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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

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The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
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This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.27:2015.

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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 3200.2.27:1996, *Approval and test specification—Medical electrical equipment*, Part 2.27: *Particular requirements for safety—Electrocardiographic monitoring equipment*.

The objective of this Standard is to establish particular requirements for basic safety and essential performance of electrocardiographic (ECG) monitoring equipment, which are defined as devices including electrodes, lead wires and interconnecting means for the monitoring and/or recording of heart action potentials from one patient and displaying the resultant data.

The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015, which is referred to in the source document as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-27, Ed.3.0 (2011), *Medical electrical equipment*, Part 2-27: *Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*, and its Corrigendum 1 (2012), which is incorporated into the source text.

As this Standard is reproduced from an International Standard, a full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS IEC	
60601	Medical electrical equipment	60601	Medical electrical equipment
60601-2-2	Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	60601.2.2	Part 2.2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

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