

Hygienic reprocessing

HEINE Binocular Loupes

HR, HRP, HR-C, C2.3, C2.3K

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.
	Immersion disinfection, machine cleaning/disinfection, ultrasound cleaning and sterilisation of the loupes are not permitted.
	Hard and/or metallic brushes and/or abrasive treatment mediums lead to scratches and therefore deterioration of the optics.
	Before using it again, ensure that the device is completely dry after reprocessing.
	For the polarisation filter, do not use any alcoholic reprocessing agents.
Limitations on reprocessing	Periodically check the integrity of the device. Polarisation filter may be reprocessed up to 50 times.

Choice of the reprocessing procedure



The hygienic classification (Spaulding classification) of the instruments, 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.

Choose from the following reprocessing methods for the binocular loupes, lens protectors, close-up lenses, polfilters and the steri levers:

- Wipe disinfection of the binocular loupes, lens protectors, close-up lenses and polfilters (**Chapter A**)
- Cleaning under running water of the HR, HRP, HR-C binocular loupe (**Chapter B**) (not for C2.3, C2.3K)
- Automated cleaning and disinfection, steam sterilization of the steri levers (**Chapter C**)
- Manual cleaning and disinfection and steam sterilization of the steri levers (**Chapter D**)

Chapter A: Wipe disinfection of the binocular loupes, lens protectors, close-up lenses and polfilters

1. Preparation

Remove the steri levers from the instrument and reprocess it separately.

Remove the lens protectors, close-up lenses, and polfilters from the instrument and reprocess it separately by wiping.

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.

Clean and disinfect the optical surfaces only if necessary, using a disinfectant wipe. Otherwise, or to remove residues, clean them according to the instructions "Cleanliness of your HEINE device's optical parts" (MED 234574)

Equipment

- Cleaning agent, if necessary: enzymatic (e. g. neodisher MediClean)
- Disinfectant wipes:
alcoholic (e. g. Incides N or mikrozid universal wipes)
- For the S-Frame (if available): quaternary ammonium compounds (e.g. Cleanisept Wipes, Mikrobac Tissues or Sani-Cloth AF3)

Implementation

- For heavier soiling, you can first clean with a wipe soaked with cleaning agent before disinfecting with a disinfectant wipe.
- Clean and disinfect the binocular loupes, options, the headbands or the S-Frame manually.
- Pay particular attention to areas that are difficult to access.
- Thoroughly wipe the touched areas.
- Clean the paddings of the headband with a wipe soaked with water or if necessary, with a disinfection wipe.
- 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. Reprocess again if necessary.
- 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: Cleaning under running water of the HR, HRP, HR-C binocular loupe

(not for C2.3, C2.3K)

1. Preparation

Remove the steri levers from the instrument and reprocess it separately.

Remove the lens protectors, close-up lenses, and polifilters from the instrument and reprocess it separately by wiping.

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.

Clean and disinfect the optical surfaces only if necessary, using a disinfectant wipe. Otherwise, or to remove residues, clean them according to the instructions "Cleanliness of your HEINE device's optical parts" (MED 234574)

Equipment

- Cleaning agent, if necessary: enzymatic (e. g. neodisher MediClean)
- Disinfectant wipes:
alcoholic (e. g. Incides N or mikrozyd universal wipes)
- For the S-Frame (if available): quaternary ammonium compounds (e.g. Cleanisept Wipes, Mikrobac Tissues or Sani-Cloth AF3)

Implementation

- For heavier soiling, the loupes can first be washed under running water, before being disinfected with a disinfectant wipe.
- Clean and disinfect the binocular loupes, options, the headbands or the S-Frame manually.
- Pay particular attention to areas that are difficult to access.
- Thoroughly wipe the touched areas.
- Clean the paddings of the headband with a wipe soaked with water or if necessary, with a disinfection wipe.
- 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. Reprocess again if necessary.
- 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 C: Automated cleaning and disinfection, steam sterilization of the steri levers

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. Preparation

Remove the steri levers from the device.

4. Cleaning and disinfection



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

4.1 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. CIDEZYME by ASP or neodisher MediClean Forte).
- 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.
- Choose 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)

5. Inspection and function testing



- Check the steri levers for any visible contaminants. Reprocess again if necessary.
- Do not use the steri levers if there are visible signs of damage.

6. Packaging for sterilization

Pack the adjuster sleeve individually in single standardized sterilization pouches suitable for the selected sterilization process.

7. Steam sterilization

Equipment

- Steam sterilizer (Class B according to DIN EN 13060)

Implementation

Use one of the following programs (ISO 17665):

Fractionated vacuum procedure (at least 3 pre-vacuum cycles) and Gravitation procedure:

- Sterilization temperature: at least 132 °C (max. 134 °C)
- Exposure time/holding time: at least 3 min.
- Drying time: at least 20 min.

8. Storage

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

Chapter D: Manual cleaning and disinfection and steam sterilization of the steri levers

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. Preparation

Remove the steri levers from the device.

4. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP or neodisher MediClean Forte).
- Warm (30 - 40 °C) demineralized water
- Soft plastic brushes

Implementation

- Use the detergent at the maximum recommended concentration.
- Soak the steri levers completely for at least 5 min. submerged in the cleaning solution (30 - 40°C).
- Clean all surfaces of the steri levers by brushing (submerged in the cleaning solution):
- Brush all surfaces thoroughly until no more contamination is visible and at least 5 times (in total at least 3 min.).
- Then brush with a small round plastic brush at least 5 times the difficult to access areas (in total at least 3 min.).
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times specified by the manufacturer of the cleaning agent.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

5. Manual immersion disinfection

Equipment

- Disinfecting agent (fungicidal, bactericidal (including mycobacteria) und virucidal) for immersion disinfection (compatible with cleaning agent): ortho-phthalaldehyde (e. g. Cidex OPA)

Implementation

- Immerse the steri levers in the disinfectant solution completely as specified by the manufacturer of the disinfectant.
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times specified by the manufacturer of the disinfection agent.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the manufacturer of the disinfectant.

6. Inspection and function testing



- Check the steri levers for any visible contaminants. Reprocess again if necessary.
- Do not use the steri levers if there are visible signs of damage.

7. Packaging for sterilization

Pack the adjuster sleeve individually in single standardized sterilization pouches suitable for the selected sterilization process

8. Steam sterilization

Equipment

- Steam sterilizer (Class B according to DIN EN 13060)

Implementation

Use one of the following programs (ISO 17665):

Fractionated vacuum procedure (at least 3 pre-vacuum cycles) and Gravitation procedure:

- Sterilization temperature: at least 132 °C (max. 134 °C)
- Exposure time/holding time: at least 3 min.
- Drying time: at least 20 min.

9. Storage

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