

AS IEC 60601.2.57:2014
IEC 60601-2-57:2011

AS IEC 60601.2.57:2014



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**



This Australian Standard® was prepared by Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 10 September 2014.

This Standard was published on 2 October 2014.

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
-

This Standard was issued in draft form for comment as DR AS IEC 60601.2.57:2014.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

Keeping Standards up-to-date

Australian Standards® are living documents that reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued.

Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments that may have been published since the Standard was published.

Detailed information about Australian Standards, drafts, amendments and new projects can be found by visiting www.standards.org.au

Standards Australia welcomes suggestions for improvements, and encourages readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to Standards Australia, GPO Box 476, Sydney, NSW 2001.

AS IEC 60601.2.57:2014

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

First published as AS IEC 60601.2.57:2014.

COPYRIGHT

© Standards Australia Limited

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968.

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 1 74342 850 4

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:

<i>Reference to International Standard</i>	<i>Australian/New Zealand Standard</i>
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.

CONTENTS

201.1	Scope, object and related standards.....	8
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	19
201.9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	20
201.10	Protection against unwanted and excessive radiation HAZARDS.....	20
201.11	Protection against excessive temperatures and other HAZARDS.....	21
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 (informative)	Particular guidance and rationale.....	24
Annex BB (informative)	Exposure limit values	26
Annex CC (informative)	Protective eyewear for LS EQUIPMENT	30
Annex DD (informative)	Summary of MANUFACTURER'S requirements	31
Annex EE (informative)	Symbols on marking.....	32
Bibliography	33
Index of defined terms used in this particular standard.....		34
Figure 201.101 – Example of explanatory label for a device with multiple HAZARD spectral regions		18
Figure 201.102 – Warning label – HAZARD symbol.....		19
Table 201.101 – EMISSION LIMITS for risk groups of LS EQUIPMENT		14
Table 201.102 – Risk group time base criteria for classification of LS EQUIPMENT		15
Table 201.103 – Applicable ANGLE OF ACCEPTANCE for the assessment of accessible emission from LS EQUIPMENT		15
Table 201.104 – Requirements for labelling of LS EQUIPMENT according to risk group classification.....		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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- Looking for additional Standards? Visit Intertek Inform Infostore
 - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-