INTERNATIONAL STANDARD

ISO 9680

Second edition
2007-06-15

Dentistry — Operating lights

Art dentaire — Appareils d'éclairage

Reference number
ISO 9680:2007(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9680 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This second edition cancels and replaces the first edition (ISO 9680:1993) and ISO 9680:1993/Cor.1:1995 which have been technically revised via the following changes:

a) the illumination pattern has been changed from a round area, A, with a diameter of 50 mm into an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm;

b) the level of illuminance shall be adjustable with a minimum level $\leqslant$ 8 000 lx and a maximum level $\geqslant$ 20 000 lx;

c) a requirement for the general colour rendering index ($Ra > 85$) for diagnostic purposes is added;

d) a requirement for UV irradiance has been added;

e) the radiant heat in pattern shall be measured as the irradiance, E, in W/m^2 ($E \leqslant 350$ W/m^2).

Introduction

The aim of this International Standard is to provide the dentist and his staff with means to enable them to work with optimum visual ease and comfort, i.e. a visual acuity of 90 % to 100 % according to zone, without adversely affecting their perception of colour or causing excessive fatigue.

In this International Standard, the safety of an operating light is assessed in combination with its power supply. Such power supplies may be incorporated in dental units or dental patient chairs.

Any item of equipment recommended by the manufacturer for use in conjunction with an operating light should not render the equipment unsafe.

In preparing this International Standard account has been taken of IEC 60598-1.

This International Standard refers to IEC 60601-1, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1.

This International Standard takes priority over IEC 60601-1 as specified in its individual clauses.

Only the specifications laid down in this International Standard are applicable.

Dentistry — Operating lights

1 Scope

This International Standard specifies requirements and test methods for operating lights used in the dental office and intended for illuminating the oral cavity of patients. It also contains specifications on manufacturers' instructions, marking and packaging.

This International Standard applies to operating lights that are intended to be permanently fixed to the ceiling, or to the wall or to the floor.

Excluded are auxiliary light sources, e.g. from dental handpieces and dental headlamps.

Also excluded are dental luminaires, which are specifically designed for use in a dental surgery.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1942[1)], *Dentistry — Vocabulary*

ISO 9687, *Dental equipment — Graphical symbols*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

IEC 60050-845, *International Electrotechnical Vocabulary. Lighting*

IEC 60598-1:2006, *Luminaires — Part 1: General requirements and tests*

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

CIE Publication 13.3, *Method of measuring and specifying colour rendering properties of light sources*

CIE Publication 15:2004, *Colorimetry*

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

1) To be published. (Replaces ISO 1942, parts 1 to 5)

ICNIRP Guidelines, *Guidelines on Limits of Exposure to Ultraviolet Radiation of Wavelengths between 180 nm and 400 nm (Incoherent Optical Radiation)* of the International Commission on Non-Ionizing Radiation Protection, Health Physics, **87**, Number 2, pp. 171-186, August 2004

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-845, IEC 60598-1, IEC 60601-1, ISO 1942 and the following apply.

3.1
luminaire
apparatus which distributes, filters or transforms the light transmitted from one or more lamps and which includes all the parts necessary for supporting, fixing and protecting the lamps, but not the lamps themselves, and where necessary circuit auxiliaries together with the means for connecting them to the supply

[IEC 60598-1:2006, 1.2.1]

3.2
lamp
light source

3.3
dental luminaire
luminaire specially designed and/or presented for use in the dental surgery

3.4
operating light
item of dental equipment specially designed for use by a dentist for illuminating the oral cavity, consisting of a luminaire (3.1) and one or more lamps

3.5
illuminance
luminous flux incident on a surface per unit of area, usually measured in lux

4 Classification

4.1 According to type of protection against electric shock

Operating lights are classified as follows:

a) Class I equipment (see IEC 60601-1:2005, 3.13)

Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of accessible conductive parts to the protective (earth) conductor in the fixed wiring of the installation in such a way that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

b) Class II equipment (see IEC 60601-1:2005, 3.14)

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

4.2 According to mode of operation

See IEC 60601-1:2005, 6.6.

Operating lights shall be suitable for continuous operation.

5 Requirements and recommendations

5.1 General requirements

Operating lights shall be designed, constructed and manufactured so that, when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they cause no danger which could reasonably be foreseen to the patient, to the personnel or to the surroundings in normal use and in single-fault condition.

If the equipment passes all the tests described in this International Standard, it shall be considered that these requirements are fulfilled.

In addition, it is recommended that edges and corners of components and parts accessible to the patient or personnel shall be finished in such a manner as to avoid injury to the patient or personnel.

Operating lights should be capable of being adjusted so as to minimize the variation in illumination of the oral cavity in all operating positions, maintaining the 1 200 lx line parallel with the bi-pupillar line in accordance with 5.2.3.1.

Test in accordance with 7.3.

5.2 Optical requirements

5.2.1 Level of illuminance

The level of illuminance shall be adjustable with a minimum level $\leqslant$ 8 000 lx and a maximum level $\geqslant$ 20 000 lx. The adjustment between these levels should be continuous.

Test in accordance with 7.3 and 7.4.2.

5.2.2 Illumination pattern

5.2.2.1 Illumination areas

The illumination areas A and B are shown in Figure 1.

The inner area of illumination, area A, is defined by an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm.

The outer area of illumination, area B, is defined as the area between the 50 % of maximum illuminance isolux line and the inner area A.

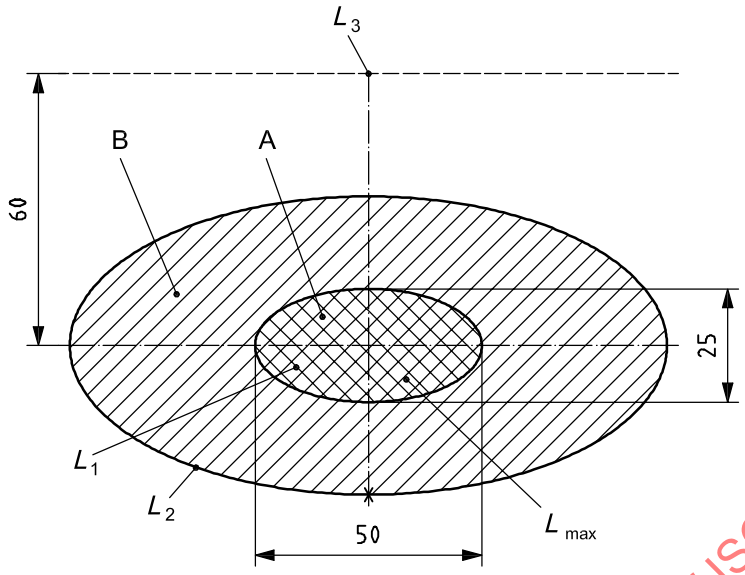
The 50 % of maximum illuminance isolux line shall be plotted in order to indicate area B (see Figure 1).

5.2.2.2 Illuminance

The point of the maximum illuminance shall lie within the area A. Throughout area A the illuminance shall not be less than 75 % of the maximum illuminance (see Figure 1).

Test in accordance with 7.4.2.

Dimensions in millimetres



Key

A inner area of illumination
B outer area of illumination

L_{max} point of maximum illuminance
L_1 illuminance within the area A
L_2 line of pattern with $L = 0{,}5\ L_{max}$
L_3 illuminance at a distance of 60 mm, $L_3 < 1\ 200$ lx

Figure 1 — Illumination pattern

5.2.2.3 Illumination uniformity

The illumination shall decrease in intensity progressively and smoothly toward the pattern edge, within the limits given in 5.2.2.2.

Test in accordance with 7.4.3.

5.2.3 Illuminance in the patient's eyes

5.2.3.1 Level of illuminance

The level of illuminance at a distance of 60 mm above a line parallel to a horizontal line through the area of maximum illuminance shall be no greater than 1 200 lx (see Figure 1) in all operating positions around the oral cavity.

Test in accordance with 7.4.2.

5.2.3.2 Glare or reflections from the reflector

No glare or reflections from the reflector should fall on to the patient's eyes during normal operation.

Test in accordance with 7.3.

5.2.4 Chromatic aberration

No chromatic aberration (colour separation) of the light incident upon the measuring screen shall be visible in area B and area A.

Test in accordance with 7.4.4.

5.2.5 Correlated colour temperature

The trichromatic co-ordinates of the four extreme points are given in Table 1. The chromaticity co-ordinates (x, y) of the light emitted by the operating lights shall be within the field defined by the coordinates in Table 1.

Test in accordance with 7.4.5.

Table 1 — Co-ordinates of colour space

Corner point	Chromaticity co-ordinates		LUV colour space of CIE 15.2	
	x	y	u'	v'
1	0,310	0,369	0,182	0,488
2	0,316	0,322	0,203	0,465
3	0,414	0,428	0,227	0,527
4	0,396	0,377	0,235	0,504
NOTE Further information on the transformation formulae is given in Annex A.				

5.2.6 Radiant heat in pattern

The radiant heat in pattern shall be measured as the irradiance, E, in W/m^2. The irradiance shall be $\leqslant$ 350 W/m^2 at the maximum illuminance level.

Test in accordance with 7.4.6.

5.2.7 Shadow

The hard shadow of a disc with 20 mm diameter at a distance of 50 mm shall have no dimension greater than 12 mm.

Test in accordance with 7.4.7.

5.2.8 General colour rendering index (Ra)

Operating lights used for diagnostic purposes shall have a general colour rendering index $Ra > 85$.

Test in accordance with 7.4.8.

5.2.9 UV irradiance

The effective UV irradiance at the maximum level of the operating light in the spectral region of 180 nm to 400 nm shall not exceed 0,008 W/m^2, spectrally weighted using the spectral weighting factors contained in Table 1 of the ICNIRP guidelines **87** (2).

Test in accordance with 7.4.9.

NOTE This requirement is equivalent to a maximum effective radiant exposure of 30 J/m^2, spectrally weighted according to the referenced document, in one hour under the specified test conditions.

5.3 Mechanical requirements

5.3.1 Moving parts

Moving parts that may constitute a hazard under normal working conditions shall be protected or guarded in order to minimize the risk of injury to the patient and personnel.

The distance between power-activated moving parts that are accessible to patients' and personnel's hands and fingers shall be less than 10 mm when fully opened or a minimum of 20 mm when fully closed.

All electric cables shall be adequately protected against wear, fracture and damage due to rubbing or strain incurred during normal operation of the operating light.

IEC 60601-1:2005, 9.2 applies.

Test in accordance with 7.5.1.

5.3.2 Operating controls

Operating controls shall be located in a position, and be of such design, as to preclude the likelihood of being accidentally activated.

Symbols for operating controls shall be used as specified in ISO 9687 where they exist.

Test in accordance with 7.3.

5.3.3 Rotary movement

Operating lights shall be designed to avoid the risk of damage to electrical conductors during rotary movement.

Test in accordance with 7.3.

5.3.4 Handling and mechanical adjustment

5.3.4.1 General stability

If the operating light is fixed to a pillar or post, it shall not be possible to tip it. If the operating light is fixed to the ceiling or wall, the fixing shall not be damaged or disrupted.

Test in accordance with 7.5.4.

5.3.4.2 Stability after positioning

Operating lights shall be free from apparent drift when positioned.

Test in accordance with 7.5.2.

5.3.4.3 Operating forces

If the operating light is adjustable by the personnel, from one position to another, it should allow quick and easy movement and be stable in its new position. The force required at the handle used to reposition the operating light shall not exceed 30 N. Minor adjustments to the position of the light source assembly shall not require a force greater than 7 N.

Test in accordance with 7.5.3.

5.3.4.4 Mechanical strength

IEC 60601-1:2005, 9.1 applies.

5.3.5 Expelled parts

The luminaire of an operating light shall be designed to provide protection against the effects of shattering lamps. No part of a shattered lamp shall be expelled.

Test in accordance with 7.5.5.

5.3.6 Suspended masses

IEC 60601-1:2005, 9.8 applies.

5.4 Cleaning and disinfection

All exterior touchable parts of the operating light shall be capable of undergoing cleaning without deterioration of the light's surface or markings by using agents recommended by the manufacturer.

All exterior touchable parts of the operating light shall be capable of undergoing disinfection without deterioration of the light's surface or markings when using chemically relevant agents recommended by the manufacturer.

All safety requirements shall be maintained after the cleaning and disinfection test.

Test in accordance with 7.6.

5.5 Electrical requirements

5.5.1 Power input

IEC 60601-1:2005, 4.11 applies.

5.5.2 Single fault conditions

IEC 60601-1:2005, 4.7 applies.

5.5.3 Protection against electric shock hazards

IEC 60601-1:2005, 8.1 applies.

5.5.4 Requirements related to classification

5.5.4.1 Class I equipment

IEC 60601-1:2005, 8.3 applies.

5.5.4.2 Class II equipment

IEC 60601-1:2005, 8.3 applies.

5.5.5 Limitation of voltage and/or energy

IEC 60601-1:2005, 8.4 applies.

5.5.6 Enclosures and protective covers

IEC 60601-1:2005, 5.9 applies.

5.5.7 Separation

IEC 60601-1:2005, 8.5 applies.

5.5.8 Protective earthing, functional earthing and potential equalization

IEC 60601-1:2005, 8.6 applies.

5.5.9 Leakage currents

IEC 60601-1:2005, 8.7 applies.

Testing shall be carried out in accordance with 7.7.1.

5.5.10 Dielectric strength

The dielectric strength shall be sufficient to withstand the test voltages as specified in IEC 60601-1:2005, 8.8.

Testing shall be carried out in accordance with 7.7.2.

5.5.11 Excessive temperature

IEC 60601-1:2005, 11.1 applies.

5.5.12 Interruption of power supply

IEC 60601-1:2005, 15.4.2.1 a), 11.8 and 9.2.5 apply.

5.5.13 Protection against incorrect output

IEC 60601-1:2005, 12.4.1 and 12.4.4 apply.

5.5.14 Components and general assembly

IEC 60601-1:2005, 15.4 applies.

5.5.15 Mains parts, components and layout

IEC 60601-1:2005, 8.11 applies.

5.5.16 Protective earthing: terminals and connections

IEC 60601-1:2005, 8.6 applies.

5.5.17 Construction and layout

IEC 60601-1:2005, 3.62, 8.8.4, 8.10.5, 8.10.6, 8.10.7, 15.4.3.5 and 15.4.8 apply.

6 Sampling

All type tests shall be made on one representative sample of the operating light.

7 Testing

7.1 General

All tests described in this International Standard are type tests.

7.2 Test conditions

7.2.1 General provisions for testing

The test sequence shall be in accordance with IEC 60601-1:2005, Annex B. Testing shall be carried out by independent test laboratories.

The operating light intended to be tested shall be new.

Since some of the tests described are destructive tests, the operating light tested shall not be used afterwards.

The rating of components shall be inspected to check that they are appropriate for the application intended. Where a component or equipment part has specified ratings exceeding those appropriate to its use in the equipment, it does not have to be tested for such a wider range.

Compliance is considered to be fulfilled if all relevant tests of this International Standard are passed successfully.

Operating lights, or parts thereof, using materials or having forms of construction different from those detailed in this International Standard shall be acceptable if it can be demonstrated that an equivalent degree of safety is obtained.

7.2.2 Environmental conditions for testing

7.2.2.1 Transport and storage

The manufacturer shall provide instructions on transport and storage.

7.2.2.2 Environment

The manufacturer shall provide instructions on environmental conditions for the operating light.

7.2.2.3 Power supply

The operating light shall be designed to operate from a mains supply with the following characteristics:

a) a rated voltage not exceeding 250 V single-phase;

b) a maximum internal impedance of 0,1 Ω;

c) voltage fluctuations generally not exceeding ± 10 % of the rated voltage, not including short time fluctuations (e.g., duration less than 1 s) at irregular intervals such as caused by operation of X-ray generators or similar equipment;

d) voltages which are practically sinusoidal and form a practically symmetrical supply system in case of polyphase supply;

e) a frequency of not more than 1 kHz;

f) a frequency which does not deviate by more than 1 kHz from the rated value up to 100 Hz and by more than 1 % from 100 Hz to 1 kHz.

The internal electric power source shall be as specified by the manufacturer.

7.2.2.4 Ambient temperature, humidity, atmospheric pressure

7.2.2.4.1 After the operating light being tested has been set up for normal use, carry out tests under operating conditions in accordance with ISO 554 at:

a) an ambient temperature of (23 ± 2) °C;

b) a relative humidity of (50 ± 5) %;

c) an atmospheric pressure within the range 860 mbar to 1 060 mbar (645 mm Hg to 795 mm Hg).

7.2.2.4.2 Protect the equipment from other conditions which might affect the validity of the tests (e.g. draughts).

7.2.2.5 Other conditions

IEC 60601-1:2005, 5.4 a), b), c) and 4.7 apply.

7.2.2.6 Special environmental conditions

Where an operating light has been specified by the manufacturer for use in environmental or operational conditions differing from those indicated in this International Standard, additional safety measures may have to be applied. However, the basic requirements of this International Standard shall always be fulfilled within the environmental and operational conditions specified by the manufacturer.

Special conditions may prevail, for example:

a) in environments with an explosion hazard;

b) at unusually high or low temperatures;

c) at abnormal humidity;

d) at unusual chemical or physical stresses;

e) in oxygen-enriched environments;

f) at atmospheric pressures exceeding the limits set down in 7.2.2.4.1.

7.2.2.7 Supply and test voltages, type of current, nature of supply, frequency

IEC 60601-1:2005, 5.5 applies.

7.2.2.8 Repairs and modifications

IEC 60601-1:2005, 5.6 applies.

7.2.2.9 Humidity preconditioning treatment

As preconditioning for the tests in IEC 60601-1:2005, 8.7 and 8.8, the operating lights, without special protection (ordinary equipment), drip-proof and splash-proof equipment or equipment parts, shall be subjected to a steady-state humidity preconditioning treatment.

Set up the equipment or equipment parts in their complete form (or, where necessary, in parts). Remove any covers used during transport and storage.

Remove those parts which can be removed without the use of a tool but treat these parts simultaneously with the major part.

Open or remove those doors, drawers and access covers which can be opened or removed without the use of a tool.

Carry out the humidity preconditioning treatment in a humidity cabinet containing air with a relative humidity of (93 ± 3) %. Maintain the temperature of the air in the cabinet, at all places where equipment may be located, within ± 2 °C of any convenient value, t, in the range + 20 °C to + 32 °C.

Before placing it in the humidity cabinet, bring the equipment to a temperature between t and $t + 4$ °C, by keeping it at this temperature for at least 4 h before the humidity treatment.

Keep the equipment and equipment parts in the humidity cabinet for

a) two days (48 h) for ordinary equipment or equipment parts;

b) seven days (168 h) for drip-proof and splash-proof equipment or equipment parts.

After the preconditioning, reassemble the equipment, if necessary; carry out the tests in accordance with IEC 60601-1:2005, 8.7.4 and 8.8.3.

Carry out the tests in IEC 60601-1:2005, 8.7.4 and 8.8.3 in the sequence indicated in IEC 60601-1:2005, Annex B.

Other tests should also be carried out in the sequence given in IEC 60601-1:2005, Annex B.

7.3 Visual inspection

Visual inspection shall be performed at normal visual acuity without magnification.

7.4 Optical tests

7.4.1 Test set-up

Aim the light beam at a measuring screen, perpendicular to the optical axis, at a distance of 700 mm measured from the external most forward part of the operating light.

Adjust the controls for illumination during the tests at the setting of the maximum illuminance level.

Draw a rectangular co-ordinate system on the measuring screen with the origin of co-ordinates (the co-ordinate axis intersection point) centrally placed in the zone of maximum illumination level and with the x-axis parallel to the largest diameter of the light spot. If there is a marked cut-off in the y-direction, take this as the positive direction.

Perform the photometric and colorimetric tests in ambient lighting not exceeding 30 lx.

7.4.2 Level of illuminance, illumination pattern and illuminance in the patient's eyes

Use the test set-up as described in 7.4.1.

Measure the illuminance levels with a photometer calibrated in accordance with CIE 69 and having a photometer head with an active receiving surface of 10 mm diameter.

Move the photometer head in order to explore the whole area. Observe the values given by the photometer head, the highest and lowest values, as well as the values on the line 60 mm above the point of highest illuminance. Record them with their location in order to check whether the requirements given in 5.2.1, 5.2.2.2, and 5.2.3.1 are fulfilled.

7.4.3 Illumination uniformity

Use the test set-up as described in 7.4.1.

The requirement is fulfilled if no bright rings or bright spots outside of the central maximum are visually apparent.

7.4.4 Chromatic aberration

Use a flat, white sheet of paper and illuminate it with the light source. Observe whether there are any colour separations when viewed by a person with normal colour vision.

7.4.5 Correlated colour temperature

Determine the trichromatic co-ordinates with the use of a tri-stimulus colorimeter or spectrophotometer at the maximum level of luminance.

7.4.6 Radiant heat in pattern

Measure the radiant heat using a radiometer with a sensitive area of not more than 30 mm diameter and a constant spectral sensitivity in the wavelength region from 300 nm to 2 500 nm.

Make measurements 30 min after switching the operating light to its maximum level of illumination.

The test shall be conducted with the light beam directed perpendicularly on to the sensor. Measure at the point with the maximum of illuminance L_{max} in Figure 1.

7.4.7 Shadow

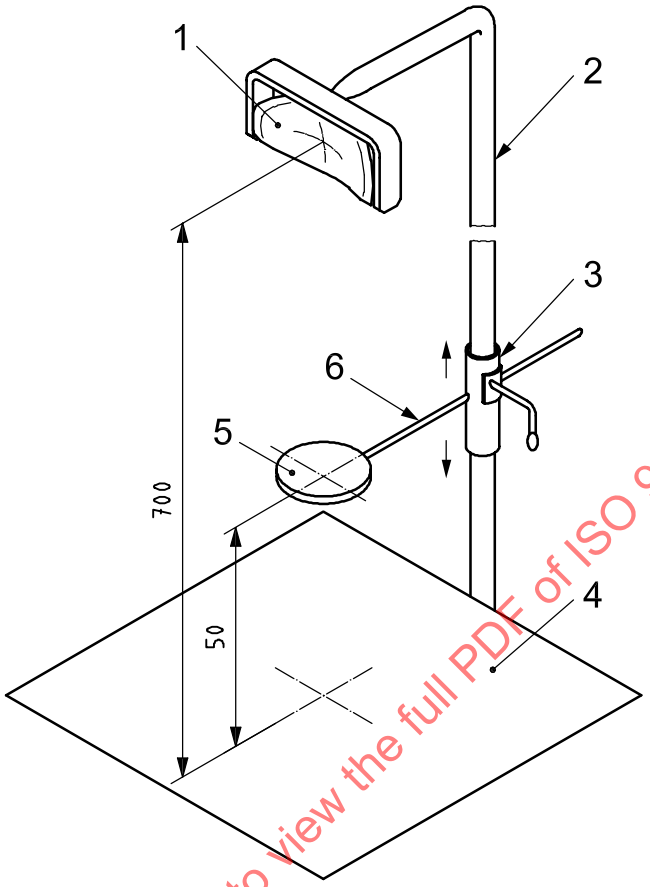
Place the operating light to be tested at a distance of 700 mm from a measuring screen marked with a rectangular co-ordinate system (see Figure 2), with the light beam normal to the measuring screen and the illumination pattern axes coincident with the measuring screen co-ordinates.

Place a support column outside the measurement area, supporting a 20 mm diameter disc that is 1 mm thick. Position the disc parallel to the measuring screen with the centre of the disc on the axis normal to the measuring screen co-ordinates at a distance of 50 mm from the screen. Measure the hard shadow cast on the target on the two main axes.

7.4.8 Colour rendering

Test in accordance with CIE 13.3.

Dimensions in millimetres



Key

1 luminaire
2 support column
3 sliding ring for adjustment
4 screen
5 disc
6 stem

Figure 2 — Device for determination of shadow reduction

7.4.9 Ultraviolet irradiance (180 nm to 400 nm)

Use the test set-up as described in 7.4.1. Position the detector at the maximum point of the irradiance pattern with the detector normal to the incident light.

Measure the irradiance over the range 180 nm to 400 nm with a calibrated spectro-radiometer having uniform sensitivity over the specified spectral range. Calculate the effective irradiance using the spectral weighting factors contained in ICNIRP Guidelines, **87** (2), Table 1.

Alternatively, effective irradiance may be directly measured with a calibrated radiometer which responds to the range 180 nm to 400 nm according to the relative spectral effectiveness defined in ICNIRP Guidelines.

7.5 Mechanical tests

7.5.1 Moving parts

Visually inspect the test sample, using the standard test finger specified in IEC 60601-1:2005, Figure 6.

Perform a visual inspection in accordance with 7.3 to determine the presence of moving parts and, where necessary, measure the maximum and minimum distances.

7.5.2 Stability

Mount the operating light according to the manufacturer's instructions. After mounting, no visible drift shall be observed in any position.

7.5.3 Operating force

Move the operating light vertically and horizontally in two directions at right angles to each other (i.e. along x, y and z axes) and measure the forces required at the handle.

7.5.4 General stability

Apply a force of 50 N at the handle of the operating light in its most unfavourable position.

7.5.5 Expelled parts

Test in accordance with IEC 60598-1:2006, 4.21, except that the fixture shall retain the expelled parts.

7.6 Cleaning and disinfection

Test in accordance with ISO 21530.

7.7 Electrical tests

7.7.1 Continuous leakage currents

Test the earth leakage current and the enclosure leakage current:

a) after the operating light has been brought up to the normal operating temperature in accordance with the requirements of IEC 60601-1:2005, 4.11;

b) after the moisture preconditioning operating as described in IEC 60601-1:2005, 5.7.

The measurements shall be carried out with equipment located outside the humidity cabinet. They shall commence 1 h after equipment has been taken out of this cabinet and placed in an environment with a temperature less than or equal to the temperature of the humidity cabinet.

During testing, those measurements which do not energize equipment shall be made first.

7.7.2 Dielectric strength

IEC 60601-1:2005, 8.8.3 applies.