
**Dentistry — Powered polymerization
activators —**

Part 2:
Light-emitting diode (LED) lamps

*Art dentaire — Activeurs électriques de polymérisation —
Partie 2: Lampes à diodes émettrices de lumière (LED)*



Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10650-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition, together with ISO 10650-1, cancels and replaces ISO/TS 10650:1999, which has been technically revised.

ISO 10650 consists of the following parts, under the general title *Dentistry — Powered polymerization activators*:

- *Part 1: Quartz tungsten halogen lamps*
- *Part 2: Light-emitting diode (LED) lamps*

Introduction

This part of ISO 10650 specifies requirements and test methods for light emitting diodes (LED) type powered polymerization activators in the 190 nm to 385 nm wavelength region and the wavelength region above 515 nm. No requirements are given for the 400 nm to 515 nm wavelength region.

This International Standard uses wavelength regions based on cut-off filters. Thus the 190 nm to 385 nm region includes not only the ultraviolet region but also the near-blue wavelength region of around 380 nm. The 400 nm to 515 nm region is taken as the blue region for powered polymerization activation. The region above 515 nm reaches approximately 1 100 nm, which is the detection limit of the detector specified in this document. 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 document. Nevertheless, the values obtained using these test methods are used in conjunction with this document.

This part of ISO 10650 refers to IEC 60601-1:2005, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:2005.

Dentistry — Powered polymerization activators —

Part 2: Light-emitting diode (LED) lamps

1 Scope

This part of ISO 10650 specifies requirements and test methods for powered polymerization activators with light-emitting diodes (LED) in the blue wavelength region intended for chair-side use in polymerization of dental polymer-based restorative materials.

This part of ISO 10650 is not applicable to powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances.

This part of ISO 10650 takes priority over IEC 60601-1:2005 where specified in the individual clauses of this part of ISO 10650.

2 Normative references

The following referenced documents are indispensable for the application 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 10650-1:2004, *Dentistry — Powered polymerization activators — Part 1: Quartz tungsten halogen lamps*

IEC 60601-1:2005, *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, ISO 10650-1, IEC 60601-1 and the following apply.

3.1

light-emitting diode (LED) lamp

semiconductor-based light emitting source

3.2

fully charged battery

battery which has at the beginning a charge of 80 % to 100 % of the first full charge

4 Classification

For the purposes of this document, powered polymerization activators with light emitting diodes are classified as specified in ISO 10650-1.

5 Requirements

5.1 General

ISO 10650-1:2004, 5.1 applies.

Test the LED lamps at each continuous irradiation mode or pulse mode of 10 s or longer stated by the manufacturer.

5.2 Radiant exitance

5.2.1 Radiant exitance in the 400 nm to 515 nm (blue) wavelength region

This part of ISO 10650 does not specify a requirement value for the radiant exitance in the 400 nm to 515 nm (blue) wavelength region. The manufacturer shall provide information on the radiant exitance in the 400 nm to 515 nm region as determined by the test method described in 7.2. The radiant exitance in the 400 nm to 515 nm region shall be not less than the manufacturer's stated value when tested in accordance with 7.2.1 and 7.2.2, at the stated operating voltage. For Type 2 polymerization activators with light-emitting diodes, an initially fully-charged powered polymerization activator shall be tested for compliance with this requirement.

5.2.2 Radiant exitance in the 190 nm to 385 nm wavelength region

The radiant exitance in the 190 nm to 385 nm region shall be no more than 2 000 W/m² (200 mW/cm²) when tested in accordance with 7.2.1 and 7.2.2, at the stated operating voltage. For Type 2 polymerization activators with light-emitting diodes, an initially fully-charged powered polymerization activator shall be tested for compliance with this requirement.

5.2.3 Radiant exitance in the wavelength region above 515 nm

The radiant exitance in the wavelength region above 515 nm shall be no more than 1 000 W/m² (100 mW/cm²) when tested in accordance with 7.2.1 and 7.2.2, at the stated operating voltage. For Type 2 polymerization activators with light-emitting diodes, an initially fully-charged powered polymerization activator shall be tested for compliance with this requirement.

5.3 Electrical requirements

ISO 10650-1:2004, 5.3 applies.

6 Sampling

ISO 10650-1:2004, Clause 6 applies.

7 Test methods

7.1 General

ISO 10650-1:2004, 7.1 applies.

Measurements of the LED lamp shall be performed at each continuous irradiation mode or pulse mode of 10 s or longer stated by the manufacturer.

Table 1 — Measurement sequence at 100 % voltage (Type 1) or initially full charge (Type 2)

Step	Filter	Time s	Operation	Reading
1	Quartz	0	Check voltage; turn on light.	
		10	Record reading; check voltage.	A
		20	Turn off light; continue running the cooling fan if it is present in the unit.	
		20 to 60	Change filter.	
		60	Begin step 2.	
2	385 nm	0	Check voltage; turn on light.	
		10	Record reading; check voltage.	D
		20	Turn off light; continue running the cooling fan if it is present in the unit.	
		20 to 60	Change filter.	
		60	Begin step 3.	
3	400 nm	0	Check voltage; turn on light.	
		10	Record reading; check voltage.	G
		20	Turn off light; continue running the cooling fan if it is present in the unit.	
		20 to 60	Change filter.	
		60	Begin step 4.	
4	515 nm	0	Check voltage; turn on light.	
		10	Record reading; check voltage.	J
		20	Turn off light; continue running the cooling fan if it present in the unit.	
		20 to 60	Change filter.	
		60	Repeat step 1 for next series of reading until 5 sets of readings (A, D, G, J) have been obtained.	

7.2 Radiant exitance

7.2.1 Apparatus

ISO 10650-1:2004, 7.2.1 applies

7.2.2 Procedures

7.2.2.1 Optical (effective) cross-sectional area of the LED light beam at the tip (i.e. optic tip)

Use the optical (effective) cross-sectional area stated by the manufacturer in 8.1 r) as Z (in square millimetres).

7.2.2.2 Measurement of radiant exitance

Set the supplying voltage at 100 % of stated voltage or have the rechargeable activator at full charge. Conduct the measurement in accordance with the sequence in Table 1.

7.2.3 Treatment of results

7.2.3.1 General

Calculate the mean values of A (M_A) using the five readings. Similarly calculate the average values of D (M_D), G (M_G) and J (M_J).

7.2.3.2 Calculation of radiant exitance

ISO 10650-1:2004, 7.2.3.2 applies.

7.2.3.3 Reporting of results

Report the calculated values as indicated in Table 2.

Report whether the powered polymerization activator complies with the requirements of 5.2.

Table 2 — Expression of results

Operation mode _____

Wavelength range nm	Radiant exitance
190 to 385	Insert test data here
400 to 515	Insert test data here
> 515	Insert test data here

8 Information to be supplied by the manufacturer

8.1 Instructions for use

LED lamp shall be accompanied by documents containing the following information:

- a) name and/or trademark and address of the manufacturer or distributor;
- b) trade name of LED lamp;
- c) rated electrical characteristics (voltage, frequency, fuse values, if applicable);
- d) recommended mode of operation, classification, environmental conditions;
- e) method to check the performance of the LED lamp;
- f) precautions on blue wavelength, ultraviolet and thermal radiation;
- g) recommendation on the effective use of protective filter glasses by dentists and dental assistants to decrease exposure;
- h) methods of cleaning and disinfecting the parts coming in contact with the patient;
- i) methods of sterilization, if the manufacturer claims it is applicable;
- j) statement as to whether the LED lamp is field-repairable;
- k) order information (e.g. order code, part number) of replacement parts (e.g. light guide) stated "field replaceable" by the manufacturer;

- l) method of replacement or exchange of the light guide;
- m) minimum radiant exitance between 400 nm and 515 nm for each continuous irradiation mode or pulse mode (as measured in accordance with 7.2);
- n) accessories recommended by the manufacturer;
- o) information on indication of “power low” (applicable to Type 2 activators – powered with a rechargeable battery supply);
- p) information on battery replacement (applicable to Type 2 activators – powered with a rechargeable battery supply);
- q) wavelength peak(s) of the LED lamp powered polymerization activator for polymerizing dental resin-based materials;
- r) designed value of optic (effective) cross-sectional area in square millimetres.

NOTE The designed value of the diameter of the cross section could be given if the optical cross section is circular.

8.2 Technical description

ISO 10650-1:2004, 8.2 applies.

9 Marking

ISO 10650-1:2004, Clause 9 applies.

For Type 2 activators (powered with a rechargeable battery supply) the supply voltage, frequency, fuses, wattage or current consumption of the charger shall be marked.

Annex A
(normative)

Sequence of testing

The sequence of testing is essentially aligned with IEC 60601-1:2005, Annex C. It is adjusted to the particular requirements of powered polymerization activators used in dentistry.

1

Bibliography

- [1] IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

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