

Instruction Manual

For Sales Orders and Product Information Contact:

Manufactured by:

Den-Mat[®] Holdings, LLC 2727 Skyway Drive Santa Maria, CA 93456

Distributed by:

Den-Mat* Holdings, LLC 2727 Skyway Drive Santa Maria, CA 93456 Tel: 800-445-0345 info@denmat.com www.denmat.com

International:

international@denmat.com

Or contact your local distributor for further information.

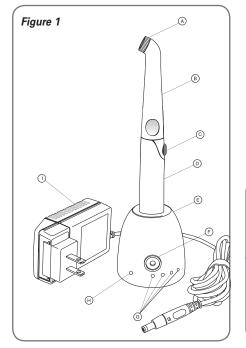


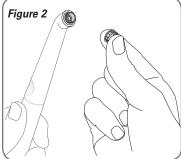


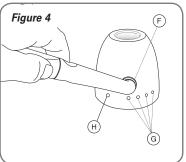


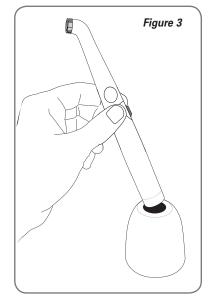




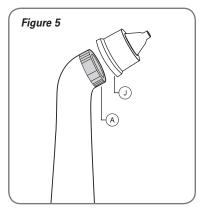








- A. Lens Cap
- B. Extension
- C. On/Off Switch
- D. Base Handle
- E. Charger Base
- F. Radiometer Aperture
- G. Output Intensity LEDs
- H. Charger Status LED
- I. AC/DC Wallplug Adapter
- J. Tacking Tip



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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).



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)

Note: International units include power adapters.



Class II Equipment



Type B Applied Part



Caution Consult Accompanying Documents



Recycle or Dispose of Properly



LED Light

Direct Current

Technical Data

Flashlite Magna 4.0

Battery: Lithium-lon
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)

Flashlite 2.0

Battery: Lithium-Ion
Wavelength Range: 460-480 nm
Light Intensity: 1100 mW/cm²±200

Total Continuous Runtime with Fully Charged Battery:

Fully Charged Battery: 210 minutes

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)

^{*} Additional Accessories Available





Safety

- The Flashlite LED Curing Light must be used in strict accordance with the following operating instructions. Den-Mat[®] Holdings, LLC accepts no liability for any damage resulting from the use of this unit for any purpose.
- Exposure must be restricted to the area of the oral cavity in which clinical treatment is intended.
- Use only chargers and adapters supplied for Flashlite LED curing lights. 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.
- Do not allow cleaning agents to directly enter the unit as this may cause premature failure. See Maintenance and Care.
- Only a Den-Mat® Holdings, LLC authorized representative can service the unit. Please call Den-Mat Holdings, LLC with any questions. Phone numbers are on the back of this manual.
- 6 Do not use on patients with a history of photo biological conditions including urticarial solaris or erythropoetic protoporphyria or who are on photosensitizing medications.
- Suitable blue-light filtering safety goggles must be worn by patient and dentist during use.
- 8. Do not stare at operating curing light. May be harmful to the eyes.

RISK GROUP 2

CAUTION: POSSIBLY HAZARDOUS OPTICAL RADIATION EMITTED FROM THIS PRODUCT

Classification

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

FFC Statement

This device complies with part 15 of the FFC 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. Insure all parts contained within package match the contents list.
- 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 Techical Data for charge times. Indicator will turn green when unit is fully charged. Store light in charger when not in use.

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.

Duty Cycle

Intermittent use of 10 to 40 second curing times, with twice the cooling time, within maximum of 6 minutes.

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.

Note: Your Flashlite LED Curing Light has been designed for continuous use without thermal shut-down.

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Audible beeps will occur every 10 seconds during operation. 1 beep indicates 10 seconds, 2 beeps indicates 20 seconds, etc. 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 LED Curing Light. It is recommended that the lens cap be replaced every 2-4 weeks.

Barrier Sleeve

To provide optimum protection, we recommend you apply a clean plastic barrier sleeve for each new patient use.

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

By using the tacking tip, light will be redirected to cure only a small amount of product (approximately 2mm radius). (see Figure 5)

- Inspect the Lens Cap prior to each use. Make certain it has no blemishes, scratches, cracks or foreign substances that may impair the optical output of the Flashlite LED Curing Light. If so, replace lens cap with a new one.
- 2. Take a new Tacking Tip. 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.

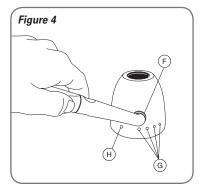
For optimal performance, place the Flashlite LED Curing Light back in charger base when not in use.

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





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 4.0 Magna LED C	Curing Light	CR1069

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of 500)
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Flashlite 2.0 LED Curing Light CR1050

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Part No.	Description
CR1024	Replacement Lens Caps (pack of 25)
CR1053	Charger Base
CR1054	AC/DC Wallplug Adapter
CR1075	Tacking Tips (pack of 5)
CR1077	Light Shield
CR1078	Barrier Sleeves (pack of 500)
22-2200	Hardness Disk

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:

- ≤ 3.4% Gluderaldehyde solution
- 70% Isopropyl alcohol
- 1.5% Phenol
- Ethanol 25-50%
- Quaterary ammonium

Take care to avoid wetting internal parts.

Avoid iodine based solutions.

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.

Flashlite recommends using a barrier sleeve over the unit prior to each use. Please reference product accessory number CR1078.

Disposal: Dispose of device with its internal battery according to the corresponding legal requirements in your country. 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

Den-Mat 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 Den-Mat 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.

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4. Plug in charger base and place hand held device into

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 inb 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.	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.	 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.

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.