INTERNATIONAL STANDARD

ISO 10650

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Dentistry — Powered polymerization activators

Médecine bucco-dentaire — Activateurs électriques de polymérisation

Reference number
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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 (see 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 (see 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 first edition of ISO 10650 cancels and replaces ISO 10650-1:2004 and ISO 10650-2:2007, which have been technically revised with the following changes:

— limitation of blue wavelength region to: 200 nm to 385 nm;

— test procedure 7.2 radiant exitance was adopted to LED-diode lamps;

— information to be supplied by the manufacturer and marking requirements were updated.

Introduction

This International Standard specifies requirements and test methods in the 200 nm to 385 nm wavelength region and the wavelength region above 515 nm for powered polymerization activators. No minimum requirement value is given for the 385 nm to 515 nm wavelength region. The value in the 385 nm to 515 nm wavelength region is no less than the manufacturer's stated value.

This International Standard uses wavelength regions based on cut-off filters. Thus, the 200 nm to 385 nm region includes not only the ultraviolet region but also the near blue wavelength region of around 380 nm. The 385 nm to 515 nm region is taken as the region for powered polymerization activation. The region above 515 nm reaches approximately 1100 nm, which is the detection limit of the detector specified in this International Standard. The test methods described do not give absolute values nor do they reflect energy emitted as black body radiation. The measured values are not true radiant exitance but are values obtained using the methods described in this International Standard. Nevertheless, the values obtained using these test methods are used in conjunction with this International Standard.

This International Standard refers to IEC 60601-1, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1.

Dentistry — Powered polymerization activators

1 Scope

This International Standard specifies requirements and test methods for powered polymerization activators in the 385 nm – 515 nm wavelength region intended for chairside use in polymerization of dental polymer-based materials. This International Standard applies to quartz-tungsten-halogen lamps and light-emitting diode (LED) lamps. Powered polymerization activators could have internal power supply (rechargeable battery powered) or be connected to external (mains) power supply. Lasers or plasma arc devices are not covered by this International Standard.

This International Standard does not cover powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures, or other oral dental appliances. This International Standard takes priority over IEC 60601-1 where specified in the individual clauses of this International Standard.

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 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*

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

IEC 60601-1-2, *Medical electrical equipment — Part 1: General requirements for safety — 2. Collateral Standard: Electromagnetic compatibility — Requirements and test*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and IEC 60601-1 apply.

NOTE The issue corresponds to IEC 60601-1:2005+A1:2012, Clause 3.

3.1
powered polymerization activator
device producing light primarily in the 385 nm to 515 nm region, intended for chairside use in polymerizing polymer-based filling, restorative, and luting materials

3.2
light-emitting diode lamps
semiconductor-based light emitting lamps

3.3
fully charged battery
battery which at the beginning is 100 % of the first full charge

4 Classification

Powered polymerization activators are classified, according to their lamps and power supply, as follows:

Class 1: Quartz-tungsten-halogen lamps

Type 1: Polymerization activators powered with mains supply.

Type 2: Polymerization activators powered with rechargeable battery supply.

Class 2: Light-emitting diode (LED) lamps

Type 1: Polymerization activators powered with mains supply.

Type 2: Polymerization activators powered with rechargeable battery/capacitor.

5 Requirements

5.1 General

5.1.1 Design

The construction of powered polymerization activators shall provide for safe and reliable operation. If field-repairable, the powered polymerization activator shall be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer. IEC 60601-1:2005+A1:2012 applies.

5.1.2 Connection

Powered polymerization activators shall be capable of being disconnected and reconnected from the supply for cleaning and disinfection.

Compliance shall be checked by manual inspection.

5.1.3 Operating controls

Operating controls shall be designed and located to minimize accidental activation.

Testing shall be carried out by visual and manual inspection.

5.1.4 Cleaning, disinfection, and sterilization

IEC 60601-1 applies.

The issue corresponds to IEC 60601-1:2005+A1:2012, 7.9.2.12.

5.1.5 Excessive temperatures

IEC 80601-2-60 applies.

NOTE The issue corresponds to IEC 80601-2-60:2012, 201.11.1.

5.2 Radiant exitance

The requirements for radiant exitance shall be met when tested at each continuous irradiation mode or pulse mode time period as specified by the manufacturer. If no time period is specified, the time period shall be 10 s.

5.2.1 Radiant exitance in the 385 nm to 515 nm (blue) wavelength region

This International Standard does not specify a requirement value for the radiant exitance in the 385 nm to 515 nm wavelength region. The manufacture shall provide information on the radiant exitance in this region as determined by the test method in 7.2. The radiant exitance in the 385 nm to 515 nm region shall not be less than the manufacturer's stated value at 90 %, 100 %, and 110 % of the operating voltage for Class 1 Type 1 and Class 2 Type 1. For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

5.2.2 Radiant exitance in the 200 nm to 385 nm wavelength region

The radiant exitance in the 200 nm to 385 nm regions shall be no more than 2 000 W/m^2 (200 mW/cm^2) for Class 1 Type 1 and Class 2 Type 1 at 90 %, 100 % and 110 % of the operating voltage when tested in accordance with 7.2. For Class 1 Type 2 and Class 2 Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

5.2.3 Radiant exitance in the wavelength region above 515 nm

The radiant exitance in the wavelength region above 515 nm shall be no more than 1 000 W/m^2 (100 mW/cm^2) at the operating voltage for Class 1 Type 1 and Class 2 Type 1 at 90 %, 100 % and 110 % of the operating voltage when tested in accordance with 7.2. For Class 1 Type 2 and Class 2 Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

5.3 Electrical safety requirements

The requirements for safety are in accordance with IEC 80601-2-60, IEC 60601-1, and IEC 60601-1-2.

If the powered polymerization activator is claimed usable in connection or in corporation with other equipment, e.g. dental unit, the powered polymerization activator shall comply with IEC 60601-1, IEC 60601-1-2, and IEC 80601-2-60 in the connected or incorporated condition.

If the powered polymerization activator is claimed usable in connection with other equipment, e.g. dental unit, test shall be performed in the connected condition.

6 Sampling

One powered polymerization activator, using all the available light guides delivered on a regular sale, shall be evaluated for compliance with this International Standard.

7 Test methods

7.1 General

7.1.1 General provisions for tests

All tests described in this International Standard are type tests. Type tests shall be made on one representative sample of the item being tested.

Tests are to be conducted at each continuous irradiation mode or pulse mode time period as specified by the manufacturer. If no time period is specified the time period shall be 10 s.

Also, test at each irradiation mode with different radiant exitances, specified by the manufacturer's instructions for use.

Tests are to be conducted for each light guide supplied with the powered polymerization activator.

IEC 60601-1 and IEC 80601-2-60 apply.

Unless otherwise specified, do not repeat any of these tests.

7.1.2 Atmospheric conditions

After the powered polymerization activator being tested has been set up for normal use, tests shall be carried out under the following conditions:

a) ambient temperature of (23 ± 5) °C;

b) relative humidity of (50 ± 20) %.

7.2 Radiant exitance

7.2.1 Apparatus

7.2.1.1 Apparatus for measuring the optical cross-sectional area of the light guide

7.2.1.1.1 Micrometer, caliper or any other measuring device with an equivalent accuracy, reading in millimetres, with an accuracy to 0,1 mm, or any other measuring device with an equivalent accuracy.

7.2.1.2 Apparatus for measuring the irradiance

7.2.1.2.1 Radiometer, calibrated, used to measure the radiated power (in watts).

The radiometer shall have a flat response (uniform spectral sensitivity) within the wavelength region from 200 nm to 1 100 nm, independent of the angle of radiation incidence[1)].

The entrance aperture of the radiometer shall be larger than the cross-section of the light guide of the powered polymerization activator, so that all radiant emission is measured by the radiometer. The diameter of the entrance aperture shall be at least 2 mm or larger than the light guide to capture all light emission from the light guide.

7.2.1.2.2 Filters of the following types[2)]

7.2.1.2.2.1 Quartz filter, allowing transmission above 200 nm, with transmission characteristics described by a curve as shown in Figure 1.

7.2.1.2.2.2 385 nm filter, allowing transmission above 385 nm, with transmission characteristics described by a curve as shown in Figure 2.

7.2.1.2.2.3 515 nm filter, allowing transmission above 515 nm, with transmission characteristics described by a curve as shown in Figure 3.

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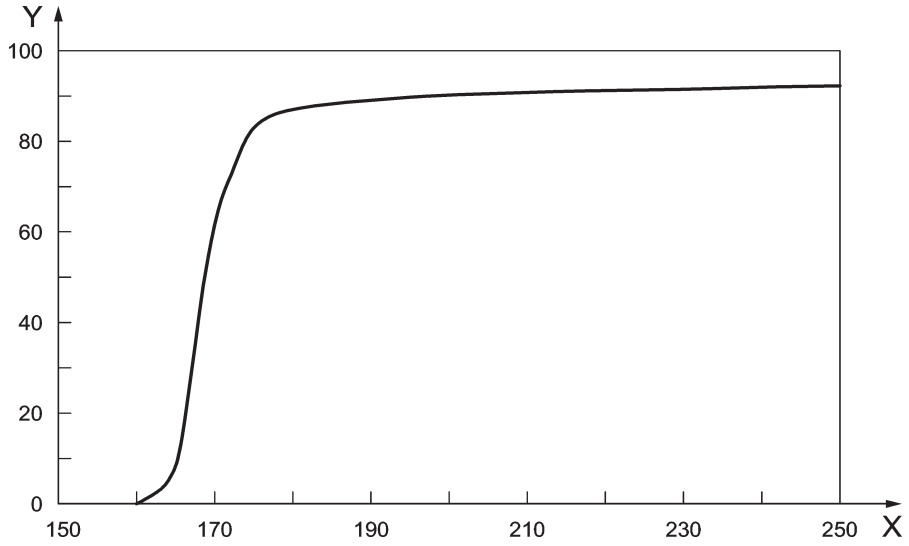
1) LabMaxTO Power Meter, Sensor PM-3 and PowerMax-Pro 150F HD. are the trade names of suitable products supplied by Coherent, Santa Clara, California 95054, USA. This information is given only for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the products named.

2) Optical quartz filter, and longpass UV filter may meet the transmission characteristics as shown in Figures 1 and 2 respectively. Schott OG515 is the trade name of a suitable product meeting the transmission characteristics shown in Figure 3. This information is given only for the convenience of users of this International standard and does not constitute an endorsement by ISO of the products named.

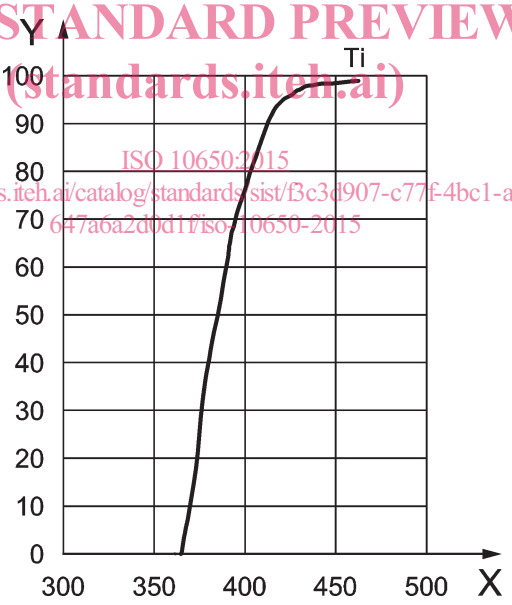


Key

X wavelength in nm

Y transmittance in %

Figure 1 — Transmittance characteristics of quartz filter



Key

X wavelength in nm

Y transmittance in %

Ti transmittance curve minus reflection loss on light entrance and light output surfaces

Figure 2 — Transmittance characteristics of 385 nm filter