

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance –
Collateral standard: Electromagnetic compatibility – Requirements and tests**

**Appareils électromédicaux –
Partie 1-2: Exigences générales pour la sécurité de base et les performances
essentielles – Norme collatérale: Compatibilité électromagnétique –
Exigences et essais**

WATERMARK



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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

INTERPRETATION SHEET

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/685/ISH	62A/694/RVD

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

Subclause 6.2.2.2 e) (ESD IMMUNITY)

(This is also applicable to Subclause 36.202.2 b) 5) in IEC 60601-1-2:2001¹⁾.)

This subclause states the following:

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

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.3.2 j) (Radiated RF IMMUNITY)

(This is also applicable to Subclause 36.202.3 b) 10) in IEC 60601-1-2:2001.)

This subclause states the following:

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

This is clarified by the following:

¹⁾ A consolidated edition 2.1 exists (withdrawn) including IEC 60601-1-2:2001 and its Amendment 1 (2006).

The test may be performed at any power input voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the EQUIPMENT or SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.4.2 e) (EFT/burst IMMUNITY)

(This is also applicable to Subclause 36.202.4 b) 5) in IEC 60601-1-2:2001.)

This subclause states the following:

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

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED power input voltages. The test may be performed at any power input frequency within the ME EQUIPMENT or ME SYSTEM RATED range. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.5.2 f) (Surge IMMUNITY)

(This is also applicable to Subclause 36.202.5 b) 6) in IEC 60601-1-2:2001.)

This subclause states the following:

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

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED power input voltages. The test may be performed at any power input frequency within the ME EQUIPMENT or ME SYSTEM RATED range. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.6.2 j) (Conducted RF IMMUNITY)

(This is also applicable to Subclause 36.202.6 b) 10) in IEC 60601-1-2:2001.)

This subclause states the following:

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

This is clarified by the following:

The test may be performed at any power input voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.7.2 c) (Voltage dips and interruptions IMMUNITY)

(This is also applicable to Subclause 36.202.7 b) 4) in IEC 60601-1-2:2001.)

This subclause states the following:

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

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED input voltages. The test shall be performed with the ME EQUIPMENT or ME SYSTEM powered at the minimum RATED power frequency. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.8.1.2 (Power-frequency magnetic field IMMUNITY)

(This is also applicable to Subclause 36.202.8.1 b) in IEC 60601-1-2:2001.)

This subclause states the following:

a) (Item 1) in IEC 60601-1-2:2001)

Only the continuous field test shall be performed.

- The test is performed at both 50 Hz and 60 Hz, with the exception that ME EQUIPMENT and ME SYSTEMS RATED for use only at one of these frequencies need only be tested at that frequency. In either case, during the test, the ME EQUIPMENT or ME SYSTEM is powered at the same frequency as the applied magnetic field.*
- If the ME EQUIPMENT or ME SYSTEM is INTERNALLY POWERED or powered from an external d.c. supply, the test is performed at both 50 Hz and 60 Hz, with the exception that ME EQUIPMENT and ME SYSTEMS intended for use only in areas supplied at one of these frequencies need be tested only at that frequency.*

b) (Item 2) in IEC 60601-1-2:2001))

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

Item b) is clarified by the following:

The test may be performed at any power input voltage within the ME EQUIPMENT or ME SYSTEM RATED power input voltage range. If the EQUIPMENT or SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

For EMISSIONS, IEC 60601-1-2 references CISPR 11. IEC 60601-1-2 does not add any clarification regarding the power input voltage and frequency during EMISSIONS testing.

Subclause 7.5.3 of CISPR 11:2009 states the following:

Mains power at the nominal voltage shall be supplied.

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 9.1 of CISPR 11:2009 states the following:

Power at the nominal voltage shall be supplied.

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

These clarifications will remain valid until a new version of IEC 60601-1-2 is published.

Withdrawn

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Withdrawn

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-1-2 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

This document cancels and replaces the second edition of IEC 60601-1-2, and constitutes a technical revision.

This edition of IEC 60601-1-2 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC subcommittee 62A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

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

FDIS	Report on voting
62A/560/FDIS	62A/567/RVD

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

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

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

- requirements and definitions: roman type.
- *test specifications: italic type*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Table 1 through Table 8, in the tables in Annex C and in statements required to appear in the technical description or instructions for use because they are intended for the OPERATOR OF RESPONSIBLE ORGANIZATION, who may not be familiar with the defined terms of IEC 60601 standards.

In referring to the structure of this standard, the term

- “clause” means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes 6.1, 6.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses, items and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

Withdrawn

INTRODUCTION

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is well recognized.

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

- safety services;
- other MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS;
- electrical equipment that is not ME 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 MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. ELECTROMAGNETIC COMPATIBILITY (see Definition 3.4) 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 MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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. MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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 OPERATOR of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this collateral standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM would also be expected to be normal.

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are used in the practice of medicine because they provide needed FUNCTIONS. If MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL 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.

This edition recognizes that there is a shared responsibility between MANUFACTURERS, RESPONSIBLE ORGANIZATIONS and OPERATORS to ensure that MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are designed and operated as intended. The MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM MANUFACTURER’S responsibility is to design and manufacture to meet the requirements of this collateral standard and to disclose information to the RESPONSIBLE ORGANIZATION or OPERATOR so that a compatible ELECTROMAGNETIC ENVIRONMENT can be maintained in order that the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will perform as intended.

Because the practice of medicine involves many specialities, there will by necessity be MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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 MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS during the ELECTROMAGNETIC IMMUNITY testing specified in this collateral standard. Because of the proven benefits of many such MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, this collateral 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 MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM meets the performance requirements of this collateral standard and to specify the characteristics of the ELECTROMAGNETIC use environment and how this environment is established, in which the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will perform as intended.

This collateral 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 collateral standard recognizes that for LIFE-SUPPORTING MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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 collateral standard specifies additional requirements for LIFE-SUPPORTING MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.

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

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS.

1.2 Object

The object of this collateral standard is to specify general requirements and tests for ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

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

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

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

1.3.2 Particular standards

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60417, *Graphical symbols for use on equipment*

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

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

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 3-3: Limits – 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 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

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 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

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

IEC 61000-4-6:2003, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*¹⁾

Amendment 1 (2004)

Amendment 2 (2006)

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

IEC 61000-4-11, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – 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 16-1-2, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Ancillary equipment – Conducted disturbances*

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

¹⁾ There exists a consolidated edition 2.2 (2006) that includes IEC 61000-4-6 (2003) and its Amendment 1 (2004) and Amendment 2 (2006).

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-8:2006 and the following definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 3 An index of defined terms is found beginning on page 121.

3.1

(IMMUNITY) COMPLIANCE LEVEL

level less than or equal to the IMMUNITY LEVEL for which the ME EQUIPMENT or ME SYSTEM meets the requirements of the applicable subclause of 6.2

NOTE Additional requirements for COMPLIANCE LEVELS are specified in 5.2.2.

3.2

*** DEGRADATION (of performance)**

undesired departure in the operational performance of ME EQUIPMENT or an ME SYSTEM from its intended performance

NOTE The term “DEGRADATION” can apply to temporary or permanent failure.

[IEV 161-01-19, modified]

3.3

*** 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

NOTE As used by the ITU and as used in Chapter 7.12 of the IEV, the term “effective radiated power” appears without qualification only when the reference antenna is a half-wave dipole.

[IEV 161-04-16, modified]

3.4

ELECTROMAGNETIC COMPATIBILITY EMC

ability of ME EQUIPMENT or an ME SYSTEM to function satisfactorily in its ELECTROMAGNETIC ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment

[IEV 161-01-07, modified]

3.5

*** ELECTROMAGNETIC DISTURBANCE**

any electromagnetic phenomenon that may degrade the performance of a device, equipment or system

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

[IEV 161-01-05, modified]

3.6**(ELECTROMAGNETIC) EMISSION**

phenomenon by which electromagnetic energy emanates from a source

[IEV 161-01-08]

3.7**ELECTROMAGNETIC ENVIRONMENT**

totality of electromagnetic phenomena existing at a given location

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

[IEV 161-01-01]

3.8**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]

3.9**ELECTROSTATIC DISCHARGE****ESD**

transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact

[IEV 161-01-22]

3.10*** 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.

3.11*** FUNCTION**

clinically significant operation that the ME EQUIPMENT or ME SYSTEM is intended to perform in the diagnosis, treatment or monitoring of a PATIENT or for compensation or alleviation of disease, injury or disability

3.12**IEC 60601 TEST LEVEL**

IMMUNITY TEST LEVEL specified in 6.2 by this collateral standard or a particular standard

3.13*** IMMUNITY (to a disturbance)**

ability of ME EQUIPMENT or an ME SYSTEM to perform without DEGRADATION in the presence of an ELECTROMAGNETIC DISTURBANCE

[IEV 161-01-20, modified]

3.14

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]

3.15

IMMUNITY TEST LEVEL

level of a test signal used to simulate an ELECTROMAGNETIC DISTURBANCE when performing an IMMUNITY test

[IEV 161-04-41]

3.16

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)

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.

[IEV 161-05-04]

3.17

*** LARGE ME EQUIPMENT OR ME SYSTEM**

ME EQUIPMENT or ME SYSTEM that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables; this includes distributed ME SYSTEMS

3.18

*** LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM**

ME EQUIPMENT or ME 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 6.2.1.10 is likely to lead to serious injury or death of a PATIENT

3.19

*** 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.

3.20

*** OPERATING FREQUENCY**

fundamental frequency of a signal, electrical or non-electrical, that is set in ME EQUIPMENT or an ME SYSTEM intended to control a physiological parameter

3.21*** PATIENT-COUPLED ME EQUIPMENT OR ME SYSTEM**

ME EQUIPMENT or ME 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 ME EQUIPMENT or ME SYSTEM and provides a path for electromagnetic energy, whether coupled conductively, capacitively or inductively and whether intended or unintended

3.22*** PHYSIOLOGICAL SIMULATION FREQUENCY**

fundamental frequency of a signal, electrical or non-electrical, used to simulate a physiological parameter such that the ME EQUIPMENT or ME SYSTEM will operate in a manner consistent with use on a PATIENT

3.23*** PROFESSIONAL ME EQUIPMENT OR ME SYSTEM**

ME EQUIPMENT or ME SYSTEM for use by healthcare professionals and that is not intended for sale to the general public

[IEV 161-05-05, modified]

3.24*** PUBLIC MAINS NETWORK**

LOW VOLTAGE electricity power lines to which all categories of consumers have access

3.25*** 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.

3.26**TYPE A PROFESSIONAL ME EQUIPMENT OR ME SYSTEM**

PROFESSIONAL ME EQUIPMENT or ME SYSTEM that complies with CISPR 11 group 2 Class B except for the third harmonic of the fundamental frequency of the ME EQUIPMENT or ME SYSTEM, in which case the third harmonic complies with the group 2 Class A electromagnetic radiation disturbance limit

NOTE See 6.1.1.1 f).

4 General requirements**4.1 General requirements for ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS****4.1.1 * ELECTROMAGNETIC COMPATIBILITY**

ME EQUIPMENT and ME SYSTEMS shall not emit ELECTROMAGNETIC DISTURBANCES that could affect radio services, other equipment or the ESSENTIAL PERFORMANCE of other ME EQUIPMENT and ME SYSTEMS. ME EQUIPMENT and ME SYSTEMS shall have adequate IMMUNITY to be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of ELECTROMAGNETIC DISTURBANCES.

Consider compliance to exist if the requirements of this collateral standard are met.

4.1.2 Electrical equipment that is not ME EQUIPMENT

Electrical equipment that is not ME EQUIPMENT and that is supplied as part of an ME SYSTEM is exempt from the EMC testing requirements of this collateral standard provided all of the following conditions are met (see also Annex G):

- a) the electrical equipment that is not ME EQUIPMENT complies with applicable international EMC standards;
- b) both the EMISSIONS and IMMUNITY of the electrical equipment that is not ME EQUIPMENT have been determined not to adversely affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM; and
- c) the EMISSIONS of the electrical equipment that is not ME EQUIPMENT have been determined not to cause the EMISSIONS of the ME SYSTEM to exceed applicable limits.

Check compliance by inspection of the documents for this determination and other appropriate documents or certificates or, if this determination is not performed, by inspection of the documents to verify that the electrical equipment that is not ME EQUIPMENT has been tested in accordance with this collateral standard.

4.2 * SINGLE FAULT CONDITION for ME EQUIPMENT

For EMC testing, the SINGLE FAULT CONDITION requirements of the general standard do not apply.

5 Identification, marking and documents

5.1 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

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

ME EQUIPMENT and ME SYSTEMS that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labelled with symbol IEC 60417-5140 (2003-04) for non-ionizing radiation. The symbol graphic is shown below.



5.1.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts for which the connector testing exemption specified in 6.2.2.2 c) is used

For ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 6.2.2.2 c) is used, symbol IEC 60417-5134 (2003-04) for ESD sensitivity shall be applied adjacent to each connector for which the testing exemption is used. The symbol graphic is shown below.



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

ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location shall be labelled with a warning that they should be used only in the specified type of shielded location (see 5.2.2.3).

Check compliance with the requirements of 5.1 by inspection.

5.2 ACCOMPANYING DOCUMENTS

5.2.1 Instructions for use

5.2.1.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

The instructions for use shall include the following:

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

5.2.1.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 6.2.2.2 c) is used

For ME EQUIPMENT and ME SYSTEMS for which the connector testing exemption specified in 6.2.2.2 c) is used, the instructions for use shall include the following:

- a) a reproduction of the ESD warning symbol (IEC 60417-5134 (2003-04), as shown in 5.1.2);
- b) 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;
- c) * a specification of the ESD precautionary procedures;
- d) * a recommendation that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures; and
- e) * a specification of the minimum contents of ESD precautionary procedure training.

5.2.1.3 Minimum amplitude or value of PATIENT physiological signal

For ME EQUIPMENT and ME SYSTEMS without a manual sensitivity adjustment and for which the MANUFACTURER specifies a minimum amplitude or value of the PATIENT physiological signal (see 6.2.1.7, first dash), the instructions for use shall include the following:

- a) the minimum amplitude or value of PATIENT physiological signal; and
- b) a warning that operation of the ME EQUIPMENT or ME SYSTEM below this amplitude or value may cause inaccurate results.

5.2.1.4 * Requirements applicable to TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS

If TYPE A PROFESSIONAL ME EQUIPMENT or a TYPE A PROFESSIONAL ME SYSTEM is intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 6.1.1.1 f)), the instructions for use shall include the following warning or equivalent:

Warning

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.

where “[me equipment or me system]” shall be replaced with the model or type reference of the me equipment or me system.

Check compliance with the requirements of 5.2.1 by inspection of the instructions for use.

5.2.2 Technical description

5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

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

- a) * A list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES with which the MANUFACTURER of the ME EQUIPMENT and ME SYSTEMS claims compliance with the requirements of 6.1 and 6.2. 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 ME EQUIPMENT or ME SYSTEM as replacement parts for internal components need not be listed.

- b) * 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 ME EQUIPMENT or ME SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.
- c) * Table 1, with the modifications specified below, which should be performed in the order in which they appear. See Annex C for examples. The flowchart in Figure 1 is the requirement in step-by-step graphical form for completion of Table 1 for CISPR 11 ME EQUIPMENT and ME SYSTEMS. The flowchart in Figure 2 is the requirement in step-by-step graphical form for completion of Table 1 for CISPR 14 and CISPR 15 equipment.
- For CISPR 11 ME EQUIPMENT and ME SYSTEMS, “[ME EQUIPMENT or ME SYSTEM]” shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.
 - For CISPR 14 and CISPR 15 ME EQUIPMENT, “[ME EQUIPMENT]” shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT.
 - For CISPR 11 group 1 ME EQUIPMENT and ME SYSTEMS, rows 5, 12 and 13 shall be deleted.
 - For CISPR 11 group 2 ME EQUIPMENT and ME SYSTEMS, rows 4, 12 and 13 shall be deleted.
 - For ME EQUIPMENT that complies with CISPR 14-1, rows 4 through 6 and row 13 shall be deleted.
 - For ME EQUIPMENT that complies with CISPR 15, rows 4 through 6 and row 12 shall be deleted.
 - For CISPR 11 ME EQUIPMENT and ME SYSTEMS that comply with Class A, including TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS, “[A or B]” in column 2 of row 6 shall be replaced with “A”. For CISPR 11 ME EQUIPMENT and ME SYSTEMS that comply with Class B, “[A or B]” shall be replaced with “B”.

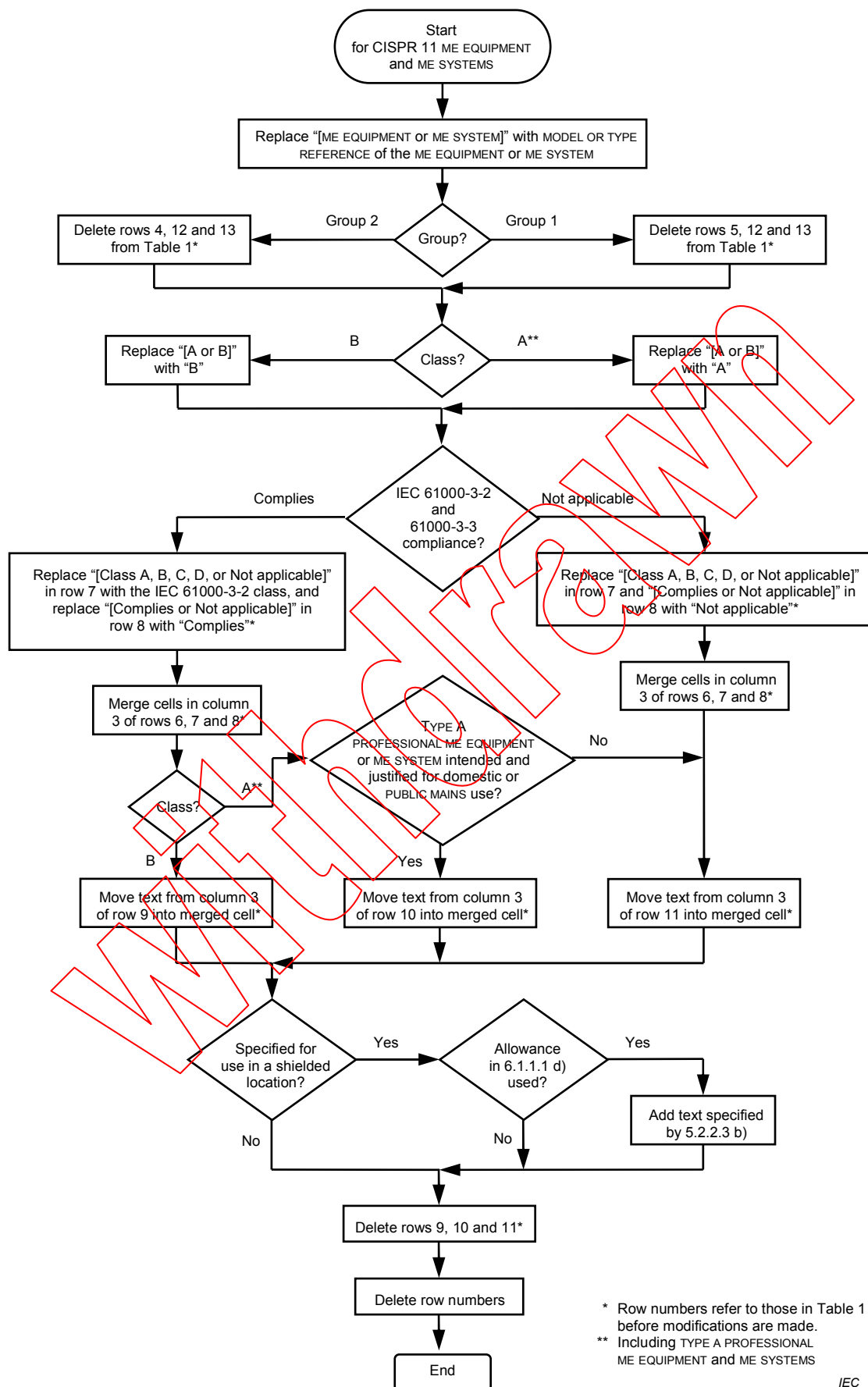
- For ME EQUIPMENT and ME SYSTEMS that comply with IEC 61000-3-2, “[Class A, B, C, D, or Not applicable]” in column 2 of row 7 shall be replaced with the class of the ME EQUIPMENT or ME SYSTEM according to IEC 61000-3-2. For ME EQUIPMENT and ME SYSTEMS that comply with IEC 61000-3-3, “[Complies or Not applicable]” in column 2 of row 8 shall be replaced with “Complies”. For ME EQUIPMENT and ME 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 ME EQUIPMENT and ME SYSTEMS, column 3 of rows 6, 7 and 8 shall be merged into one cell. For CISPR 11 ME EQUIPMENT and ME 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 TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS for which use in a domestic establishment or connection to the PUBLIC MAINS NETWORK is intended and justified (5.2.2.10 and 6.1.1.1 f) and that comply with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 10 shall be moved into the merged cell. For CISPR 11 ME EQUIPMENT and ME SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable or that comply with Class A but do not meet the requirements for TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS specified in 6.1.1.1 f), the text in column 3 of row 11 shall be moved into the merged cell.
 - For CISPR 14 or CISPR 15 ME EQUIPMENT, column 3 of rows 7 and 8 shall be merged into one cell. For CISPR 14 or CISPR 15 ME EQUIPMENT that complies 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 ME EQUIPMENT for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, the text in column 3 of row 11 shall be moved into the merged cell.
 - For ME EQUIPMENT and ME 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 6.1.1.1 d) is used, the text specified by 5.2.2.3 b) shall be added.
 - Rows 9, 10 and 11 shall be deleted.
 - The row numbers shall be deleted.
- d) * A warning that the ME EQUIPMENT or ME SYSTEM should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ME EQUIPMENT or ME SYSTEM should be observed to verify normal operation in the configuration in which it will be used.
- NOTE The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM may provide a description or list of equipment with which the ME EQUIPMENT or ME SYSTEM has been tested in a stacked or adjacent configuration and with which stacked or adjacent use is permitted.
- e) * 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.

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

(see 5.2.2.1 c))

Row

①	Guidance and manufacturer's declaration – electromagnetic emissions		
②	The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME 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 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME 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 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME SYSTEM] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.
⑪		[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME 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.
⑫	RF emissions CISPR 14-1	Complies	The [ME EQUIPMENT] is not suitable for interconnection with other equipment.
⑬	RF emissions CISPR 15	Complies	The [ME EQUIPMENT] is not suitable for interconnection with other equipment.



IEC 331/07

Figure 1 – Instructions for completing Table 1 for CISPR 11 ME EQUIPMENT and ME SYSTEMS (see 5.2.2.1 c))

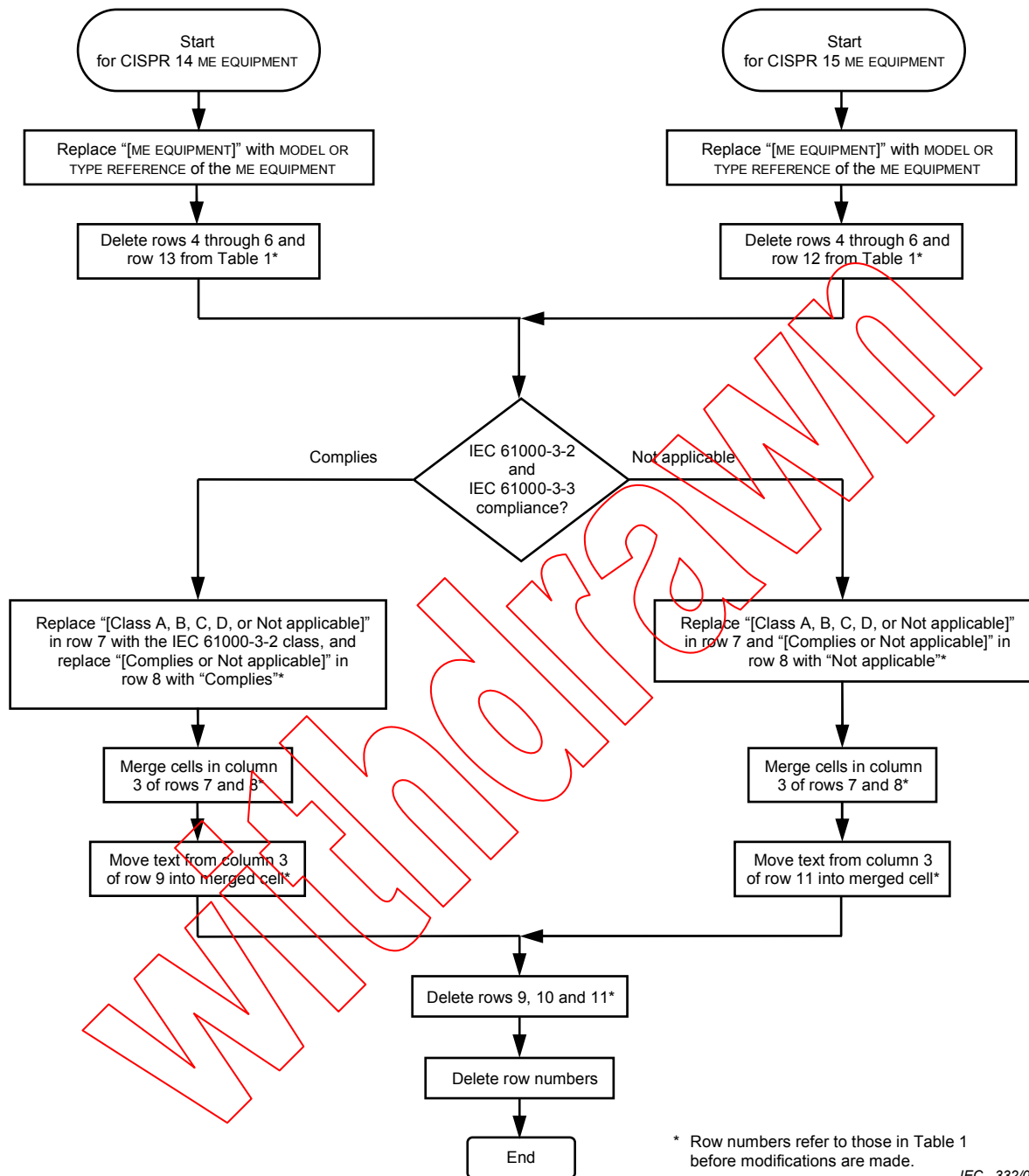


**Figure 2 – Instructions for completing Table 1
for CISPR 14 and CISPR 15 ME EQUIPMENT
(see 5.2.2.1 c))**

f) * Table 2, completed as specified below.²⁾ The flowchart in Figure 3 is the requirement in step-by-step graphical form for completion of Table 2.

- “[ME EQUIPMENT or ME SYSTEM]” shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.

NOTE There are four places in Table 2 where “[ME EQUIPMENT or ME SYSTEM]” must be replaced.

- * Column 3 of Table 2 shall be filled in with the IMMUNITY COMPLIANCE LEVEL for each test in accordance with the requirements of 5.2.2 and 6.2. 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 6.2 or the scope of the EMC basic standard a test does not apply to the ME EQUIPMENT or ME SYSTEM, or it is not possible to perform the test on the ME EQUIPMENT or ME SYSTEM, columns 3 and 4 of Table 2 shall state that the test is not applicable.
- * For the 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 6.2.2, 6.2.4, 6.2.5, 6.2.7 or 6.2.8.1, the text in column 4 in the corresponding row of Table 2 shall be replaced with a description of the actions the RESPONSIBLE ORGANIZATION or OPERATOR must take to reduce environmental levels of the ELECTROMAGNETIC 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 6.2.2, 6.2.4, 6.2.5, 6.2.7 or 6.2.8.1, the text in column 4 in the corresponding row of Table 2 may be replaced with a description of the environment for which the ME EQUIPMENT or ME SYSTEM is suitable.

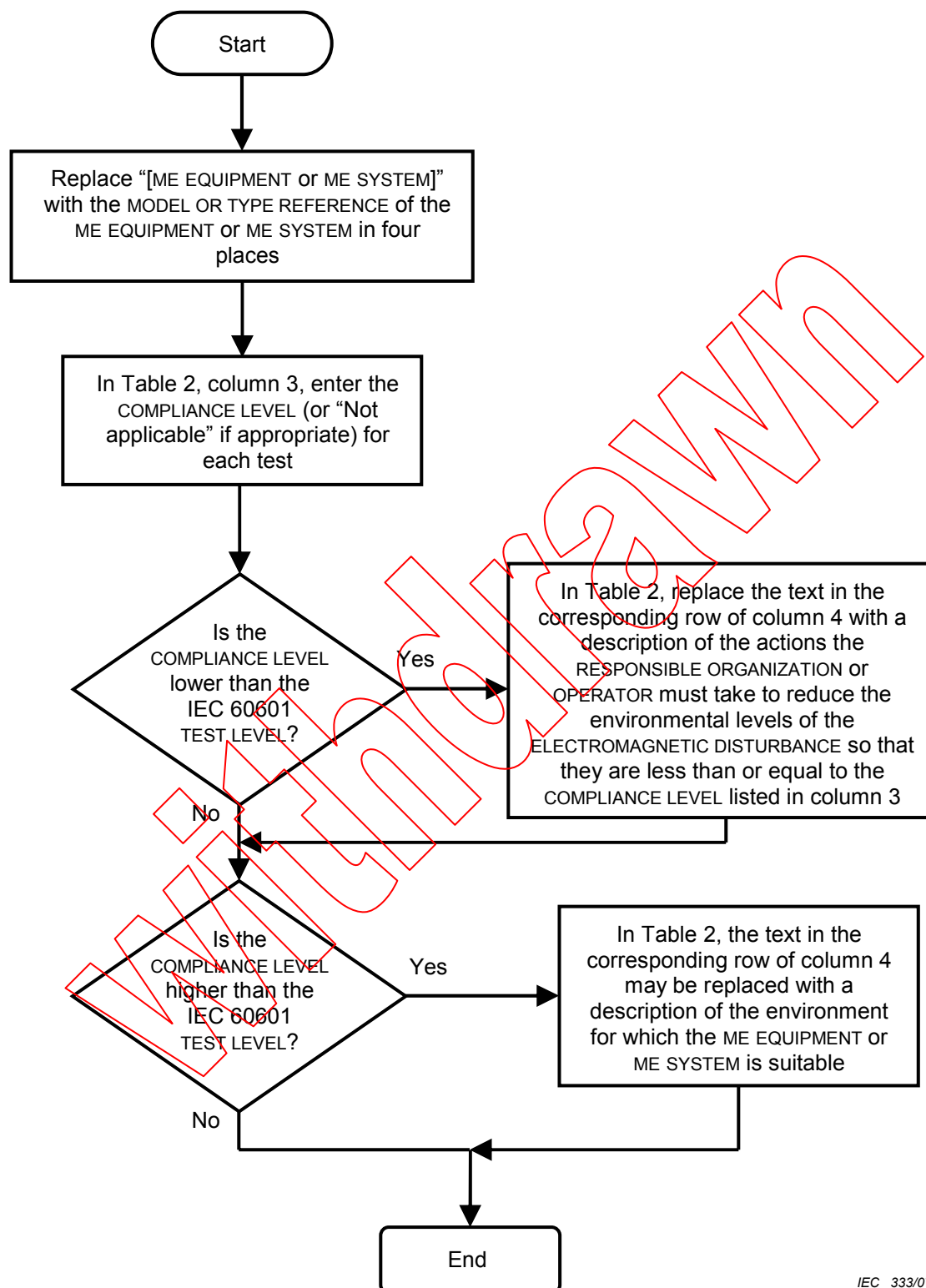
g) The performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE.

²⁾ See Annex C for an example.

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

(see 5.2.2.1 f))

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME 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 line(s) to line(s) ± 2 kV line(s) to earth		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 8 s		Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME 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.			



IEC 333/07

Figure 3 – Instructions for completing Table 2
(see 5.2.2.1 f))

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

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

The applicable tables, Table 3 and Table 5 or Table 4 and Table 6. Table 3 and Table 5 shall be used for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS. Table 4 and Table 6 shall be used for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING. The tables shall be completed for the conducted and radiated RF IMMUNITY tests as specified below.³⁾ The flowchart in Figure 4 is the requirement in step-by-step graphical form for completion of Table 3 and Table 5, and the flowchart in Figure 5 is the requirement in step-by-step graphical form for completion of Table 4 and Table 6.

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

NOTE There are six places in Table 3 and Table 4 and four places in Table 5 and Table 6 where "[ME EQUIPMENT or ME SYSTEM]" must be replaced.

- b) Column 3 of Table 3 or Table 4, as applicable, shall be filled in with the IMMUNITY COMPLIANCE LEVEL in accordance with the requirements of 5.2.2 and 6.2. 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.
- c) The expressions in square brackets ([]) that contain V_1 , V_2 and E_1 in column 4 of Table 3 or Table 4, as applicable, and in Table 5 or Table 6, 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 3 or Table 4, as applicable.
- d) Table 5 and Table 6, as applicable, shall be completed by calculating the distance corresponding to each entry in columns 2 through 5 in Table 5 or columns 2 through 4 in Table 6, 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 5 or Table 6, as applicable.
- e) If, according to 6.2 or the scope of the EMC basic standard, a test does not apply to the ME EQUIPMENT or ME SYSTEM, or it is not possible to perform the test on the ME EQUIPMENT or ME SYSTEM, the corresponding entries in columns 3 and 4 of Table 3 or Table 4 and the corresponding cells of Table 5 or Table 6 shall state "not applicable".

³⁾ See Annex C for examples.

Table 3 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS

(see 5.2.2.2)

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	$[V_2]$ V	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	$[E_1]$ V/m	$d = \left[\frac{12}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz
			$d = \left[\frac{23}{E_1} \right] \sqrt{P}$ 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 metres (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 has been incorporated into the formulae 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 [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME SYSTEM]. ^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

Table 4 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

(see 5.2.2.2)

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	$[E_1]$ V/m	$d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 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 metres (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 [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME SYSTEM].			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

Table 5 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS

(see 5.2.2.2)

Recommended separation distances between portable and mobile RF communications equipment and the [ME EQUIPMENT or ME SYSTEM]				
The [ME EQUIPMENT or ME SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [ME EQUIPMENT or ME 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	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$	$d = \left[\frac{12}{E_1} \right] \sqrt{P}$	$d = \left[\frac{23}{E_1} \right] \sqrt{P}$
0,01				
0,1				
1				
10				
100				
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 has been incorporated into the formulae 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 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

(see 5.2.2.2)

Recommended separation distances between portable and mobile RF communications equipment and the [ME EQUIPMENT or ME SYSTEM]			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [ME EQUIPMENT or ME 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 $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0,01			
0,1			
1			
10			
100			
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.			

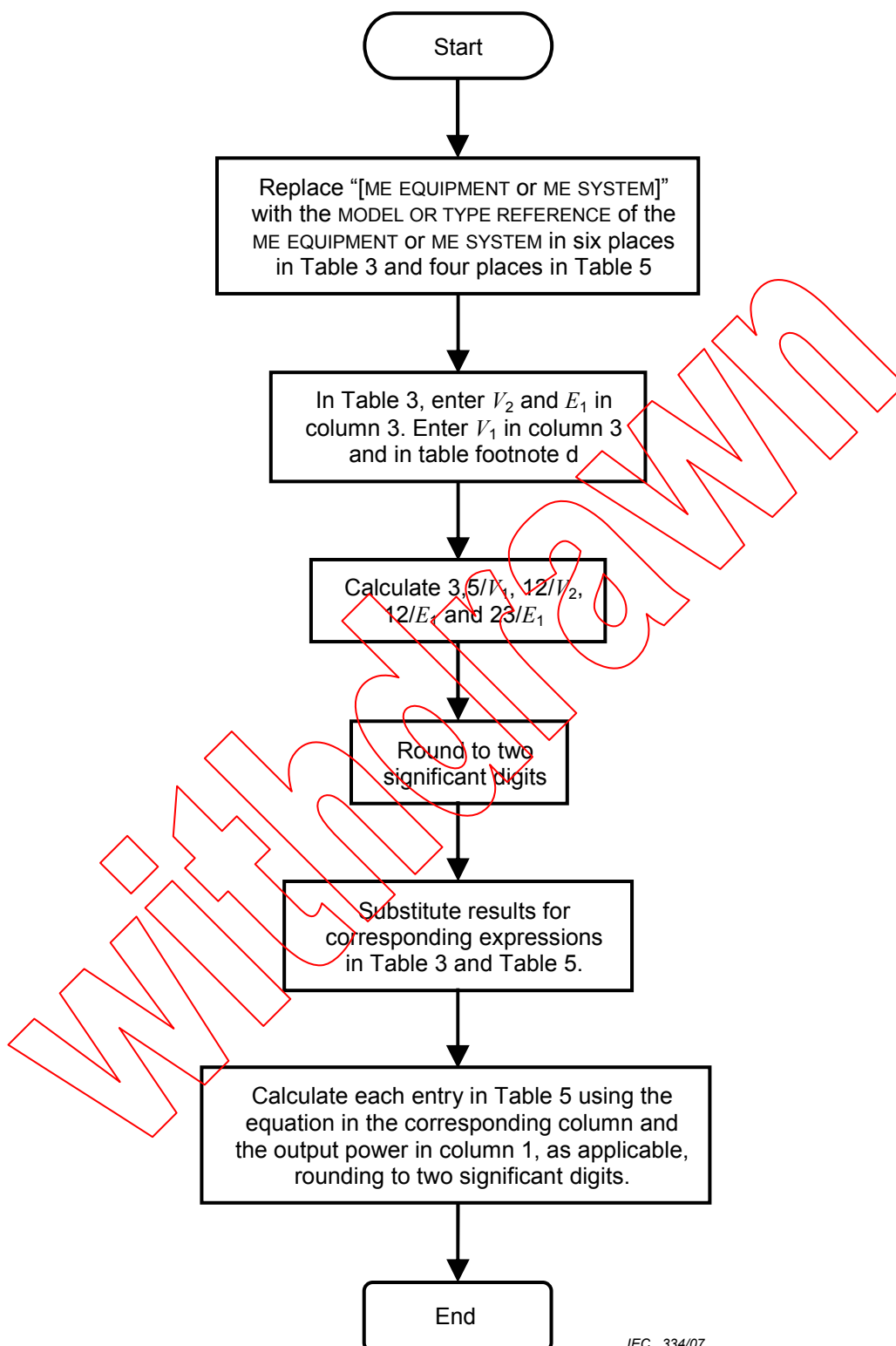


**Figure 4 – Instructions for completing Table 3 and Table 5
for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS
(see 5.2.2.2)**

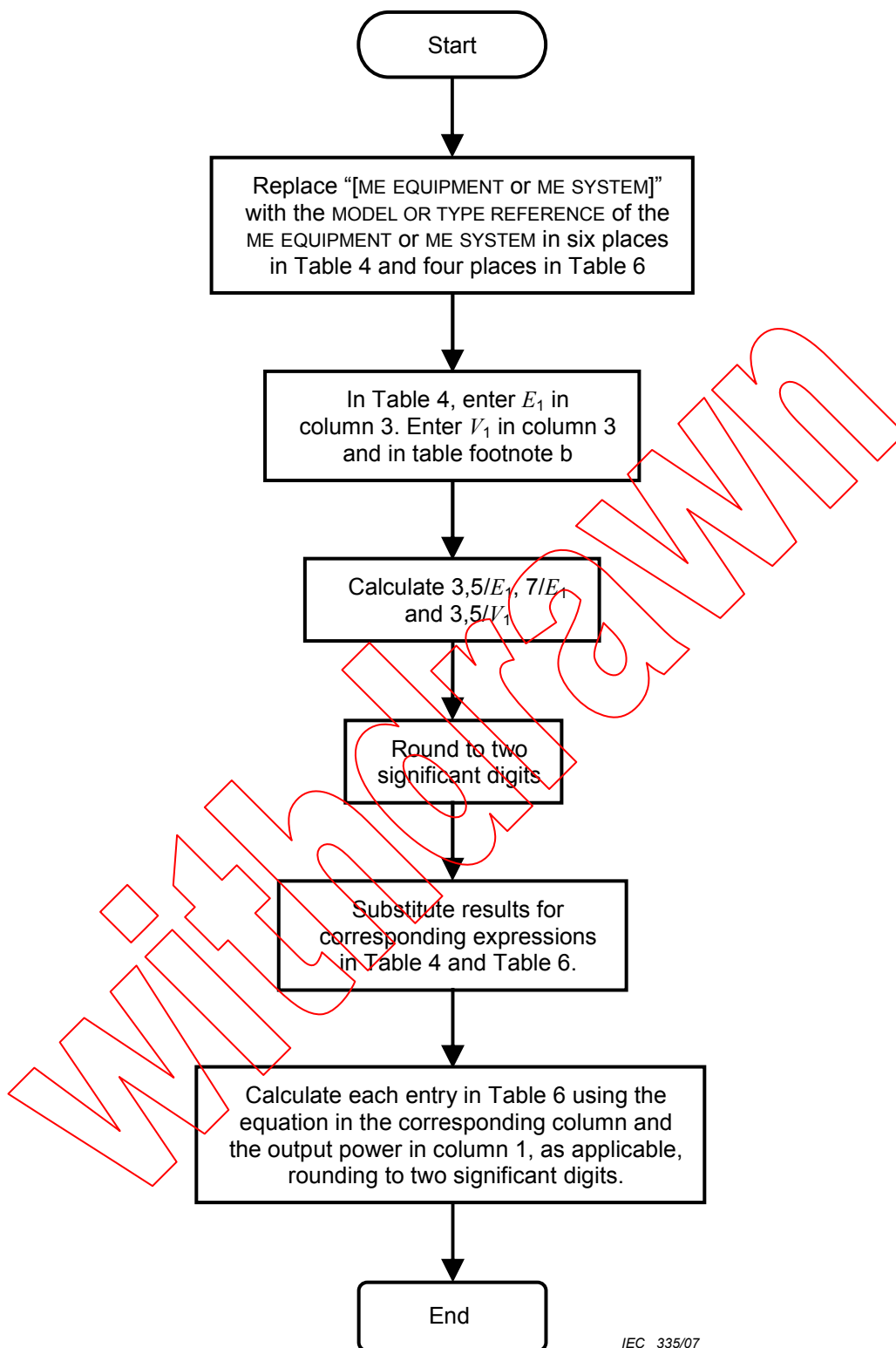


Figure 5 – Instructions for completing Table 4 and Table 6 for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING (see 5.2.2.2)

5.2.2.3 Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location

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

- a) A warning that the ME EQUIPMENT or ME SYSTEM should be used only in the specified type of shielded location.
- b) * If the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 6.1.1.1 d) is used:

- the following text, added to column 2 of the CISPR row of Table 1, after or below the CISPR class:

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

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

- the following text, appended to the beginning of the text in column 3 of Table 1 in the merged cell of the CISPR 11, IEC 61000-3-2 and IEC 61000-3-3 rows:

The [ME EQUIPMENT or ME 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 “[me equipment or me system]” shall be replaced with the model or type reference of the me equipment or me system and “[shielding effectiveness / filter attenuation specification]” shall be replaced with the specification for minimum RF shielding effectiveness and RF filter attenuation.

NOTE This specification is also used in Table 7 and Table 8 (see 5.2.2.3 d)).

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;
- 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 collateral standard;
- the following text, added to replace “The [ME EQUIPMENT or ME SYSTEM] is suitable” in the text in column 3 of Table 1 in the merged cell of the CISPR 11, IEC 61000-3-2 and IEC 61000-3-3 rows:

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

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

- the following note, added to the bottom of Table 1:

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.

- c) * A specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM, a list of specific equipment allowed or a list of types of equipment prohibited (see 6.2.3.1 c) and 6.2.6.1 c)) and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location.
- d) * The applicable table, Table 7 or Table 8. Table 7 shall be used for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS. Table 8 shall be used for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING. The tables shall be completed as follows: 4)
 - “[ME EQUIPMENT or ME SYSTEM]” shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM;

NOTE There are six places in Table 7 and Table 8. where “[ME EQUIPMENT or ME SYSTEM]” must be replaced.
 - column 3 of Table 7 or Table 8, as applicable, shall be filled in with the IMMUNITY COMPLIANCE LEVEL in accordance with the requirements of 5.2.2 and 6.2. 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 7 or Table 8, 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 b), above; “[appropriate section of ACCOMPANYING DOCUMENTS]” shall be replaced with a reference to the location in the ACCOMPANYING DOCUMENTS where the information required by 5.2.2.3 c) 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 7 or table footnote a of Table 8, as applicable, “[field strength]” shall be replaced as specified above for column 4 of the table.

5.2.2.4 Requirements applicable to ME EQUIPMENT and ME SYSTEMS that intentionally apply RF energy for diagnosis or treatment

For ME EQUIPMENT and ME 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 ME EQUIPMENT or ME SYSTEM.

4) See Annex C for examples.

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

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

- a) each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable, and the bandwidth of the receiving section of the ME EQUIPMENT or ME SYSTEM in those bands;
- b) a warning that the ME EQUIPMENT or ME SYSTEM may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

5.2.2.6 Requirements applicable to ME EQUIPMENT and ME SYSTEMS that include RF transmitters

For ME EQUIPMENT and ME 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.

Withdrawn

**Table 7 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY –
for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS that are specified
for use only in a shielded location**

(see 5.2.2.3 d))

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is suitable for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME 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 [ME EQUIPMENT or ME SYSTEM] is used exceeds [field strength] V/m, observe the [ME EQUIPMENT or ME SYSTEM] to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the [ME EQUIPMENT or ME SYSTEM] or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

Table 8 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING and are specified for use only in a shielded location

(see 5.2.2.3 d))

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME 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		The [ME EQUIPMENT or ME 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 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 [ME EQUIPMENT or ME SYSTEM] is used exceeds [field strength] V/m, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the [ME EQUIPMENT or ME SYSTEM] or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

5.2.2.7 * Requirements applicable to cables, transducers and other ACCESSORIES that could affect compliance with the requirements of 6.1 and 6.2

For cables, transducers and other ACCESSORIES that could affect compliance with the requirements of 6.1 and 6.2, the ACCOMPANYING DOCUMENTS shall include the following information:

- a list of all ME EQUIPMENT and ME 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 6.1 and 6.2 when used with the ACCESSORY, transducer or cable. References shall be specific (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE); and
- a warning that the use of the ACCESSORY, transducer or cable with ME EQUIPMENT and ME SYSTEMS other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

5.2.2.8 Requirements applicable to LARGE, PERMANENTLY-INSTALLED ME EQUIPMENT and ME SYSTEMS

For LARGE, PERMANENTLY-INSTALLED ME EQUIPMENT and ME SYSTEMS for which the exemption specified in 6.2.3.2 i) is used, the ACCOMPANYING DOCUMENTS shall include the following information:

- a) a statement that an exemption has been used and that the ME EQUIPMENT or ME SYSTEM has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 2,5 GHz;
- b) a warning that the ME EQUIPMENT or ME SYSTEM has been tested for radiated RF IMMUNITY only at selected frequencies; and
- c) * a list of the transmitters or equipment used as RF test sources and the frequency and modulation characteristics of each source.

5.2.2.9 Requirements applicable to ME EQUIPMENT and ME SYSTEMS found to have no ESSENTIAL PERFORMANCE

- a) For ME EQUIPMENT and ME SYSTEMS found 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 5.2.2.1 e) and f), 5.2.2.2, 5.2.2.3 c) and d), and 5.2.2.8, a statement that the ME EQUIPMENT or ME SYSTEM was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES.
- b) For ME EQUIPMENT and ME SYSTEMS found 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 ME EQUIPMENT or ME SYSTEM as specified in 5.2.2.1 through 5.2.2.8.

5.2.2.10 * Requirements applicable to TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS

For TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 6.1.1.1 f)), the ACCOMPANYING DOCUMENTS shall include a justification for not complying with the CISPR 11 group 2 Class B electromagnetic radiation disturbance limit at the third harmonic of the fundamental frequency of the ME EQUIPMENT or ME SYSTEM. This justification shall be based on significant physical, technological or physiological limitations that prevent compliance. The ACCOMPANYING DOCUMENTS shall also include a justification why the ME EQUIPMENT or ME SYSTEM needs to be used in domestic establishments or connected to the PUBLIC MAINS NETWORK.

Check compliance with the requirements of 5.2.2 by inspection.

6 ELECTROMAGNETIC COMPATIBILITY

6.1 EMISSIONS

6.1.1 Protection of radio services

6.1.1.1 * Requirements

ME EQUIPMENT and ME SYSTEMS, except as specified in a) through c) 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 D. ME EQUIPMENT and ME SYSTEMS shall comply with CISPR requirements, based upon their classification, with the exceptions and clarifications specified in d), e), and f) below.

a) * Simple electrical components

ME 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 ME EQUIPMENT and is not applicable to ME SYSTEMS or subsystems.

b) 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 ME EQUIPMENT and is not applicable to ME SYSTEMS or subsystems.

c) * INFORMATION TECHNOLOGY EQUIPMENT (ITE)

ITE connected to ME EQUIPMENT and ME 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 ME SYSTEMS, but CISPR 22 Class A equipment may only be used with CISPR 11 Class A ME SYSTEMS. See Annex D.

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

- For ME EQUIPMENT and ME 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 5.2.2.3 b).
- For ME EQUIPMENT and ME 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 5.2.2.3 b).

e) * ME EQUIPMENT and ME SYSTEMS that include radio equipment

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

f) * TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS

CISPR 11 group 2 PROFESSIONAL ME EQUIPMENT and ME SYSTEMS that are intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK shall comply with CISPR 11 group 2 Class B, with the exception that the third harmonic of the fundamental frequency of the ME EQUIPMENT or ME SYSTEM may comply with the CISPR 11 group 2 Class A electromagnetic radiation disturbance limit, provided this is justified based on:

- significant physical, technological or physiological limitations that prevent compliance with the CISPR 11 group 2 Class B electromagnetic radiation disturbance limit at the third harmonic of the fundamental frequency of the ME EQUIPMENT or ME SYSTEM; and
- the need for the use of the ME EQUIPMENT or ME SYSTEM in domestic establishments or connected to the PUBLIC MAINS NETWORK.

(See 5.2.1.4 and 5.2.2.10.)

g) 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 collateral standard used. This documentation shall include a description of the ME EQUIPMENT or ME SYSTEM under test, test equipment and test set-up, settings and mode(s) of the ME EQUIPMENT or ME SYSTEM, cable layout, and all PATIENT physiological, ACCESSORY and subsystem simulators used.

Check compliance by application of the tests in 6.1.1.2.

6.1.1.2 Tests

CISPR test methods shall be used, with the clarifications and exceptions specified in a), b) and c) below.

a) * PATIENT cables

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

b) * Subsystems

Compliance with the requirements of CISPR 11 may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated.

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

c) *LARGE, PERMANENTLY-INSTALLED ME EQUIPMENT and ME SYSTEMS*

LARGE, PERMANENTLY-INSTALLED ME EQUIPMENT and ME SYSTEMS that are constructed in such a way that simulated operation of subsystems is not feasible may be type tested at the premises of a typical RESPONSIBLE ORGANIZATION or OPERATOR in accordance with Clause 5 "Limits of electromagnetic disturbances," and 11.2 "Equipment in small-scale production" of CISPR 11 [1].⁵⁾

6.1.2 * Protection of other equipment from low-frequency magnetic fields

No requirements apply.

6.1.3 Protection of the PUBLIC MAINS NETWORK

6.1.3.1 Harmonic distortion

6.1.3.1.1 * Requirements

ME EQUIPMENT and ME 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 ME EQUIPMENT or an ME 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.

Check compliance by application of the tests in 6.1.3.1.2.

6.1.3.1.2 Tests

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

6.1.3.2 Voltage fluctuations and flicker

6.1.3.2.1 * Requirements

ME EQUIPMENT and ME 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 ME EQUIPMENT or an ME 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.

Check compliance by application of the tests in 6.1.3.2.2.

6.1.3.2.2 Tests

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

⁵⁾ The figures in square brackets refer to the Bibliography.

6.2 IMMUNITY

6.2.1 * General

6.2.1.1 * IMMUNITY TEST LEVELS

Subclause 6.2 specifies IMMUNITY requirements that are appropriate for ME EQUIPMENT and ME SYSTEMS intended for use in a typical health care ELECTROMAGNETIC ENVIRONMENT.

NOTE 1 For information concerning ELECTROMAGNETIC ENVIRONMENTS, refer to Annex F and the Bibliography.

Until limits are developed for other environments, the requirements of 6.2 shall apply to ME EQUIPMENT and ME 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 provided they are justified based on significant physical, technological or physiological limitations (see 5.2.2.1 e)).

NOTE 2 Writers of particular standards should refer to item a) of Clause E.2 for guidance regarding this allowance.

6.2.1.2 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 collateral standard used. This documentation shall include a description of the ME EQUIPMENT or ME SYSTEM under test, details of the compliance criteria used, test equipment and test set-up, settings and mode(s) of the ME EQUIPMENT or ME SYSTEM, cable layout and all PATIENT physiological, ACCESSORY and subsystem simulators used.

6.2.1.3 Operating mode and configuration

During IMMUNITY testing, each FUNCTION of the ME EQUIPMENT or ME SYSTEM that is associated with BASIC SAFETY or ESSENTIAL PERFORMANCE shall be tested in the mode that is most critical from a PATIENT outcome perspective, using equipment options, cable layout and ACCESSORIES in a typical configuration, consistent with NORMAL USE. If the ME EQUIPMENT or ME 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.

6.2.1.4 * Electrical equipment that is not ME EQUIPMENT

Electrical equipment that is not ME EQUIPMENT and that is supplied as part of an ME SYSTEM is exempt from the IMMUNITY testing requirements of this collateral standard provided all of the following conditions are met (see also Annex G):

- the electrical equipment that is not ME EQUIPMENT complies with applicable international IMMUNITY standards;⁶⁾
- both the EMISSIONS and IMMUNITY of electrical equipment that is not ME EQUIPMENT and that is supplied as part of an ME SYSTEM have been determined not to adversely affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.

⁶⁾ For example, see CISPR 24 [2] for ITE and IEC 61326-1 [9] for measurement, control and laboratory equipment.

6.2.1.5 * PATIENT-COUPLED ME EQUIPMENT and ME SYSTEMS

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

6.2.1.6 * Variable gain

ME EQUIPMENT and ME 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 ME EQUIPMENT or ME SYSTEM, the test shall be performed using the normal software. If this requirement cannot be met using the normal software of the ME EQUIPMENT or ME 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.

6.2.1.7 * PATIENT simulation

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

- For ME EQUIPMENT and ME 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 5.2.1.3. 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 ME EQUIPMENT or ME SYSTEM operates as intended.
- For ME EQUIPMENT and ME SYSTEMS with a manual sensitivity adjustment, the simulated PATIENT physiological signal shall be set according to the MANUFACTURER'S sensitivity adjustment guidelines with the ME EQUIPMENT or ME SYSTEM operating at its most sensitive setting.

If simulated PATIENT physiological signals are not required to verify normal operation of the ME EQUIPMENT or ME SYSTEM, the ME EQUIPMENT or ME SYSTEM shall be tested as specified in 6.2.1.3 without PATIENT physiological signal simulation.

6.2.1.8 * Testing of normally non-observable FUNCTIONS

If a FUNCTION associated with ESSENTIAL PERFORMANCE (e.g. HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS) 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.

6.2.1.9 * Subsystems

Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated.

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

6.2.1.10 * Compliance criteria

Under the test conditions specified in 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, 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 would interfere with diagnosis, treatment or monitoring;
- artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
- failure of automatic diagnosis or treatment ME EQUIPMENT and ME SYSTEMS to diagnose or treat, even if accompanied by an alarm.

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

The ME EQUIPMENT or ME SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from MANUFACTURER'S specifications) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

6.2.1.11 * ME EQUIPMENT and ME SYSTEMS that include radio equipment

For ME EQUIPMENT and ME 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 collateral 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 6.2.1.1. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the IMMUNITY requirements of this collateral standard shall apply.