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ISO 10650

Dentistry — Powered polymerization activators

*Médecine bucco-dentaire — Activeurs électriques de
polymérisation*

**Third edition
2026-06**

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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.

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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.