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Interested committees:

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This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

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For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 10650

Dentistry — Powered polymerization activators

Médecine bucco-dentaire — Activeurs électriques de polymérisation

ICS: 11.060.20

ISO/TC 106/SC 6

Secretariat: **DIN**

Voting begins on:
2025-02-17

Voting terminates on:
2025-05-12

This document is circulated as received from the committee secretariat.

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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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This document was prepared by Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 6, Dental equipment.

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

The main changes are as follows:

- an addition in the Introduction on blue light hazard to the retina from exposure to emission from power polymerization activators and the use of protective filtering devices;
- [Figure 5](#) in the test procedure using filters (Method B, [7.4.2](#)) is corrected;
- a change in [8.2](#) (h) from “recommendation on the effective use of protective filter glasses by dentist, dental assistant, and patient to decrease exposure” to “recommendation on the effective use of protective filtering devices intended for use with powered polymerization activators by dentist, dental assistant, and patient to decrease exposure”;
- an addition to the Instruction for Use: “[8.5](#) “Revision date or other version identifier of the instructions for use”;
- editorial update.

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

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.

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 dental healthcare professionals may be exposed to visible light from powered polymerization activators. Exposure may 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. This document recommends the effective use of protective filter devices by dentist, dental assistant, and patient to decrease exposure. A standard for protective filtering devices for use with powered polymerization activators is being developed.

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.