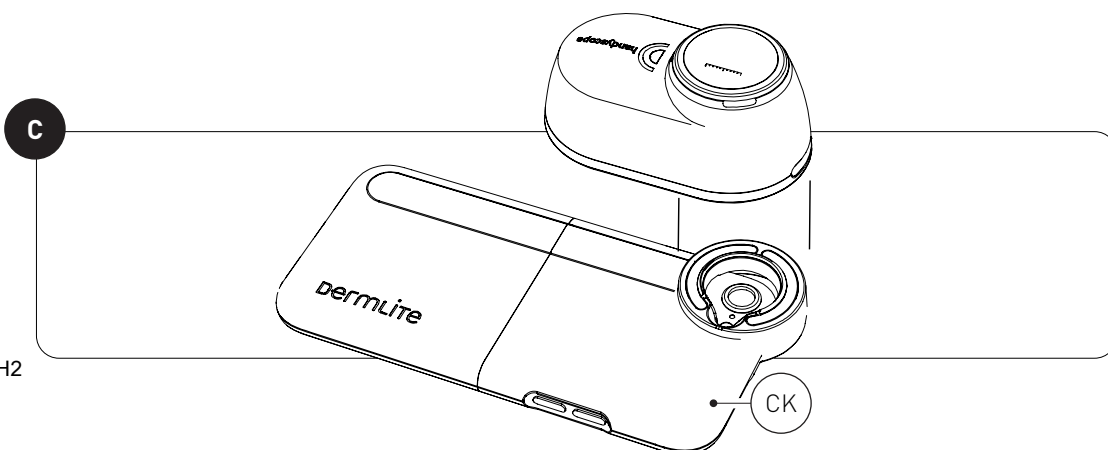
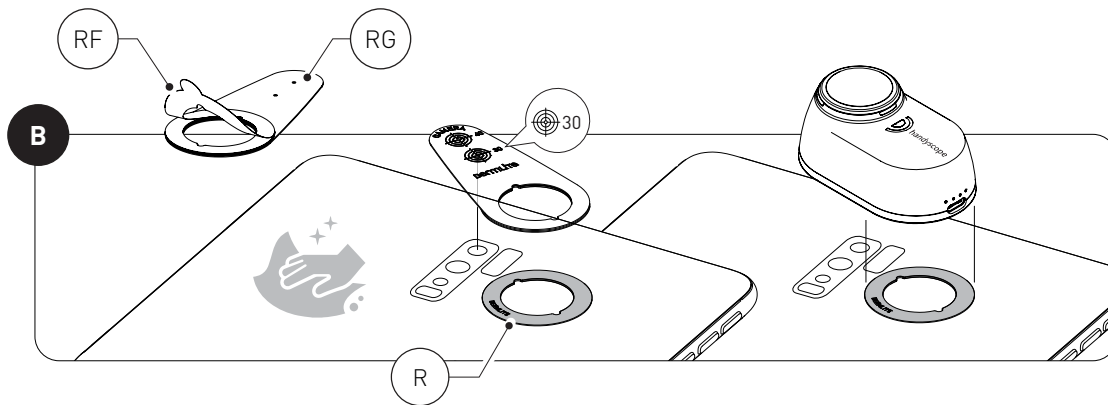
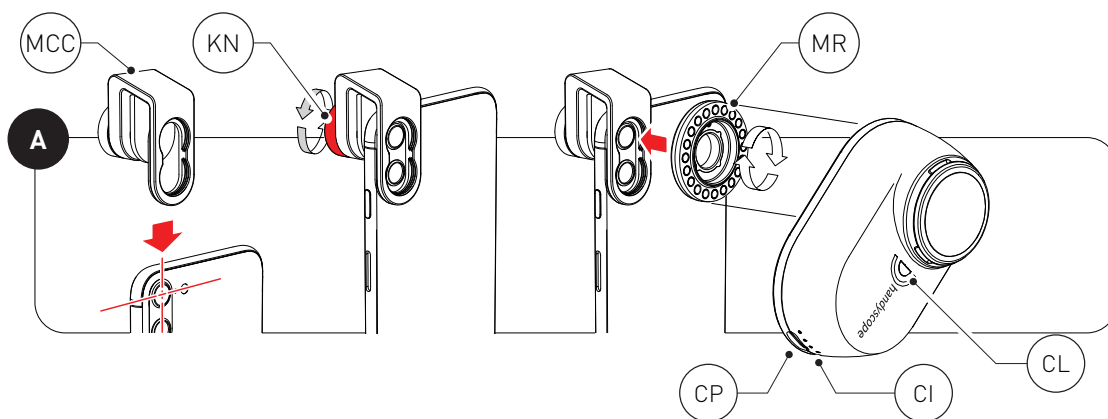


dermLite handyscope



Instructions

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: This product contains magnets. Do not use in proximity of pacemakers or other magnetically sensitive devices or items. **WARNING:** Do not use this item with any Qi wireless charging products. The metal parts may cause extreme heat resulting in burns and/or damage to your device.

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.

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.

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. Any changes/modifications to this equipment not approved by DermLite could void the user's authority to operate the equipment. **IMPORTANT:** Before initial use, please charge the internal lithium ion battery. See "Battery and Charging" for details.

Directions for Use

DermLite handyscope® is a smartphone dermatoscope with polarized and non-polarized light, clinical illumination and wireless functionality. It may be attached to most smartphones & tablets using the included MagnetiConnect® Clamp adapter (MCC). For certain mobile devices with a backside not made of glass, the included adhesive ring (R) adapter may be used.

Using the MagnetiConnect Clamp Adapter (Fig. A)

Position the clamp (MC) over your smartphone's main camera, then fasten it by tightening the knob (KN). Attach the threaded magnetic ring and place DermLite handyscope on it.

Using the Adhesive Ring (Fig. B)

If your device has a backside not made of glass, you may use the adhesive Ring (R). Center the 30 mm crosshairs of the supplied Ring Applicator (RA) over the camera and determine if your smartphone or tablet computer (or its case) has a flat, unobstructed area for placing the steel Ring (R). If so, clean the area with the included isopropyl alcohol wipe, remove the ring's adhesive film (RF) to expose its adhesive and press the Ring firmly on your device while keeping the crosshairs aligned over your camera. Remove the Ring Applicator. Place Handyscope on the Ring, aligning its lens with your smartphone camera. Handyscope will 'click' into place when properly placed.

Using the DermLite Connection Kit (Fig. C)

Handyscope may also be used with DermLite Connection Kits (CK), which are designed specifically for each iPhone model and sold separately.

Using DermLite handyscope

Press the power button (P) to activate the unit in polarized mode, press it again to activate non-polarized light. For clinical illumination, press the power button a third time. For best dermatoscopic results, contact the skin lesion with the center of Handyscope's glass contact plate (FP) and avoid using zoom. Push and hold the button for about 1 second to turn off the unit. In order to save power, the device turns off automatically after 3 minutes.

Glass Faceplate

The snap-on glass faceplate (FP) may be removed at the fingernail notches (FN).

Smartphone Pairing

To wirelessly pair Handyscope with your smartphone, refer to a Handyscope-compatible app.

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 670 mAh 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. To change the battery, contact DermLite or your local DermLite dealer.

Troubleshooting

Please check www.derm-lite.com for the most current troubleshooting information. If your device requires servicing, visit 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: 5 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.

The Handyscope set includes:

Handyscope smartphone dermatoscope (3 polarized, 3 non-polarized LEDs), MagnetiConnect® Clamp (MCC), 2 snap-in glass contact plates, 3 Ring Applicators with adhesive Ring, soft carrying case, lanyard, IceCap sample supply, USB to USB-C charging cable

Technical Description

Visit www.derm-lite.com/technical or contact your local DermLite dealer.