

Australian/New Zealand Standard™

**Medical electrical equipment—
Part 2.5: Particular requirements for
safety—Ultrasonic physiotherapy
equipment (IEC 60601-2-5:2000, MOD)**

AS/NZS 3200.2.5:2002

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 22 October 2002 and on behalf of the Council of Standards New Zealand on 15 October 2002. It was published on 31 December 2002.

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Australasian Society for Ultrasound in Medicine
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Australian Radiation Protection and Nuclear Safety Agency
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Commonwealth Department of Health and Ageing
Department of Defence (Australia)
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Medical Industry Association of Australia
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Australian/New Zealand Standard™

Medical electrical equipment— Part 2.5: Particular requirements for safety—Ultrasonic physiotherapy equipment (IEC 60601-2-5:2000, MOD)

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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 3200.2.5—1992, *Approval and test specification—Medical electrical equipment—Part 2.5: Particular requirements for safety—Ultrasonic therapy equipment*.

This Particular Standard modifies, and has been reproduced from, IEC 60601-2-5:2000, *Medical electrical equipment, Part 2.5: Particular requirements for the safety of ultrasonic physiotherapy equipment* and supplements the corresponding Clauses of IEC 60601-1:1999, *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.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-5. These changes are indicated by a rule in the margin against each Clause affected.

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 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, references
.....in smaller roman type
- (c) Headings, of sub-clauses and test specifications
..... *in italic type*
- (d) Terms used throughout the Standard, which have been defined in Clause 2
..... 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) Substitute a full point (.) for a comma (,) where it appears as a decimal marker.

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

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

<i>Reference to International Standard</i>	<i>Australian/New Zealand Standard</i>
IEC	AS/NZS
60601 Medical electrical equipment	3200 Medical electrical equipment
60601-1 Part 1: General requirements for safety	3200.1.0 Part 1.0: General requirements for safety— Parent Standard
60601-1-1 Part 1: General requirements for safety Section 1—Collateral Standard: Safety requirements for medical electrical systems	3200.1.1 Part 1.1: General requirements for safety Collateral Standard: Safety requirements for medical electrical systems
60601-1-2 Part 1: General requirements for safety Section 2—Collateral Standard: Electromagnetic compatibility – Requirements and tests	3200.1.2 Part 1.2: General requirements for safety Collateral Standard: Electromagnetic compatibility – Requirements and tests
60601-1-4 Part 1: General requirements for safety Section 4—Collateral Standard: Programmable electrical medical systems	3200.1.4 Part 1.4: General requirements for safety Collateral Standard: Programmable electrical medical systems

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INTRODUCTION

This Particular Standard specifies requirements and tests for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT. It amends and supplements IEC 60601-1 (second edition, 1988) including Amendments 1 and 2, hereinafter referred to as the General Standard. This Particular Standard takes into account IEC 60601-1-2 and IEC 61689.

A first edition of this Particular Standard was published in 1984, based on the first edition (1977) of IEC 60601-1 and making reference to IEC 60150. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above. The title has been changed to better reflect its scope based on developments in the therapeutic application of ultrasound and in line with changes in the above IEC standards.

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 the 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.

The clauses and subclauses which have corresponding rationale statements are marked with an asterisk * before their number.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.5:

Particular requirements for safety — Ultrasonic physiotherapy equipment (IEC 60601-2-5:2000, MOD)

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object**1.1 Scope**

Addition:

This Particular Standard specifies the requirements for safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

This Particular Standard does not apply to:

- EQUIPMENT in which a tool is driven by ULTRASOUND (for example EQUIPMENT used in surgery or dentistry);
- EQUIPMENT in which focused ULTRASOUND pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotrites) (for information refer to IEC 60601-2-36);
- ULTRASONIC PHYSIOTHERAPY EQUIPMENT in which focused ULTRASOUND pulse waves are used.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, 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).

For brevity, Part 1 is referred to in this Particular Standard as the “General Standard” .

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.