INSTRUCTIONS FOR USE

MAQUET
GETINGE GROUP

CARDIOHELP System

Validity of this document

Revision 2.3, issue date 2025-01

This document applies to the device CARDIOHELP-i with software release 03.04.10.00 or higher.

Documents for lower software releases do not apply to the device CARDIOHELP-i with software release 03.04.10.00 or higher.

CAUTION!

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

Subject to technical changes

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

Manufacturer

Maquet Cardiopulmonary GmbH
Kehler Strasse 31
76437 Rastatt
GERMANY
www.getinge.com
info.cp@getinge.com

Contents

1 General

1.1 Information on these Instructions for Use

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

1.1.1 Symbols

References

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

Action and reaction

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

Example:

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

Buttons and menus

The buttons and menus are shown in square brackets.

Example:

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

1.1.2 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
AC	Alternating current
DC	Direct current
Hb	Hemoglobin
Hct	Hematocrit
HF	High frequency
lpm	Liters per minute (unit)
rpm	Revolutions per minute (unit)

S_VO_2	Venous oxygen saturation
thApp	Therapy application

WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.
The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

2 Safety

2.1 Intended Purpose

2.1.1 Indications for Use

The CARDIOHELP System are devices that use a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

- Partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
- Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

2.1.2 Intended User

The CARDIOHELP System must be operated by trained medical staff only.

2.1.3 Intended Patients

The device can be used with the appropriate disposables for all patients irrespective of age, size and weight.

2.1.4 Intended Environment

The device is intended to be used in a surgical environment.

2.1.5 Contraindications

When the CARDIOHELP System is used as intended, no contraindications are known. Contraindications may, however, arise as a result of the use of a disposable with the CARDIOHELP System (⇨ Instructions for Use of relevant disposable).

2.1.6 Side Effects

If the flow stops during application, one possible side effect is that the heat of the motor can be transferred to the blood in the pump resulting in potential blood trauma, e.g. clotting.

2.2 General Safety Instructions

2.2.1 General Risks When Using the Device

Technical resources alone cannot ensure the safe use of the device. Because of this, the knowledge and skills of the user are critical.

WARNING!

- A lack of knowledge on use of the device can result in serious injuries to or death of the patient.
  - The system must be monitored and operated by qualified medical staff trained in cardiopulmonary bypass (⇨ "Intended User", page 13).
  - Patients who are supported by the CARDIOHELP System must be continuously monitored by a monitoring system and qualified medical staff.
  - The physician in charge of treatment is responsible for the procedure and correct use of the device.
- You should always keep a replacement unit on standby in order to ensure continuous operation in the event of a complete system failure.
- The improper use of the device can lead to insufficient patient care or to other life-threatening situations for the patient. The system must only be used in accordance with the respective Instructions for Use of the components used.
- The use of an improper tube set can lead to the ingress of air into the patient, to insufficient patient care or to other life-threatening situations for the patient. Check the integrity, completeness, and proper connection of the tube system before and during application.
  Observe the Instructions for Use for the disposables used.
  For the de-airing of the tube system, observe the Instructions for Use for the disposable used.
  Disposables which are exposed to mechanical shocks during transport (e.g., caused by falling) must be checked for damage.
  Always have disposables readily available to enable quick replacement during application.
- The improper connection of the oxygenator to the gas supply can lead to insufficient patient care or to other life-threatening situations for the patient or third parties. Check that the gas supply is correctly connected.
- The user may sustain burns when using the CARDIOHELP-i: With a high ambient temperature, a high flow rate, covered ventilation openings or defective fans, the CARDIOHELP-i and the connections for attaching the disposables may heat up to above 41°C.
  Check that the ventilation openings are not covered, reduce the ambient temperature and, where medically acceptable, reduce the flow rate. If a fan is defective, use a replacement device and have the fans replaced by authorized service personnel.

WARNING!

- During surgical use of the CARDIOHELP-i, the medical personnel must always be able to resuscitate and intubate the patient.
- Given the risk of negative pressure in the venous vascular system, all artificial venous vascular accesses (e.g., catheters and cannulae) must be protected against the ingress of air.
  Before placing the artificial vascular access, it must be de-aired. If administering medications to a patient, particular care must be taken to ensure they are delivered free of bubbles. Given the risk of negative pressure, a safety measure (ligature or similar) must be taken prior to the surgical opening of the venous vessel to prevent the ingress of air.

2.2.2 Position of Use and Operation and Positioning of the CARDIOHELP-i

The position of use is determined by the requirements of the disposable (e.g., only operate the oxygenator pump unit with gas inlet at the top and do not operate the disposable above the patient level).

The CARDIOHELP-i 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 CARDIOHELP-i 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).
- When you fix the CARDIOHELP Emergency Drive to the holder of the CARDIOHELP-i or to other holders provided, ensure that there is sufficient room to use the hand crank of the CARDIOHELP Emergency Drive.
- Ensure that you can see the touchscreen and LEDs of the CARDIOHELP-i as well as any optical warning signals at all times. In noisy environments, there is a risk that acoustic warning signals emitted by the CARDIOHELP-i may not be heard.
- Do not use the system in explosive environments or near escaping flammable or combustible gases.
- Ensure that the patient, user or third parties do not come into contact with the housing, plug connections or conducting parts when additional measures are being performed, e.g., defibrillation, or while the patient is connected to an electrical current.

WARNING!

- The use of this device directly next to other devices or stacked with other devices should be avoided since this could result in malfunction. If use as described above is nonetheless necessary, this device and the other devices should be observed to ensure that they are working properly.
- Only operate the CARDIOHELP-i within the specified ambient conditions (⇨ "Ambient Conditions", page 200).
  Ambient temperatures outside of the specified conditions can disrupt the sensors' measurements. This may result in incorrect measurements, which may cause incorrect values to be displayed and trigger alarms. There must be no risk of condensation. Condensation may occur when the device is taken from a cold environment into a warm room and vice versa.
- Do not attach any components to the CARDIOHELP-i other than the disposable, the CARDIOHELP Emergency Drive and the listed accessories (⇨ "Accessories", page 194). Otherwise, the limits of the safe workload may be exceeded and the mechanical stability of the CARDIOHELP-i may be affected.
- Check that the speaker opening is not covered. There is a risk that acoustic warning signals may not be heard.
- Ensure that the ventilation openings are not covered. There is a risk that the CARDIOHELP-i will overheat.
- Only operate the CARDIOHELP-i in RPM mode when using ultrasound devices.
- To avoid the risk of electric shock, this device may be connected only to a power supply with a protective ground conductor.
- If the CARDIOHELP-i is connected to the mains power supply, ensure equipotential bonding for protection against electrical shock, if technically possible.

2.2.3 Handling the CARDIOHELP-i

WARNING!

- Treat the CARDIOHELP-i particularly carefully when it is not fixed (e.g., when moving from one attachment to another).
- Use the carrying handle of the CARDIOHELP-i to carry it, not the safety bar.
- 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.

- Do not touch the plugs of the CARDIOHELP-i as electrostatic charges and moisture may cause damage.
- If there is a risk of fire or electrocution due to a technical defect, the device must be disconnected from the power supply. For this reason, the CARDIOHELP-i must be positioned in such a way that the external power supply can be disconnected easily at any time.
- Maintenance work and repairs on the device and changes or modifications to it may only be performed by service personnel authorized by Maquet Cardiopulmonary. In order to ensure the safe use of the device, it is imperative that regular inspections are carried out.
- Changes or modifications made by the operator are not permitted.
- If changes are made to the equipment, authorized service personnel must perform an inspection and tests to ensure that safe use is still guaranteed.
- The user must check the device regularly (weekly). The user must check whether the hand crank of the CARDIOHELP Emergency Drive is working. The LED speed display must be lit according to the speed.
- The user must check the availability and function of the CARDIOHELP Emergency Drive prior to each application.
- Before the user touches the patient or connects or removes sensors, he/she must discharge his/her body on the housing of the CARDIOHELP-i through grounding or on a large piece of metal.

WARNING!

- Protect any connections not in use with the protective caps supplied.
- Protect the venous probe from fluids (other than for cleaning).
- Prevent the fiber optic end of the venous probe from scratches and dirt.

2.2.4 General Precautionary Measures During Use

WARNING!

- The use of CARDIOHELP-i is restricted to a single patient at any one time.
- Pay attention to the minimum and maximum approved values of the disposable for blood flow and pressure (⇨ Instructions for Use of the disposable).
- If possible, avoid high negative pressures in excess of -75 mmHg during perfusion in order to prevent cavitation and hemolysis. In addition, a rapid transition from a low to a high negative pressure in the venous line should be avoided.
- Do not use the CARDIOHELP-i as surgical suction device.

- Only use the CARDIOHELP-i with a valve or other adequate systems or methods (e.g., tube clamp) which prevent a backflow.

WARNING!

- If the pump stops or the backflow prevention or the zero flow mode is activated during an application, the blood flow will be interrupted and supply to the patient will cease.
  Please ensure that the cause of the pump stop, backflow prevention or zero flow mode is remedied as quickly as possible and that the flow is started again as quickly as possible.
- During application, it must be ensured that the CARDIOHELP Emergency Drive is immediately available.
- The CARDIOHELP Emergency Drive can be used to manually drive the disposable if the CARDIOHELP-i should fail. If the electrical drive is functioning, the emergency mode can be used.
  Possible side effects during a pump stop are a temperature transfer into the blood and thrombosis.
- If the flow stops during application, the heat of the motor can be transferred to the blood in the pump.
- If the centrifugal pump makes any abnormal noises, the disposable on the CARDIOHELP-i (e.g., HLS Set Advanced or QUADROX-iR) should be changed.
- Make sure that there is no contact between high-frequency instruments or ultrasound instruments and the measuring system or tubes, as this may cause the sensors to malfunction.
- Do not touch the patient and the external interfaces of the device at the same time.
- Do not remove any components during operation of the CARDIOHELP-i.
- Do not remove the disposable product during normal operation.
- Do not operate the pump drive with empty disposables.
- Do not bend or clamp the tube while the pump is running to avoid damage to blood and cavitation.

Stopping the Perfusion

WARNING!

- If necessary, before clamping the tube, switch from LPM mode to RPM mode (⇨ "Activating LPM/RPM Mode", page 92).
- Clamp the tube behind the pump in the direction of flow.
- Immediately reduce the speed to 0 rpm to prevent hemolysis.

- If the pump is running, only clamp the tube leading away from the patient (venous side) if the tube leading to the patient (arterial side) has already been clamped.
- If the flow stops during application, the heat of the motor can be transferred to the blood in the pump.

Starting the Perfusion

WARNING!

- Only open the clamp once the pump pressure is 10 … 20 mmHg higher than behind the clamp.
- The clamp on the arterial side must not be released when the pump is running if the venous side is still clamped. Do not open the tube clamp at high speed.

2.2.5 Monitoring and Sensors

WARNING!

Only attach the accessories listed (⇨ "accessories", page 194) to the CARDIOHELP-i.

Patient monitoring

WARNING!

The following vital parameters of the patient must be monitored by an external monitoring system and qualified medical staff during application:

- Continuous measurements:
  - Verified temperature measurement including the core body temperature
  - Invasive arterial pressure
  - ECG
  - Central venous pressure (CVP)
  - Peripheral oxygen saturation
- Regular measurements:
  - Activated clotting time (ACT)
  - Blood gas analysis
- Regular measurements for use over 6 hours in duration:
  - Antithrombin 3
  - Partial thromboplastin time (PTT)
- In addition, the following continuous measurements are recommended:
  - Pulmonary arterial pressure (PAP)

Flow monitoring

WARNING!

- Only use the CARDIOHELP-i with flow monitoring which triggers an alarm.

Pressure monitoring

WARNING!

- Only use the CARDIOHELP-i with activated pressure monitoring which triggers an alarm and, if necessary, an intervention.

Bubble monitoring

WARNING!

Only use the CARDIOHELP-i with activated arterial and optional venous bubble monitoring which triggers an intervention and/or an alarm when bubbles are detected.

- Install the bubble monitoring system according to the instructions.
- Test the arterial and, if installed, venous bubble monitoring before each use.
- A bubble stop malfunction may occur with the initially imperfect mixing of blood and priming liquid due to a difference in the acoustic properties of the fluids.
- Use more than one procedure to prevent bubbles developing. The responsibility for taking precautions lies with the user.

WARNING!

- With an activated intervention, the detection of bubbles by the flow/bubble sensor triggers a pump stop and detection by the venous bubble sensor triggers backflow prevention or a pump stop. Microbubbles ≤ 5 mm can also cause the pump to stop or trigger backflow prevention. During the intervention, the blood flow will be interrupted and supply to the patient will cease. Whilst the pump is stopped, a backflow may occur.
- The pump increases the revolutions to the value last set if the user actively resets the bubble alarm.
- Ensure that trained medical personnel are always present and able to respond to a bubble alarm immediately, remove the cause and reset the bubble alarm.
- Prevent large movements and strain on the tube during perfusion in order to ensure the functioning of the sensor.

WARNING!

- The bubble sensor can trigger an unexpected pump stop or backflow prevention in the following circumstances:
  - During administration of contrast agents for diagnostics due to a difference in the acoustic properties of the fluids
  - During contrast echocardiography with microbubble contrast agents
- Using contrast agents with microbubbles can lead to venous air embolism or arterial air embolism via veno-arterial shunt in the patient.
- Using contrast agents with microbubbles can lead to arterial air embolism during veno-arterial application of the CARDIOHELP System.

Blood Gas Values

WARNING!

- Please note the possible failure of the venous probe.
- In the event of a failure of the venous probe, values for S_VO_2, Hb, Hct and T_{Ven} can no longer be displayed and monitored. Alarms for these values are no longer triggered.

WARNING!

- The measurement of hemoglobin (Hb) and hematocrit (Hct) can be influenced by sickle-cell anemia, macrocytic anemia and hyperlipidemia.
- The venous parameters of the CARDIOHELP-i are calibrated with physiological values of bilirubin, lipids, beta-carotene, carboxyhemoglobin, methemoglobin and sulfhemoglobin.
  Methylene blue, indocyanine green, Evans blue, fetal hemoglobin and unusual values of bilirubin, lipids, beta-carotene, carboxyhemoglobin, methemoglobin and sulfhemoglobin in the blood affect the optical properties of the blood and can thereby influence the optical measurement of oxygen saturation (S_VO_2).
- Prior to diagnosis and treatment of a patient based on the measured values S_VO_2, Hb, Hct and T_{Ven}, laboratory testing for referencing must be performed.
- Since it is possible for the venous probe to provide an incorrect value, the parameters displayed must be regularly checked according to the patient situation by means of a laboratory blood gas analysis. Prior to a therapeutic measure based on the parameters displayed, a laboratory blood gas analysis must be performed.

2.2.6 Extended Applications

WARNING!

- Check the function of the speaker and the warning buzzer prior to each application and during application at least once daily (⇨ "Changing and Testing the Brightness/Volume", page 74).
- Carry out the flow calibration at least once daily. Calibration is only possible with a pump and flow stop (⇨ "Flow Off-Set Calibration of the Flow/Bubble Sensor", page 117).

2.3 Intra-hospital Patient Transport

The CARDIOHELP System can be used for intra-hospital patient transport.

Intra-hospital patient transport is conveyance of the patient within the hospital, which does not involve leaving the surgical environment (e.g. transport from catheter laboratory to operating room).

WARNING!

If the patient is repositioned or transported, there is a risk of decannulation and mechanical damage caused by strain on the tubing or knocks.
The greatest care should therefore be exercised when carrying out these measures.

- Take care in confined spaces, such as doorways and elevators.
- Do not allow tubes or cables to hang down.
- Ensure that there is no strain on tubes or cables.
- Avoid mechanical impacts and knocks.
- Avoid kinking tubes or cables.
- Do not drop any of the components.

WARNING!

If the oxygen supply is inadequate, the patient's blood cannot be oxygenated.
Please therefore note:

- Always start with full oxygen bottles.
- Ensure that a sufficient gas supply is available at all times.
- Ensure that the available oxygen is adequate for the purpose. Take enough spare oxygen bottles with you.
- Use the hospital's oxygen supply so as to conserve the oxygen bottles.

WARNING!

An inadequate power supply can put the CARDIOHELP-i out of service. Please therefore note:

- Only ever start the application when the batteries of the CARDIOHELP-i are fully charged and calibrated.
- Check the battery function before transport.
- Ensure that a sufficient energy supply is available at all times.
- Use the hospital's power supply so as to conserve the batteries.
- Take the CARDIOHELP Emergency Drive with you when transporting the patient. Keep it at the ready for stop-gap manual operation in the event of pump drive failure.

WARNING!

- During patient transport, please also note the requirements regarding positioning and operation during transport (⇨ "Position of Use and Operation and Positioning of the CARDIOHELP-i", page 15).
- Take at least six tube clamps with you when transporting the patient. Keep the tube clamps at the ready for clamping tubes in the event of leakage.
- All the components must be attached to the holders provided and securely fixed, as intended.

WARNING!

- Follow the instructions supplied with other components of the system and the holders used. With regard to the transport approval of a given disposable as well as to the environment suitable for its intended purpose, please refer to the respective Instructions for Use of the disposables.
- Protect components from moisture. If water may have penetrated the housing, take the CARDIOHELP-i out of service after use, and have the CARDIOHELP-i checked by authorized service personnel.

WARNING!

The entire CARDIOHELP System can tolerate ESD pulses of up to ± 15 kV. The controls (touchscreen, rotary knob, buttons) can withstand ESD impulses up to ± 15 kV.

To avoid damaging the device, the user should discharge his/her body by touching a large or grounded piece of metal before he/she touches the patient or connects/disconnects sensors.

2.4 Electromagnetic Compatibility

The CARDIOHELP System complies with the requirements of the IEC 60601-1-2 standard on electromagnetic compatibility. The system and all accessories and sensors meet the EMC requirements of a surgical environment (⇨ "Electromagnetic Compatibility (EMC)", page 207).

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

The essential purpose of the CARDIOHELP-i is to pump blood in cardiopulmonary bypass, with the aid of a centrifugal pump.

The essential purpose may not be limited by or fail due to electromagnetic interference. If the essential purpose is limited or fails, the cardiopulmonary bypass cannot be maintained.

In the event of a total failure of the CARDIOHELP-i due to unforeseeable interferences or malfunctions, the centrifugal pump must be driven manually using the CARDIOHELP Emergency Drive.

WARNING!

Excessive electromagnetic interference can interfere with sensors, distort measurements and thereby cause incorrect pump control or incorrect interventions.

- Do not use the CARDIOHELP System in the environment of RF communications equipment (e.g., cell phones). These can cause excessively strong electromagnetic interference that exceeds the compliance level of the CARDIOHELP System.
- Using RF surgical devices or defibrillators directly next to the CARDIOHELP-i and its sensors can lead to interference or even malfunction. When using RF surgical devices or defibrillators, observe the correct function of the CARDIOHELP-i.
- Observe normal precautions regarding minimal relative humidity and the electrical conductivity of non-synthetic clothing in order to minimize the build-up of electrostatic charges.
- To ensure compliance with the relevant requirements, the length of all connection cables of the CARDIOHELP-i must not be changed.
- Only use the specified accessories (⇨ "Accessories", page 194). The use of other accessories can result in increased electromagnetic interference or decreased electromagnetic immunity of the device and lead to a malfunction.

- Only use RPM mode for intra-hospital patient transport. In LPM mode, the pump control can be impaired by incorrect flow values. Please note that flow values may be displayed with reduced accuracy.

2.5 Symbols

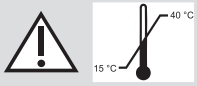
The touchscreen symbols can be found in section ⇨ "User Interface", page 41.

Rating plates

	Notice! Observe the warnings and safety precautions given in the accompanying documentation.
	Observe the instructions in the Instructions for Use!
	Order number
	Serial number
	Classification in accordance with IEC 60601-1: Defibrillator-protected Type CF applied part
	Alternating current
	Direct current
	Date of manufacture: Month-Year in which the device was made.
	Manufacturer as defined by Directive 93/42/EEC concerning medical devices.
	Separate collection of electric and electronic devices in accordance with Directive 2012/19/EU: 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 essential requirements of Directive 93/42/EEC concerning medical devices. 0124 is the number of the notified body involved (DEKRA Certification GmbH)
	The device meets the essential requirements of Directive 93/42/EEC concerning medical devices.

SGS c us 710165	The device meets Canadian and American safety standards. Tested by the Nationally Recognized Test Laboratory SGS North America, Inc.
IPX1	Protection type in accordance with IEC 60529: Protection against vertically dripping water
IPX4	Protection type in accordance with IEC 60529: Protection against splashing water from any direction
IP 33	Protection type in accordance with IEC 60529: Protection against access to hazardous parts with a tool, the ingress of solid foreign bodies of 2.5 mm or more in diameter and spraying water

Symbols on the CARDIOHELP-i

	Follow the Instructions for Use!
	Notice! Observe the warnings and safety precautions given in the accompanying documentation.
	The device is fully functional in a temperature range of 15°C to 40°C.

LEDs and buttons

	"Battery" LED	⇨ ""Battery" and "AC/DC power supply" LEDs", page 36
	"AC/DC power supply" LED	⇨ ""Battery" and "AC/DC power supply" LEDs", page 36
	Safety button	⇨ "Safety button", page 36
	"Zero flow mode" LED and button	⇨ "Zero flow mode", page 36
	"Lock/unlock" LED and button	⇨ ""Lock/Unlock" LED and Button", page 37
	"On/Off" LED and button	⇨ ""On/Off" LED and Button", page 37

Front connections

	"Alarm outlet" connection	Not fail-safe as defined by the IEC 60606-1-8 standard ⇨ "Connecting an External Alarm System", page 69
	Ethernet connection	Not used
	"Emergency mode" button	⇨ "Using the Emergency Mode", page 147
	USB port	⇨ "Connecting External Devices (Optional)", page 68 ⇨ "Data Recording", page 96
	Alternating current	⇨ "Setting Up and Connecting the CARDIOHELP-i", page 65
	Equipotential bonding	⇨ "Setting Up and Connecting the CARDIOHELP-i", page 65
	Direct current	
CAN	"CAN" connection	Not used
ECG	"ECG" interface	Not used

Rear connections

	Attaching disposables	⇨ "Attaching the Disposable for the HLS Retainer", page 101
	Removing the disposable	⇨ "On Completion of the Application", page 152
p_{Ven} p_{Int} p_{Art} p_{Aux}	Connections for external pressure sensors	⇨ "Connecting External Pressure Sensors", page 110
	Connection for sensors of disposable	⇨ "Connecting the Integrated Sensors of the Disposable", page 103

	Connection for clamp	Not used
	Connection for bubble sensor	⇨ "Connecting the Venous Bubble Sensor", page 107
	Connection for venous probe	⇨ "Connecting the Venous Probe", page 70
	Connection for level sensor	Note: Level monitoring only in thApp „MECC“.

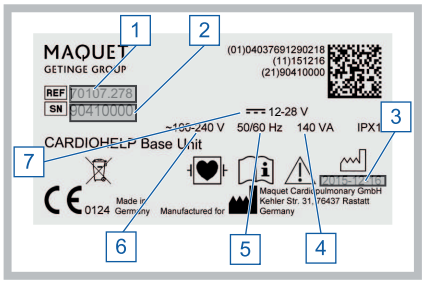
WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

T_{Ven} T_{Art}	Connections for external temperature sensors	⇨ "Connecting External Temperature Sensors", page 109
	Connection for flow/bubble sensor	⇨ "Connecting the Combined Arterial Flow/Bubble Sensor ", page 106
	Connection for Battery Calibration Unit	⇨ "Calibrating the Batteries", page 85

2.6 Rating Plate

The rating plate is fixed on the rear of the CARDIOHELP-i.



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

3 System Description

3.1 System Definition

3.1.1 CARDIOHELP System

The CARDIOHELP System is a compact perfusion system with which cardiopulmonary bypass can be driven, controlled, monitored and recorded.

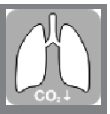
The CARDIOHELP System consists of the following components:

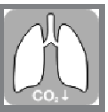
- CARDIOHELP-i device (CARDIOHELP Device)
  The CARDIOHELP-i device drives the disposable using an integrated pump, it controls and monitors cardiopulmonary bypass, and can communicate with other devices.
- CARDIOHELP Emergency Drive
  The CARDIOHELP Emergency Drive is used in emergencies to manually drive the disposable if the CARDIOHELP-i fails.
- Accessories (⇨ "Accessories", page 194)

3.1.2 thApp-specific Parameters and Functions

WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.
The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

thApps	 Car-diopul-monary support	 Circula-tory sup-port	 MECC	 Pul-monary support	 CO_2 re-moval
Displayed / monitored parameters:					
■ Level	-	-	X	-	-
■ p_{Int}	X	-	X	X	X
■ p_{Aux}	-	-	X	-	-

thApps	 Cardiopulmonary support	 Circulatory support	 MECC	 Pulmonary support	 CO_2 removal
■ Δ_p	X	-	X	X	X
■ T_{Art}	X	-	X	X	-
Screens:					
■ "Transport" screen	X	X	-	X	X
■ Parameter list	X	-	X	X	X
Other functions:					
■ Night mode	X	X	-	X	X
■ Deactivate automatic locking	-	-	X	-	-

3.1.3 Activatable Modes

RPM and LPM mode

The CARDIOHELP-i can be operated in the LPM or RPM mode:

- RPM mode (speed control, "revolutions per minute")
  In RPM mode, you can set the pump's setpoint speed. The CARDIOHELP-i operates the pump constantly at the set speed. As a result, the flow can vary according to the afterload of the circuit and/or the patient.
- LPM mode (flow control, "liters per minute")
  In LPM mode, you can set the setpoint flow. The CARDIOHELP-i controls the pump in such a way that the set flow is maintained. Consequently, the speed varies according to the afterload of the circuit and/or the patient.

"Global Override" mode

In "Global Override" mode, all interventions, acoustic alarms and backflow prevention are disabled.

Emergency mode

The emergency mode can be used in the event of failure of the touchscreen or other components in order to operate the disposable and control its speed directly via the rotary knob. All controls (with the exception of the [Emergency mode] button and the rotary knob) and functions as well as alarms and interventions are deactivated.

Zero flow mode

In the zero flow mode, the CARDIOHELP-i aims at a flow of 0 l/min by controlling the pump accordingly. In this way, both forward and backward flow can be prevented.

3.1.4 System Modes

Backflow prevention

The backflow prevention can detect and respond to a backflow of blood. For this, the CARDIOHELP-i monitors the blood flow, displays any alarms and activates the zero flow mode automatically to prevent any backflow.

Bubble detection

Only use the CARDIOHELP-i with activated arterial and optional venous bubble monitoring which triggers an intervention and/or an alarm when bubbles are detected. With an activated intervention, the detection of bubbles by the flow/bubble sensor triggers a pump stop and detection by the venous bubble sensor triggers backflow prevention.

To ensure the safety of the perfusion, the flow/bubble sensor must be positioned on the arterial side and the optional bubble sensor must be positioned on the venous side.

NOTE

The use of the optional bubble sensor does not replace the flow/bubble sensor and leads to another intervention.

NOTE

The alarm must be actively reset (⇨ "Resetting the Bubble Stop", page 146).

Once the CARDIOHELP-i has detected bubbles, it generates the following alarms, depending on the setting:

- With a deactivated intervention a low-priority alarm is generated.
- With an activated intervention of the arterial flow/bubble sensor, a high-priority alarm and a pump stop are generated.
- With an activated intervention of the venous bubble sensor, a high-priority alarm and backflow prevention are generated. If a lack of flow is detected by the arterial flow/bubble sensor, a pump stop is generated instead of a backflow prevention.

3.1.5 Data Recording

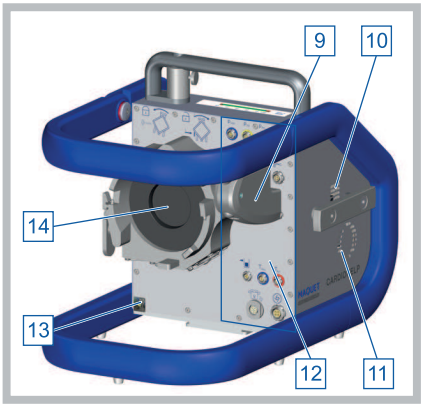
The CARDIOHELP-i can make data available for online recording or save it offline:

- Online recording
  Online recording continuously makes data available at the Type B USB port. The data can be analyzed by an external data recording system.
  The availability of online data is automatically active.
- Offline recording
  This function enables you to record data in an internal memory. The data can later be exported to a USB stick.
  The offline recording must be explicitly started in order to save the data.

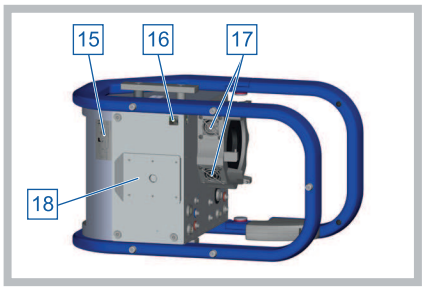
The interval for data recording can be changed. This setting applies to online and offline recording.

3.2 System Overview

1 Control Panel
2 Speed indicator
3 Carrying handle
4 Holder for CARDIOHELP Emergency Drive
5 Safety bar
6 Standard slide rail
7 Front connections
8 Protective cover



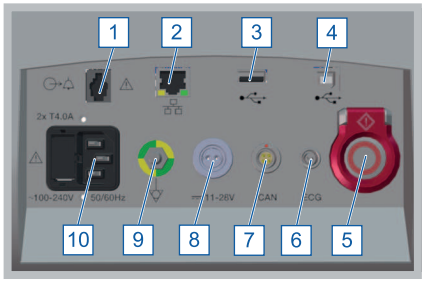
9 Venous probe
10 Ventilation opening
11 Speaker opening
12 Sensor connections
13 Security seal
14 Pump drive



15 Rating plate
16 Security seal
17 Pump drive ventilation opening
18 Sled for mobile holder HKH 8860

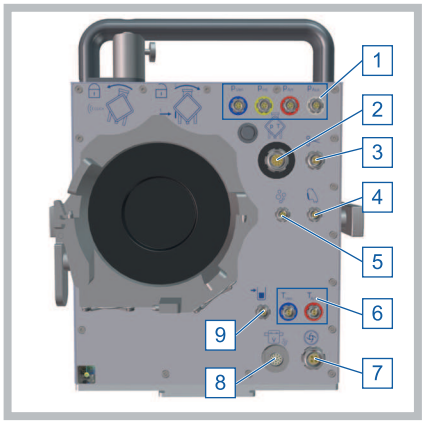
3.2.1 Connectors

Front connections



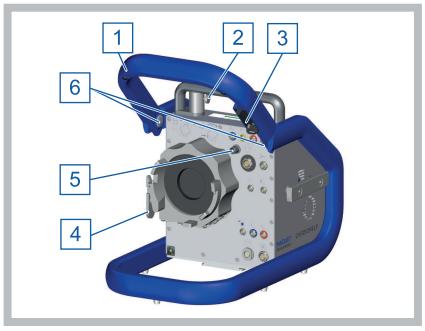
1 "Alarm outlet" connection
2 Ethernet connection (cannot be used)
3 USB port type A (for data export to USB memory stick)
4 USB port type B (for data recording system)
5 "Emergency mode" button
6 ECG connection (cannot be used)
7 CAN connection (cannot be used)
8 DC device socket
9 Equipotential bonding connection
10 AC connector plug with fuse module

Sensor connections



1 Connections for external pressure sensors
2 Connection for sensors of disposable
3 Venous clamp (cannot be used)
4 "Venous probe" connection
5 "Bubble sensor" connection
6 "External temperature sensors" connections
7 Connection for "Battery calibration unit"
8 "Flow/bubble sensor" connection
9 "Level sensor" connection

3.2.2 Controls



1 Safety bar
2 "Emergency mode" release mechanism (CARDIOHELP Emergency Drive)
3 Holder for venous probe
4 "Disposable" release mechanism
5 Holder for "disposable" connection cable
6 "Safety bar" release mechanism

Safety bar

The safety bar protects the CARDIOHELP-i and the attached disposable. It also serves as a holder for the venous probe when it is not in use.

The safety bar can be folded open in order to connect the disposable and sensors. The safety bar hinges are locked in the open and closed positions to prevent accidental opening and closing.

Venous probe holder

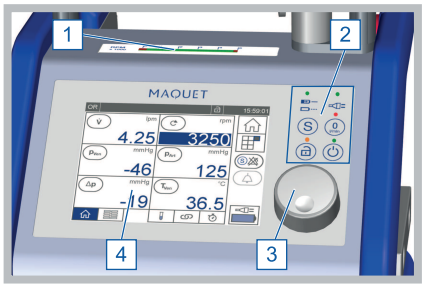
The venous probe can be parked in the holder when not in use. The holder also features a black reference surface, which is necessary for initializing the probe.

"Emergency Mode" button

With the "Emergency mode" button you can change to and exit the emergency mode. The LED ring on the button displays the status.

LED ring		
	LED ring is unlit	The CARDIOHELP-i is now off. You can only change to emergency mode when the CARDIOHELP-i is on.
	LED ring is illuminated	The CARDIOHELP-i is on and is operating in normal mode. To change to emergency mode, press the button (⇨ "Using the Emergency Mode", page 147).
	LED ring is flashing	The CARDIOHELP-i is in emergency mode. To exit the emergency mode, you must turn the CARDIOHELP-i off; press the "Emergency mode" button (⇨ "Exiting emergency mode and switching off the CARDIOHELP-i", page 148).

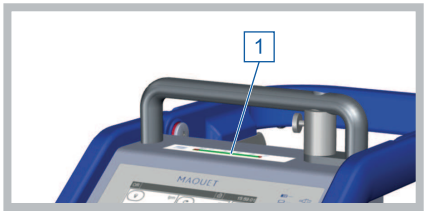
3.3 Control Panel

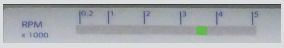
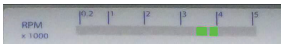
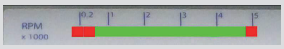


1 LED speed indicator
2 Keypad
3 Rotary knob
4 Touchscreen

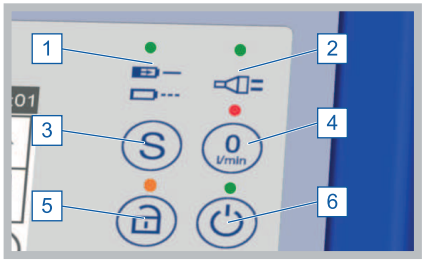
3.3.1 LED Speed Indicator

The speed indicator LED on the top of the CARDIOHELP-i displays the speed independently of the touchscreen. Use the values of the LED speed indicator in emergency mode (⇨ "Using the Emergency Mode", page 147) or if the touchscreen does not display the speed.



	LEDs	Meaning
	Illuminated LEDs from 0 to 5000 rpm	The LEDs display the current speed (in the example approx. 3500 rpm).
	One illuminated LED	When you change the speed setpoint, the LED shows the speed setpoint for 2 seconds (in the example approx. 3500 rpm).
	Two illuminated LEDs	When you change the speed setpoint, the LEDs show the speed setpoint for 2 seconds. The setpoint is between the values of the two LEDs (in the example approx. 3900 rpm).
	Red illuminated LEDs	The LEDs display the maximum speed (in the example ≥ 5000 rpm).

3.3.2 Keypad



1 "Battery" LED
2 "AC/DC power supply" LED
3 Safety button
4 "Zero flow mode" LED and button
5 "Lock/unlock" LED and button
6 "On/Off" LED and button

"Battery" and "AC/DC power supply" LEDs

The "Battery" and "AC/DC power supply" LEDs display the status of the battery and the power supply, independently of the touchscreen.

	Element	Meaning
	"Battery" LED	■ LED illuminated: Battery is being charged. ■ LED flashes once/s: Remaining capacity < 20% ■ LED flashes twice/s: Remaining capacity < 10% ■ LED is off: Battery is not being charged (may already be fully charged).
	"AC/DC power supply" LED	■ LED illuminated: CARDIOHELP-i is connected to external power supply. ■ LED is off: CARDIOHELP-i is not connected to external power supply.

Safety button

	Button	Meaning
	Safety button	Certain functions can only be triggered when the safety button is pressed at the same time. This prevents these functions being activated inadvertently: ■ ⇨ "Zero flow mode", page 36 ■ ⇨ ""Global Override" Mode", page 143 ■ ⇨ "Activating/Deactivating Interventions with Button Combinations", page 125 ■ ⇨ "Calibrate Touchscreen", page 84

Zero flow mode

In the zero flow mode, the CARDIOHELP-i aims at a flow of 0 l/min by controlling the pump accordingly. In this way, a backflow can be prevented.

The zero flow mode can be activated manually or is activated automatically by a negative flow (⇨ "Backflow Prevention", page 128).

	Zero flow mode		
	Deactivated	To activate the zero flow mode, hold down the safety button and press the "Zero flow mode" button.	
	Activated	The CARDIOHELP-i aims at a flow of 0 l/min. To deactivate the zero flow mode, press the "Zero flow mode" button.	

"Lock/Unlock" LED and Button

The controls (rotary knob, buttons and touchscreen) are locked automatically after 3 minutes of inactivity. This prevents settings being inadvertently altered or functions inadvertently called up.

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

NOTE

In the thApp "MECC" you can deactivate the automatic lock (⇨ "thApp "MECC": Deactivate Automatic Locking", page 73). In this case, the controls are not locked automatically.

The LED and the lock symbol in the status bar display whether the CARDIOHELP-i is locked:

	Unlock	Meaning
	 CARDIOHELP-i is locked	To be able to use the CARDIOHELP-i, the lock must be removed. To unlock the controls, press the "Lock/unlock" button for 1 second.
	 CARDIOHELP-i not locked	You can use the controls until they are locked again automatically. To lock the controls, press the "Lock/unlock" button.

"On/Off" LED and Button

Use the "On/Off" button to switch the CARDIOHELP-i on and off. The "On/Off" LED indicates whether the CARDIOHELP-i is on or off.

	"On/Off" LED	
	Off	To switch the CARDIOHELP-i on, press the button (⇨ "Switching on the CARDIOHELP-i, Self-Test", page 71).
	On	To switch the CARDIOHELP-i off, press the button for at least 3 seconds and confirm the message (⇨ "On Completion of the Application", page 152).

3.3.3 Rotary Knob

The rotary knob enables you to change the setpoint speed or the setpoint flow (⇨ "RPM mode: changing the speed", page 93 and ⇨ "LPM mode: changing the flow", page 95). Alternatively you can change the setpoint speed via the touchscreen.

3.3.4 Touchscreen

You can make all the necessary settings using the touchscreen. This simultaneously acts as a display field.

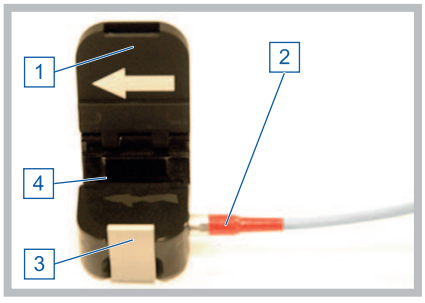
3.4 Sensors

3.4.1 Flow/Bubble Sensor

The combined flow/bubble sensor is for flow measurement and arterial bubble monitoring.

WARNING!

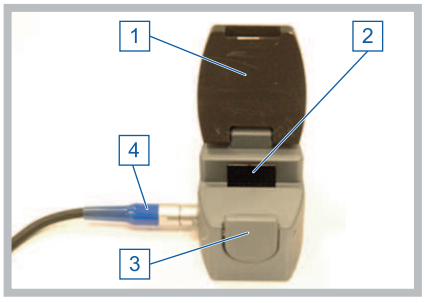
Note the direction of flow. Attach the sensor so that the blood flows in the direction of the arrow on the sensor cover.



1 Cover with flow direction indication
2 Connecting cable
3 Locking device
4 Tube retainer

3.4.2 Bubble Sensor

The separate bubble sensor is for venous bubble monitoring.

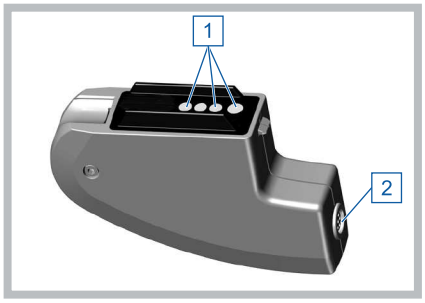


1 Cover
2 Tube retainer
3 Locking device
4 Connecting cable

WARNING!

Do not open the rear of the bubble sensor. This damages the sensor and it can no longer be used.

3.4.3 Venous Probe

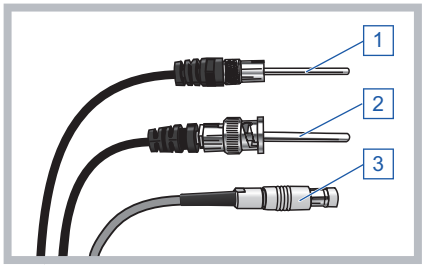


1 Optical sensors
2 Connection for venous probe sensor cable

The venous probe of the CARDIOHELP-i measures the venous blood parameters S_VO_2, Hb, Hct and temperature.

For measurement, the probe is connected to the disposable's measuring cell. When the probe is not in use, it is hooked into the holder on the safety bar to protect the sensors.

3.4.4 External Temperature Sensors

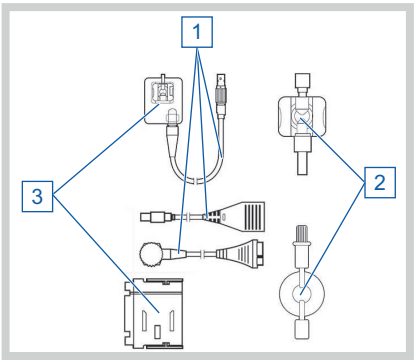


1 Temperature sensor
2 Temperature sensor
3 Temperature sensor plug

Depending on the sensors of the disposable used, you will need various external sensors (⇨ "Preparing Application", page 101).

3.4.5 Pressure Sensor

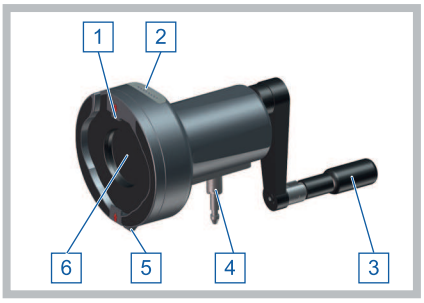
Depending on the sensors of the disposable used, you will need various external pressure sensors.



1 Pressure sensor cable
2 Pressure dome
3 Pressure dome holder

3.5 CARDIOHELP Emergency Drive

The CARDIOHELP Emergency Drive is used in emergencies to manually drive the disposable if the CARDIOHELP-i fails.



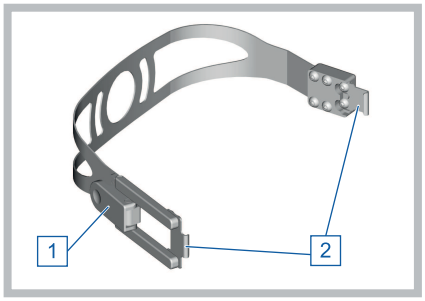
1 Locating lug
2 LED speed indicator
3 Hand crank (unfolded)
4 Fastening bolt
5 Locking device
6 Pump drive

3.6 Accessories for Intra-hospital Patient Transport

The following components are accessories for the CARDIOHELP System for intra-hospital patient transport. Intra-hospital patient transport is conveyance of the patient within the hospital.

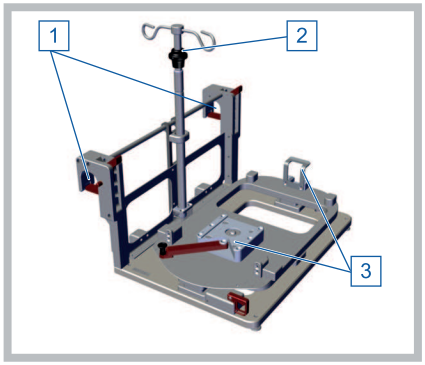
- Transport guard (Transport Guard for CARDIOHELP Disposables)
  The transport guard secures a HLS Set Advanced.
- Cardiohelp Mobile Holder HKH 8860
  The mobile holder serves as a support for the CARDIOHELP System and the connected disposable. It can be attached to a stretcher with two lockable hooks. A telescopic infusion pole for bags or bottles is optionally available.

3.6.1 System Components



Transport Guard for CARDIOHELP Disposables

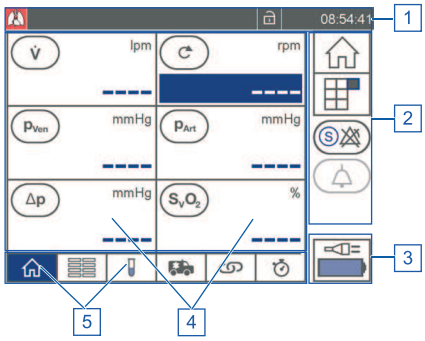
1 Lock
2 Fixing hooks for CARDIOHELP-i



Cardiohelp Mobile Holder HKH 8860

1 Attachment point for stretcher
2 Infusion pole (optional)
3 Attachment point for CARDIOHELP-i

3.7 User Interface

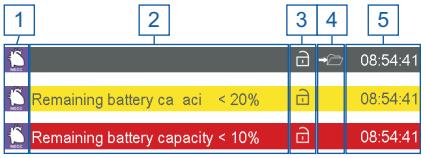


Touchscreen

1 Status Bar
2 Toolbar
3 Power supply status
4 Parameter Display
5 Tab bar

3.7.1 Status Bar

The top of the touchscreen displays the status bar with the following information:



1 Current thApp (⇨ "thApp-specific Parameters and Functions", page 29)
2 Alarm signal (only for alarm)
3 "Lock" symbol (⇨ ""Lock/Unlock" LED and Button", page 37)
4 "Offline recording" symbol (⇨ "Record data offline", page 97)
5 Current time

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 157). In emergency mode, the status bar of the touchscreen continually displays the message [EMERGENCY MODE] but no other messages or alarms (⇨ "Using the Emergency Mode", page 147).
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 high-priority alarm situations simultaneously, alarms which are warning of a technical defect or triggering a pump stop or backflow prevention are preferably displayed in the status bar.
If there are several alarm situations with different priorities simultaneously, the status bar displays the most recent alarm situation with the highest priority.

In the alarm list, the 6 most recent alarms are shown, independent of their priority (⇨ "Alarm List", page 158).

In addition, the touchscreen displays alarm situations with the parameter's symbol (⇨ "Status of physiological alarms and interventions", page 46) or the "Menu" symbol (⇨ "Menu Screen", page 49).

3.7.2 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
 "Startup screen"	Switch to startup screen (⇨ "Startup Screen", page 48).
 "Menu"	Switch to the menu (⇨ "Menu Screen", page 49).
 "Global Override"	Disable all interventions, acoustic alarms and backflow prevention (⇨ ""Global Override" Mode", page 143).
 "Current alarm pause"	Pausing the current alarm (⇨ "Pausing the Current Alarm", page 50).

3.7.3 Power Supply Status

The touchscreen displays symbols for the power supply status at the bottom right of all screens.

Mains operation	Battery operation	Meaning
		Battery capacity ≥ 20%
		Battery capacity < 20%
		Battery capacity < 10%
		Disconnected from external power supply Flashes alternately with the remaining battery capacity until this is acknowledged.
		No battery detected

3.7.4 Tab Bar

The bottom of the touchscreen displays the tab bar. This allows you to navigate between different screens. The symbol of the selected screen is shown on a blue background.

Symbol	Meaning
"Startup screen"	Switch to startup screen (⇨ "Startup Screen", page 48)
"Parameter list"	Switch to parameter list (⇨ "Parameter List", page 53)
"Blood parameters"	Switch to "Blood parameters" screen (⇨ ""Blood Parameters" Screen", page 53).
"Transport"	Switch to "Transport" screen (⇨ ""Transport" Screen", page 54)
"Interventions"	Switch to "Interventions" screen (⇨ ""Interventions" Screen", page 54)
"Timer"	Switch to "Timer" screen (⇨ "Timer Screen", page 55).

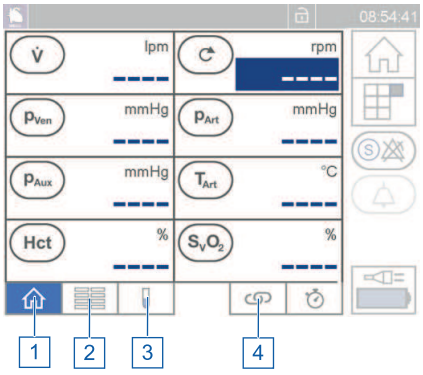
Physiological alarms status

The color of the screen tab shows whether any alarms for the screen's parameters are present. If necessary, switch to the corresponding screen to read the alarm-generating parameters.

Meaning
No alarm situation
High-priority alarm: The status bar displays a message (⇨ "Physiological Alarms", page 158).
Medium- and low-priority alarm: The status bar displays a message.

3.7.5 Parameter Display

The touchscreen displays parameters in different screens:



1 ⇨ "Startup Screen", page 48

2 ⇨ "Parameter List", page 53

3 ⇨ ""Blood Parameters" Screen", page 53

4 ⇨ ""Interventions" Screen", page 54

Values displayed

WARNING!

- Check the pressure values for plausibility. Implausible pressures of -500 mmHg, 0 mmHg and "outside of measuring range" can occur due to a malfunction or a short circuit of the cable.
- Check the temperature transfer via external devices or ambient temperatures if the blood temperature is outside the tolerable range.

The touchscreen displays the flow and speed in all screens. The display of other parameters depends on the sensors connected and the screen.

	Parameter	Description
$\dot{V}$	Flow	Flow measurement on the flow/bubble sensor. The flow is displayed in lpm (liters per minute). It is visible in all screens.
	Speed	The speed is displayed in rpm (revolutions per minute). It is visible in all screens.
	Pressures:	
p_{Ven}	■ Venous pressure	Disposables with integrated sensors: Pressure at blood inlet of the disposable. Disposables without integrated sensors: Pressure at external pressure sensor P_{ven}.
p_{Int}	■ Internal pressure	Disposables with integrated sensors: Pressure between pump and oxygenator/gas transfer module. Disposables without integrated sensors: Pressure at external pressure sensor P_{Int}.
p_{Art}	■ Arterial pressure	Disposables with integrated sensors: Pressure at blood outlet of the disposable. Disposables without integrated sensors: Pressure at external pressure sensor p_{Art}.
p_{Aux}	■ Additional external pressure	Pressure at external pressure sensor p_{Aux}.
Δp	■ Pressure drop	Calculated pressure drop between p_{Int} and p_{Art}. For disposables with integrated sensors: Pressure drop of the oxygenator or gas transfer module. If there is no valid value for p_{Int} or p_{Art}, no pressure drop is calculated.

	Parameter	Description
	Temperatures:	
T_{Ven}	■ Venous temperature	Disposables with integrated sensors: Disposables with venous measuring cell. Disposables without integrated sensors: Temperature at external venous temperature sensor.
T_{Art}	■ Arterial temperature	Disposables with integrated sensors: Temperature at blood outlet. Disposables without integrated sensors: Temperature at external venous temperature sensor.
	Bubble monitoring:	
Ven	■ Venous bubbles	Bubbles on the bubble sensor.
Art	■ Arterial bubbles	Bubbles on the flow/bubble sensor.
	Level monitoring	Level at the level sensor pad.
	Note: Levelmonitoring only in thApp „MECC“.	

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

	Parameter	Description
	Blood parameters:	
S_vO_2	■ Venous oxygen saturation	Oxygen saturation in the measuring cell in %.
Hb	■ Hemoglobin	Hemoglobin in the measuring cell in g/dl.
Hct	■ Hematocrit	Hematocrit in the measuring cell in %.

Status of physiological alarms and interventions

The parameter symbol and the chain symbol show whether an alarm and an intervention have been activated for the parameter:

Example: Symbol p_{Art}	Meaning
 Parameter symbol	No alarm situation, the intervention for the parameter is deactivated.
 Additional symbol "Intervention activated"	Intervention for the parameter is activated.
 Red parameter symbol	High-priority alarm: The status bar displays a message (⇨ "Physiological Alarms", page 158).
 Yellow parameter symbol	■ Medium-priority alarm: The status bar flashes and displays a message. ■ Low-priority alarm: The status bar displays a message.

Status of measured values

The parameter's values display the status:

Display	Meaning
 Numerical value	Valid measured value available.
 Bubble monitoring: Tick	Valid measured value, no alarm situation.
 Bubble monitoring: Cross	Valid measured value, alarm situation, intervention deactivated.
 Bubble monitoring: Cross	Valid measured value, alarm situation, intervention activated.
 Dashes	■ Measured values not available (e.g., sensor not connected, ⇨ "Switching on the CARDIOHELP-i, Self-Test", page 71) ■ Parameters not supported (disposable-specific functions) ■ Values outside valid range (⇨ "Measured Data and Displayed Data", page 201)
 RPM in white figures on blue background	RPM mode active, the actual speed is displayed.
 RPM in light-blue figures on blue background	RPM mode active, the currently desired speed set-point is displayed (⇨ "RPM mode: changing the speed", page 93).

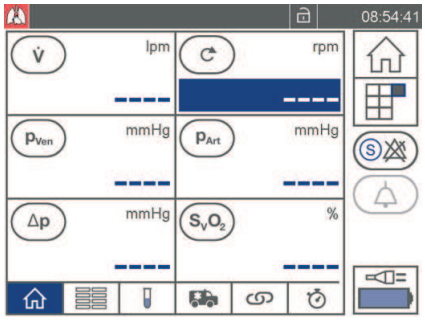
Display	Meaning
 LPM in white figures on blue background	LPM mode active, the actual flow is displayed.
 LPM in light-blue figures on blue background	LPM mode active, the currently desired flow set-point is displayed (⇨ "LPM mode: changing the flow", page 95).

3.8 Startup Screen

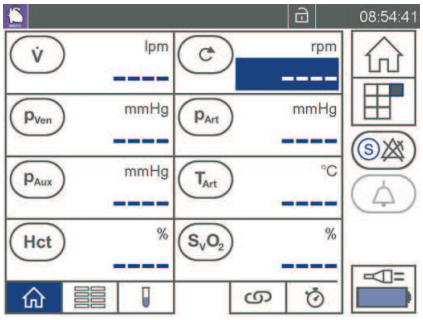
In this screen, the touchscreen displays the start parameters.

- To switch to this screen, tap the "Startup screen" symbol.
- The screen is displayed automatically after the CARDIOHELP-i is switched on.

In this screen, the touchscreen displays different parameters, depending on the thApp. Consult the table in chapter ⇨ "thApp-specific Parameters and Functions", page 29 for further information.



thApp "Cardiopulmonary support"



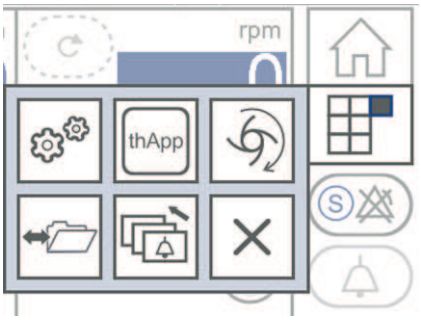
thApp "MECC"

NOTE

Do not use thApp “Circulatory support”, thApp “Pulmonary support”, thApp “CO_2 removal”, or thApp “MECC”.

3.9 Menu Screen

In the menu, the touchscreen displays symbols with which you can select further functions.



- To switch to the menu, touch the "Menu" symbol.

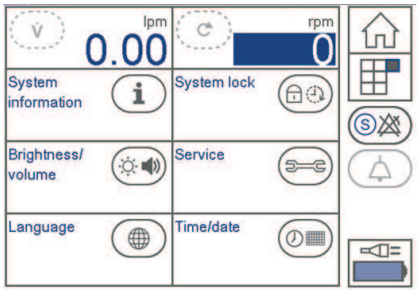
Symbol	Meaning
"Settings"	Changing general settings (⇨ "General Settings", page 50).
"thApp"	⇨ "Switching thApp", page 90
"Pump"	Changing the control mode (⇨ "Activating LPM/RPM Mode", page 92).
"Data recording"	Changing the interval for data recording, recording data offline and exporting recorded data (⇨ "Data Recording", page 96).
"Alarm list"	Displaying alarm list (⇨ "Alarm List", page 158).
"Close"	To close the menu and return to the last screen displayed, touch the symbol.

Technical alarms status

The "Menu" symbol indicates whether any technical alarms are present:

Meaning
No alarm situation
Technical alarm: The status bar displays a message (⇨ "Technical Alarms", page 171).

3.9.1 General Settings



- To set the general settings, touch the [Settings] symbol in the "Menu" screen.
- ▸ The "General settings" screen opens.

	Function	Meaning
	System Information	⇨ "Displaying System Information", page 79
	System lock	⇨ "thApp "MECC": Deactivate Automatic Locking", page 73

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

	Function	Meaning
	Brightness and volume	⇨ "Changing and Testing the Brightness/Volume", page 74
	Service	The [Service] function is password-protected and may only be used by authorized personnel (⇨ "Key User Functions", page 81).
	Language	⇨ "Changing the Display Language", page 76
	Time/date	⇨ "Changing the Time, Date and Formats", page 76

3.10 Pausing the Current Alarm

WARNING!

During the alarm pause, none of the alarm signals of the current alarms are transmitted at the "Alarm outlet" interface.

NOTE

When you switch thApp, the alarm pause for current acoustic alarms ends (⇨ "Switching thApp", page 90).

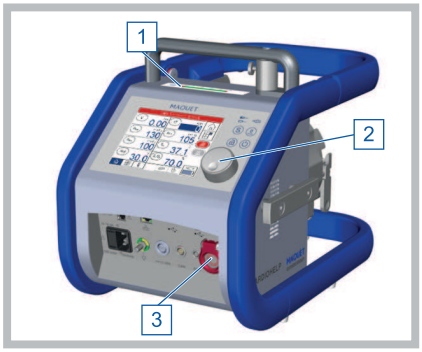
When alarms are paused, the alarm is only displayed optically. The acoustic alarm pause lasts for a maximum of one minute.

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 CARDIOHELP-i 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. To end the alarm pause, touch the symbol.
Not possible	There is no current alarm that could be paused.

3.11 Emergency Mode

The emergency mode can be used in the event of failure of the touchscreen or other components in order to operate the disposable and control its speed directly via the rotary knob. All controls (with the exception of the "Emergency mode" button and the rotary knob) and functions as well as alarms and interventions are deactivated.



- To switch to the emergency mode and to exit it again, use the "Emergency mode" button [3].
- ▸ When exiting the emergency mode, the CARDIOHELP-i is switched off.

In the emergency mode, the disposable is operated in RPM mode and can be controlled directly via the rotary knob [2]. The LED speed indicator [1] also shows the speed in emergency mode (⇨ "LED Speed Indicator", page 35).

WARNING!

- All of the alarms and interventions are deactivated in emergency mode. There is a risk of dangerous situations not being recognized and endangering the patient.
- When the locking of the controls is deactivated, there is a risk that settings may be inadvertently changed, resulting in an unsuitable setpoint speed being set.

3.11.1 Functioning of Individual Controls in Emergency Mode

- "Emergency Mode" Button
  The emergency mode is activated with the "Emergency mode" button. On ending the emergency mode, the CARDIOHELP-i is switched off.
- Touchscreen
  In the emergency mode, the status bar of the touchscreen continually displays the message [EMERGENCY MODE] but no other messages or alarms. The touchscreen is for display purposes only and has no control function.
  All the available sensors are displayed in the startup screen. Only the startup screen of the relevant thApp is displayed regardless of which screen was selected prior to emergency mode.
- Power supply status
  In emergency mode, the LEDs for "Battery" and "AC/DC power supply" continue to display the status of the battery and power supply (⇨ ""Battery" and "AC/DC power supply" LEDs", page 36).
  The touchscreen continues to display symbols for the power supply status at the bottom right of all screens (⇨ "Power Supply Status", page 43).
  In addition, the CARDIOHELP-i generates acoustic warnings when the battery status is low (⇨ "CARDIOHELP-i Device", page 196):

Acoustic warnings	Meaning
1 signal / second	Remaining capacity < 20%
Continuous signal	Remaining capacity < 10%

- Data recording and saving of alarms
  In the emergency mode, offline recording on the internal memory is switched off. User events, service events and online recording still function (⇨ "Using the Emergency Mode", page 147).

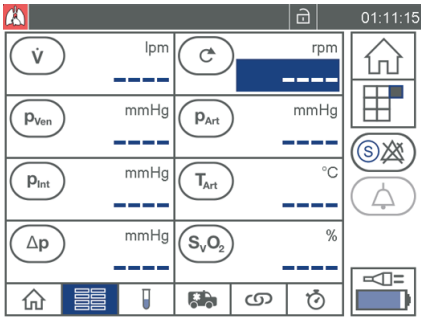
3.12 Screens in the Tab Bar

3.12.1 Parameter List

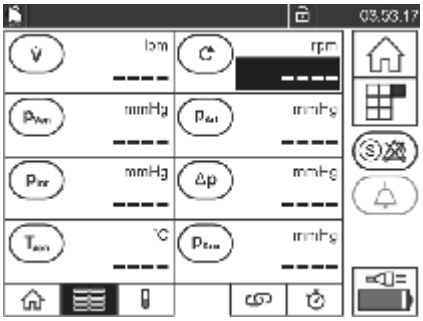
In this screen, the touchscreen displays the pressure and temperature parameters as well as the pressure drop.

- To switch to this screen, tap the "Parameter list" symbol.

In this screen, the touchscreen displays different parameters, depending on the thApp. Consult the table in chapter ⇨ "thApp-specific Parameters and Functions", page 29 for further information.



thApp "Cardiopulmonary support"



thApp "MECC"

NOTE

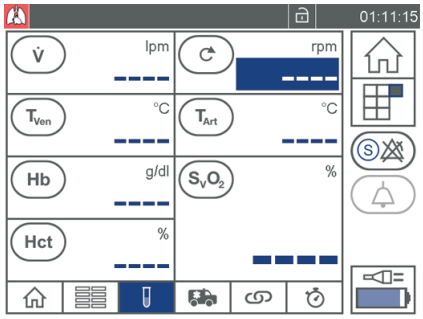
Do not use thApp “Circulatory support”, thApp “Pulmonary support”, thApp “CO_2 removal”, or thApp “MECC”.

3.12.2 "Blood Parameters" Screen

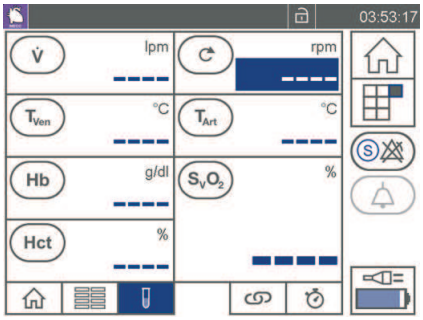
In this screen, the touchscreen displays the arterial and venous temperature as well as the blood parameters S_VO_2, Hb and Hct.

- To switch to this screen, tap the "Blood parameters" symbol.

In this screen, the touchscreen displays different parameters, depending on the thApp. Consult the table in chapter ⇨ "thApp-specific Parameters and Functions", page 29 for further information.



thApp "Cardiopulmonary support"



thApp "MECC"

NOTE

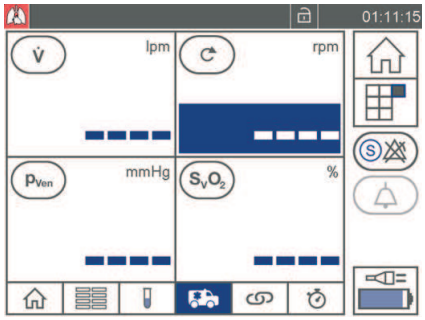
Do not use thApp “Circulatory support”, thApp “Pulmonary support”, thApp “CO_2 removal”, or thApp “MECC”.

3.12.3 "Transport" Screen

In this screen, the touchscreen displays parameters in large digits.

- To switch to this screen, tap the "Transport" symbol.

In this screen, the touchscreen displays different parameters, depending on the thApp. Consult the table in chapter ⇨ "thApp-specific Parameters and Functions", page 29 for further information.



thApp "Cardiopulmonary support"

thApp "MECC"
Screen not available

NOTE

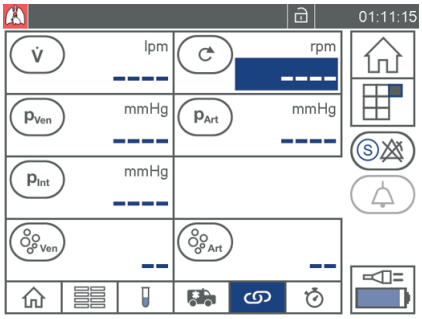
Do not use thApp “Circulatory support”, thApp “Pulmonary support”, thApp “CO_2 removal”, or thApp “MECC”.

3.12.4 "Interventions" Screen

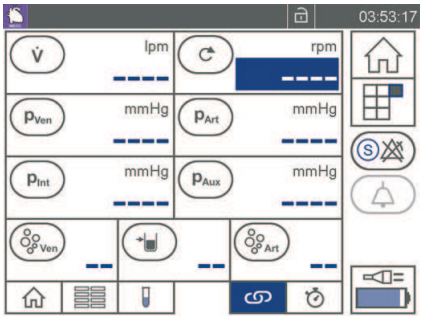
In this screen, the touchscreen displays all parameters for which an intervention can be activated.

- To switch to this screen, tap the "Interventions" symbol.

In this screen, the touchscreen displays different parameters, depending on the thApp. Consult the table in chapter ⇨ "thApp-specific Parameters and Functions", page 29 for further information.



thApp "Cardiopulmonary support"



thApp "MECC"

NOTE

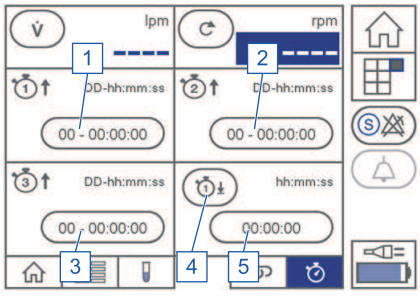
Do not use thApp “Circulatory support”, thApp “Pulmonary support”, thApp “CO_2 removal”, or thApp “MECC”.

3.12.5 Timer Screen

WARNING!

Do not use for diagnosis
Do not use the timers for diagnostic purposes. The timers are intended for providing additional information.

In the "Timer" screen, the touchscreen displays four timers, which can measure time independently of each other. To switch to this screen, touch the "Timer" symbol.



1 "Timer 1" button
2 "Timer 2" button
3 "Timer 3" button
4 "Countdown timer" symbol
5 "Countdown timer" button

"Timer" screen

Timers 1 to 3 count upwards. The countdown timer counts down from the start time.

Once the countdown time has elapsed, the countdown timer issues a low-priority alarm. The symbol turns yellow.

The status bar shows the following message: [Countdown time elapsed].

When the maximum runtime of the timers 1 to 3 has elapsed, the timer stops and is reset to 0. The touchscreen shows the following message: [Timer … elapsed]. Observe the maximum application time of 6 hours.

3.13 Basic Handling Information for Software

3.13.1 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. ■ The CARDIOHELP-i uses the new, changed settings. ■ The window is closed.
	Reject	To reject inputs or changes, touch the "Reject" symbol. ■ The CARDIOHELP-i leaves the settings unchanged. ■ The window is closed.

3.13.2 Selecting Settings

For various functions, there are several possible settings that you can select. To this end, the touchscreen displays the following buttons:

	Function	Description
	The setting has been selected.	To change the setting, the other button must be selected. Or To change the setting, the button must be selected again.
	The setting has not been selected.	

3.13.3 Changing Numerical Settings

To change numerical settings, touch the field with the value of the setting. The touchscreen displays the value on a blue background and the symbols [+] and [–]:

- To increase the value, touch the [+] symbol.
- To reduce the value, touch the [–] symbol.

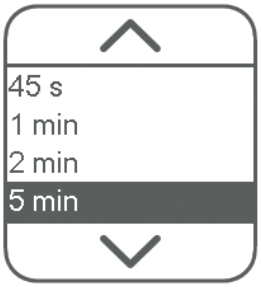
3.13.4 Displaying or Changing Parameter Settings

If you touch the symbol of the parameter, you can display or change its settings for alarms and interventions. (⇨ "Physiological Alarms and Interventions", page 121).

With the "Speed" symbol, you can adjust the speed setpoint by touching the symbol. (⇨ "RPM mode: changing the speed", page 93).

3.13.5 Using a Selection List

The touchscreen displays selection lists in which you can select a value using the arrow buttons or by touching directly.
The setting with gray background is selected. To select a different setting, touch the arrow symbols until the desired setting is selected or touch the desired element directly.



4 System Preparation

4.1 Installing the Holder

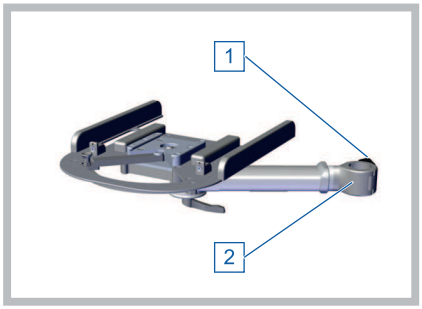
4.1.1 Holder for CARDIOHELP-i

WARNING!

- Please note the requirements regarding position of use and operation and positioning (⇨ "Position of Use and Operation and Positioning of the CARDIOHELP-i", page 15).

Holder for mast HKH 9102-M

The holder is intended for a mast diameter of 38 mm. Appropriate adapters must be used for masts of 30 and 33 mm in diameter (⇨ "Accessories", page 194).



1 Attach the holder at an appropriate point.
2 Undo the locking knob [1] on the mast retainer [2].
3 Position the holder so that the mast fits into the mast retainer, align the holder as required and screw the locking knob tight.
4 Make sure that the locking knob is properly tightened and the holder is securely fixed.

To detach the holder, follow the same procedure in reverse order.

4.2 Installing Accessories for Intra-hospital Patient Transport

WARNING!

- All components must be installed in such a way that the user can monitor and operate them during patient transport.
- Attach all components to the holders provided for the purpose and fix them securely as intended.

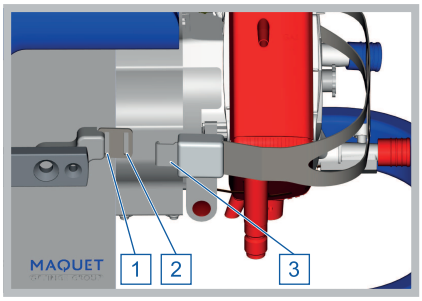
4.2.1 Securing the Disposable with the Transport Guard for CARDIOHELP Disposables

The disposable can come loose from the CARDIOHELP-i due to strong mechanical forces. Use the SPRINTER CART or SPRINTER CART XL for intra-hospital patient transport. Secure the disposable using the Transport Guard for CARDIOHELP Disposables if you cannot use any SPRINTER CART or SPRINTER CART XL for the intra-hospital patient transport. Check that the lock of the Transport Guard for CARDIOHELP Disposables is closed.

1 Ensure that the disposable is correctly installed.

2 Check that the lock of the Transport Guard for CARDIOHELP Disposables is open.

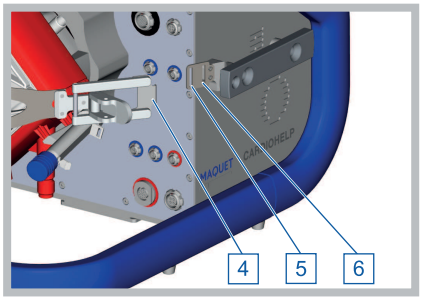
3 When using a HLS Set Advanced 7.0, hang the fixing hook [3] into opening [2].
Or
When using a HLS Set Advanced 5.0, hang the fixing hook [3] into opening [1].



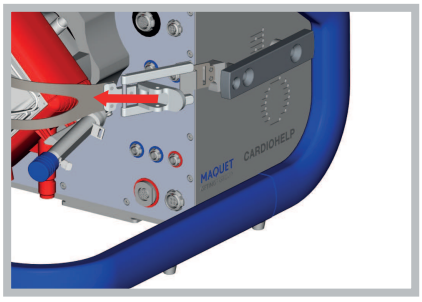
4 Place the Transport Guard for CARDIOHELP Disposables around the disposable.

5 If the venous probe is already installed on the measuring cell, make sure that the cable of the venous probe is below the bracket.

6 When using a HLS Set Advanced 7.0, hang the fixing hook on the locking side [4] into opening [5].
Or
When using a HLS Set Advanced 5.0, hang the fixing hook on the locking side [4] into opening [6].



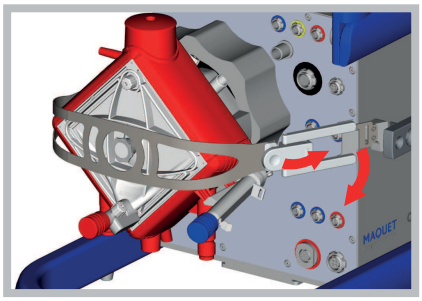
7 Close the lock.



8 Make sure that both fixing hooks are properly attached and the lock is securely closed.

Removing the Transport Guard for CARDIOHELP Disposables

- Open the fastener of the Transport Guard for CARDIOHELP Disposables and remove the fixing hooks from the openings.

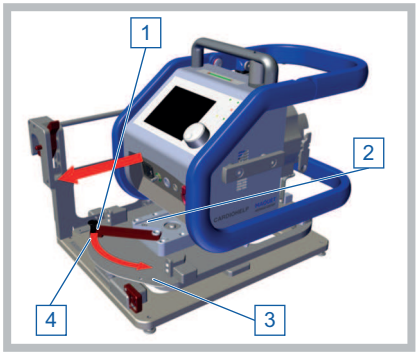


4.2.2 Attaching the CARDIOHELP to the Mobile Holder HKH 8860

CAUTION!

The Cardiohelp Mobile Holder HKH 8860 is mounted on the left-hand side on delivery: The position of operation of the CARDIOHELP-i is on the left side of the mobile holder.
If the position of operation is required on the right side, the mobile holder must be converted.

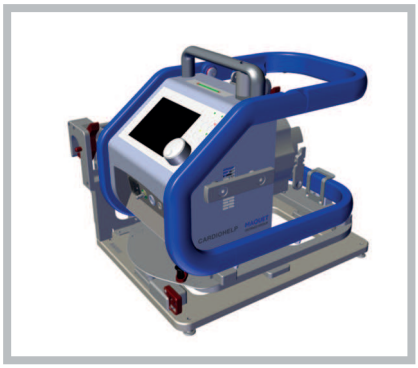
1 Check that the locking device is open.



- ▸ Locking lever [1] on the [Open] symbol [4].

2 Slide the CARDIOHELP-i onto the mobile holder.

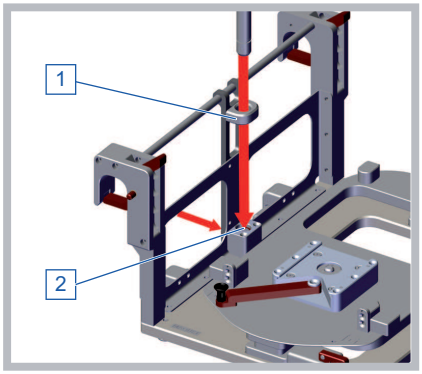
3 Ensure that the sled on the underside of the CARDIOHELP-i slides into the retainer [2].



4 Lock the CARDIOHELP-i: Set the locking lever [1] to the [Locked] symbol [3].
5 Ensure that the locking device has correctly clicked into place and that the CARDIOHELP-i is securely fixed.

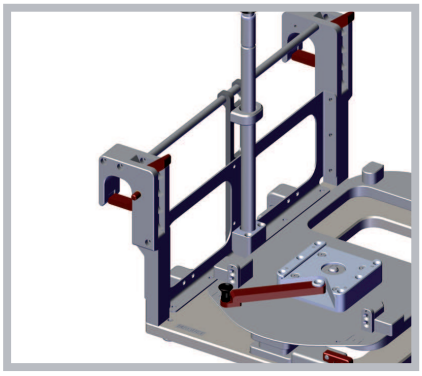
4.2.3 Attaching and Adjusting the Infusion Mast (Optional)

1 In order to attach the infusion mast, press and hold the locking device of the mast retainer [2].



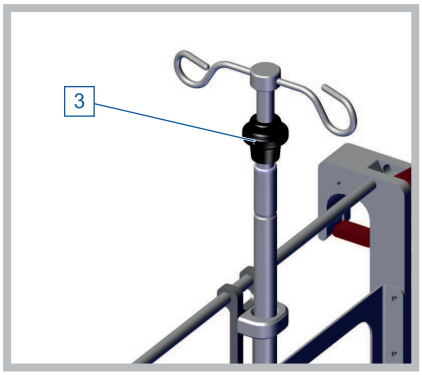
2 Insert the mast through the holder [1] into the retainer [2] from above and release the locking device.

3 Make sure that the locking device is firmly engaged and that the infusion mast is securely fixed in place.



4 In order to adjust the height of the infusion mast, move the plastic ring [3] upward.

5 Set the upper part of the mast to the desired height and release the plastic ring.



6 Make sure that the upper part of the mast has engaged.

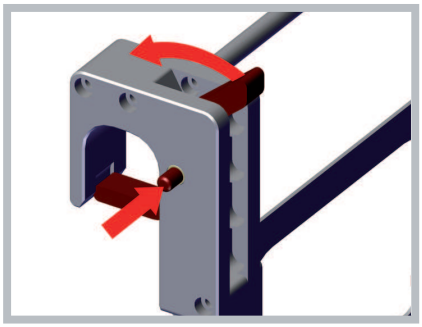
4.2.4 Attaching the Mobile Holder to a Stretcher

You can attach the mobile holder to a stretcher using the two lockable hooks.

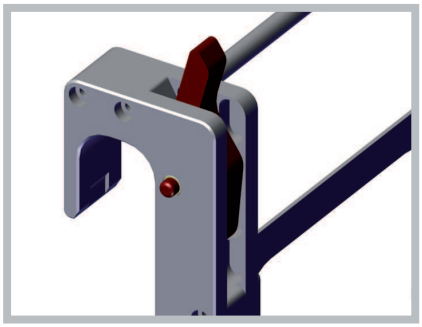
WARNING!

Ensure that by attaching the mobile holder the permissible load of the stretcher is not exceeded. Please take the weight of the loaded mobile holder into account (⇨ "Accessories for Intra-Hospital Patient Transport", page 199).
An unfastened mobile holder can be knocked out of the hooks by vibrations or impacts. Make sure that both hooks are properly attached to the stretcher and securely locked.

1 To open the locking mechanism of the hook, press the locking button and press the lever upward.



- If you push the lever all the way up, the lock engages and remains open.



2 Attach the mobile holder to the stretcher with both hooks.

3 Press on the locking button, to close the lock again.
   ▸ The hook is locked.
4 Make sure that both hooks are properly attached to the stretcher and securely locked.

4.3 Positioning the CARDIOHELP Emergency Drive

4.3.1 Fitting the CARDIOHELP Emergency Drive Holder

The following holding devices are available for the CARDIOHELP Emergency Drive:

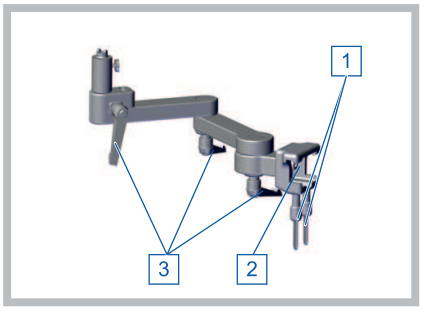
- Holder for slide rail HKH 9101-R (accessory)
- Holder for mast HKH 9101-M (accessory)
- CARDIOHELP-i holder

WARNING!

- Please note the requirements regarding position of use and operation and positioning of the device CARDIOHELP-i (⇨ "Position of Use and Operation and Positioning of the CARDIOHELP-i", page 15).
- Ensure that the operating position requirements of the attached disposable are complied with (⇨ Instructions for Use of the disposable).
- Install the holder near the CARDIOHELP-i so that you can easily switch the disposable from the CARDIOHELP-i to the CARDIOHELP Emergency Drive.
- Ensure that there is sufficient room to use the hand crank of the CARDIOHELP Emergency Drive.

Holder for slide rail HKH 9101-R

1 Loosen the pendulum screws [1] on the slide rail retainer [2].

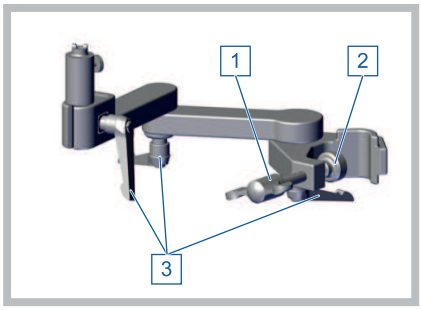


2 Position the holder so that the slide rail fits into the slide rail retainer and screw the pendulum screws tight.
3 Align the articulated arms as required and tighten the locking lever [3].
4 Make sure that the pendulum screws and locking lever are properly tightened and the holder is securely fixed.

To detach the holder, follow the same procedure in reverse order.

Holder for mast HKH 9101-M

1 Undo the wing bolt [1] on the mast retainer [2].



2 Position the holder so that the mast fits into the mast retainer and tighten the wing bolt.
3 Align the articulated arms as required and tighten the locking lever [3].
4 Make sure that the wing bolt and locking lever are properly tightened and the holder is securely fixed.

To detach the holder, follow the same procedure in reverse order.

4.3.2 Fitting the CARDIOHELP Emergency Drive

The CARDIOHELP Emergency Drive can be used to drive the disposable manually if the CARDIOHELP-i should fail.

WARNING!

- Only use the holders listed as accessories (⇨ "Accessories", page 194) or the holder on the CARDIOHELP-i.
- Ensure that there is sufficient room to use the hand crank of the CARDIOHELP Emergency Drive.
- If you operate the CARDIOHELP-i on the SPRINTER CART XL, ensure that the operating position requirements of the attached disposable are complied with (⇨ Instructions for Use of the disposable).

The CARDIOHELP Emergency Drive can be fixed to the holders provided or to the holder of the CARDIOHELP-i.

1 Insert the CARDIOHELP Emergency Drive into the coupling [1] on the holder or on the CARDIOHELP-i.

Holder for CARDIOHELP Emergency Drive HKH 9101-R or HKH 9101-M:

1 Coupling for CARDIOHELP Emergency Drive
2 Coupling release mechanism

2 Ensure that the coupling clicks properly into place.

Dismantling the CARDIOHELP Emergency Drive

- Press on the coupling release mechanism [2] and pull out the CARDIOHELP Emergency Drive.

4.4 Setting Up and Connecting the CARDIOHELP-i

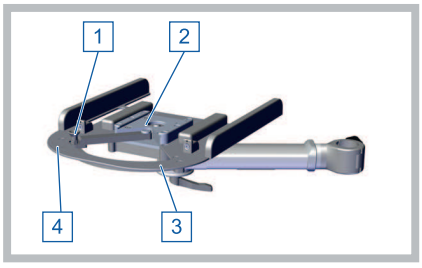
WARNING!

- Please note the requirements regarding position of use and operation and positioning (⇨ "Position of Use and Operation and Positioning of the CARDIOHELP-i", page 15).

1 Position the CARDIOHELP-i in a suitable place.
Or
2 Position the CARDIOHELP-i on suitable holders.
Or
3 Position the CARDIOHELP-i on the SPRINTER CART / SPRINTER CART XL (⇨ SPRINTER CART / SPRINTER CART XL Instructions for Use).

4.4.1 Fixing the CARDIOHELP-i on the Holder HKH 9102-M

1 Check that the locking device is open.



- Locking lever [1] on the [Open] symbol [4].

2 Slide the CARDIOHELP-i onto the holder.

3 Ensure that the sled on the underside of the CARDIOHELP-i slides into the retainer [2].

4 Lock the CARDIOHELP-i: Set the locking lever [1] to the [Locked] symbol [3].
5 Ensure that the locking device has correctly clicked into place and that the CARDIOHELP-i is securely fixed.

NOTE

Only use the connecting cables listed as accessories (⇨ "Accessories", page 194).

1 Connect the CARDIOHELP-i to the external power supply:

- Alternating current: Connect the AC power supply cord to the AC connector plug [1].

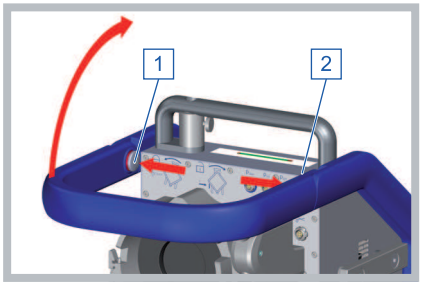
2 Connect a suitable equipotential bonding conductor to the equipotential bonding connection [2].
- Ensure that suitable equipotential bonding conductors and equipotential bonding cables which meet national requirements are used.

NOTE

Equipotential bonding conductor
When the CARDIOHELP-i is connected to an external power supply, ensure that the protective ground equipotential bonding is assured and the equipotential bonding conductor is connected.
The equipotential bonding conductor enables the electrical device to be connected to the equipotential bonding busbar of the electrical installation directly. 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 setup of medical electrical equipment, please refer to the standard IEC 60601-1 Chapter 16.

4.4.2 Opening the Safety Bar

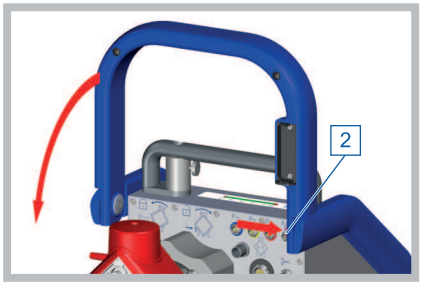
1 Press the release mechanisms [1] and [2] and fold the safety bar up.



2 Ensure that the safety bar release mechanism [2] clicks into place.

4.4.3 Closing the Safety Bar

1 Press the release mechanism [2] and fold the safety bar down.

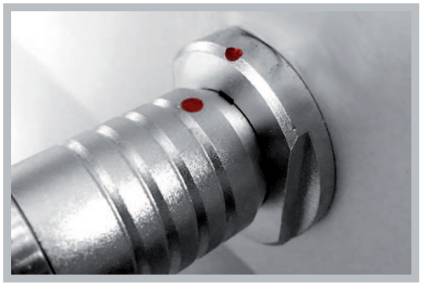


2 Ensure that both release mechanisms of the safety bar click into place.

4.4.4 Connecting the Sensors

The sensor connections and plugs are each marked with a red dot.

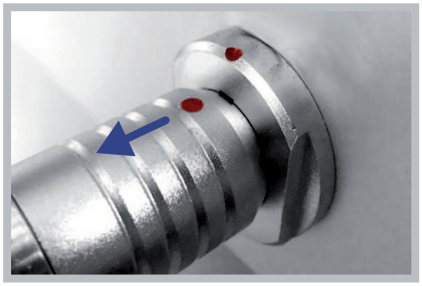
1 Align the plug using the red dots.



2 Insert the sensor into the appropriate CARDIOHELP-i connection.
   ▸ The sensor is connected and fixed to the device.

4.4.5 Removing the Sensors

- Pull back the locking ring on the plug and remove the sensor from the CARDIOHELP-i.



4.5 Connecting External Devices (Optional)

WARNING!

- If you are using the CARDIOHELP-i together with other medical devices, check the total leakage currents.
- Only connect the device to interfaces that are specified by Maquet.
- Ensure that devices which are connected to the digital interface of the CARDIOHELP-i fulfill the following specifications:
  – 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)
- Only select system components which satisfy the requirements for the medical environment in which they are used (in particular IEC/EN 60601-1 Chapter 16). If in doubt, contact the manufacturers of the system components.
- Do not touch the patient and the interfaces of the device at the same time.
- Only use the connections for the respectively intended devices.

- Only use the type B USB port to connect an external data recording system for recording data online. Not all data displayed by the CARDIOHELP-i will be transferred to the external data recording system. Therefore, do not rely on the recorded data to make treatment decisions. Monitor all displays on the CARDIOHELP-i.
- Protect any connections not in use with the protective caps supplied.

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

The connections for external devices are located on the front of the CARDIOHELP-i (⇨ "Connectors", page 33).

4.5.1 Connecting a Data Recording System

NOTE

Only use a type A/type B USB 2.0 cable which is listed as an accessory (⇨ "Accessories", page 194).

- Connect external data recording systems to the type B USB connection [1].

- ▸ This enables the transfer of data from the CARDIOHELP-i to an external system.

4.5.2 Connecting an External Alarm System

WARNING!

External alarm is not guaranteed

- The transmission of the alarm signal to an external alarm system is not fail-safe within the meaning of the IEC 60601-1-8 standard. Do not rely on the external alarm system to generate an alarm. There is a risk that alarm situations may not be recognized.
- Alarm signals are only transmitted when the CARDIOHELP-i generates an acoustic alarm.
- In "Global Override" mode, no alarm signals are transmitted at the "Alarm outlet" interface (⇨ "Pausing the Current Alarm", page 50).
- During the alarm pause no alarm signals are transmitted at the "Alarm outlet" interface (⇨ "Pausing the Current Alarm", page 50).

NOTE

In order to connect an external alarm system, the operator must use a specially adapted cable (plug type RJ22, max. line voltage 40 V, max. rated capacity 500 mAh).

You can connect an external alarm system to monitor and transmit alarms.

- Connect the external alarm system to the "Alarm outlet" interface [1].

- ▸ This enables the transfer of data from the CARDIOHELP-i to an external system.

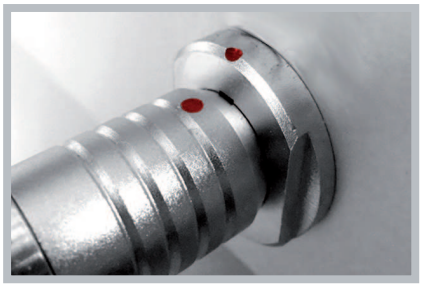
4.6 Connecting the Venous Probe

WARNING!

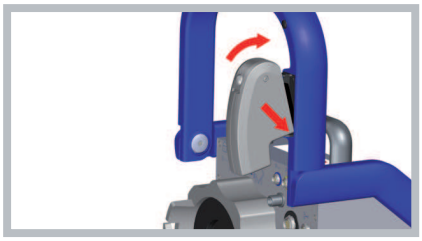
Only use the venous probe connecting cable listed as an accessory (⇨ "Accessories", page 194).

1 Connect the sensor cable to the venous probe [1].

2 Connect the sensor cable to the "Venous probe" interface [2].
The port and plug are each marked with a red dot. Use the two red dots to align the plug correctly (⇨ "Connecting the Sensors", page 68).



3 Fix the venous probe in its holder on the safety bar of the CARDIOHELP-i.



4 Ensure that the venous probe has clicked into place.

4.7 Switching on the CARDIOHELP-i, Self-Test

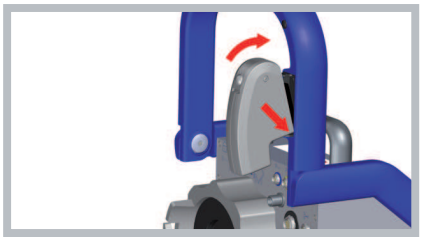
WARNING!

Attaching the venous probe to the holder
The holder on the safety bar of the CARDIOHELP-i contains a black reference surface against which the venous probe can be initialized.
Ensure that the venous probe is located in the holder during initialization. Otherwise, initialization may produce measurements which cause false value displays and alarms.

NOTICE!

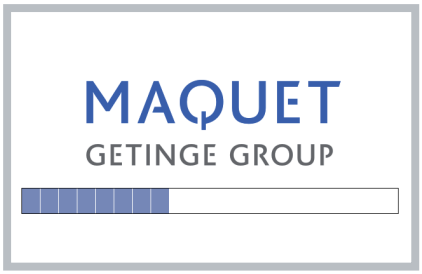
Do not use the touchscreen/rotary knob during the self-test
During the self-test, the CARDIOHELP-i also tests the function of the touchscreen and rotary knob. Do not use the touchscreen or rotary knob during the self-test. Otherwise, the CARDIOHELP-i could interpret a malfunction.

1 Fix the venous probe in its holder on the safety bar of the CARDIOHELP-i.



2 Ensure that the venous probe has clicked into place.
3 Connect the disposable's integrated sensors (⇨ "Connecting the Integrated Sensors of the Disposable", page 103).
4 Press the "On/Off" button.

5 Check that the speaker and warning buzzer generate acoustic signals.

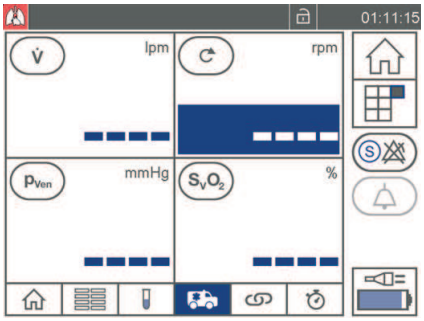


- The CARDIOHELP-i will automatically perform a self-test after being switched on.
- The CARDIOHELP-i initializes the venous probe against the black reference surface on its holder.

6 Check that initialization of the venous probe was successful ⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112.

4.7.1 Display Following Successful Self-Test

After the self-test, the CARDIOHELP-i displays the startup screen (⇨ "Startup Screen", page 48).



thApp "Cardiopulmonary support" Analogous for other thApps.

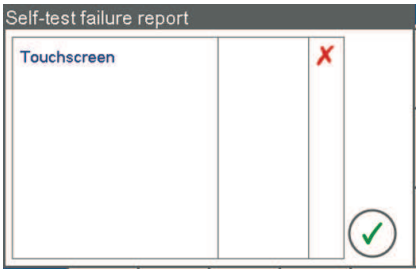
NOTE

thApp after start-up
The CARDIOHELP-i always starts with the thApp that was active before switching off (⇨ "thApp-specific Parameters and Functions", page 29).

4.7.2 Display in Case of Error

If an error occurs during the self-test, the touchscreen displays a self-test failure report (⇨ "Self-Test Failure Report", page 183).

1 Touch the symbol [Confirm] to close the failure report.



2 Carry out the actions suggested in the relevant chapter (⇨ "Self-Test Failure Report", page 183).
Or
Take the CARDIOHELP-i out of service and have it tested by the authorized service personnel.

4.8 System Configuration

4.8.1 thApp "MECC": Deactivate Automatic Locking

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

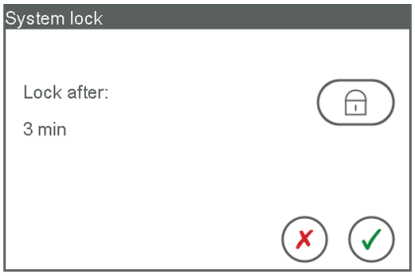
WARNING!

Risk from accidental changing of the settings
When the locking of the controls is deactivated, there is a risk that settings may be unintentionally changed, resulting in unsuitable warning and alarm limits and interventions being set.

This function enables you to deactivate the automatic locking of controls (⇨ ""Lock/Unlock" LED and Button", page 37).

1 Touch the [Settings] symbol in the menu.

2 Touch [System lock] in the "Settings" screen.



3 To activate or deactivate the automatic lock, touch the [AutoLock] symbol.

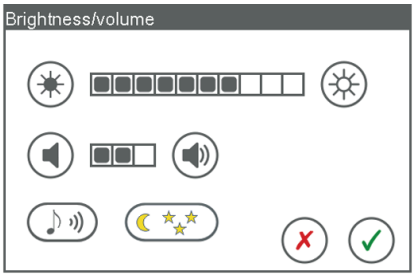
4 To accept the changes, touch the [Confirm] symbol.
Or
To reject the changes, tap the [Reject] symbol.

	AutoLock symbol	Meaning
	Deactivated	The controls are not locked automatically. To activate the automatic lock, touch the symbol.
	Activated	The controls are locked automatically. To deactivate the automatic lock, touch the symbol.

4.8.2 Changing and Testing the Brightness/Volume

This function enables you to change the brightness of the display and the volume of acoustic signals. In addition, the speaker and alarm buzzer functions can be tested.

1 Touch the [Settings] symbol in the menu.



2 Touch [Brightness/volume] in the "Settings" screen.

Changing the brightness

NOTE

The "Brightness" setting cannot be changed when night mode is active.

1 Touch the appropriate symbol to change the brightness.
   - The CARDIOHELP-i changes the brightness to enable you to assess the selected brightness.
2 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

Changing the volume

1 Touch the appropriate symbol to change the volume.
2 To accept the changes, touch the [Confirm] symbol.
Or
3 To reject the changes, touch the [Reject] symbol.

Testing the speaker/warning buzzer

1 To test the speaker and warning buzzer, touch the [Test speaker] symbol.
   - The speaker and alarm buzzer of the CARDIOHELP-i generate acoustic signals with which the function and volume can be checked.
2 To accept the changes, touch the [Confirm] symbol.
   Or
   If you wish to reject the changes, touch the [Reject] symbol.

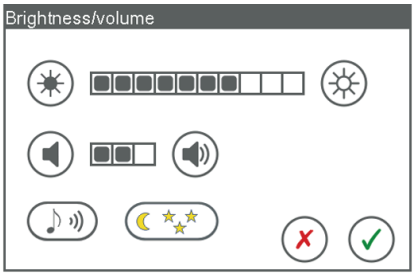
4.8.3 Activating Night Mode

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

In night mode, the brightness of the touchscreen is reduced.

1 Touch the [Settings] symbol in the menu.
2 Touch [Brightness/volume] in the "Settings" screen.



   - The [Night mode] symbol is not available in the thApp "MECC". The touchscreen does not display the symbol.
3 Touch the [Night mode] symbol.
4 To accept the changes, touch the [Confirm] symbol.
   Or
5 To reject the changes, tap the [Reject] symbol.

Night mode symbol	Meaning
	Deactivated
	Activated

NOTE

If night mode is active and you switch to thApp "MECC", night mode is deactivated automatically. If you return to another thApp, night mode remains deactivated.

4.8.4 Changing the Display Language

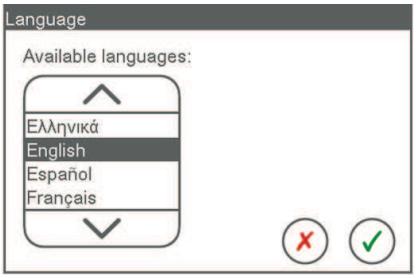
NOTE

Only when pump is at a standstill
This function is only possible in RPM mode when the pump is at a standstill.

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

1 Touch the [Settings] symbol.

2 Touch [Language] in the "Settings" screen.

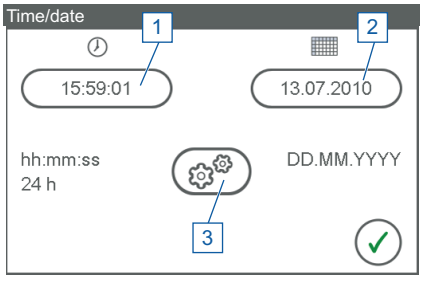


3 Select the desired language from the list.
- If the list is gray, a selection cannot be made because the pump is operating.

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

4.8.5 Changing the Time, Date and Formats

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



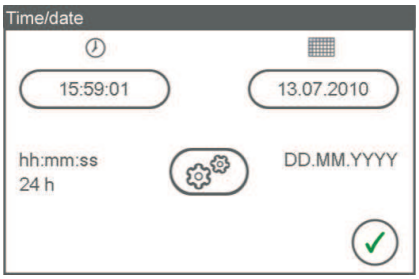
"Time/date" screen

1 Change time
2 Changing the date
3 Change time/date format

Change time

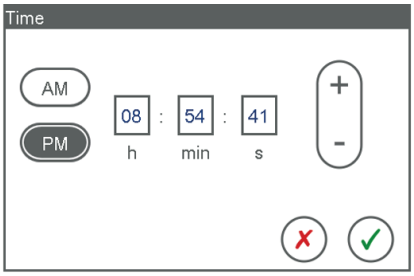
1 Touch the [Settings] symbol in the menu.

2 Touch [Time/date] in the "Settings" screen.



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

- The touchscreen displays the [Time] screen.



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

5 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].
NOTE: The [AM] and [PM] buttons are only visible in the 12-hour format.

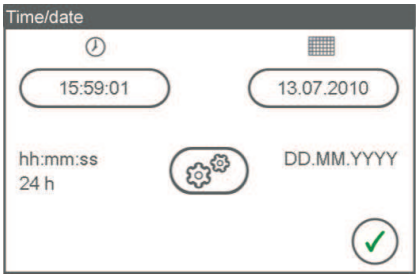
6 To accept the changes, touch the [Confirm] symbol.
Or
To reject the changes, touch the [Reject] symbol.
- The touchscreen shows the [Time/date] screen again.

7 To close the screen, touch the [Confirm] symbol.

Changing the date

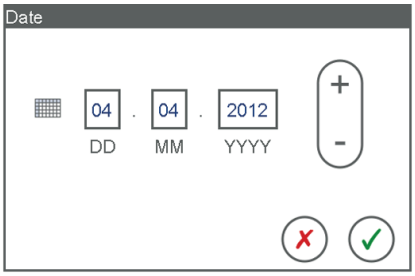
1 Touch the [Settings] symbol in the menu.

2 Touch [Time/date] in the "Settings" screen.



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

- The touchscreen displays the [Date] screen.
  In this example the format DD.MM.YYYY.



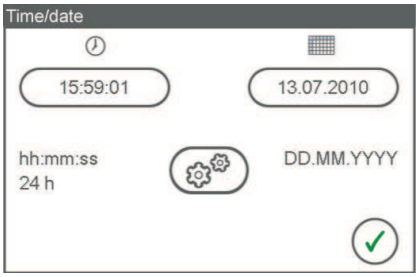
4 Set the current date. To do this, touch the fields and adjust the values.
5 To accept the changes, touch the [Confirm] symbol.
Or
To reject the changes, touch the [Reject] symbol.
- The touchscreen shows the [Time/date] screen again.

6 To close the screen, touch the [Confirm] symbol.

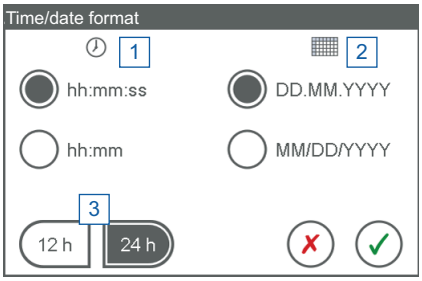
Changing the time/date format

1 Touch the [Settings] symbol in the menu.

2 Touch [Time/date] in the "Settings" screen.



3 To change the time and date format, touch the [Settings] symbol.
- The touchscreen displays the [Time/date format] screen.



4 Set the current date. To do this, touch the fields and adjust the values.
5 Select the desired time and date format [1], [2]. To do this, touch the appropriate buttons.
NOTE: During data recording (⇨ "Data Recording", page 96) the seconds are also recorded, even if you select the hh:mm format here.
6 Choose between 12 and 24 hour format [3]. To do this, touch the corresponding buttons.

7 To accept the changes, touch the [Confirm] symbol.
Or
To reject the changes, touch the [Reject] symbol.
- The touchscreen shows the [Time/date] screen again.

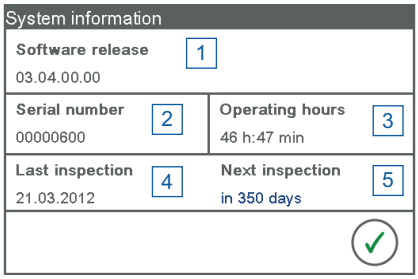
8 To close the screen, touch the [Confirm] symbol.

4.9 System Information

4.9.1 Displaying System Information

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

1 Touch the [Settings] symbol in the menu.
2 Touch [System information] in the "Settings" screen.
- The touchscreen displays the following window:



1 Software version
2 Device serial number
3 Operating time since installation
4 Date of last inspection (⇨ "Maintenance", page 187)
5 Time until next inspection (⇨ "Maintenance", page 187)

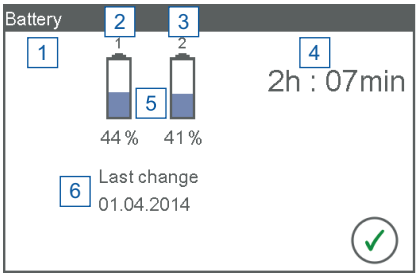
3 To close the screen, touch the [Confirm] symbol.

4.9.2 Displaying Battery Status

The battery status displays the charge status of the batteries and the date of the last battery change.

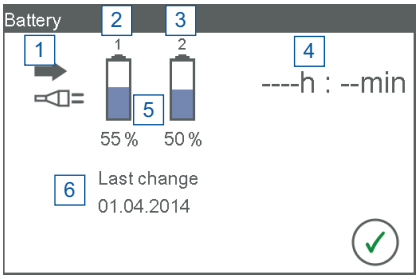
1 Touch the [Status of the power supply] symbol (in the bottom right of all screens).

- "Battery" window during battery operation.



1 Charging and power supply status (not visible)
2 Battery compartment 1 (corresponds to label on battery compartment)
3 Battery compartment 2 (corresponds to label on battery compartment)
4 Approximate remaining battery time
5 Battery status
6 Date of last battery change

- "Battery" window during mains operation.



1 Charging and power supply status
2 Battery compartment 1 (corresponds to label on battery compartment)
3 Battery compartment 2 (corresponds to label on battery compartment)
4 Approximate remaining battery time (blank)
5 Battery status
6 Date of last battery change

2 To close the screen, touch the [Confirm] symbol.

	AC/DC power supply status	Meaning
	Battery charging	Battery is being charged.
	AC/DC power supply	CARDIOHELP-i is connected to an external power supply.

	Battery status	Meaning
	Remaining capacity	Approximate remaining capacity.
	Calibration required	⇨ "Calibrating the Batteries", page 85
	Battery not detected	Have CARDIOHELP-i checked by authorized service personnel.

4.10 Key User Functions

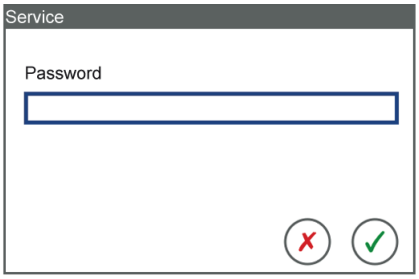
The [Service] screen is password-protected and may only be used by authorized personnel.

If the touchscreen is wrongly calibrated, you may not be able to access the "Service" screen via the touchscreen. If this is the case, you can call up touchscreen calibration using a button combination instead (⇨ "Calibrate Touchscreen", page 84).

4.10.1 Calling Up the "Service" Screen

1 Touch the [Settings] symbol in the menu.

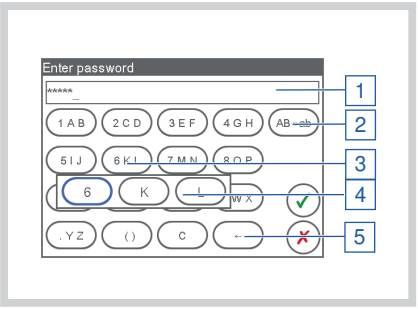
2 Touch [Service] in the "Settings" screen.



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

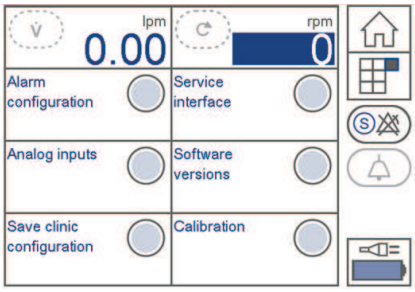
3 Touch the input field.

- 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:
5 Touch the button [3] which contains the necessary character.
   - The touchscreen displays a selection window [4] with the button's three characters.
6 Touch the desired character.
7 To accept the input, touch the [Confirm] symbol.
   Or
   Touch the [Reject] symbol to reject the input.



- If you have correctly entered and confirmed the password, you have the following options:
  ⇨ "Define the Alarm Configuration", page 83
  ⇨ "Save Hospital Configuration", page 83

  Calibration:
  ⇨ "Calibrate Touchscreen", page 84
  ⇨ "Calibrating the Batteries", page 85

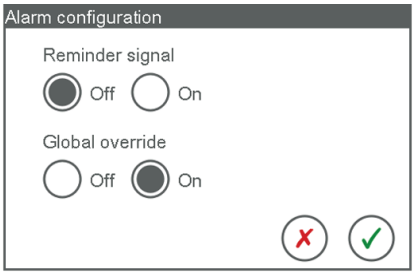
All the other functions are only relevant for authorized service personnel.

4.10.2 Define the Alarm Configuration

With this function you can define whether the CARDIOHELP-i generates reminder signals. If the reminder signal is disabled, the user is not reminded acoustically that the "Global Override" or the emergency mode is active, for example.

You can also specify whether the user is able to use the "Global Override" function. If the "Global Override" function is disabled, the "Global Override" symbol has no function.

1 Call up the "Service" screen (⇨ "Calling Up the "Service" Screen", page 81).
2 Touch Alarm configuration in the "Service" screen.
   - The touchscreen displays the "Alarm configuration" window.



3 To disable the reminder signal, touch [Off].
   Or
   To enable the reminder signal, touch [On].
4 To permit use of the "Global Override" mode, touch [On].
   Or
   To prevent use of the "Global Override" mode, touch [Off].
5 To accept the input, touch the [Confirm] symbol.
   Or
   If you wish to reject the input, touch the [Reject] symbol.

4.10.3 Save Hospital Configuration

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

This function enables you to save the settings as a clinic configuration. The configuration is used automatically when the CARDIOHELP-i is switched on.

NOTE

Clinic configuration
The following settings are part of the clinic configuration:

- Deactivation of the automatic lock (⇨ "thApp "MECC": Deactivate Automatic Locking", page 73)
- Language (⇨ "Changing the Display Language", page 76)
- Recording interval (⇨ "Change the interval for data recording", page 97)
- Alarm configuration (⇨ "Define the Alarm Configuration", page 83)
- Warning limits, alarm limits and intervention (⇨ "Physiological Alarms and Interventions", page 121)

1 Call up the "Service" screen (⇨ "Calling Up the "Service" Screen", page 81).
2 In the "Service" screen, touch [Save clinic configuration].
   ▸ The CARDIOHELP-i saves the settings and displays the following message:
   [Data saved successfully].
3 To confirm the message, tap the [Confirm] symbol.

4.10.4 Calibrate Touchscreen

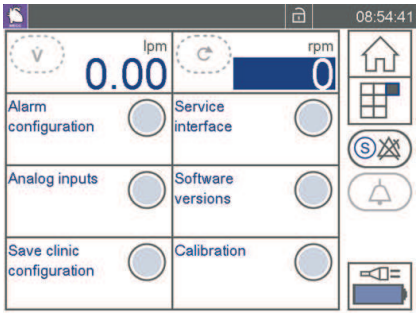
NOTE

Only when pump is at a standstill
This function is only possible in RPM mode when the pump is at a standstill.

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.

1 Activate the RPM mode (⇨ "Activating LPM/RPM Mode", page 92).

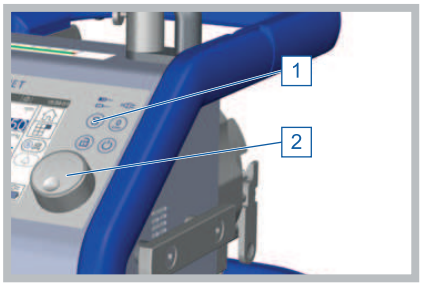


2 Turn the rotary knob counterclockwise until the rpm value 0 is displayed.
   ▸ The pump stops.

3 Call up the "Service" screen (⇨ "Calling Up the "Service" Screen", page 81).

4 In the "Service" screen, touch [Calibration].

5 Touch [Touchscreen calibration].
Or
If the touchscreen is wrongly calibrated, you may not be able to access the "Service" screen via the touchscreen. If this is the case, you can call up touchscreen calibration using the following button combination instead: Hold down the safety button [1] and at the same time press the rotary knob [2] for at least 10 seconds.



- The touchscreen displays the red cross at various positions.

6 Always touch exactly the center of the red cross.
- The CARDIOHELP-i checks the positions touched and calibrates the touchscreen accordingly.

7 If you have accessed the "Service" screen via the touchscreen, touch the [Back] symbol to close the "Calibration" screen.

4.10.5 Calibrating the Batteries

NOTE

Only when pump is at a standstill
This function is only possible in RPM mode when the pump is at a standstill.

NOTE

Ambient conditions
- Carry out the calibration at room temperature.

NOTE

Power supply

- The CARDIOHELP-i must be connected to an external AC power supply during calibration.
- If the CARDIOHELP-i is disconnected from the external power supply during calibration, calibration must be restarted.

To enable the most accurate display possible of the remaining battery life, the batteries must be calibrated regularly. How often calibration is required, depends on the ambient conditions and use of the CARDIOHELP-i (⇨ "Maintenance by the operator", page 187).

The CARDIOHELP-i performs calibration automatically with the battery calibration function. The calibration cycle comprises the following steps:

1 "Charging to 100%": Batteries are fully charged.
2 "Discharging": Batteries are fully discharged.
3 "Charging to 100%": Batteries are fully charged.

Calibration takes several hours, during which the CARDIOHELP-i cannot be used. Depending on the battery state, more than one calibration cycle may be necessary until calibration is successfully concluded.

The calibration cycles are performed automatically and are displayed below "Cycle". The first number shows the current cycle of the CARDIOHELP System. The second number shows the maximum number of calibration cycles.

In the case of two or more cycles, only the last cycle is concluded with step 3. If more than 3 cycles are necessary, the batteries must be replaced.

The remaining time shown is only approximate. The time actually needed may be shorter or longer, depending on the age and condition of the batteries and their power intake.

Symbol	Meaning
[no symbol]	Step active or not started.
OK	Step completed successfully.
Failed	Step aborted (e.g., after interruption of power supply).

- Calibration can be aborted at any time. To do so, touch the [Reject] symbol (⇨ "Aborting calibration", page 89).
- If a calibration step fails, calibration is aborted.
- If calibration is aborted, it must be restarted and carried out completely (⇨ "Calibration failed", page 89).

Battery Calibration Unit (optional)

The time required for calibration can be significantly reduced with the Battery Calibration Unit. This cuts the time needed for discharging by about three quarters. The Battery Calibration Unit has no effect on discharging or remaining battery life except during calibration.

WARNING!

The Battery Calibration Unit becomes hot during discharging, especially around the ventilation openings.

- Ensure that the Battery Calibration Unit ventilation openings are not covered.
- Place the Battery Calibration Unit in a way that the heat can disperse easily.
- Do not place any heat-sensitive objects or materials directly above, below or next to the Battery Calibration Unit.

Calibrating

NOTE

Only when pump is at a standstill
This function is only possible in RPM mode when the pump is at a standstill.

NOTE

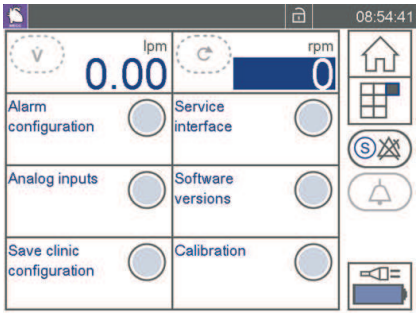
Calibration takes several hours, during which the CARDIOHELP-i cannot be used.

1 Connect the CARDIOHELP-i to the external AC power supply (⇨ "Setting Up and Connecting the CARDIOHELP-i", page 65).

2 Connect the Battery Calibration Unit to interface [1] if available.

▸ This considerably reduces the time required for battery calibration.

3 Call up the "Service" screen (⇨ "Calling Up the "Service" Screen", page 81).

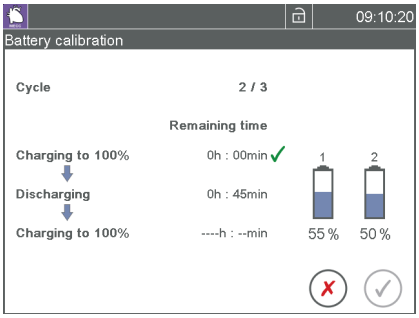


4 In the "Service" screen, touch [Calibration].

5 Touch [Battery calibration].

- The CARDIOHELP-i shows the following message: [Battery calibration takes several hours. Device must be connected to AC power supply. Proceed?]

6 Touch the [Confirm] symbol to start battery calibration.



- The CARDIOHELP-i must be connected to the external power supply.
- The [Battery calibration] screen is opened.
- You can follow the progress and status of battery calibration.

7 Once calibration has finished, you can close the [Battery calibration] window by touching the [Confirm] symbol.

8 To return to the "Service" screen, touch [Return].
Note: The [Confirm] symbol is active as soon as the batteries reach 40% charge. However, it is recommended to charge the batteries fully.

9 If connected, disconnect the Battery Calibration Unit from the CARDIOHELP-i.

10 Check the battery status: Touch the symbol for the status of the power supply (in the lower right of all screens).

11 If the symbol "Calibration required" is displayed in the [Battery] window, you must carry out calibration again.

12 Record the successful calibration in your device documentation or the CARDIOHELP-i medical device logbook.

WARNING!

Charge level after calibration is completed
If you confirm calibration prematurely (battery charge status approx. 40%), the batteries are not fully charged.

- Connect the CARDIOHELP-i to the external power supply.
- Do not use the CARDIOHELP-i again until the batteries are fully charged.

Aborting calibration

You can abort calibration at any time.

1 To do this, touch the [Reject] symbol.
   - The touchscreen shows the following message: [Really abort? Calibrating batteries again takes several hours].
2 To confirm you want to abort, touch the [Confirm] symbol.
   Or
   To cancel aborting instead, touch the [Reject] symbol.
3 To return to the "Service" screen, touch [Return].

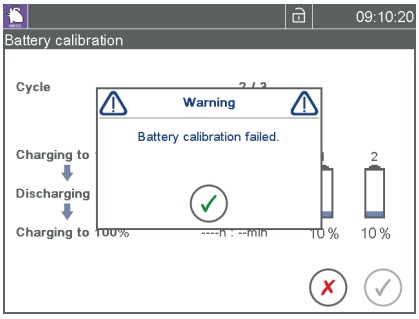
WARNING!

Charge level after calibration has been discontinued
After calibration has been aborted, the batteries may be in a partly or fully discharged state.

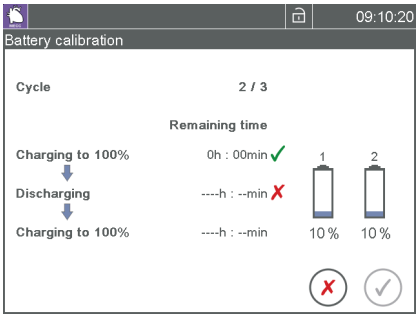
- Connect the CARDIOHELP-i to the external power supply once calibration has been aborted.
- Do not use the CARDIOHELP-i again until the batteries are fully charged.

Calibration failed

1 To close the error message, touch the [Confirm] symbol.



2 To close the "Battery calibration" window, touch the [Reject] symbol.



3 Start calibration again (⇨ "Calibrating", page 87).
4 If calibration fails again, have the batteries replaced by authorized service personnel.

WARNING!

Battery operation not possible
If the batteries cannot be calibrated successfully, they must be replaced in order to ensure safe use of the CARDIOHELP-i.
- Notify the authorized service (⇨ "Authorized Service", page 189).

4.11 User Functions

Under User Functions you will find basic information on the use of thApps, modes and other key functions.

4.11.1 Switching thApp

WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.
The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

WARNING!

- Ensure that the selected thApp is suitable and safe for the patient and the current situation.
- If you switch to another thApp, only the warning and alarm limits and interventions that are available in the new thApp are applied. Warning and alarm limits and interventions that are not available are not applied (⇨ "thApp-specific Parameters and Functions", page 29).
  Ensure that the selected warning and alarm limits and interventions used are suitable and safe for the patient and current situation.
- After switching the thApp, check whether the settings, limits and interventions are suitable and safe for the patient and the current situation.

WARNING!

Monitoring of pAux only in the thApp "MECC"

- Remember that the auxiliary external pressure sensor pAux is only monitored in the thApp "MECC". In other thApps, the CARDIOHELP-i generates no alarms and will not carry out any interventions if the measured value is outside the warning or alarm limits.
- The intervention is automatically deactivated when you switch from the thApp "MECC" to another thApp.

WARNING!

Changing to the "MECC" thApp
When you switch back from another thApp to the "MECC" thApp, the level intervention and the intervention for the p_{Aux} parameter remain deactivated. Check the necessary interventions and activate these.

NOTE

Changing the thApp deactivates the alarm pause

- When you switch thApp, the alarm pause for current acoustic alarms ends (⇨ "Pausing the Current Alarm", page 50).

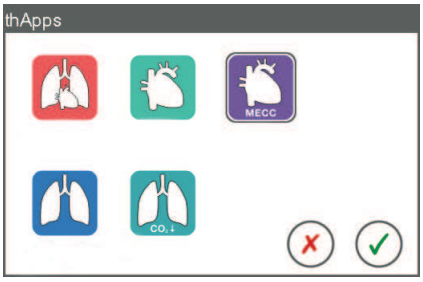
With this function you can switch between the thApps (⇨ "thApp-specific Parameters and Functions", page 29).

Switching is not possible during USB export (⇨ "Export recorded data", page 98), in emergency mode, during battery calibration or during touchscreen calibration (⇨ "Calibrate Touchscreen", page 84).

NOTE

In order not to change the thApp, you can abort the procedure at any time with the [Reject] symbol.

1 Touch the "thApp" symbol in the menu.



2 Touch the symbol of the desired thApp.
3 To accept the changes, touch the [Confirm] symbol.
   ▸ The touchscreen shows the following message: [Do you want to change the thApp]?
4 To change the thApp, touch the [Confirm] symbol.
   ▸ The touchscreen shows the following message: [Check the settings and limit values].
5 To confirm the message, tap the [Confirm] symbol.
   ▸ The selected thApp is active.

4.11.2 Activating LPM/RPM Mode

WARNING!

- Only use RPM mode for intra-hospital patient transport. In LPM mode, the pump control can be impaired by incorrect flow values.

WARNING!

LPM mode

- Set the speed monitor's patient-specific alarm limits and activate the intervention (⇨ "LPM Mode: Speed Monitoring", page 129). An excessive speed can harm the patient.
- Constantly monitor patients, their volume status, and circulation parameters when in LPM mode.
- If you detect any incorrect flow values in LPM mode, switch to RPM mode.
- Do not clamp the tube in LPM mode. When the tube is clamped, the pump can reach maximum speed, even with a setpoint flow of 0 l/min.

NOTE

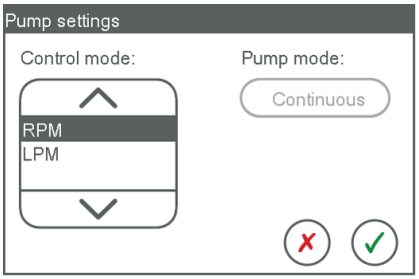
When changing from LPM to RPM, an RPM intervention, if set, is deactivated. When changing again to LPM mode, the intervention is still deactivated and must be activated again manually.

NOTE

Automatic switch to RPM mode in the event of a sensor error
If a flow/bubble sensor fault occurs in the LPM mode, the CARDIOHELP-i automatically switches to the RPM mode, maintains the current speed and displays the following message:
[Mode switched (LPM ↔ RPM)].

After switching on, the CARDIOHELP-i is always automatically in RPM mode.

1 Touch the [Pump] symbol in the menu.



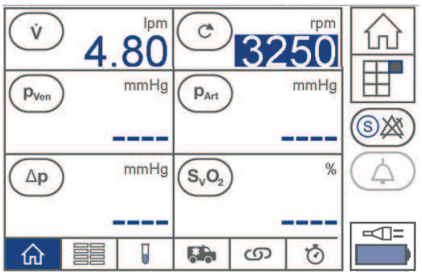
- The pump cannot be changed. The pump mode is set to [Continuous].

2 Select the desired mode from the [Control mode] list.
- RPM: The CARDIOHELP-i switches to RPM mode. The current speed is accepted as the setpoint value.
- LPM: The CARDIOHELP-i switches to LPM mode. The current flow is accepted as the setpoint value.
- You will find further information under ⇨ "RPM and LPM mode", page 30.
  Note: In the event of a fault in the flow/bubble sensor, you cannot switch to LPM mode.

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

RPM mode: changing the speed

In RPM mode, the setpoint speed can be changed in all screens. The value of the [Speed] parameter is shown on a blue background. The touchscreen displays the currently measured value.



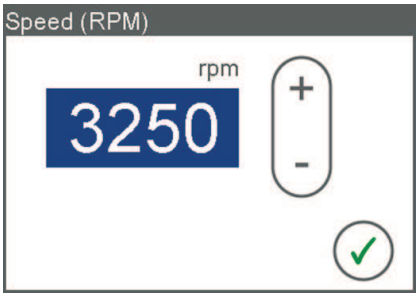
You can change the setpoint value using the touchscreen or the rotary knob.

Change using the rotary knob

- To change the setpoint value, turn the rotary knob.
- The touchscreen displays the specified setpoint value in gray and switches back to display the measured value after 2 seconds.

Change using the touchscreen

1 Touch the [Speed] symbol.



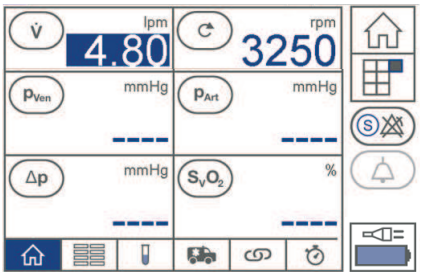
2 To change the setpoint value, touch the field and adjust the value.
   - The touchscreen displays the specified setpoint value in gray and switches back to display the measured value after 2 seconds.
   - The change is applied automatically.
3 To close the window, touch the [Confirm] symbol.
   - The CARDIOHELP-i operates the pump constantly at the set speed. As a result, the flow can vary according to the afterload of the circuit and/or the patient.

WARNING!

Using flow monitoring
The patient-specific warning limits for flow monitoring must be set in the RPM and LPM modes (⇨ "Flow Monitoring", page 127).

LPM mode: changing the flow

In LPM mode, the setpoint flow can be changed in all screens. The value of the flow parameter is shown on a blue background. The touchscreen displays the currently measured value.



You can only change the setpoint with the rotary knob.

- Turn the rotary knob to change the setpoint.
- The touchscreen displays the specified setpoint value in gray and switches back to display the measured value after 2 seconds.
- The CARDIOHELP-i controls the pump in such a way that the set flow is maintained. The speed is varied according to the afterload of the circuit and/or the patient.

4.11.3 "Global Override" Mode

WARNING!

In "Global Override" mode, all interventions, acoustic alarms and backflow prevention are disabled (⇨ "Physiological Alarms and Interventions", page 121 and ⇨ "Backflow Prevention", page 128).

- There is a risk that excessively high or low speeds, flows or pressures, the ingress of air or a backflow may cause harm to the patient.
- Monitor the system continuously.
- Take appropriate measures to avoid excessively high or low speeds, flows or pressures, the ingress of air and a backflow.
- There is a risk that alarms may not be noticed. Therefore, pay attention to optical alarms on the touchscreen.
- In "Global Override" mode, no alarm signals are transmitted at the "Alarm outlet" interface.

NOTE

Deactivated reminder signal and "Global Override"
Authorized persons can specify in the alarm configuration whether the CARDIOHELP-i is to generate reminder signals. If the reminder signal is not activated, you will not be acoustically reminded that the CARDIOHELP-i is in "Global Override" mode.
Furthermore, authorized persons can specify whether you can use the "Global Override" function. If the "Global Override" function is deactivated, the "Global Override" symbol has no function (⇨ "Key User Functions", page 81).

Activating "Global Override"

- Hold the safety button down and touch the [Global Override] symbol.
- ▸ The "Global Override activated" symbol is displayed.
- ▸ All interventions, acoustic alarms and backflow prevention are disabled.
- ▸ In "Global Override" mode, the CARDIOHELP-i generates a reminder signal once per minute, if the "reminder signal" has been activated (⇨ "Define the Alarm Configuration", page 83).

Deactivating "Global Override"

- Touch the "Global Override activated" symbol.
- ▸ The "Global Override" symbol is displayed.
- ▸ All interventions, acoustic alarms and backflow prevention are active again.

"Global Override" cannot be activated

The "Global Override" function has been deactivated by an authorized user and cannot be used (⇨ "Define the Alarm Configuration", page 83).

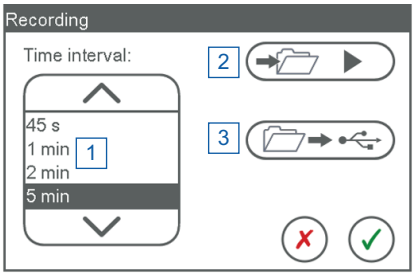
4.11.4 Data Recording

NOTE

Data recording in emergency mode
In the emergency mode, offline recording on the internal memory is switched off. User events, service events and online recording still function (⇨ "Using the Emergency Mode", page 147).

For data recording, use the [Recording] window. Touch the "Recording" symbol in the menu to call it up.

The touchscreen displays the following window:



1 Interval
2 Offline recording
3 Export data

You have the following options:

- Change the interval for data recording.
- Record data offline.
- Export recorded data.

Change the interval for data recording

This function changes the interval for data recording. This setting applies to online and offline recording.

1 Touch the "Recording" symbol in the menu.
2 Select from the [Time interval] list the desired interval at which CARDIOHELP-i records data.
3 To accept the changes, touch the [Confirm] symbol.
Or
If you wish to reject the changes, touch the [Reject] symbol.

Record data offline

This function enables you to record data in an internal memory. The data can later be exported to a USB stick.

NOTE

Starting the recording erases previously recorded data
When you start a recording, previously recorded data is erased from the internal memory.

1 Touch the [Recording] symbol in the menu.
The touchscreen displays the [Recording] window.
2 Start or stop the offline recording by touching the "Offline Recording" symbol.
- While recording is running, the status bar displays the "Offline recording" symbol (⇨ "Status Bar", page 42).

- If the capacity of the internal memory has been reached, the CARDIOHELP-i stops the recording and displays the following message: [Internal memory full – Offline recording stopped].

3 To close the [Recording] window, touch the [Confirm] or [Reject] symbol.

	Offline recording	Meaning
	Stopped	Touch the symbol to start the recording.
	Running	Touch the symbol to stop the recording.
	Not possible	If you have stopped the offline recording, it can only be started again after the window has been closed and opened again.

NOTE

If there is no SD card or the SD card is defective, offline recording is not possible. The [Recording] symbol is deactivated.

Export recorded data

NOTE

Only when pump is at a standstill
This function is only possible in RPM mode when the pump is at a standstill.

NOTE

Only when offline recording has stopped
This function is only possible when no offline recording is running (⇨ "Record data offline", page 97).

The data recorded offline can be exported to a USB stick. The CARDIOHELP-i exports the recorded data in a compressed file, which is named after the start of offline recording (format hhmmDDMM.chp).

Example: Start of offline recording on 29.05.2010, 9:45 – file name 09452905.chp).

WARNING!

Do not touch the patient and the interfaces of the device at the same time.

NOTICE!

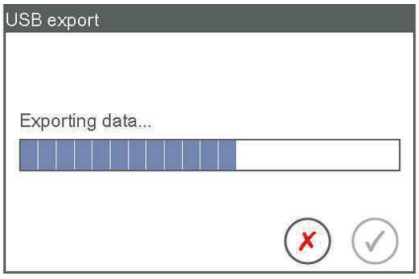
- If the USB stick already contains a file of the same name, it will be overwritten.

NOTE

No switching of the thApp during USB export
During the USB export, the thApp cannot be changed (⇨ "Switching thApp", page 90).

1 Connect the USB stick to the type A USB port [1] on the front.

2 Touch the "Recording" symbol in the menu.
   - The touchscreen displays the [Recording] window.
3 To start the export, touch the "Data export" symbol.
   - The CARDIOHELP-i saves the data on the USB stick.



4 To cancel the export, touch the [Reject] symbol.
   - If you cancel the export, an incomplete file may remain on the USB stick, which does not contain all the recorded data.
   Or
5 To close the [USB export] window, touch the [Confirm] symbol.
6 To close the [Recording] window, touch the [Confirm] or [Reject] symbol.

NOTE

Converting a chp file
The Maquet CSV converter for converting the exported chp file is provided on the USB memory stick supplied. You will also find the Instructions for Use as a pdf file on the USB stick.

5 Preparing Application

5.1 Application Overview for Disposables

Various disposables are available from Maquet Cardiopulmonary for the CARDIOHELP-i. They are tailored for different fields of application, and differ in their integrated sensors, among other things.

Pump drive	Disposable	Connecting cable for disposable	Integrated sensors		Possible external sensors
			P_{Ven}, P_{Int}, P_{Art}	T_{Art}	
HLS retainer	QUADROX-iR	Simple cable, short	No	No	T_{Art}, P_{Ven}, P_{Int}, P_{Art}, P_{Aux}
	HLS Set Advanced	Simple cable, short	Yes	Yes	P_{Aux}

WARNING!

- In order to read out the coding of the venous measuring cell, insert the cable for the integrated sensors prior to turning on the CARDIOHELP-i. The venous probe initializes itself to the venous measuring cell.
- If you change the disposable of the same application area during operation, initialize the venous probe again ⇨ "Initializing the Venous Probe", page 114.

NOTE

Integrated sensor/venous measuring cell and external sensors
If valid values for the integrated sensors are available, the value of the external sensor is ignored. Otherwise, the value of the external sensor is used.

5.2 Preparing Perfusion (HLS Retainer)

5.2.1 Attaching the Disposable for the HLS Retainer

WARNING!

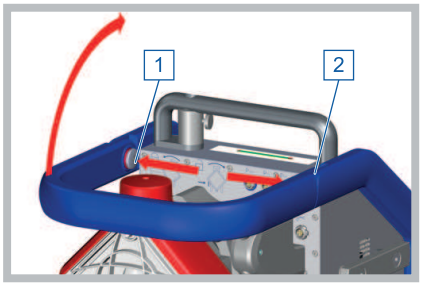
- Only use tubes which are approved for this system (⇨ "Tubing", page 198). Other tubes may collapse, distort flow measurements, cause defective flow regulation and trigger interventions incorrectly. When selecting the flow sensor, take note of the corresponding diameter of the tube used.
- Check that the disposable is securely attached during operation.
- Do not attach any additional devices or products to the disposable.

- Do not route connecting cables or tubes over the safety bar or though the lower protective frame. This ensures you will be able to switch the disposable over to the emergency drive quickly in an emergency (⇨ "Using the Emergency Drive with the Disposable HLS Retainer", page 148).

NOTE

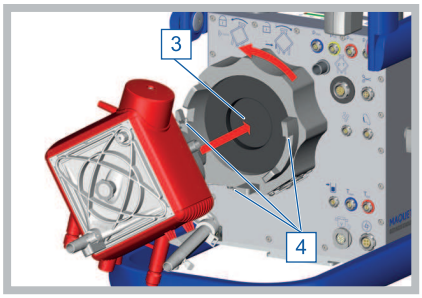
Connecting the disposable
If the disposable is not pre-connected, connect it in the tube system before attaching it to the CARDIOHELP-i (⇨ Disposable Instructions for Use).

1 Open the safety bar (⇨ "Opening the Safety Bar", page 67).



2 Ensure that the safety bar release mechanism [1] and [2] clicks into place.

3 Position the disposable on the pump drive [3] turned through approx. 10° clockwise.



4 Turn the disposable counterclockwise until vertical.
5 Ensure that the three guide pins [4] are in the corresponding holes in the disposable and the locking device clicks into place.

6 Ensure that the disposable is correctly positioned and securely fixed.

7 Connect the connecting cable to the disposable [5].
8 Connect the measuring sensors required.

5.2.2 Connecting the Integrated Sensors of the Disposable

NOTE

Only for disposables with integrated sensors
The connecting cable can only be connected to disposables with integrated sensors.

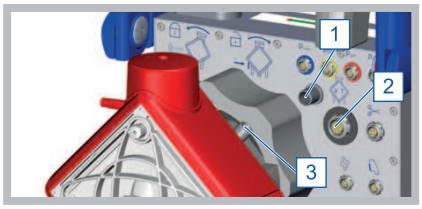
WARNING!

- Only use the disposable connecting cable listed as an accessory and which is suitable for the disposable used (⇨ "Accessories", page 194).
- Refer to the application overview for disposables to ensure that the correct connecting cable is used (⇨ "Application Overview for Disposables", page 101). If the wrong connecting cable is used, the sensor values measured cannot be assigned to the correct parameter value.

WARNING!

Insert the cable for the integrated sensors prior to turning on the CARDIOHELP-i in order to recognize the coding of the venous measuring cell. The venous probe initializes itself to the venous measuring cell.
If you change the disposable during operation, initialize the venous probe again (⇨ "Initializing the Venous Probe", page 114).

1 Plug the connecting cable into the connection for sensors of the disposable [2] on the CARDIOHELP-i.



2 Connect the connecting cable to the disposable [3].
   - Observe the information in the Instructions for Use for the disposable.

5.2.3 Attaching the Venous Probe to the Measuring Cell

WARNING!

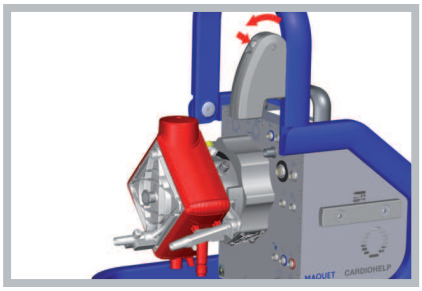
Connect the cable for the integrated sensors before switching the CARDIOHELP-i on in order to detect the coding of the venous measuring cell and retain correct measured values. The venous probe initializes as per the connected venous measuring cell.
If you change the disposable during operation, monitor the status of the venous probe and the measuring cell (⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112).

For measurement, the probe is connected to the disposable's measuring cell. The measuring cell is integrated in the oxygenator pump unit (HLS Set Advanced).

NOTE

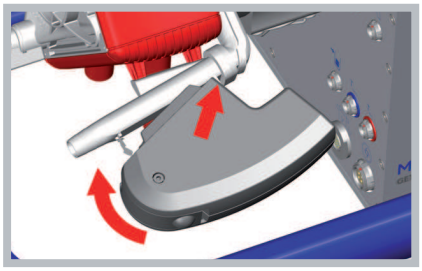
Set breaking point of the integrated measuring cell
A set breaking point of the measuring cell retaining hook prevents the entire disposable being dislodged or damaged if a strain is put on the connecting cable.
In order to prevent the retaining hook breaking off at the set breaking point, attach the venous probe to the measuring cell carefully.

1 Press down the round button on the venous probe.



2 Remove the probe from the holder.

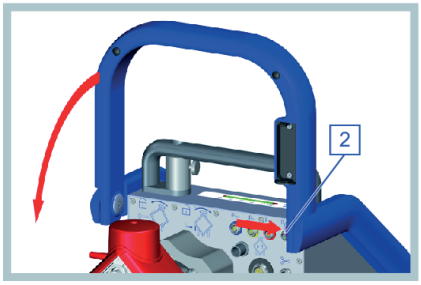
3 Insert the lug on the probe into the tab of the measuring cell of the disposable.



4 Press the probe carefully onto the disposable's measuring cell until the retaining hook clicks into place in the probe.

5 Ensure that the probe is correctly positioned and securely fixed.

6 Press the release mechanism [2] and fold the safety bar down.



7 Ensure that both release mechanisms of the safety bar click into place.
8 Ensure that the measuring cell is recognized correctly (⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112).

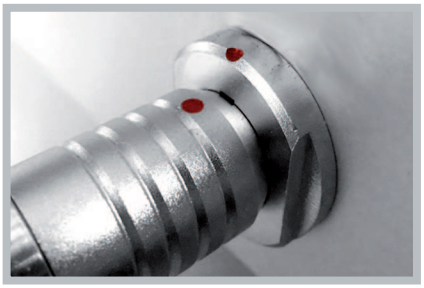
5.3 Connecting the Sensors

WARNING!

- Incorrect values from the flow/bubble sensor can cause a pump stop if an intervention is triggered.
- Incorrect values from the bubble sensor can cause backflow prevention if an intervention is triggered.
- Ensure that the connected sensors are not defective.
  Sensors may not be used if they have visible damage, e.g., a defective measuring cell, a lost cover, a damaged cable or a defective connector.
- Do not route connecting cables over the safety bar or through the lower protective frame. This ensures you will be able to open the safety bar quickly in an emergency.
- Protect any connections not in use with the protective caps supplied.
- Observe the instructions supplied with the sensors used.
- The sensors must be kept clean. Clean and disinfect the sensors by wiping with disinfection solution or with disinfection spray. Do not immerse the sensors in solutions or water!

The connections for sensors are on the rear of the CARDIOHELP-i (⇨ "Connectors", page 33).

Connections and plugs are each marked with a red dot. Use the two red dots to align the plug correctly.



You can also connect a sensor while the device is in operation. The CARDIOHELP-i recognizes it automatically.

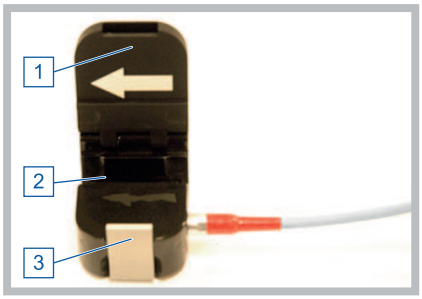
If you disconnect a sensor from the CARDIOHELP-i while it is operating, the CARDIOHELP-i generates an alarm and deactivates the interventions of the relevant parameter if necessary.

5.3.1 Connecting the Combined Arterial Flow/Bubble Sensor

WARNING!

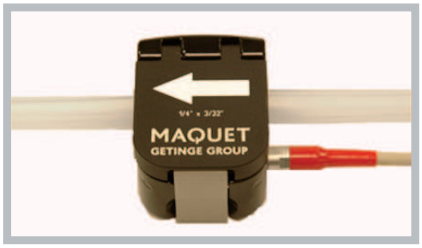
- Only use the flow/bubble sensor listed as an accessory and which is suitable for the tube size used (⇨ "Accessories", page 194).
- Ensure that the correct sensor variant is used for the tube used. The correct tube size must be checked using the stamped label on the foldable cover of the sensor.
- A flow/bubble sensor that is not properly connected can lead to air embolisms or insufficient supply to the patient.
  - Note the correct direction of flow, taking the arrow into account.
  - Position the flow/bubble sensor on the arterial side.
  - Prior to operation ensure that the tube is inserted correctly and that the locking device of the flow/bubble sensor has clicked into place.
- In order not to impair the functioning of the sensor, please note when inserting the tube:
  - Insert the dry tube with your hands.
  - Do not use tools, e.g., screwdrivers, scissors or other items.
  - Do not use gel.
- Note any additional information on positioning in the Instructions for Use of the disposable used.
- Ensure during operation that the tube and locking device are not released accidentally. This can lead to an incorrect pump stop if an intervention is activated. The blood flow is interrupted and supply to the patient ceases.

1 Press on the locking device [3] and open the cover [1].



2 Secure the flow/bubble sensor so that the tube fits into the retainer [2] and the arrows on the flow/bubble sensor point in the direction of flow.

3 Close the cover so that the locking device [3] clicks into place.



4 Connect the sensor to the "Flow/bubble sensor" interface [4].

5 Ensure that the cover and the locking device are closed properly and the tube is fixed securely.

6 Before use, test the bubble monitoring function (⇨ "Bubble Monitoring: Function Test", page 115).

7 Before using the disposable, perform flow off-set calibration (⇨ "Flow Off-Set Calibration of the Flow/Bubble Sensor", page 117).

5.3.2 Connecting the Venous Bubble Sensor

WARNING!

- The optional bubble sensor must not be used without the combined flow/bubble sensor.
- Only use the bubble sensors listed as accessories (⇨ "Accessories", page 194).
- Ensure that the correct sensor variant is used for the tube used. The correct tube size must be checked using the stamped label on the foldable cover of the sensor.

- Prior to operation, ensure that the tube is inserted correctly and that the locking device of the bubble sensor has clicked into place. Otherwise bubbles are not recognized and there is a risk of potentially fatal air embolisms.
- Note any additional information on positioning in the Instructions for Use of the disposable used.

WARNING!

- Ensure during operation that the tube and locking device are not released accidentally. This can lead to incorrect backflow prevention if an intervention is activated. The blood flow is interrupted and supply to the patient ceases.
- In order not to impair the functioning of the sensor, please note when inserting the tube:
  - Insert the dry tube with your hands.
  - Do not use tools, e.g., screwdrivers, scissors or other items.
  - Do not use gel.

WARNING!

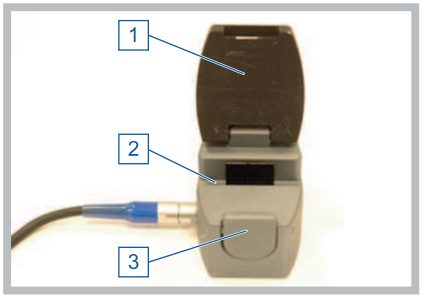
The sensor is designed as a clamp sensor.
The tube is squeezed by the hinged lid. It is a compromise between:

- Secure clamping and strong resistance to tube movement
- Acceptable handling and convenience when removing and inserting the tube
- Avoid pulling or torsion on the tube during operation.

WARNING!

Do not open the rear of the bubble sensor. This damages the sensor and it can no longer be used.

1 Press on the locking device [3] and open the cover [1].



2 Position the bubble sensor on the venous side, at least 30 cm upstream of the blood inlet of the disposable.

3 Secure the bubble sensor such that the tube lies evenly in the retainer [2] and has contact with the surfaces of the sensor.

4 Close the cover so that the locking device [3] clicks into place.

5 Connect the sensor to the "Bubble sensor" interface [4].

6 Ensure that the cover and the locking device are closed properly and the tube is fixed securely.

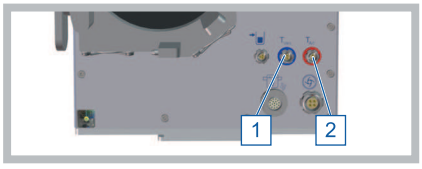
7 Before application, test the bubble monitoring function (⇨ "Bubble Monitoring: Function Test", page 115).

5.3.3 Connecting External Temperature Sensors

WARNING!

- It is the user's responsibility to position the connected sensors at suitable places in the system.
- Only use the sensors listed as accessories (⇨ "Accessories", page 194).

1 Connect the required sensors to the corresponding connections [1, 2].



1 Venous temperature sensor T_{Ven} (blue)

2 Arterial temperature sensor T_{Art} (red)

2 Position the sensors at a suitable point in the system.

WARNING!

Integrated sensor/venous measuring cell and external sensors

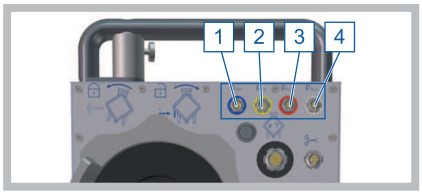
- If valid values of the venous measuring cell for T_{Ven} are available, the value of the T_{Ven} external sensor is ignored. Otherwise, the value of the external sensor is used.
- If the integrated sensors T_{Art} are connected, the value of the T_{Art} external sensor is ignored. Otherwise, the value of the external sensor T_{Art} is used.

5.3.4 Connecting External Pressure Sensors

WARNING!

- It is the user's responsibility to position the connected sensors at suitable places in the system.
- Only use the sensors listed as accessories (⇨ "Accessories", page 194).

1 Connect the required sensors to the corresponding connections [1, 2, 3, 4].



1 Sensor for venous pressure p_{Ven} (blue)
2 Sensor for internal pressure p_{Int} (yellow)
3 Sensor for arterial pressure p_{Art} (red)
4 Auxiliary external pressure sensor p_{Aux} (white)

2 Position the sensors at a suitable location in the system.

NOTE

Color code sensors
The connections for the external pressure sensors are color-coded.
- The venous pressure sensor p_{Ven} is blue.
- The internal pressure sensor p_{Int} is yellow.
- The arterial pressure sensor p_{Art} is red.
- The external pressure sensor p_{Aux} is white.
  Color code the connecting cables of the sensors used at the plug end and at the sensor end with the same colors. This will make it easier to assign the various sensors.
  Corresponding labels are supplied with the sensors.

Depending on the sensors of the disposable used, you will need various external sensors (⇨ "Preparing Application", page 101).

NOTE

Integrated and external sensors for p_{Ven}, p_{Int}, p_{Art}
If valid values of an integrated sensor are available, the corresponding value of an external sensor of type p_{Ven}, p_{Int} and p_{Art} are ignored. Otherwise, the values of the external sensors are used.

5.4 Function Test

5.4.1 Switching on the CARDIOHELP-i, Self-Test

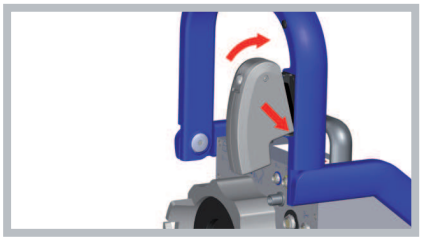
WARNING!

Attaching the venous probe to the holder
The holder on the safety bar of the CARDIOHELP-i contains a black reference surface against which the venous probe can be initialized.
Ensure that the venous probe is located in the holder during initialization. Otherwise, initialization may produce measurements which cause false value displays and alarms.

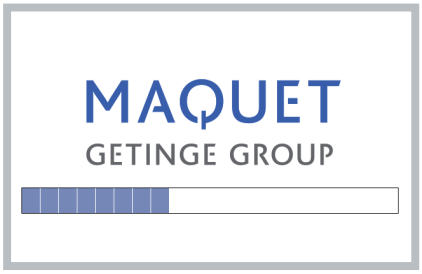
NOTICE!

Do not use the touchscreen/rotary knob during the self-test
During the self-test, the CARDIOHELP-i also tests the function of the touchscreen and rotary knob. Do not use the touchscreen or rotary knob during the self-test. Otherwise, the CARDIOHELP-i could interpret a malfunction.

1 Fix the venous probe in its holder on the safety bar of the CARDIOHELP-i.



2 Ensure that the venous probe has clicked into place.
3 Connect the disposable's integrated sensors (⇨ "Connecting the Integrated Sensors of the Disposable", page 103).
4 Press the "On/Off" button.
5 Check that the speaker and warning buzzer generate acoustic signals.



- The CARDIOHELP-i will automatically perform a self-test after being switched on.
- The CARDIOHELP-i initializes the venous probe against the black reference surface on its holder.

6 Check that initialization of the venous probe was successful ⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112.
   - The touchscreen displays the startup screen (⇨ "Display Following Successful Self-Test", page 72).
7 Check the parameter display of the flow (lpm).
- If the flow display of the flow sensor located on a tube filled with liquid shows a value of < ± 1 lpm with the pump stopped, perform flow off-set calibration (⇨ "Flow Off-Set Calibration of the Flow/Bubble Sensor", page 117).

WARNING!

If, after switching off, the flow display of a flow sensor located on a tube filled with liquid shows a value of > ± 1 lpm with the pump stopped, you should have the device checked by authorized service personnel to rule out flow inaccuracies.

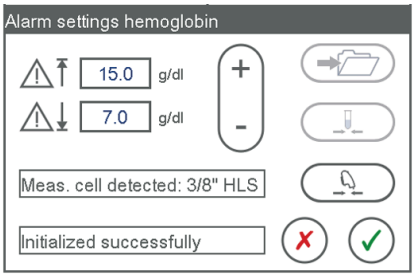
5.4.2 Checking the Status of the Venous Probe and Measuring Cell

WARNING!

Insert the cable for the integrated sensors prior to turning on the CARDIOHELP-i in order to recognize the coding of the venous measuring cell. The venous probe initializes itself to the venous measuring cell. Should you change the disposable during operation, initialize the venous probe again once the coding of the measuring cell has been detected (⇨ "Initializing the Venous Probe", page 114).

Before application, check whether the venous probe has been initialized correctly and whether the correct measuring cell was detected:

1 Touch the symbol of one of the blood parameters (S_VO_2, Hb or Hct) in the "Blood parameters" screen.



   - The "Alarm settings ..." window is opened.
2 Check that the correct measuring cell is displayed:
   - [Measuring cell detected: 3/8" HLS] for HLS Module or QUADROX-iR

WARNING!

Ensure that the necessary measuring cell for your application is used and detected.

1 Check that the venous probe is [Initialized successfully].
2 If the venous probe could not be initialized, carry out initialization of the venous probe again (⇨ "Initializing the Venous Probe", page 114).
3 Touch the [Confirm] or [Reject] symbol.
   ▸ The "Alarm settings ..." window is closed.

Incorrect measuring cell detected

If the CARDIOHELP-i has detected an incorrect measuring cell, proceed as follows:

1 Switch off the CARDIOHELP-i.
2 Check the internal sensor connection.
3 Fix the venous probe in its holder on the safety bar of the CARDIOHELP-i.
4 Switch on the CARDIOHELP-i.
5 Initialize the venous probe.
6 Check the status of the venous probe and the measuring cell.

Venous probe status messages

In the table below you will find more detailed information on the messages which may indicate that the venous probe is not connected or that a measuring cell is either incorrect or has not been detected.

Measuring cell status

Message	Meaning	Task
Measuring cell detected: 3/8" HLS	■ Venous probe is installed and integrated sensor cable is connected to HLS module. ■ Venous probe is installed and integrated sensor cable is not connected.	
No measuring cell detected	■ Venous probe is not installed. ■ Venous probe is not yet initialized. ■ In combination with the error message [[Venous probe incompatible]]: Venous probe is not compatible.	■ Install the venous probe. ■ Attach the venous probe to the holder. ■ Perform manual initialization. ■ If the initialization continues to fail, notify the manufacturer's technical service.

Probe status

Message	Meaning	Task
Initialization successful	■ Venous probe is compatible and successfully initialized.	
Initialization failed	■ Venous probe was not connected to the reference surface during start-up. ■ Venous probe was not connected to the reference surface during manual initialization. ■ Venous probe was not calibrated by technical service for this specific CARDIOHELP-i.	■ Use original venous probe of the corresponding CARDIOHELP-i. ■ Attach the venous probe to the holder. ■ Perform manual initialization. ■ If the initialization continues to fail, notify the manufacturer's technical service.
Ven. probe incompatible	■ Venous probe is not compatible with the measuring cell.	■ Notify the manufacturer's technical service.

5.4.3 Initializing the Venous Probe

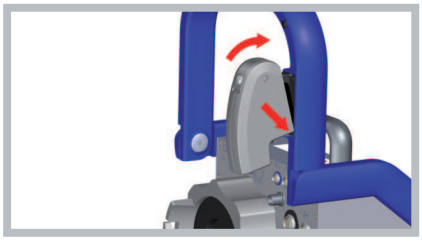
NOTICE!

Attaching the venous probe to the holder
The holder on the safety bar of the CARDIOHELP-i contains a black reference surface against which the venous probe can be initialized.
Ensure that the venous probe is located in the holder during initialization.
Otherwise, initialization may produce measurements which cause false value displays and alarms.

The CARDIOHELP-i initializes the venous probe against the black surface on its holder, after being switched on. Should the initialization fail, no blood parameters can be measured or monitored.

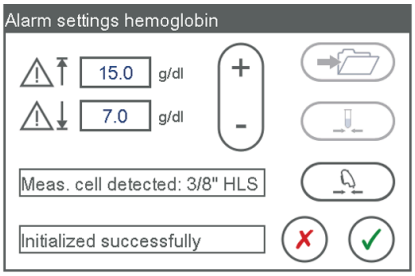
The initialization can be repeated at any time to enable the measurement of blood parameters. This is not possible during calibration of the touchscreen or battery.

1 Fix the venous probe in its holder on the safety bar of the CARDIOHELP-i.



2 Ensure that the venous probe has clicked into place.

3 Touch the symbol of one of the blood parameters (S_VO_2, Hb or Hct) in the "Blood parameters" screen.



- The "Alarm settings ..." window is opened.

4 Touch the "Initialize probe" symbol.
- The CARDIOHELP-i initializes the probe against the black reference surface on its holder.
  NOTE: During initialization, the saved offset values for S_VO_2, Hb and Hct are deleted.

5 The CARDIOHELP-i displays the status and result of the initialization in the field at the bottom left. After successful initialization and calibration, the touchscreen displays the following message: [Initialized successfully]

6 Touch the [Confirm] or [Reject] symbol.
- The "Alarm settings ..." window is closed.

5.4.4 Bubble Monitoring: Function Test

WARNING!

Perform the function test both for the venous bubble sensor and for the arterial flow/bubble sensor.

WARNING!

The system must be filled with liquid to prevent a defect in the centrifugal pump.

1 Switch the arterial bubble intervention on.
2 Start the pump.
3 Open the arterial flow/bubble sensor.
- The pump stops. The CARDIOHELP-i indicates bubble detection and generates a visual and acoustic high-priority alarm.

4 Close the arterial flow/bubble sensor.
5 Reset the bubble monitoring.
- The pump starts.

6 Add the function test if an optional bubble sensor is used.
7 Switch the venous bubble intervention on.
8 Open the venous bubble sensor.
- The backflow prevention is activated The CARDIOHELP-i indicates bubble detection and generates a visual and acoustic high-priority alarm.

9 Close the venous bubble sensor.
10 Reset the bubble monitoring.
- The pump revolutions increase.

11 Switch the arterial bubble intervention off
12 Open the venous bubble sensor.
- The pump stops. The CARDIOHELP-i indicates bubble detection and generates a visual and acoustic high-priority alarm.

13 Close the venous bubble sensor.
14 Reset the bubble monitoring.
- The pump starts.

15 Switch the arterial bubble intervention on.

5.5 Calibration

Various calibrations are to be performed before and during application. More detailed information is given in this chapter.

Some calibrations may only be performed by authorized persons. For more information, refer to ⇨ "Key User Functions", page 81.

5.5.1 Integrated Pressure Sensors: Carrying Out Zero Calibration

WARNING!

Calibration with empty system
The system must be free of liquids for calibrating the integrated pressure sensors. For this reason, carry out the calibration before priming.
Otherwise the calibration may produce incorrect measurements, which cause false value displays, alarms and interventions.

Carry out the calibration for each pressure parameter of the integrated sensors. Calibration is only possible if the pump is at a standstill (speed 0 rpm).

1 To calibrate a sensor, touch "Zero calibration" in the [Alarm settings] window of the parameter.
The touchscreen displays the following message: [Is the system free of liquids?]
2 Confirm that the system is free of liquids by touching the [Confirm] symbol.
- The sensor has now been calibrated.

3 To close the [Alarm settings] window, touch the [Confirm] or [Reject] symbol.

5.5.2 Flow Off-Set Calibration of the Flow/Bubble Sensor

WARNING!

If, after switching off, the flow display of a flow sensor located on a tube filled with liquid shows a value of > ± 1 lpm with the pump stopped, you should have the device checked by authorized service personnel to rule out flow inaccuracies.

WARNING!

If you carry out zero calibration during an application, the blood flow will be interrupted and supply to the patient will cease.

- Carry out the procedure before each application.
- This procedure must therefore be performed as quickly as possible.
- This procedure may only be performed by trained specialist medical personnel.

WARNING!

Only calibrate when the tube is clamped upstream and downstream of the flow sensor.

1 Activate the RPM mode (⇨ "Activating LPM/RPM Mode", page 92).
2 Turn the rotary knob counterclockwise until the rpm value 0 is displayed.
   ▸ The pump stops.
3 Clamp the arterial tube upstream and downstream of the flow/bubble sensor.
4 Touch the "Zero Calibration" symbol in the [Alarm settings flow (LPM)] window.
   The touchscreen shows the following message:
   [Is the tube clamped upstream and downstream of the flow sensor?]
5 Confirm that you have clamped the tube upstream and downstream of the flow/bubble sensor by touching the [Confirm] symbol.
   ▸ The sensor has now been calibrated.
6 To close the [Alarm settings flow (LPM)] window, touch the [Confirm] or [Reject] symbol.

5.5.3 External Pressure Sensors: Carrying Out Zero Calibration

WARNING!

For the calibration of an external pressure sensor, the pressure sensor must be closed to the system and open to the ambient pressure.
Otherwise the calibration may produce incorrect measurements, which cause false value displays, alarms and interventions.

Carry out the calibration for all the external pressure sensors. Observe the Instructions for Use for the external pressure sensor used.

1 To calibrate a sensor, touch the "Zero calibration" symbol in the [Alarm settings] window of the parameter.
The touchscreen shows the following message:
[Is the pressure sensor closed to the system and open to the ambient pressure?]
2 Confirm that the pressure sensor is closed to the system and open to the ambient pressure by touching the [Confirm] symbol.

The sensor has now been calibrated.

To close the [Alarm settings] window, touch the [Confirm] or [Reject] symbol.

5.6 Checklists

5.6.1 Check Before Every Application

WARNING!

Taking the CARDIOHELP-i out of service
Take the CARDIOHELP-i out of service in the following situations, and have the CARDIOHELP-i checked by authorized service personnel:

- If the acoustic signals malfunction.
- If the message [Device defective] is displayed.
- If the CARDIOHELP-i has been exposed to mechanical shocks (e.g., caused by falling).
- If the touchscreen malfunctions.
- Following total failure of the device.

1 Before application, ensure that the CARDIOHELP-i is securely fixed.
2 Check that the security seals are present and undamaged (⇨ "Security seal damaged or missing", page 189).
3 Before starting the application, check that the disposable is securely and correctly installed (⇨ "Attaching the Disposable for the HLS Retainer", page 101).
4 Switch the CARDIOHELP-i on (⇨ "Switching on the CARDIOHELP-i, Self-Test", page 71).
5 Check the function of the following controls:
   - Keypad
   - LEDs
   - Touchscreen
   If any of the controls are defective, have the CARDIOHELP-i checked by authorized service personnel.

6 Ensure that the flow/bubble sensor is positioned as described (⇨ "Connecting the Combined Arterial Flow/Bubble Sensor ", page 106).
7 Ensure that the bubble sensor is positioned as described (⇨ "Connecting the Venous Bubble Sensor", page 107).
8 Check every intervention selected by simulating an alarm condition (⇨ "Function Test", page 111).
9 Check that the speed displayed by the LED speed indicator is the same as on the touchscreen.
10 Check the CARDIOHELP Emergency Drive and ensure the following:
- CARDIOHELP Emergency Drive is available at all times and securely fixed (⇨ "Positioning the CARDIOHELP Emergency Drive", page 63).
- CARDIOHELP Emergency Drive can be driven with the hand crank.
- The disposable used can be installed directly on the CARDIOHELP Emergency Drive.
- The LED speed indicator is lit according to the speed.

11 Calibrate the flow/bubble sensor (⇨ "Flow Off-Set Calibration of the Flow/Bubble Sensor", page 117).
12 Calibrate every external pressure sensor (⇨ "External Pressure Sensors: Carrying Out Zero Calibration", page 117).
13 Calibrate all of the integrated sensors' pressure parameters (⇨ "Integrated Pressure Sensors: Carrying Out Zero Calibration", page 116).
14 Only ever start the application when the batteries of the CARDIOHELP-i are fully charged and calibrated (⇨ "Displaying Battery Status", page 79).

5.6.2 Check Before Every Use in Intra-hospital Transportation

NOTICE!

Carry out the checks before each use (⇨ "Check Before Every Application", page 118).

1 Check the components for transportation.
- If required, check that the mobile holder HKH 8860 and Transport Guard for CARDIOHELP Disposables are present.
- Check that the power supply cable is present.
- Check that the components for transportation are functioning correctly.
- Check that the components for transportation have been correctly installed and secured.

2 Check the oxygen supply.
- Check that the oxygen supply available is sufficient for the journey.

3 Check that the supplies for emergencies/failures of the components are functioning correctly:
- Check that the CARDIOHELP Emergency Drive is positioned correctly.

- Check that a spare disposable set is available.
- Check that the emergency priming line is fully functional.

4 Check the battery function before transportation.
- Disconnect the CARDIOHELP-i from the external power supply.
- Check that the CARDIOHELP-i switches to battery operation automatically (⇨ "Battery Operation", page 144).
- Check that the batteries are fully charged.

5 Switch the CARDIOHELP-i off again (⇨ "On Completion of the Application", page 152).

6 During the Application

WARNING!

Only operate the CARDIOHELP-i with activated pressure and temperature sensors. Ensure that the warning and alarm limits, as well as interventions, are suitable for the patient and current situation (⇨ "Physiological Alarms and Interventions", page 121).

6.1 Physiological Alarms and Interventions

6.1.1 Overview

WARNING!

- Incorrect or unused warning and alarm limits cause a risk of dangerous situations not being recognized and endangering the patient.
- Do not set any extreme warning or alarm limits which could make the function of the alarm system ineffective.
- If other devices with the same or similar alarm signals are used in the same environment, there is a risk that the user may misinterpret a signal.
- Before beginning the application, ensure that the selected warning and alarm limits, as well as interventions, are suitable and safe for the patient and the current situation.
- Before beginning the application, check every intervention selected by simulating an alarm condition (⇨ "Key User Functions", page 81).
- In "Global Override" mode, all interventions, acoustic alarms and backflow prevention are disabled (⇨ "Pausing the Current Alarm", page 50).

WARNING!

- If the flow stops during application, the heat of the motor can be transferred to the blood in the pump.

WARNING!

- The insertion and removal of wet sensor plugs or protective caps can lead to non-conforming measured values. In certain situations, the removal of a sensor plug from the CARDIOHELP-i is not detected and does not trigger any alarm. Wet sensor plugs and protective caps must be dried before insertion or removal.

WARNING!

- Do not remove any components during operation of the CARDIOHELP-i.

CAUTION!

- If you do remove a component during operation, an alarm is triggered which can only be reset by switching the CARDIOHELP-i off and back on again.

The warning and alarm limits and interventions enable you to define when the CARDIOHELP-i triggers physiological alarms and interventions in order to detect and respond to dangerous situations (⇨ "Warning Limits, Alarm Limits and Interventions", page 122 and ⇨ "Defining Monitoring Settings", page 126).

Interventions can also be activated or deactivated using a button combination (⇨ "Activating/Deactivating Interventions with Button Combinations", page 125).

Independent of this, the CARDIOHELP-i monitors the blood flow in order to detect and respond to a backflow of blood (⇨ "Backflow Prevention", page 128).

A list of physiological alarms can be found in section ⇨ "Alarm List", page 158.

6.1.2 Warning Limits, Alarm Limits and Interventions

The CARDIOHELP-i monitors different parameters, displays alarms under set conditions and can intervene, i.e., intervene in the pump control.

Warning limits, alarm limits and interventions must be defined for this purpose.

- Warning limits
  The warning limits enable the conditions for an alarm to be set. The alarm condition is fulfilled when the parameter value lies outside the warning limits, i.e.:
  - Measured value above the upper warning limit
  - Measured value below the lower warning limit
- Alarm limits
  The alarm limits enable the conditions for an alarm and an intervention to be set. The alarm and intervention conditions are fulfilled when the parameter value lies outside the alarm limits, i.e.:
  - Measured value above the upper alarm limit
  - Measured value below the lower alarm limit
    The intervention is only triggered if the intervention has been activated.

- Intervention
  This function enables you to specify whether an intervention is triggered if the intervention condition is fulfilled. The following interventions are possible:
  – Increase or reduce the speed so that the parameter value is within the alarm limits again.
  – Pump stop
  – Backflow Prevention
  If you have activated interventions for a parameter, the touchscreen displays the additional symbol "Interventions activated" next to the parameter symbol in all relevant screens (⇨ "Parameter Display", page 44).

6.1.3 Pump Control Priorities

The pump's speed is influenced and controlled by the following criteria (with decreasing priority):

Priority	Criterion	Possible causes
1	Pump stop (speed 0 rpm)	■ Technical fault ■ Sensor intervention ■ User-defined setpoint speed of 0 rpm (⇨ "RPM mode: changing the speed", page 93)
2	Speed control through level intervention	Level of liquid below limit Note: Levelmonitoring only in thApp „MECC“.

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

Priority	Criterion	Possible causes
3	Zero flow mode due to bubble monitoring by the venous bubble sensor	Intervention due to bubble monitoring by the venous bubble sensor (⇨ "Bubble Monitoring", page 133)
4	Speed control through pressure intervention	Pressure outside the alarm limits (⇨ "Pressure Monitoring", page 130)
5	Zero flow mode	Activated by the user (⇨ "Zero flow mode", page 31)
6	Backflow prevention	Backflow (⇨ "Backflow Prevention", page 128)
7	Speed intervention (in LPM mode)	LPM Mode: Speed outside the alarm limits (⇨ "LPM Mode: Speed Monitoring", page 129)

Priority	Criterion	Possible causes
8	Setpoint speed (in RPM mode) or setpoint flow (in LPM mode)	■ RPM Mode: User-defined setpoint speed > 0 rpm (⇨ "RPM mode: changing the speed", page 93) ■ LPM Mode: User-defined setpoint flow results in speed of > 0 rpm (⇨ "LPM mode: changing the flow", page 95)

If more than one intervention condition is fulfilled, the criterion with higher priority (i.e., the one named first here) has priority.

6.1.4 Deactivating Warning/Alarm Limits

WARNING!

Deactivated warning and alarm limits cause a risk of dangerous situations not being recognized and endangering the patient. For this reason, pay attention to the parameter values on the touchscreen.

WARNING!

The p_{Aux} intervention can only be activated if either the upper or lower alarm limit is specified.

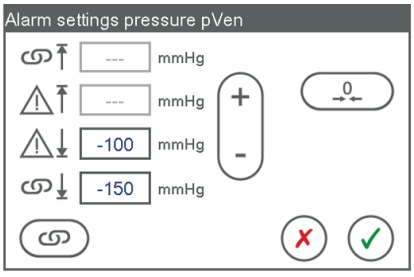
If both alarm limits or neither are specified, the p_{Aux} intervention cannot be activated.

WARNING!

Monitoring of pAux only in the thApp "MECC"

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

	Limits
	Upper alarm limit
	Upper warning limit
	Lower warning limit
	Lower alarm limit



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

The touchscreen displays [– – –] instead of a value for deactivated warning and alarm limits.

Deactivating upper limit

NOTE

The upper alarm limit can only be deactivated following deactivation of the upper warning limit.

1 Touch the upper limit field.
   - The selected field is highlighted in blue.
2 Keep touching [+] until the touchscreen displays [– – –].
   - The upper limit is deactivated.

To reactivate the limit, touch [–] until the touchscreen displays the desired limit value.

Deactivating lower limit

NOTE

The lower alarm limit can only be deactivated following deactivation of the lower warning limit.

1 Touch the lower limit field.
   - The selected field is highlighted in blue.
2 Keep touching [-] until the touchscreen displays [– – –].
   - The lower limit is deactivated.

To reactivate the limit, touch [+] until the touchscreen displays the desired limit value.

6.1.5 Activating/Deactivating Interventions with Button Combinations

Interventions can also be activated or deactivated using a button combination. This enables you to directly control an intervention from different screens without having to open each [Alarm settings …] window.

NOTE

In order to activate the interventions with a button combination, the necessary alarm limits must be specified (⇨ "Defining Monitoring Settings", page 126).

To do this, hold down the safety button and touch the respective parameter symbol.

	Example: Symbol for arterial pressure	Meaning	
	Intervention deactivated	To activate the intervention, hold down the safety button and touch the symbol [pArt].	
	Intervention activated	To deactivate the intervention, hold down the safety button and touch the symbol [pArt].	

NOTE

Bubble intervention (arterial sensor)
- The intervention cannot be activated during a bubble alarm.

NOTE

Bubble intervention (venous sensor)
- The intervention cannot be activated during a bubble alarm.

6.2 Defining Monitoring Settings

You can define the settings for alarms and interventions for the following parameters:

- LPM Mode: Speed monitoring (⇨ "LPM Mode: Speed Monitoring", page 129)
- Bubble monitoring (⇨ "Bubble Monitoring", page 133)

You can define the settings for warnings for the following parameters:

- Flow monitoring (⇨ "Flow Monitoring", page 127)
- Pressure monitoring (⇨ "Pressure Monitoring", page 130)
- Pressure drop monitoring (⇨ "Pressure Drop Monitoring", page 136)
- Temperature monitoring (⇨ "Temperature Monitoring", page 137)
- Blood parameter monitoring (⇨ "Blood Parameter Monitoring", page 138)

NOTE

"Global Override" mode
In "Global Override" mode, all interventions, acoustic alarms and backflow prevention are disabled (⇨ "Pausing the Current Alarm", page 50). The "Interventions" symbol is deactivated.

NOTE

Interventions end when sensor is disconnected
A malfunction in the touchscreen may prevent interventions from being deactivated in some circumstances. To deactivate them, disconnect the relevant sensor's connecting cable from the CARDIOHELP-i.
Interventions end when the relevant sensor is disconnected from the CARDIOHELP-i. The speed returns to the setpoint value if no additional interventions are active.

6.2.1 Flow Monitoring

This function monitors the blood flow. For this purpose, warning limits must be set.

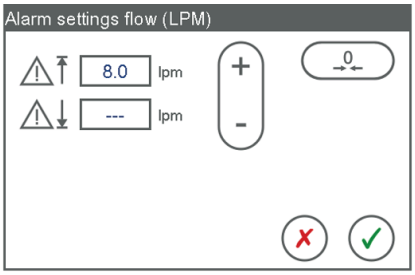
If the measured value is outside the alarm limits, the CARDIOHELP-i generates a high-priority alarm.

The alarm ends as soon as the measured value is within the warning limits again.

Defining "Flow" warning limits

0	Zero calibration (only when pump is stationary) ⇨ "Flow Off-Set Calibration of the Flow/Bubble Sensor", page 117

1 Touch the [Flow] symbol.
   - The flow alarm settings are displayed.



2 Touch the field to be changed.
   - The field to be changed is highlighted in blue.
3 Adjust the value with [+] or [-].
4 To accept the changes, touch the [Confirm] symbol.
   Or
   To reject the changes, touch the [Reject] symbol.

NOTE

Confirming zero calibration
With zero calibration, the CARDIOHELP-i displays a message, which you must confirm in order to carry out zero calibration (⇨ "Flow Off-Set Calibration of the Flow/Bubble Sensor", page 117).
The calibration then still applies if you touch the [Reject] symbol in the [Alarm settings …] window.

Backflow Prevention

WARNING!

The user is responsible for preventing backflow by taking appropriate measures, independent of the backflow prevention function.

WARNING!

Under the following conditions, backflow prevention does not intervene in the pump control; instead it only triggers an alarm.

- RPM Mode: Setpoint speed 0 rpm
- LPM Mode: Setpoint flow 0 l/min
- "Global Override" mode active
  If the pump is stopped because of a fault or an intervention, the backflow prevention triggers neither an intervention nor an alarm.
  If the [Zero flow mode] button fails, the intervention can only be deactivated by removing the flow/bubble sensor from the device.

The backflow prevention can detect and respond to a backflow of blood. To this end, the CARDIOHELP-i monitors the blood flow, displays alarms under set conditions, and can intervene in the pump control.

A backflow of -0.1 l/min is predefined as the fixed alarm limit.

- If the measured backflow is below the alarm limit for at least 1 second, the CARDIOHELP-i generates a medium-priority alarm.
  The alarm ends as soon as the measured value is above the alarm limit again.
- If the measured backflow is below the alarm limit for at least 6 seconds, the CARDIOHELP-i generates a high-priority alarm and activates the zero flow mode automatically (⇨ "Zero flow mode", page 31).
  The CARDIOHELP-i shows the following message:
  [Press "Zero flow" button to leave backflow prevention]
  To confirm the message, touch the [Confirm] symbol.

WARNING!

Backflow prevention triggered through negative flow
To reset the backflow prevention, press the "Zero flow mode" button.
If the backflow continues, the backflow prevention is activated again after 6 seconds.

6.2.2 LPM Mode: Speed Monitoring

This function monitors the speed of the pump and is only available in LPM mode. For this purpose, you set alarm limits and can activate the intervention.

- Intervention activated
  If the measured value is outside of the alarm limits, the CARDIOHELP-i generates a medium-priority alarm and reduces or increases the speed, so that the speed is within the alarm limits again.
  The intervention and alarm end as soon as the measured value is within the alarm limits again.
- Intervention deactivated
  If the measured value is outside the alarm limits, the CARDIOHELP-i generates a low-priority alarm.
  The alarm ends as soon as the measured value is within the alarm limits again.

NOTE

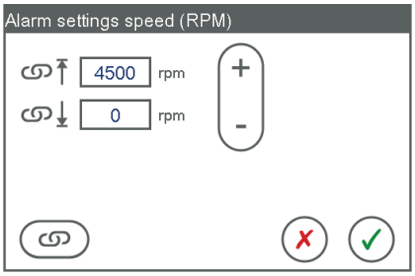
Speed intervention at the start below lower alarm limit
In LPM mode, if you start to increase the flow below the lower RPM alarm limit, the intervention remains deactivated until the speed is over the lower alarm limit.

NOTE

No speed monitoring in RPM mode
In RPM mode, the speed is not monitored, as it is directly controlled by the user.
In RPM mode, you can change the setpoint speed instead, using the "Speed" symbol (⇨ "RPM mode: changing the speed", page 93).

To display or change the settings, touch the "Speed" symbol. The touchscreen displays the following window:

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



	Limits	
	Upper alarm limit	To change a limit value, touch the field and adjust the value.
	Lower alarm limit	To change a limit value, touch the field and adjust the value.

	Interventions	
	Deactivated	To activate the intervention, touch the symbol.
	Activated	The pump drive adjusts the speed if the value is outside of the alarm limits. To deactivate the intervention, touch the symbol.

6.2.3 Pressure Monitoring

This function monitors the pressure. For this purpose, you set warning and alarm limits and can activate the intervention.

You can set the lower warning and alarm limits for p_{Ven}. Monitoring the upper limits is not possible.

You can set the upper warning and alarm limits for p_{Art} und p_{Int}. Monitoring the lower limits is not possible.

You can set the upper and lower warning and alarm limits for p_{Aux}. You can only activate the intervention for p_{Aux} if either the upper or lower alarm limit is set. If both alarm limits or neither are set, intervention is not possible.

- Warning limits
  If the measured value is outside of the warning limits, the CARDIOHELP-i generates a low-priority alarm.
  The alarm ends as soon as the measured value is within the warning limits again.
- Intervention activated
  – If the measured value is more than 10 mmHg outside the alarm limits, the CARDIOHELP-i generates a high-priority alarm and stops the pump.

The pump starts again and the alarm ends as soon as the measured value is within the alarm limits again.

– If the measured value is 10 mmHg at the most outside the alarm limits, the CARDIOHELP-i generates a medium-priority alarm and controls the pump in such a way that the pressure is within the alarm limits again.
  If the values of more than one sensor are 10 mmHg at the most outside the alarm limits, it is the intervention which has occurred first that is carried out.
  The intervention and alarm end as soon as the measured value is within the alarm limits again.

- Intervention deactivated
  If the measured value is outside the alarm limits, the CARDIOHELP-i generates a low-priority alarm.
  The alarm ends as soon as the measured value is within the alarm limits again.

WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.
The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

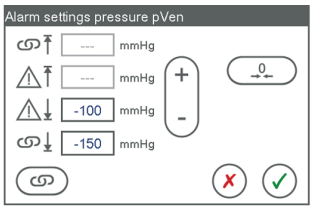
NOTE

Monitoring p_{Int}: Not in the thApp "Circulatory support"
The parameter p_{Int} is not monitored in the thApp "Circulatory support" . The CARDIOHELP-i does not generate any alarms, nor does it perform any interventions if the measured value is outside the warning and alarm limits for p_{Int} set in other thApps.
When you change from thApp "Circulatory support" to another thApp, the intervention for p_{Int} is automatically deactivated.

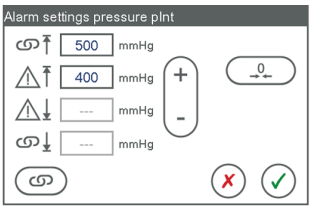
NOTE

Monitoring p_{Aux}: Only in thApp "MECC"
The parameter p_{Aux} is only monitored in the thApp "MECC".
In other thApps the CARDIOHELP-i does not generate any alarms, nor does it perform any interventions if the measured value is outside the warning and alarm limits for p_{Aux}.
When you change from another thApp to thApp "MECC" the intervention for p_{Aux} is automatically deactivated.

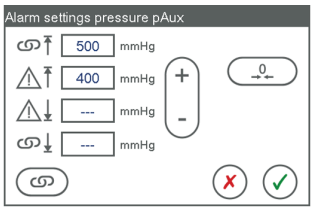
To display or change the settings, touch the symbol of the corresponding pressure parameter. The touchscreen displays the following window:



Warning and alarm limits for p_{Ven}



Warning and alarm limits for p_{Int}. Analogous for p_{Art}



Warning and alarm limits for p_{Aux}

	Limits	
	Upper alarm limit	To change a limit value, touch the field and adjust the value.
	Upper warning limit	To change a limit value, touch the field and adjust the value.
	Lower warning limit	To change a limit value, touch the field and adjust the value.
	Lower alarm limit	To change a limit value, touch the field and adjust the value.

	Interventions	
	Deactivated	To activate the intervention, touch the symbol.
	Activated	The pump drive adjusts the speed or stops if the value is outside of the alarm limits. To deactivate the intervention, touch the symbol.
	Not possible	You can only activate the intervention for p_{Aux} if either the upper or lower alarm limit is set. If both alarm limits or neither are set, an intervention is not possible.

Zero calibration	■ External Pressure Sensors: Carrying out zero calibration (⇨ "External Pressure Sensors: Carrying Out Zero Calibration", page 117) ■ Integrated Pressure Sensors: Carrying out zero calibration (⇨ "Integrated Pressure Sensors: Carrying Out Zero Calibration", page 116)

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

NOTE

Confirming zero calibration
With zero calibration, the CARDIOHELP-i displays a message, which you must confirm in order to carry out zero calibration (⇨ "External Pressure Sensors: Carrying Out Zero Calibration", page 117 and ⇨ "Integrated Pressure Sensors: Carrying Out Zero Calibration", page 116).
The calibration then still applies if you touch the [Reject] symbol in the [Alarm settings …] window.

6.2.4 Bubble Monitoring

This function monitors the occurrence of bubbles. For this purpose, you can activate the intervention.

- Intervention activated
  - When a bubble is detected on the arterial flow/bubble sensor, the CARDIOHELP-i generates a high-priority alarm and stops the pump.
    To restart the pump and end the alarm, you must reset the bubble alarm.
  - When a bubble is detected on the venous bubble sensor, the CARDIOHELP-i generates a high-priority alarm and backflow prevention is activated (⇨ "Backflow Prevention", page 128).
    To deactivate backflow prevention again, to restart the pump and to end the alarm, you must reset the bubble alarm.
- Intervention deactivated
  When a bubble is detected, the CARDIOHELP-i generates a low-priority alarm.
  To stop the alarm, you must reset the bubble alarm.

WARNING!

At a flow rate of less than 50 ml/min, it is possible that the venous bubble sensor will not detect any air bubbles present.

WARNING!

The measurement of a flow/bubble sensor or optional bubble sensor which is not fitted or not fitted on the appropriate tube is interpreted as "Arterial bubble detected" or "Venous bubble detected" and triggers the corresponding alarms and interventions.

Interventions	
Deactivated	To activate the intervention, touch the symbol. The touchscreen displays the following message for the arterial flow/bubble sensor: [As soon as a bubble is detected, the pump stops.] The following message is displayed for the venous bubble sensor: [Backflow prevention activated if bubble detected] To confirm the message, touch the [Confirm] symbol.
	The intervention cannot be activated during a bubble alarm.
Activated	The pump stops or backflow prevention is activated if a bubble is detected. To deactivate the intervention, touch the symbol.
RESET Reset	To reset the alarm and the intervention after a bubble alarm, touch the symbol (⇨ "Resetting the Bubble Stop", page 146). The bubble alarm is only reset if you confirm the change by touching the [Confirm] symbol.

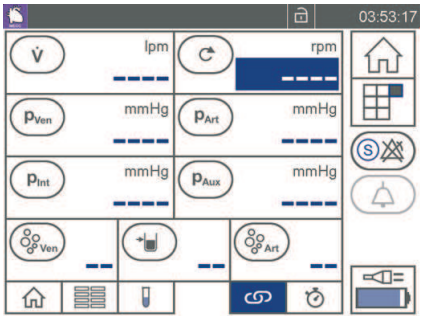
Activating "Bubbles" Intervention

WARNING!

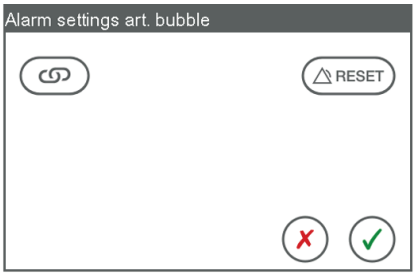
- With an activated intervention, the detection of bubbles by the flow/bubble sensor triggers a pump stop and detection by the venous bubble sensor triggers backflow prevention or a pump stop. Microbubbles ≤ 5 mm can also cause the pump to stop or trigger backflow prevention.
- The measurement of a flow/bubble sensor or optional bubble sensor which is not fitted or not fitted on the appropriate tube is interpreted as "Arterial bubble detected" or "Venous bubble detected" and triggers the corresponding alarms and interventions.
- The pump increases the revolutions to the value last set if the user actively resets the bubble alarm. During the intervention, the blood flow will be interrupted and supply to the patient will cease.

- During a pump stop, retrograde blood flow may occur.
- Ensure that trained medical personnel are always present and able to respond to a bubble alarm immediately, remove the cause and reset the bubble alarm.
- The intervention cannot be activated during a bubble alarm.

1 Switch to the "Intervention" screen.



2 Touch the relevant "Bubble" symbol.



- The "Alarm settings bubbles" window opens.

3 Touch the "Interventions" symbol.

4 The warning message [As soon as a bubble is detected, the pump stops. (arterial sensor)] appears.

Or

5 The warning message [Backflow prevention is activated if bubble detected] (venous sensor) appears.

6 Touch the [Confirm] symbol once you have read the warning message.

7 To accept the changes, touch the [Confirm] symbol.

- The intervention is active.

Or

8 To reject the changes, touch the [Reject] symbol.

- The intervention is not active.

6.2.5 Pressure Drop Monitoring

This function monitors the calculated pressure drop between p_{Int} and p_{Art}. For this purpose, warning limits must be set.

If the calculated value is outside of the warning limits, the CARDIOHELP-i generates a low-priority alarm. The alarm ends as soon as the calculated value is within the warning limits again.

	Limits	
	Upper warning limit	To change a limit value, touch the field and adjust the value.
	Lower warning limit	To change a limit value, touch the field and adjust the value.

Defining pressure drop warning limits

WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.

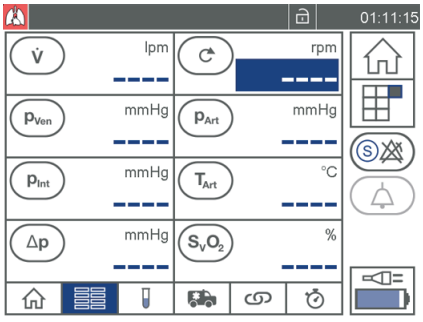
NOTE

Pressure drop monitoring: Not in the thApp "Circulatory support".

The parameter pInt is not monitored in the thApp "Circulatory support" . The CARDIOHELP-i does not generate any alarms if the calculated value is outside the warning limits for the pressure drop.

1 Switch to the "Parameter list" screen.

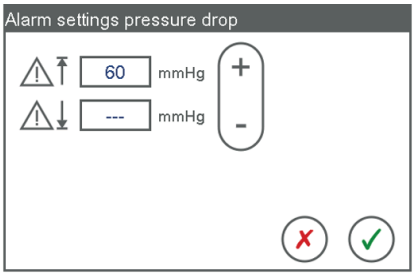
2 Touch the [Δp] symbol.



- The "Alarm settings pressure drop" window opens.

3 Touch the field to be changed.

- The field to be changed is highlighted in blue.



4 Adjust the value with [+] or [-].
5 To accept the changes, touch the [Confirm] symbol.
Or
To reject the changes, tap the [Reject] symbol.

6.2.6 Temperature Monitoring

This function monitors the blood temperature. For this purpose, warning limits must be set.

If the measured value is outside of the warning limits, the CARDIOHELP-i generates a low-priority alarm. The alarm ends as soon as the measured value is within the warning limits again.

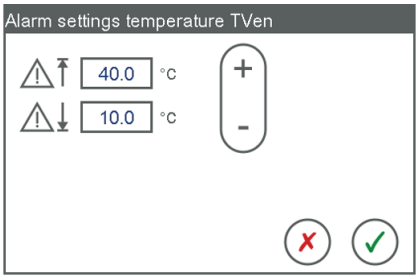
WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.

NOTE

Monitoring of T_{Art}: Not in the thApp “Circulatory Support” and “CO_2 Removal”.
The parameter T_{Art} is not monitored in the thApps “Circulatory Support” and “CO_2 Removal”. The CARDIOHELP-i does not generate any alarms if the measured value for T_{Art} is outside the warning limits.

To display or change the settings, touch the symbol of the corresponding temperature parameter. The touchscreen displays the following window:



Warning limits for venous temperature. Analogous for arterial temperature.

	Limits	
	Upper warning limit	To change a limit value, touch the field and adjust the value.
	Lower warning limit	To change a limit value, touch the field and adjust the value.

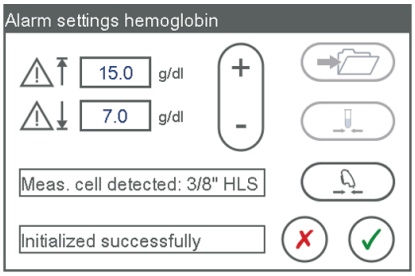
To accept the changes, touch the [Confirm] symbol. To reject them instead, touch the [Reject] symbol.

6.2.7 Blood Parameter Monitoring

This function monitors the blood parameters. For this purpose, warning limits must be set.

If the measured value is outside of the warning limits, the CARDIOHELP-i generates a low-priority alarm. The alarm ends as soon as the measured value is within the warning limits again.

To display or change the settings, touch the symbol of the corresponding blood parameter. The touchscreen displays the following window:



Warning limits for Hb and initializing/recalibrating the venous probe.
Analogous for S_VO_2 and Hct.

	Limits	
	Upper warning limit	To change a limit value, touch the field and adjust the value.
	Lower warning limit	To change a limit value, touch the field and adjust the value.

 Save reference values	Save reference values (⇨ "Saving reference values", page 139).
 Recalibrate values	Enter the determined blood parameters (⇨ "Entering the Determined Blood Parameters", page 140).
 Initialize probe	Initialize venous probe (⇨ "Initializing the Venous Probe", page 114).

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

6.3 User Modes and User Functions

Various modes and functions are available to assist the user during application. These include:

- Recalibrating blood parameters
- Zero flow mode
- Timers
- "Global Override" mode

6.3.1 Recalibrating Blood Parameters

You can recalibrate the measured values for S_VO_2, Hb and Hct with laboratory values.

The following procedure is specified for this:

- Save current values as reference values (⇨ "Saving reference values", page 139).
- At the same time, take reference blood and then have the blood parameters determined in the laboratory.
- Resave the blood parameters with the aid of the values determined in the laboratory. For this, use the saved reference values (⇨ "Entering the Determined Blood Parameters", page 140).

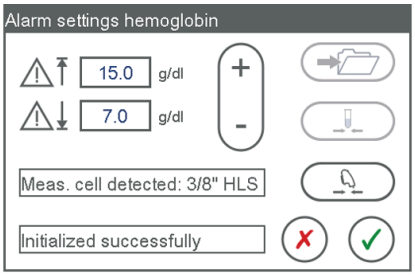
You can call up the recalibration in the alarm settings for S_VO_2, Hb or Hct.

Saving reference values

WARNING!

Take the blood sample when the patient's oxygen saturation values are as stable as possible.

1 Touch the symbol of one of the blood parameters (S_VO_2, Hb or Hct) in the "Blood parameters" screen.



- The "Alarm settings…" window is opened.

2 Touch the [Save reference values] symbol.
- The CARDIOHELP-i only saves reference values for those parameters for which valid values are available.
- If you have already saved reference values, but not yet used them for recalibration, the touchscreen displays the following message: [Really overwrite already saved reference values? (Cancel = keep saved values)]
  To overwrite the previous reference values, touch the [Confirm] symbol. In this case, you must no longer use the laboratory values of the old blood samples for recalibration. You must take a new sample and have it analyzed.
  To keep the previous reference values, touch the [Reject] symbol.

3 At the same time, take reference blood for laboratory analysis.

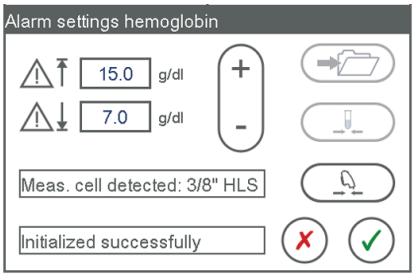
4 Touch the Confirm or [Reject] symbol.
- The "Alarm settings…" window is closed.

Entering the Determined Blood Parameters

WARNING!

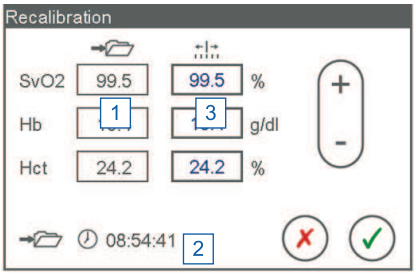
If the determined blood parameters deviate from the expected adjustment range, check that the laboratory values determined are correct.

1 Touch the symbol of one of the blood parameters (S_VO_2, Hb or Hct) in the "Blood parameters" screen.



- The "Alarm settings …" window is opened.

2 Touch the [Recalibrate values] symbol. The touchscreen displays the following window:



1 Saved reference values
2 When saved
3 Fields for laboratory values

- If no valid reference values have been saved, the touchscreen displays [– – –].
- The touchscreen shows values in red which deviate from the expected adjustment range.

3 Check that the laboratory values you are using for recalibration relate to the time they were saved [2].

4 Enter the laboratory values in the fields [3].
- The current laboratory values can only be entered once. Repeated entry of determined blood values is not possible for blood values which have already been recalibrated.

5 To accept the changes, touch the [Confirm] symbol. To reject them instead, touch the [Reject] symbol.
- If any of the input values are outside the expected adjustment range (⇨ "Recalibrating Blood Gas Values", page 206), the touchscreen displays the following message:
  [At least one of the values is outside the expected range. Save anyway?]
  To accept the changes, touch the [Confirm] symbol. To reject them instead, touch the [Reject] symbol.

6 Touch the [Confirm] or [Reject] symbol.
- The "Alarm settings …" window is closed.

6.3.2 Zero Flow Mode

In the zero flow mode, the CARDIOHELP-i aims at a flow of 0 l/min by controlling the pump accordingly. In this way, a backflow can be prevented.

Activating the zero flow mode

- Hold down the safety button and press the "Zero flow mode" button.
- The "Zero flow mode" LED lights up.
- The CARDIOHELP-i aims at a flow of 0 l/min.

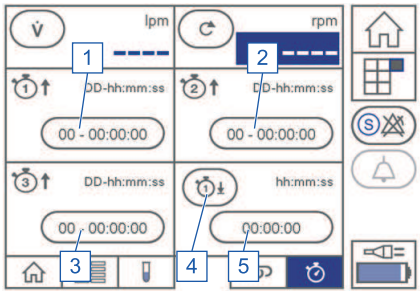
Deactivating the zero flow mode

- Press the "Zero flow mode" button.
- ▸ Zero flow mode is deactivated.

6.3.3 Using the Timers

WARNING!

Do not use for diagnosis
Do not use the timers for diagnostic purposes. The timers are intended for providing additional information.



1 "Timer 1" button (countup timer)
2 "Timer 2" button (countup timer)
3 "Timer 3" button (countup timer)
4 "Countdown timer" symbol
5 "Countdown timer" button

"Timer" screen

Using timers 1 - 3

Start the timer

- Touch the desired "Timer" button.
  - ▸ The selected timer counts up the time.

When the maximum runtime of the timers 1 to 3 has elapsed, the timer stops and is reset to 0. The touchscreen shows the following message: [Timer … elapsed]. Observe the maximum application time of 6 hours.

Stop the timer

- Touch the desired "Timer" button.
  - ▸ The selected timer stops.

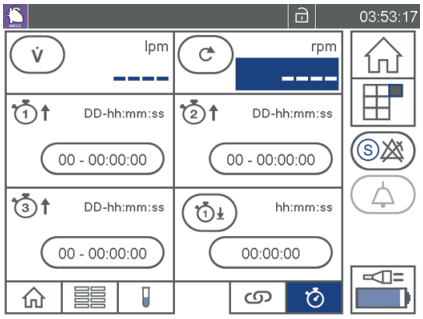
Reset the timer

- Keep the button pressed.
  - ▸ The selected timer is reset to 0.

Using the countdown timer

- Set the countdown timer

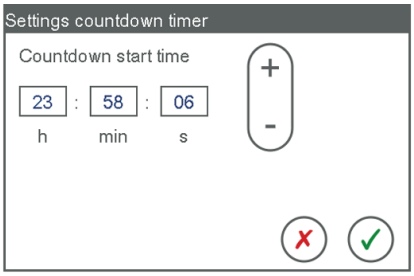
1 Touch the [Timer] symbol.



- The "Timer" screen is opened.

2 Touch the [Countdown timer] symbol.

- The "Settings countdown timer" window is opened.



3 Set the desired start time.
To do this, touch the fields and adjust the values with [+] and [-].

4 To accept the changes, touch the [Confirm] symbol.
Or

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

- Start the countdown timer

6 Touch the desired "Countdown timer" button.

- The countdown timer counts down from the start time.
- When the countdown time has elapsed, the touchscreen displays the following message:
[Countdown time elapsed].
- To reset the alarm, open the "Settings countdown timer" dialog.
- Select [Confirm].
Stop the countdown timer

7 Touch the desired "Countdown timer" button.

- The countdown timer stops.
Reset the countdown timer

8 Keep the button pressed.

- The countdown timer is reset to the start time.

6.3.4 "Global Override" Mode

In "Global Override" mode, the following functions are disabled:

- Acoustic alarms (⇨ "Physiological Alarms and Interventions", page 121)

- Interventions (⇨ "Physiological Alarms and Interventions", page 121)
- Backflow prevention (⇨ "Backflow Prevention", page 128)

In "Global Override" mode, the CARDIOHELP-i generates a reminder signal once per minute if the "Reminder signal" option has been activated (⇨ "Define the Alarm Configuration", page 83).

	Global Override	
	Deactivated	To activate the "Global Override" mode, hold down the safety key and touch the "Global Override" symbol.
	Activated	Interventions, acoustic alarms and backflow prevention are disabled. To deactivate the "Global Override" mode, touch the "Global Override" symbol.
	Not possible	The "Global Override" function has been deactivated by an authorized user and cannot be used (⇨ "Define the Alarm Configuration", page 83).

6.4 Emergency Procedures

6.4.1 Battery Operation

WARNING!

Continuously monitor the CARDIOHELP-i when it is running on battery power.

WARNING!

Displayed remaining life is not guaranteed
The actual remaining life and capacity depend on the age and condition of the batteries, power consumption of the CARDIOHELP-i and other factors. The displayed remaining life and capacity is only approximate. The actual remaining life can be shorter or longer.

The CARDIOHELP-i switches automatically to battery operation upon any interruption in the external power supply. Once external power returns, the CARDIOHELP-i will switch back to the external power supply automatically.

The batteries are charged automatically when the CARDIOHELP-i is connected to the external power supply.

WARNING!

When the device is off
When the CARDIOHELP-i is connected to the external power supply and is not switched on, the batteries are fully charged once. If stored for a prolonged period (with or without being connected to the external power supply), the batteries can discharge slowly. One-off recharging only begins again when the CARDIOHELP-i is switched on briefly and is connected to the external power supply.

WARNING!

When the CARDIOHELP-i is stored or not used, check the charge status of the batteries at regular intervals in order to prevent deep discharging.

NOTE

When the batteries are discharged during battery operation, it is not possible switch on the CARDIOHELP-i. If you press the On/Off button, the LED on the controls film flashes briefly, but the CARDIOHELP-i does not start.

The CARDIOHELP-i generates acoustic signals and displays appropriate messages for battery operation:

Status	Alarms
After switching on	Message [Check battery capacity].
Switch from mains power to battery operation	Message [Switched to battery supply] and an acoustic signal. The acoustic signal is repeated until you confirm the message or the external power supply becomes available again.
Battery calibration required	[Perform battery calibration promptly] (⇨ "Calibrating", page 87).
Battery capacity < 20%	Medium-priority alarm.
Battery capacity < 10%	High-priority alarm.
Battery capacity = 0%	Message [Battery discharged].

6.4.2 Resetting the Bubble Stop

WARNING!

If the pump stops during an application, the blood flow will be interrupted and supply to the patient will cease. Please ensure that the cause of the interruption to the pump is remedied as quickly as possible and that the pump is started up again as quickly as possible.

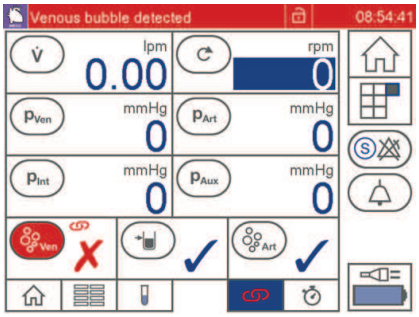
WARNING!

Mortal danger to patients from gas emboli
Before resetting the bubble sensor, ensure that the cause is corrected and that the system is free of bubbles.

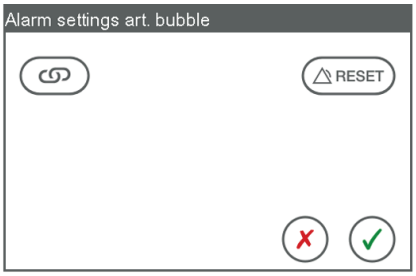
The bubble monitoring function monitors the appearance of bubbles (⇨ "Bubble Monitoring", page 133). If a bubble is detected when an intervention has been activated, the CARDIOHELP-i generates a high-priority alarm and stops the pump (arterial bubble), or backflow prevention (venous bubble) is activated. The status bar displays the following message: [Arterial bubble detected] or [Venous bubble detected].

To restart the pump and end the alarm, you must reset the bubble alarm.

1 Switch to the "Interventions" screen. To do this, touch the "Interventions" symbol.



2 To reset the bubble sensor, touch the "Bubbles" symbol.



3 Touch the "Reset" symbol.
4 Touch the [Confirm] symbol to confirm the reset.

- ▸ The CARDIOHELP-i starts the pump again and displays the "Interventions" screen.
  Or

5 Touch the [Reject] symbol instead.
- ▸ The bubble stop is not reset, i.e., the pump remains at a standstill or in backflow prevention.

6.4.3 Using the Emergency Mode

In this mode the revolutions are only controlled with the rotary button. None of the other controls are available.

WARNING!

- All of the alarms and interventions are deactivated. There is a risk of dangerous situations not being recognized and endangering the patient.
- As a result of the deactivated locking of the controls, there is a risk that settings may inadvertently be changed.

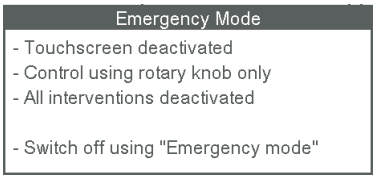
You can only activate the emergency mode when the CARDIOHELP-i is switched on.

1 Open the cover of the "Emergency mode" button [1] and keep the button pressed for 3 seconds.

- ▸ The CARDIOHELP-i generates three acoustic signals.

2 Release the "Emergency mode" button after the third signal falls silent.
- ▸ The CARDIOHELP-i switches to the emergency mode. The current speed is accepted as the setpoint value.

3 The touchscreen displays a message. The message disappears automatically after 5 seconds.
Or



- ▸ If you keep the button depressed for more than 15 seconds, the CARDIOHELP-i does not switch to the emergency mode and, instead, generates another acoustic signal.

In the emergency mode, the status bar continually displays the message [EMERGENCY MODE] and no other alarms. The CARDIOHELP-i generates a reminder signal once per minute, the LED ring of the "Emergency mode" button flashes.

NOTE

Suppressed reminder signal
Authorized persons can specify in the alarm configuration whether the CARDIOHELP-i is to generate reminder signals. If the reminder signal is suppressed, you are not reminded acoustically that the CARDIOHELP-i is in emergency mode (⇨ "Key User Functions", page 81).

Changing the speed in emergency mode

To change the setpoint value, turn the rotary knob. When you change the speed setpoint, the LEDs show the speed setpoint for 2 seconds (⇨ "LED Speed Indicator", page 35).

Exiting emergency mode and switching off the CARDIOHELP-i

You can only exit the emergency mode by switching off the CARDIOHELP-i with the "Emergency mode" button:

1 Open the cover of the "Emergency mode" button and keep the button pressed.
   - ▸ The CARDIOHELP-i generates several short acoustic signals and a long signal after 10 seconds.
2 Release the "Emergency mode" button after the long signal has fallen silent.

▸ The CARDIOHELP-i is now off.

6.4.4 Using the Emergency Drive with the Disposable HLS Retainer

The CARDIOHELP Emergency Drive can be used to drive the disposable manually if the CARDIOHELP-i should fail.

WARNING!

When switching the disposable to the CARDIOHELP Emergency Drive, the blood flow is interrupted and supply to the patient will cease.

- This procedure must therefore be performed as quickly as possible.
- This procedure may only be performed by trained specialist medical personnel.
- Practice this procedure regularly.

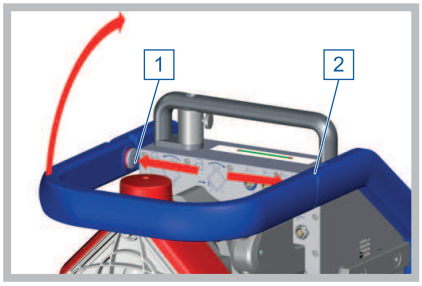
WARNING!

A speed of more than 5000 rpm may lead to increased blood trauma or to increased pressure in the perfusion system.

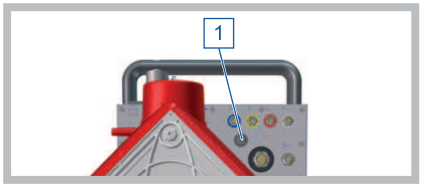
- Pay attention to the LED speed indicator (⇨ "CARDIOHELP Emergency Drive", page 199).
- The maximum speed of the CARDIOHELP Emergency Drive is not restricted. The speed is only controlled by the speed at which the user operates the hand crank.

1 Close the arterial and the venous tube clamps.

2 Open the safety bar (⇨ "Opening the Safety Bar", page 67).



▸ The release mechanism [2] clicks into place.



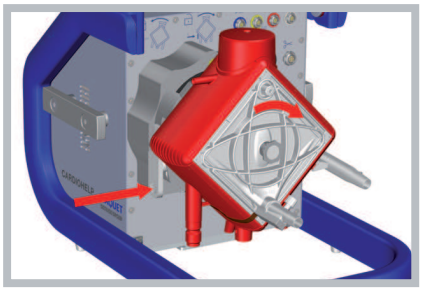
3 Detach the connecting cable for the integrated sensors, if fitted, from the disposable.

4 Remove the venous probe from the measuring cell of the disposable:

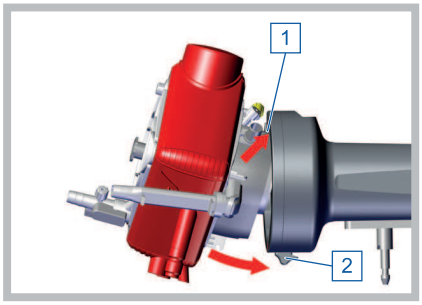
5 Press down the round button on the probe. Remove the probe from the cell and pull it out of the tab of the cell.

6 Remove the Transport Guard for CARDIOHELP Disposables when used (⇨ "Removing the Transport Guard for CARDIOHELP Disposables", page 60).

7 Press the disposable's locking device to the middle, turn the disposable clockwise slightly and remove from the CARDIOHELP-i.

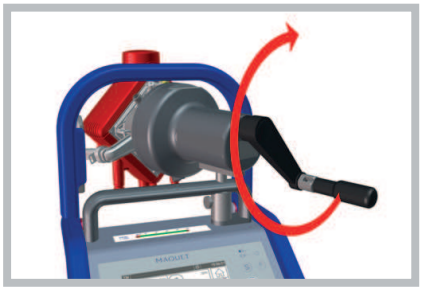


8 Fix the disposable to the CARDIOHELP Emergency Drive:



- Fit the disposable under the upper locating lug [1] from below.
- Open the lower locking device [2]. Swing the disposable right up to the pump drive and release the lower locking device so that it fixes the disposable.
- Ensure that the locking device has clicked into place and that the disposable is fixed securely.

9 Unfold the handle of the hand crank.



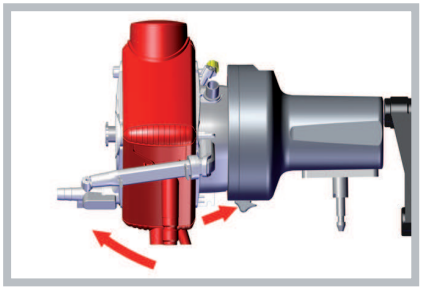
10 Open the clamp on the venous side and turn the hand crank clockwise.
- The LED speed indicator shows the speed (⇨ "CARDIOHELP Emergency Drive", page 199). Ensure that you can see the LED speed indicator at all times.
  Turning counterclockwise has no function.

11 Once the speed is sufficiently high, open the clamp on the arterial side.

Removing the disposable from the CARDIOHELP Emergency Drive

1 Open the lower locking device.

2 Remove the disposable and release the lower locking device.



7 Concluding the Application

7.1 On Completion of the Application

7.1.1 Switch Off the CARDIOHELP-i

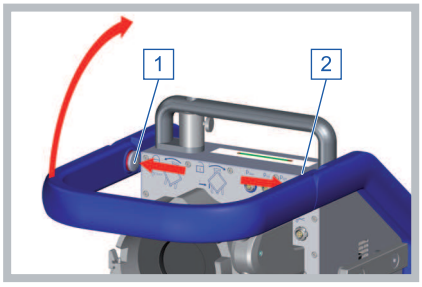
1 Press the "On/Off" button for at least 3 seconds.

- The touchscreen displays the following message: [Do you want to switch off the system?]

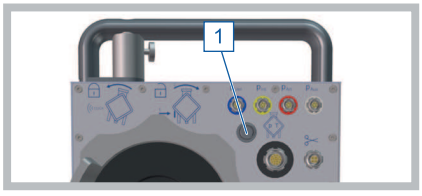
2 Touch the [Confirm] symbol within 3 seconds.
- The CARDIOHELP-i is switched off.

7.1.2 Removing the Sensors

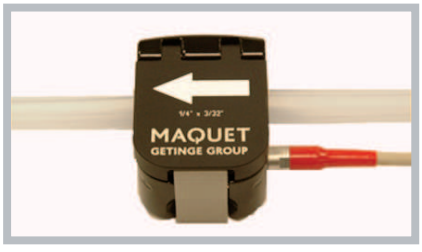
1 Open the safety bar (⇨ "Opening the Safety Bar", page 67).



2 Detach the disposable connecting cable from the disposable and place it on the holder [1] provided.



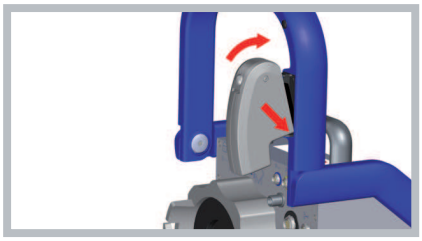
3 Open the cover of the flow/bubble sensor and remove the tube from the sensor.



4 Open the cover of the bubble sensor and remove the tube from the sensor.

- Press down the round button on the probe. Remove the probe from the measuring cell and pull it out of the tab of the measuring cell.

5 Secure the venous probe in its holder on the safety bar of the CARDIOHELP-i. Ensure that the venous probe has clicked into place.

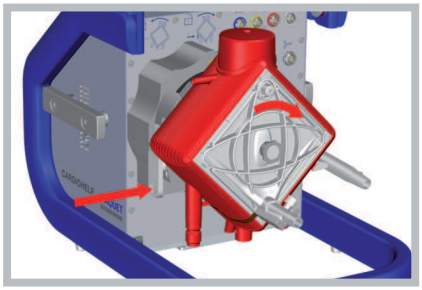


6 Remove all the other sensors.

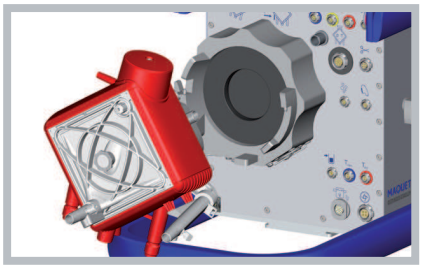
7.1.3 Removing the Disposable with HLS Drive

1 Remove the Transport Guard for CARDIOHELP Disposables when used (⇨ "Removing the Transport Guard for CARDIOHELP Disposables", page 60).

2 Press the disposable's locking device to the middle, turn the disposable clockwise slightly and remove from the CARDIOHELP-i.



3 Dispose of the disposable according to your hospital's rules and national regulations.



4 Clean and disinfect the CARDIOHELP-i and the accessories used (⇨ "Cleaning and Disinfection", page 184).

7.2 Check list: Concluding the Application

1 Switch off the CARDIOHELP-i (⇨ "Switch Off the CARDIOHELP-i", page 152).
2 Remove the sensors (⇨ "Removing the Sensors", page 152).
3 Remove the disposable (⇨ "Removing the Disposable with HLS Drive", page 153).
4 Clean and disinfect the CARDIOHELP-i (⇨ "Surface Cleaning and Disinfecting After Each Use", page 184).
5 Leave the CARDIOHELP-i connected to the external power supply to allow the batteries to be charged automatically (⇨ "Battery Operation", page 144).

8 Troubleshooting

WARNING!

Contact authorized service personnel
If you detect a fault or failure of controls, display elements or sensors, have the CARDIOHELP-i checked by authorized service personnel.

Error	Description/possible consequences	Possible remedies
Touchscreen malfunction	Operation via touchscreen not possible.	■ Unlock by pressing the "Lock/unlock" button. ■ If possible, calibrate the touchscreen. ■ Adjust the pump using the rotary knob. ■ Switch to emergency mode. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Use the emergency drive.
Touchscreen malfunction during intervention	Interventions can no longer be deactivated.	■ Disconnect the relevant sensor's connecting cable from the CARDIOHELP-i. This automatically deactivates the intervention. ■ Switch to emergency mode.
Touchscreen malfunction during bubble stop	The bubble sensor or combined flow/bubble sensor cannot be reset.	■ Eliminate the cause of the bubble stop. ■ Disconnect the connecting cable of the bubble sensor or combined flow/bubble sensor from the CARDIOHELP-i. This automatically deactivates the intervention. ■ Switch to emergency mode.

Error	Description/possible consequences	Possible remedies
"Zero flow mode" button failure	The zero flow mode cannot be activated.	■ Switch to LPM mode and set a setpoint flow of 0 l/min. This causes the CARDIOHELP-i to aim at a flow of 0 l/min. ■ Switch the device off and on again.
"Zero flow mode" button failure	The zero flow mode cannot be deactivated.	■ RPM mode only: Set a setpoint speed of 0 rpm. or ■ Disconnect the connecting cable of the flow/bubble sensor from the CARDIOHELP-i and reconnect. ■ Switch the device off and on again. ■ Activate the "Global Override" mode to switch off backflow prevention.
Rotary knob defective	The setpoint speed or the setpoint flow cannot be changed using the rotary knob.	■ Change the setpoint speed via the touchscreen. ■ If the CARDIOHELP-i is in LPM mode, switch into RPM mode.

9 Messages

9.1 Saving Alarms

Alarms, interventions, measurements and events (e.g., pressed buttons) are saved and can be read out after the device has been switched off and back on.

NOTE

Alarm List
The last 6 alarms can be displayed in the alarm list (⇨ "Alarm List", page 158).

- Online recording
  The online recording exports data asynchronously and exports measured values cyclically at the type B USB port. The cyclical export takes place at set intervals (⇨ "Change the interval for data recording", page 97).
  Use the online recording for documentation only.
  If the CARDIOHELP-i is not switched off properly due to the external power supply and the batteries failing at the same time, the data of at most one interval cannot be exported.
- Offline recording
  The offline recording saves data asynchronously and saves measured values cyclically. The cyclical saving takes place at set intervals (⇨ "Change the interval for data recording", page 97).
  The data can later be exported to a USB stick (⇨ "Export recorded data", page 98).
  If the CARDIOHELP-i is not switched off properly due to the external power supply and the batteries failing at the same time, the data of at most one interval may be lost.
- Internal log
  Events (e.g., pressed buttons) are stored in an internal log and can be read out by an authorized service agent.
  If the CARDIOHELP-i is not switched off properly due to the external power supply and the batteries failing at the same time, the data of at most the last event may be lost.
  If the capacity of the internal memory has been reached, the oldest data is overwritten.

NOTE

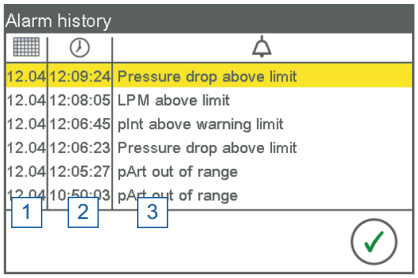
Data recording in emergency mode
In the emergency mode, offline recording on the internal memory is switched off. User events, service events and online recording still function (⇨ "Using the Emergency Mode", page 147).

9.2 Alarm List

The alarm list shows the last 6 alarms.

- Touch the "Alarm list" symbol in the menu.

The touchscreen displays the following window:



1 Date
2 Time
3 Alarm message

The touchscreen displays date, time and alarm message. The CARDIOHELP-i displays current alarms, according to priority, on a colored background:

- Red: High-priority alarm
- Yellow: Low or medium-priority alarm

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

9.3 Physiological Alarms

NOTE

Physiological alarm priorities
Physiological alarms are prioritized as follows:

- High-priority:
  - Physiological alarm conditions which lead to a pump stop
  - Flow monitoring alarms
  - Backflow prevention interventions
- Medium-priority:
  Physiological alarm conditions which lead to a pump intervention.

- Low-priority:
  Physiological alarm conditions which lead to a warning or an alarm without intervention
  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.

The touchscreen displays physiological alarm situations via the status bar (⇨ "Status Bar", page 42) and the parameter symbol (⇨ "Status of physiological alarms and interventions", page 46).

Warning limits, alarm limits and interventions are set by the user (⇨ "Physiological Alarms and Interventions", page 121).

9.3.1 High-priority

WARNING!

If the pump stops during an application, the blood flow will be interrupted and supply to the patient will cease. Please ensure that the cause of the interruption to the pump is remedied as quickly as possible and that the pump is started up again as quickly as possible.

Message	Possible causes/consequences	Possible remedies
p_{Ven} below stop limit	Medical grounds, blockage in front of the pump inlet, incorrect measurement or incorrectly set limit. Consequence: Pump stop.	■ Volume administration as per volume status. ■ Removal of blockage ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the limit is exceeded.

p_{Int} above stop limit	Medical grounds, blockage in the gas transfer module and/or behind the pump outlet, incorrect measurement or incorrectly set limit. Consequence: Pump stop.	■ Replace disposable. ■ Removal of blockage ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the value falls below the limit.
p_{Art} above stop limit	Medical grounds, blockage on the arterial side, incorrect measurement or incorrectly set limit. Consequence: Pump stop.	■ Removal of blockage ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the value falls below the limit.
p_{Aux} above stop limit	Medical grounds, blockage downstream of the pressure measurement point, incorrect measurement or incorrectly set limit. Consequence: Pump stop.	■ Check position of the pressure transducer. ■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Volume administration as per volume status. ■ Pump starts again automatically at the setpoint when the value falls below the limit. ■ In the event of a malfunction, switch off intervention, if necessary, in order to ensure vital blood flow.

WARNING!

Monitoring of pAux only in the thApp "MECC"

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

p_{Aux} below stop limit	Medical grounds, blockage upstream of the pressure measurement point, incorrect measurement or incorrectly set limit. Consequence: Pump stop.	■ Check position of the pressure transducer. ■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Volume administration as per volume status. ■ Pump starts again automatically at the setpoint when the limit is exceeded. ■ In the event of a malfunction, switch off intervention, if necessary, in order to ensure vital blood flow.

WARNING!

Monitoring of pAux only in the thApp "MECC"

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

LPM above limit	Medical grounds, reduced resistance downstream of the pump, incorrect measurement or incorrectly set limit. Consequence: Flow adjustment to the changed peripheral resistance or blood loss.	■ Correct the set connections and cannula position. ■ Check the peripheral resistance of the patient. ■ Adjust limit. ■ Adjust flow.

LPM below limit	Medical grounds, blockage upstream or downstream of the pump, blockage in the gas transfer module, incorrect measurement or incorrectly set limit, air in the perfusion system. Consequence: Flow adjustment to the changed peripheral resistance or reduced perfusion of the patient.	■ Removal of blockage. ■ Increase RPM. ■ Correct the flow sensor. ■ Reduce the peripheral resistance. ■ Replace disposable. ■ Adjust limit. ■ Correct the cannula position.
Arterial bubble detected	Gas bubbles in the system, or combined flow/bubble sensor removed from tubing. Intervention activated. Consequence: Pump stop.	■ De-air or replace system. ■ To continue perfusion, reset bubble alarm (⇨ "Resetting the Bubble Stop", page 146). WARNING: Risk of air embolism!
Venous bubble detected	Gas bubbles in the system or bubble sensor removed from tubing. Intervention activated. Consequence: Backflow prevention	■ De-air system, replace, or clamp the bubble sensor on the tube correctly. ■ To continue perfusion, reset bubble alarm (⇨ "Resetting the Bubble Stop", page 146). WARNING: Risk of air embolism!
Backflow prevention	Negative flow for 6 seconds. Backflow prevention was automatically activated.	■ To continue perfusion: Press the "Zero flow mode" button and set sufficient speed for correct perfusion.

9.3.2 Medium Priority

Message	Possible causes/consequences	Possible remedies
p_{Ven} below alarm limit	Medical grounds, blockage on the venous side, incorrect measurement or incorrectly set limit.	■ Volume administration as per volume status. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the limit is exceeded.
p_{Int} above alarm limit	Medical grounds, blockage behind the pump outlet, e.g., in the oxygenator, and/or on the arterial side, incorrect measurement or incorrectly set limit.	■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the value falls below the limit.
p_{Art} above alarm limit	Medical grounds, blockage on the arterial side, incorrect measurement or incorrectly set limit.	■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the value falls below the limit.

p_{Aux} above alarm limit	Medical grounds, blockage downstream of the pressure measurement point, incorrect measurement or incorrectly set limit.	■ Check position of the pressure transducer. ■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Volume administration as per volume status.

WARNING!

Monitoring of pAux only in the thApp "MECC"

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p_{Aux} below alarm limit	Medical grounds, blockage upstream of the pressure measurement point, incorrect measurement or incorrectly set limit.	■ Check position of the pressure transducer. ■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Volume administration as per volume status.

WARNING!

Monitoring of pAux only in the thApp "MECC"

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Pressure drop above limit	Blockage in the oxygenator, incorrect measurement or incorrectly set limit.	■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer.
RPM above limit	Medical grounds, incorrect measurement or incorrectly set alarm limit.	■ Removal of blockage. ■ Adjust limit.
RPM below limit	Medical grounds, incorrect measurement or incorrectly set alarm limit.	■ Correct the set connections and cannula position. ■ Check the peripheral resistance of the patient. ■ Adjust limit. ■ Adjust flow.
RPM outside of measuring range	Measured value outside of valid range.	■ Reduce RPM. ■ Taking the CARDIOHELP-i out of service
LPM outside of measuring range	Measured value outside of valid range.	■ Correct the set connections and cannula position. ■ Check the peripheral resistance of the patient. ■ Adjust flow.
Negative LPM detected	Flow detected against the set direction.	■ Ensure that the flow/bubble sensor is correctly aligned. Ensure sufficient speed; if necessary, recalibrate the flow sensor.
Control unit restarted	The control unit has been restarted.	■ Check settings and confirm "Operator unit restarted. Please check settings" window. ■ Notify the authorized service.
Device restarted	The processor has been restarted.	■ Check settings and confirm "Device restarted. Please check settings" window. ■ Notify the authorized service.

9.3.3 Low Priority

Message	Possible causes/consequences	Possible remedies
p_{Ven} outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Replace sensor cable. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Dry pressure transducer.
p_{Ven} below warning limit	Medical grounds, blockage on the venous side, incorrect measurement or incorrectly set limit.	■ Volume administration as per volume status. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the limit is exceeded.
p_{Int} outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Replace sensor cable. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Dry pressure transducer.
p_{Int} above warning limit	Medical grounds, blockage in the oxygenator and/or on the arterial side, incorrect measurement or incorrectly set limit.	■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Pump starts again automatically when the value falls below the limit.

p_{Art} outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Replace sensor cable. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Dry pressure transducer.
p_{Art} above warning limit	Medical grounds, blockage on the arterial side, incorrect measurement or incorrectly set limit.	
p_{Aux} above warning limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check position of the pressure transducer. ■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Volume administration as per volume status. ■ Pump starts again automatically when the value falls below the limit.

WARNING!

Monitoring of pAux only in the thApp "MECC"

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

p_{Aux} below warning limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check position of the pressure transducer. ■ Replace disposable. ■ Removal of blockage. ■ Adjust limit. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Use larger cannula. ■ Volume administration as per volume status. ■ Pump speed is automatically reduced to the setpoint when the limit is exceeded.

WARNING!

Monitoring of pAux only in the thApp "MECC"

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

p_{Aux} outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Replace sensor cable. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Dry pressure transducer.
Pressure drop outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Replace sensor cable. ■ Calibrate pressure transducer. ■ Replace pressure transducer. ■ Dry pressure transducer.
T_{Ven} above limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Adjust limit. ■ Replace sensor. ■ Check sensor position.

T_{Ven} below limit.	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Adjust limit. ■ Replace sensor. ■ Check sensor position.
T_{Ven} outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Adjust limit. ■ Replace sensor. ■ Check sensor position.
T_{Art} above limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Adjust limit. ■ Replace sensor. ■ Check sensor position.
T_{Art} below limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Adjust limit. ■ Replace sensor. ■ Check sensor position.
T_{Art} outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Adjust limit. ■ Replace sensor. ■ Check sensor position.
RPM above limit	Medical grounds, incorrect measurement or incorrectly set warning limit.	■ Removal of blockage. ■ Adjust limit.
RPM below limit	Medical grounds, incorrect measurement or incorrectly set warning limit.	■ Correct the set connections and cannula position. ■ Check the peripheral resistance of the patient. ■ Adjust limit. ■ Adjust flow.
Positive. Flow when pump is stationary	Blood continues to flow even when pump is stationary. Any bubbles are transported further.	■ Clamp arterial and venous tube
Arterial bubble detected	Gas bubbles in the system or flow/bubble sensor removed from tubing.	■ Clamp, de-air or replace system. Reset the bubble alarm (⇨ "Resetting the Bubble Stop", page 146). WARNING: Risk of air embolism!

Venous bubble detected	Gas bubbles in the system or bubble sensor removed from tubing.	■ Clamp, de-air or replace system. Reset the bubble alarm (⇨ "Resetting the Bubble Stop", page 146). WARNING: Risk of air embolism!
S_vO_2 above limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Check for shunt and correct. ■ Calibrate blood parameter measurement.
S_vO_2 below limit.	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Check oxygen supply. ■ Adjust flow. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.
S_vO_2 outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Check oxygen supply. ■ Adjust flow. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.
Hct above limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.
Hct below limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.

Hct outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.
Hb above limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.
Hb below limit	Medical grounds, incorrect measurement or incorrectly set limit.	■ Check plausibility. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.
Hb outside of measuring range	Measured value outside of valid range.	■ Check plausibility. ■ Check and correct hemoglobin level ■ Calibrate blood parameter measurement. ■ Check measuring cell detection.

9.4 Technical Alarms

NOTE

Technical alarm priorities

Technical alarms are prioritized as follows:

- High-priority:
  Technical alarm conditions which lead to a pump stop.
- Medium-priority:
  Technical alarm conditions which can soon lead to a pump stop.
- Low-priority:
  Technical alarm conditions which can soon become a medium-priority alarm condition or which are merely warnings.

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.

The touchscreen displays technical alarm situations via the status bar (⇨ "Status Bar", page 42) and the "Menu" symbol (⇨ "Menu Screen", page 49).

9.4.1 High Priority

WARNING!

- If the pump stops during an application, the blood flow will be interrupted and supply to the patient will cease. Please ensure that the cause of the interruption to the pump is remedied as quickly as possible and that the pump is started up again as quickly as possible.
- The CARDIOHELP Emergency Drive can be used to manually drive the disposable if the CARDIOHELP-i should fail (⇨ "Using the Emergency Drive with the Disposable HLS Retainer", page 148).

Message	Possible causes/consequences	Possible remedies
Device defective	Serious fault. 0x00000 defines an error code. This varies depending on the cause of the fault and is required by service in order to diagnose the fault.	■ Continually check perfusion on the CARDIOHELP-i and by monitoring the patient. ■ Check settings and confirm "Operator unit restarted. Please check settings" window. ■ If necessary, change to emergency mode or if necessary, use the emergency drive. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Remaining battery capacity < 10%	Remaining battery capacity below 10%.	■ Use other power supply or prepare for use of emergency drive.

No batteries detected	No batteries detected. Battery operation is not possible.	■ Use other power supply. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
RPM control error	Speed control error. Drive restarts.	■ Taking the CARDIOHELP-i out of service ■ Notify authorized service.
Runaway error	Pump runaway. Drive restarts.	■ Taking the CARDIOHELP-i out of service ■ Notify authorized service.
Device defective - Stop!	Pump standstill due to serious technical fault.	■ Use emergency drive. Replace the CARDIOHELP-i. ■ Notify authorized service.
Pump disposable error - Stop	Pump stop in the disposable e.g., due to thrombus.	■ Place disposable correctly in drive or, if necessary, replace.
Art. bubble sensor defective		■ Replace external sensor
Venous bubble sensor defective		■ Replace external sensor.
Battery discharged	Battery is discharged.	■ Use other power supply or emergency drive.
Overcurrent! Device may fail	Battery defective. Battery power is not guaranteed.	■ Avoid battery operation. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.

9.4.2 Medium Priority

Message	Possible causes/consequences	Possible remedies
Device defective (0x00000)	Serious technical fault. 0x00000 defines an error code. This varies depending on the cause of the fault and is required by service in order to diagnose the fault. Example: 0x33281 Supply voltage 3.3 V defective.	■ Continually check perfusion on the CARDIOHELP-i and by monitoring the patient. ■ If necessary, continue perfusion with emergency drive. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Unknown error		■ Continually check perfusion on the CARDIOHELP-i and by monitoring the patient. ■ If necessary, continue perfusion with emergency drive. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Device temp. too high	Temperature of CARDIOHELP-i too high.	■ Reduce the ambient temperature. ■ Remove the heat sources. ■ Keep the ventilation openings of the CARDIOHELP-i free. ■ If necessary replace the CARDIOHELP-i. ■ Notify authorized service.
Venous probe incompatible		■ Notify authorized service.
Flow/bubble sensor incompatible		■ Notify authorized service.
Remaining battery capacity < 20%	Remaining battery capacity below 20%.	■ Use other power supply.

Battery defective	Battery defective.	■ Do not operate the CARDIOHELP-i using batteries. ■ Do not disconnect the CARDIOHELP-i from external power supply. ■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
No disposable detected	Pump in disposable not detected.	■ Place disposable correctly in drive or, if necessary, replace.
Drive temp. not available	Temperature of drive not available.	■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
AC voltage fault	Mains power supply fault.	■ Check connection to mains power supply. ■ If necessary replace plug or cable. ■ If necessary use other power supply. ■ If necessary replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Battery very low	Battery is discharged.	■ Use other power supply or prepare for use of emergency drive.
Battery 1 not charging	Battery 1 not charging	■ Only operate the CARDIOHELP-i with the external power supply. ■ Restart the CARDIOHELP-i. ■ Taking the CARDIOHELP-i out of service ■ Notify authorized service.

Battery 2 not charging	Battery 2 not charging	■ Only operate the CARDIOHELP-i with the external power supply. ■ Restart the CARDIOHELP-i. ■ Taking the CARDIOHELP-i out of service. ■ Notify authorized service.
Call Service Check alarm settings		■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Mode switched (LPM ↔ RPM)	Control mode (RPM/LPM) was automatically changed.	■ Check flow measurement.
Software error	System unstable. Possible automatic restart shortly.	■ Notify authorized service.
Wrong target LPM	Deviation between target flow and actual flow.	■ Restart control: Set target flow to 0 l/min, then reselect the desired flow rate.
Wrong target RPM	Deviation between target speed and actual speed.	■ Restart control: Set target speed to 0 rpm, then reselect the desired speed.
Control unit restarted	The control unit has been restarted.	■ Check settings and confirm "Operator unit restarted. Please check settings" window. ■ Notify authorized service.
Device restarted	The processor has been restarted.	■ Check settings and confirm "Device restarted. Please check settings" window. ■ Notify authorized service.

9.4.3 Low Priority

Message	Possible causes/consequences	Possible remedies
pVen sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i or replace external sensor or cable for the sensors.
pVen sensor defective		■ Replace external sensor or cable for sensor system.
pInt sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i or replace external sensor or cable for the sensors.
pInt sensor defective		■ Replace external sensor or cable for sensor system.
pArt sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i or replace external sensor or cable for the sensors.
pArt sensor defective		■ Replace external sensor or cable for sensor system.
pAux sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i or replace external sensor or cable for the sensors.
pAux sensor defective		■ Replace external sensor or cable for sensor system.
TVen sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i or replace external sensor or cable for the sensors.
TVen sensor defective		■ Replace external sensor
TArt sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i or replace external sensor or cable for the sensors.
TArt sensor defective		■ Replace external sensor

Flow sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i.
Flow sensor defective		■ Replace external sensor
No flow signal	No valid flow signal	■ Correct positioning of flow sensor. If necessary replace flow sensor.
Flow sensor offset too high		■ Replace flow sensor.
Art. bubble sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i.
Ven. bubble sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i.
SvO2 sensor defective		■ Replace venous probe or cable.
SvO2 sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i.
Hct sensor defective		■ Replace venous probe or cable.
Hct sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i.
Hb sensor defective		■ Replace venous probe or cable.
Hb sensor disconnected	Sensor was disconnected.	■ Reconnect sensor to CARDIOHELP-i.
Checking battery capacity	Remaining battery capacity below 90%.	■ Check battery capacity.
Battery 1 needs service	Limited battery capacity. Remaining time is not displayed correctly.	■ Avoid battery operation. Notify authorized service.
Battery 2 needs service	Limited battery capacity. Remaining time is not displayed correctly.	■ Avoid battery operation. Notify authorized service.
Both batteries need service	Limited battery capacity. Remaining time is not displayed correctly.	■ Avoid battery operation. Notify authorized service.

Switched to battery operation	No external power supply. CARDIOHELP-i has automatically switched to battery operation.	■ If necessary, acknowledge acoustic signal via battery dialog.
Ext. TVen not calibrated	Temperature sensor not calibrated. Temperatures are not displayed correctly.	■ Notify authorized service.
Ext. TArt not calibrated	Temperature sensor not calibrated. Temperatures are not displayed correctly.	■ Notify authorized service.
Battery 1 not charging	Battery cannot be charged. Battery power is not guaranteed. With DC power supply: Voltage below 11 V. Or: Temperature of the battery < 0°C or > 50°C	**NOTICE!** Do not use DC power supply. ■ With DC power supply: Check for insufficient power (voltage < 11 V). Switch to AC power supply if possible and check whether error message is still displayed. ■ With AC power supply: Use other power supply. Replace the CARDIOHELP-i as quickly as possible. Notify authorized service. Avoid battery operation. ■ If battery temperature too low or too high: Bring battery temperature to > 0°C or < 45°C and check whether the error continues to be displayed.
Battery charger defective	Battery charger defective.	■ Avoid battery operation. Replace the CARDIOHELP-i as quickly as possible. Notify authorized service.

Battery 2 not charging	Battery cannot be charged. Battery power is not guaranteed. With DC power supply: Voltage below 11 V. Or: Temperature of the battery < 0°C or > 50°C	**NOTICE!** Do not use DC power supply. ■ With DC power supply: Check for insufficient power (voltage < 11 V). Switch to AC power supply if possible and check whether error message is still displayed. ■ With AC power supply: Use other power supply. Replace the CARDIOHELP-i as quickly as possible. Notify authorized service. ■ If battery temperature too low or too high: Bring battery temperature to > 0°C or < 45°C and check whether the error continues to be displayed.
AC supply fan defective	Power supply fan defective.	■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Housing fan 1 defective	Housing fan defective.	■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Housing fan 2 defective	Housing fan defective.	■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Drive fan 1 defective	Drive fan defective.	■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.
Drive fan 2 defective	Drive fan defective.	■ Replace the CARDIOHELP-i as quickly as possible. ■ Notify authorized service.

Internal memory full Offline recording stopped	Memory for perfusion data is full. Data recording was stopped. Continuing to save data will delete existing data.	
Operating time limit is reached	Operating time limit reached.	■ Notify authorized service.
Last application lost	Last thApp selection not saved. When restarted CARDIOHELP-i will not use the last thApp.	■ After restarting; check the thApp, change if necessary.
	Storage medium defective.	■ Notify authorized service.
Timer 1 elapsed	Time recording outside the recordable range.	
Timer 2 elapsed	Time recording outside the recordable range.	
Timer 3 elapsed	Time recording outside the recordable range.	
Software error	System unstable. Possible automatic restart shortly.	■ Notify authorized service.

9.5 Messages

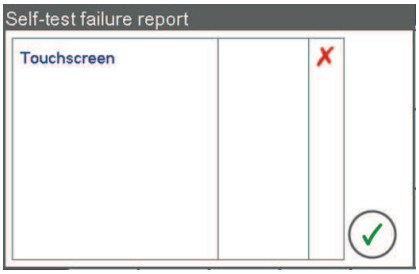
Message	See
Countdown time elapsed	■ ⇨ "Using the Timers", page 142.
System locked To unlock, keep the "Lock/Unlock" button depressed for 1 s or touch symbols 1, 2 one after the other.	■ ⇨ ""Lock/Unlock" LED and Button", page 37.
Do you want to change the application?	■ ⇨ "Switching thApp", page 90.
Check the settings and limit values	
Do you want to switch off the system?	■ ⇨ "On Completion of the Application", page 152.
Notice! Pump control mode was changed	■ ⇨ "Activating LPM/RPM Mode", page 92.

Overwrite? Really overwrite already saved reference values? Cancel = keep saved values At least one of the values is outside the expected range. Save anyway?	■ ⇨ "Recalibrating Blood Parameters", page 139.
Is the tube clamped upstream and downstream of the flow sensor?	■ ⇨ "Flow Off-Set Calibration of the Flow/ Bubble Sensor", page 117.
Is the system free of liquids?	■ ⇨ "Integrated Pressure Sensors: Carrying Out Zero Calibration", page 116.
Is the pressure sensor closed to the system and open to the ambient pressure?	■ ⇨ "External Pressure Sensors: Carrying Out Zero Calibration", page 117.
Check system Press "Zero flow" button to leave backflow prevention	■ ⇨ "Backflow Prevention", page 128.
Deleting failed USB export failed	■ ⇨ "Export recorded data", page 98.
Initialization failed	■ ⇨ "Initializing the Venous Probe", page 114.
No measuring cell detected	■ ⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112.
Measuring cell detected: 3/8" HLS	■ ⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112.
Control unit restarted. Please check settings.	■ Settings have been reset to factory settings. Check all the settings, including the warning limits, alarm limits and interventions (⇨ "Physiological Alarms and Interventions", page 121).
Wrong password	■ ⇨ "Key User Functions", page 81.

Message	**Possible causes/consequences**	**Possible remedies**
Reduce the RPM or remove air.	The motor has reached its power output limit and cannot reach the set speed.	■ Reduce the speed (RPM) or remove the air from the system.

9.6 Self-Test Failure Report

The CARDIOHELP-i will automatically perform a self-test after being switched on. Should an error occur during the self-test, the touchscreen displays a self-test failure report:



- Touch the symbol [Confirm] to close the failure report.

Message	Possible causes/consequences	Possible remedies
Error: Loading of system configuration failed	System configuration not available. CARDIOHELP-i automatically uses factory settings.	■ Check settings. Notify authorized service.
Error: Loading of clinic configuration failed	Clinic configuration not available. CARDIOHELP-i automatically uses factory settings.	■ Check settings. Adapt settings and save as clinic configuration.
CRC error: Loading of EEPROM data failed Error: Loading of EEPROM data failed	Internal data not available. Only thAPP MECC is available. Touchscreen calibration possibly faulty.	■ Replace the CARDIOHELP-i as quickly as possible. Notify authorized service.
Inspection interval has expired		■ Have inspection carried out.

10 Cleaning and Disinfection

10.1 Surface Cleaning and Disinfecting After Each Use

WARNING!

- Switch off the device and disconnect it from the external power supply before cleaning.

WARNING!

- Do not use chemical solvents and do not spill anesthetics.
- Only clean with a damp cloth.
- Do not spray the device with liquids.

10.1.1 Surface Cleaning

- Moisten a cloth with an aqueous alcohol solution (70% ethanol/30% water).
- To remove soiling or residual blood, clean the device and cables after each use.

10.1.2 Surface Disinfection

Wipe down the surfaces with disinfectant after each use or daily.

Approved disinfectants

You can use the following disinfectants:

- Isopropyl alcohol (70% vol.)
- Bacillol (Bode Chemie)
- Mikrobac forte (Bode Chemie)
- Kohrsolin extra (Bode Chemie)
- Buraton rapid (Schülke & Mayr)

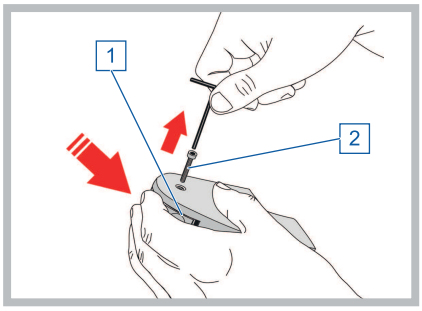
10.2 Clean the Venous Probe.

You can detach the round knob on the probe to remove any soiling between the knob and probe.

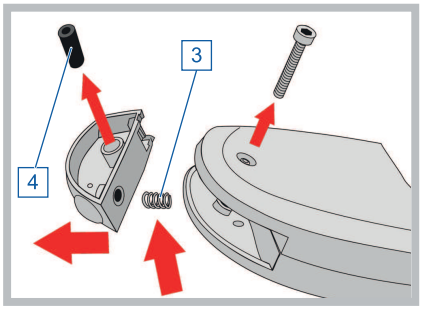
WARNING!

- Only use a lint-free cloth and water to clean the venous probe's sensors.
- Hold down the round knob when releasing the hexagon socket screw on the probe. The knob contains a spring which may jump out or distribute residual blood and other soiling.

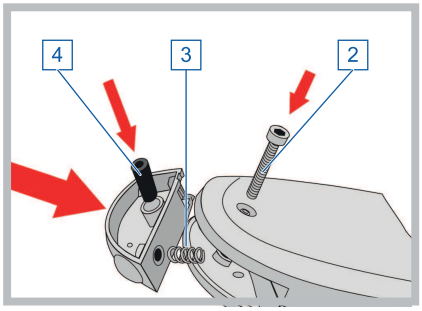
1 Remove the connection cable from the venous probe.



2 Hold down the round knob [1] on the probe.
3 Undo the screw [2] with a hexagon socket wrench and unscrew from the probe.
4 Carefully remove the round knob, paying attention to the spring [3].

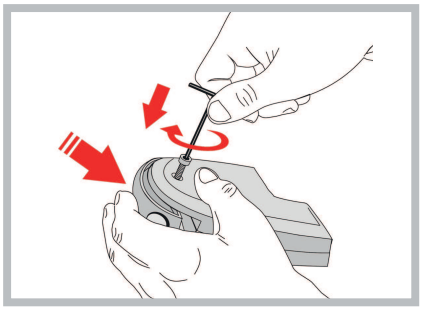


5 The round knob contains a round black sleeve [4]. Remove the sleeve.
6 Clean all component parts.
You can then refit the knob to the probe:
7 Slide the sleeve [4] into the round knob so it is flush on both sides.



8 Insert the spring [3] into the round knob.
9 Position the round knob on the probe. Make sure that the spring is not bent. Hold down the knob on the probe.
10 Insert the screw [2] through the hole in the probe.

11 Securely tighten the screw with a hexagon socket wrench.



12 Connect the connection cable to the venous probe.

11 Maintenance

Maintenance includes all measures that 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
- Changing fuses
- Inspection and maintenance by authorized service personnel
- Repair

The following actions are to be performed at regular intervals:

Interval	Task	Procedure
Every 4 months	Calibrate batteries	Operator
Every 12 months	Inspection	Authorized service
Every 48 months	Change the batteries	Authorized service

11.1 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.

11.1.1 Calibrating the Batteries

To enable the most accurate display possible of the remaining battery life, the batteries must be calibrated regularly.

How often calibration is required, depends on the ambient conditions and use of the CARDIOHELP-i. The batteries must be calibrated:

- At least every 4 months.
- If the symbol "Calibration required" is displayed in the [Battery] window (⇨ "Calibrating the Batteries", page 85).
- If the actual remaining battery life is different from the remaining battery life displayed.

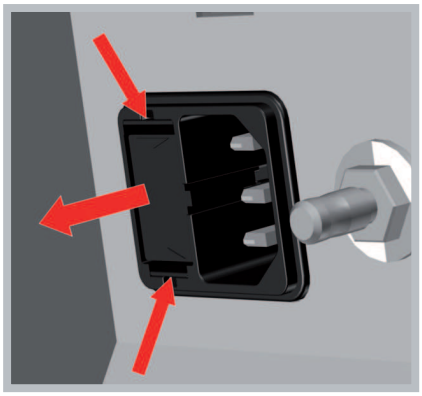
Battery calibration is included in the Key User functions and is accessed via the [Service] screen (⇨ "Calibrating the Batteries", page 85). The [Service] screen is password-protected and may only be used by authorized personnel (⇨ "Calling Up the "Service" Screen", page 81).

11.2 Changing Fuses

WARNING!

Check that you are using correct and suitable fuses (⇨ "CARDIOHELP-i Device", page 196).

1 Disconnect the CARDIOHELP-i from the external power supply.



2 Press the lever on the fuse module and pull the fuse module out.
3 Insert new fuses into the fuse module.
4 Push the fuse module back in place.

11.3 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.

11.3.1 Inspection

Have an inspection carried out by authorized service personnel every 12 months (⇨ "Repair", page 189).

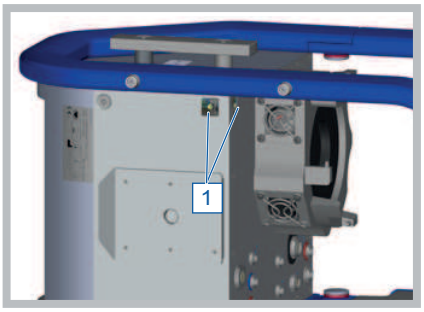
The [System information] window displays the date of the last inspection and the time remaining until the next inspection (⇨ "Displaying System Information", page 79).

Changing the batteries

Within the scope of an inspection, the batteries are changed every 48 months.

Security seal damaged or missing

If any of the security seals are damaged or missing, have an inspection carried out.



1 Security seal

11.4 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.

11.4.1 Send Device to Authorized Service Point

1 Switch off the device.
2 Remove all accessories and connection cables. Only include the accessories necessary for the inspection and repair.
3 Before packaging, decontaminate all parts in accordance with the procedures applicable to the clinic.
4 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.
5 Enclose a description of the problem together with the name, address and telephone number of the contact person.

11.5 Authorized Service

For inspection or repair, contact your local service point.

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

12 Initial Set-Up

12.1 Overview

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

WARNING!

- Before the initial setup, read the Instructions for Use and all documents included with the delivered device.
- The initial setup must only be carried out by persons who have been trained in and authorized for the initial setup.
- The initial setup must be documented by the operator.

The initial setup comprises the following steps:

- ⇨ "Unpacking and Checking the Delivery", page 190
- ⇨ "Checking Setup Prerequisites", page 191
- ⇨ "Assembly", page 191
- ⇨ "Function Test", page 192
- ⇨ "Complete Initial Set-Up", page 193

12.2 Unpacking and Checking the Delivery

1 Check the shipping packaging for visible damage.
2 Unpack the delivered components.
   ▸ During unpacking, ensure that the CARDIOHELP Emergency Drive and the cartons at the side do not fall out.
3 Check the completeness of the delivery (⇨ delivery note).
4 Check the components for any shipping damage or other visible damage like scratches or cracks.
   Pay particular attention to the following components:
   ▸ All plug connectors
   ▸ Touchscreen
   ▸ Holder for the venous probe
5 Check that the security seals are present and not damaged (⇨ "Security seal damaged or missing", page 189).
6 Clean the components of any shipping soiling.

12.3 Checking Setup Prerequisites

Ensure that the following prerequisites have been met:

- The initial setup training for this or an identical device has been completed.
- The EoL report for the device delivered is present.
  The EoL report ("End of Line") documents extensive functional testing at the end of production. It is the proof that, prior to shipping, the device is in a proper and functional condition.
- The Instructions for Use for the delivered device is present.

Check that the following requirements are met:

- Requirements regarding the electrical power supply and its fuse protection.
- Requirements regarding the installation location (⇨ "Position of Use and Operation and Positioning of the CARDIOHELP-i", page 15).
- Requirements regarding the ambient conditions (⇨ "Ambient Conditions", page 200).
  There must be no risk of condensation. Condensation may occur when the device is taken from a cold environment into a warm room and vice versa.
- Requirements regarding the electromagnetic environment (⇨ "Electromagnetic Compatibility", page 24 and ⇨ "Electromagnetic Compatibility (EMC)", page 207.

12.4 Assembly

1. Remove the protective film from the touchscreen of the CARDIOHELP-i.
2. Install the holders for the CARDIOHELP-i (⇨ "Installing the Holder", page 58).
3. Position the CARDIOHELP Emergency Drive (⇨ "Fitting the CARDIOHELP Emergency Drive", page 64).
4. Set up the CARDIOHELP-i and connect the device (⇨ "Setting Up and Connecting the CARDIOHELP-i", page 65).
5. Connect the venous probe (⇨ "Connecting the Venous Probe", page 70).
6. Fully charge the device's batteries.
   At the time of shipping, the batteries are fully charged. Depending on the duration of shipping and storage, the batteries may lose some of their charge and must be recharged. Leave the device connected to the power supply until the "Battery" LED goes out.

12.5 Function Test

12.5.1 Checking Mechanical Components

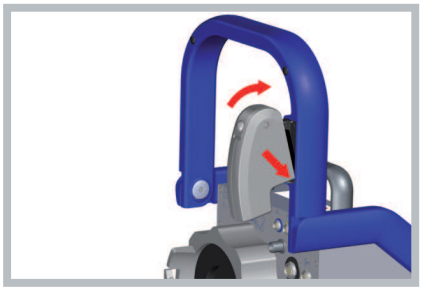
Check the mechanical function of the following components:

- Locking/release mechanism of the safety bar (⇨ "Closing the Safety Bar", page 67)
- Locking/release mechanism of the holder for the CARDIOHELP Emergency Drive
- Locking/release mechanism for the disposable
- Holder for the venous probe
- CARDIOHELP Emergency Drive:
  - Can be driven with the hand crank.
  - The LED speed indicator is lit according to the speed.

12.5.2 Switching On the Device, Self-Test

1 Fix the venous probe in its holder on the safety bar of the CARDIOHELP-i.

2 Ensure that the venous probe has clicked into place.

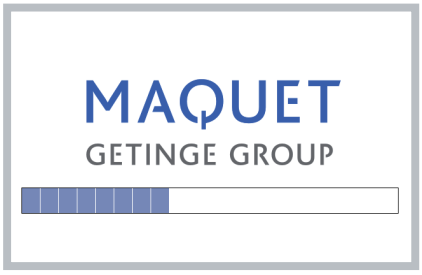


3 Connect the disposable's integrated sensors (⇨ "Connecting the Integrated Sensors of the Disposable", page 103).

4 Press the "On/Off" button.

5 Check that the speaker and warning buzzer generate acoustic signals.

▸ The CARDIOHELP-i will automatically perform a self-test after being switched on.



▸ The CARDIOHELP-i initializes the venous probe against the black reference surface on its holder.

6 Check successful initialization of the venous probe (⇨ "Checking the Status of the Venous Probe and Measuring Cell", page 112).

If the self-test does not proceed as described, do not operate the device and have it tested by authorized service personnel.

12.5.3 Checking the Controls

Check the function of the following controls:

- Keypad
- LEDs
- Touchscreen

If any of the controls are defective, do not operate the device.

12.6 Complete Initial Set-Up

1 Switch the CARDIOHELP-i off:
   - ▸ Press the "On/Off" button for at least 3 seconds.
     The touchscreen displays the following message: [Do you want to switch off the system?]
   - ▸ To confirm switching off, touch the [Confirm] symbol within 3 seconds.
2 Record the initial setup in accordance with national regulations and the operator's instructions.

For storage up to the first use in accordance with the intended purpose, please observe the ambient conditions for storage (⇨ "Ambient Conditions", page 200).

13 Accessories

13.1 Overview

Sensors	
Flow/bubble sensor	■ FBS 3/8" x 3/32" L0.9 (standard accessory)
Bubble sensor	■ BS 3/8" x 3/32" L1.7
Venous probe	Venous probe
Connection cable for venous probe	■ CC-VP L0.32
Connection cable for disposable:	
■ for HLS Set / QUADROX-iR (simple cable, short)	CC-D P16 L0.21
External temperature sensors	■ TPO-D L1.8 Adult (dia. 0.125" x L1.77")
External pressure sensors:	MTK 960 LogiCal (CARDIOHELP Medex LogiCal Transducer Kit)

Connecting cables	
AC power supply cord	according to IEC 60320 with country-specific plug, maximum length 2.5 m
Unit for battery calibration	Battery Calibration Unit

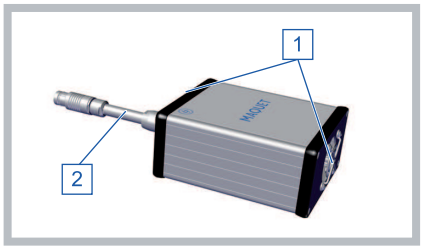
Holder	
CARDIOHELP-i	
■ For mast	HKH 9102-M
CARDIOHELP Emergency Drive	
■ For slide rail	HKH 9101-R
■ For mast	HKH 9101-M
Adapter for mast system:	
■ dia. 30 mm	Mast adapter D30 H45
■ dia. 33 mm	Mast adapter D33 H45
Bed adapter for slide rail	HKHZ 9103-R

Intra-hospital Patient Transport	
Mobile holder	HKH 8860
CARDIOHELP Infusion Mast (70104.9213)	included with Cardiohelp Mobile Holder HKH 8860
Transport securing device	Transport Guard for CARDIOHELP Disposables

Storage and non-operating transport	
Protection cover	CARDIOHELP Protection Cover (included with Cardiohelp Mobile Holder HKH 8860)
Transport box	Transport case for CARDIOHELP-i
Trolley Transport System	

Data exchange	
USB 2.0 cable type A / type B	
■ Length 1.8 m	
■ Length 3 m	
■ Length 5 m	
USB memory stick	XM-USB 4 GB

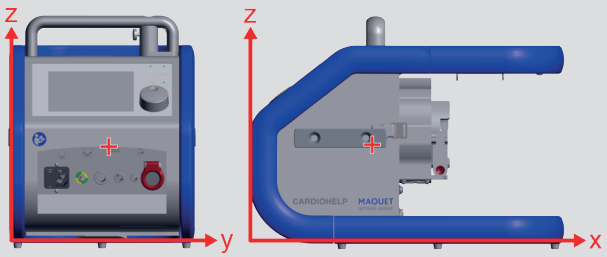
13.1.1 Battery Calibration Unit (Optional)



1 Ventilation openings
2 Connecting cable

14 Technical Data

14.1 CARDIOHELP-i Device

Classification in accordance with Council Directive 93/42/ EEC concerning medical devices, Appendix IX	Class IIb
Degree of protection in accordance with IEC 60529	■ IPX1 (protection against vertically dripping water) ■ IP33 when unsing the protective cover (CARDIOHELP Protection Cover)
Classification in accordance with IEC 60601-1	Defibrillator-protected Type CF applied part
Protection class in accordance with IEC 60601-1	■ Protection class I device (with protective ground connection) ■ Device with internal power supply
Dimensions (W x H x D)	Safety bar closed: 255 x 315 x 427 mm Safety bar open: 255 x 455 x 427 mm
Weight	Approx. 12 kg
Center of gravity ■ y axis: 132 mm ■ z axis: 136 mm ■ x axis: 157 mm	
Touchscreen	LCD with background lighting, 5.7", 640 x 480 pixels
Front connections	■ "Alarm outlet" connection ■ Ethernet connection (not used) ■ USB port type A ■ USB port type B ■ AC power cord receptacle ■ Equipotential bonding connection ■ DC device socket ■ CAN connection (not used) ■ Interface for ECG data (not used)

Rear connections	■ 4 external pressure sensors ■ Sensors of disposable ■ Clamp (not used) ■ Bubble sensor ■ Venous probe ■ Level sensor ■ 2 external temperature sensors ■ Flow/bubble sensor ■ Battery Calibration Unit
Speaker for acoustic signals	Volume depends on the priority of the alarm (⇨ "Messages", page 157) and the volume set by the user (⇨ "Changing and Testing the Brightness/Volume", page 74). Minimum … maximum volume (approx.): ■ High priority: 54 … 79 db(A) ■ Medium priority: 49 … 75 db(A) ■ Low priority: 41 … 68 db(A) Measuring radius: 1 m
Storage capacity of the USB memory stick	■ Online recording: 4 GB
Storage capacity of the internal memory	■ Offline recording: 60 MB (~250000 events)[a] ■ Internal log: 300 MB
Maximum runtime of the timers 1 to 3	■ 100 days[b]

a. The time required until the storage capacity is reached depends on the data recording interval (⇨ "Data Recording", page 96)

b. Technical maximum. Observe the maximum application time of 6 hours.

Power supply		
Power consumption	140 VA	
AC power supply:		
■ Mains voltage	100 … 240 V	
■ Frequency	50 / 60 Hz	
■ Line fuse	2 x T4.0A / 250 V~ / H	
DC power supply:		
■ Mains voltage	12 … 28 V	
Battery:		
■ Type	2 x Lithium-ion, 10.8 V/6450 mAh	2 x Lithium-ion, 10.8 V/8280 mAh
■ Battery life	At least 90 mins (fully charged batteries)	At least 90 mins (fully charged batteries)

Power supply		
■ Charging time[ab]	5 h max.	7 h max.

a. The specified charging time relates to devices with 0 rpm or when the device is switched off.

b. Depending on the set speed (rpm), the charging time can increase during operation of the CARDIOHELP-i.

Acoustic signals		
Alarms:		
■ High priority	2 x 5 signals	2.5 s
■ Medium priority	3 signals	4 s
■ Low priority	2 signals	8 s
Reminder signal	1 signal	60 s
Self-test	2 signals	Not repeated
Audio test	1 signal	Not repeated
Emergency mode:		
■ Switching on	3 signals	Not repeated
■ Reminder signal	1 signal	60 s
■ Battery capacity < 20%	1 signal	1 s
■ Battery capacity < 10%	Continuous tone	
■ Switching off	9 short signals, after 10 s one long signal	Not repeated

14.2 Applied Parts

Integrated pressure sensors
External pressure sensors
External temperature sensors

14.3 Tubing

Usable tubes / sets	
HLS Set Advanced	3/8" x 3/32" PVC

14.4 Sensors

Bubble sensor BS 3/8" x 3/32" L1.7 / BS 3/8" x 1/16" - 1/4" x 3/32" L1.7	
Bubble sensor	Ultrasound
Backflow prevention (with activated intervention)	Air bubbles dia. ≥ 5 mm

Flow/bubble sensor FBS 3/8" x 3/32" L0.9 / FBS 1/4" x 3/32" L0.9	
Flow sensor	Ultrasound
Bubble sensor	Ultrasound
Pump stop (with activated intervention)	Air bubbles dia. ≥ 5 mm

Venous Probe	
Sensors S_VO_2, Hb, Hct	optical (contactless, spectrometric measurement)
Sensor T_{Ven}	non-invasive, thermopile infrared sensor

14.5 CARDIOHELP Emergency Drive

Degree of protection in accordance with IEC 60529		IPX4 (protection against splashing water from any direction)
Coupling		Magnetic
LED speed indicator	0 … 2225 rpm ± 50 rpm	Red LEDs
	2275 … 4725 rpm ± 50 rpm	Green LEDs, resolution 500 rpm
	> 4775 rpm ± 50 rpm	Red LED
Gear	Ratio	1:55
Speed ratios	Hand crank: ~18 rpm	Pump: 1000 rpm
	Hand crank: ~36 rpm	Pump: 2000 rpm
	Hand crank: ~54 rpm	Pump: 3000 rpm
	Hand crank: ~72 rpm	Pump: 4000 rpm
Dimensions (diameter × length)	Hand crank folded in	160 × 200 mm
	Hand crank unfolded	220 × 300 mm
Weight		Approx. 1.5 kg

14.6 Accessories for Intra-Hospital Patient Transport

Service life	10 years
Materials:	
■ Mobile holder, Transport Guard for CARDIOHELP Disposables	Aluminum, stainless steel

Dimensions	W x H x D
Cardiohelp Mobile Holder HKH 8860	465 x 264 x 374 mm
Transport Guard for CARDIOHELP Disposables	250 x 150 x 50 mm

Weights	
Cardiohelp Mobile Holder HKH 8860	4.2 kg
CARDIOHELP-i	Approx. 12 kg
Infusion bag	■ Max. 2 kg per bag ■ Max. 4 kg in total
Transport Guard for CARDIOHELP Disposables	150 g

Ambient conditions	
Temperature	15 … 40°C
Relative humidity	15 … 95% (no condensation)

Approved oxygen bottles	
■ Gas bottle	Medical oxygen bottle approved for transport
■ Length	At least long enough to permit secure fixing with the two securing belts
■ Diameter	100 mm
■ Maximum weight (full)	7 kg

14.7 Ambient Conditions

	Ambient temperature	Relative humidity (non-condensing)	Air pressure (absolute)
Application in a surgical environment	+15 … +30 °C	30 … 75 %	700 … 1060 hPa
Device storage[a]	-20 … +45 °C	0 … 95%	500 … 1060 hPa
Device transport[b]	-20 … +55 °C	0 … 95%	500 … 1060 hPa

a. After storage at minimum or maximum ambient temperature, it can take up to 4 hours before the CARDIOHELP-i is ready for use. After storage in a surgical environment between applications, the CARDIOHELP-i is ready for use immediately.

b. Applies exclusively to transportation of device alone when not being used for patient support.

14.8 Measured Data and Displayed Data

NOTE

Measuring accuracies related to the entire system
The measuring accuracies named each relate to the entire measurement system, consisting of the sensor and the CARDIOHELP-i device.

Parameter	Display range	Display Resolution	Measuring accuracy
Flow	-9.99 … 9.99 l/min	0.01	⇨ "Flow", page 202
Speed	-999 … 5025 rpm	1	± 20 rpm
Integrated sensor pressures:			
■ p_{Ven}, p_{Int}, p_{Art}, p_{Aux}	-500 … +900 mmHg	1	⇨ "Pressure", page 202
■ Δp	-500 … +900 mmHg	1	Calculated value[a]
External sensor pressures:			
■ p_{Ven}, p_{Int}, p_{Art}, p_{Aux}	-500 … +900 mmHg	1	⇨ "Pressure", page 202
■ Δp	-500 … +900 mmHg	1	Calculated value[a]
Integrated sensor temperatures:			
■ T_{Ven}, T_{Art}	10.0 … 40.0°C	0.1	⇨ "Temperature", page 202
External sensor temperatures:			
■ T_{Ven}, T_{Art} with QUADROX-iR and HLS Module	10.0 … 40.0°C	0.1	⇨ "Temperature", page 202
Blood gas values:			
■ S_VO_2[b]	40.0 … 99.9%	0.1	± 5% (absolute)[c]
■ Hb[b]	5.0 … 15.0 g/dl	0.1	± 1.5 g/dl[c]
■ Hct[b]	15.0 … 50.0%	0.1	± 5% (absolute)[c]

a. The accuracy is dependent on the accuracy of the measured values p_{Int} and p_{Art} (⇨ "Pressure", page 202).

b. It is recommended that all of the displayed parameters be checked every 30 minutes via a laboratory blood gas analysis.

c. The measuring accuracies indicated apply in the case of a flow rate between 0.1 and 7 l/min.

14.8.1 Flow

	Measuring accuracy
Flow 0 … 1 l/min	± 0.16 l/min
Flow > 1 l/min	± 7% of the measured value ± 0.06 l/min

14.8.2 Pressure

External sensors	Measuring accuracy[a]
Pressure range -30 … +100 mmHg	± 3 mmHg device accuracy ± 3 mmHg sensor accuracy
Pressure range +101 … +300 mmHg	± 3% device accuracy ± 3% sensor accuracy

Integrated sensors of the disposable	Measuring accuracy	Drift
Pressure -500 … -151 mmHg	± 7 % of the measured value	
Pressure -150 … +249 mmHg	± 10 mmHg	
Pressure +250 … +900 mmHg	± 7 % of the measured value	
Offset drift in the range -100 ... 0 mmHg[a]		max. 3 mmHg in 6 hours

a. In the case of continuously measured pressure values outside of this range, larger measurement inaccuracies are possible.

14.8.3 Temperature

Ambient temperature	Blood temperature	Measuring accuracy [a]
Venous probe		
+20 … +24 °C	+24 … +37 °C	± 0.7°C
+15 … +30°C	+24 … +37 °C	± 1.0°C
Integrated sensors of the disposable		
+20 … +24 °C	+32 … +40 °C	± 0.7°C
+15 … +40 °C	+32 … +37 °C	± 1.0°C

Ambient temperature	Blood temperature	Flow rate	Measuring accuracy [a]
External sensors			
+20 … +24 °C	+37 … +40 °C	3.0 ... 7.0 l/min	-0.8 ... -0.1 °C
		0.5 ... 3.0 l/min	-1.4 ... 0 °C
+15 … +30°C	+32 … +37 °C	3.0 ... 7.0 l/min	-0.9 ... +0.3 °C
		0.5 ... 3.0 l/min	-1.6 ... +1.6 °C
+15 … +30°C	+28 … +32 °C	3.0 ... 7.0 l/min	-0.6 ... +0.5 °C
		0.5 ... 3.0 l/min	-1.6 ... +1.6 °C

Ambient temperature	Blood temperature	Flow rate	Measuring accuracy [a]
+15 … +30°C	+18 … +28 °C	3.0 ... 7.0 l/min	-0.4 ... +1.3 °C
		0.5 ... 3.0 l/min	-1.6 ... +1.6 °C

A. Outside of the ranges listed, larger measurement inaccuracies are possible.

14.9 Components Supplied

CARDIOHELP-i device	X
CARDIOHELP Emergency Drive	X
Flow/bubble sensor FBS 3/8" x 3/32" L0.9	X
AC power supply cord	X
Instructions for Use	X
Venous probe with connecting cable	X
Connecting cable for disposable	X
USB stick with CARDIOHELP CSV Converter program (decompressing exported data)	X
Protective caps for connections	X
Transport Guard for CARDIOHELP Disposables	X

14.10 Possible Settings and Factory Settings

14.10.1 Speed/Flow

Speed	0 … 5000 rpm
Flow	0 … 9.9 lpm (with HLS Module)[a]

a. Observe the maximum flow limit of the disposables (⇨ Instructions for Use of the disposables).

14.10.2 Warning Limits, Alarm Limits and Interventions

NOTE

Possible settings

Alarm and warning limits can be set as follows:

- Upper alarm limit ≥ Upper warning limit
- Upper warning limit > Lower warning limit
- Lower warning limit ≥ Lower alarm limit
- Deactivate alarm limit or warning limit

Parameter	Possible settings		Factory setting	
	Limits	Resolution	Lower / upper limit	Intervention
Flow	0 … 9.9 l/min	0.1	0.0 / 8.0	deactivated
Speed	0 … 5000 rpm	1	0 / 4500	deactivated
Pressures:				
■ p_{Int}[a], p_{Art}	-500 … +900 mmHg[b]	1	Warning: – / 400 Alarm: – / 500	deactivated
■ p_{Ven}	-500 … +900 mmHg[b]	1	Warning: -100 / – Alarm: -150 / –	deactivated
■ p_{Aux}[a]	-500 … +900 mmHg[b]	1	Warning: deactivated / 400 Alarm: deactivated / 500	deactivated
■ Δp	-500 … +900 mmHg[b]	1	deactivated / 60	–
Bubbles:				
■ Venous	–	–	–	deactivated
■ Arterial	–	–	–	activated
Level	–	–	–	activated[b]
Note: Level monitoring only in thApp „MECC“.				

WARNING!

The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

Parameter	Possible settings		Factory setting	
	Limits	Resolution	Lower / upper limit	Intervention
T_{Ven}, T_{Art}[a]	10 … 40 °C	0.1	10.0 / 40.0	–
Blood gas values:				
■ S_vO_2	40.0 … 99.9 %	0.1	60.0 / deactivated	–
■ Hb	5.0 … 15.0 g/dl	0.1	7.0 / 15.0	–
■ Hct	15.0 … 50.0 %	0.1	21.0 / 40.0	–

a. Depending on the thApp used (⇨ "thApp-specific Parameters and Functions", page 29).

b. When using external sensors: Limits depend on the measuring range of the sensor (⇨ Specification of the external sensor).

14.10.3 General Settings

Option	Possible settings	Factory setting
thApp	Cardiopulmonary support, cardiac support, MECC, pulmonary support, CO_2 elimination	MECC

WARNING!

Only use thApp “Cardiopulmonary Support”.
The thApp “Circulatory Support”, “Pulmonary Support”, and “CO_2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System.
The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

Option	Possible settings	Factory setting
Pump:		
■ Control mode	RPM, LPM	RPM
Data recording:		
■ Interval	3 s, 15 s, 30 s, 45 s, 1 min, 2 min, 5 min, 10 min	5 min
■ Offline recording	started, stopped	stopped
Locking:		
■ Automatic lock	activated, deactivated[a]	deactivated
Brightness/volume:		
■ Brightness	1 … 10 (in increments of 1)	10
■ Volume	1 … 3 (in increments of 1)	3
■ Night mode	activated[a], deactivated	deactivated
Language	Czech, Danish, German, Greek, English, Spanish, French, Italian, Hungarian, Dutch, Japanese, Norwegian, Polish, Portuguese, Russian, Slovak, Finnish, Swedish, Turkish, Chinese	English

Option	Possible settings	Factory setting
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. Depending on the thApp used (⇨ "thApp-specific Parameters and Functions", page 29).

14.10.4 Recalibrating Blood Gas Values

NOTE

Possible settings
The following settings are possible:
- All values within the measurement or display range of the relevant parameter (⇨ "Measured Data and Displayed Data", page 201).

If the laboratory value determined deviates from the expected adjustment range, the CARDIOHELP-i displays a message (⇨ "Recalibrating Blood Parameters", page 139):

Parameter	Expected adjustment range
S_VO_2	±5% absolute
Hb	± 2 g/dl
Hct	5% absolute

14.11 Availability of Physiological Alarms for External Devices

Physiological alarms are made available to external devices without any delay.

15 Applied Standards

15.1 Electromagnetic Compatibility (EMC)

The objective of the EMC declaration is to enable the responsible organization to decide whether the CARDIOHELP-i is suitable for its electromagnetic environment.

Guidance and manufacturer's declaration – electromagnetic emissions

The CARDIOHELP-i 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 CISPR 11	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 CISPR 11	Class A/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	Class A	

Guidance and manufacturer's declaration – Electromagnetic immunity

The CARDIOHELP-i 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	±8 kV contact	±8 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%.
	±15 kV air	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV at 100 kHz repetition frequency	±2 kV at 100 kHz repetition frequency	Mains power quality should be that of the environment of professional healthcare facilities or the environment of domestic healthcare areas.
	±1 kV at 100 kHz repetition frequency for input/output lines	±1 kV at 100 kHz repetition frequency for input/output lines	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Surges IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of the environment of professional healthcare facilities or the environment of domestic healthcare areas.
	±2 kV common mode	±2 kV common mode	
Voltage interruptions, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	0% U_T for ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	Mains power quality should be that of the environment of professional healthcare facilities or the environment of domestic healthcare areas. 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.
	0% U_T for 1 cycle	0% U_T for 1 cycle	
	70% U_T for 25/30 cycles (50/60 Hz)	70% U_T for 25/30 cycles (50/60 Hz)	
	0% U_T for 250/300 cycles (50/60 Hz)	0% U_T for 250/300 cycles (50/60 Hz)	
Note: U_T is the AC supply voltage prior to application of the test level.			
Magnetic field with a power frequency (50/60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m	The strength of power-frequency magnetic fields should be that of the environment of professional healthcare facilities or the environment of domestic healthcare areas.
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz outside the ISM bands[a]	3 V	
	6 V_{eff} 150 kHz to 80 MHz within the ISM bands[a]	6 V	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	**WARNING!** Portable RF communications equipment (including its accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of manufacturer-designated parts and cables of the CARDIOHELP-i device. Failure to comply may lead to a reduction in the performance features of the device
High-frequency electromagnetic fields in the immediate vicinity of wireless communications equipment according to IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	27 V/m	
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	28 V/m	
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	28 V/m	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
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 by structures, objects and people.			
Magnetic fields in the vicinity, according to IEC 61000-4-39	30 kHz, modulation, CW 8 A/m	8 A/m	
	134.2 kHz, 2.1 kHz, PM 65 A/m	65 A/m	
	13.56 MHz, 50 kHz, PM 7.5 A/m	7.5 A/m	

a. The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

Separation distances from RF communication equipment.

WARNING!

Portable RF communications equipment (including its accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) or manufacturer-designated parts and cables of the CARDIOHELP-i device. Failure to comply may lead to a reduction in the performance of the device.

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

MAQUET
GETINGE GROUP

Maquet Cardiopulmonary GmbH
Kehler Strasse 31
76437 Rastatt
GERMANY
www.getinge.com
info.cp@getinge.com