Australian/New Zealand Standard™

Medical electrical equipment

Part 2.30: Particular requirements for safety—Automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999, MOD)

Standards Australia

STANDARDS NEW ZEALAND

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 28 June 2001 and on behalf of the Council of Standards New Zealand on 19 October 2001. It was published on 12 November 2001.

The following interests are represented on Committee HE-003:
Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Aged Care
Medical Industry Association of Australia
Ministry of Economic Development, New Zealand
Royal Australasian College of Radiologists

Additional interests participating in the preparation of this Standard:

Canterbury Health, New Zealand
Commonwealth Department of Health and Aged Care
Monash Medical Centre, Vic.
N.S.W. Department of Public Works and Services
Prince Henry Hospital, N.S.W.
Royal Prince Alfred Hospital, N.S.W.
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.30: Particular requirements for safety—Automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999, MOD)

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Subcommittee HE-003-07, Patient Monitoring Equipment, under the responsibility of Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.30:1996, *Medical electrical equipment*, Part 2.30: *Particular requirements for safety—Automatic cycling indirect blood pressure monitoring equipment.*

This Particular Standard has been adopted with national modifications and has been reproduced from IEC 60601-2-30:1999 *Medical electrical equipment*—Part 2-30*: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment,* 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 and is hereinafter referred to as the General Standard.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-30. These changes are indicated by a rule in the margin against the Clause affected.

The General Standard details electrical safety requirements for the design and manufacture of medical electrical equipment which makes physical or electrical contact with the patient. A Particular Standard details additional safety requirements for a medical device, or related group of medical 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.

It is recommended that, to interpret a Particular Standard or a Collateral Standard, a copy of the General Standard should be readily available.

In the text of this Standard, the following fonts are used:

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

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

(c) Headings, of sub-clauses and test specifications ……...*in italic type*

(d) Terms used throughout the Standard, which have been defined in Clause 2 ……IN SMALL CAPITALS

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

(i) Its number does not appear on each page 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’ where ever they appear.

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

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

Some pages of IEC 60601-2-30, which relate to IEC administrative matters, are also omitted from this version.

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’ one is for information or guidance.

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/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety Amendment 1 (1991) Amendment 2 (1995)	3200.1.0*	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
60601-1-4	Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems	3200.1.4	Part 1.4: General requirements for safety—Collateral Standard: Programmable electrical medical systems
60601-2-2	Part 2: Particular requirements for the safety of high frequency surgical equipment	3200.2.2	Part 2.2: Particular requirements for safety—High frequency surgical equipment
CISPR 11	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment (excluding surgical diathermy apparatus)	2064	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radiofrequency equipment
ISO		AS ISO	
1000	SI units and recommendations for the use of their multiples and of certain other units	1000	The international system of units (SI) and its application

Any international Standards not listed do not have an Australian/New Zealand equivalent.

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* This edition incorporates the IEC amendments.

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SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTRODUCTION

This Particular Standard concerns the safety of automatic cycling non-invasive blood pressure monitoring equipment. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled *"Medical electrical equipment – Part 1: General requirements for safety".*

A "General guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

It is considered that a 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, this annex does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in annex AA.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.30
Particular requirements for safety—Automatic cycling non-invasive blood pressure monitoring equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as defined in 2.102, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard does not apply to blood pressure measuring equipment which uses finger transducers or to semi-automatic blood pressure measuring equipment, typically in which each determination needs to be initiated manually.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT, with special attention being paid to the avoidance of hazards due to the inflation process.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1: 1988, Medical electrical equipment – Part 1: General requirements for safety, as amended by its amendment 1 (1991) and amendment 2 (1995). The General Standard also takes into account IEC 60601-1-2: 1993, Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests, and IEC 60601-1-4:1996, Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems.

For brevity, IEC 60601 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.