International Standard

ISO 10650

Dentistry — Powered polymerization activators

Médecine bucco-dentaire — Activateurs électriques de polymérisation

Third edition
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Foreword

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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 document 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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

The main changes are as follows:

— content has been added to the Introduction on blue light hazard to the retina from exposure to emission from power polymerization activators and the use of protective filtering devices;

— an additional classification of powered polymerization activators along with corresponding requirements and test methods have been added (i.e. Type 3, polymerization activators powered by connection to a dental unit);

— Figure 3 and Figure 5 in the test procedure using filters (Method B, 7.4.2) have been corrected;

— requirements duplicated in the document from other medical device international standards (i.e. references to IEC 60601-1 [1], IEC 60601-1-2 [2], IEC 62366-1 [3] and IEC 80601-2-60 [4]) have been deleted;

— a requirement for the manufacturer to provide information about protective filtering devices has been added in 8.1, list item i);

— content was added to Clause 8: “Revision date or other version identifier of the instructions for use”;

— editorial updates.

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

Powered polymerization activators are used in dentistry to polymerize light-activated dental materials by emitting optical radiation within specified wavelength ranges. They are commonly used in restorative, orthodontic and preventive dental procedures to cure polymer-based materials, adhesives, sealants and related materials. Powered polymerization activators are designed to deliver controlled irradiance, spectral output and exposure duration to achieve adequate polymerization while minimizing thermal and biological risks. The performance and safety of dental curing lights are critical to the clinical outcome, durability of dental restorations and protection of patients and oral healthcare providers, necessitating standardized requirements and test methods.

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 oral healthcare providers can be exposed to visible light from powered polymerization activators. Exposure can 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.

IEC 60601-1 [1] specifies requirements pertaining to the basic safety and essential performance of medical electrical equipment and medical electrical systems. IEC 80601-2-60 [4] specifies requirements pertaining to the basic safety and essential performance of dental units, dental patient chairs, dental handpieces and dental operating lights. Requirements of IEC 60601-1 [1] and IEC 80601-2-60 [4] applicable to powered polymerization activators are not duplicated in this document.

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 is applicable to quartz-tungsten-halogen lamps and light-emitting diode (LED) lamps. Powered polymerization activators can be powered by an internal power supply (rechargeable battery powered) or can be powered by external (mains) power or can be powered by a dental unit. Lasers or plasma arc devices are not covered by this document.

This document does not apply to 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 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

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 lamp
LED lamp
semiconductor-based light emitting lamp