



Instruction for use

HEINE direct

ophthalmoscopes

DEUTSCH | ENGLISH | FRANÇAIS | ESPAÑOL | ITALIANO



HEINE Direct Ophthalmoscopes

ENGLISH

These instructions apply to the following products of the HEINE Direct Ophthalmoscope series: BETA 200 LED, BETA 200 S LED, K180 LED, mini 3000 LED.

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

Intended Use

HEINE Direct ophthalmoscopes are intended for transient examination of the media (cornea, aqueous humour, lens, vitreous humour) and retina of the eye. The instruments feature an optical examination system and an illumination unit powered by a battery or rechargeable battery. The product may only be used by qualified medical professionals and in professional healthcare facilities.

For U.S. only:
Federal law restricts this device to sale by or on the order of a Physician or Practitioner.

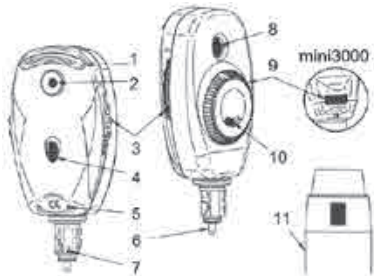
Warnings and Safety Information

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. This notes are important, but no related to hazardous situations.

Product overview

- 1 Spectacle rest
- 2 Viewing aperture
- 3 Lens wheel
- 4 Diopter readout
(plus = green or black,
minus = red)
- 5 Thumbrest
- 6 HEINE bulb
- 7 Connector
- 8 Viewing window
- 9 Aperture wheel
- 10 Filter selector
(interference red-free filter)
- 11 HEINE Handle



Lens wheel (3) correction values

BETA200 LED | K180 LED

+ in 1D steps: 1-10 | 15 | 20 | 40 | D
- in 1D steps: 1-10 | 15 | 20 | 25 | 35 D

BETA200 S LED

+ in 1D steps: +1 through +38 D
- in 1D steps: -1 through -36 D

mini3000 LED

+ | 1 | 2 | 3 | 4 | 6 | 8 | 10 | 15 | 20 D
- | 1 | 2 | 3 | 4 | 6 | 8 | 10 | 15 | 20 D

Setting up

To set up the HEINE devices, screw the instrument head into the HEINE battery handle or plug it on the HEINE rechargeable handle.

Verify that the lamp voltage complies with the supply voltage of the handle. The coloured marking on the bottom of the lamp shows you the lamp voltage:

White ring = HEINE 2.5 V bulb

only for use with the HEINE BETA battery handle

Red ring = HEINE 3.5 V XHL bulb

Black ring = HEINE 3.5 V LED bulb

only for use with the HEINE BETA rechargeable handle and HEINE wall transformer.

This does not apply to the HEINE ophthalmoscopes of the mini3000 series. Their lamp voltage is always 2.5 V independently of the handle.

Operation

During the examination, place your index finger on the lens wheel (3) and start the examination using the smallest aperture setting. Place your thumb in the thumbrest (5) or on the attachment clip (mini3000 instruments). In the diopter readout (4), you can read the set diopter value of the lens (negative values are shown in red). You can also operate the aperture wheel (9) with your index finger. With the filter selector (10) you can switch on the red-free filter.

Depending on the instrument, you can choose between different apertures:



From left to right: MicroSpot, medium aperture, large aperture, blue filter, fixation star with polar coordinates, fixation star, slit aperture, hemispace, red-free filter.

HEINE Ophthalmoscopes are intended for a transient examination of less than < 2 minutes with a 15 minutes break until the next application.

Please hold the device as close to the eye as possible.

The setup and operation of the HEINE handles are described in a separate instruction document.

If you realize a significant drop of brightness or a flashing of the lightning immediately after switching on the device, please change the batteries.

Hygienic reprocessing

The instruction is available:

- at www.heine.com

- in a paper version which you can request from the address listed

Maintenance

Changing the light source

Verify that the lamp voltage complies with the supply voltage of the handle.
Allow the device to cool down before changing the bulb.

mini3000 LED

With these ophthalmoscopes, the LED cannot be changed.

BETA 200 LED | BETA 200 S LED | K180 LED

Detach the ophthalmoscope from the handle and remove the bulb (6). Insert the new bulb until it locks into place. The lug must fit inside the groove of the guide tube.

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, when the device is normal used and the warning and safety information as well as the maintenance instructions are observed, is 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.

For the examination please use as little light as possible. To do so, you can use the fixation star as it is combined with a neutral grey filter which reduces the brightness to 30 %. Please ensure to switch off the light after each examination.

General Warnings

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

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

This product is not allowed to enter or be used in areas with strong magnetic fields e.g. 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.

Light exposure hazard

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm², unless additional action is taken by the user to minimize exposure, after ____ (see table below, column "Recommended maximum").

The risk of retinal injury at an exposure of 2.2 J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than ____ (see table exposure guidelines, column "Maximum").

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

- Exposure guidelines

- Explanation of the used symbols

