

HEINE QUALITY
MADE IN GERMANY

➤ **HEINE DELTA[®]one**
HEINE DELTA[®]30




CE



V-200.00.324

HEINE DELTA[®]one

HEINE DELTA[®]30

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

Intended use

DELTAone and DELTA30 Dermatoscope

The dermatoscope is an internally powered medical examination light for non-invasive transient contact and non-contact examination of the skin.

In contact mode, skin showing a pathological change or a change due to a disease can be examined. The examination of wounds is only permitted in non-contact mode. The contact plate must be removed for non-contact mode.


It should only be operated by qualified medical personnel within a professional healthcare facility. The application is not limited to any patient demography.


DELTAone and DELTA30 Dermatoscope with "Smartphone Adapter" option

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.

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

Product overview

HEINE DELTA[®]one

- 1 On/Off switch
- 2 Focusing ring
- 3 Contact plate DELTAone
- 4 Micro-USB connector
- 5 Charge indicator
- 6 Brightness control (right)
- 7 Polarisation button (left)
- 8 Polarisation indicator



HEINE DELTA[®]30

- 9 On/Off switch
- 10 Polarisation button
- 11 Brightness control
- 12 Contact plate DELTA30
- 13 Focusing ring
- 14 Polarisation indicator
- 15 Micro-USB connector
- 16 Charge indicator

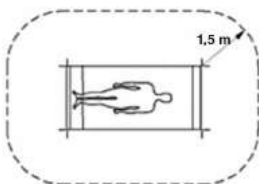


Setting up

Charge the instrument fully before first use.

Charging

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



Charging via USB (DELTAone and DELTA30)

Use a USB cable to connect the USB connector (4, 15) of the dermatoscope to a USB power supply (e.g. HEINE® E4-USB, PC or laptop).

Using the charging station (DELTA30)

Use the charging station to charge DELTA30. The blue LED on the charging station indicates contact with the dermatoscope. The charge indicator is located on DELTA30.

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

When using DELTA30, make sure that the charging station and DELTA30 are not contaminated.

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

Charge indicator

A charge indicator (5, 16) is located on the side or underside of the dermatoscope.


DELTAone

Instrument	Charger	Battery	Charge indicator
switched off	connected	charging	green, flashing
		full	green
switched on	not connected	full ($\geq 25\%$)	green
		empty ($< 25\%$)	orange
		residual capacity ($< 10\%$)	orange, flashing

DELTA30

Instrument	Charger	Battery	Charge indicator segments		
			Green - 1	Green - 2	Orange - 3
switched off	connected	100 %	on	on	on
		full (99 % – 66 %)	flashing	on	on
		sufficiently charged (66 % – 33 %)	off	flashing	on
		empty ($\leq 33\%$)	off	off	flashing
switched on	not connected	full ($\geq 66\%$)	on	on	on
		sufficiently charged (66 % – 33 %)	off	on	on
		empty (33 % – 10 %)	off	off	on
		residual capacity ($< 10\%$)	off	off	flashing

If the device is switched off, the charge indicator remains on for a further 3 seconds and then goes off.

 Do not look directly into the light source when checking the charge level.

Operation

To switch on the illumination, press the button (1, 9) on the instrument. The device starts with the last selected brightness level and in polarisation mode.

Press the button (6, 11) to adjust the brightness in three steps.

The device switches off automatically after 10 minutes if the polarisation buttons or the brightness control are not used.

Contact mode (with contact plate)

Place the contact plate (3, 12) on the instrument, making sure that it snaps into place.

Place the instrument with the contact plate onto the area of skin being examined. With DELTAone, extend the contact plate (3) over the focusing ring (2).

When carrying out examinations with polarised illumination, you do NOT need any contact liquid such as immersion oil or disinfection spray. In polarised mode, the polarisation indicator (8, 14) lights up blue.

Use the polarisation button (7, 10) to switch to non-polarised mode. In this case, use a contact fluid such as immersion oil.

Adjusting the focus in contact mode

Your eye needs to be at a distance of approximately 2 cm from the focusing ring (2, 13). 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 (3, 12) and hold the device at a distance of approximately 1 cm above the area of skin being examined. Use the polarisation button (7, 10) to switch to non-polarised mode.

Adjusting the focus in non-contact mode

Your eye needs to be at a distance of approximately 2 cm from the focusing ring (2, 13).

With DELTA30, rotate the focusing ring (13) until you see a sharp image.

With DELTAone, the focus is adjusted via the distance between the skin and the optics. There is no need to rotate the focusing ring (2).

The image has 10-fold magnification.

Smartphone Adapter


To connect the dermatoscope to a smartphone, you need a suitable adapter for your smartphone.

Place the adapter onto the focusing ring (2, 13). 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
- in a paper version which you can request from the address listed


Maintenance

The device is maintenance free.

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.

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.

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.

General warnings

 Use only CE marked USB power supplies (5 V) from reputable manufacturers that conform with the safety requirements from the IEC 60950-1 Information technology or IEC 60601-1 Medical electrical equipment.

Do not use power supplies where damage has been detected.

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).

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.

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

The dermatoscopes are not suitable for eye examination.

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