



LED Dental Curing Lights

Instruction Manual

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LED Dental Curing Lights

Figure 1

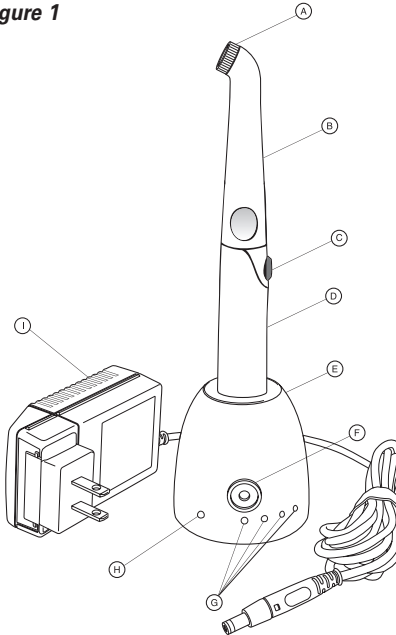


Figure 2

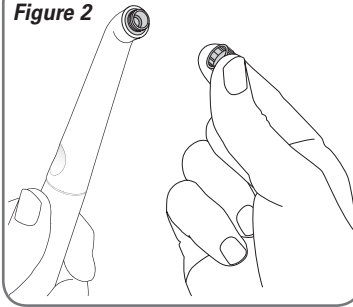


Figure 4

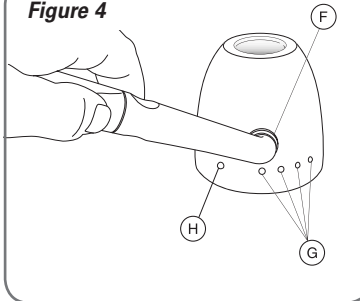


Figure 3

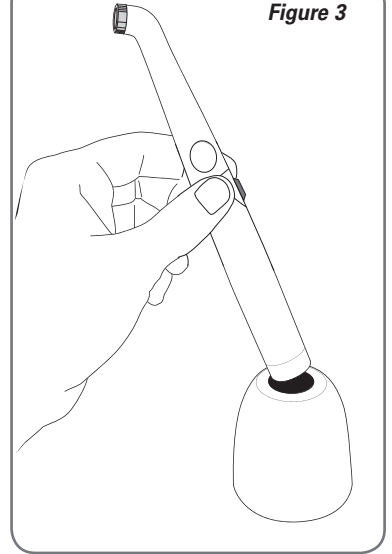
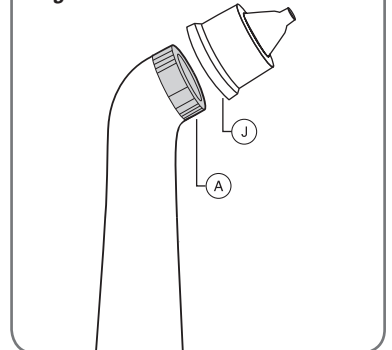


Figure 5



- A. Lens Cap
- B. Extension
- C. On/Off Switch
- D. Base Handle
- E. Charger Base
- F. Radiometer Aperture
- G. Output Intensity LEDs
- H. Charger Status LED
- I. AC/DC Wallplug Adapter
- J. Tacking Tip

Product Description

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



Precaution:

The curing intensity of the Flashlite LED Curing Light can result in build up of heat around the tip of the device. Prospective users are asked to take extra precaution to prevent direct contact with the skin, oral mucous membrane, or the gingiva during use. ***This device is for professional use only.***

Contents* (See Illustrations on page 2.)

- AC/DC Wall Plug Adapter
- Charger Base with Built-in Radiometer
- Flashlite LED Curing Light
- Three Replacement Lens Caps
- One Triangular Multi-tiered Hardness Curing Disk
- Instruction Manual
- Light Shield (included with Flashlite Magna 4.0)
- Tacking Tip (pack of 5)

* Additional Accessories Available

Note: International units include power adapters.



Class II Equipment



Type B Applied Part
(The applied part is the extension of the handpiece)



Caution Consult
Accompanying
Documents



Recycle or Dispose of Properly



LED Light



Direct Current



Not for use in oxygen
rich environment



Users must read
Instruction Manual

Technical Data

Flashlite Magna 4.0

Battery:	Lithium-Ion
Wavelength Range:	440-490 nm
Light Intensity:	1300 mW/cm ² ±200
Total Continuous Runtime with Fully Charged Battery:	120 minutes
Dimensions:	Diameter: .86 in / 22 mm Length: 8.6 in / 219 mm 4.3 oz / 121 g
Weight:	

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/cm ² ±200
Total Continuous Runtime with Fully Charged Battery:	210 minutes
Dimensions:	Diameter: .86 in / 22 mm Length: 7.8 in / 198 mm 3.8 oz / 105 g
Weight:	

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%

LED Dental Curing Lights



Warnings and Precautions

1. The Flashlite LED 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 LED 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 LED 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 LED 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 and dentist 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.

RISK GROUP 2

CAUTION: Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes.

WARNING: No modification of this equipment is allowed.

Classification

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

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 LED Curing Light into the charger base. Allow the Flashlite LED 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 LED Curing Light. These form a Medical Device System. The Flashlite Curing Light device is used separately after fully charged.

Operation

The Flashlite LED Curing Light is supplied with the lens cap attached. A button on the Flashlite LED 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: The curing intensity of the FLASHlite LED 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.

Duty Cycle

Flashlite Magna 4.0 – Intermittent use of 10-20 seconds curing times with twice the cooling time.

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

The Flashlite LED 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.

WARNING: Rated for non-continuous operation

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 LED Curing Light. It is recommended that the lens cap be replaced every 2-4 weeks.

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 LED Curing Light by assembling the shield over the tip and sliding into place.

Tacking Tip (See Fig. 5)

Take a tacking tip to redirect 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.

Note: The Tacking Tip is disposable and should be replaced after every use.

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.**

Multi-Tiered Triangular Hardness Disk

The multi-tiered triangular hardness disk enables you to measure various depths of composite shades. Each point of the triangle offers a different depth (2, 3 or 4 mm). The triangular disk is made of a plastic material, which mimics the properties of cured composite. To measure the depth of cure, place the desired amount of composite into the appropriate tip well of the “cure” side of the triangle. Cure the material for the length of time suggested by the manufacturer. Next, check the hardness of the cured material by scraping the “test” side surface with a tungsten carbide instrument. Measure its hardness against that of the surrounding surface of the disk. The surface of the cured material should feel equal to or harder than that of the disk material. The disk has a Barcol hardness of 75 +/- 5 and represents a complete cure.

Charger with Built in Radiometer

To charge, place the Flashlite LED 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 LED Curing Light can be used.

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

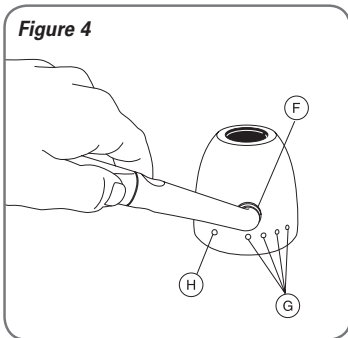
LED Dental Curing Lights

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 LED 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 light up, 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 LED Curing Light. Portable and/or handheld radiometers have been shown to have variability in accuracy and precision in measuring total spectral output.

Accessories and Replacement Parts

Flashlite Magna 4.0 LED Curing Light CR1079

Part No.	Description
CR1082	Replacement Lens Caps (pack of 25)
CR1083	Charger Base
CR1074	AC/DC Wallplug Adapter
CR1075	Tacking Tips (pack of 5)
CR1077	Light Shield
CR1078	Barrier Sleeves (pack of 500)

Flashlite 2.0 LED Curing Light

CR1080

Part No.	Description
CR1024	Replacement Lens Caps (pack of 25)
CR1063	Charger Base
CR1074	AC/DC Wallplug Adapter
CR1075	Tacking Tips (pack of 5)
CR1077	Light Shield
CR1078	Barrier Sleeves (pack of 500)

Maintenance and Care

Keep the Flashlite LED 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 Disinfecting Agents:

- 70% Isopropyl Alcohol
- Mild Soap Solution

Avoid iodine based solutions.

Avoid wetting of internal parts.

Do not spray disinfecting solution directly onto the curing light. Dampen a clean cloth and wipe down the unit per your disinfectant product instructions. 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.

Transport and Storage

Ambient Temperature – 4°F to 104°F (–20°C to 40°C)

Relative Humidity 10% to 90% Non-condensing

Atmospheric Pressure .5 atm to 1.0 atm (500 hPa to 1060 hPa)

2-year Warranty

DenMat Holdings, LLC warranties your Flashlite LED 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.

Trouble Shooting Guide

Problem	Causes	Solution
1 Continuous slow beeps	Low battery.	Recharge battery. Light will turn off automatically when battery is low.
2 Continuous fast beeps	Device too warm.	Place device in the charger. Allow device to cool.
3 No light, no beeps	Device malfunction or very low battery.	Recharge battery. Contact customer service.
4 No light, one beep	Device in charger.	Device will not turn on when in charger. Remove the device from the charger to operate.
5 Lens cap cracked	Damage due to dropping. Damage due to cleaning material over-exposure. Wear and tear.	<ol style="list-style-type: none"> Carefully remove lens cap Replace with new lens cap.
6 Light is completely charged (green indicator), but beeps while in use	Handle bottom or charger pins contaminated with debris.	<ol style="list-style-type: none"> Unplug the charger base. Wipe pins in the base to remove debris. Do not allow any liquid to drip into the base. Check bottom of handle for debris. Wipe with dry cloth to remove debris. Plug in charger base and place hand held device into base.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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.

Emissions	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11 Power Line Harmonics IFC/EN 61000-3-2	Group A Group A	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:
Power Line Harmonics IFC/EN 61000-3-2	Complies.	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.