INTERNATIONAL STANDARD

ISO 9680

Third edition
2014-10-15

Dentistry — Operating lights

Médecine bucco-dentaire — Appareils d'éclairage

Reference number
ISO 9680:2014(E)

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Published in Switzerland

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Foreword

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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, whereever 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.[14] 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.

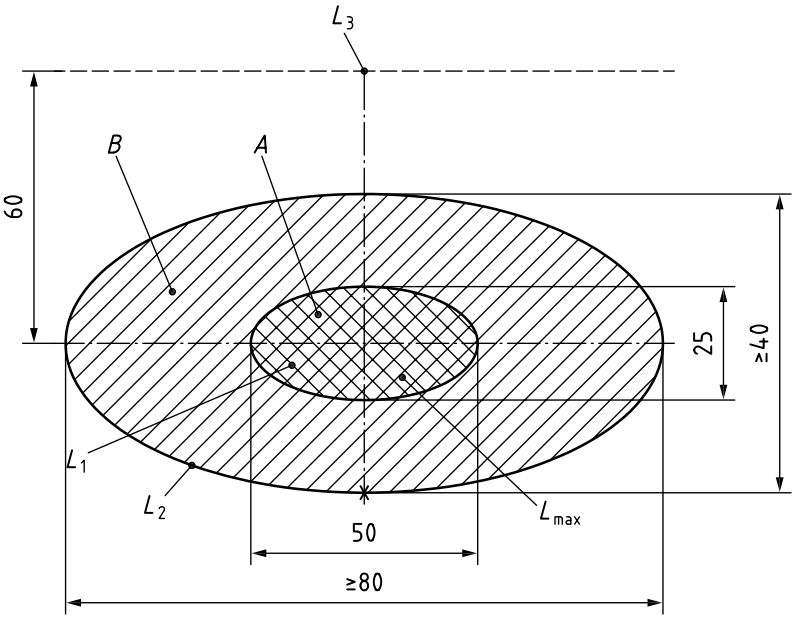
The inner area of illumination, area A, is defined by an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm, in which the point of maximum illuminance, L_{Max}, shall lie. Throughout area A the illuminance shall not be less than 75 % of L_{Max} (see Figure 1). Test in accordance with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