

American  
National  
Standard



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

MEDICAL ELECTRICAL EQUIPMENT – Part  
1-2: General requirements for basic safety  
and essential performance – Collateral  
Standard: Electromagnetic disturbances –  
Requirements and tests

# 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 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests**

Approved 10 March 2014 by  
**Association for the Advancement of Medical Instrumentation**

Approved 9 May 2014 by  
**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. They are in addition to the requirements of the general standard and serve as the basis for particular standards. Applicability of this collateral standard includes ME equipment and ME systems that have been found to have no essential performance.

**Keywords:** electromagnetic compatibility, EMC, electromagnetic disturbance

## AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

**CAUTION NOTICE:** This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at [www.aami.org](http://www.aami.org).

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

### *Published by*

Association for the Advancement of Medical Instrumentation  
4301 N. Fairfax Drive, Suite 301  
Arlington, VA 22203-1633  
[www.aami.org](http://www.aami.org)

© 2014 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at [www.aami.org](http://www.aami.org) or contact AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: 703-525-4890; Fax: 703-525-1067.

Printed in the United States of America

ISBN 1-57020-524-8

# CONTENTS

Glossary of equivalent standards.....	vii
Committee representation.....	viii
Background of ANSI/AAMI adoption of IEC 60601-1-2:2014.....	ix
FOREWORD .....	x
INTRODUCTION .....	xiii
1 Scope, object and related standards .....	1
1.1 * Scope .....	1
1.2 Object.....	1
1.3 Related standards .....	1
1.3.1 IEC 60601-1 .....	1
1.3.2 Particular standards .....	1
2 Normative references .....	2
3 Terms and definitions.....	4
4 General requirements.....	7
4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS .....	7
4.2 * Non-ME EQUIPMENT used in an ME SYSTEM .....	7
4.3 General test conditions .....	8
4.3.1 * Configurations .....	8
4.3.2 Artificial hand .....	8
4.3.3 * Power input voltages and frequencies .....	9
5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents .....	11
5.1 Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT .....	11
5.2 ACCOMPANYING DOCUMENTS .....	12
5.2.1 Instructions for use.....	12
5.2.2 Technical description .....	13
6 Documentation of the tests.....	14
6.1 General .....	14
6.2 Test plan .....	15
6.3 Test report.....	15
7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS.....	15
7.1 Protection of radio services and other equipment .....	15
7.1.1 * General.....	15
7.1.2 Operating modes.....	15
7.1.3 Multimedia equipment .....	15
7.1.4 * Subsystems .....	15
7.1.5 ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT .....	15
7.1.6 ME EQUIPMENT and ME SYSTEMS that include radio equipment .....	16
7.1.7 * ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices .....	16

7.1.8	ME EQUIPMENT and ME SYSTEMS containing X-ray generators.....	16
7.1.9	PATIENT physiological simulation.....	16
7.1.10	Artificial hand .....	17
7.1.11	PATIENT-coupled cables .....	17
7.1.12	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS .....	17
7.2	Protection of the PUBLIC MAINS NETWORK.....	17
7.2.1	* Harmonic distortion .....	17
7.2.2	* Voltage fluctuations and flicker .....	18
7.3	EMISSIONS requirements summary .....	18
8	Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS .....	18
8.1	* General.....	18
8.2	PATIENT physiological simulation.....	22
8.3	Termination of PATIENT-COUPLED parts .....	22
8.4	HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD .....	22
8.5	* Subsystems .....	23
8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS.....	23
8.7	* Operating modes.....	24
8.8	* Non-ME EQUIPMENT .....	24
8.9	* IMMUNITY TEST LEVELS .....	24
8.10	* IMMUNITY to proximity fields from RF wireless communications equipment.....	32
9	* Test report.....	34
Annex A	(informative) General guidance and rationale .....	37
A.1	Safety and performance.....	37
A.2	Testing of normally non-observable functions .....	37
A.3	Rationale for particular clauses and subclauses .....	37
Annex B	(informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS .....	52
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts.....	52
B.2	ACCOMPANYING DOCUMENTS, instructions for use .....	52
B.3	ACCOMPANYING DOCUMENTS, technical description .....	52
Annex C	(informative) Guidance in classification according to CISPR 11 .....	54
C.1	General .....	54
C.2	Separation into groups .....	54
C.3	Division into classes .....	55
Annex D	(informative) Guidance in the application of IEC 60601-1-2 to particular standards .....	56
D.1	General .....	56
D.2	Recommended modifications .....	56
D.2.1	Testing requirements.....	56
D.2.2	ACCOMPANYING DOCUMENTS.....	56
D.3	Cautions.....	56
Annex E	(informative) Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS .....	58
E.1	General .....	58

E.2	Summary of method for E.1 a) .....	61
E.3	Summary of method for E.1 b), c) and d) .....	61
E.4	Determination of EM DISTURBANCE level reduction .....	61
E.5	Assessment of EM DISTURBANCE sources .....	61
E.6	Reasonably foreseeable maximum EM DISTURBANCE levels .....	62
E.7	Determination of IMMUNITY TEST LEVELS .....	62
E.8	RF radiators in SPECIAL ENVIRONMENTS .....	63
E.9	Examples of mitigations and special conditions .....	63
Annex F (informative) RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES .....		65
F.1	General .....	65
F.2	General requirements for RISK MANAGEMENT .....	66
F.3	RISK ANALYSIS .....	67
F.4	RISK EVALUATION .....	71
F.5	RISK CONTROL .....	71
F.5.1	RISK CONTROL option analysis .....	71
F.5.2	Implementation of RISK CONTROL measure(s) .....	71
F.5.3	RESIDUAL RISK EVALUATION .....	72
F.5.4	RISK/benefit analysis .....	72
F.5.5	RISKS arising from RISK CONTROL measures .....	72
F.5.6	Completeness of RISK CONTROL.....	72
F.6	Evaluation of overall RESIDUAL RISK acceptability .....	73
F.7	RISK MANAGEMENT report.....	73
F.8	Production and post-production information.....	73
Annex G (informative) Guidance: Test plan .....		74
G.1	Test plan contents .....	74
Annex H (informative) PATIENT-coupled cables EMISSIONS.....		76
H.1	* Protection of other equipment from PATIENT cable conducted EMISSIONS .....	76
H.2	Test method .....	76
H.3	Rationale.....	76
Annex I (informative) Identification of IMMUNITY pass/fail criteria .....		78
I.1	General .....	78
I.2	IMMUNITY pass/fail criteria principles .....	78
I.2.1	General.....	78
I.2.2	IMMUNITY pass/fail criteria for non-ME EQUIPMENT used in an ME SYSTEM.....	78
I.2.3	IMMUNITY pass/fail criteria determination.....	78
I.3	IMMUNITY pass/fail criteria examples .....	79
I.3.1	General examples .....	79
I.3.2	Example of IMMUNITY pass/fail criteria for a radiological table system .....	80
Bibliography .....		82
Index of defined terms used in this collateral standard.....		85

Figure 1 – RC element of the artificial hand .....	9
Figure 2 – PORTS of ME EQUIPMENT and ME SYSTEMS.....	19
Figure 3 – Examples of environments of INTENDED USE .....	26
Figure A.1 – Examples of PORTS (from IEC 61000-6-1:2005).....	42
Figure A.2 – IEC 61000-4-2 Figure A.1 – Maximum values of electrostatic voltages to which OPERATORS can be charged while in contact with the materials mentioned in A.2 .....	48
Figure E.1 – Test plan development flow when SPECIAL ENVIRONMENTS are known .....	59
Figure E.2 – Sub-process for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS .....	60
Figure F.1 – Function of this collateral standard in the RISK MANAGEMENT PROCESS .....	65
Figure F.2 – Examples of multiple VERIFICATION methods for improving confidence in RISK levels .....	66
Figure H.1 – Setup for PATIENT-COUPLED cables conducted EMISSIONS test for ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27 .....	77
Table 1 – Power input voltages and frequencies during the tests (1 of 2).....	10
Table 2 – EMISSION limits per environment.....	18
Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal .....	20
Table 4 – * ENCLOSURE PORT .....	27
Table 5 – * Input a.c. power PORT (1 of 2).....	28
Table 6 – Input d.c. power PORT .....	30
Table 7 – * PATIENT coupling PORT.....	31
Table 8 – Signal input/output parts PORT .....	32
Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment .....	33
Table 10 – * Minimum test report contents (1 of 2) .....	34
Table A.1 – IEC/TR 61000-2-5 information considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY TEST .....	44
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts.....	52
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use.....	52
Table B.3 – ACCOMPANYING DOCUMENTS, technical description .....	53
Table E.1 – Examples of specific mitigations / environmental conditions .....	64
Table F.1 – Examples of EM phenomena that should be considered in a RISK ANALYSIS.....	68
Table G.1 – Recommended minimum test plan contents (1 of 2).....	74
Table H.1 – PATIENT-COUPLED conducted EMISSIONS recommended limit .....	76
Table I.1 – Example of IMMUNITY pass criteria for a radiological table system .....	81



## **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](http://www.aami.org/standards/glossary.pdf)

## Committee representation

### Association for the Advancement of Medical Instrumentation Electromagnetic Compatibility (EMC) Committee

The adoption of IEC 60601-1-02 as a revision of ANSI/AAMI/IEC 60601-1-02:2007 was initiated by the AAMI EMC Committee, which serves as the U.S. TAG (technical advisory group) for IEC/SC 62A/MT 23. U.S. representatives played an active role in developing the IEC standard.

Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI EMC Committee** had the following members:

<i>Cochairs</i>	Donald N. Heirman, University of Oklahoma Curtis L. Sponberg, Medtronic Inc.
<i>Members</i>	Eric V. Anderson, Philips Electronics North America Michael Bacik, Steris Corporation Alan S. Berson, PhD, Bioresearch Funding Group Steve Cantwell, Spacelabs Medical Inc. Lyle Cookson, Mindray DS USA Inc. Yadin David, EdD, CCE, PE, HCSP, Biomedical Engineering Consultants LLC Joseph F. Dyro, CCE, PhD Rich Eaton, Medical Imaging & Technology Alliance, a Division of NEMA Jeffrey L. Eggleston, MS, PE, Covidien Wally R. Elliott, CCE, University of Vermont Daniel J. Farley, GE Healthcare James J. Greco, Medapprove Inc. Rickey L. Hampton, Premier Inc. Byju Karipal, Hill-Rom Holdings Joshua Kim, Welch Allyn Inc. Ronald Reitan, Boston Scientific Corporation Stefan M. Robert, Cyberonics Inc. Bernard N. Segal, PhD, Jewish General Hospital/McGill University Donald Sherratt, Terumo BCT Jeffrey L. Silberberg, FDA/CDRH Ray P. Silkaitis, PhD, Merck & Co Inc. James D. Stewardson
<i>Alternates</i>	Richard Gardner, GE Healthcare Gaurav Gupta, Boston Scientific Corporation David McCall, Steris Corporation Ashwin A. Patel, Hospira Worldwide Inc. Bruce Qualey, Spacelabs Medical Inc. Dave Tyler, Terumo BCT Donald M. Witters, Jr., FDA/CDRH

---

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 60601-1-2:2014

As indicated in the foreword to the main body of this document (page x), 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 Technical Committee (TC) 62, *Electrical equipment in medical practice*, Subcommittee (SC) 62A, *Common aspects of electrical equipment used in medical practice*, to provide terminology, requirements, general recommendations and guidance for medical electrical equipment and medical electrical systems manufacturers and for technical committees responsible for particular standards.

U.S. participation in IEC/SC 62A is organized through the U.S. Technical Advisory Group to IEC/SC 62A. Experts from the United States make a considerable contribution to this standard.

ANSI/AAMI/IEC 60601-1-2:2014 was approved by the American National Standards Institute (ANSI) on 9 May 2014. This standard is one of the collateral or general standard within the IEC 60601-1 umbrella and is applicable to all of the particular or device specific standards (IEC 60601-2-xx), unless otherwise specified.

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.

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 recommended practice. “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.

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

---

NOTE—Beginning with the foreword on page x, this American National Standard is identical to IEC 60601-1-2:2014.

---

# INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

## MEDICAL ELECTRICAL EQUIPMENT –

### **Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests**

#### 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.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 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 60601-1-2 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 cancels and replaces the third edition of IEC 60601-1-2, published in 2007, and 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.

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

FDIS	Report on voting
62A/916/FDIS	62A/924/RVD

Full information on the voting for the approval of this 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 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 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.

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 “color inside” logo on the cover page of this publication indicates that it contains colors which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a color 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).



## 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);
- "this collateral standard" designates IEC 60601-1-2 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

#### 1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.