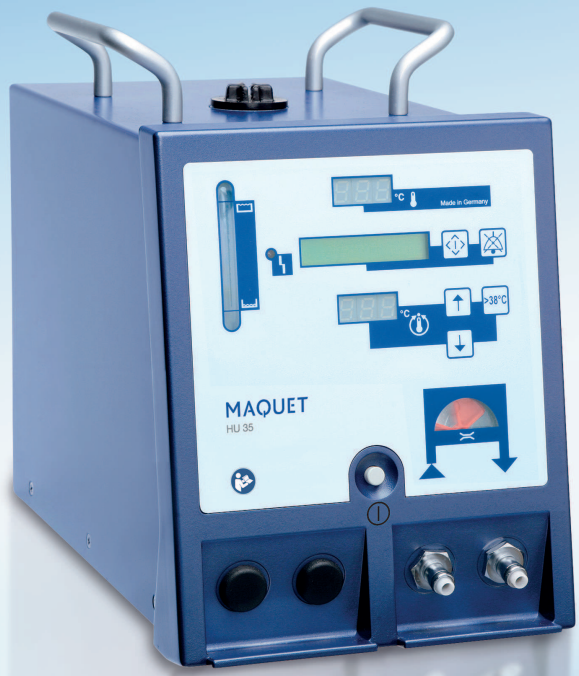
Interim Guide, April 2017

Cleaning, Descaling, Sanitizing

HEATER UNIT
HU 35

MAQUET
GETINGE GROUP



Subject to technical changes

Owing to our policy of continuous product development, the illustrations and technical data contained in this document may differ slightly from the current version of the device.

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1 General

1.1 Information on these revised Instructions for Use

These revised instructions for cleaning, descaling and sanitizing replace chapter 6 "Cleaning and disinfection" of the previous Instructions for Use for the hyperthermia device HU 35.

1.1.1 Validity of these revised Instructions for Use

These revised Instructions for Use for Cleaning, Descaling and Sanitizing shall apply until further notice for all instructions for the Heater Unit HU 35.

1.1.2 Symbols

References

References to other pages in these Instructions for Use begin with the arrow sign "⇨".

Action and reaction

The operator's actions are identified with numbered paragraphs "1", while the "▸" symbol identifies the reaction triggered in the system.

Example:

1 Switch the light switch on.
   ▸ The lamp lights up.
2 Switch the light switch off.

Buttons and menus

The buttons and menus are shown in square brackets.

Example:

■ Press the [DOWN] button in the [Operation] menu.

1.1.3 Definitions

DANGER!

Identifies an immediate, serious risk to people which will result in death or serious injury.

WARNING!

Identifies a general, serious risk to people which can result in death or serious injury.

CAUTION!

Identifies a possible risk which can result in injury.

NOTICE!

Identifies a possible risk to property which can result in equipment damage and/or data loss.

Structure of the other information

Information concerning events without personal injury or equipment damage is indicated as follows:

NOTE

Additional support and other helpful information.

2 Surface Cleaning and Disinfecting the Device after Each Use

WARNING!

Only use specified liquids and substances with the HU 35.

WARNING!

When cleaning the surfaces of the HU 35 the safety instructions from the cleaning agent manufacturer must be observed.

WARNING!

Pay attention to hand hygiene and protective barriers by routine hand washing and using disposable gloves.

WARNING!

For surface cleaning of the HU 35 housing use a damp cloth.

WARNING!

For surface cleaning of the HU 35 use disinfectants based on aldehydes, amonium components or alcohol only. Avoid the use of phenol derivates.

WARNING!

Switch the HU 35 off and unplug the HU 35 from the external power supply before surface cleaning.

WARNING!

Do not use chemical solvents such as ether or acetone and do not spill anesthetics such as Foram (isoflurane). They can damage the HU 35.

WARNING!

Do not allow liquid to penetrate the HU 35.

WARNING!

If the Hansen connectors at the tubes are not connected to any heat exchanger the couplings shall be connected using the cleaning connector.

Surface cleaning

1 Use a cloth moistened with an aqueous alcohol solution (70% ethanol/30% water) or a suitable cleaning solution for sensitive medical devices.
2 Clean the device and cables after each use to remove soiling and residual blood.

Surface disinfection

Disinfect the surfaces after each use. You can use the following disinfectants:

- Tosylchloramide sodium (Chloramine T)
- Alcohol (ethanol, isopropyl, 70% by vol.)
- Bacillol (Bode Chemie)
- Buraton 10F (Schülke & Mayr)
- Buraton rapid (Schülke & Mayr)
- Mikrobac forte (Bode Chemie)
- PeraSafe (DuPont)
- Pursept (Merz)

3 Descaling and sanitizing of the water circuit

The water circuit of the HU 35 comprises a pump, water tank, couplings and all tubing for the HU 35.

The quick reference guide for routine sanitation does not replace hygiene monitoring. It may be necessary to shorten the interval.

Depending on how contaminated the HU 35 is and the hygienic situation in the hospital, the necessary water quality may not be achieved after routine sanitation, and the procedure must therefore be repeated. If there are atypical *mycobacteria* in the water system, highly effective sanitation must be performed.

Equipment for descaling/sanitizing

The following equipment is required for descaling/sanitizing:

- Sterile inline filter with a pore size of 0.2 µm
- Personal protective clothing (as specified on the safety data sheet for the descaling/disinfection agent)
  - Chemical-resistant gloves made of nitrile or butyl rubber
  - Dust mask for P2 respiratory protection
  - Protective goggles
  - Laboratory coat

The following equipment is additionally required:

- Canister (chemical-resistant, for example made of polypropylene) with a capacity of at least 10 l.
- Measuring spoon (chemical-resistant)
- Powder funnel (chemical-resistant) for approx. 100 ml
- Scales for weighing the descaling/disinfection agent
- Beaker (chemical-resistant) for approx. 3 l
- Small flat tray (chemical-resistant) for the disinfection of cleaning connectors, approx 190 x 120 x 40 mm (L x W x H) in size

WARNING!

Disinfection and sanitation are two separate processes. The processes are no substitute for each other. Do not perform them at the same time.

WARNING!

When descaling and sanitation have to be performed, perform the descaling before sanitation.

WARNING!

Only use specified agents for descaling/sanitation.

WARNING!

In order to sanitize the HU 35 water circuit use tosylchloramide sodium, known as Chloramine-T or another chemically identical agent.

WARNING!

Chloramine-T has been tested for use with the HU 35. Other sanitizers/ disinfectants may influence the material compatibility. Use of any other, not chemically identical agents is explicitly not allowed.

WARNING!

Thoroughly follow the manufacturer's safety instructions for the sanitizer/ descaling agent during the sanitation/descaling of the HU 35.

WARNING!

Check the water level in the HU 35 water tank. If the water level is too low, fill up the tank to the maximum mark of the water level display.

WARNING!

If HU 35 is used in an operating room (OR): Do not fill the HU 35 during surgery. Do not open the cap of the water filler neck during surgery. Do not disconnect the tubing in the sterile OR field.

WARNING!

Provide adequate ventilation for the sanitation process. Avoid generation of dust from the sanitizer. Do not breathe in dust from the sanitizer. Avoid contact of the sanitizer with skin, eyes and clothes.

WARNING!

Use personal protection equipment (e.g. gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the sanitizer/descaling agent.

WARNING!

The system must be checked before descaling/sanitation starts:

- device self test ok
- no leakage in water line or leakage of the device
- water flow ok
- water level in tank ok.

WARNING!

All connected parts, devices, and modules must be firmly and correctly connected. Check the mechanical stability.

WARNING!

Do not kink the tubes. Do not touch the tubes with pointed or sharp objects.

WARNING!

The sanitizer/descaling agent must only be used pre- and postoperatively, never intraoperatively.

WARNING!

During the sanitation/descaling procedure of the HU 35 the heat exchanger must be replaced by a cleaning connector. The sanitizer/descaling agent could damage or contaminate the heat exchanger.

WARNING!

Perform the descaling process every 6 months with a concentration of 2% citric acid in the water system of the HU 35.

WARNING!

If the HU 35 is used regularly, sanitation must be performed every 7 days as well as after each use with 2% Chloramine-T in the water system of the HU 35.

WARNING!

If the HU 35 is out of use, empty it, remove the cap of the water filler neck and store the HU 35 in a dry place.

WARNING!

If atypical *Mycobacteria* are present in the water system, perform the highly effective sanitation process with a concentration of 5% Chloramine-T in the water system of the HU 35.

WARNING!

For an effective descaling/sanitation, the required amount of descaling agent/ sanitizer has to be determined depending on the tubing lengths connected to the HU 35.

WARNING!

The results of hygienic vigilance microbiological monitoring shall be used to determine the appropriate sanitizer concentration required for each HU 35.

WARNING!

The re-commissioning of the device shall only be performed by accompanied regular hygienic monitoring.

WARNING!

Use a sterile inline-filter with 0.2 µm porosity for filling the HU 35 with water.

WARNING!

The HU 35 tank shall be filled with soft sterile filtered water. Do not use deionized water.

WARNING!

The HU 35 tank shall be filled with sterile filtered water with a water hardness of ≤ 14 °dH (2.5 mmol/l $CaCO_3$). Do not use deionized water.

WARNING!

De-air the system to achieve an even distribution of the sanitizer/descaling agent in the water system.

WARNING!

After the descaling/sanitation procedure, rinse the device 3 times to remove residual descaling agent/sanitizer.

WARNING!

If the Hansen connectors at the tubes are not connected to any heat exchanger the couplings shall be connected using the cleaning connector.

3.1 Descaling Process for HU 35

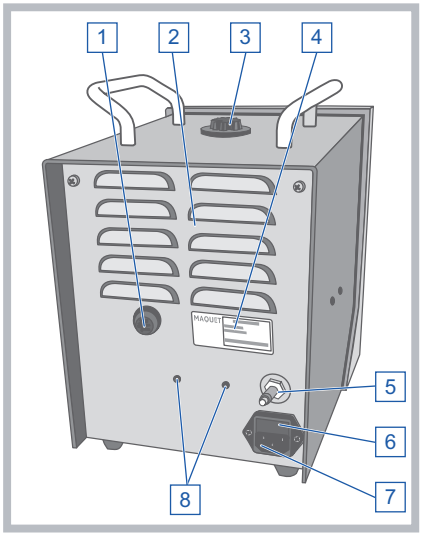
The descaling process is performed every 6 months with a concentration of 2% citric acid in the complete water volume of the HU 35.

Perform the following steps for descaling the system:

- Emptying the HU 35.
- Descaling of the HU 35.
- Rinsing the HU 35.

3.1.1 Emptying the HU 35

1 Switch the device off.
2 Disconnect the device from the power supply.
3 Disconnect the heat exchanger connected to the water circuit.
4 Disconnect the water tubes from the HU 35.
5 Empty the water tubes through the Hansen couplings over an outflow.
6 Put a container under the HU 35 or place the HU 35 over an outflow or other means of drainage.
7 Unscrew the filler neck cap ([3]) (e.g., using a coin).



8 Unscrew the cap of the outflow point ([1]) to drain the water.
9 Tip the HU 35 backwards to an angle of 45°. Do not lose the sealing rings of the two caps.
10 Tip the HU 35 further back to an angle of 90° to completely empty the HU 35 unit.
11 Close the outflow point ([1]).
12 Connect the water tubes to the HU 35.

▸ HU 35 is emptied.

3.1.2 Descaling of the HU 35

WARNING!

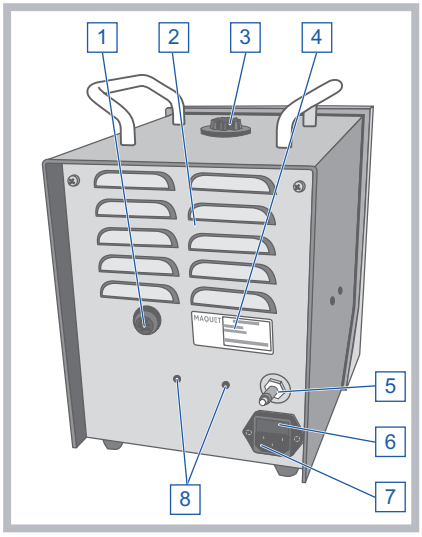
Use personal protection equipment (e.g. gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the sanitizer/descaling agent.

1 Connect the open hose ends to the cleaning connector supplied.

2 Produce a citric acid solution:
When connecting hoses measuring 2 x 1.5 m to the HU 35: Use a powder funnel to put 30 g of citric acid into a chemical-resistant 10 liter canister with watertight lid. Add 1.5 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the citric acid by shaking.
Or
When connecting hoses measuring 2 x 3 m to the HU 35: Use a powder funnel to put 34 g of citric acid into a chemical-resistant 10 liter canister with watertight lid. Add 1.7 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the citric acid by shaking.

3 Fill the citric acid solution up to the maximum mark on the tank's water level indicator.

4 Close the cap on the filler neck ([3]) (e.g., using a coin).



5 Connect the device to the power supply.

6 Switch on the device.

7 Run the HU 35 for approx. 20 seconds.

- The hoses are filled with citric acid solution.

8 When connecting hoses measuring 2 x 3 m to the HU 35:
Switch off the device.
Unscrew the cap on the filler neck ([3]) (e.g., using a coin).
Fill the device with the remaining citric acid solution up to the maximum mark on the water level indicator.
Close the cap on the filler neck ([3]) (e.g., using a coin).
Switch on the device.
9 Set the setpoint temperature to +38 °C.
10 Run the HU 35 for 60 minutes.
11 Switch off the device.
12 Disconnect the device from the mains.
13 Empty the HU 35.

NOTE

Use a suitable drain for disposing of the disinfection/descaling agent solutions.

- Descaling of the HU 35 is now complete.
- The HU 35 is now empty.

3.1.3 Rinsing the HU 35

1 Disconnect the cleaning connector and disinfect it and the Hansen couplings.
2 Connect the open hose ends to the cleaning connector supplied.
3 Fill the HU 35 with sterile filtered water up to the maximum mark on the water level indicator.
4 Connect the device to the power supply.
5 Close the cap on the filler neck (e.g., using a coin).
6 Switch on the device.
7 Set the setpoint temperature to +37°C.
8 Run the HU 35 for 3 minutes.
9 Switch off the device.
10 Disconnect the device from the mains.
11 Empty the HU 35.

NOTE

Use a suitable drain for disposing of the disinfection/descaling agent solutions.

12 Repeat the rinsed steps outlined above twice so that the HU 35 is rinsed a total of **three times**.
13 Fill the HU 35 with sterile filtered water up to the maximum mark on the water level indicator.

14 Close the cap on the filler neck (e.g., using a coin).

- The HU 35 has now been rinsed.

3.2 Sanitation Process for HU 35

If the HU 35 is used regularly, sanitation must be performed every 7 days as well as after each use with 2% Chloramine-T in the water system of the HU 35.

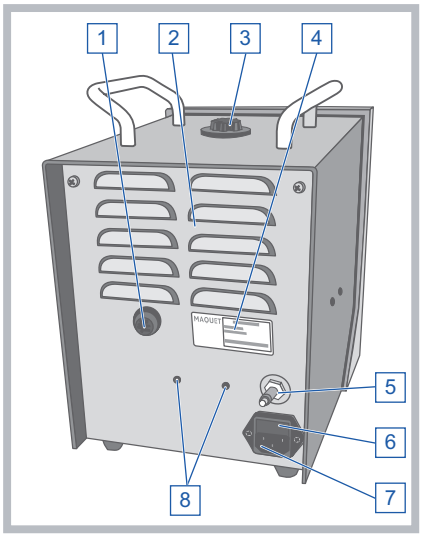
Perform the following steps for sanitation:

- Empty the HU 35.
- Sanitize the HU 35.
- Rinse of the HU 35

If there are atypical *mycobacteria* in the water system, a 5% Chloramine-T concentration must be used in the entire water volume of the HU 35. Special, highly effective sanitation supporting biofilm removal with 5% Chloramine-T are described in chapter 3.3, page 21.

3.2.1 Emptying the HU 35

1 Switch the device off.
2 Disconnect the device from the power supply.
3 Disconnect the heat exchanger connected to the water circuit.
4 Disconnect the water tubes from the HU 35.
5 Empty the water tubes through the Hansen couplings over an outflow.
6 Put a container under the HU 35 or place the HU 35 over an outflow or other means of drainage.
7 Unscrew the filler neck cap ([3]) (e.g., using a coin).



8 Unscrew the cap of the outflow point ([1]) to drain the water.
9 Tip the HU 35 backwards to an angle of 45°. Do not lose the sealing rings of the two caps.
10 Tip the HU 35 further back to an angle of 90° to completely empty the HU 35 unit.

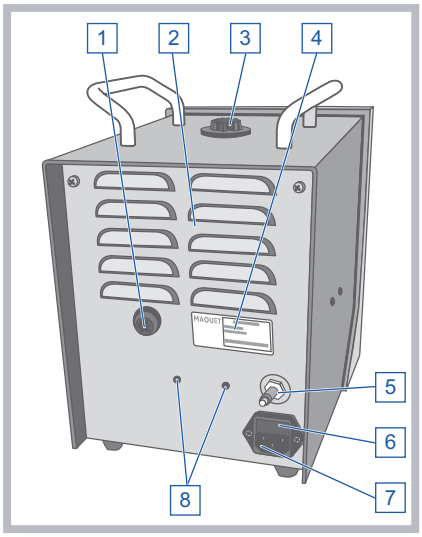
11 Close the outflow point ([1]).
12 Connect the water tubes to the HU 35.
- HU 35 is emptied.

3.2.2 Sanitation of the HU 35

WARNING!

Use personal protection equipment (e.g. gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the sanitizer/descaling agent.

1 Connect the open hose ends to the cleaning connector supplied.
2 Create a Chloramine-T solution.
When connecting hoses measuring 2 x 1.5 m to the HU 35: Use a powder funnel to put 30 g of Chloramine-T into a chemical-resistant 10 liter canister with watertight lid. Add 1.5 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.
Or
When connecting hoses measuring 2 x 3 m to the HU 35: Use a powder funnel to put 34 g of Chloramine-T into a chemical-resistant 10 liter canister with watertight lid. Add 1.7 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.
3 Fill the Chloramine-T solution up to the maximum mark on the tank's water level indicator.
4 Close the cap on the filler neck ([3]) (e.g., using a coin).



5 Connect the device to the power supply.
6 Switch on the device.
7 Run the HU 35 for approx. 20 seconds.
   ▸ The hoses are filled with Chloramine-T solution.
8 When connecting hoses measuring 2 x 3 m to the HU 35:
   Switch off the device.
   Unscrew the cap on the filler neck ([3]) (e.g., using a coin).
   Fill the device with the remaining Chloramine-T solution up to the maximum mark on the water level indicator.
   Close the cap on the filler neck ([3]) (e.g., using a coin).
   Switch on the device.
9 Set the setpoint temperature to +38 °C.
10 Run the HU 35 for 90 minutes.
11 Switch off the device.
12 Disconnect the device from the mains.
13 Empty the HU 35.

NOTE

Use a suitable drain for disposing of the sanitizing/descaling agent solutions.

- ▸ Sanitation of the HU 35 is now complete.
- ▸ The HU 35 is now empty.

3.2.3 Rinsing the HU 35

1 Disconnect the cleaning connector and disinfect it and the Hansen couplings.
2 Connect the open hose ends to the cleaning connector supplied.
3 Fill the HU 35 with sterile filtered water up to the maximum mark on the water level indicator.
4 Connect the device to the power supply.
5 Close the cap on the filler neck (e.g., using a coin).
6 Switch on the device.
7 Set the setpoint temperature to +37°C.
8 Run the HU 35 for 3 minutes.
9 Switch off the device.
10 Disconnect the device from the mains.
11 Empty the HU 35.

NOTE

Use a suitable drain for disposing of the sanitizing/descaling agent solutions.

12 Repeat the rinsed steps outlined above twice so that the HU 35 is rinsed a total of **three times**.
13 Fill the HU 35 with sterile filtered water up to the maximum mark on the water level indicator.
14 Close the cap on the filler neck (e.g., using a coin).

▸ The HU 35 has now been rinsed.

3.3 Highly effective Sanitation and supported Biofilm Removal Process for HU 35

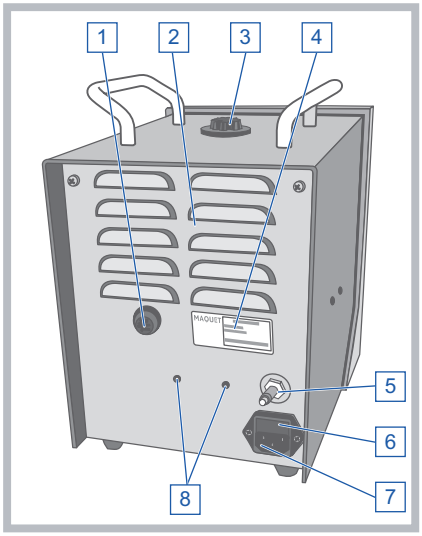
If atypical *Mycobacteria* are present in the water system, a concentration of 5% Chloramine-T in the complete water volume of the HU 35 must be used for highly effective sanitation supporting biofilm removal. This process requires 24 hours contact time with Chloramine-T.

Perform the following steps for highly effective sanitation supporting biofilm removal:

- Emptying HU 35.
- Highly effective sanitizing of the HU 35.
- Rinsing HU 35.

3.3.1 Emptying the HU 35

1 Switch the device off.
2 Disconnect the device from the power supply.
3 Disconnect the heat exchanger connected to the water circuit.
4 Disconnect the water tubes from the HU 35.
5 Empty the water tubes through the Hansen couplings over an outflow.
6 Put a container under the HU 35 or place the HU 35 over an outflow or other means of drainage.
7 Unscrew the filler neck cap ([3]) (e.g., using a coin).



8 Unscrew the cap of the outflow point ([1]) to drain the water.
9 Tip the HU 35 backwards to an angle of 45°. Do not lose the sealing rings of the two caps.
10 Tip the HU 35 further back to an angle of 90° to completely empty the HU 35 unit.

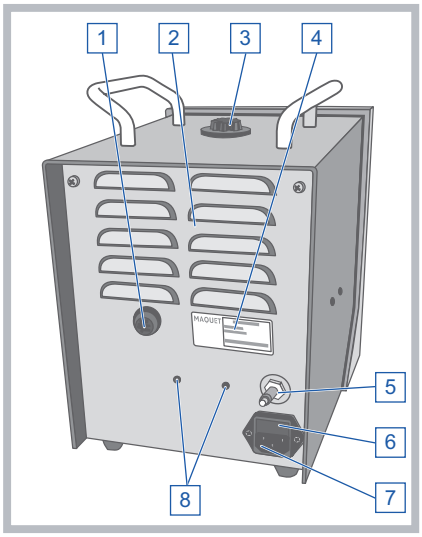
11 Close the outflow point ([1]).
12 Connect the water tubes to the HU 35.
▸ HU 35 is emptied.

3.3.2 Highly effective Sanitation of the HU 35

WARNING!

Use personal protection equipment (e.g. gloves resistant to chemicals made of Nitrile rubber or Butyl caoutchouc (butyl rubber), dust mask for respiratory protection P2, goggles and a protective lab coat) according to the Safety Data Sheet for the sanitizer/descaling agent.

1 Connect the open hose ends to the cleaning connector supplied.
2 Create a Chloramine-T solution.
When connecting hoses measuring 2 x 1.5 m to the HU 35: Use a powder funnel to put 75 g of Chloramine-T into a chemical-resistant 10 liter canister with watertight lid. Add 1.5 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.
Or
When connecting hoses measuring 2 x 3 m to the HU 35: Use a powder funnel to put 85 g of Chloramine-T into a chemical-resistant 10 liter canister with watertight lid. Add 1.7 liters of sterile, filtered, warm water (approx. +35°C). Close the canister, check that it is leak-tight and dissolve the Chloramine-T by shaking.
3 Fill the Chloramine-T solution up to the maximum mark on the tank's water level indicator.
4 Close the cap on the filler neck ([3]) (e.g., using a coin).



5 Connect the device to the power supply.
6 Switch on the device.
7 Run the HU 35 for approx. 20 seconds.
   ▸ The hoses are filled with Chloramine-T solution.
8 When connecting hoses measuring 2 x 3 m to the HU 35:
   Switch off the device.
   Unscrew the cap on the filler neck ([3]) (e.g., using a coin).
   Fill the device with the remaining Chloramine-T solution up to the maximum mark on the water level indicator.
   Close the cap on the filler neck ([3]) (e.g., using a coin).
   Switch on the device.
9 Set the setpoint temperature to +38 °C.
10 Run the HU 35 for 90 minutes.
11 Switch off the device.
12 Disconnect the device from the mains.
13 **Leave the Chloramine-T to work for 24 hours in the water system.**
14 Connect the device to the power supply.
15 Switch on the device.
16 Run the HU 35 for 5 minutes.
17 Switch off the device.
18 Disconnect the device from the mains.
19 Empty the HU 35.

NOTE

Use a suitable drain for disposing of the sanitizing/descaling agent solutions.

- ▸ Highly effective sanitation of the HU 35 is now complete.
- ▸ The HU 35 is now empty.

3.3.3 Rinsing the HU 35

1 Disconnect the cleaning connector and disinfect it and the Hansen couplings.
2 Connect the open hose ends to the cleaning connector supplied.
3 Fill the HU 35 with sterile filtered water up to the maximum mark on the water level indicator.
4 Connect the device to the power supply.
5 Close the cap on the filler neck (e.g., using a coin).
6 Switch on the device.
7 Set the setpoint temperature to +37°C.
8 Run the HU 35 for 3 minutes.
9 Switch off the device.
10 Disconnect the device from the mains.

11 Empty the HU 35.

NOTE

Use a suitable drain for disposing of the sanitizing/descaling agent solutions.

12 Repeat the rinsed steps outlined above twice so that the HU 35 is rinsed a total of **three times**.
13 Fill the HU 35 with sterile filtered water up to the maximum mark on the water level indicator.
14 Close the cap on the filler neck (e.g., using a coin).

▸ The HU 35 has now been rinsed.

For local contact:
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