




Instruction for use
HEINE BETA X Otoscope



HEINE BETA X Otoscope

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

Intended use

The HEINE BETA X Otoscope is intended for the transient examination of the ear, the external auditory canal and tympanum. The instrument has a main light which combines an optical magnifying equipment and an illumination equipment powered by a rechargeable battery.


The BETA X Otoscope can also be used for instrumentation in the ear with non-active medical devices.


The instrument has also the additional light HEINE inSPECT for non-contact, non invasive and transient examination of the body, for oral cavity and throat examination as well as anterior segment of the eye examination and the pupil reflex observation. The nose can only be examined transient with disposable tips and if the skin is uninjured.

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 with moderate or severe 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 Slit | 6 X CHANGE System 3x Magnifier |
| 2 Viewing window | 7 X CHANGE System 4.2x Magnifier |
| 3 Insufflation port | 8 Insufflation bulb |
| 4 Additional light HEINE inSPECT | 9 HEINE SANALON S tips (re-use) |
| 5 HEINE X CHANGE System | 10 HEINE AllSpec tips (single use) |



Setting up

To start using the instrument, make sure that the X CHANGE system magnification attachment is properly locked into the bayonet mount. Before using the device for the first time, remove all protective films and fully charge the device.



Operation


 The maximum temperature at the application part, with an ambient temperature of 35° C and continuous operation, is 42,5° C.




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 different X CHANGE system magnifications can be exchanged as needed (optional accessory). They are attached to the instrument via a bayonet mount (2) by turning it clockwise. The otoscopes also feature a connection point (3) for the optional bulb (8) available as an accessory. Tympanic examination can be performed using the bulb.

Apply the pressure carefully with the insufflation bulb.

By pressing any button, you switch the device on. This will immediately activate the otoscopy light at maximum brightness. Use the Power Button  to switch the device off. The button  allows you to turn the otoscopy light on directly, and by pressing the same button again, you can decrease | increase the brightness.

The button  also activates the HEINE inSPECT additional lighting. Pressing the same button again will increase | decrease the brightness. When changing the light source, the previous light source will automatically be switched off, ensuring that only one light source is active at a time.

Button	Designation	Function	Application site
	HEINE inSPECT	Additional lighting: On Min Max	Minimum brightness level: anterior segment of the eye pupil Maximum brightness level: skin, oral cavity & throat. Not suitable for eye examinations.
	Otoscopy F.O.	otoscopy lighting: On Max Min	Both levels: ear, ear canal and eardrum. Not suitable for eye examinations.
	ON OFF	switch the device on and off	n a

If no button is pressed for 5 minutes, the instrument will automatically switch off.

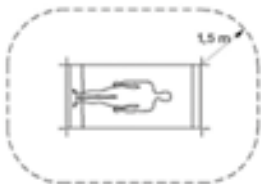
Hard Reset:

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 Otoscope. Connect the USB cable to the USB-C port of the otoscope 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

▲ The HEINE AllSpec® disposable tip is a single-use product. Under no circumstances should it be reused, as this may cause severe mechanical damage.


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, 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.

In case of failure of the pneumatic test, ensure that the X CHANGE magnifying attachment, as well as the adapter and bulb, are securely attached.

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

Charge your device during longer storage periods to protect the battery from deep discharge.

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.

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 the otoscopy light into the eyes. Ensure that the HEINE inSPECT additional light is activated at the minimal brightness level for this purpose.

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.

Check the tip before each use for rough surfaces and edges. Disposable tips (HEINE AllSpec | HEINE UniSpec) are for single use only. Do not use the device to examine injured tissue.


The maximum surface temperature at the application part, with an ambient temperature of 35°C and continuous operation, is 42°C.

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.

Although no acute optical hazards have been identified with the HEINE BETA X Otoscope, it is recommended that only the HEINE inSPECT lighting at the low setting be used for eye examinations. Using any lighting setting other than the HEINE inSPECT lighting at the low setting for eye examinations increases the risk of eye damage. The light source must be positioned at a distance of 50 mm or more from the patient's eye. Children, aphakic individuals, and people with eye diseases are at higher risk. The risk may also be increased if the person being examined has already been examined with this or any other ophthalmic instrument within the last 24 hours, especially if the eye was exposed to a fundus camera.

ISO 15004-2:2007: Group 2 – inSPECT Additional Light at 100mm Working Distance



 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 exceeds the recommended threshold for hazard.

ANSI Z80.36-2021: Group 2 – inSPECT Additional Light at 100mm Working Distance

 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 29 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.

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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