

Stomatoloogias kasutatav töövalgustus

Dentistry - Operating lights

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 9680:2007 sisaldab Euroopa standardi EN ISO 9680:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 21.08.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 9680:2007 consists of the English text of the European standard EN ISO 9680:2007. This document is endorsed on 21.08.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.
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Käsitlusala: Käesolev standard kehtib mistahes konstruktsiooniga stomatoloogiliste töövalgustite kohta, mida kasutatakse suuõõne valgustamiseks. Standard esitab nõuded ja testimismeetodid. Standard sisaldab ka tehnilisi andmeid seoses tootja poolt antavate juhiste, märgistuse ja pakendamisega.	Scope: This International Standard specifies requirements and test methods for dental operating lights intended for illuminating the oral cavity of patients. It also contains specifications on manufacturer's instructions, marking and packaging.
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ICS 11.060.20

Võtmesõnad: hambaraviaparatuur, liigitus, märgistus, pakendamine, stomatoloogia, tehnilised andmed, tehniliste andmete lehed, testimine, valgustusseadmed

English Version

Dentistry - Operating lights (ISO 9680:2007)

Art dentaire - Appareils d'éclairage (ISO 9680:2007)

Zahnheilkunde - Behandlungsleuchten (ISO 9680:2007)

This European Standard was approved by CEN on 9 June 2007.

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Foreword

This document (EN ISO 9680:2007) 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of an identical text or by endorsement, at the latest by December 2007, and conflicting national standards shall be withdrawn at the latest by December 2007.

This document supersedes EN ISO 9680:1996.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 9680:2007 has been approved by CEN as EN ISO 9680:2007 without any modifications.

Dentistry — Operating lights

Art dentaire — Appareils d'éclairage



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Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 Classification.....	2
4.1 According to type of protection against electric shock.....	2
4.2 According to mode of operation.....	3
5 Requirements and recommendations.....	3
5.1 General requirements.....	3
5.2 Optical requirements.....	3
5.3 Mechanical requirements.....	6
5.4 Cleaning and disinfection.....	7
5.5 Electrical requirements.....	7
6 Sampling.....	8
7 Testing.....	9
7.1 General.....	9
7.2 Test conditions.....	9
7.3 Visual inspection.....	11
7.4 Optical tests.....	11
7.5 Mechanical tests.....	14
7.6 Cleaning and disinfection.....	14
7.7 Electrical tests.....	14
8 Manufacturer's instructions.....	15
8.1 Documents.....	15
8.2 General.....	15
8.3 Instructions for use.....	15
8.4 Technical description.....	15
8.5 Check.....	15
9 Packaging.....	15
10 Marking.....	16
10.1 Marking on the outside of mains-operated operating lights.....	16
10.2 Marking on the inside of operating lights.....	16
10.3 Marking of operating controls.....	16
10.4 Graphical symbols.....	16
10.5 Colours of insulation conductors.....	16
10.6 Indicator lights and push-buttons.....	16
Annex A (informative) Transformation formulae.....	17
Bibliography.....	18

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 second edition cancels and replaces the first edition (ISO 9680:1993) and ISO 9680:1993/Cor.1:1995 which have been technically revised via the following changes:

- a) the illumination pattern has been changed from a round area, A, with a diameter of 50 mm into an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm;
- b) the level of illuminance shall be adjustable with a minimum level $\leq 8\,000$ lx and a maximum level $\geq 20\,000$ lx;
- c) a requirement for the general colour rendering index ($R_a > 85$) for diagnostic purposes is added;
- d) a requirement for UV irradiance has been added;
- e) the radiant heat in pattern shall be measured as the irradiance, E , in W/m^2 ($E \leq 350 \text{ W/m}^2$).

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.

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, wherever relevant, by stating the respective clause numbers of IEC 60601-1.

This International Standard takes priority over IEC 60601-1 as specified in its individual clauses.

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, marking and packaging.

This International Standard applies to operating lights that are intended to be permanently fixed to the ceiling, or to the wall or to the floor.

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

Also excluded are dental luminaires, which are specifically designed for use in a dental 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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1942¹⁾, *Dentistry — Vocabulary*

ISO 9687, *Dental equipment — Graphical symbols*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

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

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

IEC 60598-1:2006, *Luminaires — Part 1: General requirements and tests*

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

CIE Publication 13.3, *Method of measuring and specifying colour rendering properties of light sources*

CIE Publication 15:2004, *Colorimetry*

CIE Publication 69, *Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications*

1) To be published. (Replaces ISO 1942, parts 1 to 5)

ICNIRP Guidelines, *Guidelines on Limits of Exposure to Ultraviolet Radiation of Wavelengths between 180 nm and 400 nm (Incoherent Optical Radiation)* of the International Commission on Non-Ionizing Radiation Protection, Health Physics, **87**, Number 2, pp. 171-186, August 2004

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-845, IEC 60598-1, IEC 60601-1, ISO 1942 and the following apply.

**3.1
luminaire**
apparatus which distributes, filters or transforms the light transmitted from one or more lamps and which includes all the parts necessary for supporting, fixing and protecting the lamps, but not the lamps themselves, and where necessary circuit auxiliaries together with the means for connecting them to the supply

[IEC 60598-1:2006, 1.2.1]

**3.2
lamp**
light source

**3.3
dental luminaire**
luminaire specially designed and/or presented for use in the dental surgery

**3.4
operating light**
item of dental equipment specially designed for use by a dentist for illuminating the oral cavity, consisting of a luminaire (3.1) and one or more lamps

**3.5
illuminance**
luminous flux incident on a surface per unit of area, usually measured in lux

4 Classification

4.1 According to type of protection against electric shock

Operating lights are classified as follows:

a) Class I equipment (see IEC 60601-1:2005, 3.13)

Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of accessible conductive parts to the protective (earth) conductor in the fixed wiring of the installation in such a way that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

b) Class II equipment (see IEC 60601-1:2005, 3.14)

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.