



Hygienic reprocessing

HEINE DELTA[®] one HEINE DELTA[®] 30 HEINE DELTA[®] 30 PRO

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.

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|-----------------------------|---|
| | 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 because it may bleach the material. |
| Limitations on reprocessing | Periodically check the integrity of the device. Steam sterilization of the contact plates/diSTANCE: Max. 25 cycles |



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:**
 - Wipe disinfection of the contact plate/diSTANCE (**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/diSTANCE (**Chapter C**)
(Not for small contact plates: Cat. No. K-000.34.206, K-000.24.207)



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

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: Wipe disinfection of the dermatoscope

(and the smartphone case with the smartphone and the smartphone adapter)

1. Preparation

Switch off the device and let it cool down.

DELTAone and DELTA 30: Remove the contact plate from the instrument and reprocess it separately.

DELTA 30 PRO: To protect the DELTA 30 PRO, leave the contact plate on the dermatoscope for reprocessing. To reprocess the contact plate or the diSTANCE more thoroughly (chapter C), please remove it.

Remove the smartphone with its mounting case from the dermatoscope and reprocess the smartphone and the mounting case 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 mikrozyd universal wipes)
or
alcoholic + quarternary ammonium compounds (e. g. Super Sani-Cloth)
- If you use other than the recommended reprocessing agents, make sure that they do not foam.
- Make sure that the reprocessing agent is approved for use with your smartphone. (e. g. mikrozyd® universal wipes).

Implementation

- Clean and disinfect the dermatoscope, the smartphone adaptor, the smartphone mounting case and the smartphone 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.
- 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 C: Wipe disinfection and steam sterilization of the contact plate or the diSTANCE

(Not for small contact plates: Cat. No. K-000.34.206, K-000.24.207)

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.