AS 60601.2.20:2018

Australian STANDARD

Medical electrical equipment

Part 2.20: Particular requirements for the basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2016 (ED. 2.1) MOD)

STANDARDS Australia

AS 60601.2.20:2018

This Australian Standard® was prepared by HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 27 June 2018.

This Standard was published on 23 July 2018.

The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australian and New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Biomedical College, Engineers Australia
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This Standard was issued in draft form for comment as DR AS 60601.2.20:2018.

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ISBN 978 1 76072 147 3

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First published as AS 60601.2.20:2018.

Published by SAI Global Pty Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia.

Preface

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify safety requirements for infant transport incubators.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-20:2009+AMD1:2016 (ED. 2.1), *Medical electrical equipment, Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators.* The modifications are additional requirements and are set out in Appendix ZZ, which has been added at the end of the source text. Appendix ZZ lists the variations for the application of this Standard in Australia.

As this document has been reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms 'normative' and 'informative' are used in Standards to define the application of the appendices or annexes to which they apply. A 'normative' appendix or annex is an integral part of a Standard, whereas an 'informative' appendix or annex is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

FOREWORD

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This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-20 bears the edition number 2.1. It consists of the second edition (2009-02) [documents 62D/731/FDIS and 62D/757/RVD], its corrigendum 1 (2012-02), its corrigendum 2 (2013-02) and its amendment 1 (2016-04) [documents 62D/1325/FDIS and 62D/1346/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-2-20 has been prepared by IEC Subcommittee 62D Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-20 published in 1990 and its Amendment 1 (1996). This edition constitutes a technical revision. This edition of IEC 60601-2-20 was revised to structurally align with the 2005 edition of IEC 60601-1.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT TRANSPORT INCUBATOR equipment.

This particular standard amends and supplements IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows*:*

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT TRANSPORT INCUBATOR equipment, as defined in 201.3.211 of this standard, also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT TRANSPORT INCUBATORS but alternate methods of compliance with a specific clause by demonstrating equivalent safety will not be judged as non compliant if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

– devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information see IEC 80601-2-35 [1][1)];
– INFANT INCUBATORS which are not INFANT TRANSPORT INCUBATOR; for information see IEC 60601-2-19 [2];
– INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [3];
– INFANT PHOTOTHERAPY; for information, see IEC 60601-2-50 [4].

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT TRANSPORT INCUBATORS as defined in 201.3.211, which minimize HAZARDS to the PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

1) Figures between square brackets refer to the Bibliography.