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2014-10-15

Dentistry — Operating lights

Médecine bucco-dentaire — Appareils d'éclairage



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Contents

Page

Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
4.1 According to type of protection against electric shock.....	2
4.2 According to mode of operation.....	2
5 Requirements and recommendations	2
5.1 General requirements.....	2
5.2 Optical requirements.....	3
5.3 Mechanical requirements.....	6
5.4 Cleaning and disinfection.....	7
5.5 Electrical requirements.....	7
5.6 Usability.....	7
6 Sampling	7
7 Testing	7
7.1 General.....	7
7.2 Visual inspection.....	7
7.3 Optical tests.....	8
7.4 Mechanical tests.....	11
7.5 Cleaning and disinfection.....	11
8 Manufacturer's instructions	11
8.1 Documents.....	11
8.2 General.....	12
8.3 Instructions for use.....	12
8.4 Technical description.....	12
8.5 Check.....	12
9 Packaging	12
10 Marking	13
10.1 Marking on the outside of mains-operated operating lights.....	13
10.2 Marking on the inside of operating lights.....	13
10.3 Graphical symbols.....	13
10.4 Colours of the insulation of conductors.....	13
10.5 Indicator lights and push-buttons.....	13
Annex A (informative) Transformation formulas	14
Annex B (normative) Normalized absorbance of camphorquinone	15
Bibliography	17

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

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.