AS/NZS 3200.2.4:2006
IEC 60601-2-4:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.4: Particular requirements for safety—Cardiac defibrillators

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 12 January 2006 and on behalf of the Council of Standards New Zealand on 20 January 2006.
This Standard was published on 17 February 2006.

The following 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
Canterbury District Health Board, New Zealand
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Ageing
Department of Defence (Australia)
Medical Industry Association of Australia Inc
Ministry of Consumer Affairs, New Zealand
Ministry of Economic Development, New Zealand
Testing Interests (Australia)
The Royal Australian and New Zealand College of Radiologists
Wairarapa District Health Board, New Zealand

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

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 or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 04241.

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.4: Particular requirements for safety—Cardiac defibrillators

Originated as AS 3201.4—1973.
Previous edition AS/NZS 3200.2.4:1993.
Second edition 2006.

Jointly published by Standards Australia, GPO Box 476, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 7263 3

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment to supersede AS/NZS 3200.2.4:1993, *Approval and test specification—Medical electrical equipment,* Part 2.4*:Particular requirements for safety—Cardiac defibrillators and cardiac defibrillator-monitors.*

The objective of this revision is to adopt the 2002 edition of IEC 60601-2-4, so as to update references to the publications and documents through some changes to the technical content.

This Particular Standard has been reproduced from, and is identical to, IEC 60601-2-4:2005, *Medical electrical equipment*, Part 2-4: *Particular requirements for the safety of cardiac defibrillators,* 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 *Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard* and is hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

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 Clause 6.1 aa) and in Appendix L, reference should be made to IEC 61672-1, *Electroacoustics—Sound level meters*—Part 1: *Specifications*, instead of IEC 60651, *Sound level meters*, which has been superseded. In Annex AA, reference should be made to ANSI/AAMI DF2-1996 instead of ANSI/AAMI DF-2-1989(4.3.17).

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) Notes, explanations, advice, introductions, general statements, exceptions and references .....in smaller roman type

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

(d) Terms defined in Clause 2 of the General Standard or this Particular Standard ..... 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’ wherever they appear.

(iii) The substitution of a full point (.) for a comma (,) when it appears as a decimal marker.

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 and guidance.

Some pages of the original, which relate to IEC administrative matters, do not appear in this version.

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

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60300	Dependability management	3931	Risk analysis of technological systems—Application guide
60300-3-9	Part 3-9: Application guide—Risk analysis of technological systems		
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-2-27	Part 2-27: Particular requirements for the safety of electrocardiographic monitoring equipment	3200.2.27	Part 2.27: Particular requirements for safety—Electrocardiographic monitoring equipment
60651*	Sound level meters	—	
61000	Electromagnetic compatibility (EMC)	61000	Electromagnetic compatibility (EMC)
61000-4-2	Part 4-2: Testing and measurement techniques—Electrostatic discharge immunity test	61000.4.2	Part 4.2: Testing and measurement techniques—Electrostatic discharge immunity test
61000-4-3	Part 4-3: Testing and measurement techniques—Radiated radio-frequency electromagnetic field immunity test	61000.4.3	Part 4.3: Testing and measurement techniques—Radiated radio-frequency electromagnetic field immunity test
61000-4-4	Part 4-4: Testing and measurement techniques—Electrical fast transient/burst immunity test—Basic EMC Publication	—	
61000-4-5	Part 4-5: Testing and measurement techniques—Surge immunity test	61000.4.5	Part 4.5: Testing and measurement techniques—Surge immunity test
61000-4-6	Part 4-6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields	61000.4.6	Part 4.6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields
61000-4-8	Part 4-8: Testing and measurement techniques—Power frequency magnetic field immunity test	61000.4.8	Part 4.8: Testing and measurement techniques—Power frequency magnetic field immunity test

* IEC 60651 has been superseded by IEC 61672-1, *Electroacoustics—Sound level meters,* Part 1: *Specifications,* see Preface.

CONTENTS

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

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS;
ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

SECTION 101 – ADDITIONAL REQUIREMENTS RELATING TO SAFETY

INTRODUCTION

This Particular Standard concerns the safety of CARDIAC DEFIBRILLATORS. It amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, including its amendments 1 (1991) and 2 (1995), hereinafter referred to as the General Standard.

A first edition of this Particular Standard, based on the first edition (1977) of IEC 60601-1 was published in 1983. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above through minor changes to the technical content.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of this Particular 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.

Clauses and subclauses for which a corresponding rationale statement is given in Annex AA are marked with an asterisk * before their number in the text.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.4
Particular requirements for safety—Cardiac defibrillators

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 of CARDIAC DEFIBRILLATORS as defined in 2.1.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand alone CARDIAC MONITORS (which are standardized by IEC 60601-2-27). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which address considerations in waveform selection.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101.

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).

AS/NZS 3200.2.4:2006 Medical electrical equipment - Particular requirements for safety - Cardiac defibrillators