LED Dental Curing Lights

Instruction Manual
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Product Description
The Flashlite® Curing Lights are revolutionary dental curing lights utilizing a light emitting diode (LED) for the polymerization of composite materials that contain the photo-initiator camphorquinone (CQ). The Flashlite Curing Lights are powered by a rechargeable lithium-ion battery pack that comes with a charger and a 9V/2A wall plug adapter.

Precautions for electromagnetic compatibility (EMC):
Equipment in medical environments, including this product, can produce electromagnetic interference (EMI). These effects are prevented by the use of equipment with EMI characteristics below proven recognized limits for the specified operating environment. In the event of suspected electrical interference with other equipment, cycle the power on the Flashlite to remedy the EMI effect.

Contents* (See Illustrations on page 2)
- AC/DC Wall Plug Adapter
- Charger Base with Built-in Radiometer
- Flashlite Curing Light
- Three Replacement Lens Caps
- Instruction Manual
- Light Shield (included with Flashlite Magna 4.0)
- Tacking Tip (pack of 5)

* Additional Accessories Available

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. For suitable replacement cables and maximum lengths of cables, contact DenMat directly.

Note: International units include power adapters.

Technical Data
Flashlite Magna® 4.0
- Battery: Lithium-ion
- Wavelength Range: 440-490 nm
- Light Intensity: 1300 mW/cm² ±200
- Total Continuous Runtime with Fully Charged Battery: 120 minutes
- Dimensions:
  - Diameter: .86 in / 22 mm
  - Length: 8.6 in / 219 mm
  - Weight: 4.3 oz / 121 g
- AC/DC Wall Plug Adapter – Class II
  - Input Voltage: 100-240V ~ 50/60Hz 600mA
  - Output Voltage: 9V /2.0A max

Charger Base with Built-in Radiometer – Class II
- Time to Charge Discharged Battery: Max 5 hours
- Operating Temperature: 15°C - 32°C (59°F - 90°F)
- Operating Humidity: 10% - 93%

Flashlite® 2.0
- Battery: Lithium-ion
- Wavelength Range: 460-480 nm
- Light Intensity: 1100 mW/cm² ±200
- Total Continuous Runtime with Fully Charged Battery: 210 minutes
- Dimensions:
  - Diameter: .86 in / 22 mm
  - Length: 7.8 in / 198 mm
  - Weight: 3.8 oz / 105 g
- AC/DC Wall Plug Adapter – Class II
  - Input Voltage: 100-240V ~ 50/60Hz 600mA
  - Output Voltage: 9V /2.0A max

Charger Base with Built-in Radiometer – Class II
- Time to Charge Discharged Battery: Max 5 hours
- Operating Temperature: 15°C - 32°C (59°F - 90°F)
- Operating Humidity: 10% - 93%
Warnings and Precautions

1. The Flashlite Curing Light must be used in strict accordance with the following operating instructions. DenMat accepts no liability for any damage resulting from the use of this unit for any purpose.

2. Exposure must be restricted to the area of the oral cavity in which clinical treatment is intended.

3. Do not touch the tip to the patient especially during and after activation of the light. Do not point the light into the eyes.

4. Avoid having the Flashlite Curing Light in contact with the patient.

5. The use of third party chargers and/or AC/DC wall plug adapters may result in damage to the unit, may be hazardous to users/patients and will void warranty. Use only supplied wall plug adapter with the supplied charger for Flashlite Curing Lights. Do not use wall plug adapter to power other devices.

6. Removing the wall plug adapter from the wall outlet is the means of isolating this Flashlite Curing Light from the supply means.

7. Do not allow cleaning agents to directly enter the unit as this may cause premature failure. See Maintenance and Care.

8. Do not use on patients with a history of heat sensitivity or photo biological conditions including urticarial solaris or erythropoetic protoporphyria or are on photosensitizing medications.

9. Suitable blue-filtering safety goggles must be worn by patient, dentist, and assistant during use.

10. Do not use any of these components/devices if damaged or potentially damaged from impact.

11. Only a DenMat Authorized Representative can service the unit. Please call DenMat with any questions. Phone numbers are on the back of this manual.

12. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Classification

- Conforms to IEC 60601-1, IEC 60601-1-2, IEC 62471

Compliance with Emissions and Immunity Standards:

Complies with Emission Test RF Emissions CISPR 11 Group 1 Class B and Group 2, IEC 61000-3-2 A and IEC 61000-3-3; and Immunity Test IEC 61000-4 ESD, EFT, Surge, Power Frequency, Voltage Dips, Conducted RF and Radiated RF.

FCC Statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Unpacking / Setup

1. Ensure all parts contained within package match the contents list.

2. Plug the AC/DC wall plug adapter into the mating connector on the back of the charger base.

3. Plug the AC/DC wall plug adapter connector into an AC outlet.

4. Place the Flashlite Curing Light into the charger base. Allow the Flashlite Curing Light to fully charge prior to first use. Refer to Technical Data for charge times. Indicator will turn green when unit is fully charged. Store light in charger when not in use.

NOTE: The AC/DC wall plug adapter provides power to the charger base. In turn, the charger base provides power (at a lower voltage) to the Flashlite Curing Light. These form a Medical Device System. The Flashlite Curing Light device is used separately after fully charged.

Operation

The Flashlite Curing Light is supplied with the lens cap attached. A button on the Flashlite Curing Light turns the light on and off. Simply press the button once and release to activate or de-activate the light. A clean barrier sleeve must be used for each new patient use. Aim the beam at the area of the oral cavity in which clinical treatment is intended and activate the light. Deactivate the light right after treatment. Do not touch the tip to the patient especially during and after activation of the light.

WARNING: No modification of this equipment is allowed.
**Duty Cycle**
Flashlite Magna 4.0 – Intermittent use of 10-20 second curing times with twice the cooling time.

Flashlite 2.0 – Intermittent use of 10-20 second curing times with twice the cooling time, or continuous for maximum of 2 minutes curing with twice the cooling time.

The Flashlite Curing Light produces several audible signals including:

- **Flashlite Magna 4.0 Timing Beeps**
  Audible beeps will occur every five seconds during operation. After 20 seconds a long beep will sound and the light will automatically shut off.

- **Flashlite Magna 4.0 Audible Indicators**
  10 slow beeps — low battery warning
  25 fast beeps — overheat alarm

- **Flashlite 2.0 Timing Beeps**
  Audible beeps will occur every 10 seconds during operation: 1 beep indicates 10 seconds, 2 beeps indicates 20 seconds, etc. The system counts up to 6 beeps indicating 60 seconds and then repeats starting with 1 beep. Unit will only shut off after manual press of power button.

- **Flashlite 2.0 Audible Indicators**
  10 slow beeps — low battery warning
  25 fast beeps — overheat alarm.

**Lens Cap (See Fig. 2)**
The lens cap should be inspected prior to each use for blemishes, scratches, cracks or foreign substances that may impair the optical output of the Flashlite Curing Light. It is recommended that the lens cap be replaced every 2-4 weeks.

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**WARNING:** The curing intensity of the Flashlite Curing Light can result in a buildup of heat around the tip of the device. In worst case conditions (which included 32°C ambient conditions), tip temperatures of 61°C (142°F) have been measured. Do not use on patients who cannot give immediate and clear feedback to the clinician in the event any elevated temperatures are causing pain. Use extreme caution if using on patients with increased oral heat sensitivity or with conditions or medications which might cause increased oral heat sensitivity. This device is for professional use only.

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**Barrier Sleeve**
To provide optimum protection, a clean plastic barrier sleeve should be used for each new patient.

**Light Shield**
To help block reflected light, the light shield can be attached to the Flashlite Curing Light by assembling the shield over the tip and sliding into place.

**Tacking Tip (See Fig. 5)**
Use a tacking tip to direct the light to cure only a small amount of product (approximately 2mm radius). Align the wide end of the tacking tip with the lens cap and use moderate pressure to push into place. To avoid the possibility of the tacking tip falling off during use, make certain that it is tightly and properly attached on the lens cap.

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**Cure Times**
Due to the variation in VLC (visible light cured) materials, curing times will differ. Review manufacturer product instructions for recommended curing times. **ALWAYS bench test new materials before use in vivo.**

**Curing Test Rings**
DenMat recommends the following steps when using the enclosed curing test rings for this purpose:

a. Fill the 2mm deep well of the test ring and level material.

b. Position the light transmitting element perpendicular to and approximately 2mm-5mm above the top surface of the ring.
   - With Flashlite lights (all models) start with 10-second exposures.
   - With Sapphire PAC lights (all models) start with 5-second exposures.
   - For all other curing lights; halogen, LED and other refer to the manufacturer instructions. A minimum of 10-30 seconds is recommended.

c. Use a dental probe to scrape test the hardness of the top and bottom surfaces. The bottom surface should be as hard as the top surface.

d. If the bottom surface is not completely cured repeat steps (b) to (c). Repeat until the bottom surface is completely cured.

e. Maintain a log including material, shade and associated curing exposure time. Use the log to monitor system performance.

Note: If a cavity preparation is deep, curing exposure times must also be increased due to beam divergence and angular placement of the light transmitting element to the restoration. An incremental filling technique is recommended and each increment should be fully cured prior to applying additional layers.
Charger with Built in Radiometer
To charge, place the Flashlite Curing Light into the charger base contact side down. (See Fig. 3) The light indicator (See Fig. 4) on the charger base will provide you with the information needed:
• Amber Light – Unit is charging
• Green Light – Unit is fully charged

Note: Even if the light is indicating a charging status (amber light), the Flashlite Curing Light can be used.

For optimal performance, place the Flashlite Curing Light back in charger base when not in use.

Measuring Output Intensity
Light intensity can be measured using the radiometer built into the charging base (See Fig. 4). To measure the intensity of the light being emitted from the unit, place the lens tip directly onto the black aperture located on the charger base. Activate the Flashlite Curing Light by pressing the on/off button. The number of indicator lights that illuminate will identify the output of the light:
• 4 lights: 100% of the light intensity available
• 3 lights: 80% of the light intensity available
• 2 lights: 60% of the light intensity available
• 1 light: 40% of the light intensity available

Note: If only 3 lights are illuminated, try tilting the Flashlite at a slight angle to illuminate all 4 lights.

Accurate light measurements are only possible with the charger of the Flashlite Curing Light. Portable and/or handheld radiometers have been shown to have variability in accuracy and precision in measuring total spectral output.

Maintenance and Care
Keep the Flashlite Curing Light in charger when not in use. Take care to keep charging contacts on the bottom of the device and charger pins in the charger base clean and dry.

Recommended Cleaning Agents:
• 70% Isopropyl Alcohol
• Mild Soap Solution
Avoid iodine based solutions.
Avoid wetting of internal parts.

Do not spray cleaning solution directly onto the curing light. Dampen a clean cloth and wipe down the unit. Be careful not to let solution soak into the power button or inside the lens cap.

Use of barrier sleeve over the unit is a must. Clean and sanitize unit prior to every use.

DISPOSAL: Device components are electronic and handpiece has internal lithium-ion battery. Dispose or recycle device per local or country laws. Please contact your local disposal contractor.

Note: This unit contains a lithium-ion battery. As a result please be sure to not store the unit uncharged for an extended period of time as this may cause the battery to discharge and reduce the lifetime of the unit.

Transport and Storage
Ambient Temperature – 4ºF to 104ºF (−20ºC to 40ºC)
Relative Humidity 10% to 90% Non-condensing
Atmospheric Pressure .5 atm to 1.0 atm (500 hPa to 1060 hPa)

2-year Warranty
DenMat warranties your Flashlite Curing Light against defects in material and workmanship for 24 months from date of purchase with proper usage. During that 24-month warranty period, DenMat will repair or replace a defective unit at no cost to you.

Please contact your local DenMat Representative for any additional questions, comments or product information.

Defects caused by misuse, neglect, accident, or abuse are not covered by warranty. If the required repairs are not covered by warranty, DenMat will contact you promptly with a price quotation for the cost of repair(s) or replacement prior to performing any services.
## Accessories and Replacement Parts

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR1082</td>
<td>Replacement Lens Caps (pack of 25)</td>
</tr>
<tr>
<td>CR1083</td>
<td>Charger Base</td>
</tr>
<tr>
<td>CR1074</td>
<td>AC/DC Wallplug Adapter</td>
</tr>
<tr>
<td>CR1075</td>
<td>Tacking Tips (pack of 5)</td>
</tr>
<tr>
<td>CR1077</td>
<td>Light Shield</td>
</tr>
<tr>
<td>CR1078</td>
<td>Barrier Sleeves (pack of 500)</td>
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<tr>
<td>043952220</td>
<td>Curing Rings (100 pcs)</td>
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</table>

## Troubleshooting Guide

<table>
<thead>
<tr>
<th>Problem</th>
<th>Causes</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Continuous slow beeps</td>
<td>Low battery</td>
<td>Recharge battery. Light will turn off automatically when battery is low.</td>
</tr>
<tr>
<td>2. Continuous fast beeps</td>
<td>Device too warm</td>
<td>Place device in the charger. Allow device to cool.</td>
</tr>
<tr>
<td>3. No light, no beeps</td>
<td>Device malfunction or very low battery</td>
<td>Recharge battery. Contact Customer Service.</td>
</tr>
<tr>
<td>4. No light, one beep</td>
<td>Device in charger</td>
<td>Device will not turn on when in charger. Remove the device from the charger to operate.</td>
</tr>
<tr>
<td>5. Lens cap cracked</td>
<td>Damage due to dropping</td>
<td>1. Carefully remove lens cap.</td>
</tr>
<tr>
<td></td>
<td>Damage due to cleaning material</td>
<td>2. Replace with new lens cap.</td>
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<tr>
<td></td>
<td>over-exposure</td>
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<td></td>
<td>Wear and tear</td>
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</tr>
<tr>
<td>6. Light is completely charged (green indicator), but beeps while in use</td>
<td>Handle bottom or charger pins contaminated with debris</td>
<td>1. Unplug the charger base.</td>
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<tr>
<td></td>
<td></td>
<td>2. Wipe pins in the base to remove debris. Do not allow any liquid to drip into the base.</td>
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<tr>
<td></td>
<td></td>
<td>3. Check bottom of handle for debris. Wipe with dry cloth to remove debris.</td>
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<tr>
<td></td>
<td></td>
<td>4. Plug in charger base and place hand held device into base.</td>
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## Guidance and Manufacturer's Declaration

The Flashlite Magna 4.0 and 2.0 Curing Lights are intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Flashlite Dental Curing Lights, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
### Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Curing Lights use RF energy only for their internal functions. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group A</td>
<td>The Curing Lights are suitable for use in all establishments other than domestic and may be used in domestic establishments in those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is needed:</td>
</tr>
<tr>
<td>Power Line Harmonics IFC/EN 61000-3-2</td>
<td>Group A</td>
<td>The Curing Lights are suitable for use in all establishments other than domestic and may be used in domestic establishments in those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is needed:</td>
</tr>
<tr>
<td>Power Line Harmonics IFC/EN 61000-3-2</td>
<td>Complies</td>
<td>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Curing Light or shielding the location.</td>
</tr>
</tbody>
</table>