smartLite™ PS
PEN-STYLE HIGH POWER LED CURING LIGHT

SMART TO BE SMALL

With the compliments of
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1 Introduction

Unlike conventional halogen lamps, light emitting diodes (LED) produce light in the visible range of the electromagnetic spectrum via quantum mechanical effects using doped semiconductors. LED lamps emit highly efficient light in a limited wavelength range. The LED needs less power than a halogen light bulb, in which the light is generated by heating a tungsten filament in the presence of a halogen gas.

Due to the fact that the emission spectrum of the blue LED closely matches the absorbance peak of camphorquinone – the most commonly used photo initiator in visible light cured dental materials –, the LED units represent a considerable improvement over halogen lamps due to the improved conversion efficiency and longer LED life time.

Thus, this technology is an ideal basis for cordless devices improving the convenience of the curing procedure in the dental surgery. Noisy and uncomfortable cooling fans, necessary in traditional Quartz-Tungsten-Halogen (QTH) curing lights, are not needed due to the higher efficiency of LEDs.

SmartLite PS is an LED curing light that is small and easy to use, yet powerful and swift in curing. The following information will provide details on the curing performance and demonstrate the high efficiency and safety of this new curing device. Properties that make it ideal as replacement of traditional QTH curing units.

2 SmartLite PS Design

2.1 LED-Tip

The black anodized aluminium tip of the SmartLite PS comprises a grip, enabling the operator to rotate the tip in an easy manner. Furthermore, an easy orientation of the LED-tip is given even in situations of low brightness and limited space by a crosshair on the backside of the tip, indicating the direction of the light.
2.2 Hand piece

Due to the compact design of the hand piece the SmartLite PS is very easy and precise to handle. Pressing the ON/OFF button activates the 10-sec standard cure. Several visual and acoustic signals give the operator information on the battery status and/or if the LED-tip is not properly connected to the hand piece.

The hand piece comprises a rechargeable Nickel-Metal-Hydride (NiMH) battery, which provides a minimum of 150 curing cycles at 10 seconds with a stable power output even at a low battery charging status. This is achieved by means of a microprocessor-controlled technology.

2.3 Charger

Four charger types are available adjusted to the specific plugs and voltage of the respective countries:

- EU-plug: 220 – 240 V
- UK-plug: 220 – 240 V
- US-plug: 110 – 130 V
- Japan-plug: 90 – 110 V

3 Intensity and Spectral Output

By using the Cure Rite™ photometer the intensity of a standardised area is measured and directly indicated for all lamps.

The SmartLite PS has a powerful 5W LED with an average light output of more than 950 mW/cm². This value is comparable to most other LED lights and some more powerful halogen lights (Figure 1).
The SmartLite PS does not - unlike the widely used Quartz-Tungsten-Halogen (QTH) lamp - emit light with wavelengths beyond the absorbance range of camphorchinone (CQ). CQ is the most commonly used photo initiator in almost all visible light cured dental materials. Thus the light emitted by the SmartLite PS corresponds to the absorbance maximum of CQ, which ensures a very efficient activation and curing of the restorative material (Figure 2).
4 Light output stability

It is well known from conventional halogen lights (QTH) that the curing performance is strongly dependent on the bulb. Towards the end of the bulb’s lifetime the output is seen to drop dramatically. As this can not be checked automatically, it is of outmost importance to test the QTH curing lamp on a regular basis in order to detect any deterioration in its curing performance. The LED technology offers the advantage that the LED light source does not deteriorate over the life time of approximately 10,000 hours and therefore does not require maintenance or constant monitoring.

As shown in Figure 3, a fully charged battery provides approx. 150 ten-second cures (approx. 25 minutes operating time) with constant light output. Therefore, under most conditions of use, the device only needs to be recharged over night.

When the battery light flashes red (fast), the battery needs to be recharged. Another 2 minutes exposure time is then left for completion of the treatment. Light output is not reduced during this period. After these 2 minutes, the device switches off automatically and continues to flash red (slowly) indicating the need to recharge.

![Figure 3](image-url)  
**Figure 3** Light output upon repeated cycles.
5 Thermal radiation

Besides the emission of visible light in the spectral range of approximately 400-500 nm all curing lamps radiate heat as well. The amount of heat that is radiated towards the tooth depends on the output power and the exposure time. A balance between high light power and low heat irradiation is needed to avoid the risk that heat may have on the pulp tissue and the oral mucosa.

5.1 In-vitro tooth heating study

A tooth heating study was conducted at the Department of Oral Rehabilitation, Medical College of Georgia (head: Professor F. Rueggeberg, DDS, MS). The purpose of this investigation was to simulate and determine in vitro the intra-pulpal temperature rise in a model using extracted human bicuspids (Figure 4) comparing the SmartLite PS to a variety of commercial light-curing units (Figure 5).

![Figure 4](image_url)  
**Figure 4**  In-vitro simulation of light curing and measurement of intra-pulpal temperature rise (Rueggeberg)
The temperature rise after a 10sec exposure using the SmartLite PS ranged from 2.4 to 2.8°C and was significantly lower than of the following commercially available LED and halogen units: L. E. Demetron 1, Elipar FreeLight 2, Optilux 501, and Spectrum800. Moreover, longer exposure times have shown that the SmartLite PS emits and transfers less heat onto the tooth than other widely used LED and halogen curing lights.

### 5.2 Temperature of the LED Tip

ISO 60601 requires that equipment parts that may have a brief contact with a patient must not be warmer than 50 °C. If SmartLite PS is used according to the directions for use, which request a waiting period of 30 seconds between 10-second curing cycles, the device is in compliance with the above-mentioned standard.

If, in deviation from the directions for use, the device is used with shorter waiting periods or for longer curing cycles, the temperature of the LED Tip may rise above 50 °C. However, experiments for curing cycles up to 30 seconds long have shown that, if typical direct restorative procedures are simulated, the resulting temperatures do not create any hazard regarding tissue compatibility and do not negatively affect the lifespan of the LED light. Still, SmartLite PS must not be used for the luting of indirect restorations as this process is associated with many consecutive and long curing cycles.
6  Curing performance

6.1  Depth of Cure according to ISO 4049:2000

The depth of cure of a restorative material correlates directly with the light output of a curing light. The higher the intensity of a curing light the more efficient the depth of cure. This usually is the result of a higher degree of conversion, which leads to a stronger material and an increase in durability of the resulting restoration.

Depth of cure was measured for SmartLite PS, along with other LED lights, and a strong halogen light according to the method described in the ISO 4049:2000.

It is important to note that this particular method defines the depth of cure as 50 % of the actual thickness of the cured cylindrical specimen: A sample of the material is exposed to the light source and the un-polymerised material is scraped away using a spatula. The thickness of the remaining sample is then divided by 2 resulting in the depth of cure according to ISO. The results are shown in Figure 6 and Figure 7.

![Figure 6](image)

**Figure 6**  Depth of Cure (ISO 4049:2000) of Spectrum TPH A2 after a 10sec cure with various curing units
The above data demonstrate that even for dark shades such as Spectrum TPH A4 a depth of cure of 2mm thickness can be achieved with SmartLite PS after 10sec exposure.

6.2 Barcol hardness

Another method to determine the curing performance of a curing light is to measure the hardness of the exposed surface and the hardness at a given depth using Barcol hardness.

By curing a 2mm thick sample of the restorative material (Spectrum TPH A2, A4) the obtained hardness values for the illuminated (top) and the non-illuminated (bottom) side of the sample, as well as the bottom/top hardness ratio, were measured. The results demonstrate again that a 2 mm depth of cure can be achieved by using SmartLite PS for 10 seconds (Figure 8, Figure 9).
6.3 Compressive strength

Additionally, measurements of the curing performance of the SmartLite PS were compared to that of the Spectrum800@800 by measuring the compressive strength of EsthetX A2 and A4 and Spectrum TPH A2 and A4 shades, respectively. Results are shown in Figure 10. The obtained values for the compressive strength of the cured materials confirm that there is no difference between the curing performance of the SmartLite PS and the Spectrum800 at 800 mW/cm².
7 Clinical data

7.1 Consumer preference evaluation

General dental practitioners were given the opportunity to use SmartLite PS for standard restorative treatment over a time period of several weeks. They were asked to report on their experience and to rate their grade of satisfaction with the light by means of a questionnaire. Results are listed in Tables 1 to 3.

The data show a high degree of customer satisfaction:
Consumer Preference Evaluation:

**Table 1** Consumer Preferences

<table>
<thead>
<tr>
<th>Functionality of charging unit</th>
<th>Very good</th>
<th>Good</th>
<th>Satisfactory</th>
<th>Poor</th>
<th>Very Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80%</td>
<td>20%</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ergonomics of hand piece with LED tip attached</th>
<th>Very good</th>
<th>Good</th>
<th>Satisfactory</th>
<th>Poor</th>
<th>Very Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>60%</td>
<td>40%</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Battery capacity</th>
<th>Very good</th>
<th>Good</th>
<th>Satisfactory</th>
<th>Poor</th>
<th>Very Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>60%</td>
<td>40%</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</table>

<table>
<thead>
<tr>
<th>Overall rating of design and function</th>
<th>Very good</th>
<th>Good</th>
<th>Satisfactory</th>
<th>Poor</th>
<th>Very Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80%</td>
<td>20%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Table 2** Advantageous Properties of SmartLite PS

- Small size
- Easy to use
- Light in weight
- Well balanced
- Excellent access anywhere in the mouth
- Not clumsy
- Efficient
- Powerful
- Excellent charging mechanism
- Directness of light source
- Protective sleeve
- Shield system
Table 3  Preference for additional curing light

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all likely</td>
<td>0</td>
</tr>
<tr>
<td>Not very likely</td>
<td>0</td>
</tr>
<tr>
<td>Somewhat likely</td>
<td>0</td>
</tr>
<tr>
<td>Very likely</td>
<td>60%</td>
</tr>
<tr>
<td>Extremely likely</td>
<td>40%</td>
</tr>
</tbody>
</table>

7.2 Clinical post-marketing surveillance study, Republic of South Africa

Main Investigator

Dr. Paul D. Brandt, University of Pretoria (ZA)

Objective

The objective of this investigation is to prove that the performance of posterior composite restorations is the same when cured with

a) a conventional halogen curing light with 20-second curing cycles.

b) SmartLite PS with 10-second curing cycles.

Design

Prospective controlled postmarketing surveillance investigation.

Under the conditions of general daily practice, each of up to 10 investigators places eighty Class I and II posterior composite restorations and monitors the performance of these restorations for up to 16 months.

Half of the restorations are cured with a halogen curing light (with an output of more than 300 mW/cm², measured with a CureRite device) which is routinely used in the surgery. The curing time for each 2mm-increment of composite is 20 seconds.
The other half of the restorations is light-cured with SmartLite PS. The curing time for each 2mm increment of composite is 10 seconds.

The investigators monitor the performance of the restorations with regard to any report of post-operative sensitivity or other side effects received from the patient and/or when the respective restorations become available for inspection during routine examinations.

**Patient/Case Selection**
Routine patients in need for direct tooth-coloured posterior restorations (Class I and II cavities in molars and premolars). Tooth to be vital on the day of treatment, with no symptoms of pulp inflammation/irritation, and not in need of direct pulp capping or endodontic treatment. There should be no hypersensitivity or sensitivity to percussion.

For inclusion into the study, the following additional requirements have to be met:
- Successful cavity isolation (no contamination)
- Patient was *expressly* asked to report back if any sensitivity occurs
- Light output was measured immediately after treatment and exceeded 300mW/cm² for the halogen curing light and 720 mW/cm² for SmartLite PS.

**Reporting**
Reports to DENTSPLY are provided by the investigators by means of a set of forms for each restoration to be monitored.

**Interim report August 2003:**
First data from 4 investigators were analysed and prove that for all criteria measured there is no difference in safety and efficacy between a standard halogen light with a curing time of 20 seconds per increment and SmartLite PS with a curing time of 10 seconds per increment for the curing of posterior composite restorations. Data on post-operative sensitivity are provided in Figure 11.
8 Conclusion

The information that is provided in this document represents a small excerpt of all investigations performed internally and externally, proving that the SmartLite PS fully equals strong QTH curing lights like the Spectrum 800 with regard to curing performance. The convenient size, the ease of use and the device’s lightness makes it an ideal curing light for all-day usage within direct restorative treatment.

9 Indications, contra-indications, warnings, and precautions

Indications
Intra-oral light curing of direct restorative materials, adhesives, and sealants which cure at a wavelength of 450 - 490 nm.
Contra-indications
Use for indirect restorations:
SmartLite PS should not be used for curing of luting cements for indirect restorations (e.g. ceramic inlays) as continuous curing cycles will result in heat build-up of the LED tip which may cause discomfort or burns.

Use in patients prone to photobiological reactions:
Do not use the SmartLite PS on patients with a history of photobiological reactions (including patients with Urticaria solaris or erythropoietic protoporphyrie) or those currently undergoing treatment with photosensitising pharmaceuticals.

Warnings
SmartLite PS should not be used as a tissue retractor, as this may damage the connection between LED tip and hand piece.

Do not use a damaged device, e.g. if among others the glass cover of the LED Tip is scratched, broken or missing.
Do not use for voltages different to the range indicated on the charging unit.
Note: To disrupt the power supply, the charging device has to be plugged out.

Always unplug the charger before disinfecting.

Precautions
Anyone with a history of retinopathy should consult their eye specialist before operating this unit. Use the SmartLite PS extremely carefully and comply with all the necessary safety precautions (including wearing suitable, light filtering safety glasses).

Anyone who has had a cataract operation may be especially sensitive to light and should be advised against undergoing treatment with a SmartLite PS unless adequate safety precautions are taken such as wearing safety glasses which filter out blue/violet and ultra-violet light.

Do not use a device which has not been properly disinfected (see Chapter Maintenance). Protect LED Tip from contamination by applying a disposable, single patient use sleeve (DENTSPLY Disposa-Shield®).

Never aim the light directly at unprotected soft tissues, as this may cause injury or irritation. Do not aim the light at eyes.
Light reflected from the tooth surface may also injure eyes. Use the protective shield supplied with the unit or suitable safety glasses, which shield effectively against blue spectrum light.

If time intervals between exposures are too short, the LED tip may overheat and potentially cause soft tissue injury. Therefore, wait for at least 30 seconds between exposures. Limit the action of the light to the area being treated.

10 Directions for use

10.1 Installation and charging

1 Plug in charging unit.
2 Insert the hand piece [1] into the charging unit [3].
   The battery light will be flashing green, indicating ongoing charging of the battery.
3 Charge the device for at least 10 hours prior to first use. Complete charge of the curing light is indicated by a continuously green light.
4 The completely charged device allows approx. 150 ten-second cures (total operating time approx. 25 minutes). Thus, under most conditions of use, the device will normally need recharging at the end of each practice day.
10.2 Operation

Operation at a glance

1.1) ON/OFF KEY
Activates device and starts or disrupts the 10-second exposure cycle.

1.2) BATTERY LIGHT

*Continuously green*
(only indicated when SmartLite PS hand piece is inserted into the charger):
SmartLite PS is fully re-charged and ready for operation

*Flashing green*
(only indicated when SmartLite PS hand piece is inserted into the charger):
SmartLite PS is still being re-charged.

*Fast flashing red:*
2 minutes exposure time left - SmartLite PS needs re-charging.

*Slowly flashing red:*
Battery is fully discharged (no exposure time left) and needs re-charging.

1. **Attach the LED Tip [2]** to the hand piece [1]. The device is now ready for operation.

2. Protect LED Tip from contamination by applying a disposable, single patient use sleeve (DENTSPLY Disposa-Shield®)

3. Attach the eye protecting shield to the tip or use safety glasses which shield effectively against blue spectrum light.
4. **Adjust the LED Tip**: The LED Tip rotates by 360°, thus the position of light emission may be freely adjusted. The tip must be adjusted to an angle that most optimal curing of the restoration is possible. The tip must not touch the restoration material but should be positioned as close as possible to the restoration.

5. **Polymerisation**: Shortly press the ON/OFF key [1.1]. The start of the 10-second exposure cycle is indicated by an acoustic signal. The end of 10-second exposure cycle is likewise indicated by an acoustic signal.

   For detailed information on curing times for DENTSPLY light cured products, please see the Curing Guide supplied. For products other than those from DENTSPLY, please refer to the curing times given by the respective manufacturer.

   Wait for at least 30 seconds between exposures. If time intervals between exposures are too short, this may lead to a potentially tissue injurious overheating of the LED Tip.

### 10.3 Maintenance

**Prevention of cross infection, cleaning, disinfection, and storage**

The use of the sleeve is an additional precautionary measure against contamination and does not substitute disinfection of the device.

After use, remove sleeve. Clean and disinfect LED Tip and hand piece with commercial alcohol based surface disinfecting solution (Dürr FD 322, Henkel Incidin Liquid, S&M Mikrozid Liquid, B.Braun Meliseptol rapid). Keep other solvents or flammable liquids as well as intense sources of heat away from the unit as they may damage its plastic housing.

Always safeguard charger, hand piece, and LED Tip against moisture as this may cause electrical short-circuit or dangerous malfunction.

**Light output control**

Make sure that the LED aperture is clean and scratch-free, otherwise light output will be reduced and may be insufficient for proper curing of the material.

Control of light efficiency is recommended (e. g. by using CureRite™). The CureRite output should exceed 730 mW/cm².

**Battery maintenance**

The battery needs a total of 10 hours to be fully re-charged.

When the battery is charging, the battery light flashes green.

Upon complete recharging, the battery light remains continuously green.
Fully charged, the battery has a capacity of approx. 150 ten-second cures (approx. 25 minutes operating time). Therefore, under most conditions of use, the device only needs to be recharged over night.

When the battery light flashes red (fast), the battery needs to be recharged. Another 2 minutes exposure time is then left for completion of the treatment. Light output is not reduced during this period. After these 2 minutes, the device switches off automatically and continues to flash red (slowly) indicating the need to recharge.

To maintain the maximum capacity of the rechargeable battery, discharge the device by regular use at least every 6 months and recharge the battery immediately thereafter.

**High voltages are present inside the charger. Do not open charger or the hand piece.** Use only under dry conditions. Do not use if the charger is wet. Store dry. Only authorised technicians should repair the SmartLite PS LED Tip, hand piece or charger.

### 11 Guarantee terms

DENTSPPLY grants a 2-year guarantee on hand piece and charger and a 6-month guarantee on the LED Tip commencing on the date of purchase. Within the guarantee period, DENTSPPLY will eliminate free of charge any defects in the appliance resulting from faults in material or workmanship either by repairing or exchanging parts or exchanging the whole device at DENTSPPLY's discretion.
# 12 Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AC Supply connection:</strong></td>
<td>90…110 V~ 50…60 Hz 2.5W</td>
</tr>
<tr>
<td></td>
<td>110…130 V~ 50…60 Hz 2.5 W</td>
</tr>
<tr>
<td></td>
<td>220…240 V~ 50…60 Hz 2.5 W</td>
</tr>
<tr>
<td><strong>Power input:</strong></td>
<td>2.5 W</td>
</tr>
<tr>
<td><strong>Protection from ingress of liquids:</strong></td>
<td>IP X4</td>
</tr>
<tr>
<td><strong>Operation:</strong></td>
<td>Continuous operation with intermittent loading, duty cycle of 10 seconds ON/30 seconds OFF (^1)</td>
</tr>
<tr>
<td></td>
<td>10 – 32°C.</td>
</tr>
<tr>
<td></td>
<td>30 – 100%</td>
</tr>
<tr>
<td></td>
<td>500 - 1060 hPa</td>
</tr>
<tr>
<td><strong>Storage:</strong></td>
<td>Ambient temperature: -10 - +35 °C/14 – 95 °F</td>
</tr>
<tr>
<td></td>
<td>Relative humidity: 30% - 80% (non-condensing)</td>
</tr>
<tr>
<td></td>
<td>Atmospheric pressure: 500 - 1060 hPa</td>
</tr>
<tr>
<td><strong>Transport:</strong></td>
<td>Ambient temperature: -10 - +60 °C/14 – 140 °F</td>
</tr>
<tr>
<td></td>
<td>Relative humidity: 30% - 80% (non-condensing)</td>
</tr>
<tr>
<td></td>
<td>Atmospheric pressure: 500 - 1060 hPa</td>
</tr>
<tr>
<td><strong>Battery performance:</strong></td>
<td>Hand piece will allow a minimum of 150 10-sec cycles upon complete recharging. Time to battery recharge: maximum 10 hours</td>
</tr>
<tr>
<td><strong>Battery over current protection</strong></td>
<td>Resetable fuse</td>
</tr>
<tr>
<td><strong>Battery life</strong></td>
<td>Minimum 400 full recharge cycles</td>
</tr>
<tr>
<td><strong>Light emitting diode:</strong></td>
<td>5 W LED</td>
</tr>
<tr>
<td><strong>Output peak wavelength range:</strong></td>
<td>450 – 490 nm</td>
</tr>
<tr>
<td><strong>Unit hand piece dimensions:</strong></td>
<td>Length 159 mm</td>
</tr>
<tr>
<td></td>
<td>Width 28 mm</td>
</tr>
<tr>
<td><strong>Tip dimensions:</strong></td>
<td>Length 87 mm</td>
</tr>
<tr>
<td></td>
<td>Width 13 mm</td>
</tr>
<tr>
<td><strong>Unit weight:</strong></td>
<td>Hand piece and tip 100 grams</td>
</tr>
<tr>
<td></td>
<td>Charger 45 grams</td>
</tr>
</tbody>
</table>

\(^1\) According EN 60601