

Hygienic reprocessing




HEINE DELTA[®] 30 UV

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. Avoid liquid entry into the device. Automated reprocessing of the dermatoscope cannot be performed. If a reprocessing procedure other than that described in these instructions is used, an approved and validated reprocessing procedure must be carried out. Do not switch on the device during reprocessing.
	Do not use Octenisept or Softasept because it may bleach the material. Ensure that only completely dry contact plates are placed on the dermatoscope.
Limitations on reprocessing	Periodically check the integrity of the device. Steam sterilization of the contact plates/diSTANCE: Max. 25 cycles The small contact plate must not be steam-sterilized.

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/diSTANCE:

- **In case of non-critical use of the dermatoscope and the contact plate/diSTANCE:**
 - Wipe disinfection of the contact plate (K-000.34.220) / diSTANCE (**Chapter A**)
 - Manual cleaning and disinfection of the small contact plate (K-000.34.206) / diSTANCE (**Chapter B**)
 - Wipe disinfection of the dermatoscope (**Chapter C**)
- **After examination of infectious skin:**
 - Wipe disinfection and steam sterilization of the contact plate (K-000.34.220) / diSTANCE (**Chapter D**)
 - Manual cleaning and disinfection and steam sterilization of the diSTANCE (**Chapter E**)

Component	Intermediate-level disinfection	High-level disinfection	Sterilisation
 <p>Contact plate</p>	Cleaning wipe disinfection ✓	Manual cleaning with brushes and immersion disinfection --	Steam sterilization ✓
 <p>Small contact plate</p>	--	✓	--
 <p>diSTANCE</p>	✓	✓	✓
 <p>DELTA 30 UV without / with the contact plate attached (not with the small contact plate attached)</p>	✓	--	--

✓ = suitable

-- = not applicable

Chapter A: Wipe disinfection of the contact plate or the diSTANCE

(Not for the small contact plate (K-000.34.206))

1. Preparation

Remove the contact plate or the diSTANCE 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 or the diSTANCE 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 (Cat. No. K-000.34.206, K-000.24.207). Wipe the glass attachment with rotating movements.
- Remove the residues thoroughly with a wipe soaked in clean water and dry the contact plate or the diSTANCE. Additionally, follow the instructions of the manufacturer of the reprocessing agent.

3. Inspection and function testing



Check the device for any visible contaminants. 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: Manual cleaning and disinfection of the small contact plate / diSTANCE

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 / diSTANCE from the dermatoscope.

4. Manual cleaning by brushing

This reprocessing may result in cosmetic changes to the contact plate / diSTANCE. This does not impair the function of the product.

Equipment

- Cleaning agent: Enzymatic or neutral to mildly alkaline (e. g. Helizyme), which is suitable for sensitive surfaces.
- Warm (30 - 40 °C) demineralized water, soft plastic brushes.

Implementation

- Clean the contact plate / diSTANCE 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 areas that are difficult to access.
- Thoroughly brush the knurling in the direction of its pattern.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

5. Manual immersion disinfection

Equipment

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

Implementation

- Disinfect the contact plate / diSTANCE 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.

6. Inspection and function testing

Check the contact plate / diSTANCE for any visible contaminants. Reprocess again if necessary. Dispose if the contaminants cannot be removed.

7. Storage

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

Chapter C: Wipe disinfection of the dermatoscope

(and the smartphone and the smartphone adapter)

1. Preparation

Switch off the device and let it cool down.

The contact plate can be attached to the dermatoscope during hygienic reprocessing or reprocessed separately. The small contact plate must be removed from the dermatoscope before hygienic reprocessing and reprocessed separately.

Remove the smartphone with its mounting case from the dermatoscope and reprocess the smartphone and the mounting case 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.

2. Manual cleaning wipe 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 + quaternary ammonium compounds (e. g. Super Sani-Cloth®)

Procedure

- Clean and disinfect the dermatoscope, contact plates and smartphone adapter manually.
- Wipe all surfaces thoroughly until no more contamination is visible, at least 3 times (each with a new disinfectant wipe).
- A nylon brush can be used if necessary for hard-to-reach areas.
- Remove the residues thoroughly 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 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 D: Wipe disinfection and steam sterilization of the contact plate/diSTANCE

(Not for the small contact plate (K-000.34.206))

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 or the diSTANCE 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.

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 or the diSTANCE manually.
- Wipe all surfaces thoroughly with circular movements until no more contamination is visible, at least 3 times (each with a new disinfectant wipe).
- Remove the residues thoroughly with a wipe soaked in clean water and dry the contact plate. Additionally, follow the instructions of the manufacturer of the reprocessing agent.

5. Inspection and function testing



Check the contact plate or the diSTANCE for any visible contaminants. Reprocess again if necessary. Dispose if the contaminants cannot be removed.

6. Packaging for sterilization

Pack the contact plates or the diSTANCE 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 E: Manual cleaning and manual disinfection and steam sterilization of the diSTANCE

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 diSTANCE from the dermatoscope.

4. Manual cleaning by brushing

This reprocessing may result in cosmetic changes to the diSTANCE. This does not impair the function of the product.

Equipment

- Cleaning agent: Enzymatic or neutral to mildly alkaline (e. g. neodisher MediClean or Cidezyme) which is suitable for sensitive surfaces.
- Warm (30 - 40 °C) demineralized water, soft plastic brushes.

Implementation

- Clean the diSTANCE 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 access areas.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

5. Manual immersion disinfection

Equipment

- Disinfectant:
Based on succinic dialdehyde (e.g. gigasept FF (neu)) or agent ortho-phthalaldehyde (e. g. Cidex® OPA)

Implementation

- Disinfect the diSTANCE 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.

6. Inspection and function testing

Check the diSTANCE for any visible contaminants. Reprocess again if necessary. Dispose if the contaminants cannot be removed.

7. Packaging for sterilization

Pack the diSTANCE 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.