AS/NZS 3200.1.2:2005
IEC 60601-1-2:2004

AS/NZS 3200.1.2:2005

Australian/New Zealand Standard™

Medical electrical equipment

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

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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.
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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
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Canterbury District Health Board, New Zealand
College of Biomedical Engineering Institution of Engineers Australia
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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.

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Medical electrical equipment

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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:

Reference to International Standard or other Publication		*Australian/New Zealand Standard*	
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