List of Titles

American National Standard

ANSI/AAMI/IEC 60601-1-2:2001

Medical electrical equipment—Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests

AAMI Association for the Advancement of Medical Instrumentation

The 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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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 decisionmaking.

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 Manager for Technical Development. 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*.

American National Standard ANSI/AAMI/IEC 60601-1-2:2001

Medical electrical equipment—Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests

Approved 24 September 2001 by
Association for the Advancement of Medical Instrumentation

Approved 6 November 2001 by
American National Standards Institute, Inc.

Abstract: Specifies requirements and tests for electromagnetic compatibility of equipment and/or systems and serves as the basis of electromagnetic compatibility requirements and tests in Particular Standards.

Keywords: EMC, electromedical device, electromagnetic interference, medical electrical equipment

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AAMI Standard

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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.

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International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:200x[1]	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations

International designation	U.S. designation	Equivalency
ISO 11607:200x[1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
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ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2001	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

[1] FDIS approved; being prepared for publication.

Committee representation

Association for the Advancement of Medical Instrumentation

Electromagnetic Compatibility Committee

The adoption of this standard was initiated by the Electromagnetic Compatibility Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of this standard does not necessarily imply that all committee members voted for its approval.

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

Chairs: Jeffrey L. Silberberg
Michael D. Willingham

Members: Keith Anderson, P.R. Glassel & Associates
Art Augustine, ECRI
Alan S. Berson, PhD, LDR Bioengineering Research Group
Robert G. Britain, National Electrical Manufacturers Association (NEMA)
Steve Cantwell, Spacelabs Medical Inc.
Yadin David, PhD, Texas Childrens Hospital
Brent DeWitt, Datex-Ohmeda Inc.
Joseph F. Dyro, PhD, Biomedical Research Group
Michael Gusel, Datascope Corp.
Donald N. Heirman, University of Oklahoma
Robert Jenkins, Welch Allyn Protocol Inc.
Bernie Liebler, Advanced Medical Technology Association (AdvaMed)
Albert Lozano-Nieto, PhD, Penn State University
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Willard Tuthill, Underwriters Laboratories Inc.
David Tyler, Gambro BCT Inc.
R. Barry Wallen, TUV Product Service Inc.
Richard J. Wessels, Guidant Corp.
Michael Willingham, Medtronic Physio-Control

Alternates: Donald Koller, GE Medical Systems – Information Technologies
Steve Kreinick, Abbott Laboratories
Richard A. Sunderland, Welch Allyn Protocol Inc.
Stan Wiley, Spacelabs Medical Inc.
Donald M. Witters, Jr., U.S. Food and Drug Administration

NOTE—Participation by federal agency representatives in the development of this American National Standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of IEC 60601-1-2, Second edition, 2001-09

As indicated in the foreword to the main body of this document (page x), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this standard.

International Standard IEC 60601-1-2 was developed by Working Group (WG) 13, *Electromagnetic compatibility*, of Subcommittee (SC) 62A, *Common aspects of electrical equipment used in medical practice*, to provide minimum safety requirements that will help assure a reasonable level of clinical efficacy and patient safety.

U.S. participation in IEC/SC 62A/WG 13 is organized through the U.S. Technical Advisory Group for IEC/SC 62A, administered by the Advanced Medical Technology Association (AdvaMed) on behalf of the United States National Committee, which is a committee of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for IEC/SC 62A on behalf of the United States, and U.S. experts made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international standards as much as possible. The AAMI Electromagnetic Compatibility (EMC) Committee held joint meetings with the U.S. Technical Advisory Group for IEC/SC 62A to formulate the U.S. position and comments while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for IEC/SC 62A, AdvaMed granted AAMI permission to consider adoption of IEC 60601-1-2, Second edition, 2001-09 as an American National Standard. Following AAMI procedures, the AAMI EMC Committee voted to adopt the IEC standard as written.

The concepts incorporated into 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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE 1—This background does not contain provisions of the AAMI/IEC standard, *Medical electrical equipment, Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests* (ANSI/AAMI/IEC 60601-1-2:2001), but it does provide important information about the development and intended use of the document.

NOTE 2—Beginning with the text on page viii, this American National Standard is identical to IEC 60601-1-2, Second edition, 2001-09.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT—

Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. 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. The 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 the 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 National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports, or guides, and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-1-2 has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-1-2 cancels and replaces the first edition published in 1993 and constitutes a technical revision.

This second edition constitutes a Collateral Standard to IEC 60601-1*, Medical electrical equipment—Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

The text of this Collateral Standard is based on the following documents:

FDIS	Report on voting
62A/336/FDIS	62A/341/RVD

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

In the IEC 60601 series of publications, Collateral Standards specify general requirements for safety applicable to:

— a group of MEDICAL ELECTRICAL EQUIPMENT (e.g., radiological equipment);

— a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g., ELECTROMAGNETIC COMPATIBILITY).

In addition, IEC 60601-1-1 has expanded the scope of the General Standard to include MEDICAL ELECTRICAL SYSTEMS. In recognition of that expanded scope, this edition of the EMC Collateral Standard takes into account the fact that the General Standard now applies to MEDICAL ELECTRICAL SYSTEMS as well as MEDICAL ELECTRICAL EQUIPMENT and includes EMC requirements that are, in most cases, applicable to all parts of the SYSTEM.

The numbering of sections, clauses, and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this Collateral Standard, the following print types are used:

— requirements, compliance with which can be tested and definitions: in roman type;

— explanations, advice, general statements, exceptions, and references: in smaller type;

— *test specifications: in italic type;*

— TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

NOTE—Defined terms are not printed in SMALL CAPITALS in Tables 201–208, in the tables in annex BBB and in statements required to appear in the ACCOMPANYING DOCUMENTS or instructions for use because they are intended for the customer or user, who may not be familiar with the defined terms of IEC 60601 standards.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) in the left margin of a clause or subclause indicates the presence of additional information in annex AAA.

Annex FFF forms an integral part of this standard.

Annexes AAA, BBB, CCC, DDD, EEE, and the bibliography are for information only.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

— reconfirmed;

— withdrawn;

— replaced by a revised edition; or

— amended.

INTRODUCTION

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS (referred to as EQUIPMENT and SYSTEMS, respectively, in this Collateral Standard) is well recognized.

In particular, the existence of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

— safety services;

— other EQUIPMENT and SYSTEMS;

— non-medical electrical equipment (e.g., computers);

— telecommunications (e.g., radio/TV, telephone, radio-navigation).

Of even more importance, the existence of ELECTROMAGNETIC IMMUNITY standards is essential to assure safety of EQUIPMENT and SYSTEMS. ELECTROMAGNETIC COMPATIBILITY (see definition 2.204) differs from other aspects of safety covered by IEC 60601-1 because the electromagnetic phenomena exist, with varying degrees of severity, in the normal use environment of all EQUIPMENT and SYSTEMS and by definition the equipment must "perform satisfactorily" within its intended environment in order to establish ELECTROMAGNETIC COMPATIBILITY. This means that the conventional single fault approach to safety is not appropriate for application to ELECTROMAGNETIC COMPATIBILITY standards. The ELECTROMAGNETIC DISTURBANCE environment can be compared to ambient temperature, humidity, and atmospheric pressure. EQUIPMENT and SYSTEMS may experience environmental conditions within the expected range at any time, and for extended periods of time. As with atmospheric pressure and humidity, the user of the EQUIPMENT or SYSTEM[1] may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the EQUIPMENT or SYSTEM would also be expected to be normal.

IEC 60513 states that the distinction between safety and performance standards is often unclear. EQUIPMENT and SYSTEMS are used in the practice of medicine because they provide needed FUNCTIONS. If an EQUIPMENT or SYSTEM does not provide its needed FUNCTION, because of a lack of IMMUNITY to events expected in the normal use environment, this interferes with the practice of medicine and cannot be considered an acceptable situation. Therefore, this second edition of IEC 60601-1-2 departs from the first edition by establishing a minimum baseline of performance in the presence of expected levels of ELECTROMAGNETIC DISTURBANCE.

This second edition recognizes that there is a shared responsibility between manufacturers, customers, and users to ensure that EQUIPMENT and SYSTEMS are designed and operated as intended. The EQUIPMENT or SYSTEM manufacturer's responsibility is to design and manufacture to meet the requirements of this standard and to disclose information to the customer or user so that a compatible ELECTROMAGNETIC ENVIRONMENT can be maintained in order that the EQUIPMENT or SYSTEM will perform as intended.

Because the practice of medicine involves many specialties, there will by necessity be EQUIPMENT and SYSTEMS that are designed to perform a variety of FUNCTIONS. Some FUNCTIONS involve, for example, measurement of signals from a PATIENT that are of very low levels when compared to ELECTROMAGNETIC NOISE levels that can be coupled into EQUIPMENT and SYSTEMS during the ELECTROMAGNETIC IMMUNITY testing specified in this standard. Because of the proven benefits of many such EQUIPMENT and SYSTEMS, this standard allows the IMMUNITY TEST LEVELS to be lowered, provided there is sufficient justification based on physical, technological, or physiological limitations. In this case, the manufacturer is required to disclose the levels at which the EQUIPMENT or SYSTEM meets the performance requirements of this standard and to specify the characteristics of the ELECTROMAGNETIC use environment and how this environment is established, in which the EQUIPMENT or SYSTEM will perform as intended.

This standard also recognizes that for certain environments, higher IMMUNITY LEVELS may be required. Research necessary to determine how to identify the environments that may require higher IMMUNITY LEVELS, as well as what the levels should be, is in progress.

Finally, this standard recognizes that for LIFE-SUPPORTING EQUIPMENT and SYSTEMS, higher levels of IMMUNITY are necessary in order to establish a broader safety margin, even for use in the general medical use environment. Therefore, this standard specifies additional requirements for LIFE-SUPPORTING EQUIPMENT and SYSTEMS.

This second edition allows a risk analysis to be used to determine the ESSENTIAL PERFORMANCE and safety of MEDICAL ELECTRICAL EQUIPMENT that must be examined during IMMUNITY testing and whether testing according to this standard is required for non-medical electrical equipment that is combined with MEDICAL ELECTRICAL EQUIPMENT to form a SYSTEM.

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[1] In this standard, "or" should be understood to include "and."

This standard is based on existing IEC standards prepared by SC 62A, TC 77 (Electromagnetic compatibility between electrical equipment including networks) and CISPR (International special committee on radio interference).

The ELECTROMAGNETIC COMPATIBILITY requirements specified by this standard are generally applicable to EQUIPMENT and SYSTEMS as described in 1.201. For certain types of EQUIPMENT and SYSTEMS, these requirements may need to be modified by the special requirements of a Particular Standard. Writers of Particular Standards are encouraged to refer to annex DDD for guidance in the application of this standard.

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List of Titles

MEDICAL ELECTRICAL EQUIPMENT—

Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests

SECTION ONE—GENERAL

1 Scope and object

*1.201 Scope

This standard applies to ELECTROMAGNETIC COMPATIBILITY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereinafter referred to as EQUIPMENT and SYSTEMS, respectively.

1.202 Object

This standard specifies requirements and tests for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS and serves as the basis of ELECTROMAGNETIC COMPATIBILITY requirements and tests in Particular Standards.

2 Terminology and definitions

For the purposes of this standard, the following definitions apply:

2.201 (IMMUNITY) COMPLIANCE LEVEL: Level less than or equal to the IMMUNITY LEVEL for which the EQUIPMENT or SYSTEM meets the requirements of the applicable subclause of 36.202.

NOTE—Additional requirements for COMPLIANCE LEVELS are specified in 6.8.3.201.

***2.202 DEGRADATION (of performance):** Undesired departure in the operational performance of an EQUIPMENT or SYSTEM from its intended performance. [IEV 161-01-19, modified]

NOTE—The term "DEGRADATION" can apply to temporary or permanent failure.

***2.203 EFFECTIVE RADIATED POWER (ERP):** Power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device. [IEV 161-04-16, modified]

NOTE—As used by the ITU and as used in Chapter 712 of the IEV, the term "effective radiated power" appears without qualification only when the reference antenna is a half-wave dipole.

***2.204 ELECTROMAGNETIC COMPATIBILITY (EMC):** Ability of an EQUIPMENT or SYSTEM to function satisfactorily in its ELECTROMAGNETIC ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment. [IEV 161-01-07, modified]

***2.205 ELECTROMAGNETIC DISTURBANCE:** Any electromagnetic phenomenon that may degrade the performance of a device, equipment, or system. [IEV 161-01-05, modified]

NOTE—An ELECTROMAGNETIC DISTURBANCE may be an ELECTROMAGNETIC NOISE, an unwanted signal or a change in the propagation medium itself.

2.206 (ELECTROMAGNETIC) EMISSION: Phenomenon by which electromagnetic energy emanates from a source. [IEV 161-01-08]

***2.207 ELECTROMAGNETIC ENVIRONMENT:** Totality of electromagnetic phenomena existing at a given location. [IEV 161-01-01, modified]

NOTE—In general, the ELECTROMAGNETIC ENVIRONMENT is time dependent and its description may need a statistical approach.

2.208 ELECTROMAGNETIC NOISE: Time-varying electromagnetic phenomenon apparently not conveying information and which may be superimposed on or combined with a wanted signal. [IEV 161-01-02]

2.209 ELECTROSTATIC DISCHARGE (ESD): A transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact. [IEV 161-01-22]

2.210 ESSENTIAL PERFORMANCE (of an EQUIPMENT or SYSTEM): Performance characteristics necessary to maintain the residual risk within acceptable limits. [IEC 60601-1, 3rd ed.,[2] definition 3.30]

NOTE—See also 3.201.2.

***2.211 EXCLUSION BAND:** Frequency band for intentional receivers of RF electromagnetic energy that extends from −5 % to +5 % of the frequency, or frequency band, of reception for frequencies of reception greater than or equal to 80 MHz and from −10 % to +10 % of the frequency, or frequency band, of reception for frequencies of reception less than 80 MHz.

NOTE—Other definitions of this term are sometimes used for other purposes in national radio regulations.

***2.212 FUNCTION (of an EQUIPMENT or SYSTEM):** Clinically significant feature that the EQUIPMENT or SYSTEM is intended to provide.

2.213 IEC 60601 TEST LEVEL: IMMUNITY TEST LEVEL specified in 36.202 by this standard or a Particular Standard.

***2.214 IMMUNITY (to a disturbance):** Ability of an EQUIPMENT or SYSTEM to perform without DEGRADATION in the presence of an ELECTROMAGNETIC DISTURBANCE. [IEV 161-01-20, modified]

2.215 IMMUNITY LEVEL: Maximum level of a given ELECTROMAGNETIC DISTURBANCE incident on a particular device, equipment, or system for which it remains capable of operating at a required degree of performance. [IEV 161-03-14]

***2.216 IMMUNITY TEST LEVEL:** Level of a test signal used to simulate an ELECTROMAGNETIC DISTURBANCE when performing an IMMUNITY test. [IEV 161-04-41, modified]

2.217 INFORMATION TECHNOLOGY EQUIPMENT (ITE): Equipment designed for the purpose of

a) receiving data from an external source (such as a data input line or via a keyboard);

b) performing some processing functions on the received data (such as computation, data transformation, or recording, filing, sorting, storage, transfer of data);

c) providing a data output (either to other equipment or by the reproduction of data or images).

[IEV 161-05-04]

NOTE—This definition includes electrical or electronic units or systems that predominantly generate a multiplicity of periodic binary pulsed electrical or electronic waveforms and are designed to perform data processing functions such as word processing, electronic computation, data transformation, recording, filing, sorting, storage, retrieval and transfer, and reproduction of data as images.

***2.218 LARGE EQUIPMENT or SYSTEM:** EQUIPMENT or SYSTEM that cannot fit within a 2 m × 2 m × 2.5 m volume, excluding cables; this includes distributed SYSTEMS.

***2.219 LIFE-SUPPORTING EQUIPMENT or SYSTEM:** EQUIPMENT or SYSTEM that includes at least one FUNCTION that is intended to actively keep alive or resuscitate PATIENTS and the failure of which to comply with the requirements of 36.202.1 j) is likely to lead to serious injury or death of a PATIENT.

***2.220 LOW VOLTAGE:** Line-to-line or line-to-neutral voltage that is less than or equal to 1,000 V a.c. or 1,500 V d.c.

***2.221 MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as SYSTEM):** Combination of items of equipment, at least one of which must be MEDICAL ELECTRICAL EQUIPMENT and interconnected by FUNCTIONAL CONNECTION or use of a MULTIPLE PORTABLE SOCKET-OUTLET. [IEC 60601-1-1, definition 2.201]

NOTE—Equipment, when mentioned in connection with a SYSTEM, should be taken to include EQUIPMENT.

***2.222 OPERATING FREQUENCY:** Fundamental frequency of a signal, electrical or non-electrical, that is set in an EQUIPMENT or SYSTEM intended to control a physiological parameter.

***2.223 PATIENT-COUPLED EQUIPMENT or SYSTEM:** EQUIPMENT or SYSTEM that contains at least one APPLIED PART whereby contact with the PATIENT provides a sensing or treatment point necessary for the normal operation of the EQUIPMENT or SYSTEM and provides a path for electromagnetic energy, whether coupled conductively, capacitively, or inductively, and whether intended or unintended.

[2] In preparation.

***2.224 PHYSIOLOGICAL SIMULATION FREQUENCY:** Fundamental frequency of a signal, electrical, or non-electrical, used to simulate a physiological parameter such that the EQUIPMENT or SYSTEM will operate in a manner consistent with use on a PATIENT.

***2.225 PUBLIC MAINS NETWORK:** LOW VOLTAGE electricity power lines to which all categories of consumers have access.

***2.226 RADIO FREQUENCY (RF):** Frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion; frequency useful for radio transmission.

NOTE—The limits are generally accepted to be 9 kHz to 3,000 GHz.

3 General requirements

3.201 General requirements for electromagnetic compatibility of equipment and systems

*3.201.1 Electromagnetic compatibility

EQUIPMENT and SYSTEMS shall not emit ELECTROMAGNETIC DISTURBANCES that could affect radio services, other equipment, or the ESSENTIAL PERFORMANCE of other EQUIPMENT and SYSTEMS. The ESSENTIAL PERFORMANCE of EQUIPMENT and SYSTEMS shall have adequate IMMUNITY to ELECTROMAGNETIC DISTURBANCES.

Compliance is considered to exist if the requirements of this standard are met.

*3.201.2 Essential performance

The ESSENTIAL PERFORMANCE of EQUIPMENT and SYSTEMS shall be identified by a risk analysis. If this risk analysis is not performed, all FUNCTIONS of the EQUIPMENT or SYSTEM shall be considered ESSENTIAL PERFORMANCE for the purpose of IMMUNITY testing (see 36.202.1 j)).

Compliance is checked by inspection of the documents for this risk analysis or, if this risk analysis is not performed, by inspection of the documents to verify that all FUNCTIONS of the EQUIPMENT or SYSTEM have been tested in accordance with 36.202.

3.201.3 Medical electrical equipment

MEDICAL ELECTRICAL EQUIPMENT shall meet the requirements of this standard.

Compliance is considered to exist if the requirements of this standard are met.

*3.201.4 Non-medical electrical equipment

Non-medical electrical equipment that is supplied as part of a SYSTEM and the EMISSIONS and IMMUNITY of which can be reasonably expected not to affect the ESSENTIAL PERFORMANCE of the SYSTEM or increase the EMISSIONS of the EQUIPMENT is exempt from the EMC testing requirements of this standard, provided the non-medical electrical equipment complies with applicable international EMC standards. The determination of reasonable expectation not to affect the ESSENTIAL PERFORMANCE of the SYSTEM shall be based upon a risk analysis. This risk analysis is not required if the non-medical electrical equipment supplied as part of a SYSTEM is tested for EMC in accordance with this standard.

Compliance is checked by inspection of the documents for this risk analysis and other appropriate documents or certificates or, if this risk analysis is not performed, by inspection of the documents to verify that the non-medical electrical equipment has been tested in accordance with this standard.

6 Identification, marking, and documents

6.1.201 Marking on the outside of EQUIPMENT or EQUIPMENT parts

*6.1.201.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts that include RF transmitters or that apply RF electromagnetic energy for diagnosis or treatment

EQUIPMENT and SYSTEMS that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with the following symbol for non-ionizing radiation [IEC 60417-5140]:

6.1.201.2 Marking on the outside of EQUIPMENT or EQUIPMENT parts for which the connector testing exemption specified in 36.202.2 b) 3) is used

For EQUIPMENT and SYSTEMS for which the connector testing exemption specified in 36.202.2 b) 3) is used, the following symbol for ESD sensitivity shall be applied adjacent to each connector for which the testing exemption is used [IEC 60417-5134]:

6.1.201.3 Marking on the outside of EQUIPMENT and SYSTEMS that are specified for use only in a shielded location

EQUIPMENT and SYSTEMS specified for use only in a shielded location shall be labeled with a warning that they should be used only in the specified type of shielded location (see 6.8.3.201 c)).

Compliance is checked by inspection.

6.8.201 Accompanying documents

6.8.2.201 Instructions for use

a) Requirements applicable to all EQUIPMENT and SYSTEMS

Instructions for use shall include the following:

1) a statement that MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;

2) a statement that portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

b) Requirements applicable to EQUIPMENT and SYSTEMS for which the connector testing exemption specified in 36.202.2 b) 3) is used

For EQUIPMENT and SYSTEMS for which the connector testing exemption specified in 36.202.2 b) 3) is used, the instructions for use shall include the following:

1) a reproduction of the ESD warning symbol (IEC 60417-5134, as shown in 6.1.201.2);

2) a warning that pins of connectors identified with the ESD warning symbol should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used;

*3) a specification of the ESD precautionary procedures;

*4) a recommendation that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures;

*5) a specification of the minimum contents of ESD precautionary procedure training.

c) Minimum amplitude or value of PATIENT physiological signal

For EQUIPMENT and SYSTEMS without a manual sensitivity adjustment and for which the manufacturer specifies a minimum amplitude or value of the PATIENT physiological signal (see 36.202.1 g), first dash), the instructions for use shall include the following:

1) the minimum amplitude or value of PATIENT physiological signal;

2) a warning that operation of the EQUIPMENT or SYSTEM below this amplitude or value may cause inaccurate results.

Compliance is checked by inspection.

6.8.3.201 Technical description

a) Requirements applicable to all EQUIPMENT and SYSTEMS

For all EQUIPMENT and SYSTEMS, the ACCOMPANYING DOCUMENTS shall include the following information:

*1) A list of all cables and maximum lengths of cables (if applicable), transducers, and other ACCESSORIES with which the manufacturer of the EQUIPMENT or SYSTEM claims compliance with the requirements of 36.201 and 36.202. ACCESSORIES that do not affect compliance with the requirements of these subclauses need not be listed. ACCESSORIES, transducers, and cables may be specified either generically (e.g., shielded serial cable, load impedance) or specifically (e.g., by manufacturer and model or part number).

NOTE—Transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components need not be listed.

*2) A warning that the use of ACCESSORIES, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.

*3) Table 201, with the modifications specified below.[3, 4] The flowchart in Figure 201 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 11 EQUIPMENT and SYSTEMS. The flowchart in Figure 202 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 14 and CISPR 15 EQUIPMENT.

— For CISPR 11 EQUIPMENT and SYSTEMS, "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.

— For CISPR 14 and CISPR 15 EQUIPMENT, "[EQUIPMENT]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT.

— For CISPR 11 Group 1 EQUIPMENT and SYSTEMS, rows 5, 11, and 12 shall be deleted.

— For CISPR 11 Group 2 EQUIPMENT and SYSTEMS, rows 4, 11, and 12 shall be deleted.

— For EQUIPMENT that complies with CISPR 14-1, rows 4 through 6 and row 12 shall be deleted.

— For EQUIPMENT that complies with CISPR 15, rows 4 through 6 and row 11 shall be deleted.

— For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class A, "[A or B]" in column 2 of row 6 shall be replaced with "A". For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B, "[A or B]" shall be replaced with "B".

— For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-2, "[Class A, B, C, D, or Not applicable]" in column 2 of row 7 shall be replaced with the class of the EQUIPMENT or SYSTEM according to IEC 61000-3-2. For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-3, "[Complies or Not applicable]" in column 2 of row 8 shall be replaced with "Complies." For EQUIPMENT and SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, "[Class A, B, C, D, or Not applicable]" and "[Complies or Not applicable]" shall each be replaced with "Not applicable."

— For CISPR 11 EQUIPMENT and SYSTEMS, column 3 of rows 6, 7, and 8 shall be merged into one cell. For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B and with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class A or for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, the text in column 3 of row 10 shall be moved into the merged cell.

— For CISPR 14 or CISPR 15 EQUIPMENT, column 3 of rows 7 and 8 shall be merged into one cell. For CISPR 14 or CISPR 15 EQUIPMENT that comply with IEC 61000-3-2 and with IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For CISPR 14 or CISPR 15 EQUIPMENT for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, the text in column 3 of row 10 shall be moved into the merged cell.

[3] See annex BBB for examples. These modifications should be performed in the order in which they appear.

[4] Row numbers refer to those in Table 201 before modifications are made.

— For EQUIPMENT and SYSTEMS specified for use only in a shielded location and for which the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 36.201.1 a) 4) is used, the text specified by 6.8.3.201 c) 2) shall be added.

— Rows 9 and 10 shall be deleted.

— The row numbers shall be deleted.

*4) A warning that the EQUIPMENT or SYSTEM should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the EQUIPMENT or SYSTEM should be observed to verify normal operation in the configuration in which it will be used.

NOTE—The manufacturer of the EQUIPMENT or SYSTEM may provide a description or list of equipment with which the EQUIPMENT or SYSTEM has been tested in a stacked or adjacent configuration, and with which stacked or adjacent use is permitted.

*5) A justification for each COMPLIANCE LEVEL that is lower than the IEC 60601 TEST LEVEL for that IMMUNITY test. These justifications shall be based only on physical, technological, or physiological limitations that prevent compliance at the IEC 60601 TEST LEVEL.

*6) Table 202, completed as specified below.[5] The flowchart in Figure 203 is the requirement in step-by-step graphical form for completion of Table 202.

— "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.

NOTE—There are four places in Table 202 where "[EQUIPMENT or SYSTEM]" must be replaced.

*— Column 3 of Table 202 shall be filled in with the IMMUNITY COMPLIANCE LEVEL for each test in accordance with the requirements of 6.8.3.201 and 36.202. If a COMPLIANCE LEVEL lower or higher than the IEC 60601 TEST LEVEL is claimed, it shall be one of the levels listed in the referenced basic EMC IMMUNITY standard unless the COMPLIANCE LEVEL is outside the range of levels listed. If the COMPLIANCE LEVEL is outside the range of levels listed in the referenced basic EMC IMMUNITY standard, the actual IMMUNITY LEVEL shall be stated, rounded to one significant digit. If, according to 36.202 or the scope of the EMC basic standard, a test does not apply to the EQUIPMENT or SYSTEM, or it is not possible to perform the test on the EQUIPMENT or SYSTEM, columns 3 and 4 of Table 202 shall state that the test is not applicable.

*— For the electrostatic discharge (ESD) IMMUNITY test (IEC 61000-4-2), the electrical fast transient/burst IMMUNITY test (IEC 61000-4-4), the surge IMMUNITY test (IEC 61000-4-5), the voltage dips, short interruptions, and voltage variations IMMUNITY test (IEC 61000-4-11) and the power frequency magnetic fields IMMUNITY test (IEC 61000-4-8):

- If a COMPLIANCE LEVEL is lower than an IMMUNITY TEST LEVEL specified in 36.202.2, 36.202.4, 36.202.5, 36.202.7, or 36.202.8.1, the text in column 4 in the corresponding row of Table 202 shall be replaced with a description of the actions the customer or user must take to reduce environmental levels of the DISTURBANCE so that they are less than or equal to the COMPLIANCE LEVEL listed in column 3.
- If a COMPLIANCE LEVEL is higher than an IMMUNITY TEST LEVEL specified in 36.202.2, 36.202.4, 36.202.5, 36.202.7, or 36.202.8.1, the text in column 4 in the corresponding row of Table 202 may be replaced with a description of the environment for which the EQUIPMENT or SYSTEM is suitable.

*b) Requirements applicable to EQUIPMENT and SYSTEMS other than those specified for use only in a shielded location

For EQUIPMENT and SYSTEMS other than those specified for use only in a shielded location, the ACCOMPANYING DOCUMENTS shall include the following information:

The applicable tables, 203 and 205 or 204 and 206. Tables 203 and 205 shall be used for LIFE-SUPPORTING EQUIPMENT and SYSTEMS. Tables 204 and 206 shall be used for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING. The tables shall be completed for the conducted and radiated RF IMMUNITY tests as specified below.[6] The flowchart in Figure 204 is the requirement in step-by-step graphical form for completion of Tables

[5] See annex BBB for an example.

[6] See annex BBB for examples.

203 and 205, and the flowchart in Figure 205 is the requirement in step-by-step graphical form for completion of Tables 204 and 206.

1) "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.

NOTE—There are six places in Tables 203 and 204 and four places in Tables 205 and 206 where "[EQUIPMENT or SYSTEM]" must be replaced.

2) Column 3 of Table 203 or 204, as applicable, shall be filled in with the IMMUNITY COMPLIANCE LEVEL in accordance with the requirements of 6.8.3.201, and of 36.202. If a COMPLIANCE LEVEL lower or higher than the IEC 60601 TEST LEVEL is claimed, it shall be one of the levels listed in the referenced basic EMC IMMUNITY standard unless the COMPLIANCE LEVEL is outside the range of levels listed. If the COMPLIANCE LEVEL is outside the range of levels listed in the referenced basic EMC IMMUNITY standard, the actual IMMUNITY LEVEL shall be stated, rounded to one significant digit.

3) The expressions in square brackets ([ ]) that contain V_1, V_2, and E_1 in column 4 of Table 203 or 204, as applicable, and in Table 205 or 206, as applicable, shall be calculated, rounded to two significant digits, and the results substituted in place of the corresponding expressions. V_1 and V_2 are the COMPLIANCE LEVELS for the IEC 61000-4-6 test and E_1 is the COMPLIANCE LEVEL for the IEC 61000-4-3 test. V_1 and V_2 are in V, and E_1 is in V/m. The value of V_1 shall also be substituted for "[V_1]" in the table footnote in Table 203 or 204, as applicable.

4) Table 205 or 206, as applicable, shall be completed by calculating the distance corresponding to each entry in columns 2 through 5 in Table 205 or columns 2 through 4 in Table 206, as applicable, using the equation in that column and the output power that appears in column 1 of that row. The calculated distances shall be rounded to two significant digits and entered in Table 205 or 206, as applicable.

c) Requirements applicable to EQUIPMENT and SYSTEMS specified for use only in a shielded location

For EQUIPMENT and SYSTEMS specified for use only in a shielded location, the ACCOMPANYING DOCUMENTS shall include the following information:

1) A warning that the EQUIPMENT or SYSTEM should be used only in the specified type of shielded location.

*2) If the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 36.201.1 a) 4) is used:

— the following text, added to column 2 of the CISPR row of Table 201, after or below the CISPR class:

(The [EQUIPMENT or SYSTEM] in combination with the shielded location)

where "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM;

— the following text, appended to the beginning of the text in column 3 of Table 201 in the merged cell of the CISPR 11, IEC 61000-3-2 and IEC 61000-3-3 rows:

The [EQUIPMENT or SYSTEM] must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of [shielding effectiveness / filter attenuation specification].

where "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM and "[shielding effectiveness / filter attenuation specification]" shall be replaced with the specification for minimum RF shielding effectiveness and RF filter attenuation.[7] The specification for minimum RF shielding effectiveness and RF filter attenuation shall meet the following requirements:

- the specified RF shielding effectiveness and RF filter attenuation shall be expressed in dB, shall be rounded to the nearest integer, and shall be at least 20 dB;
- the RF shielding effectiveness and RF filter attenuation specification shall include the frequency range over which the RF shielding effectiveness and RF filter attenuation apply, and this frequency range shall be at least one decade in width;

[7] This specification is also used in Tables 207 and 208 (see 6.8.3.201 c) 4)).

- the specified value(s) for minimum RF filter attenuation shall be identical to the specified value(s) for minimum RF shielding effectiveness in each frequency range for which they are specified;
- in frequency ranges for which the minimum RF shielding effectiveness and RF filter attenuation are not specified or are specified to be less than 20 dB, the RF shielding effectiveness and RF filter attenuation shall be assumed to be 0 dB for the purpose of this standard;

— the following text, added to replace "The [EQUIPMENT or SYSTEM] is suitable" in the text in column 3 of Table 201 in the merged cell of the CISPR 11, IEC 61000-3-2 and IEC 61000-3-3 rows:

The [EQUIPMENT or SYSTEM], when installed in such a shielded location, is suitable

where "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM;

— the following note, added to the bottom of Table 201:

NOTE—It is essential that the actual RF shielding effectiveness and filter attenuation of the shielded location be verified to ensure that they meet or exceed the specified minimum values.

*3) A specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the EQUIPMENT or SYSTEM, a list of specific equipment allowed or a list of types of equipment prohibited (see 36.202.3 a) 3) and 36.202.6 a) 3)), and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location.

*4) The applicable table, 207 or 208. Table 207 shall be used for LIFE-SUPPORTING EQUIPMENT and SYSTEMS. Table 208 shall be used for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING. The tables shall be completed as follows:[8]

— "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM;

NOTE—There are six places in Tables 207 and 208 where "[EQUIPMENT or SYSTEM]" must be replaced.

— column 3 of Table 207 or 208, as applicable, shall be filled in with the IMMUNITY COMPLIANCE LEVEL in accordance with the requirements of 6.8.3.201 and of 36.202. If an IMMUNITY COMPLIANCE LEVEL lower or higher than the IEC 60601 TEST LEVEL is claimed, it shall be one of the levels listed in the referenced basic EMC IMMUNITY standard unless the COMPLIANCE LEVEL is outside the range of levels listed. If the COMPLIANCE LEVEL is outside the range of levels listed in the referenced basic EMC IMMUNITY standard, the actual IMMUNITY LEVEL shall be stated, rounded to one significant digit;

*— in column 4 of Table 207 or 208, as applicable, "[shielding effectiveness / filter attenuation specification]" shall be replaced with the specification for minimum RF shielding effectiveness and RF filter attenuation, which shall meet the requirements specified in 2), above; "[appropriate section of ACCOMPANYING DOCUMENTS]" shall be replaced with a reference to the location in the ACCOMPANYING DOCUMENTS where the information required by 6.8.3.201 c) 3) can be found; and "[field strength]" shall be replaced with the maximum field strength in V/m, rounded to one significant digit, of fixed RF transmitters that when attenuated by the specified minimum RF shielding effectiveness and filter attenuation, will not exceed the COMPLIANCE LEVEL for any of the frequency ranges. For calculating "[field strength]", the COMPLIANCE LEVELS for the IEC 61000-4-6 test shall be considered to be in units of V/m;

— in table footnote b of Table 207 or table footnote a of Table 208, as applicable, "[field strength]" shall be replaced as specified above for column 4 of the table.

d) Requirements applicable to EQUIPMENT and SYSTEMS that intentionally apply RF energy for diagnosis or treatment

For EQUIPMENT and SYSTEMS that intentionally apply RF energy for diagnosis or treatment, the ACCOMPANYING DOCUMENTS shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects on other equipment that may result from operation of the EQUIPMENT or SYSTEM.

[8] See annex BBB for examples.

e) Requirements applicable to EQUIPMENT and SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation

For EQUIPMENT and SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation, the ACCOMPANYING DOCUMENTS shall include the following information:

1) each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable; and the bandwidth of the receiving section of the EQUIPMENT or SYSTEM in those bands;

2) a warning that the EQUIPMENT or SYSTEM may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

f) Requirements applicable to EQUIPMENT and SYSTEMS that include RF transmitters

For EQUIPMENT and SYSTEMS that include RF transmitters, the ACCOMPANYING DOCUMENTS shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation, and the EFFECTIVE RADIATED POWER.

*g) Requirements applicable to cables, transducers, and other ACCESSORIES that could affect compliance with the requirements of 36.201 and 36.202

For cables, transducers, and other ACCESSORIES that could affect compliance with the requirements of 36.201 and 36.202, the ACCOMPANYING DOCUMENTS shall include the following information:

1) a list of all EQUIPMENT and SYSTEMS with which the ACCESSORY, transducer, or cable may be used and that are claimed by the manufacturer of the ACCESSORY, transducer, or cable to be in compliance with the requirements of 36.201 and 36.202 when used with the ACCESSORY, transducer, or cable. References shall be specific (e.g., by manufacturer and MODEL OR TYPE REFERENCE);

2) a warning that the use of the ACCESSORY, transducer, or cable with EQUIPMENT and SYSTEMS other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.

h) Requirements applicable to LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS

For LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS for which the exemption specified in 36.202.3 b) 1) is used, the ACCOMPANYING DOCUMENTS shall include the following information:

1) a statement that an exemption has been used and that the EQUIPMENT or SYSTEM has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 2.5 GHz;

2) a warning that the EQUIPMENT or SYSTEM has been tested for radiated RF IMMUNITY only at selected frequencies;

*3) a list of the transmitters or equipment used as RF test sources and the frequency and modulation characteristics of each source.

i) Requirements applicable to EQUIPMENT and SYSTEMS found by a risk analysis to have no ESSENTIAL PERFORMANCE

1) For EQUIPMENT and SYSTEMS found by a risk analysis to have no ESSENTIAL PERFORMANCE and which were not tested for IMMUNITY or for which the IMMUNITY COMPLIANCE CRITERIA were considered to allow all DEGRADATIONS, the ACCOMPANYING DOCUMENTS shall include, instead of the information specified in 6.8.3.201 a) 5) and 6), b), c) 3) and 4), and h), a statement that the EQUIPMENT or SYSTEM was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES.

2) For EQUIPMENT and SYSTEMS found by a risk analysis to have no ESSENTIAL PERFORMANCE and for which FUNCTIONS were tested for IMMUNITY and the IMMUNITY COMPLIANCE CRITERIA were considered to apply to all DEGRADATIONS, the ACCOMPANYING DOCUMENTS shall include information applicable to the EQUIPMENT or SYSTEM as specified in 6.8.3.201 a) through h).

Table 201—Guidance and manufacturer's declaration—electromagnetic emissions—for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 3))

Row			
1	**Guidance and manufacturer's declaration—electromagnetic emissions**		
2	The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment—guidance**
4	RF emissions CISPR 11	Group 1	The [EQUIPMENT or SYSTEM] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Group 2	The [EQUIPMENT or SYSTEM] must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
6	RF emissions CISPR 11	Class [A or B]	
7	Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	
8	Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	
9		[See 6.8.3.201 a) 3) and Figure 201]	The [EQUIPMENT or SYSTEM] is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
10		[See 6.8.3.201 a) 3) and Figure 201]	The [EQUIPMENT or SYSTEM] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
11	RF emissions CISPR 14-1	Complies	The [EQUIPMENT] is not suitable for interconnection with other equipment.
12	RF emissions CISPR 15	Complies	The [EQUIPMENT] is not suitable for interconnection with other equipment.

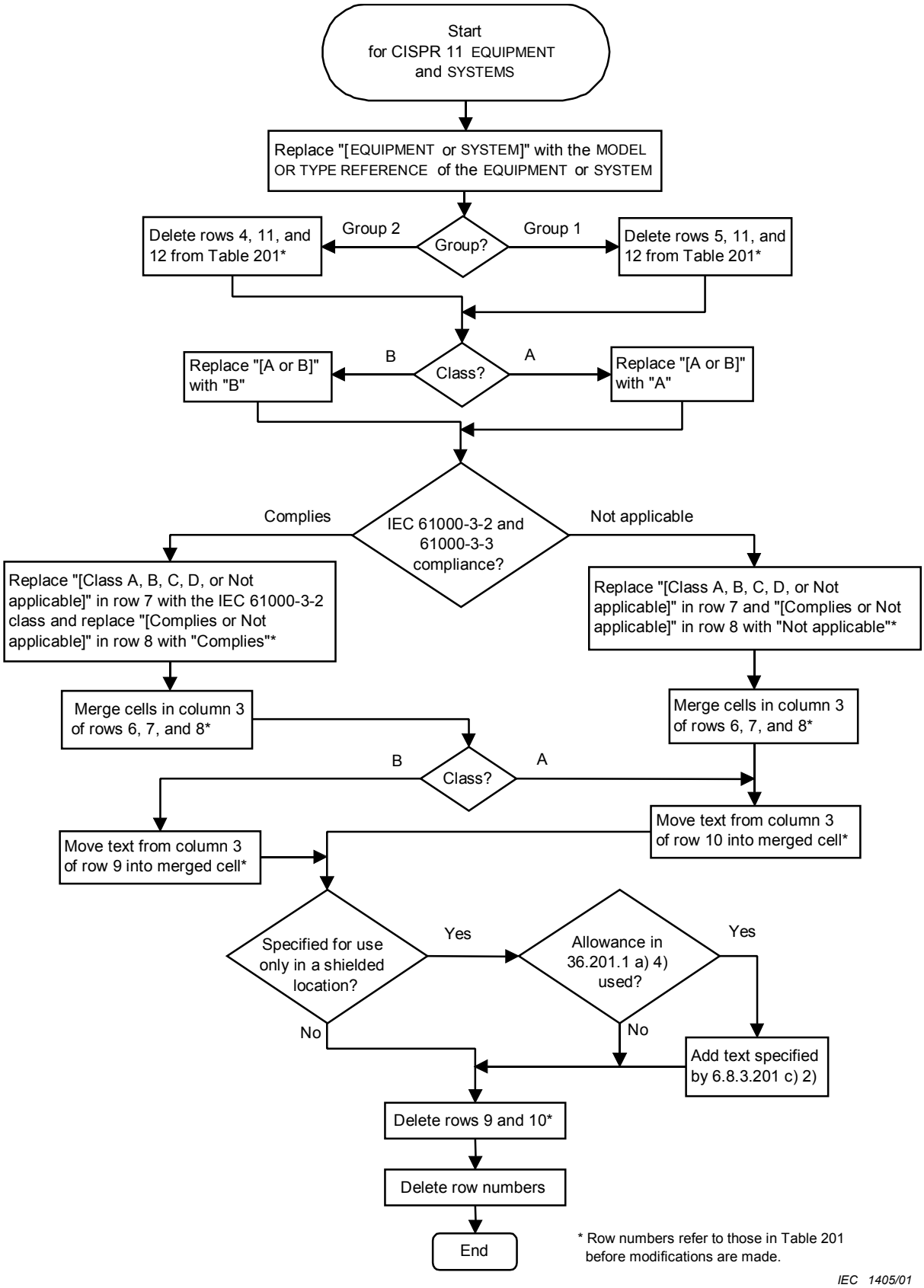

Figure 201—Instructions for completing Table 201 for CISPR 11 EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 3))

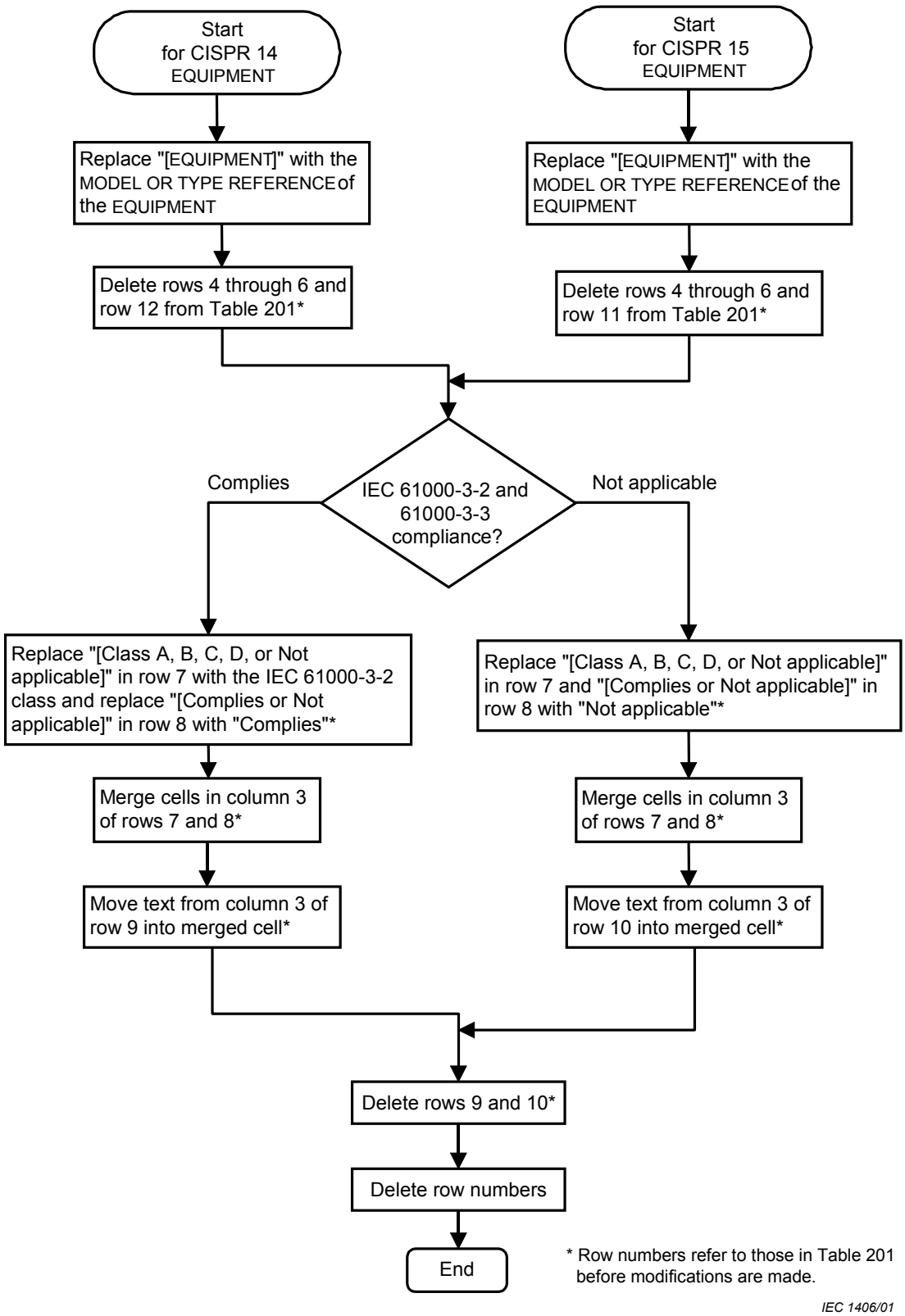

Figure 202—Instructions for completing Table 201 for CISPR 14 and CISPR 15 EQUIPMENT (see 6.8.3.201 a) 3))

Table 202—Guidance and manufacturer's declaration—electromagnetic immunity—for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 6))

Guidance and manufacturer's declaration—electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air		Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE—U_T is the a.c. mains voltage prior to application of the test level.			

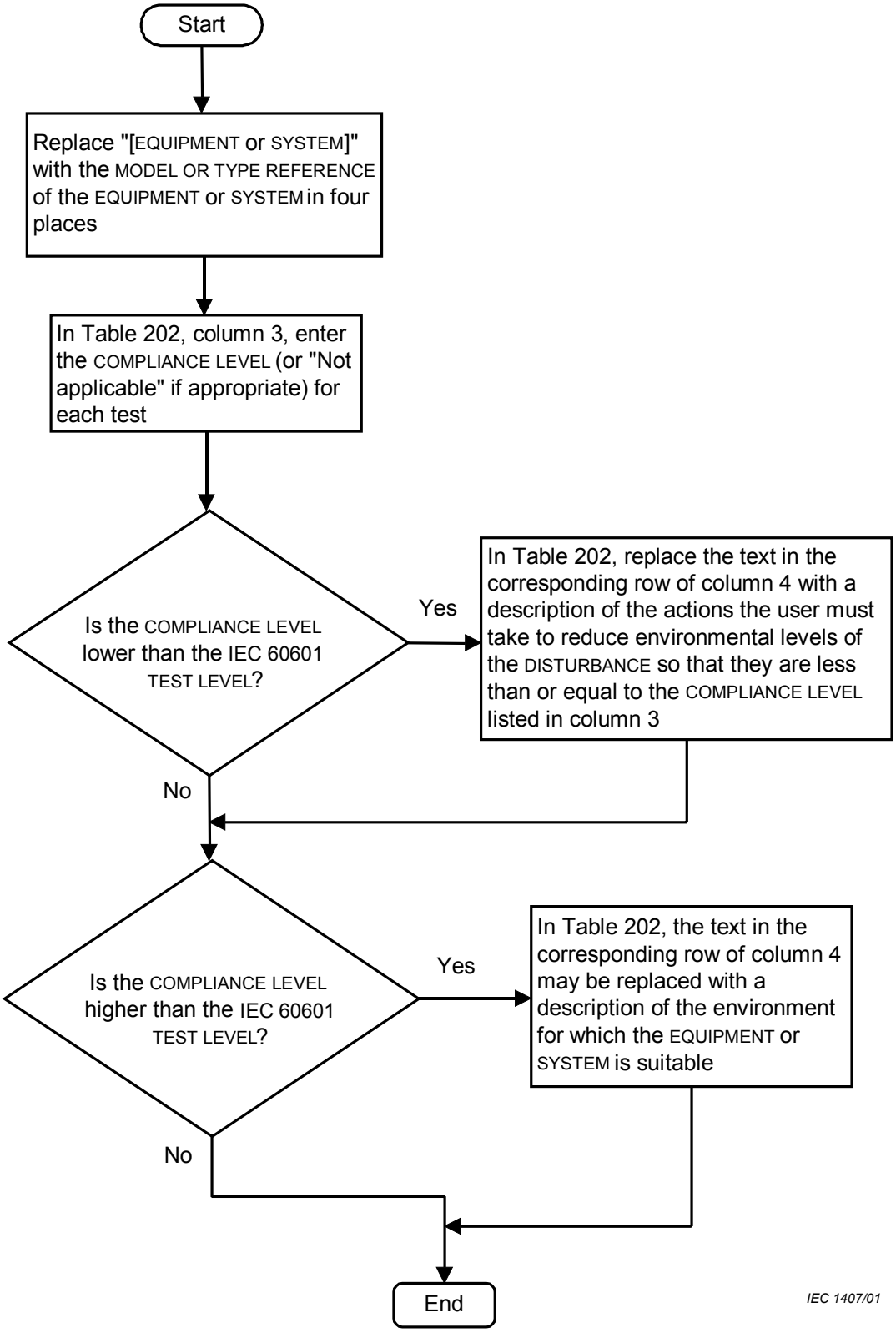

Figure 203—Instructions for completing Table 202 (see 6.8.3.201 a) 6))

Table 203—Guidance and manufacturer's declaration—electromagnetic immunity—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS (see 6.8.3.201 b))

Guidance and manufacturer's declaration—electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	[V_1] V	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}] \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	[V_2] V	$d = [\frac{12}{V_2}] \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	[E_1] V/m	$d = [\frac{12}{E_1}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [EQUIPMENT or SYSTEM].

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Table 204—Guidance and manufacturer's declaration—electromagnetic immunity—for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Guidance and manufacturer's declaration—electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V_1] V	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	$d = [\frac{3.5}{E_1}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [EQUIPMENT or SYSTEM]. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.			

Table 205—Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS (see 6.8.3.201 b))

Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]				
The [EQUIPMENT OR SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [EQUIPMENT OR SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [EQUIPMENT OR SYSTEM] as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01				
0.1				
1				
10				
100				
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				
NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.				
NOTE 2—The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.				
NOTE 3—An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.				
NOTE 4—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				

Table 206—Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM—for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b)

Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]			
The [EQUIPMENT or SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [EQUIPMENT or SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [EQUIPMENT or SYSTEM] as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}] \sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}] \sqrt{P}$
0.01			
0.1			
1			
10			
100			
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

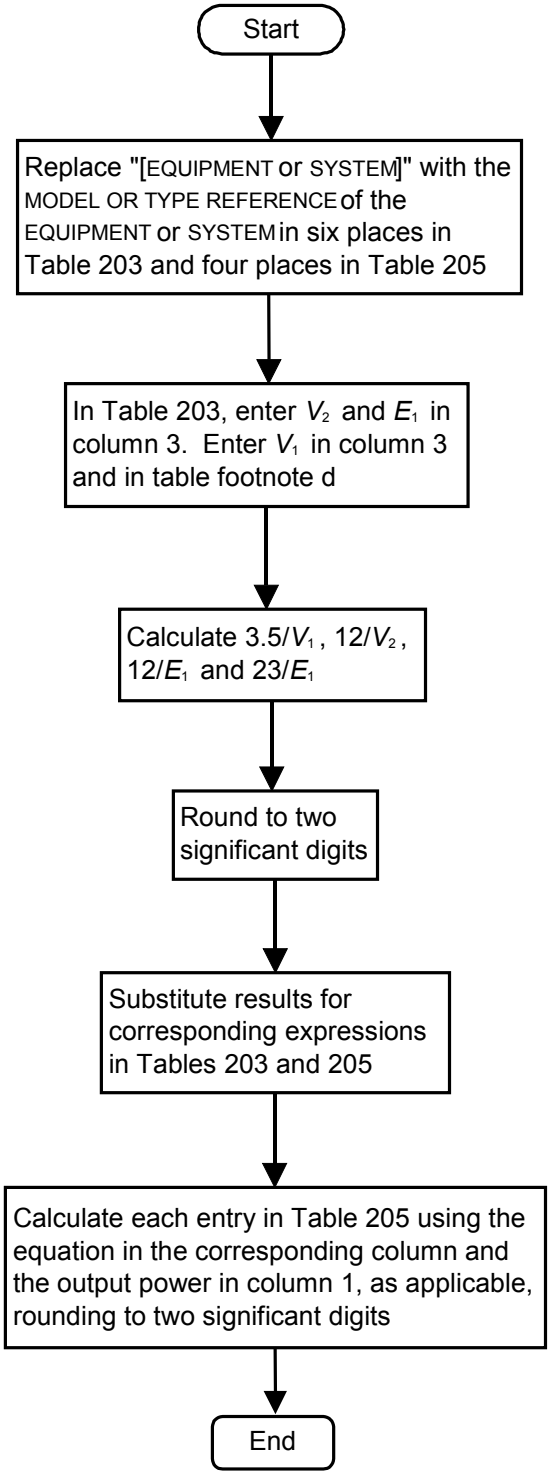

Figure 204—Instructions for completing Tables 203 and 205 for LIFE-SUPPORTING EQUIPMENT and SYSTEMS (see 6.8.3.201 b))

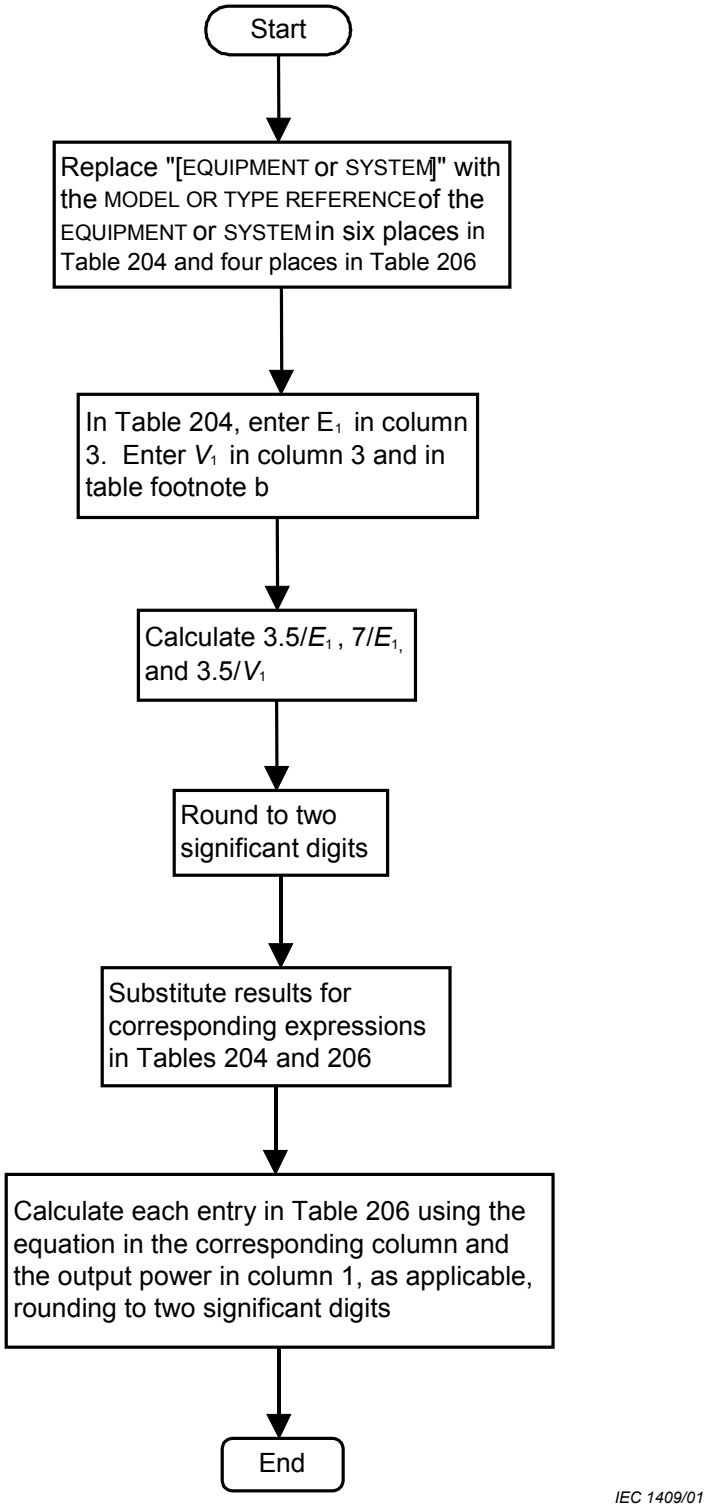

Figure 205—Instructions for completing Tables 204 and 206 for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Table 207—Guidance and manufacturer's declaration—electromagnetic immunity—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS that are specified for use only in a shielded location (see 6.8.3.201 c) 4))

Guidance and manufacturer's declaration—electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is suitable for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an electromagnetic environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]		The [EQUIPMENT or SYSTEM] must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of [shielding effectiveness / filter attenuation specification]. See [appropriate section of ACCOMPANYING DOCUMENTS]. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than [field strength] V/m.[b]
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz		Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. NOTE 2—It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			
[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. [b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the [EQUIPMENT or SYSTEM] is used exceeds [field strength] V/m, observe the [EQUIPMENT or SYSTEM] to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the [EQUIPMENT or SYSTEM] or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

Table 208—Guidance and manufacturer's declaration—electromagnetic immunity—for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and are specified for use only in a shielded location (see 6.8.3.201 c) 4))

Guidance and manufacturer's declaration—electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an electromagnetic environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz		The [EQUIPMENT or SYSTEM] must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of [shielding effectiveness / filter attenuation specification]. See [appropriate section of ACCOMPANYING DOCUMENTS]. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than [field strength] V/m.[a] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. NOTE 2—It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the [EQUIPMENT or SYSTEM] is used exceeds [field strength] V/m, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the [EQUIPMENT or SYSTEM] or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

SECTIONS TWO TO FOUR—NOT USED

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36 Electromagnetic compatibility

36.201 Emissions

36.201.1 Protection of radio services

*a) Requirements

EQUIPMENT and SYSTEMS, except as specified in 1) through 3) below, shall be classified as Group 1 or Group 2 and Class A or Class B in accordance with CISPR 11, based on their intended use, as specified by the manufacturer, using the guidelines in annex CCC. EQUIPMENT and SYSTEMS shall comply with CISPR requirements, based upon their classification, with the exceptions and clarifications specified in 4) and 5) below.

*1) Simple electrical components

MEDICAL ELECTRICAL EQUIPMENT containing only simple electrical components like motors and switches and not utilizing any electronic circuitry that generates or uses frequencies above 9 kHz (e.g., some dental drills, some ventilators, some operating tables) may be classified in accordance with CISPR 14-1. Classification to CISPR 14-1, however, is limited to stand-alone EQUIPMENT and is not applicable to SYSTEMS or sub-SYSTEMS.

2) Lighting equipment

Lighting equipment used in medical applications (e.g., equipment for illumination of X-ray films, lighting devices for operating theatres) may be classified in accordance with CISPR 15. Classification to CISPR 15, however, is limited to stand-alone EQUIPMENT and is not applicable to SYSTEMS or sub-SYSTEMS.

*3) Information technology equipment (ITE)

ITE connected to EQUIPMENT and SYSTEMS may be classified in accordance with CISPR 22 with the following restriction: CISPR 22 Class B equipment may be used with CISPR 11 Class A or Class B SYSTEMS, but CISPR 22 Class A equipment may only be used with CISPR 11 Class A SYSTEMS.[9]

*4) EQUIPMENT and SYSTEMS specified for use only in a shielded location

— For EQUIPMENT and SYSTEMS that are specified for use only in a shielded location, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification meets the requirements specified in 6.8.3.201 c) 2).

— For EQUIPMENT and SYSTEMS that are specified for use only in a shielded location, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that exit the shielded location, provided the minimum RF filter attenuation specification meets the requirements specified in 6.8.3.201 c) 2).

*5) EQUIPMENT and SYSTEMS that include radio equipment

EQUIPMENT and SYSTEMS that include radio equipment and have been tested and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits. EQUIPMENT and

[9] See annex CCC.

SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this standard in the dedicated transmission band of the transmitter. Otherwise, and for EQUIPMENT and SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this standard shall apply.

6) Documentation of the test

The documentation of the test shall include the test methods used to verify compliance with the requirements of this subclause and justification for any allowances of this standard used. This documentation shall include a description of the EQUIPMENT or SYSTEM under test, test equipment and test set-up, settings and mode(s) of the EQUIPMENT or SYSTEM, cable layout, and all PATIENT physiological, ACCESSORY, and sub-SYSTEM simulators used.

Compliance is checked by the following tests:

b) Tests

CISPR test methods shall be used, with the clarifications and exceptions specified in 1) and 2) below.

**1) PATIENT cables*

PATIENT-coupled cables shall be considered interconnecting cables in accordance with the requirements of CISPR 11. Any PATIENT-coupled cable termination used shall be described in the documentation of the test. If simulated PATIENT physiological signals are required to simulate normal operation of the EQUIPMENT or SYSTEM, they shall be provided. The PATIENT coupling point shall not have an intentional conductive or capacitive connection to ground during testing. Unintentional capacitance between the PATIENT coupling point and ground should be no greater than 250 pF.

**2) Sub-SYSTEMS*

Compliance with the requirements of CISPR 11 may be demonstrated by testing each sub-SYSTEM of a SYSTEM, provided that normal operating conditions are simulated.

When EQUIPMENT is being evaluated that interacts with other EQUIPMENT to form a SYSTEM, then the evaluation may be carried out using either additional EQUIPMENT to represent the total SYSTEM or with the use of simulators.

3) LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS

LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS that are constructed in such a way that simulated operation of sub-SYSTEMS is not feasible may be type tested at the premises of a typical user in accordance with CISPR 11, Clause 5, Limits of electromagnetic disturbances*, and 11.2,* Equipment in small-scale production.[10]

36.201.2 Protection of other equipment

***36.201.2.1 Low frequency magnetic fields**

No requirements apply.

36.201.3 Protection of the PUBLIC MAINS NETWORK

36.201.3.1 Harmonic distortion

*a) Requirements

EQUIPMENT and SYSTEMS with a RATED input current up to and including 16 A per phase and that are intended to be connected to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-2. If an EQUIPMENT or SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-2.

Compliance is checked by the following tests:

b) Tests

The test methods and test equipment specified by IEC 61000-3-2 shall apply.

[10] See CISPR 11:1997.

36.201.3.2 Voltage fluctuations and flicker

*a) Requirements

EQUIPMENT and SYSTEMS with a RATED input current up to and including 16 A per phase and that are intended to be connected to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-3. If an EQUIPMENT or SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-3.

Compliance is checked by the following tests:

b) Tests

The test methods and test equipment specified by IEC 61000-3-3 shall apply.

36.202 Immunity

*36.202.1 General

*a) IMMUNITY TEST LEVELS

Subclause 36.202 specifies IMMUNITY requirements that are appropriate for EQUIPMENT and SYSTEMS intended for use in a typical health care ELECTROMAGNETIC ENVIRONMENT.[11] Until limits are developed for other environments, the requirements of 36.202 shall apply to EQUIPMENT and SYSTEMS used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher IMMUNITY TEST LEVELS, these higher IMMUNITY TEST LEVELS shall take precedence. Lower IMMUNITY COMPLIANCE LEVELS are allowed,[12] provided they are justified based on significant physical, technological, or physiological limitations (see 6.8.3.201 a) 5)).

b) Documentation of the test

The documentation of the test shall include the test methods used to verify compliance with the requirements of this subclause and justification for any allowances of this standard used. This documentation shall include a description of the EQUIPMENT or SYSTEM under test, details of the compliance criteria used, test equipment and test set-up, settings and mode(s) of the EQUIPMENT or SYSTEM, cable layout, and all PATIENT physiological, ACCESSORY, and SUB-SYSTEM simulators used.

*c) Operating mode and configuration

During IMMUNITY testing, each FUNCTION of the EQUIPMENT or SYSTEM that is associated with ESSENTIAL PERFORMANCE shall be tested in the mode that is most critical from a PATIENT outcome perspective, based upon a risk analysis, using equipment options, cable layout, and ACCESSORIES in a typical configuration, consistent with NORMAL USE. This risk analysis is not required if all modes of the EQUIPMENT or SYSTEM are tested. If the EQUIPMENT or SYSTEM is not RATED for continuous duty, the operating mode may instead be selected such that reliable operation is obtained for the applicable test duration.

*d) Non-medical electrical equipment

Non-medical electrical equipment that is supplied as part of a SYSTEM and the use of which in the SYSTEM can be reasonably expected not to affect the ESSENTIAL PERFORMANCE or safety of the SYSTEM if the non-medical electrical equipment exhibits DEGRADATION, is exempt from the IMMUNITY testing requirements of this standard, provided the non-medical electrical equipment complies with applicable international IMMUNITY standards.[13] The determination of reasonable expectation not to affect the ESSENTIAL PERFORMANCE or safety of the SYSTEM shall be based upon a risk analysis. This risk analysis is not required if the non-medical electrical equipment supplied as part of a SYSTEM is tested for IMMUNITY in accordance with 36.202.

*e) PATIENT-COUPLED EQUIPMENT and SYSTEMS

PATIENT-COUPLED EQUIPMENT and SYSTEMS shall be tested so that the PATIENT coupling point is within the test environment. The PATIENT coupling point shall not have an intentional conductive or capacitive connection to

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[11] For information concerning ELECTROMAGNETIC ENVIRONMENTS, refer to annex EEE and the bibliography.

[12] Writers of Particular Standards should refer to DDD.2 a) for guidance regarding this allowance.

[13] For example, see CISPR 24 for ITE and IEC 61326-1 for measurement, control, and laboratory equipment.

ground during testing, except as otherwise specified in a subclause of this standard. Unintentional capacitance between the PATIENT coupling point and ground should be no greater than 250 pF.

*f) Variable gain

EQUIPMENT and SYSTEMS that incorporate a variable gain shall be tested at the highest gain setting that allows proper operation.

If this requirement can be met with the normal software of the EQUIPMENT or SYSTEM, the test shall be performed using the normal software. If this requirement cannot be met using the normal software of the EQUIPMENT or SYSTEM, a method shall be provided to implement this operational mode. The use of special software may be required. If special software is used, it shall not inhibit changes in gain that may occur as a result of testing.

*g) PATIENT simulation

If simulated PATIENT physiological signals are required to verify normal operation of the EQUIPMENT or SYSTEM, they shall be provided during IMMUNITY testing. The simulator used shall not provide an intentional conductive or capacitive connection to ground during testing, except as otherwise specified in a subclause of this standard. Unintentional capacitance between the PATIENT coupling point and ground should be no greater than 250 pF. Prior to the beginning of the test, the simulated signal shall be adjusted as follows:

— For EQUIPMENT and SYSTEMS without a manual sensitivity adjustment, the simulated PATIENT physiological signal shall be set to the lowest amplitude or value consistent with normal operation as specified by the manufacturer. If this minimum amplitude or value is specified by the manufacturer, it shall be included in instructions for use as specified in 6.8.2.201 c). If the lowest amplitude or value consistent with normal operation is not specified by the manufacturer, then the simulated PATIENT physiological signal shall be set to the minimum amplitude or value at which the EQUIPMENT or SYSTEM operates as intended.

— For EQUIPMENT and SYSTEMS with a manual sensitivity adjustment, the simulated PATIENT physiological signal shall be set according to the manufacturer's sensitivity adjustment guidelines with the EQUIPMENT or SYSTEM operating at its most sensitive setting.

— If simulated PATIENT physiological signals are not required to verify normal operation of the EQUIPMENT or SYSTEM, the EQUIPMENT or SYSTEM shall be tested as specified in 36.202.1 c) without PATIENT physiological signal simulation.

*h) Testing of normally non-observable FUNCTIONS

If the operation of a FUNCTION associated with ESSENTIAL PERFORMANCE (e.g., a critical alarm) cannot normally be observed or verified during the test, a method shall be provided (e.g., display of internal parameters) for determining compliance. The use of special software or hardware may be needed.

*i) Sub-SYSTEMS

Compliance with the requirements of this standard may be demonstrated by testing each sub-SYSTEM of a SYSTEM, provided that normal operating conditions are simulated.

When EQUIPMENT is being evaluated that interacts with other EQUIPMENT to form a SYSTEM, then the evaluation may be carried out using either additional EQUIPMENT to represent the total SYSTEM or with the use of simulators.

*j) Compliance criteria

Under the test conditions specified in 36.202, the EQUIPMENT or SYSTEM shall be able to provide the ESSENTIAL PERFORMANCE and remain safe. The following DEGRADATIONS associated with ESSENTIAL PERFORMANCE and safety shall not be allowed:

— component failures;

— changes in programmable parameters;

— reset to factory defaults (manufacturer's presets);

— change of operating mode;

— false alarms;

— cessation or interruption of any intended operation, even if accompanied by an alarm;

— initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;

— error of a displayed numerical value sufficiently large to affect diagnosis or treatment;

— noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals;

— artifact or distortion in an image in which the artifact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;

— failure of automatic diagnosis or treatment EQUIPMENT and SYSTEMS to diagnose or treat, even if accompanied by an alarm.

For EQUIPMENT and SYSTEMS with multiple FUNCTIONS, the criteria apply to each FUNCTION, parameter, and channel.

The EQUIPMENT or SYSTEM may exhibit DEGRADATION of performance (e.g., deviation from manufacturer's specifications) that does not affect ESSENTIAL PERFORMANCE or safety.

*k) EQUIPMENT and SYSTEMS that include radio equipment

For EQUIPMENT and SYSTEMS that include radio equipment and in which the IMMUNITY of the radio communication FUNCTION has been tested and found to comply with applicable national radio regulations, the radio equipment is exempt from testing to the IMMUNITY requirements of this standard, provided the IMMUNITY requirements of the applicable national radio regulations for the exempted IMMUNITY test are greater than or equal to those determined in accordance with 36.202.1 a) of this standard. Otherwise, and for EQUIPMENT and SYSTEMS intended only for countries with no national radio regulations, the IMMUNITY requirements of this standard shall apply.

36.202.2 Electrostatic discharge (ESD)

*a) Requirements

EQUIPMENT and SYSTEMS shall comply with the requirements of 36.202.1 j) at IMMUNITY TEST LEVELS of ±2 kV, ±4 kV, and ±8 kV for air discharge, and ±2 kV, ±4 kV, and ±6 kV for contact discharge.

Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j), based upon the response of the EQUIPMENT or SYSTEM, considering each discharge individually.

b) Tests

The test methods and equipment specified by IEC 61000-4-2 apply, with the following modifications:

**1) The time between discharges shall have an initial value of 1 s. Longer time between discharges may be required in order to be able to distinguish between a response caused by a single discharge and a response caused by a number of discharges.*

**2) Contact discharges shall be applied to conductive ACCESSIBLE PARTS of the EQUIPMENT or SYSTEM and coupling planes.*

**3) Air discharges shall be applied to non-conductive ACCESSIBLE PARTS of the EQUIPMENT or SYSTEM and conductive non-accessible portions of ACCESSIBLE PARTS. If the EQUIPMENT or SYSTEM is labeled with the IEC 60417-5134 symbol adjacent to a connector, that connector is exempt from this testing. (See 6.1.201.2 and 6.8.2.201 b).)*

**4) EQUIPMENT and SYSTEMS that are INTERNALLY POWERED, are of CLASS II, or contain circuitry isolated from protective earth shall be tested in such a way as to ensure that there is no appreciable charge retention between individual test discharges. The potential on the EQUIPMENT or SYSTEM may be equalized with that of the ground plane, between individual test discharges, by temporarily grounding it through two 470 kΩ resistors connected in series. This potential equalization connection shall be disconnected and moved away from the EQUIPMENT or SYSTEM during application of a test discharge.*

5) The test may be performed with the EQUIPMENT or SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

36.202.3 Radiated RF electromagnetic fields

*a) Requirements

*1) General

EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING EQUIPMENT and SYSTEMS except as specified in 3) below or in the EXCLUSION BAND as specified in 4) below shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of 3 V/m over the frequency range 80 MHz to 2.5 GHz.

*2) LIFE-SUPPORTING EQUIPMENT and SYSTEMS

LIFE-SUPPORTING EQUIPMENT and SYSTEMS except as specified in 3) below or within the EXCLUSION BAND as specified in 4) below shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of 10 V/m over the frequency range 80 MHz to 2.5 GHz.

*3) EQUIPMENT and SYSTEMS specified for use only in a shielded location

EQUIPMENT and SYSTEMS specified for use only in a shielded location, except within the EXCLUSION BAND as specified in 4) below, may comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL that is reduced from the test level specified in 1) or 2) above, as applicable, in proportion to the applicable specified value of minimum RF shielding effectiveness and RF filter attenuation, provided the RF shielding effectiveness and filter attenuation specification meets the requirements specified in 6.8.3.201 c) 2).

*4) EQUIPMENT and SYSTEMS that include receivers of RF electromagnetic energy

EQUIPMENT and SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation are exempt from the ESSENTIAL PERFORMANCE requirements of 36.202.1 j) in the EXCLUSION BAND; however, in the EXCLUSION BAND, the EQUIPMENT or SYSTEM shall remain safe and the other FUNCTIONS of the EQUIPMENT or SYSTEM shall comply with the requirements specified in 1) or 2) above, as applicable. EQUIPMENT and SYSTEMS shall comply with the requirements specified in 1) or 2) above, as applicable, outside of the EXCLUSION BAND.

Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j).

b) Tests

The test methods and equipment specified by IEC 61000-4-3 apply, with the following additions and modifications:

1) The test frequency shall be swept or stepped from 80 MHz to 2.5 GHz.

2) The uniform field calibration steps specified in 6.2 h) of IEC 61000-4-3 shall be no greater than 1 % of the fundamental frequency.[14]

**3) The test signal shall be 80 % amplitude modulated at the modulation frequency specified in Table 209, based upon the intended use of the EQUIPMENT or SYSTEM. (Unmodulated and modulated waveforms normalized to a generator output of 1.0 Vrms are shown in Figure 1 of IEC 61000-4-3.)*[15] *For EQUIPMENT and SYSTEMS for which testing at 2 Hz is required, it is not necessary to additionally test at 1 kHz. For EQUIPMENT and SYSTEMS intended to monitor or measure a physiological parameter, the PHYSIOLOGICAL SIMULATION FREQUENCY restrictions specified in Table 209 shall apply. For EQUIPMENT and SYSTEMS intended to control a physiological parameter, the OPERATING FREQUENCY restrictions specified in Table 209 shall apply.*

[14] See IEC 61000-4-3:1995.

[15] See IEC 61000-4-3:1995.

Table 209—Modulation frequency, PHYSIOLOGICAL SIMULATION FREQUENCY, and OPERATING FREQUENCY

Intended use	Modulation frequency Hz	PHYSIOLOGICAL SIMULATION FREQUENCY and OPERATING FREQUENCY Hz
Control, monitor, or measure a physiological parameter	2	<1 or >3
All other	1,000	Not applicable

*4) *For the frequency step and dwell method (Clause 8 of IEC 61000-4-3):*[16]

The minimum dwell time shall be based upon the time required for the EQUIPMENT or SYSTEM to be exercised (if applicable) and adequately respond to the test signal. The dwell time shall be at least 3 s for EQUIPMENT and SYSTEMS tested with a 2 Hz modulation frequency and 1 s for all other EQUIPMENT and SYSTEMS, and shall be no less than the response time of the slowest responding FUNCTION plus the settling time of the radiated RF IMMUNITY test system. For EQUIPMENT and SYSTEMS that average data over time for which faster-responding signals cannot be used to determine the effect of the test signal on the EQUIPMENT or SYSTEM, the dwell time shall be no less than 1.2 times the averaging period. If the averaging period is adjustable, the averaging period used to determine dwell time shall be that which is expected to be used most often in clinical application of the EQUIPMENT or SYSTEM. For EQUIPMENT and SYSTEMS for which faster-responding signals can be used to determine the effect of the test signal on the EQUIPMENT or SYSTEM, the dwell time may be reduced if the faster-responding signals are monitored. In this case, the dwell time shall be no less than the response time of the signal or of the monitoring system, whichever is greater, plus the response time of the radiated RF IMMUNITY test system, but in no case less than 3 s for EQUIPMENT and SYSTEMS tested with a 2 Hz modulation frequency and 1 s for all other EQUIPMENT and SYSTEMS. For EQUIPMENT and SYSTEMS that have multiple individual parameters or sub-SYSTEMS, each of which would yield a different dwell time, the value used shall be the maximum of the individually-determined dwell times.

The frequency step size shall not exceed 1 % of the fundamental. (The next test frequency is less than or equal to the previous test frequency times 1.01.)

*5) *For the continuous frequency sweep method (Clause 8 of IEC 61000-4-3):*[17]

The rate of sweep shall not be greater than

$$\frac{4.5 \times 10^{-3}}{X} \quad \text{decades/s}$$

where X is the dwell time in seconds determined from 4) above (the dwell time specified above for the frequency step and dwell method using a 1 % step size).

6) Objects other than the EQUIPMENT or SYSTEM and necessary simulation equipment shall not be introduced into the test area or between the field generating antenna and the location of the EQUIPMENT or SYSTEM during the uniform field calibration and during the IMMUNITY test. Necessary simulation equipment shall as much as possible be selected and located to minimize disruption of the uniform field. Special care shall be taken with monitoring equipment used to determine performance, such as cameras and conductive connections to the EQUIPMENT or SYSTEM.

7) Test conditions for EQUIPMENT and SYSTEMS with a receiving section for RF electromagnetic energy:

The receiving section of the EQUIPMENT or SYSTEM shall be tuned to the preferred frequency of reception. If the receiving section of the EQUIPMENT or SYSTEM has no preferred frequency of reception, the receiving section of the EQUIPMENT or SYSTEM shall be tuned to the center of the frequency range from which the frequency of reception can be selected.

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16 See IEC 61000-4-3:1995.

17 See IEC 61000-4-3:1995.

*8) *PATIENT-coupled cables used during the test shall be the longest allowed by the manufacturer, as specified in the ACCOMPANYING DOCUMENTS. The PATIENT coupling point shall not have an intentional conductive or capacitive connection to ground, including through the PATIENT physiological signal simulation, if used. Unintentional capacitance between the PATIENT coupling point and ground should be no greater than 250 pF. The interface between the PATIENT physiological signal simulation, if used, and the EQUIPMENT or SYSTEM shall be located within 0.1 m of the vertical plane of the uniform field area in one orientation of the EQUIPMENT or SYSTEM.*[18]

*9) *LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS that are constructed in such a way that simulated operation of sub-SYSTEMS is not feasible are exempt from the testing requirements specified by IEC 61000-4-3. If this exemption is used, such LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS shall be type tested either at one installation site or on an open area test site, using the ambient RF sources (e.g., radio (cellular/cordless) telephones, walkie-talkies, other legal transmitters) that occur in a typical health care environment. In addition, testing shall be performed in the range 80 MHz to 2.5 GHz at frequencies designated by the ITU for ISM use. The power of, and distance from, the source shall be adjusted to provide the applicable test level specified in a) above, with the exception that the actual modulations may be used (e.g., for radio (cellular/cordless) telephones, walkie-talkies). This testing allowance does not affect the requirements specified in 36.202.6. (See also 6.8.3.201 h).)*

10) *The test may be performed with the EQUIPMENT or SYSTEM powered at any one of its NOMINAL input voltages and frequencies.*

36.202.4 Electrical fast transients and bursts

*a) Requirements

EQUIPMENT and SYSTEMS shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of ±2 kV for a.c. and d.c. power lines and ±1 kV for signal and interconnecting cables. Signal and interconnecting cables specified to be (i.e., restricted to) less than 3 m in length by the manufacturer of the EQUIPMENT or SYSTEM and all PATIENT-coupled cables are not tested directly. However, the effects of any coupling between cables that are tested directly and cables that are not tested directly shall be taken into account.

Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j).

b) Tests

The test methods and equipment specified by IEC 61000-4-4 shall apply, with the following modifications:

1) *PATIENT-coupled cables of EQUIPMENT and SYSTEMS are not tested directly, but shall be attached during the testing of power lines and of all other cables that are tested. The entire length of PATIENT-coupled cables, including the PATIENT coupling point, shall be within the test environment. As much as possible, PATIENT-coupled cables shall be arranged as in NORMAL USE. They shall not be arranged so that coupling to them from cables that are tested directly is greater than the coupling that would be expected in NORMAL USE.*

2) *For INTERNALLY POWERED EQUIPMENT and SYSTEMS without the option of a.c. or d.c. power inputs, all cables are tested except PATIENT-coupled cables and signal and interconnecting cables specified to be less than 3 m in length. If such an EQUIPMENT or SYSTEM has only PATIENT-coupled cables and signal and interconnecting cables specified to be less than 3 m in length, this test does not apply.*

*3) *PATIENT-coupled parts of EQUIPMENT and SYSTEMS shall be terminated during the test as specified below.*

— *For PATIENT coupling points that do not have a conductive contact, the PATIENT coupling point shall be terminated with the artificial hand and RC element specified in CISPR 16-1. The metal foil of the artificial hand shall be sized and placed to simulate the approximate area and location of PATIENT coupling in NORMAL USE. The metal foil of the artificial hand shall be connected to terminal M of the RC element and the other terminal of the RC element shall be connected to the ground reference plane.*

— *For PATIENT coupling points that have conductive contact to the PATIENT, terminal M of the RC element (see CISPR 16-1) shall be connected directly to the conductive PATIENT connection, and the other terminal of the RC element shall be connected to the ground reference plane. If normal*

[18] See Figure AAA.1 for an example cable arrangement.

operation of the EQUIPMENT or SYSTEM cannot be verified with terminal M connected to the coupling point, an insulating material with a maximum thickness of 5 mm may be applied between the metal foil of the artificial hand (see CISPR 16-1) and the PATIENT coupling point. In this case, the metal foil of the artificial hand shall be sized and placed to simulate the approximate area and location of PATIENT coupling in NORMAL USE, and terminal M of the RC element shall be connected to the metal foil but not to the PATIENT coupling point. The other terminal of the RC element shall be connected to the ground reference plane in all cases.

— *For EQUIPMENT and SYSTEMS that have multiple PATIENT coupling points intended to be connected to a single PATIENT, each PATIENT coupling point and each PATIENT-coupled part shall have an artificial hand applied as specified above. The artificial hands shall be connected to a single common connection and this common connection shall be connected to terminal M of the RC element, as specified in CISPR 16-1. For EQUIPMENT and SYSTEMS intended to be connected to multiple PATIENTS, artificial hands shall be applied as specified above and a separate common connection and RC element shall be used for each PATIENT for which the capacitive coupling effect and RF impedance is to be simulated. The other terminal of the RC element(s) shall be connected to the ground reference plane in all cases.*

— *If a PATIENT physiological simulator is intended to simulate PATIENT physiological signals and also the capacitive coupling effect and RF impedance of the PATIENT, the PATIENT physiological simulator must provide, between the coupling point(s) and the ground reference plane, an impedance equivalent to that of the artificial hand and RC element as specified above.*

**4) HAND-HELD EQUIPMENT and parts of EQUIPMENT intended to be hand-held in NORMAL USE shall be tested with an artificial hand applied as specified in CISPR 16-1, sized and placed to simulate the approximate area and location of OPERATOR coupling in NORMAL USE. The metal foil of the artificial hand shall be connected to terminal M of an RC element, as specified in CISPR 16-1, and the other terminal of the RC element shall be connected to the ground reference plane.*

5) For EQUIPMENT and SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltages. The test may be performed with the EQUIPMENT or SYSTEM powered at any one of its NOMINAL power frequencies.

6) For EQUIPMENT and SYSTEMS with internal battery backup, it shall be verified that the EQUIPMENT or SYSTEM continues operation from mains power after the tests specified in this subclause.

36.202.5 Surges

*a) Requirements

The EQUIPMENT or SYSTEM shall comply with the requirements of 36.202.1 j) at IMMUNITY TEST LEVELS of ±0.5 kV, ±1 kV, and ±2 kV for a.c. power line(s) to ground, and ±0.5 kV and ±1 kV for a.c. power line(s) to line(s). All other EQUIPMENT and SYSTEM cables are not tested directly. The determination of compliance with this requirement shall be based on the response of the EQUIPMENT or SYSTEM, considering each surge individually, taking into account the effects of any coupling between cables that are tested directly and cables that are not tested directly.

Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j).

**b) Tests*

The test methods and equipment specified by IEC 61000-4-5 for the combination wave test shall apply, with the following modifications:

1) Only power lines and a.c. inputs to a.c.-to-d.c. converters and battery chargers are tested; however, all EQUIPMENT and SYSTEM cables shall be attached during the test.

2) Five surges at each voltage level and polarity shall be applied to each power line at each of the following a.c. voltage waveform angles: 0° or 180°, 90°, and 270°.

NOTE—While testing at both 0° and 180° is allowed, testing at only one of these two phase angles, in addition to 90° and 270°, is required.

**3) EQUIPMENT and SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ±2 kV line(s) to ground and ±1 kV line(s) to line(s). However, in case of dispute, the EQUIPMENT or SYSTEM shall comply at all the IMMUNITY TEST LEVELS specified in 36.202.5 a).*

*4) *Class II EQUIPMENT and SYSTEMS without any grounded interconnections are exempt from line(s) to ground testing.*

5) *For INTERNALLY POWERED EQUIPMENT and SYSTEMS without the option of a.c. or d.c. power inputs, this test does not apply.*

6) *For EQUIPMENT and SYSTEMS that have, for power input, multiple voltage settings, or autoranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltages. The test may be performed with the EQUIPMENT or SYSTEM powered at any one of its NOMINAL power frequencies.*

7) *For EQUIPMENT and SYSTEMS with internal battery backup, it shall be verified that the EQUIPMENT or SYSTEM continues operation from mains power after the tests specified in this subclause.*

36.202.6 Conducted disturbances, induced by RF fields

*a) Requirements

*1) General

EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING, except as specified in 3), 4), and 5) below, shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of 3 Vrms over the frequency range beginning at the start frequency determined as specified in 6) below and extending to 80 MHz.

*2) LIFE-SUPPORTING EQUIPMENT and SYSTEMS

LIFE-SUPPORTING EQUIPMENT and SYSTEMS, except as specified in 3), 4), and 5) below, shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of 3 Vrms over the frequency range beginning at the start frequency determined as specified in 6) below and extending to 80 MHz, and 10 Vrms in the industrial, scientific, and medical (ISM) frequency bands between the start frequency and 80 MHz.

*3) EQUIPMENT and SYSTEMS specified for use only in a shielded location

EQUIPMENT and SYSTEMS specified for use only in a shielded location, except within the EXCLUSION BAND as specified in 4) below, may comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL that is reduced from the test level specified in 1) or 2) above, as applicable, in proportion to the applicable specified value of minimum RF shielding effectiveness and filter attenuation, provided the RF shielding effectiveness and filter attenuation specification meets the requirements specified in 6.8.3.201 c) 2).

*4) EQUIPMENT and SYSTEMS that intentionally receive RF electromagnetic energy

EQUIPMENT and SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation are exempt from the ESSENTIAL PERFORMANCE requirements of 36.202.1 j) in the EXCLUSION BAND; however, in the EXCLUSION BAND, the EQUIPMENT or SYSTEM shall remain safe and the other FUNCTIONS of the EQUIPMENT or SYSTEM shall comply with the requirements specified in 1) or 2) above, as applicable. EQUIPMENT and SYSTEMS shall comply with the requirements specified in 1) or 2) above, as applicable, outside of the EXCLUSION BAND.

*5) INTERNALLY POWERED EQUIPMENT

INTERNALLY POWERED EQUIPMENT that cannot be used during battery charging, is of less than 1 m maximum dimension including the maximum length of all cables connected[19], and has no connection to ground, telecommunications systems, any other EQUIPMENT or SYSTEM, or a PATIENT, is exempt from the requirements of 36.202.6.

6) Start frequency

The start frequency (lower end of the test frequency range) used for testing each cable of the EQUIPMENT or SYSTEM shall be determined as follows:

— For INTERNALLY POWERED EQUIPMENT and SYSTEMS that cannot be used during battery charging, do not have an option for a.c. power input, and have no connection to ground, telecommunications systems, any other EQUIPMENT or SYSTEM, or a PATIENT, the start frequency shall be determined

[19] See Figure AAA.2 for guidance on determination of the maximum dimension.

from Figure B.1 of IEC 61000-4-6, using the maximum dimension of the EQUIPMENT or SYSTEM, including the maximum length of each cable connected.[20]

— For all other EQUIPMENT and SYSTEMS, the start frequency shall be 150 kHz.

Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j).

b) Tests

The method and equipment specified by IEC 61000-4-6 shall apply, with the following modifications:

1) The following provisions of IEC 61000-4-6 are modified or clarified: [21]

*— The terms “direct injection” and “injection using a coupling and decoupling network” are used throughout IEC 61000-4-6. In that standard, “direct injection” means that no capacitors are used in the injection circuit. The term "CDN" (coupling and decoupling network) is used in this standard to indicate the network that is appropriate for the individual cable under test as specified by IEC 61000-4-6, whether or not the coupling/decoupling network includes a capacitor.

*— *Subclause 6.2.2.1, last dash, does not apply.*

*— *Subclause 6.4.1 is modified such that:*

- *The calibration accuracy of the IMMUNITY TEST LEVEL shall be between –0 % and +25 % for linear quantities or –0 dB and +2 dB for log quantities.*
- *Calibration for current injection clamps shall be performed in a 150 Ω system.*
- *Calibrations shall be performed using a frequency step size no greater than 1 % of the fundamental.*

*— *Subclause 7.1.2 is replaced by the following:*

- *At least one representative cable of each FUNCTION on the EQUIPMENT or SYSTEM shall be tested.*
- *All PATIENT-coupled cables shall be tested, either individually or bundled, as specified in 7.1.1.*
- *The power input cable shall be tested.*
- *The POTENTIAL EQUALIZATION CONDUCTOR shall be tested.*

*— *Subclause 7.3 shall be modified so that the reduced current injected under this condition is greater than or equal to the I_{max} specified, by the accuracy values of between –0 % and +25 % for linear quantities or –0 dB and +2 dB for log quantities.*

*— *The alternative method of 7.5 may only be applied when there is only one configuration of the SYSTEM.*

2) Cables selected for testing for which a CDN is suitable shall have the CDN in place during the test. All CDNs that are not being used to inject the test signal shall be terminated with a 50 Ω load.

**3) PATIENT-coupled cables shall be tested using a current clamp. In cases where a current clamp is not suitable, an EM clamp shall be used. CDNs are not suitable for, and shall not be applied to, PATIENT-coupled cables.*

PATIENT-coupled parts of EQUIPMENT and SYSTEMS shall be terminated during the test as specified below. No intentional decoupling device shall be used between the injection point and the PATIENT coupling point in all cases.

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[20] See Figure AAA.2 for guidance on determination of the maximum dimension.

[21] See IEC 61000-4-6:1996.

— *For PATIENT coupling points that do not have a conductive contact, the PATIENT coupling point shall be terminated with the artificial hand and RC element specified in CISPR 16-1. The metal foil of the artificial hand shall be sized and placed to simulate the approximate area and location of PATIENT coupling in NORMAL USE. The metal foil of the artificial hand shall be connected to terminal M of the RC element, and the other terminal of the RC element shall be connected to the ground reference plane.*

— *For PATIENT coupling points that have conductive contact to the PATIENT, terminal M of the RC element (see CISPR 16-1) shall be connected directly to the conductive PATIENT connection, and the other terminal of the RC element shall be connected to the ground reference plane. If normal operation of the EQUIPMENT or SYSTEM cannot be verified with terminal M of the artificial hand connected to the coupling point, an insulating material with a maximum thickness of 5 mm may be applied between the metal foil of the artificial hand (see CISPR 16-1) and the PATIENT coupling point. In this case, the metal foil of the artificial hand shall be sized and placed to simulate the approximate area of PATIENT coupling in NORMAL USE, and terminal M of the RC element shall be connected to the metal foil but not to the PATIENT coupling point. The other terminal of the RC element shall be connected to the ground reference plane in all cases.*

— *For EQUIPMENT and SYSTEMS that have multiple PATIENT coupling points intended to be connected to a single PATIENT, each PATIENT coupling point and each PATIENT-coupled part shall have an artificial hand applied as specified above. The artificial hands shall be connected to a single common connection, and this common connection shall be connected to terminal M of the RC element, as specified in CISPR 16-1. For EQUIPMENT and SYSTEMS intended to be connected to multiple PATIENTS, artificial hands shall be applied as specified above and a separate common connection and RC element shall be used for each PATIENT for which the capacitive coupling effect and RF impedance is to be simulated. The other terminal of the RC element(s) shall be connected to the ground reference plane in all cases.*

— *If a PATIENT physiological simulator is intended to simulate PATIENT physiological signals and also the capacitive coupling effect and RF impedance of the PATIENT, the PATIENT physiological simulator must provide, between the coupling point(s) and the ground reference plane, an impedance equivalent to that of the artificial hand and RC element as specified above.*

**4) HAND-HELD EQUIPMENT and parts of EQUIPMENT intended to be hand-held in NORMAL USE shall be tested with an artificial hand applied as specified in CISPR 16-1, sized and placed to simulate the approximate area and location of OPERATOR coupling in NORMAL USE, with the exception that PATIENT-coupled cables are tested as specified in 3), above. The metal foil of the artificial hand shall be connected to terminal M of an RC element, as specified in CISPR 16-1, and the other terminal of the RC element shall be connected to the ground reference plane.*

**5) POTENTIAL EQUALIZATION CONDUCTORS shall be tested using an M1 CDN. (See Figure D.2 of IEC 61000-4-6.)*

**6) For each cable injection, the test signal shall be 80 % amplitude modulated at the modulation frequency specified in Table 209 (see 36.202.3 b) 3), based upon the intended use of the EQUIPMENT or SYSTEM. (Unmodulated and modulated waveforms normalized to a generator output of 1.00 Vrms are shown in Figure 4 of IEC 61000-4-6.)[22] For EQUIPMENT and SYSTEMS for which testing at 2 Hz is required, it is not necessary to test additionally at 1 kHz. For EQUIPMENT and SYSTEMS intended to monitor or measure a physiological parameter, the PHYSIOLOGICAL SIMULATION FREQUENCY restrictions specified in Table 209 shall apply. For EQUIPMENT and SYSTEMS intended to control a physiological parameter, the OPERATING FREQUENCY restrictions specified in Table 209 shall apply.*

**7) For the frequency step and dwell method (Clause 8 of IEC 61000-4-6): [23]*

The minimum dwell time shall be based upon the time required for the EQUIPMENT or SYSTEM to be exercised (if applicable) and adequately respond to the test signal. The dwell time shall be at least 3 s for EQUIPMENT and SYSTEMS tested with a 2 Hz modulation frequency and 1 s for all other EQUIPMENT and SYSTEMS, and shall be no less than the response time of the slowest responding FUNCTION plus the settling time of the conducted RF IMMUNITY test system. For EQUIPMENT and SYSTEMS that average data over time for which faster-responding signals cannot be used to determine the effect of the test signal on the EQUIPMENT or SYSTEM, the dwell time shall be no less than 1.2 times the averaging period. If the

[22] See IEC 61000-4-6:1996.

[23] See IEC 61000-4-6:1996.

averaging period is adjustable, the averaging period used to determine dwell time shall be that which is expected to be used most often in clinical application of the EQUIPMENT or SYSTEM. For EQUIPMENT and SYSTEMS for which faster-responding signals can be used to determine the effect of the test signal on the EQUIPMENT or SYSTEM, the dwell time may be reduced if the faster-responding signals are monitored. In this case, the dwell time shall be no less than the response time of the signal or of the monitoring system, whichever is greater, plus the response time of the conducted RF IMMUNITY test system, but in no case less than 3 s for EQUIPMENT and SYSTEMS tested with a 2 Hz modulation frequency and 1 s for all other EQUIPMENT and SYSTEMS. For EQUIPMENT and SYSTEMS that have multiple individual parameters or sub-SYSTEMS, each of which would yield a different dwell time, the value used shall be the maximum of the individually-determined dwell times.

The frequency step size shall not exceed 1 % of the fundamental. (The next test frequency is less than or equal to the previous test frequency times 1.01.)

**8) For the continuous frequency sweep method (Clause 8 of IEC 61000-4-6):[24]*

The rate of sweep shall not be greater than

$$\frac{4.5 \times 10^{-3}}{X} \quad \text{decades/s}$$

where X is the dwell time in seconds determined from 7) above (the dwell time specified above for the frequency step and dwell method using a 1 % step size).

9) Test conditions for EQUIPMENT and SYSTEMS with a receiving section for RF electromagnetic energy:

The receiving section of the EQUIPMENT or SYSTEM shall be tuned to the preferred frequency of reception. If the receiving section of the EQUIPMENT or SYSTEM has no preferred frequency of reception, the receiving section of the EQUIPMENT or SYSTEM shall be tuned to the center of the frequency range from which the frequency of reception can be selected.

10) The test may be performed with the EQUIPMENT or SYSTEM powered at any one of its NOMINAL power voltages and frequencies.

36.202.7 Voltage dips, short interruptions, and voltage variations on power supply input lines

*a) Requirements

1) EQUIPMENT and SYSTEMS with a RATED input power of 1 kVA or less and all LIFE-SUPPORTING EQUIPMENT and SYSTEMS shall comply with the requirements of 36.202.1 j) at the IMMUNITY TEST LEVELS specified in Table 210. For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and for which the RATED input power is greater than 1 kVA and the RATED input current is less than or equal to 16 A per phase, deviation from the requirements of 36.202.1 j) is allowed at the IMMUNITY TEST LEVELS specified in Table 210, provided the EQUIPMENT or SYSTEM remains safe, experiences no component failures, and is restorable to the pre-test state with OPERATOR intervention. Determination of compliance is based upon performance of the EQUIPMENT or SYSTEM during and after application of the test sequence. EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and for which the RATED input current exceeds 16 A per phase are exempt from the testing specified in Table 210.

*2) EQUIPMENT and SYSTEMS are allowed a deviation from the requirements of 36.202.1 j) at the IMMUNITY TEST LEVEL specified in Table 211, provided the EQUIPMENT or SYSTEM remains safe, experiences no component failures, and is restorable to the pre-test state with OPERATOR intervention. Determination of compliance is based upon performance of the EQUIPMENT or SYSTEM during and after application of the test sequence.

LIFE-SUPPORTING EQUIPMENT and SYSTEMS for which this allowance for a deviation from the requirements of 36.202.1 j) is used shall provide an alarm complying with applicable international standards to indicate cessation or interruption of an intended operation related to ESSENTIAL PERFORMANCE.

[24] See IEC 61000-4-6:1996.

Table 210—IMMUNITY TEST LEVELS for voltage dips

Voltage test level % U_T	Voltage dip % U_T	Duration periods
<5	>95	0.5
40	60	5
70	30	25
NOTE—U_T is the a.c. mains voltage prior to application of the test level.		

Table 211—IMMUNITY TEST LEVEL for voltage interruption

Voltage test level % U_T	Voltage dip % U_T	Duration s
<5	>95	5
NOTE—U_T is the a.c. mains voltage prior to application of the test level.		

b) Tests

The test methods and equipment specified by IEC 61000-4-11 shall apply, with the following modifications:

1) Multiple phase EQUIPMENT and SYSTEMS shall be tested one phase at a time.

2) Test voltage changes shall be step changes and start at a zero crossing. For multiple phase EQUIPMENT and SYSTEMS, the zero crossing shall be referenced to the phase under test.

3) EQUIPMENT and SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the manufacturer of the EQUIPMENT or SYSTEM. The IMMUNITY TEST LEVELS shall be applied to the a.c. power input of the converter.

4) For EQUIPMENT and SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltages. The test shall be performed at the minimum RATED power frequency.

5) For EQUIPMENT and SYSTEMS with internal battery backup, it shall be verified that the EQUIPMENT or SYSTEM resumes operation from mains power after the tests specified in Tables 210 and 211.

***36.202.8 Magnetic fields**

36.202.8.1 Power frequency magnetic fields

*a) Requirements

EQUIPMENT and SYSTEMS shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of 3 A/m.

Compliance is checked by the following tests and determined during and after the tests in accordance with 36.202.1 j).

b) Tests

The methods and equipment specified by IEC 61000-4-8 shall apply, with the following modifications:

**1) Only the continuous field test shall be performed.*

— *The test shall be performed at both 50 Hz and 60 Hz, with the exception that EQUIPMENT and SYSTEMS RATED for use only at one of these frequencies need only be tested at that frequency. In either case, during the test, the EQUIPMENT or SYSTEM shall be powered at the same frequency as the applied magnetic field.*

— *If the EQUIPMENT or SYSTEM is INTERNALLY POWERED or powered from an external d.c. supply, the test shall be performed at both 50 Hz and 60 Hz, with the exception that EQUIPMENT and SYSTEMS*

intended for use only in areas supplied at one of these frequencies need be tested only at that frequency.

2) The test may be performed with the EQUIPMENT or SYSTEM powered at any one of its NOMINAL power voltages.

***36.202.8.2 Pulsed magnetic fields**

No requirements apply.

***36.202.8.3 Damped oscillatory magnetic fields**

No requirements apply.

***36.202.9 Conducted disturbances in the range 0 Hz to 150 kHz**

No requirements apply.

***36.202.10 Oscillatory waves**

No requirements apply.

***36.202.11 Harmonics, interharmonics including mains signaling at a.c. power port**

No requirements apply.

***36.202.12 Ripple on d.c. power supply**

No requirements apply.

***36.202.13 Unbalance**

No requirements apply.

36.202.14 Variations of power frequency

The requirements of 10.2.2 of IEC 60601-1 apply.

SECTIONS SIX TO TEN—NOT USED

Annex AAA
(informative)

General guidance and rationale

Subclause 1.201

The scope of this standard includes INFORMATION TECHNOLOGY EQUIPMENT (ITE) used in MEDICAL ELECTRICAL SYSTEMS through the definition of MEDICAL ELECTRICAL SYSTEMS. This standard should not be applied, without modification, to implantable MEDICAL ELECTRICAL EQUIPMENT.

Electrical/electronic infrastructure (e.g., existing local area networks, telecommunications networks, power networks) need not be tested for EMC in accordance with this standard as part of a MEDICAL ELECTRICAL SYSTEM. However, the effects of such electrical/electronic infrastructure should be considered as part of a risk assessment in accordance with IEC 60601-1-4 or ISO 14971, and electrical/electronic infrastructure intended to be used as part of a MEDICAL ELECTRICAL SYSTEM should be simulated during testing. Equipment provided by the manufacturer of the MEDICAL ELECTRICAL SYSTEM and intended to be connected to the SYSTEM by way of existing electrical/electronic infrastructure should meet the requirements of this standard. If local area networks or telecommunications networks are supplied as part of a MEDICAL ELECTRICAL SYSTEM by the manufacturer of the SYSTEM, they should be tested for EMC as specified in this standard, as part of the SYSTEM.

Subclause 2.202

The IEV definition has been modified in this standard by replacing “any device, equipment, or system” with “an EQUIPMENT or SYSTEM” and by printing “DEGRADATION” in SMALL CAPITALS.

Subclause 2.203

The IEV definition has been modified for this standard by revising the note to make it easier to understand. The note appears in IEV 161-04-16 as follows:

NOTE—For the ITU and in Chapter 712, the term “effective radiated power” without qualification is used only when the reference antenna is a half-wave dipole.

Subclause 2.204

The IEV definition has been modified for this standard by printing defined terms in SMALL CAPITALS.

Subclause 2.205

In this Collateral Standard for MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS, it is inappropriate to imply that an ELECTROMAGNETIC DISTURBANCE might “adversely affect living (or inert) matter.” As a consequence, in an otherwise unchanged text, this phrase of IEV definition 161-01-05 has not been retained. The IEV definition has also been modified for this standard by printing defined terms in SMALL CAPITALS.

Subclause 2.207

The IEV definition has been modified for this standard by printing defined terms in SMALL CAPITALS.

Subclause 2.211

This definition is adapted from the “alignment range” specifications of I-ETS 300 220 and from ETS 300 741.

Subclause 2.212

The following are examples of the FUNCTIONS of an EQUIPMENT or SYSTEM:

— The FUNCTIONS of a heart-rate monitor include measurement and display of heart rate, and may additionally include audible and visual alarms and display of the ECG waveform.

— The FUNCTIONS of an automatic external defibrillator include ECG analysis and defibrillation, and may additionally include ECG monitoring, pacing, and logging.

Subclause 2.214

The IEV definition has been modified in this standard by replacing “a device, equipment, or system” with “an EQUIPMENT or SYSTEM” and by printing defined terms in SMALL CAPITALS.

Subclause 2.216

The IEV definition has been modified in this standard by printing defined terms in SMALL CAPITALS.

Subclause 2.218

The size chosen for this definition was based upon the limitations of typical test facilities. Physical limitations of door sizes and the uniform field area were considered.

Subclause 2.219

Both categories of EQUIPMENT and SYSTEMS, those used to keep PATIENTS alive and those used to resuscitate PATIENTS, are differentiated from other types of EQUIPMENT and SYSTEMS by the requirement to actively intervene to support life.

Subclause 2.220

This is consistent with definition IEV 601-01-26 (“a set of voltage levels used for the distribution of electricity and whose upper limit is generally accepted to be 1,000 V a.c.”) and with the scope of European Union Directive 73/23/EEC, commonly known as the “Low-voltage directive” (“equipment designed for use with a voltage rating of between 50 V and 1,000 V for alternating current and between 75 and 1,500 V for direct current”).

Subclause 2.221

The SYSTEM includes those ACCESSORIES that are needed for operating the SYSTEM as specified by the manufacturer. The meaning of the note, which is copied verbatim from IEC 60601-1-1, is that a MEDICAL ELECTRICAL SYSTEM can consist of MEDICAL ELECTRICAL EQUIPMENT used in combination with other MEDICAL ELECTRICAL EQUIPMENT, as well as non-medical electrical equipment used in combination with MEDICAL ELECTRICAL EQUIPMENT.

Subclause 2.222

For example, the OPERATING FREQUENCY (fundamental) for a ventilator could be 0.1 Hz (a rate of 6 breaths per minute). The signal could also contain harmonics to properly replicate the wave shape (I/E ratio) of a human respiratory cycle.

Subclause 2.223

This definition does not include inactive, mechanical PATIENT supports (e.g., bed rails, braces).

Subclause 2.224

For example, the simulation frequency (fundamental) for an ECG monitor could be 0.92 Hz (a heart rate of 55 beats per minute). The signal could also contain harmonics of several hundred Hz in order to have a wave shape that mimics that of a human.

Subclause 2.225

The PUBLIC MAINS NETWORK is referred to in Table 201 as the “public low-voltage power supply network that supplies buildings used for domestic purposes” to harmonize somewhat with CISPR 11 and because the tables are for the customer or user, who may not be familiar with this standard and its definitions. In CISPR 11, the PUBLIC MAINS NETWORK is called the “low-voltage power supply network which supplies buildings used for domestic purposes” and “domestic electricity power supplies,” and in IEC 61000-3-2 and IEC 61000-3-3 it is called the “public supply system,” the “public low-voltage system,” and the “public low-voltage distribution system.”

Subclause 2.226

This definition has been adapted from the definition of radio frequency (data transmission) in ANSI/IEEE 100:1996 by modifying the NOTE.

Subclause 3.201.1

Compliance with this requirement is demonstrated by compliance with the requirements of this standard. Compliance with the requirement that EQUIPMENT and SYSTEMS shall not emit ELECTROMAGNETIC DISTURBANCES that could affect radio services, other equipment, or the ESSENTIAL PERFORMANCE of other EQUIPMENT and SYSTEMS is demonstrated by

compliance with the requirements of Clause 6 and 36.201 of this standard. Compliance with the requirement that ESSENTIAL PERFORMANCE of EQUIPMENT and SYSTEMS have adequate IMMUNITY to ELECTROMAGNETIC DISTURBANCES is demonstrated by compliance with the requirements of Clause 6 and 36.202 of this standard.

Subclause 3.201.2

If this risk analysis is performed and the ESSENTIAL PERFORMANCE of the EQUIPMENT or SYSTEM has been identified, the ESSENTIAL PERFORMANCE should meet the requirements of 36.202. If this risk analysis is not performed, all FUNCTIONS of the EQUIPMENT or SYSTEM are considered ESSENTIAL PERFORMANCE for the purpose of IMMUNITY testing and must meet the requirements of 36.202.

Consideration should be given to ISO 14971 and IEC 60601-1-4 for this risk analysis.

Subclause 3.201.4

Consideration should be given to ISO 14971 and IEC 60601-1-4 for this risk analysis.

Subclause 6.1.201.1

EQUIPMENT that applies RF electromagnetic energy for diagnosis or treatment is usually CISPR 11 Group 2. This requirement does not apply to monitoring EQUIPMENT and SYSTEMS (e.g., impedance plethysmography (respiration or apnea) monitors).

Subclause 6.8.2.201 b) 3)

Staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a hand-held TOOL unless proper precautionary procedures have been followed.

Precautionary procedures include:

— methods to prevent build-up of electrostatic charge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing);

— discharging one's body to the frame of the EQUIPMENT or SYSTEM or to earth or a large metal object;

— bonding oneself by means of a wrist strap to the EQUIPMENT or SYSTEM or to earth.

Subclause 6.8.2.201 b) 4)

Staff that could touch connectors identified with the ESD warning symbol should receive this explanation and training. This includes clinical/biomedical engineering and health-care staff.

Subclause 6.8.2.201 b) 5)

ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice, and the damage that can be done to electronic components if they are touched by an OPERATOR who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the EQUIPMENT or SYSTEM, or bond oneself by means of a wrist strap to the EQUIPMENT or SYSTEM or to earth prior to making a connection.

Subclause 6.8.3.201 a) 1) and 2)

The use of ACCESSORIES, cables, and transducers other than those for which the EQUIPMENT or SYSTEM was designed can significantly degrade EMISSIONS and IMMUNITY performance. Therefore, a warning on the use of ACCESSORIES, transducers, and cables other than those specified in the ACCOMPANYING DOCUMENTS is necessary to help ensure that the user will be able to operate the EQUIPMENT or SYSTEM as intended.

Subclause 6.8.3.201 a) 3)

Unless EQUIPMENT and SYSTEMS have an extremely high level of IMMUNITY (e.g., radiated IMMUNITY of 200 V/m, ESD IMMUNITY of 35 kV) and a low level of EMISSIONS (e.g., CISPR 11 Group I, Class B), it will always be necessary for the customer or the user to manage the ELECTROMAGNETIC ENVIRONMENT. The tables and other guidance that are required to be included in the ACCOMPANYING DOCUMENTS provide information to the customer or user that is essential in determining the suitability of the EQUIPMENT or SYSTEM for the ELECTROMAGNETIC ENVIRONMENT of use, and in managing the ELECTROMAGNETIC ENVIRONMENT of use to permit the EQUIPMENT or SYSTEM to perform as intended without disturbing other EQUIPMENT and SYSTEMS or non-medical electrical equipment.

Subclause 6.8.3.201 a) 4)

The EMISSIONS limits, IEC 60601 TEST LEVELS, and tests specified by this standard do not address ELECTROMAGNETIC COMPATIBILITY of electrical equipment at very close distances. Unless all electrical equipment is compatible with respect to both electrical fields and magnetic fields at very close distances over the entire range of expected frequencies, separation is prudent. If it is essential to use the EQUIPMENT or SYSTEM very close to other electrical equipment, it is prudent to determine, by observation, if the performance of either product is affected by unintended electromagnetic coupling.

Subclause 6.8.3.201 a) 5)

A justification for lower COMPLIANCE LEVELS is required to be included in the ACCOMPANYING DOCUMENTS to convey to the customer or user that there are physical, technological, or physiological limitations to the ability of the EQUIPMENT or SYSTEM to perform as intended in the presence of ELECTROMAGNETIC DISTURBANCES. This will also help to emphasize the importance of the associated additional guidance, in the tables, for managing the ELECTROMAGNETIC ENVIRONMENT.

For the IEC 61000-4-11 IMMUNITY test, "lower COMPLIANCE LEVELS" (36.202.1 a)) means shorter duration of the voltage dip or interruption, or less of a dip in voltage. Similarly, "higher COMPLIANCE LEVELS" means longer duration of the voltage dip or interruption, or a greater dip in voltage.

Subclause 6.8.3.201 a) 6)

Unless EQUIPMENT and SYSTEMS have an extremely high level of IMMUNITY (e.g., radiated IMMUNITY of 200 V/m, ESD IMMUNITY of 35 kV), it will always be necessary for the customer or the user to manage the ELECTROMAGNETIC ENVIRONMENT. The tables that are required to be included in the ACCOMPANYING DOCUMENTS provide information to the customer or user that is essential in determining the suitability of the EQUIPMENT or SYSTEM for the ELECTROMAGNETIC ENVIRONMENT of use, and in managing the ELECTROMAGNETIC ENVIRONMENT of use to permit the EQUIPMENT or SYSTEM to perform as intended.

Subclause 6.8.3.201 a) 6) second dash

The restriction on lower and higher COMPLIANCE LEVELS that can be claimed is intended to ensure that if lower COMPLIANCE LEVELS are justified or higher levels claimed, they differ from the IEC 60601 TEST LEVEL by an amount that is significant from an EMC standpoint.

All IMMUNITY tests are applicable unless the EQUIPMENT or SYSTEM is outside the scope of an EMC basic standard, 36.202 specifies that the test is not applicable, or it is not possible to perform the test for the particular EQUIPMENT or SYSTEM. For example, the IEC 61000-4-11 test would not be applicable for INTERNALLY POWERED EQUIPMENT that has no provision for connection to mains power.

Subclause 6.8.3.201 a) 6) third dash

If the COMPLIANCE LEVEL equals the IEC 60601 TEST LEVEL of this standard for each IMMUNITY test, no changes to the guidance in column 4 of Table 202 should be made. For IMMUNITY tests for which the COMPLIANCE LEVEL is lower than the IEC 60601 TEST LEVEL of this standard (and justified), example text for column 4 of Table 202 appears below. If the COMPLIANCE LEVEL is higher than the IEC 60601 TEST LEVEL of this standard for an IMMUNITY test, the manufacturer of the EQUIPMENT or SYSTEM may choose either to use the existing text in column 4 of Table 202 without modification, or to describe the characteristics of the ELECTROMAGNETIC ENVIRONMENT in which the EQUIPMENT or SYSTEM is suitable due to its higher IMMUNITY. One example of text for column 4 of Table 202 for EQUIPMENT and SYSTEMS for which the COMPLIANCE LEVEL is higher than the IEC 60601 TEST LEVEL for the IEC 61000-4-11 test appears below (see Re: 36.202.2, *Electrostatic discharge (ESD)* and Re: 36.202.7, *Voltage dips, short interruptions, and voltage variations on power supply input lines*).

— Re: 36.202.2, *Electrostatic discharge (ESD)*

  For example, if test level 2 of IEC 61000-4-2 (±4 kV contact discharge and ±4 kV air discharge) is claimed (and justified), it may be necessary to recommend the use of anti-static materials or higher relative humidity. If test level 4 of IEC 61000-4-2 (±8 kV contact discharge and ±15 kV air discharge) is claimed, the EQUIPMENT or SYSTEM could be specified for use in a dry environment.

— Re: 36.202.4, *Electrical fast transients and bursts*

  For example, if a lower COMPLIANCE LEVEL is claimed (and justified), it may be necessary to recommend the use of filters on power input lines or minimum separation between signal lines and power lines.

— Re: 36.202.5, *Surges*

For example, if a lower COMPLIANCE LEVEL is claimed (and justified), it may be necessary to recommend the use of surge suppression devices.

— Re: 36.202.7, *Voltage dips, short interruptions, and voltage variations on power supply input lines*

For this test, "lower COMPLIANCE LEVELS" (see 36.202.1 a)) means shorter duration of the voltage dip or interruption, or less of a dip in voltage. Similarly, "higher COMPLIANCE LEVELS" means longer duration of the voltage dip or interruption, or a greater dip in voltage.

If a lower COMPLIANCE LEVEL is claimed (and justified), it may be necessary to make additional recommendations regarding the use of uninterruptible power supplies, batteries, or other power conditioning equipment.

For EQUIPMENT and SYSTEMS with internal batteries that can meet a higher IMMUNITY TEST LEVEL for the IEC 61000-4-11 voltage interruption test, the guidance in column 4 of Table 202 may be revised accordingly. If, for example, a ventilator meets the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of <5 % U_T for 24 h, the text in column 4 of Table 202 could be replaced with the following (or equivalent):

> Mains power quality should be that of a typical commercial or hospital environment. If an interruption of mains power occurs, the [EQUIPMENT or SYSTEM] is capable of continued operation for a minimum of 24 h, provided the batteries are charged prior to the interruption of mains power.

— Re: 36.202.8.1, *Power frequency magnetic fields*

For example, if a lower COMPLIANCE LEVEL is claimed (and justified), it may be necessary to recommend positioning the EQUIPMENT or SYSTEM further from sources of power frequency magnetic fields or installation of magnetic shielding.

Subclause 6.8.3.201 b)

See annex BBB for examples of completion of Tables 203, 204, 205, and 206.

See annex AAA, subclause 6.8.3.201 a) 6).

The restriction on lower and higher COMPLIANCE LEVELS that can be claimed is intended to ensure that if lower IMMUNITY TEST LEVELS are justified or higher levels claimed, they differ from the IEC 60601 TEST LEVEL by an amount that is significant from an EMC standpoint.

The increased radiated RF IMMUNITY TEST LEVEL for LIFE-SUPPORTING EQUIPMENT and SYSTEMS is intended as an additional safety margin to decrease the likelihood that mobile/portable communications equipment, such as a radio (cellular/cordless) telephone, could cause DEGRADATION of an EQUIPMENT or SYSTEM that results in harm to a PATIENT if the portable/mobile communications equipment is brought into PATIENT areas. This requirement is not intended to permit the use of such mobile/portable communications equipment closer to EQUIPMENT and SYSTEMS. Therefore, for LIFE-SUPPORTING EQUIPMENT and SYSTEMS, the calculation of the recommended maximum field strength and minimum separation distance takes this safety margin into account. An additional factor of 10/3 is used in the recommended separation distance equations for the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz.

Four equations are used to calculate the recommended separation distances in Tables 203 and 205, and three equations are used to calculate the recommended separation distances in Tables 204 and 206. V_1 and V_2 are used in the frequency range 150 kHz to 80 MHz because the IEC 61000-4-6 conducted RF IMMUNITY test is used as a substitute for radiated RF IMMUNITY testing in that frequency range. The equations are derived from equation F.1 in annex F of IEC 61000-4-3[25] by solving for d and substituting the variable that represents the COMPLIANCE LEVEL for *E*. The constants used in the equations are based on the following assumptions regarding mobile/portable RF transmitters:

— the radiated field strength in free space at a given distance from the antenna approximates that of an ideal half-wave dipole for transmitters with frequencies above 800 MHz (k = 7);

— the radiated field strength in free space at a given distance from the antenna is approximately half that of an ideal half-wave dipole for transmitters with frequencies below 800 MHz (k = 3.5);

— antennas with gain are not usually used in mobile/portable communications equipment.

[25] See Amendment 1 (1998) of IEC 61000-4-3:1995.

For EQUIPMENT and SYSTEMS that are specified for use only in a shielded location and that comply with reduced RF IMMUNITY TEST LEVELS based upon the minimum RF shielding effectiveness and filter attenuation specified for the shielded location (see 36.202.3 a) 3) and 36.202.6 a) 3)), it is not meaningful to discuss separation distances. For this reason, Table 207 is used instead of Tables 203 and 205, and Table 208 is used instead of Tables 204 and 206. (See also 6.8.3.201 c) 4).)

Subclause 6.8.3.201 c) 2)

EQUIPMENT and SYSTEMS may need to be specified for use only in a shielded location as a result of either the EMISSIONS or IMMUNITY characteristics of the EQUIPMENT or SYSTEM. The specifications for the shielded location that result from the EMISSIONS characteristics and the specifications for the shielded location that result from the IMMUNITY characteristics of the EQUIPMENT or SYSTEM must be identical because they apply to the same shielded location.

The specified value(s) for minimum RF shielding effectiveness and minimum RF filter attenuation must be identical in each frequency range for which they are specified so that radiated RF will not bypass the filters and conducted RF will not bypass the shielding. This is true even if use in a shielded location is specified only to comply with the IEC 61000-4-6 test. In this case, the specified value(s) for minimum RF shielding effectiveness must also be identical to the specified minimum value(s) for RF filter attenuation in each frequency range for which they are specified because, although the test is performed on cables, it is intended to simulate the effect of radiated RF sources.

If use only in a shielded location is specified as a result of the IMMUNITY characteristics of the EQUIPMENT or SYSTEM, the manufacturer may choose not to use the EMISSIONS allowance in 36.201.1 a) 4). If this allowance is not used, it is not necessary to add the text specified in 6.8.3.201 c) 2) to Table 201.

Subclause 6.8.3.201 c) 3)

For example, a manufacturer might specify that equipment such as high-frequency surgery EQUIPMENT, walkie-talkies, and radio (cellular/cordless) telephones should be prohibited from inside the shielded location or be turned off when the EQUIPMENT or SYSTEM is in use. A manufacturer might also make recommendations regarding other EQUIPMENT or SYSTEMS that are also specified for use only in a shielded location, e.g., that they be prohibited from inside the same shielded location or be turned off when the EQUIPMENT or SYSTEM of the manufacturer making the recommendation is in use.

Whether or not use only in a shielded location is specified as a result of the IMMUNITY characteristics of the EQUIPMENT or SYSTEM (e.g., it could be specified as a result of the EMISSIONS characteristics), RF reflections in a shielded location result in field strengths at various locations within the room that do not necessarily decrease with distance as predicted by the equations in Tables 203 through 206. Therefore, caution would dictate that RF transmitters should not be used inside the specified shielded location.

A recommendation should be made to the customer to post signs at all entrances to shielded locations regarding equipment allowed or prohibited because of the importance of this requirement and the fact that the information in the ACCOMPANYING DOCUMENTS is not likely to be readily available to health-care providers, PATIENTS, or visitors.

Subclause 6.8.3.201 c) 4)

See annex BBB for examples of completion of Tables 207 and 208.

See annex AAA, subclause 6.8.3.201 a) 6).

The restriction on lower and higher COMPLIANCE LEVELS that can be claimed is intended to ensure that if lower IMMUNITY TEST LEVELS are justified or higher COMPLIANCE LEVELS are claimed, they differ from the IEC 60601 TEST LEVEL by an amount that is significant from an EMC standpoint.

For EQUIPMENT and SYSTEMS that are specified for use only in a shielded location and that comply with reduced RF IMMUNITY TEST LEVELS based upon the specified minimum RF shielding effectiveness and filter attenuation of the shielded location (see 36.202.3 a) 3) and 36.202.6 a) 3)), it is not meaningful to discuss separation distances. For this reason, Table 207 is used instead of Tables 203 and 205, and Table 208 is used instead of Tables 204 and 206.

Subclause 6.8.3.201 c) 4), third dash

See annex AAA, subclause 6.8.3.201 c) 2).

Subclause 6.8.3.201 g)

The use of an ACCESSORY, cable, or transducer other than those for which the EQUIPMENT or SYSTEM was designed or tested can significantly degrade EMISSIONS and IMMUNITY performance. Therefore, a warning on the use of the ACCESSORY, transducer, and cable with EQUIPMENT and SYSTEMS other than those specified in the ACCOMPANYING DOCUMENTS is necessary to help assure that the user will be able to operate EQUIPMENT and SYSTEMS as intended. If a

third-party supplier offers ACCESSORIES, cables, or transducers for use with an EQUIPMENT or SYSTEM and they are not listed or specified in the ACCOMPANYING DOCUMENTS for the EQUIPMENT or SYSTEM, it is the responsibility of that third-party supplier or the customer to determine compliance with the requirements of this standard for the EQUIPMENT or SYSTEM when used with the ACCESSORY, cable, or transducer.

Subclause 6.8.3.201 h) 3)

Types of modulation are listed in the ITU Radio Regulations, Volume 2, *Appendices*, Appendix S1, *Classification of emissions and necessary bandwidths*, Section II—*Classification*, Sub-Section IIA, *Basic characteristics*.

Subclause 36.201.1 a)

For MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS, the CISPR 11 product family standard is used as a basic EMC standard. See also definition 2.221, *MEDICAL ELECTRICAL SYSTEM*.

Subclause 36.201.1 a) 1)

It is likely that when CISPR 14 EQUIPMENT is combined with other (e.g., CISPR 11) EQUIPMENT to form a SYSTEM, its interconnecting cables would emanate RF electromagnetic energy generated by other sources. Therefore, additional EMISSIONS testing in accordance with CISPR 11 would be required.

Subclause 36.201.1 a) 3)

The definition of CISPR 11 Group 1, Class A and Class B (ISM) equipment is generally similar to that of CISPR 22 Class A and Class B (ITE). The conducted and radiated DISTURBANCE limits and the measuring methods are similar in both standards. This means that equipment complying with the CISPR 22 Class A requirements automatically complies with the CISPR 11, Group 1, Class A requirements and equipment complying with the CISPR 22 Class B requirements also complies with the CISPR 11, Group 1, Class B requirements. As both standards address subsystem testing and the requirements are essentially identical, there is no need to require testing of the SYSTEM to ensure that the incorporation of compliant ITE does not degrade the performance of the SYSTEM.

While ITE used as part of a MEDICAL ELECTRICAL SYSTEM may be classified in accordance with CISPR 22, EQUIPMENT and SYSTEMS may not be classified in accordance with CISPR 22.

Subclause 36.201.1 a) 4)

See annex AAA, subclause 6.8.3.201 c) 2).

If it is necessary to specify use only in a shielded location as a result of the IMMUNITY characteristics of the EQUIPMENT or SYSTEM, a manufacturer could choose not to take advantage of this EMISSIONS testing allowance.

Subclause 36.201.1 a) 5)

If, for example, the applicable national radio regulations do not have mains terminal disturbance voltage limits, then for CISPR 11 EQUIPMENT and SYSTEMS, the mains terminal disturbance voltage requirements of CISPR 11 apply. Also, if the applicable national radio regulations do not specify limits in a frequency band for which CISPR 11 specifies limits, then for CISPR 11 EQUIPMENT and SYSTEMS, the requirements of CISPR 11 in that frequency band apply.

For EQUIPMENT and SYSTEMS that include radio equipment, this standard is not intended to substitute for the EMISSIONS requirements of national radio regulations.

Subclause 36.201.1 b) 1)

CISPR 11 requires the attachment of all cables and a NORMAL USE condition for the EQUIPMENT or SYSTEM. PATIENT cables are considered part of this requirement. It is necessary to provide sufficient simulation so that the EQUIPMENT or SYSTEM can operate in a NORMAL USE condition. This PATIENT simulation should be designed so as not to reduce the EMISSIONS of the EQUIPMENT or SYSTEM or to add unintentional EMISSIONS from the simulator. The effect of the PATIENT on EMISSIONS is not considered critical; however, if a general PATIENT RF model is developed, this will be reconsidered.

To avoid shunting too much current to ground during the test, it is necessary to specify an upper bound for unintentional capacitance. The 250-pF value specified in this standard is harmonized with the artificial hand specified in CISPR 16-1.

Subclause 36.201.1 b) 2)

Because of the variety of SYSTEM configurations, testing of sub-SYSTEMS is allowed. Any simulator used in lieu of an actual EQUIPMENT should properly represent the electrical and, in some cases, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types.

Subclause 36.201.2.1

Magnetic field EMISSIONS requirements below 9 kHz are under consideration.[26]

Subclause 36.201.3.1 a)

IEC 61000-3-2 and IEC 61000-3-3 are applicable only to equipment with a RATED MAINS VOLTAGE greater than or equal to 220 V and that is intended for connection to the PUBLIC MAINS NETWORK. If an EQUIPMENT or SYSTEM is not intended to be connected to the PUBLIC MAINS NETWORK, this requirement is not applicable. Examples of locations connected to the PUBLIC MAINS NETWORK are residences, doctors' offices, and small clinics. A location is served from the PUBLIC MAINS NETWORK if more than one customer is served from the same output of a medium or high voltage electric distribution transformer.

Subclause 36.201.3.2 a)

See annex AAA, subclause 36.201.3.1 a).

Subclause 36.202.1

For IMMUNITY testing, the test methods and guidance for selection of test levels that appear in the associated basic EMC IMMUNITY standards have been followed, except in cases where there are special considerations particular to EQUIPMENT and SYSTEMS. Deviations from the basic EMC IMMUNITY standards have been kept to a minimum.

Subclause 36.202.1 a)

The practice of medicine involves many specialties; thus, there will by necessity be EQUIPMENT and SYSTEMS that are designed to perform a variety of FUNCTIONS. Some FUNCTIONS involve, e.g., measurement of signals from a PATIENT that are of very low levels when compared to ELECTROMAGNETIC NOISE levels that can be coupled into EQUIPMENT and SYSTEMS during the ELECTROMAGNETIC IMMUNITY testing specified in this standard. Because of the proven benefit of many such EQUIPMENT and SYSTEMS, this standard allows the IMMUNITY TEST LEVELS to be lowered, provided there is sufficient justification based on physical, technological, or physiological limitations. There is a recommendation in DDD.2 a) that this allowance be removed when this standard is applied in a product-specific standard because, for a specific product, it should be possible to specify a minimum level of IMMUNITY. Thus, if justified, IMMUNITY TEST LEVELS lower than the IEC 60601 TEST LEVELS of this standard may be specified in Particular Standards (IEC 60601-2-X); however, an allowance for even lower levels than that should not be made, i.e., should be removed.

Subclause 36.202.1 c)

Consideration should be given to ISO 14971 and IEC 60601-1-4 for this risk analysis.

Subclause 36.202.1 d)

Consideration should be given to ISO 14971 and IEC 60601-1-4 for this risk analysis.

Non-medical electrical equipment often has IMMUNITY requirements that are different from those specified by this standard. The exclusion from IMMUNITY testing according to this standard of non-medical electrical equipment that is not expected to affect the ESSENTIAL PERFORMANCE or safety of the SYSTEM, if the non-medical electrical equipment exhibits DEGRADATION, permits the use in a SYSTEM of non-medical electrical equipment that may not comply with the requirements of this standard. An example of such equipment is a printer used in a SYSTEM in which the information to be printed remains in the memory of an EQUIPMENT until it is intentionally deleted, and the information can be re-transmitted to the printer and re-printed in the case of interference with printer operation. Instructions for use of the MEDICAL ELECTRICAL SYSTEM should caution the user to verify proper operation of the printer before deleting stored data. In contrast, a non-medical electrical equipment (e.g., ITE) used as a PATIENT monitoring central station would likely be subject to the IMMUNITY requirements of this standard, depending upon the results of a risk analysis, because loss or corruption of PATIENT information at the monitoring central station can reasonably be expected to affect the safety of the PATIENT.

Once equipment that could affect the ESSENTIAL PERFORMANCE or safety of the SYSTEM has been identified, that equipment should meet the requirements of 36.202.

[26] Under consideration by IEC SC 77A and IEC SC 62A.

Subclause 36.202.1 e)

The requirement that PATIENT-COUPLED EQUIPMENT and SYSTEMS shall be tested so that the PATIENT coupling point is within the test environment and does not have an intentional conductive or capacitive connection to ground during testing, except as otherwise specified in a subclause of this standard, is to ensure that the PATIENT cable is tested in a worst-case condition. In cases where an intentional capacitive connection has been specified (i.e., the artificial hand and RC element), this is considered the worst case. Unintentional capacitance between the PATIENT coupling point and ground should be limited to 250 pF. IEC 60601-1 treats the conditions in which the PATIENT is floating and in which the PATIENT is grounded as NORMAL CONDITIONS. However, from an RF perspective, it is unlikely that a PATIENT would ever be as effectively grounded in a medical environment as would be the case in an EMC test environment if a direct ground reference were used. As a result, the artificial hand and RC element specified in CISPR 16-1 are used to represent the grounded condition.

Subclause 36.202.1 f)

The requirement to test variable gain EQUIPMENT and SYSTEMS at the highest gain setting that allows proper operation is necessary because the signal-to-noise ratio in this mode would be significantly worse than if tested with a low gain setting, which might lead to an erroneous determination of satisfactory performance.

Subclause 36.202.1 g)

Details of simulators used for PATIENT-COUPLED EQUIPMENT, using the guidelines in this standard, should be defined more specifically in Particular Standards (IEC 60601-2-X and ISO standards based on IEC 60601-1). Care should be taken that the simulators used perturb the test minimally and do not exhibit DEGRADATION as a result of the IMMUNITY TEST LEVEL. The PATIENT physiological simulator is not intended to represent the RF characteristics of the human body. As a result, there may be differences between the RF energy coupled into the EQUIPMENT or SYSTEM when using only a PATIENT physiological simulator as compared to use on an actual PATIENT.

See annex AAA, subclause 36.202.1 e).

The requirements for EQUIPMENT or SYSTEM sensitivity adjustments and setting of the simulated PATIENT physiological signal are intended to ensure that the EQUIPMENT or SYSTEM will operate as intended over the range of input PATIENT physiological signals for which the EQUIPMENT or SYSTEM was designed.

For EQUIPMENT and SYSTEMS without manual sensitivity adjustments (non-adjustable gain or automatic gain control), it is assumed that during use of the EQUIPMENT or SYSTEM, an OPERATOR will not always be present to monitor the PATIENT signal and ensure that the EQUIPMENT or SYSTEM is operating according to the ACCOMPANYING DOCUMENTS. However, it is assumed that an OPERATOR would be able to see an indication of inadequate signal strength. For this case, it is appropriate to test the EQUIPMENT or SYSTEM with the input simulated PATIENT physiological signal set to either the lowest amplitude or value consistent with normal operation specified by the manufacturer or to the minimum amplitude or value at which the EQUIPMENT or SYSTEM operates as intended. Requirements for the minimum amplitude or value at which the EQUIPMENT or SYSTEM should operate as intended can be defined more specifically in Particular Standards (IEC 60601-2-X and ISO standards based on IEC 60601-1).

For EQUIPMENT and SYSTEMS that have a manual sensitivity adjustment, it is assumed that during use of the EQUIPMENT or SYSTEM, the OPERATOR will be present to monitor the PATIENT signal and ensure that the EQUIPMENT or SYSTEM is operating according to the ACCOMPANYING DOCUMENTS. For this case, it is appropriate to test the EQUIPMENT or SYSTEM while it is operating at its most sensitive setting with a simulated PATIENT physiological signal set according to the manufacturer's sensitivity adjustment guidelines.

Subclause 36.202.1 h)

While the effect of the IMMUNITY TEST LEVEL on some FUNCTIONS of an EQUIPMENT or SYSTEM (e.g., tidal volume delivered by a ventilator, O_2 value displayed by an inspired O_2 monitor) may be readily apparent during IMMUNITY testing, others (e.g., air bubble detection in a dialysis SYSTEM) may not. It is essential that the ability of the EQUIPMENT or SYSTEM to provide the ESSENTIAL PERFORMANCE be assessed, in a practical manner, during IMMUNITY testing.

In the case of critical alarms, for example, it may not be practical, particularly during radiated RF IMMUNITY testing, to repeatedly establish normal values of PATIENT or EQUIPMENT or SYSTEM parameters, simulate an alarm condition, re-establish normal values, and reset the EQUIPMENT or SYSTEM. For parameters that are normally displayed, it would be sufficient to observe the displayed values to determine if they are influenced by a DISTURBANCE in a manner that could cause the EQUIPMENT or SYSTEM to fail to alarm under alarm conditions. EQUIPMENT and SYSTEMS should be designed to permit observation and verification, during the test, of parameters associated with ESSENTIAL PERFORMANCE (e.g., used to derive critical alarms). However, for parameters that are not normally displayed, that are used to perform ESSENTIAL PERFORMANCE FUNCTIONS (e.g., triggering of critical alarms) and on which the effect of the DISTURBANCE might not be readily apparent during IMMUNITY testing, special test software or hardware must be used so that the effect of the DISTURBANCE on these parameters can be observed during the test.

NOTE—Assessment of displayed values depends in part on the ability of the observer to correctly distinguish between a normally-functioning display and a "frozen" display.

In many cases, analog circuitry is more sensitive to DISTURBANCES than digital circuitry. Further, in modern equipment, digital systems are often used to process and display analog signals. Therefore, if analog signals are sensed, amplified properly, and correctly displayed, it can in many cases be assumed that the logical decisions of the EQUIPMENT or SYSTEM would be correct. However, as digital circuitry can sometimes be affected by DISTURBANCES as well, care should be exercised in assessing proper display of values and proper logical decisions.

An example of a FUNCTION associated with ESSENTIAL PERFORMANCE and the operation of which can normally be observed and verified during IMMUNITY testing is the tidal volume delivered by a ventilator. This parameter would normally be measured with the use of a ventilator tester in order to assess the performance of the ventilator during the test.

Another example of a FUNCTION associated with ESSENTIAL PERFORMANCE and the operation of which can normally be observed and verified during IMMUNITY testing is an EQUIPMENT or SYSTEM that displays inspired O_2. Assuming that the displayed O_2 value is used to trigger alarms and that it can be determined that the display continues to be updated normally, it can be assumed that if the accuracy of the O_2 value displayed during IMMUNITY testing remains within an acceptable range, then a low O_2 alarm would be activated if the actual O_2 were to fall below a typical alarm threshold. It would not be necessary to adjust the alarm threshold so that an alarm actually occurred, as this would slow the testing considerably.

An example of a FUNCTION associated with ESSENTIAL PERFORMANCE and the operation of which cannot normally be observed or verified during IMMUNITY testing is a bubble detection alarm in dialysis EQUIPMENT. Because the value sensed from the bubble detector is not normally displayed, it would be necessary to add a display of, for example, viscosity or acoustical impedance in order to determine if this parameter would be affected by the IMMUNITY TEST LEVEL in a way that would prevent the bubble alarm from activating.

Subclause 36.202.1 i)

Any simulator used in lieu of actual EQUIPMENT should properly represent the electrical and, in some cases, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types.

Subclause 36.202.1 j)

A reasonable starting point to quantify the amount of DEGRADATION (e.g., error) that might be acceptable during IMMUNITY testing, in accordance with the requirements of 36.202.1 j), is the manufacturer's accuracy specification in the ACCOMPANYING DOCUMENTS, with the modification that all other sources of error normally accounted for in the accuracy specification are disregarded and the total accuracy deviation is allocated to the response of the EQUIPMENT or SYSTEM to the IMMUNITY TEST LEVEL. If additional accuracy deviations are considered acceptable, the deviation should be determined from consultations with clinicians whose experience and area of expertise include the use of the particular EQUIPMENT or SYSTEM, and this information should be included in the ACCOMPANYING DOCUMENTS.

If lower COMPLIANCE LEVELS are justified as specified in 36.202.1 a), the IMMUNITY LEVEL may be determined by reducing the IMMUNITY TEST LEVEL until the compliance criteria in 36.202.1 j) are met. For example, if lower COMPLIANCE LEVELS are justified and the IEC 60601 TEST LEVEL results in false PATIENT alarms, the IMMUNITY TEST LEVEL may be reduced to the point just below which the false PATIENT alarms do not occur. This reduced test level will be the IMMUNITY LEVEL. The COMPLIANCE LEVEL can then be determined from the IMMUNITY LEVEL as specified in 6.8.3.201 a) 6) second dash, 6.8.3.201 b) 2), or 6.8.3.201 c) 4) second dash.

Examples of conformance to the compliance criteria:

— an imaging SYSTEM displays an image that may be altered, but in a way that is recognizable as other than physiologic and that would not affect the diagnosis or treatment;

— a heart rate monitor displays a heart rate that may be in error, but by an amount that is not clinically significant;

— a PATIENT monitor exhibits a small amount of noise or a transient on a waveform, and the noise or transient is recognizable as other than physiologic and does not affect diagnosis or treatment.

Examples of EQUIPMENT and SYSTEMS with multiple FUNCTIONS:

— multi-parameter monitors;

— anesthesia SYSTEMS with monitors;

— ventilators with monitors;

— multiple instances of the same FUNCTION (e.g., multiple invasive blood pressure sensors).

Failure of therapy EQUIPMENT to terminate a treatment at the intended time is considered cessation or interruption of an intended operation related to ESSENTIAL PERFORMANCE.

If the effect of the test signal on an EQUIPMENT or SYSTEM is so brief as to be transparent to the PATIENT or OPERATOR and does not affect diagnosis, monitoring, or treatment of the PATIENT, this can be considered not to be cessation or interruption of an intended operation. For example, if in response to the IMMUNITY TEST LEVEL a ventilator stops pumping for 50 ms and then resumes operation such that accuracy is within acceptable limits, this would not be considered cessation or interruption of an intended operation.

Subclause 36.202.1 j) requires that EQUIPMENT and SYSTEMS remain safe under the test conditions of 36.202. A risk analysis should be performed to identify the safety criteria to be monitored during IMMUNITY testing. Consideration should be given to ISO 14971 and IEC 60601-1-4 for this risk analysis.

Subclause 36.202.1 k)

If, for example, national radio regulations specify IMMUNITY requirements only for radiated RF electromagnetic fields, then the other IMMUNITY tests of this standard shall apply to the radio equipment. Note that according to 36.202.3 a), receivers of RF electromagnetic energy are exempt from radiated RF electromagnetic field IMMUNITY requirements in the EXCLUSION BAND of the receiver.

See annex AAA, subclause 6.8.3.201 a) 5) regarding the meaning of lower IMMUNITY TEST LEVELS for the IEC 61000-4-11 IMMUNITY test. In addition, if, for example, the national radio regulations specify radiated RF electromagnetic field IMMUNITY over a more narrow frequency range than does this standard, those requirements are not considered to be greater or equal to those determined in accordance with 36.202.1 a) of this standard.

For EQUIPMENT and SYSTEMS that include radio equipment, this standard is not intended to substitute for the IMMUNITY requirements of national radio regulations.

Subclause 36.202.2 a)

According to IEC 61000-4-2, the IMMUNITY TEST LEVEL of ±4 kV for both air and contact discharge are adequate for the materials of wood, concrete, and ceramic at all humidity levels (e.g., when floors consist of these materials).[27] However, the IMMUNITY TEST LEVEL of ±8 kV for air and ±6 kV for contact is appropriate for the majority of medical environments.

EQUIPMENT and SYSTEMS must meet 36.202.1 j) during the IMMUNITY test. However, for many FUNCTIONS of EQUIPMENT and SYSTEMS, it is not practical to assess performance during individual transient DISTURBANCES (e.g., in the ESD, Electrical fast transient and burst, and Surge IMMUNITY tests). Therefore, for these FUNCTIONS, "during . . . the test" may be interpreted in the general sense, i.e., during the whole of the test sequence, rather than during, e.g., an individual impulse. See also annex AAA, subclause 36.202.1 j) regarding the interpretation of "cessation or interruption" for brief effects on the EQUIPMENT or SYSTEM.

Similarly, EQUIPMENT and SYSTEMS must meet 36.202.1 j) after the IMMUNITY test. However, there are also practical limitations on the interpretation of "after." Occasionally, the effects of an IMMUNITY TEST LEVEL may not manifest until after the DISTURBANCE is removed (e.g., for the radiated RF electromagnetic fields IMMUNITY test). There can also be latent effects caused by the IMMUNITY TEST LEVEL. However, in general, if the EQUIPMENT or SYSTEM continues to meet 36.202.1 j) for a reasonable period of time (e.g., the dwell time of the EQUIPMENT or SYSTEM determined according to 36.202.2 b) 4) or the recovery time of the EQUIPMENT or SYSTEM specified by the manufacturer) after the IMMUNITY test sequence is completed, this may be interpreted as meeting 36.202.1 j) "after the test."

Subclause 36.202.2 b) 1)

The requirement that the determination of compliance be based upon the application of individual ELECTROSTATIC DISCHARGES ensures that the test is representative of actual use conditions. During testing, the application, to each test point, of multiple, repeated discharges (e.g., at approximately 1 s intervals) permits improved test statistics and allows the test to be completed quickly. However, for EQUIPMENT and SYSTEMS such as PATIENT monitors, the discharges could be misinterpreted as a PATIENT signal with a rate equal to the discharge repetition rate. Because it is highly unlikely that the EQUIPMENT or SYSTEM would be exposed to ELECTROSTATIC DISCHARGES repeated at such a rate in actual use, and to avoid penalizing such EQUIPMENT and SYSTEMS unnecessarily, the test results are evaluated based on considering the response of the EQUIPMENT or SYSTEM to each discharge individually.

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[27] See IEC 61000-4-2:1995.

Subclause 36.202.2 b) 2) and 3)

ACCESSIBLE PART is a defined term in IEC 60601-1 that is used in this subclause to specify that discharges are applied only to points on the equipment enclosure that can be touched by the IEC test finger specified in IEC 60601-1 and to points internal to the enclosure that can be accessed without the use of an extra-corporeal device (TOOL). Non-accessible portions of ACCESSIBLE PARTS include female connector contacts and any other recessed connector contact that cannot be touched by the IEC test finger. Many connector ports are designed to handle high-frequency information, either analog or digital, and therefore cannot be provided with sufficient overvoltage protection devices.[28] To ensure proper operation of the EQUIPMENT or SYSTEM, labeling is required, on the EQUIPMENT or SYSTEM and in the ACCOMPANYING DOCUMENTS, for connectors that are not tested for IMMUNITY to ESD.

Subclause 36.202.2 b) 4)

Any electrical charge that has accumulated on INTERNALLY POWERED or CLASS II EQUIPMENT must be dissipated between each discharge of the ESD test generator so that the true effect of each discharge can be determined. Care must be taken in the discharge method used, to avoid over-testing the EQUIPMENT or SYSTEM. Hence, between discharges of the ESD generator, it is recommended to dissipate any accumulated charge on this kind of EQUIPMENT or SYSTEM through the specified resistor network. However, the resistor network should be disconnected and moved away during discharge of the ESD test generator, so that the test discharge and the resulting transient electric and magnetic fields are not affected.

Subclause 36.202.3 a)

See annex AAA, subclause 36.202.2 a) for further information regarding “during and after.”

Subclause 36.202.3 a) 1) and 2)

It is expected that some PATIENT-COUPLED EQUIPMENT and SYSTEMS will use as a justification for a lower IMMUNITY COMPLIANCE LEVEL the fact that some physiological signals can be substantially below those induced by a field strength of 3 V/m.

The increased radiated RF IMMUNITY TEST LEVEL for LIFE-SUPPORTING EQUIPMENT and SYSTEMS is intended as an additional safety margin to decrease the likelihood that mobile/portable communications equipment, such as a radio (cellular/cordless) telephone, could cause DEGRADATION of an EQUIPMENT or SYSTEM that results in harm to a PATIENT if the mobile/portable communications equipment were to be brought into PATIENT areas. This requirement is not intended to permit the use of such mobile/portable communications equipment closer to EQUIPMENT and SYSTEMS. The safety margin for LIFE-SUPPORTING EQUIPMENT and SYSTEMS provided by the specified 10 V/m IMMUNITY TEST LEVEL in the frequency band 80 MHz to 2.5 GHz is particularly important because this band is used by hand-held and mobile two-way radios, digital portable telephones, and digital mobile telephones. EQUIPMENT and SYSTEMS, particularly those that have not been tested in accordance with this standard, have been found to be more susceptible to transmissions from digital portable and mobile telephones than from older, analog portable and mobile telephones of the same RATED maximum output power, and even more susceptible to transmissions from hand-held and mobile two-way radios (walkie-talkies), which often transmit with a higher output power than do portable and mobile telephones.

The frequency of 2.5 GHz was selected as the upper end of the test frequency range to cover the 2.400 GHz to 2.500 GHz ISM band. Until the frequency range 2.5 GHz to 3.0 GHz is more heavily used, testing in this range will provide little additional benefit.

Subclause 36.202.3 a) 3)

For EQUIPMENT and SYSTEMS specified for use only in a shielded location, it is appropriate to reduce the RF IMMUNITY TEST LEVEL by the minimum RF shielding effectiveness and filter attenuation specified for the shielded location by the manufacturer of the EQUIPMENT or SYSTEM. However, if it is necessary to specify use only in a shielded location as a result of the EMISSIONS characteristics of the EQUIPMENT or SYSTEM, a manufacturer could choose not to take advantage of this IMMUNITY testing allowance.

See annex AAA, subclause 6.8.3.201 c) 2).

For EQUIPMENT and SYSTEMS specified for use only in a location that is well-shielded and well-filtered, the IMMUNITY TEST LEVEL may be reduced below a level produced by CISPR-compliant EMISSIONS; therefore, it is necessary to provide the user with recommendations as to what restrictions should be placed upon other devices used in this shielded location. See 6.8.3.201 c) 3).

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[28] This text is from Amendment 2 (2000) of IEC 61000-4-2:1995.

The frequency of 2.5 GHz was selected as the upper end of the test frequency range to cover the 2.400 GHz to 2.500 GHz ISM band. Until the frequency range 2.5 GHz to 3.0 GHz is more heavily used, testing in this range will provide little additional benefit.

Subclause 36.202.3 a) 4)

In medical practice, equipment is used that is tuned to a specific frequency in order to detect RF electromagnetic signals emanating from a PATIENT (e.g., MRI EQUIPMENT), or transmit data for remote monitoring of PATIENTS (e.g., telemetry). When an intentional receiver of RF electromagnetic energy is tuned to its frequency of reception, it is impossible for that section of the EQUIPMENT or SYSTEM to be immune to a test signal in its passband. Therefore, DEGRADATION of the receiving section is permitted. However, the other operational FUNCTIONS of the EQUIPMENT or SYSTEM must continue to operate as intended.

The frequency of 2.5 GHz was selected as the upper end of the test frequency range to cover the 2.400 GHz to 2.500 GHz ISM band. Until the frequency range 2.5 GHz to 3.0 GHz is more heavily used, testing in this range will provide little additional benefit.

Subclause 36.202.3 b) 3)

The 2 Hz modulation frequency is a compromise that has been selected to be within physiological passbands and yet avoid the additional testing time that would result if every passband were tested. It is between the typical physiological passbands of respiratory and cardiology EQUIPMENT and SYSTEMS, and it corresponds to a secondary modulation frequency of some types of radio (cellular/cordless) telephones. The use of 1 kHz for EQUIPMENT and SYSTEMS that do not measure or control physiological parameters aligns with the requirements of IEC 61000-4-3. The PHYSIOLOGICAL SIMULATION FREQUENCY and the OPERATING FREQUENCY are required to be separated from the modulation frequency to make the identification of interference more obvious. Groups writing Particular Standards (IEC 60601-2-X and ISO standards based on IEC 60601-1) are encouraged to use the modulation frequency, PHYSIOLOGICAL SIMULATION FREQUENCY and OPERATING FREQUENCY requirements specified in this standard unless they are found to be inadequate for the specific product. For multi-parameter SYSTEMS, this will minimize the testing burden that would otherwise be imposed by the requirement to test over the entire frequency range at each different modulation frequency specified by the individual “Part two” standard for each sub-SYSTEM.

Subclause 36.202.3 b) 4) and 5)

The minimum dwell time requirement of 3 s for EQUIPMENT and SYSTEMS for which 2 Hz modulation is used is calculated from the maximum frequency sweep speed (1.5×10^{-3} decades/s) and maximum frequency step size (1 %) requirements of IEC 61000-4-3, with the result rounded to the nearest whole second. It assures that the EQUIPMENT or SYSTEM under test will be exposed to at least six cycles of the modulation. The minimum dwell time requirement of 1 s for all other EQUIPMENT and SYSTEMS is required so that performance DEGRADATION that might occur in response to the IMMUNITY TEST LEVEL can be observed by test engineers.

The use of adequate dwell time (or a correspondingly slow sweep rate) can be particularly important to IMMUNITY testing of EQUIPMENT and SYSTEMS. While interference with a video display unit can be perceived instantly, EQUIPMENT and SYSTEMS can have a very slow response time and may require a long dwell time in order to assess performance during the test. For example:

— A pulse oximeter may display a value averaged over several cardiac cycles.

— It may take several minutes to determine that the flow rate of an infusion pump has remained within an acceptable range.

— A ventilator may require several breath cycles to respond to a test signal.

NOTE—Some slow sensors, e.g., chemical/biochemical sensors, may have response times of several minutes but are not susceptible to RF fields. In such instances, the response of the electronics, including filtering or averaging in hardware or software, would be the appropriate response time to consider in the determination of the dwell time.

Subclause 36.202.3 b) 8)

Inclusion of the PATIENT may significantly affect the ELECTROMAGNETIC ENVIRONMENT of the EQUIPMENT or SYSTEM under test (the PATIENT may function as an antenna). For this reason, the development of adequate PATIENT models and test methodology will require extensive research for each type of PATIENT coupling. The requirement that the PATIENT coupling point does not have an intentional conductive or capacitive connection to ground during testing is to ensure that the PATIENT cable is tested in a worst-case condition. IEC 60601-1 treats the conditions in which the PATIENT is floating and in which the PATIENT is grounded as NORMAL CONDITIONS. Unintentional capacitance between the PATIENT coupling point and ground should be limited to a maximum of 250 pF. This is considered to be a worst case, ignoring the fact that the human body can act as an antenna that can significantly increase or decrease the amount of RF

electromagnetic energy coupled into the EQUIPMENT or SYSTEM at a particular frequency, depending upon the physical configuration. SC 62A does not plan to develop an RF PATIENT model.

Subclause 36.202.3 b) 9)

If operation of sub-SYSTEMS cannot be simulated, it is not practical to test LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS for IMMUNITY to radiated RF fields in accordance with IEC 61000-4-3 on a test site. Therefore, they should be tested using communications equipment (legal use of transmitters) as RF test sources.

Subclause 36.202.4 a)

A.2 of IEC 61000-4-4 recommends level 3 (±2 kV for power supply and protective earth ports and ±1 kV for signal, data, and control ports) for environments where "there is poor separation between power supply, control, signal, and communication cables." This can sometimes be the case in hospitals. In addition, level 3 provides a greater safety margin than would be provided, e.g., by level 2.

PATIENT cables are generally not long enough to run in parallel to mains cables for a sufficient distance to couple a DISTURBANCE that would justify the application of the capacitive coupling clamp test. Furthermore, even in very long PATIENT cables, it is undesirable to arrange the cable near mains cables for electrical safety and noise reduction reasons. The requirement to have PATIENT cables attached will yield a realistic result of the effect on PATIENT cables, in NORMAL USE, of the electromagnetic phenomenon represented by the IMMUNITY TEST LEVEL.

While signal and interconnecting cables specified to be (i.e., restricted to) less than 3 m in length and all PATIENT-coupled cables are not tested directly, a failure of the EQUIPMENT or SYSTEM to meet the requirements of 36.202.1 j), even if it occurs due to coupling from cables that are tested directly to cables that are not tested directly, still constitutes failure of the EQUIPMENT or SYSTEM to meet the IMMUNITY requirements of this standard for this test.

See annex AAA, subclause 36.202.2 a) for further information regarding "during and after."

Subclause 36.202.4 b) 3)

The artificial hand and RC element replicate the coupling path to ground through the PATIENT and are required to complete this coupling path during testing. The artificial hand simulates the capacitive coupling effect of the PATIENT, and the RC element simulates the RF impedance of the PATIENT with respect to ground. Of the tests specified by this standard, use of the artificial hand and RC element are only appropriate for this test and for the IEC 61000-4-6 test because the artificial hand, RC element, and interconnecting wire (see CISPR 16-1) are not well-characterized for use with higher-frequency IMMUNITY tests.

Subclause 36.202.4 b) 4)

The artificial hand and RC element replicate the coupling path to ground through the OPERATOR and are required to complete this coupling path during testing. The artificial hand simulates the capacitive coupling effect of the OPERATOR, and the RC element simulates the RF impedance of the OPERATOR with respect to ground. Of the tests specified by this standard, use of the artificial hand and RC element are only appropriate for this test and for the IEC 61000-4-6 test because the artificial hand, RC element, and interconnecting wire are not well-characterized for use with higher-frequency IMMUNITY tests.

Foil and RC elements separate from those used to simulate the PATIENT(S) should be used for OPERATOR simulation, unless the OPERATOR of a particular EQUIPMENT or SYSTEM is always the PATIENT.

Subclause 36.202.5 a)

While only power lines and a.c. inputs to a.c.-to-d.c. converters and battery chargers are tested directly, a failure of the EQUIPMENT or SYSTEM to meet the requirements of 36.202.1 j), even if it occurs due to coupling from power lines and a.c. inputs that are tested directly to cables that are not tested directly, still constitutes failure of the EQUIPMENT or SYSTEM to meet the IMMUNITY requirements of this standard for this test.

See annex AAA, subclause 36.202.2 a) for further information regarding "during and after."

Subclause 36.202.5 b)

The combination wave test is performed with a 2 Ω generator source impedance for the line(s) to line(s) test and a 12 Ω generator source impedance for the line(s) to ground test.

Subclause 36.202.5 b) 3)

The surge test is mainly a test for the ability of the power supply to withstand this high-energy pulse. If no surge protection device is installed in the EQUIPMENT or SYSTEM, a test at only the highest IMMUNITY TEST LEVEL specified in

36.202.5, ±2 kV for a.c. power line(s) to ground and ±1 kV for a.c. power line(s) to line(s), will be the worst case. In that case, testing at lower IMMUNITY TEST LEVELS is not useful and would provide no additional information. If a surge protection device is installed in the EQUIPMENT or SYSTEM, testing at lower IMMUNITY TEST LEVELS is necessary to verify proper operation of the surge protection device.

Subclause 36.202.5 b) 4)

CLASS II EQUIPMENT and SYSTEMS do not have a PROTECTIVE EARTH CONDUCTOR; therefore, application of the line(s) to ground surge is not possible with the standard coupling network. CLASS II EQUIPMENT and SYSTEMS are required to have a dielectric strength rating of 3 kV between the mains power input and the ENCLOSURE for input MAINS VOLTAGES greater than 50 V and less than or equal to 150 V, and a dielectric strength rating of 4 kV between mains and the ENCLOSURE for input MAINS VOLTAGES greater than 150 V and less than or equal to 250 V. In both cases, the required dielectric strength is greater than the surge IMMUNITY TEST LEVEL, so applying surges between line(s) and the ENCLOSURE would provide no additional information.

Subclause 36.202.6 a)

See annex AAA, subclause 36.202.2 a) for further information regarding “during and after.”

Subclause 36.202.6 a) 1)

It is expected that some PATIENT-COUPLED EQUIPMENT and SYSTEMS will use as a justification for a lower IMMUNITY COMPLIANCE LEVEL the fact that some physiological signals can be substantially below those induced by the 3 Vrms IMMUNITY TEST LEVEL.

Subclause 36.202.6 a) 2)

The increased conducted RF IMMUNITY TEST LEVEL in the ISM frequency bands between 150 kHz and 80 MHz for LIFE-SUPPORTING EQUIPMENT and SYSTEMS is intended as an additional safety margin to decrease the likelihood that mobile/portable communications equipment, such as a two-way radio (walkie-talkie), could cause DEGRADATION of an EQUIPMENT or SYSTEM that results in harm to a PATIENT if the mobile/portable communications equipment were to be brought into PATIENT areas. This requirement is not intended to permit the use of such mobile/portable communications equipment closer to EQUIPMENT or SYSTEMS. The safety margin for LIFE-SUPPORTING EQUIPMENT and SYSTEMS provided by the specified 10 Vrms IMMUNITY TEST LEVEL in the ISM frequency bands between 150 kHz and 80 MHz is particularly important because mobile/portable communications equipment using these bands often has output power greater than 1 W.

Subclause 36.202.6 a) 3)

For EQUIPMENT and SYSTEMS specified for use only in a shielded location, it is appropriate to reduce the RF IMMUNITY TEST LEVEL by the minimum RF shielding effectiveness and filter attenuation specified for the shielded location by the manufacturer of the EQUIPMENT or SYSTEM. However, if it is necessary to specify use only in a shielded location as a result of the EMISSIONS characteristics of the EQUIPMENT or SYSTEM, a manufacturer could choose not to take advantage of this IMMUNITY testing allowance.

See annex AAA, subclause 6.8.3.201 c) 2).

For EQUIPMENT and SYSTEMS specified for use only in a location that is well-shielded and well-filtered, the COMPLIANCE LEVEL may be reduced below a level produced by CISPR-compliant EMISSIONS; therefore, it is necessary to provide the user with recommendations as to what restrictions should be placed upon other devices used in this shielded location. See 6.8.3.201 c) 3).

Subclause 36.202.6 a) 4)

In medical practice, equipment is used that is tuned to a specific frequency in order to detect RF electromagnetic signals emanating from a PATIENT (e.g., MRI EQUIPMENT). When an intentional receiver of RF electromagnetic energy is tuned to its frequency of reception, it is impossible for that section of the EQUIPMENT or SYSTEM to be immune to a test signal in its passband. Therefore, disturbance of the receiving section is permitted. However, the other operational FUNCTIONS of the EQUIPMENT or SYSTEM must continue to operate as intended.

Subclause 36.202.6 a) 5)

Such EQUIPMENT and SYSTEMS are exempt from the requirements of 36.202.6, because it is unlikely that RF energy in the frequency range 150 kHz to 80 MHz will be coupled into the EQUIPMENT or SYSTEM. Examples include some infrared thermometers, infusion pumps, and defibrillators.

Subclause 36.202.6 b) 1), first dash

The interface characteristic impedance and associated injection parameters for EQUIPMENT and SYSTEMS vary more widely than for ITE devices, for which IEC 61000-4-6 was developed. This modification allows for more appropriate matching of the IMMUNITY stimulus to the EQUIPMENT or SYSTEM under test.

Subclause 36.202.6 b) 1), second dash

For EQUIPMENT and SYSTEMS, the requirements of IEC 61000-4-6, subclause 6.2.2.1 are not compatible with the LEAKAGE CURRENT requirements of IEC 60601-1 and IEC 60601-1-1.

Subclause 36.202.6 b) 1), third dash, first bullet

This requirement modifies the tolerances specified in IEC 61000-4-6 for calibration (±2 dB) to ensure that the IMMUNITY TEST LEVEL will always be equal to or greater than NOMINAL, as is the case in IEC 61000-4-3 (–0 dB to +6 dB).

Subclause 36.202.6 b) 1), third dash, second bullet

Calibration in a 150 Ω system reduces system uncertainty by harmonizing the characteristic impedance with that of the test environment, which is specified by IEC 61000-4-6 to be 150 Ω.

Subclause 36.202.6 b) 1), third dash, third bullet

This modification is intended to clarify an unstated parameter within IEC 61000-4-6 by matching the maximum calibration step size to the maximum test step size. The effect is to avoid undetected variations in the characteristics of the calibration system that might distort the test results.

Subclause 36.202.6 b) 1), fourth dash

These modifications are intended to harmonize the IEC 61000-4-6 test environment with the prescribed safety environment of IEC 60601-1 for EQUIPMENT and SYSTEMS.

Subclause 36.202.6 b) 1), fifth dash

See annex AAA, subclause 36.202.6 b) 1), third dash, first bullet.

Subclause 36.202.6 b) 1), sixth dash

For EQUIPMENT and SYSTEMS in which the system configuration can vary, an assumption of IMMUNITY of short interconnections (≤1 m) would not be appropriate.

Subclause 36.202.6 b) 3)

EQUIPMENT and SYSTEMS will in general not tolerate the impedance that would be added to PATIENT cables by a CDN. Additionally, it is desirable to allow some RF signal to reach the PATIENT coupling point so that it can be determined whether demodulation or other coupling occurring at this point during the IMMUNITY test affects the performance of the EQUIPMENT or SYSTEM. Termination as specified, to the ground reference plane of the PATIENT end of PATIENT-coupled cables, is necessary when using current clamp injection in order to complete the injection circuit, including the PATIENT coupling point. IEC 60601-1 treats the conditions in which the PATIENT is floating and in which the PATIENT is grounded as NORMAL CONDITIONS. The way the PATIENT cables have been treated is considered to be the worst case for this IMMUNITY test. The artificial hand simulates the capacitive coupling effect of the PATIENT, and the RC element simulates the RF impedance of the PATIENT with respect to ground. These requirements should not be changed in Particular Standards (IEC 60601-2-X and ISO standards based on IEC 60601-1).

See annex AAA, subclause 36.202.4 b) 3).

Of the tests specified by this standard, use of the artificial hand and RC element are only appropriate for this test and for the IEC 61000-4-4 test because the artificial hand, RC element, and interconnecting wire (see CISPR 16-1) are not well-characterized for use with higher-frequency IMMUNITY tests.

Subclause 36.202.6 b) 4)

The artificial hand and RC element replicate the coupling path to ground through the OPERATOR. The artificial hand simulates the capacitive coupling effect of the OPERATOR, and the RC element simulates the RF impedance of the OPERATOR with respect to ground. If an EQUIPMENT or SYSTEM does not have PATIENT-coupled cables, the artificial hand and RC element simulating the capacitive coupling effect and RF impedance of the OPERATOR are required to complete the coupling path during testing. Of the tests specified by this standard, use of the artificial hand and RC

element are only appropriate for this test and for the IEC 61000-4-4 test because the artificial hand, RC element, and interconnecting wire are not well-characterized for use with higher-frequency IMMUNITY tests.

Foil and RC elements separate from those used to simulate the PATIENT(S) should be used for OPERATOR simulation, unless the OPERATOR of a particular EQUIPMENT or SYSTEM is always the PATIENT.

Subclause 36.202.6 b) 5)

This ensures that the equipotential ground is tested.

Subclause 36.202.6 b) 6)

See annex AAA, subclause 36.202.3 b) 3).

For EQUIPMENT and SYSTEMS that control, monitor, or measure a physiological parameter, the IMMUNITY test signal applied to each cable should be modulated at 2 Hz, i.e., not just for the PATIENT-coupled cables. This ensures that the operation of the PATIENT FUNCTIONS are evaluated appropriately, even when testing power lines and interconnecting cables.

Subclause 36.202.6 b) 7) and 8)

See annex AAA, subclause 36.202.3 b) 4) and 5).

Subclause 36.202.7 a)

The scope of IEC 61000-4-11 is limited to equipment with a RATED input current not exceeding 16 A per phase. However, this standard extends the application of IEC 61000-4-11 beyond 16 A per phase for LIFE-SUPPORTING EQUIPMENT and SYSTEMS because of the critical application. In addition, this standard applies the 5 s interruption test to all EQUIPMENT and SYSTEMS, along with an allowance for deviation from the requirements of 36.202.1 j), because the equipment necessary to perform this test is readily available.

For this test, "lower COMPLIANCE LEVELS" (see 36.202.1 a)) means shorter duration of the voltage dip or interruption, or less of a dip in voltage.

See annex AAA, subclause 36.202.2 a) for further information regarding “during and after.”

Subclause 36.202.7 a) 2)

For LIFE-SUPPORTING EQUIPMENT and SYSTEMS for which an alarm is required, it is likely that the alarm will need to be powered by stored energy during power interruptions. A test should be performed to verify that sufficient stored energy is available to operate this alarm for an extended period of time, e.g., 5 minutes or as may be specified in Particular Standards (IEC 60601-2-X).

Subclause 36.202.8

Additional magnetic field IMMUNITY requirements are under consideration.[29]

Subclause 36.202.8.1 a)

It is expected that video display terminals and other electron-beam devices (e.g., X-ray image intensifiers) will use a justification for lower IMMUNITY COMPLIANCE LEVELS as allowed by 36.202.1 a).

NOTE—An IMMUNITY TEST LEVEL of 3.00 A/m is equivalent to a magnetic flux density of 3.78 μT (0.0378 Gs) in free space.

See annex AAA, subclause 36.202.2 a) for further information regarding “during and after.”

Subclause 36.202.8.1 b) 1)

Short-duration tests are not applicable to EQUIPMENT and SYSTEMS.

Subclause 36.202.8.2

This test is mainly applicable to products intended to be installed in electrical plants. The general hospital environment differs substantially from that influenced by high-voltage, high-power switchgear. Therefore, this test is not applicable to EQUIPMENT and SYSTEMS.

[29] Under consideration by IEC TC 77 and IEC SC 62A.

Subclause 36.202.8.3

This test is mainly applicable to products intended to be installed in high-voltage substations. The general hospital environment differs substantially from that influenced by high-voltage, high-power switchgear. Therefore, this test is not applicable to EQUIPMENT and SYSTEMS.

Subclause 36.202.9

This test is intended for very special equipment in large installations, of which mains and interconnecting cable length is at least approaching a quarter wavelength at 150 kHz. For 150 kHz, $\lambda/4$ = 500 m. Cables 500 m in length are generally not used in a hospital environment. Moreover, radio services in this frequency band are either short-range equipment or maritime navigation systems. Therefore, no requirements apply to EQUIPMENT and SYSTEMS.

Subclause 36.202.10

The ring wave and damped oscillatory wave tests are not applicable to EQUIPMENT and SYSTEMS because IMMUNITY to transients on power mains is already established sufficiently by the surge and burst tests. Comparing the power density spectra of ring waves and surges shows the severity of the ring wave (with the same voltage level) to be lower than that of the surge. In addition, power line filters commonly found in equipment to control EMISSIONS also impede frequencies around 100 kHz from entering equipment. In practice, equipment that passes the surge test also passes the ring wave test.

Subclause 36.202.11

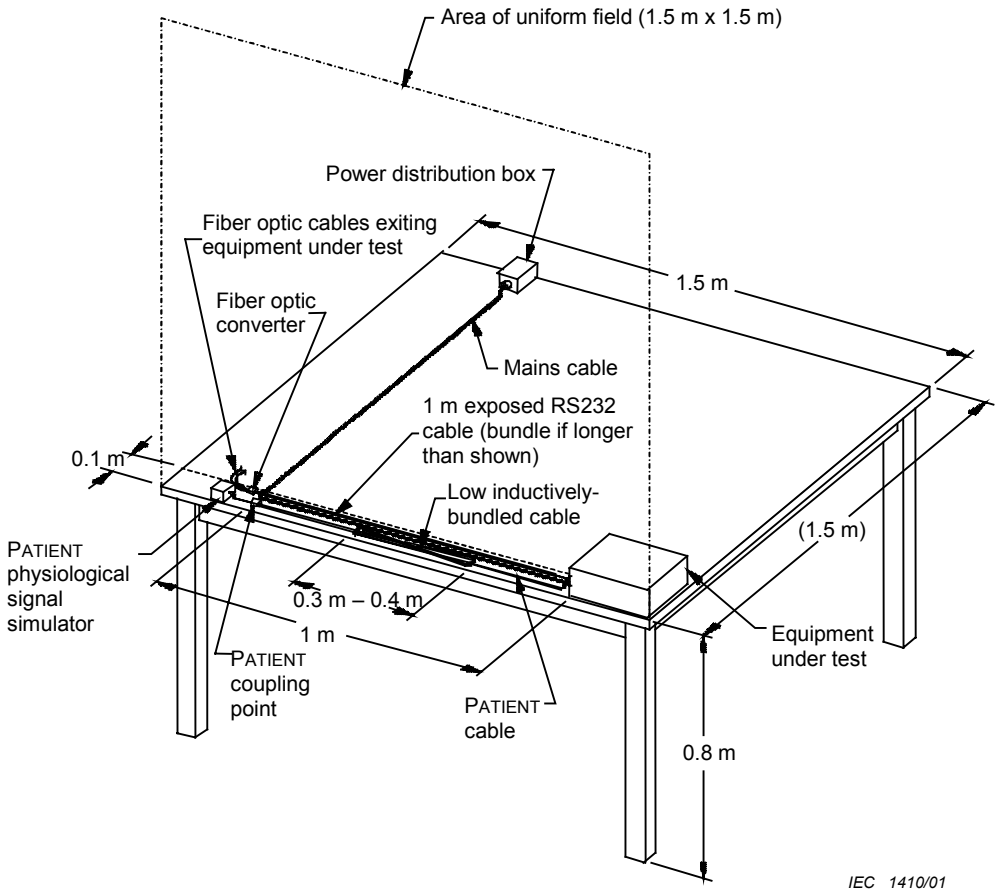
This test is mainly applicable to products sensitive to the precise time of the zero crossing of the a.c. MAINS VOLTAGE. MEDICAL ELECTRICAL EQUIPMENT and SYSTEMS for use in the general hospital environment are, as a rule, not susceptible to small changes in the time of the zero crossing of the a.c. MAINS VOLTAGE. Therefore, no requirements apply to EQUIPMENT and SYSTEMS.

Subclause 36.202.12

This standard is under development; therefore, no requirements apply to EQUIPMENT and SYSTEMS.

Subclause 36.202.13

This standard is under development; therefore, no requirements apply to EQUIPMENT and SYSTEMS.



NOTE—Only one orientation is shown.

Figure AAA.1—Example of cable arrangement for radiated IMMUNITY test (see 36.202.3 b) 8)

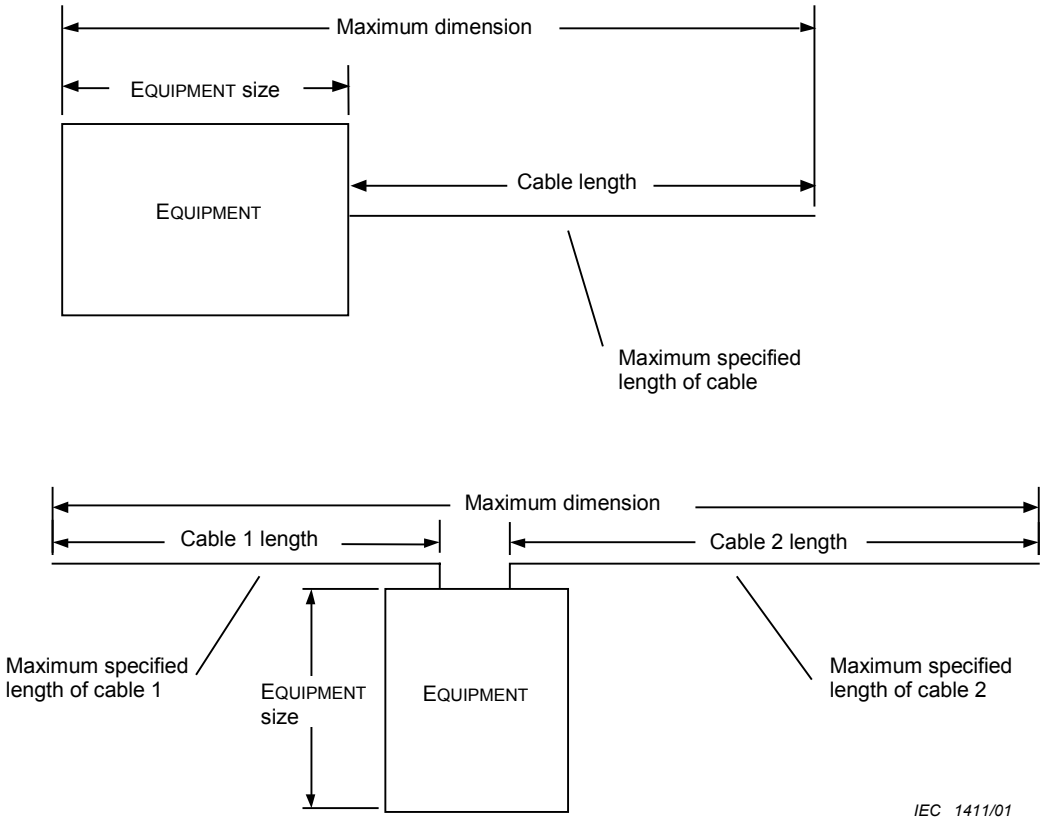


Figure AAA.2—Examples showing maximum dimension for an EQUIPMENT with one and with two cables (see 36.202.6 a) 5) and 6)

Annex BBB
(informative)

Example completion of Tables 201 through 208

BBB.1 Example (1) completion of Table 201

This example is a hypothetical CISPR 11 Group 1 EQUIPMENT or SYSTEM that complies with Class B, IEC 61000-3-2 Class A, and IEC 61000-3-3. For the purpose of this example, the hypothetical EQUIPMENT or SYSTEM is a particular manufacturer's model 001.

Table 201 then appears as shown in Table BBB.1.

Table BBB.1—Example (1) of completed Table 201

Guidance and manufacturer's declaration—electromagnetic emissions		
The Model 001 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 001 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment—guidance**
RF emissions CISPR 11	Group 1	The Model 001 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 001 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

BBB.2 Example (2) completion of Table 201

This example is a hypothetical CISPR 11 Group 2 EQUIPMENT or SYSTEM that complies with Class A and for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable. For the purpose of this example, the hypothetical EQUIPMENT or SYSTEM is a particular manufacturer's Model 002.

Table 201 then appears as shown in Table BBB.2.

Table BBB.2—Example (2) of completed Table 201

Guidance and manufacturer's declaration—electromagnetic emissions		
The Model 002 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 002 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment—guidance**
RF emissions CISPR 11	Group 2	The Model 002 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Model 002 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

BBB.3 Example (3) completion of Table 201

This example is a hypothetical magnetic resonance imaging (MRI) SYSTEM that is specified for use only in a shielded location, complies with CISPR 11 Class A when installed in the specified type of shielded location, and for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable. For the purpose of this example, the hypothetical MRI SYSTEM is a particular manufacturer's Model 003. (See also BBB.8.)

Table 201 then appears as shown in Table BBB.3.

Table BBB.3—Example (3) of completed Table 201

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration—electromagnetic emissions</th></tr>
<tr><td colspan="3">The Model 003 MRI system is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 003 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment—guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 2</td><td>The Model 003 MRI system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A
(The Model 003 MRI system in combination with the shielded location)</td><td rowspan="3">The Model 003 MRI system must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 80 dB from 10 MHz to 20 MHz, 100 dB from 20 MHz to 80 MHz, and 80 dB from 80 MHz to 100 MHz. (The minimum at 20 MHz is 100 dB and the minimum at 80 MHz is 80 dB.)
The Model 003 MRI system, when installed in such a shielded location, is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
<tr><td colspan="3">NOTE—It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specifications.</td></tr>
</table>

BBB.4 Example completion of Table 202

This example is a hypothetical image intensifier that complies with all IEC 60601 TEST LEVELS of this standard except for the power frequency magnetic field IMMUNITY requirement. The power frequency magnetic field IMMUNITY of the example image intensifier is 0.3 A/m. For the purpose of this example, the hypothetical image intensifier is a particular manufacturer's Model 004.

Table 202 then appears as shown in Table BBB.4.

Table BBB.4—Example of completed Table 202

Guidance and manufacturer's declaration—electromagnetic immunity			
The Model 004 Image Intensifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 004 Image Intensifier should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 004 Image Intensifier requires continued operation during power mains interruptions, it is recommended that the Model 004 Image Intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	If image distortion occurs, it may be necessary to position the Model 004 Image Intensifier further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE—U_T is the a.c. mains voltage prior to application of the test level.			

BBB.5 Example completion of Tables 203 and 205

This example is a hypothetical LIFE-SUPPORTING EQUIPMENT or SYSTEM. Thus, Tables 203 and 205 are used. For the purpose of this example, the hypothetical EQUIPMENT or SYSTEM is a particular manufacturer's Model 005. The Model 005 meets the IEC 60601 TEST LEVEL of this standard for the radiated IMMUNITY test but not for the conducted IMMUNITY tests. It is assumed that the justification for this is sufficient and is provided in the ACCOMPANYING DOCUMENTS. Because the claimed COMPLIANCE LEVELS must be an IMMUNITY TEST LEVEL of the basic EMC standard, the COMPLIANCE LEVELS are lower than the actual IMMUNITY LEVELS, as shown in Table BBB.5.

Table BBB.5—Example (1) test, IMMUNITY and COMPLIANCE LEVELS

IMMUNITY test	IEC 60601 TEST LEVEL	Actual IMMUNITY LEVEL	COMPLIANCE LEVEL
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	2 Vrms	1 Vrms
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz in ISM bands	2 Vrms	1 Vrms
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	13 V/m	10 V/m

Thus, V_1 = 1, V_2 = 1, and E_1 = 10. Calculating the expressions in square brackets in Tables 203 and 205 and rounding to two significant digits yields the following:

$$\frac{3.5}{V_1} = \frac{3.5}{1} = 3.5 \qquad \frac{12}{V_2} = \frac{12}{1} = 12 \qquad \frac{12}{E_1} = \frac{12}{10} = 1.2 \qquad \frac{23}{E_1} = \frac{23}{10} = 2.3$$

These values are then used to complete Table 203, as shown in Table BBB.6, and Table 205, as shown in Table BBB.7.

Table BBB.6—Example of completed Table 203

Guidance and manufacturer's declaration—electromagnetic immunity			
The Model 005 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 005 should assure that it is used in such an electromagnetic environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 005, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	1 Vrms	$d = 3.5\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	1 Vrms	$d = 12\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 005 is used exceeds the applicable RF compliance level above, the Model 005 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 005.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table BBB.7—Example of completed Table 205

Recommended separation distances between portable and mobile RF communications equipment and the Model 005				
The Model 005 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 005 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 005 as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = 3.5\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 12\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.35	1.2	0.12	0.23
0.1	1.1	3.8	0.38	0.73
1	3.5	12	1.2	2.3
10	11	38	3.8	7.3
100	35	120	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				
NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.				
NOTE 2—The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.				
NOTE 3—An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.				
NOTE 4—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				

BBB.6 Example completion of Tables 204 and 206

This example is a hypothetical EQUIPMENT or SYSTEM that is not LIFE-SUPPORTING and that meets the IEC 60601 TEST LEVELS of this standard for the radiated and conducted IMMUNITY tests. Thus, Tables 204 and 206 are used. For the purpose of this example, the hypothetical EQUIPMENT or SYSTEM is a particular manufacturer's Model 006.

Using the IEC 60601 TEST LEVELS, $V_1 = 3$ and $E_1 = 3$. Calculating the expressions in square brackets in Table 204 and 206 and rounding to two significant digits yields the following:

$$\frac{3.5}{V_1} = \frac{3.5}{3} \approx 1.2 \qquad \frac{3.5}{E_1} = \frac{3.5}{3} \approx 1.2 \qquad \frac{7}{E_1} = \frac{7}{3} \approx 2.3$$

These values are then used to complete Table 204, as shown in Table BBB.8, and Table 206, as shown in Table BBB.9.

Table BBB.8—Example of completed Table 204

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">The Model 006 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 006 should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment—guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Model 006, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 006 is used exceeds the applicable RF compliance level above, the Model 006 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 006.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Table BBB.9—Example of completed Table 206

Recommended separation distances between portable and mobile RF communications equipment and the Model 006			
The Model 006 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 006 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 006 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

BBB.7 Example completion of Table 207

This example is a hypothetical EQUIPMENT or SYSTEM that is LIFE-SUPPORTING and that is specified for use only in a shielded location with a minimum RF shielding effectiveness and filter attenuation of 31 dB over the frequency range 150 kHz to 2.5 GHz. Thus, Table 207 is used. For the purpose of this example, the hypothetical EQUIPMENT or SYSTEM is a particular manufacturer's Model 007, and the required list of equipment that is allowed or prohibited inside the shielded location with the Model 007 is found on page 48 of the service manual.

The actual IMMUNITY LEVELS are below the lowest level listed in the basic EMC IMMUNITY standard; therefore, the COMPLIANCE LEVELS are equal to the actual IMMUNITY LEVELS, as shown in Table BBB.10. These values are then used to complete Table 207, as shown in Table BBB.11.

Table BBB.10—Example (2) test, IMMUNITY and COMPLIANCE LEVELS

IMMUNITY test	**IEC 60601 TEST LEVEL**	**Actual IMMUNITY LEVEL**	**COMPLIANCE LEVEL**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	0.3 Vrms	0.3 Vrms
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz in ISM bands	0.3 Vrms	0.3 Vrms
Radiated RF IEC 61000-4-3	10 V/m 800 MHz to 2.5 GHz	0.3 V/m	0.3 V/m

Table BBB.11—Example of completed Table 207

Guidance and manufacturer's declaration—electromagnetic immunity			
The Model 007 is suitable for use in the electromagnetic environment specified below. The customer or the user of the Model 006 should assure that it is used in such an electromagnetic environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	0.3 Vrms	The Model 007 must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 31 dB over the frequency range 150 kHz to 2.5 GHz. See page 48 of the service manual.
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	0.3 Vrms	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 10 V/m.[b]
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	0.3 V/m	Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 2—It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the Model 007 is used exceeds 10 V/m, observe the Model 007 to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the Model 007 or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

BBB.8 Example completion of Table 208

This example is a hypothetical magnetic resonance imaging (MRI) SYSTEM that is specified for use only in a shielded location with a minimum RF shielding effectiveness and filter attenuation of 80 dB over the frequency range 10 MHz to 20 MHz, 100 dB over the frequency range 20 MHz to 80 MHz, and 80 dB over the frequency range 80 MHz to 100 MHz. (At 20 MHz and 80 MHz, the higher frequency range applies.) Thus, Table 208 is used. For the purpose of this example, the hypothetical MRI SYSTEM is a particular manufacturer's Model 003, and the required list of equipment that is allowed or prohibited inside the shielded location with the Model 003 is found on page 25 of the service manual. (See also BBB.3.)

Some of the actual IMMUNITY LEVELS are below the lowest level listed in the basic EMC IMMUNITY standard; therefore, those COMPLIANCE LEVELS are equal to the actual IMMUNITY LEVELS, as shown in Table BBB.12. These values are then used to complete Table 208, as shown in Table BBB.13.

Table BBB.12—Example (3) test, IMMUNITY and COMPLIANCE LEVELS

IMMUNITY test	IEC 60601 TEST LEVEL	Actual IMMUNITY LEVEL	COMPLIANCE LEVEL
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 10 MHz	3 Vrms	3 Vrms
Conducted RF IEC 61000-4-6	3 Vrms 10 MHz to 20 MHz	0.3 mVrms	0.3 mVrms
Conducted RF IEC 61000-4-6	3 Vrms 20 MHz to 80 MHz	0.03 mVrms	0.03 mVrms
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 100 MHz	0.3 mV/m	0.3 mV/m
Radiated RF IEC 61000-4-3	3 V/m 100 MHz to 2.5 GHz	3 V/m	3 V/m

Table BBB.13—Example of completed Table 208

Guidance and manufacturer's declaration—electromagnetic immunity			
The Model 003 MRI system is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 003 MRI system should assure that it is used in such an electromagnetic environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 10 MHz 0.3 mVrms 10 MHz to 20 MHz 0.03 mVrms 20 MHz to 80 MHz	The Model 003 MRI system must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 80 dB from 10 MHz to 20 MHz, 100 dB from 20 MHz to 80 MHz, and 80 dB from 80 MHz to 100 MHz. (The minimum at 20 MHz is 100 dB and the minimum at 80 MHz is 80 dB.) See page 25 of the service manual. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m.[a] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	0.3 mV/m 80 MHz to 100 MHz 3 V/m 100 MHz to 2.5 GHz	
NOTE 1—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. NOTE 2—It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the Model 003 MRI system is used exceeds 3 V/m, the Model 003 MRI system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the Model 003 MRI system or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

Annex CCC
(informative)

Guidance in classification according to CISPR 11

CCC.1 General

Rules for classification and separation into groups of equipment are specified in CISPR 11. The purpose of this annex is to provide additional guidance in the assignment of an EQUIPMENT or SYSTEM to the appropriate CISPR 11 group and class.

According to CISPR 11 (subclause 4.1: *Separation into groups*):[30]

— *Group 1* contains all ISM equipment in which there is intentionally generated or used conductively coupled RF energy that is necessary for the internal functioning of the equipment itself.

— *Group 2* contains all ISM equipment in which RF energy is intentionally generated or used in the form of electromagnetic radiation for the treatment of material, and spark erosion equipment.

According to CISPR 11 (subclause 4.2, *Division into classes*):[31]

— *Class A equipment* is equipment suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

NOTE—Although Class A limits have been derived for industrial and commercial establishments, administrations may allow, with whatever additional measures are necessary, the installation and use of Class A ISM equipment in a domestic establishment or in an establishment connected directly to domestic electricity power supplies. [32]

— *Class B equipment* is equipment suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Annex A of CISPR 11 gives examples of equipment classification. "Medical equipment" is listed as an example of Group 1 equipment, whereas "medical apparatus" is listed as an example of Group 2 equipment. Only short wave and microwave therapy equipment is mentioned explicitly. No other type of EQUIPMENT or SYSTEM is mentioned.

CCC.2 Separation into groups

Most types of EQUIPMENT and SYSTEMS generate or use RF energy only for their internal functioning and therefore belong to Group 1.

Examples of Group 1 EQUIPMENT and SYSTEMS are as follows:

— Electro- and magneto-cardiography EQUIPMENT and SYSTEMS

— Electro- and magneto-encephalography EQUIPMENT and SYSTEMS

— Electro- and magneto-myography EQUIPMENT and SYSTEMS

Group 1 also includes EQUIPMENT and SYSTEMS intended to deliver energy to the PATIENT, but in a form that is other than RF electromagnetic. Examples are as follows:

— Medical imaging EQUIPMENT and SYSTEMS:

- diagnostic X-ray systems for radiography and fluoroscopy (including cinefluoroscopy) for general purpose but also for special purposes, e.g., angiography, mammography, therapy planning, dentistry
- computed tomography SYSTEMS

30 See CISPR 11:1997.

31 See CISPR 11:1997.

32 Note 2 from 4.2 of CISPR 11:1997.

- SYSTEMS for nuclear medicine
- diagnostic ultrasound EQUIPMENT

— Therapy EQUIPMENT and SYSTEMS:

- therapeutic X-ray SYSTEMS
- dental EQUIPMENT
- electron beam accelerators
- ultrasound EQUIPMENT for therapy
- EQUIPMENT for extracorporeal lithotripsy
- infusion pumps
- radiant warmers
- infant incubators
- ventilators

— Monitoring EQUIPMENT and SYSTEMS:

- impedance plethysmography monitors
- pulse oximeters

Only a few EQUIPMENT and SYSTEMS apply RF energy to material (in this case to PATIENTS) and are therefore members of Group 2.

Examples are as follows:

— Medical imaging EQUIPMENT:

- SYSTEMS for magnetic resonance imaging

— Therapy EQUIPMENT:

- diathermy EQUIPMENT (short wave, ultra-short wave, microwave therapy EQUIPMENT)
- hyperthermy EQUIPMENT

Additionally, high frequency surgical EQUIPMENT and SYSTEMS, when active, should be classified as Group 2 equipment (similar to spark erosion equipment), because they apply RF energy to the PATIENT.

CCC.3 Division into classes

EQUIPMENT and SYSTEMS predominantly intended for use in domestic environments and connected to the PUBLIC MAINS NETWORK (e.g., home care EQUIPMENT and EQUIPMENT for doctors offices in residential areas) should meet the requirements for CISPR 11 Class B.

EQUIPMENT and SYSTEMS that are intended to be connected (e.g., in hospitals) to dedicated supply systems (normally fed by separation transformers) should meet the requirements for either CISPR 11 Class A or Class B.

EQUIPMENT and SYSTEMS that are specified for use only in a shielded location may be classified based on compliance of the system formed by the EQUIPMENT or SYSTEM together with the specified type of shielded location, i.e., with the assumption that the EQUIPMENT or SYSTEM has been installed in a shielded location meeting the EQUIPMENT or SYSTEM manufacturer's specifications for minimum RF shielding effectiveness and minimum RF filter attenuation. If classification is made on this basis, 6.8.3.201 c) 2) of this standard requires a statement of this fact to appear in Table 201, as well as a recommendation to verify the actual shielding effectiveness and filter attenuation of the shielded location.

Annex DDD
(informative)

Guidance in the application of IEC 60601-1-2 to Particular Standards

DDD.1 General

This annex contains recommendations to standards committees writing EMC requirements for Particular Standards (IEC 60601-2-X ("Part two") standards and ISO standards based on IEC 60601-1) to help ensure consistency in the application of IEC 60601-1-2. Such committees are encouraged to contact SC 62A with questions that arise in doing so.

This annex identifies the provisions of IEC 60601-1-2 that should be modified when this standard is applied to Particular Standards and provides guidance in doing so. It also identifies the provisions that should not be modified. In addition to this annex, the rationales in annex AAA should be consulted for additional information and guidance in the application of this standard.

DDD.2 Recommended modifications

Writers of Particular Standards are encouraged to make modifications or add additional information or clarification as follows:

a) Delete the last sentence of 36.202.1 a). If the particular EQUIPMENT or SYSTEM cannot meet the IMMUNITY TEST LEVELS specified in 36.202, the Particular Standard should specify the minimum COMPLIANCE LEVEL allowed for each test and provide justification based upon physical, technological, or physiological limitations. Once a lower IMMUNITY TEST LEVEL has been set and justified in a Particular Standard, the allowance for even lower COMPLIANCE LEVELS (the last sentence of 36.202.1 a)) should then be explicitly disallowed by the Particular Standard.

b) Make modifications to 36.202.1 c), f), g), and h) to be more specific for the particular EQUIPMENT or SYSTEM, while maintaining the intent of this standard.

c) Make modifications to or supplement 36.202.1 j) to provide specific performance criteria for the particular EQUIPMENT or SYSTEM that follow the intent of that subclause.

d) If selection of one or two of the following four possibilities for the applicability of Tables 203 through 208 can be made for a Particular Standard, this may be specified in 6.8.3.201:

   — Tables 203 and 205 apply (i.e., the particular EQUIPMENT or SYSTEM is LIFE-SUPPORTING and not specified for use only in a shielded location);

   — Tables 204 and 206 apply (i.e., the particular EQUIPMENT or SYSTEM is not LIFE-SUPPORTING and not specified for use only in a shielded location);

   — Table 207 applies (i.e., the particular EQUIPMENT or SYSTEM is LIFE-SUPPORTING and is specified for use only in a shielded location);

   — Table 208 applies (i.e., the particular EQUIPMENT or SYSTEM is not LIFE-SUPPORTING and is specified for use only in a shielded location).

e) The IMMUNITY TEST LEVELS in column 2 of Tables 202 through 208 may be modified as specified in DDD.2 a) above, DDD.4 below, and 6.8.3.201. If modifications are made to the IMMUNITY TEST LEVELS, the descriptions of the suitable ELECTROMAGNETIC ENVIRONMENT in column 4 should be modified accordingly.

f) For LIFE-SUPPORTING EQUIPMENT and SYSTEMS for which an alarm is required in accordance with 36.202.7 a) 2), it is likely that the alarm will need to be powered by stored energy during power interruptions. To assure safety of the LIFE-SUPPORTING EQUIPMENT or SYSTEM, it may be necessary to add a requirement and a test to verify that sufficient stored energy is available to operate this alarm for an extended period of time, e.g., 5 minutes.

DDD.3 Cautions

Writers of Particular Standards are cautioned against making other modifications, particularly those listed below.

a) The Foreword, Introduction, Clause 1, and Clause 2 should not be modified. Tables 201 and 202 should not be deleted. Other than the modifications described in DDD.2 d) and e) above and DDD.3 b) below, no other

changes should be made to Tables 201 through 208. Tables 201 through 208 provide the customer or user with essential information about the suitable electromagnetic use environment in a format common to all EQUIPMENT and SYSTEMS.

b) Subclause 36.201 should not be modified, except for specification of Group 1 or 2 classification, using the guidance in annex CCC, and classification to Class B, if the specific EQUIPMENT and SYSTEMS should only be classified as Class B. These changes may be indicated in 6.8.3.201 a) 3) or in Table 201. Particular Standards are not free to modify the EMISSIONS requirements or test methods specified in CISPR 11 without the consent of CISPR Subcommittee B.

c) Subclauses 36.202.3 b) 3) and 36.202.6 b) 6) should not be modified. The modulation frequencies chosen are adequate as is. If Particular Standards modify the modulation frequencies, additional testing would be required for SYSTEMS that use the EQUIPMENT, as the SYSTEM would then need to be tested over the entire frequency range at each different modulation frequency specified in each applicable Particular Standard, as well as at the modulation frequency specified in this (general) Collateral Standard.

d) Subclauses 36.202.3 b) 4) and 5) and 36.202.6 b) 7) and 8) should not be modified.

e) Subclauses 36.202.1 e), 36.202.4 b) 3), and 36.202.6 b) 3) should not be modified. The PATIENT cables are treated differently in different tests. The default termination requirements specify that no intentional conductive or capacitive connection be made to ground because either the termination is not considered relevant (i.e., in the surge IMMUNITY test) or the prohibited termination is considered less stringent (i.e., in the ESD and radiated RF tests). In specific tests, the artificial hand and RC element from CISPR 16-1 have been specified because, for these tests, it is either necessary for the artificial hand and RC element to be in place to properly perform the test, or the use of the artificial hand and RC element was considered to be the worst case. IEC 60601-1 treats the conditions in which the PATIENT is floating and in which the PATIENT is grounded as NORMAL CONDITIONS. However, from a RF perspective, it is unlikely that a PATIENT in a medical environment would ever be as effectively grounded as in an EMC test environment in which a direct ground reference is used. As a result, the artificial hand and RC element specified in CISPR 16-1 are used to represent the grounded condition. The treatment of PATIENT cables in this standard has been chosen to represent a condition of use that is worst case for each IMMUNITY test.

f) Subclause 36.202.3 b) 6) should not be modified. The introduction of metallic objects into the test area will distort the uniform field and increase testing uncertainty. The use of a metal plate to represent a PATIENT is discouraged.

DDD.4 Additional recommendations

a) If the expected electromagnetic characteristics of the intended use environment justify specification of higher IMMUNITY TEST LEVELS, the particular compliance criteria specified at the higher levels should follow the intent of 36.202.1 j) of this standard.

b) If additional assurance of safety is needed, a second set of IMMUNITY TEST LEVELS may be specified for safety-only compliance criteria (e.g., specific types of safe failures allowed, ESSENTIAL PERFORMANCE not required). Any criteria specified for safety only should supplement, rather than replace, particular compliance criteria that follow the intent of 36.202.1 j) of this standard. IMMUNITY TEST LEVELS applicable to any safety-only compliance criteria should be significantly higher than those applicable to compliance criteria that follow the intent of 36.202.1 j) of this standard.

NOTE—IEC 61000-1-2 recommends setting, for safety-critical equipment, two sets of test levels and criteria: one for functional performance and another, at higher test levels, for safety. This edition of IEC 60601-1-2 specifies IMMUNITY TEST LEVELS and criteria for both safety and ESSENTIAL PERFORMANCE.

c) As an alternative to specifying safety-only compliance criteria at a higher IMMUNITY TEST LEVEL, additional assurance of safety can be achieved by specifying particular compliance criteria, following the intent of 36.202.1 j), that shall be met at higher IMMUNITY TEST LEVELS than the IEC 60601 TEST LEVELS specified in 36.202 of this standard. This has the advantage that it reduces by half the amount of testing that would be required by performing an ESSENTIAL PERFORMANCE test at the IEC 60601 TEST LEVEL of this standard and then a safety-only test at a higher IMMUNITY TEST LEVEL. However, similar to the recommendation in b) above, this higher IMMUNITY TEST LEVEL should be significantly higher than the IEC 60601 TEST LEVEL of this standard.

Annex EEE
(informative)

Electromagnetic environments

Although Tables 202 through 208 are valid for a typical health care environment for EQUIPMENT and SYSTEMS, it would be useful to describe environments other than “typical health care” so that EQUIPMENT and SYSTEMS could be specified for use in these other environments.

Examples of ELECTROMAGNETIC ENVIRONMENTS are given in Table EEE.1.

Table EEE.1—Electromagnetic environments

Environment	Locations	General characteristics
Typical health care	Hospital, large clinic, doctor’s office	Partly controlled, covered by the general requirements of this standard
Residential	Doctor’s office, small clinic	Not controlled, health care professional present
Residential	Home	Not controlled, health care professional not normally present
Transport, mobile	Car, aircraft (fixed-wing and helicopter), ambulance	Not controlled, wide variations, critical receivers nearby, harsh environments for ESD, RF, electric, and magnetic fields
Special	Operating theatre, emergency room	Case-by-case examination of environment

Once sufficient information on the electromagnetic characteristics of a particular environment has been collected, specific IMMUNITY requirements may be proposed.

Annex FFF
(normative)

Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60050(161):1990, *International Electrotechnical Vocabulary (IEV)—Chapter 161: Electromagnetic compatibility*
Amendment 1 (1997)
Amendment 2 (1998)

IEC 60417-2:1998, *Graphical symbols for use on equipment—Part 2: Symbol originals*

IEC 60601-1:1988, *Medical electrical equipment—Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:2000, *Medical electrical equipment—Part 1: General requirements for safety—1. Collateral standard: Safety requirements for medical electrical systems*

IEC 61000-3-2, *Electromagnetic compatibility (EMC)—Part 3-2: Limits—Limits for harmonic current emissions (equipment input current ≤16 A per phase)*

IEC 61000-3-3, *Electromagnetic compatibility (EMC)—Part 3: Limits—Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤16 A*

IEC 61000-4-2, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 2: Electrostatic discharge immunity test—Basic EMC Publication.*

IEC 61000-4-3, *Electromagnetic compatibility (EMC)—Part 4-3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 4: Electrical fast transient/burst immunity test—Basic EMC Publication*

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

IEC 61000-4-6, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 6: Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 8: Power frequency magnetic field immunity test—Basic EMC Publication*

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

CISPR 11, *Industrial, scientific and medical (ISM) radio-frequency equipment—Electromagnetic disturbance characteristics—Limits and methods of measurement*

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

CISPR 15, *Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment*

CISPR 16-1, *Specification for radio disturbance and immunity measuring apparatus and methods—Part 1: Radio disturbance and immunity measuring apparatus*

CISPR 22, *Information technology equipment—Radio disturbance characteristics—Limits and methods of measurement*

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ANSI/IEEE 100:1996, *Standard Dictionary of Electrical and Electronics Terms*

CISPR 16-2:1996, *Specification for radio disturbance and immunity measuring apparatus and methods—Part 2: Methods of measurement of disturbances and immunity* [33]
Amendment 1 (1999)

CISPR 24, *Information technology equipment—Immunity characteristics—Limits and methods of measurement*

ETSI I-ETS 300 220:1993, *Radio Equipment and Systems (RES); Short Range Devices (SRDs); Technical characteristics and test methods for radio equipment to be used in the 25 MHz to 1,000 MHz frequency range with power levels ranging up to 500 mW*

ETSI ETS 300 741:1998, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for wide-area paging equipment*

European Union Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits

IEC 60050(601):1985, *International Electrotechnical Vocabulary (IEV)—Chapter 601: Generation, transmission and distribution of electricity—General*
Amendment 1 (1998)

IEC/TR3 60513:1994, *Fundamental aspects of safety standards for medical electrical equipment*

IEC 60601-1, *Medical electrical equipment—Part 1: General requirements for safety and essential performance* [34]

IEC 60601-1-4:1996, *Medical electrical equipment—Part 1: General requirements for safety 4. Collateral Standard: Programmable electrical medical systems*
Amendment 1 (1999) [35]

IEC/TS 61000-1-2, *Electromagnetic compatibility (EMC)—Part 1-2: General—Methodology for the achievement of functional safety of electrical and electronic equipment with regard to electromagnetic phenomena* [36]

IEC/TR2 61000-2-5:1995, *Electromagnetic compatibility (EMC)—Part 2: Environment—Section 5: Classification of electromagnetic environments—Basic EMC Publication*

IEC/TS 61000-3-4:1998, *Electromagnetic compatibility (EMC)—Part 3-4: Limits—Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A*

IEC/TR2 61000-3-5:1994, *Electromagnetic compatibility (EMC)—Part 3: Limits—Section 5: Limitations of voltage fluctuations and flicker in low-voltage power supply systems for equipment with rated current greater than 16 A*

IEC 61000-4-1:2000, *Electromagnetic compatibility (EMC)—Part 4-1: Testing and measurement techniques—Overview of IEC 61000-4 series*

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 2: Electrostatic discharge immunity test—Basic EMC Publication* [37]
Amendment 1 (1998)
Amendment 2 (2000)

[33] There exists a consolidated edition 1.1 (1999) that includes CISPR 14-1:1996 and its amendment 1 (1999).

[34] Third edition, in preparation.

[35] There exists a consolidated edition 1.1 (2000) that includes IEC 60601-1-4:1996 and its amendment 1 (1999).

[36] To be published.

[37] There exists a consolidated edition 1.2 (2001) that includes IEC 61000-4-2 (1995) and its amendment 1 (1998) and amendment 2 (2000).

IEC 61000-4-3:1995, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 3: Radiated, radio-frequency, electromagnetic field immunity test* [38]
Amendment 1 (1998)
Amendment 2 (2000)

IEC 61000-4-6:1996, *Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 6: Immunity to conducted disturbances, induced by radio-frequency fields* [39]
Amendment 1 (2000)

IEC/TR3 61000-5-1:1996, *Electromagnetic compatibility (EMC)—Part 5: Installation and mitigation guidelines—Section 1: General considerations—Basic EMC Publication*

IEC 61000-5-2:1997, *Electromagnetic compatibility (EMC)—Part 5: Installation and mitigation guidelines—Section 2: Earthing and cabling*

IEC/TR 61000-5-6, *Electromagnetic compatibility (EMC)—Part 5-6: Installation and mitigation guidelines—Mitigation of external EM influences* [40]

IEC 61326-1, *Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 1: General requirements*

ISO 14971:2000, *Medical devices—Application of risk management to medical devices*

ITU:1998, *Radio Regulations—Volume 2: Appendices*

[38] There exists a consolidated edition 1.2 (2001) that includes IEC 61000-4-3 (1995) and its amendment 1 (1998) and amendment 2 (2000).

[39] There exists a consolidated edition 1.1 (2001) that includes IEC 61000-4-6 (1996) and its amendment 1 (2000).

[40] To be published.