

AS/NZS 3200.1.8:2005  
(IEC 60601-1-8:2003)

AS/NZS 3200.1.8:2005

Australian/New Zealand Standard™

## Medical electrical equipment

### Part 1.8: General requirements for safety—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems



## **AS/NZS 3200.1.8:2005**

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 5 September 2005 and on behalf of the Council of Standards New Zealand on 28 October 2005.

This Standard was published on 10 November 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  
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## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

The objective of this Standard is to specify basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application.

This Standard is identical with, and has been reproduced from IEC 60601-1-8:2003, *Medical electrical equipment—Part 1-8: General requirements for safety—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*. It is supplementary to AS/NZS 3200.1.0:1998, *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard*.

IEC 60601-1-8 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 60601-1-8 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.

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

- (a) Requirements and definitions..... in large roman type
- (b) Notes, examples, explanations, advice, introductions, general statements and references  
..... in smaller roman type
- (c) Test specifications and guidance in Annex AAA .....in italic type
- (d) Terms defined in Clause 2 of the General Standard, or in this Collateral Standard or as note  
.....IN SMALL CAPITALS

An asterisk (\*) is placed before each Clause or sub 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.

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

References to international Standards should be replaced by reference 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	
60417	Graphical symbols for use on equipment	60417	Graphical symbols for use on equipment
60417-2	Part 2: Symbol originals	60417.2.1	Part 2.1: General application
		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
60601-1-6	Part 1-6: Collateral Standard: Usability	—	
		AS IEC	
60651	Sound level meters	61672	Electroacoustics—Sound level meters
		61672.1	Part 1: Specifications
ISO			
3744	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane	—	
7000	Graphical symbols for use on equipment—Index and synopsis	—	

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