INSTRUCTIONS FOR USE

MAQUET
GETINGE GROUP

# HEATER-COOLER UNIT
# HCU 40

## Validity of this document

Revision 1.0, issue date 2016-11

This document applies to the device HCU 40 with software release 1.2.1.0 or higher.

Documents for lower software releases do not apply to the device HCU 40 with software release 1.2.1.0 or higher.



## 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 Instructions for Use

These Instructions for Use will familiarize you with the features of the Maquet device.

### 1.1.1 Symbols

#### References

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

#### Action and reaction

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

Example:

- Switch the light switch on.

#### Buttons and menus

The buttons and menus are shown in square brackets.

Example:

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

### 1.1.2 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. |

## 1.2 Environmental Protection

### 1.2.1 Packaging

All packaging materials are made of environmentally safe materials. On request, Maquet will be happy to dispose of the packaging materials.

### 1.2.2 Batteries

Batteries can be disposed of via the local recycling center.

### 1.2.3 Disposal

To ensure optimal utilization of the raw materials, the device as well as the components and accessories must not be disposed of with normal domestic waste. Keep separate from domestic waste and dispose of in an environmentally safe way in compliance with local regulations.

- Before disposal, decontaminate all parts in accordance with the procedures applicable in clinical practice.
- In order to prevent risks during disposal, contact the authorized service personnel.

## 1.3 Abbreviations

| Abbreviation | Meaning |
| --- | --- |
| CAN | Controller Area Network |
| CPLG | Cardioplegia |
| CU | Control unit |

| | |
|---|---|
| HCU | Heater-cooler unit |
| $T_{ext}$ | Temperature measured at the external sensor |
| $T_{out}$ | Temperature measured at the water outlet |
| $T_{set}$ | Setpoint temperature |
| $T_{tank}$ | Temperature measured in the tank |
| USB | Universal serial bus |
| ΔT | Setpoint gradient |

# 2 Safety

## 2.1 Intended Use

**NOTE**

**Heat exchanger**
Please observe the Instructions for Use for the employed heat exchangers with regard to the indications, intended use, intended user, intended patient, intended environment, and contraindications.

### 2.1.1 Indications

The intended purpose of the heater-cooler unit HCU 40 is cooling and warming a patient and maintaining the patient temperature at the required level during cardiovascular interventions. Temperature changes are effected by means of a combined oxygenator with heat exchanger in the extracorporeal perfusion circuit.

The system comprises two separate water circuits with temperature regulation. The first circuit is for connecting the oxygenator heat exchanger and/or the warming/cooling blanket; the second circuit is intended for connecting the cardioplegia heat exchanger. Heat exchange between the patient and the cardioplegic fluid occurs by the temperature-regulated water flowing through the heat exchanger and/or the warming/cooling blanket. The water temperature of the patient water circuit and the cardioplegia water circuit can be regulated independently of each other. The water temperature can be set between 1°C and 40.5°C.

External temperature sensors can be optionally combined with the HCU 40, and can be used to operate the HCU 40 in gradient mode. The purpose of this mode is to provide physiologically optimized warming and cooling of the patient.

### 2.1.2 Intended Use

The heater-cooler unit HCU 40 is intended for cooling or warming a patient connected to the extracorporeal perfusion circuit and keeping the required patient temperature constant. The temperature transfer occurs via a heat exchanger in the patient perfusion circuit and/or cardioplegia water circuit and/or via a warming/cooling blanket.

### 2.1.3 Intended User

The HCU 40 may only be operated by trained specialist medical staff.

### 2.1.4 Intended Patient

The device can be used for all patients irrespective of age, body weight and gender.

### 2.1.5 Intended Environment

The HCU 40 is used in a clinical environment.

### 2.1.6 Contraindications

When the heater-cooler unit HCU 40 is used by specially trained personnel under the supervision of a physician and in compliance with the intended use, no contradictions are to be expected.

## 2.2 General Safety Instructions

### 2.2.1 Precautionary Measures

**WARNING!**

- The system must be monitored by a trained member of specialist medical staff. Clinical procedures and methods are the responsibility of the physician.
- You should always keep a replacement unit on standby in order to ensure continuous operation in the event of a complete system failure.
- Prior to using the system, please read these Instructions for Use and the Instructions for Use of all the disposables and supplies used.
- The HCU 40 and all the system components used must comply with the requirements of IEC 60601-1: 2005, section 16. In case of doubt, contact the manufacturer of the system components used.

**WARNING!**

- It is not permitted to change or modify the device or its accessories.
- Switch the unit off and disconnect it from the external power supply before maintenance, cleaning, or storage.
- Only use the stated substances for descaling/disinfection (⇨ "Cleaning, descaling and disinfection", page 91).
- If a defective warming/cooling blanket is used with an electrosurgical unit which is either not grounded or incorrectly grounded, this may result in burns to the patient (⇨ "Connecting a Heat Exchanger", page 52).

### 2.2.2 Position of Use and Operation and Positioning of the HCU 40

The HCU 40 must be positioned so that the user can see all of the displays at all times, can operate all of the controls and components and access interfaces, and so that the HCU 40 is not interfered with by other devices or vice versa.

**WARNING!**

- Ensure that the operating position requirements of the attached disposable are complied with (⇨ Instructions for Use of the disposable).
- Ensure that you can see the touchscreen of the HCU 40 as well as any optical warning signals at all times. In noisy environments, there is a risk that acoustic warning signals emitted by the HCU 40 may not be heard.
- Do not use the system in the presence of escaping flammable or combustible gases.
- Only operate the HCU 40 within the specified ambient conditions (⇨ "Ambient Conditions", page 137).
  Ambient temperatures outside of the specified conditions can disrupt the sensors' measurements.
- Whenever the device is moved, the mains voltage must be checked by personnel authorized for this purpose. In the event of any extreme difference in voltage from the rated voltage (lower/higher: see rating plate), adjustment may be carried out by authorized service personnel.

**WARNING!**

- Only attach the intended components to the HCU 40. Otherwise, the limits of the safe workload may be exceeded and the mechanical stability of the HCU 40 may be affected.
- The standard slide rail on the rear of the HCU 40 has a maximum load capacity of 15 kg. Ensure that you do not exceed this load limit.
- All connected parts, devices, and modules must be firmly and correctly connected. Check mechanical stability.
- Ensure that the speaker openings are not covered. There is a risk that acoustic warning signals may not be heard.
- Make sure that the ventilation openings are not obstructed and the HCU 40 is not covered. There is a risk that the HCU 40 will overheat and fail. Ensure a minimum distance of 50 cm from other devices, objects, or the wall.

### 2.2.3 Handling the HCU 40

**WARNING!**

- During an application, only use devices and equipment which are functioning perfectly.
- Do not connect equipment which does not form part of this system.
- Do not touch the touchscreen with sharp or pointed objects.
- Only use the approved liquids as per the Instructions for Use in and on the HCU 40.
- Do not touch the plugs of the HCU 40 as electrostatic charges and moisture may cause damage.
- Do not disconnect any plugs or cables from the HCU 40 or the control unit (CU) during operation.
- If the CAN connection cable between HCU 40 and control unit (CU) is not connected during operation, immediately reconnect the cable (⇨ "Connecting a Control Unit", page 39).
- If a cable proves to be defective, replace it with a cable which functions correctly.
- If a plug is faulty, do not operate the device.
- If the touch screen of the control unit (CU) does not display anything or fails to react, the CU must be reset. Disconnect and reconnect CAN connection cable between HCU 40 and CU. Check the set values.
- If, during a power failure, no visual or acoustic alarms are emitted by the HCU 40, it is possible that the independent power supply (UPS) is defective. Have the device checked/repaired by authorized service personnel. Use a replacement device in an emergency.

### 2.2.4 Water Circuits and Heat Exchangers

**WARNING!**

- Switch the device off before intra-hospital transportation. Remove all connected cables.
- Observe the shipping information (⇨ "Send Device to Authorized Service Point", page 131).

**WARNING!**

- Observe the Instructions for Use for the heat exchangers employed.
- Observe the permissible values for heat exchangers (⇨ "Permissible Heat Exchangers", page 136).
- The pressure limit must be set by the authorized service personnel in accordance with the permissible pressure of the heat exchangers. Have the pressure limit adjusted by the authorized service personnel if you use other heat exchangers with a lower permissible maximum pressure than the set pressure limit.
- Use the HCU 40 and heat exchanger at the same height in order to avoid an increase in pressure between the HCU 40 and the heat exchanger.
- The water tank must only be filled with sterile filtered water and other substances which have been specified by Maquet.
- Check all water tubes and tube connections for leaks prior to the application.
- Keep the tubes away from sources of heat.
- The length of the tube from the HCU 40 to the heat exchanger must be at least 1 m.

**WARNING!**

- Turn the cardioplegia water circuit pump off if no cardioplegic solution is required.
- If the tubes are not connected to a heat exchanger, connect the ends of the tubes to the cleaning connector.

### 2.2.5 Monitoring and Sensors

**WARNING!**

- The water quality can influence the ice sensors which, in turn, can influence ice formation. Perform a visual inspection of the actual ice size and adjust the setpoint ice block size should the actual ice size differ from the setpoint size.
- The following parameters must be monitored continually by an independent monitoring and alarm system during application.
  - Temperature of the patient
  - Blood temperature in the perfusion system
  - Contact surface temperature of the warming/cooling blanket
- The external temperature sensors are intended for operating the HCU 40 in gradient mode. They must not be used for measuring the patient's core body temperature, and their use does not replace independent, external monitoring of the blood temperature in the perfusion system.
- The precision of external temperature measurement depends on the temperature sensor and the disposable.
- External temperature sensors must not be autoclaved.
- Only use the external temperature sensors, with shielding, listed under "Supplies" for the HCU 40.
- When operating the unit in gradient mode, the user can set temperature limits. An alarm is given if the temperature either falls below or exceeds the limit value.
- The temperature limits must be set on the basis of physiological criteria.
- If an alarm occurs, the setpoint and actual temperatures of the water and the patient's temperature must be checked.
- After data have been input by the user, the HCU 40 must not be switched off immediately, as saving the data may take up to 10 seconds.

### 2.2.6 Extended Applications

**WARNING!**

While performing longer normothermal applications, avoid abrupt hypothermia, which could endanger the patient's health, by employing the following measures:

- Do not add any ice;
- Deactivate the ice formation or do not use any ice (⇨ "Changing the Setpoint Ice Block Size", page 61).

### 2.2.7 Electromagnetic Compatibility

The HCU 40 complies with the requirements of the IEC 60601-1-2 standard on electromagnetic compatibility. The system and all accessories and sensors fulfill the EMC requirements of a typical clinical environment. (⇨ "Electromagnetic Compatibility (EMC)", page 143)

The user is responsible for ensuring that the clinical environment complies with the limits prescribed in IEC 60601-1-2. Exceeding these limits may impair the system's efficiency and safety.

**WARNING!**

- Do not use the HCU 40 in the vicinity of devices that emit high-frequency signals (e.g., cell phones or high frequency devices). These can cause excessively strong electromagnetic interference that exceeds the compliance level of the HCU 40.
- Observe normal precautions regarding relative humidity and the electrical conductivity of clothing in order to minimize the build-up of electrostatic charges.
- To ensure safe use, the length of all connection cables of the HCU 40 must not be changed.
- Only use the specified accessories (⇨ "Accessories", page 133). The use of other devices, systems, or accessories may increase RF emissions or reduce the immunity to interference.

## 2.3 Symbols

**Symbols on the rating plates of the HCU and control unit (CU)**

Notice! Observe the warnings and safety precautions given in the accompanying documentation.

Warning: Dangerous voltage

Observe the instructions in the Instructions for Use!

**IP22** Protection type in accordance with IEC 60529: Protection against ingress of solid foreign objects larger than 12.5 mm and dripping water when tilted up to 15°.

| | |
|---|---|
|  | Classification in accordance with IEC 60601-1: Type B applied part. |
|  | Alternating current |
|   | Date of manufacture: Month-Year in which the device was made. |
|  | Manufacturer as defined by Council Directive 93/42/EEC concerning medical devices. |
|  | Top |
|  | Fragile |
|  | Do not expose to direct sunlight |
|  | Store in a dry place |
|  | Temperature restriction |
|  | Air humidity restriction |
|  | Air pressure restriction |
|  | Separate collection of electric and electronic devices in accordance with Directive 2012/96/EC: Do not dispose of the device with normal domestic waste. Keep separate from domestic waste and dispose of in an environmentally safe way in compliance with local regulations. |
|   | The device meets the requirements of Council Directive 93/42/EEC concerning medical products. |
|   | The device confirms to Canadian and American safety standards CSA C22.2 No. 601.1 and UL 60601-1. |

Follow the Instructions for Use!

## Symbols on HCU

"Control unit (CU)" connection

Patient water circuit 1

Patient water circuit 2

Cardioplegia water circuit

Water outlet

Water inlet (backflow)

Port for external power supply

Equipotential bonding

## Symbols on the housing of the control unit (CU)


"$T_{ext}$" connection for cardioplegia water circuit


"HLM" connection (not used)


"HCU" connection

USB port


"$T_{ext}$" connection for patient water circuit

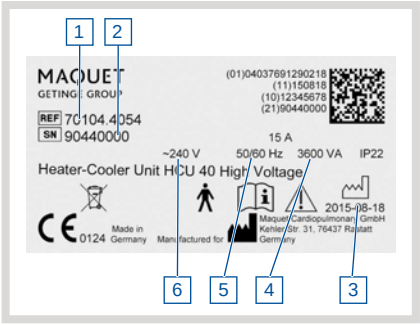
### Symbols on the supply to the warming/cooling blanket

Classification in accordance with IEC 60601-1: Type BF applied part

## 2.4 Rating Plates

### HCU 40

The rating plate is on the rear of the HCU 40.

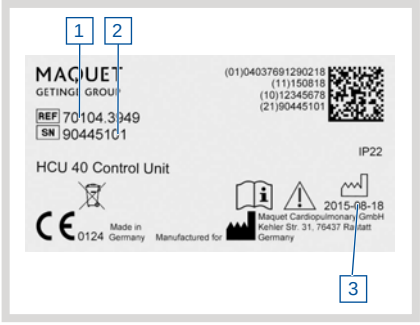



1 Order number
2 Device-specific serial number
3 Device-specific date of manufacture
4 Power consumption
5 Frequency
6 AC power supply

The values on the rating plate shown are examples and may differ from the rating plate on the device.

### Control unit (CU)

The rating plate is on the rear of the control unit (CU).




1 Order number
2 Device-specific serial number
3 Device-specific date of manufacture

# 3 System Description

## 3.1 How the HCU 40 Functions

The heater-cooler unit HCU 40 can be used to cool or warm a patient during cardiovascular interventions and to regulate patient temperature.

The system includes two separate water circuits, the temperature of which can be regulated independently of each other.

### Patient water circuit

The patient water circuit is used to regulate the temperature of the patient. The heat transfer to the patient is effected via a heat exchanger, which is generally integrated in an oxygenator, and/or via a warming/cooling blanket with water flowing through it.

### Cardioplegia water circuit

The cardioplegia water circuit is used to regulate the temperature of cardioplegic solution. The heat transfer is effected via a cardioplegia heat exchanger.

The following combinations of circuits and heat exchangers are possible:

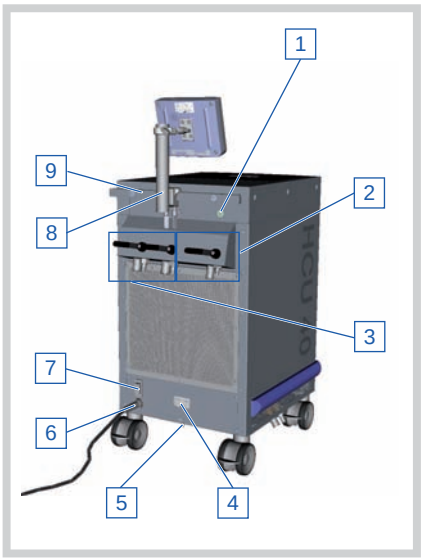
| Patient water circuit 1 (P1) | Patient water circuit 2 (P2) | Cardioplegia water circuit (CPLG) |
|---|---|---|
| Oxygenator heat exchanger | - | - |
| Oxygenator heat exchanger | - | Cardioplegia heat exchanger |
| - | - | Cardioplegia heat exchanger |
| Oxygenator heat exchanger | Warming/cooling blanket | Cardioplegia heat exchanger |
| Pressure reducer | Warming/cooling blanket | Cardioplegia heat exchanger |

In cases of emergency, other combinations are also possible in order to bridge the failure of a water circuit, for example, (⇨ "Emergency Procedures", page 74 ).

## 3.2 System Overview


Front view

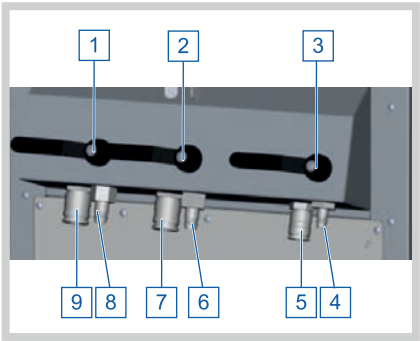
1 Control unit (⇨ "Control Unit CU", page 24)
2 Tank cover




Rear view

1 On/Off switch with LED ring
2 Stopcocks and connections for cardioplegia water circuit
3 Stopcocks and connections for patient water circuit
4 Rating plate
5 Equipotential bonding connection
6 AC power cord
7 Mains circuit breaker
8 "Control unit (CU)" holder
9 Standard slide rail at rear

## 3.3 Water Circuit Controls




Patient water circuit 1 (P1):

1 Stopcock

8 Water outlet 1/2"

9 Water inlet 1/2" (backflow)

Patient water circuit 2 (P2):

2 Stopcock

6 Water outlet 1/2"

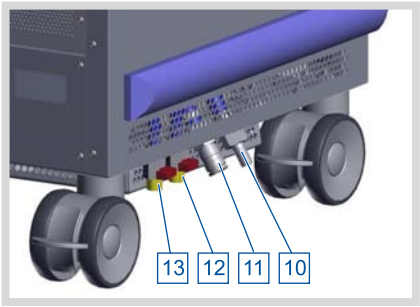
7 Water inlet 1/2" (backflow)

Cardioplegia water circuit (CPLG):

3 Stopcock

4 Water outlet 3/8"

5 Water inlet 3/8" (backflow)




Tank drain/overflow:

10 Tank overflow

11 Tank drainage coupling

12 Stopcock for cardioplegia water circuit pump (optional)

13 Stopcock for patient water circuit pump (optional)

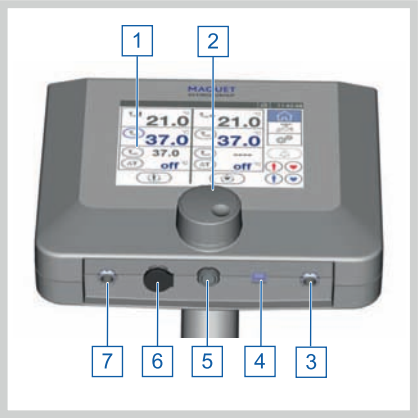
## 3.4 Controls for Electrical Connections

### 3.4.1 Status of the On/Off switch

The On/Off switch displays the status of the HCU 40 via the LED ring:

| Status of On/Off switch | Explanation/cause |
|---|---|
| LED ring is not lit. | Device switched off. |
| LED ring is steady green. | Device running, no errors. |
| LED ring flashes green. | ■ Self-test during start-up (⇨ "Switching On the HCU 40, Self-Test", page 43)<br>■ Diagnosis running (⇨ "Perform Diagnosis", page 129)<br>■ Control unit not connected up (⇨ " Connecting a Control Unit", page 39) |

## 3.5 Control Unit CU




1 Touchscreen
2 Rotary knob with button function
3 "$T_{ext}$" connection for cardioplegia water circuit
4 Type B USB port (e.g., for JOCAP XL or other data recording systems)
5 "HCU" connection
6 "HLM" connection
7 "$T_{ext}$" connection for patient water circuit

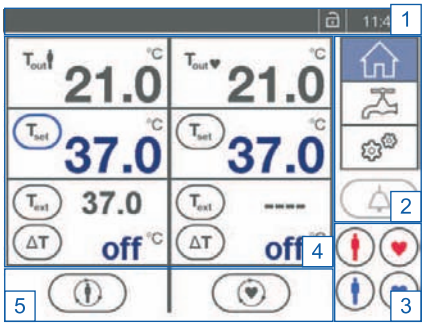
### 3.5.1 Rotary Knob with Button Function

The rotary knob can be used – in addition to the touchscreen – to navigate through menu items, change settings, and select functions. By using the button function of the knob (pressing), you can confirm the selected function, selection, or setting.

### 3.5.2 Touchscreen

The touchscreen can be used to navigate through menu items, change settings, and select functions.

## 3.6 Touchscreen, Display Areas




Main screen with external temperature sensors

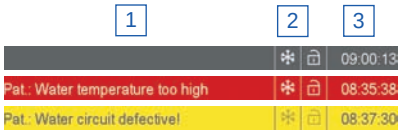
1 Status bar (⇨ "Status Bar", page 25)
2 Toolbar (⇨ "Toolbar", page 26)
3 "Warming" and "Cooling" hotkeys (⇨ ""Warming" and "Cooling" Hotkeys", page 26)
4 Parameter display (⇨ "Parameter Display", page 27)
5 Pump control (⇨ "Pump Control", page 28)

**NOTE**

**Patient water circuit on left, cardioplegia water circuit on right**
The values, settings, and functions for the patient and cardioplegia water circuit can be displayed, set, and activated independently of each other.
- Right side: Cardioplegia water circuit
- Left side: Patient water circuit

### 3.6.1 Status Bar

The status bar shows the following information:




1 Alarm signal (only for alarm)
2 Symbols
3 Current time

| Symbol | Meaning |
|---|---|
| Compressor running. | Compressor control (⇨ "Compressor Control", page 31). |
| HCU 40 locked/not locked. | Locked controls (⇨ "Locked Controls", page 36). |

The color of the status bar shows the current alarm situation:

| Status bar | |
|---|---|
| Gray | No alarm situation. |
| Red | High-priority alarm: The status bar flashes quickly and displays a message (⇨ "Messages", page 81). |
| Yellow, flashing | Medium-priority alarm: The status bar flashes slowly and displays a message. |
| Yellow | Low-priority alarm: The status bar displays a message. |

If there are several alarm situations with the same priority simultaneously, the status bar displays the last alarm situation to occur. If there are several alarm situations with different priorities simultaneously, the status bar displays the alarm situation with the highest priority.

### 3.6.2 Toolbar

The touchscreen displays the toolbar on the right. This allows you to navigate between different screens, call up functions, as well as activate and deactivate settings.

| Symbol | Meaning |
|---|---|
|  "Main screen" | Switch to the main screen (⇨ "Main Screen", page 28). |
|  "Functions" | Switch to the "Functions" screen (⇨ "Functions", page 29 ). |
|  "Settings" | Switch to the "Settings" screen (⇨ "Settings", page 32). |
|  "Current alarm pause" | Pausing the current alarm (⇨ "Pausing the Current Alarm", page 34). |

### 3.6.3 "Warming" and "Cooling" Hotkeys

The hotkeys are only visible in the main screen.

You can use the hotkeys to call up stored values for setpoint temperatures and setpoint gradients directly instead of having to enter or change them individually. The use of hotkeys thus allows considerable time savings for frequently selected temperatures. The values can be set in the hotkey settings in advance (⇨ " Changing the Hotkey Settings", page 59).

You can use two separate hotkeys for cooling and warming. You can set the values for the patient circuit and cardioplegia water circuit independently of each other for each hotkey.

| Symbol | |
|---|---|
|  | Hotkey [Warm patient water circuit] |
|  | Hotkey [Warm cardioplegia water circuit] |
|  | Hotkey [Cool patient water circuit] |
|  | Hotkey [Cool cardioplegia water circuit] |

### 3.6.4 Parameter Display

**WARNING!**

If you change the setpoint temperature, check the temperature change at the water outlet to ensure it is reasonable.

| Parameters | | Meaning |
|---|---|---|
| $T_{out}$  | Actual temperature at outlet | Temperature measured at the water outlet. |
| $T_{out}$  | | |
| $T_{set}$ | Setpoint temperature | To change the setpoint ice block size, touch the symbol (⇨ "Setting and Changing Setpoint Temperatures", page 45 ). |
| Only with connected external temperature sensors: | | |
| $T_{ext}$ | Temperature of external sensors | Measured temperature of the external temperature sensor. To display or change the alarm limits, touch the symbol (⇨ "Setting the Warning Limits for the External Temperature", page 48). |
| ΔT | Gradient | Maximum permissible temperature difference between water outlet ($T_{out}$) and the externally measured temperature ($T_{ext}$). To activate the Gradient mode and change the gradient, touch the symbol (⇨ "Gradient Mode", page 49). |

**NOTE**

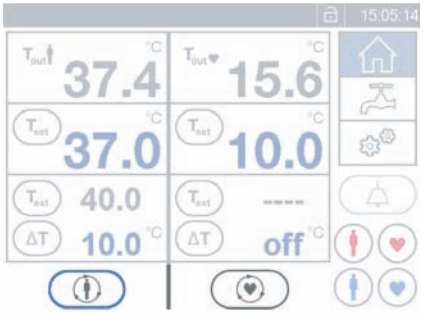
**Patient water circuit on left, cardioplegia water circuit on right**

The setpoint temperature ($T_{set}$) always refers to the temperature at the water outlet ($T_{out}$).

Even once the required temperature is reached at the water outlet ($T_{out}$), the externally measured temperature ($T_{ext}$) may deviate because of heat/cold loss between the water outlet and the external temperature sensor. The loss depends on different factors such as tube lengths and the ambient temperature.

### 3.6.5 Pump Control

You can control the pumps of the patient and cardioplegia water circuits independently of each other and thereby start or stop the circulations. To this end, the touchscreen displays symbols for the pump controls in all screens.

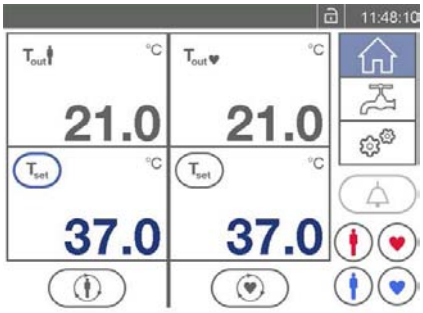



The symbols display whether the respective pump is running or not. In addition, you can also switch the pumps on and off:

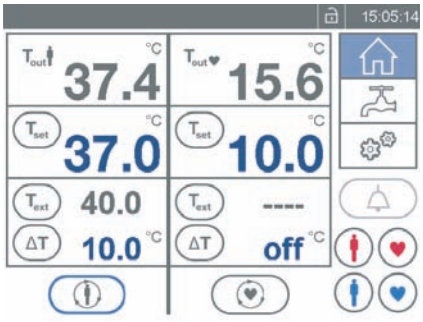
| Patient water circuit | Cardioplegia water circuit | Meaning |
|---|---|---|
|  |  | The pump is not running; no circulation. To switch the pump on and start the circulation, touch the symbol. |
|  |  | The pump is running, the circuit circulates. To switch the pump off and stop the circulation, touch the symbol. |
|  |  | The pump is running, the circuit is de-aired (⇨ "De-airing the Circuits", page 56). |
|  |  | The pump is running, the circuit's tubes are emptied (⇨ " Emptying Water Circuits", page 58). |
|  |  | Pump control deactivated (e.g., during diagnosis (⇨ "Perform Diagnosis", page 129)).<br>The pump cannot be switched on or off. |
|  |  | Errors in the pump or circulation. |
|  |  | Alarm of the pump or circulation. |

## 3.7 Main Screen

In this screen, the touchscreen displays the most important parameters. The screen is displayed automatically after the HCU 40 is switched on. The [Main screen] symbol can be used to switch to the main screen at any time.




Main screen without external temperature sensors
(Left: Patient water circuit, right: Cardioplegia water circuit)



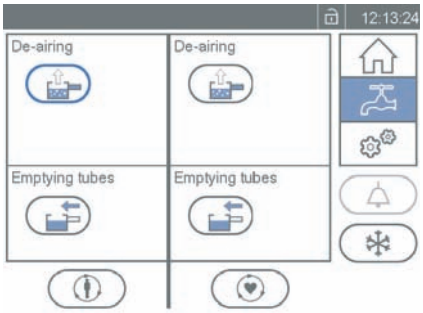

Main screen with external temperature sensors
(Left: Patient water circuit, right: Cardioplegia water circuit)

You have the following options:

- Configure the system (⇨ "System Configuration", page 59)
- Display system information (⇨ "System Information", page 66)
- Set and change setpoint temperatures (⇨ "Setting and Changing Setpoint Temperatures", page 45)
- Set warning limits for $T_{ext}$ (⇨ "Setting the Warning Limits for the External Temperature", page 48)
- Start/stop circulation (⇨ "Starting/Stopping Circulation", page 46)
- Activate Gradient mode (⇨ "Gradient Mode", page 49)
- Use hotkeys (⇨ "Using Hotkeys", page 47)

## 3.8 Functions

The [Functions] symbol opens the "Functions" screen.




Left side: Patient water circuit
Right side: Cardioplegia water circuit

| Function | Meaning |
|---|---|
| De-airing. | De-air the circuits (⇨ "De-airing the Circuits", page 56) |
| Emptying the tubes. | Empty the tubes of the patient and cardioplegia water circuit (⇨ "Emptying Water Circuits", page 58) |
| Compressor control. | Compressor control (⇨ "Compressor Control", page 31) |

### 3.8.1 De-airing the Circuits

**WARNING!**

With the "De-airing" function, ice-cold water is pumped from the tank into the tubes and the heat exchanger. The perfusion circuit in which the heat exchanger being de-aired is integrated must not be operated, as it could provoke a cardiac arrest if a patient is connected.

This function can be used to de-air the patient circuit and cardioplegia water circuit independently of each other prior to the application. To this end, the touchscreen displays the symbols for de-airing in the "Functions" screen.

| Function | Meaning |
|---|---|
| De-airing can be started. | To start the de-airing, touch the symbol of the circuit that you want to de-air. |
| De-airing running. | To stop the de-airing, touch the symbol. |
| De-airing completed, temperature regulation running. | The circuit is de-aired; the temperature of the water is being regulated. |
| De-airing and temperature regulation completed. | The outlet temperatures have attained the setpoint temperatures. |

| Function | Meaning |
|---|---|
|  De-airing cannot be started. | Possible causes:<br>■ Normal circulation is running.<br>■ Emptying of the tubes in progress. |

### 3.8.2 Emptying Tubes

This can be used to empty the tubes of the patient circuit and cardioplegia water circuit independently of each other after the application.

| Function | | Meaning |
|---|---|---|
|  | Emptying can be started. | To start the emptying, touch the symbol of the circuit whose tubes you want to de-air. |
|  | Emptying is in progress. | To stop the emptying, touch the symbol. |
|  | Emptying completed. | The tubes are empty. |
|  | Emptying cannot be started. | Possible causes:<br>■ Normal circulation is running.<br>■ De-airing of the tubes in progress. |

**NOTE**

With this function, you only empty the tubes of the selected circuit. If you want to empty the entire system, including the tank, ice block, etc., instead, use the "Empty system" function (⇨ "Empty tank", page 125).

### 3.8.3 Compressor Control

The compressor for ice formation is controlled automatically.

**NOTE**

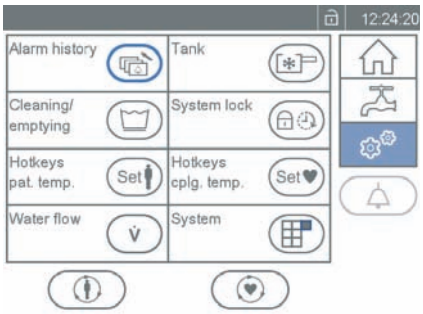
Symbol in the status bar
The status bar indicates when the compressor is running by displaying a symbol (⇨ "Status Bar", page 25).

The [Compressor control] button is visible in the "Functions" screen. You can also use this button to switch the compressor on and off manually.

| Meaning | |
|---|---|
| Compressor not running. | To switch the compressor on manually, touch the symbol. The compressor is automatically controlled again and starts automatically when cooling is required.<br>After a time limit of 20 minutes, the compressor is controlled again automatically, even if you have not switched it back on again. |
| Compressor running. | To switch off the compressor manually, touch the symbol. The HCU 40 stops the compressor, which therefore does not provide any more cooling. In this case, the cooling capacity contained in the ice and cold tank water is available for cooling. |
| Compressor stopped following restart. | You can only start the compressor again once the displayed time has expired. |
| Compressor was stopped automatically. | The stopping of the compressor may have the following causes:<br>■ The time for the restart is too short.<br>■ The setpoint ice block size has been reached or exceeded. There is no ice demand.<br>■ Power consumption of the compressor and the electrical heater is controlled automatically. During warming, the compressor is switched off as a function of the current available in favor of the heater. |

## 3.9 Settings

The [Settings] symbol opens the "Settings" screen.
In this screen, you have the following options:

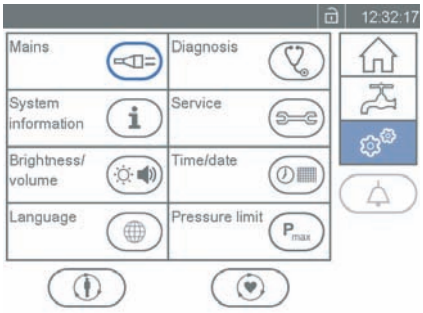



| Function | Meaning |
|---|---|
| Alarm list | Alarm list (⇨ "Alarm List", page 81) |
| Tank | ■ Displaying tank status (⇨ "Displaying the Tank Status ", page 66)<br>■ Displaying ice block size (⇨ "Displaying the Ice Block Size", page 67) |

| Function | Meaning |
|---|---|
| Cleaning/emptying | ■ Cleaning/emptying system status (⇨ "Cleaning/ Emptying System Status", page 69)<br>■ Inspection and maintenance by authorized service personnel (⇨ "Inspection and Maintenance by Authorized Service Personnel", page 130)<br>■ Emptying the tank (Emptying the Tank) |
| System lock | Changing the settings for locking the controls (⇨ "Changing the Settings for Locking the Controls", page 62) |
| Patient water circuit hotkeys | Changing the hotkey settings (⇨ "Changing the Hotkey Settings", page 59) |
| Cardioplegia water circuit hotkeys | Changing the hotkey settings (⇨ "Changing the Hotkey Settings", page 59) |
| Water flow | Changing the water flow (⇨ "Changing the Water Flow", page 62) |
| System | System settings (⇨ "System Settings", page 33) |

### 3.9.1 System Settings

The "Settings" screen can be used to open the "System settings" screen.




| Function | Meaning |
|---|---|
| Power supply | Displaying the power supply status (⇨ "Displaying the Power Supply Status", page 70) |
| Diagnosis | Perform diagnosis (⇨ "Perform Diagnosis", page 129) |
| System information | Display system information (⇨ "Displaying System Information", page 70) |

| Function | Meaning |
|---|---|
|  Service | The [Service] function is password-protected and may only be used by authorized personnel (⇨ "Key User Functions", page 75). |
|  Brightness/volume | Changing the brightness/volume (⇨ "Changing the Brightness/Volume", page 63) |
|  Time/date | Change the time, date and formats (⇨ "Changing the Time, Date and Formats", page 63) |
|  Language | Change the display language (⇨ "Changing the Display Language", page 65) |
|  Pressure limitation | Displaying pressure limits (⇨ "Displaying the Pressure Limits", page 68) |

## 3.10 Pausing the Current Alarm

When alarms are paused, the alarm is only displayed optically. The acoustic alarm pause lasts for a maximum of one minute.

The alarm pause can only be activated during an alarm. It only applies to the current alarms. If a new alarm is triggered during the pause, the HCU 40 will generate another acoustic alarm.

| Alarm pause | |
|---|---|
|  Acoustic alarms enabled | To pause the current alarms, touch the symbol. |
|  Pausing the current alarms | Acoustic alarms are generated again once the pause expires or new alarm situations arise.<br>To end the alarm pause, touch the symbol. |
|  Not possible | There is no current alarm that could be paused. |

## 3.11 Basic Handling Information for Software

### 3.11.1 Confirming or Rejecting Inputs/Changes

If you enter or change data you must confirm or reject it. To this end, the touchscreen displays the following symbols:

| | Symbol | Description |
|---|---|---|
|  | Confirm | To confirm the inputs or changes, touch the symbol.<br>The HCU 40 uses the new, changed settings. |

| Symbol | Description |
|---|---|
| Reject | To reject or cancel the inputs or changes, touch the symbol.<br>The HCU 40 uses the previous, unaltered settings. |

Once you have confirmed or rejected data, the HCU 40 automatically closes the relevant window.

### 3.11.2 Switching Functions On and Off

You can switch between different functions. To this end, the touchscreen displays the following buttons:

| Function | Description |
|---|---|
| The function is activated. | To deactivate the function, touch the other button. |
| The function is deactivated. | To activate the function, touch the button. |

### 3.11.3 Changing Numerical Settings

You can change the settings via the touchscreen or the rotary knob:

**Setting via the touchscreen**

1 Touch the field with the setting value.
   - ▸ The setting with blue background is selected.
2 To increase the value, touch the [+] symbol.
   Or
   To reduce the value, touch the [–] symbol.

**Setting via the rotary knob**

1 Turn the rotary knob until the required field is selected.
   - ▸ The selected field is shown with a blue frame.
2 Press the rotary knob to confirm the selection.
   - ▸ Active fields with a numerical display are shown with blue background and white lettering.
     Or
     Selected symbols lead to selected screen.
3 To increase the value, turn the rotary knob clockwise.
   Or
   To reduce the value, turn the rotary knob counterclockwise.
4 Press the rotary knob to confirm the setting.

5 To adopt the setting, turn the rotary knob to the [Confirm] field and press the rotary knob again.
Or
To reject the setting, turn the rotary knob to the [Reject] field and press the rotary knob again.

### 3.11.4 Using a Selection List

The touchscreen displays lists with arrow symbols from which you can select a value.
The setting with gray background is selected.
To select a different setting, touch the arrow symbols until the required setting is selected.


### 3.11.5 Using a Wizard

The touchscreen displays wizards for different functions, which guide you step by step. The wizard shows at every step how you should proceed and waits for your confirmation. You have the following options:

| Symbol | | Description |
|---|---|---|
| | Continue | To confirm that you have followed the instructions, touch the symbol. The wizard continues with the next step. |
| | Reject | To cancel the wizard, touch the symbol. The touchscreen displays a prompt asking whether you really want to quit. To continue canceling, touch the [Confirm] symbol. |
| | Confirm | To confirm the completion, touch the symbol. The wizard is completed. |

### 3.11.6 Locked Controls

The controls (rotary knob, buttons and touchscreen) can be locked after a period of inactivity which can be set. Locking prevents settings from being inadvertently altered or functions inadvertently called up.

**NOTE**

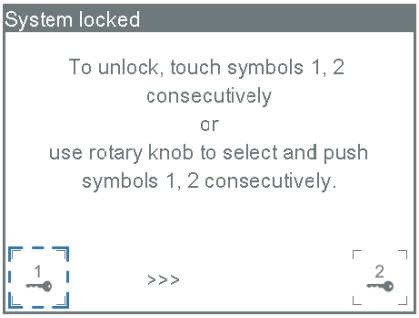
**Deactivate automatic locking**
Whether and after what period of time the lock is activated, can be defined in the settings (⇨ "Changing the Hotkey Settings", page 59).

The padlock symbol in the status bar shows whether the HCU 40 is locked:

| Unlock | | Meaning |
|---|---|---|
| | HCU 40 locked | To be able to use the HCU 40, the lock must be removed. |

| Unlock | | Meaning |
|---|---|---|
|  | HCU 40 not locked | You can use the controls until they are locked again automatically. |

If the HCU 40 is locked and you try to use the controls, the touchscreen displays the following message:




You can cancel the lock in the following ways:

1 Touch the symbols "key 1" and "key 2" one after the other.

2 Select and confirm the symbols "key 1" and "key 2" one after the other with the rotary knob.

- The HCU 40 removes the lock. You can use the controls until they are locked again automatically.

# 4 Operation

## 4.1 Positioning and Connecting the Device

### 4.1.1 Setting up and Connecting the HCU 40

**WARNING!**

- Please note the requirements regarding position of use and operation and positioning (⇨ "Position of Use and Operation and Positioning of the HCU 40" , page 13).
- Please note the requirements regarding the power supply and supply line (⇨ " Technical Data", page 135).
- The HCU 40 should only ever be connected to a power supply with a functional protective ground conductor.

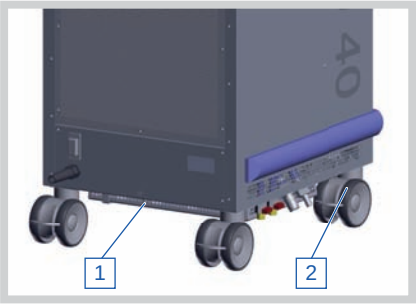
**NOTE**

**Equipotential bonding pin**
The equipotential bonding pin enables the electrical device to be directly connected to the equipotential bonding busbar of the electrical installation. This is in addition to the protective ground conductor in the power cord. Especially with medical electrical equipment, the risk of excessive enclosure leakage currents can be reduced by using the equipotential bonding connection.
For details concerning the correct setting up of medical electrical equipment, please refer to the IEC 60601-1-1 standard.

1 Position the HCU 40 at a suitable place in your existing system.

2 **WARNING!** To prevent undesired movement, lock the HCU 40.

Apply the parking brakes on the front wheels [2] of the HCU 40. by pressing the lever down.



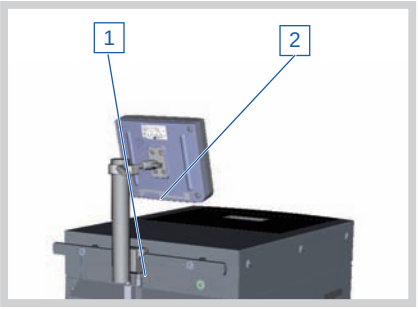

3 Connect the HCU 40 to the external power supply: Connect a suitable equipotential bonding conductor to the equipotential bonding connection [1].

4 Ensure that suitable equipotential bonding conductors and equipotential bonding cables which meet national requirements are used.

### 4.1.2 Connecting a Control Unit

The CAN connection cable supplies the control unit with power and transfers data between the HCU 40 and the control unit.

1 Connect the CAN connection cable to the "CU" [1] connection on the HCU 40.




2 Connect the CAN connection cable to the "HCU" [2] connection on the CU control unit.

### 4.1.3 Connecting External Devices (Optional)

**WARNING!**

- If you are using the HCU 40 together with other medical devices, check the total leakage current.
- Only connect the device to connections that are intended to be connected to other powered devices during normal operation.
- Ensure that devices which are connected to the USB port of the HCU 40 fulfill the specifications of the following standards:
  - IEC 60950 (for data processing equipment located more than 1.5 meters from the operating table)
  - IEC 60601 (for data processing equipment located within 1.5 meters of other medical devices)
- Do not touch the patient and the device at the same time.
- Only use the interfaces for the respectively intended devices.

Please observe the Instructions for Use of the external device for its setup and operation.

The connections for external devices are located on the underside of the control unit CU (⇨ "Control Unit CU", page 24).

### 4.1.4 Connecting External Temperature Sensors (Optional)

You can connect external temperature sensors to the HCU 40 in order to display the measured temperatures (⇨ "Parameter Display", page 27) and to use the gradient mode (⇨ "Gradient Mode", page 49).

The connections for sensors are located on the underside of the control unit CU.

1 Connect the temperature sensor for the patient water circuit to the connection "T $_{ext}$" patient water circuit [1].


2 Connect the temperature sensor for the cardioplegia water circuit to the connection "$T_{ext}$" cardioplegia circuit [2].
3 Position the sensors according to clinical requirements.

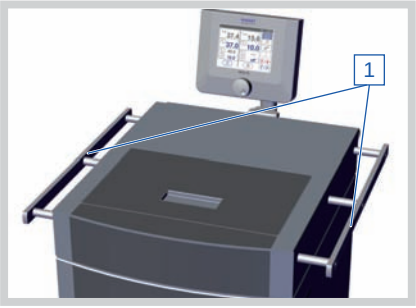
**NOTE**

Observe the connection requirements when using the (⇨ "Gradient Mode", page 49 ).

### 4.1.5 Securing Set of Slide Rails for Tubing Holder (Optional)

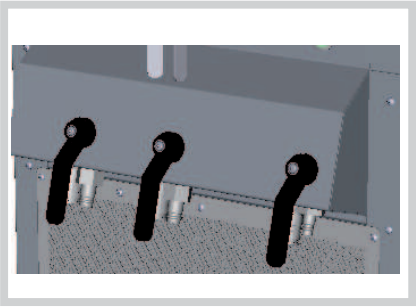
1 Release the three screws of the cover on the right and left side of the HCU 40 .

2 Attach the slide rails [1] to the right and left side of the HCU 40.

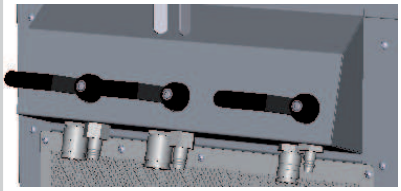



### 4.1.6 Opening/Closing Stopcocks

1 Turn the desired stopcock to the vertical position to open it.



2 Turn the desired stopcock to the horizontal position to close it.



### 4.1.7 Filling/Topping Up Water

**WARNING!**

- Only use clear water containing no particles or foreign bodies.
- The HCU 40 tank must be filled with sterile filtered water with a hardness of ≤ 14 °dH (2.5 mmol/l $CaCO_3$). Do not use deionized or completely distilled water.
- Do not use deionized water. Deionized water is highly corrosive and can damage the device.
  Distilled and deionized water has a lower freezing point, which can prevent the formation of ice at temperatures far below 0°C. Vibrations at temperatures below 0°C (e.g., from turning on the pump) can cause the tank contents to freeze completely all of a sudden, with the result that circulation is no longer possible.

**WARNING!**

- Use a terminal water sterile filter with a pore size of 0.2 µm to fill the HCU 40 with water.
- Do not use hot water for filling the tank. The water should be as cold as possible in order to accelerate the formation of ice after filling.

**NOTE**

Pay attention to level adjustment
Level adjustment between the cardioplegia tank and the main tank can be delayed if filling is performed very quickly.

1 Open the tank cover.
2 Add water up to no higher than the level marking in the cardioplegia tank (1 cm above the evaporizer plates).
3 Close the tank cover.

### Reducing water hardness

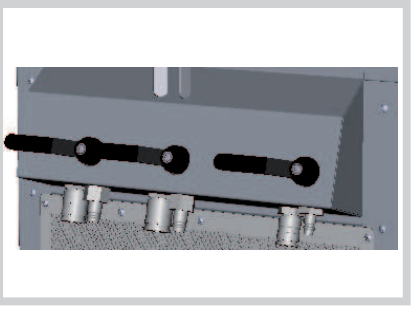
To reduce hard water to 2.5 mmol/l $CaCO_3$ (14 °dH), you must add distilled water to the tap water in the applicable mixing ratio:

| Hardness of tap water | | Mixing ratio tap water : distilled water |
|---|---|---|
| 3 mmol/l $CaCO_3$ | 17 °dH | 5 : 1 |
| 4 mmol/l $CaCO_3$ | 22 °dH | 1.7 : 1 |
| 5 mmol/l $CaCO_3$ | 28 °dH | 1 : 1 |
| 6 mmol/l $CaCO_3$ | 34 °dH | 1 : 1.4 |
| 7 mmol/l $CaCO_3$ | 39 °dH | 1 : 1.8 |
| 8 mmol/l $CaCO_3$ | 45 °dH | 1 : 2.2 |
| 9 mmol/l $CaCO_3$ | 50 °dH | 1 : 2.6 |
| 10 mmol/l $CaCO_3$ | 56 °dH | 1 : 3 |

## 4.1.8 Connecting/Removing Water Tubes

### Connecting the water tubes

1 Close the stopcocks.



2 Connect the tube to the corresponding water inlet or water outlet. Ensure that you feel the quick-release coupling click into place.

**NOTE**

Before opening the stopcocks, you must create a circuit by:

- Connecting the oxygenator heat exchanger to the water circuit P1(⇨ " Connecting a Heat Exchanger", page 52).
- Connecting the warming/cooling blanket to the water circuit P2 (⇨ " Connecting a Heat Exchanger", page 52).
- Establishing the water circuit with the cleaning connector (double Hansen coupling) (⇨ "Creating a Water Circuit", page 52).

### Removing the water tubes

1 Empty the tube system (⇨ "Emptying Water Circuits", page 58).

2 **CAUTION!** Close the stopcocks before removing the water tubes.

Pull back the ring on the quick-release coupling.

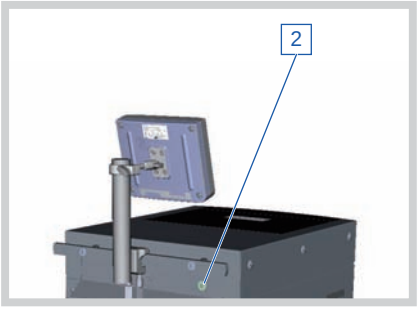
3 Remove the tube.

## 4.2 Using the System

### 4.2.1 Switching On the HCU 40, Self-Test

1 Ensure that the mains circuit breaker [1] is turned on and there is power to the unit.


2 Press the On/Off switch [2].





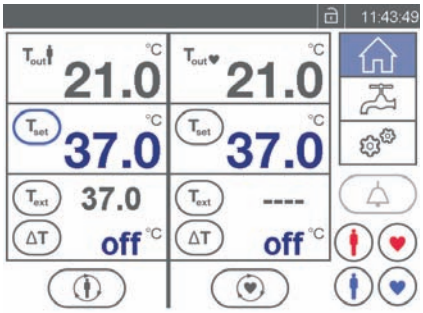
- The HCU 40 will automatically perform a self-test after being switched on.
- The LED ring on the On/Off switch flashes.
- The touchscreen displays the startup screen.

**NOTE**

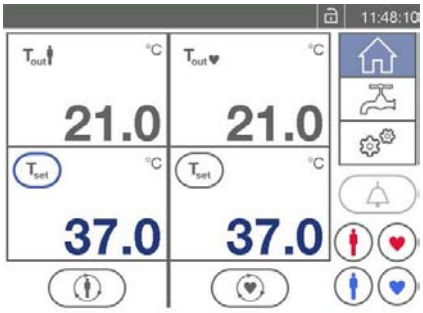
Recommendation for operating the HCU 40:
The HCU 40 should always remain connected to the power supply and turned on to ensure that there is always sufficient ice in the tank. As soon as the set ice block size is attained, the machine switches automatically to Ice maintenance mode.
In Ice maintenance mode an increased quantity of ice is formed over a period of several days without use of the HCU 40. To prevent the tank from freezing up completely, the max. setpoint ice block size selected is automatically reduced to "Medium ice block" (standard setting) from the 4th day in continuous Ice maintenance mode (⇨ "Changing the Setpoint Ice Block Size", page 61).

### Display following successful self-test

After the self-test, the touchscreen displays the main screen (⇨ "Main Screen", page 28):




Main screen with external temperature sensors

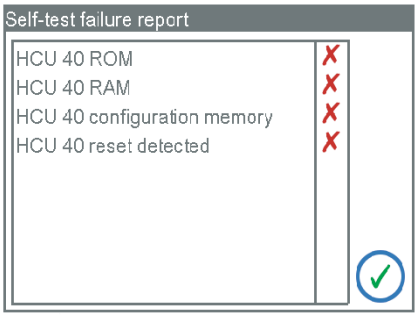



Main screen without external temperature sensors

### Display in case of error

Should an error occur during the self-test, the touchscreen displays a self-test failure report.

1 To close the failure report touch the [Confirm] symbol.




2 Take the HCU 40 out of service and have it tested by the authorized service personnel.

### 4.2.2 Setting and Changing Setpoint Temperatures

**NOTE**

Preset temperature
After switching on the HCU 40, the setpoint temperature setting is always 37°C.

You can set the setpoint temperatures ($T_{set}$) for the patient circuit and cardioplegia water circuit independently of each other.

**NOTE**

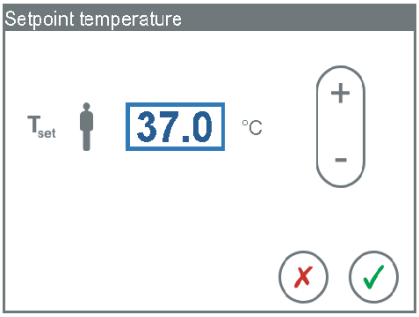
**Hotkeys**
You can use hotkeys to call up the values for setpoint temperatures and setpoint gradients directly instead of having to change them individually (⇨ "Changing the Hotkey Settings", page 59).

**NOTE**

**Maximum cooling capacity**
If you set a setpoint temperature of 1°C, the internal mixing valve opens completely to the tank. This provides the maximum available cooling capacity.

1 Touch the symbol "$T_{set}$" for the circuit whose setpoint temperature you wish to change.

2 Touch the field and adjust the value (⇨ " Changing Numerical Settings", page 35).




- The touchscreen displays the following messages (see table below) if the setpoint temperature may be harmful to health:

3 Ensure that the selected setting is suitable and safe for the patient and the current situation.

4 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol instead.

- The touchscreen displays the set temperature ($T_{set}$) in the main screen.

| Cause | Message |
|---|---|
| 39.5 T↑ Setpoint temperature > 39.4°C | Temperature setting may be harmful to health! |
| 19.0 T↓ 15.5°C < setpoint temperature < 33.0°C | Temperature setting may lead to ventricular fibrillation or cardiac arrest! |
| 9.3 T↓ Setpoint temperature < 15.6°C | Temperature setting may be harmful to health! |

### 4.2.3 Starting/Stopping Circulation

**NOTE**

**Turn off cardioplegia water circuit when not required**
Turn the cardioplegia circuit off if no cardioplegic solution is required. This prevents the ice in the cardioplegia tank from melting prematurely.

1 Touch [Patient water circuit pump] and/or [Cardioplegia water circuit pump] (⇨ "Pump Control", page 28).

- The HCU 40 starts the activated pump and displays the [Pump running] symbol.
- The HCU 40 cools or warms the water in the circuits until the measured temperatures at the water outlets have attained the setpoint temperature, and maintains these temperatures.

2 Touch [Patient water circuit pump] and/or [Cardioplegia water circuit pump].

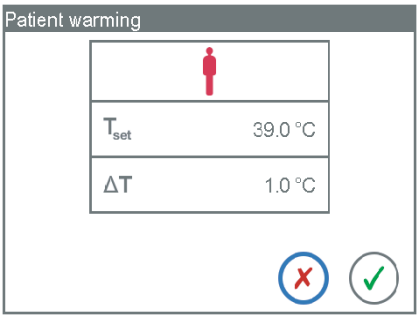
- The HCU 40 stops the activated pump and displays the [Pump not running] symbol.

### 4.2.4 Using Hotkeys

The following instructions apply for the patient water circuit and the cardioplegia water circuit. Hotkey [Warm patient water circuit] is shown.

1 Touch a hotkey in order to use its values, e.g., [Warm patient water circuit].

- The touchscreen displays the values set for the hotkey: $T_{set}$" for setpoint temperature, [ΔT] for setpoint gradient.




- The touchscreen displays a warning symbol if the setting may be harmful to health (see table below).

2 Ensure that the selected setting is suitable and safe for the patient and the current situation.

3 To confirm and use the displayed values, touch the [Confirm] symbol.

- In this case, the HCU 40 adopts the values of the hotkey as the setpoint temperature and setpoint gradient.
- The setpoint gradient is only used if external temperature sensors are connected. Gradient mode is deactivated with the value [Off].

Or

4 If you do not want to use the values, touch the [Reject] symbol instead.

| Cause | Message |
|---|---|
| Setpoint temperature > 39.4°C | Temperature setting may be harmful to health! |
| Setpoint temperature < 33.0°C | |
| Gradient > 8.0°C | |

### 4.2.5 Setting the Warning Limits for the External Temperature

**WARNING!**

- Incorrect or unused warning limits pose a risk of dangerous situations not being recognized, thereby endangering the patient.
- Do not set any extreme warning limits which could make the function of the alarm system ineffective.
- When the alarm limits are deactivated, pay special attention to the parameter values on the touchscreen and the external patient temperature monitoring.

**WARNING!**

- If the same or similar alarm signals are used on different devices in the same environment (e.g., in the cardiac operating room), there is a risk that the user may misinterpret a signal.
- Before beginning the application, ensure that the warning limits used are suitable and safe for the patient and the current situation.

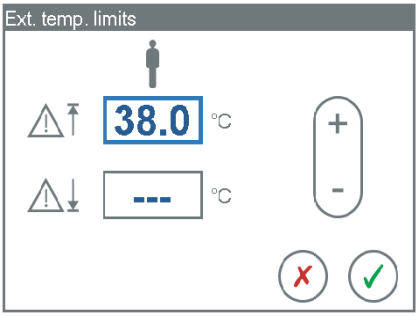
The warning limits enable you to define when the HCU 40 triggers physiological alarms in order to detect and react to dangerous situations.

You can set the warning limits for the monitoring of the external temperature sensors. If the measured value is outside of the alarm limits, the HCU 40 generates an alarm. The alarm ends as soon as the measured value is within the warning limits again.

You can deactivate warning and alarm limits. The deactivated limit is not monitored and does not generate an alarm.

1 To display or change the settings, touch the symbol of the corresponding temperature sensor.

   ▸ The touchscreen displays the following window:




Example: warning limits for external temperature sensor patient circuit with deactivated lower warning limit.
The same applies for the cardioplegia water circuit.

2 To accept the changes, touch the [Confirm] symbol.
Or
To reject them instead, touch the [Reject] symbol.

| Limits | | |
|---|---|---|
|  | Upper warning limit | To change a limit value, touch the field and adjust the value.<br>To deactivate the limit, increase the value until the touchscreen displays [– – –].<br>To reactivate the limit, touch [–] until the touchscreen displays the desired limit value. |
|  | Lower warning limit | To change a limit value, touch the field and adjust the value.<br>To deactivate the limit, decrease the value until the touchscreen displays [– – –].<br>To reactivate the limit, touch [+] until the touchscreen displays the desired limit value. |

### 4.2.6 Gradient Mode

In gradient mode, setpoint gradients for the patient water circuit and cardioplegia water circuit can be used for physiologically optimized warming and cooling.

The gradient (ΔT) is the temperature difference between the water outlet ($T_{out}$) and the externally measured temperature ($T_{ext}$).

When the temperature sensor is connected in the venous line / in the venous reservoir, the gradient for the patient water circuit is the maximum permissible temperature difference between the circulating water and the venous blood.

The maximum permissible gradient for the cardioplegia water circuit is the temperature difference between the circulating water and the cardioplegic fluid.

#### How Gradient mode functions

The maximum permissible gradient can be set in the Gradient mode. The HCU 40 then controls the warming/cooling in such a way that the water temperature does not deviate from the externally measured water temperature by more than the set maximum gradient. This means that the HCU 40 automatically adjusts the water output temperature to the venous patient or cardioplegia temperature measured by the sensor until the setpoint temperature ($T_{set}$) at the water outlet is attained.

The Gradient mode thus protects the patient from too abrupt warming/cooling.

### Activating Gradient mode

**NOTE**

**Only use for support**

The ambient temperature and behavior of the heat exchanger can affect the functioning of the Gradient mode and lead to inaccuracies.

- Consequently, the Gradient mode should only be used as a supporting function and you should additionally monitor the patient temperature.
- Monitor the temperature of the patient with an independent monitoring and alarm system.

The HCU 40 requires the measured values from the external temperature sensors for the Gradient mode.

The Gradient mode is automatically deactivated for circuits where no external temperature sensors are connected.

You can activate the Gradient mode for the patient and cardioplegia water circuit independently of each other.

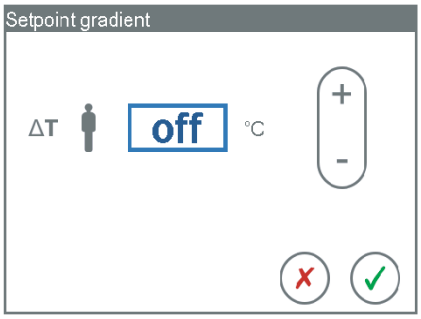
1 Connect the external temperature sensor to the control unit (⇨ "Connecting External Temperature Sensors (Optional)", page 39).

   ▸ The touchscreen displays the temperatures ($T_{ext}$) measured externally for the patient and cardioplegia water circuit as well as fields for the gradients (ΔT) (⇨ "Parameter Display", page 27).
   **NOTE:** Also follow the instructions for use of the disposable being used.

2 For the patient water circuit connect the temperature sensor in the venous line or to the venous reservoir.
   Or
   For the cardioplegia water circuit connect the temperature sensor to the cardioplegia heat exchanger.

3 Touch the symbol of the corresponding circuit.
   ▸ The Gradient mode is not automatically active; the fields display [Off].

4 To set the gradient, touch [+] until the touchscreen displays the desired limit value.



- The touchscreen displays messages if the gradient is selected too high and as a result might be harmful to health (see table below).

5 To accept the changes, touch the [Confirm] symbol.
Or
To reject the changes, touch the [Reject] symbol.

- The touchscreen displays the set gradient (ΔT) in the main screen.

| Cause | Message |
|---|---|
| 15.0 T↓ Gradient > 8.0°C | Temperature setting may be harmful to health! |

### Changing or deactivating gradients

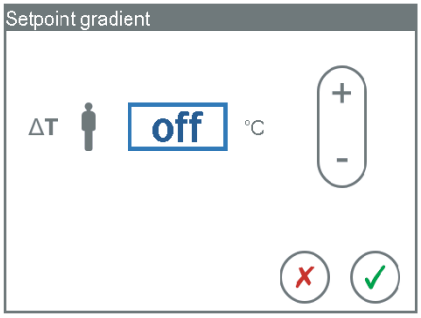
**NOTE**

**Hotkeys**
You can use hotkeys to call up the values for setpoint temperatures and setpoint gradients directly instead of having to change them individually (⇨ "Changing the Hotkey Settings", page 59).

You can change or deactivate the Gradient mode for the patient and cardioplegia water circuit independently of each other. When Gradient mode is deactivated, the device adjusts the output temperature to suit the setpoint temperature again – without taking a gradient into account.

1 Touch the symbol of the corresponding circuit.

2 Touch the field with the value for the gradient.




3 Adjust the value.

4 To deactivate Gradient mode, select the value [off]. To do so, touch the symbol [–] until the field displays [Off].
Or
To reactivate Gradient mode, touch [+] until the touchscreen displays the desired limit value.

5 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol instead.

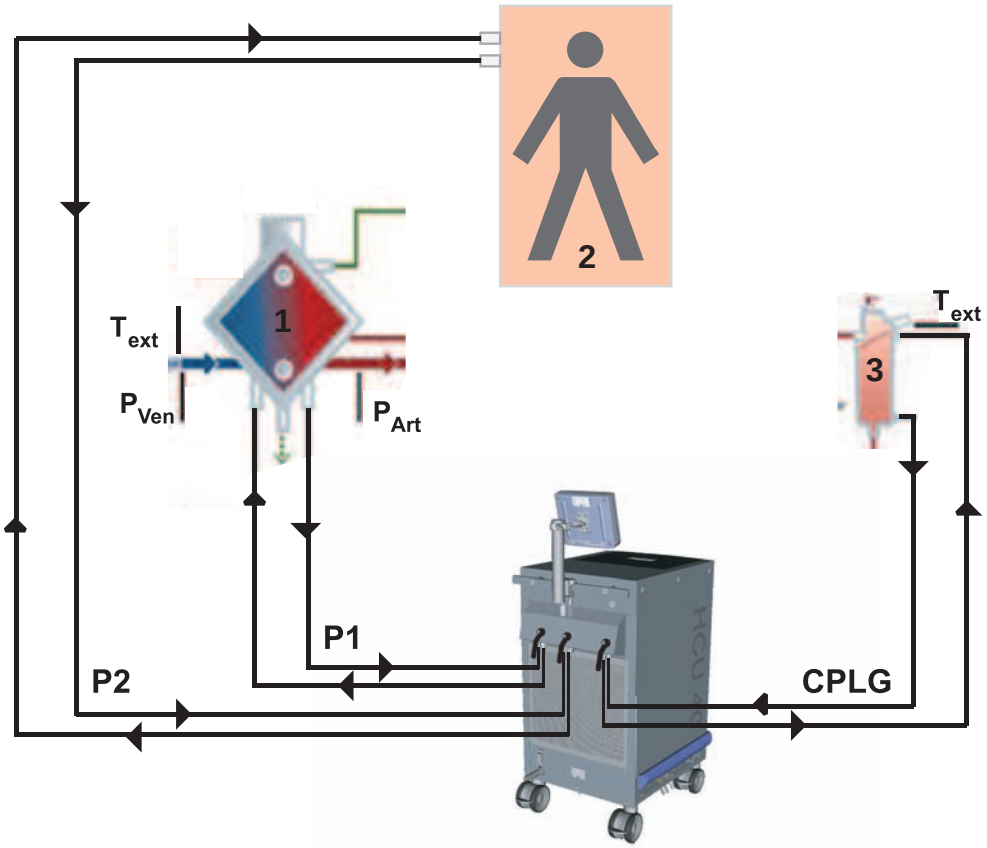
## 4.3 Water Circuits

### 4.3.1 Creating a Water Circuit

Before you can operate the HCU 40, the required water circuits must be connected and de-aired. Proceed as follows:

1 Close the stopcocks (⇨ "Opening/Closing Stopcocks", page 40).
2 Connect the water tubes (⇨ "Connecting/Removing Water Tubes", page 42).
3 Connect the heat exchanger and/or the warming/cooling blanket (⇨ " Connecting a Heat Exchanger", page 52).
4 Open the stopcocks.
5 De-air the water circuits (⇨ "De-airing the Circuits", page 56).

### 4.3.2 Connecting a Heat Exchanger




1 Oxygenator heat exchanger
2 Warming/cooling blanket

| | |
|---|---|
| 3 | Cardioplegia heat exchanger |
| P1 | Patient water circuit 1 |
| P2 | Patient water circuit 2 |
| CPLG | Cardioplegia water circuit |
| $P_{Ven}$ | Venous pressure sensor |
| $P_{Art}$ | Arterial pressure sensor |
| $T_{ext}$ | External temperature sensor |

| Patient water circuit 1 (P1) | Patient water circuit 2 (P2) | Cardioplegia water circuit (CPLG) |
|---|---|---|
| Oxygenator heat exchanger | – | – |
| Oxygenator heat exchanger | – | Cardioplegia heat exchanger |
| – | – | Cardioplegia heat exchanger |
| Oxygenator heat exchanger | Warming/cooling blanket | Cardioplegia heat exchanger |
| Pressure reducer | Warming/cooling blanket | Cardioplegia heat exchanger |

### Connecting the oxygenator heat exchanger to water circuit P1

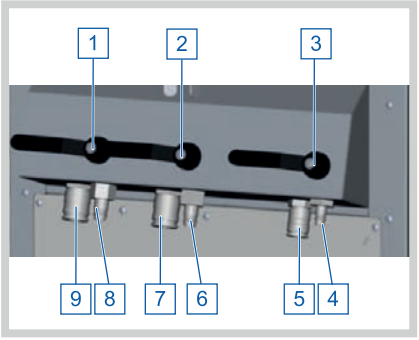
**WARNING!**

- Before use, check the pressure resistance of the heat exchanger, as shown on the manufacturer's data sheet.
- The heat exchanger used must be approved for a water flow of at least 2 l/min.

**WARNING!**

- The tubes of the perfusion system used should not be too long.
- Insert the external temperature sensors (optional) fully into the measurement device in the perfusion system and lock into place.

1 Connect the water tube from the water outlet [8] to the water inlet of the oxygenator heat exchanger.



2 Connect the water tube from the water inlet (backflow) [9] to the water outlet of the oxygenator.
**NOTE:** Ensure that the Hansen couplings are correctly connected to the water inlet and outlet of the respective heat exchangers. The couplings are coded with symbols for the patient water circuit and for the direction of flow.
3 Open the stopcock [1] of the patient water circuit P1.
- ▸ The handle is in the vertical position: The stopcock is open.

4 Ensure that the stopcocks that are not part of a water circuit are closed.
5 **WARNING!** Ensure that the oxygenator heat exchanger is connected to the patient circuit P1.
De-air the patient water circuit (⇨ "De-airing the Circuits", page 56).

### Connecting the cardioplegia heat exchanger to the CPLG water circuit

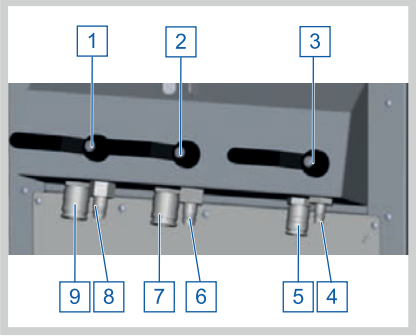
**WARNING!**

- Before use, check the pressure resistance of the heat exchanger, as shown on the manufacturer's data sheet.
- The heat exchanger used must be approved for a water flow of at least 2 l/min.

**WARNING!**

- The tubes of the perfusion system used should not be too long.
- Insert the external temperature sensors (optional) fully into the measurement device in the perfusion system and lock into place.

1 Connect the water tube from the water outlet [4] to the water inlet of the cardioplegia heat exchanger.




2 Connect the water tube from the water inlet (backflow) [5] to the water outlet of the cardioplegia heat exchanger.
**NOTE:** Ensure that the Hansen couplings are correctly connected to the water inlet and outlet of the respective heat exchangers. The couplings are coded with symbols for the patient water circuit and for the direction of flow.
3 Open the stopcock [1] of the patient water circuit P1.
- ▸ The handle is in the vertical position: The stopcock is open.

4 Ensure that the stopcocks that are not part of a water circuit are closed.

5 **WARNING!** Ensure that the cardioplegia heat exchanger is connected to the cardioplegia water circuit.
De-air the cardioplegia water circuit (⇨ "De-airing the Circuits", page 56).

### Connecting the warming/cooling blanket to the water circuit P2

**WARNING!**

- When operating the warming/cooling blanket, use a pressure reducer to reduce the pressure to the permissible level for the warming/cooling blanket; or only operate the warming/cooling blanket in addition to a water circuit with a connected oxygenator heat exchanger or the supplied pressure reducer to avoid overpressure in the warming/cooling blanket.
- Place a dry, absorbent sheet with a moisture barrier on the warming/cooling blanket to protect the patient against any leakage from the blanket.
- The warming of transdermal medication (e.g. plasters) may increase the amount of active ingredient administered, and so harm the patient.
- When the HCU 40 is off, it is possible that the patient's body temperature will fall.
- Only connect the warming/cooling blanket with the short tubes intended for it ((⇨ "Accessories", page 133), 6 m (3 m + 3 m)) in order to minimize the deviation between the setpoint and actual temperature of the warming/cooling blanket.

#### Indications

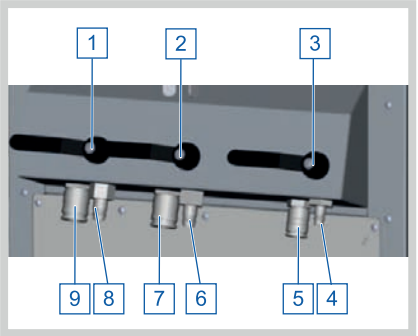
To prevent or treat hypo/hyperthermia.

Use of the warming/cooling blanket with the heater-cooler unit HCU 40 helps to regulate the patient's body temperature. For this purpose, temperature-controlled water is passed through a hypo/hyperthermia warming mat via a connection tube. This mat acts as the interface that either keeps the patient warm or cool. Its temperature is adjusted to a preset value by the heater-cooler unit.

**NOTE**

Observe the corresponding Instructions for Use when connecting and using the warming/cooling blanket.

1 Connect the tubes for the warming/ cooling blanket to the water outlet [6] and water inlet [7] of the patient water circuit 2.




2 Connect the pressure reducer on the water outlet [8] and water inlet [9] of the patient water circuit 1 if you are not using an oxygenator.
3 Open the stopcocks [1] and [2].
   - The handle is in the vertical position: The stopcock is open.
4 Ensure that the stopcocks that are not part of a water circuit are closed.
5 De-air the patient water circuit (⇨ "De-airing the Circuits", page 56).

### 4.3.3 De-airing the Circuits

**WARNING!**

With the "De-airing" function, ice-cold water is pumped from the tank into the tubes and the heat exchanger. The perfusion circuit in which the heat exchanger being de-aired is integrated must not be operated, as it could provoke a cardiac arrest if a patient is connected.

**NOTE**

After switching on the HCU 40, the setpoint temperature setting is always 37°C. If no setpoint temperature is entered before de-airing, the HCU 40 will automatically set the temperature of the circulating water to 37°C after de-airing. Therefore, to reduce the time required before the machine is ready for cooling, the setpoint temperature should always be entered prior to de-airing.

This function can be used to de-air the patient water circuit and cardioplegia water circuit independently of each other prior to the application. To this end, the touchscreen displays symbols for the de-airing in the "Functions" screen.

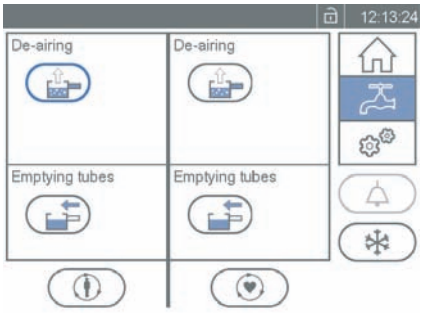
It generally makes sense to de-air the circuits with connected heat exchangers. In exceptional situations, it is also possible to de-air without heat exchangers (⇨ " Key User Functions", page 75).

1 Create the required water circuit (⇨ "Creating a Water Circuit", page 52).

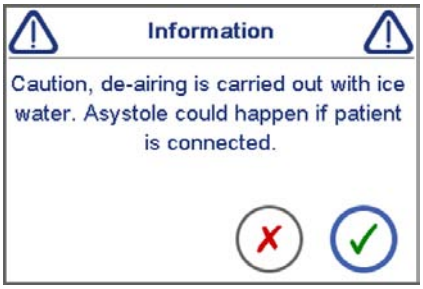
- P1: Oxygenator heat exchanger to water circuit P1 (⇨ "Connecting a Heat Exchanger", page 52).
  Or
- P1: Pressure reducer for warming/cooling blanket (⇨ "Connecting a Heat Exchanger", page 52).
- P2: Connecting the warming/cooling blanket to the water circuit P2 (⇨ " Connecting a Heat Exchanger", page 52).
  Or
- CPLG (⇨ "Connecting a Heat Exchanger", page 52).

2 Set the required setpoint temperature for the corresponding circuit (⇨ "Setting and Changing Setpoint Temperatures", page 45).
- The default temperature is set as 37°C.

3 Touch the [Functions] symbol in the main screen.




4 Touch the [De-airing] symbol of the required circuit.
- The touchscreen shows the following message:




5 To confirm the message, touch the [Confirm] symbol.
- The HCU 40 starts the pump to de-air the circuit.
- A status bar displays the progress of the de-airing.
  **NOTE:** You can cancel the de-airing by touching the [De-airing] symbol during the de-airing.
- Once the circuit has been de-aired, a green check mark appears next to the [De-airing] symbol.
- The de-airing is followed by temperature regulation. The water is regulated to the preset temperature.
  **NOTE:** During de-airing, water is taken from the tank, and water flows into

the tubes and heat exchanger. Depending on the length of the tubes, it may be necessary to top up water (⇨ "Filling/Topping Up Water", page 41 ).

6 When the setpoint temperature is reached, a green check mark is displayed next to the symbols "$T_{out}$" and "$T_{Set}$". Once the medically required temperature is reached, you can attach the patient to the connected heat exchanger.

**NOTE**

**Canceling temperature regulation in an emergency**
If strong cooling is required immediately for a patient, you can cancel the temperature process of regulating once the medically required setpoint temperature is reached.

### 4.3.4 Emptying Water Circuits

**WARNING!**

Do not empty the tubes until the perfusion has ended.

This function can be used to empty the patient and cardioplegia water circuit independently of each other after the application. To this end, the touchscreen displays the symbols for emptying in the "Functions" screen.

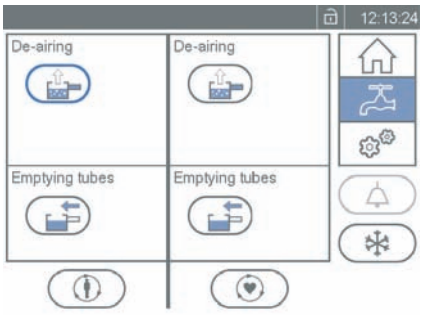
Emptying cannot be started when the symbol is inactive. This can be due to the following reasons:

- Normal circulation is running (Pump in operation).
- De-airing of the tubes in progress.

**NOTE**

This function only empties the selected water circuit. If you want to empty the entire system, including the tank, ice block, etc., instead, use the [Empty system] function (Emptying the Tank).

1 Touch the [Functions] symbol.




2 Stop the circulation (⇨ "Starting/Stopping Circulation", page 46).

3 Touch the [Empty tubes] symbol for the corresponding circuit.
- The HCU 40 starts the pump to empty the tubes. During the emptying, the touchscreen displays a progress bar under the [Emptying] symbol.
- The touchscreen shows the following message:


4 To confirm the message, touch the [Confirm] symbol.
- The emptying is complete once the [Emptying complete] is displayed.
- The water circuit is emptied.

If the maximum water level of the tank is reached during emptying, the process will stop, and the system outputs the message [Tank overflow!]. In this case you must let water out of the tank and then start emptying again. To do so, proceed as follows:

5 Connect the supplied drainage tube to the tank drainage coupling.
6 Place a suitable container under the tank overflow to catch overflowing water.

If tubes are connected to both patient water circuits P1 and P2, then these can only be emptied sequentially. To do so, proceed as follows:

7 Empty the first patient water circuit via the function [Empty tubes] and then close the stopcock of this water circuit.
8 De-air the second patient water circuit so as to remove the air in the internal tubing (⇨ "De-airing the Circuits", page 56).
9 Empty the second patient water circuit via the function [Empty tubes].

**NOTE**

You can cancel the emptying by touching the [Emptying] symbol during the emptying.

The HCU 40 cancels the emptying if a time limit of 2 minutes expires or the maximum water level of the tank is achieved.

## 4.4 System Configuration

### 4.4.1 Changing the Hotkey Settings

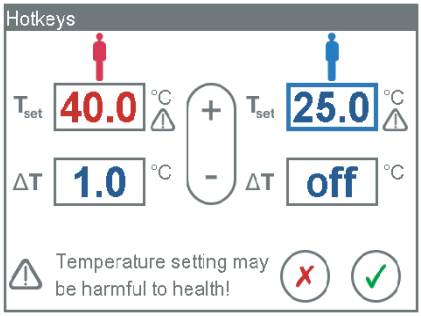
You can set the gradients for the patient and cardioplegia water circuit independently of each other.

With this function, you can change the temperature values called up with the [Warming] and [Cooling] hotkeys (⇨ ""Warming" and "Cooling" Hotkeys", page 26 ). The following instructions apply for the patient water circuit and the cardioplegia water circuit. The patient water circuit is shown.

1 Touch the [Settings] symbol.

2 Touch [Hotkeys Pat. Temp] or [Hotkeys Cplg.Temp].

- The touchscreen displays the current values set for the [Cooling] and [Warming] hotkeys: "$T_{set}$" for setpoint temperature, [ΔT] for gradient.
- The touchscreen displays the following window:




3 To change the values, touch the corresponding field and adjust the value (⇨ " Changing Numerical Settings", page 35).

- The touchscreen displays a warning symbol if the setting may be harmful (see table below).

4 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

| Cause | Message |
|---|---|
| Setpoint temperature > 39.4°C | Temperature setting may be harmful to health! |
| 15.5°C < setpoint temperature < 33.0°C | Temperature setting may lead to ventricular fibrillation or cardiac arrest |
| Setpoint temperature < 15.6°C | Temperature setting may be harmful to health! |
| Gradient > 8.0°C | Temperature setting may be harmful to health! |

### 4.4.2 Changing the Setpoint Ice Block Size

**WARNING!**

The water quality can influence the ice sensors which, in turn, can influence ice formation.
The displayed, detected ice block size may therefore deviate from the actual ice size.

- Open the tank cover and check the actual ice size visually.
- Adjust the setpoint ice block size if the actual ice size differs from the setpoint size.

**NOTE**

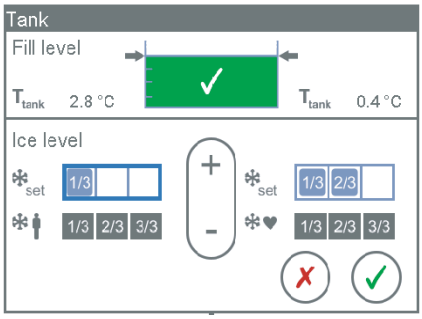
**Reduce the ice block size if continuous patient warming is maintained for longer than six hours**

If ice formation and patient warming operate in parallel for several hours, it may result in severe ice formation in the patient circuit tank.

- In this case, you should decrease the setpoint ice block size for the patient circuit or deactivate the setpoint ice block size completely. This prevents the tank from freezing up and consequent loss of circulation.

1 Touch the [Settings] symbol.

2 Touch the [Tank] symbol.




3 Touch the [Setpoint ice block size] symbol of the circuit concerned.
   ▸ The selected symbol is now framed and can be set.
4 Touch the symbol [–] or [+] for the required ice block size (see table below).
5 To accept the changes, touch the [Confirm] symbol.
   Or
   To reject the changes, touch the [Reject] symbol.

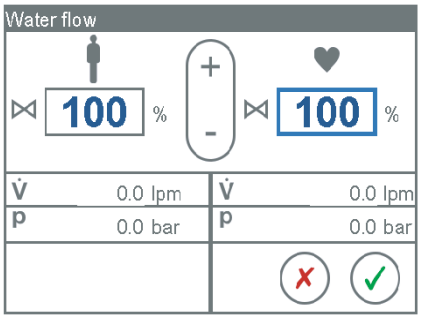
| Ice size parameter | Meaning |
|---|---|
| No ice | No ice is to be formed. |
| Setpoint ice block size: Small ice block | A small ice block is to be produced. |

| Ice size parameter | Meaning |
|---|---|
| Setpoint ice block size: Medium ice block | A medium ice block is to be produced (standard setting). |
| Setpoint ice block size: Large ice block | A large ice block is to be produced. |

### 4.4.3 Changing the Water Flow

This function can be used to change the flows for the patient and cardioplegia water circuit.

1 Touch the [Settings] symbol.
2 Touch the [Water flow] symbol.
3 To change the values, touch the corresponding field and adjust the value (⇨ "Changing Numerical Settings", page 35).




4 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

### 4.4.4 Changing the Settings for Locking the Controls

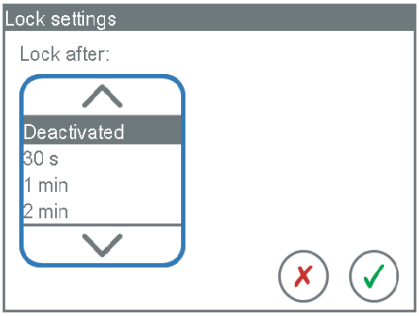
**WARNING!**

Risk from accidental changing of the settings.
When the locking of the controls is deactivated, there is a risk that settings may be inadvertently changed, resulting in unsuitable values being accidentally set.

This function enables you to change the automatic locking of controls (⇨ "Locked Controls", page 36). In addition, you can also deactivate the automatic locking.

1 Touch the [Settings] symbol.
2 Touch the [System lock] symbol.
3 Select from the list the period of inactivity after which the HCU 40 is locked automatically.

4 To deactivate the automatic lock, select [Deactivated].

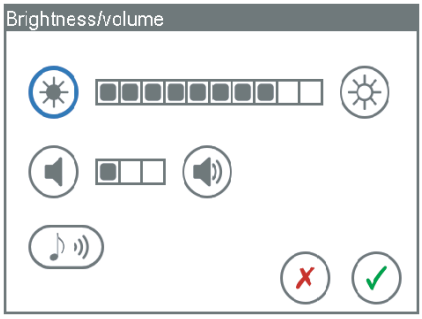



5 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

### 4.4.5 Changing the Brightness/Volume

This function enables you to change the brightness of the display and the volume of acoustic signals.

1 Touch the [Settings] symbol.
2 Touch the [System] symbol.
3 Touch the [Brightness/volume] symbol.
4 Touch the appropriate symbol to change the brightness.




- The HCU 40 changes the brightness to enable you to assess the selected brightness.

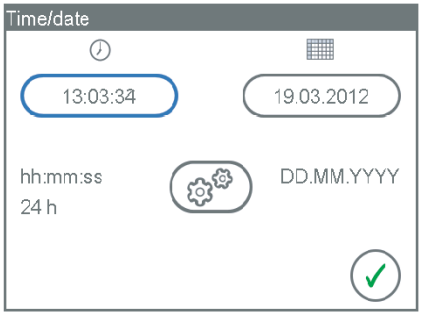
5 Touch the appropriate symbol to change the volume.
6 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

### 4.4.6 Changing the Time, Date and Formats

This function enables you to change the time, date and formats that the touchscreen displays.

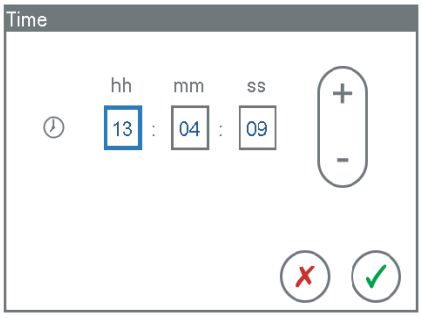
1 Touch the [Settings] symbol.
2 Touch the [System] symbol.

3 Touch the [Time/date] symbol.




4 To change the current time, touch the button under the [Time] symbol.

5 Set the current time. To do this, touch the fields and adjust the values.

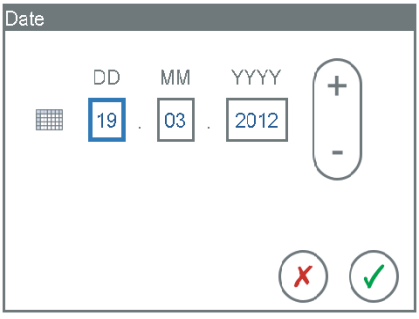



6 If the 12-hour format is selected, set AM or PM according to the current time. To do this, touch the button [AM] or [PM].

7 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.
- The touchscreen shows the [Time/date] window.

8 To change the current date, touch the button under the [Date] symbol.

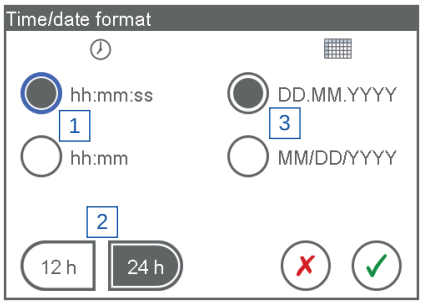
9 Set the current date. To do this, touch the fields and adjust the values.




10 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.
- The touchscreen shows the [Time/date] window.

11 To change the time and date format, touch the [Time/date format] symbol.

- The touchscreen displays the following window:




1 Time format
2 12 or 24 hour format
3 Date format

12 Select the desired time and date format. To do this, touch the appropriate buttons.
13 Choose between 12 and 24 hour format. To do this, touch the corresponding buttons.
14 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.
- The touchscreen shows the [Time/date] window.

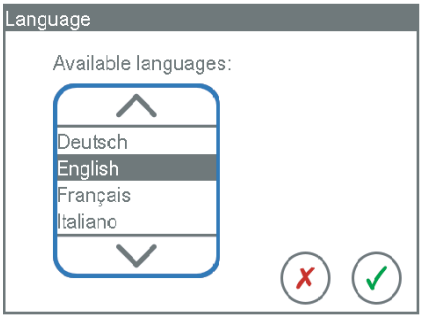
15 To close the [Time/date] window, touch the [Confirm] symbol.

### 4.4.7 Changing the Display Language

This function enables you to change the language in which the touchscreen displays information.

1 Touch the [Settings] symbol.
2 Touch the [System] symbol.
3 Touch the [Language] symbol.

- The touchscreen displays the following window:




4 Select the desired language from the list.
5 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

## 4.5 System Information

### 4.5.1 Displaying the Tank Status

The tank status displays various parameters for the tank.

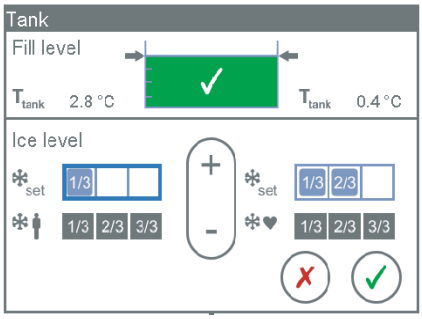
If the water level is too high, the touchscreen displays a message.

**WARNING!**

Operating the pump with an empty tank can damage the device!
If the tank is empty, the pump can run dry and be damaged.

1 Touch the [Settings] symbol.
2 Touch the [Tank] symbol.

- The touchscreen displays the following window:




Left side: Patient water circuit
Right side: Cardioplegia water circuit

| Ice level | Meaning |
|---|---|
| Water level too low/tank empty | Filling/topping up water (⇨ "Filling/Topping Up Water", page 41) |
| Top up water | Filling/topping up water (⇨ "Filling/Topping Up Water", page 41) |
| Water level low | Filling/topping up water (⇨ "Filling/Topping Up Water", page 41) |
| Water level normal | Water level normal, no action necessary. |
| Water level too high | Drain water (⇨ "Causes of Faults and Measures to Take", page 78) |
| Water level cannot be displayed. | Device defective. Notify authorized service. |

| Parameter | | Meaning |
|---|---|---|
| $T_{tank}$ | Actual temperature in tank | Temperature measured in the tank |

### 4.5.2 Displaying the Ice Block Size

This function can be used to check the set and actual size of the ice blocks for the patient and cardioplegia water circuit.

**NOTE**

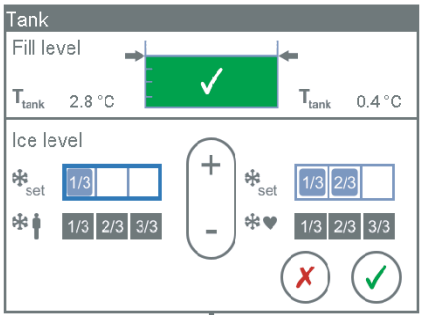
Reducing the ice block size for patient warming over several hours
If ice formation and patient warming operate in parallel for several hours, it may result in severe ice formation in the patient water circuit tank. In this case, you should reduce the setpoint ice block size for the patient water circuit or deactivate the setpoint ice block size completely (⇨ "Changing the Setpoint Ice Block Size", page 61)

**NOTE**

The displayed ice block size may deviate from the actual ice size. Open the tank cover and check the actual ice size visually.

1 Touch the [Settings] symbol.

2 Touch the [Tank] symbol.




- You are shown the following information.

| Parameter | | Meaning |
|---|---|---|
| $\text{set}$ | Setpoint ice block size | To change the setpoint ice block size, touch the symbol (⇨ "Gradient Mode", page 49). |
| | Ice formation status patient water circuit | Ice formation status (ice buildup) in patient water circuit tank |
| | Ice formation status cardioplegia water circuit | Ice formation status (ice buildup) in cardioplegia water circuit tank |

| Ice size parameter | Meaning |
|---|---|
| No ice | No ice should be formed. |
| Setpoint ice block size: Small ice block | A small ice block is to be produced. |
| Setpoint ice block size: Medium ice block | A medium ice block is to be produced. |
| Setpoint ice block size: Large ice block | A large ice block is to be produced. |
| No ice buildup | The compressor is switched off, no ice demand. |
| Ice buildup active | The compressor is switched on, ice buildup taking place until setpoint ice block size is reached. |
| Ice buildup completed | The compressor is switched off; the setpoint ice block size has been reached. |

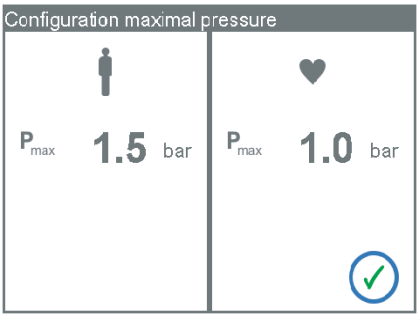
### 4.5.3 Displaying the Pressure Limits

**WARNING!**

- You must only use disposables (heat exchangers) which have a permissible maximum pressure equal to or higher than the set pressure limit.

You can use this function to check the set pressure limits for the circuits.

1 Touch the [Settings] symbol.
2 Touch the [System] symbol.
3 Touch the [Pressure limit] symbol in the system settings.




4 To close the window, touch the [Confirm] symbol.

### 4.5.4 Testing the Functioning of the Speaker and Warning Buzzer

**WARNING!**

Mortal danger to patient if acoustic signals do not sound!

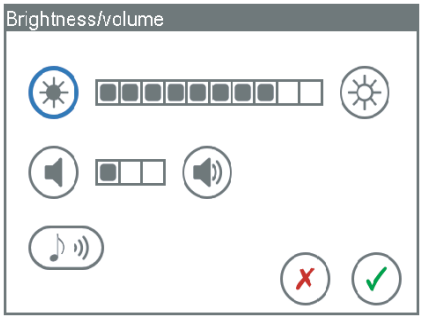
- If no acoustic signals sound, stop using the device and contact the authorized service (⇨ "Authorized Service", page 131).

This function can be used to test the functioning of the speaker and warning buzzers.

1 Touch the [Settings] symbol.

2 Touch the [System] symbol.

3 Touch the [Brightness/volume] symbol.




4 To test the function and volume of the speaker and warning buzzer, touch the symbol [Test speaker.]

▸ The speaker in the control unit (CU) and the warning buzzers of the HCU 40 each generate an acoustic signal at the same time.

### 4.5.5 Testing Alarm Functions

You can test the alarm function as follows:

1 Close one of the stopcocks on the rear of the HCU 40 with circulation in progress.

▸ The touchscreen display alarms for a lack of or insufficient flow and increasing pressure, and generates an acoustic alarm.

2 Open the stopcock again.

### 4.5.6 Cleaning/Emptying System Status

With the [Cleaning/emptying] function, you can start the system cleaning and tank emptying, and the following maintenance data are displayed:

- Date of last cleaning and time remaining until next cleaning. An interval of 30 days is set at the factory.
- Date of last water change and time remaining until next water change. An interval of 14 days is set at the factory.

The factory-set intervals can be changed by the authorized service (⇨ "Inspection and Maintenance by Authorized Service Personnel", page 130).

1 Touch the [Settings] symbol.

2 Touch the [Cleaning/emptying] symbol.

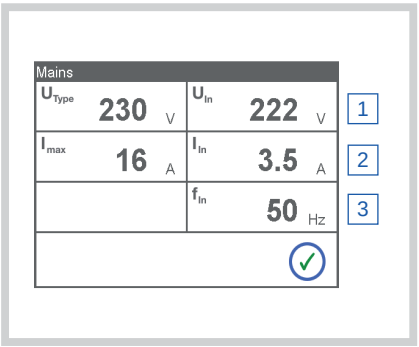

- The maintenance data are displayed.

### 4.5.7 Displaying the Power Supply Status

This function causes the touchscreen to display various parameters about the power supply. This information can be very important for the authorized service.

1 Touch the [Settings] symbol.
2 Touch the [System] symbol.
3 Touch the [Power supply] symbol.

- The touchscreen displays the following window:




1 Line voltage: set in factory and instantaneous voltage
2 Current: maximum and instantaneous current
3 Measured frequency

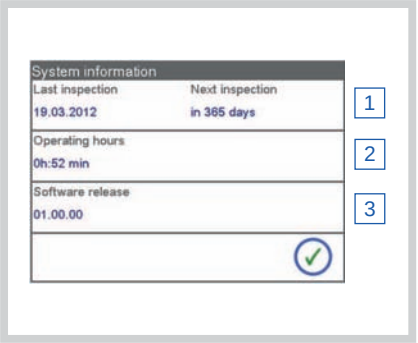
4 To close the window, touch the [Confirm] symbol.

### 4.5.8 Displaying System Information

This function causes the touchscreen to display various data about the device.

1 Touch the [Settings] symbol.
2 Touch the [System] symbol.
3 Touch the [System information] symbol.

- The touchscreen displays the following window:




1 Date of last inspection and time remaining until next inspection (⇨ "Inspection and Maintenance by Authorized Service Personnel", page 130)
2 Operating time since installation
3 Software release number

4 To close the window, touch the [Confirm] symbol.

## 4.6 Putting into Operation

**NOTE**

Recommendation for operating the HCU 40
The HCU 40 should always remain connected to the power supply and turned on to ensure that there is always sufficient ice in the tank. As soon as the set ice block size is attained, the machine switches automatically to Ice maintenance mode.

### 4.6.1 Before First Use

**NOTE**

**Duration of start-up**
Starting up the HCU 40 can take up to 4 hours until it is completely ready for use.
Complete readiness for use is attained once the formation of the ice blocks is complete. The time required until the ice blocks are completely formed depends on the water temperature and ambient temperature.

1 Set up the HCU 40 and connect the HCU 40 (⇨ "Setting up and Connecting the HCU 40", page 38).
2 Connect the control unit (⇨ "Connecting a Control Unit", page 39).

3 Connect external devices (optional) (⇨ "Connecting External Devices (Optional)", page 39).
4 Connect external temperature sensors (optional) (⇨ "Connecting External Temperature Sensors (Optional)", page 39).
5 Close the stopcocks (⇨ "Opening/Closing Stopcocks", page 40).
6 Add water (⇨ "Filling/Topping Up Water", page 41).
7 Switch the HCU 40 on (⇨ "Switching On the HCU 40, Self-Test", page 43).
8 Create the necessary water circuits (⇨ "Creating a Water Circuit", page 52).
9 Configure the HCU 40 (⇨ "System Configuration", page 59).
10 Test the system (⇨ "Check Before Every Application", page 72).
11 Use the system / start up the system.

### 4.6.2 Check Before Every Application

**WARNING!**

Ensure that all the following requirements are met before every use:
- The self-test completed without any error when the system was switched on (⇨ "Switching On the HCU 40, Self-Test", page 43).
- The size of the ice blocks is sufficient.
- Crushed ice is available.
- There are no leaks in the water tubes or tube connections or heat exchangers.
- The water flow is sufficient.
- The water level in the tank is within the required range.
- The values of the (optional) external temperature sensors are plausible.

#### System test

- The alarm functions are functioning correctly (⇨ "Testing Alarm Functions", page 69).

#### Connectors

- The Instructions for Use for the employed heat exchangers have been observed. In particular the connection requirements, e.g., direction of flow and maximum possible pressure.
- The set pressure limits for the circuits are equal to or lower than the permissible maximum pressure for the heat exchangers (⇨ "Displaying the Pressure Limits", page 68).
- The patient circuit and cardioplegia water circuits are correctly connected:
  – the patient water circuit is connected to the oxygenator heat exchanger.
  – the cardioplegia water circuit is connected to the cardioplegia heat exchanger.

- The warming/cooling blanket is connected to the patient water circuit P2 and the patient water circuit P1 is connected as follows (if used):
  - the oxygenator heat exchanger is connected to the patient water circuit P1.
    Or
  - the pressure reducer is connected to the patient water circuit P1.
- The stopcocks at the outlets where no tubes are connected are closed.
- The water circuits are de-aired (⇨ "De-airing the Circuits", page 56).

### 4.6.3 During the Application

#### Filling with ice

**NOTE**

Starting up the HCU 40 can take up to 4 hours until it is completely ready for use.
If the tank is full at this time, you will need to drain some water before filling with ice.

If not enough ice is available for the application, you can add crushed ice to the tank. To do so, proceed as follows:

1 Touch the [Settings] symbol, and then touch [Tank] in the "Settings" screen (⇨ "Displaying the Tank Status", page 66).
2 Open the tank cover.
3 Ready a suitable container for draining the water.

**WARNING!**

Draining of the water begins as soon as the drainage tube is connected to the tank drainage coupling.

4 Connect the supplied drainage tube to the tank drainage coupling.
5 Pour crushed ice into the tank. When doing so, pay attention to the tank status.
6 If the water level rises too high as a result of the added ice, the touchscreen displays the message [Water level too high] (⇨ "Causes of Faults and Measures to Take", page 78).
7 Close the tank cover.

### 4.6.4 On Completion of the Application

1 Stop the pumps.
2 Empty the tubes and the connected heat exchanger (⇨ "Emptying Water Circuits", page 58).

3 Close the stopcocks for the circuits used (⇨ "Opening/Closing Stopcocks", page 40).
4 Disconnect the tubes from the heat exchangers.
5 Store the tubes on the machine.
6 Do not switch the HCU 40 off.

**NOTE**

Recommendation for operating the HCU 40
The HCU 40 should always remain connected to the power supply and turned on to ensure that there is always sufficient ice in the tank. As soon as the set ice block size is attained, the machine switches automatically to Ice maintenance mode.

## 4.7 Emergency Procedures

In emergencies, the following combinations of circuits and heat exchangers are permissible as a temporary measure if components fail:

| Patient water circuit 1 | Patient water circuit 2 | Cardioplegia water circuit | Remarks |
|---|---|---|---|
| Defective | Defective | Oxygenator heat exchanger | If the patient water circuits fail |
| Oxygenator heat exchanger | Cardioplegia heat exchanger | Defective | If the cardioplegia water circuit fails |

**NOTE**

If an oxygenator heat exchanger is operated on the cardioplegia water circuit, you must expect reduced warming and cooling performance as the flow rate of the cardioplegia water circuit is lower than that of the patient water circuit.

### 4.7.1 De-airing in an Emergency During Perfusion

**WARNING!**

With the "De-airing" function, ice-cold water is pumped from the tank into the tubes and the heat exchanger. The perfusion circuit in which the heat exchanger being de-aired is integrated must not be operated, as it could provoke a cardiac arrest if a patient is connected.

**WARNING!**

Ensure that the water circuits have been de-aired.

Water circuits that have not been de-aired may reduce the flow and cause the water pump to stop.

In order to de-air the one water circuit of the HCU 40 while perfusion is running, you will require the supplied cleaning connector (double Hansen coupling).

1 Connect the inlet and outlet tubes of the water circuit to the cleaning connector.
2 Open the stopcocks.
   - The handle is in the vertical position: The stopcock is open.
3 Select the setpoint temperature (⇨ "Setting and Changing Setpoint Temperatures", page 45).
4 **WARNING!** With the "De-airing" function, ice-cold water is pumped from the tank into the tubes and the heat exchanger. The perfusion circuit in which the heat exchanger being de-aired is integrated must not be operated, as it could provoke a cardiac arrest if a patient is connected.
   Start the "De-airing" function.
5 Stop the water circuit pump once the setpoint temperature is reached.
6 Close the stopcocks.
   - The handle is in the horizontal position: The stopcock is closed.
7 Clamp off the ends of the tubes in front of and behind the cleaning connector.
8 Remove the cleaning connector.
9 Connect the heat exchanger.
10 Remove the clamps.
11 Open the stopcocks.
   - The handle is in the vertical position: The stopcock is open.
12 Start the pump of the water circuit.

- The small amount of air still remaining in the water circuit is removed via the air separator.

**NOTE**

The remaining air in an unfilled warming/cooling blanket cannot be removed via the air separator.

## 4.8 Key User Functions

The "Service" screen is password-protected and may only be used by authorized personnel.

### 4.8.1 Calling Up the "Service" Screen

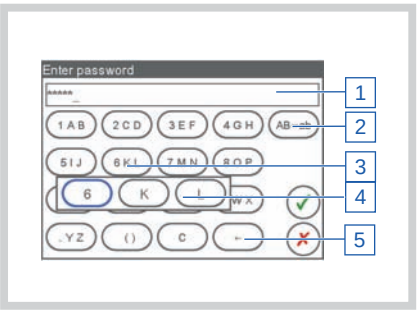
1 Touch the [Settings] symbol, and then touch the [System] symbol in the [Settings] screen.

2 Touch the [Service] symbol in the "System settings" screen.

- The touchscreen displays the [Enter password] input field.

3 Touch the input field.

- The touchscreen displays a virtual keyboard:

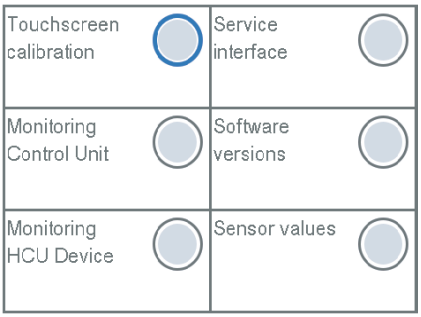



1 Input field
2 Switch between upper and lower case
3 Example: Button for the characters 6, K and L
4 Selection window with the three characters of the touched button
5 Delete right-hand character in the input field

4 Enter the password using the virtual keyboard:
To select a character, touch the button that contains the character.
The touchscreen displays a selection window [4] with the button's three characters.
Touch the desired character.

5 To accept the input, touch the [Confirm] symbol.
Or
If you wish to reject the input, touch the [Reject] symbol.

- If you have correctly entered and confirmed the password, the touchscreen displays the following screen:



- You have the following option:
  Calibrating the touchscreen.
  The other functions are only relevant for authorized service personnel.
  **NOTE:** Abort not possible.
  The calibration cannot be aborted. It must be carried out completely and is checked for plausibility at the end. If the check fails, the calibration starts again from the beginning automatically.

6 The touchscreen is calibrated with this function. In the “Service” screen, touch [Touchscreen calibration].

7 Always touch exactly in the center of the red cross.


- The HCU 40 checks the positions touched and calibrates the touchscreen accordingly.

# 5 Troubleshooting

**NOTE**

The On/Off switch displays the status of the HCU 40 via the LED ring (⇨ "Status of the On/Off switch", page 23).:

The HCU 40 displays most of the faults that can arise during operation of the unit as messages on the touchscreen (⇨ "Messages", page 81). There are simple measures you can take yourself to remedy faults (⇨ "Causes of Faults and Measures to Take", page 78). In addition, diagnosis can also help to identify possible causes of errors (⇨ "Perform Diagnosis", page 129).

## 5.1 Causes of Faults and Measures to Take

There are simple measures you can take yourself to remedy faults.

| Fault | Explanation/cause | Recommended action by user |
|---|---|---|
| Tank status [Water level too low/tank empty] and [Top up water]  | Water level too low.<br>Water level in the main tank too low when pump is running. | ■ Fill/top up water (⇨ "Filling/ Topping Up Water", page 41), while observing the tank status (⇨ "Displaying the Tank Status", page 66). |
| Tank status [Water level too high]  | Water level too high. | ■ Connect the drainage tube to the tank drainage coupling.<br>■ Drain surplus water off, while observing the tank status (⇨ "Displaying the Tank Status", page 66).<br>■ Disconnect the tube from the tank drain.<br>■ Increase the setpoint ice block size (⇨ "Gradient Mode", page 49). |
| Ice status [No ice]  | No ice. | ■ During the application (⇨ " During the Application", page 73). |

| Fault | Explanation/cause | Recommended action by user |
|---|---|---|
| Too much ice | Too intense production of ice due to parallel operation of ice production and patient warming for several hours. | ■ Reduce the setpoint ice block size of the patient water circuit (⇨ "Changing the Setpoint Ice Block Size ", page 61). |
| Water flow too low | Limit pressure set too low. | ■ Notify authorized service.<br>■ Request authorized service to increase limit pressure. Caution: Max. pressure of the disposables used must not be exceeded! |
| Limit pressure set too low. | No de-airing. | ■ De-air the water circuit (⇨ " De-airing the Circuits", page 56) |
| | Water outlet stopcock closed. | ■ Open water outlet stopcock (⇨ "Opening/Closing Stopcocks", page 40). |
| | Water tube kinked. | ■ Remove kink. |
| No connection between HCU 40 and CU. | CAN connection cable between HCU 40 and CU not connected during operation. | ■ Reconnect cable (⇨ " Connecting a Control Unit", page 39). |
| | CAN connection cable defective. | ■ Replace CAN connection cable with functioning cable (⇨ "Connecting a Control Unit", page 39). |
| | Connection to HCU 40 or CU defective. | ■ Take HCU 40 or CU out of service.<br>■ Use replacement device. |
| Touchscreen of the CU is blank or does not react | The CU must be reset. | ■ Disconnect and reconnect CAN connection cable between HCU 40 and CU.<br>■ Check the set values. |
| HCU 40 and CU not functioning | Internal power supply defective / Defective power plug or power cord. | ■ Take HCU 40 and CU out of service.<br>■ Use replacement device. |
| | External power supply defective. | ■ Check external power supply. |

| Fault | Explanation/cause | Recommended action by user |
|---|---|---|
| Power failure and no visual or electrical alarm | Defective UPS. | ■ Have device checked/ repaired by authorized service personnel.<br>■ Maintenance required every 2 years.<br>■ Use replacement device. |
| De-airing cannot be performed. | Overly large ice blocks impair water circulation. | ■ Reduce setpoint ice block size. |
| | The stopcock is not fully open. | ■ Open the stopcock of the relevant circuit (⇨ " Opening/Closing Stopcocks", page 40). |
| | Water tube kinked. | ■ Remove kink. |

If you cannot confirm a fault, switch the HCU 40 off and back on again. If the fault occurs repeatedly, contact Maquet (⇨ "Authorized Service", page 131) service.

# 6 Messages

## 6.1 Alarms

### 6.1.1 Duration and Intervals for Acoustic Alarms

Higher priority alarms generate more alarm tones than alarms with lower priority. Higher priority alarm tones are repeated at shorter intervals than alarms tones with lower priority.

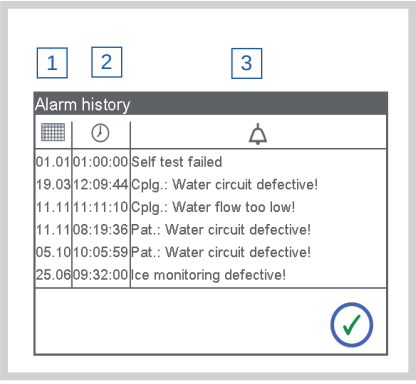
| Priority | Alarm tones | Repeat interval |
|---|---|---|
| High | 3+2 (c, d, e+f, g) | 2.5 seconds |
| Medium | 3 (c, d, e) | 7.5 seconds |
| Low | 2 (c, e) | 20 seconds |

## 6.2 Alarm List

The alarm list shows the last 6 alarms.

1 Touch the [Settings] symbol in the menu, and then touch [Alarm history] in the "Settings" screen.

- The touchscreen displays the following window:




1 Date 2 Time
3 Message

- The touchscreen displays date, time, and message (⇨ "Physiological Alarms", page 82) and (⇨ "Technical Alarms", page 82).
- The HCU 40 displays current alarms, according to priority, on a colored background: Red: high-priority alarm, Yellow: low or medium-priority alarm.

2 To close the alarm list, touch the [Confirm] button.

## 6.3 Physiological Alarms

### 6.3.1 Medium Priority

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Pat.: Ext. temp. above max. limit | | External temperature above warning limit | Check connection of temperature sensors. Check setpoint and actual temperature. Check the patient parameters. |
| Pat.: Ext. temp. below min. limit | | External temperature below warning limit | Check connection of temperature sensors. Check setpoint and actual temperature. Check the patient parameters. |
| Cplg.: Ext. temp. above max. limit | | External temperature above warning limit | Check connection of temperature sensors. Check setpoint and actual temperature. Check the patient parameters. |
| Cplg.: Ext. temp. below min. limit | | External temperature below warning limit | Check connection of temperature sensors. Check setpoint and actual temperature. Check the patient parameters. |

## 6.4 Technical Alarms

**WARNING!**

- If the "Water pressure too high" alarm is emitted, check whether the outlet valve is closed or if a tube is kinked.

**WARNING!**

Operating the pump with an empty tank can damage the device!
If the tank is empty, the pump can run dry and be damaged.

### 6.4.1 High Priority

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Cplg.: Heater temperature too high! | Patient temperature not regulated until device cools down. | Temperature turned off because temperature at outlet too high. | Use replacement device. |
| | | Operation in too hot environment | Reduce temperature at outlet to below 39.5°C: allow device to cool down. Place device in cooler environment. Supply cold air. Use replacement device. |
| | | Temperature in device too high | |
| | | Temperature sensor defective | Check plausibility of the temperature display on the CU. Notify the authorized service in case of defects. Use replacement device. |
| Cplg.: Water temperature too high | | Outlet temperature above warning limit | Check setpoint temperature and reduce if necessary. Message disappears automatically when temperature drops below warning limit. |
| Pat.: Heater temperature too high! | Patient temperature not regulated until device cools down. | Temperature turned off because temperature at outlet too high. | |
| | | Operation in too hot environment | Reduce temperature at outlet to below 39.5°C: allow device to cool down. Place device in cooler environment. Supply cold air. Use replacement device. |
| | | Temperature in device too high (temperature build-up in standby) | |
| | | Temperature sensor defective | Check plausibility of the temperature display on the CU. Notify the authorized service in case of defects. Use replacement device. |

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Pat.: Water temperature too high | Temperature at the outlet too high. If error is not rectified: the device heats up further until a safety shutdown is initiated. The device can then no longer be used for a period of time. | Overshoots generated by regulator | Reduce setpoint temperature in order to avoid overshoots. If the fault still recurs, notify authorized service. |
| Mains power fail | No circulation and thus no temperature regulation possible. | Mains power has failed | Restore mains supply. Confirm the error message on the CU. Switch off active circuits. Machine is ready for use again (internal UPS buffers control unit for 10 mins). Use replacement device. |
| Safety pump stop! Valve calibration (~100s)! Start pump after valve calibration. | | Valve calibration | Wait 100 seconds. |

### 6.4.2 Medium Priority

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Cplg.: Water flow too low! | No circulation and thus no temperature regulation possible. | Outlet valve closed. | Open outlet valve. |
| | | Tube kinked. | Remove kink. |
| Cplg.: No gradient mode possible... | Gradient mode not available. | External temperature sensor defective or connection faulty. | Check connection to external temperature sensor. Reconnect if necessary. |
| Cplg.: Water pressure too high! | No circulation and thus no temperature regulation possible. | Outlet valve closed. | Open outlet valve. |
| | | Tube kinked. | Remove kink. |
| Cplg.: Tank temperature too high! | If the water temperature exceeds 42°C: The safety shutdown is triggered. No circulation until the water has cooled down. | Temperature in the tank too high or temperature sensor defective | Activate ice formation. Replace water in tank with colder water. If the error occurs again: Notify authorized service. Use replacement device. |

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Cplg.: Water circuit faulty! Change device or use patient circuit. Check temperature! | The pump is switched off. The water circuit cannot be used any more. | The temperature sensor at the outlet is defective, the pressure sensor is defective, or a broken wire has been detected by the pump control. | Have device checked/ repaired by authorized service personnel. Use replacement device. |
| Device defective! | | Device defective. | Notify authorized service. Use replacement device. |
| HCU restart! | Set settings and setpoint values are not adopted. | The device has been restarted. | Confirm the message, check the settings and setpoint values. |
| Control unit reset detected! | Set settings and setpoint values are not adopted. | Control unit reset. | Confirm the message, check the settings and setpoint values. |
| Connection to control unit faulty! | Device cannot be controlled. | Communication between HCU 40 and control unit (CU) faulty. | Notify authorized service. Use replacement device. |
| Water tank empty | No circulation and thus no temperature regulation possible. | No water in tank. | Fill the water tank. |
| | | Level sensors defective. | If the error occurs again: Notify authorized service. |
| Tank overflow! Water level too high | Water may flow out of the tank overflow and onto the floor. | Too much water in the tank. | Drain some water from the tank. |
| | | Level sensors defective. | If the error occurs again: Notify authorized service. |
| Pat.: Water flow too low! | No circulation and thus no temperature regulation possible. | Outlet valve closed. | Open outlet valve. |
| | | Tube kinked. | Remove kink. |
| | | Blanket operated without pressure reducer. | Connect pressure reducer. |
| Pat.: No gradient mode possible | Gradient mode not available. | External temperature sensor defective or connection faulty. | Check connection to external temperature sensor. Reconnect if necessary. |
| Pat.: Water pressure too high! | No circulation and thus no temperature regulation possible. | Outlet valve closed. | Open outlet valve. |
| | | Tube kinked. | Remove kink. |
| | | Blanket operated without pressure reducer. | Connect pressure reducer. |

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Pat.: Water circuit faulty! Change the device or use the cardioplegia circuit if possible. Check temperature. | The pump is switched off. The water circuit cannot be used any more. | Temperature sensor on outlet defective, heater defective, or temperature protection switch has triggered an alarm. | Have device checked/repaired by authorized service personnel. Use replacement device. |
| Pat.: Tank temperature too high! | If the water temperature exceeds 42°C: The safety shutdown is triggered. No circulation until the water has cooled down. | Patient water circuit: Temperature in the tank too high. | Activate ice formation. Replace water in tank with colder water. |
| | | Temperature sensor defective. | Notify authorized service. Use replacement device. |
| HCU incompatible with control unit! | Device cannot be controlled. | HCU 40 and control unit (CU) incompatible. | Connect a compatible control unit (CU). Notify authorized service. Use replacement device. |
| Plausibility error in temperature regulation | Setpoint temperature is not reached. | Mixing valve defective or cooling/heating capacity too low. | Switch off the compressor. Notify authorized service. Use replacement device. |
| Mains voltage too low | Component malfunctions | Voltage supply too low. | Compare required device voltage with mains voltage. Ensure sufficient and stable power supply. In case of frequent mains voltage disruptions, notify authorized service and have the device adjusted to a lower input voltage. |
| Fan defective! Compressor off! | Ice formation disrupted. | Fan 1 or 2 defective or blocked. | Clean the fan or if necessary have it replaced by authorized service. |
| Self-test failed | HCU 40 functions affected | Broken cable, controller defective, incorrect mains voltage or mains frequency, water level too high/low, heater defective or sensors defective. | Switch the HCU 40 off and back on again. Change mains input voltage if possible. Notify authorized service. Use replacement device. |

### 6.4.3 Low Priority

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Compressor temperature too high! | No ice formation. | Cooling fluid too warm (>60°C). | Allow HCU 40 to cool down. Keep/use replacement device. |
| | | Ventilation does not work correctly. | Clean filters. Keep/use replacement device. |
| Cplg.: Tank temperature too low. Danger of frozen tank! Check ice thickness visually. If necessary, reduce ice formation. | Tank may freeze. | Sensor faulty. | Reduce setpoint ice block size. Check ice thickness visually. |
| Cplg.: Water flow low. | If error is not rectified: circulation is switched off, and therefore temperature regulation not possible. | Outlet valve closed. | Open outlet valve. |
| | | Tube kinked | Remove kink. |
| Cplg.: No ice detected! After 6 hours of compressor running time, no ice formation detected in the cplg-tank. Device defective! Use crushed ice. | No ice formation, and thus no cooling possible. | Ambient temperature or tank temperature too high. | Check ice formation and restart if necessary. Place device in cooler environment. In case of emergency, use crushed ice. Keep/use replacement device. |
| Cplg.: External temp. sensor defective! | Gradient mode not available. | External temperature sensor defective! | Change external temperature sensor. |
| | | Control unit defective. | If the error occurs again: Notify authorized service. |
| Cplg.: Ext. temp. sensor disconnected! | Gradient mode not available. | External temperature sensor disconnected. | Reconnect sensor or confirm disconnection, if necessary. |
| Cplg.: Ext. temp. out of range | Gradient mode not available. | External temperature sensor defective! | Check the actual temperature. Change external temperature sensor. |
| Cplg.: Tank temp. sensor defective! / Visually check ice. | Displayed tank temperature is incorrect. There may not be any cooling of the patient | Temperature sensor defective. | Notify authorized service. Use replacement device. |

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Water level and ice sensor defective! Danger of frozen tank! If necessary, stop compressor to reduce ice thickness! Vis. check water and ice level. | Tank frozen. | Water level and ice sensor defective! | Vis. check water and ice level. If necessary, stop compressor to reduce ice thickness! Notify authorized service. Keep/use replacement device. |
| HLM connection faulty! | Device cannot be controlled via heart-lung machine. | CAN communication with HLM interrupted. | Check connection visually. Notify the authorized service if necessary. |
| Ice monitoring defective! Change device or operate the compressor manually. Check ice. | If ice formation is too great: the water tank may freeze. No circulation and thus no temperature regulation possible. | Ice sensor defective. | Start the ice formation manually if necessary. Replace device as quickly as possible. Notify authorized service. Use replacement device. |
| | Too little ice | Water level and ice sensor defective! | Fill with ice (⇨ "During the Application", page 73). |
| Water level sensor defective! Check water level visually | Displayed water level is incorrect | Level sensors defective. | Notify authorized service. Use replacement device. Check water level visually. Top up water if necessary. |
| Top up water in tank | If water level falls further: No circulation with empty tank, and therefore no temperature regulation possible. | Too little water in the tank. | Fill the water tank. |
| | | Level sensors defective. | If the error occurs again: Notify authorized service. Use replacement device. |
| Pat.: Tank temperature too low. Danger of frozen tank! Check ice thickness visually. If necessary, reduce ice formation. | Tank may freeze. | Sensor faulty. | Reduce setpoint ice block size. Check ice thickness visually. |

| Message | Possible consequences | Possible cause | Possible action |
|---|---|---|---|
| Pat.: Water flow low. | If error is not rectified: circulation is switched off, and therefore temperature regulation not possible. | Outlet valve closed. | Open outlet valve. |
| | | Tube kinked. | Remove kink. |
| | | Blanket operated without pressure reducer. | Connect pressure reducer. Use replacement device. |
| Pat.: No ice detected! After 6 hours of compressor running time, no ice formation detected in the patient tank. Device defective! Use crushed ice. | No ice formation, and thus no cooling possible. | Ambient temperature or tank temperature too high. | Check ice formation and restart if necessary. Place device in cooler environment. In case of emergency, use crushed ice. Use replacement device. |
| Pat.: External temp. sensor defective! | Gradient mode not available. | External temperature sensor defective! | Change external temperature sensor. |
| | | Control unit defective. | If the error occurs again: Notify authorized service. Use replacement device. |
| Pat.: Ext. temp. sensor disconnected! | Gradient mode not available. | External temperature sensor disconnected. | Reconnect sensor or confirm disconnection, if necessary. |
| Pat.: Ext. temp. out of range! | Gradient mode not available. | External temperature sensor defective! | Check the actual temperature. Change external temperature sensor. |
| | | Control unit defective. | If the error occurs again: Notify authorized service. |
| Pat.: Tank temp. sensor defective! Check ice visually. | Displayed tank temperature is incorrect. There may not be any cooling of the patient. | Tank temperature sensor defective! | Notify authorized service. Use replacement device. |
| Mains voltage too high. | Device can overheat and be damaged. | Supply voltage too high or voltage measurement incorrect. | Check supply voltage at HCU 40 (CU). In case of doubt, contact service. |

## 6.5 Messages

| Text of message | Meaning |
|---|---|
| System locked! | Locked controls (⇨ "Locked Controls", page 36) |
| Next date for inspection in <x> days! | Inspection and maintenance by authorized service personnel (⇨ "Inspection and Maintenance by Authorized Service Personnel", page 130) |
| Inspection interval has expired! | Inspection and maintenance by authorized service personnel (⇨ "Inspection and Maintenance by Authorized Service Personnel", page 130) |
| Cleaning interval has expired! Perform cleaning. | Inspection and maintenance by authorized service personnel (⇨ "Inspection and Maintenance by Authorized Service Personnel", page 130) |

# 7 Cleaning, descaling and disinfection

**WARNING!**

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

**NOTE**

"Cleaning the system" function
The system needs to be cleaned regularly as part of maintenance. The HCU 40 supports you with a wizard to guide you step by step (Cleaning the System).

## 7.1 Surface Cleaning and Disinfecting the Device after Each Use

**WARNING!**

- Switch the HCU 40 off and disconnect the HCU 40 from the external power supply before cleaning the exterior.
- Do not use chemical solvents (such as ether or acetone) and do not spill anesthetics (such as Foram (isoflurane)). They may damage the HCU 40.
- Use a moist cloth to clean the exterior of the HCU 40.
- Do not spray the device with liquids.
- When cleaning, descaling and disinfecting the HCU 40, the safety instructions of the manufacturer of the cleaning, descaling and disinfection agents must be observed.

### 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 cable after each use to remove soiling and blood residues.

### 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)

## 7.2 Descaling and disinfection of the water circuits

### Equipment for descaling/disinfection

The following equipment is required for descaling/disinfection:

- Sterile inline filter with a pore size of 0.2 µm
- Personal protective clothing (in accordance with the details 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 example for the disinfection of cleaning connectors, approx 190 x 120 x 40 mm (L x W x H) in size

If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:

- Flat tray (chemical-resistant) which is placed below the HCU 40, approx. 450 x 300 x 50 mm (L x W x H) in size

**WARNING!**

- Descaling and disinfection are two distinct procedures. They cannot replace each other, nor may they be performed simultaneously.
- When descaling and disinfection are to be performed, descaling must precede disinfection.
- In order to disinfect the HCU 40 water circuits, use the approved disinfectant Clorina (active agent: tosylchloramide sodium, known as Chloramine-T) or a chemically identical disinfectant.
- The disinfectant Clorina has been tested for use in combination with HCU 40. Other disinfectants also potentially have an impact on material compatibility. The use of other disinfectants which are not chemically identical is expressly forbidden.
- When cleaning, descaling and disinfecting the HCU 40, the safety instructions of the manufacturer of the cleaning, descaling and disinfection agents must be observed.
- Sufficient ventilation must be ensured during disinfection. Avoid dust formation from the disinfectant. Do not inhale disinfectant dust. Prevent the disinfectant from coming into contact with the skin, eyes and clothing.
- Personal protective clothing is to be worn as per the instructions in the safety data sheet for the disinfection/descaling agent (e.g., chemical-resistant nitrile or butyl rubber gloves, dust mask for P2 respiratory protection, protective goggles and laboratory coat).
- The descaling/disinfection agent may only be used pre- and post-operatively, and never during the actual intervention.

**WARNING!**

- During descaling/disinfection of the HCU 40, the heat exchangers must be replaced by cleaning connectors. The descaling/disinfection agent could otherwise damage or contaminate the heat exchangers.
- As a hygiene measure for the water system of the HCU 40, routine disinfection is to be performed as described.
- If there are atypical *mycobacteria* in the water system, highly effective disinfection must be performed with 5% Chloramine-T in the water system of the HCU 40.
- To ensure effective descaling/disinfection, the necessary amount of descaling/disinfection agent must be determined based on the length of the tubes connected to HCU 40.
- The ideal disinfectant concentration for the relevant HCU 40 is based on the results of microbiological monitoring as part of hygiene controls.
- To achieve an even distribution of descaling/disinfection agent in the water system, the system must be de-aired.
- Rinse the device three times following de-scaling/disinfection in order to remove any descaling/disinfection agent residues.
- Only use warming/cooling blankets once. To prevent microbiological contamination, do not reuse blankets.
- Observe the instructions displayed by the wizard on the touchscreen.

**NOTE**

**Time of next system cleaning**

The time of next system cleaning is shown on the touchscreen.

- Touch the [Settings]  symbol.
- Touch the [Cleaning/emptying] symbol  .

– The date of last system cleaning and the length of time until the next system cleaning are displayed.
– If a time period of 30 days is set, an authorized service technician must change the period to 7 days.

The water circuits of the HCU 40 must be cleaned, descaled and disinfected regularly, including the pumps, water tank, tube couplings and tubes. The HCU 40 supports you with a wizard to guide you step by step.

The intervals can be found in the overview (⇨ "Maintenance", page 128). Routine disinfection cannot replace hygiene monitoring. It may be necessary to shorten the interval.

Depending on how contaminated the HCU 40 is and the hygienic situation in the hospital, the necessary water quality may not be achieved after routine disinfection, and therefore disinfection must be repeated. If there are atypical *mycobacteria* in the water system, highly effective disinfection must be performed.

### 7.2.1 Performing Descaling

**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 disinfectant/descaling agent.

Descaling is performed every 3 months with 2% citric acid in the entire water volume of the HCU 40. The cleaning wizard guides you through descaling.

Total duration: approx. 150 to 200 minutes (depending on the amount of ice present and the power supply).

Follow the wizard's instructions.

During this procedure, the following steps are performed in succession:

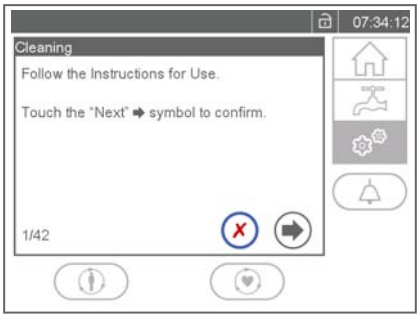
- Emptying of tank
- Descaling
- Rinsing cycle 1
- Rinsing cycle 2
- Rinsing cycle 3

**NOTE**

The cleaning wizard provides additional support if one step in the cleaning routine cannot be completed due to an operating error (example: shut-off valve not open during pumping) A warning to this effect is shown. You can continue the cleaning routine by pressing the [Next] symbol.

1 Touch the [Settings] symbol.
2 Touch the [Cleaning/emptying] symbol.
3 Touch the [Cleaning] symbol.

- You will see a wizard that will guide you through descaling.



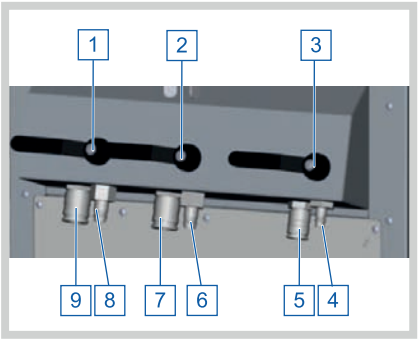

4 Touch the [Next] symbol.

### Emptying of tank

1 Disconnect all heat exchangers which are connected to the patient water circuit and/or the cardioplegia water circuit, and connect the supplied cleaning connectors instead.

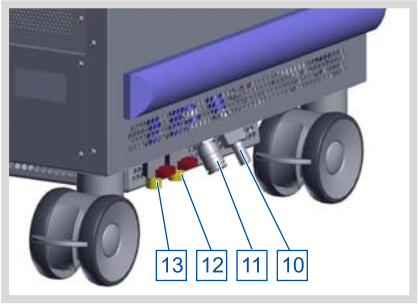
2 Touch the [Next] symbol and wait until the melting process is complete.
- The HCU 40 melts the ice block and adjusts the temperature of the tank water to 20°C. Duration: 30 up to a maximum of 75 minutes (depending on the amount of ice present and the power supply).

3 If there were no tubes connected to the HCU 40 during melting, connect a tube to the outlet of the patient water circuit and a second tube to the outlet of the cardioplegia water circuit.
Or
If the tubes for the patient and cardioplegia water circuits were connected to the cleaning connectors on the HCU 40 during melting, remove these cleaning connectors.




Patient water circuit 1:
1 Stopcock
8 Water outlet 1/2"
9 Water inlet 1/2" (backflow)
Patient water circuit 2:
2 Stopcock
6 Water outlet 1/2"
7 Water inlet 1/2" (backflow)
Cardioplegia water circuit:
3 Stopcock
4 Water outlet 3/8"
5 Water inlet 3/8" (backflow)

4 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.
5 Touch the [Next] symbol to start pumping.
   ▸ The HCU 40 pumps the water out.
6 Wait until the HCU 40 is empty.
7 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
   Remove the yellow caps from the water pump stopcocks.
   Open both stopcocks of the water pumps in order to empty the latter.
   Connect the drainage tube to the tank drainage coupling and drain away any residual water.
   Or
   If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).

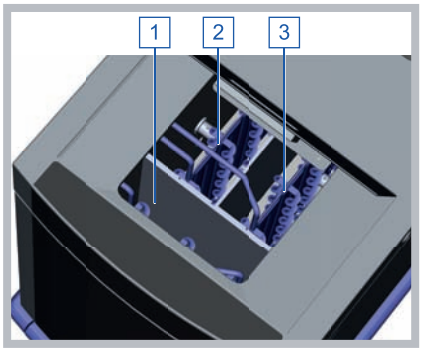



Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

8 Touch the [Next] symbol.
9 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
   Or
   Disconnect the drainage tube.
10 Touch the [Next] symbol.
11 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
12 Perform surface cleaning and disinfect the device (⇨ "Surface Cleaning and Disinfecting the Device after Each Use", page 91).
13 Connect the cleaning connectors.
14 Touch the [Next] symbol.

### Descaling

1 Fill the HCU 40 with sterile filtered water up to the second mark on the water level indicator.
2 Touch the [Next] symbol.
3 Put on protective clothing.
4 Produce a citric acid solution:
For descaling (every 3 months) with the HCU 40 standard tube (4 x 6 m in length for the patient water circuit and 2 x 6 m for the cardioplegia water circuit):
Use a powder funnel to put 640 g of citric acid into a chemical-resistant 10 liter canister with watertight lid. Add 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.
If longer or shorter tubes are connected to the HCU 40 establish the correct amount of citric acid for the required solution concentration of 2% (⇨ "Solution Concentration with Different Tube Lengths", page 141).

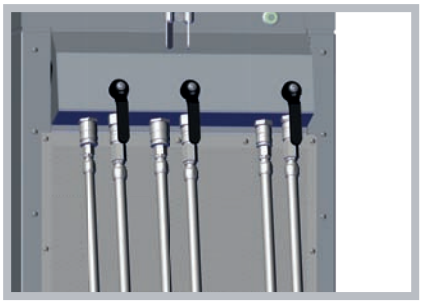



5 Put the following quantities of the citric acid solution into the three tank chambers:
1.4 l to the cardioplegia water circuit ([1]),
1.8 l to the patient water circuit 2 ([2]),
1.8 l to the patient water circuit 1 ([3]),
(valid for the standard tube (4 x 6 m in length for the patient water circuit and 2 x 6 m for the cardioplegia water circuit)).
Fill the remaining solution in the canister in equal parts into the three tank chambers.
6 Touch the [Next] symbol.
7 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).

- The water level is shown on the 4th marking

8 Touch the [Next] symbol.

9 Open the stopcocks of the patient and cardioplegia water circuits.



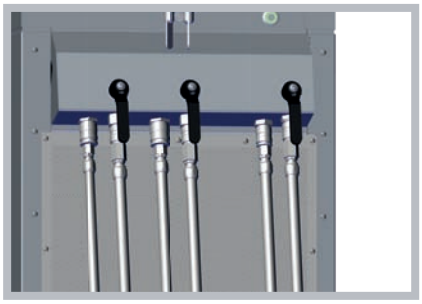
10 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
11 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
12 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
13 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps. Remove the yellow caps from the water pump stopcocks. Open both water pump stopcocks and drain off around 200 ml from each stopcock. Connect the drainage tube to the tank drainage coupling and drain around 400 ml from the internal lines.
   Or
   If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Connect the drainage tube to the tank drainage coupling and drain around 400 ml from the internal lines.
14 Touch the [Next] symbol.
15 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
   Or
   Disconnect the drainage tube.
16 Touch the [Next] symbol.
   - The HCU 40 performs cleaning (duration approx. 90 minutes).
17 Close the stopcocks of the patient and cardioplegia water circuits.
18 Disconnect the cleaning connectors.
19 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

**NOTE**

Use a suitable outflow to dispose of the disinfection/descaling agent solutions.

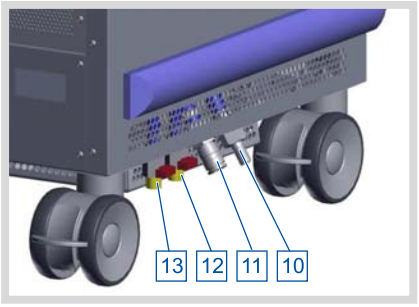
20 Touch the [Next] symbol.

21 Open the stopcocks of the patient and cardioplegia water circuits.



22 Touch the [Next] symbol.
- The HCU 40 pumps the water out.

23 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

**NOTE**

Use a suitable outflow to dispose of the disinfection/descaling agent solutions.

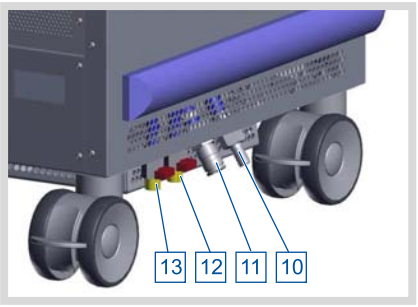
24 Touch the [Next] symbol.
25 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
26 Touch the [Next] symbol.

### Rinsing cycle 1

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
- The HCU 40 de-airs the cardioplegia and patient water circuits.

5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.
7 Touch the [Next] symbol.
- The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

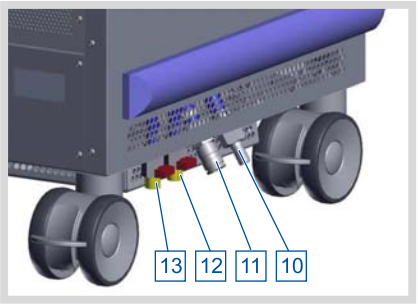
9 Touch the [Next] symbol.
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
11 Touch the [Next] symbol.

### Rinsing cycle 2

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
▸ The HCU 40 de-airs the cardioplegia and patient water circuits.
5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

7 Touch the [Next] symbol.
   - The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

9 Touch the [Next] symbol.
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
11 Touch the [Next] symbol.

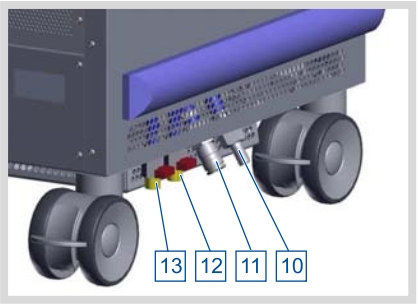
### Rinsing cycle 3

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
5 Disconnect the cleaning connectors.

6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

7 Touch the [Next] symbol.
- ▸ The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

9 Touch the [Next] symbol.

10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.

11 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).

12 To exit the wizard after the last step, touch the [Confirm] symbol.
Or
To cancel the wizard instead, touch the [Reject] symbol.

- ▸ Descaling completed.

### 7.2.2 Performing weekly routine disinfection

**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 disinfectant/descaling agent.

Disinfection is performed once a week with 2% Chloramine-T in the entire water volume of the HCU 40. A cleaning wizard guides you through routine disinfection.

Total duration: approx. 150 to 200 minutes (depending on the amount of ice present and the power supply).

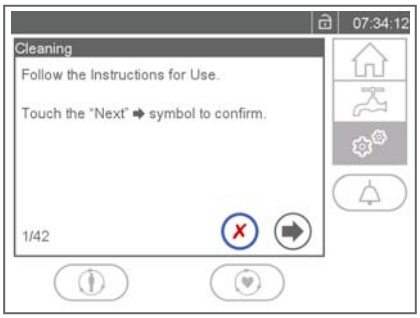
During this procedure, the following steps are performed in succession:

- Emptying of tank
- Routine disinfection
- Rinsing cycle 1
- Rinsing cycle 2
- Rinsing cycle 3

**NOTE**

The cleaning wizard provides additional support if one step in the cleaning routine cannot be completed due to an operating error (example: shut-off valve not open during pumping) A warning to this effect is shown. You can continue the cleaning routine by pressing the [Next] symbol.

1 Touch the [Settings] symbol.
2 Touch the [Cleaning/emptying] symbol.
3 Touch the [Cleaning] symbol.
   ▸ You will see a wizard that will guide you through disinfection.



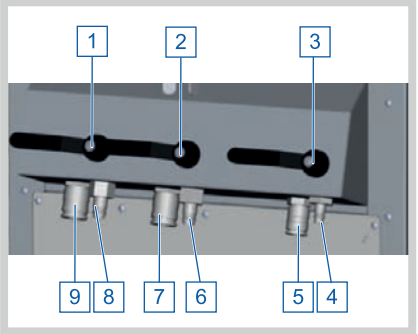

4 Touch the [Next] symbol.

### Emptying of tank

1 Disconnect all heat exchangers which are connected to the patient water circuit and/or the cardioplegia water circuit, and connect the supplied cleaning connectors instead.

2 Touch the [Next] symbol and wait until the melting process is complete.
- The HCU 40 melts the ice block and adjusts the temperature of the tank water to 20°C. Duration: 30 up to a maximum of 75 minutes (depending on the amount of ice present and the power supply).

3 If there were no tubes connected to the HCU 40 during melting, connect a tube to the outlet of the patient water circuit and a second tube to the outlet of the cardioplegia water circuit.
Or
If the tubes for the patient and cardioplegia water circuits were connected to the cleaning connectors on the HCU 40 during melting, remove these cleaning connectors.



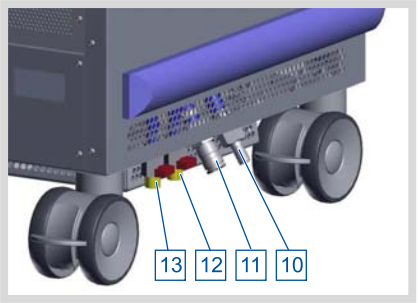

Patient water circuit 1:
1 Stopcock
8 Water outlet 1/2"
9 Water inlet 1/2" (backflow)
Patient water circuit 2:
2 Stopcock
6 Water outlet 1/2"
7 Water inlet 1/2" (backflow)
Cardioplegia water circuit:
3 Stopcock
4 Water outlet 3/8"
5 Water inlet 3/8" (backflow)

4 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

5 Touch the [Next] symbol to start pumping.
- The HCU 40 pumps the water out.

6 Wait until the HCU 40 is empty.

7 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

8 Touch the [Next] symbol.
9 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
10 Touch the [Next] symbol.
11 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
12 Perform surface cleaning and disinfect the device (⇨ "Surface Cleaning and Disinfecting the Device after Each Use", page 91).
13 Connect the cleaning connectors.
14 Touch the [Next] symbol.

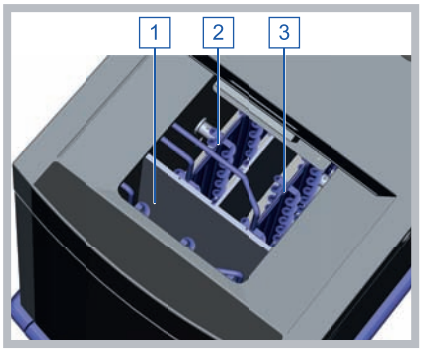
### Routine disinfection

1 Fill the HCU 40 with sterile filtered water up to the second mark on the water level indicator.

2 Touch the [Next] symbol.
3 Put on protective clothing.

4 Produce a Chloramine-T solution:
For weekly routine disinfection with the HCU 40 standard tube (4 x 6 m in length for the patient water circuit and 2 x 6 m for the cardioplegia water circuit):
Use a powder funnel to put 640 g of Chloramine-T powder into a chemical-resistant 10 liter canister with watertight lid. Add 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.
If longer or shorter tubes are connected to the HCU 40 establish the correct amount of Chloramine-T for the required solution concentration of 2% (⇨ " Solution Concentration with Different Tube Lengths", page 141).

5 Put the following quantities of the Chloramine-T solution into the three tank chambers:
1.4 l to the cardioplegia water circuit ([1] ),
1.8 l to the patient water circuit 2 ([2]),
1.8 l to the patient water circuit 1 ([3]),
(valid for the standard tube (4 x 6 m in length for the patient water circuit and 2 x 6 m for the cardioplegia water circuit)).
Fill the remaining solution in the canister in equal parts into the three tank chambers.



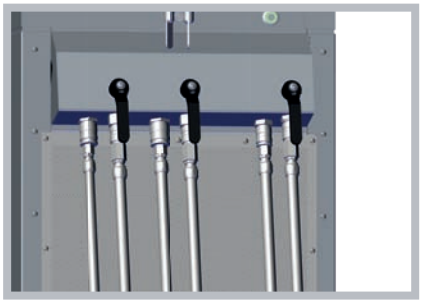

6 Touch the [Next] symbol.

7 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).

- The water level is shown on the 4th marking

8 Touch the [Next] symbol.

9 Open the stopcocks of the patient and cardioplegia water circuits.



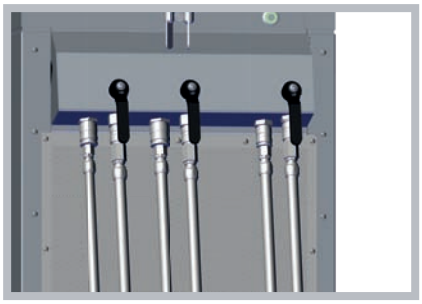
10 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
11 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
12 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
13 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps. Remove the yellow caps from the water pump stopcocks. Open both water pump stopcocks and drain off around 200 ml from each stopcock. Connect the drainage tube to the tank drainage coupling and drain around 400 ml from the internal lines.
   Or
   If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Connect the drainage tube to the tank drainage coupling and drain around 400 ml from the internal lines.
14 Touch the [Next] symbol.
15 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
   Or
   Disconnect the drainage tube.
16 Touch the [Next] symbol.
   - The HCU 40 performs cleaning (duration approx. 90 minutes).
17 Close the stopcocks of the patient and cardioplegia water circuits.
18 Disconnect the cleaning connectors.
19 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

**NOTE**

Use a suitable outflow to dispose of the disinfection/descaling agent solutions.

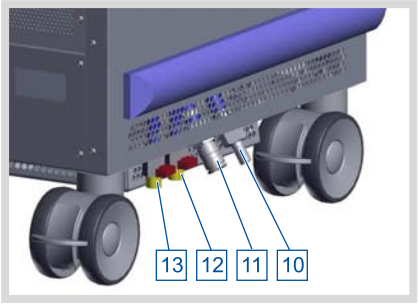
20 Touch the [Next] symbol.

21 Open the stopcocks of the patient and cardioplegia water circuits.



22 Touch the [Next] symbol.
- The HCU 40 pumps the water out.

23 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

**NOTE**

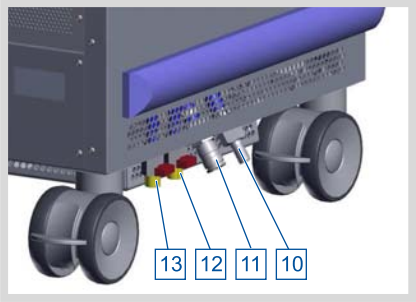
Use a suitable outflow to dispose of the disinfection/descaling agent solutions.

24 Touch the [Next] symbol.
25 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.

26 Touch the [Next] symbol.

### Rinsing cycle 1

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
   ▸ The HCU 40 de-airs the cardioplegia and patient water circuits.
5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.
7 Touch the [Next] symbol.
   ▸ The HCU 40 pumps the water out.
8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
   Remove the yellow caps from the water pump stopcocks.
   Open both stopcocks of the water pumps in order to empty the latter.
   Connect the drainage tube to the tank drainage coupling and drain away any residual water.
   Or
   If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).
9 Touch the [Next] symbol.




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

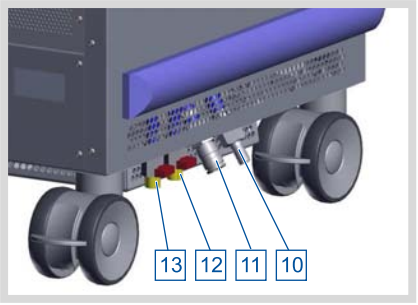
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
11 Touch the [Next] symbol.

### Rinsing cycle 2

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
- The HCU 40 de-airs the cardioplegia and patient water circuits.

5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.
7 Touch the [Next] symbol.
- The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

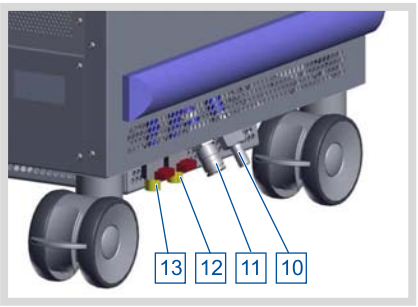
9 Touch the [Next] symbol.
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
11 Touch the [Next] symbol.

### Rinsing cycle 3

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
▸ The HCU 40 de-airs the cardioplegia and patient water circuits.
5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

7 Touch the [Next] symbol.
   ▸ The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
   Remove the yellow caps from the water pump stopcocks.
   Open both stopcocks of the water pumps in order to empty the latter.
   Connect the drainage tube to the tank drainage coupling and drain away any residual water.
   Or
   If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

9 Touch the [Next] symbol.
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
   Or
   Disconnect the drainage tube.
11 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
12 To exit the wizard after the last step, touch the [Confirm] symbol.
   Or
   To cancel the wizard instead, touch the [Reject] symbol.

▸ Weekly routine disinfection completed.

### 7.2.3 Performing highly effective disinfection and biofilm removal

**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 disinfectant/descaling agent.

If there are atypical *mycobacteria* in the water system, a 5% Chloramine-T concentration must be used in the entire water volume of the HCU 40 for special highly effective disinfection and biofilm removal. The Chloramine-T solution must be allowed to act for 24 hours. A cleaning wizard guides you through highly effective cleaning and biofilm removal.

Total duration: Approx. 150 to 200 minutes (depending on the amount of ice present and the power supply) plus 24 hour exposure time for Chloramine-T.

During this procedure, the following steps are performed in succession:

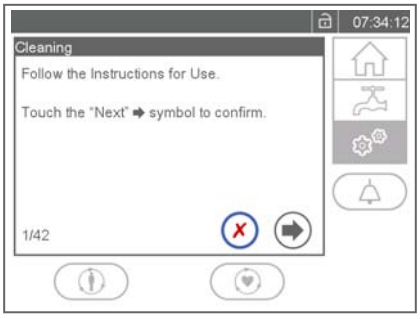
- Emptying of tank
- Highly effective disinfection and biofilm removal
- Rinsing cycle 1
- Rinsing cycle 2
- Rinsing cycle 3

**NOTE**

The cleaning wizard provides additional support if one step in the cleaning routine cannot be completed due to an operating error (example: shut-off valve not open during pumping) A warning to this effect is shown. You can continue the cleaning routine by pressing the [Next] symbol.

1 Touch the [Settings] symbol.
2 Touch the [Cleaning/emptying] symbol.
3 Touch the [Cleaning] symbol.

▸ You will see a wizard that will guide you through disinfection.



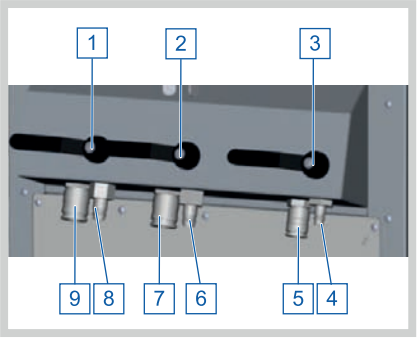
4 Touch the [Next] symbol.

### Emptying of tank

1 Disconnect all heat exchangers which are connected to the patient water circuit and/or the cardioplegia water circuit, and connect the supplied cleaning connectors instead.

2 Touch the [Next] symbol and wait until the melting process is complete.
- ▸ The HCU 40 melts the ice block and adjusts the temperature of the tank water to 20°C. Duration: 30 up to a maximum of 75 minutes (depending on the amount of ice present and the power supply).

3 If there were no tubes connected to the HCU 40 during melting, connect a tube to the outlet of the patient water circuit and a second tube to the outlet of the cardioplegia water circuit.
Or
If the tubes for the patient and cardioplegia water circuits were connected to the cleaning connectors on the HCU 40 during melting, remove these cleaning connectors.



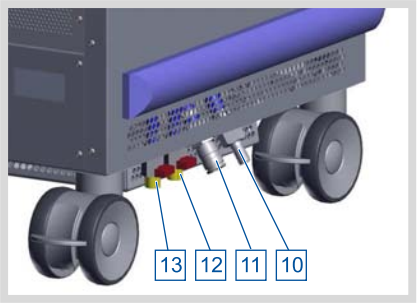

Patient water circuit 1:
1 Stopcock
8 Water outlet 1/2"
9 Water inlet 1/2" (backflow)
Patient water circuit 2:
2 Stopcock
6 Water outlet 1/2"
7 Water inlet 1/2" (backflow)
Cardioplegia water circuit:
3 Stopcock
4 Water outlet 3/8"
5 Water inlet 3/8" (backflow)

4 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

5 Touch the [Next] symbol to start pumping.
- ▸ The HCU 40 pumps the water out.

6 Wait until the HCU 40 is empty.

7 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

8 Touch the [Next] symbol.
9 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
10 Touch the [Next] symbol.
11 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
12 Perform surface cleaning and disinfect the device (⇨ "Surface Cleaning and Disinfecting the Device after Each Use", page 91).
13 Connect the cleaning connectors.
14 Touch the [Next] symbol.

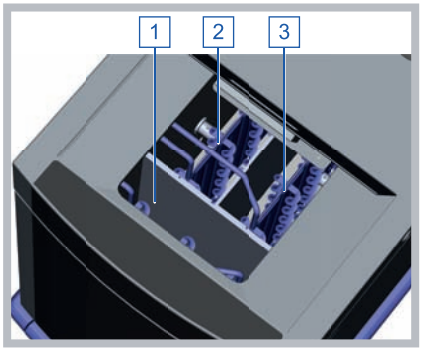
### Highly effective disinfection and biofilm removal

1 Fill the HCU 40 with sterile filtered water up to the second mark on the water level indicator.

2 Touch the [Next] symbol.
3 Put on protective clothing.

4 Produce a Chloramine-T solution:
For highly effective disinfection with the HCU 40 standard tubes (4 x 6 m in length for the patient water circuit and 2 x 6 m for the cardioplegia water circuit):
Use a powder funnel to put 805 g of Chloramine-T powder into a chemical-resistant 10 liter canister with watertight lid. Add 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.
Use a powder funnel to put 805 g of Chloramine-T powder into a second chemical-resistant 10 liter canister with watertight lid. Add 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.
If longer or shorter tubes are connected to the HCU 40 establish the correct amount of Chloramine-T for the required solution concentration of 5% (⇨ " Solution Concentration with Different Tube Lengths", page 141).

5 Put the following amounts of the Chloramine-T solution from each canister into the three tank chambers:
2 l to the cardioplegia water circuit ([1]),
2.5 l to the patient water circuit 2 ([2]),
2.5 l to the patient water circuit 1 ([3]),
(valid for the standard tube (4 x 6 m in length for the patient water circuit and 2 x 6 m for the cardioplegia water circuit)).
Fill the remaining solution in the canister in equal parts into the three tank chambers.



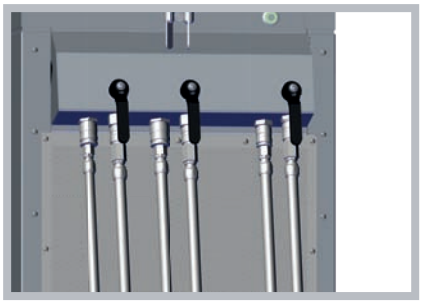

6 Touch the [Next] symbol.

7 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).

- The water level is shown on the 4th marking

8 Touch the [Next] symbol.

9 Open the stopcocks of the patient and cardioplegia water circuits.



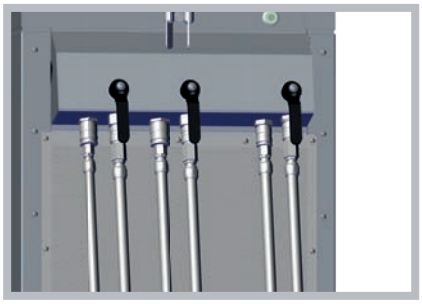
10 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
11 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
12 Touch the [Next] symbol.
   - The HCU 40 de-airs the cardioplegia and patient water circuits.
13 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps. Remove the yellow caps from the water pump stopcocks. Open both water pump stopcocks and drain off around 200 ml from each stopcock. Connect the drainage tube to the tank drainage coupling and drain around 400 ml from the internal lines.
   Or
   If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
   Connect the drainage tube to the tank drainage coupling and drain around 400 ml from the internal lines.
14 Touch the [Next] symbol.
15 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
   Or
   Disconnect the drainage tube.
16 Touch the [Next] symbol.
   - The HCU 40 performs cleaning (duration approx. 90 minutes).
17 Close the stopcocks of the patient and cardioplegia water circuits.
18 **Leave the Chloramine-T to work for 24 hours in the water system**
19 Disconnect the cleaning connectors.
20 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

**NOTE**

Use a suitable outflow to dispose of the disinfection/descaling agent solutions.

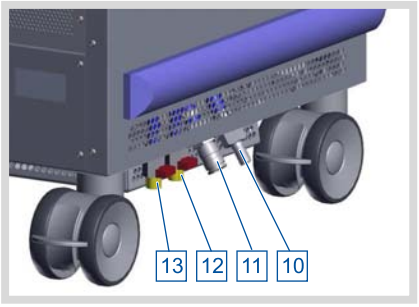
21 Touch the [Next] symbol.

22 Open the stopcocks of the patient and cardioplegia water circuits.



23 Touch the [Next] symbol.
- The HCU 40 pumps the water out.

24 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

**NOTE**

Use a suitable outflow to dispose of the disinfection/descaling agent solutions.

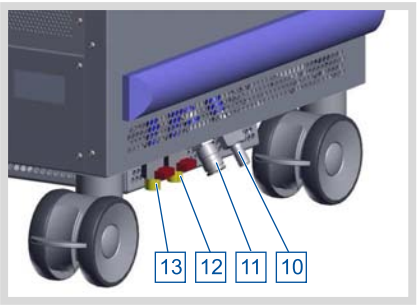
25 Touch the [Next] symbol.
26 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
27 Touch the [Next] symbol.

### Rinsing cycle 1

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
- The HCU 40 de-airs the cardioplegia and patient water circuits.

5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.
7 Touch the [Next] symbol.
- The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

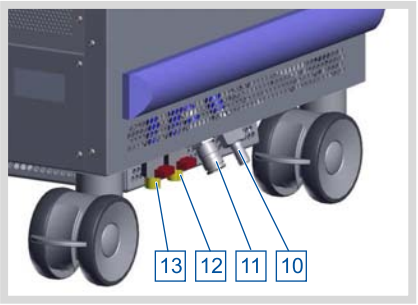
9 Touch the [Next] symbol.
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
11 Touch the [Next] symbol.

### Rinsing cycle 2

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
▸ The HCU 40 de-airs the cardioplegia and patient water circuits.
5 Disconnect the cleaning connectors.
6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

7 Touch the [Next] symbol.
   ▸ The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

9 Touch the [Next] symbol.
10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.
11 Touch the [Next] symbol.

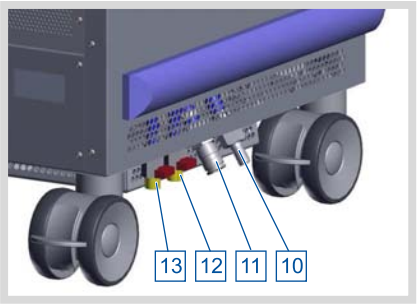
### Rinsing cycle 3

1 Disconnect the cleaning connectors and disinfect the Hansen couplings and the cleaning connectors.
2 Connect the cleaning connectors.
3 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).
4 Touch the [Next] symbol.
   ▸ The HCU 40 de-airs the cardioplegia and patient water circuits.
5 Disconnect the cleaning connectors.

6 Place the open ends of the tubes (without touching any contaminated surfaces) in an outflow and open the stopcocks of the patient and cardioplegia water circuits.

7 Touch the [Next] symbol.
- ▸ The HCU 40 pumps the water out.

8 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock cardioplegia water circuit pump
13 Stopcock patient water circuit pump

9 Touch the [Next] symbol.

10 Close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
Disconnect the drainage tube.

11 Fill the HCU 40 up to the white mark in the tank with sterile filtered water (1 cm above the cooling plates).

12 To exit the wizard after the last step, touch the [Confirm] symbol.
Or
To cancel the wizard instead, touch the [Reject] symbol.

- ▸ Highly effective disinfection and biofilm removal completed.

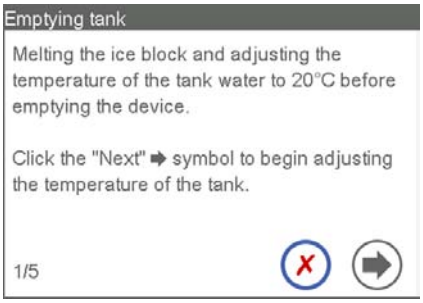
### 7.2.4 Emptying the Tank

This function empties the tank. You must use this function to change the water.

If you only want to empty the tubes of a circuit instead, you can use the "Empty tubes" function (⇨ "Emptying Water Circuits", page 58).

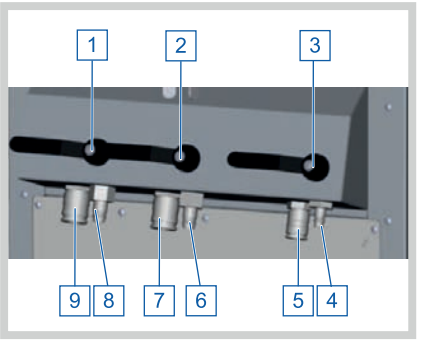
The HCU 40 supports you during emptying with a wizard to guide you step by step.

1 Touch the [Settings] symbol.
2 Touch the [Cleaning/emptying] symbol.
3 Touch the [Emptying the tank] symbol.
4 You will see a wizard that will guide you through the emptying process.




5 Disconnect all heat exchangers which are connected to the patient water circuit and/or the cardioplegia water circuit, and connect the supplied cleaning connectors instead.
6 Touch the [Next] symbol and wait until the melting process is complete.
   - The HCU 40 melts the ice block and adjusts the temperature of the tank water to 20°C. Duration: 30 up to a maximum of 75 minutes (depending on the amount of ice present and the power supply).

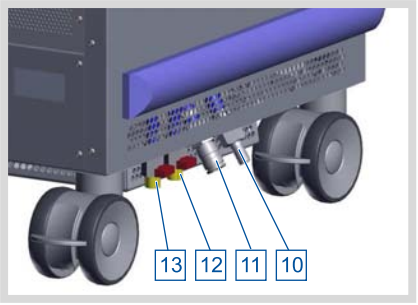
7 If there were no tubes connected to the HCU 40 during melting, connect a tube to the outlet of the patient water circuit and a second tube to the outlet of the cardioplegia water circuit.
Or
If the tubes for the patient and cardioplegia water circuits were connected to the cleaning connectors on the HCU 40 during melting, remove these cleaning connectors.




Patient water circuit 1:
1 Stopcock
8 Water outlet 1/2"
9 Water inlet 1/2" (backflow)
Patient water circuit 2:
2 Stopcock
6 Water outlet 1/2"
7 Water inlet 1/2" (backflow)
Cardioplegia water circuit:
3 Stopcock
4 Water outlet 3/8"
5 Water inlet 3/8" (backflow)

8 Place the open ends of the tubes in an outflow and open the stopcocks of the patient and cardioplegia water circuits.
9 Touch the [Next] symbol to start pumping.
10 Wait until the HCU 40 is empty.

11 If stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Place a suitable container (e.g., a flat stainless steel tray) below the stopcocks of the water pumps.
Remove the yellow caps from the water pump stopcocks.
Open both stopcocks of the water pumps in order to empty the latter.
Connect the drainage tube to the tank drainage coupling and drain away any residual water.
Then close the water pump stopcocks, reattach the yellow caps and disconnect the drainage tube.
Or
If no stopcocks for the pumps of the patient and cardioplegia water circuits are mounted underneath the HCU 40:
Connect the drainage tube to the tank drainage coupling and collect the remaining water (2 to 3 liters) in a suitable container (e.g., a flat stainless steel tray).
Next disconnect the drainage tube.




Tank drain/overflow:
10 Tank overflow
11 Tank drainage coupling
12 Stopcock for cardioplegia water circuit pump (optional)
13 Stopcock for patient water circuit pump (optional)

12 To exit the wizard after the last step, touch the [Confirm] symbol.
Or
To cancel the wizard instead, touch the [Reject] symbol.

## 7.3 Cleaning the Air Filter

A soiled air filter can impair the cooling capacity.

- Clean the air filter from the outside with a vacuum cleaner every 4 weeks.

# 8 Maintenance

Maintenance includes all measures which ensure the device is functioning properly and is free of damage in order to enable safe use for the intended purpose:

- Maintenance by the operator
- Inspection and maintenance by authorized service personnel
- Repair

| Interval | Task | Procedure |
|---|---|---|
| After each use | Surface cleaning and disinfection of the device | Operator |
| Daily | Daily inspection by the operator | Operator |
| Weekly | ■ Perform routine disinfection of the water circuits<br>■ Perform diagnosis | Operator |
| Monthly | Clean the air filter | Operator |
| Every 3 months | Perform descaling | Operator |
| Every 12 months | Inspection | Authorized service |

## 8.1 Maintenance by the Operator

This section contains all of the regular inspection and maintenance measures which are required to ensure the device is functioning properly and is free of damage.

### 8.1.1 Daily Inspection by the Operator

Check the following points every day:

- The water level in the tank is sufficient (setpoint water level: level marking in the cardioplegia tank, approx. 1 cm above the evaporizer plates).
- The size of the ice block is sufficient.
- The interior walls of the tank must not be touched by the ice in order to allow sufficient flow.

### 8.1.2 Perform Diagnosis

**WARNING!**

- To ensure safe use of the HCU 40, perform fault diagnosis once a week.
- If an error occurs during diagnosis, you must not continue to use the device. Notify the authorized service.

**WARNING!**

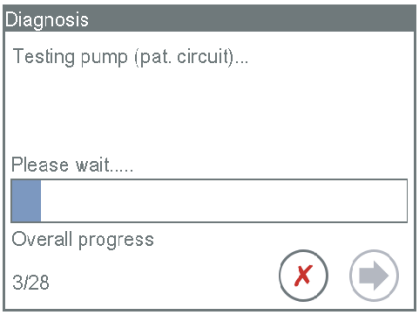
The diagnosis can only be carried out under the following conditions:
The water temperature in the tank is < 25°C.
The bypass tubes for diagnosis are connected and de-aired.
No other tubes or heat exchangers are connected to the system.
Otherwise the diagnosis will not be successful.

The diagnosis is an intensive self-test of the system, which can help to identify possible error causes. The HCU 40 supports you with a wizard to guide you step by step.

The navigation and pump control are inactive during diagnosis. However, you can cancel the diagnosis in order to be able to navigate and control the pumps again.

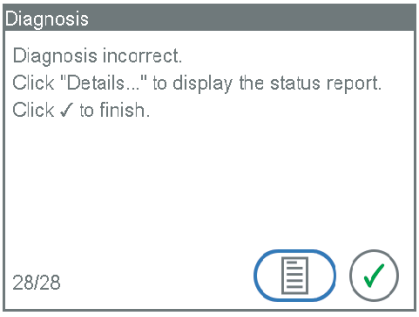
1 Stop the pumps.
2 Empty the water circuits (⇨ "Emptying Water Circuits", page 58).
3 Close the stopcocks of all circuits (⇨ "Opening/Closing Stopcocks", page 40).
4 Disconnect the tubes from the HCU 40.
5 Connect one of the supplied bypass tubes (1 m) to the patient water circuit 1.
6 Connect the other supplied bypass tube (1 m) to the cardioplegia water circuit.
7 Open the stopcocks of the patient water circuit 1 and the cardioplegia water circuit (⇨ "Opening/Closing Stopcocks", page 40).
8 Touch the [Functions] symbol in the main screen.
9 Touch the [De-airing] symbol of both circuits.
   ▸ Once the circuit has been de-aired, a green check mark appears next to the [De-airing] symbol.
10 Touch the [Settings] symbol.
11 Touch the [Diagnosis] symbol.
12 Follow the wizard's instructions.
13 To confirm that you have followed the instructions, touch the [Continue] symbol.

- The diagnosis starts.

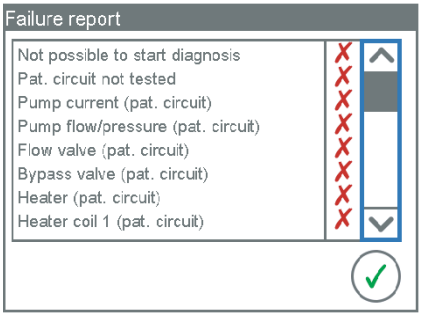



14 If you wish to abort the diagnosis, touch the [Reject] symbol.

- Once the diagnosis is complete, the touchscreen displays the result.




15 If the diagnosis has identified an error, touch the [Details] symbol to display a detailed diagnosis report.




16 To exit the wizard after the last step or to close the diagnosis report, touch the [Confirm symbol.]

## 8.2 Inspection and Maintenance by Authorized Service Personnel

The regular inspection and maintenance by authorized service personnel includes a safety check and extensive maintenance measures.

**WARNING!**

The inspection may only be carried out by a service technician authorized by Maquet.

### 8.2.1 Inspection

The [System information] window displays the date of the last inspection and the time remaining until the next inspection (⇨ "Displaying System Information", page 70).

### 8.2.2 Maintenance

The maintenance measures are defined in the Service Manual, which can be requested from the authorized service personnel.

## 8.3 Repair

Repairing restores the proper functioning of the device and ensures it is free from damage. It is necessary if, for example, a fault has occurred in the device.

**WARNING!**

Repairs may only be carried out by a service technician authorized by Maquet.

### 8.3.1 Send Device to Authorized Service Point

1 Switch off the device.
2 Empty the device completely (Emptying the Tank).
3 Remove all accessories and connection cables. Only include the accessories necessary for the inspection and repair.
4 Before packaging, decontaminate all parts in accordance with the procedures applicable to the clinic.
5 Package the device so that it is protected from damage. If possible, use the original packaging or the packaging of a loaned or replacement device.
6 Enclose a description of the problem together with the name, address and telephone number of the contact person.

## 8.4 Authorized Service

For an inspection or repair, contact your local service agent.

This can be found on the Maquet website (http://www.maquet.com). Select your country or region. Click on "Contact" and fill out the contact form.

# 9 Initial Installation

Initial installation includes all measures required to make the device ready for use and ensure its initial use is safe and as intended.

**WARNING!**

Initial installation may only be carried out by a service technician authorized by Maquet (⇨ "Send Device to Authorized Service Point", page 131).

**NOTE**

**Permissible maximum pressure**

As part of the initial installation, the permissible maximum pressure is adapted to suit the heat exchangers employed.

You can use the touchscreen to display which pressure limits have been specified (⇨ "Displaying the Pressure Limits", page 68).

# 10 Accessories

| Power cables | |
|---|---|
| Equipotential bonding conductor | ■ Length 1 m<br>■ Length 2 m<br>■ Length 3 m<br>■ Length 6 m |

| Operator devices |
|---|
| Second control unit (CU, replacement device, optional) |

| Holder |
|---|
| Set of slide rails for tubing holder (optional) |

| Tube and coupling sets | |
|---|---|
| Tubing set for oxygenator/heat exchanger with 1/2" Hansen coupling | ■ 2 x 6 m<br>■ 2 x 10 m<br>■ 2 x 15 m |
| Tubing set for cardioplegia heat exchanger with 3/8" Hansen coupling | ■ 2 x 6 m<br>■ 2 x 10 m<br>■ 2 x 15 m |
| Blanket connection kit (incl. pressure reducer for warming/cooling blankets) | ■ 6 m (3 + 3 m)<br>■ 9 m (6 + 3 m) |
| Pressure reducer for blanket connection kit | For warming/cooling blankets. Contained in the blanket connection kit for the HCU 40. |
| Warming/cooling blanket | ■ Adult (Gaymar; CBA 20-730)<br>■ Pediatric (Gaymar; CBA 20-731) |
| Bypass tubing set (for diagnosis) | ■ for patient water circuit (with 1/2" Hansen coupling, length 1 m)<br>■ for cardioplegia water circuit (with 3/8" Hansen coupling, length 1 m) |
| Drainage tube | |
| Hansen coupling kit for patient water circuit | ■ 1/2" straight<br>■ 1/2" angled |
| Hansen coupling kit for cardioplegia water circuit | ■ 3/8" straight<br>■ 3/8" angled |

| Sensors | |
|---|---|
| External temperature sensors | ■ TPO-D L1.8 (dia. 0.125" x L1.77")<br>■ TPO-D L1.8 Pediatric (dia. 0.095" x L1.38") |

| Data exchange | |
|---|---|
| USB 2.0 cable type A – type B | ■ Length 3 m<br>■ Length 5 m |
| CAN connection cable for connecting HCU 40 to control unit (CU) | ■ Length 7 m<br>■ Length 10 m<br>■ Length 15 m |

| Cleaning |
|---|
| Disinfectant, powder, 500 g, (active ingredient: tosylchloramide sodium (Chloramine-T)) |
| Mixing bottle for diluting the disinfectant |
| Cleaning connector (double Hansen coupling) |

# 11 Technical Data

## 11.1 HCU 40 Device

| | |
|---|---|
| Classification in accordance with Council Directive 93/42/EEC concerning medical devices, Appendix IX | IIb |
| Degree of protection in accordance with IEC 60529 | IP 22 (Protection against ingress of solid foreign objects larger than 12.5 mm and dripping water when tilted up to 15°) |
| Classification in accordance with IEC 60601-1 | ■ HCU 40 - Type B applied part<br>■ Ext. temperature sensors – Defibrillator-protected type CF applied part<br>■ Oxygenator heat exchanger – type B applied part<br>■ Cardioplegia heat exchanger – type B applied part<br>■ Warming/cooling blanket – type BF applied part |
| Dimensions (HxWxD) | 1133 x 508 x 703 mm<br>(880 x 508 x 688 mm without CU and holder) |
| Weight (incl. CU and holder, excl. tubes) | 154 kg |
| Volume (at 3 m distance) | ■ 40.4 dB (at 50 Hz), 44.3 dB (at 60 Hz) (patient and cardioplegia pump turned on, compressor turned off)<br>■ 44.8 dB (at 50 Hz), 46.8 dB (at 60 Hz); (patient and cardioplegia pump turned on, compressor turned on) |
| Speaker for acoustic alarms | Volume depends on the priority of the alarm (⇨ " Alarms", page 81) and the volume set by the user (⇨ "Changing the Settings for Locking the Controls", page 62).<br>Maximum … minimum volume (approx.):<br>■ High priority: 71 … 57<br>■ Medium priority: 60 … 42<br>■ Low priority: 55 … 40 |

| **Cooling system** | |
|---|---|
| Compression cooling system, ice-forming | |
| Tank capacity | 28 liters |
| Quantity of ice | 15 kg |
| Initial cooling capacity | 6350 kJ |

| Cooling system | |
|---|---|
| Continuous cooling capacity of the compressor | 4867 kJ/h (1352 W) |

| Heating system | |
|---|---|
| Electrical heaters | |
| Heating capacity | ■ 2 x 3000 W (200 … 240 V)<br>■ 2 x 1500 W (110 … 120 V) |

| Power supply | |
|---|---|
| Max. power consumption | ■ 1760 … 1920 VA (110 … 120 V, 16 A)<br>■ 2760 … 2880 VA (230 … 240 V, 12 A)<br>■ 2990 VA (230 V, 13 A)<br>■ 3000 … 3600 VA (200 … 240 V, 15 A)<br>■ 3200 … 3840 VA (200 … 240 V, 16 A) |
| AC power supply: | |
| ■ Mains voltage (set at the factory) | 110/115/120/200/208/220/230/240 V |
| ■ Frequency | 50/60 Hz |
| ■ Line fuse | 25 A (110 … 240 V) |
| Supply line (Building installation requirements) | ■ Exclusively used for HCU 40<br>■ Designed for current rating > 16 A (country-specific)<br>■ Protected by type C circuit-breaker type C and ground fault circuit interrupter |

| Water supply | |
|---|---|
| Water hardness | ≤ 2.5 mmol/l CaCO3 (14 °dH) |
| Do not use deionized water! | |

## 11.2 Control Unit CU

| | |
|---|---|
| Dimensions (H x W x D) | 174 x 210 x 70 mm |
| Weight (incl. holder) | 1.3 kg |
| Touchscreen | LCD, 115.2 x 86.4 mm, 640 x 480 pixels |

## 11.3 Permissible Heat Exchangers

### 11.3.1 Oxygenator and Cardioplegia Heat Exchangers

| | |
|---|---|
| Permissible water flow | Cardioplegia heat exchanger: at least 2 l/min<br>Oxygenator heat exchanger: at least 3 l/min |

| | |
|---|---|
| Permissible pressure | The HCU 40 can generate a maximum pressure of 2 bar.<br>For oxygenator heat exchangers and cardioplegia heat exchangers with lower permissible maximum pressures, a lower pressure limit of the HCU 40 must be set.<br>Oxygenator heat exchangers with a maximum permissible pressure of < 1.5 bar can be used with a HCU 40 in 60 Hz mains operation in the cardioplegia water circuit. |

### 11.3.2 Blanket Connection Kit (incl. Pressure Reducer)

| | |
|---|---|
| Nominal pressure of pressure reducer | Max. 1.2 bar |

## 11.4 Components Supplied

| |
|---|
| HCU 40 |
| Power cable |
| Instructions for Use |
| Control unit CU (incl. holder and pole for securing) |
| CAN connection cable for HCU 40 – CU connection, length 1 m |
| Tubing set for oxygenator/heat exchanger with 1/2" Hansen coupling (straight or angled), 2 x 6 m |
| Tubing set for cardioplegia heat exchanger with 3/8" Hansen coupling (straight or angled), 2 x 6 m |
| 2 cleaning connectors (double Hansen connectors) |
| Drainage tube |
| Bypass tubing set for patient water circuit with 1/2" Hansen coupling, length 1 m |
| Bypass tubing set for cardioplegia water circuit with 3/8" Hansen coupling, length 1 m |
| Disinfectant, powder, 500 g (active ingredient: Tosylchloramide sodium (Chloramine T)) |
| Mixing bottle for diluting the disinfectant |

## 11.5 Ambient Conditions

| | Operation | Storage and transport |
|---|---|---|
| Temperature | +10 … +30ºC | -20 … +60ºC |
| Relative humidity (non-condensing) | 0 … 85% | 10 … 96% |
| Air pressure (absolute) | 800 … 1060 hPa | 700 … 1060 hPa |

## 11.6 Measured Data and Displayed Data

| Parameters | Measuring range | Resolution | Measuring accuracy |
|---|---|---|---|
| Separate for cardioplegia and patient water circuit: | | | |
| ■ Temperature at water outlet $T_{out}$ | -9.9°C … +59.9°C | 0.1 | ± 0.3°C |
| ■ Temperature in tank $T_{tank}$ | -9.9°C … +59.9°C | 0.1 | ±2.0°C |
| ■ Flow in circuit V | 0.3 … 50 l/min | 0.1 | ±0.5 l/min |
| ■ Pressure in circuit P | 0 … 3 bar | 0.1 | ±0.2 bar |
| ■ Heating capacity | 0 … 100 % | Displayed as bar graph | |
| ■ Size of ice block | -0 … +59.5°C[a] | Displayed via 3 different symbols | |
| Temperature of external sensor (blood temperature) $T_{ext}$ | -0 … +59.5°C[a] | 0.1 | ±0.2°C[b] |
| General data: | | | |
| ■ Water level in tank | | Displayed via 6 different symbols | |
| ■ Current consumption I | | 0.1 | |
| ■ Mains voltage U | | 1 | |

a. The measuring range depends on the sensor's measuring range (⇨ Specification of the external sensor).

b. The measuring range depends on the disposable.

## 11.7 Possible Settings and Factory Settings

### 11.7.1 Temperatures and Water Flows

| Parameter | Possible values | Resolution | Factory setting |
|---|---|---|---|
| Setpoint temperature: | | | |
| ■ Cardioplegia water circuit | 1 … 40.5°C | 0.1°C | 37°C |
| ■ Patient water circuit | 1 … 40.5°C | 0.1°C | 37°C |
| Gradient: | | | |
| ■ Cardioplegia water circuit | Off, 1.0 ... 15.0°C | 0.1°C | Off |

| Parameter | Possible values | Resolution | Factory setting |
|---|---|---|---|
| ■ Patient water circuit | Off, 1.0 ... 15.0°C | 0.1°C | Off |
| Flow at outlet at 50 Hz:[a] | | | |
| ■ Cardioplegia water circuit | 3.0 … 9.5 l/min[b] | 0.1 l/min | |
| ■ Patient water circuit | 3.0 … 18.5 l/min[b] | 0.1 l/min | |
| Flow at outlet at 60 Hz:[a] | | | |
| ■ Cardioplegia water circuit | 3.0 … 11.0 l/min[b] | 0.1 l/min | |
| ■ Patient water circuit | 3.0 … 22.0 l/min[b] | 0.1 l/min | |

a. Changes remain when device is turned off and on.

b. The max. attainable flow depends on the tube length, the employed heat exchanger, and the height gradient to be overcome.

### 11.7.2 Accuracy of the Temperature Control

| Parameter | Accuracy |
|---|---|
| Warming (20°C to 40°C) | ±0.5°C |
| Cooling (40°C to 20°C) | ±1.5°C |

### 11.7.3 Hotkeys

| Option | Possible settings[a] | Factory setting |
|---|---|---|
| Pump control | | |
| ■ Cardioplegia water circuit | On, off | Off |
| ■ Patient water circuit | On, off | Off |
| Acoustic alarm | On, temporarily off | On |
| Compressor control: | | |
| ■ Compressor | On, off | – (automatic control) |
| Size of ice block:[b] | | |
| ■ Cardioplegia water circuit | 1 ... 3 (in increments of 1) | 3 |
| ■ Patient water circuit | 1 ... 3 (in increments of 1) | 3 |
| Automatic blocking[b] | deactivated, 30 s, 1 min, 2 min, 5 min, 10 min | deactivated |
| Brightness/volume:[b] | | |
| ■ Brightness | 1 ... 10 (in increments of 1) | 5 |

| Option | Possible settings[a] | Factory setting |
|---|---|---|
| ■ Volume | 1 ... 3 (in increments of 1) | 3 |
| Languages[b] | German, English, Spanish, French, Portuguese | English |
| Time/date: | | |
| ■ Date format | DD.MM.YYYY, MM/DD/YYYY | DD.MM.YYYY |
| ■ Time format | hh:mm:ss, hh:mm | hh:mm:ss |
| | 12 h, 24 h | 24 h |

a. The possible values correspond to the setpoint temperatures and gradients.
b. Changes remain when device is turned off and on.

| Parameter | Factory setting "Cooling" hotkey | "Warming" hotkey |
|---|---|---|
| Setpoint temperature: | | |
| ■ Cardioplegia water circuit[a] | 4°C | 37°C |
| ■ Patient water circuit[a] | 34°C | 37°C |
| Setpoint gradient: | | |
| ■ Cardioplegia water circuit | Off | Off |
| ■ Patient water circuit | Off | Off |

a. Changes remain when device is turned off and on.

## 11.8 Availability of Physiological Alarms for External Devices

No physiological alarms are provided for external devices.

## 11.9 Essential Performance Characteristics

The HCU 40's safety system monitors the temperature regulation. When a water temperature of 42.0 ± 0.5°C is attained, the safety system switches off the pump and heaters of the machine immediately, and a high-priority visual and acoustic alarm is triggered. The pump can only be switched back on again once the water temperature has fallen below 41.0°C.

Temperature overshoots can be a maximum of 0.5°C (± 0.5°C measuring accuracy) above 41.0°C for 10 seconds. When this limit is exceeded, the heater switches off immediately, and a high-priority alarm is emitted optically and acoustically.

A water temperature of 42.0 ± 0.5°C can occur in a type 1 error situation for a maximum of 60 seconds.

When the water pressure exceeds 2.0 bar in the patient water circuit and 1.5 bar in the cardioplegia water circuit, the HCU 40's safety system switches the respective pump off immediately. 1.5 bar and 1.0 bar are set at the factory for the patient water circuit and the cardioplegia water circuit respectively.

In accordance with DIN EN 80601-2-35, the mean value of the setpoint temperature for the warming/cooling blanket does not deviate by more than ±1°C. When this limit is exceeded, an alarm is emitted optically and acoustically

## 11.10 Solution Concentration with Different Tube Lengths

### 11.10.1 2 per cent citric acid concentration for descaling various tube lengths

| 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) | Citric acid |
|---|---|---|---|---|---|---|
| | 82 ml/m | 132 ml/m | 132 ml/m | Tubing | HCU 40 | 2% |
| 2 x 15 m | 2.45 | 3.95 | 3.95 | 10.35 | 38.4 | **770 g** |
| 2 x 10 m | 1.64 | 2.64 | 2.64 | 6.92 | 34.9 | **700 g** |
| 2 x 6 m | 0.98 | 1.58 | 1.58 | 4.14 | 32.1 | **640 g** |
| 2 x 1 m | 0.16 | 0.26 | 0.26 | 0.69 | 28.0 | **560 g** |

### 11.10.2 2 per cent Chloramine-T concentration for weekly routine disinfection of various tube lengths

| 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) | Chlor-amine-T |
|---|---|---|---|---|---|---|
| | 82 ml/m | 132 ml/m | 132 ml/m | Tubing | HCU 40 | 2% |
| 2 x 15 m | 2.45 | 3.95 | 3.95 | 10.35 | 38.4 | **770 g** |
| 2 x 10 m | 1.64 | 2.64 | 2.64 | 6.92 | 34.9 | **700 g** |
| 2 x 6 m | 0.98 | 1.58 | 1.58 | 4.14 | 32.1 | **640 g** |
| 2 x 1 m | 0.16 | 0.26 | 0.26 | 0.69 | 28.0 | **560 g** |

### 11.10.3 5 per cent Chloramine-T concentration for highly effective disinfection and biofilm removal of various tube lengths

| 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) | Chlor-amine-T |
|---|---|---|---|---|---|---|
| | 82 ml/m | 132 ml/m | 132 ml/m | Tubing | HCU 40 | 5 % |
| 2 x 15 m | 2.45 | 3.95 | 3.95 | 10.35 | 38.4 | **2 x 960 g** |
| 2 x 10 m | 1.64 | 2.64 | 2.64 | 6.92 | 34.9 | **2 x 875 g** |
| 2 x 6 m | 0.98 | 1.58 | 1.58 | 4.14 | 32.1 | **2 x 805 g** |
| 2 x 1 m | 0.16 | 0.26 | 0.26 | 0.69 | 28.0 | **2 x 700 g** |

# 12 Applied Standards

## 12.1 Electromagnetic Compatibility (EMC)

The objective of the EMC declaration is to enable the responsible organization to decide whether the HCU 40 is suitable for its electromagnetic environment.

Essential performance characteristics:

- Water output temperature < 42.0 ± 0.5 °C
- If the temperature limit is exceeded (risk to patient), the pumps and heaters are stopped immediately and an alarm is emitted.
- If the outlet pressure limit is exceeded, the corresponding pump is switched off and an alarm emitted.

### Guidance and manufacturer's declaration – electromagnetic emissions

The HCU 40 is intended for operation in the electromagnetic environment detailed below. The customer or the user of the device should ensure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment – guidance |
|---|---|---|
| RF emissions in accordance with CISPR11 | Group 1 | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electrical equipment. |
| RF emissions in accordance with CISPR11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

### Guidance and manufacturer's declaration – Electromagnetic immunity

The HCU 40 is intended for operation in the electromagnetic environment detailed below. The customer or the user of the device should ensure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact | ±6 kV contact | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| | ±8 kV air | ±8 kV air | |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| | ±1 kV for input/output lines | ±1 kV for input/output lines | |
| Surges IEC 61000-4-5 | ±1 kV differential mode | ±1 kV differential mode | Mains power quality should be that of a typical commercial or hospital environment. |
| | ±2 kV common mode | ±2 kV common mode | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5% $U_T$ for ½ cycle (> 95% dip) | < 5% $U_T$ for ½ cycle (> 95% dip) | Mains power quality should be that of a typical commercial or hospital environment.<br>Thanks to its built-in battery, the device continues to operate during power mains interruptions. It therefore does not need to be powered from an uninterruptible power supply or external battery. |
| | 40% $U_T$ for 5 cycles (60% dip) | 40% $U_T$ for 5 cycles (60% dip) | |
| | 70% $U_T$ for 25 cycles (30% dip) | 70% $U_T$ for 25 cycles (30% dip) | |
| | < 5% $U_T$ for 5 s (> 95% dip) | < 5% $U_T$ for 5 s (> 95% dip) | |
| Magnetic field with a power frequency (50/60 Hz) as per IEC 61000-4-8 | 3 A/m | 3 A/m | The strength of power-frequency magnetic fields should correspond to that of a typical commercial or hospital environment. |
| **Note:** $U_T$ is the AC supply voltage prior to application of the test level. | | | |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance: |
| Conducted RF IEC 61000-4-6 | 3 $V_{eff}$ 150 kHz to 80 MHz | 10 $V_{eff}$ | $d = 0.35 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3↓V/m 80 MHz to 2.5 GHz | 10 V/m | $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz |
| | | | $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz |

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---|---|---|---|
| | | | Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:  |
| **Note 1:** At 80 MHz and 800 MHz, the higher frequency range applies.<br>**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is to be recommended. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b. Over the frequency range 150 kHz – 80 MHz field strengths should be less than 10 V/m.

### Recommended separation distances from RF communication equipment.

The HCU 40 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device, as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter [W] | Separation distance according to frequency of transmitter [m] | | |
|---|---|---|---|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |
| | $d = 0.35 \sqrt{P}$ | $d = 0.35 \sqrt{P}$ | $d = 0.7 \sqrt{P}$ |
| 0.01 | 0.035 | 0.035 | 0.07 |
| 0.1 | 0.11 | 0.11 | 0.22 |
| 1 | 0.35 | 0.35 | 0.7 |
| 10 | 1.11 | 1.11 | 2.21 |
| 100 | 3.5 | 3.5 | 7 |
| For transmitters rated at an output power not listed above, the distance can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| **Note 1:** At 80 MHz and 800 MHz, the higher frequency range applies.<br>**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

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