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Dentistry — Powered polymerization activators

Médecine bucco-dentaire — Activeurs électriques de polymérisation



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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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 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.