SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Operating Instructions

Heater-Cooler System 3T • Operating Instructions

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Indications for Use

The Stöckert Heater-Cooler System 3T is used with a Stöckert S3 heart-lung machine and/or any other heart-lung-machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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Operating Instructions
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Firmware version No. 2.XX

Table of Contents

5 Operation

6 Routine maintenance

7 Appendix

Notes:

1 Introduction

1.1 About these operating instructions

These operating instructions are solely intended for qualified perfusionists as the basis for using, operating, and maintaining the heater-cooler. Therefore, in the interest of the safety of both, the patient and the operator:

Read these operating instructions thoroughly before using the heater-cooler for the first time!

!

These operating instructions provide valuable information even for the experienced user. Apart from purely describing operational steps they also contain information on how to avoid dangerous situations and errors. Moreover, they supply instructions for quick troubleshooting.

1.1.1 Symbols used in these operating instructions

The symbols are intended to help the user find special text passages. The meaning of the symbols is as follows:

!	Danger! Failure to pay attention may cause danger to the patient's and/or the operator's life and health.
!	Warning! Failure to pay attention may cause damage to the machine or other equipment.
✓	A check list for a quick and safe follow up on whether operational steps have been carried out completely.
◗	Primary list (main groups)
➜	Secondary list (subgroups)

1.1.2 The chapters in these operating instructions

In chapter...		you will find the following information:
1	Introduction	➜ Symbols used in these operating instructions ➜ Overview on chapters (this table)
2	Safety	➜ Important safety instructions for the operation and maintenance of the heater-cooler
3	System description	➜ Complete overview ➜ Delivery scope
4	Installation	➜ Installation of the base unit
5	Operation	➜ Initial operation ➜ Function checks ➜ Usage ➜ Instructions for troubleshooting
6	Routine maintenance	➜ Cleaning and disinfecting ➜ Maintenance intervals and instructions ➜ Safety checks
7	Appendix	➜ Specifications ➜ Part numbers ➜ Warranty

2 Safety

2.1 Approvals

The heater-cooler has been designed to meet the following standards and regulations:

CE 0123	– Declaration of Conformity
◗ IEC 60601-1	– Medical Electrical Equipment General Requirements for Safety
◗ IEC 60601-1-2	– EMC (Electromagnetic Compatibility)
◗ MDD	– Medical Device Directive 93/42/EEC
◗ DIN EN ISO 13485	– Quality Management System
◗ UVV	– Regulations for the Prevention of Accidents

The heater-cooler system is a medical device, class IIb (MDD 93/42/ECC). A Declaration of Conformity has been issued for the heater-cooler.

2.2 Regulations and safety instructions

2.2.1 Intended use

- In accordance with the applicable regulations, the heater-cooler is intended for use with a Stöckert/Sorin S3/S5/C5 heart-lung machine and/or any other heart-lung machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours. The water circuits are used for cooling/heating blood (in the oxygenator), hypothermia blankets or cardioplegic solutions.

!

Instructions for use

- Any use beyond this specification is not in accordance with the regulations and SORIN GROUP DEUTSCHLAND GMBH will not assume any liability for damage in such a case. Usage in accordance with regulations also includes compliance with the operating instructions, as well as repair and maintenance according to the maintenance instructions.
- Relevant accident prevention measures according to existing local policy and employees' health and safety regulations must be complied with. SORIN GROUP DEUTSCHLAND GMBH will not assume any liability for damage due to non-compliance with these regulations.
- SORIN GROUP DEUTSCHLAND GMBH will not assume any liability for injuries and/or damage caused by failure to observe the safety instructions or by the operator not taking due care. This also applies if the operator's duty to take due care has not been specifically expressed to the user.

2.2.2 Contraindications

- There are no known contraindications for the heater-cooler.
  The attending physician is solely responsible for the use of the system.

2.2.3 General safety instructions

- The heater-cooler has been designed according to current state-of-the art technology and accepted safety standards. Although this is the case, danger may arise for the patient, the user or for other equipment during operation.
- The heater-cooler may only be used by trained and qualified perfusionists and may only be maintained by trained and qualified personnel.
- The heater-cooler must not be used in the presence of explosive substances.

!

- The heater-cooler may only be operated when the equipment is in good technical running order and, when used, in accordance with the applicable regulations and the operating instructions. Be sure to take note of cautions and warnings.

Usage in accordance with: See chap. 2.2.1 on page 2.2

- The operating instructions must be available close to the heater-cooler at all times. Incomplete or illegible operating instructions must be replaced immediately.
- According to the European Directive 93/42 and the national standards based on this directive, the heater-cooler must be subjected to **a regular maintenance check** by an authorized service representative. The maintenance check must be performed after every **1,000 operating hours** or **at least once every 12 months**, whichever comes first.
- In addition to the operating instructions, the relevant legal, general and binding regulations concerning the prevention of accidents must be observed.
- In order to take situations into account which are clinic-specific and outside of normal routines, e.g. certain working procedures, the operating instructions must be supplemented with relevant instructions (supervision and registration requirements, etc).
- Personnel operating the heater-cooler must have acquainted themselves thoroughly with the operating instructions prior to working on the system!
- If modifications affecting safety or system performance are noticed when the heater-cooler is not in use in the O.R., power it down immediately and have it checked by an authorized service technician.
- Do not perform any modifications or extensions to the heater-cooler unless they have been tested and approved by SORIN GROUP DEUTSCHLAND GMBH, or else SORIN GROUP DEUTSCHLAND GMBH cannot assume any liability or responsibility.
- Keep the heater-cooler clean! Doing so will prevent possible contact errors and faults due to dirt.
- Remove water spills from the OR floor using suitable disinfectants.

2.2.4 Operational safety

- Prior to working with the heater-cooler, the user must have thoroughly read the operating instructions and have become familiar with the device functions!
- Ensure that the heater-cooler is placed on a horizontal surface and the castor brakes have been locked prior to operation.
- Pay attention to hand hygiene and protective barriers by disinfecting your hands and using disposable gloves prior to connecting tubing or filling the tanks.
- Use filtered tap water that has been filtered by using e.g. a disposable Pall-Aquasafe water filter with an 0.2 µm membrane (Pall part reference in the U.S.: “AQINA”; “AQIN” in other countries). Alternatively, use a filter of equivalent performance that meets the requirements for bacterial retention according to the ASTM standard*, i.e. which retains Brevundimonas diminuta to ≥ 10^7 CFU/cm^2 of effective filtration area.

* (American Standard Test Method F838-05 “Determining Bacteria Retention of Membrane Filters Utilized for Liquid Filtration”)

- If available, use demineralized tap water.
- Check the water level of the tanks prior to each operation. Only operate the heater-cooler, if the water level is sufficient, i.e., is above the minimum water level (one segment of the bar graph display).
- Prior to operation, check all cables, tubings, connectors and other accessories in view of correct connections, leaks and proper function. Replace all damaged components at once. !
- Check the actual temperature displays on the heater-cooler regularly.
- Check the patient’s blood temperature and the temperature of the cardioplegic solution with an appropriate temperature measurement system regularly, independent of the displays on the heater-cooler (e.g. at the HLM). !
- For emergencies, e.g. in case of a total failure, ensure that a replacement with compatible connectors is ready for operation. !
- Activate the pumps of the primed and filled system prior to its first operation. Watch the water level display on the heater-cooler control panel and monitor the connected heat exchanger (e.g. oxygenator, heating/cooling blanket). A leakage in a water circuit will influence the water level in the connected tank.
- Do not use self-closing tubing connectors. Compared to “open” connectors, self-closing connectors reduce the water flow.
- Ensure that the cables and tubings are laid out as straightly as possible and do not kink or twist them. Kinked or twisted cables or tubings could pose a hazard for personnel (who could stumble, or get caught on the tubing).
- A primed and filled heater-cooler must not exceed a total weight of 125 kg (275.5 lbs.).

- Ensure optimum ventilation at the ventilation grills and the fan. Insufficient ventilation may result in excessive heating of the heater-cooler.
- The minimum distance of 70 cm to the wall or other devices must be observed!
- Modifications or extensions to the device, as well as the use of spare parts which have not been tested and approved by SORIN GROUP DEUTSCHLAND GMBH, may have negative effects on the safety and function of the system. SORIN GROUP DEUTSCHLAND GMBH cannot accept any liability or responsibility in such cases.
- Accessories and supplementary devices which have not been tested and approved by SORIN GROUP DEUTSCHLAND GMBH must prove that their use does not pose a safety hazard (see chap. 7.4 “Accessories” on page 7.6).

2.2.5 Electrical safety

- Accessories and supplementary devices must comply with the relevant IEC or ISO standards (e.g. IEC 60950 regarding information technology equipment). In addition, any configuration must meet the requirements for medical electrical systems (see IEC 60601-1-1 or paragraph 16 of IEC 60601-1, 3rd edition). Any person connecting additional devices to medical electrical equipment is considered a system configurer and is thus responsible for ensuring that the system meets the standard-related requirements for systems. Please note that local legislation takes precedence over the above-mentioned standard-related requirements.
- Check the functional safety of all electrical connections, cables and sockets regularly!
- Mains power quality should be that of a typical commercial or hospital environment.
- The heater-cooler must be connected to a power supply network with protective conductor (earth) to protect the device against electric shock.

2.2.6 Safety instructions for routine maintenance

- Routine maintenance work must only be performed by qualified personnel.
- The heater-cooler must be cleaned completely prior to operating it for the first time.
- The water circuits **must** be disinfected prior to operating the heater-cooler for the first time and when placing the system in storage. The disinfection cycle must then be repeated every 14 days (even on systems in storage).
- Disconnect the heater-cooler from the power supply prior to performing routine maintenance.
- Do not fail to observe the regulations concerning routine maintenance, as well as the prescribed maintenance intervals stated in these operating instructions.
- Ensure that no liquids or cleaning agents enter the housing through the vents or other openings.
- Use recommended cleaning agents and disinfectants. Follow the instructions of the chemical manufacturer for storage and use condition.
- Repair work on the heater-cooler must only be carried out by authorized service personnel. Only original spare parts from SORIN GROUP DEUTSCHLAND GMBH must be used in order to guarantee the proper functioning of the system.
- The repair work of the cooling circuit and the disposal of the refrigerant must only be performed by an expert for refrigerant systems. Please see chap. 6.1.3 “Regular maintenance checks by authorized service technicians” on page 6.4.
- Routine decalcification is not required. If needed, decalcification must be carried out by authorized service personnel.

2.3 Safety features of the heater-cooler

- The heater-cooler runs a self-test during power-up. Check whether all LEDs, the 7-segment displays and the beep alarm function correctly.
- Visual and audible alarms indicate when an internal error has occurred.
- The water pumps are stopped if the water level is too low. This is indicated by a corresponding alarm.

3 System description

3.1 General description

The Stöckert Heater-Cooler System is an independent (i.e. independent of the water supply) 3-circuit-heating/cooling system. The three separate water circuits have been developed to serve as:

- Two circuits for the patient (for the heating/cooling blanket, the oxygenator), common temperatures ranging from 2°C to 41°C, tank volume 6 l
- Interchangeable heating/cooling circuit for cardioplegia, temperatures ranging from 2°C to 10°C (cooling) and/or from 15°C to 41°C (heating), volume 2 x 3 l

If required, the circuits for the patient and the circuit for cardioplegia can be switched off separately, in order to increase the activated functional group's heating and/or cooling performance.

3.1.1 Components

The common delivery scope contains the standard components stated below. For further components ("optional components"), please contact SORIN GROUP DEUTSCHLAND GMBH, or your local SORIN GROUP DEUTSCHLAND GMBH distributor.

Standard components

- Heater-cooler base unit
- 3 pcs. tubing connectors 1/2", 90° angle, with venting valve
- 3 pcs. tubing connectors 1/2", straight
- Potential equalization cable
- Operating instructions

Optional components

- Heating/cooling blanket (dim. 55 x 150 cm)

3.2 Structure of the heater-cooler

3.2.1 Complete overview

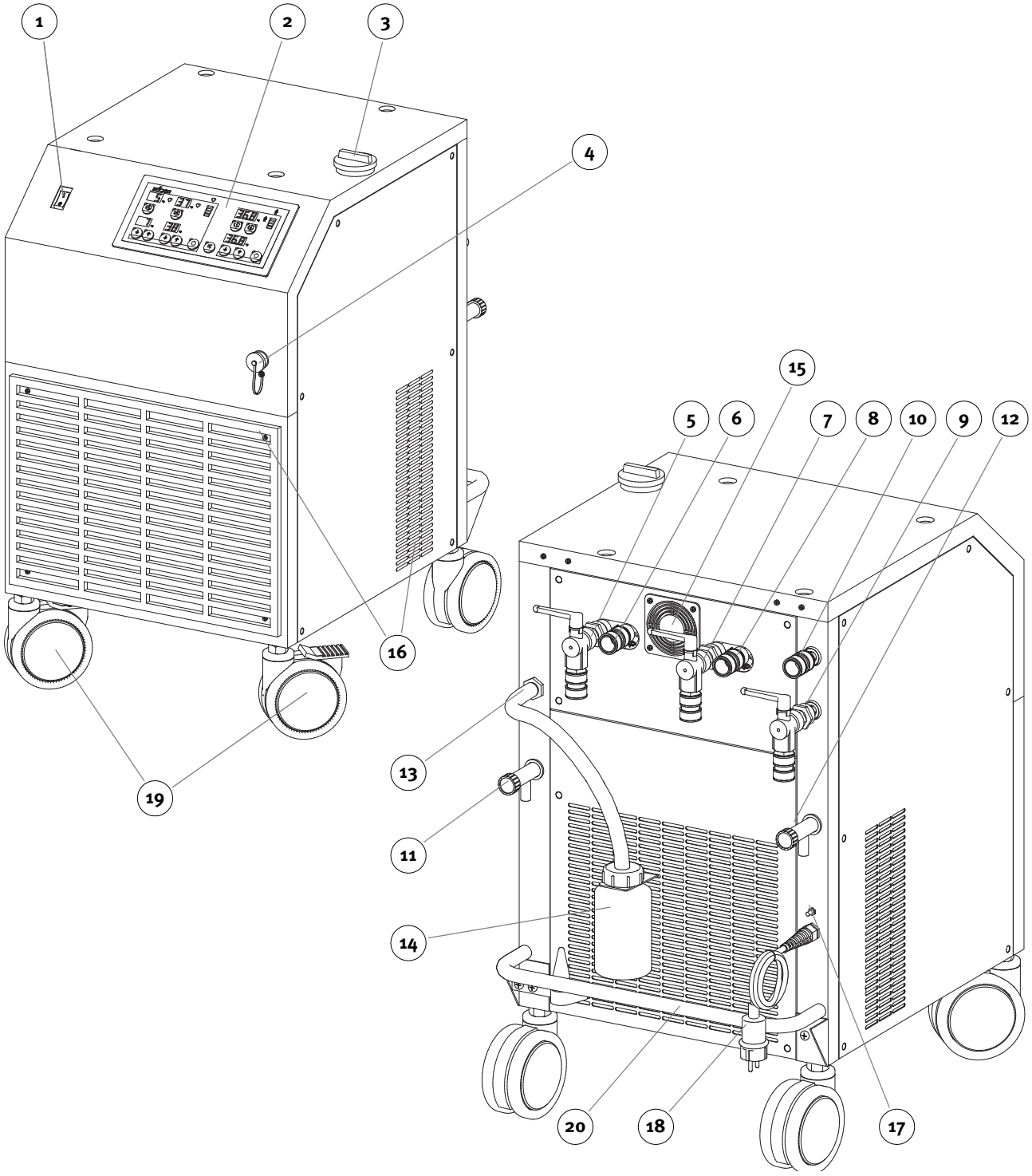


Fig. 1: Overview

Item	Designation	Function
1	Mains power switch	➜ Powering the heater-cooler up/down ➜ Integrated automatic cutout
2	Control panel	➜ For separated operation and configuration of the two functional groups (3 water circuits) – patient circuits and – cardioplegia circuit
3	Filler neck with cover	➜ For filling all tanks with filtered tap water.
4	CAN-Bus connector with cover	
5	Outlet patient circuit 2 with venting valve	➜ All inlets and outlets with fast (Hansen-type) connectors 1/2"
6	Inlet patient circuit 2	
7	Outlet patient circuit 1 with venting valve	
8	Inlet patient circuit 1	
9	Outlet cardioplegia circuit with venting valve	
10	Inlet cardioplegia circuit	
11	Drain valve of the patient circuits	➜ Emptying of the tanks
12	Drain valve of the cardioplegia circuit	
13	Overflow outlet	➜ For collecting the excess water (during filling)
14	Overflow bottle (with tubing)	
15	Fan	➜ Ventilation of the heater-cooler
16	Ventilation grill	
17	Potential equalization point	➜ Connection of the potential equalization cable
18	Power cable	➜ Power supply of the heater-cooler
19	Castors	➜ Front castors with brakes
20	Bumper	Mounting upon delivery (by Sorin service staff).

3.2.2 Overview - control panel

The control panel manages all control and monitoring functions of the heater-cooler. These are:
- Adjusting the set values,
- Starting and stopping the pumps,
- The display of all set and actual temperatures,
- The display of the water level and the alarm.

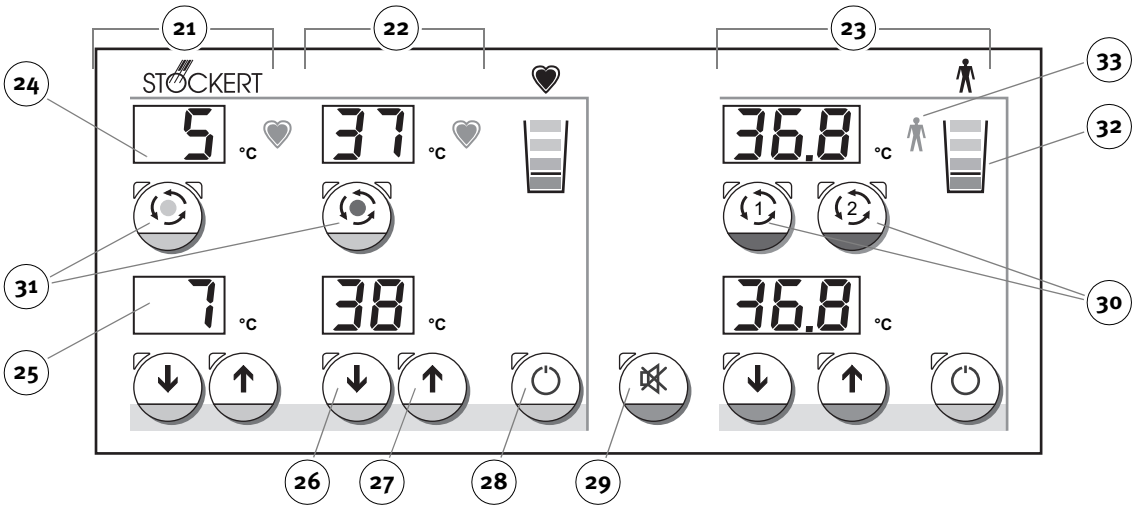


Fig. 2: Control panel

Item	Designation	Function
21	Cardioplegia cooling circuit elements	→ Displays and controls all settings of the individual circuits
22	Cardioplegia heating circuit elements	
23	Elements of the patient circuits	
24	7-segment displays *Actual temperatures*	→ Displays the actual and the set temperatures
25	7-segment displays *Set temperatures*	
26	Keys *Lower set temperature*	→ for increasing and/or decreasing the set value gradually (in steps)
27	Keys *Raise set temperature*	
28	Keys *Standby*	→ Switching on and off the functional group (standby mode)
29	Key *Audio alarm off*	→ Switches off the audio alarm (in case of alarm) for a maximum of 2 minutes, press the key again to switch the alarm back on.
30	Keys *Circuit Start/Stop* (patient circuits)	→ Starting and stopping the circuit in question individually.
31	Keys *Circuit Start/Stop* (cardioplegia circuit) heating tank: red dot cooling tank: blue dot	→ Starting and stopping the circuit as well as switching between the heating and the cooling tanks.
32	Bar graph display *Water level*	→ Display of the water level
33	Display *Alarm*	→ Red LED lights up in case of alarm

3.2.3 Overview - control panel S5/C5 System

If the heater-cooler is operated with the S5/C5 System, no further connections or steps are necessary. The settings of the heater-cooler may either be performed via the menu of the S5/C5 System or directly on the base unit of the heater-cooler.

Please see the separate operating instructions of the S5/C5 System for information on the displays of the heater-cooler menus when the heater-cooler is operated with the S5/C5 System.

Notes:

4 Installation

4.1 Preparing the installation

Apart from the components included in the delivery, you still need the following components for installing your heater-cooler:

- Compatible tubing sets for connecting the heating/cooling blanket and the oxygenator.
- A replacement for the heater-cooler in emergencies, e.g. a total system failure.

!

4.1.1 General and technical requirements

- Only operate the heater-cooler at an ambient temperature ranging between +10°C and +35°C (50°F through 95°F).
- Store the heater-cooler in a cool and dry place (0°C/32°F through 40°C /104°F max.).
- The heater-cooler complies with the requirements for protection class 1 (IEC 60601-1). It must be powered by a separately fused and properly grounded power supply.
- The heater-cooler must be connected to a potential equalization point for the patient's and the user's safety.
- The electrical installations must be in accordance with the requirements and standards IEC 60364-7-710, or the corresponding equivalent local regulations.

4.2 Performing the installation

4.2.1 Placing the heater-cooler

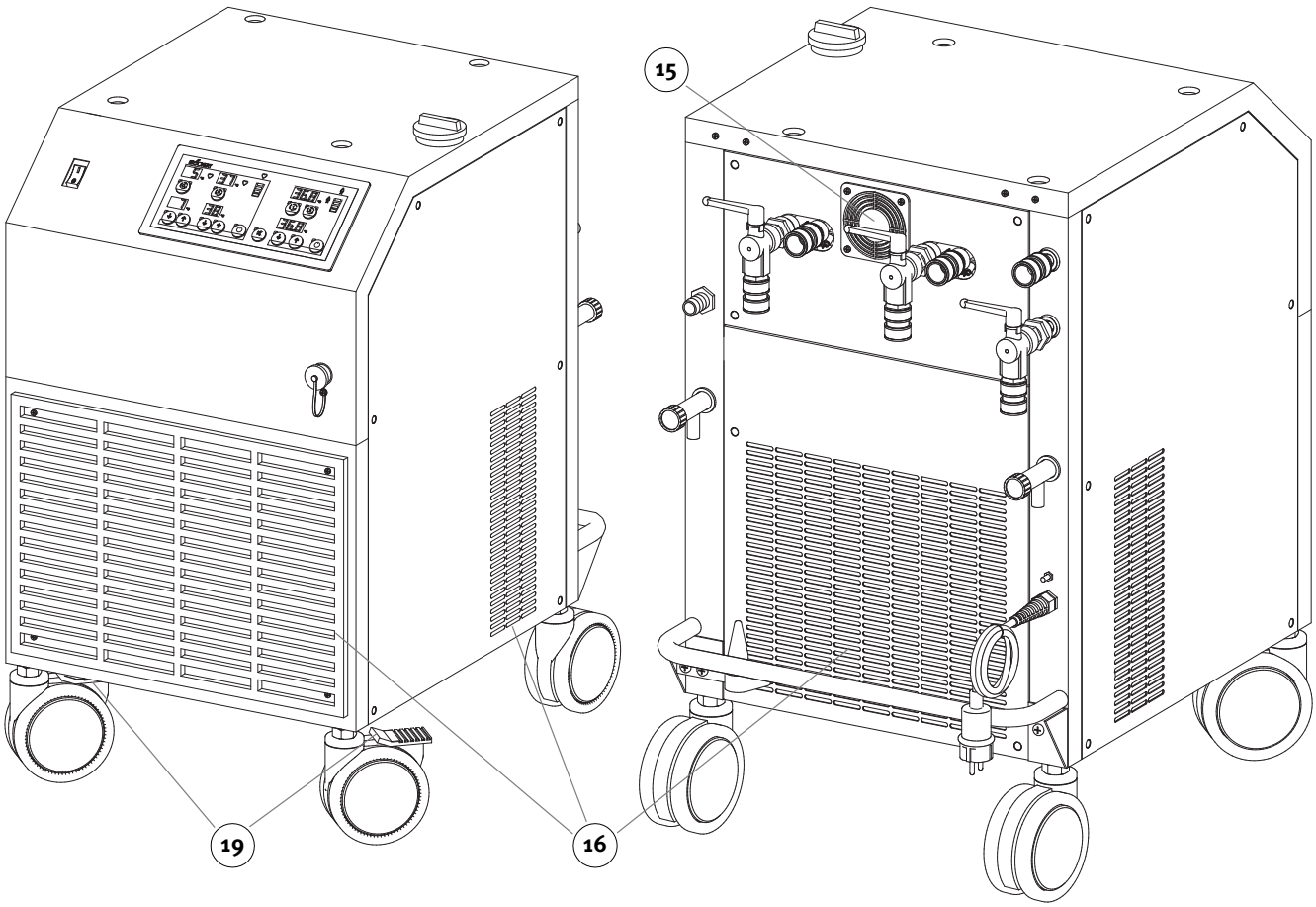


Fig. 3: Placing the heater-cooler

- Place the heater-cooler on even floors only.
- Lock the brakes (at the front castors **19**), after having placed the heater-cooler.
- Ensure that the ventilation grill **16** and the fan **15** are not covered and the heater-cooler is placed at a sufficient distance from the walls (about 70 cm / 2.5 ft.) and other devices.
- In order to avoid disturbances in the laminar flow area of the operating room, make sure that the heater-cooler is placed in such a way that the exhaust flow is not directed towards the operating field, but towards the exhaust vent system.
- To minimize noise exposure and avoid disturbing the air flow in the operating room, the system can be operated in an adjoining room provided that the technical construction allows for this setup. In this case, the system can be controlled via the HLM system panel. The length of the tubing between the heater-cooler and heat exchangers and the heating blanket must not exceed 5 m (16.4 ft).

4.2.2 Water connections

Connecting tubings to the water circuits

Note:
Pay attention to hand hygiene and protective barriers by disinfecting your hands and using disposable gloves.

Requirements for connection:

- Disinfect the connectors and fittings on the tubings before connecting them to the heater-cooler (see chap. 6.2).
- Do not use self-closing connectors. Compared to “open connectors”, they reduce the water flow.
- Prior to operation, check all tubings, connectors and other accessories to ensure a good seal at all water connections. Replace all damaged components immediately.
- Ensure that the tubings are straight and do not bend or twist them. Apart from occluding the water flow, bent or twisted tubings can pose a hazard for the personnel (they could stumble).
- Close inactive circuits with a suitable piece of tubing (making a “short” or closed circuit).

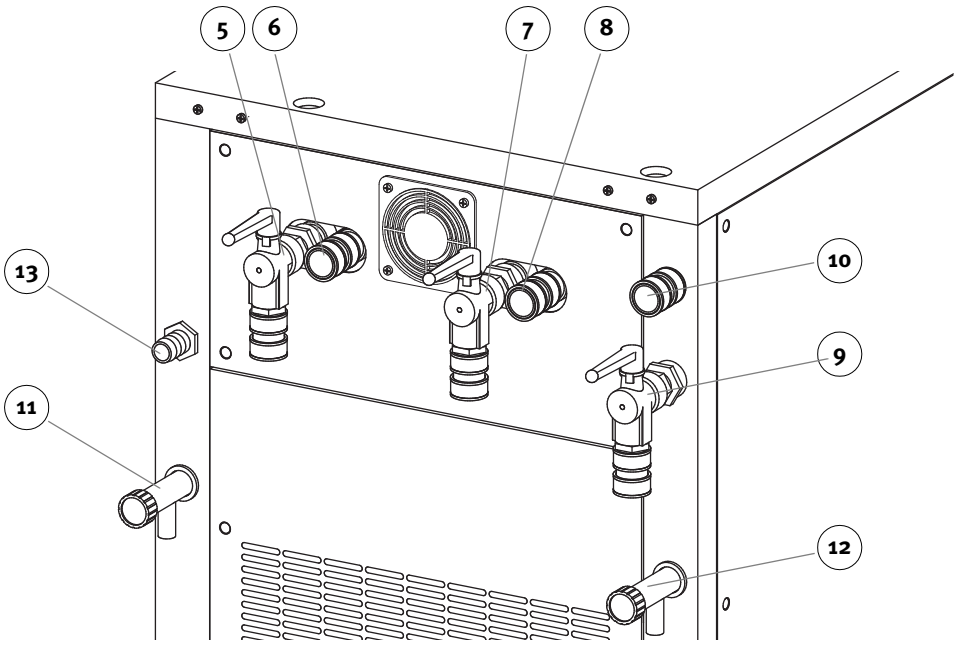


Fig. 4: Description of the connections

5	Outlet patient circuit 2 with venting valve	➜ All outlets and inlets with 1/2" fast (Hansen-type) connectors
6	Inlet patient circuit 2	
7	Outlet patient circuit 1 with venting valve	
8	Inlet patient circuit 1	
9	Outlet cardioplegia circuit with venting valve	
10	Inlet cardioplegia circuit	
11	Drain valve of the patient circuits	➜ For emptying the tanks
12	Drain valve of the cardioplegia circuit	
13	Overflow outlet	➜ For connecting an overflow tube

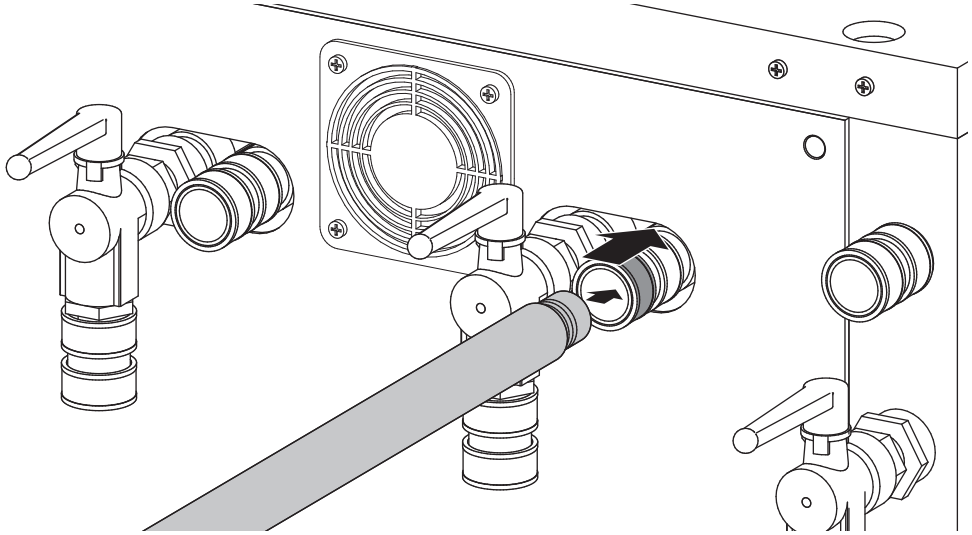


Fig. 5: Connecting the tubings

- Push the ring of the fast (Hansen-type) connector in the direction of the arrow to insert or remove the tubings.
- Insert the tubings with connector and allow the locking ring to return to its original position.
- The locking ring should click into place. Ensure that the tubings are correctly seated by gently pulling on the tubings.

!

Connecting the overflow tube

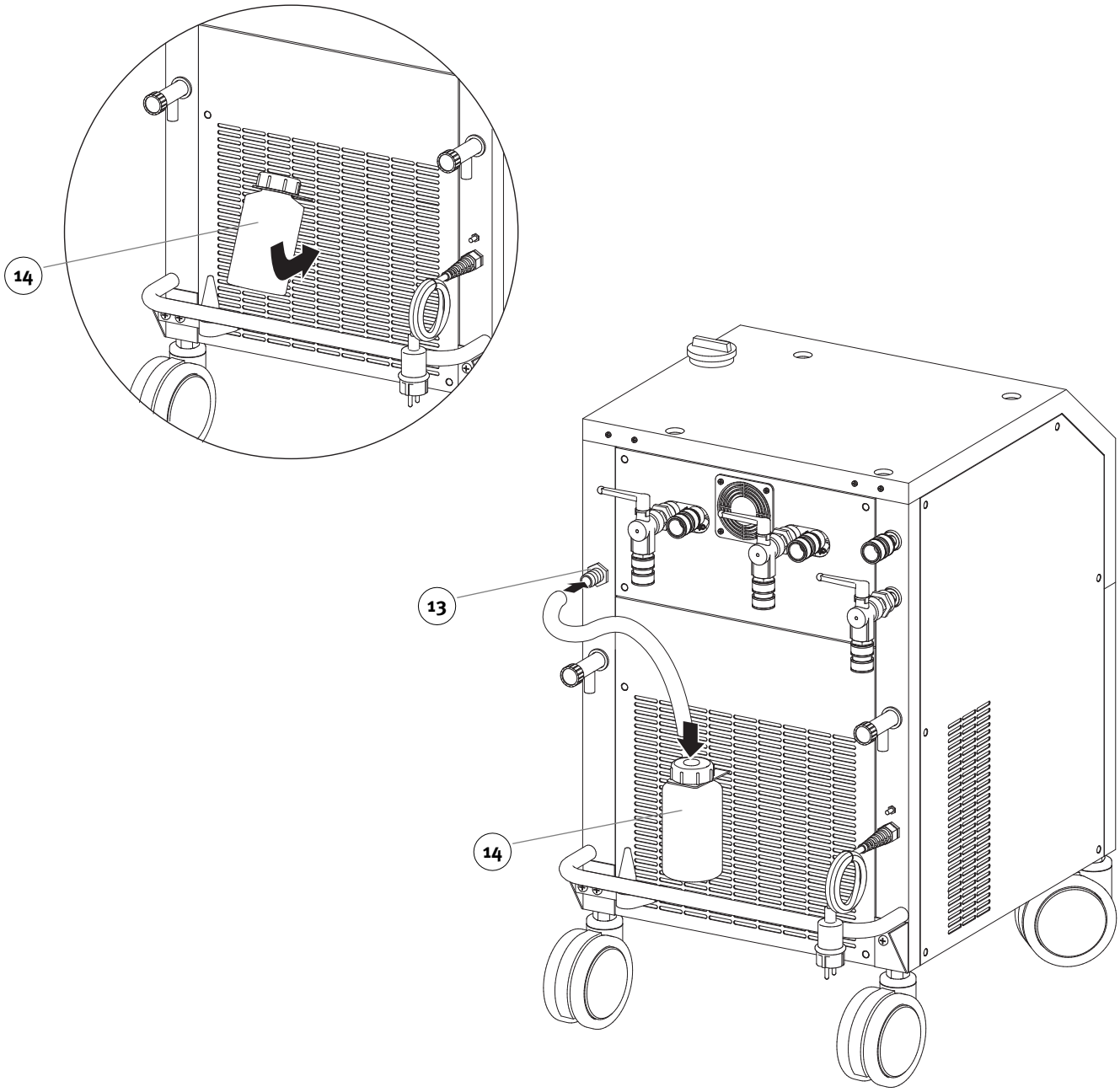


Fig. 6: Connecting the overflow tube

- Hang the overflow bottle **14** with its holder on the ventilation grill at the rear of the heater-cooler.
- Connect a 1/2" tubing to the overflow outlet **13**.
- Insert the other end of the tubing into the lid of the bottle **14** to collect excess water (during filling).

Overview connecting additional devices to the Heater-Cooler System 3T

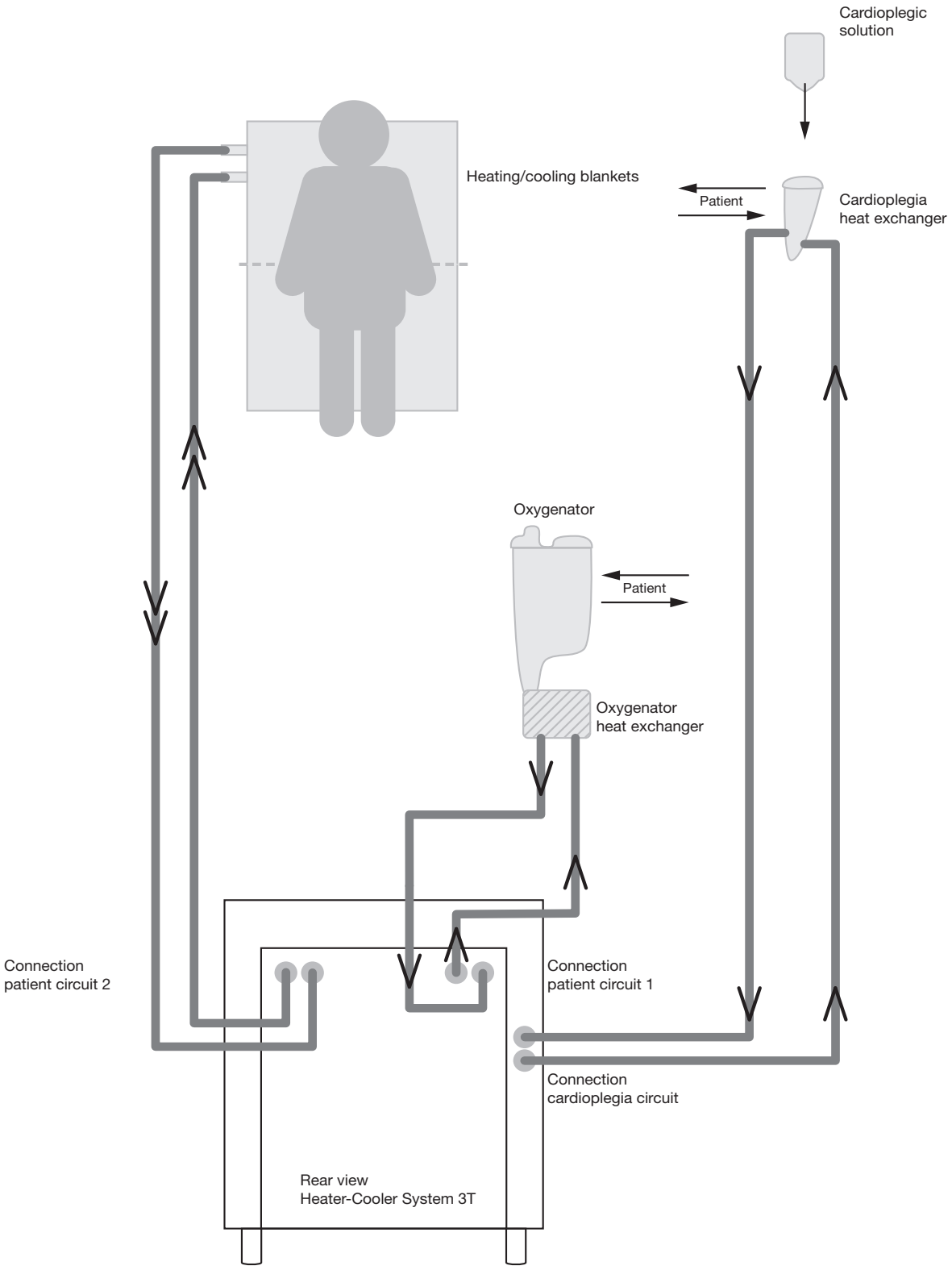


Fig. 7: Overview connecting additional devices

All components used in conjunction with the Heater-Cooler System 3T (please see the above overview) have been tested and determined safe and effective to the extent possible.
Please also see chap. 7.4 on page 7.6 for information about safe usage of the disposables.

Opening/closing the venting valves

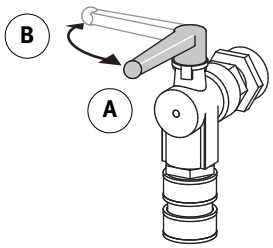


Fig. 8: Opening/closing the venting valves

For operating the heater-cooler, the venting valves have to be opened (position **A**).
For emptying the tubing system, the venting valves have to be closed (position **B**).

Disconnecting the tubings

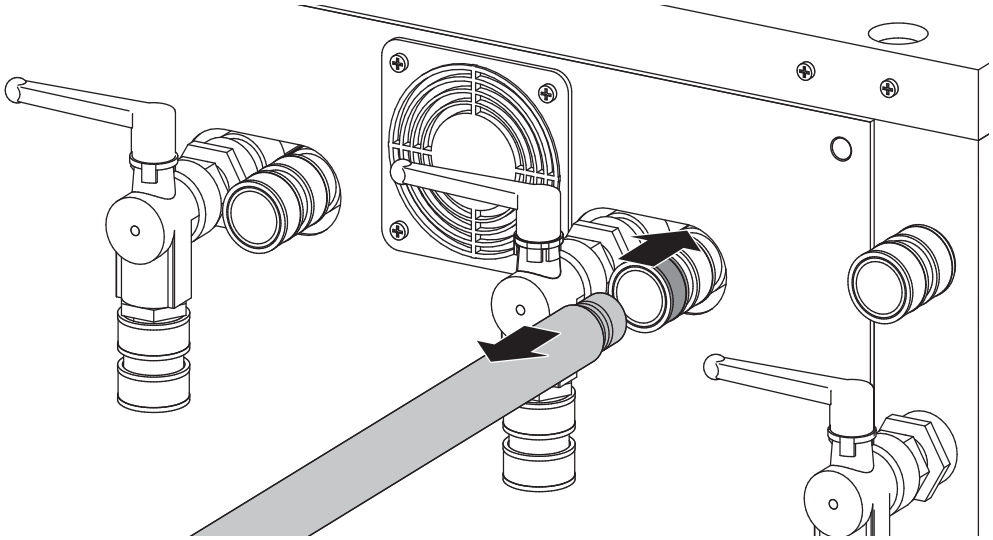


Fig. 9: Disconnecting the tubings

To disconnect a tubing from the heater-cooler:

- Empty the tubing system.
- Disconnect the tubing, push the locking ring of the Hansen connector toward the back panel of the base unit.
- Gently pull off the tubing.

4.2.3 Electrical connections

Power supply

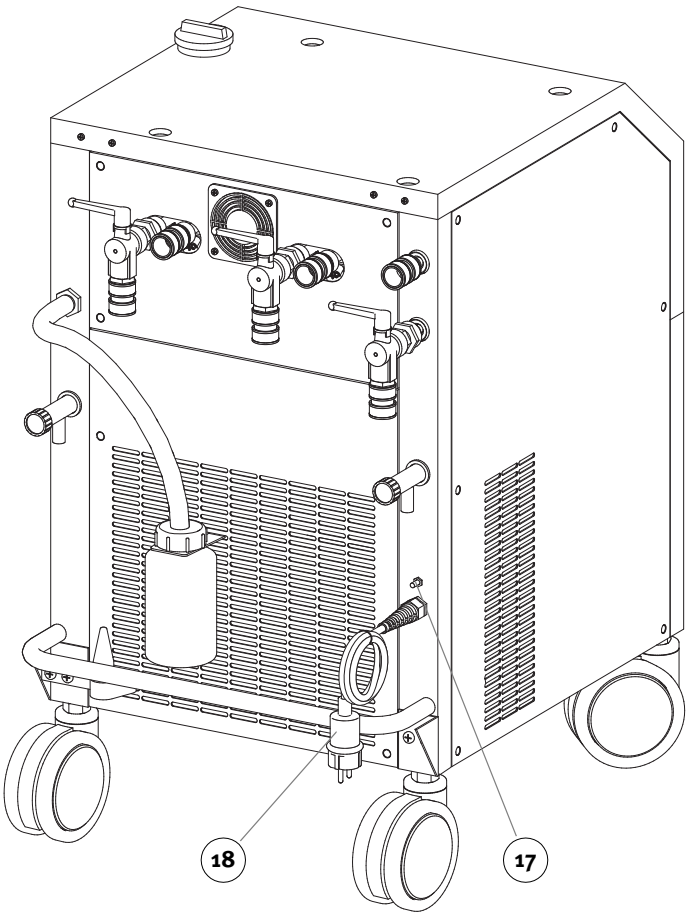


Fig. 10: Connection to the power supply

The heater-cooler requires an AC line rated at **16 A**. Ideally, the heater-cooler should be connected to a separate dedicated AC-line.

- Connect the equipotential equalization cable to the potential equalization point ⏚ **17** of the heater-cooler.
- Connect the other end to the potential equalization point at the operating room's central ground.
- Check if the voltage present in the OR correlates with the specifications indicated on the ID label attached at the rear of the device before connecting the unit to AC power.
- Connect the AC-cable **18** to an appropriate outlet.

Note (during operation):

The following applies when AC power is available again after a mains power failure:

Duration of power failure	
‹ 10 sec (less than 10 seconds)	➜ pumps restart automatically
› 10 sec (longer than 10 seconds)	➜ pumps have to be started manually

4.2.4 Operation with the S5/C5 System

No additional remote control modules are required for operation of the heater-cooler with the S5/C5 System.
No further connections or steps are necessary.

Notes:

5 Operation

Please read the following chapter thoroughly **before** operating the heater-cooler for the first time.

!

5.1 General information

The heater-cooler can be operated individually.

5.2 Filling the water tanks

The three tanks for the patient circuits and the cardioplegia circuit (warm/cold) are filled via the common filler neck **3**.

Note:
Pay attention to hand hygiene and protective barriers by disinfecting your hands and using disposable gloves.

Please take note of the following information related to filling the tanks:

- Use filtered tap water that has been filtered by using e.g. a disposable Pall-Aquasafe water filter with an 0.2 µm membrane (Pall part reference in the U.S.: "AQINA"; "AQIN" in other countries). Alternatively, use a filter of equivalent performance that meets the requirements for bacterial retention according to the ASTM standard*, i.e. which retains Brevundimonas diminuta to ≥ 10^7 CFU/cm^2 of effective filtration area.

* (American Standard Test Method F838-05 "Determining Bacteria Retention of Membrane Filters Utilized for Liquid Filtration")

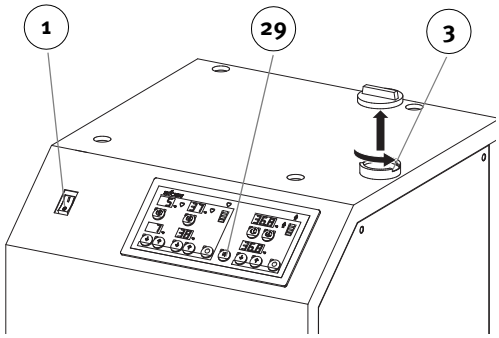
Note:
Do not use de-ionized or reverse osmosis processed water. This water can cause deterioration on the refrigeration system.

- In order to prevent microbial growth, add 150 ml (5 US fl. oz.) of medical grade 3% hydrogen peroxide solution to the tank contents.

Note:
Medical grade 3% hydrogen peroxide solution mixed with filtered tap water at a 1:91 ratio results in a concentration of use dilution of 1.1% (the outcome of this is a peroxide concentration of 330 ppm).

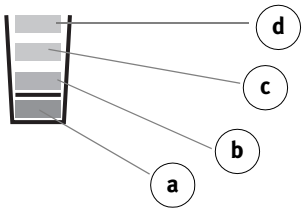
- Pay attention to the expiry date and storage conditions for hydrogen peroxide.
- If you need to refill water, pre-mix medical grade 3% hydrogen peroxide solution with filtered tap water at a 1:91 ratio (e.g. 10 ml (0.4 US fl. oz.) hydrogen peroxide mixed with 910 ml (34 US fl. oz.) filtered tap water). Add the mixture to the tank until the second green LED **d** of the water level display for the patient circuit lights up (see illustration on page 5.4).
- Check the correct functioning of the water level displays when changing or disinfecting the water. After the tank contents have been drained, the bottom segments of both displays must light up (red).

Filling the water tanks



- Switch on the heater-cooler (by pressing the mains power switch **1**) in order to use the water level displays.
- Press the key *Audio alarm off* **29**.
- Remove the cover of the filler neck **3** by turning it 90° counterclockwise.
- Fill the tanks. Internally, the tanks are filled in the following order:
  - ➜ cardioplegia cooling circuit
  - ➜ cardioplegia heating circuit
  - ➜ patient circuit

Explanation of the colors in the water level display

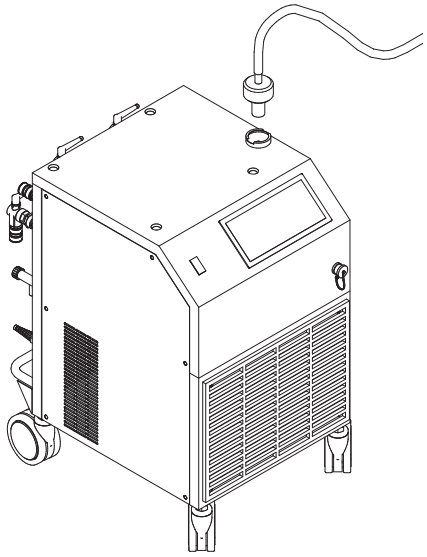


Segment **a**: red

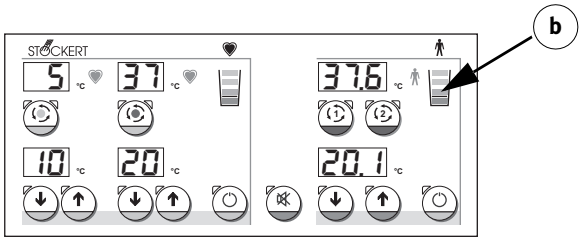
Segment **b**: orange

Segment **c**: green

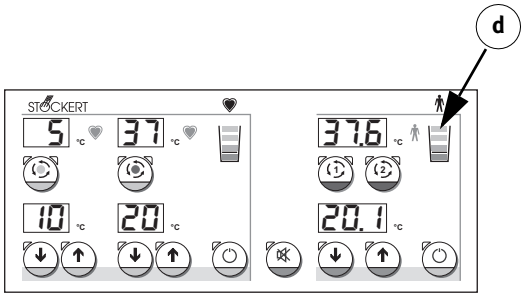
Segment **d**: green

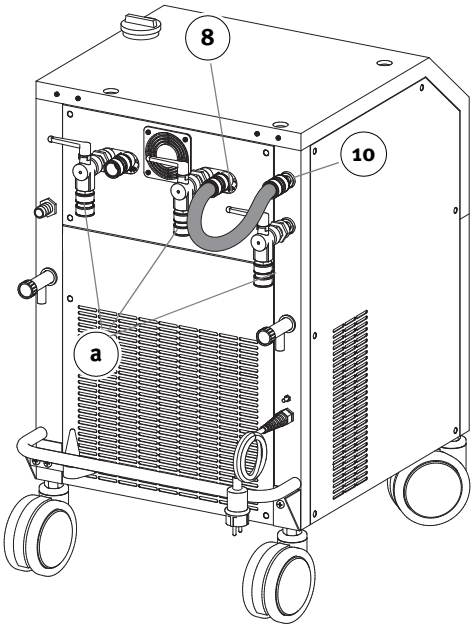


- Fill the water tanks with filtered tap water until the orange LED **b** of the water level display for the patient circuit lights up.



- Pour 150 ml (5 US fl. oz.) of medical grade 3 % hydrogen peroxide solution into the tank using a measuring cup.
- Complete filling the tanks with filtered tap water until the second green LED **d** of the water level display for the patient circuit lights up.



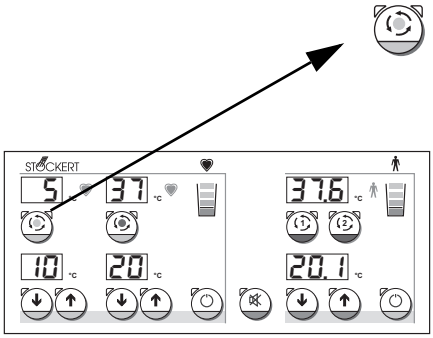


To ensure a homogeneous hydrogen peroxide solution in all of the water tanks:

- Close and lock the cover by turning it 90° clockwise.
- Close the three venting valves **a** at the rear of the heater-cooler.
- Establish a connection between the inlet of the cardioplegia circuit **10** and the inlet of the patient circuit **8**.

Please note that a temperature alarm can be triggered if the temperature deviates in the individual tanks.
To avoid this alarm, adjust the set temperature values of the warm cardioplegia circuit and the patient circuit to 20°C (68°F). Set the cold cardioplegia circuit to 10°C (50°F).
(see chap. 5.4.1 “Adjusting the set values”)

Mixing the tank content



- Press the key *Circuit Start/Stop* **31** on the heater-cooler to start the **cooling** circuit (cooling tank = blue dot).
- ➜ The green key LEDs flash alternately.

- After 5 minutes, press the key *Circuit Start/Stop* **31** again to stop the circuit.

The mixing process is completed.

- Disconnect the inlet of the cardioplegia circuit **10** from the inlet of the patient circuit **8** and connect the required tubings of the water circuits.

5.3 Powering up and configuring the heater-cooler

The heater-cooler is powered independently of the HLM System. As soon as the heater-cooler is powered up, either the heating and/or the cooling is activated since the last set temperature values have been saved.

5.3.1 Power-up and self-test

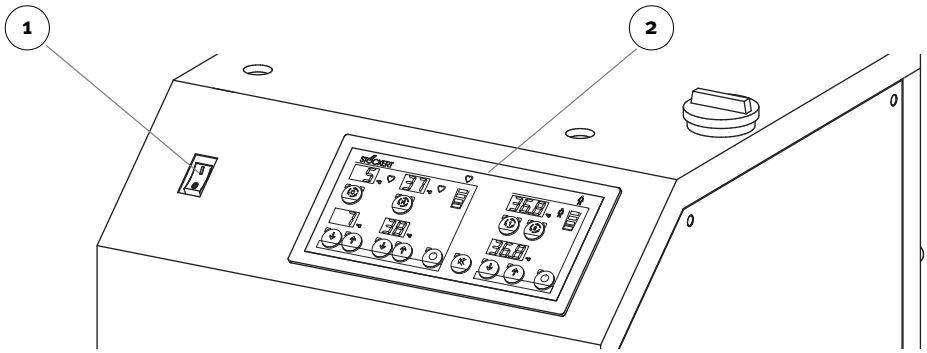


Fig. 11: Powering up the heater-cooler

Powering up

- Set the mains power switch **1** to position “I”.
- ➜ The heater-cooler runs a self-test during power-up.
- ➜ For a duration of 2 seconds, all LEDs and 7-segment displays on the control panel **2** are activated. A beep tone sounds simultaneously. Ensure the correct functioning of all displays in order to avoid misinterpretations caused by defective displays.
- ➜ Then, the version number of the device’s firmware (EPROM) is displayed for the duration of about one second. This displayed number and the version number indicated in the operating instructions (please refer to the inner front cover) should be identical. SORIN GROUP DEUTSCHLAND GMBH will furnish you with the corresponding authorized version of the operating instructions upon request.
- ➜ The heater-cooler is powered up.

Switching off unused functional groups (standby mode)

- For switching off a certain functional group, press key **28** on the heater-cooler.
- ➜ The unused functional group is set to the standby mode, the remaining functional group is fully operational.

Powering down completely

- Set the mains power switch **1** to position “o”.

5.3.2 Displays after power-up

If all of the heater-cooler displays flash, the device is in service mode. Only qualified service personnel is allowed to use this operating mode for test and diagnostic purposes.
It must, **under no conditions**, be used during the operation. Power the heater-cooler down and then up again to close the service mode.

!

Displays after successful completion of the self-test

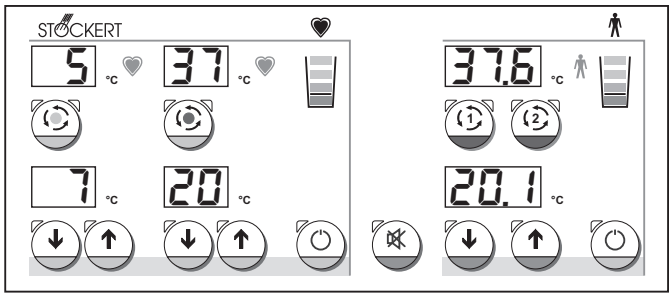


Fig. 12: Displays after power-up

After power-up and sucessful completion of the self-test, the following displays are shown:

- The green LEDs of the *Standby*-keys of the heater-cooler are not lit (here, the LEDs indicate the **active** standby mode and/or the powering down).
- The last set temperature values are displayed.
- The segments of the water level control (if filled correctly) display the corresponding maximum of the water level (both green LEDs are lit).

Heating or cooling starts immediately after power-up.

Error displays

In case of any error arising during the self-test, the following error codes are shown on the displays:

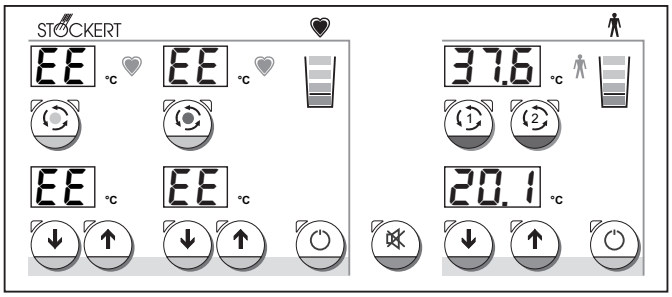


Fig. 13: Error displays

- The 7-segment display(s) show “EE(E)”, alternating with an error code (1...63). This display indicates an internal error of the heater-cooler. The circuit in question cannot be used. The other circuit, however, functions without restrictions.

For detailed information please refer to chap. 5.5 “Alarm and error displays” on page 5.13.

5.3.3 Function check prior to operation

The function check of the heater-cooler must be performed prior to each operation!

Check list: check during installation

- Has the heater-cooler been placed horizontally?
- Have the castor brakes been locked?
- Has the power supply cable been connected correctly?
- Did the water connectors click into place (Hansen connectors)?
- Have the water tubings been damaged or do they leak?
- Has the overflow bottle been mounted and connected?
- Is a replacement with compatible connectors ready for operation?
- If connected to the S5/C5 System: Has the control cable been connected?

Check list: check during and after powering up

Upon powering up:
- Do all LED- and 7-segment displays light up for 2 seconds during the self-test?
- Does the version number on the display correspond to the version number indicated on the inner front cover of the operating instructions?
- Was there a beep tone at the end of the self-test?

After powering up:
- Do the displays on the base unit indicate the correct functioning of the heater-cooler (see “Displays after successful completion of the self-test” on page 5.7)?
- Have you checked the water level?

In case of any “no”, please check and/or correct minor problems prior to use (leaking water tubings etc.). In case of any error displays on the heater-cooler (e.g. E-Codes), you cannot use

- the respective circuit or
- the heater-cooler base unit.

Please refer to cahp 5.5 “Alarm and error displays” on page 5.13 to find out which of the two possibilities mentioned above applies. If any such error occurs before operating the heater-cooler, please have the device checked by a service technician and use a substitute.

Having carried out all checks successfully, the heater-cooler is now ready for operation.

5.4 Operation of the heater-cooler

5.4.1 Adjusting the set values

Adjusting the set values on the heater-cooler

For adjusting the set values on the heater-cooler:

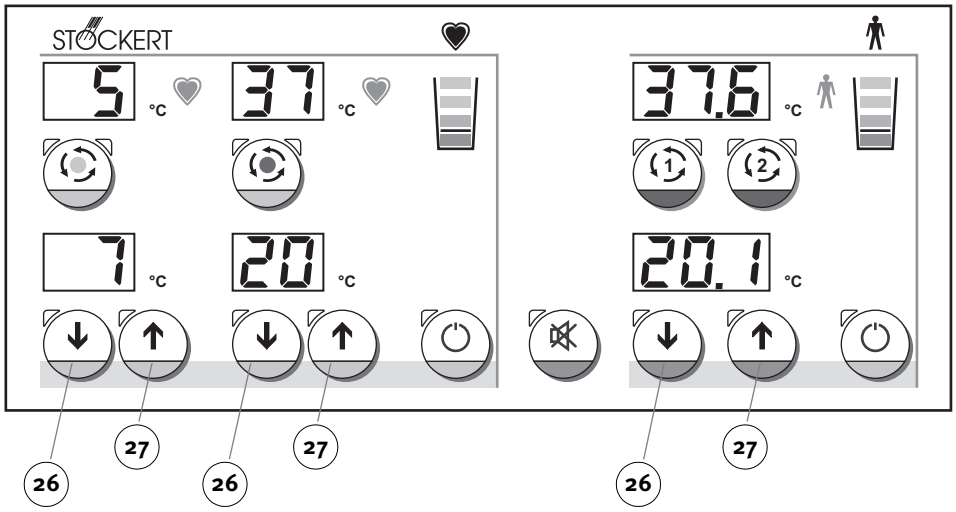


Fig. 14: Adjusting the set values on the base unit

- Press the arrow keys *Set value down* **26** / *Set value up* **27**, in order to change the set value.

➜ The green LED of the key in question flashes during the setting of the values. The new set value is only implemented, when the LED has stopped flashing.

Special key functions of the *Set value up/down* -keys:

- Pressing the arrow keys **once**, changes the values in steps of 0.1°C (patient circuit) and/or in steps of 1°C (cardioplegia circuit).
- The values can be changed by pressing the arrow keys continuously. The speed that the values change at accelerates as follows:

➜ initially, in steps of 0.1°C,

➜ then, in steps of 1°C

- Pressing the arrow keys once, immediately after having changed over a larger range of values, changes the values in steps of 1 °C. For example: You change the value from 27°C to 35°C by pressing the key continuously, then let go, then press the key twice. In doing so, the set value increases from 35°C to 37°C.
- Pressing one key continuously, and briefly pressing the second (opposite) key, causes the change in set value to shift to the next higher speed without delay.

If no further settings are made, the entry mode is stopped automatically after a brief timeout.

5.4.2 Starting and stopping circuits

Priming

Prior to using the heater-cooler for the operation, the external components of the circuits (tubings, heat exchanger) must be primed. When activating a circuit for the first time, an error message (**E08** on the display of the cardioplegia cooling circuit as well as **E19** and **E23** on the display of the patient circuits) is shown on the heater-cooler due to the air present in the tubing system.
During priming, these error messages are normal. They disappear as soon as the system is completely primed.

- Use the cardioplegia **cooling** circuit for priming.(Do not use the heating circuit for priming since an alarm is triggered which causes a pump stop)
- Only operate the system after the error messages have disappeared.
- After priming, check the water levels of the tanks. Refilling may be necessary, depending on the volume of the external circuit.

The cardioplegia circuit

The cardioplegia circuit can be supplied with water from either the heating or the cooling tank. The pumps are running continuously, the powering up/down and the cutover are subject to an internally controlled mechanism.

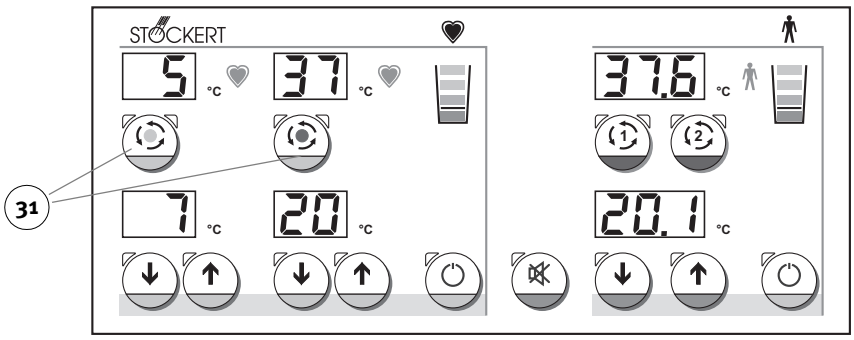


Fig. 15: Starting/stopping the cardioplegia circuit

Starting the cardioplegia circuit

Press the key *Circuit Start/Stop* **31** on the heater-cooler to start the required circuit (heating tank: red dot/cooling tank: blue dot).

➜ The circuit is supplied with water from the selected tank.

➜ The green LEDs on the key flash (alternatingly on the heater-cooler).

Stopping the cardioplegia circuit

Press the key *Circuit Start/Stop* a second time to stop the active circuit.
➜ The water supply is stopped.
➜ The green LEDs on the key are inactive.

Switching between the cardioplegia circuits

Press the key *Circuit Start/Stop* of the circuit which is inactive at present.
➜ Now, the selected tank supplies the circuit. This changeover takes about 5 seconds.
➜ The green LEDs on the key flash (alternatingly on the heater-cooler).

When activating the cardioplegia cooling circuit, it automatically has priority over the patient circuits. As a consequence, the cooling performance of the patient circuits is significantly reduced. Therefore, deactivate the cardioplegia cooling circuit at once, as soon as it is no longer required.

The patient circuits

The two patient circuits are supplied with water via two separate pumps (from a common tank).

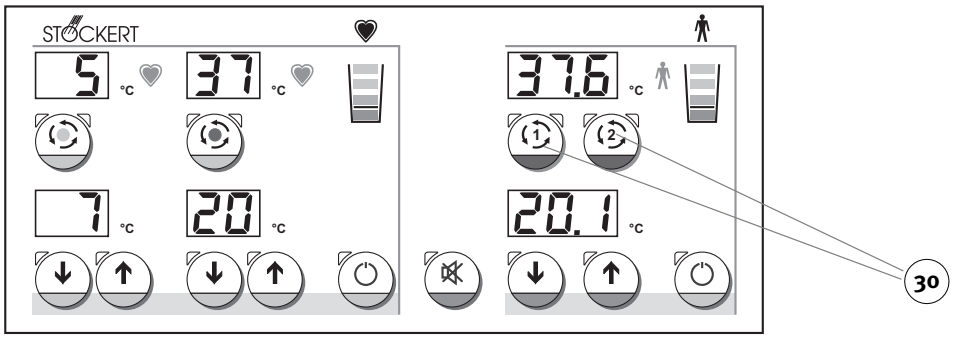


Fig. 16: Starting/stopping the patient circuit

Starting the patient circuit

Press the key *Circuit Start/Stop* **30** on the heater-cooler to start the required circuit.
➜ The pump of the selected circuit starts running.
➜ The green LEDs of the key flash (alternatingly on the heater-cooler).

Stopping the patient circuit

Press the key *Circuit Start/Stop* again to stop the activated circuit.
➜ The pump of the selected circuit stops.
➜ The green LEDs of the key have stopped flashing.

5.5 Alarm and error displays

If all of the heater-cooler displays flash, the device is in service mode. Only qualified service personnel are allowed to use this operating mode for test and diagnostic purposes.
It must, **under no conditions**, be used during the operation. Power the heater-cooler down and then up again to close the service mode.

!

5.5.1 Alarm displays

Operation-related alarms (i.e. no error code displays are shown simultaneously) only concern the circuit for which the alarm is displayed. The corresponding other circuit remains unaffected.

Water level alarm

Please note that the refilling of water (to the maximum water level) will have a brief influence upon the actual temperature of **all circuits** (dependent on the temperature of the refilled water).

!

◗ **Display** ➜ **Cause**	◗ **Effects** ➜ **Measures**
 ◗ Water level display: The orange LED flashes	◗ This preliminary alarm has no direct influence upon operation.
➜ Preliminary stage of the water level alarm	➜ Refill filtered water immediately. A further decrease of the water level will trigger alarm and thus stop the water circuits.
 ◗ Water level display: The red LED lights up, the alarm tone sounds  ◗ The symbol of the corresponding circuit flashes	◗ The pumps of the corresponding circuit stop.
➜ The minimum water level has been reached	➜ Refill filtered water immediately. Then, the water circuit in question has to be restarted manually.

Temperature alarm

◗ **Display** ➜ **Cause**	◗ **Effects** ➜ **Measures**
◗ The symbol of the corresponding patient circuit lights up, the alarm tone sounds (on the control panel)	◗ The pumps of the corresponding circuit stop.
➜ Maximum deviations between the patient's temperature and the water temperature during heating/cooling have been exceeded	➜ You can keep the water circuit running (if neccessary) by continuously pressing the corresponding *Circuit Start/Stop* key. ➜ You may adjust the values for the maximum deviation ("Delta") on the H/C menu. ➜ You may wait until the deviation drops within the normal tolerance range again. Then, start the pumps again.
◗ The symbol of the corresponding circuit lights up, the alarm tone sounds ◗ The actual value temperature display shows **41°C** or more	◗ The pumps of the corresponding circuit stop.
➜ Temporary temperature deviation during operation	➜ Wait a for short time until the temperature stabilizes at its set temperature, restart the pumps.
➜ Excess temperature, Defective temperature control	➜ You may reoperate the circuit shortly by opening the overflow valve, allowing the water of the corresponding circuit to run out and by refilling it with cold water. This solution is, however, only suitable for an interim period and if no replacement unit is available, since the temperature control is out of order. ➜ Pass the heater-cooler on to your service technician.

5.5.2 Error displays

Most error messages indicating “Error Codes” simultaneously trigger alarms which always lead to a total standstill of the respective functional group. For example: An error in the temperature control of the cardioplegia circuit stops this circuit; the patient circuits, however, are not affected. Errors affecting the entire heater-cooler, lead to a total standstill of all circuits.

Error displays on the heater-cooler (base unit)

◗ Display ➜ Possible causes	◗ Effects ➜ Corrective measures
 ◗ Two or three dashes on one of the actual temperature 7-segment displays	◗ Incorrect or no actual temperature measurement
➜ Illogical values below 0°C or above 50°C indicate a defective temperature sensor	➜ The circuit in question cannot be used. Pass the device on to your service technician as soon as possible.
 ◗ “EE(E)” flashes on one or several 7-segment displays, alternatingly with an error code:	◗ Dependent on the kind of error (error code number), the error has an impact upon the function of – a single circuit or – the entire heater-cooler
During priming	
➜ **Error Code 08, 19, 23**:	◗ The error messages disappear as soon as the system is completely primed. See page 5.11
During operation	
➜ **Error Code 0... 59**: Error in the heater-cooler base unit	◗ The heater-cooler cannot be, or only partly be used. ◗ If this error only has an impact upon **one** circuit, the remaining circuit can be used. Only the affected circuit is non-operational. ➜ Notify the designated service technician.

You can try to clear the “Error Codes” by means of a “Cold start” (switch the unit off for about 10 seconds and restart).

- If the error code remains, there is in any case a defect and the device should not be used.
- If the error code is cleared, the heater-cooler should be checked by the designated service technician at the earliest opportunity.

6 Routine maintenance

Regular maintenance and care are important factors for the operation of the heater-cooler as they result in operational safety, reliability and increased service life.

The instructions for routine maintenance, given in the following sections, are part of the operating conditions for the heater-cooler. This applies to the routine maintenance performed by the user of the heater-cooler, as well as to the preventive maintenance and safety checks performed by SORIN GROUP representatives or competent service personnel.

!

The heater-cooler has no user-serviceable internal components. All service must be performed by SORIN GROUP or qualified personnel.

!

6.1 General instructions for maintenance

6.1.1 Safety instructions for routine maintenance

- It is essential for the safe operation of the heater-cooler that the hygiene measures (cleaning and disinfection) are carried out regularly and completely.
- Disconnect the heater-cooler from the power supply and empty the water tanks prior to carrying out routine maintenance.
- The water circuits must be disinfected prior to operating the heater-cooler for the first time and when placing the system in storage. The heater-cooler water circuits include the pump, heating and cooling tanks, fittings and all interconnecting tubing. Detailed information on this subject is provided in chap. 6.3.
- Re-use of disposables, in particular of single-use heating blankets, is not allowed. Re-used heating blankets are a breeding ground for microbes and can lead to the contamination of the heater-cooler.
- Only use tubings that are certified for drinking water systems.
- Do not fail to observe the regulations concerning routine maintenance, as well as the prescribed maintenance intervals stated in these operating instructions.
- Only use cleaning agents and disinfectants in compliance with chap. 6.2 and 6.3.
- Wear protective gloves when cleaning and disinfecting the system!
- Wear protective goggles during the disinfection process.
- Wear protective gloves when disconnecting used tubing systems and disposables!
- All ventilation grills must be cleaned at regular intervals or in case of contamination. Detailed information on this subject is provided in chap. 6.6.
- Routine maintenance work must only be performed by qualified personnel.
- Repairs must only be carried out by authorized service technicians. Only original spare parts from SORIN GROUP DEUTSCHLAND GMBH may be used in order to guarantee the safe functioning of the heater-cooler.

6.1.2 Timelines for disinfection and related tasks

Time / Interval	Task	For details refer to ...
◗ prior to inital operation ◗ prior to storing the heater-cooler	➜ surface disinfection and disinfection of water circuits	chap. 6.2 and chap. 6.3
◗ after every operation	➜ surface disinfection	chap. 6.2
◗ every 7 days	➜ water change; add hydrogen peroxide to the tanks ➜ disinfection of overflow bottle	chap. 6.4 chap. 6.9
◗ every 14 days (also applies for systems in storage)	➜ disinfection of water circuits	chap. 6.3.1
◗ once per year	➜ exchange the tubings used with the system	chap. 6.7

6.1.3 Regular maintenance checks by authorized service technicians

According to the European Directive 93/42 and other national standards
SORIN GROUP DEUTSCHLAND GMBH defines that a preventive maintenance check has to be carried out after every 1,000 operating hours or at least after every 12 months, whichever comes first.

This preventive maintenance includes but is not limited to
- Status checks
- Electrical safety checks
- Operational safety checks
- Status of the water circuits/ tanks for calcification and biofilm
- Decalcification and/or disinfection as needed

The operator/owner is responsible for assignment of this preventive maintenance to SORIN GROUP representatives or qualified service personnel

6.1.4 Disposal in accordance with environmental regulations

- The heater-cooler is not subject to disposal in accordance with EU directive 2002 96 EC WEEE or the derivative German ordinance ElektroG because it must be regarded as potentially infectious at the end of its life cycle.

- All disposables used in conjunction with the heater-cooler must be disposed of in accordance with the local environmental regulations. Observe hospital regulations when disposing of these items.

- The cooling circuit of the heater-cooler is filled with a CFC-free HFC-(hydrofluorocarbons) refrigerant. Please see the system label for further information about the type and volume of the refrigerant to be used. Repair work on the cooling circuit and disposal of the refrigerant must only be performed by an expert for refrigerant systems.

6.2 Cleaning and disinfection of surfaces

Apart from the hygienic aspect, it is essential for the operational safety of the heater-cooler that the system is clean. Perform the following cleaning routine **every time the system has been used**.

- Close the CAN-jack with the matching cover.

Required material

– ready-to-use disinfectant tissues

The following disinfectant tissues have been tested for material compatibility with the heater-cooler:

Product name	Manufacturer
Bacillol	Bode
CaviWipe	Metrex
Super Sani Cloth	PDI
Meliseptol HBV	B. Braun
Mikrozid AF	Schülke & Mayr

- **Clean all accessible system surfaces.**
  - ➜ Use pre-soaked, ready-to-use disinfectant tissues.
  - ➜ Always wipe off spills (blood, etc.) from the system immediately.
  - ➜ **Never** use cleaning agents containing oil or grease.
  - ➜ **Never** use cleaning agents containing acetone, as these may cause damage to the plastic components and painted surfaces.
  - ➜ Avoid using cloths which cause static charge (polyester, etc.).
  - ➜ Liquids must not enter the housing. Therefore, do not use sprays.

- **Disinfect all accessible system surfaces.**
  - ➜ Use pre-soaked, ready-to-use disinfectant tissues.
  - ➜ The disinfectant tissues must be approved by the manufacturer for surface disinfection on medical devices.
  - ➜ No disinfectant residue must remain on the treated surfaces.
  - ➜ When disinfecting, ensure that no liquids enter the housing.

6.3 Disinfection of the water circuits

Prior to operating the heater-cooler for the first time, when placing the system in storage and **during regular operation,** the water circuits must be disinfected at intervals of 14 days.

The Heater-Cooler 3T water circuits include the pump, heating and cooling tanks, fittings and all interconnecting tubing.

For disinfection of the water circuits, use Clorox Regular Bleach (active ingredient: 8.25% sodium hypochlorite), Minncare Cold Sterilant or another SORIN GROUP approved disinfectant.
Note that Clorox Regular Bleach and Minncare Cold Sterilant have been tested for the use with the heater-cooler. Other disinfectants with the same peracetic acid or sodium hypochlorite concentration can contain different additives which may influence the material compatibility. Thus, the use of any other disinfectant is explicitly not recommended.

- During the disinfection cycle, thoroughly follow the manufacturer's safety instructions that are provided with Clorox Regular Bleach or Minncare Cold Sterilant.
- Clorox Regular Bleach or Minncare Cold Sterilant must only be used pre- and postoperatively, **never during a surgical intervention**.
- Pay attention to hand hygiene and protective barriers by disinfecting your hands and using disposable gloves.

Required material

Material for filling the water tanks:

- Pall-Aquasafe water filter with an 0.2 µm membrane (Pall part reference in the U.S.: “AQINA”; “AQIN” in other countries) or a filter of equivalent performance meeting the requirements for bacterial retention according to the ASTM standard*
- tube for filling the tank
- 3 short circuit tubing bridges (part number 73-300-160)

* Filter retains Brevundimonas diminuta to ≥ 10^7 CFU/cm^2 of effective filtration area (American Standard Test Method F838-05 “Determining Bacteria Retention of Membrane Filters Utilized for Liquid Filtration”)

Material for disinfecting the water circuits:

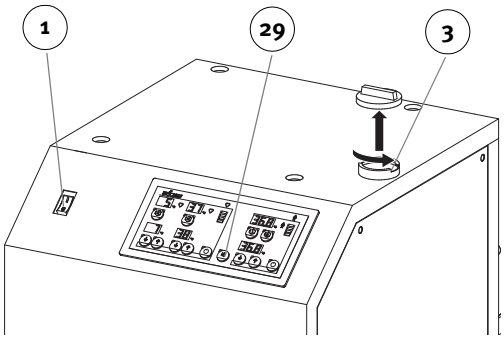
- Pall-Aquasafe water filter with an 0.2 µm membrane (Pall part reference in the U.S.: “AQINA”; “AQIN” in other countries) or a filter of equivalent performance meeting the requirements for bacterial retention according to the ASTM standard*
- tube for filling the tank
- 3 short circuit tubing bridges (part number 73-300-160)
- 1 measuring cup with a minimum capacity of 500 ml
- Clorox Regular Bleach (active ingredient: 8.25% sodium hypochlorite) or Minncare Cold Sterilant

* Filter retains Brevundimonas diminuta to ≥ 10^7 CFU/cm^2 of effective filtration area (American Standard Test Method F838-05 “Determining Bacteria Retention of Membrane Filters Utilized for Liquid Filtration”)

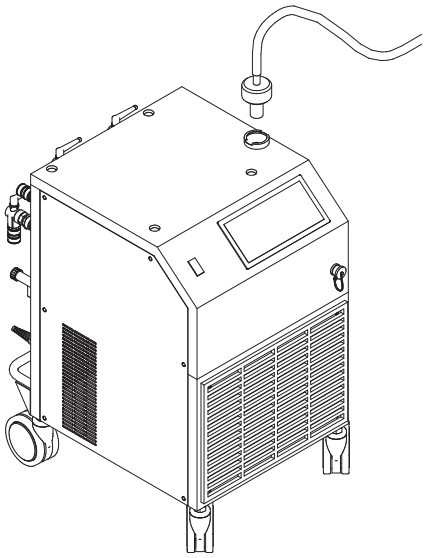
Material for draining:

- one or two buckets with a capacity of 10 l each
- cellulose tissues for removing liquid spills

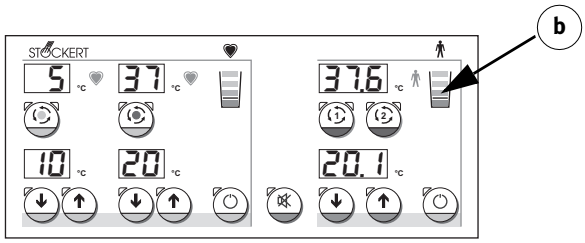
6.3.1 Disinfection procedure



- Make sure that the heater-cooler is switched off.
- Drain the water tanks.
- Make sure that the three venting valves at the rear of the heater-cooler are closed.
- Press the mains power switch **1** to power up the heater-cooler.
- Press the key *Audio alarm off* **29**.
- Remove the cover of the filler neck **3** by turning it 90° counterclockwise.



- Fill the water tanks with filtered tap water until the orange LED **b** of the water level display for the patient circuit lights up.



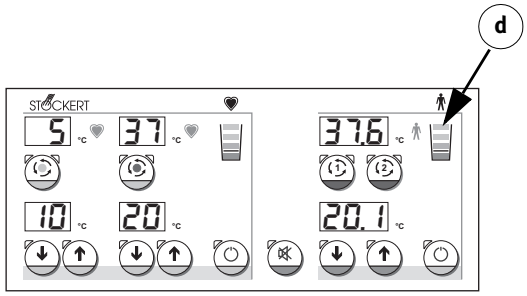
- Dose the disinfectant to be used (Minncare Cold Sterilant or Clorox Regular Bleach) with a measuring cup:

➜ 450 ml (15 US fl. oz.) of concentrated Minncare Cold Sterilant
Note: Minncare Cold Sterilant mixed with filtered tap water at a 1:30 ratio results in a concentration of use dilution of 3.3%.

OR

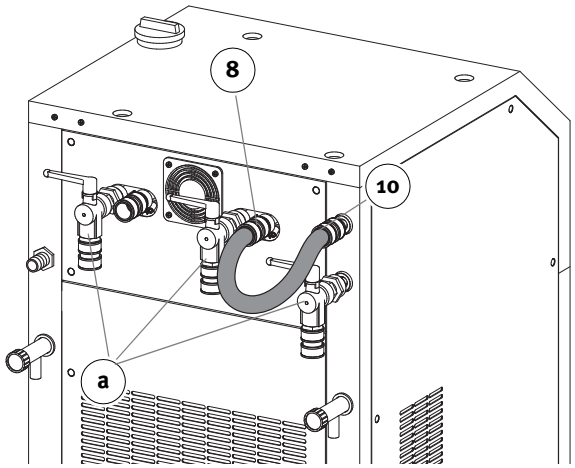
➜ 180 ml (6 US fl. oz.) of concentrated Clorox Regular Bleach
Note: Clorox Regular Bleach solution (active ingredient: sodium hypochlorite concentration 8.25%) mixed with filtered tap water at a 1:77 ratio results in a concentration of use dilution of 1.3%.

- Pour the disinfectant into the water tanks.
- Complete filling the tanks with filtered tap water until the second green LED **d** of the water level display for the patient circuit lights up.



To ensure a homogeneous disinfectant distribution in all of the water tanks:

- Close the cover of the filler neck.
- Make sure that the three venting valves **a** at the rear of the heater-cooler are closed.
- Establish a connection between the inlet of the cardioplegia circuit **10** and the inlet of the patient circuit **8**.



Please note that a temperature alarm can be triggered if the temperature deviates in the individual tanks.
To avoid this alarm, adjust the set temperature values of the warm cardioplegia circuit and the patient circuit to 20°C (68°F). Set the cold cardioplegia circuit to 10°C (50°F).
(see chap. 5.4.1 “Adjusting the set values”)

Starting the cold cardioplegia circuit

- Press the key *Circuit Start/Stop* **31** on the heater-cooler to **start** the **cooling** circuit (cooling tank = blue dot).

➜ The green key LEDs flash alternately.

- After 5 minutes, press the key *Circuit Start/Stop* again to stop the circuit.

Disinfection of the tubing system (circulation through all circuits)

- Disconnect the inlet of the cardioplegia circuit **10** from the inlet of the patient circuit **8**.
- Establish connections between all circuits (connect **5** to **6**, **7** to **8**, **9** to **10**). For the short circuit of the tubing, use a suitable short circuit adapter **a** (part number 73-300-160). Short circuit the unused connection(s) with a suitable piece of short circuit tubing (consisting of a tube and two suitable plug connectors).
- Open the three venting valves at the rear of the heater-cooler.

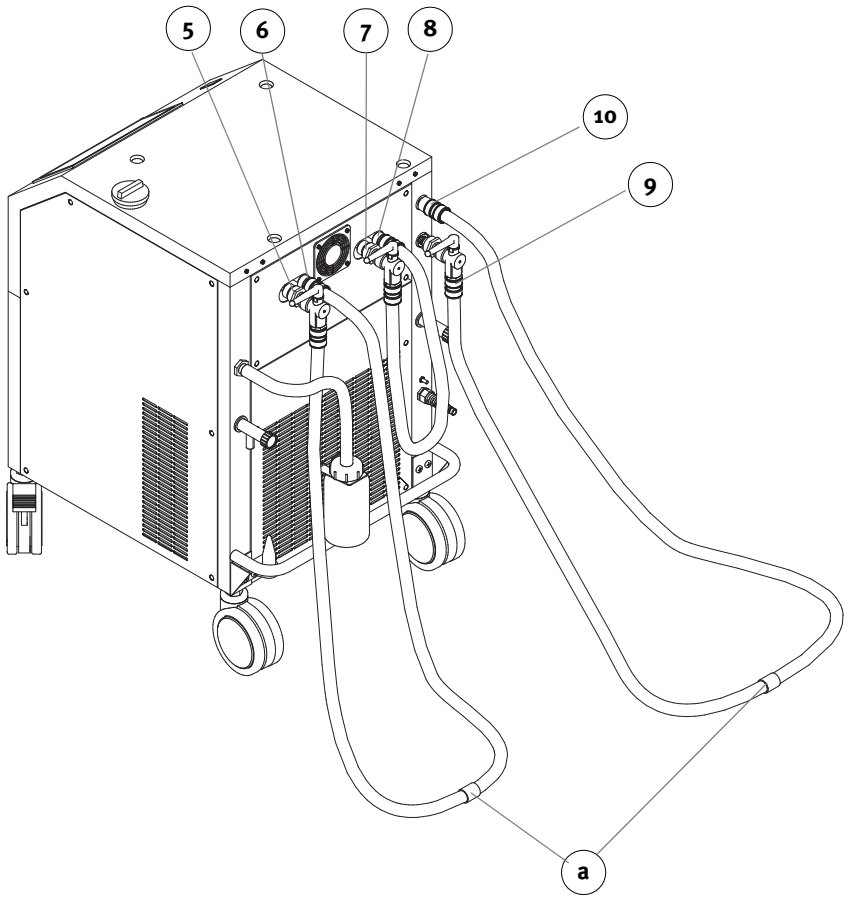
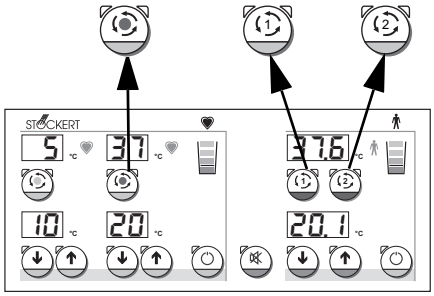


Fig. 17: Heater-cooler ready for circulation through all circuits

a	Short circuit adapter for connecting the inlet and outlet tubing
5 + 6	Patient circuit 2
7 + 8	Patient circuit 1
9 + 10	Cardioplegia circuit

Starting circulation in patient circuit 1 and 2 and in the warm cardioplegia circuit



- Press the keys *Circuit Start/Stop* **30** and **31** of the warm cardioplegia circuit (heating tank = red dot) and of the patient circuit to start the circuits.

➜ The green key LEDs flash alternately.

The circulation in the circuits changes the water level.

➜ If the orange LED flashes, add 0.5 l to 1 l (17 US fl. oz. to 34 US fl. oz.) of filtered water.

An alarm is triggered if the level drops any further (see "Water level alarm" on page 5.19).

Stopping circulation in the circuits

- End the disinfection cycle after 10 minutes. By closing the venting valves at the rear of the heater-cooler during ongoing circulation, the pumps will drain the tubing completely.
- Press the keys *Circuit Start/Stop* **30** and **31** of the warm cardioplegia circuit (heating tank = red dot) and of the patient circuit to stop all circuits.

➜ Water circulation is stopped.

➜ The green LEDs of the keys *Circuit Start/Stop* go out.

Draining the water tanks

- Open the drain valves **11** and **12**.
- Drain the solution containing Clorox Regular Bleach or Minncare Cold Sterilant. Use buckets and observe hospital regulations when disposing of these items.

To remove residual disinfectant solution from the system, rinse the tanks after every disinfection cycle two (2) times as follows:

- Make sure that the drain valves **11** and **12** are closed.
- Fill the tanks with filtered tap water.
- Press the keys *Circuit Start/Stop* **30** and **31** of the warm cardioplegia circuit (heating tank = red dot) and of the patient circuit to start the pumps.
- Let the water circulate for approx. 3 minutes.
- By closing the venting valves at the rear of the heater-cooler during ongoing circulation, the pumps will drain the tubing completely.
- Press the keys *Circuit Start/Stop* **30** and **31** to stop circulation.
- Open the drain valves **11** and **12** and drain the water.

Filling the tanks for heater-cooler operation

- Fill the tanks for operation as described in chap. 5.2.

6.4 Changing the water

The water in the water circuits must be changed every 7 days.
In order to prevent microbial growth, add 150 ml (5 US fl. oz.) of medical grade 3% hydrogen peroxide solution to the tank contents.

Note:
Medical grade 3% hydrogen peroxide solution mixed with filtered tap water at a 1:91 ratio results in a concentration of use dilution of 1.1% (the outcome of this is a peroxide concentration of 330 ppm).

Note:
Pay attention to hand hygiene and protective barriers by disinfecting your hands and using disposable gloves.

Note:
Do not use de-ionized or reverse osmosis processed water. This water can cause deterioration on the refrigeration system.

- Drain the water tanks and ensure that the drain valves are closed once the tanks are empty.
- Fill the tanks as described in chap. 5.2.

Note:
The hydrogen peroxide concentration in the water can be measured semiquantitatively during the draining procedure by visual comparison of the reaction zone of a test strip with the fields of a color scale (e.g. MQuant, Peroxide Test, Method: colorimetric with test strips, 100 - 1,000 mg/l H_2O_2, Reference 1.10337.0001). Before measuring, water should be drained for at least 10 seconds with fully opened drain valves.

The hydrogen peroxide concentration will decrease over the 7-day-period until the next water change, but should not drop below 100 ppm. If you measure concentrations below 100 ppm, perform the disinfection as described in chap. 6.3.1.

6.5 Preparing the heater-cooler for storage

To prepare the heater-cooler for storage, proceed as follows:

- Clean and disinfect the heater-cooler and the tubings in accordance with the instructions described in chap. 6.2 and chap. 6.3.
- Drain the tanks.
- Disconnect all tubings.
- Dry the tubings. Store the tubings in a dry place that is free of dust.
- Even during storage, the heater-cooler must be disinfected at intervals of 14 days, as described in chap. 6.3.

6.6 Cleaning the interior

The cleaning measures described below are required if the fan behind the grill **16** is running too quickly and/or too loudly. The likely cause for this is that dust has collected inside, inhibiting the air circulation.

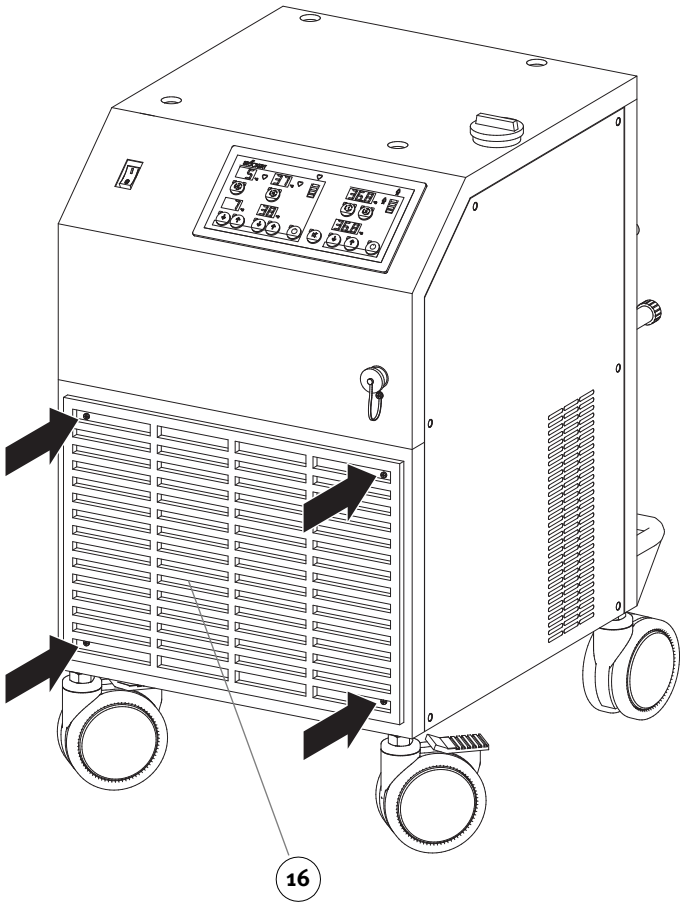


Fig. 18: Removing the ventilation grill

- Disconnect the heater-cooler from the AC prior to opening the housing.
- Remove the four screws holding the front side of the ventilation grill **16** and then remove the ventilation grill.

- **Only remove this ventilation grill.** The side and rear panels of the heater-cooler may, **under no conditions**, be opened.
- Clean the accessible areas of the interior with a vacuum cleaner or pressurized air.
- Remount the ventilation grill with all four screws.

6.7 Instructions for handling the tubings

- Include the tubings normally used with the heater-cooler in the disinfection procedure for the heater-cooler described in chap. 6.3.1. To this end, connect the tubings during the disinfection cycle to the heater-cooler.
- Tubings that are used with the heater-cooler must be replaced at least once a year.
- Only use tubings that are certified for drinking water systems, such as SORIN part number 75-510-218.

6.8 Safety checks and functional checks

Regularly check whether all system components are in perfect condition and operating correctly. Regular checks help to minimize or even exclude the risk of malfunctions during operation. For a detailed description of the functional check, please refer to chap. 5.3.4 “Function check prior to operation” on page 5.13.

6.8.1 Safety checks

Be sure to check the following components:

- All device plugs and sockets
  - ➜ Are the cable jackets tightly connected to the plugs?
  - ➜ Are the contacts clean?
  - ➜ Are the plugs mechanically undamaged (housing, bent pins)?
  - ➜ Are all sockets attached firmly to the respective housings?

- All cables
  - ➜ Are all cable jackets undamaged along the entire length of the cable (cracks, cuts, clearly visible kinks)?

- Water circuits
  - ➜ Are the water tubings free from damage and leaks?
  - ➜ Are the fast (Hansen-type) connectors clean, free from damage and leaks?
  - ➜ Do the Hansen connectors lock/unlock smoothly?

If the answer is “**no**” to any of these questions, use the system only after the defects have been rectified:

- ➜ Clean the system at once, if required.
- ➜ Replace defective accessories.
- ➜ If you cannot rectify the defects yourself (e.g. in cases of loose or damaged sockets), pass the heater-cooler on to an authorized service technician.
- ➜ Have defective accessories checked by the service technician.

6.9 Check lists: maintenance intervals

Use the following check lists to ensure that the full scope of the maintenance and inspection routines are carried out when they are due.

Check list: daily or every time the device has been used

- Dispose of used disposables in accordance with environmental regulations (wear protective gloves). ✓
- Empty the overflow bottle.
- Automatic chemical-thermal disinfection in a washer-disinfector at intervals of 7 days is recommended for the overflow bottle.
- Clean the heater-cooler in compliance with the instructions given in chap. 6.2 “Cleaning and disinfection of surfaces”.
- Clean and check all accessories (tubings, blankets, etc.) as described in the separate operating instructions.
- Record the operating hours of the heater-cooler to ensure that the “regular preventive maintenance check” by an authorized service technician is scheduled when it falls due.
- Have defective or damaged components checked immediately by an authorized service technician.

Check list: additional maintenance intervals

In addition to the maintenance routines and checks which are performed daily: ✓

- **Every 1,000 operating hours or yearly**: Notify the authorized service technician for the regular preventive maintenance check of the heater-cooler.

Notes:

7 Appendix

7.1 Specifications

7.1.1 Dimensions, weights, operating conditions

Heater-cooler	
Width	500 mm (19.8 in.)
Height	840 mm (33.2 in.)
Depth	680 mm (26.8 in.)
Weight (empty)	110 kg (242.5 lbs.)

Operating conditions	
Operating temperature	+10°C/50°F through +35°C/95°F
Storage temperature	0°C /32°F through +40°C/104°F
Relative humidity (operation and storage)	30% through 75%
Operating altitude (atmospheric pressure)	0 ... 3,000 m (700 hPa ... 1060 hPa)

7.1.2 Electrical specifications

Heater-cooler	
Drip-proof	IPX1
Input current	16 A
Input voltage (Variants are device-specific)	240 V ~ / 60 Hz Allowed voltage tolerance: ± 10% max.
	208 V ~ / 60 Hz Allowed voltage tolerance: ± 10% max.
	120 V ~ / 60 Hz Allowed voltage tolerance: ± 10% max.
Please refer to the product label at the rear of the heater cooler to obtain detailed information about the specific input voltage of your device.	

7.1.3 General performance data

General data	
Heating performance (2x pat., 1x c-plegia)	3 x 1,350 W (input voltage 240 V ~)
	3 x 1,000 W (input voltage 208 V ~)
	3 x 650 W (input voltage 120 V ~)
Cooling performance	2.1 kW at an ambient and tank temperature of 20°C / 68°F
Noise level	≤ 56 dB (A)

Volume and flow	
Minimum level patient circuits	4.5 l (11.6 l total volume)
Maximum level patient circuits	6.5 l (13.8 l total volume)
Water flow patient circuits	15 - 17 l
Water flow cardioplegia circuit	9 - 11 l
Water pressure in the circuits	0.7 bar max. -0.3 bar min.

Temperature ranges	
Normal range patient circuits	from 2°C / 35.6°F through 41°C / 105.8°F ± 0.5°C / 0.9°F
Normal range cardioplegia-cooling circuit	from 2°C / 35.6°F through 10°C /50°F ± 2°C / 3.6°F
Normal range cardioplegia-heating circuit	from 15°C / 59.0°F through 41°C / 105.8°F ± 1°C / 1.8°F

7.1.4 Information about Global Warming Potentials

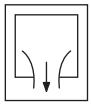
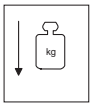
The cooling circuit of the heater-cooler is filled with a CFC-free HFC-(hydrofluorocarbons) refrigerant. Please see the device label and chap. 7.2 to obtain further information about the type and volume of the refrigerant.

Global warming potentials (abbreviation: GWP)

Refrigerant	R-134/HFC-134a The mixture of the refrigerant may vary.
GWP	1,300 GWP (according to IPCCIII (2001/ Appendix I): baseline data in EU F-gas regulation
Active life span	100 years according to IPCCII (1996) source document for the Kyoto protocol

7.2 Labeling and tagging

Designations and icons on the nameplates:

	Degree of protection against electrical shock: type B
	Protection class I
IPX1	Drip proof (vertical)
REF	Purchase order number
SN	Serial number
	Date of manufacture
	Manufacturer
	Potential equalization point
	Drain valve of the patient circuits, Drain valve of the cardioplegia circuit
	Follow instructions for use (white icon on blue background)
	General warning sign (yellow)
	A primed and filled heater-cooler must not exceed a total weight of 125 kg (275.5 lbs.).
Rx ONLY	Only applies in the U.S.A.: Sale (and prescription) is restricted to physicians

Tagging on the additional label:

This cooling system contains fluorinated greenhouse gases covered by the Kyoto protocol:		This cooling system contains fluorinated greenhouse gases covered by the Kyoto protocol:
Refrigerant:	R 134a	Refrigerant (R 134a) (Hydrofluorocarbons)
Filling charge:	1.1 kg	Filling charge
PS high pressure:	18 bar	PS high pressure
PS low pressure:	10 bar	PS low pressure

7.3 Part numbers

Heater-Cooler System 3T (240 V ~ / 60 Hz)		**16-02-81**
Heater-Cooler System 3T (208 V ~ / 60 Hz)		**16-02-82**
Heater-Cooler System 3T (120 V ~ / 60 Hz)		**16-02-85**

Accessories		
CAN connection cable for the S5/C5 System		**45-12-16**
Adapter cable for CAN connection cable 45-12-16		**45-12-92**

Heating/cooling blanket	dim. 55 x 150 cm (21.65 x 59.06 in.)	**16-10-50**
Tubing set for heating/cooling blankets		**16-10-55**
1 set of adapters for heating/cooling blankets		**16-10-10**
Tubing connector 1/2", 90° angle, with venting valve		**16-10-17**
Tubing connector 1/2", straight		**73-300-019**
Water tubing 1/2", blue	25 m	**75-510-218**
Hansen coupling for oxygenator, straight, 3/8" with 1/2" tubing insert		**73-300-089**
Hansen coupling for oxygenator, 90° angle, 3/8" with 1/2" tubing insert		**73-300-090**

Short circuit tubing bridge for 3/8" Hansen couplings, 3/8" with 1/2" tubing insert		**73-300-160**

Overflow bottle		**96-410-765**
Holder for overflow bottle		**96-410-766**
Potential equalization cable	5 m (16.4 feet)	**45-10-50**

Graduated beaker	250 ml	**74-400-611**

7.4 Accessories

Compatibility of the Heater-Cooler System 3T with the products listed in the table below has been tested by SORIN GROUP DEUTSCHLAND GMBH and is thus guaranteed.
The disposables listed must be used in compliance with their separate operating instructions:

Product	**Manufacturer**
Heating/cooling blanket dim. 55 x 150 cm (21.65 x 59.06 in.)	Cincinnati Sub-Zero
Oxygenator	Sorin
Heat exchanger for cardioplegic solutions	Sorin
Tubing set/cardioplegia tubing set	Sorin

SORIN GROUP DEUTSCHLAND GMBH assumes no responsibility for the use of components other than those listed above; nor is such usage covered by warranty.

7.5 Warranty

The contractually agreed upon warranty conditions are valid.

7.6 Information about electromagnetic compatibility (EMC) for 240 V ~ and 208 V ~ System

7.6.1 Guidance and manufacturer's declaration

Note:
Medical electrical equipment needs precautions regarding electromagnetic compatibility and has to be installed and put into service according to the EMC information provided in the following guidance and the manufacturer's declaration.

Portable and mobile RF-communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emission

The Stöckert Heater-Cooler System 3T is intended for use in the electromagnetic environment specified below. The customer or the user of the Stöckert Heater-Cooler System 3T should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Stöckert Heater-Cooler System 3T uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Stöckert Heater-Cooler System 3T 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 and IEC 61000-3-2	Complies	However, the device must only be connected to a power supply network the impedance of which is less than or equal to 0.391Ω + j0.244Ω . [a]

[a] NOTE: Only for Heater-Cooler System 3T 240 V ~ and 208 V ~ .

Guidance and manufacturer's declaration – electromagnetic immunity

The Stöckert Heater-Cooler System 3T is intended for use in the electromagnetic environment specified below. The customer or the user of the Stöckert Heater-Cooler System 3T should assure 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 ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for sensor lines	± 2 kV for power supply lines ± 1 kV for sensor lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	‹ 5 % UT (›95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles ‹ 5 % UT (›95 % dip in UT) for 5 sec	‹ 5 % UT (›95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles ‹ 5 % UT (›95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Stöckert Heater-Cooler System 3T requires continued operation during power mains interruptions, it is recommended that the Stöckert Heater-Cooler System 3T be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a. c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The Stöckert Heater-Cooler System 3T is intended for use in the electromagnetic environment specified below. The customer or the user of the Stöckert Heater-Cooler System 3T should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Stöckert Heater-Cooler System 3T, 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	3 V_{eff} 150 kHz to 80 MHz	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (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.
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 should be considered. If the measured field strength in the location in which the Stöckert Heater-Cooler System 3T is used exceeds the applicable RF compliance level above, the Stöckert Heater-Cooler System 3T should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Stöckert Heater-Cooler System 3T.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Stöckert Heater-Cooler System 3T

The Stöckert Heater-Cooler System 3T is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Stöckert Heater-Cooler System 3T can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Stöckert Heater-Cooler System 3T as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7.7 Information about electromagnetic compatibility (EMC) for 120 V ~ System

7.7.1 Guidance and manufacturer's declaration

Note:
Medical electrical equipment needs precautions regarding electromagnetic compatibility and has to be installed and put into service according to the EMC information provided in the following guidance and the manufacturer's declaration.

Portable and mobile RF-communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emission

The Stöckert Heater-Cooler System 3T is intended for use in the electromagnetic environment specified below. The customer or the user of the Stöckert Heater-Cooler System 3T should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Stöckert Heater-Cooler System 3T uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Stöckert Heater-Cooler System 3T 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	not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3 and IEC 61000-3-2	not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The Stöckert Heater-Cooler System 3T is intended for use in the electromagnetic environment specified below. The customer or the user of the Stöckert Heater-Cooler System 3T should assure 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 ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for sensor lines	± 2 kV for power supply lines ± 1 kV for sensor lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	‹ 5 % UT (›95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles ‹ 5 % UT (›95 % dip in UT) for 5 sec	‹ 5 % UT (›95 % dip in UT) for 1/2 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles ‹ 5 % UT (›95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Stöckert Heater-Cooler System 3T requires continued operation during power mains interruptions, it is recommended that the Stöckert Heater-Cooler System 3T be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a. c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The Stöckert Heater-Cooler System 3T is intended for use in the electromagnetic environment specified below. The customer or the user of the Stöckert Heater-Cooler System 3T should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Stöckert Heater-Cooler System 3T, 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} 150 kHz to 80 MHz	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (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.
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 should be considered. If the measured field strength in the location in which the Stöckert Heater-Cooler System 3T is used exceeds the applicable RF compliance level above, the Stöckert Heater-Cooler System 3T should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Stöckert Heater-Cooler System 3T.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Stöckert Heater-Cooler System 3T

The Stöckert Heater-Cooler System 3T is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Stöckert Heater-Cooler System 3T can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Stöckert Heater-Cooler System 3T as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7.8 Technical description

Note:
The use of cables other than those specified below may result in increased emissions or decreased immunity of the heater-cooler and/or the heart-lung machine.

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For detailed information about cables that may be used for the overall system, please refer to the relevant HLM operating instructions.

Cables/sensors	Length	Part no.
Potential equalization cable	5 m	**45-10-50**
Mains cable for heater-coolers with male connector "Hospital Grade Green Dot" or "Hospital transparent" (NEMA 6-20: for 240 V ~ or 208 V ~ supply) (NEMA 5-20: for 120 V ~ supply)	approx. 7 m	
CAN connection cable for the S5/C5 System	6 m	**45-12-16**
Adapter cable for CAN connection cable 45-12-16		**45-12-92**

Notes:

CE 0123