AS IEC 60601.1.8:2017
IEC 60601-1-8:2006+AMD1:2012+AMD2:
2020 CSV
(Incorporating Amendment No. 1)

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Medical electrical equipment

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

AS IEC 60601.1.8:2017

This Australian Standard ® was prepared by HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 10 May 2017.

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The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers In Medicine
Australian and New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Canterbury District Health Board
Certification Body Australia (Certification Interests Australia)
College of Biomedical Engineering Engineers Australia
Department of Defence (Australian Government)
Engineers Australia
Therapeutic Goods Administration

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Originated as AS/NZS 3200.1.8:2005.
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Preface

This Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.1.8:2005, 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.

〈A1〉Amendment No. 1 (June 2022) to this Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment.〈A1〉

The objective of this Standard is to specify basic safety and essential performance requirements and tests for alarm systems in medical equipment (ME) and ME 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.

This Standard does not specify the following:

(a) whether any particular ME equipment or ME system is required to be provided with alarm systems;

(b) the particular circumstances which initiate an alarm condition;

(c) the allocation of priorities to a particular alarm condition; or

(d) the means of generating alarm signals.

〈A1〉This Standard is identical with, and has been reproduced from IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 CSV (ED. 2.1), *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*.〈A1〉

As this Standard is reproduced from an International Standard, the following applies:

(i) In the source text 'this International Standard' should read 'this Australian Standard'.

(ii) A full point substitutes for a comma when referring to a decimal marker.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

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