TECHNICAL SPECIFICATION

ISO/TS 10650

First edition
1999-10-15

Dental equipment — Powered polymerization activators

Matériel dentaire — Activateurs électriques de polymérisation

Reference number
ISO/TS 10650:1999(E)

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Printed in Switzerland

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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 3.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

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

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

Introduction

This Technical Specification specifies requirements and test methods for powered polymerization activators. The requirements are for activators having optic tips no more than 78,5 mm^2 in area or 10 mm in diameter. Optic tips larger than 78,5 mm^2 or 10 mm in diameter are not covered by this Technical Specification.

This Technical Specification 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.

This Technical Specification uses wavelength regions based on cut-off filters. Thus the 190 nm to 400 nm region includes not only the ultraviolet region but also the near blue wavelength region of around 380 nm to 400 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 Technical Specification.

Dental equipment — Powered polymerization activators

1 Scope

This Technical Specification gives requirements and test methods for polymerization activators with powered tungsten-halogen lamps in the blue wavelength region intended for chairside use in polymerization of dental resin-based materials. This Technical Specification is also applicable to rechargeable battery-powered polymerization activators.

It does not cover powered polymerization activators used in laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances.

This Technical Specification takes priority over IEC 60601-1:1988 where specified in the individual clauses of this Technical Specification.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Technical Specification. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Specification are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942-4, *Dental vocabulary — Part 4: Dental equipment.*

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

IEC 60601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety — 2. Collateral Standard: Electromagnetic compatibility — Requirements and test.*

3 Terms and definitions

For the purposes of this Technical Specification, the terms and definitions given in ISO 1942-4 and in clause 2 of IEC 60601-1:1988 apply.

4 Classification

Powered polymerization activators may be classified as follows:

— Type 1: Polymerization activators powered with mains supply.

— Type 2: Polymerization activators powered with 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 in accordance with 7.2.1.

5.1.4 Cleaning and disinfection

IEC 60601-1:1988, 44.7 applies.

5.1.5 Excessive temperatures

IEC 60601-1:1988, clause 42 applies.

5.2 Radiance

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

The radiance in the 400 nm to 515 nm region shall be no less than 3 000 W/m^2 (300 mW/cm^2) and no more than 10 000 W/m^2 (1 000 mW/cm^2) at the operating voltage, 90 % of the operating voltage or 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.

5.2.2 Radiance in the 190 nm to 400 nm wavelength region

The radiance in the 190 nm to 400 nm region shall be no more than 1 000 W/m^2 (100 mW/cm^2) at the operating voltage, 90 % of the operating voltage or 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 Radiance in the wavelength region above 515 nm

The radiance in the wavelength region above 515 nm shall be no more than 500 W/m^2 (50 mW/cm^2) at the operating voltage, 90 % of the operating voltage or 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

5.3.1 Power input

IEC 60601-1:1988, clause 7 applies.

5.3.2 Single fault conditions

IEC 60601-1:1988, 3.6 and clause 56 apply.

5.3.3 Protection against electric shock hazards

IEC 60601-1:1988, clause 13 applies.

5.3.4 Enclosures and protective covers

IEC 60601-1:1988, clause 16 applies.

5.3.5 Leakage

IEC 60601-1:1988, 44.4 applies.

5.3.6 Protective earthing

IEC 60601-1:1988, clause 58 applies.

5.3.7 Continuous leakage currents

IEC 60601-1:1988, clause 19 applies.

5.3.8 Dielectric strength

IEC 60601-1:1988, clause 20 applies.

5.3.9 Interruption of the power supply

IEC 60601-1:1988, clause 49 applies.

5.3.10 Abnormal operating and fault conditions

IEC 60601-1:1988, clause 52 applies.

5.3.11 Components and general assembly

IEC 60601-1:1988, clause 56 applies.

5.3.12 Mains parts, components and assembly

IEC 60601-1:1988, clause 57 applies.

5.3.13 Electromagnetic compatibility

IEC 60601-1-2:1993 applies.

5.4 Instructions for use

Compliance with the requirements for instructions for use, technical description and marking shall be verified visually (see clauses 8 and 9).

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 Technical Specification.

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 Technical Specification 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 of (23 ± 2) °C for 4 h before testing.

7.1.7 Repairs and modifications

IEC 60601-1:1988, 4.9 applies.

7.2 Radiance

7.2.1 Measurement of the optical cross-sectional area of the optic tip

7.2.1.1 Apparatus

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 Procedure

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 Measurement of irradiation

7.2.2.1 Apparatus

7.2.2.1.1 Radiometer, calibrated[1)], used to measure the radiated power (in watts).

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 not be closer than 2 mm from the edge of the entrance aperture.

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.

7.2.2.1.2 Filters

The following filters are required.

a) Filter (quartz) allowing transmission above 190 nm, having the same thickness as the filters in 7.2.2.1.2 b) and 7.2.2.1.2 c), with transmission characteristics producing a curve as shown in Figure 1;

b) Filter allowing transmission above 400 nm with transmission characteristics of Schott GG 400 producing a curve as shown in Figure 2;

c) Filter allowing transmission above 515 nm with transmission characteristics of Schott OG 515 producing a curve as shown in Figure 3.

7.2.2.1.3 Variable power source, able to deliver 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.

7.2.2.1.4 Voltmeter, capable of measuring voltages to ± 1 V for the range of stated operating voltage ± 10 %. The voltmeter calibration shall be traceable to a primary standard.

7.2.2.1.5 Timer, with an accuracy of ± 1 s.

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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.

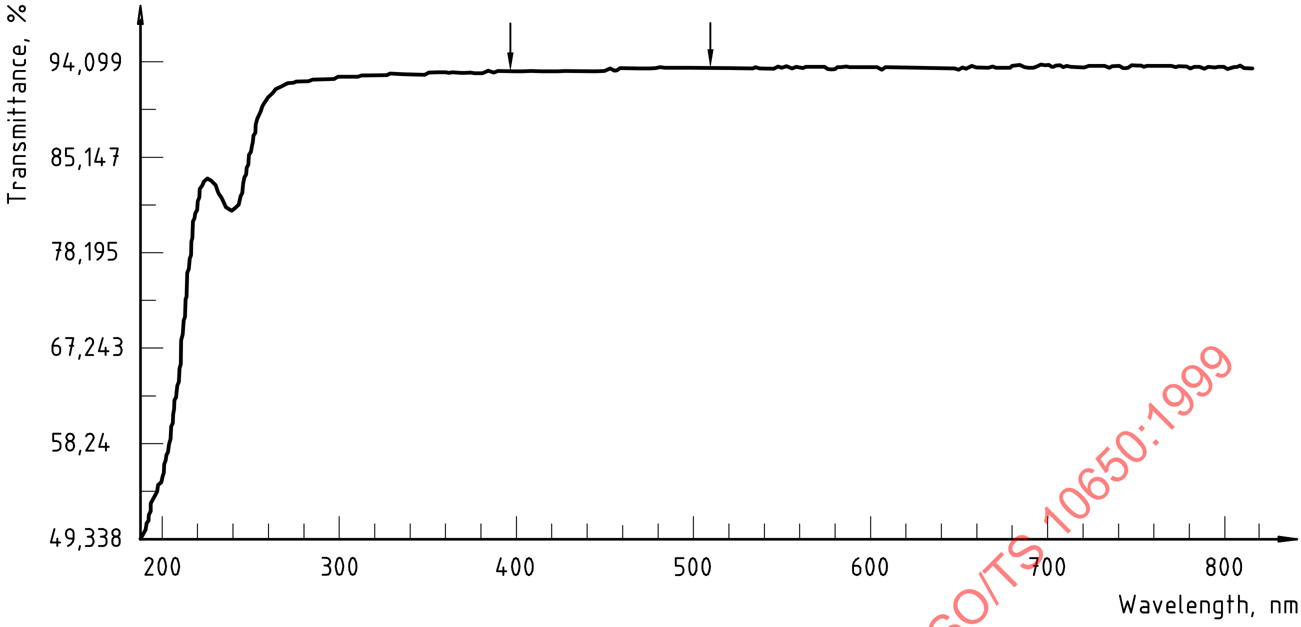


Figure 1 — Transmission curve of quartz filter [7.2.2.1.2 a)]

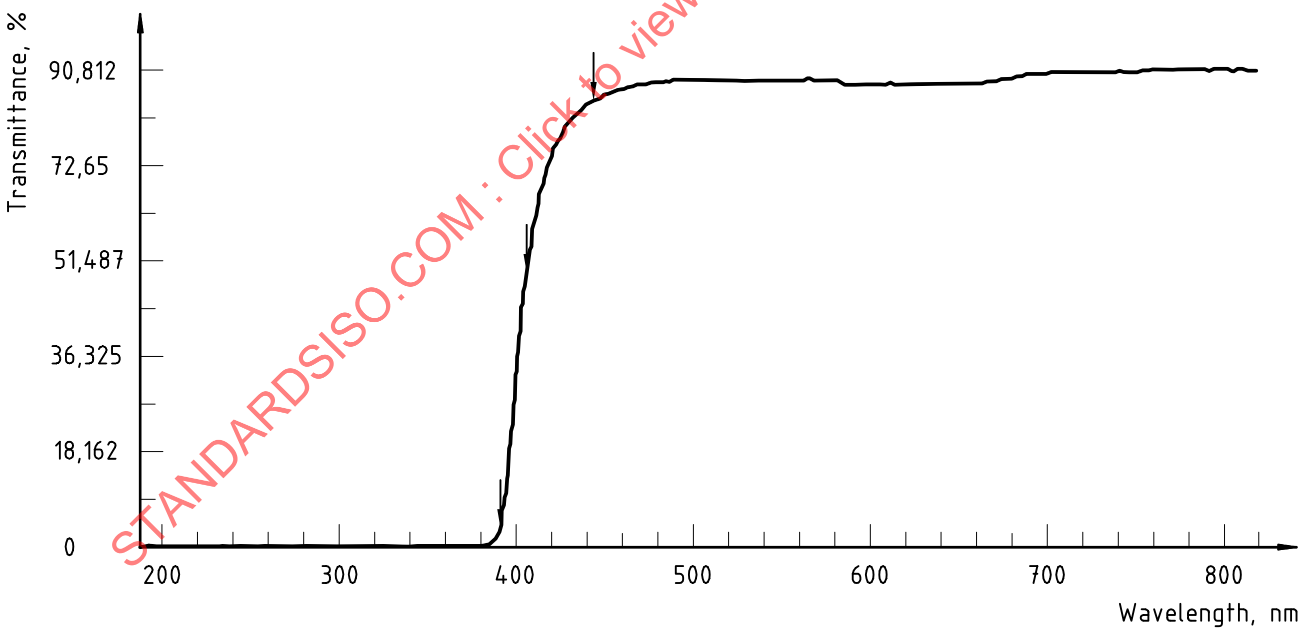


Figure 2 — Transmission curve of 400 nm filter [7.2.2.1.2 b)]

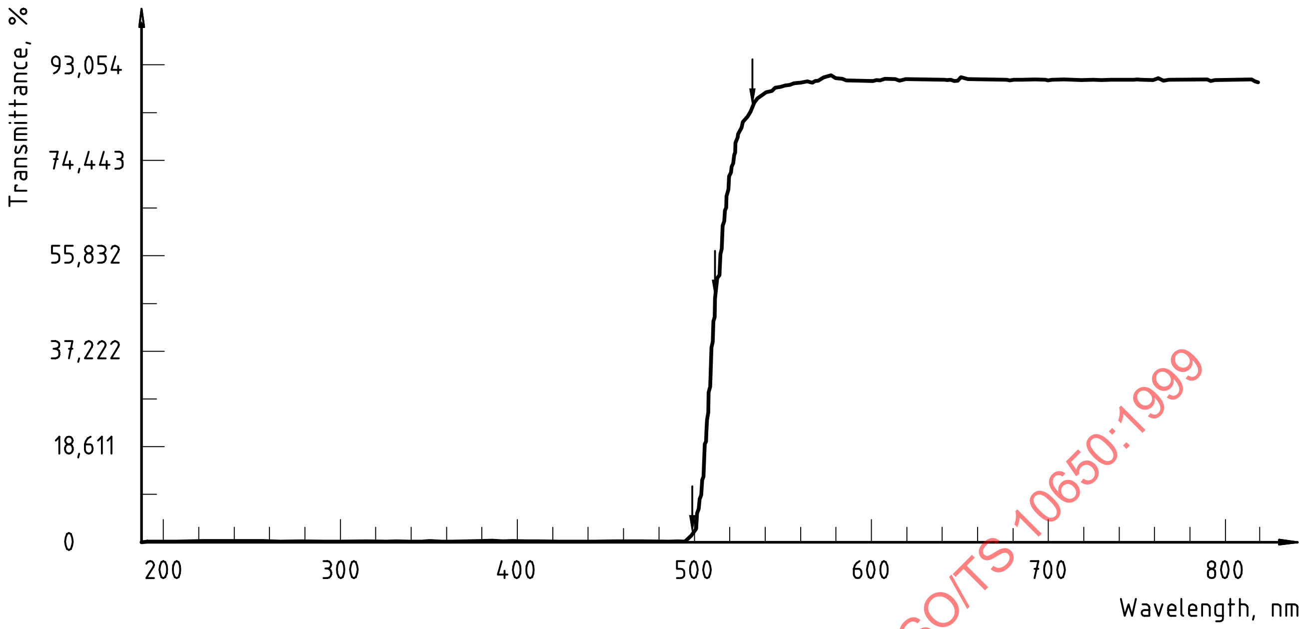
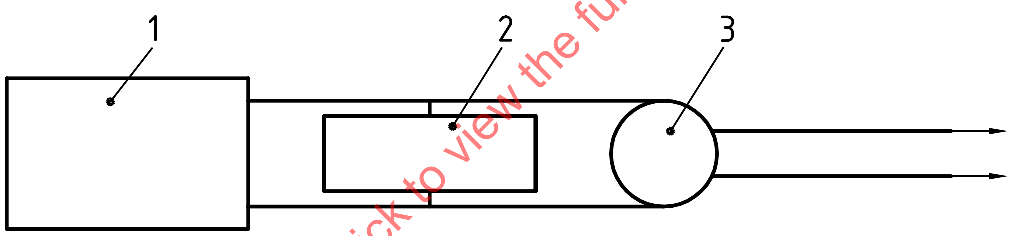


Figure 3 — Transmission curve of 515 nm filter [7.2.2.1.2 c)]



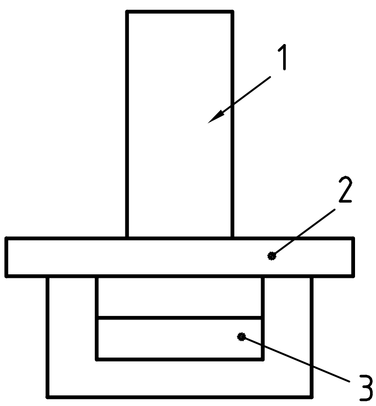
Key

1 Powered polymerization activator

2 Voltmeter

3 Variable power source

Figure 4 — Schematic diagram of electrical connections to variable power source, voltmeter and powered polymerization activators



Key

1 Optic tip

2 Filter

3 Detector of radiometer

Figure 5 — Schematic arrangement of apparatus for radiation measurement

7.2.2.2 Procedure

7.2.2.1.1 General

- Type 1 : Measure the radiance at stated operating voltage, 90 % of the stated operating voltage and 110 % of the stated operating voltage.
- Type 2 : Measure the radiance 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 4.

7.2.2.2.2 Measurements using quartz filter

Place the quartz filter on the detector. Place the optic tip of the powered polymerization activator on the quartz filter so that all the radiant emission will be captured by the detector, as shown in Figure 5.

a) Adjust the variable voltage source to set the input voltage to the powered polymerization activator at the stated operating voltage.

   Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (A). Run the activator for a total of 40 s (in sequence if necessary).

   Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

b) Set the input voltage to the powered polymerization activator at 90 % of the stated operating voltage.

   Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (B). Run the activator for a total of 40 s (in sequence if necessary).

   Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

c) Set the input voltage to the powered polymerization activator at 110 % of the stated operating voltage.

   Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (C). Run the activator for a total of 40 s (in sequence if necessary).

   Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

Conduct the measurement procedures five times.

7.2.2.2.3 Measurement using 400 nm filter

Replace the quartz 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.

a) Set the input voltage to the powered polymerization activator at the stated operating voltage.

   Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (D). Run the activator for a total of 40 s (in sequence if necessary).

   Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

b) Set the input voltage to the powered polymerization activator at 90 % of the stated operating voltage.

Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (E). Run the activator for a total of 40 s (in sequence if necessary).

Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

c) Set the input voltage to the powered polymerization activator at 110 % of the stated operating voltage.

Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (F). Run the activator for a total of 40 s (in sequence if necessary).

Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

Conduct the measurement procedures five times.

7.2.2.2.4 Measurements using 515 nm filter

Replace the filter that allows transmission above 400 nm 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.

a) Set the input voltage to the powered polymerization activator at the stated operating voltage.

Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (G). Run the activator for a total of 40 s (in sequence if necessary).

Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

b) Set the input voltage to the powered polymerization activator at 90 % of the stated operating voltage.

Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (H). Run the activator for a total of 40 s (in sequence if necessary).

Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

c) Set the input voltage to the powered polymerization activator at 110 % of the stated operating voltage.

Set the powered polymerization activator to irradiate for 40 s. Turn on the powered polymerization activator and simultaneously start the timer. Record the radiometer reading at (20 ± 1) s as (I). Run the activator for a total of 40 s (in sequence if necessary).

Turn off the irradiation and allow the cooling system to continue running. Wait (20 ± 1) s.

Conduct the measurement procedures five times.

7.2.3 Treatment of results

7.2.3.1 Calculation of radiance at the stated operating voltage

a) Calculate the radiance in the 190 nm to 400 nm wavelength region per unit cross-sectional area as $[(A) - (D)]/(Z)$ for each measurement.

b) Calculate the radiance in the 400 nm to 515 nm (blue) wavelength region per unit cross-sectional area as $[(D) - (G)]/(Z)$ for each measurement.

c) Calculate the radiance above 515 nm per unit cross-sectional area as $(G)/(Z)$ for each measurement.

7.2.3.2 Calculation of radiance at 90 % of the stated operating voltage

a) Calculate the radiance in the 190 nm to 400 nm wavelength region per unit cross-sectional area as $[(B) - (E)]/(Z)$ for each measurement.

b) Calculate the radiance in the 400 nm to 515 nm (blue) wavelength region per unit cross-sectional area as $[(E) - (H)]/(Z)$ for each measurement.

c) Calculate the radiance above 515 nm per unit cross-sectional area as $(H)/(Z)$ for each measurement.

7.2.3.3 Calculation of radiance at 110 % of the stated operating voltage

a) Calculate the radiance in the 190 nm to 400 nm wavelength region per unit cross-sectional area as $[(C) - (F)]/(Z)$ for each measurement.

b) Calculate the radiance in the 400 nm to 515 nm (blue) wavelength region per unit cross-sectional area as $[(F) - (I)]/(Z)$ for each measurement.

c) Calculate the radiance above 515 nm per unit cross-sectional area as $(I)/(Z)$ for each measurement.

8 Information to be supplied by the manufacturer

8.1 Instructions for use

8.1.1 IEC 60601-1:1988, 6.8.2 a) and d) apply. In addition, each powered polymerization activator shall be supplied with instructions for use detailing operation, operator maintenance, safety and servicing.

8.1.2 Powered polymerization activators shall be accompanied by documents containing the following information:

a) name and/or trademark and address of manufacturer or distributor;

b) model number;

c) rated electrical characteristics (voltage, frequency, fuse values);

d) mode of intermittent operation;

e) recommended mode of operation, classification, environmental conditions;

f) model number of replacement bulbs;

g) wattage of the replacement bulbs;

h) instructions for bulb replacement;

i) method to check the performance of the powered polymerization activators;

j) precautions on blue wavelength, ultraviolet and thermal radiation;