AS/NZS IEC 60601.2.2:2016
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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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 1 February 2016 and on behalf of the Council of Standards New Zealand on 21 January 2016.
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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
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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.

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.2:2015.

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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 3200.2.2:1999, *Medical electrical equipment*, Part 2.2: *Particular requirements for safety—High frequency surgical equipment*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for medical electrical equipment, including associated accessories intended for the performance of surgical operations, such as, the cutting or coagulation of biological tissues by means of high frequency currents.

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 referred to in the source document as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-2, Ed.5.0 (2009), *Medical electrical equipment*, Part 2-2: *Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*, and its Corrigendum 1 (2014), 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.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS IEC	
61000	Electromagnetic compatibility (EMC)	61000	Electromagnetic compatibility (EMC)
61000-4-3	Part 4-3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test	61000.4.3	Part 4.3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test
61000-4-6	Part 4.6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields	61000.4.6	Part 4.6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields
CISPR		AS/NZS CISPR	
11	Industrial, scientific and medical (ISM) radio-frequency equipment—Electromagnetic disturbance characteristics—Limits and methods of measurement	11	Industrial, scientific and medical (ISM) radio-frequency equipment—Electromagnetic disturbance characteristics—Limits and methods of measurement

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

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

Page

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 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 high frequency surgical equipment.

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the 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.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.2:
Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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 HF SURGICAL EQUIPMENT as defined in 201.3.222.

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W (for example for micro-COAGULATION, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this particular standard. These exemptions are indicated in the relevant requirements.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HF SURGICAL EQUIPMENT as defined in 201.3.222.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-8 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11[2)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

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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.*

2) IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* (in preparation).