

Australian/New Zealand Standard™

## Medical electrical equipment

### Part 1.2: General requirements for safety—Collateral standard: Electromagnetic compatibility— Requirements and tests



## **AS/NZS 3200.1.2:2005**

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 20 January 2005 and on behalf of the Council of Standards New Zealand on 28 January 2005.

This Standard was published on 7 April 2005.

---

The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine  
Australian Society for Ultrasound in Medicine  
Australian Chamber of Commerce and Industry  
Australian Dental Association  
Australian Institute of Radiography  
Australian Radiation Protection and Nuclear Safety Agency  
Australian Society of Anaesthetists  
Australian and New Zealand College of Anaesthetists  
Canterbury District Health Board, New Zealand  
College of Biomedical Engineering Institution of Engineers Australia  
Commonwealth Department of Health and Ageing  
Department of Defence (Australia)  
Medical Industry Association of Australia  
Ministry of Economic Development, New Zealand  
Royal Australian and New Zealand College of Radiologists  
Testing Interests (Australia)  
Wairarapa District Health Board, New Zealand

---

### **Keeping Standards up-to-date**

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at [www.standards.com.au](http://www.standards.com.au) or Standards New Zealand web site at [www.standards.co.nz](http://www.standards.co.nz) and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

---

*This Standard was issued in draft form for comment as DR 04242.*

# Australian/New Zealand Standard™

## Medical electrical equipment

### Part 1.2: General requirements for safety—Collateral standard: Electromagnetic compatibility— Requirements and tests

Originated as AS/NZS 3200.1.2:1995.  
Second edition 2005.

#### COPYRIGHT

© Standards Australia/Standards New Zealand

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

Jointly published by Standards Australia, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 6544 0

## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.1.2:1995, *Approval and test specification—Medical electrical equipment, Part 1.2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests*.

This Standard has been reproduced from, and is identical to, IEC 60601-1-2:2004, *Medical electrical equipment, Part 1-2: General requirements for safety—Collateral Standard: Electromagnetic compatibility—Requirements and tests*.

The consolidated version of IEC 60601-1-2:2004 is based on its 2001 edition and its Amendment 1:2004. A vertical line in the margin shows where the 2001 publication has been modified by Amendment 1.

IEC 60601-1-2 modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998 *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard* and is herein referred to as the General Standard.

IEC 60601-1-2 is a Collateral Standard. Collateral Standards specify safety requirements for groups of equipment (for example, radiology equipment) or for a characteristic common to all medical electrical equipment not covered by the General Standard.

The objective of this Standard is to establish a minimum baseline of performance in the presence of expected levels of electromagnetic disturbance. This edition also recognizes that there is a shared responsibility between manufacturers, customers and users to ensure that equipment and systems are designed and operated as intended.

In the text of this Standard, the following print types are used:

- (a) Requirements, compliance with which can be tested and definitions ..... in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references ..... in smaller roman type
- (c) Test specifications ..... *in italic type*
- (d) Terms defined in Clause 2 of the General Standard or this Particular Standard and which are also in the index ..... IN SMALL CAPITALS

An asterisk (\*) is placed before each Clause for which additional information is included in Annex AAA.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover.

For the purpose of this Standard, the IEC text should be modified as follows:

- (i) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the word ‘this International Standard’ wherever they appear.
- (ii) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.
- (iii) *References* The references to international Standards, listed in Annex FFF should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

| <i>Reference to International Standard or other Publication</i> |                                                                                                                                                                        | <i>Australian/New Zealand Standard</i> |                                                                                                                                                                                                 |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IEC                                                             |                                                                                                                                                                        | AS                                     |                                                                                                                                                                                                 |
| 60050 (161)                                                     | International electrotechnical vocabulary (IEV)<br>Chapter 161: Electromagnetic compatibility                                                                          | —                                      |                                                                                                                                                                                                 |
| 60417                                                           | Graphical symbols for use on equipment                                                                                                                                 | 1104                                   | Informative symbols for use on electrical and electronic equipment                                                                                                                              |
| 60417-2                                                         | Part 2: Symbol originals                                                                                                                                               |                                        |                                                                                                                                                                                                 |
|                                                                 |                                                                                                                                                                        | AS/NZS                                 |                                                                                                                                                                                                 |
| 60601                                                           | Medical electrical equipment                                                                                                                                           | 3200                                   | Medical electrical equipment                                                                                                                                                                    |
| 60601-1                                                         | Part 1: General requirements for safety                                                                                                                                | 3200.1.0                               | Part 1.0: General requirements for safety—Parent Standard                                                                                                                                       |
| 60601-1-1                                                       | Part 1-1: Collateral Standard: Safety requirements for medical electrical systems                                                                                      | 3200.1.1                               | Part 1.1: Collateral Standard: Safety requirements for medical electrical systems                                                                                                               |
| 61000                                                           | Electromagnetic compatibility                                                                                                                                          | 61000                                  | Electromagnetic compatibility (EMC)                                                                                                                                                             |
| 61000-3-2                                                       | Part 3-2: Limits—Limits for harmonic current emissions (equipment input current $\leq 16$ A per phase)                                                                 | 61000.3.2                              | Part 3.2: Limits—Limits for harmonic current less than or equal to 16 A per phase)                                                                                                              |
| 61000-3-3                                                       | Part 3-3: Limits—Limitation of voltage changes, voltage fluctuations and flicker in low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase | 61000.3.3                              | Part 3.3: Limits—Limitation of voltage fluctuations and flicker in low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase and not subject to conditional connection |
| 61000-4-2                                                       | Part 4-2: Testing and measurement techniques—Electrostatic discharge immunity test—Basic EMC Publication                                                               | 61000.4.2                              | Part 4.2: Testing and measurement techniques—Electrostatic discharge immunity test                                                                                                              |
| 61000-4-3                                                       | Part 4-3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test                                                            | 61000.4.3                              | Part 4.3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test                                                                                     |
| 61000-4-4                                                       | Part 4-4: Testing and measurement techniques—Electrical fast transient/burst immunity test—Basic EMC Publication                                                       | —                                      |                                                                                                                                                                                                 |
| 61000-4-5                                                       | Part 4-5: Testing and measurement techniques—Surge immunity test                                                                                                       | 61000.4.5                              | Part 4.5: Testing and measurement techniques—Surge immunity test                                                                                                                                |
| 61000-4-6                                                       | Part 4-6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields                                                     | 61000.4.6                              | Part 4.6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields                                                                              |

| IEC        |                                                                                                                                                  | AS/NZS           |                                                                                                                     |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------------------------------------------------------------------------|
| 61000-4-8  | Part 4-8: Testing and measurement techniques—Power frequency magnetic field immunity test—Basic EMC Publication                                  | 61000.4.8        | Part 4.8: Testing and measurement techniques—Power frequency magnetic field immunity test                           |
| 61000-4-11 | Part 4-11: Testing and measurement 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 | 3200<br>3200.1.2 | Medical electrical equipment<br>Part 1.2: Collateral Standard: Electromagnetic compatibility—Requirements and tests |
| 14-1       | Electromagnetic compatibility—Requirements for household appliances, electric tools and similar apparatus—Part 1: Emission                       | —                |                                                                                                                     |
| 15         | Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment                              | —                |                                                                                                                     |
| 16-1       | Specification for radio disturbance and immunity measuring apparatus and methods—Part 1: Radio disturbance and immunity measuring apparatus      | —                |                                                                                                                     |
| 22         | Information technology equipment—Radio disturbance characteristics—Limits and methods of measurement                                             | —                |                                                                                                                     |

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annexes to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

## CONTENTS

### SECTION ONE – GENERAL

|       |                                                                                      |   |
|-------|--------------------------------------------------------------------------------------|---|
| 1     | Scope and object.....                                                                | 1 |
| 1.201 | Scope.....                                                                           | 1 |
| 1.202 | Object.....                                                                          | 1 |
| 2     | Terminology and definitions .....                                                    | 1 |
| 3     | General requirements .....                                                           | 4 |
| 3.201 | General requirements for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS..... | 4 |
| 6     | Identification, marking and documents .....                                          | 5 |

### SECTIONS TWO TO FOUR – NOT USED

### SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

|        |                                    |    |
|--------|------------------------------------|----|
| 36     | ELECTROMAGNETIC COMPATIBILITY..... | 27 |
| 36.201 | EMISSIONS .....                    | 27 |
| 36.202 | IMMUNITY .....                     | 29 |

### SECTIONS SIX TO TEN – NOT USED

|                         |                                                                                                                                                  |    |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Annex AAA (informative) | General guidance and rationale .....                                                                                                             | 44 |
| Annex BBB (informative) | Example completion of Tables 201 through 208.....                                                                                                | 70 |
| Annex CCC (informative) | Guidance in classification according to CISPR 11 .....                                                                                           | 82 |
| Annex DDD (informative) | Guidance in the application of IEC 60601-1-2 to Particular Standards .....                                                                       | 85 |
| Annex EEE (informative) | ELECTROMAGNETIC ENVIRONMENTS.....                                                                                                                | 88 |
| Annex FFF (normative)   | Normative references .....                                                                                                                       | 89 |
| Annex GGG (informative) | Guidance in the identification of essential performance .....                                                                                    | 91 |
| Annex HHH (informative) | Guidance for determining if non-medical electrical equipment used in a SYSTEM is exempt from the EMC testing requirements of this standard ..... | 91 |
| Bibliography            | .....                                                                                                                                            | 93 |

|                                                                                                             |    |
|-------------------------------------------------------------------------------------------------------------|----|
| Figure 201 – Instructions for completing Table 201 for CISPR 11 EQUIPMENT and SYSTEMS .....                 | 15 |
| Figure 202 – Instructions for completing Table 201 for CISPR 14 and CISPR 15 EQUIPMENT .....                | 16 |
| Figure 203 – Instructions for completing Table 202 .....                                                    | 18 |
| Figure 204 – Instructions for completing Tables 203 and 205 for LIFE-SUPPORTING EQUIPMENT and SYSTEMS ..... | 23 |

|                                                                                                                                                                                                     |    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| Figure 205 – Instructions for completing Tables 204 and 206 for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING .....                                                                            | 24 |
| Figure AAA.1 – Example of cable arrangement for radiated IMMUNITY test .....                                                                                                                        | 68 |
| Figure AAA.2 – Examples showing maximum dimension for an EQUIPMENT with one and with two cables .....                                                                                               | 69 |
| Figure HHH.1 – Procedure for determining if non-medical electrical equipment used in a SYSTEM is exempt from the EMC testing requirements of this standard .....                                    | 92 |
| Table 201 – Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS .....                                                                               | 14 |
| Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS .....                                                                                | 17 |
| Table 203 – Guidance and manufacturer's declaration – electromagnetic immunity – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS .....                                                                    | 19 |
| Table 204 – Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING .....                                                       | 20 |
| Table 205 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS .....                  | 21 |
| Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING .....     | 22 |
| Table 207 – Guidance and manufacturer's declaration – electromagnetic immunity – for LIFE-SUPPORTING EQUIPMENT and SYSTEMS that are specified for use only in a shielded location .....             | 25 |
| Table 208 – Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and are specified for use only in a shielded location ..... | 26 |
| Table 209 – Modulation frequency, PHYSIOLOGICAL SIMULATION FREQUENCY, and OPERATING FREQUENCY .....                                                                                                 | 33 |
| Table 210 – IMMUNITY TEST LEVELS for voltage dips .....                                                                                                                                             | 41 |
| Table 211 – IMMUNITY TEST LEVEL for voltage interruption .....                                                                                                                                      | 42 |
| Table BBB.1 – Example (1) of completed Table 201 .....                                                                                                                                              | 70 |
| Table BBB.2 – Example (2) of completed Table 201 .....                                                                                                                                              | 71 |
| Table BBB.3 – Example (3) of completed Table 201 .....                                                                                                                                              | 72 |
| Table BBB.4 – Example of completed Table 202 .....                                                                                                                                                  | 73 |
| Table BBB.5 – Example (1) test, IMMUNITY and COMPLIANCE LEVELS .....                                                                                                                                | 74 |
| Table BBB.6 – Example of completed Table 203 .....                                                                                                                                                  | 75 |
| Table BBB.7 – Example of completed Table 205 .....                                                                                                                                                  | 76 |
| Table BBB.8 – Example of completed Table 204 .....                                                                                                                                                  | 77 |
| Table BBB.9 – Example of completed Table 206 .....                                                                                                                                                  | 78 |
| Table BBB.10 – Example (2) test, IMMUNITY and COMPLIANCE LEVELS .....                                                                                                                               | 78 |
| Table BBB.11 – Example of completed Table 207 .....                                                                                                                                                 | 79 |
| Table BBB.12 – Example (3) test, IMMUNITY and COMPLIANCE LEVELS .....                                                                                                                               | 80 |
| Table BBB.13 – Example of completed Table 208 .....                                                                                                                                                 | 81 |
| Table EEE.1 – Electromagnetic environment .....                                                                                                                                                     | 88 |

## INTRODUCTION

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

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

- safety services;
- other EQUIPMENT and SYSTEMS;
- non-medical electrical equipment (e.g. computers);
- telecommunications (e.g. radio/TV, telephone, radio-navigation).

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

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

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

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

<sup>1</sup> In this standard, “or” should be understood to include “and”.

to disclose the levels at which the EQUIPMENT or SYSTEM meets the performance requirements of this standard and to specify the characteristics of the ELECTROMAGNETIC use environment and how this environment is established, in which the EQUIPMENT or SYSTEM will perform as intended.

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

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

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

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

## AUSTRALIAN/NEW ZEALAND STANDARD

**Medical electrical equipment**

## Part 1.2

**General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests**

## SECTION ONE – GENERAL

**1 Scope and object****\*1.201 Scope**

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

**1.202 Object**

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

**2 Terminology and definitions**

For the purposes of this Collateral Standard, the terms and definitions given in IEC 60601-1:1988, IEC 60601-1-1:2000, IEC 60601-1-8:2003 and ISO 14971:2000 and the following apply:

**2.201****(IMMUNITY) COMPLIANCE LEVEL**

level less than or equal to the IMMUNITY LEVEL for which the EQUIPMENT or SYSTEM meets the requirements of the applicable subclause of 36.202

NOTE Additional requirements for COMPLIANCE LEVELS are specified in 6.8.3.201.

**\*2.202****DEGRADATION (of performance)**

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

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

[IEV 161-01-19, modified]

**\*2.203****EFFECTIVE RADIATED POWER (ERP)**

power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

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

[IEV 161-04-16, modified]

**\*2.204****ELECTROMAGNETIC COMPATIBILITY (EMC)**

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

[IEV 161-01-07, modified]

**\*2.205****ELECTROMAGNETIC DISTURBANCE**

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

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

[IEV 161-01-05, modified]

**2.206****(ELECTROMAGNETIC) EMISSION**

phenomenon by which electromagnetic energy emanates from a source

[IEV 161-01-08]

**\*2.207****ELECTROMAGNETIC ENVIRONMENT**

totality of electromagnetic phenomena existing at a given location

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

[IEV 161-01-01, modified]

**2.208****ELECTROMAGNETIC NOISE**

time-varying electromagnetic phenomenon apparently not conveying information and which may be superimposed on or combined with a wanted signal

[IEV 161-01-02]

**2.209****ELECTROSTATIC DISCHARGE (ESD)**

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

[IEV 161-01-22]

**\*2.211****EXCLUSION BAND**

frequency band for intentional receivers of RF electromagnetic energy that extends from –5 % to +5 % of the frequency, or frequency band, of reception for frequencies of reception greater than or equal to 80 MHz and from –10 % to +10 % of the frequency, or frequency band, of reception for frequencies of reception less than 80 MHz

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

**\*2.212****FUNCTION (of an EQUIPMENT or SYSTEM)**

clinically significant operation that the EQUIPMENT or SYSTEM is intended to perform in the diagnosis, treatment or monitoring of a PATIENT

**2.213****IEC 60601 TEST LEVEL**

IMMUNITY TEST LEVEL specified in 36.202 by this standard or a Particular Standard

**\*2.214****IMMUNITY (to a disturbance)**

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

[IEV 161-01-20, modified]

**2.215****IMMUNITY LEVEL**

maximum level of a given ELECTROMAGNETIC DISTURBANCE incident on a particular device, equipment or system for which it remains capable of operating at a required degree of performance

[IEV 161-03-14]

**\*2.216****IMMUNITY TEST LEVEL**

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

[IEV 161-04-41, modified]

**2.217****INFORMATION TECHNOLOGY EQUIPMENT (ITE)**

equipment designed for the purpose of

- a) receiving data from an external source (such as a data input line or via a keyboard);
- b) performing some processing functions on the received data (such as computation, data transformation or recording, filing, sorting, storage, transfer of data);
- c) providing a data output (either to other equipment or by the reproduction of data or images)

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]

**\*2.218****LARGE EQUIPMENT OR SYSTEM**

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

**\*2.219****LIFE-SUPPORTING EQUIPMENT OR SYSTEM**

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

**\*2.220****LOW VOLTAGE**

line-to-line or line-to-neutral voltage that is less than or equal to 1 000 V a.c. or 1 500 V d.c.

**\*2.221****MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as SYSTEM)**

combination of items of equipment, at least one of which must be MEDICAL ELECTRICAL EQUIPMENT and interconnected by FUNCTIONAL CONNECTION or use of a MULTIPLE PORTABLE SOCKET-OUTLET

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

[IEC 60601-1-1; definition 2.201]

**\*2.222****OPERATING FREQUENCY**

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

**\*2.223****PATIENT-COUPLED EQUIPMENT or SYSTEM**

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

**\*2.224****PHYSIOLOGICAL SIMULATION FREQUENCY**

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

**\*2.225****PUBLIC MAINS NETWORK**

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

**\*2.226****RADIO FREQUENCY (RF)**

frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion; frequency useful for radio transmission

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

**\*2.227****PROFESSIONAL EQUIPMENT or SYSTEM**

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

[IEV 161-05-05, modified]

**2.228****TYPE A PROFESSIONAL EQUIPMENT or SYSTEM**

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

NOTE See 36.201.1 a) 6).

**3 General requirements****3.201 General requirements for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS****\*3.201.1 ELECTROMAGNETIC COMPATIBILITY**

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

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

### 3.201.2 Essential performance

Either the essential performance of the EQUIPMENT or SYSTEM shall be identified (see Annex GGG for guidance on identifying the essential performance) or the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM shall be considered essential performance for the purpose of IMMUNITY testing (see 36.202.1 j)). The essential performance shall be disclosed in the ACCOMPANYING DOCUMENTS.

*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS or, if this identification is not performed, by inspection of the documents to verify that the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM has been tested in accordance with 36.202.*

### 3.201.3 MEDICAL ELECTRICAL EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT shall meet the requirements of this standard.

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

### 3.201.4 Non-medical electrical equipment

Non-medical electrical equipment that is supplied as part of a SYSTEM is exempt from the EMC testing requirements of this standard, provided all of the following conditions are met (see also Annex HHH):

- a) the non-medical electrical equipment complies with applicable international EMC standards;
- b) both the EMISSIONS and IMMUNITY of the non-medical electrical equipment have been determined not to adversely affect the essential performance or safety of the SYSTEM;
- c) the EMISSIONS of the non-medical electrical equipment have been determined not to cause the EMISSIONS of the SYSTEM to exceed applicable limits.

*Compliance is checked 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 non-medical electrical equipment has been tested in accordance with this standard.*

### \*3.201.5 General test conditions

For EMC testing, the SINGLE FAULT CONDITION requirements of the General Standard do not apply.

## 6 Identification, marking and documents

### 6.1.201 Marking on the outside of EQUIPMENT or EQUIPMENT parts

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

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



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

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



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

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

*Compliance is checked by inspection.*

## 6.8 ACCOMPANYING DOCUMENTS

### 6.8.2.201 Instructions for use

#### a) Requirements applicable to all EQUIPMENT and SYSTEMS

Instructions for use shall include the following:

- 1) a statement that MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
- 2) a statement that portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

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

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

- 1) a reproduction of the ESD warning symbol (IEC 60417-5134, as shown in 6.1.201.2);
- 2) a warning that pins of connectors identified with the ESD warning symbol should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used;
- \*3) a specification of the ESD precautionary procedures;
- \*4) a recommendation that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures;
- \*5) a specification of the minimum contents of ESD precautionary procedure training.

#### c) Minimum amplitude or value of PATIENT physiological signal

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

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

\*d) Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

If a TYPE A PROFESSIONAL EQUIPMENT or SYSTEM is intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 36.201.1 a) 6)), 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 [EQUIPMENT or SYSTEM] or shielding the location.

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

*Compliance is checked by inspection.*

### 6.8.3.201 Technical description

a) Requirements applicable to all EQUIPMENT and SYSTEMS

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

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

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

- \*2) A warning that the use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.
- \*3) Table 201, with the modifications specified below.<sup>2 3</sup> The flowchart in Figure 201 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 11 EQUIPMENT and SYSTEMS. The flowchart in Figure 202 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 14 and CISPR 15 EQUIPMENT.
  - For CISPR 11 EQUIPMENT and SYSTEMS, "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.
  - For CISPR 14 and CISPR 15 EQUIPMENT, "[EQUIPMENT]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT.
  - For CISPR 11 Group 1 EQUIPMENT and SYSTEMS, rows 5, 12 and 13 shall be deleted.
  - For CISPR 11 Group 2 EQUIPMENT and SYSTEMS, rows 4, 12 and 13 shall be deleted.
  - For EQUIPMENT that complies with CISPR 14-1, rows 4 through 6 and row 13 shall be deleted
  - For EQUIPMENT that complies with CISPR 15, rows 4 through 6 and row 12 shall be deleted.

<sup>2</sup> See Annex BBB for examples. These modifications should be performed in the order in which they appear.

<sup>3</sup> Row numbers refer to those in Table 201 before modifications are made

- For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class A, including TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS, “[A or B]” in column 2 of row 6 shall be replaced with “A.” For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B, “[A or B]” shall be replaced with “B.”
- For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-2, “[Class A, B, C, D, or Not applicable]” in column 2 of row 7 shall be replaced with the class of the EQUIPMENT or SYSTEM according to IEC 61000-3-2. For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-3, “[Complies or Not applicable]” in column 2 of row 8 shall be replaced with “Complies.” For EQUIPMENT and SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, “[Class A, B, C, D, or Not applicable]” and “[Complies or Not applicable]” shall each be replaced with “Not applicable.”
- For CISPR 11 EQUIPMENT and SYSTEMS, column 3 of rows 6, 7 and 8 shall be merged into one cell. For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B and with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS for which use in a domestic establishment or connection to the PUBLIC MAINS NETWORK is intended and justified (see 6.8.3.201 j) and 36.201.1 a) 6)) 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 EQUIPMENT and 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 EQUIPMENT and SYSTEMS specified in 36.201.1 a) 6), the text in column 3 of row 11 shall be moved into the merged cell.
- For CISPR 14 or CISPR 15 EQUIPMENT, column 3 of rows 7 and 8 shall be merged into one cell. For CISPR 14 or CISPR 15 EQUIPMENT that comply with IEC 61000-3-2 and with IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For CISPR 14 or CISPR 15 EQUIPMENT for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, the text in column 3 of row 11 shall be moved into the merged cell.
- For EQUIPMENT and SYSTEMS specified for use only in a shielded location and for which the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 36.201.1 a) 4) is used, the text specified by 6.8.3.201 c) 2) shall be added.
- Rows 9, 10 and 11 shall be deleted.
- The row numbers shall be deleted.

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

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

- \*5) A justification for each COMPLIANCE LEVEL that is lower than the IEC 60601 TEST LEVEL for that IMMUNITY test. These justifications shall be based only on physical, technological or physiological limitations that prevent compliance at the IEC 60601 TEST LEVEL.
- \*6) Table 202, completed as specified below.<sup>4</sup> The flowchart in Figure 203 is the requirement in step-by-step graphical form for completion of Table 202.
- “[EQUIPMENT or SYSTEM]” shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.

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

<sup>4</sup> See Annex BBB for an example.

- \*– Column 3 of Table 202 shall be filled in with the IMMUNITY COMPLIANCE LEVEL for each test in accordance with the requirements of 6.8.3.201 and 36.202. If a COMPLIANCE LEVEL lower or higher than the IEC 60601 TEST LEVEL is claimed, it shall be one of the levels listed in the referenced basic EMC IMMUNITY standard unless the COMPLIANCE LEVEL is outside the range of levels listed. If the COMPLIANCE LEVEL is outside the range of levels listed in the referenced basic EMC IMMUNITY standard, the actual IMMUNITY LEVEL shall be stated, rounded to one significant digit. If according to 36.202 or the scope of the EMC basic standard a test does not apply to the EQUIPMENT or SYSTEM, or it is not possible to perform the test on the EQUIPMENT or SYSTEM, columns 3 and 4 of Table 202 shall state that the test is not applicable.
- \*– For the electrostatic discharge (ESD) IMMUNITY test (IEC 61000-4-2), the electrical fast transient/burst IMMUNITY test (IEC 61000-4-4), the surge IMMUNITY test (IEC 61000-4-5), the voltage dips, short interruptions and voltage variations IMMUNITY test (IEC 61000-4-11) and the power frequency magnetic fields IMMUNITY test (IEC 61000-4-8):
  - If a COMPLIANCE LEVEL is lower than an IMMUNITY TEST LEVEL specified in 36.202.2, 36.202.4, 36.202.5, 36.202.7, or 36.202.8.1, the text in column 4 in the corresponding row of Table 202 shall be replaced with a description of the actions the customer or user must take to reduce environmental levels of the DISTURBANCE so that they are less than or equal to the COMPLIANCE LEVEL listed in column 3.
  - If a COMPLIANCE LEVEL is higher than an IMMUNITY TEST LEVEL specified in 36.202.2, 36.202.4, 36.202.5, 36.202.7 or 36.202.8.1, the text in column 4 in the corresponding row of Table 202 may be replaced with a description of the environment for which the EQUIPMENT or SYSTEM is suitable.

7) The performance of the EQUIPMENT or SYSTEM that was determined to be essential performance.

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

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

The applicable tables, 203 and 205 or 204 and 206. Tables 203 and 205 shall be used for LIFE-SUPPORTING EQUIPMENT and SYSTEMS. Tables 204 and 206 shall be used for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING. The tables shall be completed for the conducted and radiated RF IMMUNITY tests as specified below.<sup>5</sup> The flowchart in Figure 204 is the requirement in step-by-step graphical form for completion of Tables 203 and 205 and the flowchart in Figure 205 is the requirement in step-by-step graphical form for completion of Tables 204 and 206.

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

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

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

<sup>5</sup> See Annex BBB for examples.

- 3) The expressions in square brackets ([ ]) that contain  $V_1$ ,  $V_2$  and  $E_1$  in column 4 of Table 203 or 204, as applicable, and in Table 205 or 206, as applicable, shall be calculated, rounded to two significant digits, and the results substituted in place of the corresponding expressions.  $V_1$  and  $V_2$  are the COMPLIANCE LEVELS for the IEC 61000-4-6 test and  $E_1$  is the COMPLIANCE LEVEL for the IEC 61000-4-3 test.  $V_1$  and  $V_2$  are in V and  $E_1$  is in V/m. The value of  $V_1$  shall also be substituted for “[ $V_1$ ]” in the table footnote in Table 203 or 204, as applicable.
- 4) Table 205 or 206, as applicable, shall be completed by calculating the distance corresponding to each entry in columns 2 through 5 in Table 205 or columns 2 through 4 in Table 206, as applicable, using the equation in that column and the output power that appears in column 1 of that row. The calculated distances shall be rounded to two significant digits and entered in Table 205 or 206, as applicable.
- c) Requirements applicable to EQUIPMENT and SYSTEMS specified for use only in a shielded location

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

- 1) A warning that the EQUIPMENT or SYSTEM should be used only in the specified type of shielded location.
- \*2) If the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 36.201.1 a) 4) is used:

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

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

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

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

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

where “[EQUIPMENT or SYSTEM]” shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM and “[shielding effectiveness / filter attenuation specification]” shall be replaced with the specification for minimum RF shielding effectiveness and RF filter attenuation.<sup>6</sup> 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 standard;

<sup>6</sup> This specification is also used in Tables 207 and 208 (see 6.8.3.201 c) 4)).

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

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

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

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

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

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

\*4) The applicable table, 207 or 208. Table 207 shall be used for LIFE-SUPPORTING EQUIPMENT and SYSTEMS. Table 208 shall be used for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING. The tables shall be completed as follows: <sup>7</sup>

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

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

- column 3 of Table 207 or 208, as applicable, shall be filled in with the IMMUNITY COMPLIANCE LEVEL in accordance with the requirements of 6.8.3.201 and of 36.202. If an IMMUNITY COMPLIANCE LEVEL lower or higher than the IEC 60601 TEST LEVEL is claimed, it shall be one of the levels listed in the referenced basic EMC IMMUNITY standard unless the COMPLIANCE LEVEL is outside the range of levels listed. If the COMPLIANCE LEVEL is outside the range of levels listed in the referenced basic EMC IMMUNITY standard, the actual IMMUNITY LEVEL shall be stated, rounded to one significant digit;
- \*– in column 4 of Table 207 or 208, as applicable, “[shielding effectiveness / filter attenuation specification]” shall be replaced with the specification for minimum RF shielding effectiveness and RF filter attenuation, which shall meet the requirements specified in 2), above; “[appropriate section of ACCOMPANYING DOCUMENTS]” shall be replaced with a reference to the location in the ACCOMPANYING DOCUMENTS where the information required by 6.8.3.201 c) 3) can be found; and “[field strength]” shall be replaced with the maximum field strength in V/m, rounded to one significant digit, of fixed RF transmitters that when attenuated by the specified minimum RF shielding effectiveness and filter attenuation, will not exceed the COMPLIANCE LEVEL for any of the frequency ranges. For calculating “[field strength]”, the COMPLIANCE LEVELS for the IEC 61000-4-6 test shall be considered to be in units of V/m;
- in table footnote b of Table 207 or table footnote a of Table 208, as applicable, “[field strength]” shall be replaced as specified above for column 4 of the table.

<sup>7</sup> See Annex BBB for examples.

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

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

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

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

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

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

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

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

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

- 1) a list of all EQUIPMENT and SYSTEMS with which the ACCESSORY, transducer or cable may be used and that are claimed by the manufacturer of the ACCESSORY, transducer or cable to be in compliance with the requirements of 36.201 and 36.202 when used with the ACCESSORY, transducer or cable. References shall be specific (e.g. by manufacturer and MODEL OR TYPE REFERENCE);
- 2) a warning that the use of the ACCESSORY, transducer or cable with EQUIPMENT and SYSTEMS other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT or SYSTEM.

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

For LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS for which the exemption specified in 36.202.3 b) 9) is used, the ACCOMPANYING DOCUMENTS shall include the following information:

- 1) a statement that an exemption has been used and that the EQUIPMENT or SYSTEM has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 2,5 GHz;
- 2) a warning that the EQUIPMENT or SYSTEM has been tested for radiated RF IMMUNITY only at selected frequencies;

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

i) Requirements applicable to EQUIPMENT and SYSTEMS found to have no essential performance

- 1) For EQUIPMENT and 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 6.8.3.201 a) 5) and 6), b), c) 3) and 4), and h), a statement that the EQUIPMENT or SYSTEM was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES.
- 2) For EQUIPMENT and SYSTEMS found to have no essential performance and for which FUNCTIONS were tested for IMMUNITY and the IMMUNITY COMPLIANCE CRITERIA were considered to apply to all DEGRADATIONS, the ACCOMPANYING DOCUMENTS shall include information applicable to the EQUIPMENT or SYSTEM as specified in 6.8.3.201 a) through h).

\*j) Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

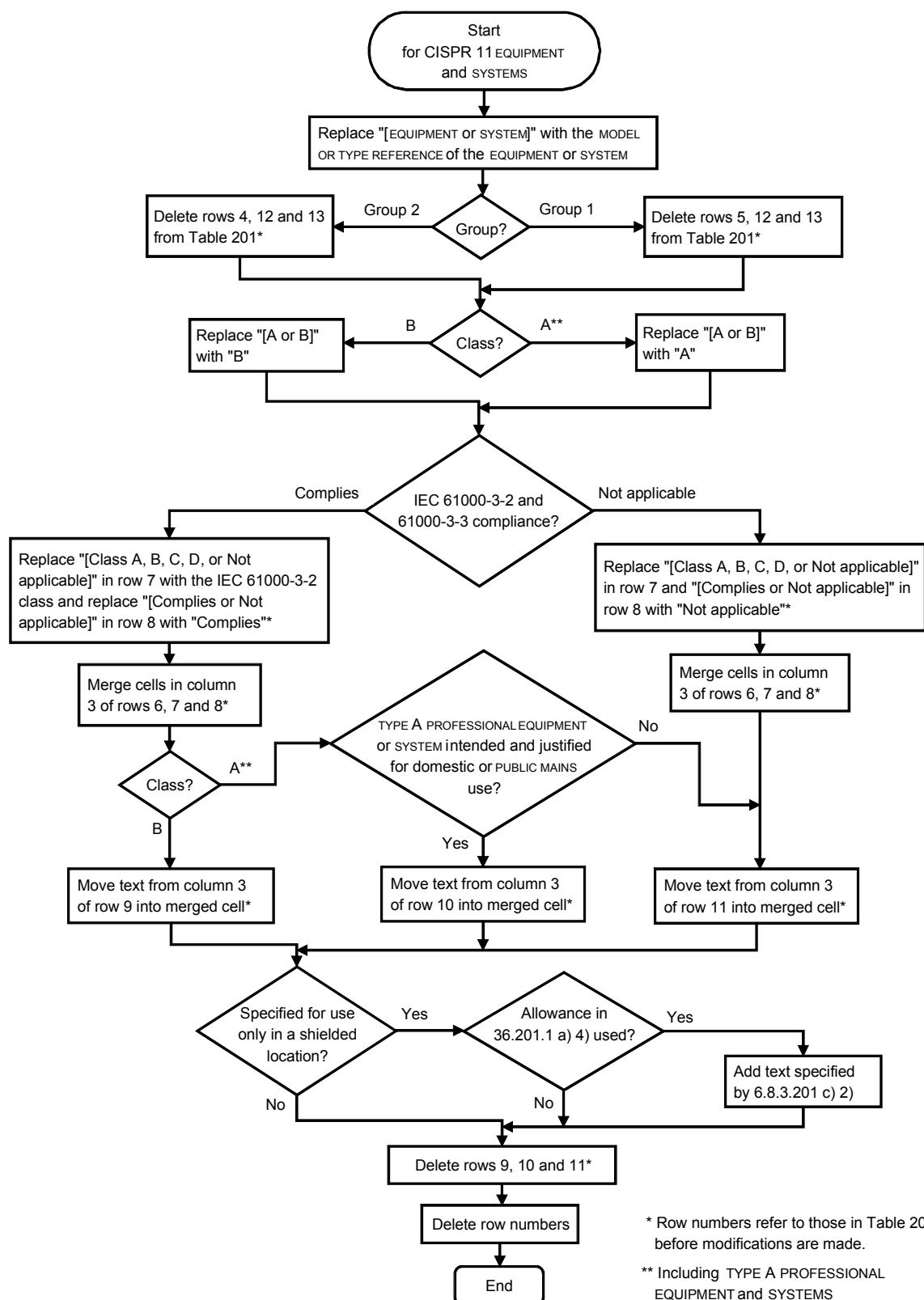
For TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 36.201.1 a) 6)), the ACCOMPANYING DOCUMENTS shall include a justification for not complying with the CISPR 11 Group 2 Class B electromagnetic radiation disturbance limit at the third harmonic of the fundamental frequency of the EQUIPMENT or 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 EQUIPMENT or SYSTEM needs to be used in domestic establishments or connected to the PUBLIC MAINS NETWORK.

*Compliance is checked by inspection.*

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

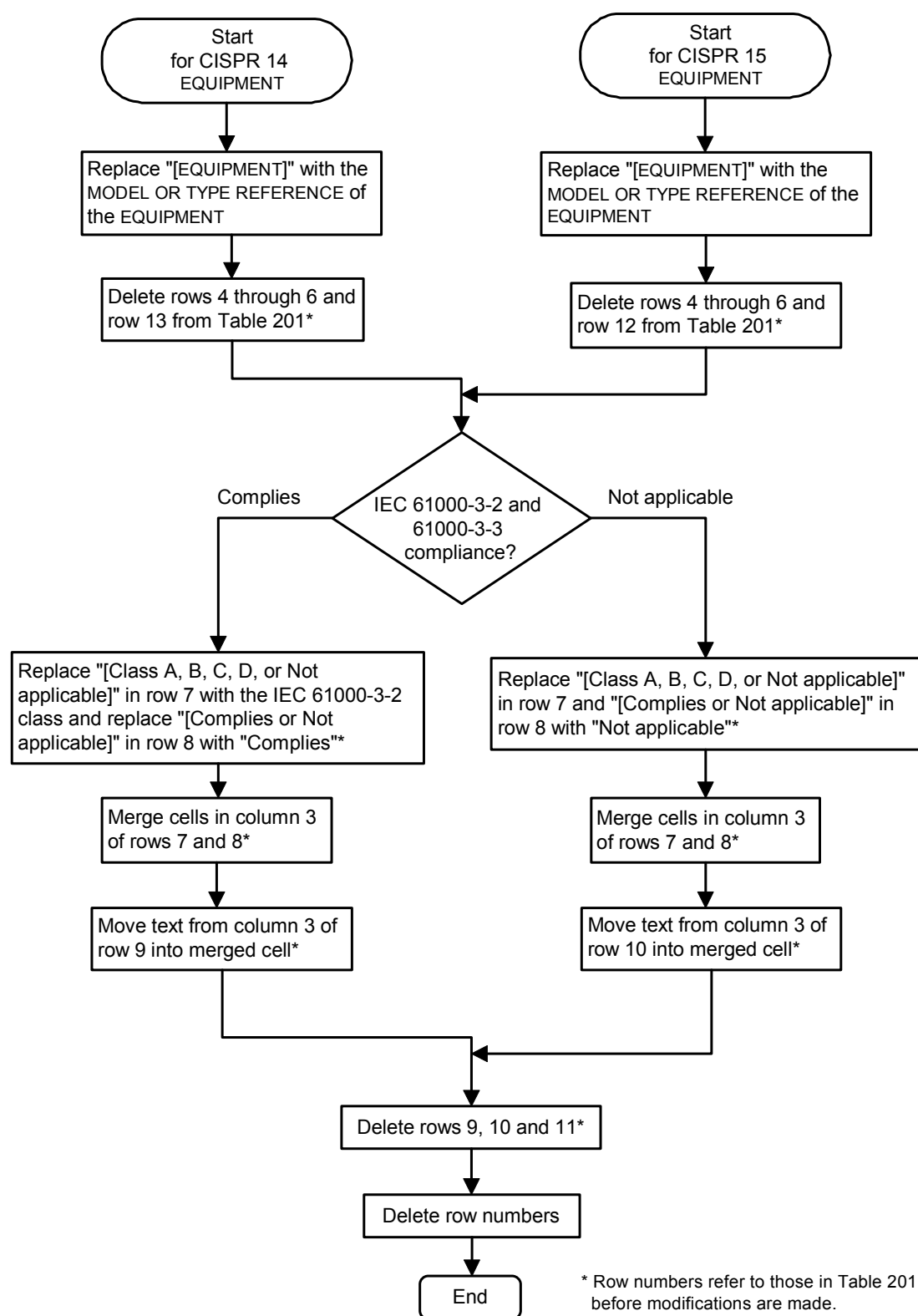
Row

|   |                                                                                                                                                                                                               |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ① | <b>Guidance and manufacturer's declaration – electromagnetic emissions</b>                                                                                                                                    |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| ② | The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment. |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| ③ | <b>Emissions test</b>                                                                                                                                                                                         | <b>Compliance</b>                     | <b>Electromagnetic environment – guidance</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| ④ | RF emissions<br>CISPR 11                                                                                                                                                                                      | Group 1                               | The [EQUIPMENT or SYSTEM] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| ⑤ | RF emissions<br>CISPR 11                                                                                                                                                                                      | Group 2                               | The [EQUIPMENT or SYSTEM] must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| ⑥ | RF emissions<br>CISPR 11                                                                                                                                                                                      | Class [A or B]                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| ⑦ | Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                                           | [Class A, B, C, D, or Not applicable] |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| ⑧ | Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3                                                                                                                                                   | [Complies or Not applicable]          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| ⑨ |                                                                                                                                                                                                               | [See 6.8.3.201 a) 3) and Figure 201]  | The [EQUIPMENT or SYSTEM] is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.                                                                                                                                                                                                                                                                                                                                                                                                                      |
| ⑩ |                                                                                                                                                                                                               | [See 6.8.3.201 a) 3) and Figure 201]  | The [EQUIPMENT or SYSTEM] is suitable for use in all establishments other than domestic, and 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:<br><b>Warning:</b> 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 [EQUIPMENT or SYSTEM] or shielding the location. |
| ⑪ |                                                                                                                                                                                                               | [See 6.8.3.201 a) 3) and Figure 201]  | The [EQUIPMENT or SYSTEM] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| ⑫ | RF emissions<br>CISPR 14-1                                                                                                                                                                                    | Complies                              | The [EQUIPMENT] is not suitable for interconnection with other equipment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| ⑬ | RF emissions<br>CISPR 15                                                                                                                                                                                      | Complies                              | The [EQUIPMENT] is not suitable for interconnection with other equipment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |



IEC 1258/04

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

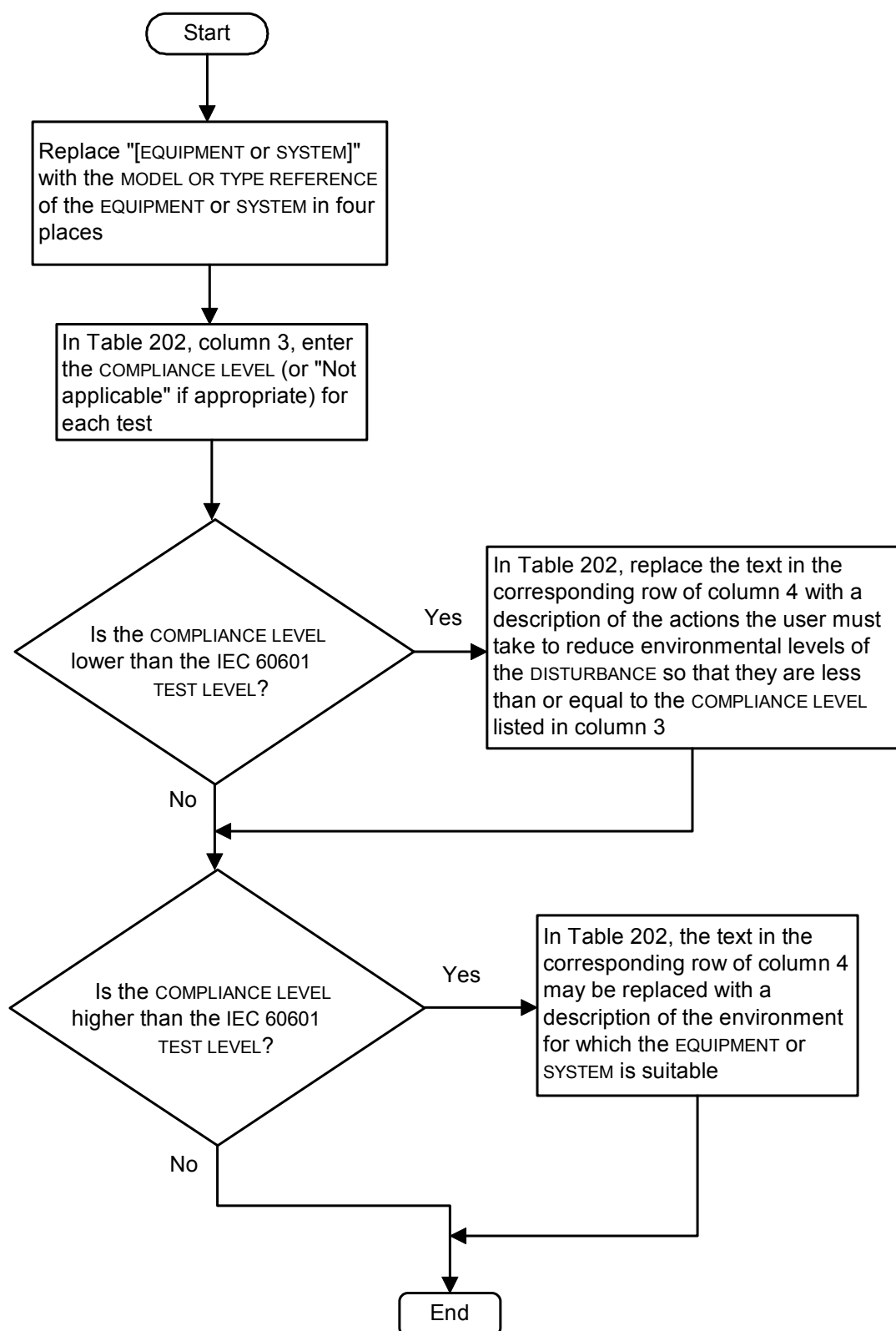


IEC 1259/04

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

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

| <b>Guidance and manufacturer's declaration – electromagnetic immunity</b>                                                                                                                                     |                                                                                                                                                                                                                                   |                         |                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment. |                                                                                                                                                                                                                                   |                         |                                                                                                                                                                                                                                                                                                            |
| <b>Immunity test</b>                                                                                                                                                                                          | <b>IEC 60601 test level</b>                                                                                                                                                                                                       | <b>Compliance level</b> | <b>Electromagnetic environment – guidance</b>                                                                                                                                                                                                                                                              |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                                                                                                                                | ±6 kV contact<br>±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<br>IEC 61000-4-4                                                                                                                                                              | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                                                                                                                      |                         | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                        |
| Surge<br>IEC 61000-4-5                                                                                                                                                                                        | ±1 kV line(s) to line(s)<br>±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<br>IEC 61000-4-11                                                                                                        | <5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 0,5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$ )<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$ )<br>for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 5 sec |                         | Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>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 1407/01

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

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

| Guidance and manufacturer's declaration – electromagnetic immunity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Immunity test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | IEC 60601 test level                                              | Compliance level      | Electromagnetic environment – guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3 Vrms<br><br>150 kHz to 80 MHz<br>outside ISM bands <sup>a</sup> | [V <sub>1</sub> ] V   | Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br><b>Recommended separation distance</b><br><br>$d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$<br><br>$d = \left[ \frac{12}{V_2} \right] \sqrt{P}$                                                                                                                                                                                                                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 10 Vrms<br><br>150 kHz to 80 MHz<br>in ISM bands <sup>a</sup>     | [V <sub>2</sub> ] V   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 10 V/m<br><br>80 MHz to 2,5 GHz                                   | [E <sub>1</sub> ] V/m | $d = \left[ \frac{12}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = \left[ \frac{23}{E_1} \right] \sqrt{P}$ 800 MHz to 2,5 GHz<br><br>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m). <sup>b</sup><br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>c</sup> should be less than the compliance level in each frequency range. <sup>d</sup><br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <sup>a</sup> 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.                                                                                                                                                                                                                                                                                       |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <sup>c</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [EQUIPMENT or SYSTEM]. |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <sup>d</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V <sub>1</sub> ] V/m.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                   |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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

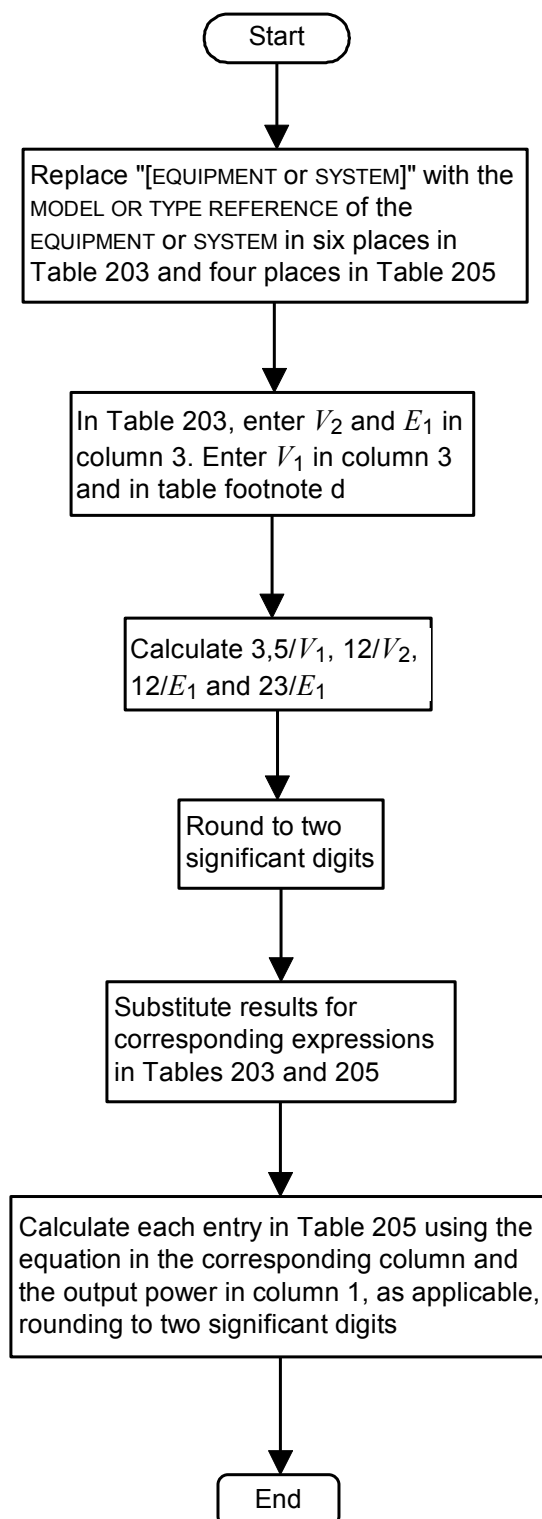
| Guidance and manufacturer's declaration – electromagnetic immunity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Immunity test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | IEC 60601 test level        | Compliance level | Electromagnetic environment – guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Conducted RF<br>IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 3 Vrms<br>150 kHz to 80 MHz | $[V_1]$ V        | <p>Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Radiated RF<br>IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 3 V/m<br>80 MHz to 2,5 GHz  | $[E_1]$ V/m      | $d = \left[ \frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [EQUIPMENT or SYSTEM].</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than <math>[V_1]</math> V/m.</p> |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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

| <b>Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]</b>                                                                                                                                                                                                                                                                                                                                             |                                                                       |                                              |                                              |                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|
| The [EQUIPMENT OR SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [EQUIPMENT OR SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [EQUIPMENT OR SYSTEM] as recommended below, according to the maximum output power of the communications equipment. |                                                                       |                                              |                                              |                                              |
| <b>Rated maximum output power of transmitter</b><br>W                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Separation distance according to frequency of transmitter</b><br>m |                                              |                                              |                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>150 kHz to 80 MHz outside ISM bands</b>                            | <b>150 kHz to 80 MHz in ISM bands</b>        | <b>80 MHz to 800 MHz</b>                     | <b>800 MHz to 2,5 GHz</b>                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$                         | $d = \left[ \frac{12}{V_2} \right] \sqrt{P}$ | $d = \left[ \frac{12}{E_1} \right] \sqrt{P}$ | $d = \left[ \frac{23}{E_1} \right] \sqrt{P}$ |
| 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 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.                                                                                                   |                                                                       |                                              |                                              |                                              |
| NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.                                                                                                                                                                                                                                                                                                        |                                                                       |                                              |                                              |                                              |

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

| <b>Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                |                                                       |                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| The [EQUIPMENT or SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [EQUIPMENT or SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [EQUIPMENT or SYSTEM] as recommended below, according to the maximum output power of the communications equipment.                                                                                                                                   |                                                                |                                                       |                                                      |
| Rated maximum output power of transmitter<br>W                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Separation distance according to frequency of transmitter<br>m |                                                       |                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 150 kHz to 80 MHz<br>$d = [\frac{3,5}{V_1}] \sqrt{P}$          | 80 MHz to 800 MHz<br>$d = [\frac{3,5}{E_1}] \sqrt{P}$ | 800 MHz to 2,5 GHz<br>$d = [\frac{7}{E_1}] \sqrt{P}$ |
| 0,01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                |                                                       |                                                      |
| 0,1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                |                                                       |                                                      |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                |                                                       |                                                      |
| 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                |                                                       |                                                      |
| 100                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                |                                                       |                                                      |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in 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.<br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |                                                                |                                                       |                                                      |



IEC 1408/01

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