International Standard

ISO 9680

Dentistry — Operating lights

Médecine bucco-dentaire — Luminaires opératoires

Fifth edition
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Foreword

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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 document 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).

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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).

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This fifth edition cancels and replaces the fourth edition (ISO 9680:2021), which has been technically revised.

The main changes are as follows:

— Clause 4 “Classification” of the fourth edition has been deleted and subsequent clauses have been re-numbered.

— Clause 5 “Requirements and Recommendations” of the fourth edition has been adapted to Clause 4 “Requirements” and technically updated.

— Clause 6 “Testing” has been technically updated.

— Subclause 7.4 “Mechanical tests” of the fourth edition and all subclauses have been deleted.

— Clause 9 “Marking” has been technically updated.

— Annex A “Transformation formulae” of the fourth edition has been deleted.

— A new informative Annex A on “Additional information for retinal blue light hazard exposure test method” has been added.

— The normative and bibliographic references have been updated.

— Editorial updates have been made.

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.

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Introduction

This document provides dentists and their staff with means to work with optimum visual ease and comfort in all zones 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 [1] has been taken into account during the preparation of this document.

IEC 60601-1 [2] specifies requirements pertaining to the basic safety and essential performance of medical electrical equipment and medical electrical systems. IEC 80601-2-60 [3] specifies requirements pertaining to the basic safety and essential performance of dental units, dental patient chairs, dental handpieces and dental operating lights. The requirements of IEC 60601-1 [2] and IEC 80601-2-60 [3] that are applicable to operating lights are not duplicated in this document.

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Dentistry — Operating lights

1 Scope

This document specifies requirements and test methods for operating lights used in dental treatment 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 and those intended for patient contact, e.g. from dental handpieces and dental headlamps, fibreoptic intraoral operating lights and 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 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical 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, *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, *Photobiological safety of lamps and lamp systems*

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

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

CIE S 017, *ILV: International Lighting Vocabulary*

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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 terminology databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
operating light
device for illuminating the oral cavity of a patient, which includes a fixed base and an adjustable arm

3.2
light-activated restorative material
dental material intended for oral use that incorporates a monomer system, and the polymerization is activated by light

4 Requirements

4.1 Optical requirements

4.1.1 General

Optical requirements are specified at a distance of 700 mm. This standardized measurement distance enables comparison of manufacturer specifications for different operating lights under the same conditions. For clarity, the design of an operating light may be optimized for other distances and optical properties may be reported by the manufacturer at additional distances at their discretion.

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4.1.2 Adjustable level of illuminance

The level of illuminance shall be adjustable. The adjustment of illuminance may be either continuous or in discrete levels.

The manufacturer shall provide specifications corresponding to the lowest and highest illuminance settings for the maximum illuminance on a plane perpendicular to the optical axis at a distance of 700 mm from the operating light. The manufacturer's specification for illuminance at the highest illuminance setting shall be at least 15 000 lx. The measured maximum illuminance values at the lowest and highest illuminance settings shall be within 20% of their respective specifications.

Test in accordance with 6.2 and 6.3.2.

The requirements of 4.1.2 do not apply to any operating mode(s) intended only for use while handling light-activated restorative materials.

4.1.3 Illumination pattern

4.1.3.1 Illumination areas and illuminance levels

The illumination pattern shall be measured with the operating light adjusted to the maximum illuminance level to determine the maximum illuminance, $E_{v,max}$, and the following iso-illuminance lines in accordance with 6.3.2: 0,90 × $E_{v,max}$, 0,75 × $E_{v,max}$, 0,50 × $E_{v,max}$, 0,10 × $E_{v,max}$ and 1 200 lx.

An area A is defined as the area bounded by the iso-illuminance line corresponding to 75 % of the maximum illuminance. The 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

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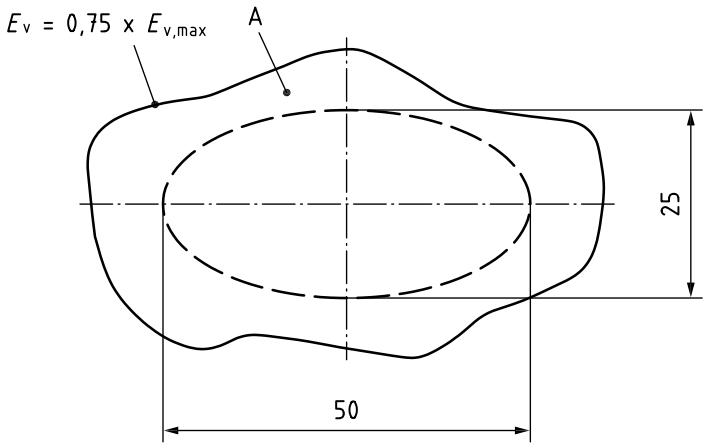
axis and minor axis of the illumination pattern, respectively (see Figure 1). The illuminance shall not be less than 75 % of $E_{v,max}$ throughout the ellipse. Test in accordance with 6.3.2.

An area B is defined as the area bounded by the iso-illuminance line corresponding to 50 % of the maximum illuminance. The 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 6.3.2.

Dimensions in millimetres



Key

A illumination area A

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

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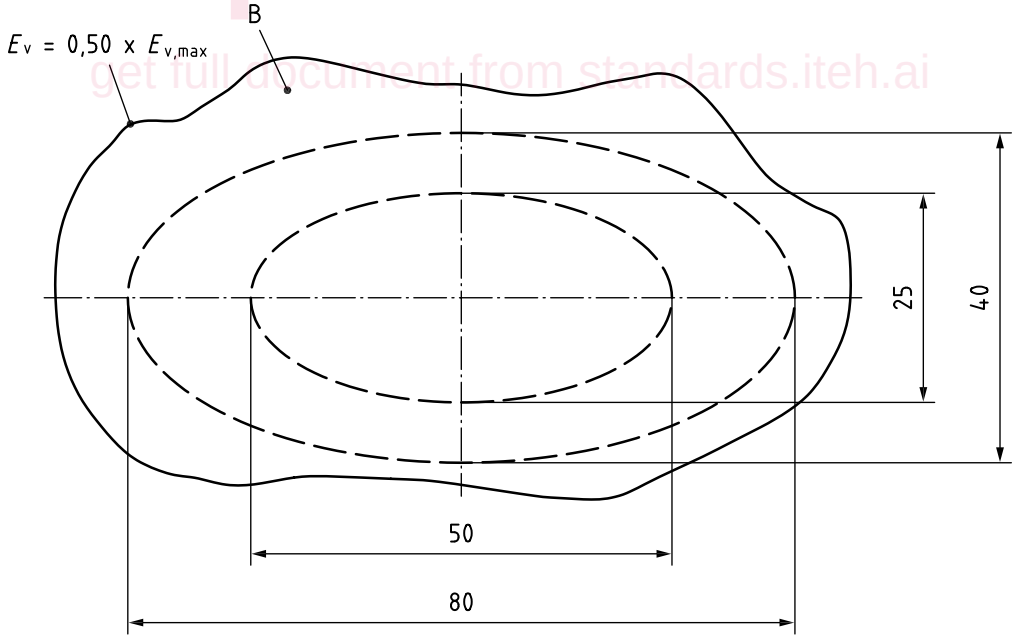
Dimensions in millimetres



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Key

B illumination area B

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

4.1.3.2 Illuminance uniformity

The illuminance shall decrease in intensity progressively and smoothly toward the pattern edge.

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