Medical electrical equipment—Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators, including Amendment 1

Approved 21 November 2018 by
AAMI

Approved 11 January 2019 by
American National Standards Institute, Inc.

Abstract: This consolidated version includes the amendment which updates references and clarifies the scope as well as provides additional information for AEDs, defibrillator electrodes, audible warnings and cables.

Keywords: cardiac defibrillators, automated external defibrillators, defibrillator electrodes
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.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

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.

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

© 2019 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee representation</td>
<td>v</td>
</tr>
<tr>
<td>Foreword</td>
<td>vii</td>
</tr>
<tr>
<td>201.1 Scope, object and related standards</td>
<td>1</td>
</tr>
<tr>
<td>201.2 Normative references</td>
<td>3</td>
</tr>
<tr>
<td>201.3 Terms and definitions</td>
<td>3</td>
</tr>
<tr>
<td>201.4 General requirements</td>
<td>6</td>
</tr>
<tr>
<td>201.5 General requirements for testing of me equipment</td>
<td>6</td>
</tr>
<tr>
<td>201.6 Classification of me equipment and me systems</td>
<td>7</td>
</tr>
<tr>
<td>201.7 Me equipment identification, marking and documents</td>
<td>7</td>
</tr>
<tr>
<td>201.8 Protection against electrical hazards from me equipment</td>
<td>11</td>
</tr>
<tr>
<td>201.9 Protection against mechanical hazards of me equipment and me systems</td>
<td>18</td>
</tr>
<tr>
<td>201.10 Protection against unwanted and excessive radiation hazards</td>
<td>18</td>
</tr>
<tr>
<td>201.11 Protection against excessive temperatures and other hazards</td>
<td>18</td>
</tr>
<tr>
<td>201.12 * Accuracy of controls and instruments and protection against hazardous outputs</td>
<td>20</td>
</tr>
<tr>
<td>201.13 Hazardous situations and fault conditions</td>
<td>22</td>
</tr>
<tr>
<td>201.14 Programmable electrical medical systems (pems)</td>
<td>22</td>
</tr>
<tr>
<td>201.15 Construction of me equipment</td>
<td>22</td>
</tr>
<tr>
<td>201.16 Me systems</td>
<td>27</td>
</tr>
<tr>
<td>201.17 Electromagnetic compatibility of me equipment and me systems</td>
<td>27</td>
</tr>
<tr>
<td>201.101 * Charging time</td>
<td>27</td>
</tr>
<tr>
<td>201.102 Internal electrical power source</td>
<td>27</td>
</tr>
<tr>
<td>201.103 * Endurance</td>
<td>30</td>
</tr>
<tr>
<td>201.104 * Synchronizer</td>
<td>32</td>
</tr>
<tr>
<td>201.105 * Recovery of the monitor and/or ECG input after defibrillation</td>
<td>33</td>
</tr>
<tr>
<td>201.106 * Disturbance to the monitor from charging or internal discharging</td>
<td>36</td>
</tr>
<tr>
<td>201.107 * Requirements for rhythm recognition detector</td>
<td>37</td>
</tr>
<tr>
<td>201.108 Defibrillator electrodes</td>
<td>38</td>
</tr>
<tr>
<td>201.109 * External pacing</td>
<td>40</td>
</tr>
<tr>
<td>202 * Electromagnetic compatibility – Requirements and tests</td>
<td>45</td>
</tr>
<tr>
<td>Annex C (informative) Guide to marking and labelling requirements for me equipment and me systems</td>
<td>48</td>
</tr>
<tr>
<td>Annex AA (informative) Particular guidance and rationale</td>
<td>50</td>
</tr>
<tr>
<td>Bibliography</td>
<td>70</td>
</tr>
<tr>
<td>Index of defined terms used in this particular standard</td>
<td>71</td>
</tr>
<tr>
<td>Figure 201.101 – Dynamic test for limitation of energy from different parts of the me equipment</td>
<td>13</td>
</tr>
<tr>
<td>Figure 201.102 – Allowed current versus applied test voltage</td>
<td>17</td>
</tr>
<tr>
<td>Figure 201.103 – Examples of cord anchorages that require testing</td>
<td>26</td>
</tr>
</tbody>
</table>

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

PREVIEW COPY
Figure 201.104 – Test apparatus for flexible cords and their anchorages .................................................................27
Figure 201.105 – Arrangement for test of recovery after defibrillation .................................................................34
Figure 201.106 – Arrangement of monitoring electrodes on sponge .................................................................35
Figure 201.107 – Arrangement for recovery test after defibrillation .................................................................35
Figure 201.108 – Arrangement for test of disturbance from charging and internal discharging ............................37
Figure 201.109 – Test circuit for offset instability/ internal noise determination .........................................................
Figure 201.110 – Test circuit for defibrillator overload test of pacing output circuitry .................................................45

Table 201.101 – Distributed essential performance requirements .................................................................................. 6
Table 201.102 – Rhythm recognition detector categories .........................................................................................37
Table 201.C.101 – Marking on the outside of a cardiac defibrillator or its parts ....................................................48
Table 201.C.102 – Marking of controls and instruments of a cardiac defibrillator ....................................................48
Table 201.C.103 – Accompanying documents, general ..............................................................................................49
Table 201.C.104 – Accompanying documents, instructions for use ........................................................................49
Table 201.C.105 – Accompanying documents, technical description ........................................................................49
Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010 .................................................................65

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Committee representation

Association for the Advancement of Medical Instrumentation
Defibrillator Committee

The adoption of IEC 60601-2-4:2010/A1 as an amendment to an existing national standard, ANSI/AAMI/IEC 60601-2-4:2010, was initiated by the AAMI Defibrillator Committee. U.S. representatives played an active role in developing the IEC standard.

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:

**Cochair:** Oscar Tovar-Calderon, MD

**Members:**
- Regis DeSilva, MD, American College of Surgeons
- Ram Dhurjaty
- Nicole Hurley, PhD, WL Gore & Associates
- Janice Jenkins, PhD, University of Michigan School of Dentistry
- Amanda Jones, Health Canada
- Shen Luo, PhD, Mindray
- Christina McKenzie, Maryland Occupational Safety and Health
- Bokang Motlotle, New York Presbyterian Hospital
- David Selvitelli, Cardinal Health
- Kok-Swang Tan, PhD, Medical Devices Bureau Health Canada
- Ann Thorn, Philips
- Oscar Tovar-Calderon, MD, FDA/CDRH
- Gero Van Wagner, Spacelabs Healthcare
- Jeffrey Wiser, 3M Healthcare
- Brian Young, G. E. Healthcare

**Alternates:**
- Joe Basta, Spacelabs
- Loriano Galeotti, PhD, FDA/CDRH
- Don Lin, PhD
- Nancy Moreyra, Philips
- Bob Zito, Stryker Instruments

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.
Background of ANSI/AAMI adoption of IEC 60601-2-4:2010/A1:2018

As indicated in the foreword to the main body of this document (page vii), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising of all national electrotechnical committees. The United States is one of the IEC members that took an active role in the development of this amendment, which was developed by the IEC Technical Subcommittee 62D, Electromedical equipment.


AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft of the Amendment to IEC 60601-2-4, the AAMI DF, Defibrillator Committee decided to adopt it verbatim. This consolidated version contains the Amendment as well as the 2010 standard which has already been adopted by AAMI.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other IEC and ISO standards. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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 advances are made in technology and as new data come 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 Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE-This background does not contain provisions of the American National Standard, Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators, (ANSI/AAMI/IEC 60601-2-4), but it does provide important information about the development and intended use of the document.

NOTE-Beginning with the foreword on page vii, this American National Standard is identical to IEC 60601-2-4, A1.
Foreword

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). 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. 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 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 IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

DISCLAIMER
This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-4 bears the edition number 3.1. It consists of the third edition (2010-12) [documents 62D/857/FDIS and 62D/878/RVD] and its amendment 1 (2018-02) [documents 62D/1549/FDIS and 62D/1555/RVD]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.
This third edition constitutes a technical revision, revised to structurally align it with IEC 60601-1:2005 and to implement the decision of IEC SC 62A that the clause numbering structure of particular standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The principle technical changes are as follows:

- 201.8.8.3, test 4: added additional test options;
- Figure 201.105: provided example of stainless steel plates. Added note for 10 Hz generator or shockable rhythm generator;
- Figure 201.101: Changed orientation of the lower diode at the oscilloscope connection;
- 202.6.1, .2, .4: "Additions" and "Replacements" corrected to be as originally intended;
- 201.101.1: Clarified preconditioning of a non-rechargeable battery;
- 201.3.207: Clarified definition of DUMMY COMPONENT;
- 201.15.4.101: In paragraph b), added reduced flex requirements for sterilizable internal paddles with specified limit on sterilization cycles;
- 201.15.4.3.103: Added an option for devices having non-changeable pre-programmed energy-setting sequences;
- 201.102.3.1, 2: Changed from specified defibrillation cycles to use of pre-programmed defibrillation sequence;
- 202.6.2.2.1: Changed ESD discharge sequence to match IEC 60601-1-2, third edition.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- Test specifications: italic type.
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title Medical electrical equipment, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be
• reconfirmed,
• withdrawn,
• replaced by a revised edition, or
• amended.

IMPORTANT – The ‘colour inside’ logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Medical electrical equipment—Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators, including Amendment 1

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to implantable DEFIBRILLATORS, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [2]). 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. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

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 addresses considerations in waveform selection.

---

1 The general standard is IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

2 Numbers in square brackets refer to the bibliography.