

Hygienic reprocessing

HEINE DELTA[®]one

HEINE DELTA[®]30

General warning and safety information



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



HINWEIS! This symbol is used for information regarding installation, operation or maintenance that are important but are not associated with dangers.

	<p>Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines. They must be implemented in the hospital / practice internal rules and guidelines.</p>
	<p>In the event of suspected contamination, carry out hygienic reprocessing of the instrument.</p> <p>The described reprocessing measures do not replace the specific rules applicable for your institution/ department.</p> <p>HEINE Optotechnik 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>Ensure that moisture does not penetrate the area of the USB connector.</p> <p>Automated reprocessing cannot be performed.</p>
	<p>For important details regarding the processing procedures, please refer to the FAQs for Hygienic Reprocessing on our website.</p>
<p>Limitations on reprocessing</p>	<p>Hygienic reprocessing only has a minor influence on the product life as this is determined mainly by wear and tear during use. Periodically check the integrity of the device!</p>



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.

In case of semicritical use of the contact plate, sterilisation is obligatory after wiping.
High-level disinfection cannot be achieved by wiping.

Choose from the following reprocessing methods for the dermatoscope and the contact plate:

- **In case of non-critical use of the dermatoscope and the contact plate:**
 - Wipe disinfection of the contact plate (**Chapter A**)
 - Wipe disinfection of the dermatoscope (**Chapter B**)
- **In case of semicritical use of the contact plate:**
 - Wipe disinfection and steam sterilization of the contact plate (**Chapter C**)



Chapter A: Wipe disinfection of the contact plate

1. Preparation

Remove the contact plate from the instrument and reprocess it.

2. Manual cleaning and disinfection (intermediate level)



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 mikrozyd® universal wipes),
quarternary ammonium compounds (e. g. Cleanisept® Wipes , Mikrobac® Tissues or Sani-Cloth® AF3),
or
alcoholic + quarternary ammonium compounds (e. g. Super Sani-Cloth®)

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 contact plates manually.
- Wipe all surfaces thoroughly with circular movements until no more contamination is visible, at least 3 times (each with a new disinfectant wipe).
- Wipe with clean water afterwards.
- 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: Wipe disinfection of the dermatoscope

1. Preparation

In the event of suspected contamination, carry out hygienic reprocessing of the instrument. Switch off the device and let it cool down.

Remove the contact plate from the instrument and reprocess it separately.

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

- Disinfectant:
alcoholic (e. g. Incides® N or mikrozid® universal wipes)
or
alcoholic + quarternary ammonium compounds (e. g. Super Sani-Cloth®)

Implementation

- Clean and disinfect the dermatoscope manually.
- Wipe all surfaces thoroughly until no more contamination is visible, at least 3 times (each with a new disinfectant wipe).
- Pay particular attention to difficult to access areas.
- Thoroughly wipe the touched areas.
- 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 C: Wipe disinfection and steam sterilization of the contact plate

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 contact plate from the dermatoscope.

4. Manual cleaning and disinfection (intermediate level)



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.

In case of semicritical use of the contact plate, sterilisation is obligatory after wiping.

Equipment

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

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 contact plates manually.
- Wipe all surfaces thoroughly with circular movements until no more contamination is visible, at least 3 times (each with a new disinfectant wipe).
- Wipe with clean water afterwards.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.

5. Inspection and function testing



- Check the contact plate for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Do not use the device if there are visible signs of damage.

6. Packaging for sterilization

Pack the contact plates 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.

