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NSAI Standards

Irish Standard
I.S. EN ISO 9680:2014

Dentistry - Operating lights (ISO 9680:2014)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9680

October 2014

ICS 11.060.20

Supersedes EN ISO 9680:2007

English Version

Dentistry - Operating lights (ISO 9680:2014)

Médecine bucco-dentaire - Appareils d'éclairage (ISO 9680:2014)

Zahnheilkunde - Behandlungsleuchten (ISO 9680:2014)

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Foreword

This document (EN ISO 9680:2014) 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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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

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INTERNATIONAL STANDARD

ISO 9680

Third edition
2014-10-15

Dentistry — Operating lights

Médecine bucco-dentaire — Appareils d'éclairage

Reference number
ISO 9680:2014(E)

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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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This third edition cancels and replaces the second edition (ISO 9680:2007), which has been technically revised via the following changes:

a) The scope was expanded to consider any light source technology, including light emitting diodes (LEDs);

b) Normative references have been updated;

c) The requirement for the adjustable level of illuminance has been changed to eliminate an upper limit on the minimum illuminance level and to reduce the lower limit on maximum illuminance to 15 000 lx;

d) The requirement for the Illumination pattern has been revised to specify a minimum size and shape of the outer area of illumination, area B;

e) A requirement has been added to measure, plot and report the 10 %, 50 % and 75 % of maximum illuminance isolux lines;

f) The CIE chromaticity coordinates for corner point 1 in Table 1 have been changed to set this corner point within 0,02 of the Planckian locus in the CIE 1960 Uniform Chromaticity Space [i.e. (u,v) chromaticity space];

g) The colour rendering index requirement was revised to exclude LED operating lights since current LED operating lights may not meet the requirement and an accepted method for measuring the colour rendering properties of white LEDs is not yet established;

h) In the requirement for ultraviolet light irradiance the lower limit of the wavelength range was changed from 180 nm to 200 nm in order to reflect the measurement range of available radiometers;

i) A requirement for compatibility with light-activated restorative materials has been added;

j) The requirement for operating forces has been simplified;

k) The requirement for expelled parts has been revised;

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l) References in electrical requirements were updated and simplified;

m) A requirement on usability has been added;

n) Requirements for test conditions have been simplified;

o) Electrical tests have been deleted due to reference to IEC 60601-1:2005+A1:2012;

p) Optical tests have been clarified and a test for compatibility with light-activated restorative materials has been added;

q) The requirements for instructions for use and technical description have been revised;

r) The requirements for marking on the outside of mains-operated operating lights have been revised;

s) The requirement for marking of operating controls has been eliminated in favour of the broader requirement for graphical symbols;

t) The Bibliography has been expanded.

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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 nor affect its qualities adversely.

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

This International Standard takes priority over IEC 60601-1 as specified in the individual Clauses of this International Standard.

Only the specifications laid down in this International Standard are applicable.

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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 for use, marking and packaging.

This International Standard applies to operating lights, irrespective of the technology of the light source.

This International Standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 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 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

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

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

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance* + A1:2012

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

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

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

CIE 013.3, *Method of measuring and specifying colour rendering properties of light sources*

CIE S 017, ILV: International Lighting Vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in CIE S 017, IEC 60050-845, IEC 60598-1, IEC 60601-1, ISO 1942, ISO 4073 and the following apply.

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