

Hygienic reprocessing

BETA X Otoscopes

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.

	Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines. The described reprocessing measures do not replace the specific rules applicable for your institution/ department.
	In the event of suspected contamination, carry out hygienic reprocessing of the instrument. HEINE Optotechnik GmbH & Co. KG only approves the agents and procedures listed in this instruction. Hygienic reprocessing is to be carried out by persons with adequate hygienic expertise. Please consider the instructions of the manufacturer for the applied reprocessing media. If a reprocessing procedure other than that described in these instructions is used, an approved and validated reprocessing procedure must be carried out. Avoid liquid entry into the device. The reusable tips have to be reprocessed after each use. Disposable tips (HEINE AllSpec®/HEINE UniSpec®) are for single use only.
Limitations on reprocessing	Periodically check the integrity of the device. The reusable tips can be reprocessed up to 360 cycles.

Hygienic reprocessing



The hygienic classification (Spaulding classification) of the devices and 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.

Choose one of the following reprocessing methods:

Chapter A: Wipe disinfection – Otoscopes

Chapter B: Automated cleaning and disinfection – Reusable tips

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

Chapter A: Wipe disinfection – Otoscopes

(and the smartphone case and the smartphone adapter)

1. Preparation

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

Disposable tips (HEINE AllSpec®/HEINE UniSpec®) are intended for single use only and must be removed.

Remove the smartphone with its mounting case from the otoscope and reprocess it separately.



The reprocessing described here does not include the reprocessing of a smartphone. Check whether the reprocessing you have selected is suitable for your smartphone. HEINE does not provide any guarantee for this.

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),
 - or
 - alcoholic + quaternary ammonium compounds (e. g. Super Sani-Cloth)
- If you use other than the recommended reprocessing agents, make sure that they do not foam.

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).
- Clean and disinfect the smartphone adapter, the smartphone mounting case and the smartphone manually.
- If the inner funnel has been contaminated, remove the eyepiece and manually clean and disinfect the inside of the inner funnel with a disinfectant wipe (wipe cleaning and wipe disinfection). To reach it to its tip, wrap the disinfectant wipe around a thin object and wipe the funnel over the large opening to the tip.
- 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
- Remove the residues with a wipe soaked in clean water and dry the device. Additionally, follow the instructions of the manufacturer of the reprocessing agent.

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.
- Check the correct operation of the device before use! Do not use the device if there are visible signs of damage.

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. Preparation

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

2. 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.

2.1 Manual 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

- Position the tips / specula firmly on the washer/disinfector's rinsing nozzles.
- The information provided by the manufacturers of the treatment agents and the washer/disinfector must be observed.
- Select a suitable cleaning agent and program (in accordance with DIN EN ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 minutes at 93°C or an alternative, equivalent program. (e.g. Vario TD program by Miele)

3. Inspection and function testing



- Check the parts for visible soiling or wear and reprocess them if necessary or dispose of them if the soiling cannot be removed.

4. 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. Preparation

Remove coarse soiling promptly after use (e.g. by wiping with a damp single-use cloth or an enzymatic pre-cleaner).

2. Manual cleaning with brushes

Equipment

- Cleaning agent: Enzymatic or neutral to mildly alkaline (e.g. neodisher MediClean Forte)
- Warm (30 – 40°C) demineralised water
- Soft plastic brushes (round brushes for internal surfaces and cavities; the diameter of the brush is adapted to the tip's / speculum's diameter)

Implementation

- Clean reusable tips and specula manually (in an immersion bath).
- Soak the parts in cleaning solution (30 – 40°C) for at least one minute.
- Clean all internal and external surfaces by brushing (immersed in cleaning solution).
- Pay particular attention to hard-to-reach areas
- Remove the cleaning agent residues and dry off the parts as required by the cleaning agent manufacturer

3. Manual immersion disinfection

Equipment

- Disinfectant: Based on succinic dialdehyde (e.g. gigasept FF (new))

Implementation

- The reusable tips must be disinfected manually (in an immersion bath).
- Place the parts in the disinfectant solution according to the information provided by the disinfectant manufacturer.
- Pay particular attention to the specified concentrations, temperatures and exposure times.
- Remove the disinfectant residues and dry off the device as required by the manufacturer.

4. Inspection and function testing

- Check the parts for visible soiling or wear and reprocess them if necessary or dispose of them if the soiling cannot be removed.



5. Storage

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