



Revised American National Standard/
American Dental Association
Standard No. 89

Dental Operating Lights

Identical adoption of ISO 9680:2014, *Dentistry – Operating lights*

ADA American
Dental
Association®

Standards Committee on Dental Products

2018

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REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 89 FOR DENTAL OPERATING LIGHTS

The ADA Standards Committee on Dental Products (SCDP) has approved Revised ANSI/ADA Standard No. 89 for Dental Operating Lights. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA SCDP. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Committee has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No. 89 as an American National Standard on December 21, 2017.

The ADA Standards Committee on Dental Products thanks the members of Working Group 6.37 Dental Operatory Lights and the organizations with which they were affiliated at the time the specification was developed:

Wayne Wozniak (chairman), Individual Representative, Port Saint Joe, FL;

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Foreword

(This Foreword does not form a part of Revised ANSI/ADA Standard No. 89 for Dental Operating Lights).

This standard is an identical adoption of ISO 9680:2014, Dentistry – Operating Lights. ADA SCDP Working Group 6.37 Dental Operatory Lights examined the international standard and found it acceptable for identical adoption as revised ANSI/ADA Standard No. 89.

The proposed revision of ANSI/ADA Standard No. 89 for Dental Operating Lights cancels and replaces ANSI/ADA Standard No. 89:2008 (R2013), which was an identical adoption of ISO 9680:2007.

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Introduction

The aim of this 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 color or causing excessive fatigue.

In this 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 standard account has been taken of IEC 60598-1.

This 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 standard takes priority over IEC 60601-1 as specified in the individual clauses of this standard.

Only the specifications laid down in this standard are applicable.

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1 Scope

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

This 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.

1 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*

ISO/CIE 19476, *Characterization of the performance of illuminance meters and luminance meters*

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or www.adacatalog.org. Other ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

2 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.

3.1

operating light

device designed for use by an operator for illuminating the oral cavity, which distributes, filters and/or transforms the light 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

LED operating light

operating light using at least one light emitting diode (LED) as the light source

3.3

illuminance

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

3.4

light-activated restorative material

dental material intended for restoring teeth that incorporates a monomer system, the polymerization of which is activated by blue light

NOTE Polymer-based materials of this type are classified in ISO 4049 as Class 2 materials and water-based materials of this type are classified in ISO 9917-2 as Class 2 or Class 3 materials.

3 Classification

3.1 According to type of protection against electric shock

Operating lights are classified in accordance with IEC 60601-1 as follows:

- a) Class I equipment, see IEC 60601-1;
- b) Class II equipment, see IEC 60601-1.

3.2 According to mode of operation

Operating lights shall be suitable for continuous operation. IEC 60601-1:2005+A1:2012, 6.6 applies.

4 Requirements and recommendations

4.1 General requirements

Operating lights shall be designed, constructed and manufactured so that, when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they cause no danger which could 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 standard, it shall be considered that these requirements are fulfilled.

Test in accordance with 6.3.

4.2 Optical requirements

4.2.1 Adjustable level of illuminance

The level of illuminance shall be adjustable between a minimum level and maximum level specified by the manufacturer. The maximum level of illuminance shall be at least 15 000 lx.

NOTE Manufacturers are advised that there is indication in the dental ergonomics literature that a higher specified level of illuminance up to a certain limit may be warranted.^[14] This requirement will be evaluated in the next revision of this Standard and modified with respect to the lower limit and/or upper limit for maximum illuminance, if appropriate, with consideration for current research.

The adjustment of illuminance may be either continuous or in discrete levels.

Test in accordance with 6.2 and 6.3.2.

4.2.2 Illumination pattern

4.2.2.1 Illumination areas and illuminance levels

The illumination areas A and B are shown in Figure 1.

The inner area of illumination, area A, is defined by an ellipse with a horizontal axis of 50 mm and a vertical axis of 25 mm, in which the point of maximum illuminance, L_{Max} , shall lie. Throughout area A the illuminance shall not be less than 75 % of L_{Max} (see Figure 1). Test in accordance with 6.3.2.

The outer area of illumination, area B, is defined as the area between the 50 % of maximum illuminance isolux line and the inner area A.

The 50 % of maximum illuminance isolux line shall be measured and plotted in accordance with 6.3.2 in order to indicate area B. The outer 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 (see Figure 1).

The 10 % of maximum illuminance isolux line and 75 % of maximum illuminance isolux line shall be measured and plotted in accordance with 6.3.2 for the purpose of fulfilling the manufacturer's instructions requirement specified in 7.4.