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APPROVAL AND TEST SPECIFICATION FOR ELECTROMEDICAL EQUIPMENT —GENERAL REQUIREMENTS

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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

**Australian Federation for Medical and Biological Engineering
Australian Medical Association
Australian Society of Anaesthetists
Confederation of Australian Industry
Department of Defence
Department of Health
Department of Health, Qld
Department of Productivity
Department of Public Works, N.S.W.
Department of Veterans' Affairs
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Hospital Electronic Engineers
Institute of Hospital Engineers
Institution of Biomedical Engineering (Australia)
Medical Department, W.A.
Royal Australasian College of Physicians
Royal Australasian College of Surgeons**

Also represented on the committee were hospital biomedical engineers and Committee EL/2, Electrical Approvals Standards.

This standard, prepared by Committee EL/18, Electromedical Equipment, through its Subcommittee EL/18/1, Safety Requirements, was approved on behalf of the Council of the Standards Association of Australia on 31 August 1978, and was published on 1 November 1978.

To keep abreast of progress in industry, Australian standards are regularly reviewed. Suggestions for improvements to published standards, addressed to the head office of the Association, are welcomed.

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AUSTRALIAN STANDARD

APPROVAL AND TEST SPECIFICATION FOR ELECTROMEDICAL EQUIPMENT —GENERAL REQUIREMENTS

AS 3200-1978

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PREFACE

This standard was prepared by Subcommittee EL/18/1 under the supervision of Committee EL/18, Electromedical Equipment. It is a revision of AS C200—1970, Definitions and General Requirements for Electromedical Equipment, which it accordingly supersedes.

This standard incorporates general requirements for the safety of electromedical equipment (including associated accessories and materials) and is the 'parent' of a series of approval and test specifications covering requirements for a wide range of electromedical equipment. These general requirements are intended to be read in conjunction with AS C100, Definitions and General Requirements for Electrical Materials and Equipment, which prescribes the safety requirements for materials and equipment used in electrical installations complying with Part 1 of AS 3000, SAA Wiring Rules.

Specific requirements for individual items of electromedical equipment are contained in the 'particular' specifications which indicate whether or not the requirements and test methods stated in this general specification apply to the particular item of electromedical equipment and whether they are to be supplemented, modified or replaced. Under this system, the particular specification converts the general specification into the specification for the appliance or group of appliances covered by the particular specification.

The purpose of the series of specifications is to outline conditions which must be met to secure approval for the sale and use of electromedical and electrodentary equipment in Australia. Only safety matters and conditions closely allied 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 may be used.

In every State of Australia legislation has been enacted which requires that electrical equipment of a prescribed class or type shall not be marketed unless approved by the relevant Statutory Electricity Authority. In general, the basis of approval is the series of approval and test specifications referred to above.

For equipment which is not prescribed (and electromedical equipment is currently not prescribed), statutory and supply authorities may require proof that it complies with the relevant approval and test specification(s) or some requirements thereof. For this reason, voluntary examination schemes are operated by the statutory authorities.


Irrespective of the need for approval of equipment covered by these specifications, the Association emphasizes that the specifications establish minimum standards of safety for electromedical equipment. For this reason alone there is a responsibility on each manufacturer or importer of electromedical equipment to ensure that such equipment complies with these specifications in all respects.

This revision of this standard was undertaken primarily to specify that patient-circuits have degrees of isolation, from both live parts and earth, sufficient to ensure the safety of the patient from electric shock under conditions likely to be experienced in service.

The revision provides for three classes of patient-circuit (Classes A, B and Z), the minimum requirements for which are based on—

- (a) the degree of isolation or insulation of patient-circuits from earth, electrical supplies, and signal parts;
- (b) the maximum allowable current in patient-circuits under normal and/or fault conditions; and
- (c) minimal construction requirements, e.g. separation of internal circuits.

During the preparation of this standard attention was given to similar standards being developed by the International Electrotechnical Commission (IEC). While generally compatible with the requirements of IEC 601-1 this standard is significantly different with respect to the following:

- (i) It does not recognize the number of equipment classes proposed by IEC.
- (ii) The measuring instrument described in Appendix D is intended to ensure protection against high frequency burns, as well as electrocution.
- (iii) It provides for low leakage equipment enclosures to be identified as Class A , whereas IEC 601-1 provides only for high leakage enclosures to be identified.

The Australian National Committee participating in the IEC work has repeatedly argued these matters and, in particular, has stressed that only three classes of equipment should be provided.

Significant omissions from this standard at this time are requirements to cover isolating (i.e. ON-OFF) switches, and creepage and clearance distances. At the time of publication of this standard it had not been possible to reach agreement on these matters. Accordingly, it was decided to publish the standard with these matters listed as 'under consideration'. Committee investigation of these matters is continuing and an early amendment listing appropriate requirements is anticipated.

Further significant requirements not included in detail in this standard are those for transformers used in electromedical equipment. Draft requirements for these transformers have been developed as a separate approval and test specification, which at the time of publication of this standard had not reached finality.

This standard requires reference to the following Australian standards:

- | | |
|---------|---|
| AS 1169 | SAA Medical Agents and Gases Safety Code |
| AS 1200 | SAA Boiler Code |
| AS 1319 | SAA Code for Industrial Accident Prevention Signs |

- AS 1931 High Voltage Testing Techniques
Part 1 — General Definitions, Test Requirements, Test Procedures and Measuring Devices
- AS 1939 Classification of Degrees of Protection Provided by Enclosures for Electrical Equipment
- AS 2030 SAA Gas Cylinders Code
- AS 2034 Flameproof Electric Lighting Fittings for Explosive Atmospheres
- AS 3000 Rules for the Electrical Equipment of Buildings, Structures and Premises (SAA Wiring Rules)
Part 1 — Wiring Methods
- AS 3003 SAA Code for Electrical Installations in Electromedical Treatment Areas
- AS 3116 Elastomer Insulated Electric Cables and Flexible Cables for Working Voltages of 0.6/1 kV
- AS 3142 Electric Water Heaters
- AS 3147 PVC Insulated Electric Cables and Flexible Cables for Working Voltages of 0.6/1 kV
- AS 3191 Electric Flexible Cords
- AS 3201.2 Electrically-heated Incubators for Babies
- AS 3201.3 Electrocardiographs (Direct-writing Types)
- AS 3201.5 Dental and Mobile Medical X-ray Machines
- AS C100 Definitions and General Requirements for Electrical Materials and Equipment
- AS C112 Plugs and Plug Sockets
- AS C161 Thermostats and Energy Regulators
- AS Code for the Safe Operating of Fixed Diagnostic X-ray Equipment*
- AS Transformers in Electromedical Equipment*

* In course of preparation.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
APPROVAL AND TEST SPECIFICATION FOR
ELECTROMEDICAL EQUIPMENT—GENERAL REQUIREMENTS

FOREWORD

The safe use of electromedical equipment can only be assured if—

- (a) the equipment is safe, and is appropriate for the procedure;
- (b) the environment in which the procedure is to be carried out is wired in accordance with an appropriate code; and
- (c) the procedure is carried out under an appropriate set of rules that links the equipment with the type of procedure and the type of wiring in the area.

Compared with other equipment, electromedical equipment warrants special care being taken in its use, for the following reasons:

- (i) The patient may not react normally to electric shock or heat because he may be unconscious, anaesthetized, or fastened to the examination or treatment equipment.
- (ii) The normal high contact resistance between the skin and an electrical conductor is considerably reduced when electrodes are applied to the surface of the body with electrode paste; even the contact resistance resulting from casual encounter with other conductors is significantly reduced in many electromedical procedures by the presence of copious amounts of other electrolytes, such as blood and saline. Furthermore, the application of electrodes or electrically-conducting transducers to internal tissues of the body also produces very low contact resistance.

- (iii) Many electromedical procedures require the introduction of an insulated conductor into direct contact with heart muscle. Ventricular fibrillation may be induced by minute currents well below the threshold of feeling if such currents flow through a small cross-section of heart muscle. This is termed 'micro-electrocution'.
- (iv) Electromedical equipment may be used to support or to replace vital organ functions, either temporarily or permanently; it may also be used in emergencies. Failure of the equipment or the supply may result in hazard to the patient.
- (v) Care must be taken to minimize the risk of fire or explosion arising from the use of flammable medical agents.
- (vi) Some electromedical procedures entail delivery to the patient of various forms of energy (i.e. electric current, heat, ionizing radiation, etc) in excess of the levels normally considered safe.

This specification is confined to minimum standards for the safety of equipment. Requirements for the safety of the environment in which electromedical procedures are undertaken are specified in AS 3003, and a standard (in course of preparation) will cover the safe application and use of equipment. The following flowchart provides a summary of the safe application and use of electromedical equipment.