

HEINE QUALITY
MADE IN GERMANY

HEINE® iC1



CE



V-200.00.037



Please read and follow these instructions for use of and keep them for future reference.

Intended use

iC1 dermatoscope

The iC1 dermatoscope is an internally powered medical examination light. It is an reflected-light microscope for non-invasive, visual inspection of intact skin by a healthcare professional. The diagnostic is not limited to any patient demography.

iC1 dermatoscope with mounting case smartphone option

The optional mounting case for the iC1 dermatoscope enables an integration of a smartphone which optimizes the macrophotography. The digitized image display takes place within the technical capabilities of the smartphone and in its range of application and is solely for documentation and training purposes.

For U.S. only:

 Federal law restricts this device to sale by or on the order of a Physician or Practitioner.

Warnings and Safety Information

 **CAUTION!** Indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color yellow; foreground color black).

 **NOTE!** Note indicates valuable advice in terms of installation, operation, maintenance or repair. Notes are important, but not related to hazardous situations.

Product overview



- 1 Contact plate with scale
- 2 Filter insert
- 3 Toggle switch
- 4 Micro USB-charging port

- 5 Charge indicator
- 6 On/Off switch
- 7 Mounting case smartphone

Setting up

Assembly of filter insert and contact plate

Attach the insert (2) to the contact plate (1) and rotate the insert to lock the bayonet connection. To disassemble the filter (2) from the contact plate, reverse the procedure.

Attachment of contact plate

The contact plates (1) are attached by a bayonet connection. To remove the contact plate turn it counterclockwise and pull it away from the dermatoscope. To attach, reverse the procedure. Always check whether the bayonet is safely locked.

Setting up smartphone

Insert the smartphone into the appropriate mounting casing so it is firmly seated. Make sure that the camera is in the correct position.

To avoid any possible malfunctions, please deactivate all services (flight mode).

Images for documentation purposes can be taken with the standard camera app on your smartphone. Also, please deactivate the internal flash of the phone.

Operation

The iC1 allows for a rapid change from polarized to non-polarized examination mode over a toggle switch. The difference is that no immersion fluid is required in the polarized examination mode. The default setting is the polarized mode.

Turn the dermatoscope on by using the on/off switch (6). Gently place the instrument so that the lesion is in the center of the contact plate.

For non polarized mode

Prepare the skin by moistening with HEINE dermatoscopy-oil (use a cotton swab) or disinfectant spray.

 Always use the device in combination with the filter inserts. Only use contact plates from HEINE.

Switch off the device after each examination.

Brightness control

The electronic voltage regulation in the dermatoscope guarantees a constant brightness.

 An electrical conducting connection between smartphone, PC and a mains power source is not permissible during operation.

Charging

Charge indicator

First insert the power supply into the wall socket or PC and then the micro USB into the charging port (4).

When the iC1 is charged via USB, the LED will flash green.

When the battery is fully charged, the LED will be constant green.

When the battery reaches a critical charge state, the LED will light up orange. The device must now be recharged.

Charge the device outside of the patient environment (1.5 m).

Hygienic reprocessing

Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines.

Classification according to KRINKO: non-critical

Spaulding Classification USA: non-critical

 In the event of suspected contamination, carry out hygienic preparation of the instrument.

The described cleaning and disinfection measures do not replace the specific rules applicable for the establishment.

HEINE Optotechnik only approves the resources and procedures named in these instructions for use.

Cleaning and disinfection may only be carried out by personnel with sufficient hygienic knowledge.

Observe the instructions of the manufacturer of the reprocessing media.

Do not use spray or immersion disinfection, dripping wet or heavily foaming tissues.

Do not use ultrasonic reprocessing and don't sterilize.

Do not use reprocessing media including alcohol.

The contact plates have to be cleaned and/or disinfected after each use.

Procedure

Prior to hygienic reprocessing, turn the power off, remove the USB cable and extract the smartphone.

Ensure that moisture does not penetrate the area of the USB connector.

Dermatoscope

Clean and disinfect the dermatoscope manually (clean and disinfect through wiping).

Recommended agents

Cleaning agent: Neodisher® MediClean

Disinfectant agent: quaternary ammonium compounds (e.g. Cleanisept® Wipes or Microbac® Tissues)

Contact plate

Clean and disinfect the contact plate manually after removing it from the instrument (clean and disinfect through wiping).

Before cleaning or disinfection you must remove the filter insert.

Recommended agents

Cleaning agent: Neodisher® MediClean

Disinfectant agent: quaternary ammonium compounds (e.g. Microbac® Tissues)

Changing the light source

The LEDs cannot be changed.

Maintenance and service

The instrument does not require maintenance or service.

General warnings



Check the correct operation of the device before use! Do not use the device if there are visible signs of damage or the light begins to flash.

Do not use the device in fire or explosive risk area (e.g. oxygen saturated or anaesthetic environments).

Do not modify the device.

Use only original HEINE parts, spare parts, accessories and power sources.

Repairs shall only be carried out by qualified persons.

Do not look directly into the light source to avoid dazzle from the intense light. The dermatoscope is not suitable for eye examination.

General notes



The warranty for the entire product is invalidated if non-genuine HEINE products or non-original parts are used and if repairs or modifications are made to the device by persons not authorized by HEINE.

For more information, please visit www.heine.com.

Disposal



The product must be recycled as separated electrical and electronic devices. Please observe the relevant state-specific disposal regulations.

Electromagnetic compatibility

Medical electric devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). Portable and mobile high frequency communication equipment can affect medical electric devices.

 The iC1 dermatoscope, in connection with a smartphone, should not be used within the vicinity of life-sustaining medical devices.

This is a device in the domestic environment, this device may cause radio interference, so that it may be necessary in this case, to take appropriate remedial measures, as e.g. orientation, new arrangement or shielding of the device or restrict the connection to the site.

The use of accessories, converters or cables other than the ones specified by HEINE might lead to increased emission and reduced electrical immunity of the medical equipment.

The device (iC1 + smartphone) may not be stacked directly near or used directly beside other devices. If the device is to be operated in a stack or with other devices, the device should be watched to ensure it operates properly in this location.

The appendix contains following tables

- Guidance and manufacturer's declaration – Electromagnetic immunity
- Technical specification
- Explanation of the used symbols