Dentistry - Operating lights (ISO 9680:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 9680:2021 sisaldab Euroopa standardi EN ISO 9680:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 9680:2021 consists of the English text of the European standard EN ISO 9680:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.12.2021.	Date of Availability of the European standard is 01.12.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9680

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English Version

Dentistry - Operating lights (ISO 9680:2021)

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

Zahnheilkunde - Behandlungsleuchten (ISO 9680:2021)

This European Standard was approved by CEN on 15 October 2021.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 9680:2021) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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

This document supersedes EN ISO 9680:2014.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 9680:2021 has been approved by CEN as EN ISO 9680:2021 without any modification.

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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).

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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 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:

— normative references have been updated;

— requirements and test methods for the illumination pattern, illuminance in patient's eyes, colour fidelity and photobiological hazards have been updated.

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.

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 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, for example, 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 11664-1, *Colorimetry — Part 1: CIE standard colorimetric observers*

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *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/TR 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 224, *Colour Fidelity Index for accurate scientific use*

CIE S 017, *ILV: International Lighting Vocabulary*

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 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; or

b) Class II equipment.

4.2 According to mode of operation

Operating lights are classified in accordance with IEC 60601-1 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 instructions, they cause no danger which can 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.