AS/NZS IEC 60601.2.41:2022
IEC 60601-2-41:2021

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

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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 21 May 2022 and by the New Zealand Standards Approval Board on 1 June 2022.

This Standard was published on 17 June 2022.

The following are represented on Committee HE-003:

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This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.41:2022.

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Medical electrical equipment

Part 2.41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

Originated as AS/NZS 3200.2.41:2002.
Revised and redesignated as AS/NZS IEC 60601.2.41:2022.

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Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.41:2002, *Medical electrical equipment, Part 2.41: Particular requirements for safety — Surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2000, MOD).*

The objective of this document is to specify requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis, hereafter referred to as ME equipment.

This particular document does not apply to the following:

(a) Headlights.

(b) Endoscopes, laparoscopes, and their light sources, which are covered by AS/NZS IEC 60601.2.18.

(c) Luminaires used in dentistry, which are covered by ISO 9680.

(d) Luminaires for general purposes, which are covered by AS/NZS 60598.2.1 and AS 60598.2.4.

(e) Luminaires dedicated to therapeutic purposes.

(f) Special purpose lights with different conditions of use such as light sources intended solely for decontamination of air and surfaces, UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems.

(g) Lights connected to surgical instruments, such as luminous retractors.

(h) Luminaires for emergency lighting, which are covered by AS 60598.2.22.

Surgical luminaires and luminaires for diagnosis are medical devices, not general lighting equipment.

This document is identical with, and has been reproduced from, IEC 60601-2-41:2021, *Medical electrical equipment — Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis.*

As this document has been reproduced from an International document, the following apply:

(i) In the source text “this part of 60601” should read “this document”.

(ii) A full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 60601-2-41 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

An annex in this publication contains an embedded Microsoft Excel file intended to help in organizing data and calculating exposures associated with photobiological HAZARDS. This file is intended to be used as a complement and does not form an integral part of the publication.

This third edition cancels and replaces the second edition published in 2009 and Amendment 1:2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) revised the statement of essential performance;
b) added exposure limits, test conditions, calculation methods and safety warnings related to photobiological hazards;
c) removed the terms “MINOR SURGICAL LUMINAIRES” and “MAJOR SURGICAL LUMINAIRES”;

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d) added definitions of MAXIMUM ILLUMINANCE DISTANCE and REFERENCE DISTANCE and allowed MANUFACTURERS to measure some performance characteristics at the REFERENCE DISTANCE that they specify;

e) replaced the region of acceptable chromaticity in (x,y) colour space with a requirement for $D_{u,v}$;

f) added a requirement for acceptable drift of the lighthead when attached to the suspension system;

g) added a requirement for fluid ingress protection;

h) revised Table 201.101 of IEC 60601-2-41:2009 and IEC 60601-2-41:2009/AMD1:2013 and moved it to Annex BB;

i) specified a new device for measuring SHADOW DILUTION in a simulated cavity;

j) specified test conditions for luminaires equipped with distance sensors.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1859/FDIS	62D/1879/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type*;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

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The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific publication. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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INTRODUCTION

This particular standard concerns the basic safety and essential performance of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

It amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, hereinafter referred to as the "general standard".

The requirements of this particular standard take priority over those of the general standard.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

This particular 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 dedicated to therapeutic purposes;
– special purpose lights with different conditions of use such as light sources intended solely for decontamination of air and surfaces, UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems;
– lights connected to surgical instruments, such as luminous retractors;
– luminaires for emergency lighting, which are covered by IEC 60598-2-22.

NOTE See also 4.2 of the general standard.

SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS are medical devices and not general lighting equipment.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 201.3.

---

1 The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

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201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards are specified using the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, since definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to refer to the general standard, any applicable collateral standards and this particular standard taken together.

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Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

ISO/CIE 11664-1, *Colorimetry – Part 1: CIE standard colorimetric observers*

ISO/CIE 19476:2014, *Characterization of the performance of illuminance meters and luminance meters*

ANSI C78.377:2017, *Specifications for the Chromaticity of Solid State Lighting (SSL) Products*

CIE 13.3:1995, *Method of Measuring and Specifying Colour Rendering Properties of Light Sources*

CIE 15:2018, *Colorimetry*

Replacement:

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-6:2014, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and the following apply:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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NOTE An index of defined terms is found on page 55.

201.3.63
MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT

Addition:

NOTE 101 See Figure 201.101 as an example of possible ways in which power can be supplied to a SURGICAL LUMINAIRE.

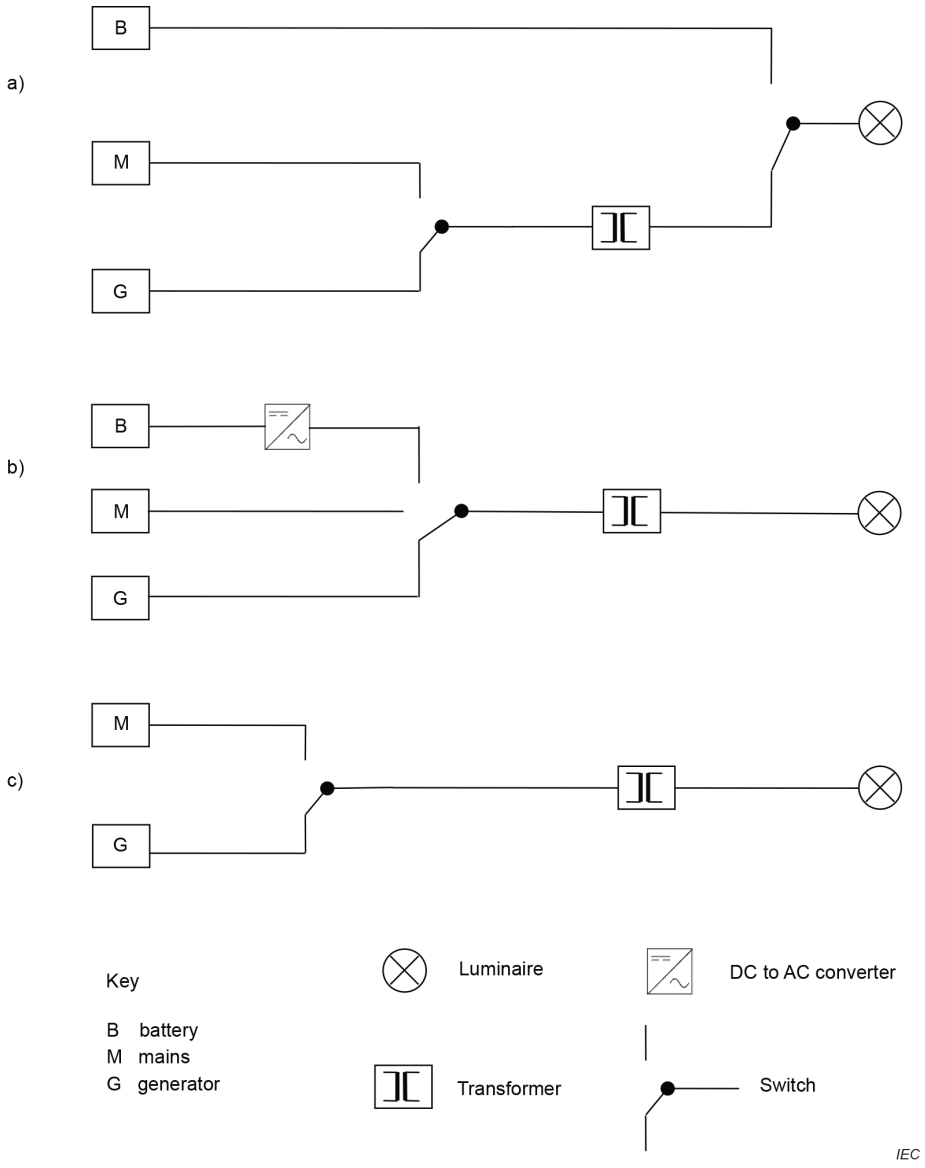

Figure 201.101 – Examples of providing power to a SURGICAL LUMINAIRE

Additional terms and definitions:

201.3.201
CENTRAL ILLUMINANCE
$E_{C,Ref}$
illuminance at the REFERENCE DISTANCE (D_{Ref}) at the LIGHT FIELD CENTRE (LFC)

SEE: Figure 201.102.

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201.3.202
DEPTH OF ILLUMINATION ABOVE 60 %
distance along the beam axis at which the illuminance reaches at least 60 % of the CENTRAL ILLUMINANCE ($E_{C,Ref}$)

201.3.203
DETACHABLE HANDLE
ACCESSORY that is intended to be grasped by the user to allow positioning and adjustment of the luminaire, and which can be removed from the ME EQUIPMENT

Note 1 to entry: The DETACHABLE HANDLE can be sterilisable to allow it to be contacted directly without compromising aseptic technique. A single-use handle cover is not considered a DETACHABLE HANDLE.

201.3.204
LIGHT FIELD CENTRE
LFC
point of maximum illuminance in a plane perpendicular to the beam direction

Note 1 to entry: The LIGHT FIELD CENTRE is the reference point for measurements of the spatial distribution of the light field.

201.3.205
LIGHT FIELD DIAMETER
d_{10}
average distance along lines through the LIGHT FIELD CENTRE between points where the illuminance reaches 10 % of $E_{C,Ref}$

Note 1 to entry: This definition does not require or imply that the light field is round.

201.3.206
LUMINAIRE FOR DIAGNOSIS
luminaire to illuminate the body of the PATIENT locally to support treatment and diagnosis which could be interrupted without causing a HAZARDOUS SITUATION for the PATIENT

Note 1 to entry: A LUMINAIRE FOR DIAGNOSIS is not intended to be used for surgery. See Annex BB for a summary of the differences in requirements between those for a LUMINAIRE FOR DIAGNOSIS and those for a SURGICAL LUMINAIRE.

201.3.207
MAXIMUM CENTRAL ILLUMINANCE
$E_{C,MI}$
maximum value of illuminance at the LIGHT FIELD CENTRE

SEE: Figure 201.102.

Note 1 to entry: $E_{C,MI}$ is obtained at the maximum illuminance distance with the MAXIMUM IRRADIANCE SETTINGS of the ME EQUIPMENT.

201.3.208
*** MAXIMUM ILLUMINANCE DISTANCE**
D_{MI}
distance from the light emitting surface of the ME EQUIPMENT to the position along the luminaire axis where the illuminance reaches its maximum value, but not less than 200 mm

SEE: Figure 201.102.

Note 1 to entry: The MAXIMUM ILLUMINANCE DISTANCE is determined by measuring the illuminance over a range of distances.

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Note 2 to entry: The MAXIMUM ILLUMINANCE DISTANCE is the distance at which measurements of exposures related to safety are taken.

201.3.209
MAXIMUM IRRADIANCE SETTINGS
settings of the ME EQUIPMENT that provide the highest irradiance at the MAXIMUM ILLUMINANCE DISTANCE

Note 1 to entry: Such settings, if adjustable, can include LIGHT FIELD DIAMETER, correlated colour temperature, illuminance level, operating mode, etc.

Note 2 to entry: There can be different MAXIMUM IRRADIANCE SETTINGS for different types of risks, such as total, actinic UV, UV-A, blue light and retinal thermal irradiance HAZARDS.

Note 3 to entry: The MANUFACTURER shall identify the MAXIMUM IRRADIANCE SETTINGS for each risk.

201.3.210
MAXIMUM RADIANCE SETTINGS
settings of the ME EQUIPMENT that provide the highest radiance

Note 1 to entry: Such settings, if adjustable, can include LIGHT FIELD DIAMETER, correlated colour temperature, illuminance level, operating mode, etc.

Note 2 to entry: There can be different MAXIMUM RADIANCE SETTINGS for different types of risks, such as blue light and retinal thermal radiance HAZARDS.

Note 3 to entry: The MANUFACTURER shall identify the MAXIMUM RADIANCE SETTINGS for each risk.

201.3.211
REFERENCE DISTANCE
D_{Ref}
distance from the light emitting surface of the ME EQUIPMENT at which reference measurements of light performance characteristics are taken

Note 1 to entry: See Figure 201.102 and Figure 201.103, and definitions 201.3.201 for CENTRAL ILLUMINANCE ($E_{C,Ref}$), 201.3.207 for MAXIMUM CENTRAL ILLUMINANCE ($E_{C,MI}$), and 201.3.208 for MAXIMUM ILLUMINANCE DISTANCE (D_{MI}).

Note 2 to entry: The REFERENCE DISTANCE is specified by the MANUFACTURER.

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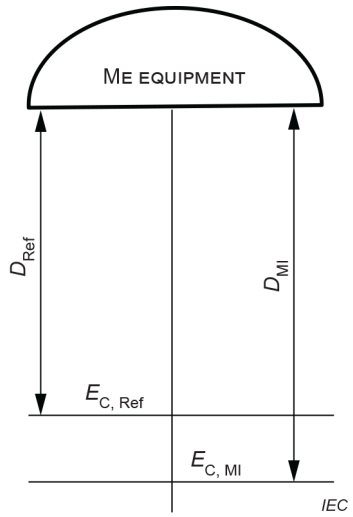
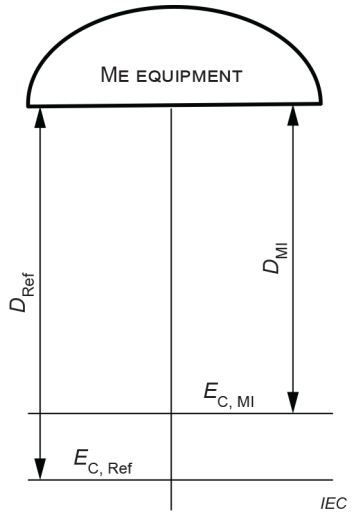


For $D_{MI} > D_{Ref}$



For $D_{MI} < D_{Ref}$

Figure 201.102 – Examples of different distance and illuminance terms

201.3.212
SHADOW DILUTION
ability of the ME EQUIPMENT to minimise the impact of shadows in the working area due to the partial obstruction by the OPERATOR of the emitted light

201.3.213
SURGICAL LUMINAIRE
ME EQUIPMENT that emits a beam of light that can be aimed independently of other light beams to provide illumination for surgery

Note 1 to entry: A SURGICAL LUMINAIRE may not be SINGLE FAULT SAFE by itself, but when used together with at least one other SURGICAL LUMINAIRE, the resulting SURGICAL LUMINAIRE SYSTEM shall be SINGLE FAULT SAFE. See Table BB.1.

201.3.214
SURGICAL LUMINAIRE SYSTEM
combination of multiple SURGICAL LUMINAIRES that is SINGLE FAULT SAFE and intended to be used during surgery to support treatment and diagnosis of the PATIENT

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Note 1 to entry: A SURGICAL LUMINAIRE SYSTEM is SINGLE FAULT SAFE and provides adequate central illuminance to locally illuminate the body of the PATIENT even in a single fault condition.

Note 2 to entry: A SURGICAL LUMINAIRE SYSTEM is not a system in the sense of Clause 16 of the general standard (ME SYSTEMS).

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

The ESSENTIAL PERFORMANCE of a SURGICAL LUMINAIRE is the delivery of sufficient light to the operating field, while limiting the delivery of radiant energy to the operating field and its observers. This is achieved by providing the capability to deliver CENTRAL ILLUMINANCE of at least 40 klx, while ensuring that the total irradiance at the LIGHT FIELD CENTRE at the MAXIMUM ILLUMINANCE DISTANCE does not exceed 700 W/m^2.

NOTE 101 There is no ESSENTIAL PERFORMANCE for a LUMINAIRE FOR DIAGNOSIS since, by definition, its performance can be interrupted without causing a HAZARDOUS SITUATION for the PATIENT (see 201.3.206).

NOTE 102 ESSENTIAL PERFORMANCE is maintained by restoring illumination within 1 s according to the requirements of 201.13.1.101 in the event of a SINGLE FAULT CONDITION. If the RISK MANAGEMENT FILE identifies that the MAXIMUM ILLUMINANCE DISTANCE does not change because of a SINGLE FAULT CONDITION, then it is acceptable to use the MAXIMUM ILLUMINANCE DISTANCE prior to the SINGLE FAULT CONDITION to verify that ESSENTIAL PERFORMANCE has been maintained.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Additional items:

aa) In order to measure stabilised performance, measurements shall be made after an ageing period not to exceed 1 000 h for which both the operating conditions and the duration are specified by the MANUFACTURER.

bb) Measurements of the luminaire shall be made after a warm-up period such that illuminance is changing less than 1 % in 30 min.

cc) All measurements shall be made with the beam axis of the luminaire directed vertically down, unless indicated otherwise.

dd) Measurements shall be made with an illuminance due to the surrounding light (light not produced by the ME EQUIPMENT) less than 500 lx.

ee) In the case of SURGICAL LUMINAIRE SYSTEMS with several different types of luminaires, all measurements shall be made for each representative type of luminaire.

ff) All tests shall be performed without any additional user-initiated adjustments (such as manual re-focusing) between testing of various quantities.

gg) Tests shall be performed with each user-selectable automated adjustment (technology that senses and responds to the external environment without user interaction, if so equipped) both enabled and disabled during the tests, if such adjustments affect measured performance.

hh) If the light field and/or the illuminance are adjustable, they shall be set such that the maximum illuminance is produced, unless indicated otherwise.

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ii) The errors of the illuminance meter, according to ISO/CIE 19476:2014, shall not exceed the following values:

f'_1: 3 %

u: 1 %

r: 1 %

f_3: 1 %

f_5: 0,5 %

jj) The diameter of the aperture of the meter shall not exceed

– 20 mm for photometric and radiometric measurements, and

– 30 mm for spectral measurements used to determine chromaticity and colour rendering, unless photometric and radiometric quantities are calculated from these spectral measurements, in which case the 20 mm limit for the diameter of the sensitive area of the meter shall apply.

kk) The measurement of exposures related to photobiological risks shall be performed with a measurement system adapted to a pupil size of 7 mm diameter.

NOTE See Annex CC for a method for correcting photometric and radiometric readings after restricting the aperture of the meter.

ll) The spectral sensitivity of the meter shall include the entire range of wavelengths associated with each specific exposure, or over the entire range of emission of the light source, if it is less.

mm) Photometric quantities, such as illuminance, can be calculated from spectral irradiance measurements weighted by the eye sensitivity curve, V_λ. This method can provide improved accuracy over using different instruments to measure irradiance and illuminance when determining the ratio of total irradiance, E_{Total}, to MAXIMUM CENTRAL ILLUMINANCE, $E_{C,MI}$ (see 201.10.101.1.4).

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.3 Protection against harmful ingress of water or particulate matter

Addition:

Reducing the ingress of dust and fluid particles into the lighthead will reduce the risk of spreading infections due to airborne or liquid borne contaminants. This is not required for LUMINAIRES FOR DIAGNOSIS.

Compliance is checked by exposing the lighthead, excluding the yoke, to water according to the method corresponding to at least IPX2, as described in IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013, followed by drying the outside of the lighthead and then inspection that there are no visible drops of water on the outside of the luminaire or falling from the luminaire after the luminaire is oriented through its full range of intended use for an observation period of 5 min. The area where the lighthead connects to the yoke may be sealed during testing. This test shall be performed with the lighthead off.

NOTE 101 The lighthead is the enclosure of the light emitting portion of the ME EQUIPMENT.

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