INTERNATIONAL STANDARD

IEC 60601-2-41

First edition
2000-02

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-41:
Règles particulières de sécurité pour les éclairages chirurgicaux et les éclairages de diagnostic

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* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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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International Standard IEC 60601-2-41 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/344/FDIS	62D/352/RVD

Full information on the voting for the approval of this 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 3.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;

– *test specifications: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2005.

At this date, in accordance with the committee's decision, the publication will be

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- withdrawn;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

A bilingual version of this standard may be issued at a later date.

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.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

14 Requirements related to classification

This clause of the General Standard applies except as follows:

14.2 a) 2)

Addition:

SURGICAL LUMINAIRES of CLASS II need a connector to a POTENTIAL EQUALIZATION CONDUCTOR.

NOTE SURGICAL LUMINAIRES are set up in operating theatres in which an equipotential bonding has been placed between exposed conductive parts.

*16 ENCLOSURES and PROTECTIVE COVERS

This clause of the General Standard applies except as follows:

Modification:

Replace

25 V a.c. by 30 V a.c.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

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

22 Moving parts

This clause of the General Standard applies except as follows:

Addition:

***22.101**

Attachment and detachment of the STERILE HANDLE: see rationale (annex AA).

The maximum attachment and detachment force of the STERILE HANDLE shall not exceed 10 N.

The maximum attachment and detachment torque shall not exceed 1 Nm.

The force for unintended detachment shall exceed 100 N.

The torque for unintended detachment shall exceed 5 Nm or require three or more 360° rotations of the STERILE HANDLE.

Compliance is checked by test (see figure 102).

At the end of the test no damage shall be detected on the shaft (or carrier) of the STERILE HANDLE or on the STERILE HANDLE itself.

24 Stability in NORMAL USE

This clause of the General Standard applies except as follows:

24.1 to **24.3** These clauses of the General Standard apply only to MOBILE EQUIPMENT.

24.101

Addition:

Ease of motion and stability

The mechanical parts of the EQUIPMENT shall be designed to have very easy motions during handling.

The EQUIPMENT shall be stable when not being moved.

Compliance is checked as follows:

The manipulation of the lighthead is tested along three perpendicular axes as described in figure 103. The application point of the force shall be in the middle of the gripping area defined by the manufacturer.

The maximum force for vertical positioning shall not exceed 55 N.

Articulation of the lighthead in the remaining axis shall not exceed 25 N.

Compliance is checked manually along one axis at a time, the other axes of rotation being locked.

25 Expelled parts

This clause of the General Standard applies except as follows:

25.1

Addition:

The EQUIPMENT shall be so designed that, in case of lamp burst, all flinders and broken parts are kept inside the EQUIPMENT in all possible positions of the lighthead in the INTENDED USE.

Compliance is checked by a test in accordance with IEC 60598-2-9.

Only the structural integrity of the enclosure shall be checked at the end of the test.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

34 Ultraviolet radiation

Replacement:

The UV-irradiance for wavelengths below 400 nm shall not exceed 10 W/m².

Compliance is checked by inspection or measurement. Measurement is to be carried out in conditions in accordance with 50.102.1.2.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

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

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

42 Excessive temperatures

This clause of the General Standard applies except as follows:

42.5 Guards

Addition:

When covers are removable without a tool for lamp changing, then touchable hot surfaces shall be marked with a warning sign for “hot surface” in accordance with IEC 60417.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

This clause of the General Standard applies except as follows:

44.6 Ingress of liquids

Addition:

Even though most EQUIPMENT is not designed to withstand water ingress, the manufacturer shall indicate the acceptable cleaning procedure in the ACCOMPANYING DOCUMENTS. (See 6.8.2 a)).

44.7 Cleaning, sterilization and disinfection

Addition:

This subclause also applies to reusable STERILE HANDLES.

49 Interruption of power supply

This clause of the General Standard applies except as follows:

***49.2.101** In the event of interruption of the SUPPLY MAINS, MAJOR SURGICAL LUMINAIRES and SURGICAL LUMINAIRE SYSTEMS shall:

– automatically changeover to additional power supply for safety services, on failure of the mains power supply,

– during the emergency operation, restore in less than 5 s the CENTRAL ILLUMINATION to not less than 40 000 lx and not less than 50 % of the CENTRAL ILLUMINANCE before the interruption,

– give a visual indication to the OPERATOR that the additional power supply for safety services is functioning,

– restore the initial illuminance within 40 s.

Compliance is tested by interruption of the SUPPLY MAINS.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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

50 Accuracy of operating data

This clause of the General standard applies except as follows:

Additional subclauses:

50.101 General

The following requirements specify the characteristics of illumination and the related tests for the EQUIPMENT or give the frame of standardized measurements so that consistent and comparable data are available to USERS.

The EQUIPMENT, in the region of the operating field, shall satisfy the following conditions as described in 50.102.1 and 50.102.3:

– give lighting with a radially tapered distribution and with attenuation of the cast shadow,

– light the bottom of deep cavities while keeping a lighting level high enough to avoid eye fatigue,

– give lighting directed adequately to give the necessary stereoscopic vision, quickly and without ambiguity,

– emit a minimum energy in the operating field (risk of drying-out of tissues in the operative cavity),

– not emit excessive energy unnecessarily uncomfortable for the OPERATOR,

– have an optical spectrum which renders all colours faithfully and which is characterized by colour temperature and the colour rendering index (see 50.102.2.1).

In order to have the lighting level appropriate to the nature of tissues and the type of cavity to be observed, while taking the characteristics of the OPERATOR's sight into consideration, any EQUIPMENT may include a device to adjust brightness.

50.102 Characteristics of illumination

50.102.1 Illuminance

50.102.1.1 General requirements

Visual differentiation of very closely graded tissues is particularly delicate and requires high levels of illumination, especially between 600 nm and 700 nm where tissue reflection is low. Moreover, in this spectral interval, human eye sensitivity is reduced.

The EQUIPMENT shall offer a good lighted surface homogeneity during observation on a flat surface or at the bottom of a deep and narrow cavity, despite obstacles, for example the OPERATOR's head or shoulders.

a) CENTRAL ILLUMINANCE

Without any obstruction of the light beam, the level of CENTRAL ILLUMINANCE of SURGICAL LUMINAIRES shall reach the minimum value of 40 000 lx and shall not exceed 160 000 lx for each single lighthead.

No minimum value is required for LUMINAIRES FOR DIAGNOSIS.

b) LIGHT FIELD DIAMETER and light distribution (see figure 104)

The minimum diameter d_{50} where the illuminance reaches 50 % of the CENTRAL ILLUMINANCE shall be at least 50 % of the LIGHT FIELD DIAMETER d_{10}.

No value is required for LUMINAIRES FOR DIAGNOSIS.

c) SHADOW DILUTION (see figures 107, 108, 112 and 113)

In the presence of masks simulating the head of one and two OPERATORS partly obstructing the light beams, the level of the remaining CENTRAL ILLUMINANCE of SURGICAL LUMINAIRES shall be measured with and without a tube simulating a cavity.

No measurement is required for LUMINAIRES FOR DIAGNOSIS.

d) DEPTH OF ILLUMINATION (see figure 115)

Length measured along the optical axis where the illuminance reaches at least 20 % of CENTRAL ILLUMINANCE.

No measurement is required for LUMINAIRES FOR DIAGNOSIS.

The ACCOMPANYING DOCUMENTS shall indicate the values of:

– CENTRAL ILLUMINANCE E_c,
– LIGHT FIELD DIAMETER d_{10},
– diameter d_{50} where the illuminance reaches 50 % of CENTRAL ILLUMINANCE,
– remaining illuminance when the beam is obstructed by one mask,
– remaining illuminance when the beam is obstructed by two masks,
– remaining illuminance at the bottom of a standardized tube (inside),
– remaining illuminance at the bottom of a standardized tube when the beam is obstructed by one mask,
– remaining illuminance at the bottom of a standardized tube when the beam is obstructed by two masks.

All values of remaining illuminance are relative values to CENTRAL ILLUMINANCE without obstruction by masks or tube.

50.102.1.2 General conditions for tests

The tests shall be performed at stabilized RATED voltage at the MAINS TERMINAL DEVICE of the EQUIPMENT in a thermally stable situation. The atmospheric conditions shall be in accordance with 4.5.

All photometric and radiometric measurements in the light field shall be carried out in a plane 1 m below the lowest point of the light emitting surface of the EQUIPMENT with the optical axis of the EQUIPMENT directed vertically down.

The measurements shall be carried out in such a way that the error due to stray light is below 1 %.

In the case of SURGICAL LUMINAIRE SYSTEMS with several independent lightheads, all measurements shall be carried out for each individual lighthead.

If the light field and/or the illuminance are adjustable, they shall be set in such a way that the maximum illuminance is reached if not indicated otherwise.

The errors of the illuminance meter, according to CIE 69:1987, shall not exceed the following values:

f_1: 3 %
u: 1 %
r: 1 %
f_3: 1 %
f_5: 0,5 %
f_9: 10 %

The diameter of the sensitive area of the photometer head of the illuminance meter shall be not more than 20 mm.

Irradiance measurements shall be carried out using a radiometer having a sensitive area of diameter not more than 30 mm. Its spectral sensitivity shall be constant in the wavelength region from 300 nm to 2 500 nm.

Spectral measurements shall be carried out using a calibrated spectral radiometer having a sensitive area with a diameter of not more than 30 mm.

50.102.1.3 Test to be performed

a) CENTRAL ILLUMINANCE

Maximum illuminance measured in the light field centre (lfc) (see figure 105).

b) LIGHT FIELD DIAMETER d_{10}

Average of the values for d_{10} measured along four cross-sections through the LIGHT FIELD CENTRE (LFC) (see figure 106).

c) Diameter d_{50}

Average of the values for d_{50} where the illuminance reaches 50 % of CENTRAL ILLUMINANCE, measured along four cross-sections through the LIGHT FIELD CENTRE (LFC) (see figure 106).

d) Remaining illuminance with one mask

Illuminance measured at the LIGHT FIELD CENTRE (LFC) (see figure 107) when the beam is obstructed by one mask. It is given as a percentage of the CENTRAL ILLUMINANCE.

e) Remaining illuminance with two masks

Average of four illuminance measurements performed at the LIGHT FIELD CENTRE (LFC), with the pair of masks in four successive positions 45° apart, without any motion of both the EQUIPMENT under test and the photometer head of the illuminance test (see figures 108 and 109).

The average is given as a percentage of CENTRAL ILLUMINANCE.

f) Remaining illuminance with tube

A tube with a diameter and a height as defined in figure 110 is positioned around the detector of the illuminance meter at the LIGHT FIELD CENTRE (LFC). Its internal surface shall be matt black coated and textured to avoid stray reflections. An example of its internal surface is shown in figure 111.

Remaining illuminance is given as a percentage of CENTRAL ILLUMINANCE.

g) Remaining illuminance with tube and one mask

Same conditions as item f), with the addition of one mask (see figure 112).

Remaining illuminance is given as a percentage of CENTRAL ILLUMINANCE.

h) Remaining illuminance with tube and two masks

Same conditions as item f), with the addition of two masks (see figure 113).

Average of four measurements performed at the LIGHT FIELD CENTRE (LFC), with the pair of masks in four successive positions 45° apart, as shown in figure 114, without any motion of the EQUIPMENT under test and the photometer head of the illuminance test.

The average is given as a percentage of CENTRAL ILLUMINANCE.

i) DEPTH OF ILLUMINATION

The EQUIPMENT is set at 1 m for measuring CENTRAL ILLUMINANCE. From this position, the photometer head is moved above and below along a vertical line passing through the LIGHT FIELD CENTRE, until the illuminance reaches 20 % of the previous CENTRAL ILLUMINANCE. The distance between the upper and lower measurements gives the DEPTH OF ILLUMINATION (see figure 115).

***50.102.2 Spectral characteristics**

50.102.2.1 General requirements

The emission spectrum of the EQUIPMENT associated with a high illuminance level shall be appropriate for tissue differentiation. For this purpose, the colour rendering index R_a (see CIE 13.3:1995) shall be between 85 and 100.

The colour temperature of the radiation emitted shall be between 3 000 K and 6 700 K when the EQUIPMENT is set to produce a maximum illuminance in order to render exactly the slight colour differences of the operative field.

Compliance is checked by testing.

50.102.2.2 Tests to be performed

Tests are carried out in accordance with the requirements of CIE 13.3:1995 and CIE 15.2:1986.

The chromaticity co-ordinates (x, y) (reference observer CIE 1931 – see CIE 15.2:1986 or ISO/CIE 10527) of the radiation emitted by the EQUIPMENT shall be within the field defined by the following co-ordinates of six points A, B, C, D, E and F).

A: x = 0,31 y = 0,375

B: x = 0,31 y = 0,307

C: x = 0,341 y = 0,307

D: x = 0,42 y = 0,37

E: x = 0,445 y = 0,422

F: x = 0, 38 y = 0,422

50.102.3 Temperature rise in the lighted surface

50.102.3.1 General requirements

The temperature rise in the lighted surface is converted into total irradiance measurement.

At a distance of 1 m for one single lighthead, the total irradiance E_e in the lighted area shall not exceed 1 000 W/m².

This requirement applies for both LUMINAIRES FOR DIAGNOSIS and SURGICAL LUMINAIRES.

For SURGICAL LUMINAIRES, the ratio of irradiance E_e and illuminance E_c shall not exceed 6 mW/m²·lx.

If it is possible, in the case of SURGICAL LUMINAIRE SYSTEMS, to exceed an irradiance of 1 000 W/m² by overlapping the light fields of several lightheads, information shall be given in the instructions for use that there is a risk of too much heat in the operating field.

For all SURGICAL LUMINAIRES, the manufacturer shall provide the related information in the ACCOMPANYING DOCUMENTS.

Compliance is checked by measurement of irradiance and illuminance according to 50.102.1.2.1.

50.102.3.2 Tests to be performed

The total irradiance E_e is measured in a plane 1 m below the lowest point of the light emitting surface of the EQUIPMENT, at the LIGHT FIELD CENTRE (LFC).

50.102.4 Safety characteristics

a) Lamp changing shall require a TOOL if it necessitates optical filter removal.

Compliance is checked by inspection.

b) Endurance

The luminous flux emitted by the EQUIPMENT shall not vary by more than 20 % during single operation. The colour temperature and colour rendering index shall be stable and comply with 50.102.2.

Tests shall be performed at the RATED voltage of the EQUIPMENT with a 3 h operating – 1 h rest cycle, over a 10 day period.

Compliance is checked by measurement and comparing the CENTRAL ILLUMINANCE, colour temperature and colour rendering index before and after the 10 day test.

*c) Lamp failure

The failure of a lamp shall be identifiable by the OPERATOR without opening the EQUIPMENT.

Compliance is checked by inspection and testing.

When a lamp fails, MAJOR SURGICAL LUMINAIRES or SURGICAL LUMINAIRE SYSTEMS shall restore the illumination in less than 5 s. The restored CENTRAL ILLUMINANCE shall not be less than 50 % of the previous CENTRAL ILLUMINANCE and shall not be less than 40 000 lx.

Compliance is checked by testing.

d) Maintenance of the EQUIPMENT without a TOOL

During maintenance, for example replacement of a lamp, parts ensuring the safety of the EQUIPMENT in operation shall not need to be removed. Otherwise, the EQUIPMENT shall be equipped with a safety device preventing power from being turned on. In addition, safety information on the essential part shall be marked on the EQUIPMENT.

Compliance is checked by inspection and functional test.

e) Stability of the lamp

During the operating life of the lamp, the colour temperature and colour rendering index shall be stable and comply with 50.102.2. The luminous flux emitted by the EQUIPMENT shall not vary by more than 20 %. Otherwise, the manufacturer shall give information about the maintenance period in the ACCOMPANYING DOCUMENTS and there shall be a device to inform the OPERATOR that maintenance is due.

Compliance is checked by inspection.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

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

52 Abnormal operation and fault conditions

This clause of the General Standard applies except as follows:

Addition:

52.1.101

FAIL SAFE EQUIPMENT shall be so designed that even in SINGLE FAULT CONDITION no SAFETY HAZARD exists and main functions (illumination, manoeuvrability) are preserved.

During SINGLE FAULT CONDITION and after 5 s of any interruption, a FAIL SAFE EQUIPMENT shall provide CENTRAL ILLUMINANCE of not less than 40 000 lx.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

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

55 ENCLOSURES and covers

This clause of the General Standard applies except as follows:

55.1 Materials

Replacement:

Tests for resistance to heat and ignition in accordance with IEC 60695-1.

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.10 Actuating parts of controls

a) *Protection against electric shock*

Modification:

The General Standard applies with the modification of clause 16 in this Particular Standard.

57 MAINS PARTS, components and layout

This clause of the General Standard applies except as follows:

57.1 Isolation from the SUPPLY MAINS

Addition:

In the case of several SUPPLY MAINS, the EQUIPMENT shall have means to isolate its circuits electrically from the several SUPPLY MAINS, on all poles simultaneously.

59 Construction and layout

This clause of the General Standard applies except as follows:

59.1 d) Materials

Addition:

Wiring shall be made of copper or an alloy containing at least 50 % copper or a material having similar characteristics.

Conductive parts shall not be affected by corrosion.

Compliance is checked by inspection and, if necessary, by chemical analysis.

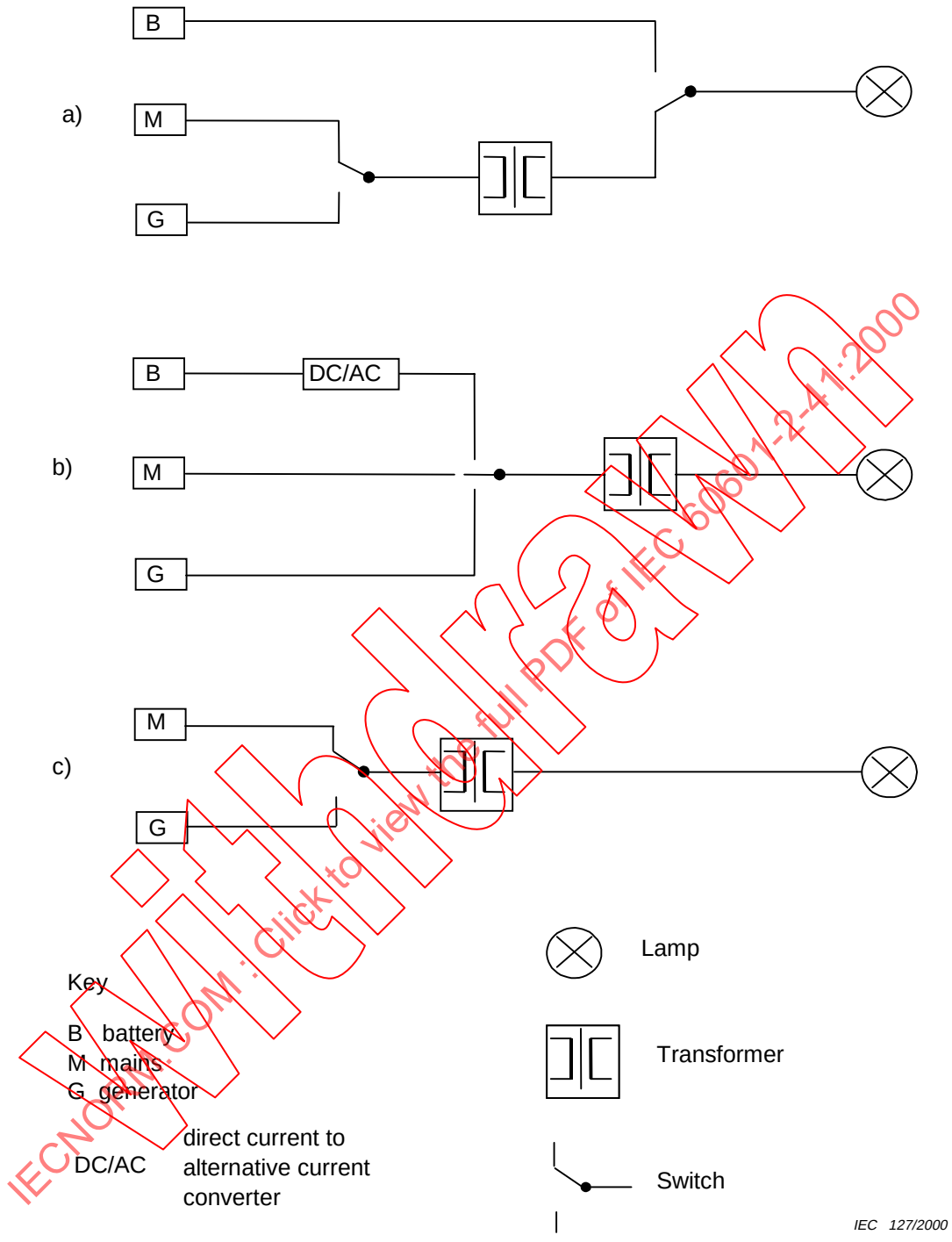


Figure 101 – Example of power supplies for SURGICAL LUMINAIRES

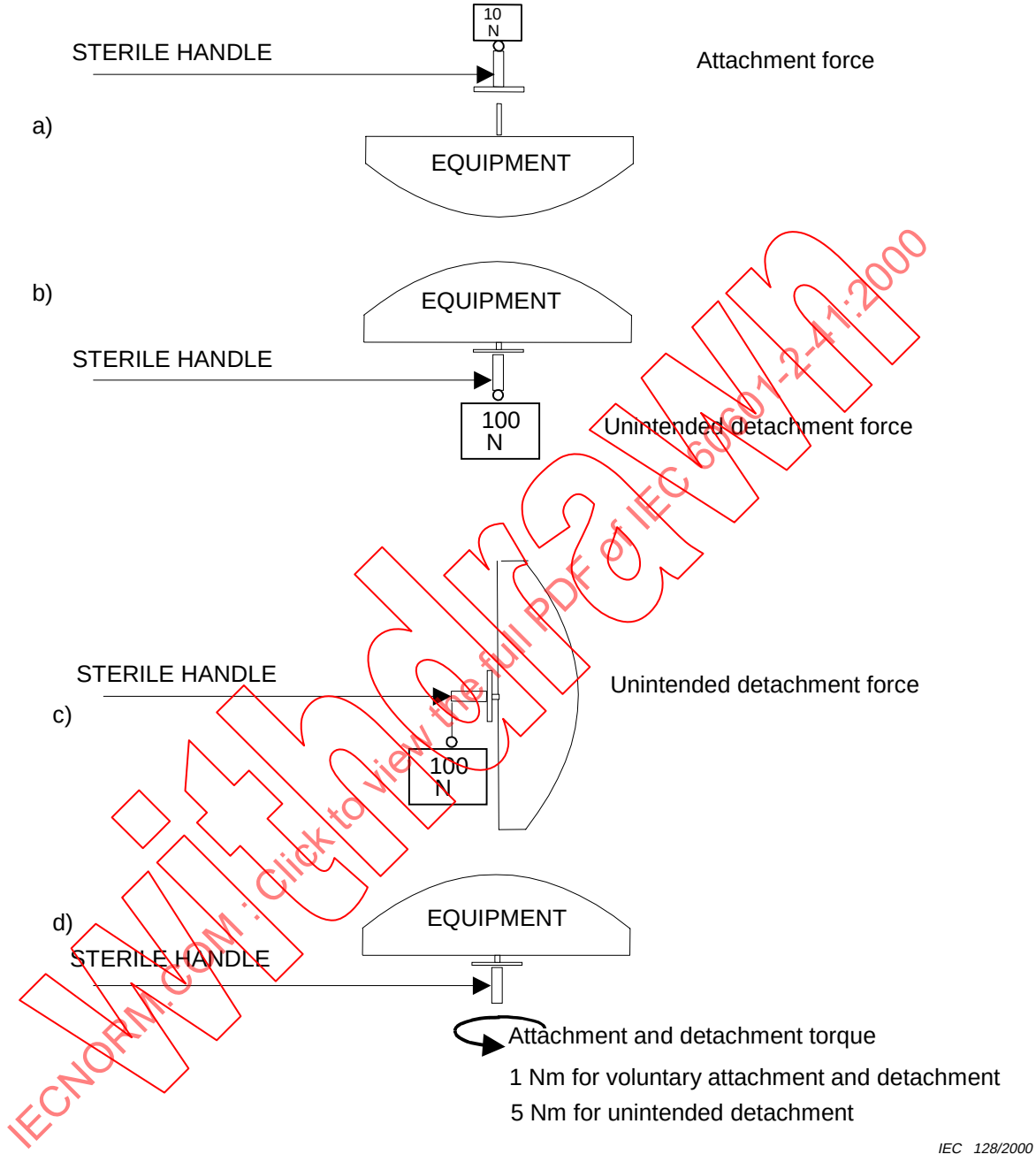


Figure 102 – STERILE HANDLE attachment and detachment tests

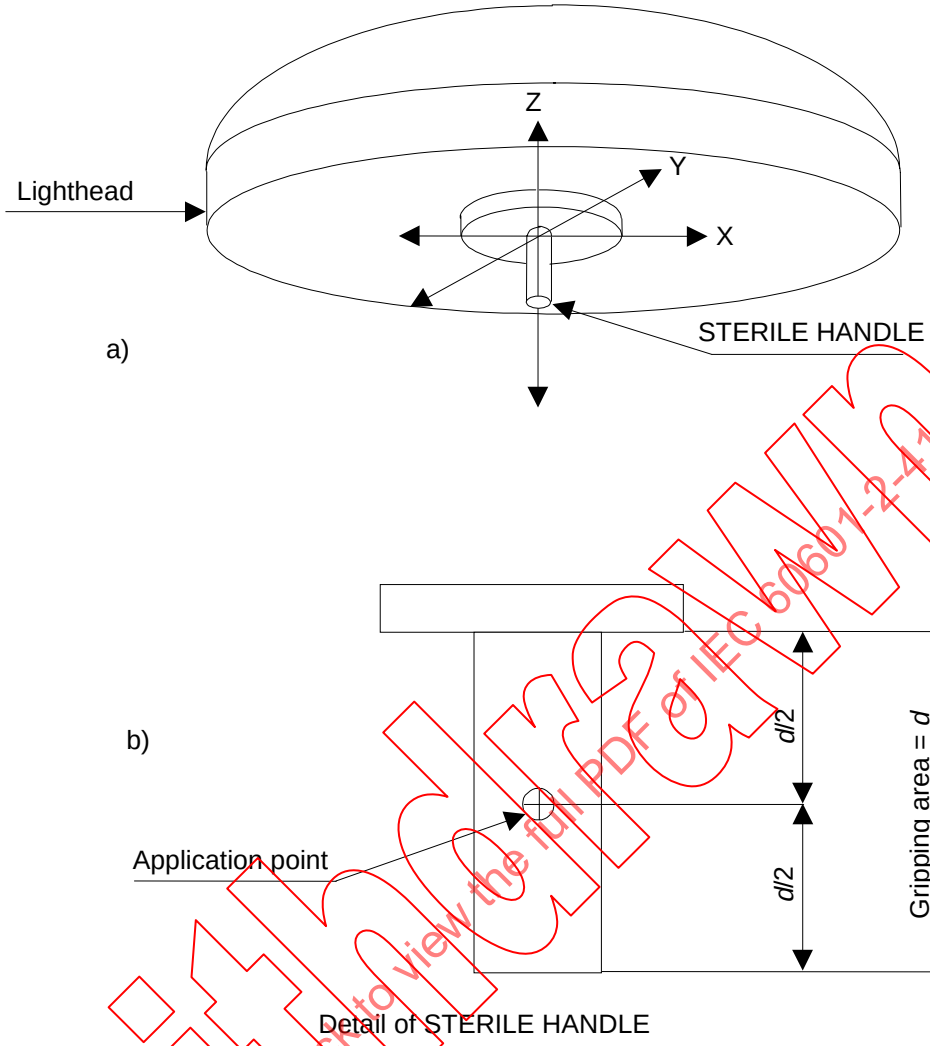


Figure 103 – Test for ease of motion

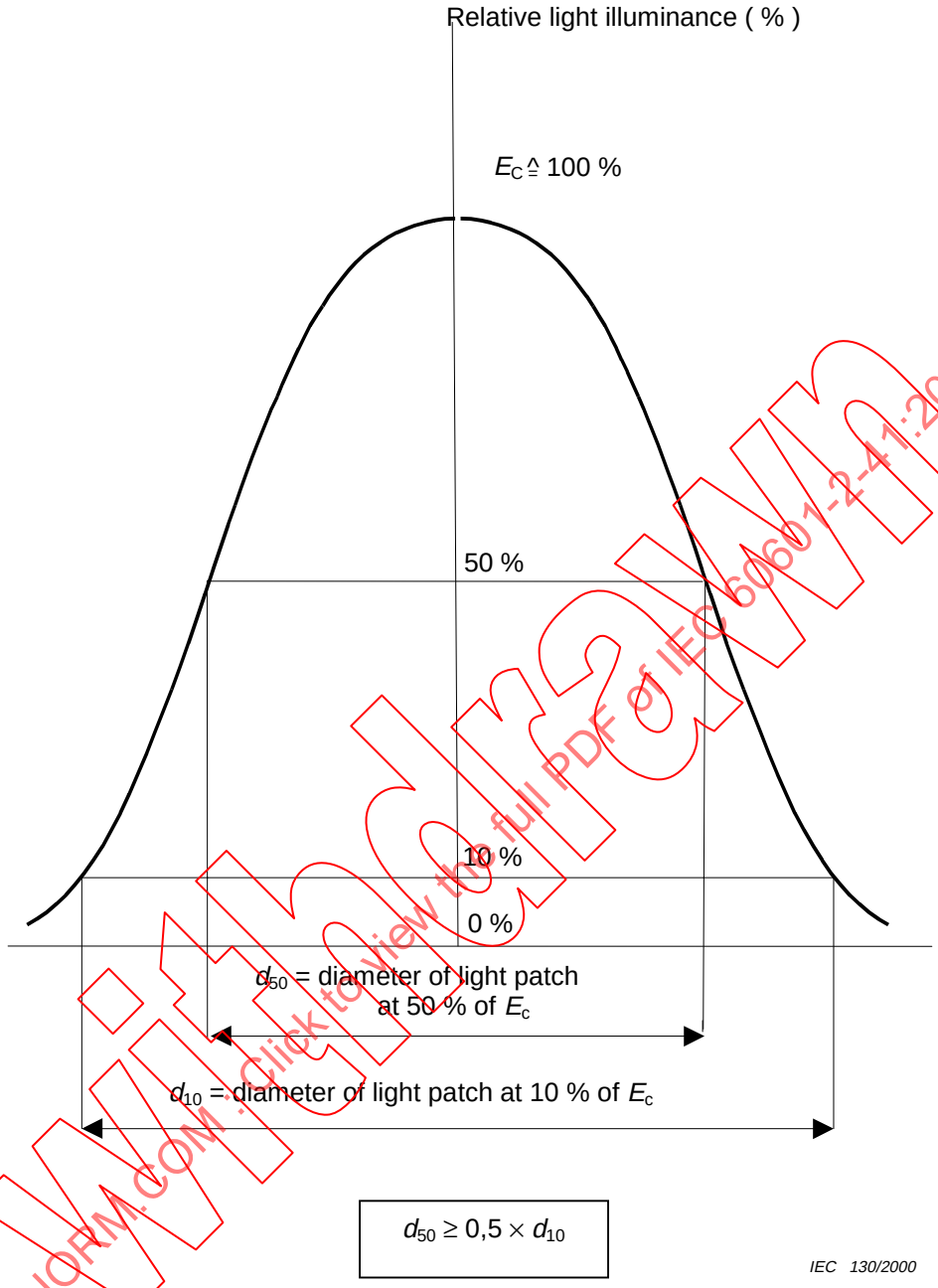
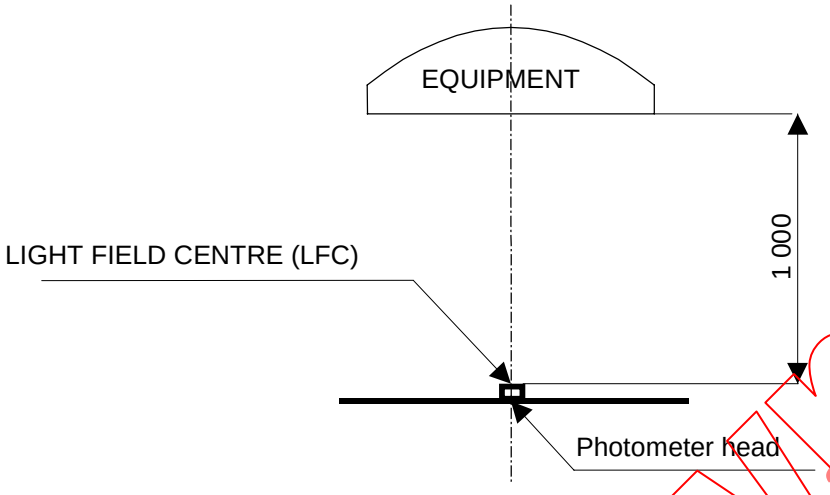


Figure 104 – Light distribution



Dimensions in millimetres

Figure 105 – CENTRAL ILLUMINANCE measurement

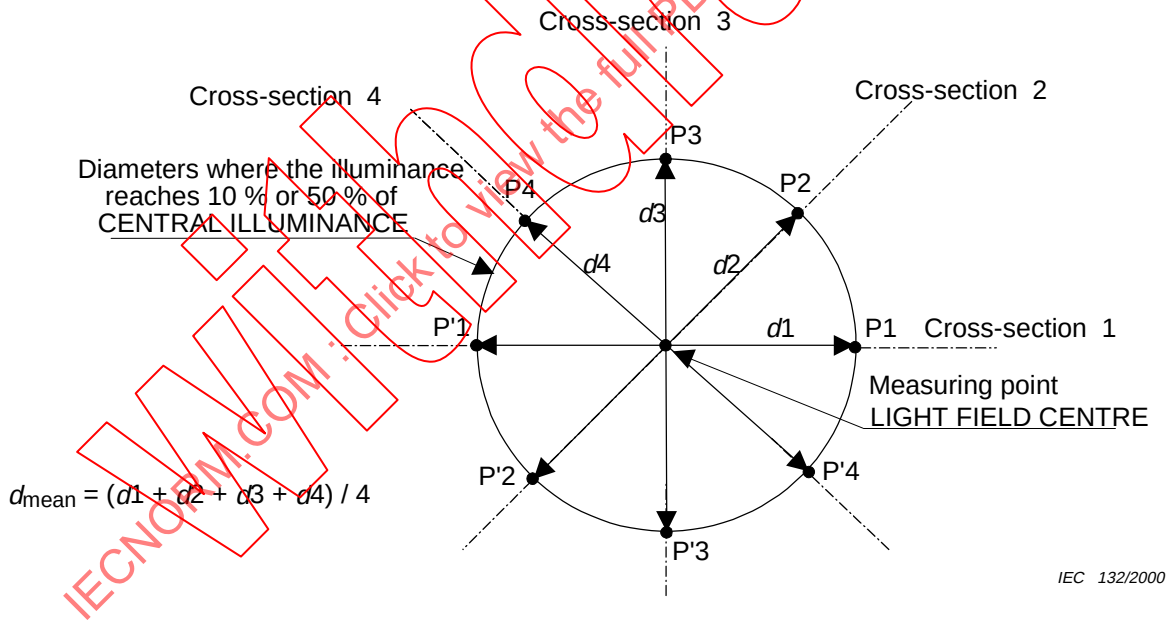
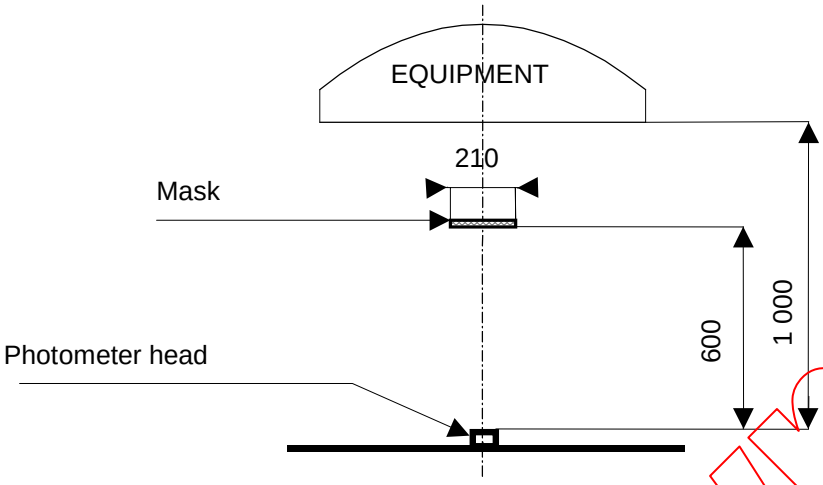


Figure 106 – Measurements of LIGHT FIELD DIAMETER and diameter at 50 % of CENTRAL ILLUMINANCE

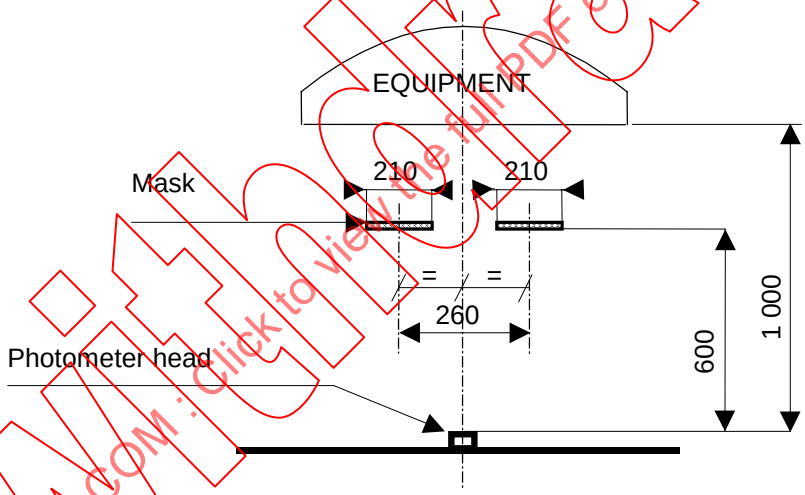


Mask: matt black circular disk of 210 mm diameter

IEC 133/2000

Dimensions in millimetres

Figure 107 – Illuminance measurement with one mask



Mask: matt black circular disk of 210 mm diameter

IEC 134/2000

Dimensions in millimetres

Figure 108 – Illuminance measurement with two masks

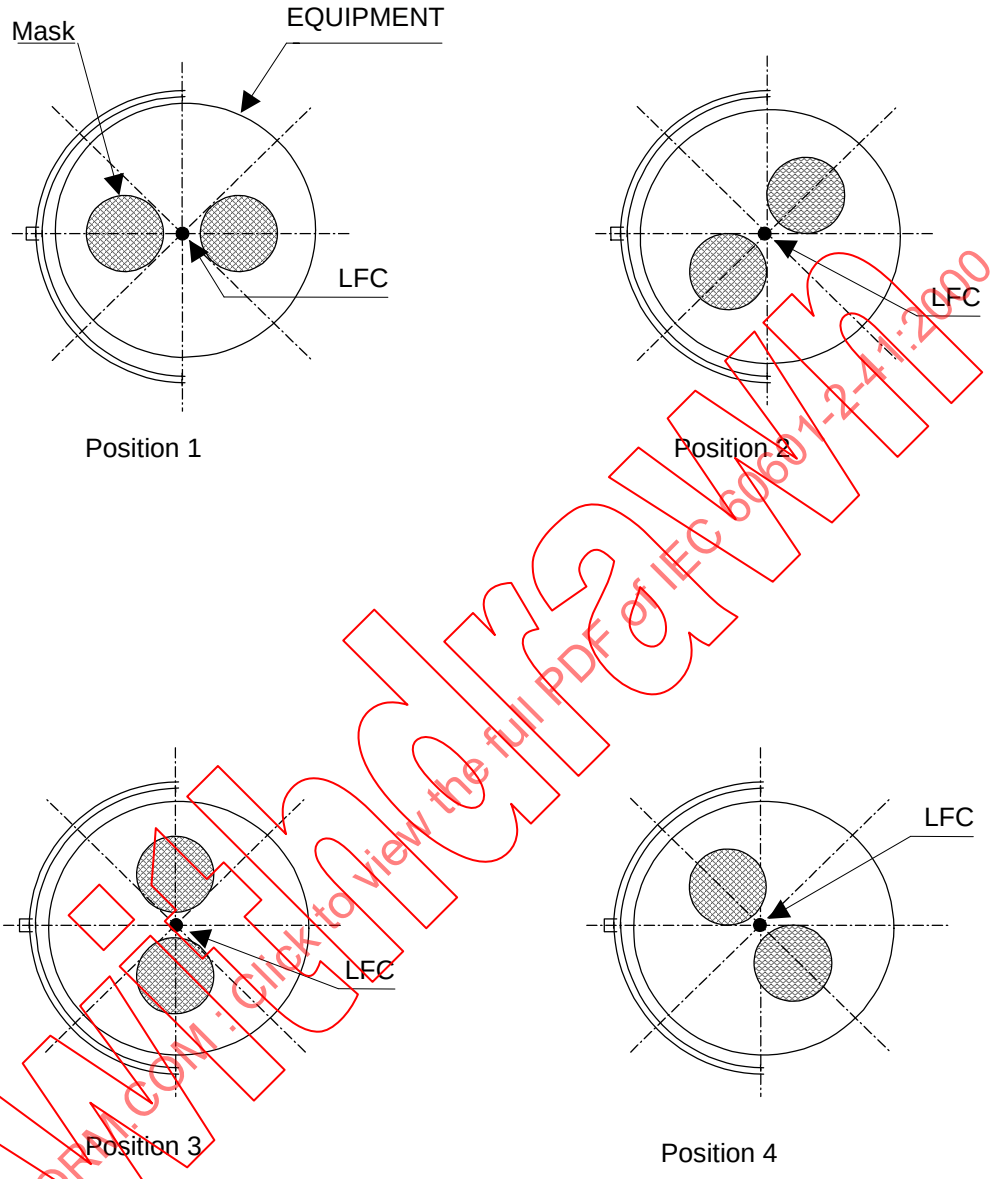
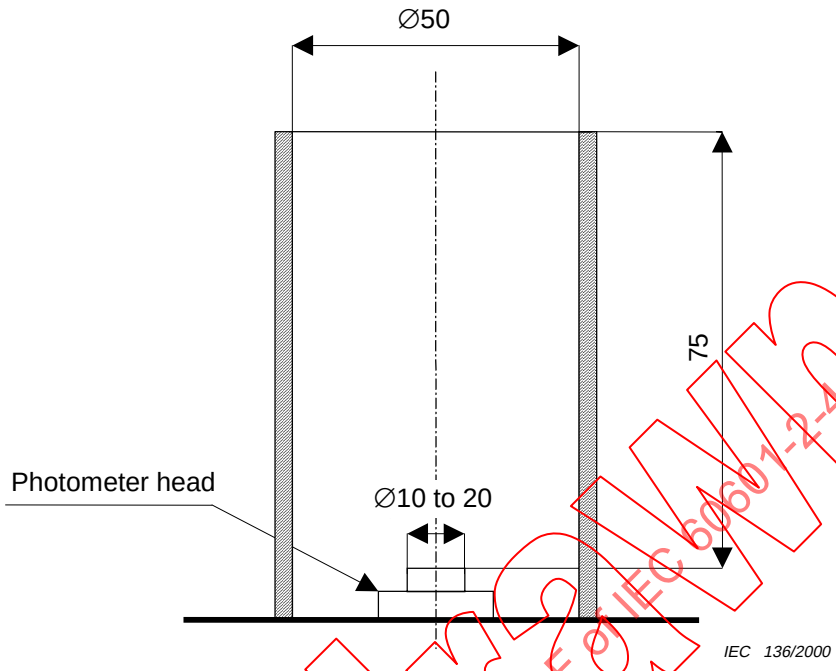
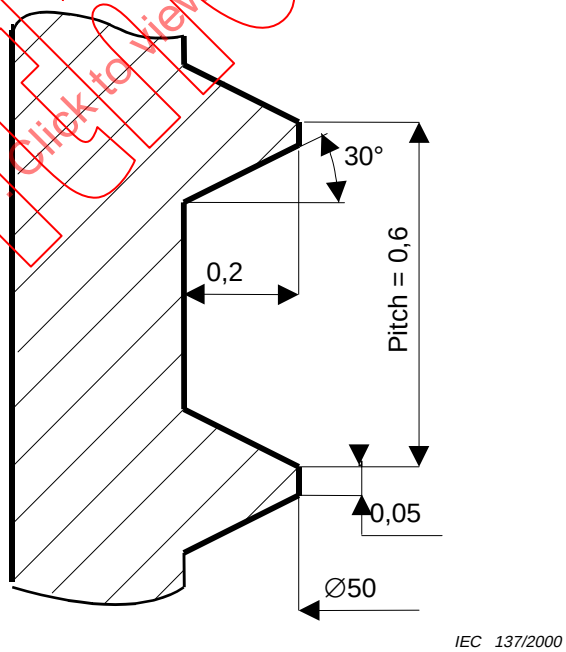


Figure 109 – Illuminance measurement with four different positions of the two masks



Dimensions in millimetres

Figure 110 – Tube for illuminance measurement



Dimensions in millimetres

Figure 111 – Detail of the inner surface of the tube (example)