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# APPROVAL AND TEST SPECIFICATION—ELECTROMEDICAL EQUIPMENT—GENERAL REQUIREMENTS

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The following interests are represented on Committee EL/18/1:

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Australian Federation for Medical and Biological Engineering
Australian Medical Devices & Diagnostics Association
Australian Private Hospitals Association
Australian Society of Anaesthetists
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# APPROVAL AND TEST SPECIFICATION—ELECTROMEDICAL EQUIPMENT—GENERAL REQUIREMENTS

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# PREFACE

This edition of this standard was prepared by the Association's Committee on Safety Requirements of Electromedical Equipment to supersede AS 3200—1980.

This amendment to the Standard is intended to—

- correct several requirements identified as necessary during application of the 1986 edition;
- remove critical conflicts with the requirements subsequently adopted in the 1990 edition of this Standard (likely to be numbered AS 3200.1, 1990);
- provide for the Standard, as modified by this amendment, to continue to be available for application as an alternative to the 1990 edition, for a period of two years after the date of publication of this amendment (after which time the Standard will be withdrawn).

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 3100, Definitions and General Requirements for Electrical Materials and Equipment, which prescribes the safety requirements for materials and equipment used in electrical installations complying with 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 electrodental 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.

The standard does not cover tests to be applied as acceptance tests or routine maintenance tests on equipment, such tests being specified in AS 3551.

This edition incorporates the following technical changes:

(a) The nomenclature for identifying patient-circuits has been changed to:

'Cardiac protected'—'Type CF' . . . . . (equivalent to old 'Class A'.)
'Body protected'—'Type BF' . . . . . (equivalent to old 'Class B'.)
'Unprotected'—'Type B' . . . . . (equivalent to old 'Class Z'.)

NOTE: This nomenclature aligns with AS 3003* and IEC 601.1† and compares with earlier classifications specified in previous editions of this standard (i.e. Type CF equivalent to Class A; Type BF equivalent to Class B; Type B equivalent to Class Z). In order to avoid confusion and provide necessary guidance to users of this edition of the standard, explanatory footnotes have been included on all pages referring to the new classification scheme for equipment and patient-circuits.

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* AS 3003 Electrical Installations—Patient Treatment Areas of Hospitals and Medical and Dental Practices.

† IEC 601.1 Medical Electrical Equipment, Part 1: General Requirements.

(b) Increased earth leakage current for Class I equipment when tested under the fault condition of having either supply conductor interrupted.

(c) Increased earth leakage current for Class I mobile X-ray equipment.

(d) Safety requirements for ceiling-supported equipment now permit devices other than a safety brake.

(e) The requirements for insulation of patient-circuits from earth have been clarified. This has allowed the complex explanation of investigation techniques for patient-circuit isolation/insulation to be deleted.

(f) The permissible temperature limits for accessible parts of equipment have been specified separately, depending on whether the equipment is likely to contact the patient during normal operation.

(g) The requirement for multi-pole overheating protective devices has been reduced for equipment where a single fault will not result in a hazard, e.g. double insulated components, and aligns with the philosophy of IEC 601.1*.

(h) Transformers in electromedical equipment are required to comply with AS 3208†.

(j) The illustration of the frequency response characteristic of the measuring device, Appendix D, Fig D1, has been corrected.

This standard requires reference to the following:

(a) *Standards*

AS 1169 Minimizing of Combustion Hazards Arising from the Medical Use of Flammable Anaesthetic Agents
AS 1200 SAA Boiler Code
AS 1319 Rules for the Design and Use of Safety Signs for the Occupational Environment
AS 2030 SAA Gas Cylinders Code
AS 2034 Electrical Equipment for Explosive Atmospheres—Flameproof Electric Lighting Fittings
AS 2398 Fixed Diagnostic X-ray Equipment—Design, Construction and Installation—Safety Requirements
AS 2500 Safe Use of Electricity in Patient Care
AS 3000 Rules for the Electrical Equipment of Buildings, Structures and Premises (SAA Wiring Rules)
AS 3003 Electrical Installations—Patient Treatment Areas of Hospitals and Medical and Dental Practices
IEC 601.1 Medical Electrical Equipment, Part 1: General Requirements

(b) *Approval and Test Specifications*

AS 3100 Definitions and General Requirements for Electrical Materials and Equipment
AS 3112 Plugs and Plug Sockets
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 3161 Thermostats and Energy Regulators
AS 3191 Electric Flexible Cords
AS 3201.2 Electrically-heated Incubators for Babies‡
AS 3205 Dental and Mobile Diagnostic X-ray Equipment
AS 3203 Electrocardiographs
AS 3208 Transformers in Electromedical Equipment
AS 3300 General Requirement for Household and Similar Electrical Appliances
AS 3551 Acceptance and In Service Testing of Electromedical Equipment.

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* IEC 601.1 Medical Electrical Equipment, Part 1: General Requirements.

† AS 3208 Approved and Test Specification—Transformers in Electromedical Equipment.

‡ Under revision.

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# 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 AS 2500 covers the safe application and use of equipment. In particular, the flowchart in AS 2500 provides a summary of the safe application and use of the various classifications of electromedical equipment.

STANDARDS ASSOCIATION OF AUSTRALIA

# Australian Standard

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## SECTION 1. SCOPE AND APPLICATION

**1.1 SCOPE.** This specification sets out the general safety requirements for electromedical equipment which are additional to those in AS 3100 and additional to those in such other SAA approval and test specifications as are applicable to the equipment and component parts thereof.

**1.2 APPLICATION.** This specification shall be read in conjunction with AS 3100 and with any other relevant approval and test specification.

As and when particular approval and test specifications dealing with specific features of the design, construction and testing of any particular class or type of electromedical equipment or parts thereof are issued, they shall supersede those general requirements of this specification which are specifically dealt with in the particular specification.

NOTE: Approvals authorities may at their discretion accept a manufacturer's declaration or an endorsed test report in respect to the testing of the whole machine or any part thereof.