

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 Standards may also be withdrawn.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 or Standards New Zealand web site at 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) 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 ≤ 16 A per phase)	61000.3.2	Part 3.2: Limits—Limits for harmonic current emissions (equipment input 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 ≤ 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 ≤ 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 3200.1.2	Medical electrical equipment 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 ¹ may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the EQUIPMENT or SYSTEM would also be expected to be normal.

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

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

Because the practice of medicine involves many 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

¹ 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 IEV, 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]