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Australian Standard®

Approval and test specification— Medical electrical equipment

Part 2.2: Particular requirements for safety—High frequency surgical equipment

[IEC title: Medical electrical equipment Part 2: Particular requirements for the safety of high frequency surgical equipment]





This Australian Standard was prepared by Committee HT/16, High Frequency Surgical and Therapy Equipment. It was approved on behalf of the Council of Standards Australia on 29 April 1992 and published on 13 July 1992.

The following interests are represented on Committee HT/16:

Australian Dental Association

Australian Physiotherapy Association

Department of Health, Housing and Community Services

Department of Health, N.S.W.

Institute of Biomedical Engineering (Australia)

Medical Industry Association of Australia

Royal Australasian College of Surgeons

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AS 3200.2.2-1992

Australian Standard®

Approval and test specification— Medical electrical equipment

Part 2.2: Particular requirements for safety—High frequency surgical equipment

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PREFACE

This Standard was prepared on behalf of the Standards Australia Multi-Technics Board to supersede AS 3202—1989, Approval and test specification—Electrosurgical equipment when AS 3200—1986 is withdrawn. It is technically equivalent to IEC 601-2-2, Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment, second edition and is technically compatible with IEC 601-1 (1988), Medical electrical equipment, Part 1: General requirements for safety, second edition.

This Standard is one of a series of Approval and Test Specifications issued by Standards Australia for individual items of electromedical equipment. It is supplementary to AS 3200.1—1990, Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety. Only safety matters and closely aligned conditions are covered. In some instances, however, these are more stringent than for most electrical appliances because of the additional requirements necessary to ensure the safety of the patient, and because of the environmental conditions, e.g. high humidity and hazardous locations, in which some equipment is likely to be used.

The clauses of this Particular Standard supplement or modify the corresponding clauses in AS 3200.1—1990. As stated in Clause 1.3 of AS 3200.1—1990, the requirements of a specific Standard take priority, where appropriate, over those of AS 3200.1—1990. Where the reference in the text of this Standard indicates an 'amendment', 'addition' or 'replacement' of the relevant requirements, tests or explanatory notes of AS 3200.1, these changes are made to the relevant text which then becomes part of the Standard.

Where the Australian requirements differ from the International specifications, to accommodate Australian conditions and well-accepted safety practices, a marginal bar is situated alongside the IEC text, and Appendix ZZ details the Australian specifications and rationale for the deviations.

For the purposes of the Australian Standard, the IEC text should be modified as follows:

- (a) The term 'NEUTRAL ELECTRODE' is to be read as 'DISPERSIVE ELECTRODE'.
- (b) Replace references to the 'General Standard' with AS 3200.1—1990, Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety.

The Standard continues to specify requirements for the safety of high frequency electrosurgical equipment only, with requirements dealing with high frequency therapeutic diathermy equipment (short wave, microwave and ultrasonic) being covered in separate Standards.

Details of the numbering of sections, clauses, subclauses, figures and appendices and of print types used in the Standard are to be found in the Introduction. Decimal places have been designated by a comma in the text of the Standard and, in keeping with Australian practice, by a full stop in Appendix ZZ.

This Standard requires reference to AS 1939—Degrees of protection provided by enclosures for electrical equipment (IP Code).

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