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APPROVAL AND TEST SPECIFICATION—
TRANSFORMERS IN ELECTROMEDICAL EQUIPMENT

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

Australian and New Zealand Intensive Care Society
Australian College of Physical Scientists in Medicine
Australian Electrical and Electronic Manufacturers Association
Australian Federation for Medical & Biological Engineering
Australian Medical Devices & Diagnostics Association
Australian Private Hospitals Association
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AUSTRALIAN STANDARD

APPROVAL AND TEST SPECIFICATION— TRANSFORMERS IN ELECTROMEDICAL EQUIPMENT

AS 3208—1988

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PREFACE

This Standard was prepared by the Association's Committee on Safety Requirements for Electromedical Equipment, and supersedes AS 3208—1981.

It is emphasized that this edition is not a general revision but merely incorporates alterations to Clause 5.7, plus some updating of references. These alterations provide for overload testing of transformers with multiple secondary windings, which may be of the 'fail-safe' design.

This Standard is one of a series of Approval and Test Specifications issued by the Association for individual items of electromedical equipment. These 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 AS 3200 series, 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edition of AS 3200 may be expanded to incorporate the requirements of this Standard at which time this Standard will be withdrawn.

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

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

(b) 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.

(c) Power levels from milliwatts to many kilowatts.

(d) Input and output voltage and current wave-forms of every kind.

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

(f) 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.

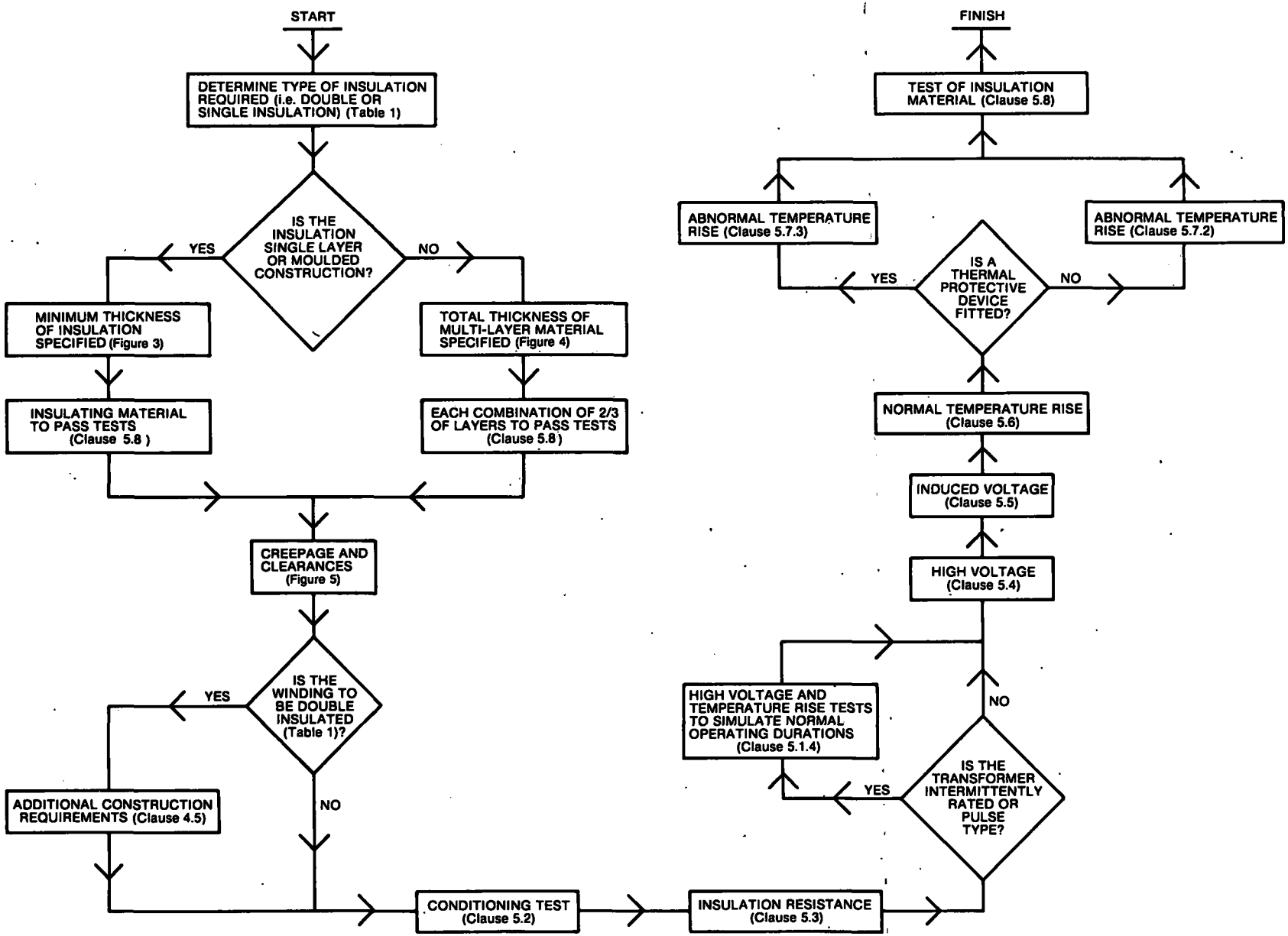
To assist in the ready identification and understanding of the requirements appropriate to transformers in electromedical equipment, a schematic users' guide is shown on page 5. The committee has tried to ensure that the various requirements in this Standard are compatible with the accepted practices 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 thickness specified herein generally align with those specified in the IEC 742, *Isolating transformers and safety isolating transformers.* 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 thickness. Overseas opinion reflected in IEC 742 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 thickness.

Further investigation 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 IEC 742 is the tabular and graphical method of presentation of insulation thickness, 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 (Figures 1 to 6).

USER GUIDE—TRANSFORMER REQUIREMENTS



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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 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.
4. This Specification also applies, as appropriate, to transformers operating at frequencies in excess of 50 Hz, e.g. switched mode power supplies.

2 APPLICATION AND REFERENCED DOCUMENTS.

2.1 Application. Transformers shall comply with 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 or construction of the transformer, whether an encapsulated transformer or otherwise.
2. The requirements of this Standard can be overridden by AS 3200 or its supplementary Specification 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.

2.2 Referenced documents. The following documents are referred to in this Standard:

AS
1194 Enamelled round copper winding wires
1931 High voltage testing techniques
3003 Electrical installations—Patient treatment areas of hospital and medical and dental practices
3100 Approval and Test Specification for definitions and general requirements for electrical materials and equipment
3200 Approval and Test Specification—Electromedical equipment—General requirements

3 DEFINITIONS. For the purpose of this Specification, definitions given in AS 3200 and those below 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 Figure 1 of AS 3100 or by the test pin described in Figure 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 Figure 1 of AS 3100 or by the test pin described in Figure 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 a 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 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 to it shall be examined to determine whether the winding is—

(a) accessible (see Clause 3.2);

(b) inaccessible (see Clause 3.3); or

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