

Hygienic reprocessing

HEINE visionPRO video laryngoscope





General warning and safety information



WARNING! This symbol draws attention to a **potentially dangerous situation**. Failure to observe it can result in moderate to severe injuries.



NOTE! This symbol is used to indicate information that is important, but not associated with danger.

	<p>The following information on hygienic reprocessing must be implemented in accordance with national standards, laws, guidelines and recommendations. The hygienic reprocessing measures described are not a substitute for the regulations applicable to the establishment in question.</p>
	<p>Dispose of the video laryngoscope blade before reprocessing. The blade is a single-use product and must not be reprocessed and reused under any circumstances.</p> <p>Where it is suspected that devices have come into contact with Creutzfeld-Jakob disease (CJD) pathogens or variants thereof, they must not be reprocessed under any circumstances and must be disposed of.</p> <p>If you use reprocessing agents that are not described by HEINE, observe the information provided by the reprocessing agent manufacturer.</p> <p>HEINE Optotechnik GmbH & Co. KG only approves the recommended agents and procedures.</p> <p>Reprocessing may only be carried out by persons with sufficient expertise in hygiene.</p> <p>HEINE Optotechnik GmbH & Co. KG has validated the effective reprocessing for the procedures and agents recommended in this document. If a reprocessing procedure other than that described in these instructions is used, an approved and validated reprocessing procedure must be carried out. It must be validated by the user (e.g. the hospital) or the manufacturers of the reprocessing devices.</p> <p>Use disinfectant solutions that are fungicidal, bactericidal (including against mycobacteria) and virucidal.</p> <p>Do not press in the visionPRO's latching balls under water.</p> <p>During reprocessing, ensure that soiling is removed from the charging pins to guarantee a good charging function.</p> <p>Steam sterilisation or automated reprocessing must not be carried out.</p> <p>The protective case for the display unit (if available) must be removed before reprocessing.</p> <p>The display protector must be replaced when treating high-risk patients.</p>
	<p>Regularly check the validity of all the information provided by the reprocessing agent manufacturer.</p> <p>The reprocessing agents on the MED 236208 list were tested to ensure material compatibility.</p> <p>Do not use agents containing hydrogen peroxide.</p> <p>Do not allow liquids to get into the device.</p>
<p>Reprocessing restrictions</p> 	<ul style="list-style-type: none"> • Regularly check that the device is intact. • Regularly check that the camera and the illumination are working. • The display protector must be replaced if damaged.

Selecting the reprocessing procedure






The hygienic classification (Spaulding classification) of the video laryngoscopes and the decision in favour of one of the reprocessing procedures offered are the responsibility of the practitioner or the qualified person who is responsible for reprocessing.

For highly infectious cases (previous or next patient) (e.g. if the patient is known to have a dangerous infectious disease (whether they are symptomatic or asymptomatic)), please observe the reprocessing requirements set out in the internal hospital / practice regulations, national guidelines and recommendations, and standards and laws.

The following reprocessing procedures are available:

- For the handle and display unit (assembled): Cleaning wipe disinfection (**see chapter A**).
- For the handle:
 - Cleaning and disinfection (fungicidal, bactericidal (including against mycobacteria) and virucidal) (manual cleaning and immersion disinfection) (**see chapter B**)
 - Sterilisation (**see chapters B and C**).

Component	Intermediate-level disinfection	High-level disinfection	Sterilisation
 Single-use blade	Cleaning wipe disinfection —	Manual cleaning with brushes and immersion disinfection —	Sterilisation with STERRAD —
 Handle and display unit (assembled)	✓ (Chapter A)	—	—
 Handle (dismantled)	—	✓ (Chapter B)	✓ (Chapter C)

✓ = suitable - = not applicable

Chapter A: Intermediate-level disinfection

Cleaning wipe disinfection of the handle and display unit (assembled)

1. Containment and transport

Reprocessing should take place as soon as possible after use.

2. Preparation

Do not switch on the device during reprocessing.



Remove the blade from the handle and dispose of it properly.

The protective case for the display unit (if available) must be removed before reprocessing.

The display protector must be replaced when treating high-risk patients.

Use disinfectant wipes that are fungicidal, bactericidal (including against mycobacteria) and virucidal, and that are confirmed to be effective against hepatitis B.

3. Pre-cleaning

After use, wipe the device with a microfibre cloth soaked in cleaning agent to prevent contamination from drying.

Use cleaning agents that are either enzymatic or neutral to mildly alkaline.

Use soft and suitable brushes for hard-to-reach areas, nooks and crannies.

Remove the cleaning agent residues and dry the display unit as required by the cleaning agent manufacturer.

The protective case for the display unit (if available) must be thoroughly wiped at least three times with a fresh disinfectant wipe on all internal and external surfaces after it has been removed from the display.

4. Manual cleaning wipe disinfection of the assembled video laryngoscope



Ensure that all surfaces are completely wetted for the entire exposure time specified by the disinfectant manufacturer. Increase the number of wiping procedures and/or the number of wipes if necessary. Dispose of the wipes in accordance with local and hospital regulations.

Equipment

Disinfectant wipes:

- Super Sani-Cloth (quaternary ammonium compounds + alcohol)

Implementation

This procedure must be repeated 3 times:

Area 1:

Wipe with a disinfectant wipe three times, starting below the on/off button (3), and moving down to the transition to the handle. Turn the handle while doing so.

Area 2:

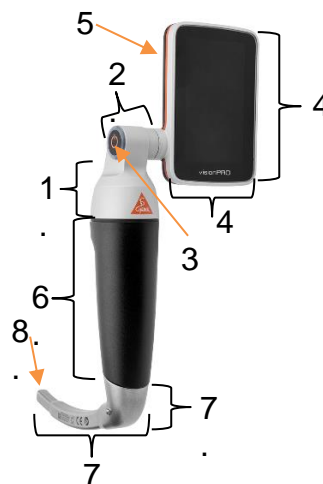
Wipe the display unit's joint area three times with the disinfectant wipe. Ensure that you use rotating movements. Pay particular attention to nooks and crannies and the hard-to-reach areas in the joint area, under the joint and at the transitions.

Area 3:

Then wipe the on/off button thoroughly three times with the disinfectant wipe. Ensure that you use circular as well as horizontal and vertical movements.

Area 4:

Wipe the edges and the glass side of the display three times. Ensure that you use vertical and horizontal



movements. Pay particular attention to nooks and crannies.

Area 5:

Wipe the back of the display three times with a new disinfectant wipe. Ensure that you use horizontal and vertical movements.

Area 6:

Starting at the top of the black part of the handle, wipe down three times with the disinfectant wipe until you reach the grey material at the bottom of the handle. Turn the handle while doing so. Pay particular attention to nooks and crannies, hard-to-reach areas and material transitions.

Area 7:

Use the disinfectant wipe to wipe the grey part of the handle three times with rotating, horizontal and vertical movements. Pay particular attention to the clip the blade is attached to. It may be necessary to use a brush for heavier contamination.

Area 8:

Finally, wipe the camera area with the wipe, using horizontal and vertical movements. Pay particular attention to nooks and crannies, and ensure that you do not scratch the camera.

- If you still see residues after wipe disinfection, brush the affected areas with surface brushes soaked in disinfectant. Remove the residues (particularly in the camera area) with a cloth soaked in distilled water or water that is at least drinking water quality (according to the information provided by the disinfectant manufacturer) and dry the video laryngoscope as required by the disinfectant manufacturer.

5. Performing an inspection and function test




- Check the components for visible soiling or wear and reprocess them if necessary or dispose of them if the soiling or wear cannot be removed.
- A function test must be carried out after reprocessing. Allow the components to dry first of all. Then check that the device is working, in particular the camera and the illumination.

6. Storage

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

Chapter B: High-level disinfection

Manual cleaning (with brushes) and immersion disinfection of the handle (dismantled)

1. **At the place of use**
Remove coarse soiling promptly after use (e.g. by wiping with a damp single-use cloth or an enzymatic pre-cleaner).
2. **Containment and transport**
Reprocessing should take place as soon as possible after use.
3. **Preparation**
Remove the blade from the handle and dispose of it.
 The handle must be rinsed after each reprocessing step so that it is free from residues to avoid reactions with subsequent treatment steps or damage to the materials.
4. **Pre-cleaning**
Immediately after use, wipe the dismantled handle with a microfibre cloth soaked in cleaning agent to prevent contamination from drying.
Use cleaning agents that are either enzymatic or neutral to mildly alkaline.
Use soft and suitable brushes for hard-to-reach areas, nooks and crannies. Remove the cleaning agent residues and dry the handle as required by the cleaning agent manufacturer.
5. **Manual cleaning with brushes**
Equipment
 - Cleaning agent: Enzymatic or neutral to mildly alkaline (neodisher MediClean Forte)
 - Warm (30 – 40°C) demineralised water
 - Soft plastic brushes: Surface brush (2.3 x 0.1 x 0.5 cm L x W x H)
 - Sufficiently large and material-resistant basinImplementation
 - Use the cleaning agent in the maximum recommended concentration.
 - Soak the handle completely in cleaning solution (30 – 40°C) for at least five minutes.
 - Clean all surfaces of the handle by brushing (immersed in cleaning solution):
 - Brush all surfaces thoroughly until no more soiling is visible and at least 5 times (at least three minutes in total). Take care not to scratch any of the camera's optical surfaces.
 - Then brush the nooks and crannies and the areas in the transition area, in the blade clip and in the camera area at least 5 times with a surface brush (at least three minutes in total).
 - Pay particular attention to the concentrations, temperatures and exposure times specified by the cleaning agent manufacturer.
 - Remove the cleaning agent residues completely with water (preferably demineralised water) and as required by the cleaning agent manufacturer and dry the handle.
6. **Manual immersion disinfection**
Equipment
 - Disinfectant for immersion disinfection (compatible with cleaning agent): CIDEX OPA (active ingredient: ortho-phthalaldehyde)Implementation with CIDEX OPA
 - Fully immerse the handle in the disinfectant solution according to the information provided by the disinfectant manufacturer
 - Pay particular attention to compliance with the concentrations (min. 0.55%), temperatures (min. 20°C) and exposure times (min. 12 minutes) specified by the disinfectant manufacturer.
 - After removing the handle from the CIDEX OPA solution, fully immerse it in plenty of water and rinse thoroughly. Use sterile water unless tap water is acceptable according to the information provided by the disinfectant manufacturer.
 - Leave the handle fully submerged for at least 1 minute

- Remove the handle and dispose of the rinsing water. Always use fresh water for all rinses. Dispose of the water after each rinse. Do not reuse the water for other rinsing processes or for other purposes.
- Repeat this procedure TWO (2) more times for a total of THREE (3) RINSES in plenty of fresh water to remove all of the CIDEX OPA solution residues.
- Allow the handle to air dry sufficiently before reusing it.

7.

Performing an inspection and function test



- Check the handle for visible soiling or wear and reprocess it if necessary or dispose of it if the soiling or wear cannot be removed.
- A function test must be carried out after reprocessing. Allow the handle and the display unit to dry completely first of all. Then assemble the two components and check that the device is working, in particular the camera and the illumination.

8.

Storage

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

Chapter C: Sterilising the handle (dismantled) with STERRAD

1. At the place of use

Remove coarse soiling promptly after use (e.g. by wiping with a damp single-use cloth or an enzymatic pre-cleaner).

2. Containment and transport

Reprocessing should take place as soon as possible after use.

3. Preparation

Remove the blade from the handle.

Disconnect the display unit from the handle.

The handle must be rinsed after manual cleaning and immersion disinfection so that it is free from residues to avoid reactions with subsequent treatment steps or damage to the materials.

4. Pre-cleaning

Immediately after use, wipe the handle with a microfibre cloth soaked in cleaning agent to prevent contamination from drying.

Use cleaning agents that are either enzymatic or neutral to mildly alkaline.

Use soft and suitable brushes for hard-to-reach areas, nooks and crannies.

Remove the cleaning agent residues and dry the handle as required by the cleaning agent manufacturer.

5. Manual cleaning with brushes

Equipment

- Cleaning agent: Enzymatic or neutral to mildly alkaline (neodisher MediClean Forte).
- Warm (30 – 40°C) demineralised water
- Soft plastic brushes: Surface brush (2.3 x 0.1 x 0.5 cm L x W x H)
- Sufficiently large and material-resistant basin

Implementation

- Use the cleaning agent in the maximum recommended concentration.
- Soak the handle completely in cleaning solution (30 – 40°C) for at least five minutes.
- Clean all surfaces of the handle by brushing (immersed in cleaning solution):
- Brush all surfaces thoroughly until no more soiling is visible and at least 5 times (at least three minutes in total).
- Then brush the nooks and crannies and the areas in the transition area, in the blade clip and in the camera area at least 5 times with a surface brush (at least three minutes in total).
- Pay particular attention to the concentrations, temperatures and exposure times specified by the cleaning agent manufacturer.
- Remove the cleaning agent residues completely with water (preferably demineralised) and as required by the cleaning agent manufacturer and dry the handle.

6. Manual immersion disinfection

Equipment

- Disinfectant for immersion disinfection (compatible with cleaning agent): CIDEX OPA (active ingredient: ortho-phthalaldehyde)
- Sufficiently large and material-resistant basin

Implementation with CIDEX OPA

- Fully immerse the handle in the disinfectant solution (in CIDEX OPA solution) for 5 minutes so that all the lumens are filled and all the air bubbles are eliminated. This must be done at a temperature of at least 20°C (68°F). Remove the device from the solution and rinse thoroughly according to the following rinsing instructions.
- Pay particular attention to compliance with the concentrations (min. 0.55%), temperatures (min. 20°C) and exposure times (min. 12 minutes) specified by the disinfectant manufacturer.
- Remove the disinfectant residues with distilled water or drinkable tap water (according to the information provided by the disinfectant manufacturer) and dry the handle as required by the disinfectant manufacturer.

- After removing the handle from the CIDEX OPA solution, fully immerse it in plenty of water and rinse thoroughly. Use sterile water unless tap water is acceptable according to the information provided by the disinfectant manufacturer.
- Leave the handle fully submerged for at least 1 minute
- Remove the handle and dispose of the rinsing water. Always use fresh water for all rinses. Dispose of the water after each rinse. Do not reuse the water for other rinsing processes or for other purposes.
- Repeat this procedure TWO (2) more times for a total of THREE (3) RINSES in plenty of fresh water to remove all of the CIDEX OPA solution residues.
- Allow the handle to air dry sufficiently before reusing it.

7. Performing an inspection and function test



- Check the handle for visible soiling or wear and reprocess it if necessary or dispose of it if the soiling cannot be removed.
- A function test of the camera and illumination must be performed before sterilisation.

8. Packaging for sterilisation

Wrap the handle individually in single or double standardised sterilisation pouches that are suitable for the selected sterilisation procedure.

9. STERRAD

Equipment

- STERRAD NX, 100NX or 100S steriliser

Implementation

Perform one of the following cycles:

STERRAD NX / 100NX Standard cycle, STERRAD 100NX Express cycle or STERRAD 100S Short cycle.

10. Storage

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