



SLOVENSKI STANDARD
SIST EN ISO 10650-1:2005

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Zobozdravstvo – Polimerizacijski aktivatorji – 1. del: Halogenske svetilke »Quartz tungsten« (ISO 10650-1:2004)

Dentistry - Powered polymerization activators - Part 1: Quartz tungsten halogen lamps (ISO 10650-1:2004)

Zahnheilkunde - Lichtpolymerisationsgeräte - Teil 1: Quartz-Wolfram-Halogenlampen (ISO 10650-1:2004)

Art dentaire - Activateurs électriques de polymérisation - Partie 1: Lampes halogenes au tungstene a quartz (ISO 10650-1:2004)

Ta slovenski standard je istoveten z: EN ISO 10650-1:2005

ICS:

11.060.20 Z[à [c @ ã } æ] ! ^ { æ Dental equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10650-1

October 2005

ICS 11.060.20

English Version

Dentistry - Powered polymerization activators - Part 1: Quartz tungsten halogen lamps (ISO 10650-1:2004)

Art dentaire - Activeurs électriques de polymérisation -
Partie 1: Lampes halogènes au tungstène à quartz (ISO
10650-1:2004)

Zahnheilkunde - Lichtpolymerisationsgeräte - Teil 1:
Quartz-Wolfram-Halogenlampen (ISO 10650-1:2004)

This European Standard was approved by CEN on 4 September 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 10650-1:2005 (E)**Foreword**

The text of ISO 10650-1:2004 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10650-1:2005 by Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2006, and conflicting national standards shall be withdrawn at the latest by April 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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The text of ISO 10650-1:2004 has been approved by CEN as EN ISO 10650-1:2005 without any modifications.

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INTERNATIONAL
STANDARD

ISO
10650-1

First edition
2004-11-01

**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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ISO 10650-1:2004(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.

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*
- <https://standards.iteh.ai/catalog/standards/sist/1087ec7b-1239-4d6f-9151-4292ea96e0d5/sist-en-iso-10650-1-2005>

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. [standards/sist/1087ec7b-1239-4d6f-9151-4292ea96e0d5/sist-en-iso-10650-1-2005](https://standards.iteh.ai/standards/sist/1087ec7b-1239-4d6f-9151-4292ea96e0d5/sist-en-iso-10650-1-2005)

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.

ISO 10650-1:2004(E)**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/m² (200 mW/cm²) 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/m² (100 mW/cm²) 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.