Hygienic reprocessing

G100 LED

General warning and safety information

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

NOTE! This symbol is used to indicate information regarding installation, operation or maintenance that is important, but not associated with danger.

	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.
	Before reprocessing, the ophthalmic lens and the illuminant must be dismantled from the head. They are not suitable for automated reprocessing or sterilisation.
	Carry out hygienic reprocessing in case of suspected contamination.
	HEINE Optotechnik GmbH & Co. KG only approves the recommended agents and procedures.
	Hygienic reprocessing may only be carried out by a person who has sufficient expertise in hygiene.
	Observe the information provided by the reprocessing equipment manufacturer.
	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.
	The reusable specula must undergo hygienic reprocessing after each use.
	Single-use tips (HEINE UniSpec®) are intended for use once only.
	Do not use spray disinfection and do not reprocess using ultrasound.
	Automated reprocessing above 65°C can lead to a reduction in the light conductor's durability and to light transmission losses.
Reprocessing restrictions	Regularly check that the device is intact. The reusable tips can be reprocessed for up to 360 cycles.

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Selecting the reprocessing procedure

The hygienic classification (Spaulding classification) of the devices 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 this purpose, the application situation in question must be taken into account and the requirements set out in internal hospital / practice regulations, national guidelines and recommendations, and standards and laws must be met.

Choose from the following reprocessing methods for the G100 LED and the specula:

- **For a non-critical application:**
  - Cleaning wipe disinfection of the G100 LED and its ophthalmic lens **(chapter A)**
- **After examining infectious animals or when used for adding instruments:**
  - Manual cleaning and disinfection of the **G100 LED and the ophthalmic lens (chapter B)**
  - Automated cleaning and disinfection of the **G100 LED without an ophthalmic lens (chapter C)**
  - Manual cleaning and disinfection of the specula and tips **(chapter D)**
  - Automated cleaning and disinfection of the specula and tips **(chapter E)**

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Chapter A: Cleaning wipe disinfection of the G100 LED and its ophthalmic lens

1. **Preparation**
   Remove the reusable tips and reprocess them separately.
   Single-use tips (HEINE UniSpec®) are intended for use once only.
2. **Manual cleaning wipe disinfection**
   This procedure is not hygienically validated.
   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.
   Equipment
   - Cleaning agent, if necessary: Enzymatic (e.g. neodisher MediClean Forte)
   - Disinfectant:
     Alcohol-based (e.g. Incides N) or
     quaternary ammonium compounds (e.g. Cleanisept Wipes or Mikrobac Tissues)

   Implementation
   - Clean and disinfect the G100 LED manually (wipe cleaning and wipe disinfection).
   - For heavier soiling, you can first of all clean with a cloth soaked in cleaning agent before disinfecting with a disinfectant wipe.
   - Pay particular attention to hard-to-reach areas.
   - Wipe the surfaces that the animal and the practitioner came into contact with particularly thoroughly.
   - Remove the residues and dry off the device as required by the disinfectant manufacturer.
3. **Performing an inspection and function test**
   Check the device for visible soiling or wear and reprocess it if necessary or dispose of it if the soiling cannot be removed.
4. **Storage**
   Store the device in such a way that it is protected from recontamination, dust and moisture.

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Chapter B: Manual cleaning and disinfection of the G100 LED and the ophthalmic lens

1. **Preparation**
   Remove the reusable tips and reprocess them separately (chapter D or E).
   Single-use tips (HEINE UniSpec®) are intended for use once only.
   Remove the swivel lens and reprocess it separately (this chapter).
   Before reprocessing, the illuminant must be dismantled from the head.
2. **Manual cleaning with brushes**
   Equipment
   - Cleaning agent: Enzymatic or neutral to mildly alkaline (e.g. neodisher MediClean Forte)
   - Warm (30 – 40°C) demineralised water,
   - soft plastic brushes (round brushes for internal surfaces and cavities; the diameters of the brushes are adapted to the cavities' internal diameters)

   Implementation
   - Clean the G100 LED and the ophthalmic lens manually (in an immersion bath).
   - Soak the parts in cleaning solution (30 – 40°C) for at least one minute.
   - Do not allow air bubbles to get into cavities.
   - Clean all internal and external surfaces and cavities (e.g. openings for the ophthalmic lens and illuminant) by brushing (immersed in cleaning solution).
   - Pay particular attention to hard-to-reach areas.
   - Remove the cleaning agent residues and dry off the device as required by the cleaning agent manufacturer.
3. **Manual immersion disinfection**
   Equipment
   Disinfectant: Based on succinic dialdehyde (e.g. gigasept FF (new))

   Implementation
   - Disinfect the G100 LED and the ophthalmic lens manually (in an immersion bath).
   - Place the parts in the disinfectant solution according to the information provided by the disinfectant manufacturer.
   - Do not allow air bubbles to get into cavities.
   - Pay particular attention to the specified concentrations, temperatures and exposure times.
   - Remove the disinfectant residues and dry off the device as required by the manufacturer.
4. **Performing an inspection and function test**
   Check the device for visible soiling or wear and reprocess it if necessary or dispose of it if the soiling cannot be removed.
5. **Assembly**
   After reprocessing, the swivel lens can be plugged back into the G100 LED.
6. **Storage**
   Store the device in such a way that it is protected from recontamination, dust and moisture.

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Chapter C: Automated cleaning and disinfection of the G100 LED without an ophthalmic lens

1. Preparation

Remove the reusable tips and reprocess them separately (chapter D or E).
Single-use tips (HEINE UniSpec®) are intended for use once only.
Remove the swivel lens and reprocess it separately (chapter B).
Before reprocessing, the illuminant must be dismantled from the head.

3. Cleaning and disinfection

If required in your establishment or country, you can perform manual cleaning by brushing before automated cleaning and disinfection.

3.1. Automated cleaning and disinfection

Equipment

- Washer/disinfector that meets the requirements set out in DIN EN ISO 15883 or with a validated procedure in accordance with DIN EN ISO 15883
- Cleaning agent: Enzymatic or neutral to mildly alkaline (e.g. neodisher MediClean Forte)
- Neutralising agent, if specified by the cleaning agent manufacturer.

Implementation

- Position the G100 LED in the washer/disinfector so that it cannot topple over.
- The information provided by the manufacturers of the treatment agents and the washer/disinfector must be observed.
- Select a suitable cleaning agent and program (in accordance with DIN EN ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 minutes at 93°C or an alternative, equivalent program. (e.g. Vario TD program by Miele)

4. Performing an inspection and function test

Check the device for visible soiling or wear and reprocess it if necessary or dispose of it if the soiling cannot be removed.

5. Assembly

After reprocessing, the separately reprocessed swivel lens can be plugged back into the G100 LED.

6. Storage

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

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Chapter D: Manual cleaning and disinfection of the specula and tips

1. **Preparation**
   Remove coarse soiling promptly after use (e.g. by wiping with a damp single-use cloth or an enzymatic pre-cleaner).
2. **Manual cleaning with brushes**
   Equipment
   - Cleaning agent: Enzymatic or neutral to mildly alkaline (e.g. neodisher MediClean Forte)
   - Warm (30 – 40°C) demineralised water,
   - soft plastic brushes (round brushes for internal surfaces and cavities; the diameter of the brush is adapted to the tip's / speculum's diameter)

   Implementation
   - Clean reusable tips and specula manually (in an immersion bath).
   - Soak the parts in cleaning solution (30 – 40°C) for at least one minute.
   - Clean all internal and external surfaces by brushing (immersed in cleaning solution).
   - Pay particular attention to hard-to-reach areas.
   - Remove the cleaning agent residues and dry off the parts as required by the cleaning agent manufacturer.
3. **Manual immersion disinfection**
   Equipment
   - Disinfectant: Based on succinic dialdehyde (e.g. gigasept FF (new))

   Implementation
   - Disinfect the reusable tips and specula manually (in an immersion bath).
   - Place the parts in the disinfectant solution according to the information provided by the disinfectant manufacturer.
   - Pay particular attention to the specified concentrations, temperatures and exposure times.
   - Remove the disinfectant residues and dry off the device as required by the manufacturer.
4. **Performing an inspection and function test**
   
   Check the parts for visible soiling or wear and reprocess them if necessary or dispose of them if the soiling cannot be removed.
5. **Storage**
   Store the device in such a way that it is protected from recontamination, dust and moisture.

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Chapter E: Automated cleaning and disinfection of the specula and tips

1. Preparation

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

3. Cleaning and disinfection

If required in your establishment or country, you can perform manual cleaning by brushing before automated cleaning and disinfection.

3.1. Automated cleaning and disinfection

Equipment

- Washer/disinfector that meets the requirements set out in DIN EN ISO 15883 or with a validated procedure in accordance with DIN EN ISO 15883
- Cleaning agent: Enzymatic or neutral to mildly alkaline (e.g. neodisher MediClean Forte)
- Neutralising agent, if specified by the cleaning agent manufacturer.

Implementation

- Position the tips / specula firmly on the washer/disinfector's rinsing nozzles.
- The information provided by the manufacturers of the treatment agents and the washer/disinfector must be observed.
- Select a suitable cleaning agent and program (in accordance with DIN EN ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 minutes at 93°C or an alternative, equivalent program. (e.g. Vario TD program by Miele)

4. Performing an inspection and function test

Check the parts for visible soiling or wear and reprocess them if necessary or dispose of them if the soiling cannot be removed.

5. Storage

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

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