SLOVENSKI STANDARD
oSIST prEN ISO 9680:2021

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Zobozdravstvo - Operacijska razsvetljava (ISO/DIS 9680:2021)

Dentistry - Operating lights (ISO/DIS 9680:2021)

Zahnheilkunde - Behandlungsleuchten (ISO/DIS 9680:2021)

Médecine bucco-dentaire - Lampes opératoires (ISO/DIS 9680:2021)

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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*.

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

The aim of this document 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 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.

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

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 manufacturers' 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, 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 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/CIE 11664-5, *Colorimetry — Part 5: CIE 1976 L*u*v* colour space and u', v' uniform chromaticity scale diagram*

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 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, *Photobiological safety of lamps and lamp systems*

IEC 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 S 017, *ILV: International Lighting Vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in CIE S 017, IEC 60598-1, IEC 60601-1, ISO 1942, ISO 4073 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 http://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

3.2
LED operating light
operating light (3.1) using at least one light emitting diode (LED) as the light source

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 60601-1:2005/AMD 1:2012 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 60601-1:2005/AMD 1:2012 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.

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.

Test in accordance with 7.2.

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

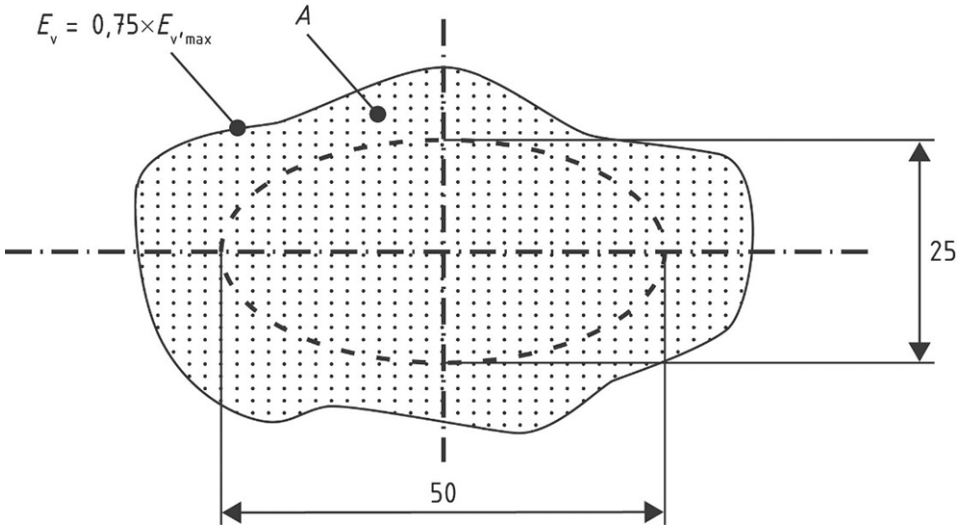
5.2.2.1 Illumination areas and illuminance levels

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 lluminance 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

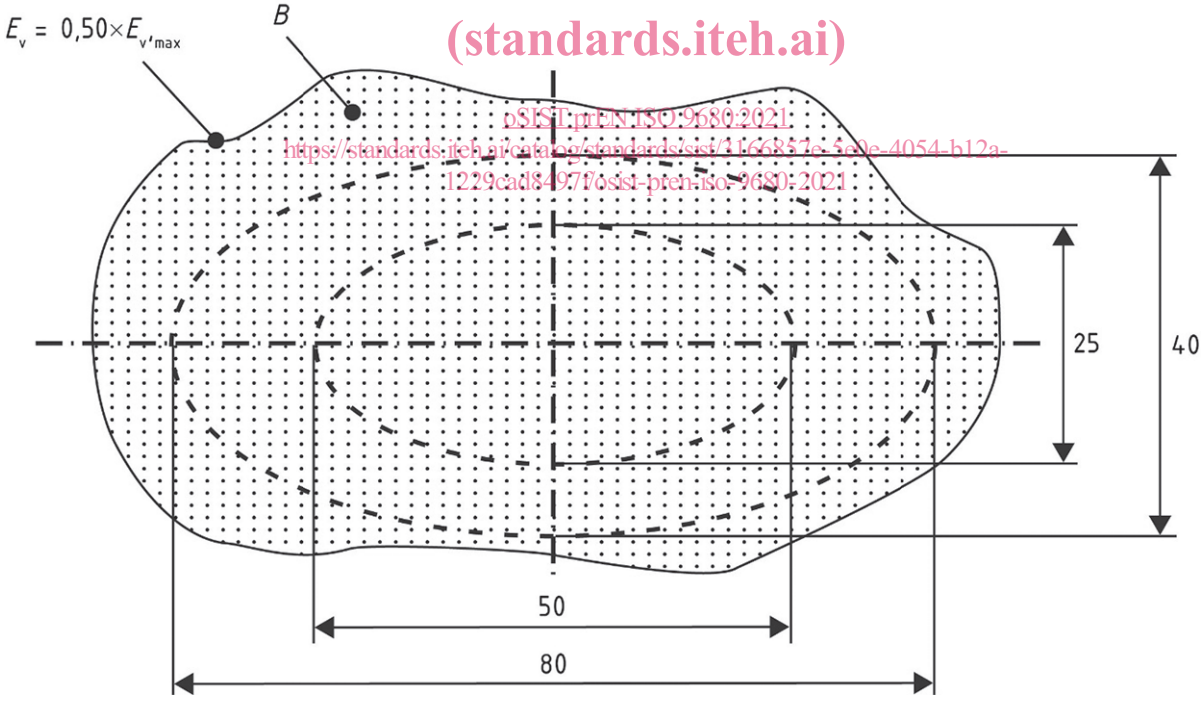


Key

A area A, inner area of illumination

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

Dimensions in millimetres



Key

B area B, outer area of illumination

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

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.