

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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AS IEC 60601.2.57:2014

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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.

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- (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 60947	Low-voltage switchgear and controlgear	AS/NZS 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
62471	Photobiological safety of lamps and lamp systems	AS/NZS 62471	IEC 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.

CONTENTS

201.1	Scope, object and related standards			
201.2	Normative references	10		
201.3	Terms and definitions	10		
201.4	General requirements	13		
201.5	General requirements for testing ME EQUIPMENT	13		
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	13		
201.7	ME EQUIPMENT identification, marking and documents	15		
201.8	Protection against electrical HAZARDS from ME EQUIPMENT			
201.9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS			
201.10	Protection against unwanted and excessive radiation HAZARDS			
201.11	Protection against excessive temperatures and other HAZARDS			
201.12	Accuracy of controls and instruments and protection against hazardous outputs	21		
201.13	HAZARDOUS SITUATIONS and fault conditions	22		
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	23		
201.15	Construction of ME EQUIPMENT	23		
201.16	ME SYSTEMS	23		
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	23		
Annexes		23		
Annex AA	A (informative) Particular guidance and rationale	24		
	3 (informative) Exposure limit values			
Annex Co	C (informative) Protective eyewear for LS EQUIPMENT	30		
Annex DI	O (informative) Summary of MANUFACTURER'S requirements	31		
Annex EE	(informative) Symbols on marking	32		
•	phy			
Index of o	defined terms used in this particular standard	34		
Figure 20	01.101 – Example of explanatory label for a device with multiple наzаrd regions	18		
-	11.102 – Warning label – Hazard symbol			
	1.101 – EMISSION LIMITS for risk groups of LS EQUIPMENT			
	1.102 – Risk group time base criteria for classification of LS EQUIPMENT	15		
emission	1.103 – Applicable ANGLE OF ACCEPTANCE for the assessment of accessible from LS EQUIPMENT	15		
	1.104 – Requirements for labelling of LS EQUIPMENT according to risk group tion	17		
Table BB	.1 – Exposure limit values for non-coherent optical radiation	26		
Table BB	$.2 - S(\lambda)$ [dimensionless], 200 nm to 400 nm	28		
Table BB	$.3-B~(\lambda),~R~(\lambda)$ [dimensionless], 300 nm to 1 400 nm	29		



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