American National Standard

ANSI/AAMI HA60601-1-11:2015 & A1:2021

Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Consolidated Text REDLINE VERSION

(IEC 60601-1-11:2015, MOD)

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI HA60601-1-11:2015
and ANSI/AAMI HA60601-1-11:2015/A1:2021
(Consolidated text)

(IEC 60601-1-11:2015, MOD)

Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Approved 07 January 2022 by
AAMI

Approved 18 February 2022 by
American National Standards Institute, Inc.

Abstract This standard applies to the safety and essential performance of medical electrical equipment and medical electrical systems, which are intended by the manufacturer for use in home care applications usually without continual professional supervision and temporarily in the clinical environment. These medical electrical equipment and medical electrical systems will frequently be used in locations where driving power and safety means of the electrical installation is not reliable. The amendment addresses changes to terminology and references since the main document was finalized.

Keywords: medical electrical equipment, medical electrical systems, safety, essential performance, home healthcare

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Committee representation

Association for the Advancement of Medical Instrumentation

Home Care and EMS Environments Committee

The adoption of IEC 60601-1-11:2015 and Amendment 1:2020 as an American National Standard was initiated by the AAMI Home Care and EMS Environments Committee. AAMI Home Care and EMS Environments Committee provides subject matter expertise to the U.S. TAG for IEC/SC 62A which is the responsible group for providing the U.S. input to the relevant group in IEC. U.S. representatives from AAMI Home Care and EMS Environments Committee and the TAG played an active part in developing the IEC document.

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

Cochairs:
Pamela Gwynn
Dennis Michael Treu

Members:
Kristofer Adam R. Shames, Core Human Factors Inc
Andrew Block, Stryker Medical Division
Peter Boge, Novo Nordisk
Ryan Paul Burke, AJW Technology Consultants Inc
Gail Bynum, Smiths Medical
Anthony Ciccarello, Philips
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Shannon Clark, UserWise Inc
Susan Dorsch, Susan Dorsch (Individual)
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JoAnn Fujikawa, FDA - CDRH
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Sara Waxberg McNew, Design Science Group, LLC

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 of ANSI/AAMI adoption of IEC 60601-1-11:2015 as HA60601-1-11 and Amendment 1:2020

As indicated in the foreword to the main body of this document (page vii), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard and its amendment, which was developed by IEC/SC 62A.

U.S. participation in IEC is organized through the U.S. Technical Advisory Group, IEC/SC 62A, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

The AAMI Home Care and EMS Environments Committee initiated the U.S. adoption of IEC 60601-1-11:2015.

The major differences between ANSI/AAMI HA60601-1-11 and IEC 60601-1-11:2015 is the removal of home care facilities as a home environment; the clarification of alternative life-supporting methods as a PRIMARY OPERATING FUNCTION when applying the USABILITY ENGINEERING PROCESS; the modification of a compliance statement to include inspection of the usability engineering file; and the inclusion of PRIMARY OPERATING FUNCTION in the glossary.

ANSI/AAMI HA60601-1-11:2015 was approved by the American National Standards Institute (ANSI) on 25 August 2015.

AAMI encourages its committees to harmonize their work with International Standards in the area of safety and essential performance for medical electrical equipment. Upon review of IEC 60601-1-11:2015 and Amendment 1:2020, the U.S. TAG for IEC/SC 62A and the AAMI Home Care and EMS Environments Committee decided to adopt the Amendment verbatim with the main document having US deviations, as Amendment 1 to ANSI/AAMI HA60601-1-11.

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

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the recommended practice. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

"May" is used to indicate that a course of action is permissible within the limits of the standard. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

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 technological advances are made and as new data comes to light.

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 1-11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* (ANSI/AAMI HA 60601-1-11:2015 & A1:2021), but it does provide important information about the development and intended use of the document.

U.S. (AAMI) Deviations from IEC 60601-1-11:2015

As part of an effort to harmonize standards throughout an increasing global industry, the AAMI Home Use Committee voted to adopt IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*. The AAMI Home Use Committee also agreed that a number of U.S. deviations to the IEC standard would improve the document. The deviations are only to the main document and not to the Amendment 1.

Deviations are listed below. A rationale for each change has also been provided by the committee. Within the document, deletions are indicated by ~~strikethrough~~ and additions are indicated by underline.

Please note that beginning with IEC Foreword, this document is identical to IEC 60601-1-11 with Amendment 1. The clauses where there are U.S. deviations are highlighted throughout the text and a hyperlink in the highlighted section will direct the reader back to this page which lists all of the deviations. Please pay particular attention to the deviations listed below as the deviations are not incorporated into the main text—just the hyperlink back to this page.

Terms and definitions

1. NOTE 2 in 3.1 modified.

   Note 1 to entry: For the purpose of this collateral standard, a nursing home~~s~~ in the United States ~~are~~ is considered ~~HOME HEALTHCARE ENVIRONMENTS~~ a professional healthcare facility

Rationale: Elder care facilities in the U.S. are not considered a 'home environment'.

8.4

2. Additional sentence added to paragraph preceding NOTE 2.

   The actions associated with providing the alternative life-supporting methods shall be considered a PRIMARY OPERATING FUNCTION when applying the USABILITY ENGINEERING PROCESS.

Rationale: Text added to reinforce that the usability engineering process is necessary for validation of the instructions for use.

10.2

3. Compliance statement modified.

   Compliance is checked by inspection and inspection of the USABILITY ENGINEERING FILE as appropriate.

Rationale: Inspection of the usability engineering file added to reinforce that the usability engineering process is necessary for validation of the instructions for use.

Index of defined terms

4. PRIMARY OPERATING FUNCTION added to glossary list

   PRIMARY OPERATING FUNCTION ..... IEC 60601-1:2005, 3.146

Rationale: The additional text in 8.4 necessitates adding the term to the index.

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.
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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.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-1-11 edition 2.1 contains the second edition (2015-01) [documents 62A/959/FDIS and 62A/978/RVD] and its amendment 1 (2020-07) [documents 62A/1395/FDIS and 62A/1410/RVD].

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 60601-1-11 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.

It is published as a double logo standard.

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

This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

– correction of test method for relative humidity control at temperatures above 35 °C;
– redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
– harmonizing with the changes to the amendments to the general standard and other collateral standards.

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

In the IEC 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 collateral 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 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.

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 mandatory implementation nationally not earlier than 3 years from the date of publication.

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.

Introduction

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the HOME HEALTHCARE ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

The potential lack of training of the LAY OPERATOR and possibly of those supervising the use of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM and their level of education need to be addressed in the development of the ACCOMPANYING DOCUMENTS and in the relevant marking on the equipment itself so that this material can be understood. This collateral standard gives special guidance on how this should be addressed in the instructions for use.

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.

INTRODUCTION to Amendment 1

The second edition of IEC 60601-1-11 was published in 2015. Since the publication of IEC 60601-1-11:2015, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the third edition of IEC 60601-1-11, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, four items were presented to the National Committees present. All four items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-11.

The "short list" of issues was documented in the design specification for Amendment 1. As IEC 60601-1-11 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 6. JWG 6 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-11:2015, the style in force at the time of publication of IEC 60601-1-11 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare 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 for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.1, and specified by the MANUFACTURER in the instructions for use. This International Standard applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

The HOME HEALTHCARE ENVIRONMENT includes:

– the dwelling place in which a PATIENT lives;
– other places where PATIENTS are present both indoors and outdoors, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, covered by IEC 60601-1-12 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-12 or this collateral standard. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the HOME HEALTHCARE ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEMS intended for both the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

NOTE HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can frequently be used in locations with unreliable electrical sources and poor electrical grounding.

1.2 Object

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.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.