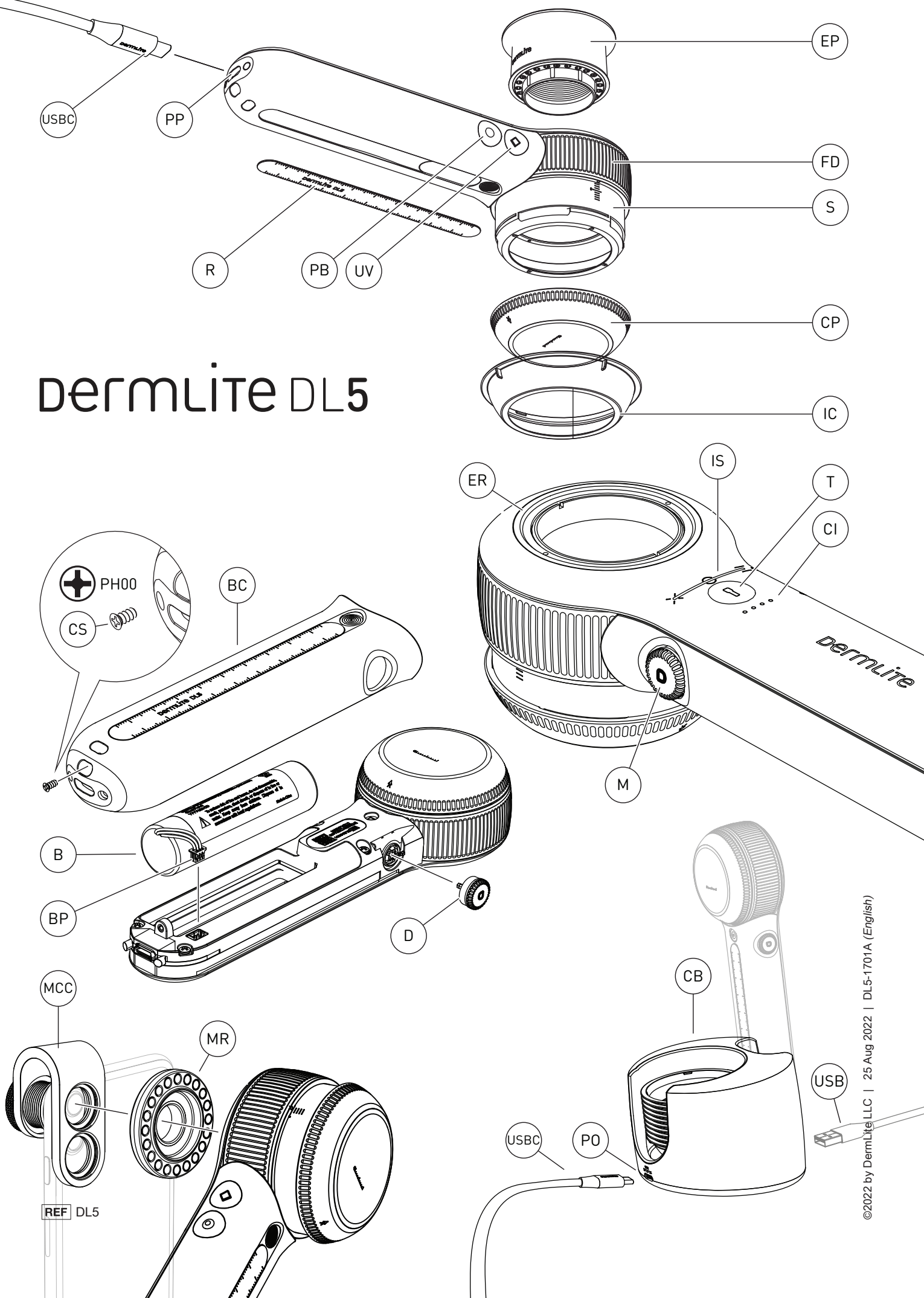


# dermLite DL5

## Instructions

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## Intended Use

This device is intended for medical purposes to illuminate body surfaces. It is used for non-invasive visual examination of intact skin.

This battery-operated product is designed for external examination only within professional healthcare facilities by medical professionals.

Check the correct operation of the device before use! Do not use the device if there are visible signs of damage.

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

In case of a serious incident with the use of this device, notify DermLite immediately and, if required by local regulations, your national health authority.

**CAUTION:** Do not use the device in fire or explosive risk area (e.g. oxygen-rich environment).

Caution: UV Light. Do not look directly at light.

**CAUTION:** This product contains magnets. Do not use in proximity of pacemakers or other magnetically sensitive devices or items.

**WARNING:** This product can expose you to chemicals including methylene chloride and hexavalent chromium, which are known to the State of California to cause cancer or reproductive toxicity. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

## Electromagnetic Compatibility

This device complies with the EMC Emissions and Immunity level requirements of the standard IEC 60601-1-2:2014. The emission characteristics of this equipment make it suitable for use in professional healthcare environment as well as residential environment (CISPR 11 Class B). This equipment offers adequate protection to radio communication service. In the rare event of interference to the radio communication service, the user might need to take mitigation measures, such as relocating or re-orienting equipment.

**WARNING:** 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.

**WARNING:** Use of accessories other than those 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.

**WARNING:** Portable RF transmitters should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the performance of this equipment could result.

Do not use this device during magnetic resonance imaging (MRI) or in an MRI environment.

**IMPORTANT:** Before initial use, please charge the internal lithium ion battery. See "Battery and Charging" for details.

DermLite DL5 is a smartphone-compatible pocket dermatoscope with 10x magnification for visualizing skin structures using variable polarized light and UV illumination.

Hold your DermLite DL5, with the LEDs aimed in the direction of the lesion to be examined, approximately 12 mm above the skin. Push the main button (M) to turn on the device in cross-polarized mode. Look through the lens and move the device closer or farther away from the skin to focus the image. For dermoscopy with skin contact, rotate the Focus Dial (FD) to extend the Spacer (S) and focus the image. Push and hold the main button (M) for about 1 second to turn off the device. To save power, the unit automatically turns off after 3 minutes.

## Variable Polarization

Tap the main button (M) to toggle between cross-polarized and non-polarized illumination. Turn the main button to move through the range of 9 polarization settings, from cross-polarized via non-polarized to parallel-polarized light. The indicator strip (IS) reflects the current polarization status, whereas "X" marks cross-polarized, "0" represents non-polarized, and "=" stands for parallel polarization.

## PigmentBoost®

While white light is active, tap (PB) to activate the orange-colored PigmentBoost lighting in addition to white light. The indicator LED next to the PB button (PB) will illuminate. Tap again to deactivate.

## UV Mode

To visualize fluorescing structures, tap the UV button (UV) to activate LEDs with a wavelength of 365 nm. The indicator LED next to the UV button (UV) will illuminate. Tap the button again to return to the previously selected white-light mode.

## Torch

To illuminate larger skin areas or body cavities, tap the torch button (T) to activate an ultra-bright white non-polarized LED. Turn the main button (M) to adjust torch brightness.

## Dermoscopic Brightness Adjustment

To adjust the brightness of the white dermoscopic LEDs, hold the torch button (T) and simultaneously turn the main button (M). While in UV or PigmentBoost mode, push & hold the UV (or PB) button and turn the main button to adjust the respective brightness. The indicator bar (IB) reflects the current brightness level during the adjustment.

## Eyepiece

For optimal viewing affix the included magnetic eyepiece (EP) at the extension ring (ER).

## Smartphone Dermoscopy

For dermoscopy using a smartphone or tablet, securely fasten the MagnetiConnect clamp adapter (MCC) to your mobile device, ensuring concentric alignment with its main camera. Attach your DL5 to the MCC ring. Prior to taking images, extend the spacer (S) to the "0" position, and wipe the glass contact plate (CP) clean.

## Removing the Contact Plate

Turn the glass contact plate (CP) counterclockwise to detach, turn it clockwise to reattach.

## Ruler

The ruler (R) is magnetically attached to the handle. Press down in the middle of the ruler and remove it to measure skin lesions.

## IceCap®

To support your infection control measures, snap one of the included disposable IceCaps (IC) over the installed faceplate (FP). To remove and dispose, simply pull it off.

## Battery and Charging

**CAUTION:** This device uses a special 3.7V 3000mAh lithium ion battery, which can only be purchased from DermLite or from an authorized DermLite dealer. Do not under any circumstances use another battery other than the one designed for this unit.

This device is equipped with a four-level Charge Indicator (CI). When the unit is turned on and fully charged, all four LEDs light up. When less than 75% of battery life remains, three LEDs are illuminated. If more than half the battery is drained, two LEDs are on, while a single LED indicates that less than 25% of battery capacity remains. To charge your device, connect the supplied USB-C to USB cable to the Charging Port (CP) and any IEC 60950-1 compliant (5V) USB port. The Charge Indicator (CI) pulses to indicate charging, with the number of pulsing LEDs corresponding with charge level. When charging is complete, all four indicator LEDs illuminate. After years of use, you may wish to re-place the battery, which is only available directly from DermLite or an authorized DermLite dealer.

After hundreds of charges, the battery's capacity will be reduced to the point where it may be more convenient to replace the battery. To change the battery (B), pull off the dial (D) by grabbing it at the fingernail notch, unscrew the cover screw (CS) using the tool supplied with each DL5 replacement battery, and sliding the battery cover (BC) off the device. Disconnect the small white battery plug (BP) and remove the battery (B). Insert a new battery, reconnect the battery plug, reattach the battery cover (BC), secure it with the cover screw (CS), and push the dial (D) in until it snaps into place.

## Charging Base

To charge your DL5 using the charging base, attach the smaller (USBC) end of the supplied USB cable to the power port (PO) on the back of the charging base (CB), and the larger (USB) end to any IEC 60950-1 compliant (5V) USB charger. Place your DL5 into the charging base, with the contact plate (CP) facing towards the charging base. The charging base is equipped with a USB charging port (CP) which may be used to charge your smartphone or other DermLite devices. The charging base may also be used for IceCap storage.

## Troubleshooting

Please check [www.derm-lite.com](http://www.derm-lite.com) for the most current troubleshooting information. If your device requires servicing, visit [www.derm-lite.com/service](http://www.derm-lite.com/service) or contact your local DermLite dealer.

## Care and Maintenance

**CAUTION:** No modification of this equipment is allowed.

Your device is designed for trouble-free operation. Repairs shall be made only by qualified service personnel.

## Cleaning

The exterior of your device, except the optical parts, may be wiped clean with isopropyl alcohol (70% vol.) prior to use on a patient. The lens should be treated as high-quality photographic equipment and should be cleaned with standard lens cleaning equipment and protected from harmful chemicals. Do not use abrasive material on any part of the equipment or immerse the device in liquid. Do not autoclave.

Warranty: 10 years for parts and labor. The battery is warranted for 1 year.

## Disposal

This device contains electronics and a lithium-ion battery that must be separated for disposal and may not be disposed of with general household waste. Please observe local disposal regulations.

## This set includes:

DermLite DL5 (16 white LEDs, 4 UV LEDs, 4 PigmentBoost LEDs, 1 white Torch LED, 32 mm lens system with 10x magnification, variable polarization system, retractable spacer, removable faceplate with 10 mm reticle, steel ruler), leather belt case, USB charging cable, charging base, magnetic eyepiece, MCC mobile device adapter, plastic belt holster (H), 5 IceCaps, microfiber cloth.

## Technical Description

Visit [www.derm-lite.com/technical](http://www.derm-lite.com/technical) or contact your local DermLite dealer.

# Explanation of Symbols



Manufacturer



Catalog Number



Serial Number



Date of Manufacture



Do not dispose as unsorted municipal waste



Temperature limits in °C for storage and transport



Humidity limitation for storage and transport



Pressure limitation for storage and transport



Follow instructions for use



Product complies with European Medical Device Regulation (2017/745)



Caution: Federal law (USA) restricts this device to sale by, or on the order of, a licensed healthcare practitioner



Type B applied part



Keep dry!



Medical Device



European authorized representative



Direct Current



Caution: UV Light. Do not look directly at light.



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