

Dentistry - Operating lights (ISO 9680:2014)

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NATIONAL FOREWORD

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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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.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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Endorsement notice

The text of ISO 9680:2014 has been approved by CEN as EN ISO 9680:2014 without any modification.

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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, wherever 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.

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.