

Australian/New Zealand Standard™

**Technical management programs for
medical devices**



AS/NZS 3551:2004

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 23 February 2004 and on behalf of the Council of Standards New Zealand on 5 March 2004.

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The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
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
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 Economic Development (New Zealand)
Testing Interests (Australia)
The Royal Australian and New Zealand College of Radiologists
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Additional Interests:

Auckland Healthcare (New Zealand)
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Subcommittee HE-003-01-02, Technical Management Programs for Medical Equipment, under the responsibility of Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3551:1996.

This Standard incorporates Amendment No. 1 (September 2005). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.

The following interests played a major role in the preparation of this Standard:

Biomedical Services, New Zealand
New South Wales Department of Public Works and Services
Prince of Wales Hospital, N.S.W.
Queensland Health
Royal North Shore Hospital, N.S.W.

The principal differences between this edition and the previous edition are as follows:

- (a) The introduction of a definition for ‘essential safety and performance parameter’.
- (b) Detailing information on repair using non-OEM spares, manufacturer approved modification and other modifications.
- (c) Amendment of the previous Compliance with Standards section on regulatory compliance to take into account the Therapeutic Goods Act and the Medical Device Directives.
- (d) The mains contact current test is required only at acceptance and when the mains isolation barrier is part of a repair.
- (e) With regard to frequency of testing, the introduction of risk management principles in assessing risks and hazards. A 12-monthly maximum interval is required if risk assessment is not followed.

The Standard was prepared for users of medical devices who need to—

- (i) ensure that the device purchased complies with the Essential Principles of Safety and Performance;
- (ii) inspect and test new devices, before commissioning, in order to ensure against manufacturing defects; and
- (iii) perform routine inspections or tests on medical devices, or both, during their service life, in order to ensure their continued safety and performance.

The safe application of medical devices depends on a variety of factors. The minimum requirements are as follows:

- (A) Medical electrical devices are used only in a patient area provided with appropriate protection and the reticulated mains wiring in accordance with AS/NZS 3003, *Electrical installations—Patient treatment areas of hospitals and medical and dental practices*.
- (B) Appropriate equipment is used for each particular application and in accordance with an appropriate set of rules linking the type of procedure with the class of device and the electrical safety facilities provided in the patient area.
- (C) Each new item of equipment is—
 - (1) acceptance tested prior to clinical use;

- (2) subjected to routine performance testing during its useable life to detect damage, wear, component failure or changed component value which might render it unsafe; and
 - (3) maintained with reference to the manufacturer's instructions using formal risk analysis.
- (D) The users of the device have to know, not only the medical procedure, but also the safety characteristics and operational details of the device. This can be achieved by learning and training under the supervision of either the manufacturer, the local representative, or users, or in biomedical engineering departments.
- (E) Users and, where applicable, the biomedical engineering department or service provider, need to ensure that safety and performance of the device is maintained by an effective maintenance scheme with regular servicing in accordance with this Standard.

Many tests in this Standard are derived from the tests specified in AS/NZS 3200.1.0, *Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard*, and in no case are intended to be more stringent than those in AS/NZS 3200.1.0.

Recommendations linking the type of medical procedures with the appropriate type and class of medical electrical equipment and the type of protective facilities in the reticulated mains wiring are not covered in this Standard but are published as AS/NZS 2500, *Guide to safe use of electricity in patient care*.

Design requirements for type examination and approval of medical electrical devices are not considered in this Standard but are set out in AS/NZS 3200.1.0 and Collateral Standards, and the relevant Part 2 Standards in the AS/NZS 3200 series. In this regard, it is important to note the following:

- (1) The test requirements of the AS/NZS 3200 Part 2 Standards can be applied to a sample of the device to verify that the basic design and manufacture complies with these Standards before the device is introduced to the market.
- (2) Many of the tests in the AS/NZS 3200 Part 2 Standards are too extensive to be applied on a routine basis to each item of equipment delivered to a hospital or health care facility. Some inspection and testing requirements of the AS/NZS 3200 Part 2 Standards are potentially destructive of the device or its components. Some of those type tests, if applied to each item of equipment purchased, would render the device inoperative or unsafe for use.
- (3) Few organizations and health care facilities have the resources to carry out type testing to the full requirements of the AS/NZS 3200 Part 2 Standards.
- (4) For the reasons outlined above, it is not appropriate, nor would it be cost effective, to carry out all the inspection and testing required in the AS/NZS 3200 Part 2 Standards on every item of equipment to be commissioned.
- (5) The AS/NZS 3200 Part 2 Standards modify the Parent Standard and are totally dependent on AS/NZS 3200.1.0 for the bulk of requirements.

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Australian/New Zealand Standard
Technical management programs for medical devices

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies procedures required to develop equipment management programs for medical devices. These include procedures for procurement, acceptance, fault management, routine testing and disposal of medical devices.

This Standard deals with essential safety and performance testing. Section 4 details how to identify the safety and performance parameters that are essential for the safe operation of each device and how to determine appropriate test intervals.

For the purposes of an equipment management program, the scope of this Standard covers non-electrical medical devices, such as ventilators, which may be solely pneumatic or fluidic in operation.

Many tests in this Standard concern medical electrical devices and are derived from the tests specified in AS/NZS 3200.1.0 and in no case are intended to be more stringent than those in that document. Where acceptance values of a AS/NZS 3200 Part 2 Standard for particular medical devices are not in agreement with the requirements of this Standard, the Part 2 Standard overrides this document. For example, the normal limit (specified in AS/NZS 3200.1.0) for mains contact current is 50 μA per applied part, while AS/NZS 3200.2.4 specifies an allowable current of 100 μA for Type CF defibrillator applied parts.

NOTE: This Standard is intended to cover all medical devices, whether hospital property, privately owned, on loan, on trial, or donated, except for the commissioning requirements of permanently installed medical electrical devices in cardiac- and body-protected patient treatment areas, for which requirements are specified in AS/NZS 3003.

1.2 APPLICATION

This Standard is intended for use by those persons involved in the procurement, testing, installation, maintenance, calibration and operation of medical devices. It is meant to address the disparate needs of teaching hospitals, small hospitals, biomedical engineering service groups and other health care providers. While the operational modes of these groups may differ widely, the overall perspective is one of keeping medical devices safe and functional.

The principles and recommendations specified herein have been framed in a manner considered suitable for application by service organizations, hospital and private, supporting the use of medical devices.

1.3 REFERENCED DOCUMENTS

This Standard has been designed, as far as practicable, as a 'stand-alone' document capable of implementation without reference to other Standards. However, the following documents are referred to in this Standard:

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|------|---|
| AS | |
| 2125 | General conditions of tendering and form of tender |
| 2472 | Valves for medical gas cylinders (including pin-indexed outlet) |