INTERNATIONAL STANDARD

ISO 9680

First edition
1993-10-15

Dental operating light

Appareil d'éclairage opératoire dentaire

Reference number
ISO 9680:1993(E)

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.

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.

International Standard ISO 9680 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 6, *Dental equipment*.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Introduction

This International Standard contains specifications on the lighting of the dental surgery and its associated areas, and of the dental laboratory.

The aim 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 a dental 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 a dental operating light should not render the equipment unsafe.

In preparing this International Standard account has been taken of IEC 598-1.

This International Standard takes priority over IEC 601-1 as specified in the individual clauses of this International Standard.

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

This International Standard refer to IEC 601-1, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 601-1.

It also contains specifications on manufacturer's instructions, marking and packaging.

This page intentionally left blank

Dental operating light

1 Scope

This International Standard applies to dental operating lights, however constructed, used for illuminating the oral cavity. Its specifies requirements and test methods. It also contains specifications on manufacturer's instructions, marking and packaging.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-4:1989, *Dental vocabulary — Part 4: Dental equipment.*

ISO 4211:1979, *Furniture — Assessment of surface resistance to cold liquids.*

ISO 9687:1993, *Dental equipment — Graphical symbols.*

IEC 598-1:1986, *Luminaires — Part 1: General requirements and tests.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

CIE 15.2:1986, *Colorimetry.*

CIE 69:1987, *Methods of characterizing illuminance meters and luminance meters; Performance, characteristics and specifications.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 1942-4 and the following definitions apply.

3.1 luminaire: Apparatus which distributes, filters or transforms the light transmitted from one or more lamps and which includes all parts necessary for supporting, fixing and protecting the lamps, but not the lamps themselves, and where necessary circuit auxiliaries together with the means of connecting them to the supply. [IEC 598-1:1986]

3.2 lamp: Light source.

3.3 dental luminaire: Luminaire specially designed and/or presented for use in the dental surgery.

3.4 dental operating light: Item of equipment specially designed for use by a dentist for illuminating the oral cavity, consisting of a dental luminaire and one or more lamps.

4 Classification

4.1 According to type of protection against electric shock

Dental operating lights are classified as follows:

a) **Class I equipment**

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**

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.

4.2 According to degree of protection against electric shock

Dental operating lights are only of type B equipment.

Type B equipment

Class I or II equipment, or equipment with an internal electrical power source providing an adequate degree of protection against electric shock particularly regarding:

— allowable leakage currents;

— reliability of the protective earth connection (if present).

Type B equipment is, for example, suitable for intentional external and internal application to the patient, excluding direct cardiac application.

4.3 According to mode of operation

Dental operating lights are a type of equipment with continuous operation.

4.4 Marking or identification

The classification shall be marked or identified in accordance with 8.2.

5 Requirements and recommendations

5.1 General

Dental 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.

The dental operating light shall have the strength and rigidity necessary to resist the stresses to which it may be subjected in normal dental practice without risk of introducing fire, electric shock or accident hazard.

Those dental operating lights which are intended to be permanently fixed on the ceiling, the wall or the floor shall have provision for this (see 5.3.4.3).

Testing shall be carried out in accordance with 7.2.

If the equipment also passes all the tests described in this International Standard, it shall be considered that these requirements are fulfilled.

In addition, it is recommended that edges and corners of components and parts accessible to the patient or personnel should be finished in such a manner as to avoid injury to the patient or personnel.

5.2 Optical

5.2.1 Level of illuminance

The level of illuminance shall be adjustable. The adjustment should preferably be continuous but, if in steps, it shall be made with at least three levels of illuminance (two approximately equal steps). The adjustment of illumination shall include a range from 8 000 lx to 15 000 lx.

Testing shall be carried out in accordance with 7.2 and 7.3.2.

5.2.2 Illumination pattern

The area of illuminance shall lie within a circle of 50 mm diameter with no illuminance less than 75 % of the maximum. If the illuminance pattern is larger than the 50 mm diameter circular area, the 50 % of maximum illuminance isolux should be plotted (see figure 1).

Testing shall be carried out in accordance with 7.3.2.

5.2.3 Illumination uniformity

The illumination shall decrease in intensity progressively and smoothly (with reversal of slope not exceeding 10 % of the centre illumination) toward the pattern edge, within the limits given in 5.2.2.

Testing shall be carried out in accordance with 7.3.2.

5.2.4 Illumination in patient's eyes

The level of illumination 60 mm above a line parallel to a horizontal line through the area of maximum illuminance shall be not greater than 1 200 lx (see figure 1).

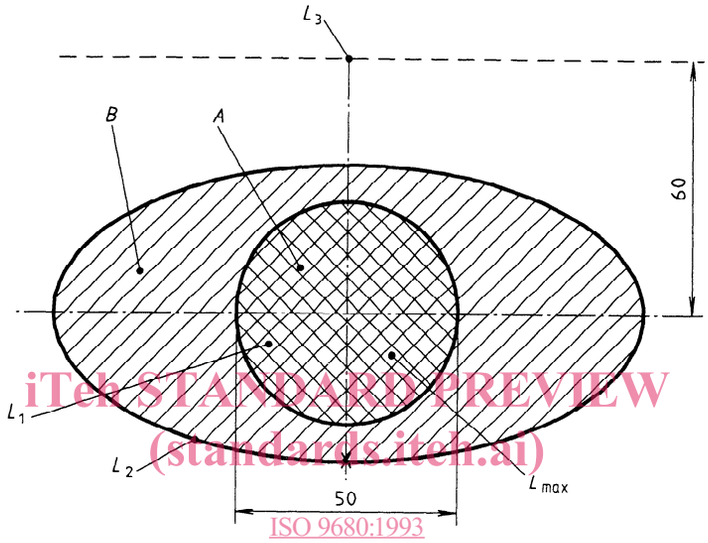
Testing shall be carried out in accordance with 7.3.2.

5.2.5 Light points in reflector

The reflector should be free of glare in the patient's eyes during normal operation.

Testing shall be carried out in accordance with 7.2.

Dimensions in millimetres



A	Area of illuminance > 0,75 L_{max}
B	Area with illumination ⩾ 0,5 L_{max} and ⩽ 0,75 L_{max}
L_{max}	Point of maximum illuminance, somewhere within the area of illuminance A
L_1	Illuminance within the area of illuminance L_1 ⩾ 0,75 L_{max}
L_2	Line of pattern with L = 0,5 L_{max}
L_3	Illumination at a distance of 60 mm L_3 ⩽ 1 200 lx

Figure 1 — Illumination pattern

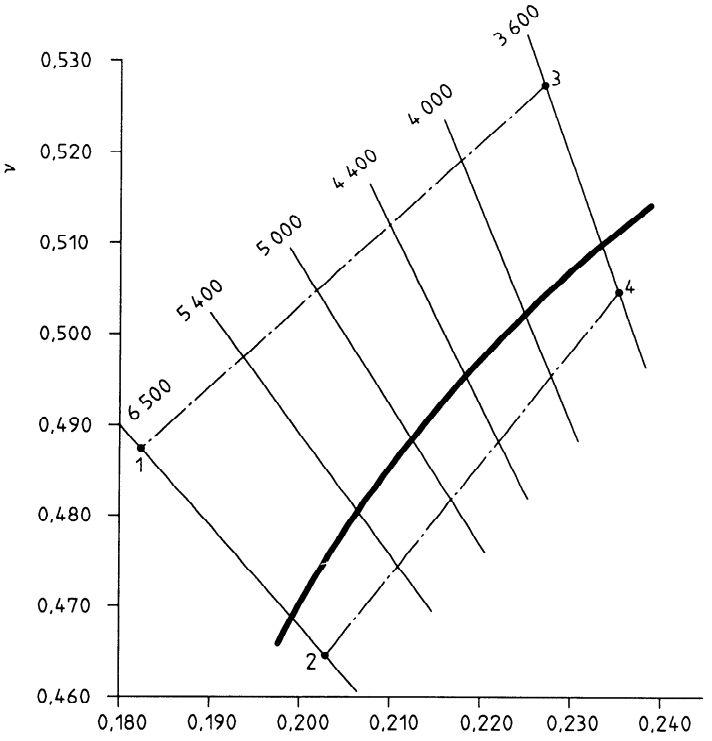


Figure 2 — Part of CIE 1976 CIELUV uniform chromaticity scale diagram

5.2.6 Chromatic aberration

No colour separation (chromatic aberration) of the light incident upon the screen shall be visible inside the 50 % of maximum illuminance isolux line.

Testing shall be carried out in accordance with 7.3.3.

5.2.7 Correlated colour temperature

The light emitted by the dental operating light shall have a correlated colour temperature between 3 600 K and 6 500 K at 15 000 lx at the origin of the coordinates of the target.

The trichromatic coordinates of the four extreme points are given in figure 2.

The manufacturer shall supply the spectrum emission curve of the dental operating light at 15 000 lx together with the black body response curve at the corresponding correlated colour temperature, so that they may be compared.

Testing shall be carried out in accordance with 7.3.4.

5.2.8 Radiant heat in pattern

The temperature rise shall be at as low a temperature as possible and not greater than 15 K at any point in the illumination pattern with the dental light operating at its maximum illuminance level.

Testing shall be carried out in accordance with 7.3.5.

5.2.9 Shadow

The hard shadow of a 20 mm object at a distance of 50 mm shall have no dimension greater than 12 mm.

Testing shall be carried out in accordance with 7.3.6.

5.3 Mechanical

5.3.1 Moving parts

Moving parts that may constitute a hazard under normal working conditions shall be protected or guarded to minimize the risk of injury to the patient and personnel.

The distance between power-activated moving parts which are accessible to patient's and personnel's hands and fingers shall be less than 10 mm when fully opened or a minimum of 20 mm when fully closed.

All electrical cables shall be adequately protected against wear, fracture and damage due to rubbing or strain incurred during normal operation of the dental operating light.

IEC 601-1:1988, clause 22 applies.

Testing shall be carried out in accordance with 7.3.7.

5.3.2 Operating controls

Controls should be located in a position, and be of such design, as to preclude the likelihood of being accidentally activated.

Operating symbols as specified in ISO 9687 shall be used where they exist.

Testing shall be carried out in accordance with 7.2.

5.3.3 Rotary movement

The light should be designed to avoid the risk of damage to electrical conductors during rotary movement.

Testing shall be carried out in accordance with 7.2.

5.3.4 Handling and mechanical adjustment

5.3.4.1 Stability after positioning

The dental operating light shall be free from apparent drift when positioned.

Testing shall be carried out in accordance with 7.3.8.

5.3.4.2 Operating forces

If the dental operating light is adjustable by the personnel from one position to another, it should allow quick and easy movement and be stable in its new position. The force required at the handle to reposition the dental operating light shall not exceed 30 N. Minor adjustments to the position of the light source assembly shall not require a force greater than 7 N.

Testing shall be carried out in accordance with 7.3.9.

5.3.4.3 General stability

If the dental operating light is fixed to a pillar or post, it shall not be possible to tip it about the base edge. If the dental operating light is fixed to the ceiling or wall, the fixing shall not be damaged or disrupted.

Testing shall be carried out in accordance with 7.3.10.

5.3.4.4 Mechanical strength

IEC 601-1:1988, clause 21 applies.

5.3.5 Water penetration

The dental operating light shall not present a hazard when tested in accordance with 7.3.11.

Immediately after the test the dental operating light shall:

— retain its physical integrity;

— withstand the dielectric strength test specified in IEC 601-1:1988, clause 20, when inspection shall show that the water which may have entered the equipment can have no harmful effect; in particular, there shall be no trace of water on insulation for which creepage distances are specified in IEC 601-1:1988, clause 57.10.

Testing shall be carried out in accordance with 7.3.11.

5.3.6 Expelled parts

The luminaire shall be designed to provide protection against the effects of shattering lamps. No part of a shattered lamp should be expelled.

Testing shall be carried out in accordance with 7.3.12.

5.3.7 Suspended masses

IEC 601-1:1988, clause 28 applies.

5.4 Disinfection and cleaning

All exterior touchable parts of the dental operating light shall be capable of undergoing disinfection without deterioration of the light's surface or markings when using chemically relevant agents recommended by the manufacturer.

All exterior touchable parts of the dental operating light shall be capable of undergoing cleaning without deterioration of the light's surface or markings by using agents recommended by the manufacturer.

All safety requirements shall be maintained after the disinfection and cleaning test.

Testing shall be carried out in accordance with 7.3.13.

5.5 Electrical

5.5.1 Power input

IEC 601-1:1988, clause 7 applies.

5.5.2 Single fault conditions

IEC 601-1:1988, clause 3.6 applies.

5.5.3 Protection against electric shock hazards

IEC 601-1:1988, clause 13 applies.