

Hygienic reprocessing

HEINE Otoscopes

BETA200 LED, BETA200, BETA400 LED, BETA400, K180, mini3000® F.O.,
mini3000® F.O. LED, BETA100, K100, mini3000®

General warning and safety information



WARNING! This symbol indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent.



NOTE! This symbol indicates valuable advice. Notes are important, but not related to hazardous situations.

	<p>Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines.</p> <p>The described reprocessing measures do not replace the specific rules applicable for your institution/ department.</p>
	<p>In the event of suspected contamination, carry out hygienic reprocessing of the instrument.</p> <p>HEINE Optotechnik GmbH & Co. KG only approves the agents and procedures listed in this instruction.</p> <p>Hygienic reprocessing is to be carried out by persons with adequate hygienic expertise.</p> <p>Please consider the instructions of the manufacturer for the applied reprocessing media.</p> <p>Avoid liquid entry into the device.</p> <p>The reusable tips have to be reprocessed after each use.</p> <p>Disposable tips (HEINE AllSpec/HEINE UniSpec) are for single use only.</p> <p>The described reprocessing procedures are represented alongside the corresponding material compatibilities. Reprocessing must be carried out in accordance with an approved processing procedure. HEINE Optotechnik GmbH & Co. KG cannot guarantee the disinfection of these procedures. This has to be validated by the user e. g. Hospital or the manufacturers of the reprocessing equipment.</p>
	<p>For important details regarding the processing procedures, please refer to the FAQs for Hygienic Reprocessing on our</p>
<p>Limitations on reprocessing</p>	<p>Periodically check the integrity of the device.</p> <p>The reusable tips can be reprocessed up to 360 cycles.</p>



Hygienic reprocessing



The hygienic classification (Spaulding classification) of the HEINE Oscopes, as well as the decision for one of the offered reprocessing procedures, is the responsibility of the user or the qualified person(s) responsible for reprocessing. Internal regulations of your hospital/ institution, national directives, recommendations, standards and laws need to be considered.

For highly infectious cases (previous or following patients) (e. g. in case of a proven existence of a dangerous infectious disease (symptomatic or asymptomatic), the reprocessing guidelines in this document are superseded by processes of your institution/practice-internal regulations, national directives, recommendations, standards and laws.

Choose one of the following reprocessing methods:

Chapter A: Wipe disinfection – Oscopes

Chapter B: Automated cleaning and disinfection – Reusable tips

Chapter C: Manual cleaning (brushing) and manual disinfection (immersion) – Reusable tips



Chapter A: Wipe disinfection – Otoscopes

1. Preparation

Remove the reusable tips from the instrument and reprocess it separately.

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

Switch off the device and let it cool down.

2. Manual cleaning and disinfection



Pay attention that all surfaces are completely moistened for the complete exposure time specified by the disinfectant manufacturer. If necessary, increase the number of wiping procedures and/or the number of wipes.

Equipment

- Cleaning agent, if necessary: enzymatic (e. g. neodisher MediClean)
- Disinfectant:
 - alcoholic (e. g. Incides N),
 - quarternary ammonium compounds (e. g. Cleanisept Wipes , Mikrobac Tissues or Sani-Cloth AF3)
 - or
 - alcoholic + quarternary ammonium compounds (e. g. Super Sani-Cloth)

Implementation

- 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).
- For heavier soiling, you can first clean with a wipe soaked with cleaning agent before disinfecting with a disinfectant wipe.
- Pay particular attention to difficult to access areas.
- Thoroughly wipe the areas touched by the patient or the user: e. g. applied parts, operating elements, rotary controls, locking elements.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.

3. Inspection and function testing



- Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.

4. Storage

Store it in such a way that it is protected from recontamination, dust and moisture.



Chapter B: Automated cleaning and disinfection – Reusable tips

1. Point of use

Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.

2. Containment and transportation

Reprocess as soon as possible following use.

3. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning by brushing before automated cleaning and disinfection.

3.1 Automated cleaning and disinfection

Equipment

- Washer/disinfector that conforms to the requirements of ISO 15883 or has a validated procedure corresponding to ISO 15883.
- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. neodisher MediClean or Cidezyme)
- Neutralizing agent if specified by the cleaning agent manufacturer.

Implementation

- The instructions from the manufacturer of the cleaning agents and the washer/disinfector must be followed.
- Chose a suitable cleaning agent and cleaning program (according to ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 min. at 93 °C or an alternative, comparable program. (e. g. Vario TD program by Miele)

4. Inspection and function testing



- Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.

5. Storage

Store it in such a way that it is protected from recontamination, dust and moisture.



Chapter C: Manual cleaning (brushing) and manual disinfection (immersion) – Reusable tips

1. Point of use

Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.

2. Containment and transportation

Reprocess as soon as possible following use.

3. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. neodisher MediClean or Cidezyme)
- Warm (30 - 40 °C) demineralized water, soft plastic brushes.

Implementation

- The reusable tips must be cleaned manually (in an immersion bath).
- Soak the item for 1 min. submerged in the cleaning solution (30 - 40 °C).
- Clean all surfaces by brushing (submerged in the cleaning solution).
- Pay particular attention to difficult to access areas.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

4. Manual immersion disinfection

Equipment

- Disinfectant:
alcoholic (e. g. rotasept)
or
agent ortho-phthalaldehyde (e. g. Cidex OPA)

Implementation

- The reusable tips must be disinfected manually (in an immersion bath).
- Immerse the item in the disinfectant solution as specified by the manufacturer of the disinfectant.
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the manufacturer of the disinfectant.

5. Inspection and function testing



- Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.

6. Storage

Store it in such a way that it is protected from recontamination, dust and moisture.

