

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.

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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 show 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
60601	Medical electrical equipment	AS/NZS	
60601-1	Part 1: General requirements for safety	3200	Medical electrical equipment
60601-1-1	Part 1-1: Collateral Standard: Safety requirements for medical electrical systems	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	—	
60651	Sound level meters	AS IEC	
		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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INTRODUCTION

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are increasingly used in medical practice. ALARM SIGNALS are frequently used to indicate unsatisfactory physiological PATIENT states, unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM or to warn the OPERATOR of potential hazards to the PATIENT or OPERATOR due to the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM. INFORMATION SIGNALS convey information that is independent of an ALARM CONDITION.

Surveys of healthcare personnel have indicated significant discontent with ALARM SIGNALS. Problems include difficulty in identifying the source of an ALARM SIGNAL, loud and distracting ALARM SIGNALS, and the high incidence of FALSE POSITIVE or NEGATIVE ALARM CONDITIONS [16]¹⁾. Surveys of manufacturers of medical monitors demonstrated a wide variety of DEFAULT ALARM PRESETS. The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS. See also bibliography.

Safety of PATIENTS depends on the ability of the OPERATOR to correctly discern the characteristics of ALARM SIGNALS. Usability is an important element in the design of ALARM SIGNALS that are readily discernible without being unnecessarily distracting or disturbing. This approach is intended to rationalize the current situation, to reduce confusion by limiting proliferation of ALARM SIGNALS and their control states, and to minimize distraction for other people. This collateral standard was developed with contributions from clinicians, engineers and applied psychologists.

The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for manufacturers of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for particular standards.

The effectiveness of any ALARM SYSTEM depends critically on its implementation by the USER. It is important that the USER configure the ALARM SYSTEM so that an OPERATOR is not able to compromise it.

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

SECTION ONE – GENERAL

1 * Scope and object

1.201 Scope

This collateral standard specifies requirements for ALARM SYSTEMS and ALARM SIGNALS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.

It also provides guidance for the application of ALARM SYSTEMS.

1.202 Object

The object of this collateral 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 is accomplished by defining alarm categories (priorities) by degree of urgency, consistent ALARM SIGNALS and consistent control states and their marking for all ALARM SYSTEMS.

NOTE See IEC 60513:1994 [4] for a description of basic safety and essential performance.

This collateral standard does not specify:

- whether any particular MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM is required to be provided with ALARM SYSTEMS;
- the particular circumstances which initiate an ALARM CONDITION;
- the allocation of priorities to a particular ALARM CONDITION; or
- the means of generating ALARM SIGNALS.

1.203 Relationship to other standards

1.203.1 IEC 60601-1

For MEDICAL ELECTRICAL EQUIPMENT, this collateral standard complements IEC 60601-1.

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

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-8 alone;
- "this standard" designates the combination of the general standard and this collateral standard.