HEINE QUALITY
MADE IN GERMANY

:· HEINE® Otoscopes

CE

HEINE

MIDMARK

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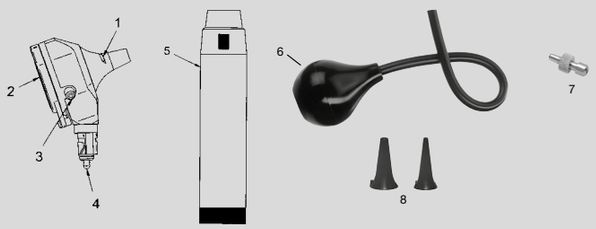
Product overview



HEINE® Otoscopes

These instructions apply to the following products of the HEINE® otoscope series: BETA200 LED, BETA200, BETA400 LED, BETA400, K180

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

Intended Use

HEINE® otoscopes are intended for the examination of the ear, the external auditory canal and the tympanum. The instruments have optical magnifying equipment and battery or rechargeable battery powered illumination equipment. The instruments may only be used by qualified medical personnel. Patients can be examined as often as necessary without any further restrictions. The devices are intended for transient examination and can also be used for instrumentation with non-active medical devices.

⚠ **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 (see figure)

1 Slit
2 Viewing window
3 Insufflation port
4 Connector plug
5 HEINE® Handle
6 Insufflation bulb
7 Insufflation port connector
8 HEINE AllSpec® tips (single use)

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

The HEINE® otoscope may only be inserted into the auditory canal when a tip is fitted.

Place the HEINE® tip on the otoscope so that the projection inside the tip fits into the bayonet slit (1). Tighten the tip by twisting it slightly to the right.

The magnifying lens is inside the viewing window (2). To facilitate instrumentation, the viewing window can be swiveled to both sides or folded up.

The otoscopes have a connection port (3) for the optionally available insufflation bulb (6, 7).

The test of tympanic mobility can be carried out when the viewing window is closed using the insufflation bulb. Apply the pressure carefully with the insufflation bulb.

If, after switching on the unit, a sharp drop in brightness or a flashing of the light is noticed, new batteries should be inserted or rechargeable batteries recharged.

Application duration

The otoscopes are intended for transient examination < 1 min with a break between applications of 10 minutes.
The maximum temperature at the application point at an ambient temperature of 35 °C and in continuous operation is 44.5 °C.

The setting up and operation of the HEINE® handles are described in a separate instruction of use.

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

⚠ 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.

Disposable tips (HEINE AllSpec®) are for single use only.

Procedure
Otoscopes: The otoscope and the insufflation bulb must be cleaned on the outside manually with a damp cloth and inside with a cotton-wool bud (wipe cleaning and wipe disinfection).

Recommended agents
Cleaning agent, if necessary: enzymatic (e. g. Cidezyme® by ASP®)
Disinfectant agent: alcoholic and/or quaternary ammonia compounds (e.g. SUPER Sani-Cloth® by PDI®, Sani-Cloth® AF3, by PDI®, Sani-Cloth® HB 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 / BETA400 / K180 (XHL-Version)
- Detach the otoscope from the handle and pull the bulb out of the guide tube of the connector plug (4) holding it at the narrow collar.
- Insert the new lamp all the way into the lamp guide.

BETA200 LED / BETA400 LED
With these otoscopes, 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.

Do not shine light of the instrument directly into the eyes.

Check the tip before each use for rough surfaces and edges.

In order not to exceed the surface temperature of 41 °C of the application part, keep within the application duration.

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.

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 otoscope, 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 IEC 62471	Exempt
Applied part	Type BF

XHL Xenon Halogen Bulbs

BETA400, BETA200, K180	#077 (2.5 V) #078 (3.5 V)

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	Temperature limits in °C for storage and transport
°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.)
	Type BF applied part
	Single use only

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