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

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Medical electrical equipment
Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
(IEC 60601-2-41:2000)

Appareils électromédicaux
Partie 2-41: Règles particulières de sécurité pour les éclairages chirurgicaux et les éclairages de diagnostic
(CEI 60601-2-41:2000)

Medizinische elektrische Geräte
Teil 2-41: Besondere Festlegungen für die Sicherheit von Operationsleuchten und Untersuchungsleuchten
(IEC 60601-2-41:2000)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62D/344/FDIS, future edition 1 of IEC 60601-2-41, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-41 on 2000-04-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-04-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-41:2000 was approved by CENELEC as a European Standard without any modification.

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SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

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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.

MEDICAL ELECTRICAL EQUIPMENT –

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

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).

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. 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 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.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

"Modification" means that the clause or subclause of the General Standard is modified as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc. and additional items aa), bb), etc.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.101
MAJOR SURGICAL LUMINAIRE
Single luminaire in the PATIENT environment which is FAIL SAFE and provides an adequate CENTRAL ILLUMINANCE to illuminate locally the body of the PATIENT. It is intended to support the treatment and diagnosis, and to be used in operating rooms. See table 101

2.102
MINOR SURGICAL LUMINAIRE (treatment luminaire)
Single luminaire in the PATIENT environment which provides an adequate CENTRAL ILLUMINANCE to illuminate the body of the PATIENT locally. It is intended to be used in operating rooms for diagnosis and treatment which can be interrupted without any hazard for the PATIENT in case of failure of the light. See table 101

2.103
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. It is not intended to be used in operating rooms. See table 101

2.104
SURGICAL LUMINAIRE SYSTEM
Combination of several SURGICAL LUMINAIRES to illuminate the body of the PATIENT locally. It is FAIL SAFE and provides an adequate CENTRAL ILLUMINANCE. It is intended to support the treatment and diagnosis, and to be used in operating rooms. See table 101

(Example: A proved fail safe combination of two or more minor surgical luminaires is a SURGICAL LUMINAIRE SYSTEM.)

2.105
SURGICAL LUMINAIRE
Generic term applicable to minor surgical luminaires, major surgical luminaires and surgical luminaire systems

Table 101 – Classification of surgical luminaires and luminaires for diagnosis

Requirements	Clause	Type of luminaire		
		Luminaires for diagnosis	Surgical luminaires	
			Minor (treatment)	Major and system
EQUIPMENT classification	14.2 a) 2)	No requirement	Class I, or Class II with connector to PA [a]	Class I, or Class II with connector to PA [a]
Fail safe	2.10.101	No	No	Yes
Anaesthesia (intended purpose)		Localized	Local/general	Local/general
Intended location		Examination room	Operating room	Operating room
Sterile handle (standard)		No	Yes	Yes
Central illuminance (E_c)	50.102.1.1 a)	No requirement	40 klx ≤ E_c ≤ 160 klx	40 klx ≤ E_c ≤ 160 klx
Light field diameter (d_{10})	50.102.1.1 b)	No requirement	Yes [b]	Yes [b]
Light distribution	50.102.1.1 b)	No requirement	Yes [c]	Yes [c]
Shadow dilution	50.102.1.1 c)	No requirement	Yes [d]	Yes [d]
Colour temperature	50.102.2.1	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	50.102.2.1	85 ≤ R_a ≤ 100	85 ≤ R_a ≤ 100	85 ≤ R_a ≤ 100
Maximum value for total irradiance E_e	50.102.3.1	Yes [e]	Yes [e]	Yes [e]

[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.
[e] Information on the total irradiance E_e for the given CENTRAL ILLUMINANCE E_c.

2.106
CENTRAL ILLUMINANCE (E_c)
Illuminance at 1 m distance from the light emitting area of the EQUIPMENT in the LIGHT FIELD CENTRE (LFC) without any obstruction of the light beam

2.107
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

2.108
LIGHT FIELD CENTRE (LFC)
Point of maximum illuminance in the light field (lighted area). It is the reference point for light field size and distribution measurements

2.109
DEPTH OF ILLUMINATION
Working distance around 1 m below the emitting surface of the EQUIPMENT, in which the illuminance reaches at least 20 % of CENTRAL ILLUMINANCE (E_c). (See figure 115)

2.110
SHADOW DILUTION
Ability of the EQUIPMENT to minimize the impact of shadows in the working area due to the partial obstruction by the OPERATOR of the emitted light

2.1.101
STERILE HANDLE
Device maintaining a sterile area in order to handle it under aseptic conditions when attached to the EQUIPMENT

2.1.5
APPLIED PART

Addition:

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

2.2.15
MEDICAL ELECTRICAL EQUIPMENT

Replacement:

Electrical EQUIPMENT, provided with one or more connections to particular SUPPLY MAINS and intended to diagnose, treat, or monitor the PATIENT under medical supervision, and which makes physical or electrical contact with the PATIENT and/or transfers energy to or from the PATIENT and/or detects such energy transfer to or from the PATIENT.

See figure 101 describing the possible SUPPLY MAINS for SURGICAL LUMINAIRES.

***2.4.3**
SAFETY EXTRA-LOW VOLTAGE (SELV)

Modification:

Voltage is changed from 25 V a.c. to 30 V a.c.

***2.10.101**

Addition:

FAIL SAFE
Capability of an EQUIPMENT to provide a minimum illuminance and to be directed on the operation area even in SINGLE FAULT CONDITION.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

Addition:

f) *In order to measure stabilized performances, the output values shall be measured after a pre-ageing period, depending on the lamp technology, at* RATED VOLTAGE *under* NORMAL CONDITIONS*. This pre-ageing period is:*

- *3 h for halogen lamps;*
- *50 h for discharge lamps;*
- *for other lamps, the pre-ageing period is determined when the performances variation does not exceed 1 % per 10 h.*

4.11 Sequence

Addition:

The photometric tests and the tests for the quality of illuminance of the EQUIPMENT *are performed after inspection of the marking (see clause C.3 of Appendix C of the General Standard).*

5 Classification

This clause of the General Standard applies except as follows:

5.6 According to the mode of operation

Modification:

Delete all but continuous operation.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

aa) RATED voltage and power consumption (6.1 g) and j)) shall be marked on each lighthead. If these values differ from power input and voltage at the MAINS TERMINAL DEVICE of the EQUIPMENT, additional marking of voltage and power consumption is required near the MAINS TERMINAL DEVICE.

6.1.101 NOMINAL power of an EQUIPMENT

The NOMINAL power in watts of the lamp(s). When the indication of the power of a lamp is not sufficient, the number of lamps and their type shall be marked too. EQUIPMENT using tungsten filament lamps shall be marked with the NOMINAL power.

6.1.102 POWER SUPPLY CORD without connector

MOBILE EQUIPMENT with a fixed flexible POWER SUPPLY CORD with no MAINS PLUG attached for connection to the SUPPLY MAINS shall have a clearly visible label to show the correct method of connection to a MAINS PLUG.

6.2.101 Marking of light sources

Identification and characteristics of lamps (power, voltage) shall be marked near the lampholder and on the lamps.

6.8.2 Instructions for use

a)

Addition:

Instructions for use shall contain information on:

- cleaning and decontamination of the EQUIPMENT,
- safety aspects of optical filters (purpose and warning to prevent removal),
- CENTRAL ILLUMINANCE,
- LIGHT FIELD DIAMETER,
- DEPTH OF ILLUMINATION (see 50.102.1, not for LUMINAIRES FOR DIAGNOSIS),
- SHADOW DILUTION (see 50.102.1, not for LUMINAIRES FOR DIAGNOSIS),
- correlated colour temperature and colour rendering index,
- total irradiance,
- cleaning, disinfection and sterilization of the STERILE HANDLE,
- handling of the lamps in case of lamp changing,
- how the USER shall respect the requirements of the national committee responsible for hygiene and disinfection,

d) *Cleaning, disinfection and sterilization of parts in contact with the PATIENT*

Addition:

This subclause also applies to the STERILE HANDLE.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of General Standard apply.