

Australian Standard®

Medical electrical equipment

Part 2.20: Particular requirements for safety—Baby incubators (transport)

[IEC title: Medical electrical equipment
Part 2: Particular requirements for safety of transport 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.
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**Part 2.20: Particular requirements
for safety—Baby incubators
(transport)**

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PREFACE

This Standard was prepared on behalf of the Standards Australia Multitechnics Standards Policy Board to supersede 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 601-2-20:1990, *Medical electrical equipment, Part 2: Particular requirements for safety of transport 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 601-2-20 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 601-2-20 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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CONTENTS

SECTION ONE — GENERAL

1. Scope and object	5
2. Terminology and definitions	5a
3. General requirements	6
4. General requirements for tests	6
5. Classification	7
6. Identification, marking and documents	7
7. Power input	9

SECTION TWO - ENVIRONMENTAL CONDITIONS

10. Environmental conditions	10
--	----

SECTION THREE - PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

20. Dielectric strength	10
-----------------------------------	----

SECTION FOUR - PROTECTION AGAINST MECHANICAL HAZARDS

21. Mechanical strength	10
22. Moving parts	11
23. Surfaces, corners and edges	11
24. Stability in NORMAL USE	12

SECTION FIVE - PROTECTION AGAINST HAZARDS FROM UNWANTED OR
EXCESSIVE RADIATIONSECTION SIX - PROTECTION AGAINST HAZARDS OF IGNITION
OF FLAMMABLE ANAESTHETIC MIXTURESSECTION SEVEN - PROTECTION AGAINST EXCESSIVE TEMPERATURES,
AND OTHER SAFETY HAZARDS

42. Excessive temperatures	14
43. Fire prevention	14
44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	15
45. Pressure vessels and parts subject to PRESSURE	16
46. Human errors	16
49. Interruption of the power supply	17

SECTION EIGHT - ACCURACY OF OPERATING DATA AND
PROTECTION AGAINST HAZARDOUS OUTPUT

50. Accuracy of operating data	17
51. Protection against hazardous output	20

SECTION NINE - ABNORMAL OPERATION AND FAULT CONDITIONS;
ENVIRONMENTAL TESTS

SECTION TEN - CONSTRUCTIONAL REQUIREMENTS

54. General	20
55. ENCLOSURES and covers	21
56. Components and general assembly	21

SECTION ELEVEN - ADDITIONAL REQUIREMENTS

101.	Alarms	22
102.	Sound pressure level	24
103.	Humidifying unit	24
104.	Maximum air velocity in the enclosure	24
105.	Concentration of carbon dioxide (CO ₂)	24
106.	Provision of oxygen	25
107.	Electrical power supply	25
ANNEX AA—GENERAL GUIDANCE AND RATIONALE		28
APPENDIX LL—REFERENCES—PUBLICATIONS MENTIONED IN THIS STANDARD .		33
APPENDIX TT—TOLERANCES FOR APPLICATION IN AUSTRALIA		33
APPENDIX ZZ—AMENDMENTS TO IEC 601-2-20 FOR APPLICATION IN AUSTRALIA		34

STANDARDS AUSTRALIA

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SECTION ONE—GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard specifies safety requirements for TRANSPORT INCUBATORS, as defined in 2.1.101 of this standard.

This standard does not apply to BABY INCUBATORS (see IEC 601-2-19).

1.2 Object

Addition:

The object of this Particular Standard is to establish requirements for TRANSPORT INCUBATORS, which minimize hazards to PATIENT and USER, and to specify tests by which compliance with the requirements can be verified.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 601-1: 1988, *Medical electrical equipment — Part 1: General requirements for safety* with its amendments 1 (1991) and 2 (1995).

For brevity, IEC 601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirements”.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over the corresponding General Requirement(s).