

American National Standard



ANSI/AAMI/ IEC 60601- 1-2:2014/ A1:2021

Medical electrical equipment—Part
1-2: General requirements for basic
safety and essential performance—
Collateral standard: Electromagnetic
disturbances—Requirements and
tests, Amendment 1

Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests, Amendment 1

Approved 07 January 2022 by
AAMI

Approved 01 February 2022 by
American National Standards Institute, Inc.

Abstract: This amendment addresses changes to terminology and references since the main document was finalized in 2014. The main document and this amendment provide requirements for the safety and essential performance for all medical electrical equipment dealing with electromagnetic disturbances.

Keywords: medical electrical equipment, medical electrical systems, safety, essential performance, electromagnetic disturbance, EMC

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Committee representation

Association for the Advancement of Medical Instrumentation

Electromagnetic Compatibility Committee

The adoption of Amendment 1 to IEC 60601-1-2:2014 as an American National Standard was initiated by the AAMI Electromagnetic Compatibility Committee. AAMI Electromagnetic Compatibility Committee provides input 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 Electromagnetic Compatibility Committee and the TAG played an active part in developing the IEC document.

At the time this document was published, the **AAMI Electromagnetic Compatibility Committee** has the following members:

Cochairs: Joshua W. Guag
Curtis L. Sponberg

Members: Eric V. Anderson, Philips
Jahan Azizi, Healthmark Industries Company Inc
Lawrence Banasky Jr., Stryker Instruments Division
Alan S. Berson, Bioresearch Funding Group
Stephen Briol, Nonin Medical Inc
Michael Britko, Draeger Medical Systems Inc
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Gerry Hutchings, Arthrex Inc
Joshua Kim, Hillrom, Inc
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Zhang Zhang, Stryker Endoscopy Division

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 Amendment 1 to IEC 60601-1-2:2014

As indicated in the foreword to the main body of this document (page v), 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, which was developed by IEC/SC 62A to publish an Amendment to IEC 60601-1-2, which updates references and other information to remain relevant and up to date.

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.

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 60601-1-2:2014/A1:2020, the U.S. TAG for IEC/SC 62A and the AAMI Electromagnetic Compatibility Committee decided to adopt it verbatim, as an Amendment to ANSI/AAMI/IEC 60601-1-2.

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 Beginning with the IEC foreword on page vii, this American National Standard is identical to IEC 60601-1-2:2014/A1:2020.

Foreword

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62A/1390/FDIS	62A/1405/RVD

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

The committee has decided that the contents of this amendment and the base 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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO 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 to Amendment 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, 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 fifth edition of IEC 60601-1-2, 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, 15 items were presented to the National Committees present. All 15 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 fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 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 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 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.

1.3.1 IEC 60601-1

Replace, in the second existing paragraph, the first two existing dashes with the following new dashes:

- "the general standard" designates IEC 60601-1 alone, including any amendments;
- "this collateral standard" designates IEC 60601-1-2 alone, including any amendments.

2 Normative references

Replace the existing references to IEC 60601-1 (including footnote 1), IEC 60601-1-8 (including footnote 2), IEC 60601-1-11, IEC 60601-1-12 (including footnote 3), IEC 61000-4-5, IEC 61000-4-11, CISPR 11 (including footnote 6), CISPR 14-1, CISPR 16-1-2 (including footnote 7), CISPR 32 and ISO 14971 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

Amendment 1:2012

Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Amendment 1:2012

Amendment 2:2020

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*

Amendment 1:2020

IEC 60601-1-12:2014, *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*

Amendment 1:2020

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*

Amendment 1:2017

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – Voltage dips, short interruptions and voltage variations immunity tests*

Amendment 1:2017

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

Amendment 1:2016

Amendment 2:2019

CISPR 14-1:2016, *Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission*

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*

Amendment 1:2017

CISPR 32:2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements*