INTERNATIONAL STANDARD

ISO 10650-1

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Dentistry — Powered polymerization activators —

Part 1: Quartz tungsten halogen lamps

Art dentaire — Activateurs électriques de polymérisation —

Partie 1: Lampes halogènes au tungstène à quartz

Reference number
ISO 10650-1:2004(E)

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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 10650-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This first edition of ISO 10650-1 together with ISO 10650-2 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*

The following part is under preparation:

— *Part 2: Light-emitting diode (LED) lamps*

Introduction

This International Standard specifies requirements and test methods for powered polymerization activators in the 190 nm to 385 nm wavelength region and the wavelength region above 515 nm. No requirement is 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 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 60601-1:1988, the basic International Standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:1988.

Dentistry — Powered polymerization activators —

Part 1:
Quartz tungsten halogen lamps

1 Scope

This part of ISO 10650 specifies requirements and test methods for powered polymerization activators in the blue wavelength region intended for chair-side use in polymerization of dental polymer-based materials. This part of ISO 10650 applies to powered tungsten-halogen lamps and rechargeable battery-powered tungsten-halogen polymerization activators.

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 60601-1:1988 where specified in the individual clauses of this International Standard.

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*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and test*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and IEC 60601-1:1988, Clause 2, and the following apply.

3.1
powered polymerization activator
device for producing light in the blue wavelength region, intended for chair-side use in polymerizing polymer-based filling, restorative and luting materials

4 Classification

For the purposes of this part of ISO 10650, powered polymerization activators are classified, according to their power supply, as follows:

— Type 1: polymerization activators powered with a mains supply;

— Type 2: polymerization activators powered with a rechargeable battery supply.

5 Requirements

5.1 General

5.1.1 Design

The construction of powered polymerization activators shall provide for safe and reliable operation. If field-repairable, the powered polymerization activator should be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer. IEC 60601-1:1988, Clause 59 applies.

5.1.2 Connection

Powered polymerization activators shall be capable of being disconnected and reconnected from the supply for cleaning and disinfection.

Compliance shall be checked by manual inspection.

5.1.3 Operating controls

Operating controls shall be designed and located to minimize accidental activation.

Testing shall be carried out by visual inspection

5.1.4 Cleaning and disinfection

IEC 60601-1:1988, Clause 44.7 applies.

5.1.5 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies.

5.2 Radiant exitance

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

This International Standard does not specify a requirement for the radiant exitance in the 400 nm to 515 nm (blue) wavelength region. The manufacturer shall provide information on the radiant exitance in this region as determined by the test method in 7.2. The radiant exitance in the 400 nm to 515 nm region shall not be less than the manufacturer's stated value when tested in accordance with 7.2. For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

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/m^2 (200 mW/cm^2) at the operating voltage, 90 % of the operating voltage and 110 % of the operating voltage when tested in accordance with 7.2. For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

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/m^2 (100 mW/cm^2) at the operating voltage, 90 % of the operating voltage and 110 % of the operating voltage when tested in accordance with 7.2. For Type 2 polymerization activators, the requirement applies only to a fully charged powered polymerization activator.

5.3 Electrical requirements

The requirements for the following equipment and conditions are governed by the cited clauses and/or subclauses of IEC 60601:

a) power input	IEC 60601-1:1988, Clause 7;
b) single-fault conditions	IEC 60601-1:1988, 3.6 and Clause 52;
c) protection against electric shock hazards	IEC 60601-1:1988, Clause 13;
d) enclosures and protective covers	IEC 60601-1:1988, Clause 16;
e) leakage	IEC 60601-1:1988, 44.4;
f) protective earthing	IEC 60601-1:1988, Clause 58;
g) continuous leakage currents	IEC 60601-1:1988, Clause 19;
h) dielectric strength	IEC 60601-1:1988, Clause 20;
i) interruption of the power supply	IEC 60601-1:1988, Clause 49;
j) abnormal operating and fault conditions	IEC 60601-1:1988, Clause 52;
k) components and general assembly	IEC 60601-1:1988, Clause 56;
l) mains parts, components and assembly	IEC 60601-1:1988, Clause 57;
m) electromagnetic compatibility	IEC 60601-1-2.

6 Sampling

At least one powered polymerization activator, with a light guide (optic tip) as specified by the manufacturer for each model series, shall be evaluated for compliance with this International Standard.

7 Test methods

7.1 General

7.1.1 General provisions for tests

The sequence of tests shall be in accordance with Annex A.

All tests described in this International Standard are type tests. Type tests shall be made on one representative sample of the item being tested.

IEC 60601-1:1988, 4.1 and 4.2 apply.

Unless otherwise specified, do not repeat any of these tests.

7.1.2 Atmospheric conditions

After the powered polymerization activator being tested has been set up for normal use, tests shall be carried out under the following conditions:

a) ambient temperature of (23 ± 2) °C;

b) relative humidity of (50 ± 10) %.

7.1.3 Other conditions

IEC 60601-1:1988, 4.6 d) applies.

7.1.4 Supply and test voltages, type of current, nature of supply, frequency

IEC 60601-1:1988, 4.7 applies.

7.1.5 Preconditioning

IEC 60601-1:1988, 4.8 applies.

7.1.6 Conditioning

The test arrangement and the powered polymerization activator shall be conditioned in an environment at (23 ± 2) °C for 4 h before testing.

7.1.7 Repairs and modifications

IEC 60601-1:1988, 4.9 applies.

7.2 Radiant exitance

7.2.1 Apparatus

7.2.1.1 Apparatus for measuring the optical cross-sectional area of the optic tip

7.2.1.1.1 Micrometer, reading in millimetres, with an accuracy to 0,02 mm, or any other measuring device with an equivalent accuracy.

7.2.1.2 Apparatus for measuring the irradiance

7.2.1.2.1 Radiometer, calibrated, used to measure the radiated power (in watts).

The radiometer shall have a flat response (uniform spectral sensitivity) within the wavelength region from 190 nm to 1 100 nm, independent of the angle of radiation incidence[1)].

The entrance aperture of the radiometer shall be larger than the cross-section of the optic tip of the powered polymerization activator, so that all radiant emission is measured by the radiometer. The edge of the optic tip should be at least 2 mm from the edge of the entrance aperture.

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1) Molectron Power Meter PM 500D-2 and Molectron Detector PM-3 are the trade names of suitable products supplied by Molectron Detector Inc. Portland, Oregon 97224, USA. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

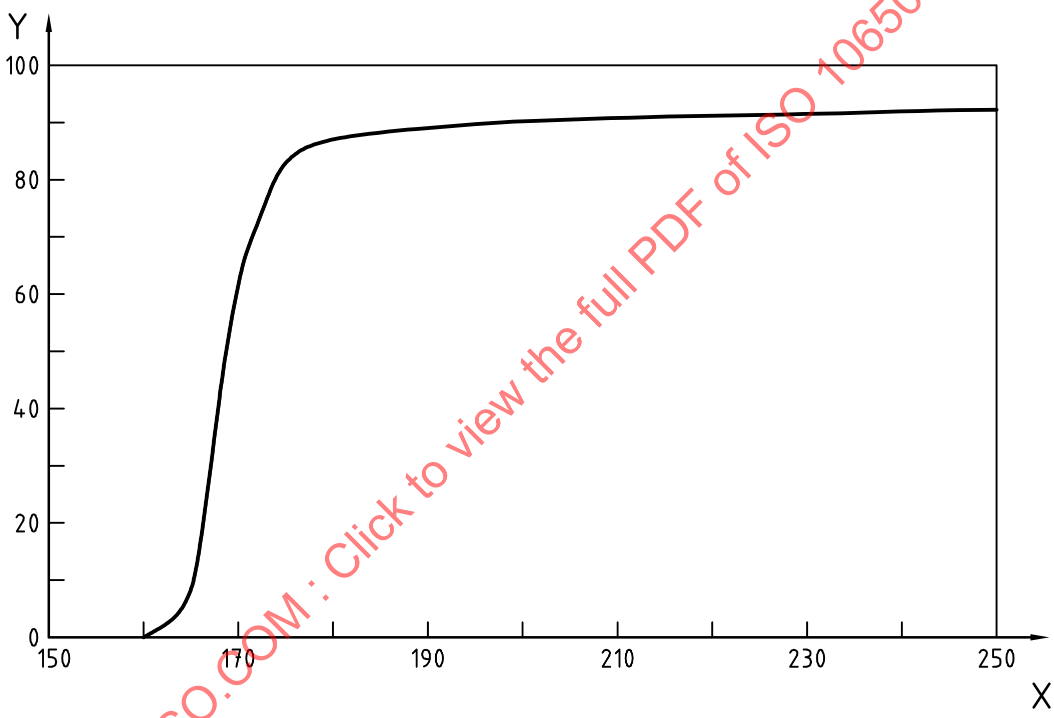
7.2.1.2.2 Filters of the following types[2]:

7.2.1.2.2.1 Filter (quartz), (3,0 ± 0,1) mm thick, allowing transmission above 190 nm, with transmission characteristics described by a curve as shown in Figure 1;

7.2.1.2.2.2 Filter, (3,0 ± 0,1) mm thick, allowing transmission above 385 nm, with transmission characteristics described by a curve as shown in Figure 2;

7.2.1.2.2.3 Filter, (3,0 ± 0,1) mm thick, allowing transmission above 400 nm with transmission characteristics described by a curve as shown in Figure 3;

7.2.1.2.2.4 Filter, (3,0 ± 0,1) mm thick, allowing transmission above 515 nm with transmission characteristics described by a curve as shown in Figure 4.



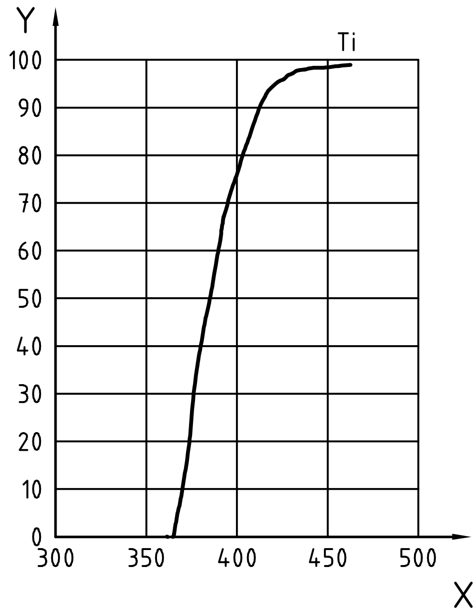
Key

X wavelength, in nanometres

Y transmission, in percent

Figure 1 — Transmission characteristics of quartz filter

2) Schott SQ1, Schott GG 385, Schott GG 400 and Schott OG 515 are the trade names of suitable products. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.



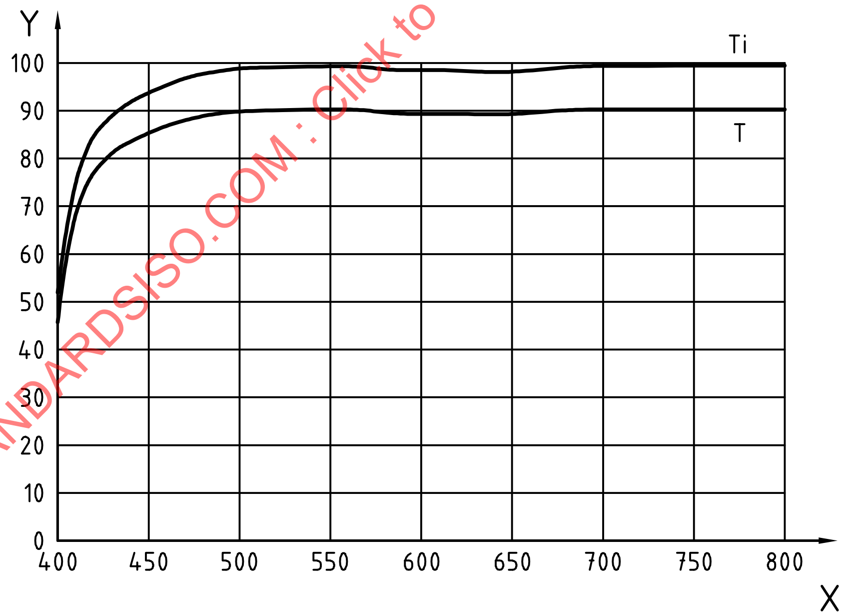
Key

X wavelength, in nanometres

Y transmission, in percent

Ti transmission curve plus reflection loss on light entrance and light output surfaces

Figure 2 — Transmission characteristics of 385 nm filter



Key

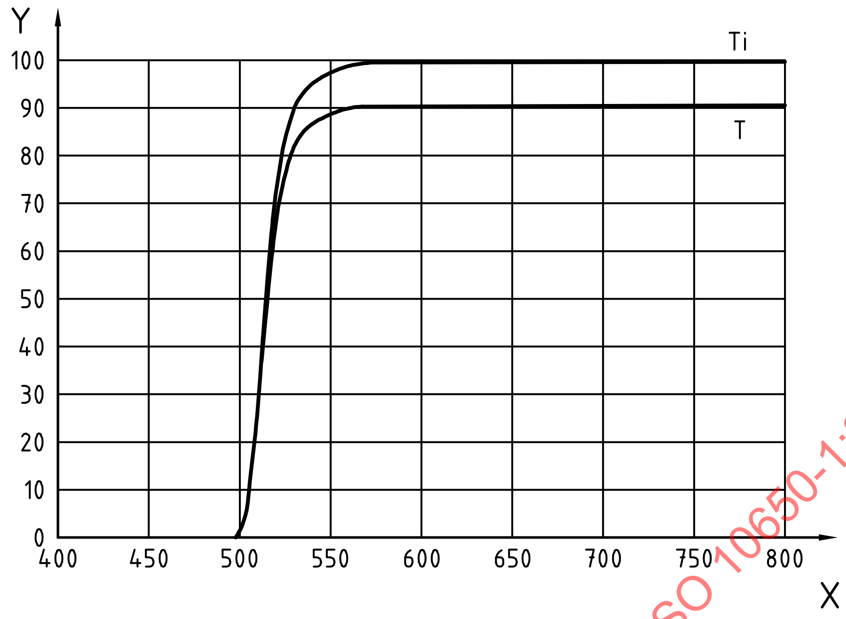
X wavelength, in nanometres

Y transmission, in percent

T transmission curve

Ti transmission curve plus reflection loss on light entrance and light output surfaces

Figure 3 — Transmission characteristics of 400 nm filter



Key

X wavelength, in nanometres

Y transmission, in percent

T transmission curve

Ti transmission curve plus reflection loss on light entrance and light output surfaces

Figure 4 — Transmission characteristics of 515 nm filter

7.2.1.2.3 Variable power source, capable of delivering the stated operating voltage for the powered polymerization activator.

It shall also enable the delivery of voltages 10 % above and 10 % below the stated operating voltage.

7.2.1.2.4 Voltmeter, capable of measuring voltages to ± 1 V within the range of ± 10 % the stated operating voltage.

The voltmeter calibration shall be traceable to a primary standard.

7.2.1.2.5 Timer, with an accuracy of ± 1 s.

7.2.2 Procedures

7.2.2.1 Procedure for measuring the optical cross-sectional area of the optic tip

Measure, with an accuracy of ± 5 %, the diameter of the optic tip if it is circular in optical cross-section. Measure the major and minor axes of the optic tip if it is elliptical in optical cross-section.

Calculate the optical cross-sectional area (Z).

7.2.2.2 Procedure for measuring the irradiance

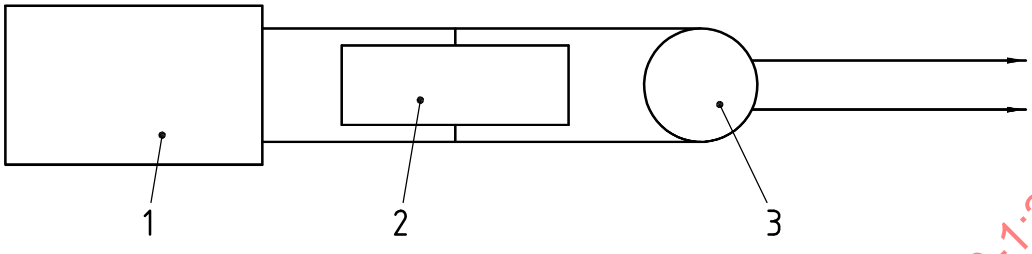
7.2.2.2.1 General

— Type 1: Measure the radiant exitance at the stated operating voltage, 90 % of the stated operating voltage and 110 % of the stated operating voltage.

— Type 2: Measure the radiant exitance at full charge.

Connect the powered polymerization activator to the variable voltage source. Connect the voltmeter across the outlets of the variable voltage source to allow measurement of the input voltage to the powered polymerization activator, as shown in Figure 5.

Turn on the activator for the warm-up time specified by the manufacturer. Operate the activator twice for 20 s each before commencing the test.



Key

1 powered polymerization activators

2 voltmeter

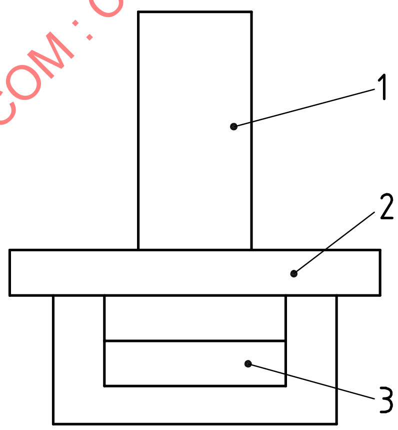
3 variable power source

Figure 5 — Schematic diagram of electrical connections to variable power source, voltmeter and powered polymerization activators

7.2.2.2.2 Measurements using filters

7.2.2.2.2.1 General

Use either method A (7.2.2.2.2.2), for which the filter remains the same and the operating voltage changes for each step [Tables 1 to 4 and 7.2.2.2.2.2 a) to 7.2.2.2.2.2 d)] or method B (7.2.2.2.2.3) for which the operating voltage remains the same and the filter changes for each step [Tables 5 to 7 and 7.2.2.2.2.3 a) to 7.2.2.2.2.3 c)].



Key

1 optic tip

2 filter

3 detector of radiometer

Figure 6 — Schematic arrangement of apparatus for radiant exitance measurement

7.2.2.2.2.2 Method A

a) Method A — Measurement using quartz filter

Place the filter on the detector. Place the optic tip of the powered polymerization activator on the quartz filter so that all the radiant emission is captured by the detector, as shown in Figure 6. Conduct the measurement in accordance with the sequence in Table 1.

Table 1 — Method A — Measurement using quartz filter

Step	Filter	Voltage %	Time s	Operation	Reading
1	Quartz	100	0	Check voltage. Turn on light.	A
			20	Record reading. Check voltage.	
			40	Turn off light. Continue running the cooling system.	
			60	Begin step 2.	
2		90	0	Check Voltage. Turn on light.	B
			20	Record reading. Check voltage.	
			40	Turn off light. Continue running the cooling system.	
			60	Begin step 3	
3		110	0	Check voltage. Turn on light.	C
			20	Record reading. Check voltage.	
			40	Turn off light. Continue running the cooling system.	
			60	Repeat step 1 for next series of reading until 5 sets of readings (A, B, C) have been obtained. Then go to 7.2.2.2.2.2 b) and Table 2.	

b) Method A — Measurement using 385 nm filter

Replace the quartz filter on the detector with the filter that allows transmission above 385 nm.

Place the optic tip of the powered polymerization activator on the filter so that all the radiant emission will be captured by the detector. Conduct the measurement in accordance with the sequence in Table 2.

Table 2 — Method A — Measurement using 385 nm filter

Step	Filter cut-off nm	Voltage %	Time s	Operation	Reading
4	385	100	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	D
			40	Turn off light. Continue running the cooling system.	
			60	Begin step 5.	
5		90	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	E
			40	Turn off light. Continue running the cooling system.	
			60	Begin step 6.	
6		110	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	F
			40	Turn off light. Continue running the cooling system.	
			60	Repeat step 4 for next series of reading until 5 sets of readings (D, E, F) have been obtained. Then go to 7.2.2.2.2.2 c) and Table 3.	

c) Method A — Measurement using 400 nm filter

Replace the 385 nm filter on the detector with the filter that allows transmission above 400 nm.

Place the optic tip of the powered polymerization activator on the filter so that all the radiant emission will be captured by the detector. Conduct the measurement in accordance with the sequence in Table 3.

Table 3 — Method A — Measurement using 400 nm filter

Step	Filter cut-off nm	Voltage %	Time s	Operation	Reading
7	400	100	0	Check voltage. Turn on light.	G
			20	Record reading. Check voltage.	
			40	Turn off light. Continue running the cooling system.	H
			60	Begin step 8.	
8		90	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	
			40	Turn off light. Continue running the cooling system.	I
			60	Begin step 9.	
9		110	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	
			40	Turn off light. Continue running the cooling system.	
			60	Repeat step 7 for next series of reading until 5 sets of readings (G, H, I) have been obtained. Then go to 7.2.2.2.2.2 d) and Table 4.	

d) Method A — Measurement using 515 nm filter

Replace the 400 nm filter on the detector with the filter that allows transmission above 515 nm.

Place the optic tip of the powered polymerization activator on the filter so that all the radiant emission will be captured by the detector. Conduct the measurement in accordance with the sequence in Table 4.

Table 4 — Method A — Measurement using 515 nm filter

Step	Filter cut-off, nm	Voltage %	Time s	Operation	Reading
10	515	100	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	J
			40	Turn off light. Continue running the cooling system.	
			60	Begin step 11.	
11		90	0	Check voltage. Turn on light.	
			20	Record reading. Check Voltage.	K
			40	Turn off light. Continue running the cooling system.	
			60	Begin step 12.	
12		110	0	Check voltage. Turn on light	
			20	Record reading. Check voltage.	L
			40	Turn off light. Continue running the cooling system.	
			60	Repeat step 10 for next series of reading until 5 sets of readings (J, K, L) have been obtained.	

7.2.2.2.2.3 Method B

Place the filter on the detector. Place the optic tip of the powered polymerization activator on the quartz filter so that all the radiant emission is captured by the detector, as shown in Figure 6.

a) Method B — Measurement at 100 % voltage

Set the supply voltage at 100 % of stated voltage. Conduct the measurement in accordance with the sequence in Table 5.

Table 5 — Method B — Measurement at 100 % voltage

Step	Voltage %	Filter	Time s	Operation	Reading
1	100	Quartz	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	A
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 2.	
2		385 nm	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	D
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 3.	
3		400 nm	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	G
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 4.	
4		515 nm	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	J
			40	Turn off light. Continue running the cooling fan.	
			40 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. Then go to 7.2.2.2.2.3 b) and Table 6.	

b) Method B — Measurement at 90 % voltage

Set the supply voltage at 90 % of stated voltage. Conduct the measurement in accordance with the sequence in Table 6.

Table 6 — Method B — Measurement at 90 % voltage

Step	Voltage %	Filter	Time s	Operation	Reading
5	90	Quartz	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	B
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 6.	
6		385 nm	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	E
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 7.	
7		400 nm	0	Check voltage. Turn on light.	
			20	Record reading. Check voltage.	H
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 8.	
8		515 nm	0	Check voltage. Turn on light	
			20	Record reading. Check voltage.	K
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Repeat step 5 for next series of reading until 5 sets of readings (B, E, H, K) have been obtained. Then go to 7.2.2.2.2.3 c) and Table 7.	

c) Method B — Measurement at 110 % voltage

Set the supply voltage at 110 % of stated voltage. Conduct the measurement in accordance with the sequence in Table 7.

Table 7 — Method B — Measurement at 110 % voltage

Step	Voltage %	Filter	Time s	Operation	Reading
9	110	Quartz	0	Check voltage. Turn on light	
			20	Record reading. Check voltage.	C
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 10.	
10		385 nm	0	Check voltage. Turn on light	
			20	Record reading. Check voltage.	F
			40	Turn off light. Continue running the cooling fan.	
			40 s to 60	Change filter.	
			60	Begin step 11.	
11		400 nm	0	Check voltage. Turn on light	
			20	Record reading. Check voltage.	I
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Begin step 12.	
12		515 nm	0	Check voltage. Turn on light	
			20	Record reading. Check voltage.	L
			40	Turn off light. Continue running the cooling fan.	
			40 to 60	Change filter.	
			60	Repeat step 9 for next series of reading until 5 sets of readings (C, F, I, L) have been obtained.	

7.2.3 Treatment of results

7.2.3.1 General

Calculate the mean radiant exitance value, $\bar{M}$, for each step using the five readings and designate these average values as $\bar{M}_{\mathrm{A}}$ through $\bar{M}_{\mathrm{L}}$ corresponding to the respective step. Calculate the values in 7.2.3.2 through 7.2.3.4 using these values together with the optical cross-sectional area, Z,

7.2.3.2 Calculation of radiant exitance at the stated operating voltage

a) Using the average values, calculate the radiant exitance in the 190 nm to 385 nm wavelength region per unit cross-sectional area as $(\bar{M}_A - \bar{M}_D)/Z$.

b) Using the average values, calculate the radiant exitance in the 400 nm to 515 nm (blue) wavelength region per unit cross-sectional area as $(\bar{M}_G - \bar{M}_J)/Z$.

c) Using the average values, calculate the radiant exitance above 515 nm per unit cross-sectional area as $\bar{M}_J/Z$.

7.2.3.3 Calculation of radiant exitance at 90 % of the stated operating voltage

a) Using the average values, calculate the radiant exitance in the 190 nm to 385 nm wavelength region per unit cross-sectional area as $(\bar{M}_B - \bar{M}_E)/Z$.

b) Using the average values calculate the radiant exitance in the 400 nm to 515 nm (blue) wavelength region per unit cross-sectional area as $(\bar{M}_H - \bar{M}_K)/Z$.

c) Using the average values, calculate the radiant exitance above 515 nm per unit cross-sectional area as $\bar{M}_K/Z$.

7.2.3.4 Calculation of radiant exitance at 110 % of the stated operating voltage

a) Using the average values, calculate the radiant exitance in the 190 nm to 385 nm wavelength region per unit cross-sectional area as $(\bar{M}_C - \bar{M}_F)/Z$.

b) Using the average values, calculate the radiant exitance in the 400 nm to 515 nm (blue) wavelength region per unit cross-sectional area as $(\bar{M}_I - \bar{M}_L)/Z$.

c) Using the average values, calculate the radiant exitance above 515 nm per unit cross-sectional area as $\bar{M}_L/Z$.

7.2.3.5 Report of results

Report the calculated values as follows:

Table 8 — Expression of results

Wavelength range nm	Radiant exitance		
	at 100 % operating voltage	at 90 % operating voltage	at 110 % operating voltage
190 to 385			
400 to 515			
> 515			

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