INTERNATIONAL STANDARD

ISO 9680

Second edition
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Dentistry — Operating lights

Art dentaire — Appareils d'éclairage

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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.

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

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

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

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

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

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

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

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

d) a requirement for UV irradiance has been added;

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

Introduction

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

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

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

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

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

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

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

Dentistry — Operating lights

1 Scope

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

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

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

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

2 Normative references

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

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

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

ISO 9687, *Dental equipment — Graphical symbols*

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

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

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

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

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

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

CIE Publication 15:2004, *Colorimetry*

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

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

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

3 Terms and definitions

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

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

[IEC 60598-1:2006, 1.2.1]

3.2
lamp
light source

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

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

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

4 Classification

4.1 According to type of protection against electric shock

Operating lights are classified as follows:

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

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

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

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

4.2 According to mode of operation

See IEC 60601-1:2005, 6.6.

Operating lights shall be suitable for continuous operation.

5 Requirements and recommendations

5.1 General requirements

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

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

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

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

Test in accordance with 7.3.

5.2 Optical requirements

5.2.1 Level of illuminance

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

Test in accordance with 7.3 and 7.4.2.

5.2.2 Illumination pattern

5.2.2.1 Illumination areas

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

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

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

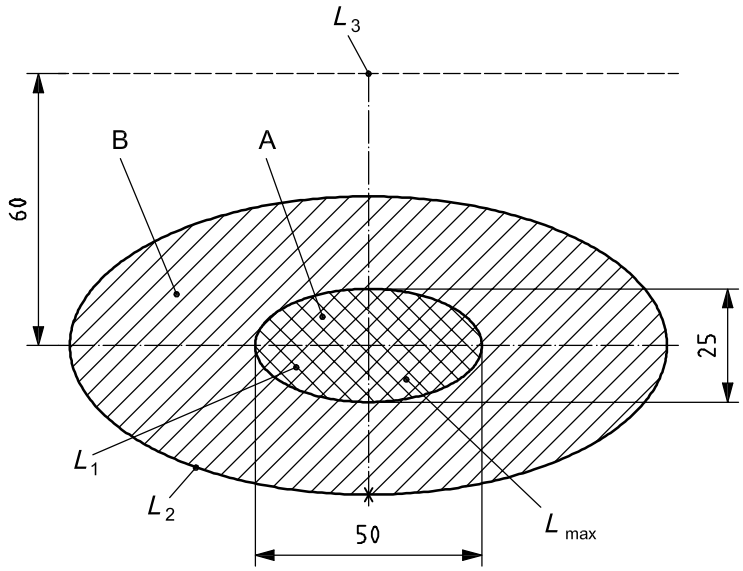
The 50 % of maximum illuminance isolux line shall be plotted in order to indicate area B (see Figure 1).

5.2.2.2 Illuminance

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

Test in accordance with 7.4.2.

Dimensions in millimetres



Key

A inner area of illumination

B outer area of illumination

L_{max} point of maximum illuminance

L_1 illuminance within the area A

L_2 line of pattern with $L = 0{,}5\ L_{max}$

L_3 illuminance at a distance of 60 mm, $L_3 < 1\ 200$ lx

Figure 1 — Illumination pattern

5.2.2.3 Illumination uniformity

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

Test in accordance with 7.4.3.

5.2.3 Illuminance in the patient's eyes

5.2.3.1 Level of illuminance

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

Test in accordance with 7.4.2.

5.2.3.2 Glare or reflections from the reflector

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

Test in accordance with 7.3.

5.2.4 Chromatic aberration

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

Test in accordance with 7.4.4.

5.2.5 Correlated colour temperature

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

Test in accordance with 7.4.5.

Table 1 — Co-ordinates of colour space

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

5.2.6 Radiant heat in pattern

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

Test in accordance with 7.4.6.

5.2.7 Shadow

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

Test in accordance with 7.4.7.

5.2.8 General colour rendering index (Ra)

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

Test in accordance with 7.4.8.

5.2.9 UV irradiance

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

Test in accordance with 7.4.9.

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