has indicated that a non-rechargeable battery needs replacement, the DEFIBRILLATOR should be able to comply with the requirements specified in Clause 101.1-101.4.

**101.3 – 101.4**

Due to requirements of a 5 s audible tone or voice prior to energy delivery for fully AUTOMATED EXTERNAL DEFIBRILLATORS (see 46.101 c)) the charge time requirement in 101.3 and 101.4 actually tightens the requirements for fully AUTOMATED EXTERNAL DEFIBRILLATORS.

**101.3 b)**

The 40 s requirement is derived from the following assumptions: 10 s self-test + 15 s ECG-analysis + 15 s charge time. In many cases the background analysis should be confirmed by a manually activated analysis period where the charging of the ENERGY STORAGE DEVICE is started during this manually started analysis.

**102.2 – 102.3**

This minimum battery capacity is a compromise between number of discharges and portability.

The test assumes that operational EQUIPMENT is normally stored and charged at room temperature but may need to be used at colder temperatures. Battery powered EQUIPMENT should be tested at 0 °C, the lowest temperature specified in the environmental conditions (see 10.2) to reveal temperature-dependent deficiencies.

The requirements should be fulfilled in the situation where the battery has been charged at minimum and maximum temperature as specified in 10.2.1 (minimum 0 – 40 °C or according to manufacturers instructions in the accompanying documents). This is due to the fact of charge acceptance for batteries at various temperatures. It is reasonable to expect that the battery will be charged in environments varying between 0 °C and 40 °C (or at the limits set by the manufacturer).

### 102.2 Requirements for MANUAL DEFIBRILLATORS

For INFREQUENT USE DEFIBRILLATORS it can not be required to perform three defibrillations in 1 min, since the charging time from discharge No. 7 – 5 should be within 25 s (see 101.2). The 90 s will assure a break between each of the three discharges and "recovery" of the battery.

### 102.3 Requirements for automated external defibrillators

This measure is the best way to look at the shock-to-shock cycle time of an AED, since the ECG analysis period will always be included in the total time required to deliver a shock. Hence the modification of 1 min to 105 s and 135 s for AEDs with respect to manual DEFIBRILLATORS in order to simulate a PATIENT remaining in VF, which the AED analyses and shocks repeatedly (up to 3 times) as quickly as possible. Requiring a shorter "charge and shock" time is inconsistent with the operation of AEDs, since the ECG analysis must be performed as part of the process. The 1 min rest period is consistent with current AHA CPR guidelines.

### 102.4

This requirement is specified to avoid unexpected depletion of the battery.

### 102.6

Rechargeable batteries should provide for a satisfactory number of discharges after a week's storage without recharging the battery. This requirement is specified to avoid unexpected depletion of the battery.

### 103 Endurance

As reliability of the EQUIPMENT has important safety implications, an endurance test is necessary.

Discharge of the DEFIBRILLATOR into open- or short-circuited electrodes is considered to be misuse. Nevertheless it may occur in practical use and hence the DEFIBRILLATOR should he able to withstand a limited number of such operations. Where such misuse is not possible, the relevant short- and/or open-circuit test is unnecessary.

### 104 Synchronizer

As different synchronization systems exist, only features influencing safety are specified:

1) It has to be clearly apparent if the DEFIBRILLATOR is in the synchronized mode; otherwise operation in an emergency is delayed.
2) The discharge has to be under the full control of the OPERATOR.
3) This requirement is based on ANSI/AAMI DF2:1989 (4.3.17). The reduced time permitted for an ECG derived by another EQUIPMENT allows for up to 35 ms processing/detection prior to signaling to the DEFIBRILLATOR.
4) As a safety feature, the DEFIBRILLATOR should always enter a mode where synchronization is disabled after power-on or when the DEFIBRILLATOR mode is entered from a mode different from the DEFIBRILLATOR mode.

 

A DEFIBRILLATOR and a monitor are normally needed to perform synchronized cardioversion. It is strongly recommended that the defibrillator monitor be integrated into a single instrument to ensure proper interfacing. However such integrated instruments are not available everywhere, and a separate defibrillator and a stand-alone monitor will inevitably be used in many instances. In such cases the USER is responsible for exercising proper care and for ensuring that the two instruments are properly interfaced and satisfy the timing requirements for safe synchronized cardioversion.

### 105 Recovery of the MONITOR/ECG input after defibrillation

In order that the success or failure of an attempt to defibrillate a PATIENT may be determined as soon as possible, a rapid recovery is necessary from the amplifier overload and electrode polarization produced by the pulse. This applies with the monitoring signal derived via the DEFIBRILLATOR ELECTRODES or via any SEPARATE MONITORING ELECTRODES.

### 106 Disturbance to the MONITOR from charging or internal discharging

The requirements allow for a level of interference which is unlikely to cause difficulties in interpretation of the ECG display.

# Annex BB
(informative)

## AUTOMATED EXTERNAL DEFIBRILLATORS: background and rationale

Approximately 40,000 AUTOMATED EXTERNAL DEFIBRILLATORS (AED) have been sold since they were first introduced on the market in the 1980s. If current studies evaluating the possible expansion of AED applications are completed, the potential market for AEDs will be several hundred thousand, larger than the market for conventional DEFIBRILLATORS.

Persons using AEDs generally have little or no training or medical skills, hence a standard is particularly needed to set requirements which ensure that AEDs are effective and safe.

### Rationale for different types of AEDs

Sudden cardiac arrest (SCA) strikes approximately 350,000 persons every year in the USA, and a comparable number in Europe. In cardiac arrest, blood flow ceases. After 5 min to 10 min, the brain suffers significant damage due to oxygen deprivation, and death occurs after 10 min to 20 min. Cardiopulmonary resuscitation (CPR) can perhaps double these times, but does not change the outcome. Defibrillation is the only method for terminating cardiac arrest due to ventricular fibrillation (VF) and restoring blood flow, and effective DEFIBRILLATORS have been commercially available for 30 years. We do not know how to predict or prevent sudden cardiac arrest, which strikes without warning any time in the day (though more often in the early morning), at home, at work, outdoors, etc., i.e., away from a hospital.

Conventional DEFIBRILLATORS can only be used by medical professionals skilled in analyzing an electrocardiogram and determining whether or not a PATIENT shall be defibrillated. In the 1960s ambulances were dispatched to the site of a presumed victim of cardiac arrest. If cardiac arrest was verified, the victim received drugs and CPR and was transported to a hospital for defibrillation. Time in cardiac arrest was very long and survival rate was extremely low, 1-3 %, making cardiac arrest the leading cause of death for adults aged 30 to 60 years.

In the 1970s it became clear that survival rate was very high (average 60 % to 80 %) if defibrillation was attempted within 1-2 min of the onset of VF, but decreased rapidly with increasing time in VF, about 7 % per minute without CPR, and 3 % to 4 % per minute with CPR.

The concept of the “chain of survival,” developed in the early 1980s, states that high survival rate from SCA requires:

- early recognition of SCA and access to the PATIENT;
- early CPR;
- early defibrillation;
- early Advanced Cardiac Life Support.

To achieve the 3rd and critical step, early defibrillation, highly trained paramedics were allowed to defibrillate beginning in the 1970s. Several years later, emergency medical technicians (EMT) received special training so they could analyze electrocardiograms and defibrillate using conventional DEFIBRILLATORS.

The next step in achieving earlier defibrillation was to advocate development of smart DEFIBRILLATORS (AEDs) which could analyze the ECG and determine whether defibrillation was needed, hence allowing use by people without electrocardiogram training. AEDs would be placed in every ambulance and in vehicles used by “first responders” such as firemen or police. The American Heart Association (AHA) published this statement in 1991.

 

To achieve the goal of early defibrillation, the AHA endorses the position that all emergency personnel shall be trained and permitted to operate an appropriately maintained DEFIBRILLATOR if their professional activities require that they respond to persons experiencing cardiac arrest. This includes all first responding emergency personnel, both hospital and non hospital (e.g., emergency medical technicians (EMTs), non-EMT first responders, firefighters, volunteer emergency personnel, physicians, nurses, and paramedics).

To further facilitate early defibrillation, it is essential that a DEFIBRILLATOR be immediately available to emergency personnel responding to a cardiac arrest. Therefore, all emergency ambulances and other emergency vehicles, that respond to or transport cardiac PATIENTS shall be equipped with a DEFIBRILLATOR.

Since 1993, the AHA has begun promoting the ultimate step in early defibrillation, “Public Access Defibrillation” (PAD) in which extremely simple, low cost, intuitive use, fully automatic AEDs are deployed in a variety of office buildings, factories, shopping malls, concert halls, etc., and can be used if needed by any bystander or lay person witnessing a possible cardiac arrest. This is still a developing concept not yet implemented, but with the support of AHA, the prospect of large scale implementation of PAD in 3–5 years is plausible.

This discussion makes it clear that three types of AEDs are needed:

1) AEDs for hospitals and ambulances. Will be used fairly frequently (possibly several times per week) by medically trained personnel. Must be sophisticated, very rugged. May offer several modes of operation and a variety of features. Must be advisory rather than automatic. May require periodic OPERATOR tests and a schedule of preventive maintenance due to complexity and frequency of use.
2) AEDs for first responders such as firemen, police officers and security officers will be used less frequently (a few times per month or less). These AEDs must be reliable in making shock recommendations and generally rugged due to the various environments outside of the hospital where they are needed. They must be very simple to use to allow for greater numbers of emergency response personnel to be trained with minimal time and skill retention. They shall perform automatic periodic tests to verify fitness for use, and minimize and/or automate maintenance to the greatest extent possible.
3) AEDs for PAD or placement in the house of a high risk survivor of cardiac arrest or heart attack. These devices will be used very infrequently (perhaps once a year), must be very inexpensive and preferable very light, must be simple enough for use by a lay person, are fully automatic and have a sophisticated schedule of fully automated functional tests, maintenance, and recalibration, if needed.

Clearly these three types of AEDs are different in design and features, and it is necessary to differentiate requirements in some parts of the standard. The main differentiation is associated with frequency of use and skill of the USER.

## Additional U.S. requirements, figures and annexes

SECTION 101 – ADDITIONAL REQUIREMENTS RELATING TO SAFETY
(Continued from page 30)

**(Clauses and subclauses marked with an asterisk * before their number have corresponding rationale in Annex CC)**

**107 Defibrillator electrodes (U.S.)**

***107.1 Defibrillator electrodes for monitoring and defibrillation, and (optionally) pacing**

***107.1.1 AC small signal impedance**

The 10 Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak, shall not exceed 3 kilohms. The impedance at 30 kHz shall be less than 5 ohms.

*Compliance is checked by connecting a pair of electrodes, gel-to-gel, applying a 10 Hz sinusoidal current of known amplitude not exceeding 100 μA p-p and observing the amplitude of the resulting voltage across the electrodes. The magnitude of the impedance is the ratio of the voltage to that of the current. An adequate current generator can be assembled utilizing a sinusoidal signal (voltage) generator with a 1 megohm resistor in series with the electrode pair.*

*The test is repeated with a 30 kHz current.*

***107.1.2 AC large signal impedance**

The impedance of an electrode pair connected gel-to-gel, in series with a 50 ohm (Ω) load and measured at the maximum rated energy of the defibrillator shall not exceed 3 ohms.

*Compliance is checked by placing a pair of electrodes gel-to-gel in series with a 50 Ω load across the output of the defibrillator. While monitoring the voltage across both the electrode pair and the resistor, the defibrillator is set to 360 J or its maximum rated energy and discharged through the circuit. The ratio of the peak voltages impressed across the electrodes should be less than or equal to 3:50.*

***107.1.3 Combined offset instability and internal noise**

A pair of electrodes connected gel-to-gel shall generate, after a 1 minute stabilization period, a voltage no greater than 100 μV peak-to-peak in the pass band of 0.5 to 40 Hz, for a period of 5 minutes following the stabilization period.

*Compliance is checked after a 1 minute stabilization period, the output voltage of the test circuit (see Figure US.1) shall not exceed 100 μV p-p over 5 minutes. Output voltage shall be measured with an instrument having a frequency response of 0.01 to 1,000 Hz and a minimum input impedance of 10 megohms.*

***107.1.4 Defibrillation recovery**

The potential of a pair of gel-to-gel electrodes in series with a 50 ohm resistor and subjected to three shocks at 360J or maximum energy at 1 minute intervals shall not exceed 400 mV at 4 seconds and 300 mV at 60 seconds after the last shock delivery.

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

  

***107.1.5 Biological response**

The electrode shall be biocompatible. For this application, with the electrode in continuous contact with the skin for the maximum duration specified by the manufacturer, biocompatibility requires evaluation of cytotoxicity, skin irritation, and skin sensitization.

*Compliance is checked by a variety of acceptable methods. It is recommended that procedures and techniques provided in the ISO 10993[+] standards be considered when addressing these requirements.*

***107.1.6 DC offset voltage**

A pair of electrodes connected gel-to-gel shall, after a 1 minute stabilization period, exhibit an offset voltage no greater than 100 mV.

*Compliance is checked by connecting the electrodes gel-to-gel to form a circuit with a DC voltmeter having a minimum input impedance of 10 megohms and a resolution of 1 mV or better. The measuring instrument shall apply less than 10 nA of bias current to the electrodes under test. The measurement shall be made after a 1 minute stabilization period but before 1.5 minutes have elapsed.*

***107.1.7 Electrode active area**

The minimum active (gel) area of self-adhesive electrodes used for defibrillation and pacing shall be

| each | together | purpose |
|---|---|---|
| 50 $cm^2$ | 150 $cm^2$ | adult transthoracic |
| 15 $cm^2$ | 45 $cm^2$ | pediatric (less than 10 kg) trans-chest |

***107.1.8 Electrode adhesion and contact to patient**

The electrode materials and construction shall ensure good adhesion and electrical contact with the patient when the electrodes are placed properly. Data on the characteristics of the adhesive (peel strength, setting time, response to perspiration, effect of temperature on these characteristics) should be available from the vendor.

*There is no reliable bench test for this characteristic. Testing is best performed in a controlled clinical environment.*

***107.1.9 Packaging and shelf life**

The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the expiration date and under the storage conditions specified by the manufacturer. At a minimum, electrodes shall comply with all performance specifications after storage for 1 year at 35 °C. One-year storage may be simulated by accelerated testing at higher temperatures. Electrodes shall comply after storage for 24 hours at -30 °C and +65 °C. Electrodes shall be returned to a temperature in the range of 15 °C to 35 °C before the test for compliance is performed. Electrodes shall be tested at both 15 °C and 35 °C or the operating temperature extremes defined by the manufacturer.

*Compliance is checked by conducting the tests of 107.1.1 through 107.1.8 at the end of the specified shelf life and at the extremes of the temperature ranges specified.*

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[+] All of the documents in the ISO 10993 series of standards on biological evaluation of medical devices have been adopted in the U.S. by AAMI. For a complete listing of current standards, visit the AAMI website at www.aami.org or call AAMI's standards department.

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

***107.1.10 Universal-function electrodes**

If the electrodes are designed and intended for use in multiple modes, i.e., monitoring, defibrillation, and pacing, the following requirements apply:

a) The electrode package shall clearly identify all functions that the electrode will perform.

b) The electrode package shall provide specific instructions for the connection, placement, and operation of the electrodes for their various functions.

c) The electrode shall meet all requirements of 107.1 after 60 minutes of pacing at the maximum current output and maximum pacing rate through a pair of gel-to-gel electrodes in series with a 50 ohm resistor.

*Compliance is checked by electrodes meeting each specification: 107.1.1-4; 107.1.6-7 following an hour of pacing. Tests shall be conducted immediately after the conclusion of pacing.*

***107.1.11 Cable length**

The electrode cables shall have an extended length of at least 2 meters. If coiled cords are used, the extension force shall be 18 newtons (4 lb) or less per paddle electrode at a distance of 2 meters.

*Compliance is checked by measurement.*

***108 External pacing (U.S.)**

External pacing may be provided as an optional feature.

**108.1 Pacing mode activation**

The pacing mode shall only be activated manually by the mode selector and shall be clearly labeled. The defibrillator shall be disarmed and the defibrillation mode disabled when the pacing mode is operative.

**108.2 Pacing delivery**

The pacing output may be delivered to the patient through either the defibrillation electrode pathway or a separate pacing electrode pathway.

**108.2.1 Separate pacing pathway**

If a separate pacing electrode pathway is provided, the following requirements apply:

a) Pacing electrode placement and connection shall be described in the operating instructions.

b) The pacing output circuitry shall be able to withstand, without damage, three 360 J defibrillation discharges 1 minute apart across the pacing electrode pads shunted by a 100 ohm load.

*Compliance is checked by performing the following test:*

*1) Connect the pacer circuit to the test circuit as indicated in Figure US.2. A defibrillator test load of 100 ohms, or its equivalent, shall be used.*

*2) Charge the capacitor to 5,000 V, with switch S1 in position A. Discharge is accompanied by actuating S1 to position B for a period of 200 ms ± 100 ms. The capacitor shall be disconnected in order to remove residual voltages and to allow recovery to commence.*

*3) After 10 seconds, verify that the pacer circuit correctly displays the test signal at an amplitude at least 50 % of its normal amplitude before the test.*

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

*4) After the test, the pacer circuit shall meet all performance requirements of this standard.*

*5) Perform the test three times with at least 30 second separation between successive discharges. The switch S1 shall withstand peak currents of 60 A in the closed position, and in the open position it shall not break down for voltages up to 5,000 V.*

**108.2.2 Combined pathway**

If the defibrillation/pacing electrode pathway also is used for ECG monitoring, the following requirements shall apply:

a) The electrode package shall clearly identify all functions that the electrode will perform.

b) Electrode placement and connection shall be described in the operating instructions.

c) The electrodes shall meet all the requirements of 107.1.

*Compliance is checked by performing the tests in 107.1.11 (c).*

**108.3 Pacing pulse shape and duration**

**108.3.1 Pace pulse duration accuracy**

The pacing pulse shape (waveform) and duration shall be specified in the operating instructions. The output waveform shall be within the limits specified in the operating instructions.

*Compliance is verified by the following test:*

*a) Connect a 50 ohm resistive test load and an oscilloscope between the pacing electrode connectors.*

*b) Activate the pacing mode.*

*c) The pacing pulse shape and duration shall fall within the limits specified for these parameters in the operating instructions.*

**108.3.2 Pace pulse duration stability**

a) If the pacemaker is battery-operated, the pulse duration shall not change by more than ± 10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

*Compliance is checked by continuing the pacer operation in 108.3.1 for the duration equivalent to the nominal operating time of the battery. Measure duration every 15 minutes. The duration shall not change by more than 10 % from the initial reading for any measurement.*

b) If the pacemaker is powered off AC-mains, the pulse duration shall not change by more than ±10% over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

*Compliance is checked by continuing the pacer operation in 108.3.1 for the duration equivalent to the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. Measure duration every 30 minutes. The duration shall not change by more than 10 % from the initial reading for any measurement.*

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

### 108.4 Pacing pulse current

#### 108.4.1 Pacing pulse current accuracy

If predetermined within the pacer, the pacing pulse current shall be described in the operating instructions.

The output waveform shall be within the limits specified in the operating instructions.

*Compliance is checked by:*

*a) Perform steps a) and b) of 108.3.1.*

*b) The pacing pulse current shall fall within the limits specified for this parameter in the operating instructions. If a pacing control is provided, the pacing pulse current shall be measured at each setting for compliance. If the pacing current control is continuously variable, measurement of the minimum and maximum settings and at least one other setting corresponding to the control's labeling shall be performed.*

#### 108.4.2 Pacing pulse current stability

a) If the pacemaker is battery-operated, the pulse current shall not change by more than ± 10 % over the duration equivalent to the nominal operating time of the battery specified in the operating instructions.

b) If the pacemaker is powered off AC-mains, the pulse current shall not change by more than ± 10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

*Compliance is checked by:*

*a) Perform steps a) and b) of 108.3.1.*

*b) With current set to maximum, verify that the pacing pulse current does not exceed ± 10 % from its original setting.*

### 108.5 Pacing rate

#### 108.5.1 Pacing rate accuracy

The output waveform shall be within the limits specified in the operating instructions.

*Compliance is checked by:*

*a) Perform the steps a) and b) of 108.3.1.*

*b) The pacing rate shall fall within the limits specified for this parameter in the operating instructions. If a pacing rate control is provided, the pacing rate shall be measured at each setting for compliance. If the pacing rate control is continuously variable, measurement of the minimum and maximum settings and at least one other setting corresponding to the controls labeling shall be performed.*

*c) Compliance with the labeling requirement for a pacing rate control, if present, can be verified by inspection.*

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

### 108.5.2 Pacing rate stability

a) If the pacemaker is battery-operated, the pulse rate shall not change by more than ± 10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

*Compliance:*

*If the pacemaker is battery-operated, continue the pacer operation in 108.5.1 for the duration equivalent to the nominal operating time of the battery. If a pacing rate control is provided, it should be set to mid-range. Measure duration every 15 minutes. The rate shall not change by more than 10 % from initial reading for any measurement.*

b) If the pacemaker is powered off AC-mains, the pulse rate shall not change by more than ± 10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

*Compliance:*

*If the pacemaker is powered off AC-mains, continue the pacer operation in 108.5.1 for the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. If a pacing rate control is provided, it should be set to mid-range. Measure duration every 30 minutes. The rate shall not change by more than 10 % from the initial reading for any measurement.*

### 108.6 Pacing protocol

Pacing may be provided in either a continuous or intermittent sequence. If predetermined within the pacer, the pacing protocol shall be described in the operating instructions. If operator selection is provided, the control that selects the pacing protocol shall be labeled with the available selections.

*Compliance is checked by inspection.*

### 108.7 Demand pacing

Demand pacing is not a required feature of defibrillators including external pacing capability. If demand pacing is available, the heart rate at which pacing begins, in a down-trending heart rate, shall be between 90 % and 100 % of the pacing rate selected on the unit. If the unit has rate settings below 40 ppm, the unit shall begin pacing when the heart rate drops below the rate setting minus 4 ppm.

*Compliance:*

*For units with the capability of monitoring and pacing through the same set of electrodes, the ECG/pacing leads are connected to a defibrillator tester capable of providing a 1 mV ECG signal to the pacing/ECG cable at a variable rate. For other units not capable of this multifunction operation, the ECG leads are connected to a defibrillator tester capable of providing an ECG signal at a variable rate. An oscilloscope probe should be placed across the inputs to the defibrillator tester to measure the pacing energy delivered into the 50 ohm load of the tester. The ECG signal rate is set to 120 beats per minute (bpm), and the pacing rate of the unit is set to 68 ppm. The unit shall not have pacing activated. Change the ECG signal rate to 60 bpm. The unit shall now have pacing activated.*

*Set the ECG signal rate to a rate of 180 bpm and the pacing rate of the unit to 134 ppm. The unit shall not have pacing activated. Change the ECG signal rate to 120 bpm. The unit shall now have pacing activated.*

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

### 108.8 Pacer lead-off indication

There shall be a clear indication by means of either a display or an indicator light that the unit is unable to deliver the pacing current because of a pacing leads-off condition. It is recommended, though not required, that the unit also provide an audible indicator of this condition.

*Compliance:*

*Connect the pacer output cable to a 250 ohm power resistor, and pace at the maximum amplitude allowed by the unit. The unit shall not indicate that a pacer lead-off condition is present.*

*Set the output to 20 mA and disconnect the pacer output cable from the load resistor. The unit shall indicate that a pacer lead-off condition is present.*

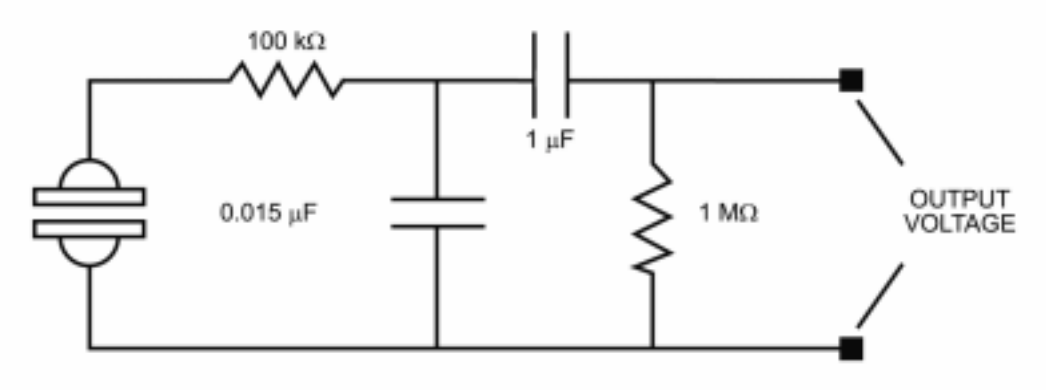


**Figure US.1—Test circuit for offset instability/internal noise determination**

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

  

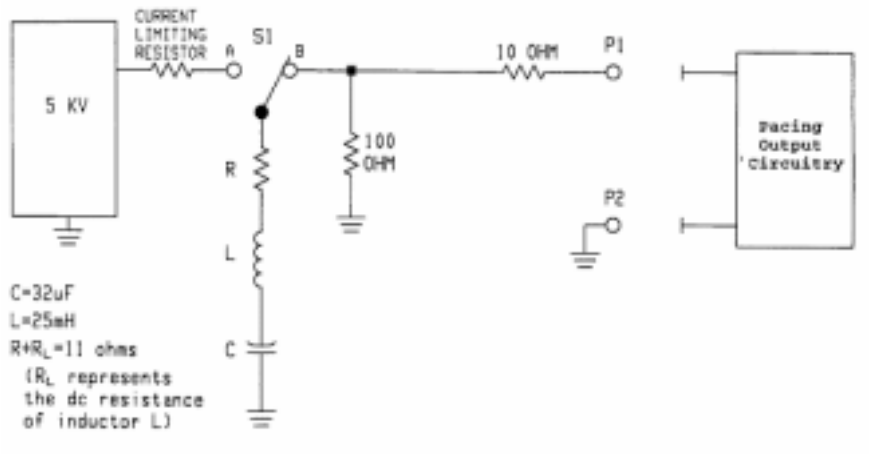


**Figure US.2—Test circuit for defibrillator overload test of pacing output circuitry**

NOTES—

1. The values of the resistors are ± 2 %. The value of the inductor is ± 5 %.

2. The 100 ohm test load may consist of a 50 ohm load in series with the 50 ohm load of a defibrillator tester; with such a circuit, the total energy delivered to the 100 ohm load is twice the energy indicated by the defibrillator tester.

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

# Annex CC (U.S.)
(informative)

## General guidance and rationale for additional U.S. requirements

This annex applies to AAMI DF80 only and is not included in IEC 60601-2-4:2002. This annex provides concise rationale for sections 107 and 108, which are additional requirements for U.S. only.

Additional subclauses:

### 107.1 Self-adhesive electrodes for monitoring and defibrillation, and (optionally) pacing

With conventional defibrillators, it has been customary to use separate pregelled ECG electrodes for monitoring and defibrillator paddle electrodes for defibrillation. The monitoring electrodes are not capable of effectively delivering a defibrillation shock, and the paddle electrodes have only limited monitoring capability. For recent applications, particularly automatic external defibrillation, it is very desirable to use self-adhesive pregelled disposable combination electrodes that perform well in the dual monitoring and defibrillation functions. These electrodes may also be used for delivery of transcutaneous pacing. Recent studies (Stults et al., 1987) also indicate that such combination electrodes may perform better than paddle electrodes for defibrillation. Hence, combination electrodes may become preferred for defibrillation, and it is appropriate in a standard for defibrillators to consider their use and to outline a few requirements for them.

Attenuator devices for pediatric electrodes used with automatic external defibrillators have been introduced. The supporting rationale for the dosing attenuation: automatic external defibrillators generally have energy ranges available beginning at 150 J. Since AEDs were not originally designed for pediatric use, the high energy doses exceed recommended clinical standards for pediatric patients (e.g., 2 J/kG) and may be potentially damaging. To cope with this problem, special electrodes with a high intrinsic resistance have been introduced. When used with standard AEDs (i.e., AEDs intended for adult use), the high resistance electrodes result in a lower energy and current being delivered to the child. This should enhance safety while maintaining effectiveness. Because of the extremely infrequent occurrence of ventricular fibrillation in pediatric patients and difficulties in obtaining informed consent for unpredictable emergency medical procedures, there are no clinical data to directly support the use of these electrodes. However, several animal studies have been conducted using swine models to simulate the pediatric subject. These studies have observed both safety (post-defibrillation cardiac function) and efficacy (defibrillation success and return of spontaneous circulation) to provide reasonable assurance of performance on pediatric patients. Furthermore, post-market surveillance studies are currently underway to capture and record actual clinical performance for future evaluation.

### 107.1 .1 AC small signal impedance

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12:2000, with particular attention to the provision that 5 kΩ is acceptable where skin preparation is minimal.

### 107.1.2 AC large signal impedance

Impedance for self-adhesive electrodes may be higher than for standard hand-held electrode paddles used with manual defibrillators. This requirement provides a reasonable limit on impedance contributed by the electrode pair during defibrillation (less than 6 %).

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

  

### 107.1.3 Combined offset instability and internal noise

This requirement is derived from ANSI/AAMI EC12:2000, with the added recognition that cardiac monitor bandwidth is more appropriate.

### 107.1.4 Defibrillation overload recovery

The fundamental rationale for this requirement is consistent with ANSI/AAMI EC12:2000 and ANSI/AAMI EC13:2002. The requirement and test are stated in terms more directly applicable to defibrillators; that is, in terms of actual exposure to defibrillation energies rather than simulated DC offsets.

### 107.1.5 Biological response

This requirement is derived from ANSI/AAMI EC12:2000. Application to broken skin is to be avoided, therefore the requirement for intracutaneous reactivity is not applicable.

### 107.1.6 DC offset voltage

This requirement is unchanged from ANSI/AAMI EC12:2000.

### 107.1.7 Electrode active area

For electrodes intended for adult use, the requirements, test, and rationale are taken exactly from ANSI/AAMI DF39:1993. The 15 $cm^2$ requirement for individual electrodes intended for pediatric use is retained from ANSI/AAMI DF2:1989. Following the logic of DF39:1993, the pediatric requirement is extended to include a combined electrode area of three times the individual area.

### 107.1.8 Electrode adhesion and contact to patient

Good adhesion and electrical contact between the electrodes and the patient are essential for defibrillation efficiency. They must be achieved for a variety of patient and environmental conditions and maintained over an extended period of time prior to electrode use. However, test and evaluation experience indicates that a bench test for evaluating adhesion performance is not practical or reliable. Proper performance assessment is best done in a controlled clinical environment. This reasoning is consistent with the committee conclusions described in ANSI/AAMI EC12:2000.

### 107.1.9 Packaging and shelf-life

Two conditions are considered: long-term storage in a presumably well-controlled environment and short-term transportation either from manufacturer to customer storage site or from storage site to site of use. For accelerated age testing according to the van't Hoff rule, a $Q_{10}$ of 2.0 may be used.

Short-term extreme conditions may be encountered during shipment from manufacturer to purchaser or during transportation with caregivers to the site of use, which could be any accident location. A duration of 12 hours, as specified in ANSI/AAMI DF39:1993, may be too short in this context. A duration of 24 hours at both extreme temperatures of –30 °C and +65 °C is considered more adequate.

### 107.1.10 Universal-function electrodes

Defibrillators may incorporate external transcutaneous pacing as either a distinct separate treatment mode or as part of a combined defibrillation/pacing/monitoring operation. Because no general performance standards exist for combination pacing/defibrillation/monitoring electrodes, the requirements define the basic minimum controls necessary to ensure safe and reliable operation.

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### 107.1.11 Cable length

To ensure that the user has adequate cable for most purposes, minimum cable length of 2 m (80 in) was specified for those units requiring cables. Although it was recognized that a minimum cable of 3 m (10 ft) might be more useful in some circumstances, it was felt that a 3 m cable would be rather cumbersome for some mobile applications and hence was not specified as a minimum requirement.

### 108 External pacing

A defibrillator may incorporate external pacing either as a distinct pacing treatment mode, separate from the defibrillation treatment mode, or as part of a combined defibrillation/pacing operating protocol. No consensus has been reached on the waveform characteristics providing greatest efficacy due to patent infringement issues and other legal concerns. Therefore, rather than requiring conformance to a specific pacing waveform shape, the standard specifies that the manufacturer should make available clinical test data to demonstrate efficacy of the device with regard to pacing. Except for this area of waveform characteristics, specific requirements are made in this standard with regard to pacing labeling, controls, indicators, and operation.

This standard includes a section on pacing stability. In the clinical setting, capture is determined empirically; in addition, the patient may be left unattended while external pacing is in progress. Therefore, absolute accuracy is not as important as stability when there is the potential that capture may be lost if the amplitude, rate, or waveform duration decreases over the length of time the patient is being paced.

This standard also includes a section on pacing leads-off indication. In the clinical setting, the leads-off indicator is important, because failure of either the pacing leads or of electrode/patient contact will result in no pacing current being delivered to the patient. While there are other component failures that may also result in this condition, improper connection or electrode placement is common enough that a clear indication needs to be provided to the clinician of the viability of the pacing electrical connection.

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

# Annex DD (U.S.)
(informative)

## Historical background on defibrillation waveforms

This annex applies to AAMI DF80 only and is not included in IEC 60601-2-4:2002. This annex provides a historical background on defibrillation waveforms. The AAMI Defibrillator Committee felt that it was important to include some background on waveforms and decided to add this section by revising the information that was listed in the third edition of ANSI/AAMI DF2:1996, *Cardiac defibrillator devices*.

**Monophasic defibrillation waveforms**

Most external and implantable defibrillators today are designed to provide defibrillation discharge waveforms in a biphasic form and are typically a derivative of a truncated exponential shape. Clinical studies show that these biphasic waveforms provide improved clinical performance when compared to monophasic waveforms. The previous American National Standard for Safety of Cardiac Defibrillators (ANSI/AAMI DF2:1996) required that new discharge waveforms be clinically tested and proven to be at equivalent in defibrillation efficacy to standard monophasic waveforms. Specifically, the third edition of ANSI/AAMI DF2 included the following requirements for waveforms other than the standard specified monophasic types:

**Other waveforms**

Other waveforms are not precluded from this standard if the following conditions are met:

a) Efficacy is demonstrated in a prospective, randomized, masked (blinded) comparative clinical trial versus control waveforms that have met the requirements of this standard.

b) Dosing procedures (e.g., electrode placement, energy delivery protocols) for the proposed waveforms are tested as part of the trial.

c) Sufficient statistical power is employed in the study, design, and analysis. The 95 % upper-confidence limit on the difference between the control and study waveform defibrillation rates should not exceed 10 %.

d) Results of the study are accepted for publication in manuscript form in a peer-reviewed journal.

e) Performance specifications for commercial devices employing the proposed waveforms are published and available. Specifications shall be sufficient to allow independent verification that the parameters of the waveform output by the device replicate the conditions of the efficacy study**."**

Only the AAMI standards for safety of defibrillators included specifications for standardization of the monophasic waveforms (both damped sinusoid and truncated exponential). As such, the monophasic waveform specifications are provided in the Annex for historical reference and use in the design of future comparative clinical studies.

Changes to the waveform specification in the third edition of ANSI/AAMI DF2 generally reflected observations on waveform performance since prior editions. The first and most apparent change was the addition of the 125 ohm specification category for all waveforms. This reflected the experience that, with the trend toward defibrillation at lower voltages, at least 10 % of patients now present transthoracic impedances greater than 100 ohms, the previous upper limit of the specification. The addition of the 125 ohm category encompasses almost all patients.

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The second general change was the accommodation of emerging defibrillation waveform and dosing techniques (e.g., biphasic waveforms, overlapping or multiple pulses, current dosing). Because the specification is revised only infrequently, a method is provided to allow and encourage innovation of commercial devices as the science progresses. This method allows manufacturers to establish the clinical efficacy of defibrillation techniques outside the older bounds set for damped sinusoid or truncated exponential waveforms. The methodology outlined demands rigorous study design and the publication of results. The waveform parameters studied must be presented in a manner that, like the older specification, allows meaningful and accurate routine testing of commercial devices. Once proven and presented using the prescribed methodology, devices may then be offered to the market under the umbrella of the standard.

**Damped sinusoidal waveform**

For many years the damped sinusoidal waveforms often referred to as the Lown, Edmark, or Pantridge waveforms have been in widespread clinical use. The efficacy of these waveforms has been reaffirmed in recent clinical studies by Pantridge et al. (1975), Campbell et al. (1977), and Gascho et al. (1979a, 1979b).

It is well established that the pulse shape and duration of these waveforms change as a function of load resistance and that actual patient resistance in the clinical setting also varies. To specify the pulse shape and duration of these waveforms more completely, four values of load resistance—25, 50, 100, and 125 ohms—were chosen for Table US.DD.1 (see also Figure US.DD.1). These values of resistance were chosen for convenience of testing and standardizing the waveform and may not correspond to the extremes or the mean values encountered in clinical practice. In the third edition of the standard, however, a load resistance of 125 ohms was added to better accommodate the observed range of patient impedances.

The values for $I_p$, $I_R$, $t_r$, $t_{50}$, and $t_{10}$ were determined in consultation with the manufacturers by overlaying waveforms from defibrillator models referenced in recent clinical studies (Pantridge et al., 1975; Campbell et al., 1977; Gascho et al., 1979a) to determine an acceptable waveform envelope, and then adding a tolerance band to account for the 20 % component variation consistent with the state-of-the-art in the manufacture of damped sinusoidal waveform defibrillators.

In the third edition of ANSI/AAMI DF2, it was recognized that the specification did not address waveform performance beyond the initial lobe and subsequent undershoot, if any. Nevertheless, improperly chosen RLC combinations can result in physiologically active current levels for considerable time, especially for high-impedance patients. Such currents are well beyond the chronaxie for defibrillation (Kroll, 1993). At longer durations, especially in highly damped circuits, RLC circuits approach exponential currents with similarities to capacitive discharges. Small, persistent currents of this type have been suspected of refibrillation phenomena (Schuder et al., 1980) and post-shock arrhythmia (Peleska, 1963). Accordingly, for waveform durations greater than 20 milliseconds, a table of maximum allowable currents (expressed as a percentage of waveform peaks) was adopted. It is of note that the original waveforms of Lown and Edmark, for which much of the published efficacy literature is based, meet the modified limits easily.

The committee elected to relax the waveform reverse current undershoot specification in view of evidence that undershoot is not detrimental to performance. Undershoot was described as a percentage of peak forward currents.

**Monophasic truncated exponential waveform**

The family of truncated exponential waveforms often referred to as Schuder waveforms has been studied extensively with animals (Schuder et al., 1980) but has not been as critically or extensively evaluated clinically as the damped sinusoidal waveform. One published study (Anderson and Suelzer, 1976) has documented the safety and efficacy of one such waveform. Other references note that defibrillators using

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this waveform have been employed with some field success (Bocka and Swor, 1991; Mols et al., 1994). This waveform also changes pulse shape and duration as a function of patient resistance. For various values of patient resistance, the voltage to which the energy storage capacitor is charged remains relatively constant; the duration, and hence the final current, is adjusted to deliver approximately the energy that has been selected. To specify the pulse shape and duration of this waveform more completely, four values of load resistance—25, 50, 100, and 125 ohms—were chosen for Table US.DD.2 (see also Figure US.DD.2). These values of resistance were chosen for convenience of testing and standardization of the waveform and may not correspond to the extremes or the mean values encountered in clinical practice.

The chosen values and range of $I_p$ and $t_d$ in the standard were compared with the waveform specifications of the manufacturer of the defibrillator model referenced in a clinical study (Anderson and Suelzer, 1976) and are consistent with the state-of-the-art in the manufacture of truncated exponential waveform defibrillators. A tolerance band was added to account for a 20 % component variation.

It was noted by the committee that few experimental reports in animals favor monophasic truncated exponential waveforms with durations of longer than 20 milliseconds. Although currents required for defibrillation decline modestly as durations approach 20 milliseconds, the energy required for defibrillation climbs sharply by 40 milliseconds (Wilson et al., 1989, Gold et al., 1979). Further, waveforms beyond 20 milliseconds have declining safety margins between those currents necessary to defibrillate and those exhibiting postshock dysfunction (Jones et al., 1980). Nevertheless, no human data were available to justify limiting the waveform duration, and the maximum duration specification was left intact.

Similarly, at durations less than 3 milliseconds, energy requirements do not decrease, but current requirements are seen to increase sharply (Holmes et al., 1980), which is exacerbated by higher waveform tilts. This is further illustrated in animal studies by rapidly changing defibrillation success contour graph profiles below 3 milliseconds (Gold et al., 1979). The committee noted that specifying the minimum duration of this waveform category to at least 3 milliseconds for energies greater than 5 joules minimizes these issues and does not impair the ability of devices to deliver effective current/energy combinations.

Tilt is recognized as an important variable in defibrillation efficacy and defibrillator efficiency. In general, higher-tilt monophasic waveforms require higher initial currents for equal efficacy than do low-tilt waveforms (Holmes et al., 1980; Bourland et al., 1978). Although exact relationships between tilt and efficacy have remained unclear, it is strongly suggested that very high-tilt monophasic waveforms (which approach pure untruncated capacitive discharges) are associated with refibrillation phenomena (Schuder et al., 1980). In adopting a tilt specification, it was noted by the committee that 80 % tilt represents energy delivery efficiencies of approximately 96 %, and tilts above that value could do little for defibrillator design.

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

**Table US.DD.1—Specifications for damped sinusoidal output waveforms**

| **Load Resistance** | | | | |
|---|---|---|---|---|
| **Waveform Parameter** | **25 Ohms** | **50 Ohms** | **100 Ohms** | **125 Ohms** |
| $I_p$ (amperes) | $96\ \alpha \geq I_p \geq 55\ \alpha$ | $66\ \alpha \geq I_p \geq 45\ \alpha$ | $46\ \alpha \geq I_p \geq 25.1\ \alpha$ | $46\ \alpha \geq I_p \geq 20\ \alpha$ |
| $\lvert I_R \rvert$ (amperes) | $\lvert I_R \rvert \leq 0.40\ I_p$ | $\lvert I_R \rvert \leq 0.40\ I_p$ | $\lvert I_R \rvert \leq 0.40\ I_p$ | $\lvert I_R \rvert \leq 0.40\ I_p$ |
| $I_{20\ max}$ (amperes) | $\lvert I_{20\ max} \rvert \leq 0.01 I_p$ | $\lvert I_{20\ max} \rvert \leq 0.015 I_p$ | $\lvert I_{20\ max} \rvert \leq 0.04 I_p$ | $\lvert I_{20\ max} \rvert \leq 0.075 I_p$ |
| $t_r$ (ms) | $1.60 \geq t_r \geq 0.50$ | $1.42 \geq t_r \geq 0.40$ | $1.25 \geq t_r \geq 0.30$ | $1.25 \geq t_r \geq 0.20$ |
| $t_{50}$ (ms) | $4.60 \geq t_{50} \geq 2.00$ | $4.17 \geq t_{50} \geq 2.10$ | $6.40 \geq t_{50} \geq 2.30$ | $6.40 \geq t_{50} \geq 2.30$ |
| $t_{10}$ (ms) | $6.90 \geq t_{10} \geq 3.00$ | $9.20 \geq t_{10} \geq 3.10$ | $19.60 \geq t_{10} \geq 4.00$ | $19.60 \geq t_{10} \geq 4.00$ |

NOTE

$\alpha$ = sqrt(E/360), where E = selected energy that would be delivered to a 50 ohm resistive load

$I_p$ = peak current of the waveform

$\lvert I_R \rvert$ = absolute value of the reverse current of the waveform

$\lvert I_{20\ max} \rvert$ = maximum current after 20 ms for any patient impedance between 25 and 125 ohms

$t_r$ = 10 % to 90 % risetime of the first lobe of the current waveform

$t_{50}$ = waveform associated with the 50 percentage points of the first lobe of the current waveform

$t_{10}$ = waveform associated with the 10 percentage points of the first lobe of the current waveform

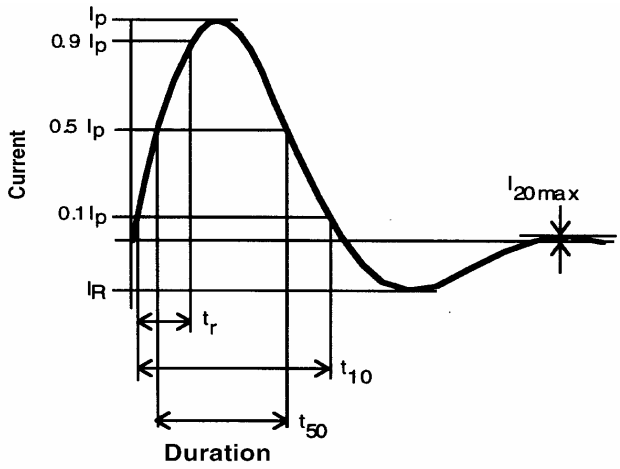


**Figure US.DD.1—Damped sinusoidal waveform parameters**

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

 

**Table US.DD.2—Specifications for monophasic truncated exponential output waveforms**

| Load Resistance | | | | |
|---|---|---|---|---|
| **Waveform Parameter** | **25 Ohms** | **50 Ohms** | **100 Ohms** | **125 Ohms** |
| $I_p$ max (amperes) | 80 | 40 | 20 | 20 |
| tilt, max (percent) | 80 | 80 | 80 | 80 |
| $t_d$ max (ms) | 20 | 24 | 40 | 40 |
| $t_d$ min (ms) | 3 | 3 | 3 | 3 |

NOTE

$I_p$ = peak current of the waveform

$I_f$ = final waveform current at time of truncation

tilt,max = $(I_p - I_f)/I_p \leq 80$ % for all patient impedances between 25 and 125 ohms

$t_d$ max = maximum waveform duration for any patient impedance between 25 and 125 ohms

$t_d$ min = minimum waveform duration for any patient impedance between 25 and 125 ohms for energies greater than 5 joules

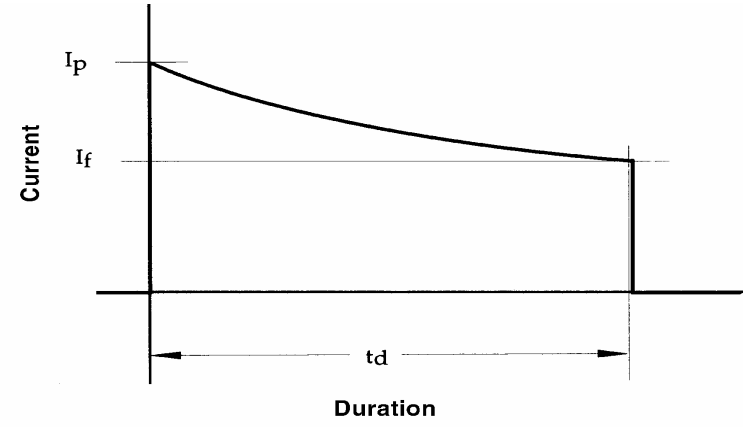


**Figure US.DD.2—Truncated exponential waveform parameters**

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

## Annex EE (U.S.)
(informative)

## Cited references in Annexes CC and DD

This annex applies to AAMI DF80 only and is not included in IEC 60601-2-4:2002. This annex consists of cited references in Annexes CC and DD, which are additional informative text for U.S. only.


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