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Irish Standard
I.S. EN ISO 10650:2015

Dentistry - Powered polymerization activators (ISO 10650:2015)

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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National Foreword

I.S. EN ISO 10650:2015 is the adopted Irish version of the European Document EN ISO 10650:2015, Dentistry - Powered polymerization activators (ISO 10650:2015)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10650

September 2015

ICS 11.060.20

Supersedes EN ISO 10650-1:2005, EN ISO 10650-2:2007

English Version

Dentistry - Powered polymerization activators (ISO 10650:2015)

Médecine bucco-dentaire - Activateurs électriques de polymérisation (ISO 10650:2015)

Zahnheilkunde - Polymerisationslampen (ISO 10650:2015)

This European Standard was approved by CEN on 22 August 2015.

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Ref. No. EN ISO 10650:2015 E

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European foreword

This document (EN ISO 10650:2015) 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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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

This document supersedes EN ISO 10650-1:2005, EN ISO 10650-2:2007.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10650:2015 has been approved by CEN as EN ISO 10650:2015 without any modification.

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INTERNATIONAL STANDARD

ISO 10650

First edition
2015-09-15

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition of ISO 10650 cancels and replaces ISO 10650-1:2004 and ISO 10650-2:2007, which have been technically revised with the following changes:

— limitation of blue wavelength region to: 200 nm to 385 nm;

— test procedure 7.2 radiant exitance was adopted to LED-diode lamps;

— information to be supplied by the manufacturer and marking requirements were updated.

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Introduction

This International Standard specifies requirements and test methods in the 200 nm to 385 nm wavelength region and the wavelength region above 515 nm for powered polymerization activators. No minimum requirement value is given for the 385 nm to 515 nm wavelength region. The value in the 385 nm to 515 nm wavelength region is no less than the manufacturer's stated value.

This International Standard uses wavelength regions based on cut-off filters. Thus, the 200 nm to 385 nm region includes not only the ultraviolet region but also the near blue wavelength region of around 380 nm. The 385 nm to 515 nm region is taken as the region for powered polymerization activation. The region above 515 nm reaches approximately 1100 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, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1.

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Dentistry — Powered polymerization activators

1 Scope

This International Standard specifies requirements and test methods for powered polymerization activators in the 385 nm – 515 nm wavelength region intended for chairside use in polymerization of dental polymer-based materials. This International Standard 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 International Standard.

This International Standard does not cover powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures, or other oral dental appliances. This International Standard takes priority over IEC 60601-1 where specified in the individual clauses of this International Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

IEC 60601-1, *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 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 and IEC 60601-1 apply.

NOTE The issue corresponds to IEC 60601-1:2005+A1:2012, Clause 3.

3.1
powered polymerization activator
device producing light primarily in the 385 nm to 515 nm region, intended for chairside use in polymerizing polymer-based filling, restorative, and luting materials

3.2
light-emitting diode lamps
semiconductor-based light emitting lamps

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