IEC 60601-2-41

Edition 2.0 2009-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-41: Exigences particulières pour la sécurité de base et les performances essentielles des éclairages chirurgicaux et des éclairages de diagnostic

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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

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

This second edition cancels and replaces the first edition published in 2000. This edition constitutes a technical revision to be consistent with the third edition of the IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/773/FDIS	62D/787/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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

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

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "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 publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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 (third Edition 2005), 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 basic safety and essential performance.

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 particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS, hereafter referred to as ME EQUIPMENT.

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 UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems;
– lights connected to surgical instruments;
– luminaires of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE See also 4.2 of the general standard.

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.

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.

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

For brevity, IEC 60601-1 is 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 standard 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of 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, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard 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 standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

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

Clause 2 of the general standard applies except as follows:

Addition:

IEC 60417, *Graphical symbols for use on equipment*

IEC 60598-2-9, *Luminaires – Part 2: Particular requirements. Section Nine: Photo and film luminaires (non-professional)*

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

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

CIE 15, *Colorimetry*

CIE 69, *Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

NOTE An index of defined terms is found beginning on page 39.

201.3.63
MEDICAL ELECTRICAL EQUIPMENT

Addition:

NOTE See Figure 201.101 as an example of possible POWER SUPPLIES for SURGICAL LUMINAIRES.

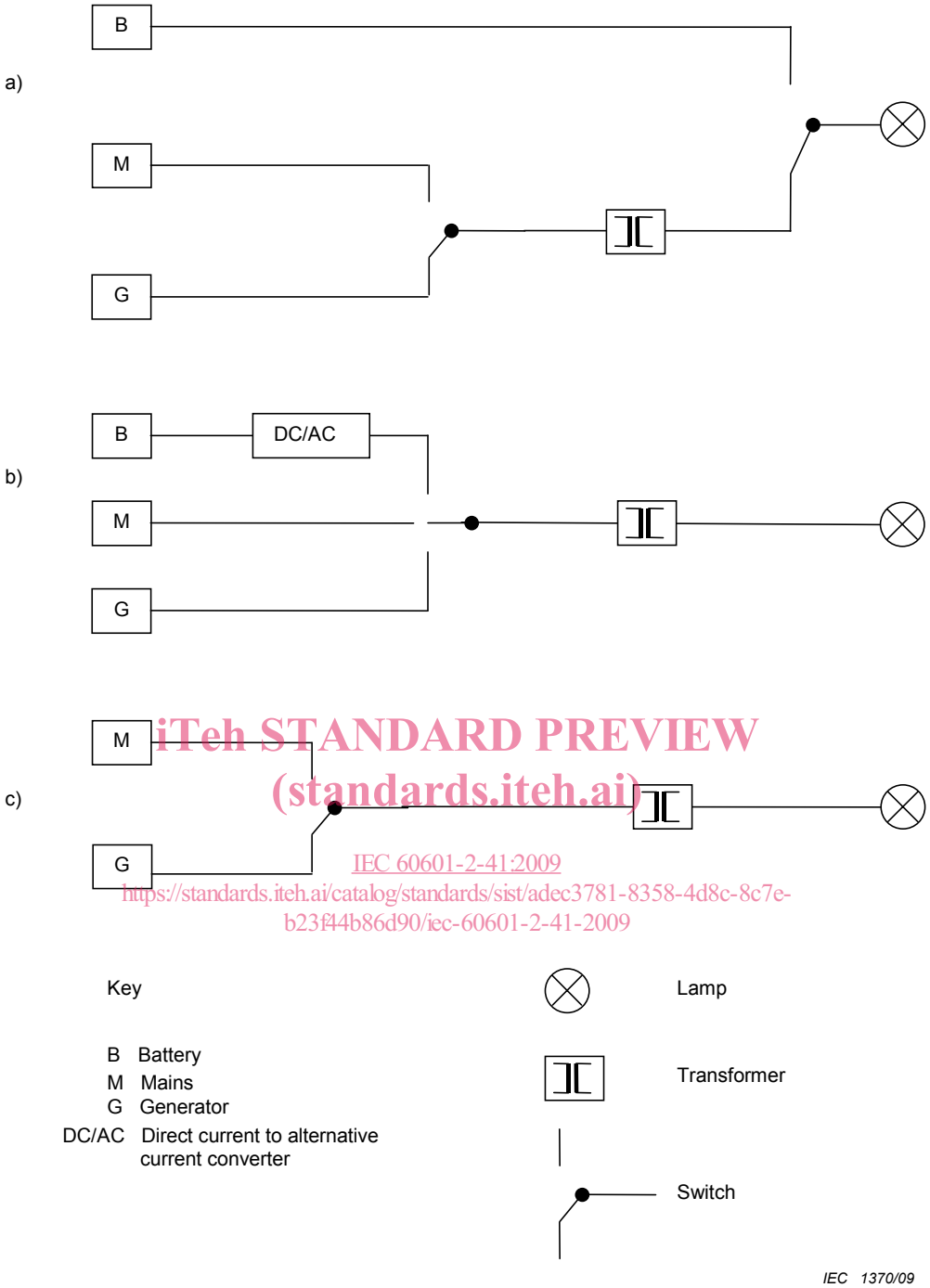

Figure 201.101 – Example of power supplies for SURGICAL LUMINAIRES

Addition:

201.3.101
CENTRAL ILLUMINANCE
E_c
illuminance at a 1 000 mm distance (or a measurement distance specified by the MANUFACTURER if the specified working range does not include 1 000 mm) from the light-emitting area of the ME EQUIPMENT in the LIGHT FIELD CENTRE without any obstruction of the light beam

201.3.102
DEPTH OF ILLUMINATION
working distance around the 1 000 mm distance (or a measurement distance specified by the MANUFACTURER if the specified working range does not include 1 000 mm) below the emitting surface of the ME EQUIPMENT, in which the illuminance reaches at least 60 % of CENTRAL ILLUMINANCE (E_c)

201.3.103
***FAIL SAFE**
capability of an ME EQUIPMENT to provide a minimum illuminance and to be directed on the operation area even in SINGLE FAULT CONDITION

201.3.104
LIGHT FIELD CENTRE
LFC
point of maximum illuminance in the light field (lighted area)

NOTE It is the reference point for light field size and distribution measurements.

201.3.105
LIGHT FIELD DIAMETER
***d*$_{10}$**
diameter of a circle around the LIGHT FIELD CENTRE (point of CENTRAL ILLUMINANCE) where the illuminance reaches 10 % of E_c

201.3.106
LUMINAIRE FOR DIAGNOSIS
luminaire to illuminate the body of the PATIENT locally in order to support diagnosis or treatment which could be interrupted without any hazard for the PATIENT in case of failure of the light

NOTE It is not intended to be used in operating rooms. See Table 201.101.

201.3.107
MAJOR SURGICAL LUMINAIRE
single luminaire in the PATIENT ENVIRONMENT which is intended to support treatment and diagnosis where interruption of the illumination would be a HAZARDOUS CONDITION and to be used in operating rooms

NOTE A MAJOR SURGICAL LUMINAIRE needs to provide an adequate CENTRAL ILLUMINANCE to illuminate locally the body of the PATIENT even in SINGLE FAULT CONDITION. See Table 201.101.

201.3.108
MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)
single luminaire in the PATIENT ENVIRONMENT which is intended to support treatment and diagnosis which can be interrupted without any HAZARD for the PATIENT in case of failure of the light and to be used in operating rooms

NOTE A MINOR SURGICAL LUMINAIRE needs to provide an adequate CENTRAL ILLUMINANCE to illuminate locally the body of the PATIENT. See Table 201.101.

201.3.109
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

201.3.110
DETACHABLE HANDLE
device that is intended to position and adjust the luminaire which can be removed from the ME EQUIPMENT

NOTE The DETACHABLE HANDLE may be sterilisable in order to maintain it under aseptic conditions.

201.3.111
SURGICAL LUMINAIRE
a generic term applicable to MINOR SURGICAL LUMINAIRES, MAJOR SURGICAL LUMINAIRES and a SURGICAL LUMINAIRE SYSTEM

NOTE See Table 201.101.

201.3.112
SURGICAL LUMINAIRE SYSTEM
combination of several SURGICAL LUMINAIRES that is intended to support treatment and diagnosis and to be used in operating rooms

NOTE 1 A SURGICAL LUMINAIRE SYSTEM needs to be FAIL SAFE and to provide an adequate CENTRAL ILLUMINANCE to illuminate locally the body of the PATIENT even in SINGLE FAULT CONDITION. See Table 201.101.

EXAMPLE A proven FAIL SAFE combination of two or more MINOR SURGICAL LUMINAIRES is a SURGICAL LUMINAIRE SYSTEM.

NOTE 2 This SURGICAL LUMINAIRE SYSTEM is not a system in the sense of Clause 16 (ME SYSTEMS).

Table 201.101 – Classification of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS

		Type of luminaire		
			SURGICAL LUMINAIRES	
Requirements	**Clause**	**Luminaires for diagnosis**	**Minor (treatment)**	**Major and system**
ME EQUIPMENT classification	201.6	No requirement	Class I, or Class II with connector to PA [a]	Class I, or Class II with connector to PA [a]
FAIL SAFE	201.3.103	No	No	Yes
Intended location		Examination room	Operating room	Operating room
Ease of motion	201.9.4.2.2.101	Yes	Yes	Yes
CENTRAL ILLUMINANCE (E_c)	201.12.1.102.1.1 a)	No requirement	40 klx ≤ E_c ≤ 160 klx	40 klx ≤ E_c ≤ 160 klx
LIGHT FIELD DIAMETER(d_{10})	201.12.1.102.1.1 b)	No requirement	Specified [b]	Specified [b]
Light distribution(d_{50})	201.12.1.102.1.1 b)	No requirement	d_{50} at least 50 % of the LIGHT FIELD DIAMETER d_{10} [c]	d_{50} at least 50 % of the LIGHT FIELD DIAMETER d_{10} [c]
SHADOW DILUTION	201.12.1.102.1.1 c)	No requirement	Specified [d]	Specified [d]
Colour temperature	201.12.1.102.2.1	3 000 K ≤ T_c ≤ 6 700 K	3 000 K ≤ T_c ≤ 6 700 K	3 000 K ≤ T_c ≤ 6 700 K
Colour rendering index	201.12.1.102.2.1	85 ≤ R_a ≤ 100	85 ≤ R_a ≤ 100	85 ≤ R_a ≤ 100
Maximum value for total irradiance E_e	201.12.1.102.3.1	E_e < 1 000 W/m^2	E_e < 1 000 W/m^2	E_e < 1 000 W/m^2
[a] PA means potential equalization conductor.				
[b] LIGHT FIELD DIAMETER(d_{10}) where the illuminance reaches 10 % of CENTRAL ILLUMINANCE E_c.				
[c] Diameter d_{50} where the illuminance reaches 50 % of CENTRAL ILLUMINANCE E_c.				
[d] Percentage of remaining illuminance when the beam is obstructed by one or two masks, with or without tube.				

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

The ESSENTIAL PERFORMANCE is the delivery of illumination and the limitation of energy to the operating field.

Table 201.102 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
DELIVERY OF A MINIMUM AND ADEQUATE ILLUMINATION ON THE OPERATING FIELD	201.12.1.102.1.1 a) and 201.12.1.102.4
LIMITATION OF ENERGY IN THE OPERATING FIELD	201.12.1.102.1.1 a) 201.10.7 and 201.12.1.102.3

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies except as follows:

201.5.4 Other conditions

Addition:

aa) In order to measure stabilised performances, the output values shall be measured after a pre-ageing period, depending on the light source technology, at RATED VOLTAGE under NORMAL CONDITIONS. This pre-aging period is:

- 3 h for halogen lamp and LED;
- 50 h for discharge lamp;
- for other light sources, the preaging period after which the performances variation does not exceed 1% per 100 h.

201.5.8 Sequence of test

Addition:

The photometric tests and the tests for the quality of illuminance of the ME EQUIPMENT are performed after inspection of the marking.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.6.2 Protection against electric shock

Addition:

NOTE Except if intended for such purpose, a SURGICAL LUMINAIRE or LUMINAIRE FOR DIAGNOSIS has no APPLIED PART on the PATIENT.

201.6.6 Mode of operation

Amendment:

Delete all but CONTINUOUS OPERATION.