AS/NZS 3200.2.6:2005

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.6: Particular requirements for safety—Microwave therapy equipment (IEC 60601-2-6:1984, MOD)

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND
Paerewa Aotearoa

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 20 January 2005 and on behalf of the Council of Standards New Zealand on 28 January 2005.
This Standard was published on 7 April 2005.

The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australian 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
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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 or Standards New Zealand at the address shown on the back cover.

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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 3200.2.6—1992, *Approval and test specification—Medical electrical equipment*—Part 2.6: *Particular requirements for safety—Microwave therapy equipment.*

The objective of this revision is to update key references and to revise presentation of the Standard according to current editorial practices and publish it as a Joint Australian/New Zealand Standard.

This Particular Standard modifies, and has been reproduced from, IEC 60601-2-6:1984, *Medical electrical equipment,* Part 2.6: *Particular requirements for the safety of microwave therapy 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, *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.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-6:1984. These changes are indicated by a rule in the margin against each Clause or Appendix affected.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical 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.

In the text of this Standard, the following print types are used:

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

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

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

(d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index.....IN SMALL CAPITALS

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

Some pages of the source document, which relate to IEC administrative matters, have been omitted from this edition.

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

(i) Its number does not appear on each page of text 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 where it appears as a decimal marker.

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.

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SECTION ONE — GENERAL

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 MICROWAVE THERAPY EQUIPMENT used in medical practice, as defined in Sub-clause 2.1.101, hereinafter referred to as EQUIPMENT.

This standard does not apply to EQUIPMENT specified for hyperthermia.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Addition:

Accessible parts of APPLICATORS and their associated connecting cables or waveguides and their connectors.

Additional definitions:

2.1.101 *MICROWAVE THERAPY EQUIPMENT*

EQUIPMENT for the treatment of the PATIENT by means of a propagated electromagnetic field in the frequency range of more than 300 MHz but not exceeding 30 GHz.

2.1.102 *APPLICATOR*

Radiator, i.e. an aerial with a directional effect, such as a dipole with reflector, a dipole array, open waveguide or dielectric radiator for local application of microwave energy to the PATIENT.

2.1.103 *PHANTOM*

Device, intended to simulate parts of the PATIENT for test purposes.