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Australian STANDARD

Medical electrical equipment

Part 2.22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

STANDARDS Australia

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- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Dental Association
- Australian Society of Anaesthetists
- College of Biomedical Engineering Engineers Australia
- Department of Defence (Australia)
- Medical Technology Association of Australia
- Testing and Certification Interests
- Therapeutic Goods Administration

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Medical electrical equipment

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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 3200.2.22:1997, *Medical electrical equipment*, Part 2-22: *Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser 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 set out requirements for the basic safety and essential performance of laser equipment for surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications, intended use on humans or animals, classified as a Class 3B or Class 4 laser product as defined by 3.22 and 3.23 in IEC 60825-1, hereafter referred to as laser equipment.

This Standard is identical with, and has been reproduced from IEC 60601-2-22:2012, *Medical electrical equipment*, Part 2-22: *Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*.

This Document is the consolidated version of IEC 60601-2-22, which consists of the third edition (2007) and its amendment 1 (2012). The technical content is identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

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 Standard*	
IEC		AS/NZS	
60825	Safety of laser products	60825	Safety of laser products
60825-1	Part 1: Equipment classification and requirements	60825.1	Part 1: Equipment classification and requirements
60947	Low-voltage switchgear and controlgear	3947	Low-voltage switchgear and controlgear
60947-3	Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	3947.3	Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units
61010	Safety requirements for electrical equipment for measurement, control and laboratory use	61010	Safety requirements for electrical equipment for measurement, control and laboratory use

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

INTRODUCTION

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*).

This standard also refers to IEC 60825-1 (2007).

The requirements of this standard are the minimum that need to be complied with, in order to achieve a reasonable level of safety and reliability during operation and application of medical laser equipment.

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. Understanding of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revisions necessitated by changes in clinical practice or by developments in technology.

AUSTRALIAN STANDARD

Medical electrical equipment

Part 2.22:
Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

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 laser equipment for either surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications, intended for its use on humans or animals, classified as a CLASS 3B or CLASS 4 LASER PRODUCT as defined by 3.22 and 3.23 in IEC 60825-1, hereafter referred to as LASER EQUIPMENT.

Throughout this International Standard, light emitting diodes (LED) are included whenever the word “laser” is used.

NOTE 1 Refer to Definition 3.49 in IEC 60825-1.

NOTE 2 Laser products for these applications classified as a CLASS 1, 1M, 2, 2M or CLASS 3R LASER PRODUCT, are covered by IEC 60825-1 and IEC 60601-1.

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 standard can also be applied to surgical, cosmetic, therapeutic and diagnostic laser equipment used for compensation or alleviation of disease, injury or disability.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the safety of surgical, cosmetic, therapeutic and diagnostic laser equipment.

NOTE Laser classification (IEC 60825-1) must not be confused with electrical classification (IEC 60601-1).