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Australian STANDARD

Medical electrical equipment

Part 2.57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

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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PREFACE

This Standard was prepared by the 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 set out requirements for the basic safety and essential performance of equipment incorporating one or more sources of optical radiation in the wavelength range 200 nm to 3000 nm, with the exception of laser radiation, intended to create non-visual photobiological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications; hereafter referred to as light source equipment (LS EQUIPMENT).

This Standard is identical with, and has been reproduced from IEC 60601-2-57:2011, *Medical electrical equipment*, Part 2-57: *Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*.

IMPORTANT—This document contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

As this Standard is 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.

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	
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
		AS/NZS IEC	
62471	Photobiological safety of lamps and lamp systems	62471	Photobiological safety of lamps and lamp systems

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

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INTRODUCTION

This particular standard amends and supplements IEC 60601-1:2005 (third edition): *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*.

The requirements of this particular standard should be taken as the minimum to comply with, in order to achieve a reasonable level of safety and reliability during operation and application of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

An asterisk (*) notes clauses for which there is rationale comment in Annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of this particular standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

AUSTRALIAN STANDARD

Medical electrical equipment

Part 2.57:
Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

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 BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment incorporating one or more sources of OPTICAL RADIATION in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and intended to create non-visual photobiological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications; hereafter referred to as light source equipment (LS EQUIPMENT).

This particular standard does not apply to equipment for sun tanning, for ophthalmic instruments or for infant phototherapy.

NOTE Safety requirements in this particular standard are intended to address only HAZARDS to the eye and skin; hazards to internal tissues are not included in its scope.

LS EQUIPMENT may consist of a single or multiple sources of OPTICAL RADIATION, with or without power supply, or may be incorporated into a complex system that includes optical, electrical or mechanical systems or sources of other radiation.

NOTE Annexes AA to EE have been included for purposes of general guidance and to illustrate many typical cases. However, the annexes should not be regarded as definitive or exhaustive.

201.1.2 Object

Replacement:

The objects of this particular standard are:

– to establish optical radiation safety, basic safety and essential performance requirements for LS EQUIPMENT;

– to specify requirements for the MANUFACTURER to supply information and establish procedures so that proper precautions can be adopted;

– to provide warning to individuals of HAZARDS associated with accessible OPTICAL RADIATION from LS EQUIPMENT through signs, labels and instructions;

– to reduce the possibility of injury by minimizing unnecessary accessible OPTICAL RADIATION; to provide means of improved control of the HAZARDS related to OPTICAL RADIATION through protective features and to assist safe use of LS EQUIPMENT;

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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.*

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