# SLOVENSKI STANDARD
# oSIST prEN ISO 10650:2025

**01-april-2025**

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**Zobozdravstvo - Polimerizacijski aktivatorji (ISO/DIS 10650:2025)**

Dentistry - Powered polymerization activators (ISO/DIS 10650:2025)

Zahnheilkunde- Polymerisationslampen (ISO/DIS 10650:2025)

Médecine bucco-dentaire - Activateurs électriques de polymérisation (ISO/DIS 10650:2025)



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# Dentistry — Powered polymerization activators

*Médecine bucco-dentaire — Activateurs électriques de polymérisation*

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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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 6, Dental equipment.



This third edition cancels and replaces the second edition (ISO 10650:2018), which has been technically revised.

The main changes are as follows:



- an addition in the Introduction on blue light hazard to the retina from exposure to emission from power polymerization activators and the use of protective filtering devices;
- Figure 5 in the test procedure using filters (Method B, 7.4.2) is corrected;
- a change in 8.2 (h) from “recommendation on the effective use of protective filter glasses by dentist, dental assistant, and patient to decrease exposure” to “recommendation on the effective use of protective filtering devices intended for use with powered polymerization activators by dentist, dental assistant, and patient to decrease exposure”;
- an addition to the Instruction for Use: “8.5 “Revision date or other version identifier of the instructions for use”;
- editorial update.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

This document specifies requirements and test methods in the wavelength region below 380 nm, the 380 nm to 515 nm wavelength region and the wavelength region above 515 nm for powered polymerization activators. No minimum requirement value is given for the 380 nm to 515 nm wavelength region. For the 380 nm to 515 nm wavelength region, the maximum radiant exitance has been specified in order to mitigate risks for patients.

There is a risk of tissue damage caused by heat development during photo-polymerization when sufficiently high irradiances are applied for long enough time. There is a risk of inadequate polymerization of resin-based materials when irradiated by powered polymerization activators with high radiant exitance for very short irradiation time resulting in insufficient combinations of irradiance and irradiation time. There is also a risk of inadequate polymerization of resin-based materials when irradiated with low irradiance and short irradiation time. There is no complete reciprocity between irradiance and curing time, i.e. a time threshold exists under which the polymerization will not proceed sufficiently. Therefore it is important to follow the instructions for use of the composite manufacturers.

The spectral emission of powered polymerization activators typically overlaps substantially with the blue-light hazard function for induction of retinal damage (peak interval between 435 nm and 440 nm). Both patients and dental healthcare professionals may be exposed to visible light from powered polymerization activators. Exposure may be either direct or indirect (i.e., reflected). Protective filtering devices intended for use with powered polymerization activators can mitigate the retinal blue-light hazard exposure by attenuating the light in the wavelength range of concern. This document recommends the effective use of protective filter devices by dentist, dental assistant, and patient to decrease exposure. A standard for protective filtering devices for use with powered polymerization activators is being developed.

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

# Dentistry — Powered polymerization activators

## 1 Scope

This document specifies requirements and test methods for powered polymerization activators in the 380 nm to 515 nm wavelength region intended for chairside use in polymerization of dental polymer-based materials.

This document 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 standard.

This document does not cover powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 9687, *Dentistry — Graphical symbols for dental equipment*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

IEC 60601-1:2005+AMD1:2012, *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 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for the 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, IEC 60601-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**powered polymerization activator**
device producing a light beam primarily in the 380 nm to 515 nm region, intended for chairside use in polymerizing polymer-based filling, restorative and luting materials

**3.2**
**light-emitting diode (LED) lamps**
semiconductor-based light emitting lamps

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

**3.4**
**radiant exitance**
quotient of the radiant flux leaving an element of the surface containing the point, by the area of the element

**3.5**
**irradiance**
quotient of the radiant flux incident on an element of the surface containing the point, by the area of the element

**3.6**
**radiant flux**
power emitted, transmitted or received in the form of radiation

# 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. Test conformity in accordance with 7.2.1.

### 5.1.2 Connection

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

Conformity shall be checked in accordance with 7.2.2.

### 5.1.3 Operating controls

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

Conformity shall be checked by 7.2.1 and 7.2.2.