

Instructions

DermLite II Multispectral Pocket Epiluminescence Device

CAUTION: Prior to using the DermLite II Multispectral, read these instructions and keep them in a safe place for future reference.

CAUTION: United States Federal Law restricts this device to sale by or on the order of a physician.

CAUTION: The DermLite II Multispectral is designed for external examination only.

Introduction

The DermLite II Multispectral is a pocket epiluminescence microscopy (PELM) device designed to view skin lesions with high magnification and clarity. A 25mm 10x lens combined with a cross-polarized four-color illumination system, allowing independent activation of four sets of eight LEDs, provides for ideal skin microscopy. While one set of eight LEDs produces glare-free white light for a daylight-type rendition of the skin, three other sets each produce unique colored light, which penetrate different skin depths, ranging from the shallow blue, and yellow to the deep red light frequency. A high quality lens with superb color correction and reduced image distortion is used to image the skin. To facilitate the use of immersion fluids, and allow for fixed digital imaging, the unit is equipped with a retractable faceplate spacer.

Directions for Use

CAUTION: Do not look directly into the bright LED light. Patients must close their eyes during facial examinations.

IMPORTANT: Before initial use, please charge the internal lithium ion battery for a minimum of 4 hours using the charger provided.

Hold the DermLite II so that the LEDs are aimed in the direction of the lesion to be examined. Place the device approximately 1" (~25mm) from the skin. Push and hold the power button (A) at the left side of the unit for 2-3 seconds to activate the LEDs.

Look through the lens with your eye placed 1" (~25mm) to 4" (~100mm) above the DermLite II. Move the device closer or further away from the lesion to obtain the desired image focus. For oil immersion imaging, or for camera use, rotate the spacer dial (B) so that the white marker is at the 12 o'clock position. For fine focusing within a range of +/- 1mm, simply rotate the dial to the left or right between the 11 and 1 o'clock markers (C).

CAUTION: If the DermLite II Multispectral is used for oil immersion imaging, place the oil only on the skin and then place the extended faceplate spacer on top of the oil. Do not allow oil to contact the USB port, DC charging port, or battery compartment.

To attach the DermLite II Multispectral to a camera, the device is equipped with a 28mm thread (D). A simple ring adapter (such as a 28-37mm stepping ring) may be required to adapt the device to your camera of choice. Please contact 3Gen or a photographic retailer for more information.

Removable Faceplate (E)

The DermLite II Multispectral is equipped with a removable faceplate. To remove this piece, rotate the spacer dial (B) to extend the spacer, and twist off the small ring in the very front of the spacer.

Light Frequencies

The button located on the right side labeled "MODE" (F) lets you toggle between four sets of eight LEDs with distinct light frequency. Each time the device is turned on, cross-polarized white light, used to examine deeper pigmentation, is automatically active. For skin surface visualization using blue light, push the "MODE" button once. To activate the yellow light, push the button again, and a third time to achieve red illumination. Push the button once again to toggle back to white light.

Rechargeable Battery

After a minimum 4-hour initial charge, the lithium-ion battery provides up to 2 hours of continuous operation, or enough power for imaging approximately 600 lesions at 30 seconds per examination. Once the battery is depleted, the unit will automatically shut off, and will need to be recharged. Plug the charging cord into the round DC charging port (G), and the red charging indicator (H) will illuminate. Once the battery is fully charged, the green indicator will light up (I). Optionally, you may use a USB cable to charge the unit via the USB port (J).

CAUTION: When charging with a USB cable, the DermLite II Multispectral must be connected only to the USB port of a computer that complies with the IEC / EN 60950 standard to ensure continued compliance of the product with the European Medical Device Directive. Refer to the operator's manual provided with your computer to

ensure that the computer complies with the above standard.

After approximately 1,000 charges, the battery's capacity will diminish and the battery may need to be replaced. To remove the battery door (K), push down on the two ovals (L) with your thumbs and slide the battery door back. Disconnect the small white battery plug, and remove the battery. Insert a new battery and reconnect the battery plug. Replace the battery door securely on the device.

The DermLite II Multispectral uses a special lithium-ion battery, which can only be purchased from 3Gen or from an authorized 3Gen dealer.

CAUTION: Do not under any circumstances use another battery other than the one designed for this unit. Doing so could result in damage to the unit. Also, do not under any circumstances use another charger other than the one supplied with the unit.

Troubleshooting

Please check our website (www.DermLite.com) for the most current troubleshooting information.

If you need to return the DermLite II Multispectral to 3Gen for servicing, please call 3Gen prior to returning the device, and a unique Return Merchandise Number (RMA) will be issued to you.

No Light

Fully recharge the battery and check again. If the condition persists, send the unit to 3Gen for evaluation and/or repair.

Weak Lighting

Recharge the battery.

LED Fails

The LEDs used in the DermLite II Multispectral are designed to last over 100,000 hours. If any of the 32 LEDs fail, contact 3Gen for repair.

Mechanical Malfunction

Please contact 3Gen to arrange for service.

Care and Maintenance

The DermLite II Multispectral is designed for trouble-free operation. There are no adjustments to be made nor is any special servicing required. Never attempt to open the device for any reason.

Cleaning and Sterilization

The DermLite II Multispectral body may be cleaned or disinfected by wiping it with Isopropyl alcohol (70% vol.). Do not use alcohol or disinfectants in the optical areas of the unit. Do not use abrasive material on any part of the equipment or immerse the device in liquid. Do not autoclave.

Cleaning the Lens and the Polarizers

The lens and the polarizing filters should be treated as high quality photographic equipment and should be cleaned with standard lens cleaning equipment and protected from harmful chemicals.

Specifications

The patent-pending DermLite II Multispectral features an innovative optical microscopy system designed for superb clarity and outstanding vision.

DermLite II Multispectral components include:

- Eight 3mm LEDs each of: White, Blue (470nm), Yellow (580nm), Red (660nm)
- 25mm Lens with 10x Magnification
- Fixed Cross-Polarization
- Retractable Faceplate Spacer with 10mm Scale
- Lithium-Ion Battery

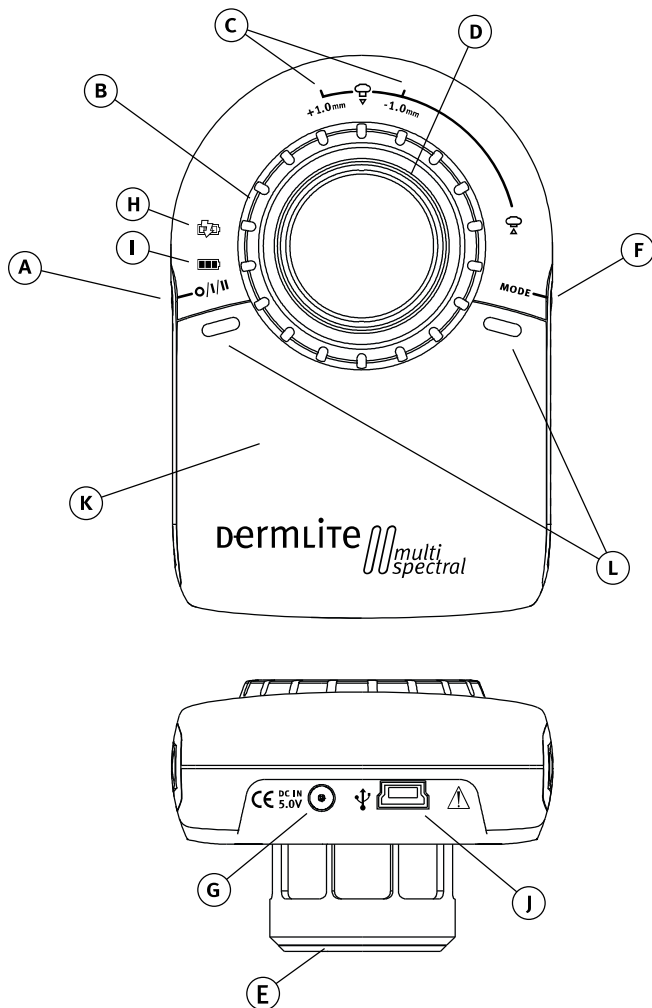
Warranty

5 years for parts and labor.

Serial number and company information are located inside the battery compartment.

3Gen

dermLite® multi spectral



DermLite is a registered trademark of

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Symbol Explanation

REF Model Number

SN Serial Number

Attention, consult accompanying document

Manufacturer

EC Representative (EU Only)

M. Devices Group, Marlborough House, Riding Street, Southport, PR8 1EW, UK. Tel: +44 1704 544 944 Fax: +44 1704 544 050

Power Button

Charging Indicator

Battery fully charged

Spacer fully extended

Spacer fully retracted

USB Charging Port