Urgent!

Field Safety Corrective Action (FSCA)

MAQUET
GETINGE GROUP

26th of October 2017

FSN Number:	2017-10-16
FSN Title:	New Water Quality Management for Heater-Cooler Units HCU 20 and HCU 30
Type of Action:	Customer Notification
Affected Product:	Heater-Cooler Units HCU 20 and HCU 30
Unique Device Identification (UDI Code):	Not Assigned
Affected product details:	The FSCA affects all models and all serial numbers of the above-mentioned devices.
Description of the problem:	The Maquet Heater-Cooler Units HCU 20 and HCU 30 are used for cooling or warming a patient connected to an extracorporeal perfusion circuit and keeping the required patient temperature constant. The thermal transfer occurs via a heat exchanger in the patient perfusion circuit and/or cardioplegia water circuit and/or via a warming/ cooling blanket. There is no contact between the patient's blood stream and the system water circulating through the heat exchanger. Note: Heater-cooler devices have never been and are not considered sterile products and have to be handled carefully in regard to hygiene conditions in an operation theater. Maquet Cardiopulmonary as well as different National Competent Authorities have received isolated reports indicating bacterial contamination in the system water of HCU 20 and HCU 30 including mycobacterial counts. For clarification: Maquet Cardiopulmonary has not received any reports that a mycobacterial infection or any other bacterial infection has been caused by a Heater-Cooler Unit HCU 20 or HCU 30. Our internal investigations showed that the currently in the User's Manuals published preparation and maintenance procedures for HCU 20 and the cleaning procedure of the HCU 30 system's water paths have to be improved. In this context it is worth knowing that a hazard to the patient due to escaping microorganisms during operation of the Heater-Cooler Units HCU 20 and HCU 30 can be excluded with almost complete certainty. An independent testing institute

has also concluded this. Its conclusion is based on test results for a simulated operating room scenario providing evidence that excessively microbial inoculated HCU 20 and HCU 30 do not emit any germs to the sterile OR field in any operation mode of the devices.

The HCU 20 and HCU 30 are designed in a way that the tank water is separated from the air flow of the active cooling system. The air flow from or to the fan does not pass the area above from the water tank and therefore cannot carry aerosols from the water tank into the operating area. Investigations by an independent testing institute have confirmed that no particles larger than 5 µm, which potentially could be a vehicle of germs, exited the HCU 20 or HCU 30 tank during heating and cooling. All measured particles were within the specified particle counts requirements for clean rooms class B.

Corrective Action:

Even though HCU 20 and HCU 30 do not emit contaminated aerosols, Getinge developed and validated new safe and user-friendly water quality management procedures to be implemented on all HCU 20 and HCU 30 systems in the field.

These new procedures will maintain the water circuits of HCU 20 and HCU 30 clean and plumbing and provide reproducible and constant system water conditions, which create a “microbial unfriendly” environment – also against atypical mycobacteria.

Disinfection is only periodic and does not mitigate microbial growth between the disinfection intervals. The new water HCU 20/ HCU 30 quality management approach continuously maintains the water quality constant for the applied interval.

The current published User’s Manual for HCU 20 Heater-Cooler Units chapter 2 “preparation for operation – filling an empty unit” and chapter 5 “maintenance” will be replaced by the Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 20 (MCV-GK-10000705) in the required language.

Correspondingly the current published User’s Manual for HCU 30 Heater-Cooler Units chapter 4.1 information to the water hardness, 4.1.2 “weekly”, 4.1.3 “monthly (or after every 100 hours of operation”) and 4.3 “cleaning” will be replaced by the Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 30 (MCV-GK-10000706) in the required language.

In order to prevent recontamination as far as possible, it is highly recommended to replace the external water hoses for HCU 20 and/or HCU 30 by new hoses, when introducing the water quality management procedures, and to follow the defined replacement interval on a yearly basis. Otherwise the HCU 20/ HCU 30 water quality management efficiency will may

be compromised.

In very rare cases, HCU 20 devices of model HCU 20-602 (and retrofitted HCU 20-601) may still be equipped with an active UV lamp in the tank. Before applying the new water quality management for HCU 20, this UV lamp has to be deactivated by a Getinge authorized service technician in order to prevent any side effects with the use of Trisodium phosphate.

Advice on action to be taken by the user:

Fill out the enclosed Acknowledgement Form and return it as soon as possible to your local Maquet representative.

- Contact your local Maquet representative for an exchange of the external connectable HCU 20 and/or HCU 30 water hoses and for the deactivation of the HCU 20 UV lamp (if applicable).
- Incorporate the new water quality management procedures into your operating processes, and conduct any training necessary.
- Continue to monitor the hygiene (contamination levels) in accordance with your internal practices.
- Immediately report any contamination findings to your local Maquet representative by filing a complaint.

Referenced documents/ attachments:

- Letter of Acknowledgement Customer
- Annex I: List of Affected Products
- Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 20 (MCV-GK-10000705-EN)
- Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 30 (MCV-GK-10000706-EN)

Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact and inform your personnel.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of this action.

Your understanding is much appreciated. Thank you for your continued support as we provide you with up-to-date information on the quality of our products. We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we shall be providing this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Maquet representative.

Sincerely,

Markus Medart
Managing Director

Bernd Rakow

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Bernd Rakow
Safety Officer

2017 -10- 26

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REVISED INSTRUCTIONS FOR USE WATER QUALITY MANAGEMENT

HEATER-COOLER UNIT
HCU 20

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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Contents

1 General

1.1 Information on these revised Instructions for Use

These revised Instructions for Use for the Heater-Cooler Unit HCU 20 describe Water Quality Management as well as the surface cleaning and surface disinfection of the device.

These revised Instructions for Use replace chapter 2 "Preparation for operation – Filling an empty unit" and chapter 5 "Maintenance" of the previous Instructions for Use for the Heater-Cooler Unit HCU 20. An overview of the maintenance work to be performed can be found in ⇨ "Maintenance Work", page 27.

The procedures described in these revised Instructions for Use do not replace the conventional clinical hygiene measures and hygiene protocols. Irrespective of the Water Quality Management, the clinical user is responsible for the hygienic handling and the hygiene status of the HCU 20 in the clinical environment.

1.1.1 Validity of these revised Instructions for Use

These revised Instructions shall apply until further notice for all manuals for the Heater-Cooler Unit HCU 20.

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 Safety

2.1 General Safety Instructions

WARNING!

The device may only be put back into operation under regular hygiene monitoring according to the current protocol. The purge interval for water circulation may need to be shortened.

WARNING!

The HCU 20 is a non-sterile device.

WARNING!

Turn off the HCU 20 before maintenance, surface cleaning and storage, and disconnect the device from the power supply.

WARNING!

Only use the warming/cooling blankets once. Avoid microbiological contamination by not using the blankets again.

WARNING!

The consumables used must be suitable for the preset maximum pressure. In case of doubt, the pressure must be adjusted by a Maquet customer service representative before use.

3 Surface Cleaning and Surface Disinfection of the Device and Other Protective Measures

WARNING!

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

WARNING!

Only use specified agents.

CAUTION!

When cleaning the surfaces of the HCU 20 the safety instructions from the cleaning agent manufacturer must always be observed.

NOTICE!

To clean the surface of the HCU 20, only use an aqueous alcohol solution (70% ethanol/30% water) or a suitable cleaning solution based on aldehyde, ammonium components or alcohol. Do not use any phenol derivatives.

NOTICE!

Do not use chemical solvents such as ether or acetone. They may damage the HCU 20.

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 HCU 20 and cables after each use to remove soiling.

Surface disinfection and other protective measures

Disinfect the surfaces of the HCU 20 before and after each use, but at least once daily.

Disinfect in particular:

- The cap of the water tank before and after each use.

NOTE

Disinfect your hands before opening the cap of the water tank.
Change your disposable gloves after opening the cap of the water tank.

- The filler of the water tank before the weekly water change or before active Circulation Purging with trisodium phosphate solution.
- All connectors before each connection.

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)

4 Operation of the Device with Sterile Filtered, Demineralized Water and Trisodium Phosphate

Water Quality Management involves operation of the HCU 20 with sterile filtered, demineralized water and the substance trisodium phosphate (for the CAS number and additional information, see ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 25 and ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 26).

Water Quality Management comprises the following activities:

Interval	Activity	Information source
1st week	Initial active Circulation Purging (initial aCP) (72-hour exposure time) + Water change (cWS)	⇨ "Initial Active Circulation Purging (Initial aCP)", page 12 ⇨ "Weekly Water Change", page 16
2nd week	Water change (cWS)	⇨ "Weekly Water Change", page 16
3rd week	Water change (cWS)	⇨ "Weekly Water Change", page 16
4th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
5th week	Routine active Circulation Purging (aCP) (6-hour exposure time) + Water change (cWS)	⇨ "4-weekly Active Circulation Purging (aCP)", page 19 ⇨ "Weekly Water Change", page 16
6th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
7th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
8th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
9th week	Routine active Circulation Purging (aCP) (6-hour exposure time) + Water change (cWS)	⇨ "4-weekly Active Circulation Purging (aCP)", page 19 ⇨ "Weekly Water Change", page 16
10th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
...	...	...

Following maintenance of the HCU 20 by Maquet or Maquet-authorized service personnel, active Circulation Purging (aCP) (⇨ "6-hourly Active Circulation Purging (aCP)", page 21) must be performed.

The introduction of Water Quality Management for the HCU 20 involves replacing the externally connectible water tubes for the right and left water circuit with new HCU 20 water tubes and additionally performing this replacement every year.

To avoid recontamination of the HCU 20 where possible, only use water tubes that meet these Water Quality Management specifications. Otherwise, the effectiveness of Water Quality Management can be impaired.

NOTE

Use a sterile inline filter with a pore size of 0.2 µm to filter the water.

Produce demineralized water from tap water using commercially available filter systems. To this end, follow the instructions provided by the filter system manufacturer.

Alternatively, demineralized water can be purchased from specialist retailers.

When operating the device with trisodium phosphate, the instructions in the trisodium phosphate manufacturer's safety data sheet must be observed.

The following equipment is required to prepare the trisodium phosphate solution:

- Personal protective clothing (as specified in the safety data sheet of the trisodium phosphate manufacturer)
  - Chemical-resistant gloves made of nitrile or butyl rubber
  - Protective goggles
  - Laboratory coat
- Measuring scoop (chemical-resistant)
- Scales for weighing the trisodium phosphate
- Beaker (chemical-resistant) for approx. 3 l

WARNING!

The water tank of the HCU 20 must be filled with demineralized, sterile filtered water.

CAUTION!

Fully demineralized or distilled water may only be used with trisodium phosphate in the concentration mentioned according to these revised Instructions for Use, as otherwise the copper of the cooling coils and the heating element could become etched.

CAUTION!

The substance trisodium phosphate has been tested for use in the water circuits of the HCU 20. Other chemical substances may affect material compatibility. The use of other substances for this purpose which are not chemically identical is expressly forbidden.

WARNING!

To ensure effective Water Quality Management, the necessary amount of the substance must be determined based on the length of the tubes connected to HCU 20.

Determine the appropriate amount of trisodium phosphate for the required solution concentration, using the following tables:

- ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 25
- ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 26

WARNING!

To achieve an even distribution of trisodium phosphate in the water system, the system must be de-aired.

WARNING!

The HCU 20 must not be operated with water tubes < 6 m. In the event of a malfunction, shorter tube lengths can lead to a water temperature of above 41°C.

CAUTION!

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

WARNING!

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

WARNING!

Dry running damages the circulation pump. The HCU 20 must never be placed on its side. If the device was unintentionally placed in a different position, it must stand upright and be switched off for at least 24 hours before operation.

WARNING!

If the connection is interrupted, or if you switch off the remote control, the circulation pump must be restarted.

Note: The use of 5 mmol trisodium phosphate in the water circuit of the heater-cooler unit HCU 20 is expressly permissible with Maquet oxygenators and Maquet cardioplegia heat exchangers; material compatibility has been tested and confirmed.

4.1 Initial Active Circulation Purging (Initial aCP)

The introduction of Water Quality Management involves **initial** active Circulation Purging (initial aCP) of the HCU 20 with a **72-hour exposure time**.

Initial active Circulation Purging (initial aCP) is performed with an aqueous trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate in the entire water volume of the device including externally connected tubes.

Perform the following steps for initial active Circulation Purging (initial aCP):

- ⇨ "Emptying", page 13
- ⇨ "One-off Rinsing", page 14
- ⇨ "72-hourly Active Circulation Purging (aCP)", page 15 with a trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate
- ⇨ "Emptying, Surface Disinfection and Replacement of the Water Tubes", page 16

WARNING!

The trisodium phosphate solution at a concentration of 25 mmol/l for active Circulation Purging (aCP) must only be used preoperatively or postoperatively, and never intraoperatively.

NOTE

A system test is required prior to starting active Circulation Purging (aCP):

- HCU 20 self-test OK.
- No leaks in the water line or the HCU 20.

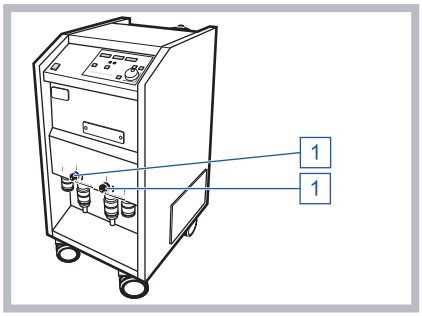
- Water flow OK.
- Water level in the water tank OK.

4.1.1 Emptying

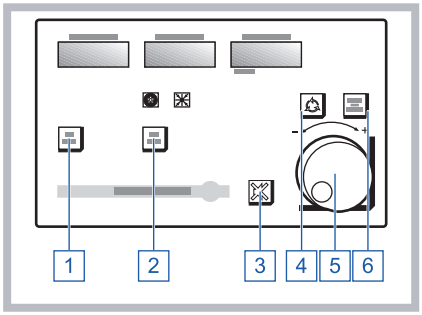
WARNING!

If the water tank of the HCU 20 is too full or a completely filled HCU 20 is moved, the tank water may discharge via the outflow outlet of the HCU 20 onto the floor.

1 Close all the stopcocks ([1]).



2 Disconnect all heat exchangers which are connected to the right and left water circuit.
3 Make sure that the open ends of the tubes end in a waste container.
4 Open all the stopcocks ([1]).
5 Press the [Circulation ON/OFF] button ([4]) to start the circulation and pump out the water.

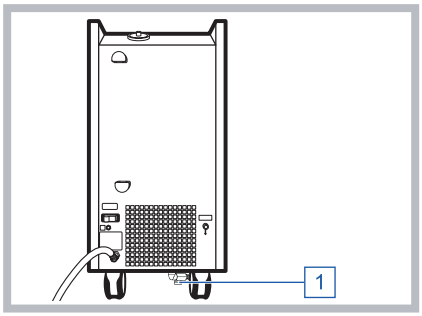


   ▸ The HCU 20 pumps the water out.
6 Once water stops flowing out, press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.

NOTE

When you empty the water tank, make sure that the HCU 20 is switched off.

7 Connect a 3/8" silicone hose to the tank drain valve ([1]).



8 Make sure that the open end of the silicone hose ends in a waste container.
9 Open the tank drain valve ([1]) in order to empty the water tank.
10 Close the tank drain valve ([1]) and disconnect the silicone hose as soon as the water tank is empty.
11 Connect the open ends of the tubes to the cleaning connectors (double Hansen connectors).

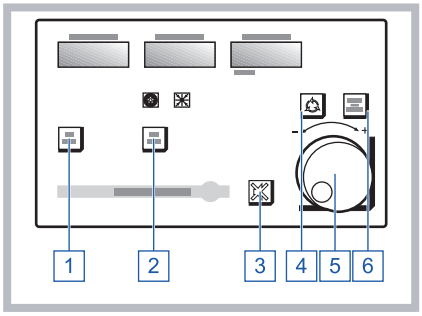
▸ The HCU 20 is now empty.

Note: Observe the local disposal regulations for trisodium phosphate water.

4.1.2 One-off Rinsing

1 Open the funnel for the water tank.

2 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.



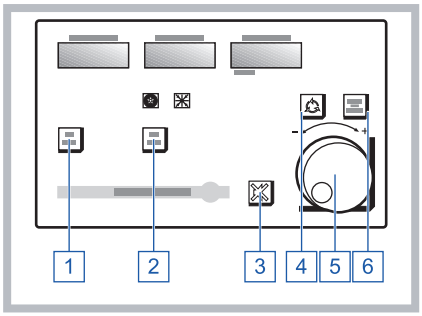
▸ The water level is shown in the middle display.

3 Fill the water tank with sterile filtered and demineralized water through the funnel up to a level of 33 liters.
4 Close the funnel for the water tank.
5 Press the [Tank Temp.] button ([2]) to exit the "level mode".
6 De-air the internal water circuit (⇨ "De-airing the Internal Water Circuit", page 24).
7 Repeat the de-airing for the internal water circuit until the tubes are completely full and no more air bubbles are visible.
8 Empty the HCU 20 as described in ⇨ "Emptying", page 20.

4.1.3 72-hourly Active Circulation Purging (aCP)

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Prepare the trisodium phosphate solution for active Circulation Purging (aCP) (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 25 mmol/l Trisodium Phosphate", page 26).
2 Open the funnel for the water tank.
3 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.



- The water level is shown in the middle display.

4 Pour the trisodium phosphate solution into the water tank through the funnel.
5 Fill the water tank with the prepared, sterile filtered and demineralized water through the funnel up to a level of 33 liters.
6 Close the funnel for the water tank.
7 Press the [Tank Temp.] button ([2]) to exit the "level mode".
8 De-air the internal water circuit (⇨ "De-airing the Internal Water Circuit", page 24).
9 Open the funnel for the water tank.
10 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.
11 Fill the water tank with the prepared, sterile filtered and demineralized water through the funnel up to a level of 33 liters.
12 Close the funnel for the water tank.
13 Press the [Tank Temp.] button ([2]) to exit the "level mode".
14 Press the [Circulation ON/OFF] button ([4]) to start the circulation.
15 Press the [Set Temp.] button ([1]) and, at the same time, set the temperature to +38°C using the control knob ([5]).
16 Run the HCU 20 for 5 minutes.
17 Switch off the HCU 20. The trisodium phosphate solution must be left to work on the water system for at least 72 hours.
18 Switch on the HCU 20 after at least 72 hours.
19 Press the [Set Temp.] button ([1]) to de-air and, at the same time, set the temperature to +2.9°C ("tank mode") using the control knob ([5]).
20 Wait until the message "TANK" stops flashing.

21 Press the [Circulation ON/OFF] button ([4]) to start the circulation.
22 Press the [Set Temp.] button ([1]) and, at the same time, set the temperature to +38°C (maximum) using the control knob ([5]).
23 Let the water circulate for 5 minutes.
24 Press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.

▸ The 72-hourly active Circulation Purging (aCP) of the HCU 20 is now complete.

4.1.4 Emptying, Surface Disinfection and Replacement of the Water Tubes

1 Empty the HCU 20 as described in ⇨ "Emptying", page 13.
2 Disinfect the surfaces of the HCU 20 as described in ⇨ "Surface Cleaning and Surface Disinfection of the Device and Other Protective Measures", page 7.
3 Replace the old water tubes with new ones.
4 Continue by filling the HCU 20 (⇨ "Filling the Device", page 18).

4.2 Continuous Water Stabilization (cWS)

Perform the following steps for continuous Water Stabilization (cWS):

- ⇨ "Weekly Water Change", page 16
- ⇨ "Daily Monitoring of the Water Quality (pH Value Measurement)", page 19

4.2.1 Weekly Water Change

Perform the following steps for the weekly water change:

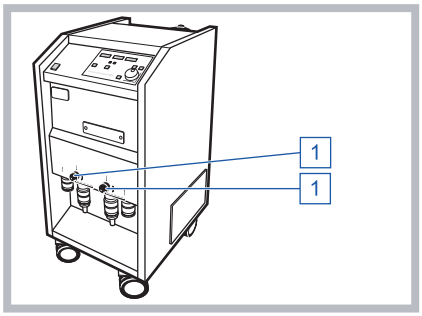
- ⇨ "Emptying", page 16
- ⇨ "Filling the Device", page 18 with a trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate

Emptying

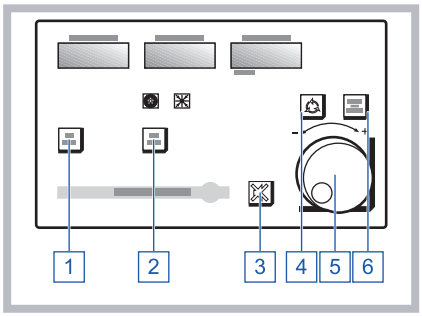
WARNING!

If the water tank of the HCU 20 is too full or a completely filled HCU 20 is moved, the tank water may discharge via the outflow outlet of the HCU 20 onto the floor.

1 Close all the stopcocks ([1]).



2 Disconnect all heat exchangers which are connected to the right and left water circuit.
3 Make sure that the open ends of the tubes end in a waste container.
4 Open all the stopcocks ([1]).
5 Press the [Circulation ON/OFF] button ([4]) to start the circulation and pump out the water.



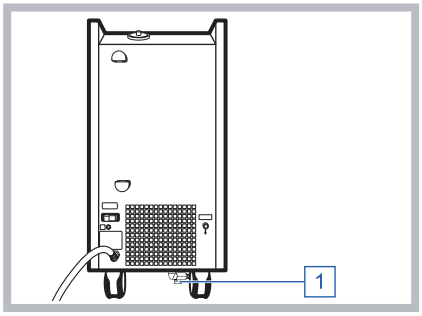
- The HCU 20 pumps the water out.

6 Once water stops flowing out, press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.

NOTE

When you empty the water tank, make sure that the HCU 20 is switched off.

7 Connect a 3/8" silicone hose to the tank drain valve ([1]).



8 Make sure that the open end of the silicone hose ends in a waste container.
9 Open the tank drain valve ([1]) in order to empty the water tank.
10 Close the tank drain valve ([1]) and disconnect the silicone hose as soon as the water tank is empty.

11 Connect the open ends of the tubes to the cleaning connectors (double Hansen connectors).

▸ The HCU 20 is now empty.

Note: Observe the local disposal regulations for trisodium phosphate water.

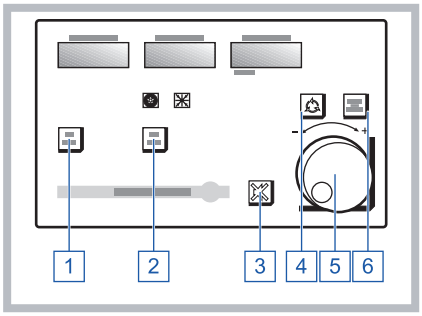
Filling the Device

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Prepare the trisodium phosphate solution for continuous Water Stabilization (cWS) (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 5 mmol/l Trisodium Phosphate", page 25).

2 Open the funnel for the water tank.

3 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.



▸ The water level is shown in the middle display.

4 Pour the trisodium phosphate solution into the water tank through the funnel.

5 Fill the water tank with the prepared, sterile filtered and demineralized water through the funnel up to a level of 33 liters.

6 Close the funnel for the water tank.

7 Press the [Tank Temp.] button ([2]) to exit the "level mode".

8 De-air the internal water circuit (⇨ "De-airing the Internal Water Circuit", page 24).

9 Open the funnel for the water tank.

10 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.

11 Fill the water tank with the prepared, sterile filtered and demineralized water through the funnel up to a level of 33 liters.

12 Close the funnel for the water tank.

13 Press the [Tank Temp.] button ([2]) to exit the "level mode".

14 Press the [Circulation ON/OFF] button ([4]) to start the circulation.

15 Press the [Set Temp.] button ([1]) and, at the same time, set the temperature to +38°C using the control knob ([5]).

16 Run the HCU 20 for 5 minutes.

17 Press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.
   - The water change of the HCU 20 is now complete.

18 Disinfect the surfaces of the HCU 20 as described in ⇨ "Surface Cleaning and Surface Disinfection of the Device and Other Protective Measures", page 7.

- The water change of the HCU 20 is now complete.

4.2.2 Daily Monitoring of the Water Quality (pH Value Measurement)

WARNING!

If atypical mycobacteria are present in the water system, perform active Circulation Purging (aCP) with a concentration of 25 mmol/l trisodium phosphate in the water system of the HCU 20.

An amount of 5 mmol/l trisodium phosphate maintains the average pH of the water at 10 to 12. A pH value above 10 is effective, a pH value below 8 (and thus close to the neutral pH of 7) is ineffective. The maximum permitted pH for continuous Water Stabilization (cWS) with trisodium phosphate is 13.

1 Monitor the pH value of the tank water in the HCU 20 daily and after each water change using pH test strips or a calibrated measuring device.
   pH < 10 ⇨ too low
   10 ≤ pH ≤ 13 ⇨ ok
   pH > 13 ⇨ too high

2 Perform the following steps, depending on the pH value:
   If the pH value is greater than or equal to 10 and less than or equal to 13, continue to use the HCU 20.
   If the pH is too low or too high, perform a water change as described in ⇨ "Continuous Water Stabilization (cWS)", page 16.
   If the pH falls below 10 within 72 hours after the last water change or after active Circulation Purging (aCP), immediately perform active Circulation Purging (aCP).

4.3 4-weekly Active Circulation Purging (aCP)

Routinely, active Circulation Purging (aCP) of the HCU 20 must be performed **every 4 weeks** with a **6-hour exposure time** (for performance time intervals, see ⇨ "Operation of the Device with Sterile Filtered, Demineralized Water and Trisodium Phosphate", page 9).

Active Circulation Purging (aCP) is performed with an aqueous trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate in the entire water volume of the device including externally connected tubes.

Perform the following steps for active Circulation Purging (aCP):

- ⇨ "Emptying", page 20
- ⇨ "6-hourly Active Circulation Purging (aCP)", page 21 with a trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate
- ⇨ "Emptying", page 23

WARNING!

The trisodium phosphate solution at a concentration of 25 mmol/l for active Circulation Purging (aCP) must only be used preoperatively or postoperatively, and never intraoperatively.

NOTE

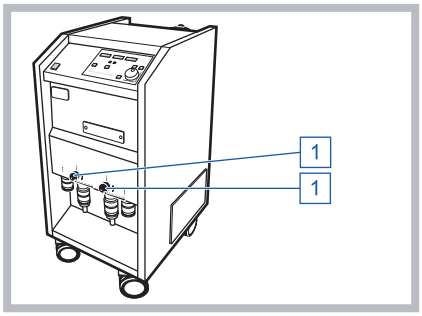
A system test is required prior to starting active Circulation Purging (aCP):
- HCU 20 self-test OK.
- No leaks in the water line or the HCU 20.
- Water flow OK.
- Water level in the water tank OK.

4.3.1 Emptying

WARNING!

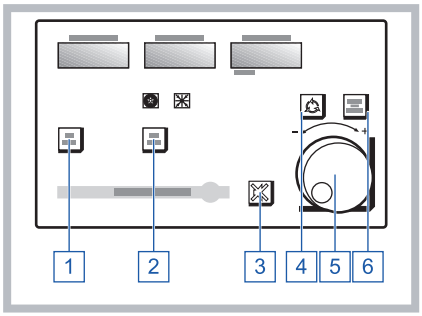
If the water tank of the HCU 20 is too full or a completely filled HCU 20 is moved, the tank water may discharge via the outflow outlet of the HCU 20 onto the floor.

1 Close all the stopcocks ([1]).



2 Disconnect all heat exchangers which are connected to the right and left water circuit.
3 Make sure that the open ends of the tubes end in a waste container.
4 Open all the stopcocks ([1]).

5 Press the [Circulation ON/OFF] button ([4]) to start the circulation and pump out the water.



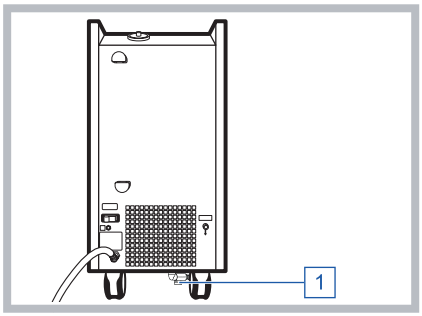
- The HCU 20 pumps the water out.

6 Once water stops flowing out, press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.

NOTE

When you empty the water tank, make sure that the HCU 20 is switched off.

7 Connect a 3/8" silicone hose to the tank drain valve ([1]).



8 Make sure that the open end of the silicone hose ends in a waste container.
9 Open the tank drain valve ([1]) in order to empty the water tank.
10 Close the tank drain valve ([1]) and disconnect the silicone hose as soon as the water tank is empty.
11 Connect the open ends of the tubes to the cleaning connectors (double Hansen connectors).

- The HCU 20 is now empty.

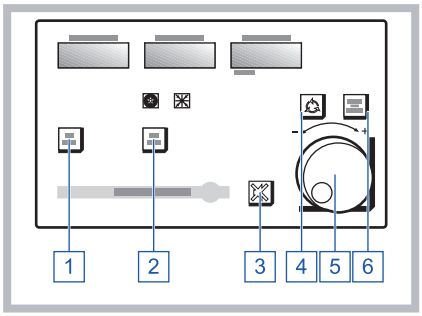
Note: Observe the local disposal regulations for trisodium phosphate water.

4.3.2 6-hourly Active Circulation Purging (aCP)

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Prepare the trisodium phosphate solution for active Circulation Purging (aCP) (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 25 mmol/l Trisodium Phosphate", page 26).
2 Open the funnel for the water tank.

3 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.



- The water level is shown in the middle display.

4 Pour the trisodium phosphate solution into the water tank through the funnel.
5 Fill the water tank with the prepared, sterile filtered and demineralized water through the funnel up to a level of 33 liters.
6 Close the funnel for the water tank.
7 Press the [Tank Temp.] button ([2]) to exit the "level mode".
8 De-air the internal water circuit (⇨ "De-airing the Internal Water Circuit", page 24).
9 Open the funnel for the water tank.
10 Press the [Set Temp.] ([1]) and [Tank Temp.] ([2]) buttons simultaneously for 3 seconds.
11 Fill the water tank with the prepared, sterile filtered and demineralized water through the funnel up to a level of 33 liters.
12 Close the funnel for the water tank.
13 Press the [Tank Temp.] button ([2]) to exit the "level mode".
14 Press the [Circulation ON/OFF] button ([4]) to start the circulation.
15 Press the [Set Temp.] button ([1]) and, at the same time, set the temperature to +38°C using the control knob ([5]).
16 Run the HCU 20 for 5 minutes.
17 Switch off the HCU 20. The trisodium phosphate solution must be left to work on the water system for at least 6 hours.
18 Switch on the HCU 20 after at least 6 hours.
19 Press the [Set Temp.] button ([1]) to de-air and, at the same time, set the temperature to +2.9°C ("tank mode") using the control knob ([5]).
20 Wait until the message "TANK" stops flashing.
21 Press the [Circulation ON/OFF] button ([4]) to start the circulation.
22 Press the [Set Temp.] button ([1]) and, at the same time, set the temperature to +38°C using the control knob ([5]).
23 Let the water circulate for 5 minutes.
24 Press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.

- The 6-hourly active Circulation Purging (aCP) of the HCU 20 is now complete.

4.3.3 Emptying

1 Empty the HCU 20 as described in ⇨ "Emptying", page 20.
2 Continue by filling the HCU 20 (⇨ "Filling the Device", page 18).

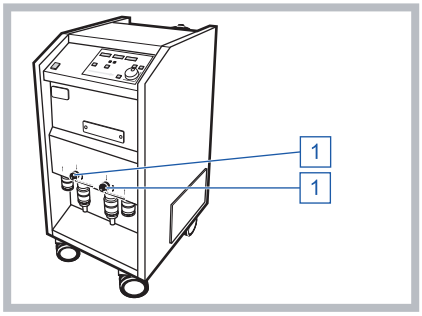
5 Procedures for Water Quality Management of the Device

5.1 De-airing the Internal Water Circuit

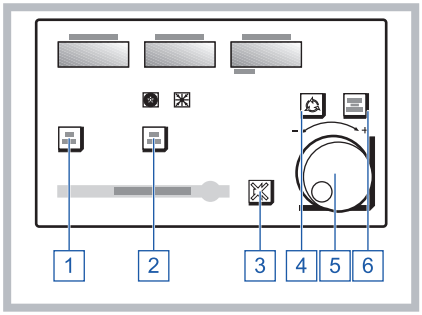
WARNING!

Do not aim the fan outlet on the back of the HCU 20 at the sterile operating field.

1 Open all the stopcocks ([1]).



2 Press the button [Set Temp.] ([1]) to de-air and, at the same time, set the temperature to +2.9°C ("tank mode") using the control knob ([5]) .



3 Wait until the message "TANK" stops flashing.
4 Press the [Circulation ON/OFF] button ([4]) to start the circulation.
5 Perform the circulation until no more bubbles are visible in the tubes and the circulation pump runs with a steady, quiet sound.
6 Press the [Circulation ON/OFF] button ([4]) to stop the circulation pump.

▸ The internal water circuit has now been de-aired.

5.2 Preparing the Trisodium Phosphate Solution in a Concentration of 5 mmol/l Trisodium Phosphate

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Determine the appropriate amount of trisodium phosphate for the required solution concentration, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 25.
2 Weigh the required amount of trisodium phosphate using scales.
3 Place the weighed trisodium phosphate in a measuring beaker.
4 Determine the required amount of water, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 25.
5 Prepare the required amount of warm, sterile filtered and demineralized water.
6 Dissolve the trisodium phosphate in 1 liter of the prepared, warm, sterile filtered and demineralized water.

Tube length per water circuit	Left water circuit	Right water circuit	Total volume (in liters)	Total volume (in liters)	Trisodium phosphate Dodecahydrate ($Na_3PO_4 \cdot 12H_2O$) CAS no.: 10101-89-0	Trisodium phosphate Anhydrate (Na_3PO_4) CAS no.: 7601-54-9
	132 ml/m	132 ml/m	Tubing	HCU 20	5 mmol/l (~1.9 g/l)	5 mmol/l (~0.8 g/l)
30 m (2 x 15 m)	3.95	3.95	7.9	40.9	**80 g**	**34 g**
20 m (2 x 10 m)	2.64	2.64	5.28	38.3	**75 g**	**31 g**
12 m (2 x 6 m)	1.58	1.58	3.16	36.2	**70 g**	**30 g**
2 m (2 x 1 m)	0.26	0.26	0.52	33.0	**65 g**	**27 g**

Tab. 1: Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.

5.3 Preparing the Trisodium Phosphate Solution in a Concentration of 25 mmol/l Trisodium Phosphate

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Determine the appropriate amount of trisodium phosphate for the required solution concentration, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 26.
2 Weigh the required amount of trisodium phosphate using scales.
3 Place the weighed trisodium phosphate in a measuring beaker.
4 Determine the appropriate amount of water, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 26.
5 Prepare the required amount of warm, sterile filtered and demineralized water.
6 Dissolve the trisodium phosphate in 1 liter of the prepared, warm, sterile filtered and demineralized water.

Tube length per water circuit	Left water circuit	Right water circuit	Total volume (in liters)	Total volume (in liters)	Trisodium phosphate Dodecahydrate ($Na_3PO_4 \cdot 12H_2O$) CAS no.: 10101-89-0	Trisodium phosphate Anhydrate (Na_3PO_4) CAS no.: 7601-54-9
	132 ml/m	132 ml/m	Tubing	HCU 20	25 mmol/l (~9.5 g/l)	25 mmol/l (~4.1 g/l)
30 m (2 x 15 m)	3.95	3.95	7.9	40.9	**390 g**	**168 g**
20 m (2 x 10 m)	2.64	2.64	5.28	38.3	**370 g**	**157 g**
12 m (2 x 6 m)	1.58	1.58	3.16	36.2	**350 g**	**148 g**
2 m (2 x 1 m)	0.26	0.26	0.52	33.0	**320 g**	**135 g**

Tab. 2: Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.

6 Maintenance Work

Daily	1	Check that the water level is 33 liters.
	2	Check that the capacitor (on the rear) has an unhindered air supply to ensure good cooling. The device should be placed at least 30 cm from the wall or cupboard.
	3	Monitor the water quality (pH value measurement) (⇨ "Continuous Water Stabilization (cWS)", page 16).
Weekly	4	Perform a water change (⇨ "Continuous Water Stabilization (cWS)", page 16).
Monthly (or after 100 operating hours)	5	Clean the capacitor with a brush.
Monthly	6	Perform active Circulation Purging (aCP) every 4 weeks (⇨ "4-weekly Active Circulation Purging (aCP)", page 19).
Annually	7	We recommend a complete maintenance service by our service technicians.

For local contact:
Please visit our website
www.maquet.com

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REVISED INSTRUCTIONS FOR USE WATER QUALITY MANAGEMENT

HEATER-COOLER UNIT
HCU 30

MAQUET
GETINGE GROUP

CAUTION!

Federal (US) law restricts sale of this device to, or on the order of, a physician.

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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Contents

1 General

1.1 Information on these revised Instructions for Use

These revised Instructions for Use for the Heater-Cooler Unit HCU 30 describe Water Quality Management as well as the surface cleaning and surface disinfection of the device.

These revised Instructions for Use replace chapters 4.1 Information on Water Hardness, 4.1.2 "Weekly", 4.1.3 "Monthly (or After Every 100 Hours of Operation)", 4.1.4 "Every 12 Months (or After Every 1000 Hours of Operation)" and 4.3 "Cleaning" in the previous Instructions for Use for the Heater-Cooler Unit HCU 30.

The procedures described in these revised Instructions for Use do not replace the conventional clinical hygiene measures and hygiene protocols. Irrespective of the Water Quality Management, the clinical user is responsible for the hygienic handling and the hygiene status of the HCU 30 in the clinical environment.

1.1.1 Validity of these revised Instructions for Use

These revised Instructions shall apply until further notice for all manuals for the Heater-Cooler Unit HCU 30.

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 Safety

2.1 General Safety Instructions

WARNING!

The device may only be put back into operation under regular hygiene monitoring according to the current protocol. The purge interval for water circulation may need to be shortened.

WARNING!

The HCU 30 is a non-sterile device.

WARNING!

The HCU 30 shall be used by instructed medical staff only.

WARNING!

Turn off the HCU 30 before maintenance, surface cleaning and storage, and disconnect the device from the power supply.

WARNING!

Only use the warming/cooling blankets once. Avoid microbiological contamination by not using the blankets again.

3 Surface Cleaning and Surface Disinfection of the Device and Other Protective Measures

WARNING!

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

WARNING!

Only use specified agents.

CAUTION!

When cleaning the surfaces of the HCU 30 the safety instructions from the cleaning agent manufacturer must always be observed.

NOTICE!

To clean the surface of the HCU 30, only use an aqueous alcohol solution (70% ethanol/30% water) or a suitable cleaning solution based on aldehyde, ammonium components or alcohol. Do not use any phenol derivatives.

NOTICE!

Do not use chemical solvents such as ether or acetone. They may damage the HCU 30.

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 HCU 30 and cables after each use to remove soiling.

Surface disinfection and other protective measures

Disinfect the surfaces of the HCU 30 before and after each use, but at least once daily.

Disinfect in particular:

- The cap of the water tank before and after each use.

NOTE

Disinfect your hands before opening the cap of the water tank.
Change your disposable gloves after opening the cap of the water tank.

- The filler of the water tank before the weekly water change or before active Circulation Purging with trisodium phosphate solution.
- All connectors before each connection.

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)

4 Operation of the Device with Sterile Filtered, Demineralized Water and Trisodium Phosphate

Water Quality Management involves operation of the HCU 30 with sterile filtered, demineralized water and the substance trisodium phosphate (for the CAS number and additional information, see ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 33 and ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 34).

Water Quality Management comprises the following activities:

Interval	Activity	Information source
1st week	Initial active Circulation Purging (initial aCP) (72-hour exposure time) + Water change (cWS)	⇨ "Initial Active Circulation Purging (Initial aCP)", page 13 ⇨ "Weekly Water Change", page 16
2nd week	Water change (cWS)	⇨ "Weekly Water Change", page 16
3rd week	Water change (cWS)	⇨ "Weekly Water Change", page 16
4th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
5th week	Routine active Circulation Purging (aCP) (6-hour exposure time) + Water change (cWS)	⇨ "4-weekly Active Circulation Purging (aCP)", page 18 ⇨ "Weekly Water Change", page 16
6th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
7th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
8th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
9th week	Routine active Circulation Purging (aCP) (6-hour exposure time) + Water change (cWS)	⇨ "4-weekly Active Circulation Purging (aCP)", page 18 ⇨ "Weekly Water Change", page 16
10th week	Water change (cWS)	⇨ "Weekly Water Change", page 16
...	...	...

Following maintenance of the HCU 30 by Maquet or Maquet-authorized service personnel, active Circulation Purging (aCP) (⇨ "6-hourly Active Circulation Purging (aCP)", page 19) must be performed.

The introduction of Water Quality Management for the HCU 30 involves replacing the externally connectible water tubes for the patient and the cardioplegia water circuit with new HCU 30 water tubes and additionally performing this replacement every year.

To avoid recontamination of the HCU 30 where possible, only use water tubes that meet these Water Quality Management specifications. Otherwise, the effectiveness of Water Quality Management can be impaired.

NOTE

Use a sterile inline filter with a pore size of 0.2 µm to filter the water.

Produce demineralized water from tap water using commercially available filter systems. To this end, follow the instructions provided by the filter system manufacturer.

Alternatively, demineralized water can be purchased from specialist retailers.

When operating the device with trisodium phosphate, the instructions in the trisodium phosphate manufacturer's safety data sheet must be observed.

The following equipment is required to prepare the trisodium phosphate solution:

- Personal protective clothing (as specified in the safety data sheet of the trisodium phosphate manufacturer)
  - Chemical-resistant gloves made of nitrile or butyl rubber
  - Protective goggles
  - Laboratory coat
- Measuring scoop (chemical-resistant)
- Scales for weighing the trisodium phosphate
- Beaker (chemical-resistant) for approx. 3 l

WARNING!

The water tank of the HCU 30 must be filled with demineralized, sterile filtered water.

CAUTION!

The substance trisodium phosphate has been tested for use in the water circuits of the HCU 30. Other chemical substances may affect material compatibility. The use of other substances for this purpose which are not chemically identical is expressly forbidden.

WARNING!

To ensure effective Water Quality Management, the necessary amount of the substance must be determined based on the length of the tubes connected to HCU 30.

Determine the appropriate amount of trisodium phosphate for the required solution concentration, using the following tables:

- ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 33
- ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 34

WARNING!

To achieve an even distribution of trisodium phosphate in the water system, the system must be de-aired.

CAUTION!

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

WARNING!

If a water tube of the HCU 30 is kinked for more than 30 sec., the internal water temperature in the heater can rise to over 43°C and the associated pump stops. The operator may have to restart the water pump. The pump only starts when the internal water temperature has fallen below 41.3°C. No alarm is triggered.

WARNING!

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

Note: The use of 5 mmol trisodium phosphate in the water circuit of the heater-cooler unit HCU 30 is expressly permissible with Maquet oxygenators and Maquet cardioplegia heat exchangers; material compatibility has been tested and confirmed.

4.1 Initial Active Circulation Purging (Initial aCP)

The introduction of Water Quality Management involves **initial** active Circulation Purging (initial aCP) of the HCU 30 with a **72-hour exposure time**.

Initial active Circulation Purging (initial aCP) is performed with an aqueous trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate in the entire water volume of the device including externally connected tubes.

Perform the following steps for initial active Circulation Purging (initial aCP):

- ⇨ "Emptying", page 13
- ⇨ "Heat Treatment Using the Internal Cleaning Program", page 14 with a trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate
- ⇨ "Emptying", page 14
- ⇨ "One-off Rinsing", page 14
- ⇨ "72-hourly Active Circulation Purging (aCP)", page 15 with a trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate
- ⇨ "Emptying, Surface Disinfection and Replacement of the Water Tubes", page 16

WARNING!

The trisodium phosphate solution at a concentration of 25 mmol/l for active Circulation Purging (aCP) must only be used preoperatively or postoperatively, and never intraoperatively.

NOTE

A system test is required prior to starting active Circulation Purging (aCP):

- HCU 30 self-test OK.
- No leaks in the water line or the HCU 30.
- Water flow OK.
- Water level in the water tank OK.

4.1.1 Emptying

1 Empty the tubes connected to the HCU 30 (⇨ "Emptying the Connected Tubes", page 21).

2 Start the cleaning program to melt the ice block (⇨ "Heating the Water and Melting the Ice Block", page 22).
3 Connect the water tubes to the HCU 30 (⇨ "Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits", page 24).
4 Empty the HCU 30 (⇨ "Emptying the Water Lines and the Water Tank", page 25).

▸ The HCU 30 is now empty.

4.1.2 Heat Treatment Using the Internal Cleaning Program

1 Open the cap of the water tank.
2 Prepare the trisodium phosphate solution for Heat Treatment (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 5 mmol/l Trisodium Phosphate", page 33).
3 Pour the trisodium phosphate solution into the water tank.
4 Fill the water tank with the prepared, sterile filtered and demineralized water to approx. 1 cm above the cooling coils.
5 Close the cap of the water tank.
6 Start the cleaning program in order to clean the HCU 30 automatically (⇨ "Automatic Cleaning", page 27).

WARNING!

Once Heat Treatment has been started during initial active Circulation Purging (initial aCP), the cap of the water tank must remain closed in order to prevent contact with hot water or steam and thus possible burns and irritation.

7 Start the cleaning program to melt the ice block (⇨ "Heating the Water and Melting the Ice Block", page 22).

▸ Heat Treatment of the HCU 30 is now complete.

4.1.3 Emptying

1 Connect the water tubes to the HCU 30 (⇨ "Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits", page 24).
2 Empty the HCU 30 (⇨ "Emptying the Water Lines and the Water Tank", page 25).

▸ The HCU 30 is now empty.

4.1.4 One-off Rinsing

1 Fill the water tank with sterile filtered and demineralized water.
2 De-air the water circuits until the water tubes are completely full and there are no more air bubbles (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
3 Empty the tubes connected to the HCU 30 (⇨ "Emptying the Connected Tubes", page 21).

4 De-air the water circuits until the water tubes are completely full and there are no more air bubbles (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
5 Empty the HCU 30 as described in ⇨ "Emptying", page 13.
▸ One-off rinsing of the HCU 30 is now complete.

4.1.5 72-hourly Active Circulation Purging (aCP)

1 Open the cap of the water tank.
2 Prepare the trisodium phosphate solution for active Circulation Purging (aCP) (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 25 mmol/l Trisodium Phosphate", page 34).

Two options are available for heating water:

Option 1: Water heating using the internal cleaning program.

1 Pour the trisodium phosphate solution into the water tank.
2 Fill the water tank with the prepared, sterile filtered and demineralized water to approx. 1 cm above the cooling coils.
3 Close the cap of the water tank.
4 Start the cleaning program to heat the water to a temperature of 38°C (⇨ "Heating the Water and Melting the Ice Block", page 22).

Option 2: Water heating without the internal cleaning program.

1 Pour the trisodium phosphate solution into the water tank.
2 Fill the water tank to approx. 1 cm above the cooling coils with the prepared, sterile filtered and demineralized water at a temperature of 38°C.
3 Close the cap of the water tank.

De-airing and start of patient and cardioplegia circulation

1 Connect the water tubes to the HCU 30 (⇨ "Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits", page 24).
2 De-air the water circuits (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
3 Deactivate the compressor (⇨ "Deactivating the Compressor", page 31).
4 Start the patient and cardioplegia circulation (⇨ "Starting the Patient and Cardioplegia Circulation", page 32). Run the HCU 30 for 5 minutes at 38°C.
5 Switch off the HCU 30. The trisodium phosphate solution must be left to work on the water system for at least 72 hours.
6 Switch on the HCU 30.
7 De-air the water circuits (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
8 Start the patient and cardioplegia circulation (⇨ "Starting the Patient and Cardioplegia Circulation", page 32). Run the HCU 30 for 5 minutes at 38°C.

- The 72-hourly active Circulation Purging (aCP) of the HCU 30 is now complete.

4.1.6 Emptying, Surface Disinfection and Replacement of the Water Tubes

1 Empty the tubes connected to the HCU 30 (⇨ "Emptying the Connected Tubes", page 21).
2 Empty the HCU 30 (⇨ "Emptying the Water Lines and the Water Tank", page 25).
   - The HCU 30 is now empty.
3 Disinfect the surfaces of the HCU 30 as described in ⇨ "Surface Cleaning and Surface Disinfection of the Device and Other Protective Measures", page 8.
4 Replace the old water tubes with new ones.
5 Continue by filling the HCU 30 (⇨ "Filling the Device", page 17).

4.2 Continuous Water Stabilization (cWS)

Perform the following steps for continuous Water Stabilization (cWS):

- ⇨ "Weekly Water Change", page 16
- ⇨ "Daily Monitoring of the Water Quality (pH Value Measurement)", page 17

4.2.1 Weekly Water Change

Perform the following steps for the weekly water change:

- ⇨ "Emptying", page 16
- ⇨ "Filling the Device", page 17 with a trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate

NOTE

Carry out the weekly water change when the device will no longer be used on the same day (e.g. in the afternoon or evening) so that ice can form overnight.

Emptying

1 Empty the tubes connected to the HCU 30 (⇨ "Emptying the Connected Tubes", page 21).
2 Start the cleaning program to melt the ice block (⇨ "Heating the Water and Melting the Ice Block", page 22).
3 Connect the water tubes to the HCU 30 (⇨ "Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits", page 24).
4 Empty the HCU 30 (⇨ "Emptying the Water Lines and the Water Tank", page 25).
- The HCU 30 is now empty.

Filling the Device

1 Open the cap of the water tank.
2 Prepare the trisodium phosphate solution for continuous Water Stabilization (cWS) (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 5 mmol/l Trisodium Phosphate", page 33).
3 Pour the trisodium phosphate solution into the water tank.
4 Fill the water tank with the prepared, sterile filtered and demineralized water to approx. 1 cm above the cooling coils.
5 Close the cap of the water tank.
6 De-air the water circuits (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
7 Start the patient and cardioplegia circulation (⇨ "Starting the Patient and Cardioplegia Circulation", page 32). Run the HCU 30 for 5 minutes.
8 Wait until the displayed amount of ice has reached the [Ice filling level] .
   - The ice formation is now complete.
   - The water change of the HCU 30 is now complete.
9 Disinfect the surfaces of the HCU 30 as described in ⇨ "Surface Cleaning and Surface Disinfection of the Device and Other Protective Measures", page 8.

4.2.2 Daily Monitoring of the Water Quality (pH Value Measurement)

WARNING!

If atypical mycobacteria are present in the water system, perform active Circulation Purging (aCP) with a concentration of 25 mmol/l trisodium phosphate in the water system of the HCU 30.

An amount of 5 mmol/l trisodium phosphate maintains the average pH of the water at 10 to 12. A pH value above 10 is effective, a pH value below 8 (and thus close to the neutral pH of 7) is ineffective. The maximum permitted pH for continuous Water Stabilization (cWS) with trisodium phosphate is 13.

1 Monitor the pH value of the tank water in the HCU 30 daily and after each water change using pH test strips or a calibrated measuring device.
   pH < 10 ⇨ too low
   10 ≤ pH ≤ 13 ⇨ ok
   pH > 13 ⇨ too high
2 Perform the following steps, depending on the pH value:
   If the pH value is greater than or equal to 10 and less than or equal to 13, continue to use the HCU 30.
   If the pH is too low or too high, perform a water change as described in ⇨ "Continuous Water Stabilization (cWS)", page 16.

If the pH falls below 10 within 72 hours after the last water change or after active Circulation Purging (aCP), immediately perform active Circulation Purging (aCP).

4.3 4-weekly Active Circulation Purging (aCP)

Routinely, active Circulation Purging (aCP) of the HCU 30 must be performed **every 4 weeks** with a **6-hour exposure time** (for performance time intervals, see ⇨ "Operation of the Device with Sterile Filtered, Demineralized Water and Trisodium Phosphate", page 10).

Active Circulation Purging (aCP) is performed with an aqueous trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate in the entire water volume of the device including externally connected tubes.

Perform the following steps for active Circulation Purging (aCP):

- ⇨ "Emptying", page 18
- ⇨ "6-hourly Active Circulation Purging (aCP)", page 19 with a trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate
- ⇨ "Emptying", page 19

WARNING!

The trisodium phosphate solution at a concentration of 25 mmol/l for active Circulation Purging (aCP) must only be used preoperatively or postoperatively, and never intraoperatively.

NOTE

A system test is required prior to starting active Circulation Purging (aCP):
- HCU 30 self-test OK.
- No leaks in the water line or the HCU 30.
- Water flow OK.
- Water level in the water tank OK.

4.3.1 Emptying

1 Empty the tubes connected to the HCU 30 (⇨ "Emptying the Connected Tubes", page 21).
2 Start the cleaning program to melt the ice block (⇨ "Heating the Water and Melting the Ice Block", page 22).
3 Connect the water tubes to the HCU 30 (⇨ "Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits", page 24).
4 Empty the HCU 30 (⇨ "Emptying the Water Lines and the Water Tank", page 25).

- ▸ The HCU 30 is now empty.

4.3.2 6-hourly Active Circulation Purging (aCP)

1 Open the cap of the water tank.
2 Prepare the trisodium phosphate solution for active Circulation Purging (aCP) (⇨ "Preparing the Trisodium Phosphate Solution in a Concentration of 25 mmol/l Trisodium Phosphate", page 34).

Two options are available for heating water:

Option 1: Water heating using the internal cleaning program.

1 Pour the trisodium phosphate solution into the water tank.
2 Fill the water tank with the prepared, sterile filtered and demineralized water to approx. 1 cm above the cooling coils.
3 Close the cap of the water tank.
4 Start the cleaning program to heat the water to a temperature of 38°C (⇨ "Heating the Water and Melting the Ice Block", page 22).

Option 2: Water heating without the internal cleaning program.

1 Pour the trisodium phosphate solution into the water tank.
2 Fill the water tank to approx. 1 cm above the cooling coils with the prepared, sterile filtered and demineralized water at a temperature of 38°C.
3 Close the cap of the water tank.

De-airing and start of patient and cardioplegia circulation

1 Connect the water tubes to the HCU 30 (⇨ "Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits", page 24).
2 De-air the water circuits (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
3 Deactivate the compressor (⇨ "Deactivating the Compressor", page 31).
4 Start the patient and cardioplegia circulation (⇨ "Starting the Patient and Cardioplegia Circulation", page 32). Run the HCU 30 for 5 minutes at 38°C.
5 Switch off the HCU 30. The trisodium phosphate solution must be left to work on the water system for at least 6 hours.
6 Switch on the HCU 30.
7 De-air the water circuits (⇨ "De-airing the Patient and Cardioplegia Water Circuits", page 29).
8 Start the patient and cardioplegia circulation (⇨ "Starting the Patient and Cardioplegia Circulation", page 32). Run the HCU 30 for 5 minutes at 38°C.

- ▸ The 6-hourly active Circulation Purging (aCP) of the HCU 30 is now complete.

4.3.3 Emptying

1 Empty the tubes connected to the HCU 30 (⇨ "Emptying the Connected Tubes", page 21).

2 Empty the HCU 30 (⇨ "Emptying the Water Lines and the Water Tank", page 25).
   - ▶ The HCU 30 is now empty.
3 Continue by filling the HCU 30 (⇨ "Filling the Device", page 17).

5 Procedures for Water Quality Management of the Device

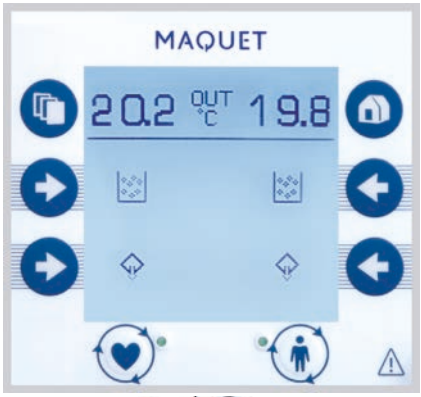
5.1 Emptying the Connected Tubes

WARNING!

If the water tank of the HCU 30 is too full or a completely filled HCU 30 is moved, the tank water may discharge via the outflow outlet of the HCU 30 onto the floor.

✓ All the stopcocks are open.

1 Press the [Menu] button to go to the "Daily maintenance" menu.

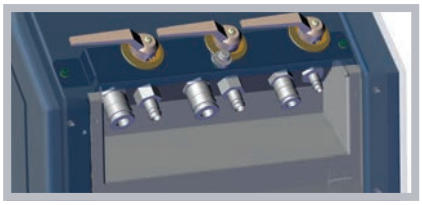


2 Press the [Empty] buttons for the patient water circuit ( ) and cardioplegia water circuit ( ) to empty the tubes connected to the HCU 30.

▸ The HCU 30 empties the connected tubes into the water tank.

5.2 Heating the Water and Melting the Ice Block

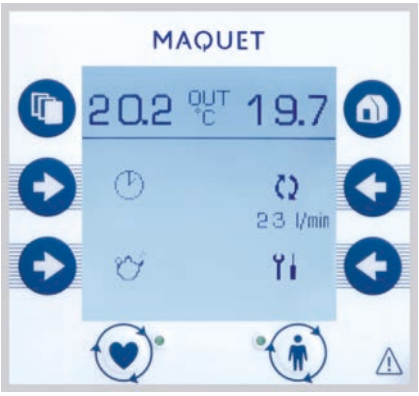
1 Close all the stopcocks.



2 Disconnect all the tubes from the HCU 30.

3 Close the cleaning door on the back of the HCU 30.

4 Press the [Menu] button to go to the "Maintenance and service" menu.



5 Press the [Timer display] button to go to the "Timer" menu.

6 Press the right button [Cleaning timer] and set the time until the start of cleaning to zero using the control knob.

7 Press both [Cleaning timer] and buttons at the same time to go to the "Cleaning" menu.

8 Open and close the cleaning door on the back of the HCU 30.

9 Press both [Cleaning] buttons at the same time to start cleaning.

- The HCU 30 melts the ice block. Duration: Between 30 and a maximum of 75 minutes (depending on the amount of ice present and the power supply).

10 Monitor the melting of the ice block.

11 When the ice block has melted, stop the heating using the [Menu] button.
Tip: If you use the internal cleaning program to heat the water, stop the heating process with the [Menu] button once the temperature displayed reaches 38°C.

- The ice block has now melted.

5.3 Connection of the Water Tubes of the Patient and Cardioplegia Water Circuits

✓ All the stopcocks are closed.

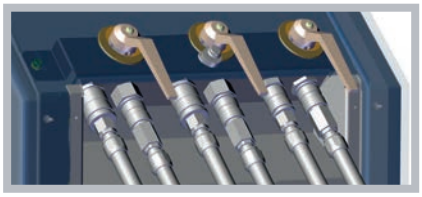
1 Open the cleaning door on the back of the HCU 30.

2 Connect the water tubes of the patient and cardioplegia water circuits to the HCU 30.

3 Disconnect all heat exchangers which are connected to the patient water circuit and/or the cardioplegia water circuit.

4 Connect the open ends of the water tubes to the cleaning connectors (double Hansen connectors).

5 Open all the stopcocks.



5.4 Emptying the Water Lines and the Water Tank

WARNING!

If the water tank of the HCU 30 is too full or a completely filled HCU 30 is moved, the tank water may discharge via the outflow outlet of the HCU 30 onto the floor.

CAUTION!

The ice must have melted before emptying the water tank.

NOTE

When you empty the water tank, make sure that the HCU 30 is switched off.

HCU 30 Type 1

✓ All the stopcocks are open.

1 Connect the drainage tube to the tank drain valve. Make sure that the open end of the drainage tube ends in a waste container.
2 Remove the ventilation grid on the rear of the HCU 30.
3 Move the tank emptying lever to the vertical position.
   ▸ The water flows out of the drainage tube into the waste container.
4 Drain off the water into the waste container.
5 Move the tank emptying lever to the horizontal position.
6 Reattach the ventilation grid and then disconnect the drainage tube.
7 Close all the stopcocks.

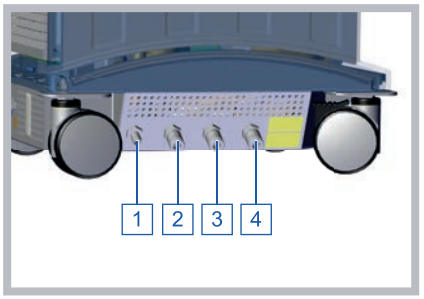
▸ The water lines and water tank of the HCU 30 are now empty.

Note: Observe the local disposal regulations for trisodium phosphate water.

HCU 30 Type 2

✓ All the stopcocks are open.

1 Connect the drainage tube to the tank drain valve ([3]). Make sure that the open end of the drainage tube ends in a waste container.



1 Tank overflow
2 Drain valve for the cardioplegia pump
3 Tank drain valve
4 Drain valve for the main pump

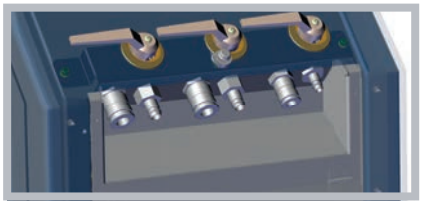
- The water flows out of the drainage tube into the waste container.

2 Disconnect the drainage tube.

3 Connect the drainage tube to the drain valve of the main pump ([4]) and drain the remaining water into the waste container. Then disconnect the drainage tube.

4 Connect the drainage tube to the drain valve of the cardioplegia pump ([2]) and drain the remaining water into the waste container. Then disconnect the drainage tube.

5 Close all the stopcocks.



- The water lines and water tank of the HCU 30 are now empty.

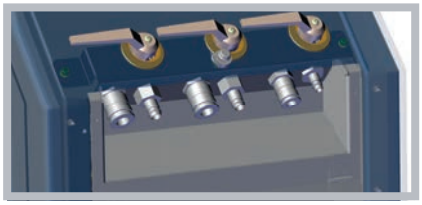
Note: Observe the local disposal regulations for trisodium phosphate water.

5.5 Automatic Cleaning

WARNING!

Once Heat Treatment has been started during initial active Circulation Purging (initial aCP), the cap of the water tank must remain closed in order to prevent contact with hot water or steam and thus possible burns and irritation.

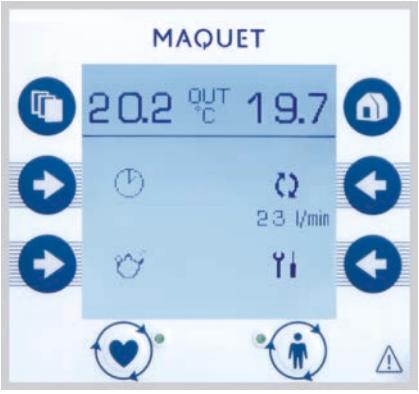
1 Close all the stopcocks.



2 Disconnect all the tubes from the HCU 30.

3 Close the cleaning door on the back of the HCU 30.

4 Press the [Menu] button to go to the "Maintenance and service" menu.



5 Press the [Timer display] button to go to the "Timer" menu.

6 Press the right [Cleaning timer] button and set the time until the start of cleaning to zero using the control knob.

7 Press both [Cleaning timer] buttons at the same time to go to the "Cleaning" menu.

8 Open and close the cleaning door on the back of the HCU 30.

9 Press both [Cleaning] buttons at the same time to start cleaning.

- The HCU 30 is cleaned automatically. Automatic cleaning is completed with the ice formation. Duration: maximum 14 hours.

- The HCU 30 is now cleaned.

NOTE

Perform automatic cleaning when the device will no longer be used on the same day (e.g. in the afternoon or evening).

5.6 De-airing the Patient and Cardioplegia Water Circuits

WARNING!

Cold water from the water tank is pumped through the circuit during the de-airing. Do not de-air while a patient is connected.

WARNING!

Do not aim the fan outlet on the back of the HCU 30 at the sterile operating field.

WARNING!

If it is not possible to de-air the system, a reason for this could be that the water level in the water tank is too low. Fill the water tank.

CAUTION!

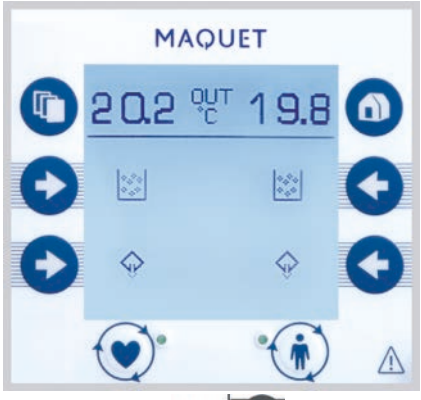
Dry running the HCU 30 damages the circulation pumps and heater. Therefore, ensure that the water level in the water tank is about 1 cm above the cooling coil prior to de-airing.

CAUTION!

The fan outlet on the back of the HCU 30 must be at least 50 cm from the wall to ensure proper cooling and to prevent the system from overheating.

✓ All the stopcocks are open.

1 Press the [Menu] button to go to the "Daily maintenance" menu.



2 Press the [De-airing] buttons for the patient water circuit ( ) and the cardioplegia water circuit ( ).
- The HCU 30 performs a de-airing.
- De-airing stops automatically after 1.5 minutes.

3 Open the cap of the water tank.

4 Fill the water tank with the prepared, sterile filtered and demineralized water to approx. 1 cm above the cooling coil.
5 Close the cap of the water tank.
6 Repeat the de-airing for both water circuits until the water tubes are completely full and there are no more air bubbles.

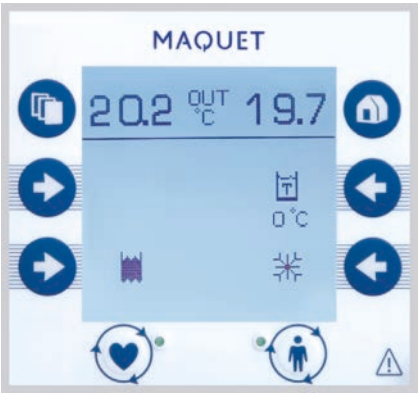
▸ De-airing of the patient and cardioplegia water circuits of the HCU 30 is now complete.

5.7 Deactivating the Compressor

WARNING!

For additional heating during warming-up, the compressor can be manually switched off. The compressor will start again after 30 minutes. Always monitor the water tank temperature during the operation to ensure cooling capacity. The compressor can be manually restarted during the 30 minute switch-off time.

1 Press the [Menu] button to go to the "Status" menu.

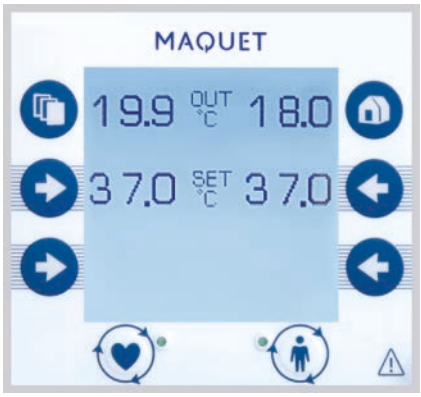


2 If the compressor is running, deactivate it by pressing the [Compressor on/off] button.

- The compressor does not operate for 30 minutes. Ice formation commences again automatically after 30 minutes.

5.8 Starting the Patient and Cardioplegia Circulation

1 Press the [Menu] button to go to the main menu.



2 Press the [Setting] 37.0 button for the patient water circuit and, at the same time, set the temperature to +38°C using the control knob.

3 Press the [Setting] 35.5 button for the cardioplegia water circuit and, at the same time, set the temperature to +38°C using the control knob.

4 Start the main pump by pressing the [Patient circulation on/off] button .
- When the circulation of the HCU 30 is operating, the green pilot lamp is lit.

5 Start the cardioplegia pump by pressing the [Cardioplegia circulation on/off] button.
- When the circulation of the HCU 30 is operating, the green pilot lamp is lit.

6 Run the HCU 30 for 5 minutes.

7 Press the [Patient circulation on/off] button and [Cardioplegia circulation on/off] buttons to stop both pumps.

5.9 Preparing the Trisodium Phosphate Solution in a Concentration of 5 mmol/l Trisodium Phosphate

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Determine the appropriate amount of trisodium phosphate for the required solution concentration, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 33.
2 Weigh the required amount of trisodium phosphate using scales.
3 Place the weighed trisodium phosphate in a measuring beaker.
4 Determine the required amount of water, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.", page 33.
5 Prepare the required amount of warm, sterile filtered and demineralized water.
6 Dissolve the trisodium phosphate in 1 liter of the prepared, warm, sterile filtered and demineralized water.

Tube length per water circuit	Cardio-plegia water circuit	Patient water circuit 1	Patient water circuit 2	Total volume (in liters)	Total volume (in liters)	Trisodium phosphate Dodecahy-drate ($Na_3PO_4 \cdot 12H_2O$) CAS no.: 10101-89-0	Trisodium phosphate Anhydrate (Na_3PO_4) CAS no.: 7601-54-9
	82 ml/m	132 ml/m	132 ml/m	Tubing	HCU 30	5 mmol/l (~1.9 g/l)	5 mmol/l (~0.8 g/l)
30 m (2 x 15 m)	2.45	3.95	3.95	10.35	36.4	**70 g**	**30 g**
20 m (2 x 10 m)	1.64	2.64	2.64	6.92	32.9	**65 g**	**27 g**
12 m (2 x 6 m)	0.98	1.58	1.58	4.14	30.1	**60 g**	**25 g**
2 m (2 x 1 m)	0.16	0.26	0.26	0.69	26.0	**50 g**	**21 g**

Tab. 1: Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 5 mmol/l trisodium phosphate according to the length of the water tubes.

5.10 Preparing the Trisodium Phosphate Solution in a Concentration of 25 mmol/l Trisodium Phosphate

Use warm, sterile filtered and demineralized water. The temperature of the water must be 38°C.

1 Determine the appropriate amount of trisodium phosphate for the required solution concentration, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 34.
2 Weigh the required amount of trisodium phosphate using scales.
3 Place the weighed trisodium phosphate in a measuring beaker.
4 Determine the appropriate amount of water, using the table ⇨ "Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.", page 34.
5 Prepare the required amount of warm, sterile filtered and demineralized water.
6 Dissolve the trisodium phosphate in 1 liter of the prepared, warm, sterile filtered and demineralized water.

Tube length per water circuit	Cardio-plegia water circuit	Patient water circuit 1	Patient water circuit 2	Total volume (in liters)	Total volume (in liters)	Trisodium phosphate Dodecahy-drate ($Na_3PO_4 \cdot 12H_2O$) CAS no.: 10101-89-0	Trisodium phosphate Anhydrate (Na_3PO_4) CAS no.: 7601-54-9
	82 ml/m	132 ml/m	132 ml/m	Tubing	HCU 30	25 mmol/l (~9.5 g/l)	25 mmol/l (~4.1 g/l)
30 m (2 x 15 m)	2.45	3.95	3.95	10.35	36.4	**350 g**	**149 g**
20 m (2 x 10 m)	1.64	2.64	2.64	6.92	32.9	**320 g**	**135 g**
12 m (2 x 6 m)	0.98	1.58	1.58	4.14	30.1	**290 g**	**123 g**
2 m (2 x 1 m)	0.16	0.26	0.26	0.69	26.0	**250 g**	**106 g**

Tab. 2: Required amount of trisodium phosphate and water for the trisodium phosphate solution in a concentration of 25 mmol/l trisodium phosphate according to the length of the water tubes.

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