DRAFT INTERNATIONAL STANDARD ISO/DIS 9680

ISO/TC **106**/SC **6** Secretariat: **DIN**

Voting begins on **2013-05-16** Voting terminates on **2013-10-16**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Dentistry — Operating lights

Médecine bucco-dentaire — Éclairage opératoire

[Revision of second edition (ISO 9680:2007)]

ICS 11.060.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 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) 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;

c) The requirement for the Illumination pattern has been revised to specify a minimum size and shape of the outer area of illumination, area B;

d) A requirement has been added to measure, plot and report the 10%, 50% and 75% of maximum illuminance isolux lines;

e) 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);

f) 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;

g) 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;

h) A requirement and test method for compatibility with light-activated restorative materials has been added;

i) The requirement for operating forces has been simplified;

j) References in electrical requirements were updated and simplified;

k) A requirement on usability has been added;

l) Requirements for test conditions have been simplified;

m) Electrical tests have been deleted due to reference to IEC 60601-1:2005+A1:2012;

n) Optical tests have been clarified and a test for compatibility with light-activated restorative materials has been added;

o) The requirements for instructions for use and technical description have been revised;

p) The requirement for marking of operating controls has been eliminated in favour of the broader requirement for graphical symbols;

q) 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, where ever 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.

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

Also excluded are operating lights which are specifically designed for use in oral 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 1942, *Dentistry — Vocabulary*

ISO 4049: 2009, *Dentistry — Polymer-based restorative materials*

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

ISO 9687, *Dental equipment — Graphical symbols*

ISO 9917-2: 2010, *Dentistry — Water-based cements — Part 2: Resin-modified cements*

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

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

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

IEC 60598-1:2008, *Luminaires — Part 1: General requirements and tests*

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

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 015:2004, *Colorimetry*

CIE S 017, *ILV: International Lighting Vocabulary*

CIE 069:1987, *Methods of characterizing illuminance meters and luminance meters; Performance, characteristics and specifications*

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 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 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 60601-1:2005+A1:2012, 3.13.

b) Class II equipment, see IEC 60601-1:2005+A1:2012, 3.14.

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

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

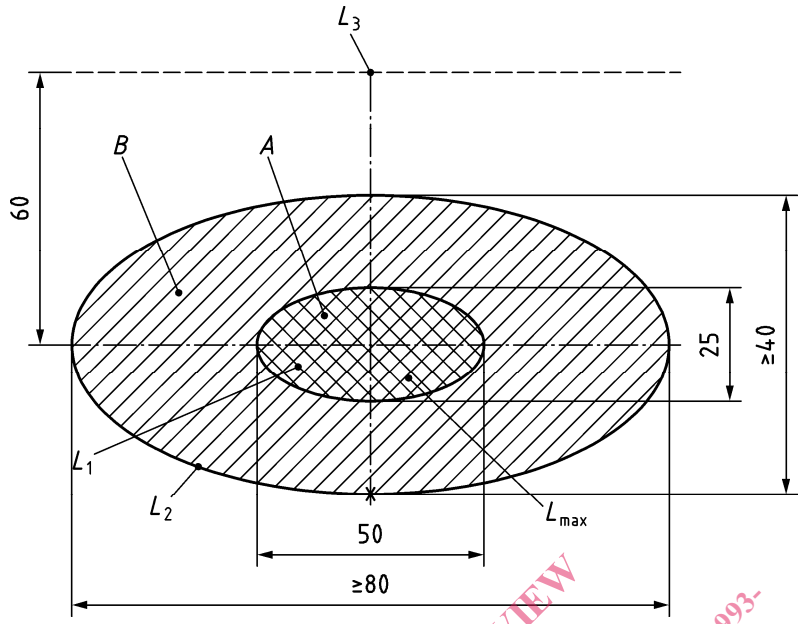
The inner area of illumination, area A, is defined by an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm.

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 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 L_{max}

L_3 illuminance at a distance of 60 mm, L_3 < 1200 lx

Figure 1 — Illumination pattern

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 7.3.2.

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 7.3.3.

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).