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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

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Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 9680

Dentistry — Operating lights

Médecine bucco-dentaire — Luminaires opératoires

ICS: 11.060.20

ISO/TC 106/SC 6

Secretariat: **DIN**

Voting begins on:
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Voting terminates on:
2025-06-23

This document is circulated as received from the committee secretariat.

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, 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).

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” has been deleted and the following Clauses have been re-numbered;
- [Clause 5](#) “Requirements and Recommendations” was adapted to [Clause 4](#) “Requirements” and technically updated;
- [Clause 7.4](#) “Mechanical tests” and all sub-clauses have been deleted;
- [Clause 9](#) “Marking” was technically updated;
- Annex A “Transformation formulae” has been deleted;
- A new informative [Annex A](#) on “Additional information for retinal blue light hazard exposure test method” has been added;
- the normative references were updated;
- editorial updates.

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

This document provides 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.

IEC 60598-1 has been taken into account during the preparation of this document.

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

Dentistry — Operating lights

1 Scope

This document specifies requirements and test methods for operating lights used in the 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, for example, from dental handpieces and dental headlamps, fiberoptic intraoral operating light 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 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/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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

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 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:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1**operating light**

device designed for use by an operator for illuminating the oral cavity, which either distributes, filters or transforms the light, or does any combination of these, 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**light-activated restorative material**

dental material intended for oral use that incorporates a monomer system, the polymerization of which is activated by light

4 Requirements**4.1 Optical requirements****4.1.1 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 specify nominal values for the minimum illuminance and maximum illuminance at a distance of 700 mm from the operating light. The maximum nominal illuminance specified by the manufacturer shall be at least 15 000 lx. The measured minimum illuminance and maximum illuminance shall be within 20% of the respective nominal values specified by the manufacturer.

Test in accordance with [6.2](#) and [6.3.2](#).

The requirements of [4.1.1](#) do not apply to any operating mode(s) intended only for use while handling light-activated restorative materials.

4.1.2 Illumination pattern**4.1.2.1 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 [6.3.2](#): $0,90 \times E_{v,max}$, $0,75 \times E_{v,max}$, $0,50 \times E_{v,max}$, $0,10 \times E_{v,max}$ and 1 200 lx.

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 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](#).