American National Standard

ANSI/AAMI DF80:2003/(R)2010

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

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.*

American National Standard

ANSI/AAMI DF80:2003/(R)2010
(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 and Reaffirmed 20 April 2010 by
American National Standards Institute, Inc.

Abstract: This standard specifies requirements for the safety of medical electrical equipment intended to defibrillate the heart by an electrical pulse via electrodes applied either to the patient's skin (external electrodes) or to the exposed heart (internal electrodes). This standard does not apply to implantable defibrillators, remote control defibrillators, or separate cardiac monitors.

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

AAMI Standard

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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All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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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.

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

MEDICAL ELECTRICAL EQUIPMENT—

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any EQUIPMENT declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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

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

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

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

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

Annexes AA and BB are for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;
– *test specifications, headings of subclauses and headings of items: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2007-08. At this date, the publication will be

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

INTRODUCTION

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

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

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of this Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this standard.

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

MEDICAL ELECTRICAL EQUIPMENT

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

SECTION ONE – GENERAL

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

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

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

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

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

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

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

1.2 Object

Replacement:

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

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment—Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995).