American National Standard

ANSI/AAMI/IEC 60601-1-12:2016

Medical electrical equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

AAMI
Advancing Safety in Healthcare Technology

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 frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare 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 decision-making.

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 AAMI Vice President, Standards Policy and Programs. 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*.

Medical Electrical Equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Approved 5 June 2016 by
AAMI

Approved 6 October 2016 by
American National Standards Institute, Inc.

Abstract: Applies to basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended for use by their manufacturers for use in the EMS environment. Does not apply to equipment and systems intended for use solely in home healthcare environment or professional healthcare facilities.

Keywords: collateral standard, MEE, ME

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. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation
Home Care and EMS Environments Committee

The adoption of IEC 60601-1-12:2014 as an American National Standard was initiated by the AAMI Home Care and EMS Environments Committee. The AAMI Home Care and EMS Environments Committee also functions as a U.S. Technical Advisory Group to the relevant work in the International Electrotechical Commission (IEC). U.S. representatives from the AAMI Home Care and EMS Environments Committee (U.S. Sub-TAG for IEC/SC62A/JWG 8) played an active part in developing the IEC standard.

At the time this document was published, the **AAMI Home Care and EMS Environments Committee** had the following members:

Cochairs:
Pamela Gwynn, UL LLC
Denny Treu, NxStage Medical Inc

Members:
Daniel Aghassian, Boston Scientific Corporation
Steve Bernard, Nestle HealthCare Nutrition Inc
Joann Brumbaugh FDA/CDRH
Ryan Burke, AJW Technology Consultants Inc
Gail Bynum, Smiths Medical
Ron Charnock, Kwikpoint/Gaia LLC
Anthony Ciccarello, Philips Electronics North America
Shannon Clark, UserWise Inc
Danny Concepcion, St Joseph Hospital Renal Center
Conor Curtin, Fresenius Medical Care
Reggie Cyrus
Susan Dorsch
Leonard Eisner, Eisner Safety Consultants
Ila Elson, Abbott Laboratories
Michael Friedman, Amgen Inc
Daryle Gardner-Bonneau, Bonneau and Associates
Donald Gillespie
Edward Halpern, Abbvie
John Hedley-Whyte, Harvard University
Dean Hooper, HE Consulting
Byron Jacobs, Sanford Healthcare
Mike Jaffe, Cardiorespiratory Consulting LLC
Kevin Jensen
Carolynn Johnson, Daedalus
Aaron Macan, Medtronic Inc Campus
Jim Milostan, Medical Specialties Distributors LLC
Wade Munsch, MET Laboratories Inc
Jan Frank Nielsen, Novo Nordisk
Pat Patterson, Agilis Consulting Group LLC
Brodie Pedersen, Logic PD
Stefan Robert, Cyberonics Inc
Adam Shames, Core Human Factors Inc
Tom Shanks, MDVentures
Yvette Simon, GFK
Nancy Stark, Clinical Device Group Inc
Bob Sugarman, RCS Performance Systems Inc
Chandresh Thakur, Becton Dickinson & Company
Bob Virag, TRIFID Medical Group LLC
Sara Wegener, Cardinal Health (MP&S)
Steve White, Medical Risk Management Consulting
Stephen Wilcox, Design Science Consulting
David Zinkus, Baxter Healthcare Corporation

Alternates:
Andy Doering, Medtronic Inc
Kesley Gallagher, Amgen Inc
Piyatida Haerr, GFK
Eric Johnson, Nestle HealthCare Nutrition Inc
Melissa Lemke, Agilis Consulting Group LLC
Debra Milamed, Harvard University
Dave Osborn, Philips Electronics North America
Robert Parks, Daedalus
Kulwinder Plahey, Fresenius Medical Care
Aftin Ross, FDA/CDRH
Allison Strochlic, UL LLC
Jon Ward, AJW Technology Consultants Inc
Joyce Young-Stewart, Baxter Healthcare

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 on AAMI adoption of IEC 60601-1-12:2014

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this standard.

International Standard IEC 60601-1-12 was developed by Joint Working Group (JWG) 8, Medical electrical equipment and systems for use in the emergency medical services environment, of Subcommittee (SC) 62A, Common aspects of electrical equipment used in medical practice, to provide terminology, requirements, and general recommendations to manufacturers of medical electrical (ME) equipment and ME systems that are intended for use in the emergency medical services environment. The object of this standard is to provide general requirements for ME equipment and ME systems carried to the scene of an emergency and used there, as well as in transport, in situations where the ambient conditions differ from indoor conditions.

U.S. participation in IEC/SC 62A/JWG 8 is organized through the U.S. Technical Advisory Group for IEC/SC 62A, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the United States National Committee. AAMI also administers the International Secretariat for IEC/SC 62A on behalf of the United States, and U.S. experts made a contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the International Standard IEC 60601-1-12:2014, the AAMI Home Care and EMS Environments Committee, which serves as the U.S. Technical Advisory sub-Group (sub-TAG) to JWG 8, decided to adopt it identically.

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.

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

NOTE—This background does not contain provisions of the American National Standard, *Medical Electrical Equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment* (ANSI/AAMI/IEC 60601-1-12:2016), but it does provide important information about the development and intended use of the document.

NOTE—Beginning with the IEC foreword on page ix, this American National Standard is identical to IEC 60601-1-12:2014.

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.
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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.

International standard IEC 60601-1-12 has been prepared by a joint working group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This first edition constitutes a collateral standard to IEC 60601-1 (third edition): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

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

FDIS	Report on voting
62A/932/FDIS	62A/938/RVD

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, this International Standard has been approved by 18 P-members out of 19 having cast a vote.

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

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral 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 COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the 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 7.3.1 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 collateral 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.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

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 "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.

NOTE The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

Introduction

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the EMERGENCY MEDICAL SERVICES ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled, rough environment is a cause for concern.

This collateral standard was developed with contributions from clinicians, engineers and regulators. The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for the development of particular standards.

Medical electrical equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, which are intended, as indicated in the instructions for use by their MANUFACTURER, for use in the EMS ENVIRONMENT (EMERGENCY MEDICAL SERVICES ENVIRONMENT), as defined in 3.1.

NOTE 1 For the purposes of this standard, the intent of the MANUFACTURER is indicated in the instructions for use. The RESPONSIBLE ORGANIZATION and the OPERATOR need to be aware that any other use outside the MANUFACTURER'S INTENDED USE can result in a HAZARDOUS SITUATION for the PATIENT.

The EMS ENVIRONMENT includes

– responding to and providing life support at the scene of an emergency to a PATIENT reported as experiencing injury or illness in a pre-hospital setting, and transporting the PATIENT, while continuing such life support care, to an appropriate professional healthcare facility for further care.
– providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the HOME HEALTHCARE ENVIRONMENT covered by IEC 60601-1-11 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-11 or this collateral standard. ME EQUIPMENT and ME SYSTEMS are often not solely intended for one environment. Such ME EQUIPMENT or ME SYSTEM can be intended for multiple use environments, and as such, if also intended for use in the EMS ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEM intended for both the EMS ENVIRONMENT and the professional healthcare facility environment.

NOTE 2 EMS ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can be used in locations with unreliable electrical sources and outdoor environmental conditions.

1.2 * Object

The object of this collateral standard is to provide general requirements for ME EQUIPMENT and ME SYSTEMS carried to the scene of an emergency and used there, as well as in transport, in situations where the ambient conditions differ from indoor conditions.

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.