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Dentistry — Operating lights

Médecine bucco-dentaire — Luminaires opératoires

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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 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 9680:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

- normative references have been updated;
- requirements and test methods for the illumination pattern, illuminance in patient's eyes, colour fidelity and photobiological hazards have been updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides 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 or photobiological injury.

In this document, 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.

IEC 60598-1 has been taken into account during the preparation of this document.

This document 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 document takes priority over IEC 60601-1 as specified in the individual clauses of this document.

Only the specifications laid down in this document are applicable.

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Dentistry — Operating lights

1 Scope

This document 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 the instructions for use, marking and packaging.

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

This document excludes auxiliary light sources, for example, 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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 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 11664-1, *Colorimetry — Part 1: CIE standard colorimetric observers*

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO/CIE 19476, *Characterization of the performance of illuminance meters and luminance meters*

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

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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

IEC/TR 62471-2:2009, *Photobiological safety of lamps and lamp systems — Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety*

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

CIE 224, *Colour Fidelity Index for accurate scientific use*

CIE S 017, *ILV: International Lighting Vocabulary*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

operating light

device designed for use by an operator for illuminating the oral cavity, which either distributes, filters or transforms the light, or does any combination of these, 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

light-activated restorative material

dental material intended for oral use that incorporates a monomer system, the polymerization of which is activated by light

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; or
- b) Class II equipment.

4.2 According to mode of operation

Operating lights are classified in accordance with IEC 60601-1 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 instructions, they cause no danger which can 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 document, it shall be considered that these requirements are fulfilled.

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 at a distance of 700 mm from the operating light.

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

Test in accordance with 7.2 and 7.3.2.

The requirements of 5.2.1 do not apply to any operating mode(s) intended only for use while handling light-activated restorative materials.

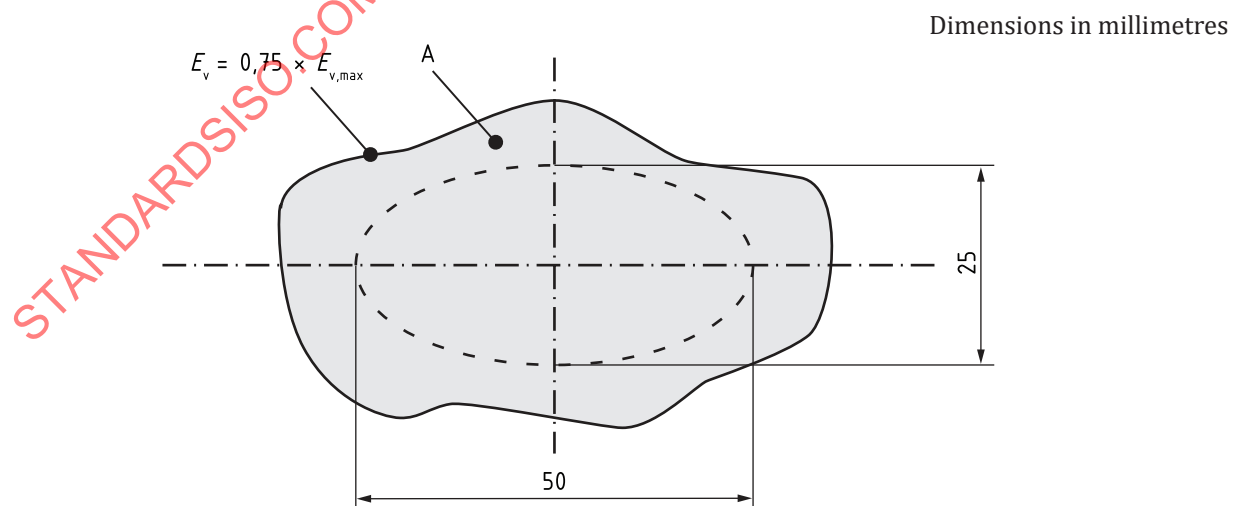
5.2.2 Illumination pattern

5.2.2.1 Illumination areas and illuminance levels

The illumination pattern shall be measured to determine the maximum illuminance, $E_{v,max}$, and the following iso-illuminance lines in accordance with 7.3.2: $0,90 \times E_{v,max}$, $0,75 \times E_{v,max}$, $0,50 \times E_{v,max}$, $0,10 \times E_{v,max}$ and 1 200 lx.

The inner area of illumination, area A, is defined as the area bounded by the iso-illuminance line corresponding to 75 % of the maximum illuminance. The outer border of area A shall be on or outside of an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm, in which the horizontal axis and vertical axis of the ellipse are aligned with the major axis and minor axis of the illumination pattern, respectively (see Figure 1). The illuminance shall not be less than 75 % of $E_{v,max}$ throughout the ellipse. Test in accordance with 7.3.2.

The outer area of illumination, area B, is defined as the area bounded by the iso-illuminance line corresponding to 50 % of the maximum illuminance. 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 and with the same axes as the smaller ellipse associated with area A (see Figure 2). Test in accordance with 7.3.2.

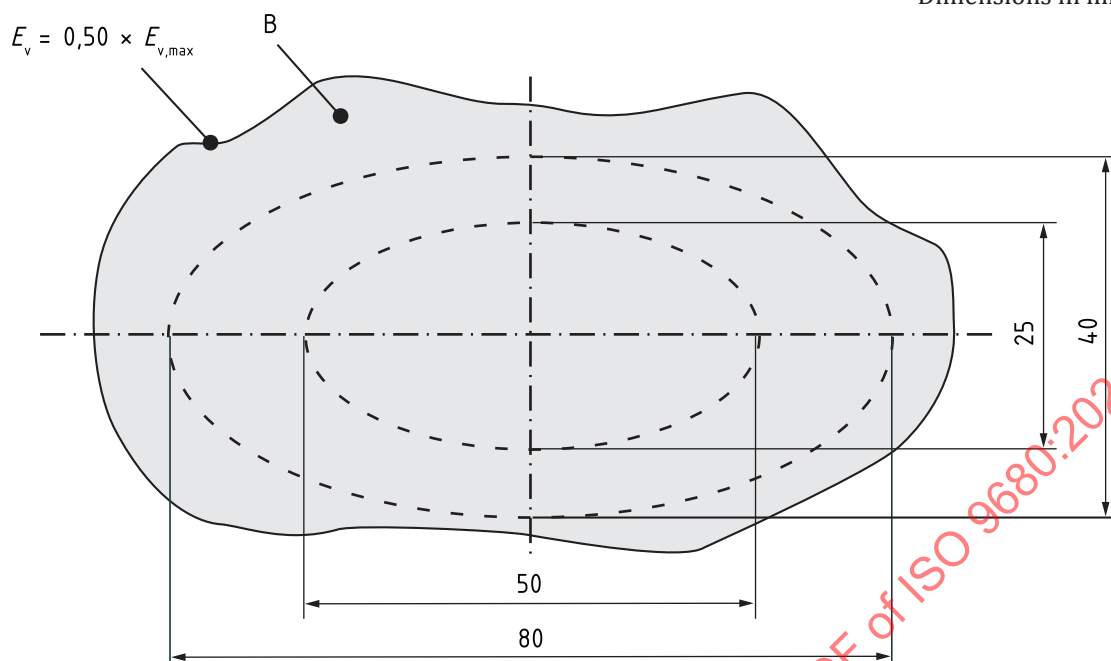


Key

A inner area of illumination

Figure 1 — Example of illumination pattern which satisfies the requirement for area A

Dimensions in millimetres



Key

B outer area of illumination

Figure 2 — Example of illumination pattern which satisfies the requirement for area B

5.2.2.2 Illuminance uniformity

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

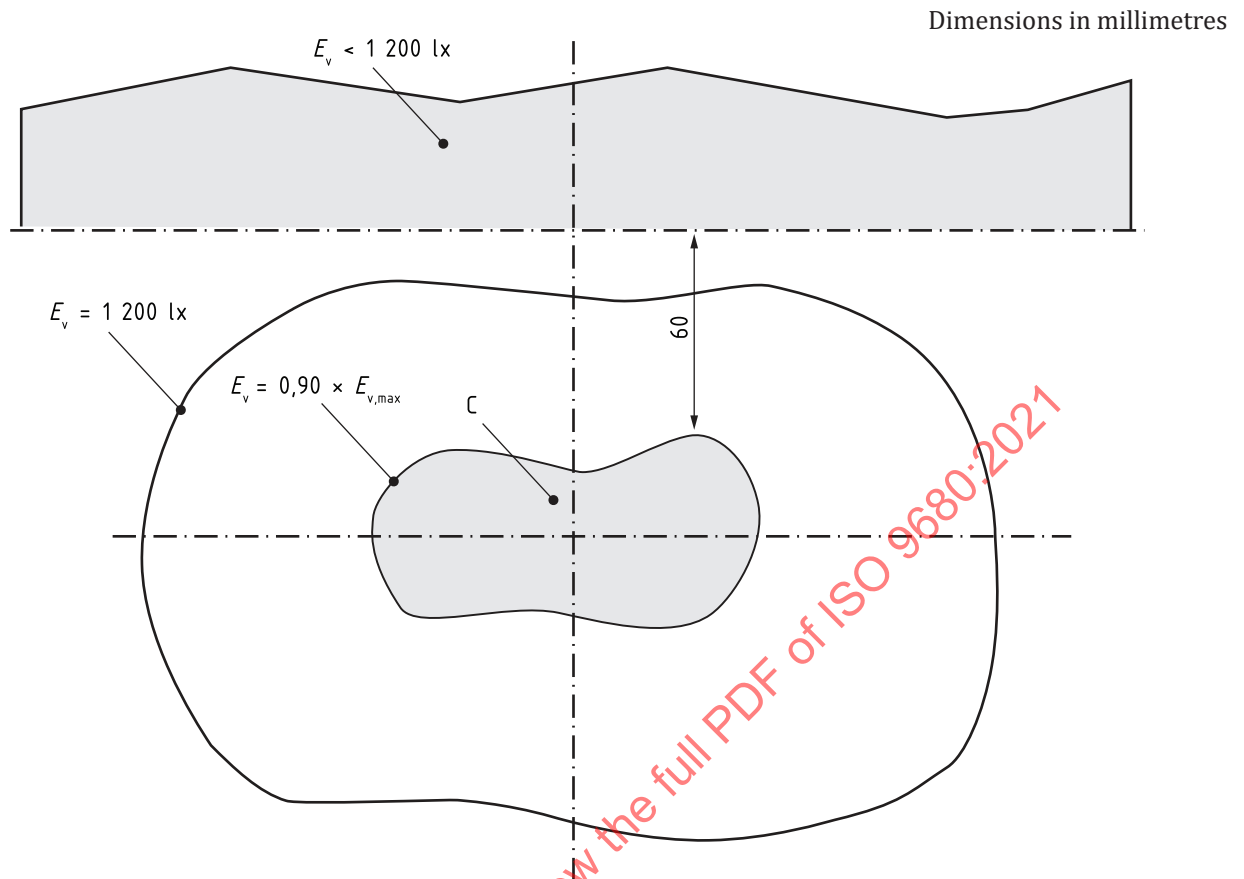
Test in accordance with [7.3.3](#).

5.2.3 Illuminance in patient's eyes

An area C is defined as the area bounded by the iso-illuminance line corresponding to 90 % of the maximum illuminance. The level of illuminance at all points on or above a horizontal line 60 mm above the uppermost point of area C shall not be greater than 1 200 lx (see [Figure 3](#)).

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](#).



Key

C area bounded by the iso-illuminance line corresponding to 90 % of maximum illuminance

Figure 3 — Example of illumination pattern which satisfies the requirement for limiting illuminance in the patient's eyes

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, as specified in ISO/CIE 11664-1, 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, as specified in ISO/CIE 11664-5, of the four corner points are also given in [Table 1](#).

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

The requirements of 5.2.5 do not apply to any operating modes intended only for use while handling light-activated restorative materials.

Table 1 — Coordinates of colour space

Corner point	CIE 1931 chromaticity coordinates		CIE 1976 chromaticity coordinates	
	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 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 7.3.7.

5.2.7 Colour fidelity

For general illumination of the oral cavity, the operating light shall have a general colour fidelity index, R_f , of at least 85.

NOTE The importance of accurately assessing colour in dental diagnosis and treatment while using an operating light supports specifying R_f as the measure for colour fidelity in this document even though CIE 224 indicates that R_f is not intended as a universal replacement for the general colour rendering index, R_a , at this time. The decision to specify R_f in this document was made in consultation with CIE.

Test in accordance with 7.3.8.

The requirements of 5.2.7 do not apply to any operating modes intended only for use while handling light-activated restorative materials.

5.2.8 Actinic UV hazard exposure for the skin and eye

The risk group classification of the operating light for actinic ultraviolet hazard (E_s) shall be Risk Group 1 or lower, as specified in IEC 62471:2006, 6.1, when tested under the conditions specified in 7.3.9. Unless the operating light is classified as an exempt group for actinic ultraviolet hazard, the permissible exposure duration, t_{max} , per IEC 62471:2006, 4.3.1 shall be calculated in accordance with 7.3.9.

Compliance with this requirement shall be verified either by documentation (e.g. test report by the light source manufacturer) which verifies that all of the light sources used in the operating light do not emit in the applicable wavelength range (200 nm to 400 nm), or by testing in accordance with 7.3.9.

5.2.9 Near-UV hazard exposure for the eye

The risk group classification of the operating light for near-UV hazard (E_{UVA}) shall be Risk Group 1 or lower, as specified in IEC 62471:2006, 6.1, when tested under the conditions specified in 7.3.10.

Unless the operating light is classified as exempt group for near-UV hazard, the permissible exposure duration, t_{max} , per IEC 62471:2006, 4.3.2 shall be calculated in accordance with 7.3.10.

Compliance with this requirement shall be verified either by documentation (e.g. test report by the light source manufacturer) which verifies that all of the light sources used in the operating light do not emit in the applicable wavelength range (315 nm to 400 nm), or by testing in accordance with 7.3.10.

5.2.10 Retinal blue light hazard exposure

The risk group classification for retinal blue light hazard (L_B) per IEC 62471:2006, 6.1 shall be Risk Group 1 or lower when tested under the conditions specified in 7.3.11.

Unless the operating light is classified as exempt group for retinal blue light hazard, the permissible exposure duration, t_{max} , per IEC 62471:2006, 4.3.3 shall be calculated in accordance with 7.3.11.

Test in accordance with 7.3.11.

5.2.11 Single fault condition for photobiological safety

Analysis under single fault condition shall be applied to the requirements for actinic UV exposure for skin and eye (see 5.2.8), near-UV exposure for the eye (see 5.2.9) and retinal blue light hazard exposure (see 5.2.10). The operating light shall be considered single fault safe (IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.7) if the risk group classification of the operating light does not exceed Risk Group 2 given in IEC 62471:2006, 6.1 under single fault condition.

NOTE A single fault condition, such as a short circuit or an open circuit of any component other than a component with high-integrity characteristics or a software failure, can lead to a higher LED driving current, increased light emission and a higher photobiological risk group classification.

5.2.12 Heat due to optical radiation

The irradiance over the wavelength range of 300 nm to 2 500 nm shall be $\leq 350 \text{ W/m}^2$ (35 mW/cm^2) at the maximum illuminance level at a distance of 700 mm from the operating light.

Test in accordance with 7.3.12.

5.2.13 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 maximum illuminance in this setting shall be at least 6 500 lx and the camphorquinone-weighted irradiance shall be less than $3,0 \text{ W/m}^2$ ($0,3 \text{ mW/cm}^2$) when tested under the conditions specified in 7.3.13. The camphorquinone-weighted irradiance is the integral of the product of the operating light irradiance spectrum and the normalized absorption spectrum of camphorquinone over the wavelength range of 400 nm to 515 nm (see 7.3.13).

NOTE The photo-initiator systems of commercial dental restorative materials are currently based on one or more of the following: camphorquinone, 1-phenyl-1,2 propanedione (PPD), or acylphosphine oxides. Each of these photo-initiators has a different absorbance spectrum. Since the absorbance spectrum of camphorquinone extends to higher wavelengths than the other photo-initiators, the overlap with the emission spectrum of operating lights is greatest with camphorquinone. Therefore, the camphorquinone absorbance spectrum is expected to represent the worst-case challenge for evaluating possible effects of dental operating lights on light-activated restorative materials.

Test in accordance with 7.3.13.

5.3 Mechanical requirements

5.3.1 Moving parts

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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+AMD1:2012+AMD2:2020, 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+AMD1:2012+AMD2:2020, 9.2 applies.

5.3.4 Handling and mechanical adjustment

5.3.4.1 Stability after positioning

Operating lights shall be free from apparent drift when positioned.

Test in accordance with [7.4.2](#).

5.3.4.2 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](#).

5.3.4.3 Mechanical hazards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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.

5.4 Reprocessing

All exterior touchable parts of the operating light shall be suitable for reprocessing using the agents and methods recommended by the manufacturer without deterioration of surfaces or labelling.

The manufacturer shall provide information on the reprocessing for the operating light in accordance with ISO 17664-1 and ISO 17664-2, as applicable. Preferably, the handles should be sterilizable or capable of accommodating reusable, sterilizable covers.

All safety requirements shall be maintained after the reprocessing test.

Testing of resistance against cleaning and disinfection shall be carried out in accordance with ISO 21530.

5.5 Electrical requirements

Operating lights shall be suitable for continuous operation. IEC 60601-1:2005+AMD1:2012+AMD2:2020 and IEC 80601-2-60 apply.

5.6 Usability

Usability evaluation shall be carried out following the process described in IEC 62366-1.

Testing shall be carried out in accordance with IEC 62366-1.

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 document are type tests.

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

All measurements of optical radiation shall be traceable to the international system of units (SI) implemented through the requirements of ISO/IEC 17025.

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 and operate until the irradiance and colour have stabilized, as determined by monitoring the running average of the measurements, before collecting measurements for the tests specified in 7.3.2 through 7.3.13 unless otherwise specified.

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 illumination pattern. If there is a marked cut-off in the y-direction, take this as the positive direction. If there is not a marked cut-off in the y-direction, arbitrarily select a direction to be the positive direction.

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

Perform optical tests in a room where light from other sources and reflected light from room surfaces are negligible.

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 ISO/CIE 19476 and having an acceptance aperture 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 an illuminance greater than 600 lx are measured.

A photometer that can indirectly record the illuminance distribution with one measurement, i.e. an imaging luminance measurement device (ILMD), may be used for this purpose. In such a case, the illuminance pattern is normally projected onto a flat, uniform, diffusely reflecting screen positioned in the measurement plane and the luminance distribution of the reflected light measured using the ILMD. The uniformity and directional response of the reflectance characteristics of the screen shall be evaluated and either corrected for or taken into account in the measurement uncertainties.

Record the measurements and their location. Determine the maximum illuminance, $E_{v,max}$. Use linear interpolation of measurements to calculate and plot the following iso-illuminance lines specified in 5.2.2.1: $0,90 \times E_{v,max}$, $0,75 \times E_{v,max}$, $0,50 \times E_{v,max}$, $0,10 \times E_{v,max}$ and 1 200 lx. Check whether the requirements given in 5.2.1 and 5.2.2.1 are fulfilled.

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

Using the illuminance pattern data from 7.3.2, determine the coordinates of the uppermost point of area C (i.e. the point along the iso-illuminance line corresponding to 90 % of the maximum illuminance which is farthest from the horizontal axis in the direction of the patient's eyes, i.e. positive y-direction). Plot a horizontal line 60 mm above the uppermost point of area C. Check whether the illuminance at any point along or above the horizontal line exceeds 1 200 lx (see Figure 3).

To confirm whether there are any areas of brightness above the horizontal line, place a flat white screen in the measurement plane. Observe whether there are areas of brightness above the horizontal line 60 mm above the uppermost point of area C 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 uppermost point of area C, 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 room 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 room light source. Place a flat white screen in the measurement plane and illuminate it with the operating light. Use three people with normal colour vision to observe whether there are any colour non-uniformities within area A and area B when viewed at a distance of 50 cm to 75 cm. The normal colour vision of the observers shall be verified within the past five years by at least one of the following:

- evaluation for colour vision by a medical practitioner or other appropriately trained person;
- the Ishihara colour vision test, either digitally or physically using colour assessment cards; or
- the Richmond HRR Pseudoisochromatic Plates 4th edition colour vision test, either digitally or physically using colour assessment cards (Good-Lite, USA).

Corrective untinted lenses may be worn.

7.3.6 Correlated colour temperature

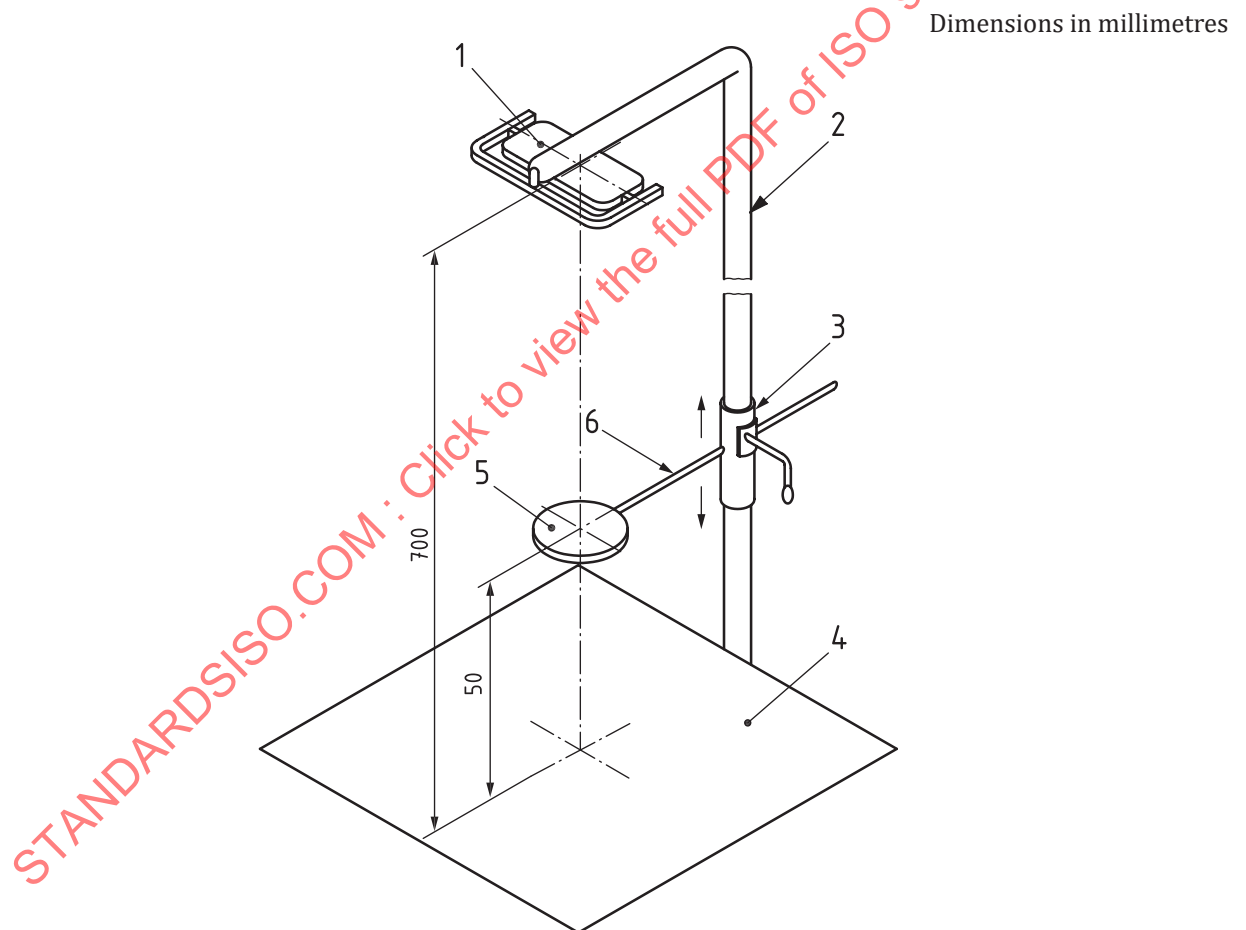
Use the test set-up as described in [7.3.1](#) with the operating light set at maximum light output.

Determine the chromaticity coordinates at the point of maximum illuminance in the measurement plane, using a tristimulus colourimeter or spectroradiometer.

7.3.7 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 4](#)), 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): 20 mm diameter × 1 mm thick
- 6 stem

Figure 4 — Device for determination of shadow reduction

7.3.8 Colour fidelity

Measure R_f in accordance with CIE 224 at the point of maximum illuminance in the measurement plane. Check whether the requirement specified in 5.2.7 is fulfilled.

7.3.9 Actinic UV hazard exposure for the skin and eye

Measure the effective ultraviolet irradiance, E_s , in accordance with IEC 62471:2006 using a measurement distance of 700 mm and a detector with an input diameter in the range of 7 mm to 30 mm.

Perform measurements with the operating light set at maximum light output. If the operating light has multiple operating modes with different normalized spectral power distributions (e.g. white light mode and mode intended for use while handling light-activated restorative materials, or white light modes with different correlated colour temperatures), perform measurements in each operating mode with the operating light set at maximum light output.

Assess the risk group classification for actinic ultraviolet hazard according to IEC 62471:2006, 6.1 for each operating mode. The highest assessed risk group classification of all operating modes is designated as the risk group classification of the operating light for actinic ultraviolet hazard.

Check whether the risk group classification of the operating light meets the requirement specified in 5.2.8.

If the risk group classification is greater than exempt group, calculate $t_{\max}$ using the following formula:

$$t_{\max} = 30/E_s$$

where

$t_{\max}$ is the permissible exposure duration, expressed in seconds (s);

E_s is the effective ultraviolet irradiance, expressed in watts per square metre (W/m²).

7.3.10 Near-UV hazard exposure for the eye

Measure the UV-A irradiance, E_{UVA} , in accordance with IEC 62471:2006 using a measurement distance of 700 mm and a detector with an input diameter in the range of 7 mm to 30 mm.

Perform measurements with the operating light set at maximum light output. If the operating light has multiple operating modes with different normalized spectral power distributions (e.g. white light mode and mode intended for use while handling light-activated restorative materials, or white light modes with different correlated colour temperatures), perform measurements in each operating mode with the operating light set at maximum light output.

Assess the risk group classification for near-UV hazard according to IEC 62471:2006, 6.1 for each operating mode. The highest assessed risk group classification of all operating modes is designated as the risk group classification of the operating light for near-UV hazard.

Check whether the risk group classification of the operating light meets the requirement specified in 5.2.9.

If the risk group classification is greater than exempt group, calculate $t_{\max}$ using the following formula:

$$t_{\max} = 10\,000/E_{\text{UVA}}$$

where

$t_{\max}$ is the permissible exposure duration, expressed in seconds (s);

E_{UVA} is the UV-A irradiance, expressed in watts per square metre (W/m^2).

7.3.11 Retinal blue light hazard exposure

7.3.11.1 General

Test according to [7.3.11.2](#), which utilizes measurements of the individual light sources (e.g. LEDs, lamps or bulbs) of the operating light, or [7.3.11.3](#), which utilizes measurements of the operating light.

7.3.11.2 Method based on individual light source test results

This test method can be used only if all of the following criteria are met:

- test results made at a measurement distance of 200 mm in compliance with IEC 62471:2006 for all light sources used in the operating light are available (e.g. reported by the light source manufacturer);
- none of the light sources are classified as Risk Group 2 or Risk Group 3 given in IEC 62471:2006, 6.1 for retinal blue light hazard ($L_B > 10\,000\text{ W}/\text{m}^2/\text{sr}$);
- the distance between the centres of any two simultaneously emitting light sources is not less than 7,7 mm.

If any of the above criteria are not met, use the method specified in [7.3.11.3](#).

Based on test results made at a measurement distance of 200 mm in compliance with IEC 62471:2006, if all of the light sources are classified as exempt group or Risk Group 1 for retinal blue light hazard ($L_B \leq 10\,000\text{ W}/\text{m}^2/\text{sr}$), the risk group classification of the operating light for retinal blue light hazard (L_B) is not greater than Risk Group 1, fulfilling the requirement specified in [5.2.10](#).

NOTE 1 Test results made at a measurement distance of 200 mm are specified in this method since that is the standard distance for evaluating lamps (i.e. light sources) per IEC 62471:2006. At the standard measurement, distance for operating lights (700 mm) L_B will be less than or equal to the value at 200 mm. Therefore, the actual risk group classification can be lower than determined by this method.

NOTE 2 A distance of 7,7 mm between light sources results in an angular subtense of 0,011 rad at 700 mm from the light source, which is the specified angular subtense for assessing Risk Group 1 classification for retinal blue light hazard. If any two simultaneously emitting light sources are spaced more closely than 7,7 mm, their combined emissions can result in the operating light having a higher risk group classification.

If the risk group classification of any of the individual light sources of the operating light is Risk Group 1, calculate t_{max} using the following formula with the greatest value for L_B if multiple light sources with different L_B values are used in the operating light:

$$t_{\text{max}} = 10^6 / L_B$$

where

t_{max} is the permissible exposure duration, expressed in seconds (s);

L_B is the blue-light weighted radiance, expressed in watts per square metre per steradian ($\text{W}/\text{m}^2/\text{sr}$).

7.3.11.3 Method based on operating light test results

Measure L_B in accordance with IEC 62471:2006 within an effective angular subtense, α_{eff} of 0,011 rad using a measurement distance of 700 mm and an aperture stop with a diameter, D , in the range of 7 mm to 30 mm.

Perform measurements with the operating light set at maximum light output. If the operating light has multiple operating modes with different relative spectral distributions (e.g. white light mode and mode intended for use while handling light-activated restorative materials, or white light modes with

different correlated colour temperatures), perform measurements in each operating mode with the operating light set at maximum light output.

If L_B does not exceed 10 000 W/m²/sr for any of the operating modes, the risk group classification of the operating light for retinal blue light hazard (L_B) is not greater than Risk Group 1, fulfilling the requirement specified in 5.2.10.

If L_B exceeds 10 000 W/m²/sr for any of the operating modes, the risk group classification of the operating light for retinal blue light hazard (L_B) is greater than Risk Group 1, and the requirement specified in 5.2.10 is not met.

NOTE 1 The specification of $\alpha_{\text{eff}} = 0,011$ rad, corresponds to the conditions specified in IEC 62471:2006 for evaluating for Risk Group 1 classification for retinal blue light hazard. Since evaluation for Risk Group 1 is sufficient to verify compliance with 5.2.10, measurements using other values of α_{eff} specified in IEC 62471:2006 do not need to be made.

NOTE 2 If the classification of operating light is determined to be not greater than Risk Group 1 by this method, the actual classification can be either exempt group or Risk Group 1.

Calculate t_{max} using the following formula:

$$t_{\text{max}} = 10^6 / L_B$$

where

t_{max} is the permissible exposure duration, expressed in seconds (s);

L_B is the blue-light weighted radiance, expressed in watts per square metre per steradian (W/m²/sr).

7.3.12 Heat due to optical radiation

Use the test set-up as described in 7.3.1.

Measure the radiant heat using a calibrated radiometer with an acceptance aperture of not more than 30 mm diameter and an adequate spectral responsivity in the wavelength region from 300 nm to 2 500 nm.

The test shall be conducted with the light beam directed perpendicularly onto the sensor. Measure at the point with the maximum of illuminance $E_{v,\text{max}}$.

7.3.13 Compatibility with light-activated restorative materials

Use the test set-up as described in 7.3.1 with a calibrated spectroradiometer having adequate responsivity over the spectral range 400 nm to 515 nm and an acceptance aperture 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 camphorquinone-weighted irradiance using the following formula:

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

where

$E_{e,\text{CQ}}$ is the camphorquinone-weighted irradiance, expressed in watts per square metre (W/m²);

$E_{e,\lambda}$ is the spectral irradiance, expressed in watts per square metre per nanometre [W/(m²·nm)];

$a(\lambda)$ is the normalized camphorquinone absorbance spectrum (unitless), tabulated in [Annex B](#);

$\Delta\lambda$ is the wavelength interval of the measurements (nm).

Determine whether the calculated value for $E_{e,CQ}$ meets the requirement given in [5.2.13](#).

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/AMD1:2012+AMD2:2020, 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 after positioning

Mount the operating light according to the 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.

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+AMD1:2012+AMD2:2020, 7.9.1 applies.

8.3 Instructions for use

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.9.2 applies.

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

- 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;
- reprocessing instructions (applicable cleaning, disinfection and sterilization processes) in accordance with ISO 17664-1 and ISO 17664-2;
- specification for replacement of the light source (e.g. lamp or bulb) if light source is replaceable;
- if the classification of the operating light is greater than exempt group for actinic UV exposure for skin and eye ([5.2.8](#)), near-UV exposure for the eye ([5.2.9](#)) or retinal blue light hazard exposure ([5.2.10](#)), a statement indicating the most restrictive risk group classification and guidance on safe operating procedures, including the most restrictive permissible exposure duration (t_{max}) if the centre of the operating light beam is directed in the patient's eyes (based on the calculated values per [5.2.8](#), [5.2.9](#) and [5.2.10](#));

- e) information about the potential need of protection either for eye or face, or both, for individuals with sensitivity to strong light sources, such as those taking a photosensitizing drug that can accumulate in eye tissue and those with certain eye diseases or photodermatoses.

8.4 Technical description

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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 fidelity index (R_f);
- 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 [5.2.13](#);
- 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 can 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+AMD1:2012+AMD2:2020, 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.