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:· HEINE Otoscopes



CE

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ENGLISH

HEINE Otoscopes

These instructions apply to the following products of the HEINE Otoscope series: BETA200 LED, BETA200, BETA400 LED, BETA400, K180, mini3000 F.O., mini3000 F.O. LED, BETA100, K100, mini3000.

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 device may only be used by qualified medical personnel and in professional healthcare facilities. Patients can be examined as often as necessary without any further restrictions. The devices are intended for short term treatment and can also be used for instrumentation with non-active medical devices.

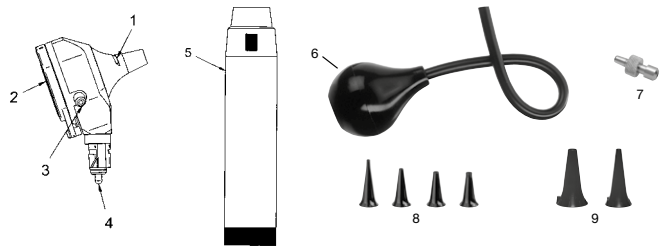
⚠ **For U.S. only:**
Federal law restricts this device to sale by or on the order of a Physician or Practitioner.

Warnings and Safety Information

⚠ **CAUTION!** 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 in terms of set up, operation, maintenance or repair, as applicable. Notes are important, but not related to hazardous situations.

Product overview



1 Slit
2 Viewing window
3 Insufflation port
4 Connector plug
5 HEINE Handle
6 Insufflation bulb
7 Insufflation port connector
8 HEINE SANALON® S tips (re-use)
9 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:

White ring = HEINE XHL® 2.5 V bulb
only for use with the HEINE BETA® Battery handle

Red ring = HEINE XHL® 3.5 V bulb
Black ring = HEINE LED illumination
only for use with the HEINE BETA® rechargeable handle and HEINE® wall unit

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

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 swivelled to both sides or folded up.

The otoscopes have a connection port (3) for the optionally available insufflation bulb (6, 7) (with the exception of the mini3000).

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

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.

BETA200 LED / BETA400 LED / mini3000 F.O. LED
With these otoscopes, the LED cannot be changed.

BETA200 / BETA400 / K180 / mini3000 F.O.
- 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.

BETA100 / K100
- Remove the tip from the otoscope and unscrew the lamp. Remove the sleeve from the old lamp.
- Refit the new bulb into the socket.
- Slide the sleeve on as far as it will go. This reduces stray light and reflections from the inside of the specula and should always be fitted.

mini3000
With this otoscope, swivel the viewing window (2) to the side and pull out the bulb backwards. Insert the new bulb as far as possible into the socket.

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.

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.

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

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

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

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	As applicable, see attachment
Test	**Compliance**
RF emissions CISPR11	Group 1 Class B
Harmonic Emissions	Passed*
Voltage Fluctuations/Flicker	Passed*

*n/a: „Not applicable“ in the internally powered mode

Technical specification

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
Protection class	Internally powered
Device classification according to IEC 62471	Exempt
Applied part	Type BF

XHL Xenon Halogen Bulbs

Types	2.5 V	3.5 V
BETA400 BETA200 K180	X-001.88.077	X-002.88.078
BETA 100 K100	X-001.88.037	X-002.88.049
mini 3000 F.O.	X-001.88.105	
mini 3000	X-001.88.110	

Erläuterung der verwendeten Symbole
Explanation of utilized symbols
Explication des symboles utilisés
Explicación de los símbolos utilizados
Spiegazione dei simboli utilizzati

CE	CE-Kennzeichnung kennzeichnet die Übereinstimmung mit der Europäischen Medizinprodukterichtlinie 93/42 EWG The CE mark indicates that the product complies with the European medical device directive 93/42/EEC. Le marquage CE indique la conformité à la directive européenne 93/42/CEE relative aux dispositifs médicaux. El marcado CE indique la conformidad con la directiva europea 93/42 /CEE relativa a los productos sanitarios. Il marchio CE indica la conformità con la direttiva europea sui dispositivi medici 93/42 CEE
REF	Katalog- oder Bestellnummer Catalogue- or order number Numéro de catalogue ou de commande Número de catálogo o de pedido Codice catalogo e di dell'ordine numero
	Hersteller Manufacturer Fabricant Fabricante Produttore
	Herstelldatum Date of manufacture Date de fabrication Fecha de fabricación Data di produzione
	Getrennte Sammlung von Elektro- und Elektronikgeräten (Europäische WEEE Richtlinie) 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) Tri sélectif des appareils électriques et électroniques (Directive européenne DEEE) Desechado separado de aparatos eléctricos y electrónicos (Directiva Europea RAEE) Raccolta differenziata di apparecchi elettrici ed elettronici (direttiva europea RAEE)
°C °C	Zulässiger Temperaturbereich in °C für Lagerung und Transport Temperature limits in °C for storage and transport Plage de température admise en °C pour le stockage et le transport Rango de temperatura permitida en °C para almacenar y transportar el producto Temperatura ammessa in °C per conservazione e trasporto
°F °F	Zulässiger Temperaturbereich in °F für Lagerung und Transport Temperature limits in °F for storage and transport Plage de température admise en °F pour le stockage et le transport Rango de temperatura permitida en °F para almacenar y transportar el producto Temperatura ammessa in °F per conservazione e trasporto

%	Zulässige Luftfeuchtigkeit für Lagerung und Transport Humidity limitation for storage and transport Humidité admise pour le stockage et le transport Humedad del aire permitida para almacenar y transportar el producto Umidità atmosferica ammessa durante il trasporto e la conservazione
	Zulässiger Luftdruck für Lagerung und Transport Pressure limitation for storage and transport Pression atmosphérique admise pendant le transport et le stockage Presión de aire permitida para almacenar y transportar el producto Pressione atmosferica ammessa durante il trasporto e la conservazione
	Vorsicht Bruchgefahr! Fragile, handle with care! Fragile ! Manipuler avec soin Atención. Frágil. Attenzione: pericolo di rottura!
	Trocken lagern! Keep dry! Conserver au sec ! Conservar en un lugar seco! Evitare ambienti umidi!
	Gebrauchsanweisung verbindlich befolgen. (Hintergrundfarbe: blau, Vordergrundfarbe: weiß) Follow instructions for use! (Background color: blue, foreground color: white.) Suivre le mode d'emploi. (Couleur de fond : bleu ; couleur du premier plan : blanc) Seguir obligatoriamente las instrucciones de uso. (Color de fondo: azul, color de primer plano: blanco) Attenersi obbligatoriamente alle istruzioni per l'uso. (Colore dello sfondo: blu, colore in primo piano: bianco)
	Anwendungsteil des Typs BF Type BF applied part Partie appliquée de type BF Pieza de aplicación del tipo BF Applicazione di tipo BF
2	Einmalgebrauch Single use only Usage unique Un solo uso Monouso
UDI	Unique Device Identification