

BS EN ISO 9680:2014



BSI Standards Publication

## Dentistry — Operating lights

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**National foreword**

This British Standard is the UK implementation of EN ISO 9680:2014. It supersedes BS EN ISO 9680:2007 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/4, Dental Instruments and Equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

## Dentistry - Operating lights (ISO 9680:2014)

Médecine bucco-dentaire - Appareils d'éclairage (ISO 9680:2014)

Zahnheilkunde - Behandlungsleuchten (ISO 9680:2014)

This European Standard was approved by CEN on 9 August 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Foreword

This document (EN ISO 9680:2014) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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

This document supersedes EN ISO 9680:2007.

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### Endorsement notice

The text of ISO 9680:2014 has been approved by CEN as EN ISO 9680:2014 without any modification.

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## 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. [www.iso.org/directives](http://www.iso.org/directives)

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This third edition cancels and replaces the second edition (ISO 9680:2007), which has been technically revised via the following changes:

- a) The scope was expanded to consider any light source technology, including light emitting diodes (LEDs);
- b) Normative references have been updated;
- c) The requirement for the adjustable level of illuminance has been changed to eliminate an upper limit on the minimum illuminance level and to reduce the lower limit on maximum illuminance to 15 000 lx;
- d) The requirement for the Illumination pattern has been revised to specify a minimum size and shape of the outer area of illumination, area B;
- e) A requirement has been added to measure, plot and report the 10 %, 50 % and 75 % of maximum illuminance isolux lines;
- f) The CIE chromaticity coordinates for corner point 1 in [Table 1](#) have been changed to set this corner point within 0,02 of the Planckian locus in the CIE 1960 Uniform Chromaticity Space [i.e. (u,v) chromaticity space];
- g) The colour rendering index requirement was revised to exclude LED operating lights since current LED operating lights may not meet the requirement and an accepted method for measuring the colour rendering properties of white LEDs is not yet established;
- h) In the requirement for ultraviolet light irradiance the lower limit of the wavelength range was changed from 180 nm to 200 nm in order to reflect the measurement range of available radiometers;
- i) A requirement for compatibility with light-activated restorative materials has been added;
- j) The requirement for operating forces has been simplified;
- k) The requirement for expelled parts has been revised;

- l) References in electrical requirements were updated and simplified;
- m) A requirement on usability has been added;
- n) Requirements for test conditions have been simplified;
- o) Electrical tests have been deleted due to reference to IEC 60601-1:2005+A1:2012;
- p) Optical tests have been clarified and a test for compatibility with light-activated restorative materials has been added;
- q) The requirements for instructions for use and technical description have been revised;
- r) The requirements for marking on the outside of mains-operated operating lights have been revised;
- s) The requirement for marking of operating controls has been eliminated in favour of the broader requirement for graphical symbols;
- t) The Bibliography has been expanded.

## 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 nor affect its qualities adversely.

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 the individual Clauses of this International Standard.

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 for use, marking and packaging.

This International Standard applies to operating lights, irrespective of the technology of the light source.

This International Standard excludes auxiliary light sources, e.g. from dental handpieces and dental headlamps and also operating lights which are specifically designed for use in oral surgery.

## 2 Normative references

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

ISO 1942, *Dentistry — Vocabulary*

ISO 4073, *Dentistry — Information system on the location of dental equipment in the working area of the oral health care provider*

ISO 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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, *Luminaires — Part 1: General requirements and tests*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance* + A1:2012

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

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

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

CIE 013.3, *Method of measuring and specifying colour rendering properties of light sources*

CIE S 017, *ILV: International Lighting Vocabulary*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in CIE S 017, IEC 60050-845, IEC 60598-1, IEC 60601-1, ISO 1942, ISO 4073 and the following apply.

**3.1**  
**operating light**

device designed for use by an operator for illuminating the oral cavity, which distributes, filters and/or transforms the light transmitted from one or more light sources and which includes all parts necessary for supporting, fixing and protecting the light sources, and circuit auxiliaries together with the means of connecting them to the supply

**3.2**  
**LED operating light**

operating light using at least one light emitting diode (LED) as the light source

**3.3**  
**illuminance**

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

**3.4**  
**light-activated restorative material**

dental material intended for restoring teeth that incorporates a monomer system, the polymerization of which is activated by blue light

Note 1 to entry: Polymer-based materials of this type are classified in ISO 4049 as Class 2 materials and water-based materials of this type are classified in ISO 9917-2 as Class 2 or Class 3 materials.

## **4 Classification**

### **4.1 According to type of protection against electric shock**

Operating lights are classified in accordance with IEC 60601-1 as follows:

- a) Class I equipment, see IEC 60601-1;
- b) Class II equipment, see IEC 60601-1.

### **4.2 According to mode of operation**

Operating lights shall be suitable for continuous operation. IEC 60601-1:2005+A1:2012, 6.6 applies.

## **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.

Operating lights shall be capable of being adjusted so as to permit illumination of the oral cavity in all patient operating positions.

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

Test in accordance with [7.3](#).

## 5.2 Optical requirements

### 5.2.1 Adjustable level of illuminance

The level of illuminance shall be adjustable between a minimum level and maximum level specified by the manufacturer. The maximum level of illuminance shall be at least 15 000 lx.

NOTE Manufacturers are advised that there is indication in the dental ergonomics literature that a higher specified level of illuminance up to a certain limit may be warranted.<sup>[14]</sup> This requirement will be evaluated in the next revision of this Standard and modified with respect to the lower limit and/or upper limit for maximum illuminance, if appropriate, with consideration for current research.

The adjustment of illuminance may be either continuous or in discrete levels.

Test in accordance with [7.2](#) and [7.3.2](#).

### 5.2.2 Illumination pattern

#### 5.2.2.1 Illumination areas and illuminance levels

The illumination areas A and B are shown in [Figure 1](#).

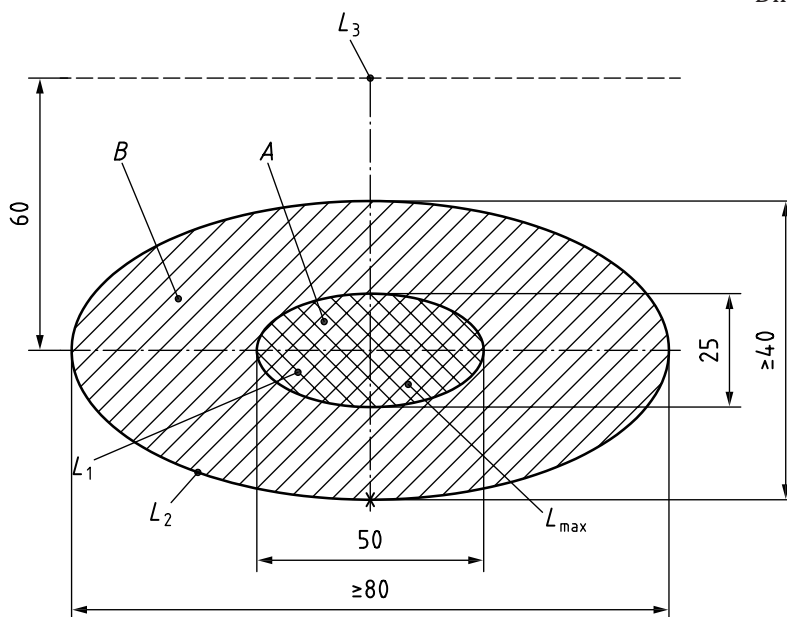
The inner area of illumination, area A, is defined by an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm, in which the point of maximum illuminance,  $L_{Max}$ , shall lie. Throughout area A the illuminance shall not be less than 75 % of  $L_{Max}$  (see [Figure 1](#)). Test in accordance with [7.3.2](#).

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 measured and plotted in accordance with [7.3.2](#) in order to indicate area B. The outer border of area B shall be on or outside of an ellipse with a horizontal axis of 80 mm and a vertical axis of 40 mm (see [Figure 1](#)).

The 10 % of maximum illuminance isolux line and 75 % of maximum illuminance isolux line shall be measured and plotted in accordance with [7.3.2](#) for the purpose of fulfilling the manufacturer's instructions requirement specified in [8.4](#).

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  $L = 0,5 \cdot L_{max}$
- $L_3$  illuminance at a distance of 60 mm,  $L_3 \leq 1\,200$  lx

**Figure 1 — Illumination pattern**

**5.2.2.2 Illumination uniformity**

The illumination shall decrease in intensity progressively and smoothly toward the pattern edge.

Test in accordance with [7.3.3](#).

**5.2.3 Illuminance in patient’s eyes**

The level of illuminance at all points on or above a horizontal line 60 mm above the centre of area A shall not be greater than 1 200 lx (see [Figure 1](#)).

The operating light should preferably be capable of rotating about the X, Y and Z axes in order to allow the operator maximum flexibility in positioning the operating light while preventing excessive illuminance in the patient’s eyes.

Test in accordance with [7.3.4](#).

**5.2.4 Chromatic uniformity**

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

Test in accordance with [7.3.5](#).

### 5.2.5 Correlated colour temperature

Over the full range of illuminance levels of the operating light, the CIE  $(x,y)$  chromaticity coordinates within areas A and B of the illuminance pattern shall be within the quadrilateral area bounded by the coordinates in [Table 1](#). The CIE  $(u',v')$  chromaticity coordinates, defined in CIE 15, of the four corner points are also given in [Table 1](#).

NOTE The colour space defined by the coordinates in [Table 1](#) corresponds to correlated colour temperatures between 3 600 K to 6 400 K.

Preferably, when the operating light is adjusted to the maximum illuminance level, the correlated colour temperature should be between 4 500 K and 6 400 K.

Test in accordance with [7.3.6](#).

**Table 1 — Coordinates of colour space**

Corner point	Chromaticity coordinates		LUV colour space of CIE 15	
	$x$	$y$	$u'$	$v'$
1	0,311	0,360	0,186	0,484
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 formulas between  $(x,y)$  and  $(u',v')$  coordinates 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  $\leq 350 W/m^2$  at the maximum illuminance level.

Test in accordance with [7.3.7](#).

### 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 [7.3.8](#).

### 5.2.8 Colour rendering

For general illumination of the oral cavity, the operating light shall have a colour rendering index  $R_a > 85$  if the operating light is not an LED operating light.

Test in accordance with [7.3.9](#).

NOTE A performance requirement for the colour rendering index of LED operating lights is not specified since some current LED operating lights may not meet this requirement and an accepted method for measuring the colour rendering properties of white LEDs is not yet established. Manufacturers are advised that a colour rendering requirement for LED operating lights will be considered in the next revision of this Standard.

### 5.2.9 UV irradiance

The effective UV irradiance at the maximum level of the operating light in the spectral region 200 nm to 400 nm shall not exceed  $0,008 W/m^2$  and shall be in accordance with the requirements of IEC 62471:2006, 4.3.1.

Test in accordance with [7.3.10](#).

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

### 5.2.10 Compatibility with light-activated restorative materials

If the operating light is equipped with a setting intended for use while handling light-activated restorative materials, the effective irradiance weighted against the normalized spectral absorbance of camphorquinone shall be less than 3,0 W/m<sup>2</sup> at an illuminance level of at least 6 500 lx.

NOTE This requirement is consistent with ISO 4049, in which the specified filtered xenon light source operated at 8 000 lx for evaluating the sensitivity of polymer-based restorative materials to ambient light produces an effective irradiance of approximately 3,5 W/m<sup>2</sup>.

Test in accordance with [7.3.11](#).

## 5.3 Mechanical requirements

### 5.3.1 Moving parts

IEC 60601-1:2005+A1:2012, 9.2 applies.

Test in accordance with [7.4.1](#).

### 5.3.2 Operating controls

Operating controls shall be designed and located to minimize accidental activation. Graphical symbols for operating controls and performance shall be in accordance with ISO 9687.

IEC 60601-1:2005+A1:2012, 15.1 applies.

### 5.3.3 Rotary movement

Operating lights shall be designed to avoid the risk of damage to electrical conductors during rotary movement of all movable elements of the operating light.

IEC 60601-1:2005+A1:2012, 9.2 applies.

### 5.3.4 Handling and mechanical adjustment

#### 5.3.4.1 General stability

If the operating light is mounted to a pillar or post, it shall not be possible to tip it. If the operating light is mounted to the ceiling or wall, the mount shall be immovable and stable under the weight and movement of the operating light, in normal function.

Test in accordance with [7.4.4](#).

#### 5.3.4.2 Stability after positioning

Operating lights shall be free from apparent drift when positioned.

Test in accordance with [7.4.2](#).

#### 5.3.4.3 Operating forces

The force required at the handle 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 [7.4.3](#).

#### **5.3.4.4 Mechanical strength**

IEC 60601-1:2005+A1:2012, 9.1 applies.

#### **5.3.5 Expelled parts**

The operating light shall be designed to provide protection against the effects of the shattering of its light source if it is possible for the light source to shatter. This requirement is not relevant for LED light sources.

The operating light shall so be designed that particles from a shattering light source cannot impair safety. This shall be verified by appropriate risk analysis in accordance with ISO 14971.

#### **5.3.6 Suspended masses**

IEC 60601-1:2005+A1:2012, 9.8 applies.

### **5.4 Cleaning and disinfection**

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

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

Test in accordance with [7.5](#).

### **5.5 Electrical requirements**

IEC 60601-1 and IEC 80601-2-60 apply.

### **5.6 Usability**

Testing shall be carried out in accordance with IEC 62366.

## **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.

Testing shall be performed at an ambient temperature of  $(23 \pm 2)$  °C. The relative humidity shall be between 30 % and 70 %.

### **7.2 Visual inspection**

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

## 7.3 Optical tests

### 7.3.1 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 from which light is emitted.

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

Establish a rectangular coordinate system in the measurement plane with the origin of coordinates (i.e. the coordinate axis intersection point) centrally placed in the zone of maximum illumination level and with the x-axis parallel to the major axis of the light beam. If there is a marked cut-off in the y-direction, take this as the positive direction.

For tests specifying visual assessment of the illuminance pattern, place a flat white screen in the measurement plane. For tests requiring instrumented measurements, place the specified detector in the measurement plane.

Perform optical tests in ambient lighting not exceeding 30 lx.

If an operating light is designed to be used at a distance other than 700 mm, the manufacturer shall state the intended operating distance in the instructions for use and include additional optical measurements at the intended operating distance in the technical description.

### 7.3.2 Level of illuminance and illuminance pattern

Use the test set-up as described in [7.3.1](#).

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

Moving the photometer within the measurement plane, make measurements at rectilinear coordinates not more than 5 mm apart, such that all points within the illuminance pattern having illuminance greater than 600 lx are measured.

Record the measurements and their location. Check whether the requirements given in [5.2.1](#), [5.2.2.1](#) and [5.2.3](#) are fulfilled. Use linear interpolation of measurements for determining specified isolux contours.

### 7.3.3 Illuminance uniformity

Use the test set-up as described in [7.3.1](#).

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

### 7.3.4 Illuminance in the patient's eyes

Use the test set-up as described in [7.3.1](#) with a calibrated photometer as described in [7.3.2](#). Moving the photometer in the measurement plane along the line 60 mm above the centre line of area A, make measurements at increments not more than 5 mm apart, such that all points along the line having illuminance greater than 600 lx are measured.

Place a flat white screen in the measurement plane. Observe whether there are areas of brightness above the horizontal line 60 mm above the centre of area A when viewed by a person with normal visual acuity at a distance of 50 cm to 75 cm. If any areas appear brighter than along the horizontal line 60 mm above the centre of area A, measure the illuminance in those areas using a calibrated photometer, as described above.

Record the measurements and their location. Check whether the requirement specified in [5.2.3](#) is fulfilled.



### 7.3.5 Chromatic uniformity

Adjust the ambient lighting to an illuminance level in the range of 1 % to 3 % of the maximum illuminance of the operating light, measured at the centre of the measurement plane with a calibrated illuminance meter oriented toward the ambient light source. Place a flat white screen in the measurement plane and illuminate it with the operating light. Observe whether there are any colour non-uniformities within area A and area B when viewed by a person with normal colour vision at a distance of 50 cm to 75 cm.

### 7.3.6 Correlated colour temperature

Determine the chromaticity coordinates with the use of a tri-stimulus colourimeter or spectrophotometer at the maximum level of illuminance.

### 7.3.7 Radiant heat in pattern

Use the test set-up as described in [7.3.1](#).

Measure the radiant heat using a radiometer with an 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.

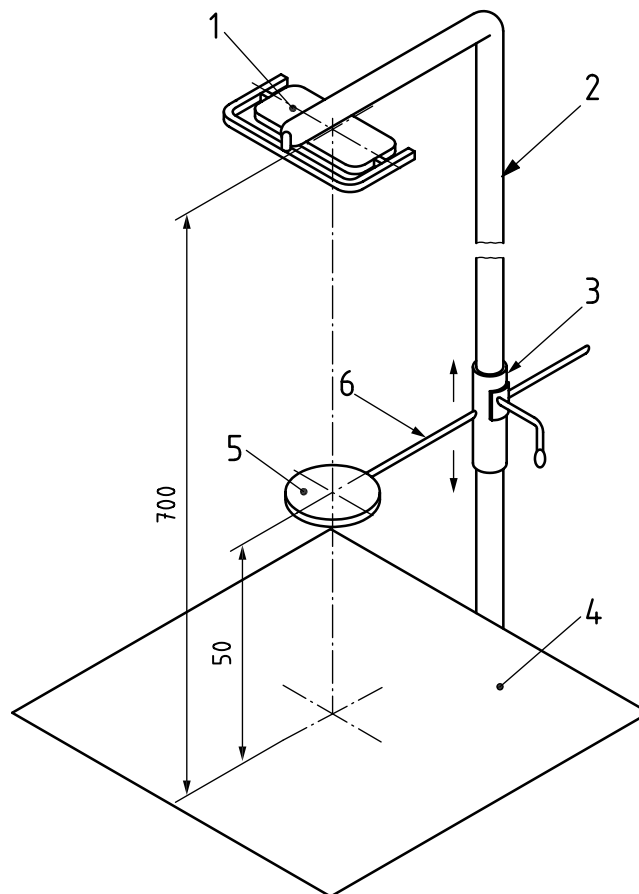
Make measurements 30 min after switching on the operating light to its maximum level of illumination.

The test shall be conducted with the light beam directed perpendicularly onto the sensor. Measure at the point with the maximum of illuminance  $L_{\max}$  in [Figure 1](#).

### 7.3.8 Shadow

Place the operating light to be tested at a distance of 700 mm from a measuring screen marked with a rectangular coordinate system (see [Figure 2](#)), with the light beam normal to the measuring screen and the illuminance pattern axes coincident with the measuring screen coordinates.

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



**Key**

- 1 operating light, or portion thereof capable of producing the illuminance pattern
- 2 pole
- 3 sliding ring for adjustment
- 4 screen
- 5 disc (opaque)
- 6 stem

**Figure 2 — Device for determination of shadow reduction**

### 7.3.9 Colour rendering

Test in accordance with CIE 013.3.

### 7.3.10 Ultraviolet Irradiance (200 nm to 400 nm)

Use the test set-up as described in [7.3.1](#). 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 200 nm to 400 nm with a calibrated spectro-radiometer having uniform sensitivity over the specified spectral range. Evaluate the values measured at each wavelength according to IEC 62471:2006, 4.3.1.

### 7.3.11 Compatibility with light-activated restorative materials

Use the test set-up as described in [7.3.1](#) with a calibrated spectro-radiometer having uniform sensitivity over the spectral range 400 nm to 515 nm and an active cell diameter of 10 mm to 20 mm. Adjust the

operating light to the setting intended for use while handling light-activated restorative materials and adjust the illuminance to the maximum level in this setting, if applicable. Position the detector at the point of maximum irradiance with the detector normal to the incident light.

Measure the spectral irradiance from 400 nm to 515 nm at uniform wavelength intervals of not more than 5 nm. Calculate the effective irradiance weighted against the normalized absorbance of camphorquinone using the following formula:

$$E_{e,\text{eff}} = \sum E_{e,\lambda} \cdot a(\lambda) \cdot \Delta\lambda$$

where

$E_{e,\text{eff}}$	is the effective irradiance weighted against the absorbance of camphorquinone, expressed in watts per square metre ( $\text{W}/\text{m}^2$ );
$E_{e,\lambda}$	is the spectral irradiance, expressed in watts per square metre per nanometre [ $\text{W}/(\text{m}^2 \cdot \text{nm})$ ];
$a(\lambda)$	is the normalized absorbance of camphorquinone (unitless), tabulated in <a href="#">Annex B</a> ;
$\Delta\lambda$	is the wavelength interval of the measurements (nm).

Determine whether the calculated value for  $E_{e,\text{eff}}$  meets the requirement given in [5.2.10](#).

## 7.4 Mechanical tests

### 7.4.1 Moving parts

Visually inspect the test sample, using the standard test finger specified in IEC 60601-1:2005+A1:2012, Figure 6.

Perform a visual inspection in accordance with [7.2](#) to determine the presence of moving parts and, where necessary, measure the maximum and minimum distances.

### 7.4.2 Stability

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

### 7.4.3 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.

### 7.4.4 General stability

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

## 7.5 Cleaning and disinfection

Test in accordance with ISO 21530.

## 8 Manufacturer's instructions

### 8.1 Documents

Documents shall be provided containing at least the information as specified in the following Subclauses.

## 8.2 General

IEC 60601-1:2005+A1:2012, 7.9.1 applies.

## 8.3 Instructions for use

IEC 60601-1:2005+A1:2012, 7.9.2 applies.

In addition, at least the following information shall be provided by the manufacturer:

- a) step-by-step procedures for the operation and routine maintenance of the operating light, including illustrations showing the location of each control and other features relating to safety;
- b) instructions for infection control, including barrier protection and/or cleaning and disinfection of the operating light.
- c) specification for replacement of the light source (e.g. lamp or bulb) if light source is replaceable.

## 8.4 Technical description

IEC 60601-1:2005+A1:2012, 7.9.3.1 and 7.9.3.2 apply.

In addition, at least the following information shall be provided by the manufacturer:

- a) information and instructions on assembly and installation, including space requirements, mounting requirements and electrical supply requirements;
- b) service documentation, including wiring diagram;
- c) overall movements;
- d) range of illuminance (if illuminance is continuously adjustable) or illuminance levels (if illuminance has discrete settings), expressed in lux;
- e) specification of colour rendering index ( $R_a$ ) except for LED operating lights;
- f) specification of correlated colour temperature (CCT);
- g) information on whether the operating light has a setting that is compatible with light-activated restorative materials, conforming to [5.2.10](#);
- h) dimensionally scaled diagram showing typical illuminance pattern contour lines corresponding to 10 %, 50 % and 75 % of the maximum illuminance when the operating light is set to its maximum illuminance setting.

## 8.5 Check

The accompanying documents shall be checked to ensure that all the information specified in [8.2](#) to [8.4](#) is provided.

## 9 Packaging

**9.1** Operating lights shall be packaged for transportation in such a way that no damage may occur during anticipated transport conditions.

**9.2** Component parts shall be specifically identified on the outside to facilitate correct assembly.

## 10 Marking

### 10.1 Marking on the outside of mains-operated operating lights

Marking on the outside of mains-operated operating lights shall be in accordance with IEC 60601-1:2005+A1:2012, 7.2.2, 7.2.5, 7.2.6, 7.2.11 (see [Table 2](#)).

In addition, at least the following information shall be provided by the manufacturer.

**Table 2 — Marking on the outside of mains-operated operating lights**

Subject	Mains operated equipment
Serial number	X
Indication of origin	X
Model or type reference	X
Connection to supply	X
Supply frequency (Hz)	X
Power input	X
Classification	X
Fuses	X

### 10.2 Marking on the inside of operating lights

Marking on the inside of operating lights shall be in accordance with IEC 60601-1:2005+A1:2012, 7.1.2, 7.3.4, 7.3.5, 7.3.7 and 7.3.8.

### 10.3 Graphical symbols

Graphical symbols used for marking, operating controls and performance shall be in accordance with ISO 9687 and ISO 15223-1.

### 10.4 Colours of the insulation of conductors

Colours of insulation conductors shall be in accordance with IEC 60601-1:2005+A1:2012, 7.7.

### 10.5 Indicator lights and push-buttons

Indicator lights and push-buttons shall be in accordance with IEC 60601-1:2005+A1:2012, 7.8.

## Annex A (informative)

### Transformation formulas

The LUV colour space of CIE 15 has a  $u'v'$ -colour table, which is a projective transformation of the  $xy$ -chromaticity diagram.

The transformation formulas from the LUV colour space of CIE 15 to the chromaticity coordinates  $(x,y)$  are:

$$x = \frac{27u'}{18u' - 48v' + 36} \quad (1)$$

$$y = \frac{12v'}{18u' - 48v' + 36} \quad (2)$$

The transformation formulas from the chromaticity coordinates  $(x,y)$  to the LUV colour space of CIE 15 are:

$$u' = \frac{4x}{-2x + 12y + 3} \quad (3)$$

$$v' = \frac{9y}{-2x + 12y + 3} \quad (4)$$

## Annex B (normative)

### Normalized absorbance of camphorquinone

The following table provides the normalized absorbance of camphorquinone at 1 nm intervals for use in calculating the effective irradiance weighted against the spectral absorbance of camphorquinone, as specified in 7.3.11. Linear interpolation may be used if spectral irradiance measurements are made with smaller wavelength intervals.

**Table B.1 — Normalized absorbance of camphorquinone**

$\lambda/\text{nm}$	$a(\lambda)$		$\lambda/\text{nm}$	$a(\lambda)$		$\lambda/\text{nm}$	$a(\lambda)$
400	0,116		439	0,653		478	0,929
401	0,122		440	0,674		479	0,913
402	0,130		441	0,694		480	0,896
403	0,136		442	0,714		481	0,874
404	0,144		443	0,735		482	0,849
405	0,152		444	0,755		483	0,820
406	0,160		445	0,774		484	0,784
407	0,169		446	0,794		485	0,743
408	0,178		447	0,813		486	0,697
409	0,187		448	0,832		487	0,644
410	0,197		449	0,850		488	0,586
411	0,206		450	0,867		489	0,527
412	0,217		451	0,882		490	0,466
413	0,227		452	0,895		491	0,408
414	0,238		453	0,905		492	0,353
415	0,249		454	0,913		493	0,302
416	0,262		455	0,921		494	0,256
417	0,275		456	0,928		495	0,215
418	0,288		457	0,933		496	0,179
419	0,302		458	0,940		497	0,148
420	0,317		459	0,947		498	0,122
421	0,332		460	0,955		499	0,101
422	0,346		461	0,962		500	0,084
423	0,361		462	0,971		501	0,070
424	0,376		463	0,979		502	0,058
425	0,390		464	0,987		503	0,049
426	0,405		465	0,992		504	0,041
427	0,420		466	0,997		505	0,035
428	0,436		467	0,999		506	0,030
429	0,452		468	1,000		507	0,026

**Table B.1** (continued)

$\lambda/\text{nm}$	$a(\lambda)$		$\lambda/\text{nm}$	$a(\lambda)$		$\lambda/\text{nm}$	$a(\lambda)$
430	0,468		469	0,999		508	0,023
431	0,487		470	0,997		509	0,019
432	0,505		471	0,993		510	0,017
433	0,525		472	0,988		511	0,015
434	0,545		473	0,981		512	0,013
435	0,566		474	0,974		513	0,012
436	0,588		475	0,965		514	0,010
437	0,609		476	0,955		515	0,009
438	0,631		477	0,943			



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