

# Hygienic reprocessing Dermatoscopes

HEINE DELTA® 20 Plus, HEINE DELTA® 20 T, HEINE mini3000® LED, HEINE 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 &amp; 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>Do not use alcoholic reprocessing agents.</p> <p>Automated reprocessing cannot be performed.</p> <p>The contact plates should only be sterilized after the treatment of high risk patients.</p> <p>Steam sterilization of the instrument heads, the filter inserts, all small contact plates and the contact plate of the DELTA 20T is not allowed.</p>
<p>Limitations on reprocessing</p>	<p>Periodically check the integrity of the device.</p> <p>The contact plates can be reprocessed up to 1000 cycles (without sterilization).</p> <p>Steam sterilization of the contact plates:</p> <ul style="list-style-type: none"> <li>• mini3000 contact plate: Max. 4 cycles</li> <li>• DELTA 20 contact plate: Max. 25 cycles.</li> </ul>



## 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 or after examination of infectious skin:**
  - Wipe disinfection and steam sterilization of the contact plate (**Chapter C**)  
(Not for small contact plates and the DELTA 20 T contact plate)



## Chapter A: Wipe disinfection of the contact plate

### 1. Preparation

Remove the contact plate from the instrument and reprocess it.

You must remove the filter insert of the DELTA 20 Plus and of the DELTA 20T.

### 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:  
quarternary 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 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).
- Pay particular attention to the difficult to reach area of the small contact plate  
Wipe the glass attachment at least 3 times with rotating movements.
- Then wipe with a cloth soaked in clean water.
- 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

Switch off the device and let it cool down.

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

### 2. Manuelle reinigende Wischdesinfektion



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 wipes:  
quarternary ammonium compounds (e. g. Cleanisept Wipes , Mikrobac Tissues or Sani-Cloth AF3)
- If you use other than the recommended reprocessing agents, make sure that they do not foam.

#### *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 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 C: Wipe disinfection and steam sterilization of the contact plate

(Not for small contact plates and the DELTA 20 T 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.

You must remove the filter insert of the DELTA 20 Plus and of the DELTA 20T.

### 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.

#### Equipment

- Cleaning agent, if necessary: enzymatic (e. g. neodisher MediClean)
- Disinfectant: quarternary 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 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).
- Then wipe with a cloth soaked in clean water.
- 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.

### 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.

