HEINE QUALITY
MADE IN GERMANY

:· HEINE® Direct Ophthalmoscopes

CE

HEINE

MIDMARK

MED 113591 2018-01-23 V-200.00.604

HEINE® Direct Ophthalmoscopes

These instructions apply to the following products of the HEINE® direct ophthalmoscope series:
BETA200 LED, BETA200, K180.

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

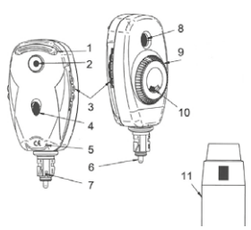
Intended Use
HEINE® direct ophthalmoscopes are intended for examination of the media (cornea, aqueous humour, lens, vitreous humour) and retina of the eye. The instruments feature an optical examination system and an illumination unit powered by a battery or rechargeable battery. They must be used only by qualified medical personnel. The instruments are intended for transient examination; patients can be examined according to the specified exposure guidelines.

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 for color print, or black in light-gray background.)

NOTE! Indicates valuable advice in terms of set up, operation, maintenance or repair, as applicable. Notes are important, but not related to hazardous situations.



Product overview
1 Spectacle rest
2 Viewing aperture
3 Lens wheel
4 Diopter readout (plus = green, minus = red)
5 Thumbrest
6 HEINE® XHL / LED 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, BETA200, K180
+ in 1D steps: 1-10 | 15 | 20 | 40 | D
- in 1D steps: 1-10 | 15 | 20 | 25 | 35 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:
Red ring = HEINE XHL® 3.5 V bulb
Black ring = HEINE LED illumination

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). In the viewing aperture (2), you can read the set diopter value of the lens (negative values are shown in red, positive in black). 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, hemispot, red-free filter.

To minimize lamp housing temperatures, on time should not exceed 2 minutes with off-time not less than 15 minutes.

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.

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

Allow the device to cool down before reprocessing.
In the event of suspected contamination, carry out hygienic reprocessing of the instrument.
The described reprocessing measures do not replace the specific rules applicable for the establishment.
Only the reprocessing agents and procedures called out in this instruction for use are approved.
The reprocessing is to be carried out by persons with adequate hygienic expertise.
Observe the instructions of the manufacturer of the reprocessing media.

Procedure
With the ophthalmoscope attached to the handle, clean and disinfect the ophthalmoscope manually (wipe clean and wipe disinfect).
Recommended agents
Cleaning agent, if necessary: enzymatic (e. g. Cidezyme® by ASP®)
Disinfectant agent: a combination of alcoholic and quaternary ammonia compounds (e. g. SUPER Sani-Cloth® by PDI®)

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.

BETA200 / K180 (XHL-Version)
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.

BETA200 LED
With these ophthalmoscopes, the LED cannot be changed.

Service
The device has some components serviceable by the end user.

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)
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.

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.midmark.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 10 years.
Beyond this period, the product may continue to be used if it has been determined to be in safe and good condition.

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.

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.

ANSI Z80.36-2016 Group 2 (LED)
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 38 sec. 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 3 min.

Exposure guidelines:

Instrument type	Distance* [mm]	Duration [min]
BETA200 LED	10	≤ 8
	50	≤ 3
	100	≤ 3
BETA200	10	≤ 10
	50	≤ 3
	100	≤ 1
K180	10	≤ 2
	50	≤ 2
	100	≤ 1

*) from instrument to patient

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

Electromagnetic disturbances – Requirements and tests	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environments.	
Statement for the operational environments:	Inside hospitals except for: near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances are high.
Performance features of the ME system that have been determined to be essential to the performance	None
Warning ⚠	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the direct ophthalmoscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
A list of all cables, transducers and other accessories that are relevant for the EMC compliance	None
Test	**Compliance**
RF emissions CISPR11	Group 1 Class B
Harmonic Emissions	Not applicable
Voltage Fluctuations/Flicker	Not applicable

Technical specifications

Environmental conditions for operation	+10 °C to +35 °C 30 % to 75 % rel. humidity 700 hPa to 1060 hPa
Environmental conditions for storage	+5 °C to +45 °C 45 % to 80 % rel. humidity 500 hPa to 1060 hPa
Environmental conditions for transport	-20 °C to +50 °C 45 % to 80 % rel. humidity 500 hPa to 1060 hPa
Nominal voltage:	3.0 V – 3.7 V
Nominal current:	XHL: max. 760 mA LED: max. 350 mA
Class:	Internally powered
Device classification according to ISO 10942	Group: B
Device classification according to ISO 15004-2	Group: 2

XHL Xenon Halogen Bulbs	**3.5 V**
BETA200	#070
K180	#086

Explanation of utilized symbols
The following symbols are used on the device or on the packaging:

CE	The CE mark indicates that the product complies with the European medical device directive 93/42/EEC.
REF	Catalogue- or order number
	Manufacturer
	Date of manufacture
	Product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal according to local provisions. (European Waste Electrical and Electronic Equipment Directive, WEEE)
°C °C	Temperature limits in °C for storage and transport
°F °F	Temperature limits in °F for storage and transport
%	Humidity limitation for storage and transport
	Pressure limitation for storage and transport
	Fragile, handle with care!
	Keep dry!
	Follow instructions for use! (Background color, blue; Foreground color, white for color print, or white on black background.)

Manufacturer
HEINE Optotechnik GmbH & Co. KG
Kientalstr. 7 · 82211 Herrsching · Germany
www.heine.com

Distributed by
Midmark Corporation
60 Vista Drive
Versailles, Ohio 45380
www.midmark.com