AS 3208—1981
UDC 621.31:621.314:615.841

Australian Standard 3208—1981

APPROVAL AND TEST SPECIFICATION FOR

TRANSFORMERS IN ELECTROMEDICAL EQUIPMENT

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

Incorporated by Royal Charter

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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)
Manufacturing and importing organizations
Public Health Department, W.A.
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
Royal Australian Nursing Federation
South Australian Health Commission
State Electricity Commission of Victoria

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

This standard, prepared by Committee EL/18/1, Safety Requirements for Electromedical Equipment, was approved on behalf of the Council of the Standards Association of Australia on 25 May 1981, and was published on 17 August 1981.

This standard was issued in draft form for public review as DR 79042.

First published 1981

ISBN 0 7262 2234 8

PREFACE

This standard was prepared by the Association's Committee on Safety Requirements for Electromedical Equipment.

It was developed following requests received during the preparation of AS 3200, Electromedical Equipment—General Requirements, for the standardization of safety requirements for transformers in electromedical equipment. These requests especially expressed concern at—

(a) the availability of transformers with very thin and/or inadequate insulation;

(b) the importance of transformers in ensuring adequate electrical safety of electromedical equipment; and

(c) the lack of any other national or international standard for these transformers.

The committee undertook very extensive investigations and consideration of overseas standards, with a view to locating a satisfactory standard, national or international, which could be adopted by cross-reference, endorsement or other means. However, the committee could not find any existing standard which it considered satisfactory or adequate for transformers in electromedical equipment and found it necessary to develop this new standard. Standards examined included those prepared by the Standards Association of Australia (AS C126 and AS C167), International Electrotechnical Commission, Underwriters Laboratories Inc., British Standards Institution, Institute of Electrical and Electronic Engineers, Canadian Standards Association, Association of German Electrical Engineers, and Telecom Australia.

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, viz AS 3200, Approval and Test Specification for Electromedical Equipment—General Requirements.

Unlike other supplementary standards in the '3200' series of approval and test specifications, this standard does not list clauses as amendments, modifications or replacements to those of the parent standard AS 3200. It is expected that the next edition of AS 3200 will be expanded to incorporate the requirements of this standard at which time this standard will become redundant.

In order to gain the widest acceptance and application of these standard requirements, the Association also approached the International Electrotechnical Commission through its Committees TC 62, SC 62A and SC 14D to undertake similar work. The IEC agreed to this request and Australia has offered this standard as a basic document for consideration.

Transformers in electromedical equipment are unique in that they operate within at least the following range of specifications:

(i) Input and output voltages from less than 1 V to in excess of 10 kV.

(ii) Voltages between windings, which are additional to the winding voltages, of between zero and many thousands of volts, both a.c. and d.c., produced by the equipment in which the transformer is installed.

(iii) Power levels from milliwatts to many kilowatts.

(iv) Input and output voltage and current waveforms of every kind.

(v) Continuous operation, operation with continuous voltage but intermittent load, and operation where both voltage and current appear only intermittently.

(vi) Some windings which should provide the equivalent of double insulation from other windings and other parts of the transformer and the equipment, and some windings which need only provide the equivalent of functional insulation.

To assist in the ready identification and understanding of the requirements appropriate to transformers in electromedical equipment, a schematic users' guide is shown on page 5. The committee has tried to ensure that the various requirements in this standard are compatible with the accepted practices of reputable local and overseas manufacturers of transformers. Ideally, transformers in imported electromedical equipment which comply with other national or IEC standards should comply with this standard.

One area of possible variance with other overseas standards for transformers is the requirement for minimum thicknesses of insulation. The insulation thicknesses specified herein generally align with those specified in the IEC draft standard 14D(Central Office)9. However, while this standard acknowledges and provides for the availability and use of sophisticated insulants much thinner than those required by other Australian standards for transformers, it does not waive all restrictions on minimum thicknesses. Overseas opinion reflected in 14D(Central Office)9 seems to provide for the waiving of all such requirements and suggests that total reliance on inspection and testing would suffice. However, as minimum insulation thickness requirements have always played a major role in Australian statutory authorities' requirements for transformers and because there are currently no satisfactory tests available to allow such total reliance, this standard includes and to a certain extent relies on minimum insulation thicknesses.

Further investigations into possible tests which may verify the long-term integrity of insulation, e.g. partial discharge tests, are being undertaken and may be considered for inclusion in the next edition of this standard.

Another area of variance from the IEC draft is the tabular and graphical method of presentation of insulation thicknesses, HV and IR testing values, and creepage and clearance distances. This standard simply recognizes two levels of insulation, functional (basic) insulation or double insulation. The required level of insulation having been determined by reference to Table 1, tests values are selected from the appropriate graphs (Figs 1 to 6).

During preparation of this standard reference was made to the following overseas standards and grateful acknowledgement is made of the assistance received therefrom:

IEC 14D drafts 14D(Central Office)7 and 14D (Central Office)9

(US) MIL-T-27D

This standard requires reference to the following Australian standards:

AS 1194	Enamelled Round Copper Winding Wires
AS 1931	High Voltage Testing Techniques
AS 3003	SAA Code for Electrical Installations in Electromedical Treatment Areas
AS 3200	Electromedical Equipment—General Requirements
AS C100	Approval and Test Specification for Definitions and General Requirements for Electrical Materials and Equipment

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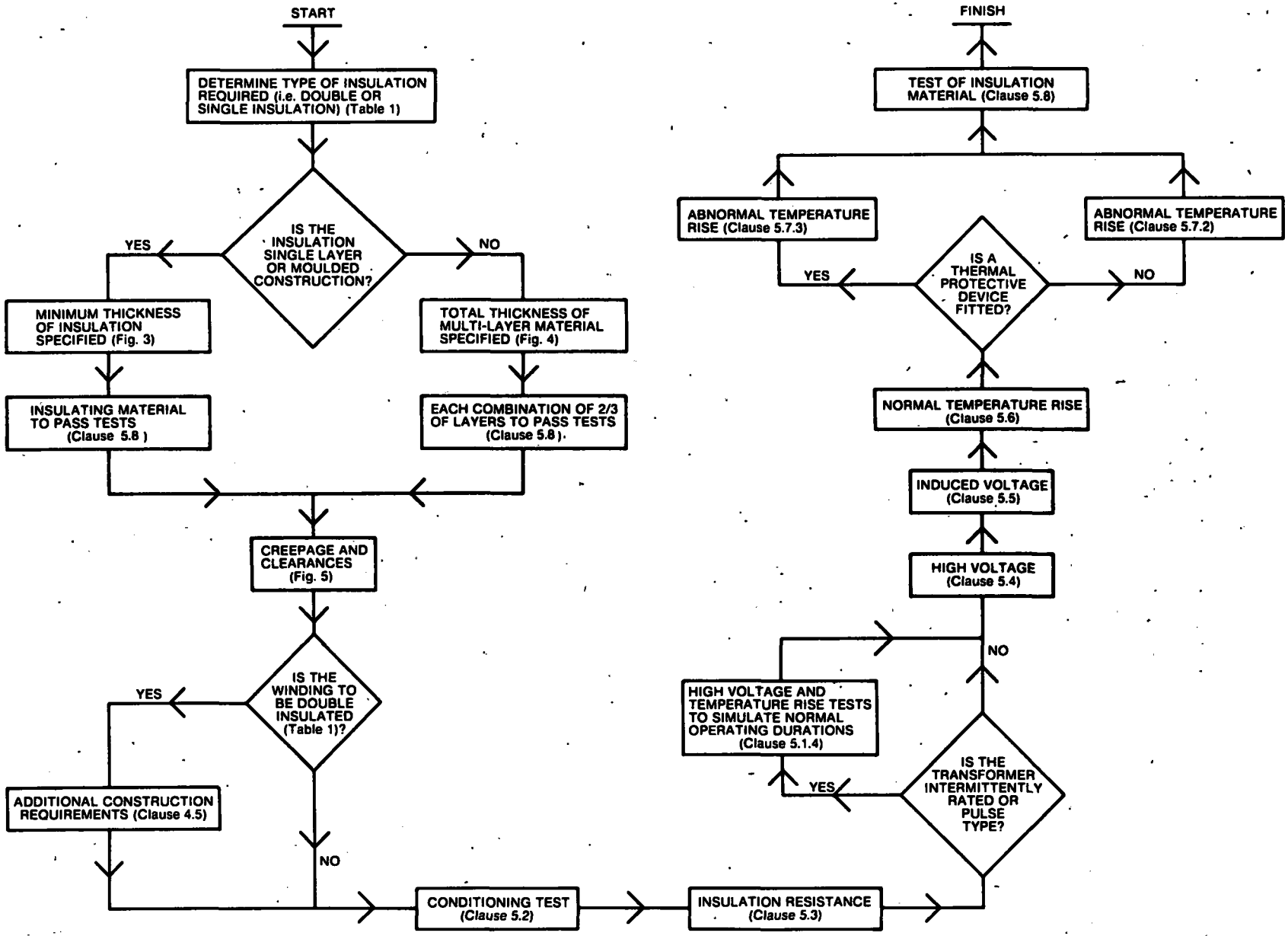
USER GUIDE—TRANSFORMER REQUIREMENTS



STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
APPROVAL AND TEST SPECIFICATION FOR TRANSFORMERS IN ELECTROMEDICAL EQUIPMENT

1 SCOPE. This specification applies to ferromagnetic transformers installed in or forming part of electromedical equipment.

The specification does not apply to—

(a) air-cored transformers;

(b) transformers not forming part of electromedical equipment but installed as part of the fixed electrical reticulation system, connected by fixed wiring and supplying power to power outlets and/or fixed electrically operated equipment; or

(c) output transformers of electrosurgical equipment.

NOTES:

1. In order to assess a transformer in terms of this specification it is necessary to identify the accessibility and function of each winding when the equipment is connected for operation under normal conditions.
2. Some of the requirements of this specification may be used for guidance for the design of special transformers not covered by this specification.
3. Requirements for isolation transformers used to reticulate protected power supplies to the fixed wiring in electromedical treatment areas are specified in AS 3003.

2 APPLICATION. Transformers shall comply with the requirements of this specification and satisfy the test requirements herein.

NOTES:

1. Approvals authorities may, at their discretion, accept a manufacturer's declaration or an endorsed test report as to the integrity of the insulation and/or construction of the transformer, whether an encapsulated transformer or otherwise.
2. The requirements of this standard can be overriden by AS 3200 or its supplementary specifications for particular types of electromedical equipment.
3. It should be recognized that any sample transformer which has been submitted to the tests prescribed in this standard should be considered as having been tested to destruction and should be discarded.

3 DEFINITIONS. For the purpose of this specification, the following definitions, in addition to the definitions in AS 3200, apply.

3.1 Transformer—a static piece of apparatus having input and output connections to winding(s) which, by electromagnetic coupling, induces voltages in the winding(s).

3.2 Accessible winding—a winding is considered to be accessible if—

(a) any bare live part of the winding or any bare conductor connected thereto can be contacted by the standard test finger described in Fig. 1 of AS C100 or by the test pin described in Fig. 8 herein; or

(b) any insulation protecting any live part of the winding or any conductor connected to a live part of the winding—

(i) is less than functional insulation, as specified in Clause 4.3 appropriate for the working voltage of the winding, or the working voltage of any other winding from which it is only functionally insulated, whichever is the greater working voltage; and

(ii) can be contacted by the standard test finger described in Fig. 1 of AS C100 or by the test pin described in Fig. 8 herein.

3.3 Inaccessible winding—a winding not accessible in terms of Clause 3.2.

3.4 Graded insulation—a winding shall be considered to incorporate graded insulation if one end of the winding is earthed or held at low voltage, and if the insulation at this end of the winding has a lower voltage rating than the insulation at the other end of the winding.

3.5 Working voltage—the maximum instantaneous peak voltage that may appear, under normal rated operating conditions, across the insulation being considered. This insulation may be between windings or between a winding and the core, housing and/or screen.

4 DESIGN AND CONSTRUCTION.

4.1 General. The transformer shall be manufactured in a substantial and workmanlike manner.

Positive means shall be employed to ensure that no turns of any winding, and no other parts of the transformer can move in such a manner as will reduce the clearance and creepage distances, or the insulation thickness, necessary to comply with the constructional and test requirements of this specification.

4.2 Type of Insulation Required. Each winding incorporated in the transformer and the conductors connected thereto shall be examined to determine whether the winding is—

(a) accessible (see Clause 3.2);

(b) inaccessible (see Clause 3.3.); and/or

(c) whether it is part of a patient circuit (see AS 3200, Clause 2.2.14).

The transformer shall then be examined with reference to Table 1 to determine whether each individual winding is to be functionally insulated or double-insulated from each other winding, the core, housing and/or screen. In order to determine the level of insulation required by Table 1, each winding is taken individually and considered as the 'winding under consideration'.