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**Dentistry — Powered polymerization  
activators —**

**Part 1:  
Quartz tungsten halogen lamps**

*Art dentaire — Activateurs électriques de polymérisation —  
Partie 1: Lampes halogènes au tungstène à quartz*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 10650-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition of ISO 10650-1 together with ISO 10650-2 cancels and replaces ISO/TS 10650:1999, which has been technically revised.

ISO 10650 consists of the following parts, under the general title *Dentistry — Powered polymerization activators*:

— *Part 1: Quartz tungsten-halogen lamps*

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The following part is under preparation:

— *Part 2: Light-emitting diode (LED) lamps*

## Introduction

This International Standard specifies requirements and test methods for powered polymerization activators in the 190 nm to 385 nm wavelength region and the wavelength region above 515 nm. No requirement is given for the 400 nm to 515 nm wavelength region. This International Standard uses wavelength regions based on cut-off filters. Thus, the 190 nm to 385 nm region includes not only the ultraviolet region but also the near-blue wavelength region of around 380 nm. The 400 nm to 515 nm region is taken as the blue region for powered polymerization activation. The region above 515 nm reaches approximately 1 100 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 60601-1:1988, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:1988.

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# Dentistry — Powered polymerization activators —

## Part 1: Quartz tungsten halogen lamps

### 1 Scope

This part of ISO 10650 specifies requirements and test methods for powered polymerization activators in the blue wavelength region intended for chair-side use in polymerization of dental polymer-based materials. This part of ISO 10650 applies to powered tungsten-halogen lamps and rechargeable battery-powered tungsten-halogen polymerization activators.

This Part of ISO 10650 is not applicable to powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances. This part of ISO 10650 takes priority over IEC 60601-1:1988 where specified in the individual clauses of this International Standard.

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### 2 Normative references (standards.iteh.ai)

The following referenced documents are indispensable for the application of this document. 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*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

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

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and IEC 60601-1:1988, Clause 2, and the following apply.

#### 3.1

##### **powered polymerization activator**

device for producing light in the blue wavelength region, intended for chair-side use in polymerizing polymer-based filling, restorative and luting materials

### 4 Classification

For the purposes of this part of ISO 10650, powered polymerization activators are classified, according to their power supply, as follows:

- Type 1: polymerization activators powered with a mains supply;
- Type 2: polymerization activators powered with a rechargeable battery supply.

## 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 should be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer. IEC 60601-1:1988, Clause 59 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 inspection

#### 5.1.4 Cleaning and disinfection

IEC 60601-1:1988, Clause 44.7 applies.

#### 5.1.5 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies.

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## 5.2 Radiant exitance

### 5.2.1 Radiant exitance in the 400 nm to 515 nm (blue) wavelength region

This International Standard does not specify a requirement for the radiant exitance in the 400 nm to 515 nm (blue) wavelength region. The manufacturer shall provide information on the radiant exitance in this region as determined by the test method in 7.2. The radiant exitance in the 400 nm to 515 nm region shall not be less than the manufacturer's stated value when tested in accordance with 7.2. For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

### 5.2.2 Radiant exitance in the 190 nm to 385 nm wavelength region

The radiant exitance in the 190 nm to 385 nm region shall be no more than 2 000 W/m<sup>2</sup> (200 mW/cm<sup>2</sup>) at the operating voltage, 90 % of the operating voltage and 110 % of the operating voltage when tested in accordance with 7.2. For 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<sup>2</sup> (100 mW/cm<sup>2</sup>) at the operating voltage, 90 % of the operating voltage and 110 % of the operating voltage when tested in accordance with 7.2. For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.



### 5.3 Electrical requirements

The requirements for the following equipment and conditions are governed by the cited clauses and/or subclauses of IEC 60601:

- |  |                                      |
|--|--------------------------------------|
| a) power input                               | IEC 60601-1:1988, Clause 7;          |
| b) single-fault conditions                   | IEC 60601-1:1988, 3.6 and Clause 52; |
| c) protection against electric shock hazards | IEC 60601-1:1988, Clause 13;         |
| d) enclosures and protective covers          | IEC 60601-1:1988, Clause 16;         |
| e) leakage                                   | IEC 60601-1:1988, 44.4;              |
| f) protective earthing                       | IEC 60601-1:1988, Clause 58;         |
| g) continuous leakage currents               | IEC 60601-1:1988, Clause 19;         |
| h) dielectric strength                       | IEC 60601-1:1988, Clause 20;         |
| i) interruption of the power supply          | IEC 60601-1:1988, Clause 49;         |
| j) abnormal operating and fault conditions   | IEC 60601-1:1988, Clause 52;         |
| k) components and general assembly           | IEC 60601-1:1988, Clause 56;         |
| l) mains parts, components and assembly      | IEC 60601-1:1988, Clause 57;         |
| m) electromagnetic compatibility             | IEC 60601-1-2.                       |

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## 6 Sampling

At least one powered polymerization activator, with a light guide (optic tip) as specified by the manufacturer for each model series, shall be evaluated for compliance with this International Standard.

## 7 Test methods

### 7.1 General

#### 7.1.1 General provisions for tests

The sequence of tests shall be in accordance with Annex A.

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

IEC 60601-1:1988, 4.1 and 4.2 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  $(23 \pm 2)$  °C;
- b) relative humidity of  $(50 \pm 10)$  %.

### 7.1.3 Other conditions

IEC 60601-1:1988, 4.6 d) applies.

### 7.1.4 Supply and test voltages, type of current, nature of supply, frequency

IEC 60601-1:1988, 4.7 applies.

### 7.1.5 Preconditioning

IEC 60601-1:1988, 4.8 applies.

### 7.1.6 Conditioning

The test arrangement and the powered polymerization activator shall be conditioned in an environment at  $(23 \pm 2)$  °C for 4 h before testing.

### 7.1.7 Repairs and modifications

IEC 60601-1:1988, 4.9 applies.

## 7.2 Radiant exitance

### 7.2.1 Apparatus

#### 7.2.1.1 Apparatus for measuring the optical cross-sectional area of the optic tip

**7.2.1.1.1 Micrometer**, reading in millimetres, with an accuracy to 0,02 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 190 nm to 1 100 nm, independent of the angle of radiation incidence<sup>1)</sup>.

The entrance aperture of the radiometer shall be larger than the cross-section of the optic tip of the powered polymerization activator, so that all radiant emission is measured by the radiometer. The edge of the optic tip should be at least 2 mm from the edge of the entrance aperture.

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1) Molecron Power Meter PM 500D-2 and Molecron Detector PM-3 are the trade names of suitable products supplied by Molecron Detector Inc. Portland, Oregon 97224, USA. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

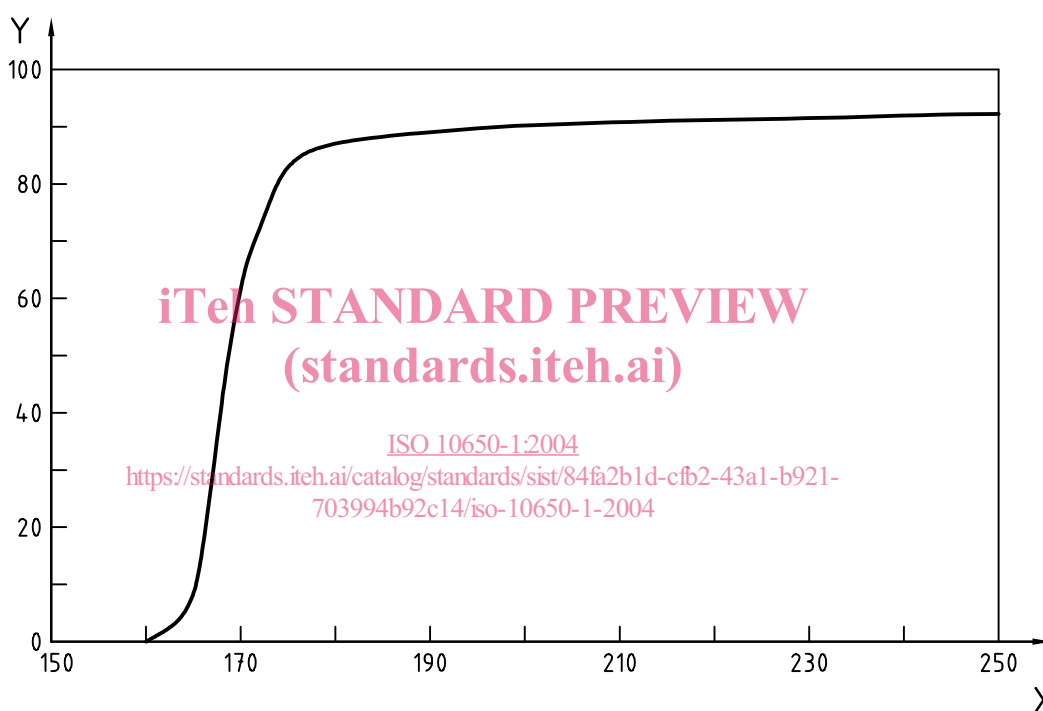
### 7.2.1.2.2 Filters of the following types<sup>2)</sup>:

**7.2.1.2.2.1 Filter** (quartz),  $(3,0 \pm 0,1)$  mm thick, allowing transmission above 190 nm, with transmission characteristics described by a curve as shown in Figure 1;

**7.2.1.2.2.2 Filter**,  $(3,0 \pm 0,1)$  mm thick, allowing transmission above 385 nm, with transmission characteristics described by a curve as shown in Figure 2;

**7.2.1.2.2.3 Filter**,  $(3,0 \pm 0,1)$  mm thick, allowing transmission above 400 nm with transmission characteristics described by a curve as shown in Figure 3;

**7.2.1.2.2.4 Filter**,  $(3,0 \pm 0,1)$  mm thick, allowing transmission above 515 nm with transmission characteristics described by a curve as shown in Figure 4.



#### Key

- X wavelength, in nanometres
- Y transmission, in percent

**Figure 1 — Transmission characteristics of quartz filter**

2) Schott SQ1, Schott GG 385, Schott GG 400 and Schott OG 515 are the trade names of suitable products. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.