




Instruction for use
HEINE BETA X
Ophthalmoscope



HEINE BETA X Ophthalmoscope

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


Intended use


The HEINE BETA X direct ophthalmoscope is intended for transient examination of the ocular media (cornea, aqueous humor, lens, vitreous humor) and the retina. The instrument features an optical examination system and an illumination unit powered by a 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 | 6 Viewing window |
| 2 Viewing aperture | 7 Aperture wheel |
| 3 Lens wheel | 8 Filter lever |
| 4 Diopter readout | (polarisation filter, without filter, red-free filter) |
| 5 Switch: HEINE focusCONTROL | 9 On Off switch and brightness control |



Lens wheel (3) correction values:
in 1 diopter steps: -36 dpt to +38 dpt

Setting up

Before using the device for the first time, remove all protective films and fully charge the device.

Operation

Use the rotary push button (9) to switch the device on and off. You can also adjust the brightness of the ophthalmoscope by turning the control button. Turning the button quickly results in a large brightness adjustment. Turning it slowly, on the other hand, produces a fine adjustment.

The aperture wheel (7) provides you with 7 different apertures for your examinations, which can be used additional to the polarisation filter or the red-free filter.

The lens wheel (3) is used to adjust the refraction compensation. You can set this in the range of -36 diopters to +38 diopters. The respective correction values are visible via the display (4) (negative values are shown in red, positive values in green).

With the focusCONTROL toggle switch (5), you can easily switch between focus on the anterior segment of the eye (C – cornea) and fundus (F – fundus).

With the filter lever (8) you can switch on the polarisation filter or the red free filter.

Possible aperture settings (7):



From left to right: blue filter, fixation star with polar coordinates, large aperture, medium aperture, MicroSpot, slit aperture, hemisplot

Possible filter settings (8):



From left to right: polarisation filter, without filter, red free filter

HEINE focusCONTROL (5):




Above: Setting for focussing on the fundus (F – fundus)

Below: Setting for focussing on the anterior segment of the eye (C – cornea)

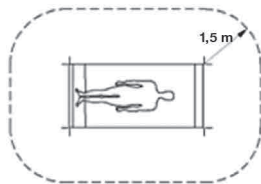
Hard-Reset:

Should a reset be necessary, it can be reset by pressing the on | off button for a period of 10 seconds.

Charging

 Mount the power supply in a way that allows you to easily unplug it.

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



Charging via USB-C

Use the equipment provided with the BETA X Ophthalmoscope. Connect the USB cable to the USB-C port of the ophthalmoscope and the HEINE power supply.

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

Battery indicator

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 (≤ 33 %)	off	off	flashing
eingeschaltet	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

Hygienic Reprocessing

The instruction is available:

- at 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.

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. For the examination please use as little light as possible. Please ensure to switch off the light after each examination.


The instrument automatically switches off after 5 minutes if the brightness control is not operated.

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

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.

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.

Do not modify the device.

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

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.


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


Lay cables in a protected position and ensure that no-one can fall over them.

Hazard from Light

Prolonged intense light exposure can damage the retina, so the use of the device for eye examination should not be unnecessarily extended, and the brightness should not be set higher than necessary for clear observation of the target structure. The exposure dose for photochemical retinal hazard is the product of irradiance and exposure time. If the irradiance is reduced by half, the exposure time may be twice as long to reach the maximum 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.

 Warning – The light from this instrument may be harmful. The risk of eye damage increases with exposure time. Exposure with this instrument at maximum intensity for longer than 2 minutes 26 seconds exceeds the recommended threshold for hazard.

 ANSI Z80.36-2021: Group 2

Caution – The light emitted by this device is potentially hazardous. The longer the exposure duration, the greater the risk of eye damage. Light exposure from this device exceeds the recommended maximum exposure (RME) of 2,2 J/cm² after 26 seconds at maximum intensity, unless the user takes additional steps to minimize exposure. The risk of retinal injury at an exposure of 2,2 J/cm² is low, but since some patients are more sensitive than others, caution is advised when this radiation level is exceeded. However, since there is a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 2 minutes 3 seconds.

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