



# Instruction for use HEINE DELTA X Dermatoscope





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

**Intended use**

The dermatoscope is a medical examination light with an internal power supply for non-invasive transient contact and non-contact examination of the skin as well as for trichoscopic examination. Skin changes can be examined. The examination of injured skin is only permitted in non-contact mode.

The device also has additional lighting for non-contact, non-invasive, and transient examination of the large areas of skin. The product may only be used by qualified medical professionals and in professional healthcare facilities. The application is not limited to any patient demography.

**Warnings and Safety Information**



**CAUTION!** This symbol indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations with moderate or severe extent. (Background color yellow; foreground color black)



**NOTE!** This symbol indicates valuable advice. This notes are important, but no related to hazardous situations.

**Product overview**



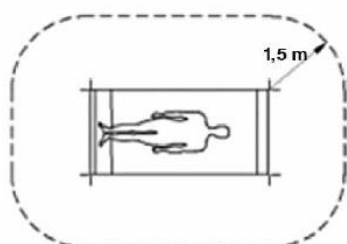
- |     |   |   |                                       |
|-----|---|---|---------------------------------------|
| 1   | Focusing ring with connector for the HEINE DELTA X Smartphone Adapter | 5 | Additional light                      |
| 2   | Operating elements  | 6 | Illumination / polarised illumination |
| 2a) | Illumination / polarised illumination                                 | 7 | Polarisation indicator                |
| 2b) | Additional light  | 8 | DELTA X CPP contact plate             |
| 2c) | On/Off  | 9 | DELTA X CPG contact plate             |
| 3   | Battery indicator   |   |                                       |
| 4   | Bayonet slot  |   |                                       |

**Setting up**

Charge the device fully before first use.

**Charging**

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



### Charging via USB-C

Use the equipment provided with the DELTA X Dermatoscope. Connect the USB cable to the USB-C port of the dermatoscope and the HEINE power supply.

### Using the charging station

For charging, insert the DELTA X into the X CS1 charging station. The charge indicator is located on the DELTA X.



Pay attention to the fact that no foreign objects are between the device and the charging station.

When using the DELTA X Dermatoscope, make sure that the charging station and the DELTA X Dermatoscope are not contaminated.

The setting up and operation of the charging station is described in a separate instruction of use.

### Battery indicator

A charge indicator is located on the handle side of the dermatoscope (3).

#### Battery indicator (3)

Device	Charger	Battery capacity	Charge indicator segments		
			Green - 1	Green - 2	Orange - 3
switched off	connected/ inserted	100 %	on	on	on
		full (99 % - 66 %)	flashing	on	on
		sufficiently charged (66 % - 33 %)	off	flashing	on
		empty (≤ 33 %)	off	off	flashing
switched on	not connected	full (≥ 66 %)	on	on	on
		sufficiently charged (66 % - 33 %)	off	on	on
		empty (33 % - 10 %)	off	off	on
		residual capacity (≤ 10 %)	off	off	flashing

### Operation

To switch on the illumination, press the button (2c) on the device. The device starts in polarisation mode. Alternatively, the dermatoscope can be switched on immediately with polarised illumination by pressing the button (2a).

Use the button (2b) to switch on the additional light.

The button (2c) is only used for switching off the device. Pressing this button switches off the dermatoscopic light or the additional light and the device.

If no button is pressed for 3 minutes, the instrument will automatically switch off.

#### Contact mode (with contact plate)

Place the contact plate (8, 9) on the device, making sure that it snaps into place. Please note that the cutout in the contact plate at the outer frame aligns with the additional light. The cutout is designed to allow the additional light to shine through.

Place the device with the contact plate onto the area of skin being examined. In polarised mode, the polarisation indicator (7) lights up blue. Use the polarisation button (2a) to switch to non-polarised mode. In this case, use a contact fluid such as immersion oil.



An unused DELTA X CCP contact plate must be used to examine the mucous membranes. This contact plate must be disposed after use. Under no circumstances should a DELTA X CPG contact plate be used for this use.

Do not use the contact plate, which is damaged.

#### Adjusting the focus in contact mode and non-contact mode

Your eye needs to be at a distance of approximately 2 cm from the focusing ring (1). Rotate the focusing ring until you see a sharp image. The image has 10-fold magnification.

#### Non-contact mode (without contact plate)

Take off the contact plate (8, 9) and hold the device at a distance of approximately 1 cm above the area of skin being examined. Use the polarisation button (2c) to switch to non-polarised mode.

#### Additional light in non-contact mode (with or without contact plate)

The additional light allows the illumination of the skin surface with and without the attached contact plate (8, 9). To operate, press button (2b).

### Reset of the device

If the device cannot be operated through the battery is sufficiently charged, press button (2a) and (2c) for 8 seconds.

### Option „Adapter Smartphone“

The "Smartphone Adapter" option can be used to mechanically connect a smartphone with a respective app. The app is designed for documentation by recording, storing and displaying images.

To connect the dermatoscope to a smartphone, you need a suitable adapter for your smartphone. Place the adapter onto the focusing ring (1). The adapter is held in place by magnetic force.

Install the corresponding app on your smartphone. The app is available in the App Store\*. To avoid any possible malfunctions, please deactivate all other services (switch on flight mode).

\*App Store is a service mark of Apple Inc.



Protecting patient data is users' sole responsibility (e. g. protection of the smartphone with a pin, data transmission via a secure connection). Ensure that your smartphone is adequately protected against access by third parties.

An electrical conducting connection between smartphone, PC and a mains power source is not permissible during the recording of the picture.



All images are saved exclusively on the smartphone in the app's sandbox. The user is responsible for the regular creation of a data backup to prevent data loss, which can happen for example through deleting the app or losing the smartphone. A data backup can be made via cable to another computer or via the network to the iCloud.

### Hygienic Reprocessing

The instruction is available:

- at [www.heine.com](http://www.heine.com)
- in a paper version which you can request from the address listed

### Maintenance

There is no regular maintenance required.

### Service

The device has no components serviceable by the end-user.

### 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](http://www.heine.com).

The expected life cycle amounts with designated use and the observation of warning and safety information as well as the maintenance instructions up to 7 years. Beyond this period, the product may continue to be used if it is in a safe and good condition.

Note to the user and/or patient:

All serious incidents that occur in connection with the product must be reported to HEINE Optotechnik GmbH & Co. KG and the member state's competent authority.

The device indicates the year of manufacturer. The service life starts from the first of January of the year of manufacturer.

Charge your device during longer storage periods to protect the battery from deep discharge.

Store and use the device only in a dry and dust-free environment.

The LOT number on the packaging refers to the contact plate.

After moving the device from a cold to a warm environment, allow sufficient time for it to acclimatize.

## General Warnings



Check the correct operation of the device before use! Do not use the device if there are visible signs of damage or flashing light or unusually bright or dimmed lightning.

Do not use the device in fire- or explosive risk area.

This product is not allowed to be entered or used in strong magnetic fields like MRI scanners.

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.

Use only CE marked USB power supplies (5 V) from reputable manufacturers that conform with the safety requirements from the IEC 60601-1 Medical electrical equipment.

Do not use power supplies or cables if you notice any damage.

Do not look directly into the light source to avoid dazzle from the intense light.

Eye examinations are not allowed with the dermatoscope.

Inform the patient that they must close their eyes during a facial examination.

Lay cables in a protected manner and ensure that no one can trip over them.

After opening the packaging, store the DELTA X CPP contact plate properly and protect it from contamination.

For separating the connection always pull on the plug, never on the cable.

## Disposal



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

The appendix contains following tables

- Electromagnetic disturbances – Requirements and tests
- Technical specification
- Explanation of the used symbols