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AS/NZS 3200.2.24:1999
IEC 60601-2-24:1998

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.24: Particular requirements for safety—Infusion pumps and controllers

[IEC title: Medical electrical equipment, Part 2.24: Particular requirements for the safety of infusion pumps and controllers]

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE/3, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 1 March 1999 and on behalf of the Council of Standards New Zealand on 1 April 1999. It was published on 5 June 1999.

The following interests are represented on Committee HE/3:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian & New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
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PREFACE

This Standard was prepared by the Joint Australian/New Zealand Standards Committee HE/3, Medical Electrical Equipment.

This Particular Standard is technically equivalent to and has been reproduced from IEC 60601-2-24:1998, *Medical electrical equipment*, Part 2-24: *Particular requirements for the safety of infusion pumps and controllers* which 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, hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-24. For the purposes of this Standard the IEC text is amended, supplemented or replaced as set out in Appendix ZZ. These changes are indicated by a rule in the margin against each clause affected.

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

(a) Requirements, compliance with which can be tested and definitions . . . . . in large roman type

(b) Explanations, advice, introductions, general statements, exceptions and references . . . . . in smaller roman type

(c) Headings of sub-clauses and text specifications . . . . . *in italic type*

(d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index . . . . . IN SMALL CAPITALS

* An asterisk is placed before each Clause for which rationale is included in Annex AA.

The even numbered pages of the original publication are in French and are omitted from this version. Some other pages of the original, which relate to IEC administrative matters, are also omitted from this edition.

As this publication has been reproduced from an international Standard, the following modifications apply:

(i) its number does not appear on each page of text and its identity is shown on the cover and title page.

(ii) the words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.

(iii) substitute a full point for a comma where it appears as a decimal marker.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS	
60521	Class 0.5, 1 and 2 alternating-current watthour meters	1284 1284.1	Electricity metering Part 1: General purpose induction watthour meters

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IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1-1	Part 1: General requirements for safety	32001.0	Part 1.0: General requirements for safety Parent Standard
60601-1-2	Part 1: General requirements for safety— 2. Collateral Standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety Collateral Standard: Electromagnetic compatibility—Requirements and tests
		AS	
60651	Sound level meters	1259	Acoustics—Sound level meters
		1259.1	Part 1: Non-integrating
60801	Electromagnetic compatibility for industrial-process measurement and control equipment	—	
60801-1	Part 1: General introduction		
60801-2	Part 2: Electrostatic discharge requirements	—	
60804	Integrating-averaging sound level meters	1259.2	Part 2: Integrating—Averaging
61000	Electromagnetic compatibility (EMC)	—	
61000-4-3	Part 4: Testing and measurement techniques—Section 3: Radiated radio-frequency, electromagnetic field immunity test		
61000-4-4	Part 4: Testing and measurement techniques—Section 4: Electrical fast transient/burst immunity test	—	
ISO		—	
3696	Water for analytical laboratory use—Specification and test methods		
3744	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane	—	
7864	Sterile hypodermic needles for single use	—	
7886	Sterile hypodermic syringes for single use	—	
7886-2	Part 2: Syringes for use with power-driven syringe pumps		
IEC		—	
8536	Infusion equipment for medical use		
8536-4	Part 4: Infusion sets for single use		

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

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