

# Australian/New Zealand Standard™

## Medical electrical equipment

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



## **AS/NZS IEC 60601.2.27:2016**

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 1 February 2016 and on behalf of the Council of Standards New Zealand on 21 January 2016.  
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The following are represented on Committee HE-003:

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Australian Dental Association  
Australian Society of Anaesthetists  
Canterbury District Health Board  
College of Biomedical Engineering Engineers Australia  
Department of Defence  
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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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## Medical electrical equipment

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

Originated as AS/NZS 3200.2.27:1996.  
Revised and redesignated as AS/NZS IEC 60601.2.27:2016.

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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:

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
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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## FOREWORD

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

## INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this standard.

## Medical electrical equipment

### Part 2.27:

### Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

##### 201.1.1 \*Scope

###### *Replacement:*

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 201.3.63 and hereinafter also referred to as ME EQUIPMENT. This particular standard applies to ME EQUIPMENT used in a hospital environment as well as when used outside the hospital environment, such as in ambulances and air transport. This particular standard also applies to ECG telemetry systems used in a hospital environment.

ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment, such as in ambulances and air transport, shall comply with this particular standard. Additional standards may apply to ME EQUIPMENT for those environments of use.

This standard is not applicable to electrocardiographic monitors for home use. However, MANUFACTURERS should consider using relevant clauses of this standard as appropriate for their INTENDED USE.

Ambulatory ("Holter") monitors, fetal heart rate monitoring, pulse plethysmographic devices, and other ECG recording equipment are outside the scope of this particular standard.

##### 201.1.2 Object

###### *Replacement:*

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 201.3.63.

##### 201.1.3 Collateral standards

###### *Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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<sup>1)</sup> The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*