AS/NZS IEC 60601.2.21:2015
IEC 60601-2-21, Ed.2.0 (2009)
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AS/NZS IEC 60601.2.21:2015

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.21: Particular requirements for the basic safety and essential performance of infant radiant warmers

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 12 October 2015 and on behalf of the Council of Standards New Zealand on 2 October 2015.
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The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.21: Particular requirements for the basic safety and essential performance of infant radiant warmers

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.21:1994, *Approval and test specification—Medical electrical equipment,* Part 2.21: *Particular requirements for safety—Infant radiant warmers*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for endoscopic equipment. The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1.

This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015, which is an identical adoption of IEC 60601-1, Ed.3.1 (2012) and is referred to in the source text as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-21, Ed.2.0 (2009), *Medical electrical equipment,* Part 2-21: *Particular requirements for the basic safety and essential performance of infant radiant warmers*, and its Corrigendum 1 (2013), which has been added at the end of the source text.

As this Standard is reproduced from an International Standard, the following applies:

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

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

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

CONTENTS

IEC FOREWORD

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 particular 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.

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 RADIANT WARMER equipment.

This particular standard amends and supplements IEC 60601-1:2005, *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.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.21:
Particular requirements for the basic safety and essential performance of infant radiant warmers

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT RADIANT WARMERS as defined in 201.3.204, 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 the safety requirements for INFANT RADIANT WARMERS, 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;
– INFANT INCUBATORS; for information see IEC 60601-2-19;
– INFANT TRANSPORT INCUBATORS, for information see IEC 60601-2-20;
– INFANT PHOTOTHERAPY EQUIPMENT, for information see IEC 60601-2-50.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT RADIANT WARMERS as defined in 201.3.204, which minimize HAZARDS to PATIENT and OPERATOR, and to specify tests by which compliance with the requirements can be verified.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*