SUPERSEDED BY: AS 3200.2.2—1992
IEC 601-2-2:1991
AS/NZS 3200.2.2:1999

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]

STANDARDS AUSTRALIA

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

South Australian Health Commission

Urological Society of Australasia

Review of Australian Standards. *To keep abreast of progress in industry, Australian Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto.*

Full details of all Australian Standards and related publications will be found in the Standards Australia Catalogue of Publications; this information is supplemented each month by the magazine 'The Australian Standard', which subscribing members receive, and which gives details of new publications, new editions and amendments, and of withdrawn Standards.

Suggestions for improvements to Australian Standards, addressed to the head office of Standards Australia, are welcomed. Notification of any inaccuracy or ambiguity found in an Australian Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

This Standard was issued in draft form for comment as DR 91010.

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

First published as part of AS 3201.1—1971 Ap.
Revised and redesignated in part as AS 3202—1979.
Second edition 1989.
Revised and redesignated AS 3200.2.2—1992.

PUBLISHED BY STANDARDS AUSTRALIA
(STANDARDS ASSOCIATION OF AUSTRALIA)
STANDARDS HOUSE, 80 ARTHUR ST, NORTH SYDNEY NSW
ISBN 0 7262 7505 0

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).*

Under arrangements made between Australia and the International Standards bodies, ISO and IEC, as well as certain other Standards organizations, users of this Australian Standard are advised that copyright is vested in Standards Australia.

CONTENTS