INTERNATIONAL STANDARD

ISO 10650

Second edition
2018-08

Dentistry — Powered polymerization activators

Médecine bucco-dentaire — Activateurs électriques de polymérisation

Reference number
ISO 10650:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 10650:2015), which has been technically revised.

The main changes compared to the previous edition are as follows:

— a test procedure using spectrometer (Method A, 7.4.1) was included;

— a test procedure using filters (Method B, 7.4.2) was modified;

— an upper limit to the radiant exitance for the 380 nm to 515 nm wavelength region was added.

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.

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 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*

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 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 terminological databases for use in standardization at the following addresses:

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

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

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.

5.1.4 Cleaning, disinfection and sterilization

Test conformity in accordance with 7.2.3.

IEC 60601-1 shall apply.

NOTE The issue corresponds to 11.6.6 and 11.6.7 of IEC 60601-1:2005+AMD1:2012.

5.1.5 Excessive temperatures

Test conformity in accordance with 7.2.3.

IEC 80601-2-60 shall apply.

NOTE The issue corresponds to 201.11.1.1 of IEC 80601-2-60:2012.

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 20 s.

For Type 1 polymerization activators, the requirement applies at the operating voltage (rated voltage).

For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

5.2.1 Radiant exitance in the 380 nm to 515 nm wavelength region

The radiant exitance in the 380 nm to 515 nm wavelength region shall not be more than 40 000 W/m^2 (4 000 mW/cm^2) when determined for conformity by the test method in 7.4.

The manufacturer shall provide information on the radiant exitance in this region as determined by the test methods in 7.4. The radiant exitance shall vary by no more than ±20 % of the manufacturer's stated radiant exitance (see 8.2 n). Test for conformity in accordance with 7.2.3.

5.2.2 Radiant exitance in the wavelength region below 380 nm

The radiant exitance in the wavelength region below 380 nm shall be no more than 2 000 W/m^2 (200 mW/cm^2) when tested for conformity in accordance with 7.4.

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) when tested for conformity in accordance with 7.4.

5.3 Electrical safety requirements

The requirements for safety shall be in accordance with IEC 80601-2-60, IEC 60601-1 and IEC 60601-1-2. Test for conformity in accordance with 7.2.2.

If the powered polymerization activator is claimed usable in connection or in combination with other equipment, e.g. dental unit, the powered polymerization activator shall be in accordance 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.

5.4 Physical and mechanical safety

The requirements for safety shall conform to IEC 80601-2-60 and IEC 60601-1.

Test for conformity in accordance with 7.2.1, 7.2.2 and 7.2.3.

5.5 Usability

IEC 62366-1 shall apply. Test for conformity in accordance with 7.2.2.

5.6 Instructions for use manual

Each powered polymerization activator shall be supplied with instructions for use detailing operation, operator maintenance, safety, and servicing. Conformity with Clause 8 shall be checked in accordance with 7.2.3.

5.7 Technical Description

IEC 60601-1 shall apply. Conformity shall be checked in accordance with 7.2.3.

NOTE The issue corresponds to 7.9.3 of IEC 60601-1:2005+AMD1:2012.

5.8 Marking

Marking shall conform to Clause 9 in accordance with 7.2.3.

5.9 Packaging

Packaging shall conform to Clause 10 in accordance with 7.2.3.

6 Sampling

One powered polymerization activator, using all supplied light guides intended for the powered polymerization activator, shall be evaluated for conformance with this document. Powered polymerization activators without light guides shall be tested under normal conditions of use.

7 Measurement and test methods

7.1 General

7.1.1 General provisions for tests

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

Tests shall 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 20 s.

Also, test at each power mode that emits a different radiant exitance as specified by the manufacturer's instructions for use.