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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

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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 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*.

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

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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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