Australian/New Zealand Standard™

Medical electrical equipment

Part 2.41: Particular requirements for safety—Surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2000, MOD)

Standards Australia

STANDARDS NEW ZEALAND

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 November 2001 and on behalf of the Council of Standards New Zealand on 16 November 2001. It was published on 6 February 2002.

The following interests are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
College of Biomedical Engineering, Institution of Engineers Australia
Department of Defence (Australia)
Commonwealth Department of Health and Aged Care
Medical Industry Association of Australia
Ministry of EconomicDeveopment, New Zealand
Royal Australasian College of Radiologists

Keeping Standards up-to-date

Standards are living documents which 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 Standards may also be withdrawn.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 which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Australia web site at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 00169.

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.41: Particular requirements for safety— Surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2000, MOD)

First published as AS/NZS 3200.2.41:2002.

Jointly published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 4246 7

PREFACE

This Standard was prepared by the Joint Standards Australia/New Zealand Committee HE-003, Medical Electrical Equipment.

This Particular Standard has been reproduced, with national modifications, from IEC 60601-2-41:2000, *Medical electrical equipment*, Part 2-41: *Particular requirements for the safety of surgical luminaires and luminaires for diagnosis* which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment*, Part 1: *General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998 and is hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for the design and manufacture of medical electrical equipment which makes physical or electrical contact with the patient. A Particular Standard details additional safety requirements for a medical device, or related group of medical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

It is recommended that, to interpret a Particular Standard or a Collateral Standard, a copy of the General Standard should be readily available.

Appendix ZZ lists the variations between this Standard and IEC 60601-2-41:2000. These changes are indicated by a rule in the margin against each Clause affected.

In the text of this Standard, the following fonts are used:

(a) Requirements, compliance with which can be tested, and definitions

..... in large roman type

(b) Explanations , advice, introductions, general statements, exceptions, references

..... in smaller roman type

(c) Headings, of sub-clauses and test specifications

.....*in italic type*

(d) Terms used throughout the Standard, which have been defined in Clause 2

..... IN SMALL CAPITALS

An asterisk (*) is placed before each Clause for which rationale is included in Annex AA.

As this publication has been reproduced from an international Standard, the following modifications apply:

(i) Its number does not appear on each page and its identity is shown on the cover and title page.

(ii) The words: ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ where ever they appear.

(iii) The substitution of a full point (.) for a comma (,) where it appears as a decimal marker.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex or appendix to which they apply. A ‘normative’ annex or appendix is an integral part of a Standard, whereas an ‘informative’ annex or appendix is only for information and guidance.

Some pages of the original which related to IEC administrative matters, do not appear in this version.

The references to International Standards should be replaced by references to the following Australian or Australian/New Zealand Standards:

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-2-18	Part 2.18: Particular requirements for the safety of endoscopic equipment	3200.2.18	Part 2.18: Particular requirements for safety—Endoscopic equipment

NOTE: Only those referenced Standards (see Annex L) adopted as Australian/New Zealand are listed above.

CONTENTS

Page

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTRODUCTION

This Particular Standard concerns the safety of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled *"Medical electrical equipment – Part 1: General requirements for safety."*

A "Guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) inserted before a clause or subclause number indicates that some explanatory notes are given in annex AA at the end of this Particular Standard.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.43:
Particular requirements for safety—Surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2000, MOD)

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows.

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard details the requirements to be applied to SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 2.101 to 2.105, hereinafter referred to as EQUIPMENT.

This standard does not apply to

– headlights,
– endoscopes, laparoscopes and their light sources, which are covered by IEC 60601-2-18,
– luminaires used in dentistry, which are covered by ISO 9680,
– luminaires for general purposes, which are covered by IEC 60598-2-1 and IEC 60598-2-4,
– luminaires of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE Luminaires used in clinical areas of hospitals other than those defined in 2.101 to 2.105 are covered by IEC 60598-2-25.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s).