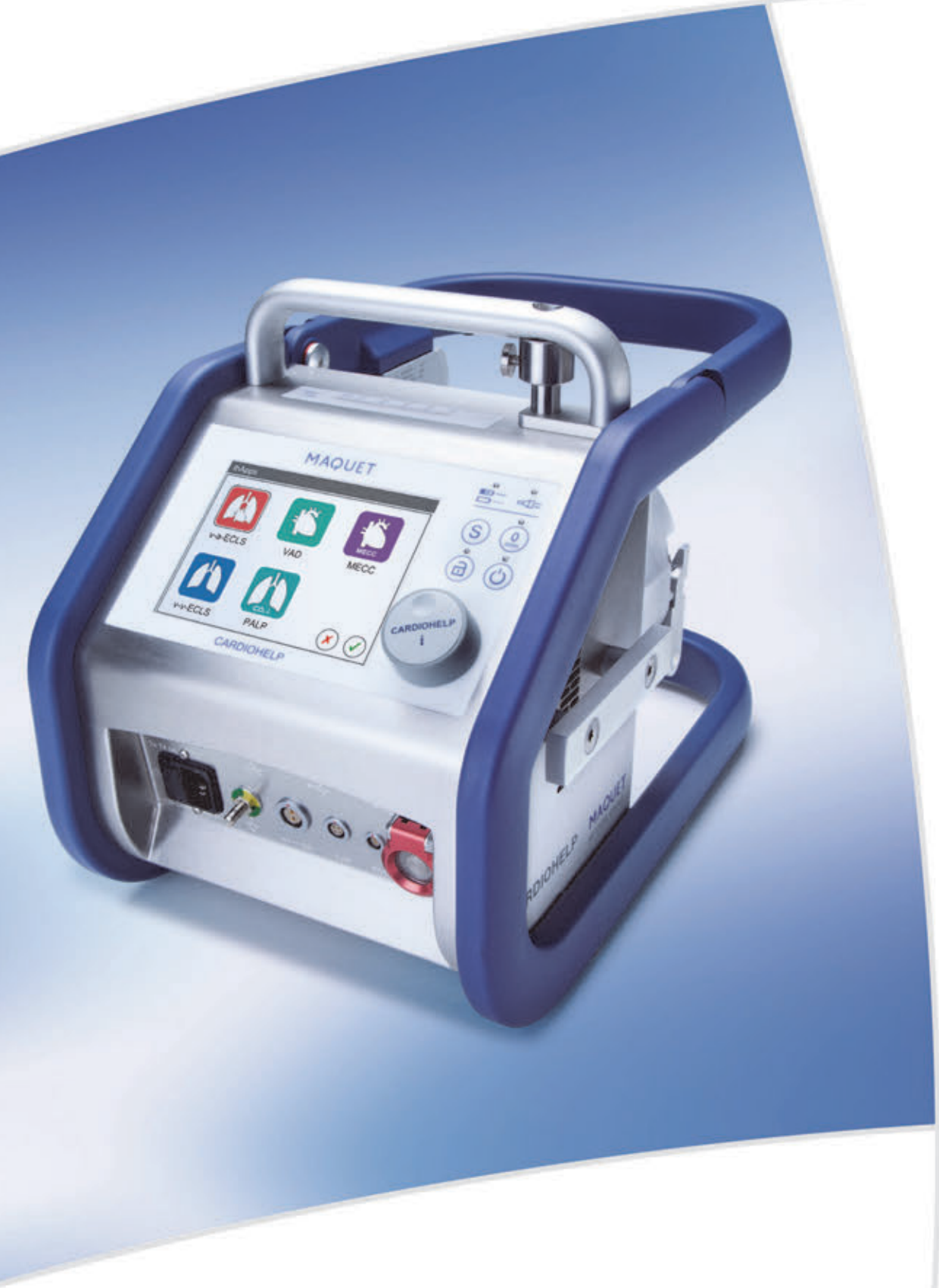
INSTRUCTION GUIDELINES

HEART-LUNG SUPPORT SYSTEM
CARDIOHELP SYSTEM

MAQUET
GETINGE GROUP



These instruction guidelines are kept by the responsible organization and may be used for carrying out further instruction of personnel.

⚠ **These instruction guidelines are no substitute for reading the Instructions for Use!**

Instructed by

Surname	Date	Signature

I hereby confirm that I have been instructed in the handling and operation of the heart-lung support system and have understood the instruction received.

Hospital	

	Surname	First name	Department	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

Contact details of your responsible MAQUET contact:

Name	
Address	
Phone	
E-mail	

Ensure that the contact details are available at all times.

☐ CARDIOHELP-i

CARDIOHELP SYSTEM

- Instructions for Use used: MCV-GA-10000724-_____.
- Instructed software version: _____.

DISPOSABLES

☐ HLS SET ADVANCED

- HLS Set Advanced G-141 Instructions for Use used:

  Revision date: _____.
- HLS Cannula Set G-139 Instructions for Use used:

  Revision date: _____.
- Percutaneous Insertion Kit G-137 Instructions for Use used:

  Revision date: _____.

☐ PALP SET

- PALP Set G-156 Instructions for Use used:

  Revision date: _____.

☐ ECLS SET 2.8

- ECLS 2.8 G-165 Instructions for Use used:

  Revision date: _____.

☐ ROTASSIST SET 2.8 / 9.9

- ROTASSIST Set 2.8 / 9.9 G-163 Instructions for Use used:

  Revision date: _____

☐ MECC-i SET

- CARDIOHELP-i Tubing Set G-261 Instructions for Use used:

  Revision date: _____.

Instructed by

Surname	Date	Signature

I hereby confirm that I have been instructed in the handling and operation of the heart-lung support system and have understood the instruction received.

Hospital	

	Surname	First name	Department	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

Contact details of your responsible MAQUET contact:

Name	
Address	
Phone	
E-mail	

Ensure that the contact details are available at all times.

1. General

1a) Description

- Heart-lung support system
- Class IIb medical device with a defibrillator-protected Type CF applied part.

1b) Safety Information and Precautions

⚠ These instruction guidelines are no substitute for reading the Instructions for Use!

1c) Disposables

See the Instructions for Use for the relevant disposable.

1d) Validity of this Document

- This document applies to the device CARDIOHELP-i with software release 3.4.2.0 or higher.
- Documents for lower software releases do not apply to the device CARDIOHELP-i with software release 3.4.2.0 or higher.

2. CARDIOHELP-i Device

2a) Controls

- LED speed indicator
- Keypad
  - Keypad for "Safety button", "Zero flow mode", "Unlock" and "On/Off".
  - Status LEDs for "Safety button", "Zero flow mode", "Unlock" and "On/Off".
  - Status LEDs for "Battery", "AC/DC power supply".
- Rotary knob
- Touchscreen
- Emergency Mode button
  - LED ring is unlit: CARDIOHELP-i is off.
  - LED ring is illuminated: CARDIOHELP-i is on and is operating in normal mode.
  - LED ring is flashing: CARDIOHELP-i is in Emergency mode.

2b) Sensor Connections

- 4 external pressure sensors (p_{Art}, p_{Ven}, p_{Int}, p_{Aux})
- Holder for connection cable of disposable
- Connection for disposable sensors (p_{Art}, p_{Ven}, p_{Int}, T_{Art})
- Clamp (not used)
- Bubble sensor (for optional bubble sensor)
- Connection for venous probe (S_vO_2, Hb, Hct, T_{Ven})
- Connection for level sensor
- Connections for external temperature sensors (T_{Art}, T_{Ven})
- Connection for flow/bubble sensor
- Connection for Battery Calibration Unit

2c) Front Connections

See CARDIOHELP System Instructions for Use, chapter "Front connections".

- Data transfer
  - Alarm output connection (nurse call system)
  - Ethernet (not used)
  - USB port type A (for data export to USB memory stick)
  - USB port type B (for data recording system)
- Power socket
  - AC power cord receptacle with fuse module: 100 … 240 V AC
  - Equipotential bonding pin
  - DC device socket: 12 … 28 V DC
- CAN connection (not used)
- ECG connection (not used)

2d) Pump Drive

- Characteristics:
  - 0 … 5000 rpm
  - Non-occlusive pump
  - The drive generates a rotating magnetic field ⇨ no moving parts in the pump drive
  - Connected disposable is heated by the pump drive
  - Three-point fixation
- Install HLS Module Advanced.

See CARDIOHELP System Instructions for Use, chapter "Preparing Perfusion (HLS Retainer)".

- Install CARDIOHELP Drive Adapter and ROTASSIST.

See CARDIOHELP System Instructions for Use, chapter "Preparing Perfusion (ROTASSIST Retainer)".

2e) Venous Probe

⚠ Only the venous probe supplied with the device is compatible with a CARDIOHELP-i. To avoid any measurement errors, venous probes from other CARDIOHELP devices should not be used here. Whenever a venous probe is replaced, compatibility with the system must be ensured by a service technician authorized by MAQUET.

- Measurement of the venous blood parameters.
  - S_VO_2, Hb, Hct are measured by an optical sensor (contactless spectrometric measurement).
  - Temperature T_{Ven} is measured by a non-invasive infrared sensor.
- Stand-by position
  - Protect the sensors when the probe is not in use.
  - Reference surface is required for the initialization of the venous probe.

  ⚠ Reference surface must not have any scratches.
- Installing and removing the venous probe on the disposable's measuring cell.
- Installing and removing the venous probe connection cable. Connection to the venous probe and the corresponding interface of the CARDIOHELP-i.

2f) Sensors

- Flow/bubble sensor "FBS 3/8" x 3/32" L0.9" or "FBS 1/4"x3/32" L0.9"
  ⚠ Observe the direction of the blood flow!
  - Measurement is by ultrasound.
  - Bubble sensor integrated in flow sensor.
  - Calibration of the "zero flow signal" required.

  ⚠ When the bubble intervention is active, the bubble recognition generates a pump stop. Microbubbles ≤ 5 mm can also generate a pump stop!
- Optional venous bubble sensor "BS 3/8" x 3/32" L1.7" or "BS 3/8" 1/16" - 1/4" x 3/32" L1.7"
  - Direction of flow is not relevant.
  - Measurement is by ultrasound.

  ⚠ When the bubble intervention is active, the bubble recognition activates the backflow prevention. Microbubbles ≤ 5 mm can activate the backflow prevention!
- Integrated sensors of the disposable

⚠ If valid values from the integrated sensors (temperature and pressure) are available, these are used and displayed. The values of the external sensors are ignored.

  - Pressure -500 ... +900 mmHg
  - Temperature 10 ... 40 °C
- External temperature sensor "TPO-D L1.8" or "TPO-D L1.8 Pediatric"
  - Temperature sensor for oxygenator TPO-D L1.8
- External pressure sensors
  - CARDIOHELP Medex Novatrans Transducer Kit MTK 860 Novatrans
  - CARDIOHELP Medex LogiCal Transducer Kit MTK 960 LogiCal
- Level sensor
  - "CLS Kit" contains the level sensor "CLS L2.0" and level sensor pads "MCP00151004".
- Measurement accuracy

2g) Additional Instructions: Handling

⚠ The safety bar must not be used as a carrying handle.

- The safety bar is designed to protect the device and the installed disposable.
- The safety bar also serves as a holder for the venous probe when the latter is not in use.
- Opening and closing the safety bar.
- Rating plate
- Holder

2h) CARDIOHELP Emergency Drive

- Intended use:
  - Essential system components.
  - Independent of the power supply.
  - In the event of complete failure of the device.
  - No sensors available.
  - Disposable can be installed in the CARDIOHELP Emergency Drive if the pump drive locking function does not function (defective).
- Handling and locking of the CARDIOHELP Emergency Drive to the CARDIOHELP-i or special MAQUET holders.

- Installing the disposable on the CARDIOHELP Emergency Drive.
  ⚠ Observe the warnings in the chapter "Using the Emergency Drive with the Disposable HLS Retainer" and "Using the Emergency Drive with the Disposable ROTASSIST Retainer"!
- CARDIOHELP Emergency Drive function and speed indication.
- Special holder is required when the CARDIOHELP System is operated on the SPRINTER CART.

3. User Interface

3a) Touchscreen

Press and explain the following buttons:

- Switch on ⇨ self-test

Explain the content of the startup screen:

- Startup screen
  - Content of the startup screen dependent on the thApp set.
- Automatic locking of the controls takes place after 3 minutes.
- thApp "MECC" ⇨ automatic locking can be deactivated.
  - The controls (rotary knob, buttons and touchscreen) are locked automatically.
  - 2 ways to unlock the controls
    - Touch the key symbols in numerical order of the [System locked] screen on the touchscreen.
    - Press the "Lock/unlock" button for 1 second.

3b) Status Bar

- Current application.
- During alarms or warnings, the status bar changes (color, flashing).
  - Low-priority alarm – yellow with message
  - Medium-priority alarm – flashing yellow with message
  - High-priority alarm – flashing red with message

⚠ In emergency mode, the status bar continually displays the message [EMERGENCY MODE] but no other messages or alarms.

- "Lock" symbol (locked / not locked).
- "Offline recording" symbol.
  - Is displayed when data are being recorded offline.
- Current time.

3c) Parameter Display in the Startup Screen

- thApp "v-a ECLS", "v-v ECLS" and "PALP"
  - Flow speed LPM
  - Pump speed RPM
  - Pressures (p_{Art}, p_{Ven}, Δp)
  - Venous oxygen saturation (S_VO_2)
- thApp "MECC"
  - Flow speed LPM
  - Pump speed RPM
  - Pressures (p_{Art}, p_{Ven}, p_{Aux})
  - Temperatures (T_{Art})
  - Hematocrit (Hct)
  - Venous oxygen saturation (S_VO_2)

- thApp "VAD"
  - Flow speed LPM
  - Pump speed RPM
  - Pressures (p_{Art}, p_{Ven})
  - Temperatures (T_{Ven})
  - Hematocrit and hemoglobin (Hct, Hb)
  - Venous oxygen saturation (S_VO_2)

Touch and briefly explain every symbol.

3d) Toolbar

- "Startup screen"
  - "Startup screen" symbol permits a fast switch to the startup screen.
  - Content of the startup screen depends on the application set.
- "Menu"
- "Global Override"
- "Current alarm pause"
  - Function is only available if an alarm is present.

3e) Power Supply Status

- Line power operation.
- Automatic switchover to battery operation if the external power supply is interrupted.
- Guide value for the available battery capacity (remaining run time and percentage capacity remaining).

3f) Tab Bar

- "Startup screen"
- "Parameter list"
  - Pressures and temperatures.
  - Priority of the integrated sensors combined with external sensors.
  - Content depends on the application set.
- "Blood parameters"
- "Transportation"
- "Interventions"
  - Content depends on the application set.
- "Timer"

4. Preparing the System

Install disposable and flow/bubble sensor.

4a) Menu – Settings

Open and explain the "Settings" screen.

- System information: Display system information.
- System lock: Change the lock settings.
  - The automatic lock can only be deactivated in the thApp "MECC".
  - Automatically locks the controls (rotary knob, buttons and touchscreen).
- Brightness/volume: Change/test the brightness/volume and activate the night mode.
- Service: Function is password-protected; see key user functions.
- Language: Change the display language.
- Time/date: Change the time, date and formats.

4b) Key User Functions

- Define the alarm configuration
  - Switch the reminder signal [On] or [Off].
  - Switch the "Global Override" mode [On] or [Off].
- Save hospital configuration
- Calibration
  - Calibrate touchscreen.
  - Calibrate batteries.
- All the other functions are only relevant for authorized service personnel.

4c) Menu – thApp

Explain the differences between the individual thApps.

⚠ Observe the warnings in the chapter "Switching thApp".

⚠ 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.

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

- Startup screen is different for each thApp.
- thApp "MECC" (minimized extracorporeal circulation)
  - Level and pressure p_{Aux} intervention only available and monitored in the thApp "MECC".
  - The application is mandatory when operating with venous reservoir or venous bubble trap.
- thApp "v-a ECLS" (cardiopulmonary support)
- thApp "v-v ECLS" (pulmonary support)
- thApp "PALP" (pump-assisted lung protection)
- thApp "VAD" (cardiac support)

4d) Menu – Pump

- Pump ⇨ Change control mode.
  ⚠ Observe the warnings in chapter "LPM/RPM mode".
  ⚠ Important values, always visible.
- RPM mode: Setpoint speed.
  - RPM mode: Change speed.
- LPM mode: Setpoint flow.
  ⚠ Observe the direction of flow of the blood and the position of the flow/bubble sensor!
  - Flow signal is mandatory in the LPM mode.
  - The system automatically switches to the RPM mode if the flow signal is not present (bubble detection, no flow signal).

4e) Menu – Data Recording

⚠ Starting the recording erases previously recorded data.

- Data recording ⇨ Change the data recording interval, record data offline and export recorded data.
- Time interval can be set from 3 seconds to 5 minutes.

⚠ Data export is only possible at 0 rpm.

Menu – Alarm list

- The alarm list shows the last 6 alarms, on a colored background according to priority.

5. Initial Set-up

Initial set-up

- Check setup prerequisites.
- Carry out functional test.
- Carry out initial configuration.
  - Hospital configuration: Document the settings in the chapter "Configuration settings", see page 43, which are saved in the CARDIOHELP-i device.
- Document the initial setup and create/fill in the medical device book.

6. Warning, Alarm and Intervention Behavior

6a) Differences Between Warning, Alarm and Intervention Limits

- 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.
- Alarm limits
  The alarm limits enable the conditions for an alarm and an intervention to be set. The alarm and intervention condition is fulfilled when the parameter value lies outside the alarm limits. 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.
  ⚠ The defined intervention is displayed in all screens with the red symbol "Intervention activated".

6b) Speed Monitoring

⚠ Important value, always visible.

⚠ The speed monitoring intervention generates a medium-priority alarm.

- Speed monitoring: Define alarm limits and activate/deactivate interventions.
  ⚠ No speed alarm limits in RPM mode.

6c) Flow Monitoring

⚠ Important value, always visible.

⚠ Flow monitoring alarms have a high priority, irrespective of whether an intervention has been activated.

- Flow monitoring: Define alarm limits and activate/deactivate interventions.
  ⚠ No flow alarm limits in LPM mode.

6d) Pressure Monitoring

⚠ When the intervention is active, if the measured value is more than 10 mmHg outside of the alarm limits, a high-priority alarm is generated and the pump is stopped.

⚠ The pressure monitoring intervention generates a medium-priority alarm.

⚠ High negative pressure can lead to hemolysis and outgassing.

- Zero calibration of the external pressure sensors.
- Zero calibration of the integrated pressure sensors.

- Pressure sensors p_{Art}, p_{Int}: upper warning and alarm limits can be specified.
  ⚠ Monitoring the lower limits is not possible.
  ⚠ Monitoring of p_{Int} is not possible in thApp VAD.
- Pressure sensor p_{Ven}: lower warning and alarm limits can be specified.
  ⚠ Monitoring the upper limits is not possible.
- Pressure sensor p_{Aux}: upper and lower warning and alarm limits can be specified.
  ⚠ Monitoring of p_{Aux} is only possible in thAp "MECC".
  - Intervention for p_{Aux} can be activated for upper and lower alarm limits.
- Pressure monitoring: Define alarm limits and activate/deactivate interventions.

6e) Bubble Monitoring

⚠ The bubble monitoring intervention at the arterial flow/bubble sensor generates a high-priority alarm and the pump is stopped.
The bubble monitoring intervention at the venous bubble sensor generates a high-priority alarm and activates the backflow prevention.

- Activate/deactivate intervention.
- Bubble alarm must be reset with "Reset" and must be confirmed by touching the "Confirm" symbol.

6f) Level Monitoring

⚠ Level monitoring is only performed in the thApp "MECC".
⚠ The level monitoring intervention generates a high-priority alarm and the pump is stopped.

- Activate/deactivate intervention.

6g) Pressure Drop Monitoring

⚠ The pressure drop monitoring generates a low-priority alarm.

- Define ∆p warning limits (not with ROTASSIST Set).

6h) Temperature Monitoring

⚠ The temperature monitoring generates a low-priority alarm.

- Define T_{Ven}, T_{Art} warning limits.

6i) Blood Parameter Monitoring

⚠ The blood parameter monitoring generates a low-priority alarm.

- Define S_vO_2, Hb, Hct warning limits.
- Initialize probe.
- Recalibrate blood parameters.
  - Save reference values.
  - Recalibrate values.

6j) Interventions in General

⚠ The defined intervention is displayed in all screens with the red symbol "Intervention activated".
⚠ Pump stop for high-priority alarms (exception: Flow alarms).

- Activate/deactivate intervention button combination:
  - Press the safety button and touch the symbol of the respective parameter.

7. Preparing Application

7a) Testing the Functioning of CARDIOHELP-i

- CARDIOHELP-i securely fixed and security seal undamaged.
- Venous probe must be secured in its holder on the safety bar before the CARDIOHELP-i is switched on.
- The connection cable of the disposable for the integrated sensors must be plugged in before the CARDIOHELP-i is switched on.
  - Simple cable (short) for QUADROX-iR and HLS Set Advanced
  - Y-cable for PALP Set and ECLS Set 2.8
  - Simple cable (long) for ROTASSIST Set
- The disposable and/or the CARDIOHELP Drive Adapter has been installed on the pump securely and correctly.
- Switch on – self-test – no messages.
- Check that the controls (buttons, LEDs, touchscreen and rotary knob) are functioning.
- Check battery status; battery must be fully charged.

7b) Functioning and Availability of CARDIOHELP Emergency Drive

- Availability and safe function of the CARDIOHELP Emergency Drive.
- Transport Case for Emergency Drive.

*Demonstrate **and practice** the transport of the CARDIOHELP Emergency Drive in the Transport Case for Emergency Drive.*

See CARDIOHELP System Instructions for Use, chapter "Use Transport Case for Emergency Drive".

7c) Preparation for the HLS Retainer

- Install the disposable.
- Connect the integrated sensors.

7d) Preparation for the ROTASSIST Retainer

- Install the CARDIOHELP Drive Adapter.
- Install the disposable.
- Position the disposable.
- Connect the integrated sensors

7e) Fitting the Holder for PALP Set or ECLS Set 2.8

- Install the CARDIOHELP Drive Adapter.
- Install the necessary additional holder.
- Install the ROTASSIST disposable.

7f) Connecting External Sensors

- Connect and position combined flow/bubble sensor "FBS 3/8" x 3/32" L0.9" (standard accessory) or for PALP, ECLS 2.8 and ROTASSIST 2.8 the combined flow/bubble sensor "FBS 1/4" x 3/32" L0.9".

  ⚠ Observe the direction of flow of the blood and the position of the sensor!
- Connect and position optional bubble sensor "BS 3/8" x 3/32" L1.7" or "BS 3/8" 1/16" - 1/4" x 3/32" L1.7".
- Connect and position external temperature sensors, only for thApp "MECC".
- Connect and position external pressure sensors, only for thApp "MECC".
- Connect level sensor, only for thApp "MECC".

7g) Calibration, Function Test Before Priming

- Switch on – self-test – no messages.
- Check the status of the venous probe and measuring cell.
  - [Measuring cell detected: 3/8" HLS] for HLS Module Advanced or QUADROX-iR
  - [Measuring cell detected: 3/8"] for ROTASSIST 9.9
  - [Measuring cell detected: 1/4"] for ROTASSIST 2.8
- Initialize venous probe.
- Carry out zero calibration of the pressure sensors.
- Prime the ECLS Set 2.8.

7h) Checking Settings

- The settings of external devices, such as gas blenders and heater-cooler units, etc. should be adapted to the particular patient and the current situation.
- The warning and alarm limits and interventions used are appropriate and safe for the particular patient and current situation.

7i) Checking the ECLS Set 2.8

⚠ Make sure that the disposable is positioned lower than the patient or at the same level, but no higher.

- Keep 4 metal tube clamps at the ready for clamping the tubes in the event of leakage.
- Ensure that the disposable is securely and correctly installed on the pump drive.
- Check all Luer lock connectors.
- Patient must always be monitored (patient monitoring).

7j) Priming Procedure for Disposables with Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

See HLS Set Advanced G-141 Instructions for Use.

See PALP Set G-156 Instructions for Use.

See ECLS Set 2.8 G-165 Instructions for Use.

See CARDIOHELP-i Tubing Set G-261 Instructions for Use (for MECC-i Set).

7k) Priming Procedure for Disposables Without Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

See ROTASSIST Set G-163 Instructions for Use.

7l) Calibration, Function Test After Priming

- Install the venous probe on the measuring cell
- Function test for bubble monitoring.
- Function test for level monitoring (only with thApp "MECC").
- Flow off-set calibration of the flow/bubble sensor.

8. During the Application

8a) Timers

- Start/stop timers 1-3.
- Set/change the countdown timer.
- Start/stop the countdown timer.

8b) Global Override

- Meaning of the Global Override.

⚠ Observe the visual alarms on the touchscreen!

⚠ All interventions, acoustic alarms and backflow prevention are disabled.

⚠ Do not use as a default function to disable the acoustic alarm!

⚠ No time restriction.

⚠ Mode generates a reminder signal once per minute.

- Activate/deactivate Global Override (use the safety button).
- Global Override and reminder signal can be set in the key-user functions.

8c) Pausing the Current Alarm

⚠ During the alarm pause, no alarm signals are transmitted at the Alarm outlet interface.

- Maximum duration is 60 seconds.
- Only applies to existing alarms; new alarms generate new acoustic alarms.
- Activate/deactivate "Pause current alarm".
- Function is only available if an alarm is present.

8d) Messages

Generate and explain all alarm priorities.

- Alarms, duration and intervals of acoustic alarms.
  - Priority: High
    - Red status bar
    - 2 x 5 alarm tones
    - Disabling of acoustic alarms is not possible ("Disable acoustic alarms" symbol).
  - Priority: Medium
    - Yellow, flashing status bar
    - 3 alarm tones
  - Priority: Low
    - Yellow status bar
    - 2 alarm tones
- Physiological alarms

  ⚠ Pump stop must be remedied as quickly as possible and the pump started up again as quickly as possible.
  - High-priority alarm condition:
    - Alarms arising from the flow monitoring and interventions of the backflow prevention lead to a pump stop.
  - Medium-priority alarm condition
    - Alarms lead to a pump intervention.
  - Low-priority alarm condition.
    - Alarms lead to a warning or an alarm without intervention.

- Physiological alarms are visually supported by the parameter's symbol turning red or yellow and the status bar changing color, depending on the alarm priority, and the appropriate message is displayed.

Show the messages of the physiological alarms in the Instructions for Use.

- Technical alarms
  - High-priority alarm condition:
    - Alarms lead to a pump stop.
  - Medium-priority alarm condition:
    - Alarms can promptly lead to a pump stop.
  - Low-priority alarm condition:
    - Alarms that can promptly become medium-priority alarm conditions or warnings.
  - Technical alarms are visually supported by the "Menu" symbol turning red/yellow and the status bar changing color, depending on the alarm priority, and the appropriate message is displayed.

Show the messages of the technical alarms in the Instructions for Use.

8e) Zero Flow Mode

See CARDIOHELP System Instructions for Use, chapter "Zero flow mode".

- The CARDIOHELP-i aims at a flow of 0 l/min by controlling the pump accordingly.
  ⚠ The flow signal is mandatory for the "Zero flow mode" function.
  ⚠ Zero flow mode can lead to a critical situation with regard to blood coagulation and oxygen supply / cardiovascular function. Therefore, the safety button must also be pressed to activate the "Zero flow mode".
- Activate the zero flow mode. - Hold down the safety button and press the "Zero flow mode" button.
- Deactivate the zero flow mode. - Press the "Zero flow mode" button.

8f) Backflow Prevention

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

- The backflow prevention can detect and respond to a backflow of blood.
- If the measured backflow is below the alarm limit for at least 1 second, the CARDIOHELP-i generates a medium-priority alarm.
- If the measured backflow is below the alarm limit for at least 6 seconds, the CARDIOHELP-i generates a high-priority alarm.
  ⇨ Zero flow mode is automatically activated.
  ⚠ Backflow prevention does **not** intervene in the pump control and only generates an alarm when
  - RPM mode: Setpoint speed 0 rpm
  - LPM mode: Setpoint flow 0 l/min
  - "Global Override" mode active

9. Emergency Procedures

9a) Battery Operation

- Old battery type: 2 x Lithium-ion batteries (10.8 V/6450 mAh per battery)
- New battery type: 2 x Lithium-ion batteries (10.8 V/9210 mAh per battery)
- Battery run time (old and new battery type): at least 90 mins (with fully charged batteries)
- Battery charging time: old battery type 5 h max.
- Battery charging time: new battery type 7 h max.
- Reference values for remaining battery capacity

Disconnect from external power supply.

- Switching from line power to battery operation generates an acoustic signal and message [Switched to battery operation].
  - The acoustic signal is repeated until you confirm the message or the external power supply becomes available again.
- Messages in the status bar
  - Battery capacity <20 %, medium-priority alarm and battery LED flashes once a second.
  - Battery capacity <10 %, high-priority alarm and battery LED flashes twice a second.

9b) Resetting the Bubble Stop

⚠ 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.

⚠ Before resetting the bubble stop, ensure that the cause has been remedied and that there are no bubbles in the system in order to prevent bubbles from entering the patient when the pump starts up.

- Open the "Interventions" screen
- Open the active bubble alarm.
- Touch the "Reset" symbol and [Confirm].

9c) Using the Emergency Mode

⚠ All of the alarms and interventions are deactivated. There is a risk of dangerous situations not being recognized and the patient being endangered.

- Activate "Emergency mode".
  - The touchscreen is for display purposes only and has no control function.
  - Status bar continuously displays the message [EMERGENCY MODE] and no alarms.
  - LED ring of the "Emergency mode" button flashes.
  - Current speed is accepted as setpoint value.
  - NOTE: With activated reminder signal, the CARDIOHELP-i generates a reminder signal once a minute (see key user functions).
- Change speed via the rotary knob.

9d) Using Emergency Drive

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

- Open the safety bar.
- Secure the disposable to the CARDIOHELP Emergency Drive.
- Open the venous clamp and turn the hand crank clockwise.
- Optimal speed range between 2250 rpm and 4750 rpm.

9e) Troubleshooting

⚠ If you detect a malfunction or failure of controls, display elements or sensors, have the CARDIOHELP-i checked by authorized service personnel.

- Incorrect external measured values (pressure, level, temperature).
  - In case of a malfunction, the components must be exchanged.

9f) Physiological and Technical Alarms

- 📖 Check the tube system for kinks or other occlusions in the case of low-flow alarms.
- Explain the message: [Device defective (0x00000)].
  - Cause/consequence: Serious technical fault; 0x00000 defines an error code, which the service personnel require for the fault diagnosis.
  - Remedy: Continuously check perfusion and patient monitoring and notify authorized service personnel, stating the error code.
- Explain the message: [Device defective – Stop],
  - Cause/consequence: Pump standstill due to serious technical fault.
  - Remedy: Use emergency drive and notify authorized service personnel.

10. Concluding the Application

10a) After the End of the Application

- Switch off the CARDIOHELP-i.
- Remove the sensors.
- Remove the disposables.
- Leave connected to external power supply.

10b) Cleaning, Sterilization and Disinfection

⚠ Only use approved cleaning agents.

- Cleaning and disinfection after each use.
- Clean the venous probe.

11. Maintenance

11a) Service Interval: 12 months

📖 See CARDIOHELP System Instructions for Use, chapter "Inspection and maintenance by authorized service personnel".

11b) Calibrating the Batteries

⚠ Connect the CARDIOHELP-i to the external power supply if you confirm or cancel the calibration prematurely.

⚠ Do not use the CARDIOHELP-i again until the batteries are fully charged.

- Calibration is only possible with the pump stopped and with AC power supply.
- Calibration depends on the ambient conditions and use of the CARDIOHELP-i. Calibration must be carried out under the following conditions:
  - At least every 4 months
  - If the actual remaining battery run time is different from the remaining battery run time displayed.
  - If the symbol "Calibration required" is displayed in the [Battery] window.
- The time required for calibration can be significantly reduced with the Battery Calibration Unit.
- In the "Service" screen, touch [Calibration] and then [Battery Calibration].

12. Disposables: HLS Set Advanced

12a) Definition of the Versions of the HLS Set Advanced

- HLS Set Advanced 5.0
- HLS Set Advanced 7.0
- HIT Set Advanced 5.0
- HIT Set Advanced 7.0

12b) General Functions of the HLS Set Advanced

See HLS Set Advanced G-141 Instructions for Use.

- Heart and lung support
- Pulmonary support
- Blood pump with active venous drainage
- Oxygenation of the blood
- Removal of CO_2 from the blood
- Temperature control (normo-, hypo- and hyperthermia)

12c) Components of the HLS Set Advanced

- HLS Module Advanced
  - Centrifugal pump for ventricular support (VAD)
  - Heat exchanger
  - Gas exchange membrane
  - Sensors
  - Venous measuring cell (for measuring S_VO_2, Hct, Hb, T_{Ven})
- Coating
- Venous and arterial tube lines 3/8"
- Priming set

Additional necessary components

- Connection cable for venous probe, short: CC-VP L0.23

12d) Connectors and Connections on the HLS Module Advanced

- Blood inlet with venous measuring cell
- Blood outlet
- Gas inlet with gas filter
- Gas outlet
- Water inlet and water outlet connections
- Luer lock (arterial side, top)
- Dialysis lock (Pos-Lock)
- Luer lock for blood analysis
- De-airing membrane with Luer lock
- Luer lock (venous side)
- Connection for internal sensors
- Sensor position for flow/bubble sensor
- Sensor position for optional bubble sensor

12e) HLS Cannulae

- Cannula length
- Cannula size
- Tip design

12f) HLS Cannulae Insertion Kit

- Components

13. Preparing Application for HLS Set Advanced

13a) Testing the Functioning of CARDIOHELP-i

- CARDIOHELP-i securely fixed and security seal undamaged.
- Venous probe must be secured in its holder on the safety bar before the CARDIOHELP-i is switched on.
- The connection cable of the disposable for the integrated sensors must be plugged in before the CARDIOHELP-i is switched on.
  - Simple cable (short) for QUADROX-iR and HLS Set Advanced
- Switch on – self-test – no messages.
- Check that the controls (buttons, LEDs, touchscreen and rotary knob) are functioning.
- Check battery status; battery must be fully charged.

13b) Functioning and Availability of CARDIOHELP Emergency Drive

- Availability and safe function of the CARDIOHELP Emergency Drive.
- Preparation for the HLS retainer
  - Install the disposable.
  - Connect the integrated sensors.
- Connect and position combined flow/bubble sensor "FBS 3/8" x 3/32" L0.9".
  ⚠ Observe the direction of flow of the blood and the position of the sensor!
- Connect and position optional bubble sensor "BS 3/8" x 3/32" L1.7".

13c) Calibration, Function Test Before Priming

- Switch on – self-test – no messages.
- Check the status of the venous probe and measuring cell.
  - [Measuring cell detected: 3/8" HLS] for HLS Module
- Initialize venous probe.
- Carry out zero calibration of the pressure sensors.

13d) Priming Procedure for Disposables with Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

See HLS Set Advanced G-141 Instructions for Use.

⚠ After priming, close the de-airing membrane with the yellow protective cap.

13e) Calibration, Function Test After Priming

- Install the venous probe on the measuring cell
- Function test for bubble monitoring.
- Flow off-set calibration of the flow/bubble sensor.

13f) Checking Settings

- The settings of external devices, such as gas blenders and heater-cooler units, must be adapted to the particular patient and the current situation.
- The warning and alarm limits and interventions used are appropriate and safe for the particular patient and current situation.

13g) Checking the HLS Set Advanced

⚠ Make sure that the disposable is positioned lower than the patient or at the same level, but no higher.

- Keep 4 metal tube clamps at the ready for clamping the tubes in the event of leakage.
- Ensure that the disposable is securely and correctly installed on the pump drive.
- Check all Luer lock connectors.
- Patient must always be monitored (patient monitoring).

13h) Transport securing device for HLS Set Advanced 5.0, 7.0, CI Set and ODP Set

*Demonstrate **and practice** the transport securing with the Transport Guard for CARDIOHELP Disposables.*

📖 See CARDIOHELP System Instructions for Use, chapter "Secure the Disposable with the Transport Guard for CARDIOHELP Disposables".

14. Emergency Measures HLS Set Advanced

⚠ The procedure for emergency measures must be decided by the user according to the current situation.

The procedures described below are intended as a guide for the user.

14a) Air in the Venous Line

⚠ This procedure is only possible if no air has entered the HLS Module Advanced.

- Place a clamp on the red line.
- Ensure that the pump is at standstill.
- Clamp the venous cannula in front of and behind the connector, without damaging the connector.
- Eliminate the cause of the ingress of air.
- Prime the emergency priming line with the help of an infusion bag or a plastic bottle.
- Connect the emergency priming line to the Pos lock connector of the HLS Module Advanced. Ensure that the connection is free of air.
- Remove the venous line from the venous cannula so that the air can escape from the tube system.
- Allow the air in the tube system to escape through the disconnected venous line and connect the venous line, free of air, to the venous cannula.
- Fasten the cannula according to the Instructions for Use.
- Start circulation again and open the clamps on the red and blue tube lines.
- If air that has entered the HLS Set Advanced cannot be removed using the emergency priming line, replace the set according to the Instructions for Use.

14b) Air Embolism in the HLS Module Advanced

- Replace the system according to the Instructions for Use.

15. User Training with HLS Set Advanced

15a) User Training Carried Out

CONNECTING

- Connect the required sensors to the CARDIOHELP-i.
- Connect the external AC power supply.
- Install the HLS training set.

- Connect the flow/bubble sensor (and also the optional bubble sensor, if fitted) to the training set.
- Connect the disposable's integrated sensors.
- Switch on the CARDIOHELP-i.
- Calibrate the pressure sensors.
- Prime the HLS Set Advanced.

APPLICATION AND SETTINGS

- Clamp the tube upstream and downstream of the flow/bubble sensor.
- Carry out the flow off-set calibration of the flow/bubble sensor (0 rpm!).
- Open the clamps.

- Start data recording.
- Activate timer 1.
- Set the countdown timer to 15 mins and activate it.
- Set the intervention of the arterial pressure to 250 mmHg.
- Increase the speed until the set pressure limit is reached.
- Open and close the clamp several times.
- Open the clamp.

- Set the intervention of the venous pressure to 100 mmHg.
- Slowly clamp the venous line.
- Open the clamp.

- Switch to the thApp "v-v ECLS".
- Set the flow to 3 l/min.
- Switch to LPM mode.
- Clamp the arterial line.
- Open the clamp.

- Switch off the intervention of the arterial and venous pressure.
- Clamp the arterial line.
- Open the clamp.
- Set the upper limit of the RPM intervention to 3000 rpm.
- Clamp the arterial line.
- Open the clamp.
- Set the intervention of the venous pressure to 100 mmHg.
- Open the clamp.

- Set LPM Mode.
- Remove the flow/bubble sensor from the tube (RPM -> LPM).
- Reattach the flow/bubble sensor.
- Reset the flow/bubble sensor.
- Activate the bubble monitoring intervention on the arterial side.
- Remove the flow/bubble sensor from the tube.
- Reattach the flow/bubble sensor.
- Reset the flow/bubble sensor.

- Activate the zero flow mode.
- Deactivate the zero flow mode.
- Remove the external power supply.
- Confirm the alarm.

- Initialize the venous probe.
- Use the venous probe to simulate the measured blood levels with a blood phantom.
- Recalibrate the blood parameters.

- End the data recording.
- Export the data to the USB stick.

EMERGENCY MEASURES

- Switch off the CARDIOHELP-i.
- Attach the HLS Module Advanced in the CARDIOHELP Emergency Drive.
- Use the HLS Set Advanced with the CARDIOHELP Emergency Drive at 4000 rpm.
- Activate the Emergency mode.
- Deactivate the Emergency mode.

16. Disposables: ROTASSIST Set 2.8 / 9.9

16a) Definition of the Versions of the ROTASSIST Set

- ROTASSIST Set 2.8
- ROTASSIST HIT Set 2.8
- ROTASSIST Set 9.9
- ROTASSIST HIT Set 9.9

16b) General Functions of the ROTASSIST Set

See ROTASSIST G-163 Set Instructions for Use.

- Blood pump with active venous drainage
- Cardiac support

16c) Components of the ROTASSIST Set

- Centrifugal pump (ROTASSIST) for ventricular support (VAD)
- Integrated sensors
- Venous measuring cell (for measuring S_VO_2, Hct, Hb, T_{Ven})
- Coating
- Venous and arterial tube lines (ROTASSIST 2.8 = 1/4"; ROTASSIST 9.9 = 3/8")
- Priming set

Additional necessary components

- CARDIOHELP Drive Adapter
- Connection cable for disposable, "simple, long"
- Connection cable for venous probe, long: CC-VP L0.55
- With ROTASSIST 2.8: FBS 1/4" x 3/32" L0.9

16d) Connectors and Connections of the ROTASSIST Set

- Blood inlet
- Blood outlet
- Connection for pressure sensors
- Venous measuring cell
- Sensor position for flow/bubble sensor
- Sensor position for optional bubble sensor

17. Preparing Application of ROTASSIST Set

17a) Testing the Functioning of CARDIOHELP-i

- CARDIOHELP-i securely fixed and security seal undamaged.
- Connection cable for venous probe, long (CC-VP L0.55) must be connected!
- Venous probe must be secured in its holder on the safety bar before the CARDIOHELP-i is switched on.
- The connection cable of the disposable for the integrated sensors must be plugged in before the CARDIOHELP-i is switched on.
  - Simple cable (long) for ROTASSIST Set
- Switch on – self-test – no messages.
- Check that the controls (buttons, LEDs, touchscreen and rotary knob) are functioning.
- Check battery status; battery must be fully charged.

17b) Functioning and Availability of CARDIOHELP Emergency Drive

- Availability and safe function of the CARDIOHELP Emergency Drive.

Preparing application

- Preparation for the ROTASSIST retainer
  - Install the CARDIOHELP Drive Adapter.
  - Install the disposable.
  - Connect the integrated sensors.
- Connect and position combined flow/bubble sensor "FBS 3/8" x 3/32" L0.9" or "FBS 1/4"x3/32" L0.9".
  ⚠ Observe the direction of flow of the blood and the position of the sensor!
- Connect and position venous bubble sensor.
  - "BS 3/8" x 3/32" L1.7" for ROTASSIST 9.9
  - "BS 3/8" 1/16" - 1/4" x 3/32" L1.7" for ROTASSIST 2.8

17c) Calibration, Function Test Before Priming

- Switch on – self-test – no messages.
- Check the status of the venous probe and measuring cell.
  - [Measuring cell detected: 3/8"] for ROTASSIST 9.9
  - [Measuring cell detected: 1/4"] for ROTASSIST 2.8
- Initialize venous probe.
- Carry out zero calibration of the pressure sensors.

17d) Priming Procedure for Disposables with Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

📖 See ROTASSIST G-163 Set Instructions for Use.

17e) Calibration, Function Test After Priming

- Install the venous probe on the measuring cell
- Function test for bubble monitoring.
- Flow off-set calibration of the flow/bubble sensor.
- Carry out function test for bubble monitoring.

17f) Checking Settings

- Adapt the warning and alarm limits and interventions used to the particular patient and current situation.

17g) Checking the ROTASSIST Set

⚠ Make sure that the disposable is positioned lower than the patient or at the same level, but no higher.

- Keep 4 metal tube clamps at the ready for clamping the tubes in the event of leakage.
- Ensure that the disposable is securely and correctly installed on the pump drive.
- Patient must always be monitored (patient monitoring).

18. Emergency Measures for ROTASSIST Set

⚠ The procedure for emergency measures must be decided by the user according to the current situation.

18a) Air Embolism in the Blood-Carrying System

- If air has entered the ROTASSIST Set, replace the set.

19. User Training with ROTASSIST Set

19a) User Training Carried Out

CONNECTING

- Connect the required sensors to the CARDIOHELP-i.
- Connect the external AC power supply.
- Install the Drive Adapter in the CARDIOHELP-i drive.
- Turn the adapter to the priming position.
- Install the ROTASSIST centrifugal pump.
- Install the ROTASSIST training set.
- Connect the flow/bubble sensor (and also the optional bubble sensor, if fitted) to the training set.
- Connect the disposable's integrated sensors.
- Switch on the CARDIOHELP-i.
- Activate the "Global Override" mode.
- Calibrate the pressure sensors.
- Prime the ROTASSIST Set.

APPLICATION AND SETTINGS

- Activate the "Global Override" mode.
- Set the speed to 3000 rpm for 2 minutes, using the rotary knob.
- Set the speed to 0 rpm using the rotary knob.
- Reset the bubble sensors with the "Reset" button.
- Set the speed to 4000 rpm for 1 minute, using the touchscreen.
- Deactivate the "Global Override" mode.
- Set the flow to 0.5 l/min.

- Clamp the tube upstream and downstream of the flow/bubble sensor.
- Carry out the flow off-set calibration of the flow/bubble sensor (0 rpm!).
- Open the clamps.

- Start data recording.
- Activate timer 1.
- Set the countdown timer to 15 mins and activate it.
- Set the intervention of the arterial pressure to 250 mmHg.
- Increase the speed until the set pressure limit is reached.
- Open and close the clamp several times.
- Open the clamp.

- Set the intervention of the venous pressure to 100 mmHg.
- Slowly clamp the venous line.
- Open the clamp.

- Switch off the intervention of the arterial and venous pressure.
- Clamp the arterial line.
- Open the clamp.
- Set the upper limit of the RPM intervention to 3000 rpm.

- Clamp the arterial line.
- Open the clamp.
- Set the intervention of the venous pressure to 100 mmHg.
- Open the clamp.

- Set LPM Mode.
- Remove the flow/bubble sensor from the tube (RPM -> LPM).
- Reattach the flow/bubble sensor.
- Reset the alarms.
- Optional: Activate the bubble monitoring intervention on the venous side.
- Remove the optional bubble sensor.
- Attach the bubble sensor.
- Reset the bubble alarm.
- Activate the bubble monitoring intervention on the arterial side.
- Remove the flow/bubble sensor from the tube.
- Reattach the flow/bubble sensor.
- Reset the bubble alarm.
- Activate the zero flow mode.
- Deactivate the zero flow mode.
- Remove the external power supply.
- Confirm the alarm.

- Initialize the venous probe.
- Use the venous probe to simulate the measured blood levels with a blood phantom.
- Recalibrate the blood parameters.

- End the data recording.
- Export the data to the USB stick.

EMERGENCY MEASURES

- Activate the Emergency mode.
- Deactivate the Emergency mode.
- Remove the ROTASSIST centrifugal pump.
- Attach the ROTASSIST centrifugal pump in the CARDIOHELP Emergency Drive.
- Use the ROTASSIST Set with the CARDIOHELP Emergency Drive at 3000 rpm.

20. Disposables: PALP Set 2.8

20a) Definition of the Versions of the PALP Set 2.8

- PALP Set 2.8
- PALP HIT Set 2.8

20b) General Functions of the PALP Set 2.8

See PALP Set G-156 Instructions for Use:

- Pump-assisted lung protection
- Blood pump with active venous drainage
- Important CO_2 removal from the blood
- Subordinate oxygenation of the blood

⚠ Be alert to the occurrence of hypothermia!

20c) Components of the PALP Set 2.8

- PALP Module
  - Gas exchange membrane
  - Sensors
  - Cables for sensors
  - Gas inlet
- ROTASSIST 2.8 Centrifugal Pump:
- Venous measuring cell (for measuring S_VO_2, Hct, Hb, T_{Ven})
- Coating
- Venous and arterial tube lines 1/4"
- Priming set

Additional necessary components

- CARDIOHELP Drive Adapter
- PALP-ECLS 2.8 HKH 8890 Disposable Holder
- Connection cable for disposable "Y-cable"
- Connection cable for venous probe, long: CC-VP L0.55

20d) Connectors and Connections of the PALP Gas Module

- Blood inlet
- Blood outlet
- Gas inlet
- Gas outlet
- De-airing membrane with Luer lock
- Luer lock at the arterial outlet
- Connection cable at the arterial outlet
- Venous measuring cell
- Sensor position for flow/bubble sensor
- Sensor position for optional bubble sensor

21. Preparing Application for PALP Set 2.8

21a) Testing the Functioning of CARDIOHELP-i

- CARDIOHELP-i securely fixed and security seal undamaged.
- Connection cable for venous probe, long (CC-VP L0.55) must be connected!
- Venous probe must be secured in its holder on the safety bar before the CARDIOHELP-i is switched on.
- The connection cable of the disposable for the integrated sensors must be plugged in before the CARDIOHELP-i is switched on.
  - Y-cable for PALP Set and ECLS Set 2.8
- Switch on – self-test – no messages.
- Check that the controls (buttons, LEDs, touchscreen and rotary knob) are functioning.
- Check battery status; battery must be fully charged.

21b) Functioning and Availability of CARDIOHELP Emergency Drive

- Availability and safe function of the CARDIOHELP Emergency Drive.

Preparing application

- Prepare perfusion for ROTASSIST retainer.
  - Install the CARDIOHELP Drive Adapter.
  - Install the PALP-ECLS 2.8 HKH 8890 Disposable Holder.
  - Install disposables.
  - Connect integrated sensors.
- Connect and position combined flow/bubble sensor "FBS 1/4" x 3/32" L0.9".
  ⚠ Observe the direction of flow of the blood and the position of the sensor!
- Connect and position optional bubble sensor.
  - "BS 3/8" 1/16" - 1/4" x 3/32" L1.7" for ROTASSIST 2.8

Calibration, function test before priming

- Switch on – self-test – no messages.
- Check the status of the venous probe and measuring cell.
  - [Measuring cell detected: 1/4"] for ROTASSIST 2.8
- Initialize venous probe.
- Carry out zero calibration of the integrated pressure sensors.
- Carry out zero calibration of the external pressure sensors.

21c) Priming Procedure for Disposables with Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

📖 See PALP Set G-156 Instructions for Use, chapters "Preparation and Installation" and "Priming the Set".

⚠ After priming, close the de-airing membrane with the yellow protective cap.

Calibration, function test after priming

- Install the venous probe on the measuring cell
- Function test for bubble monitoring.
- Flow off-set calibration of the flow/bubble sensor.
- Carry out function test for bubble monitoring.

21d) Checking Settings

- The settings of external devices, such as gas blenders, must be adapted to the particular patient and the current situation.
- Adapt the warning and alarm limits and interventions used to the particular patient and current situation.

21e) Checking the PALP Set

⚠ Make sure that the disposable is positioned lower than the patient or at the same level, but no higher.

- Keep 4 metal tube clamps at the ready for clamping the tubes in the event of leakage.
- Ensure that the disposable is securely and correctly installed on the pump drive.
- Check all Luer lock connectors.
- Patient must always be monitored (patient monitoring).

22. Emergency Measures for PALP Set 2.8

⚠ The procedure for emergency measures must be decided by the user according to the current situation.

22a) Air Embolism in the PALP Set

- The user must decide how to proceed.
- If air has entered the PALP Set, replace the PALP Set.

23. User Training with PALP Set 2.8

23a) User Training Carried Out

CONNECTING

- Connect the required sensors to the CARDIOHELP-i.
- Connect the external AC power supply.
- Install the Drive Adapter in the CARDIOHELP-i drive.
- Turn the adapter to the priming position.
- Install the holding plate for the disposable holder on the CARDIOHELP-i.
- Install the PALP training set.
- Connect the flow/bubble sensor (and also the optional bubble sensor, if fitted) to the training set.
- Connect the disposable's integrated sensors
- Switch on the CARDIOHELP-i.
- Activate the "Global Override" mode.
- Calibrate the pressures.
- Prime the PALP Set.

APPLICATION AND SETTINGS

- Set the speed to 3000 rpm for 2 minutes, using the rotary knob.
- Set the speed to 0 rpm using the rotary knob.
- Reset the bubble sensors with the "Reset" button.
- Set the speed to 4000 rpm for 1 minute, using the touchscreen.
- Deactivate the "Global Override" mode.
- Set the flow to 0.5 l/min.

- Clamp the tube upstream and downstream of the flow/bubble sensor.
- Carry out the flow off-set calibration of the flow/bubble sensor (0 rpm!).
- Open the clamps.

- Start data recording.
- Activate timer 1.
- Set the countdown timer to 15 mins and activate it.
- Set the intervention of the arterial pressure to 250 mmHg.
- Increase the speed until the set pressure limit is reached.
- Open and close the clamp several times.
- Open the clamp.

- Set the intervention of the venous pressure to 100 mmHg.
- Slowly clamp the venous line.
- Open the clamp.

- Switch off the intervention of the arterial and venous pressure.
- Clamp the arterial line.
- Open the clamp.
- Set the upper limit of the RPM intervention to 3000 rpm.
- Clamp the arterial line.
- Open the clamp.
- Set the intervention of the venous pressure to 100 mmHg.
- Open the clamp.

- Set LPM Mode.
- Remove the flow/bubble sensor from the tube (RPM -> LPM).
- Reattach the flow/bubble sensor.
- Reset the alarms.
- Activate the bubble monitoring intervention on the venous side.
- Remove the bubble sensor.
- Attach the bubble sensor.
- Reset the bubble alarm.
- Activate the bubble monitoring intervention on the arterial side.
- Remove the flow/bubble sensor from the tube.
- Reattach the flow/bubble sensor.
- Reset the bubble alarm.

- Activate the zero flow mode.
- Deactivate the zero flow mode.
- Remove the external power supply.
- Confirm the alarm.

- Initialize the venous probe.

- Use the venous probe to simulate the measured blood levels with a blood phantom.
- Recalibrate the blood parameters.

- End the data recording.
- Export the data to the USB stick.

EMERGENCY MEASURES

- Activate the Emergency mode.
- Deactivate the Emergency mode.
- Remove the ROTASSIST centrifugal pump.
- Attach the ROTASSIST centrifugal pump in the CARDIOHELP Emergency Drive.
- Use the PALP Set with the CARDIOHELP Emergency Drive at 3000 rpm.

24. Disposables: ECLS Set 2.8

24a) Definition of the Versions of the ECLS Set 2.8

- ECLS Set 2.8
- ECLS Set HIT 2.8

24b) General Functions of the ECLS Set 2.8

See ECLS 2.8 G-165 Set Instructions for Use.

- Blood pump with active venous drainage
- Oxygenation of the blood
- Removal of CO_2 from the blood
- Heart and lung support
- Pulmonary support
- Temperature control (normo-, hypo- and hyperthermia)

24c) Components of the ECLS Set 2.8

- QUADROX-iD Pediatric
  - Gas exchange membrane
  - Sensors
  - Cables for sensors
  - Heat exchanger
- ROTASSIST 2.8 centrifugal pump
- Venous measuring cell
- Coating
- Venous and arterial tube lines 1/4"
- Priming set

Additional necessary components

- CARDIOHELP Drive Adapter
- Holder arm 016061 with holder HKHZ 19 for QUADROX-iD Pediatric
- For transportation: PALP-ECLS 2.8 HKH 8890 Disposable Holder
- Connection cable for disposable "Y-cable"
- Connection cable for venous probe, long: CC-VP L0.55
- With ROTASSIST 2.8: FBS 1/4" x 3/32" L0.9
- External temperature sensor "TPO-D L1.8 Pediatric"

24d) Connectors and Connections of the ECLS Set 2.8

- Blood inlet
- Blood outlet
- Gas inlet
- Gas outlet
- Water inlet and water outlet connections
- De-airing membrane with Luer lock
- Luer lock at the arterial outlet
- Connection for sensors at the arterial outlet
- Sensor position for flow/bubble sensor
- Sensor position for optional bubble sensor

25. Preparing Application for ECLS Set 2.8

Testing the functioning of CARDIOHELP-i

- CARDIOHELP-i securely fixed and security seal undamaged.
- Connection cable for venous probe, long (CC-VP L0.55) must be connected!
- Venous probe must be secured in its holder on the safety bar before the CARDIOHELP-i is switched on.
- The connection cable of the disposable for the integrated sensors must be plugged in before the CARDIOHELP-i is switched on.
  - Y-cable for PALP Set and ECLS Set 2.8
- Switch on – self-test – no messages.
- Check that the controls (buttons, LEDs, touchscreen and rotary knob) are functioning.
- Check battery status; battery must be fully charged.

25a) Functioning and Availability of CARDIOHELP Emergency Drive

- Availability and safe function of the CARDIOHELP Emergency Drive.

Preparing application

- Prepare perfusion for ROTASSIST retainer.
  - Install the CARDIOHELP Drive Adapter.
  - Install holder arm 016061 with the holder HKHZ 19 on the SPRINTER CART.
  - Install disposables.
  - Connect integrated sensors.
- Connect and position combined flow/bubble sensor "FBS 1/4" x 3/32" L0.9".
  ⚠ Observe the direction of flow of the blood and the position of the sensor!
- Optional bubble sensor "BS 3/8" 1/16" - 1/4" x 3/32" L1.7".

Calibration, function test before priming

- Switch on – self-test – no messages.
- Check the status of the venous probe and measuring cell.
  - [Measuring cell detected: 1/4"] for ROTASSIST 2.8
- Initialize venous probe.
- Carry out zero calibration of the pressure sensors.

25b) Priming Procedure for Disposables with Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

See ECLS Set 2.8 G-165 Instructions for Use.

⚠ After priming, close the de-airing membrane with the yellow protective cap.

Calibration, function test after priming

- Install the venous probe on the measuring cell
- Function test for bubble monitoring.
- Flow off-set calibration of the flow/bubble sensor.

25c) Checking Settings

- The settings of external devices, such as gas blenders and heater-cooler units, are appropriate and safe for the particular patient and the current situation.
- The warning and alarm limits and interventions used are appropriate and safe for the particular patient and current situation.

25d) Checking the Perfusion Circuit

⚠ Make sure that the disposable is positioned lower than the patient or at the same level, but no higher.

- Keep 4 metal tube clamps at the ready for clamping the tubes in the event of leakage.
- Ensure that the disposable is securely and correctly installed on the pump drive.
- Check all Luer lock connectors.
- Patient must always be monitored (patient monitoring).

26. Emergency Measures for ECLS Set 2.8

The procedure for emergency measures must be decided by the user according to the current situation.

26a) Air Embolism in the Venous Line

- The user must decide how to proceed.
- If air has entered the ECLS 2.8 Set, replace the set.

27. User Training with ECLS Set 2.8

27a) User Training Carried Out

CONNECTING

- Connect the required sensors to the CARDIOHELP-i.
- Connect the external AC power supply.
- Install the Drive Adapter in the CARDIOHELP-i drive.
- Turn the adapter to the priming position.
- Install the holder arm 016061 with the holder HKHZ 19 on the SPRINTER CART.
- Place the QUADROX-iD in the holder.
- Install the ECLS Training Set 2.8.
- Connect the flow/bubble sensor (and also the optional bubble sensor, if fitted) to the training set.
- Connect the disposable's integrated sensors.
- Switch on the CARDIOHELP-i.
- Activate the "Global Override" mode.
- Calibrate the pressures.
- The ECLS Set 2.8 must be primed for the further steps.

APPLICATION AND SETTINGS

- Switch on the CARDIOHELP-i.
- Activate the "Global Override" mode.
- Set the speed to 3000 rpm for 2 minutes, using the rotary knob.
- Set the speed to 0 rpm using the rotary knob.
- Reset the bubble sensors with the "Reset" button.
- Set the speed to 4000 rpm for 1 minute, using the touchscreen.
- Deactivate the "Global Override" mode.
- Set the flow to 0.5 l/min.

- Clamp the tube upstream and downstream of the flow sensor.
- Calibrate the flow (0 rpm!).
- Open the clamps.

- Start data recording.
- Activate timer 1.
- Set the countdown timer to 15 mins and activate it.
- Set the intervention of the arterial pressure to 250 mmHg.
- Increase the speed until the set pressure limit is reached.
- Open and close the clamp several times.
- Open the clamp.
- Set the intervention of the venous pressure to 100 mmHg.
- Slowly clamp the venous line.
- Open the clamp.

- Switch to the thApp "v-v ECLS".
- Set the flow to 2 l/min.
- Switch to LPM mode.
- Clamp the arterial line.
- Open the clamp.

- Switch off the intervention of the arterial and venous pressure.
- Clamp the arterial line.
- Open the clamp.
- Set the upper limit of the RPM intervention to 3000 rpm.
- Clamp the arterial line.
- Open the clamp.
- Set the intervention of the venous pressure to 100 mmHg.
- Open the clamp.

- Set LPM Mode.
- Remove the flow/bubble sensor from the tube (RPM -> LPM).
- Reattach the flow/bubble sensor.
- Reset the alarms.
- Activate the bubble monitoring intervention on the venous side.
- Remove the bubble sensor.
- Attach the bubble sensor.
- Reset the bubble alarm.
- Activate the bubble monitoring intervention on the arterial side.
- Remove the flow/bubble sensor from the tube.
- Reattach the flow/bubble sensor.
- Reset the bubble alarm.

- Activate the zero flow mode.
- Deactivate the zero flow mode.
- Remove the external power supply.
- Confirm the alarm.

- Initialize the venous probe.

- Use the venous probe to simulate the measured blood levels with a blood phantom.
- Recalibrate the blood parameters.

- End the data recording.
- Export the data to the USB stick.

EMERGENCY MEASURES

- Activate the Emergency mode.
- Deactivate the Emergency mode.
- Remove the ROTASSIST centrifugal pump.
- Attach the ROTASSIST centrifugal pump in the CARDIOHELP Emergency Drive.
- Use the ECLS Set 2.8 with the CARDIOHELP Emergency Drive at 3000 rpm.

28. Disposables: MECC-i

28a) Definition of the MECC-i Set

- MECC-i Set

28b) General Functions of the MECC-i Set

See CARDIOHELP-i Tubing Set G-261 Instructions for Use.

- Heart and lung support in cardiac surgery

28c) Components of the MECC-i Set

- QUADROX-iR
- Centrifugal pump for ventricular support (VAD)
- Heat exchanger
- Gas exchange membrane
- Venous bubble trap (VBT)
- Venous measuring cell (for measuring S_VO_2, Hct, Hb, TVen)
- Venous and arterial tube lines 3/8"
- Priming set

28d) Additional Necessary Components

- Connection cable for venous probe, short: CC-VP L0.23
- External temperature sensor "TPO-D L1.8"
  - Temperature sensor for oxygenator TPO-D L1.8
- External pressure sensors
  - CARDIOHELP Medex LogiCal Transducer Kit MTK 960 LogiCal
- Level sensor
  - "CLS Kit" contains the level sensor "CLS L2.0" and level sensor pads "MCP00151004".
- Holder for venous bubble trap

28e) Connectors and Connections of the MECC-i Set

- Blood inlet with venous measuring cell
- Blood outlet
- Gas inlet with gas filter
- Gas outlet
- Water inlet and water outlet connections
- Luer lock (arterial side, top)
- Dialysis lock (Pos-Lock)
- Luer lock for blood analysis
- De-airing membrane with Luer lock
- Luer lock (venous side)
- Sensor position for arterial flow/bubble sensor
- Sensor position for venous bubble sensor (optional)

29. Preparing Application for MECC-i Set

29a) Testing the Functioning of CARDIOHELP-i

See CARDIOHELP System Instructions for Use, chapter "Checking before every application".

- CARDIOHELP-i securely fixed and security seal undamaged.
- Venous probe must be secured in its holder on the safety bar before the CARDIOHELP-i is switched on.
- The connection cable of the disposable for the integrated sensors must be plugged in before the CARDIOHELP-i is switched on.
- Simple cable (short) for QUADROX-iR
- Switch on – self-test – no messages.
- Check that the controls (buttons, LEDs, touchscreen and rotary knob) are functioning.
- Check battery status; battery must be fully charged.

29b) Functioning and Availability of CARDIOHELP Emergency Drive

- Availability and safe function of the CARDIOHELP Emergency Drive.

29c) Preparing Application

See CARDIOHELP System Instructions for Use, chapter "Preparing Perfusion (HLS Retainer)" and "Connecting External Sensors".

- Install the disposable.
- Connect the integrated sensors.
- Connect and position combined flow/bubble sensor "FBS 3/8" x 3/32" L0.9".

⚠ Observe the direction of flow of the blood and the position of the sensor!

- Connect and position optional bubble sensor "BS 3/8" x 3/32" L1.7" (optional).
- Connect and position external temperature sensors.
- Connect and position external pressure sensors.
- Connect external level sensor and position on the venous bubble trap.

29d) Calibration, Function Test Before Priming

- Switch on – self-test – no messages.
- Check the status of the venous probe and measuring cell.
- Carry out zero calibration of the pressure sensors.

29e) Priming Procedure for Disposables with Membrane for Gas Exchange

Demonstrate the priming procedure using the non-sterile training set.

See CARDIOHELP-i Tubing Set G-261 Instructions for Use.

⚠ After priming, close the de-airing membrane with the yellow protective cap.

29f) Calibration, Function Test After Priming

See CARDIOHELP System Instructions for Use, chapters "Function test" and "Calibration".

- Install the venous probe on the measuring cell.
- Function test for bubble monitoring.
- Carry out function test for level monitoring.
- Flow off-set calibration of the flow/bubble sensor.

29g) Checking Settings

- The settings of external devices, such as gas blenders, must be adapted to the particular patient and the current situation.
- Adapt the warning and alarm limits and interventions used to the particular patient and current situation.

29h) Checking the Perfusion Circuit

⚠ Make sure that the disposable is positioned lower than the patient or at the same level, but no higher.

- Keep 4 metal tube clamps at the ready for clamping the tubes in the event of leakage.
- Ensure that the disposable is securely and correctly installed on the pump drive.
- Check all Luer lock connectors.

29i) Patient must always be monitored (patient monitoring).

30. Concluding the User Instruction

For the MAQUET application specialist:

- Fill out the instruction guidelines. The persons instructed should confirm the instruction on pages 5 and 5a.
- Remove pages 5a/6a and archive the document according to the internal requirements of your MAQUET subsidiary.

30a) Advised the Customer That This Document Must Be Kept Safe

30b) Advised the Customer That He/She Must Create and Maintain a Medical Device Logbook

31. Accompanying Documents

31a) CARDIOHELP System Instructions for Use Used

- Note the MCV number* of the Instructions for Use used here and on page 6a:

  MCV-GA-10000724-_____.

31b) Instructed Software Version

- Note the instructed software version of the CARDIOHELP System here and on page 6a:

  Software version: _____.

31c) Instructed Disposables

☐ HLS Set Advanced

- Note the revision date* of the HLS Set Advanced G-141 Instructions for Use used here and on page 6a: Revision date: _____.
- Note the revision date* of the HLS Cannula Set G-139 Instructions for Use used here and on page 6a: Revision date: _____.
- Note the revision date* of the Percutaneous Insertion Kit G-137 Instructions for Use used here and on page 6a: Revision date: _____.

☐ PALP Set

- Note the revision date* of the PALP Set G-156 Instructions for Use used here and on page 6a: Revision date: _____.

☐ ECLS Set 2.8

- Note the revision date* of the ECLS Set 2.8 G-165 Instructions for Use used here and on page 6a: Revision date: _____.

☐ ROTASSIST Set 2.8 / 9.9

- Note the revision date* of the ROTASSIST Set 2.8 /9.9 G-163 Instructions for Use used here and on page 6a: Revision date: _____.

☐ MECC-i Set

- Note the revision date* of the CARDIOHELP-i Tubing Set G-261 Instructions for Use used here and on page 6a: Revision date: _____.

*The information can be found on the rear of the Instructions for Use.

32. Configuration Settings

Hospital

Serial number

Description		Factory setting	Hospital setting
Language			
	Language	English	
Data recording			
	Interval	5 minutes	
Locking			
	Duration of inactivity	180 seconds	
	Automatic lock	deactivated	
	Global Override	deactivated	
Speed			
	Upper limit	4500 rpm	
	Lower limit	0 rpm	
	Intervention	deactivated	
Flow/bubble sensor			
	Upper limit	8 l/min	
	Lower limit	0 l/min	
Pressure sensors			
p_{Ven}	Lower warning limit	-100 mmHg	
p_{Ven}	Lower alarm limit	-150 mmHg	
p_{Ven}	Intervention	deactivated	
p_{Int}	Upper warning limit	400 mmHg	
p_{Int}	Upper alarm limit	500 mmHg	
p_{Int}	Intervention	deactivated	
p_{Art}	Upper warning limit	400 mmHg	
p_{Art}	Upper alarm limit	500 mmHg	
p_{Art}	Intervention	deactivated	
p_{Aux}	Upper warning limit	400 mmHg	
p_{Aux}	Upper alarm limit	500 mmHg	
p_{Aux}	Lower warning limit	deactivated	
p_{Aux}	Lower alarm limit	deactivated	
p_{Aux}	Intervention	deactivated	
Δp	Upper limit	60 mmHg	
Δp	Lower limit	deactivated	

Description		Factory setting	Hospital setting
Flow/bubble sensor			
	Intervention	activated	
Optional bubble sensor			
	Intervention	deactivated	
Level sensor			
	Intervention	activated (only thApp "MECC")	
Temperature sensors			
T_{Ven}	Upper limit	40.0°C	
T_{Ven}	Lower limit	10.0°C	
T_{Art}	Upper limit	40.0°C	
T_{Art}	Lower limit	10.0°C	
S_VO_2			
	Upper limit	deactivated	
	Lower limit	60%	
Hb			
	Upper limit	15 g/dl	
	Lower limit	7 g/dl	
Hct			
	Upper limit	40%	
	Lower limit	21%	
Alarm configuration			
	Reminder signal	On	
	Global Override	On	

Hospital settings have been saved.

Surname	Date	Signature

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

MAQUET
GETINGE GROUP

Maquet Cardiopulmonary GmbH
Kehler Strasse 31
76437 Rastatt
GERMANY
Phone: +49 7222 932-0
Fax: +49 7222 932-1888
info.cp@maquet.com
www.maquet.com

GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. ArjoHuntleigh focuses on patient mobility and wound management solutions. GETINGE provides solutions for infection control within healthcare and contamination prevention within life sciences. MAQUET specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.