AS 3200—1980
UDC 621.3:616.073.7:615.841

Australian Standard 3200–1980

APPROVAL AND TEST SPECIFICATION FOR ELECTROMEDICAL EQUIPMENT —GENERAL REQUIREMENTS

[Title Allocated by Defence Cataloguing Authority:
MEDICAL AND DENTAL EQUIPMENT, ELECTRICAL
(Approval and Test Specification, General Safety Requirements) . . . NSC 65 GP]

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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 Association of Physical Medicine and Rehabilitation

Australian Federation for Medical and Biological Engineering

Australian Medical Association

Australian Physiotherapy 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

Health Commission of New South Wales

Health Services Department, Tas.

Health Commission, Vic.

Hospital Electronic Engineers

Institute of Hospital Engineers

Institute of Biomedical Engineers (Australia)

Public Health Department, W.A.

Royal Australasian College of Physicians

Royal Australasian College of Surgeons

Royal Australian Nursing Federation

South Australian Health Commission

Committee EL/2, Electrical Approvals Standards, was also represented on the committee.

This standard, prepared by Committee EL/18/1, Safety Requirements of Electromedical Equipment, was approved on behalf of the Council of the Standards Association of Australia on 31 July 1980, and was published on 1 October 1980.

AUSTRALIAN STANDARD

APPROVAL AND TEST SPECIFICATION FOR ELECTROMEDICAL EQUIPMENT —GENERAL REQUIREMENTS

AS 3200–1980

First published (as AS C200)	1970
AS 3200 first published	1978
Second edition	1980

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

ISBN 0 7262 2043 3

PREFACE

This standard was prepared by the Association's Committee on Safety Requirements of Electromedical Equipment to supersede AS 3200—1978.

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 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. The tests in this standard are often destructive tests and should not be used for those purposes. A new standard is being developed to cover the need for standardized acceptance and routine maintenance testing.

During the preparation of this edition attention was given to similar work being undertaken by the International Electrotechnical Commission (IEC) to revise IEC 601.1. This edition of AS 3200 is different from IEC 601.1 in respect of the following:

(a) Whilst it provides for three classes of patient-circuit technically identical with IEC, the designations Class A, B and Z which were developed in advance of the IEC, have been retained.

NOTE: The IEC classes are designated 'CF' (equivalent to Class A), 'BF' (equivalent to Class B), and 'B' (equivalent to Class Z).

(b) It provides for low leakage equipment enclosures to be identified as Class A enclosures, 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 is continuing active participation in the IEC working committees.

This edition incorporates a number of editorial and technical amendments to the 1978 edition, including a revised flowchart for the recommended application of electromedical equipment (which provides for battery operated equipment), further advice on supply switches, and corrected specifications for the measuring device used for measurement of leakage currents. These new specifications for the measuring device have also been accepted by the IEC for incorporation in IEC 601.1.

Significant requirements not included in detail in this edition are those for transformers used in electromedical equipment. Requirements for these transformers are being developed as a separate approval and test specification, which at the time of publication of this edition 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 3161	Thermostats and Energy Regulators
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 2398	Safety Requirements for Fixed Diagnostic X-ray Equipment*
AS 3208	Transformers in Electromedical Equipment*

* In course of preparation.

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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 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.