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# Australian Standard® 3211—1986

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## APPROVAL AND TEST SPECIFICATION— ULTRASONIC THERAPY EQUIPMENT



PUBLISHED BY THE STANDARDS ASSOCIATION OF AUSTRALIA  
STANDARDS HOUSE, 80 ARTHUR ST, NORTH SYDNEY, N.S.W.

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This Australian standard was prepared by Committee EL/18/2, Short-wave and Microwave Equipment. It was approved on behalf of the Council of the Standards Association of Australia on 23 January 1986 and published on 3 March 1986.

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The following interests are represented on Committee EL/18/2:

Australian Association of Physical and Rehabilitation Medicine  
Australian Physiotherapy Association  
Confederation of Australian Industry  
Department of Health, N.S.W.  
Health Commission of Victoria  
Prince Henry's Hospital, Victoria  
Royal Australian College of Surgeons  
Royal Australian Nursing Federation  
South Australian Health Commission  
The Urological Society of Australasia

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*This standard was issued in draft form for comment as DR 83164. ✓*

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## PREFACE

This edition of this standard was prepared by the Association's Committee on Short-wave and Microwave Equipment, as a partial replacement of AS 3201.1—1971, Approval and Test Specification for Electromedical Equipment, Part 1—Diathermy Equipment. The 1971 standard has been replaced by the following four standards:

AS 3202—1979, Approval and Test Specification for Electrosurgical Equipment

AS 3209—1986, Approval and Test Specification—Short-wave Therapy Equipment

AS 3210—1986, Approval and Test Specification—Microwave Therapy Equipment

AS 3211—1986, Approval and Test Specification—Ultrasonic Therapy Equipment

The series of approval and test specifications issued by the Association for individual items of electromedical equipment are supplementary to the parent approval and test specification for all electromedical equipment, i.e. AS 3200, Approval and Test Specification for Electromedical Equipment—General Requirements.

The purpose of the series is to outline conditions which must be met to secure approval for the sale and use of electromedical and electro dental equipment in Australia. Only safety matters and conditions closely aligned thereto are covered. In some instances, however, these are more stringent than for most electrical appliances because of the exacting additional requirements necessary to ensure the safety of the patient, and because of the environmental conditions, e.g. high humidity, hazardous locations, in which some equipment is liable to be used.

The clauses of this particular standard supplement or modify the corresponding clauses in AS 3200. As stated in Clause 1.2, the requirements of a particular standard take priority, where appropriate, over those of AS 3200. Where the reference in the text of this standard indicates an 'addition' or 'replacement' of the relevant requirements, tests or explanation notes of AS 3200, these changes are made to the relevant text which then becomes part of the standard. Where no changes are necessary, the words 'this Section of AS 3200 applies' are used.

The requirements of this standard are similar to those in the international standard, IEC 601.2.5, except for amendments necessary to align with AS 3200. In particular the international patient-circuit classifications have been included for the first time in an Australian standard. This inclusion follows the recent decision to adopt such classifications in the next edition of AS 3200. These classifications are—

Cardiac-protected—'Type CF' (formerly Class A)

Body-protected—'Type BF' (formerly Class B)

Unprotected—'Type B' (formerly Class Z).

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## STANDARDS ASSOCIATION OF AUSTRALIA

## Australian Standard

## APPROVAL AND TEST SPECIFICATION—ULTRASONIC THERAPY EQUIPMENT

## SECTION 1. SCOPE AND GENERAL

This Section of AS 3200 is applicable except as follows:

**ADDITION****1.1 SCOPE.** Add the following:

This specification sets out the safety requirements for ultrasonic therapy equipment, as defined in Clause 2.2, intended for operation from supply mains.

NOTE: This specification is not applicable to—

- (a) diagnostic ultrasonic equipment; or
- (b) equipment in which a mechanical tool is driven by ultrasound; or
- (c) equipment in which ultrasound pulse waves are focused to destroy conglomerates such as stones in the kidneys or the bladder (lithorites).

**ADDITION****1.2 APPLICATION.** Add the following:

**1.2.1 Compliance with AS 3200.** This specification shall be read in conjunction with AS 3200.

Unless otherwise specified or modified herein, the requirements, tests and criteria in AS 3200 shall be taken to apply to ultrasonic therapy equipment.

**1.2.2 Specific requirements of this specification.** Ultrasonic therapy equipment shall be deemed to comply with this specification only if it complies with all the requirements of this specification and satisfactorily passes the tests specified herein.

**1.2.3 Requirements of other specifications.** Electrical equipment and components, e.g. thermostats, switches, flexible cords, incorporated in ultrasonic therapy equipment shall also comply with relevant requirements of their individual approval and test specifications.

**1.2.4 Combined equipment.** In the case of combined equipment, e.g. ultrasonic therapy equipment additionally provided with a function or an applied part for electrical stimulation, such equipment shall also comply with any approval and test specification specifying safety requirements for the additional function.

**ADDITION**

Add the following new clause.

**1.3 REFERENCED DOCUMENTS.** The following documents and other publications are referred to in this standard:

- AS 2064 Limits of Electromagnetic Interference Generated by Industrial, Scientific, Medical and Similar Radio-frequency Equipment
- AS 3003 Electrical Installations—Patient Treatment Areas of Hospitals and Medical and Dental Practices
- AS 3100 Approval and Test Specification for Definitions and General Requirements for Electrical Materials and Equipment
- AS 3200 Approval and Test Specification for Electromedical Equipment—General Requirements
- AS 3208 Approval and Test Specification for Transformers in Electromedical Equipment
- IEC 150 Testing and Calibration of Ultrasonic Therapeutic Equipment
- CISPR 11 Limits and Methods of Measurement of Radio Interference Characteristics of ISM Radio Frequency Equipment.