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Australian Standard 3204—1981

APPROVAL AND TEST SPECIFICATION FOR

CARDIAC DEFIBRILLATORS

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(Approval and Test Specification, General Safety 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

Department of Health Services, Tasmania

Department of Public Works, New South Wales

Department of Veterans' Affairs

Health Commission of Victoria

Manufacturing and importing organizations

Prince Henry's Hospital, Victoria

Public Health Department, Western Australia

Royal Children's Hospital, Victoria

Royal Melbourne Hospital

Royal Prince Alfred Hospital, New South Wales

South Australian Health Commission

University of Melbourne

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PREFACE

This standard was prepared by the Association's Committee on Cardiac Equipment. It supersedes AS 3201, Part 4—1973, Approval and Test Specification for D.C. Cardiac Defibrillators.

It should be noted that this standard is one of a series of approval and test specifications issued by the Association. These approval and test specifications for individual items of electromedical equipment are supplementary to the parent approval and test specification for all electromedical equipment, i.e. AS 3200, Approval and Test Specification for Electromedical Equipment—General Requirements.

The clauses of this standard supplement or modify the corresponding clauses in AS 3200. Where the reference in the text of this standard indicates an 'addition' or 'replacement' of the relevant requirements, tests or explanation notes of AS 3200, these changes are made to the relevant text which then become part of the standard. It will be observed that when no such change is necessary, the words 'this Section of AS 3200 applies' are used.

The purpose of the series 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 is liable to be used.

The preparation of this standard was undertaken primarily to update and modify the existing standard in light of—

(a) the recent publication of the 'parent' specification for electromedical equipment, AS 3200 (see third paragraph of this Preface); and

(b) the recent draft international specification for the safety of cardiac defibrillators being developed by SC 62D of the International Electrotechnical Commission (IEC).

The revised parent specification AS 3200 (see (a)) now includes many requirements previously specified in earlier editions of the approval and test specification for cardiac defibrillators.

With regard to (b) above, the Standards Association of Australia is the Australian member body of the IEC and, through its Committee EL/18/6, is actively participating in the development of this international specification with a view to ensuring—

(i) that the international standard will, when finally published, take account of Australian safety requirements for cardiac defibrillators and our considerable experience in developing and applying such requirements; and

(ii) the maximum compatibility between the national and international safety standards for cardiac defibrillators (see Preface of AS 3200).

Significant changes from the 1974 edition of AS 3201, Part 4 include the following:

- No minimum lengths of flexible cord or patient-circuit cables are specified.
- The maximum output on external electrodes has been modified to 360 J with provision for selection of higher energy after a separate deliberate action.
- The limits previously specified for the output wave have been deleted.
- Specification of mandatory controls on the front panel of the defibrillator have been deleted.
- Synchronization requirements have been relaxed.
- The mandatory dimensional and wiring schedules for the 7-pin connector of the patient-circuit cables have been deleted.
- Provision of overcurrent protection devices and supply switches is not made mandatory in this standard.

Other significant requirements, e.g. limits for leakage current, have been incorporated in AS 3200 and reference to that specification is necessary.

Many of the changes above have resulted from the committee's desire to align, wherever possible, with the requirements for defibrillators being developed by the International Electrotechnical Commission. In particular, the Australian committee made detailed and persistent submissions to IEC/SC 62D and succeeded in having the output limitations for external and internal electrodes included.

Concerning the decision to delete output waveform characteristics, the committee was made aware of the range of different waveforms currently used for treatment of cardiac dysrhythmias. There is at present no general agreement in the medical profession on an optimum form of electrical ouput and the committee is continuing to keep the matter under review.

Regarding the provision of supply switches, the committee acknowledged that such switches may be desirable in many circumstances, but could see no justification, on the grounds of safety, for insisting that every new defibrillator in the country be provided with a supply switch.

It should be noted that Australian standards are constantly under review and that any developments in cardiac equipment, and/or research and treatment of cardiac disease which necessitate equipment design changes can be accommodated by prompt review and/or amendment of the relevant standard.

CONTENTS

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
APPROVAL AND TEST SPECIFICATION
FOR
CARDIAC DEFIBRILLATORS

SECTION 1. SCOPE AND APPLICATION

This Section of AS 3200 applies, except as follows:

ADDITION.

1.1 SCOPE. Add the following:

This specification prescribes the particular safety requirements for cardiac defibrillators, as defined in Section 2.

The specification also applies to defibrillator parts of any equipment incorporating defibrillators.

ADDITIONS.

1.2 APPLICATION. Add the following:

1.2.100 Compliance with AS 3200. This specification shall be read in conjunction with AS 3200. Unless otherwise specified or modified herein, the requirements, tests and criteria in AS 3200 shall be taken to apply to defibrillators.

1.2.101 Specific Requirements of this Specification. A defibrillator shall be deemed to comply with this specification only if it complies with all the requirements of this specification and satisfactorily passes the tests specified herein.

1.2.102 Requirements of Other Specifications. Equipment and components, e.g. flexible cords, switches, incorporated in defibrillators shall also comply with the relevant requirements of their individual approval and test specifications.

SECTION 2. DEFINITIONS

This Section of AS 3200 applies, except as follows:

ADDITIONS.

2.2 GENERAL DEFINITIONS. Add the following:

2.2.100 Cardiac defibrillator—electromedical equipment having electrodes which are externally applied to a patient's skin (external electrodes) or are directly applied to the heart (internal electrodes) for the purpose of defibrillating the heart by delivering an electrical pulse thereto.

NOTES:

1. The term 'defibrillator' is taken to include defibrillator parts incorporated in other equipment.
2. The same electrodes may be used to provide an electrocardiograph input.

2.2.101 Selected energy—the energy which the user of the defibrillator requires for a particular application and which is set by the user of the defibrillator.

2.2.102 Indicated energy—the energy which, according to the calibration of the defibrillator, is shown as being that which the defibrillator can pass as 'delivered energy'.

NOTE: 'Selected energy' and 'indicated energy' are synonymous except for defibrillators which provide an indication of delivered energy by a device which is different from that used for the selection of delivered energy.

2.2.103 Delivered energy—the energy which is passed through the patient-circuit of the defibrillator and dissipated into an impedance of specified value.

2.2.104 Firing circuit—the circuit within the defibrillator which connects the energy storage device to the patient circuit and which includes all switching connections between that storage device and the patient-circuit.

2.2.105 Synchronizer—a device allowing the defibrillator discharge to be synchronized with a specific phase of the cardiac cycle.

SECTION 3. GENERAL REQUIREMENTS

This Section of AS 3200 applies, except as follows:

REPLACEMENT. Replace Clause 3.5 with the following:

3.5 OVERCURRENT PROTECTION. Provision of an overcurrent protection device is not a mandatory requirement of this standard.

REPLACEMENT. Replace Clause 3.6 with the following:

3.6 SUPPLY SWITCH. Provision of a supply switch is not a mandatory requirement of this standard.

REPLACEMENT. Replace Clause 3.6.3 with the following:

3.6.3 Type and Provision of Indicators.

3.6.3.1 *Power indication.* Mains-powered defibrillators shall be provided with a device to visibly indicate that mains power is available at the defibrillator.

Battery-powered defibrillators shall be provided with a device to visibly indicate that the unit is switched on and that battery supply is available at the defibrillator.

Where failure of an indicator filament lamp can lead to a safety hazard, lamps specified for long life shall be used, or the supply voltage shall not exceed 80 percent of the nominal value of the lamp, or an equally effective method shall be used.

3.6.3.2 *Selection and indication of delivered energy.* The defibrillator shall be provided with means of selection and indication of the delivered energy, in joules. The selection mode may be continuous or in steps.

The arrangement shall give a clear indication of when the selected energy level has been reached, e.g. a measuring instrument or a 'charged ready' indicator.

3.6.3.3 *Battery voltage control and indicator (Battery-operated defibrillators only).*

(a) *Charge control.* Battery-operated defibrillators shall be provided with a suitable device to prevent overcharging of the batteries.

(b) *Indicator.* Battery-operated defibrillators shall be provided with a device to indicate when the battery voltage has fallen below the end point such that the requirements of this specification cannot be complied with.

REPLACEMENT. Replace Clause 3.6.5 with the following:

3.6.5 Accuracy of Output Controls and Instruments. The indicated energy and the delivered energy, when measured in accordance with Appendix AA, shall align with the selected energy subject to the following tolerances:

(a) When delivered into a 50 Ω load..... ± 4 J or ± 15 percent, whichever is the greater error.

(b) When delivered into a 25 Ω load..... ± 8 J or ± 30 percent, whichever is the greater error.

(c) When delivered into a 100 Ω load..... ± 8 J or ± 30 percent, whichever is the greater error.

ADDITIONS. Add the following:

3.6.100 Disarm Facilities. The defibrillator shall incorporate disarm facilities designed so that:

(a) The stored energy can be dissipated safely within the defibrillator without energizing the patient circuit, e.g. such as when the selected energy needs to be reduced after the storage device has been charged. This facility shall discharge the energy storage capacitor with a time constant not exceeding 10 s.

(b) In the event of failure of the supply mains, or the equipment being switched off, no energy will be available at the patient-circuit, regardless of whether the 'Defibrillate' control is operated. This requirement does not apply to defibrillators which, in the event of supply mains failure, automatically switch to operation from an internal electrical power source.

(c) Disconnection or reconnection of electrode cable connectors shall not cause the stored energy to become available at the electrode cable connector.

(d) In the event of the 'Defibrillate' control being operated with the electrodes open-circuited (i.e. not connected to a patient), the stored energy shall be automatically discharged within the defibrillator within 10 s without energizing the patient-circuit for longer than 0.1 s.

NOTE: Dissipation of the stored energy, as required in (a) to (d) above, should be within the machine, in order to prevent stored energy becoming available when the defibrillator is switched on or when the supply mains are restored.

3.6.101 Controls on Electrodes. A control shall be provided on at least one external electrode to enable the defibrillator to be discharged through the patient-circuit. If controls are on both external electrodes, the controls shall be arranged such that both must be operated before the defibrillator can discharge through the patient-circuit.

The control shall operate at potentials not exceeding extra-low voltage.

The control shall require a firm and positive action for its operation and shall be arranged to minimize the risk of inadvertent operation. The control shall be readily identifiable.

A defibrillator having provision for internal electrodes shall also be provided with a control on the front panel to enable the defibrillator to be discharged through the patient-circuit.

NOTE: Such a control on the front panel is optional for defibrillators having provision for only external electrodes.

3.6.102 Output Characteristics.

3.6.102.1 *Maximum delivered energy to external electrodes.* If a delivered energy in excess of 360 J can be selected, a means shall be provided such that an additional deliberate action is required before each charge to select any energy level greater than 360 J.

3.6.102.2 *Maximum delivered energy to internal electrodes.* If a delivered energy in excess of 100 J can be selected, a means shall be provided such that an