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Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment



American National Standard

ANSI/AAMI/IEC 60601-2-27:2011/(R)2016 (Revision of ANSI/AAMI EC13:2002/(R)2007)

Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

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Abstract: This standard specifies basic safety requirements and essential performance for electrocardiographic (ECG) monitoring equipment. It is applicable to ECG monitoring equipment used in a hospital environment. If it is used outside the hospital environment, such as in ambulances and air transport, the ECG monitoring equipment shall comply with this standard. This standard is not applicable to electrocardiographic monitors for home use and ECG telemetry systems. However, manufacturers should consider using relevant clauses of this standard as appropriate for their intended use/intended purpose. Ambulatory ("Holter") monitors, fetal heart rate monitors, pulse plethysmographic devices, and other ECG recording equipment are outside the scope of this particular standard.

Keywords: electromedical equipment, ECG, monitors, medical electrical equipment

AAMI Standard

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

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 60601-1:2005	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI	Major technical variations
Technical Corrigendum 1 and 2	ES60601-1:2005/A2:2010	
	ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC 80601-2-30:2009 and Technical	ANSI/AAMI/IEC 80601-2-30:2009 and 9	Identical (with inclusion)
Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009	C1 Identical to Corrigendum 1
	(amdt) – consolidated text	
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC_TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
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IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007 ntended to allow	VANST/AAMI/AEC)62366:2007s to evaluate	tidenticantent
IEC/TR 80002-1:2009 f the docum	ANSI/EC/TR-80002-1:2009 purchasing o	dentical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009 For a complete (ANSI/AAMI/ISO_7199:2009 cument conta	dentical/Lat
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010 + I-97	/ANSI/AAMI/ISO 863852010/WW.aami.org.	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and	Identical
Amendment 1:2006	Amendment 1:2006/(R)2009	
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2006 (2006-08-01 corrected)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11633:2009	Identical
ISO 11/3/-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
150/15 12417:2011	ANSI/AAMI/ISO 11R12417:2011	Identical
150 13408-1:2008	ANSI/AAIVII/ISO 13408-1:2008	Identical
150 13406-2.2003	ANSI/AAIVII/ISO 13406-2.2003	Identical
150 13406-3.2000	ANSI/AAMI/ISO 13406-5.2006	Identical
ISO 13408-4.2005	ANSI/AAMI/ISO 13408-4.2003	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485-2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2003((1)2003	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959 2000 Technology	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO_14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009 his is a preview	eANSI/AAMI/ISO 14987 2009 uidance docu	ndentical nd is
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007 Intended to allow	VANSI/AAMI/ISO/14971:2007/(R)2010aluale	Identical tent
ISO 15223-1:2007 and A1 2008 OCUN	ANSI/AAMI/ISO 15223-1:2007 and A1:2008 0	edentical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009For a complete of	ANSI/AAMI/ISO\15674:2009ument, conta	ddentical/ at
ISO 15675:2009 +1-97	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI/ISO TID40440:0005	Major technical variations
150/1K 10142:2000		Major tochnical variations
ISO 17665 1:2006	ANSI/AANI 31012004	
ISO 17003-1.2000 ISO/TS 17665-2:2000		
ISO 18/72:2006	ANGI/AANI/ISO 11X 17003-2.2009 ANGI/AAMI/ISO 18/72-2006//P\2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and	Identical
	A1:2005/(R)2009	
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Electrocardiograph (ECG) Committee

The adoption of IEC 60601-2-27 as a revision of ANSI/AAMI EC13:2002/(R)2007 was initiated by the AAMI ECG/Cardiac Monitor and Diagnostic ECG Working Group of the AAMI ECG 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 ECG Committee had the following members:

 Cochairs
 Carl A. Pantiskas Ahmet Turkmen, BS MS PhD

 Members:
 Arthur R. Eddy, Jr. Luis A. Melendez, Partners Healthcare George Moody, Massachusetts Institute of Technology Carl A. Pantiskas, Draeger Medical Systems Inc. Jonathan Steinberg, MD, St Lukes Roosevelt Hospital Center Richard A. Sunderland, Welch Allyn, Inc. Ahmet Turkmen, BS MS PhD, University of Wisconsin-Stout Brian J. Young, GE Healthcare Sophia Zhou, PhD FACC; Philips Electronics North America;

The AAMI EC/Cardiac Monitor and Diagnostic ECG Working Group had the following members:

Cochairs:	Luis A. Melendez
	Richard A. Sunderland
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Members:	int Spectan Dhuriaty, Dhuriaty Electronics, Censultings LLG evaluate the content Richard Diefes, ECRI Institute Greg Downs, Spacelabs Medical Inc. making a purchasing decision.
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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 60601-2-27:2011

As indicated in the foreword to the main body of this document (page ix), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprised of all national electrotechnical committees. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by the IEC Technical Subcommittee 62D, Electromedical equipment, maintenance team (MT) 22 on Electromedical diagnostic and patient monitoring equipment.

U.S. participation in IEC/SC 62D is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the U.S. National Committee of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft International Standard of IEC 60601-2-27:2011, the AAMI EC/WG 04, Cardiac Monitor and Diagnostic ECG Working Group of the AAMI ECG Committee, which serves as the U.S. Technical Advisory sub-Group to MT22, decided to adopt it verbatim as a revision of ANSI/AAMI EC13:2002/(R)2007.

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.

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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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NOTE-This background does not contain provisions of the American National Standard, Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (ANSI/AAMI/IEC 60601-2-27:2011), but it does provide important information about the development and intended use of the document.

For a complete copy of this AAMI document, contact AAMI at

NOTE-Beginning with the foreword on page ix, this American National Standard is identical to IEC 60601-2-27:2011.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT -

Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

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 cooperation 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.
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International standard IEC 60601-2-27 has been prepared by IEC subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60601-2-27 published in 2005. This edition constitutes a technical revision to the new structure of IEC 60601-1:2005 (third edition).

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

FDIS	Report on voting
62D/900/FDIS	62D/913/RVD

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

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.

Advancing Safety in Healthcare Technology

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" This is a preview edition of an AAMI guidance document and is mandatory for compliance with a requirement of a test is recommended but is not mandatory for compliance with this station gurchasers to evaluate the content
- "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 this publication 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.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereinafter referred to as the general standard.

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 requirements of this particular standard take priority over those of the general standard.

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



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American National Standard

ANSI/AAMI/IEC 60601-2-27:2011/(R)2016

MEDICAL ELECTRICAL EQUIPMENT -

Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 *Scope

Replacement:

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 201.3.63 and hereinafter also referred to as ME EQUIPMENT. This particular standard applies to ME EQUIPMENT used in a hospital environment as well as when used outside the hospital environment, such as in ambulances and air transport. This particular standard also applies to ECG telemetry systems used in a hospital environment.

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ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment, such as in ambulances and air transport, shall comply with this particular standard. Additional standards may apply to ME EQUIPMENT for those environments of use. Intended to allow potential purchasers to evaluate the content

of the document before making a purchasing decision.

This standard is not applicable to electrocardiographic monitors for home use. However, MANUFACTURERS should consider using relevant clauses of this standard as appropriate for their INTENDED USE. +1-977-249-8226 or visit www.aami.org.

Ambulatory ("Holter") monitors, fetal heart rate monitoring, pulse plethysmographic devices, and other ECG recording equipment are outside the scope of this particular standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

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