AS/NZS 3551:2012
(Incorporating Amendment Nos 1 and 2)

AS/NZS 3551:2012

Australian/New Zealand Standard™

Management programs for medical equipment

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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 19 July 2012 and on behalf of the Council of Standards New Zealand on 10 July 2012.
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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 and New Zealand College of Anaesthetists
Australian Dental Association
Australian Radiation Protection and Nuclear Safety Agency
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3551:2004.

This Standard incorporates Amendment No. 1 (October 2013) and Amendment No. 2 (September 2016). 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 principal differences between this edition and the previous edition are as follows:

(a) Principles from quality management and risk management standards have been incorporated throughout the document.

(b) Introduction of the requirements for hire and loan equipment.

(c) Introduction of the term 'performance verification' which encompasses physical, functional, and electrical testing.

(d) Change in earth leakage current tests to align with IEC 60601-1, Ed. 3.0.

(e) Addition of touch current testing to align with IEC 60601-1, Ed. 3.0.

(f) Addition of the medical electrical systems section (Section 7) to align with IEC 60601-1, Ed. 3.0.

(g) Management of medical equipment configurations during medical equipment maintenance.

(h) Introduction of test requirements for non-medical equipment used in a patient environment.

(i) Introduction of terms 'service entity' and 'responsible organization'.

(j) Introduction of requirements for management of medical equipment used in the home.

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

(i) ensure that medical equipment used in the responsible organization perform as intended by the manufacturer and is safe for clinical use;

(ii) ensure that the medical equipment complies with the essential principles of safety and performance;

(iii) inspect and test new medical equipment, before commissioning, in order to ensure against manufacturing defects; and

(iv) perform maintenance, routine inspections or tests on medical equipment during its service life, in order to ensure its continued safety and performance.

This Standard is intended to provide a practical approach and application of the testing philosophies of AS/NZS 3200.1.0 and associated Part 2 Standards, along with other essential performance verification principles, to ensure that medical equipment, in clinical use in the responsible organization, performs as intended by the manufacturer and does not compromise the safety of the patient, the operator or the environment.

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*.

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Design requirements for type examination and approval of medical electrical equipment 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:

(A) The test requirements of the AS/NZS 3200 Part 2 Standards can be applied to a sample of the medical equipment to verify that the basic design and manufacture complies with these Standards before the medical equipment is introduced to the market.

(B) 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 healthcare facility. Some inspection and testing requirements of the AS/NZS 3200 Part 2 Standards are potentially destructive of the medical equipment or its components. Some of those type tests, if applied to each item of equipment purchased, may render some or all of them inoperative or unsafe for use.

(C) Few organizations and healthcare facilities have the resources to carry out type testing to the full requirements of the AS/NZS 3200 Part 2 Standards.

(D) For these reasons, 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.

(E) 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.

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

Statements expressed in mandatory terms in notes to tables and figures are deemed to be requirements of this Standard.

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FOREWORD

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

(a) Medical electrical equipment is used only in a patient area provided with appropriate protection and the reticulated mains wiring in accordance with AS/NZS 3003, *Electrical installations—Patient areas*.

(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 medical equipment and the electrical safety facilities provided in the patient area.

(c) Each new item of equipment is—

  (i) acceptance tested prior to clinical use;

  (ii) subjected to routine performance verification during its useable life to detect damage, wear, component failure or changed component value which might render it unsafe; and

  (iii) maintained with reference to the manufacturer's instructions using formal risk analysis within a risk management framework.

(d) The users of the medical equipment must know, not only the medical procedure, but also the safety characteristics and operational details of the medical equipment. This can be achieved by learning and training under the supervision of the manufacturer, the local representative, experienced users, or staff from biomedical engineering departments or the service entity.

(e) The responsible organization needs to ensure that safety and performance of the medical equipment is maintained by an effective maintenance scheme with regular assessment, testing and maintenance in accordance with this Standard.

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Management programs for medical equipment

S E C T I O N 1 S C O P E A N D G E N E R A L

1.1 SCOPE

This Standard outlines procedures required to develop management programs for medical equipment. These include protocols and procedures for procurement, acceptance, maintenance activities throughout the service life of the medical equipment, and finally disposal of medical equipment.

This Standard applies to non-electrical medical equipment, such as ventilators, which may be solely pneumatic or fluidic in operation, as well as medical electrical equipment. Also included in the scope are products that are not generally considered to be medical equipment, but are used in the patient environment, such as computers, imaging cameras and recorders.

This Standard applies whether the medical equipment is owned by the responsible organization, privately owned, on loan, on hire, on trial or donated, and includes medical equipment provided by a responsible organization as part of a pool of medical equipment for hire. It does not apply to the electrical commissioning requirements of permanently installed medical electrical devices as specified in AS/NZS 3003.

Although this Standard is focused on the management of medical equipment within an organization, it is acknowledged that some responsible organizations may choose to use many of the protocols and procedures of this document to manage medical equipment in other areas, for example laboratories. In such circumstances, the organization, or its service entity, will have to consider the relevance of some of the requirements outlined in this document.

In developing this Standard, reference has been made to manufacturer's specifications for a wide range of commercially available medical equipment. It is not possible in this Standard to address every type of medical equipment, particularly since new treatment modalities and medical equipment will be marketed during the life of the Standard. It is therefore important to make reference to manufacturer's specifications for the operation, performance testing and calibration of any new medical equipment, and to balance this with a knowledge of professional biomedical engineering practice for similar equipment.

Where the acceptance values of an AS/NZS 3200 Part 2 Standard for a particular type of medical electrical equipment are not in agreement with the requirements of AS/NZS 3200.1.0:1998 or IEC 60601-1, Ed. 3.0 (2005), the requirements of the Part 2 Standard override these documents. 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. It should also be noted that, in some instances, allowable limits applicable for acceptance testing may be more stringent than for ongoing performance verification.

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