AS/NZS 3551:2004 (Incorporating Amendment No. 1)

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.

This Standard was published on 11 June 2004.

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

Wairarapa District Health Board

Additional Interests:

Auckland Healthcare (New Zealand) College of Biomedical Engineering Institute of Engineers Australia Wairarapa District Health Board N.S.W Dept of Commerce

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 Standards may also be withdrawn.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 01404.

AS/NZS 3551:2004 (Incorporating Amendment No. 1)

Australian/New Zealand Standard™

Technical management programs for medical devices

Originated as AS 3551—1988.
Previous edition AS/NZS 3551:1996.
Third edition 2004.
Reissued incorporating Amendment No. 1 (September 2005).

COPYRIGHT

© Standards Australia/Standards New Zealand

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

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

ISBN 0 7337 6075 9

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.



	This is a free preview.	Purchase the e	entire publication	at the link below:
--	-------------------------	----------------	--------------------	--------------------

Product Page

- Dooking for additional Standards? Visit Intertek Inform Infostore
- Dearn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation