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Dentistry — Operating lights

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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:

— updated normative references;

— updated requirements and test methods for the illumination pattern, illuminance in patient's eyes, colour fidelity and photobiological hazards.

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.

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/CIE 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 medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of 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, *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/CIE S 009:2002, *CIE S 009:2002, 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 terminological 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 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

3.3
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 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 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

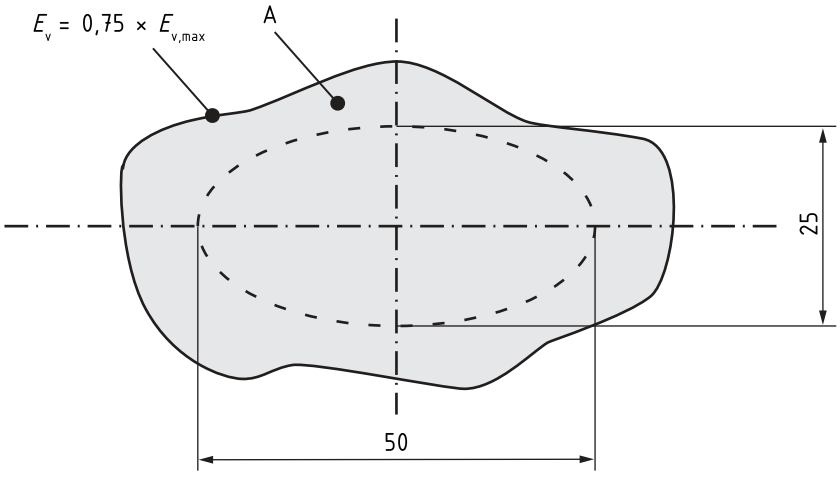
5.2.2.1 Illumination areas and illuminance levels

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 × $E_{v,max}$, 0,75 × $E_{v,max}$, 0,50 × $E_{v,max}$, 0,10 × $E_{v,max}$ 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.

Dimensions in millimetres

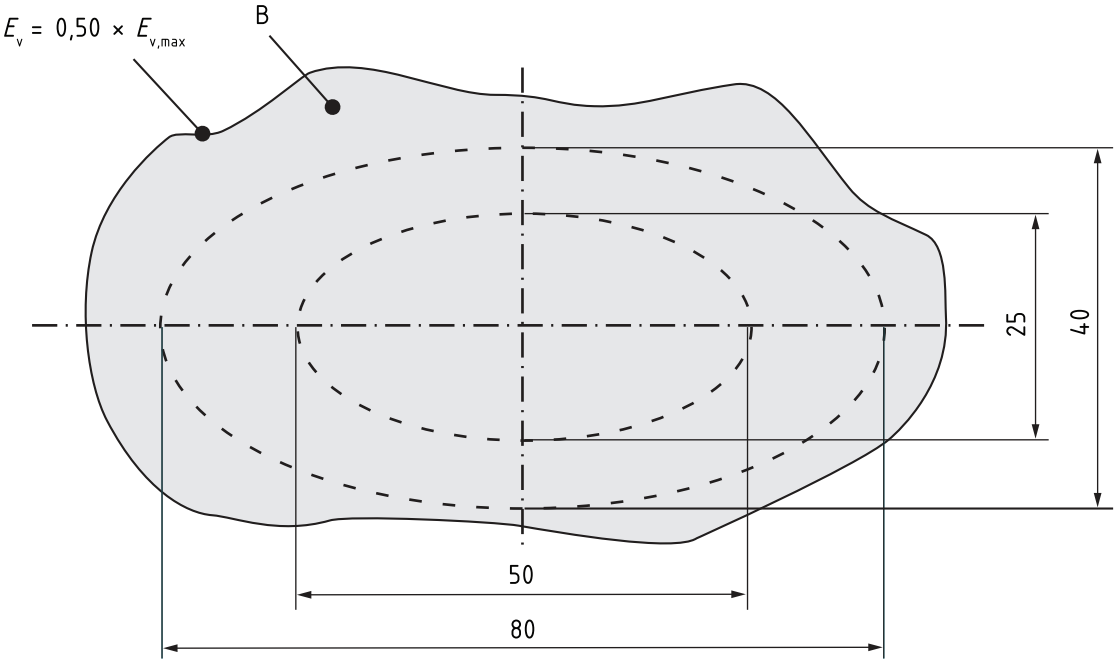


Key

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.

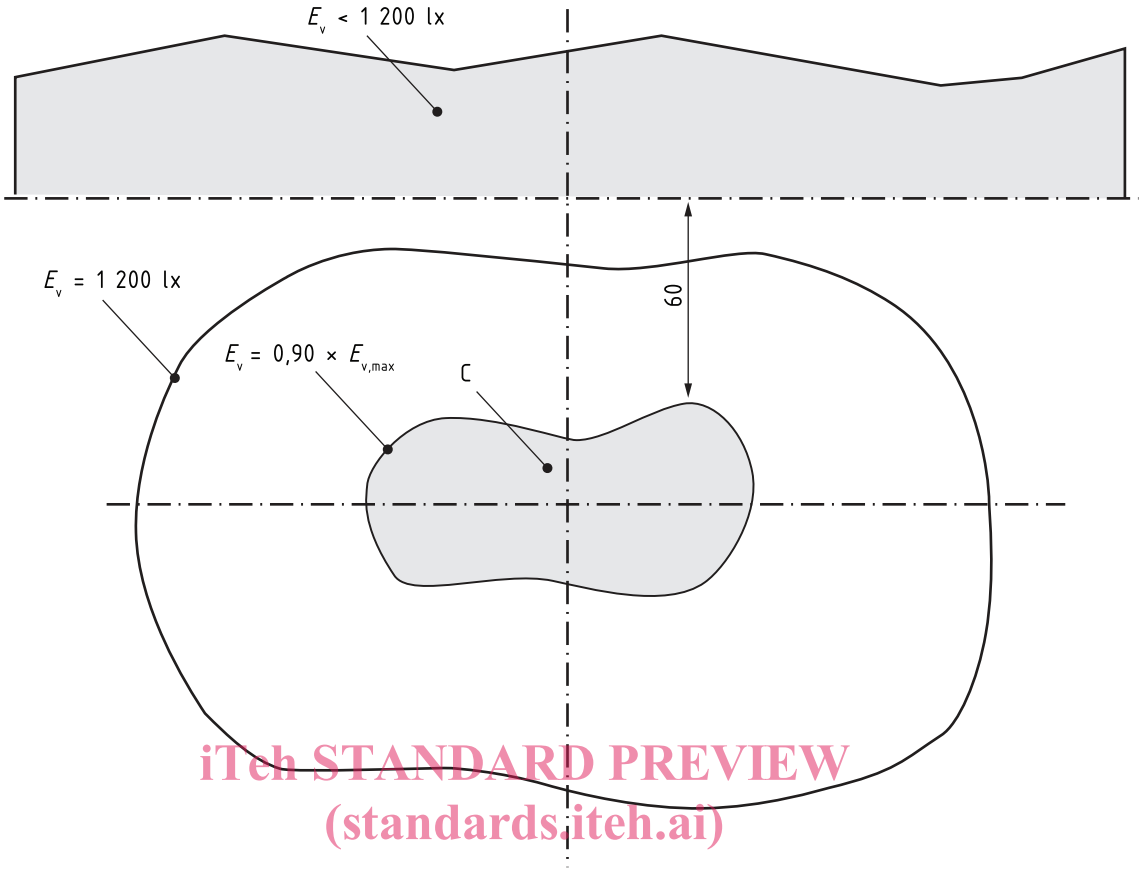
5.2.3 Illuminance in patient's eyes

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.

Dimensions in millimetres



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/CIE S 009:2002, 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/CIE S 009:2002, 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/CIE S 009:2002, 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/CIE S 009:2002, 4.3.2 shall be calculated in accordance with 7.3.10.