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Australian Standard 3207-1981

APPROVAL AND TEST SPECIFICATION FOR HAEMODIALYSIS MACHINES



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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:

Australasian Society of Nephrology
Australian Dialysis Society
Australian Kidney Foundation
Department of Veterans' Affairs
Health Commission of Victoria
Manufacturing and importing organizations
Prince Henry's Hospital, Victoria
Royal Brisbane Hospital
Royal Melbourne Hospital
South Australian Health Commission
University of New South Wales

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PREFACE

This standard was prepared by the Association's Committee on Dialysis Equipment, and incorporates requirements for the safety of haemodialysis machines.

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 purpose of the series is to specify requirements with which compliance is necessary to gain 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 is liable to be used.

The clauses of this particular standard supplement or modify the corresponding clauses in AS 3200. As stated in Clause 1.2, the requirements of a particular standard take priority, where appropriate, over those of 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 becomes part of the standard.

During preparation of this standard, the committee was made aware of the very considerable concern amongst renal physicians and surgeons in Australia that—

- (a) the current high cost of haemodialysis machines and equipment is of major concern in the provision of services to patients;
- (b) specification of unnecessary, complex accessories and monitors would further reduce the choice of equipment available and would add to the equipment cost;
- (c) physicians must be able to have use of a machine which, apart from mandatory essential safety functions, allows selection of choice of treatment;
- (d) where monitoring is provided, then physicians must be able to rely on the function/performance of such equipment; and
- (e) with the exception of those few safety devices agreed as necessary to ensure the safe operation of the equipment, the final determination of a haemodialysis machinery make-up and the choice of optional monitoring

should be the responsibility of a suitably trained physician.

The need to cater for the different 'environments' and circumstances in which haemodialysis machines are used was also recognized. In closely supervised, medically controlled environments, provision of certain alarms/monitors may not be essential and would be considered by many physicians to be superfluous. For other situations without clinical supervision, it was considered that the physician responsible for the treatment of the patient would be aware that the situation was different and may wish to use a machine with appropriate alarms/monitors.

During the deliberations, the committee also became aware of the confusion and varied interpretations of what constituted a 'monitor'. Facilities generally referred to as 'monitors' on haemodialysis equipment include a wide range of devices. For clarity, it has been necessary to separately specify provision of the following:

- (i) Automatic controls (cutouts or fail safe device/function).
- (ii) Visible and audible alarms.
- (iii) Visual display indicators ('dynamic' read-out).

Provision and function of the devices are specified in the relevant clauses of this standard, with summary tables included in Appendix AA as advisory material for information and ready reference.

However, it is stressed that the mandatory devices specified herein represent the very minimum essential for patient safety in closely supervised medical environments. Careful consideration should be given to incorporation of other individual safety devices, i.e. those specified as non-mandatory, in machines used with certain patients or in certain environments.

Attention is also drawn to the fact that a haemodialysis machine which often has the 'patient-circuit' earthed, may provide a low-impedance return path for any leakage current. In order to prevent leakage current from any appliance which may be used simultaneously in close proximity to the patient, e.g. room heater, television receiver, it is important that mains supply to these appliances also be prevented from becoming the source leakage current. To this end, this standard requires that every haemodialysis machine be marked to indicate that the machine must be operated in an area, i.e. an environment, which has the mains supply protected by an earth-leakage core-balance device. (See Clause 7.2.8.)

It should be noted that Australian standards are constantly under review and that any developments in haemodialysis machines/research/treatment can be accommodated by prompt review and/or amendment of this standard.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard

APPROVAL AND TEST SPECIFICATION FOR HAEMODIALYSIS MACHINES

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 haemodialysis machines, as defined in Section 2, which are designed for operation from extra-low voltage, low, or medium voltage power supplies. It also applies, insofar as the requirements are appropriate, to ancillary equipment which may be connected to haemodialysis machines, e.g. blood pumps, air bubble detectors.

Equipment which is not powered by and which is remote from the haemodialysis machine, e.g. video display units situated in nurses' stations, is not covered by this specification.

ADDITION.

1.2 APPLICATION. Add the following:

1.2.1 Compliance with AS 3200. This specification shall be read in conjunction with AS 3200, Approval and Test Specification for Electromedical Equipment—General Requirements.

Unless otherwise specified or modified herein, the requirements, tests and criteria in AS 3200 shall be taken to apply to haemodialysis machines.

1.2.2 Specific Requirements of This Specification. A haemodialysis machine 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.

1.2.3 Requirements of Other Specifications. Equipment and components, e.g. flexible cords, transformers, switches, incorporated in haemodialysis machines 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:

2.2.101 Dialysis—the process by which unwanted molecules and/or fluid pass through a semi-permeable membrane from an extracorporeal blood circuit into dialysing fluid and are thereby removed.

2.2.102 Dialysing fluid—a fluid containing most of the major ionic constituents of extra cellular fluid which bathes the surface of the semi-permeable dialysis membrane.

2.2.103 Dialyser—a prefabricated unit composed of semi-permeable membranes which separate blood and dialysing fluid compartments for the purpose of dialysis.

2.2.104 Haemodialysis machine—a machine designed for the purpose of dialysis by controlling and monitoring the extracorporeal circulation of blood, and the concentration, temperature and flow of dialysing fluid.

NOTE: For the purpose of this specification, the term dialysis machine is taken to refer to haemodialysis machine.

2.2.105 Arterial pressure—pressure measured in the blood line between the patient and the blood pump.

2.2.106 Venous pressure—pressure measured in the blood line between the outlet from the dialyser and the return to the patient.

2.2.107 Bypass—the process whereby dialysing fluid is directed away from (i.e. bypasses) the dialyser to protect the patient from inappropriate (e.g. incorrect temperature or concentration) dialysing fluid.

2.2.108 Blood leak—a leakage of blood within the dialyser from the blood compartment to the dialysing fluid compartment.