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Dentistry — Powered polymerization activators

Médecine bucco-dentaire — Activeurs électriques de polymérisation



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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

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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 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.

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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.