AS 3200.2.19—1992
IEC 601-2-19:1990

Australian Standard®

Medical electrical equipment

Part 2.19: Particular requirements for safety—Baby incubators (nursing)

[IEC title: Medical electrical equipment
Part 2: Particular requirements for safety of baby incubators]

This Australian Standard was prepared by Committee HT/19, Baby Incubators/Infant Care Units. It was approved on behalf of the Council of Standards Australia on 18 August 1992 and published on 21 December 1992.

The following interests are represented on Committee HT/19:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Chamber of Commerce and Industry
Australian College of Paediatrics
Australian Federation for Medical and Biological Engineering
Australian Nursing Federation
Department of Health, Housing and Community Services
Department of Health, N.S.W.
Health Department, Vic.
Institute of Hospital Engineering Australia
Medical Industry Association of Australia
Monash Medical Centre
Newborn Emergency Transport Service
Queensland Health
South Australian Health Commission
Standards New Zealand

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PREFACE

This Standard was prepared on behalf of the Standards Australia Multitechnics Standards Policy Board to supersede in part AS 3201.2—1971, *Approval and test specification for electro-medical equipment,* Part 2: *Electrically heated incubators for babies.* It is technically equivalent to and has been reproduced from IEC 601-2-19:1990, *Medical electrical equipment,* Part 2: *Particular requirements for safety of baby incubators.*

The Standard is one of a series of Approval and Test Specifications issued by Standards Australia for individual items of medical electrical equipment. It is supplementary to AS 3200.1—1990, *Approval and test specification —Medical electrical equipment,* Part 1: *General requirements for safety.* Only safety matters and closely aligned conditions are covered by this series. In some instances, however, these are more stringent than for most electrical appliances because of the additional requirements necessary to ensure the safety of the patient, and because of the environmental conditions, e.g. high humidity and hazardous locations, in which some equipment is likely to be used.

The International Standard IEC 601-2-19 modifies and supplements the corresponding clauses of IEC 601-1:1977, *Safety of medical electrical equipment,* Part 1: *General requirements,* first edition. This has since been revised and published as IEC 601-1:1988, *Medical electrical equipment,* Part 1: *General requirements for safety,* second edition. The second edition has been adopted as the Australian Standard AS 3200.1—1990, *Approval and test specification—Medical electrical equipment,* Part 1: *General requirements for safety,* hereinafter referred to as the General Standard.

In order that IEC 601-2-19 and the General Standard are compatible, the titles of the following sections, clauses and subclauses have been amended:

i) Sections 2; 6; 7; 8; and 9.
ii) Clauses 10; 24; and 55.
iii) Subclause 56.6.

The clauses of this Particular Standard supplement or modify the corresponding clauses in AS 3200.1—1990. As stated in Clause 1.3 of AS 3200.1—1990, the requirements of a Particular Standard take priority, where appropriate, over those of AS 3200.1—1990. Where the reference in the text of this Standard indicates an ‘amendment’, ‘addition’ or ‘replacement’ of the relevant requirements, tests or explanatory notes of AS 3200.1—1990, these changes are made to the relevant text which then becomes part of the Standard.

Subclauses or figures which are additional to the General Standard are numbered starting from 101, additional appendices are indicated by a sequence of double capitals e.g. AA), BB), and additional items are denoted by an aa), bb), ... sequence.

In some parts of this series the Australian requirements differ from the IEC specifications. To accommodate Australian conditions and well-accepted safety practices, a marginal bar is placed alongside the IEC text, and Appendix ZZ details the Australian specifications and rationale for the deviations.

In addition, an Australian Appendix has been developed (Appendix TT) which lists acceptable tolerances for measurements not otherwise specified in the main text of this Standard.

In the text of this Standard, the following print types are used:

- Requirements, compliance with which can be tested, and definitions: . . . . . in roman type.
- Explanations, advice, introductions, general statements, exceptions and references . . . . . in smaller roman type .
- Headings of subclauses and test specifications . . . . . *in italic type.*
- Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index . . . . . IN SMALL CAPITALS.
- An asterisk is placed before each clause for which rationale is included in Appendix AA.

This Standard requires reference to other Standards which are detailed in Appendix LL.

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