Guideline for Quality Control of Powered Polymerisation Activators for Chairside Use

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The irradiance of powered polymerisation activators for chairside use affects composite resin adhesive curing during the restorative process, whereas radiant accumulated temperature rise relates to clinical safety. Irradiance reduction and high radiant accumulated temperature will compromise the treatment results as there is a lack of curing output efficacy and safety awareness for powered polymerisation activators. Insufficient attention has been paid to the activator's quality control, irradiance attenuation and radiant accumulated temperature excessive temperature rise during its lifetime. The present manuscript has been drafted by the Society of Dental Equipment, Chinese Stomatological Association to fill the quality control gap and guide the quality control process, following tested steps, using a metered radiometer and a thermometer to record the irradiance and radiant accumulated temperature separately. The testing result may indicate the equipment's situation in service and provide information about the irradiance values and performance of the powered polymerisation activator for its usage and maintenance.

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Conducting quality control of irradiance and radiant accumulated temperature can help to obtain information about the irradiance values and performance of the powered polymerisation activators for their safety and effectiveness. Guidelines are also available for the selection, usage, maintenance and purchase of powered polymerisation activators[1,2].

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Scope

This document specifies the quality control requirements and test methods for powered polymerisation activators in the region of 385 to 515 nm wavelength intended for chairside use in polymerisation of dental polymer-based materials. This document does not cover powered polymerisation activators used in the laboratory fabrication of indirect restorations, veneers, dentures or other oral dental appliances.

Terms and definitions

Quality control period of radiant exitance

Quality control period of radiant exitance refers to the routine inspection interval for the equipment maintainer.

Radiant accumulated temperature

This refers to the maximum temperature accumulated on the surface when radiation is stopped.

Classifications

Powered polymerisation activators are classified according to their lamps and power supply as follows[3]:

- Class 1: Quartz-tungsten-halogen lamps: Type 1, polymerisation activators powered by mains electricity; and Type 2, polymerisation activators powered by a rechargeable battery supply.
- Class 2: Light-emitting diode (LED) lamps: Type 1, polymerisation activators powered by mains electricity; and Type 2, polymerisation activators powered by a rechargeable battery supply.

Suggestions for quality control

Inspections

Some dental terminology and medical electronic device inspection methods are used and conducted according to international or internal standards, including cleaning, disinfection and sterilisation as well as excessive temperatures[3-6]. Conducting visual and manual inspections can ensure whether the device's appearance, operating system, curing programme and indicator light are in good condition[7]. There is no damage inspection for the light guide and the power supply.

Radiant exitance quality control

Tests are to be conducted at each continuous irradiation mode or pulse mode time period as specified by the manufacturer. Test conformity should be in accordance with the manufacturer's documentation. Tests are to be conducted separately at each time period if time periods are specified, unless the period is 10 seconds.

Radiant existance wavelength range

This document conducts radiant exitance at the wavelength of 380 nm to 515 nm. For Type 1 polymerisation activators, the requirement applies at the operating voltage (rated voltage) in clinical use. For Type 2 polymerisation activators, the requirement applies only to a fully charged power. Radiant exitance should be in accordance with the manufacturer's documentation. If the manufacturer does not provide a minimum radiant exitance for safe and effective usage, the radiant exitance should be no less than 300 mw/cm^2 as determined by the test method; otherwise, it should be used carefully and maintained in a timely manner.

Quality control period of radiant exitance

The quality control period of radiant exitance should be no longer than 1 year. As service time is extended, the monitoring period can be shortened appropriately. Where polymerising quality problems occur, these should be monitored whenever necessary.

Provision of radiant accumulated temperature

At a single time period, the radiant accumulated temperature on an element of the surface of each radiant exitance mode shall be no more than 65 degrees.

Quality control of emitting radiant exitance time period

Emitting radiant exitance time period

The time period between each power mode with a different exitance shall be as specified in the manufacturer's instructions.

Emitting radiant exitance time period audible alarm

Audible alarming for the time period between each power mode with a different exitance should conform to the manufacturer's documentation.

Measurement and test method

General

General provisions for tests

This document specifies quality control test methods for powered polymerisation activators intended for chairside use. Tests are to be conducted at each continuous irradiation mode or pulse mode time period as specified by the manufacturer. Radiant exitance and its accumulated temperature should conform with the manufacturer's instructions. Tests are to be conducted separately at each time period if the time period is specified, unless the period is 10 seconds.

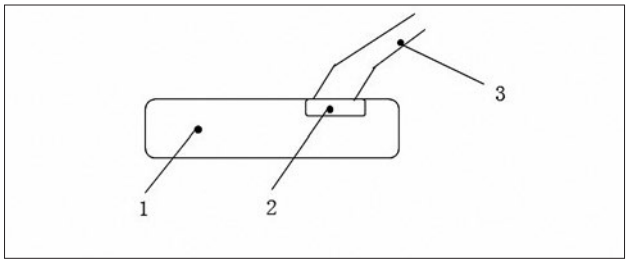

Fig 1 Schematic drawing for radiant existence measurement. 1, radiometer; 2, radiometer optical area; 3, light guide (fibre optic cable of the activator).

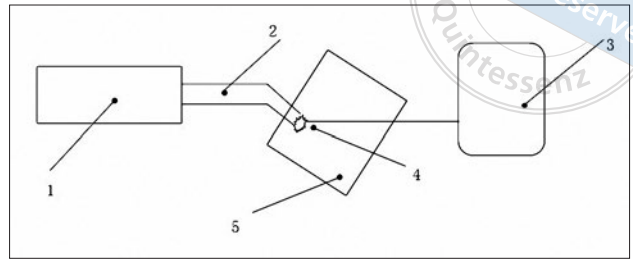

Fig 2 Schematic drawing for irradiation accumulated temperature measurement. 1, powered polymerisation activator; 2, light guide (fibre optic cable); 3, thermometer; 4, detector of thermometer; 5, white paper as the background.

Table 1 Irradiance and irradiance accumulated temperature records (example).

Ambient temperature (°C)		Test date: _____ month _____ date _____ year		
Equipment type		Irradiation time period (s)	Radiant exitance (mw/cm^2)	Radiant accumulated temperature (°C)
Emitting mode				
Mean				

Atmospheric conditions

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

- ambient temperature of 23°C ± 5°C;
- relative humidity of 50% ± 20%.

Power supply condition

For Type 1 polymerisation activators, measure the radiant exitance at 100% of the starting operating voltage (rated voltage), and for Type 2 polymerisation activators, measure the radiant exitance at full charge.

Measurement of radiant exitance

Apparatus

A calibrated radiometer (light meter) for the light-curing machine supplied by a marketable or equipment manufacturer.

Radiant exitance measurement

Connect the outlets of the light guide (fibre optic cable) tightly to the optical centre area of the radiometer (Fig 1), turn on the activator to measure the irradiance at the end of a radiant exitance time period and record it in Table 1. Activate a curing mode three times and calculate the mean as its actual irradiance when applying quality control.

Irradiance accumulated temperature measurement

Apparatus

A digital thermometer equipped with an analogue or a digital temperature sensor can detect temperature with an accuracy of ± 0.5°C.

Method for irradiance accumulated temperature measurement

Place the thermometer on white paper as the background and connect the output of the light guide tightly to the detector of the thermometer (Fig 2), turn on the activator and record the maximum irradiance accumulated temperature in a radiant exitance time period. Activate it three times and record the results in Table 1, and calculate the mean as the irradiance accumulated temperature.

Conflicts of interest

The authors declare no conflicts of interest related to this study.

Author contribution

Dr Bao Lin FAN contributed to the project administration; Drs Bao Lin FAN and Xin Ya LI drafted the manuscript; Drs Xin Ya LI, Shu Bin WU and Jian Xia WANG contributed to the data collection and quality control experiments; Dr Bao Lin FAN and Chuan Bin GUO revised the manuscripts and contributed to the construction of the guideline. All the authors and the Society of Dental Equipment, Chinese Stomatological Association contributed to the discussion of the project and approved the guideline.

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