


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
Consolidated Text REDLINE VERSION

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

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AAMI

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American National Standards Institute, Inc.

Abstract: Specifies general requirements and tests for basic safety and essential performance with regard to electromagnetic disturbances of medical electrical (ME) equipment and ME systems. Applicability of this collateral standard includes ME equipment and ME systems that have been found to have no essential performance. The amendment addresses changes to terminology and references since the main document was finalized in 2014.

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 IEC 60601-1-2:2014 and Amendment 1:2020 as an American National Standard was initiated by the AAMI Electromagnetic Compatibility Committee. AAMI Electromagnetic Compatibility Committee provides subject matter expertise to the U.S. TAG for IEC/SC 62A which is the responsible group for providing 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:

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Members: Eric V. Anderson, Philips
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Lawrence Banasky Jr., Stryker Instruments Division
Alan S. Berson, Bioresearch Funding Group
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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 60601-1-2:2014 and Amendment 1:2020

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 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.

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 and Amendment 1:2020, the U.S. TAG for IEC/SC 62A and the AAMI Electromagnetic Compatibility Committee decided to adopt both verbatim, as ANSI/AAMI/IEC 60601-1-2 and 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—This background does not contain provisions of the American National Standard, *Medical Electrical Equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances—Requirements and tests* (ANSI/AAMI/IEC 60601-1-2:2014 & A1:2021), but it does provide important information about the development and intended use of the document.

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

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

IEC 60601-1-2 edition 4.1 contains the fourth edition (2014-04) [documents 62A/916/FDIS and 62A/924/RVD] and its amendment 1 (2020-09) [documents 62A/1390/FDIS and 62A/1405/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 60601-1-2 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition constitutes a technical revision.

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

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

- specification of IMMUNITY TEST LEVELS according to the environments of INTENDED USE, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENTS;
- specification of tests and test levels to improve the safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS when PORTABLE RF communications equipment is used closer to the MEDICAL ELECTRICAL EQUIPMENT than was recommended based on the IMMUNITY TEST LEVELS that were specified in the third edition;
- specification of IMMUNITY tests and IMMUNITY TEST LEVELS according to the PORTS of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM;
- specification of IMMUNITY TEST LEVELS based on the reasonably foreseeable maximum level of ELECTROMAGNETIC DISTURBANCES in the environments of INTENDED USE, resulting in some IMMUNITY TEST LEVELS that are higher than in the previous edition; and
- better harmonization with the RISK concepts of BASIC SAFETY and ESSENTIAL PERFORMANCE, including deletion of the defined term “life-supporting”;

and the following additions:

- guidance for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS;
- guidance for adjustment of IMMUNITY TEST LEVELS when special considerations of mitigations or INTENDED USE are applicable;
- guidance on RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES; and
- guidance on identification of IMMUNITY pass/fail criteria.

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 collateral standard, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 1 includes 1.1, 1.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 1.1, 1.2 and 1.3.1 are all subclauses of Clause 1).

References to clauses within this collateral 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 collateral 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 collateral standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this collateral standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this collateral standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this collateral 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 A.

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 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 IEC publication in which to make products in accordance with the new requirements and to equip them 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 publication using a colour printer.

Introduction

The need for establishing specific standards for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is well recognized.

The requirements and tests specified by this collateral standard are generally applicable to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS as defined in 3.63 and 3.64 in the general standard. For certain types of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, these requirements might need to be modified by the special requirements of a particular standard. Writers of particular standards are encouraged to refer to Annex D for guidance in the application of this collateral standard.

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE without interfering with other equipment and systems in the ELECTROMAGNETIC ENVIRONMENTS in which they are intended by their MANUFACTURER to be used. The application of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

- safety services;
- other MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS;
- non-ME EQUIPMENT (e.g. computers);
- telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the application of ELECTROMAGNETIC IMMUNITY standards is essential to ensure safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. To ensure safety, MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE in the ELECTROMAGNETIC ENVIRONMENTS of INTENDED USE throughout their EXPECTED SERVICE LIFE.

This collateral standard specifies IMMUNITY TEST LEVELS for safety for ME EQUIPMENT and ME SYSTEMS intended by their MANUFACTURER for use in the professional healthcare facility environment or the HOME HEALTHCARE ENVIRONMENT. It recognizes that RF wireless communications equipment can no longer be prohibited from most PATIENT ENVIRONMENTS because in many cases it has become essential to the efficient provision of healthcare. This collateral standard also recognizes that, for certain SPECIAL ENVIRONMENTS, higher or lower IMMUNITY TEST LEVELS than those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT might be appropriate. This collateral standard provides guidance in determining appropriate IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS.

The IMMUNITY TEST LEVELS specified for BASIC SAFETY and ESSENTIAL PERFORMANCE are based on the reasonably foreseeable maximum of the ELECTROMAGNETIC DISTURBANCE phenomena in the applicable environments of INTENDED USE.

Not all ELECTROMAGNETIC DISTURBANCE phenomena are covered by this collateral standard, as it is not practical to do so. MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS need to address this during their RISK ASSESSMENT and evaluate if other ELECTROMAGNETIC DISTURBANCE phenomena could make their product unsafe. This evaluation should be based on the environments of INTENDED USE and the reasonably foreseeable maximum levels of ELECTROMAGNETIC DISTURBANCES expected throughout the EXPECTED SERVICE LIFE.

This collateral standard recognizes that the MANUFACTURER has the responsibility to design and perform VERIFICATION of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS to meet

the requirements of this collateral standard and to disclose information to the RESPONSIBLE ORGANIZATION or OPERATOR so that the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will remain safe throughout its EXPECTED SERVICE LIFE.

This collateral standard provides guidance in incorporating considerations regarding ELECTROMAGNETIC DISTURBANCES into the RISK MANAGEMENT PROCESS.

This collateral standard is based on existing IEC standards prepared by subcommittee 62A, technical committee 77 (ELECTROMAGNETIC COMPATIBILITY between electrical equipment including networks), ISO (International standards organization), and CISPR (International special committee on radio interference).

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.

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

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.

This collateral standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS in the presence of ELECTROMAGNETIC DISTURBANCES and to ELECTROMAGNETIC DISTURBANCES emitted by ME EQUIPMENT and ME SYSTEMS.

BASIC SAFETY with regard to ELECTROMAGNETIC DISTURBANCES is applicable to all ME EQUIPMENT and ME SYSTEMS.

1.2 Object

The object of this collateral standard is to specify general requirements and tests for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES and for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and 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.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone ~~(IEC 60601-1:2005+A1:2012)~~, including any amendments;
- "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;
- "this standard" designates the combination of the general standard and this collateral standard.