

Dentistry - Powered polymerization activators (ISO 10650:2018)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10650:2018 sisaldab Euroopa standardi EN ISO 10650:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10650:2018 consists of the English text of the European standard EN ISO 10650:2018.
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English Version

Dentistry - Powered polymerization activators (ISO
10650:2018)

Médecine bucco-dentaire - Activateurs électriques de
polymérisation (ISO 10650:2018)

Zahnheilkunde - Polymerisationslampen (ISO
10650:2018)

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European foreword

This document (EN ISO 10650:2018) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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of an identical text or by endorsement, at the latest by April 2019, and conflicting national standards shall be withdrawn at the latest by April 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10650:2015.

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

Endorsement notice

The text of ISO 10650:2018 has been approved by CEN as EN ISO 10650:2018 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
5 Requirements	2
5.1 General	2
5.1.1 Design	2
5.1.2 Connection	2
5.1.3 Operating controls	3
5.1.4 Cleaning, disinfection and sterilization	3
5.1.5 Excessive temperatures	3
5.2 Radiant exitance	3
5.2.1 Radiant exitance in the 380 nm to 515 nm wavelength region	3
5.2.2 Radiant exitance in the wavelength region below 380 nm	3
5.2.3 Radiant exitance in the wavelength region above 515 nm	3
5.3 Electrical safety requirements	3
5.4 Physical and mechanical safety	4
5.5 Usability	4
5.6 Instructions for use manual	4
5.7 Technical Description	4
5.8 Marking	4
5.9 Packaging	4
6 Sampling	4
7 Measurement and test methods	4
7.1 General	4
7.1.1 General provisions for tests	4
7.1.2 Atmospheric conditions	5
7.2 Inspections	5
7.2.1 Visual inspection of powered polymerization activator	5
7.2.2 Manual inspection of powered polymerization activator	5
7.2.3 Visual inspection of manufacturer's document	5
7.3 Measurement of the optical cross-sectional area of the light guide/light-emitting tip	5
7.3.1 Apparatus	5
7.3.2 Procedure	5
7.4 Measurement of radiant exitance	5
7.4.1 Method A using spectrometer	5
7.4.2 Method B using filters	8
8 Information (instructions for use) to be supplied by the manufacturer	12
9 Marking	13
10 Packaging	14
Bibliography	15

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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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>