

USER'S MANUAL

ROTAFLOW WITH ICU KIT
ROTAFLOW SYSTEM

MAQUET

CARDIOVASCULAR



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Subject to technical changes

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

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1 GENERAL

The MAQUET ROTAFLOW system is a centrifugal pump, which is designed for use in an extracorporeal perfusion circuit to pump blood during cardiopulmonary bypass interventions and for permanent extracorporeal pulmonary or cardiovascular support.

The ROTAFLOW System can be used for stand-alone operation, on a MAQUET heart-lung machine console, as part of the ELS System or part of the PLS System.

This User's Manual describes the ROTAFLOW Console with ICU Kit. Please also take note of the documents supplied for the other components of the system.

User's Manual applies to ROTAFLOW Console with ICU Kit

This User's Manual always refers to the ROTAFLOW Console with ICU Kit, even if the suffix "with ICU Kit" is not explicitly mentioned. The ROTAFLOW Console with ICU Kit is identified at the rear with a label stating "Upgrade ICU" (⇒ 2.1.5 "ICU Kit", page 20).

■ See below for features of the ROTAFLOW System

The flow can be kept constant independently of the pressure.

Air bubbles in the circuit can be detected to prevent any ingress in the patient.

It is possible to detect and regulate the fluid level (blood) in a reservoir if it is too low.

Under normal conditions and with fully charged, new batteries, the system can be operated for at least 1.5 hours with the battery back-up.

■ Other features with operation on a MAQUET heart-lung machine

The system provides for a more physiological, optimized, pulsatile pumping action, which is internally triggered and controlled by the patient's own ECG.

The pressure level can be monitored and regulated.

Most of the functions required during surgery can be managed using the system control panel of the heart-lung machine.

Useful signals and data are displayed.

A complete perfusion report can be recorded for subsequent analysis and printout using JOCAP XL online.

■ Use in ELS System

The ROTAFLOW Console with ICU Kit can be used as a component of the ELS System. The ELS System is used for extended respiratory and/or circulatory

support. It is approved for transportation in air and ground vehicles (mobile intensive care units and ambulances).

The ELS System is made up of the following components:

- ELS Set (disposable products)
- Holder for ELS System (Mobile ELS Holder, Mobile RFC Holder, ELS Wall Holder (optional), ELS Base Plate (optional))
- ROTAFLOW Console with ICU Kit
- ROTAFLOW Drive

During transport the ROTAFLOW Console is mounted on the Mobile RFC Holder. The ROTAFLOW Drive is installed on the Mobile ELS Holder.

■ Use in PLS System

The ROTAFLOW Console with ICU Kit can be used as a component of the PLS System. The PLS System is used for extended respiratory and/or circulatory support.

The PLS System is made up of the following components:

- PLS Set (disposable products)
- Holder for PLS System (Mobile HLM Holder, Holder for PLS System (rotating), Holder for PLS System (fixed))
- ROTAFLOW Console with ICU Kit
- ROTAFLOW Drive

1.1 SAFETY

1.1.1 SYMBOLS ON ROTAFLOW CONSOLE



Important: Refer to the accompanying documents.



Refer to the User's Manual.



IEC 60601-1 classification: Type B applied part



Alternating current

IP64

Protection class in accordance with IEC 60529: Protection against ingress of dust and splashing water



Date of manufacture: Year in which the device was made



Separate collection of electric and electronic devices in accordance with Directive 2002/96/EC: Do not dispose of the device with normal domestic waste. Keep separate from domestic waste and dispose of in an environmentally safe way in compliance with local regulations.



The device meets the requirements of Council Directive 93/42/EEC concerning medical devices.



Equipotential bonding

1.1.2 SYMBOLS OF CONTROLS AND DISPLAY ELEMENTS



Intervention LED "Level Monitoring"



Intervention LED "Bubble Monitoring"



Intervention LED "Pressure Monitoring"



Select button



Set button



“Audio off” button



“Level override” button



“Bubble override” button



“Zero adjustment” button



“Clamp” button



Rotary pressure knob



“External power” lamp

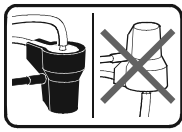


“Battery operation” lamp



“Battery charging” lamp

1.1.3 SYMBOLS ON ROTAFLOW DRIVE



Do not turn upside down.

1.1.4 SPECIAL INSTRUCTIONS

These special instructions are used in the User's Manual. Please bear them in mind.

WARNING! Risk of serious personal injury!

This is an instruction or procedure which must be observed to avoid injury to the user, patient or other persons.

ATTENTION! Risk of damage to equipment!

This is an instruction or procedure which must be observed to avoid the device being damaged.

Note

Important or explanatory information.

1.2 PRECAUTIONS

Note

Please read the User's Manual carefully before using the device!

WARNING!

- Use the system and accessories in accordance with the User's Manual and tried and tested medical practice. It is the responsibility of qualified staff to ensure that the system is used, tested and maintained in accordance with all updates of the product specification and User's Manual.
- Do not connect equipment which does not form part of this system.
- During an operation, only use devices and equipment which are functioning perfectly.
- Adjust the extracorporeal circulation properly and check it before starting operation.
- The system may be operated only by qualified staff.
- The system should only be used under supervision. The system must be continuously monitored by qualified staff to ensure patient safety. Clinical procedures and methods are the responsibility of the physician.

WARNING!

- Do not use the system near escaping flammable or combustible gases.
- During longer procedures, it is possible that the ultrasonic contact cream might dry out, which can impair the results of the flow meter. For this reason, the ultrasonic contact cream must be renewed every 48 hours or as soon as the error message [SIG!] appears.
- Do not use the ROTAFLOW System in suction mode.
- The ROTAFLOW System should only be used with a valve or other adequate systems or methods (e.g., two tube clamps) preventing a reverse flow.
- If the pump stops during an operation, 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 promptly.
- Make sure that there is no contact between high-frequency measuring equipment and the measuring system or tubes, as this may cause the flow indicator to malfunction.
- Do not touch the patient and the external interfaces of the device at the same time.
- Do not touch the plugs of the ROTAFLOW Console as electrostatic charging and moisture may cause damage.
- Bear in mind that the ROTAFLOW Console weighs approx. 15 kg.

ATTENTION!

- Switch off the mains power switch at the rear of the ROTAFLOW Console before maintenance or cleaning.
- Ask MAQUET about the most environmentally friendly method of disposing of parts.

1.2.1 CLAMPING THE TUBE

WARNING!

- First of all disable the flow regulation (⇒ 4.5 “Flow regulation”, page 36).
 - Clamp the tube to prevent a reverse flow.
 - Immediately turn the flow regulator to zero to prevent hemolysis.
 - When opening the tube clamp, simultaneously increase the speed.
- Do not open the tube clamp at a high speed to prevent magnetic uncoupling.

1.2.2 MAGNETIC UNCOUPLING

WARNING!

Magnetic uncoupling can be identified by a decrease in the flow rate and a humming sound.

If magnetic uncoupling occurs, proceed as follows:

- Disable the flow regulation immediately (⇒ 4.5 “Flow regulation”, page 36).
- Clamp the tube to prevent a reverse flow.
- Turn the speed to zero.
- Once the ROTAFLOW Centrifugal Pump stops, increase the speed and open the tube clamp simultaneously.

If magnetic uncoupling occurs again, use the ROTAFLOW Emergency Drive.

If it continues to occur, install a new ROTAFLOW Centrifugal Pump.

1.2.3 EXTERNAL DEVICES

WARNING!

- If you are using the ROTAFLOW System with other medical devices, check the total leakage currents.
- Check that all devices comply with IEC 60601-1.
- Check that all devices connected to the digital interface of the ROTAFLOW System satisfy the IEC specifications (IEC 60950 for data processing equipment located more than 1.5 meters from the operating table and IEC 60601 for data processing equipment within 1.5 meters of other medical devices).

1.2.4 MEMBRANE OXYGENATOR

Variations in pressure in a microporous membrane oxygenator (following an abrupt fall in the arterial flow) may cause gas microemboli if the blood pressure falls below the gas pressure.

WARNING!

- Monitor the pressure in the arterial tube system.
- Adjust the pump so that the pressure in the blood flow through the oxygenator is always higher than the gas pressure.

1.2.5 LEVEL AND BUBBLE MONITORING

WARNING! Mortal danger to patients from gas emboli

- Install the bubble and level monitoring system according to the instructions.
- Always test the function of the bubble and level monitoring system using fluid together with the oxygenator and reservoir before each use.
- A bubble stop malfunction may occur with initially imperfect mixing of blood and priming liquid due to a difference in the acoustic properties of the fluids.
- The arterial filter is no substitute for the function of the bubble and level monitoring system. Use more than one system. The responsibility for taking precautions still lies with the user.
- If you use the ROTAFLOW System without a bubble or level monitoring system, ensure patient safety with other adequate systems or methods.

1.2.6 BEFORE AND DURING TRANSPORT APPLICATION

WARNING! Risk from accidental changes in flow

For flow regulators without a rotary pressure function there is the risk of the knob being turned accidentally, which changes the flow.

It is therefore only permitted to use the ROTAFLOW Console with ICU Kit for transport applications.

WARNING! Danger if warning signals are not heard

In noisy environments, there is the risk that acoustic warning signals emitted by the ROTAFLOW Console may not be heard.

You should therefore position the ROTAFLOW Console so that you can see the displays and any optical warning signals at all times.

ATTENTION!

- Comply with national transportation regulations.
- Also follow the instructions supplied with other components of the ELS System.
- The person responsible for configuring the system as a whole must ensure that the complete system is permissible.
- Only use the ELS System in ground and air vehicles which have their own oxygen supply and own power supply which is suitable for the ROTAFLOW Console.

WARNING! Risk of decannulation and mechanical damage

When changing the mode of transport, repositioning the patient or moving the patient outside the mode of transport, there is a risk of decannulation and mechanical damage caused by strain on the tubes or impacts.

The greatest care should thus 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! Risk of power failure

An inadequate power supply may put the ROTAFLOW Console out of service. Please therefore note:

- Always start work with the battery of the ROTAFLOW Console fully charged.
- Use the power supply of the vehicle or hospital whenever possible so as to conserve the battery.
- Take the ROTAFLOW Emergency Drive with you when transporting the patient. Keep it at the ready for stop-gap operation in the event of pump failure.

ATTENTION!

- All components must be installed so that they can be monitored and operated by the user during transportation. There must also be sufficient space to use the ROTAFLOW Emergency Drive.
- Take at least two tube clamps with you when transporting the patient. Keep them at the ready for clamping tubes in the event of leakage.
- All components must be attached to the holders provided for this purpose and properly secured (ROTAFLOW Console on Mobile RFC Holder, ROTAFLOW Drive on Mobile ELS Holder).
- For transportation in aircraft, the Mobile ELS Holder and Mobile RFC Holder must be attached to the floor rails or to the ELS Base Plate and securely fastened. If the ELS Base Plate is used, it must be attached to the aircraft floor rails and securely fastened.
- For transportation in ground vehicles, the Mobile ELS Holder and Mobile RFC Holder must be attached to the ELS Wall Holder and securely fastened.
- During transportation, ensure that the correct ambient conditions are maintained for all components.

ATTENTION!

- Protect components from moisture.

WARNING!

When installing and using the ELS Set, follow the instructions supplied.

Recommendation: Use speed regulation in aircraft.

Extreme electromagnetic radiation may occur during transportation in aircraft – possibly impairing flow regulation.

It is therefore recommended to use speed regulation during transportation in aircraft and not flow regulation.

1.2.7 USE OF PORTABLE MULTIPLE SOCKET OUTLETS

WARNING!

- Only use the portable multiple socket outlets supplied with the system to supply power to equipment forming part of the system.
- Follow the instructions supplied with the multiple socket outlet.
- Do not put portable multiple socket outlets down on the ground. Make sure that people cannot trip over portable multiple socket outlets or cables.
- Do not connect additional portable multiple socket outlets or extension cords to the system.
- Comply with the maximum load given for the portable multiple socket outlet (⇒ Instructions supplied with multiple socket outlet).

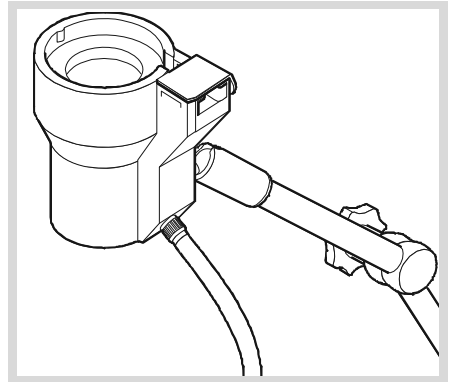
1.3 ABBREVIATIONS

HLIM	Upper speed limit (“High limit”)
LLIM	Lower speed limit (“Low limit”)
FLIM	Lower flow limit (“Flow limit”)
HLM	Heart-lung machine
rpm	Revolutions per minute
LPM	Liters per minute
l/min	
ART	⇒ 4.1 “Modes”, page 31
ART PULS	
STAND AL	
FREE	

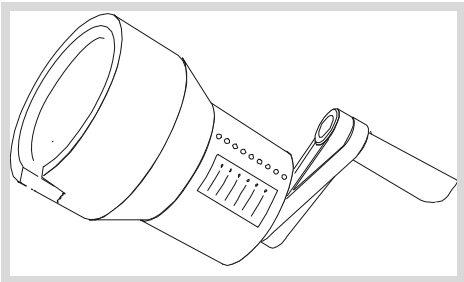
2 SYSTEM COMPONENTS



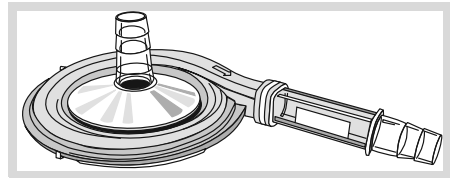
ROTAFLOW Console with ICU Kit



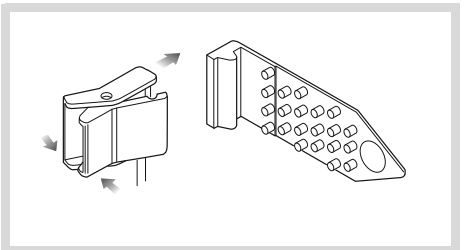
ROTAFLOW Drive



ROTAFLOW Emergency Drive



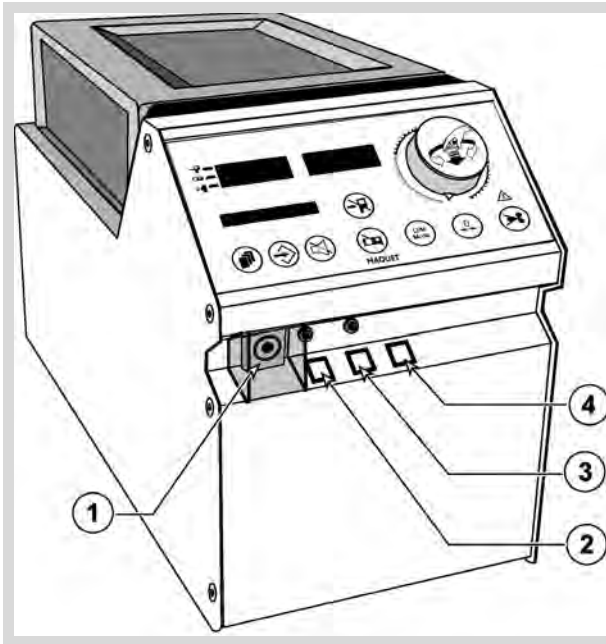
ROTAFLOW Centrifugal Pump



Capacitive level sensor with level sensor pad

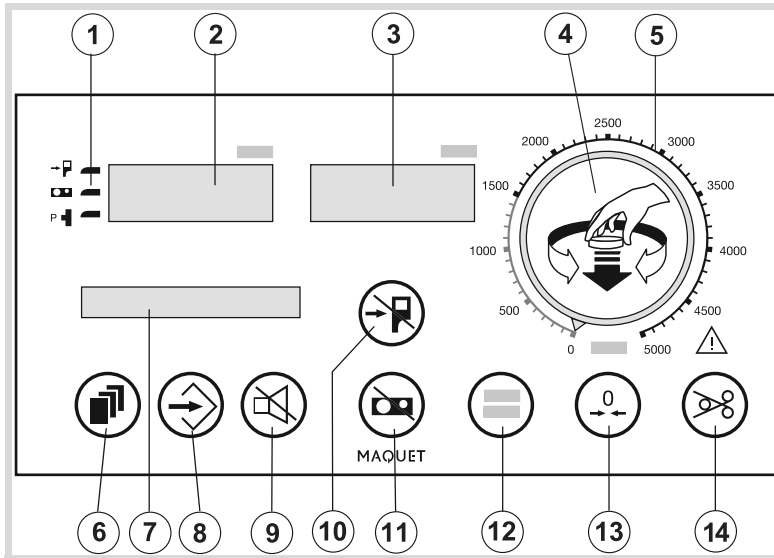
2.1 ROTAFLOW CONSOLE WITH ICU KIT

2.1.1 FRONT



- | | | |
|-----|-----------------------------------|--|
| [1] | On/off switch with cover | ⇒ 3.7 “Switch on ROTAFLOW Console, Self-test”, page 29 |
| [2] | “External power” lamp (green) | The “External power” lamp lights up when the ROTAFLOW Console is connected to an external power supply. |
| [3] | “Battery operation” lamp (orange) | The “Battery operation” lamp lights up when the internal battery is in use (⇒ 5.2 “Battery operation”, page 39) |
| [4] | “Battery charging” lamp (orange) | The “Battery charging” lamp lights up when the battery is being charged.
It extinguishes once the battery is fully charged. |

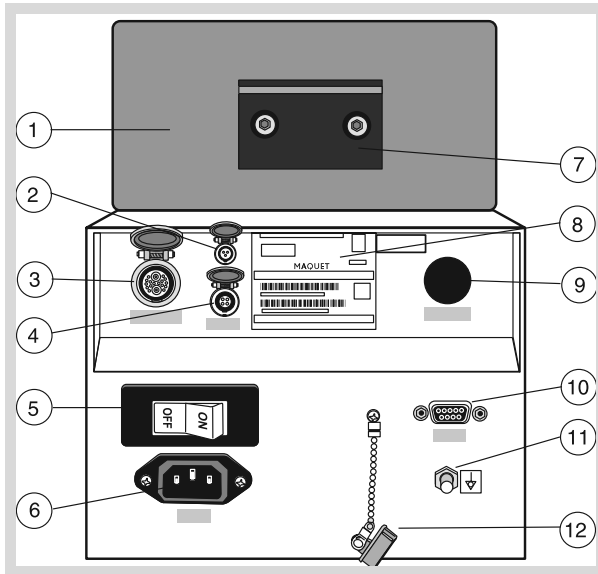
2.1.2 FRONT PANEL



- | | |
|--|---|
| <p>[1] Intervention LEDs
(only in modes “ART” and “ART PULS”)</p> | <p>The intervention LEDs indicate the interventions selected (⇒ 4.7 “Modes “ART” and “ART PULS”: Interventions”, page 38).</p> <p>■ The intervention LED flashes whenever monitoring is switched off during operation or when a fault occurs.</p> |
| <p>[2] Speed display</p> | <p>This display shows the speed in rpm (revs per minute).</p> |
| <p>[3] Flow display</p> | <p>This display shows the flow in l/min (liters per minute).</p> |
| <p>[4] Flow regulator</p> | <p>You can use the flow regulator (rotary pressure knob) to adjust the speed or flow (with flow regulation connected). To do so, press on the knob, turn and then release.</p> |
| <p>[5] Speed scale</p> | <p>The scale is provided as a guide should the speed display fail.</p> |
| <p>[6] Select button</p> | <p>The select button is used to select the required setting or value (⇒ 4.2 “Selecting settings”, page 33)</p> |
| <p>[7] Status display</p> | <p>This display shows messages about the status of the ROTAFLOW System (⇒ 9 “Messages”, page 49)</p> |
| <p>[8] Set button</p> | <p>The set button is used to confirm the setting or value selected (⇒ 4.2 “Selecting settings”, page 33).</p> |

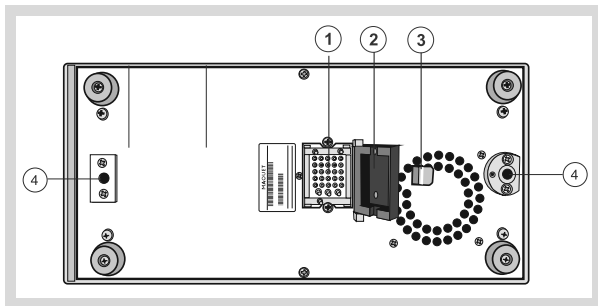
[9]	"Audio off" button	<p>The "Audio off" button is used to switch off the acoustic alarm temporarily.</p> <ul style="list-style-type: none"> ■ The button flashes when the acoustic alarm is switched off. ■ The acoustic alarm is automatically switched back on if a new alarm condition occurs.
[10]	"Level override" button (only in "STAND AL" mode)	<p>The "Level override" button is used to switch level monitoring off and on in "STAND AL" mode (⇒ 4.6.2 "STAND AL" mode: Level monitoring", page 37).</p> <ul style="list-style-type: none"> ■ To switch level monitoring off, press the button for at least 3 seconds. ■ The button flashes when level monitoring is switched off.
[11]	"Bubble override" button (only in "STAND AL" mode)	<p>The "Bubble override" button can be used to reset the bubble sensor after a bubble intervention and switch bubble monitoring on and off (⇒ 4.6.1 "STAND AL" mode: Bubble monitoring", page 37).</p> <ul style="list-style-type: none"> ■ To reset the bubble sensor after a bubble intervention, press the button briefly (less than 3 seconds). ■ To switch bubble monitoring off, press the button for at least 3 seconds. ■ The button flashes when bubble monitoring is switched off.
[12]	"LPM Mode" button	<p>Use the "LPM Mode" button to switch flow regulation ⇒ 4.5 "Flow regulation", page 36 on and off.</p> <ul style="list-style-type: none"> ■ The button lights up when flow regulation is switched on.
[13]	"Zero adjustment" button	<p>The "Zero adjustment" button can be used to calibrate flow measurement to zero (⇒ 4.3 "Priming and Zero Calibration", page 34).</p>
[14]	"Clamp" button	<p>You can use the "Clamp" button to confirm that suitable systems or methods are available (e.g., two tube clamps) to prevent a reverse flow (⇒ 3.7 "Switch on ROTAFLOW Console, Self-test", page 29).</p>

2.1.3 REAR



- [1] Battery cover
- [2] "CLS" socket (for level sensor)
- [3] "RFD Master" socket (for ROTAFLOW Drive)
- [4] Not used
- [5] Mains power switch
- [6] Power socket
- [7] Holder for ROTAFLOW Drive
- [8] Rating plate
- [9] Not used
- [10] RS232 port (serial output interface e.g., for JOCAP XL)
- [11] Grounding connection (equipotential bonding)
- [12] Cover for RS232 port

2.1.4 UNDERSIDE



For operation on a MAQUET heart-lung machine:

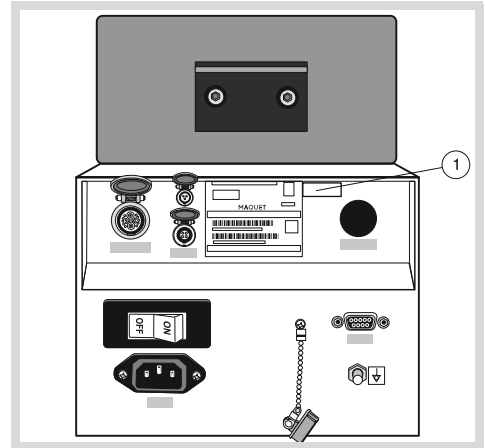
- [1] Plug
- [2] Protective plug cap
- [3] Securing mechanism for protective cover
- [4] Openings for holding pins of heart-lung machine console

2.1.5 ICU KIT

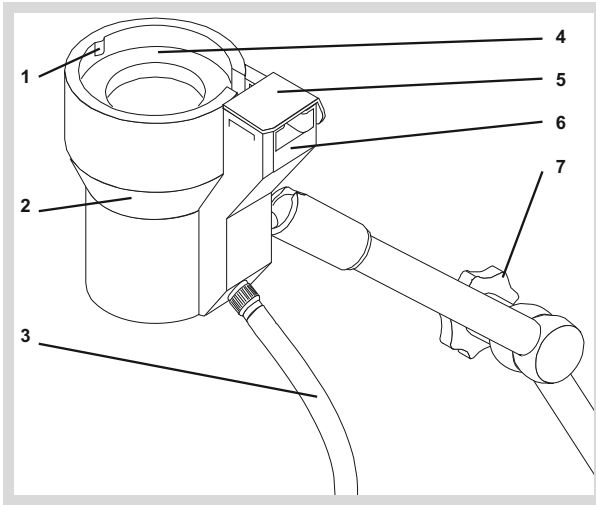
The ICU Kit equips the ROTAFLOW Console with the following components:

- Cover for on/off switch
- Rotary pressure knob for flow regulation
- Special mains power switch (rear)
- EMC filter (in housing)

The ROTAFLOW Console with ICU Kit is identified at the rear with a label stating “Upgrade ICU” [1].

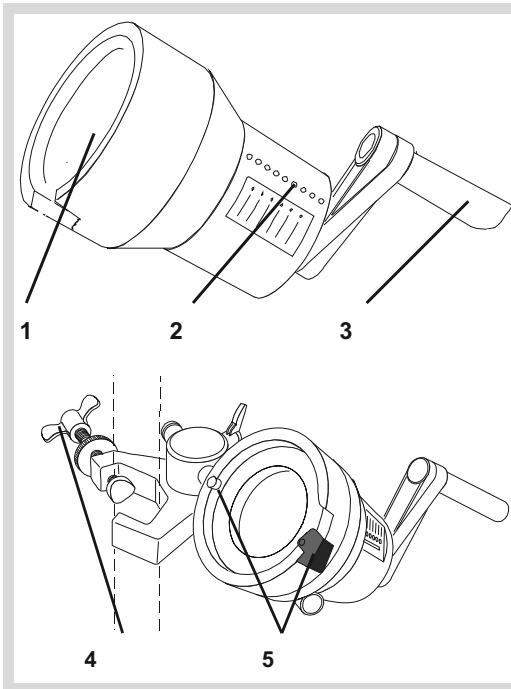


2.2 ROTAFLOW DRIVE



- [1] Holder
- [2] Ventilation slit collar
- [3] Cable
- [4] Position for ROTAFLOW Centrifugal Pump
- [5] Locking device
- [6] Flow meter and bubble sensor
- [7] Hydraulic bolt for arm joints

2.3 ROTAFLOW EMERGENCY DRIVE



- [1] Position for ROTAFLOW Centrifugal Pump
- [2] Speed display
- [3] Hand crank
- [4] Wing bolt
- [5] Holders

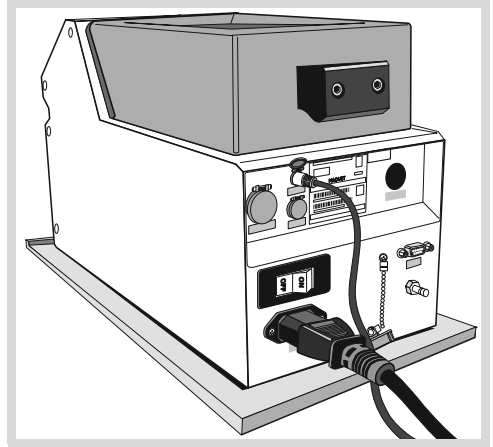
3 CONNECTION AND INSTALLATION

WARNING!

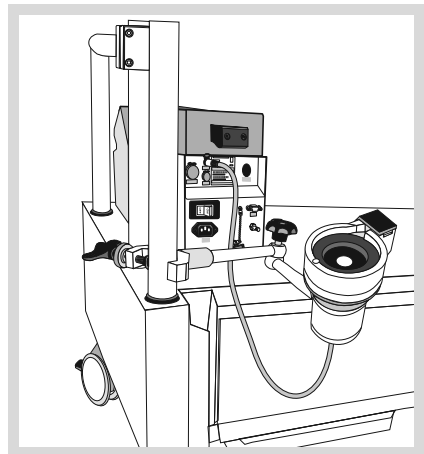
In transport applications, all components must be attached to the holders provided for this purpose and securely fastened (⇒ Instructions supplied with holders for ELS System).

3.1 OPERATION AS A STAND-ALONE DEVICE: CONNECT ROTAFLOW CONSOLE

- 1 Connect power cord to power socket.
- 2 Switch on mains power switch at rear of ROTAFLOW Console.

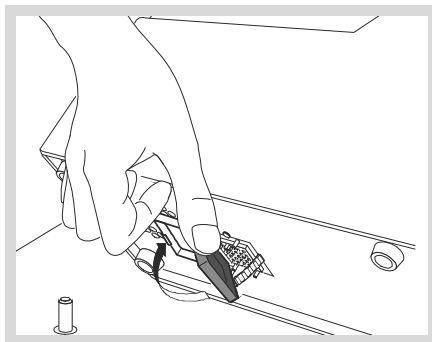


3.2 OPERATION ON A HEART-LUNG MACHINE: INSTALL ROTAFLOW CONSOLE

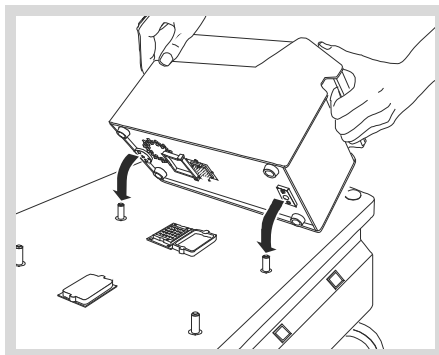


Operating position on a heart-lung machine

- 1 Please make sure that the pump switch on the console of the heart lung machine is switched off.
- 2 Remove the protective cap from the connection socket of the heart lung machine.
- 3 Open the protective plug cap of the ROTAFLOW Console and lock in the securing mechanism.



- 4 Set the ROTAFLOW Console down carefully on the console of the heart-lung machine. The holding pins must be inserted in the housing of the ROTAFLOW Console.



- 5 Switch on the pump switch on the console of the heart-lung machine.

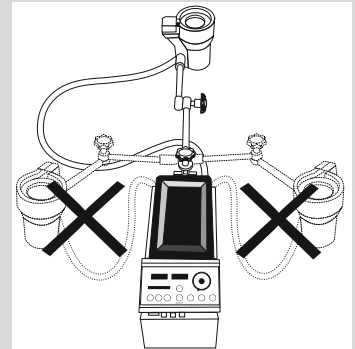
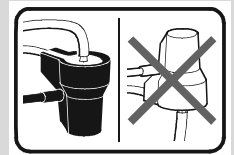
3.3 INSTALL ROTAFLOW DRIVE

WARNING!

In transport applications, all components must be attached to the holders provided for this purpose and securely fastened (⇒ Instructions supplied with holders for ELS System).

ATTENTION!

- Switch off the ROTAFLOW Console before connecting or disconnecting the cable of the ROTAFLOW Drive.
- Make sure that the ventilation slit of the ROTAFLOW Drive is not blocked during operation.
- Make sure that no liquids enter the ventilation slit of the ROTAFLOW Drive.
- Do not tip the ROTAFLOW Drive at an angle of more than 90 degrees and do not turn upside down, as liquids may enter the ventilation slit.
- When using the ROTAFLOW Drive on the ROTAFLOW Console, secure the ROTAFLOW Drive in a position above the ROTAFLOW Console to ensure greater stability.



- 1 Use the wing bolt to secure the ROTAFLOW Drive to a stable pole (diameter 25 mm ... 40 mm) or to the holder for the ROTAFLOW Drive on the ROTAFLOW Console.
- 2 Make sure that the on/off switch of the ROTAFLOW Console is switched off.
- 3 Connect the cable of the ROTAFLOW Drive to the “RFD Master” socket.

3.4 INSTALL ROTAFLOW EMERGENCY DRIVE

In emergencies operation can be maintained manually using a ROTAFLOW Emergency Drive.

Use the wing bolt to secure the ROTAFLOW Emergency Drive to a stable pole. Secure on the same side as the ROTAFLOW Drive.

3.5 OPERATION AS A STAND-ALONE DEVICE: INSTALL LEVEL SENSOR

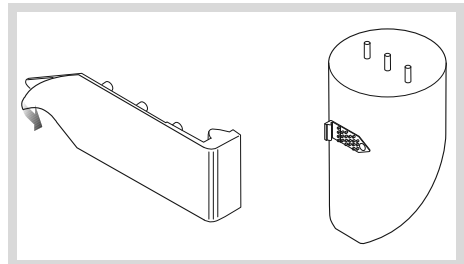
Note

In the “ART” and “ART PULS” modes, the level is monitored by the heart-lung machine (⇒ 4.7 “Modes “ART” and “ART PULS”: Interventions”, page 38 and the ⇒ User’s Manual for heart-lung machine).

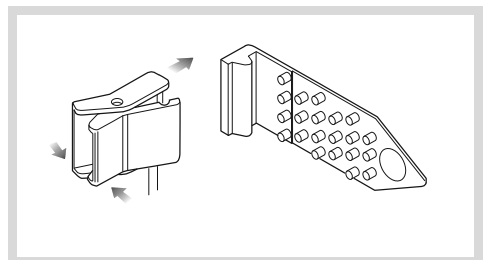
WARNING!

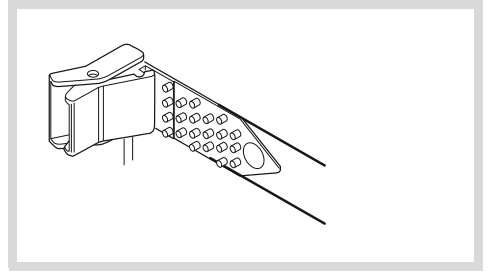
- Attach the level sensor pad where the wall of the reservoir is between 2 and 5 mm thick. Do not attach the level sensor pad to a greasy, dusty or uneven surface or to a label coated with metal. Do not attach anywhere where blood flows along the wall as a thin film of blood.
- Try to prevent liquids from coming into contact with the level sensor pad. If a level sensor pad becomes wet, replace it immediately with a dry one.
- Do not use level sensor pads which are damaged, have become detached or do not have an even contact surface.
- Do not touch the contact surface.
- Do not re-use level sensor pads as this might impair sensitivity.
- There must be at least 30 mm of liquid between the level sensor and the opposite wall.
- With reservoirs containing metal heat exchangers, the distance between the reservoir wall and the metal spiral must be at least 40 mm.
- Do not attach more than one level sensor to the reservoir.

- 1 Remove the protective paper and attach the level sensor pad onto the reservoir horizontally. The arrow must be pointing to the right at the desired height.



- 2 Attach the level sensor to the level sensor pad.





- 3 Make sure that the on/off switch of the ROTAFLOW Console is switched off.
- 4 Connect the level sensor to the “CLS” socket on the ROTAFLOW Console.
- 5 Press the “Level override” button (briefly) to switch on level monitoring.

Test the level monitoring function (⇒ 4.3.2 “Level monitoring: Performance test”, page 35).

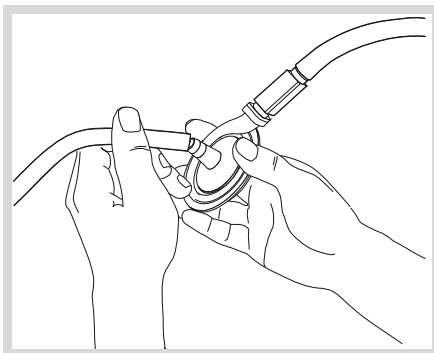
3.6 CONNECT TUBES

WARNING!

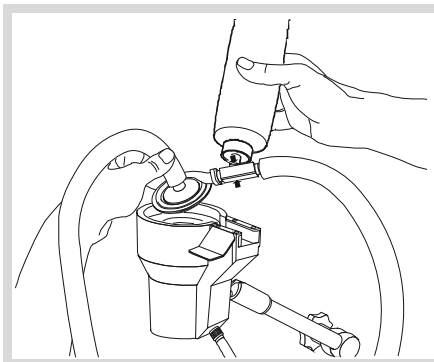
- Only use tubes which are designed for perfusion and approved for this system.
- Connect 3/8" × 3/32" PVC or silicone tubes to the ROTAFLOW Centrifugal Pump. Tubes with thinner walls might collapse.
- Connect the pump tube in the direction of the arrows on the ROTAFLOW Centrifugal Pump.
- Only use ultrasonic contact cream, which is listed as an accessory: (⇒ 8 “Accessories”, page 47).
- Check that the ROTAFLOW Centrifugal Pump is securely attached during operation.
- During longer procedures, it is possible that the ultrasonic contact cream might dry out, which can impair the results of the flow meter. For this reason, the ultrasonic contact cream must be renewed every 48 hours or as soon as the error message [SIG!] appears (⇒ 5.3 “Replacing ultrasonic contact cream”, page 41).

1 Connect the inlet tube to the inlet in the centre of the ROTAFLOW Centrifugal Pump.

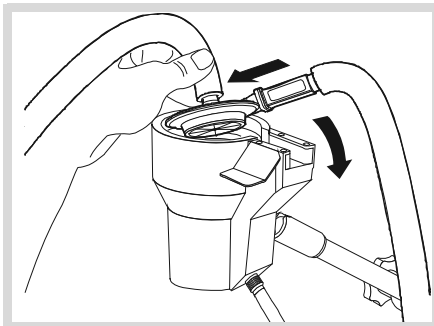
2 Connect the outlet tube to the outlet on the side of the ROTAFLOW Centrifugal Pump.



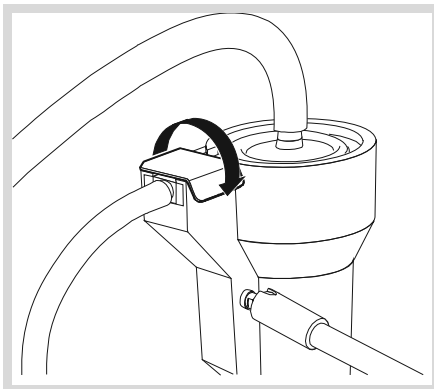
3 Apply ultrasonic contact cream to both sides (left and right) around the outlet of the ROTAFLOW Centrifugal Pump. Both sides must be completely covered with the ultrasonic contact cream.



4 Insert the ROTAFLOW Centrifugal Pump into the ROTAFLOW Drive. Check that the ROTAFLOW Centrifugal Pump is positioned under the holder of the ROTAFLOW Drive.



5 Close the lock.



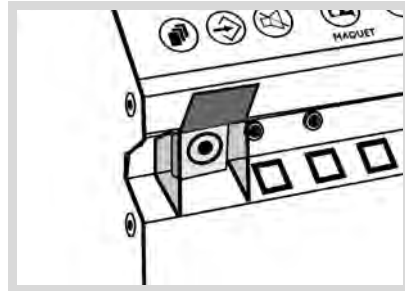
3.7 SWITCH ON ROTAFLOW CONSOLE, SELF-TEST

WARNING!

When using as a stand-alone device, switch on the mains power switch at rear of ROTAFLOW Console.

Otherwise the ROTAFLOW Console will default to battery operation after being switched on, thus discharging the batteries.

- 1 Open the cover of the on/off switch on the front.
- 2 Press the on/off switch.
- 3 Close the cover again.



The ROTAFLOW Console will automatically perform a self-test after being switched on.

- 4 At the beginning of the self-test check that all displays and LEDs are lit up and that an acoustic alarm is emitted.

The ROTAFLOW Console shows various messages during the self-test (⇒ 9.1 “Messages during self-test”, page 49).

- 5 Check whether the displays show the following messages at the end of the self-test: **[–OK– EX.X PUMP OK]**

On the display, [X.X] will indicate the software version.

- 6 If the displays then show the message **[VALVE?]**, you need to confirm that a valve or other suitable systems or methods are available (e.g., two tube clamps) to prevent a reverse flow. Press the “Clamp” button.

3.8 REMOVAL

WARNING!

If you are not using the ROTAFLOW Console, switch off using the on/off switch. If you only remove the power cord, switch off the mains power switch at the rear of the ROTAFLOW Console or the pump switch of the heart-lung machine, you will only be disconnecting the external power supply. In such cases, the ROTAFLOW Console will default to battery operation. The ROTAFLOW Console remains switched on, so discharging the batteries.

3.8.1 REMOVAL WITH OPERATION AS A STAND-ALONE DEVICE

- 1 Switch off the on/off switch of the ROTAFLOW Console.
- 2 Open the lock on the ROTAFLOW Drive and remove all the ultrasonic contact cream with a lint-free cloth.

3.8.2 REMOVAL FROM A HEART-LUNG MACHINE

ATTENTION!

Fit covers to any connection sockets not required on the console of the heart-lung machine to protect them from liquids.

- 1 Switch off the on/off switch of the ROTAFLOW Console.
- 2 Switch off the pump switch on the console of the heart-lung machine.
- 3 Remove the ROTAFLOW Console.
- 4 Release the securing mechanism of the protective plug cap on the underside of the ROTAFLOW Console and close the protective plug cap.
- 5 Fit the protective cap to the connection socket of the heart lung machine.
- 6 Open the lock on the ROTAFLOW Drive and remove all the ultrasonic contact cream with a lint-free cloth.

To clean, please refer to ⇒ 6 “Cleaning and disinfection after each use”, page 45.

4 OPERATION

WARNING!

- Always have a ROTAFLOW Emergency Drive easily accessible and ready for use.
- Set the patient-specific lower flow limit (FLIM) correctly (⇒ 4.2 “Selecting settings”, page 33). If the flow is too low, this may be dangerous and harm the patient.
- Before starting the application, check the items listed in ⇒ 4.4 “Checks before usage”, page 35.
- Only ever start the application when the battery of the ROTAFLOW Console is fully charged.

4.1 MODES

The relevant mode must be selected for the ROTAFLOW System in each case.

When selecting the mode, take note of ⇒ 4.2 “Selecting settings”, page 33 and ⇒ 5.1 “Modes “ART” and “ART PULS”: Communication error with heart-lung machine”, page 39.

WARNING! “FREE” mode: No interventions

- In “FREE” mode, no intervention is made by the monitoring system.
- Do not use “FREE” mode during an operation, except in an emergency.

Display in “SET MODE” menu	Shown in status display	Meaning
ART	ART	<p>Only with operation on a heart-lung machine:</p> <ul style="list-style-type: none"> ■ Arterial pump for continuous pumping ■ Interventions using heart-lung machine (⇒ 4.7 “Modes “ART” and “ART PULS”: Interventions”, page 38). <p>See also the User’s Manual for the heart-lung machine.</p>
ART PULS	A-P	<p>Only with operation on a heart-lung machine:</p> <ul style="list-style-type: none"> ■ Arterial pump with a pulsatile pumping option ■ Interventions using heart-lung machine (⇒ 4.7 “Modes “ART” and “ART PULS”: Interventions”, page 38). <p>See also the User’s Manual for the heart-lung machine.</p>

Display in “SET MODE” menu	Shown in status display	Meaning
STAND AL	SA	<div>■ Pump as stand-alone device.</div> <div>Interventions using an internal bubble sensor and a level sensor connected (⇒ 4.6 ““STAND AL” mode: Interventions”, page 36).</div>
FREE	FRE	<div>Pump without interventions or communication with heart-lung machine.</div> <div>This allows you to continue operation, for example, in emergencies when the ROTAFLOW System stops due to an error in the monitoring system.</div>

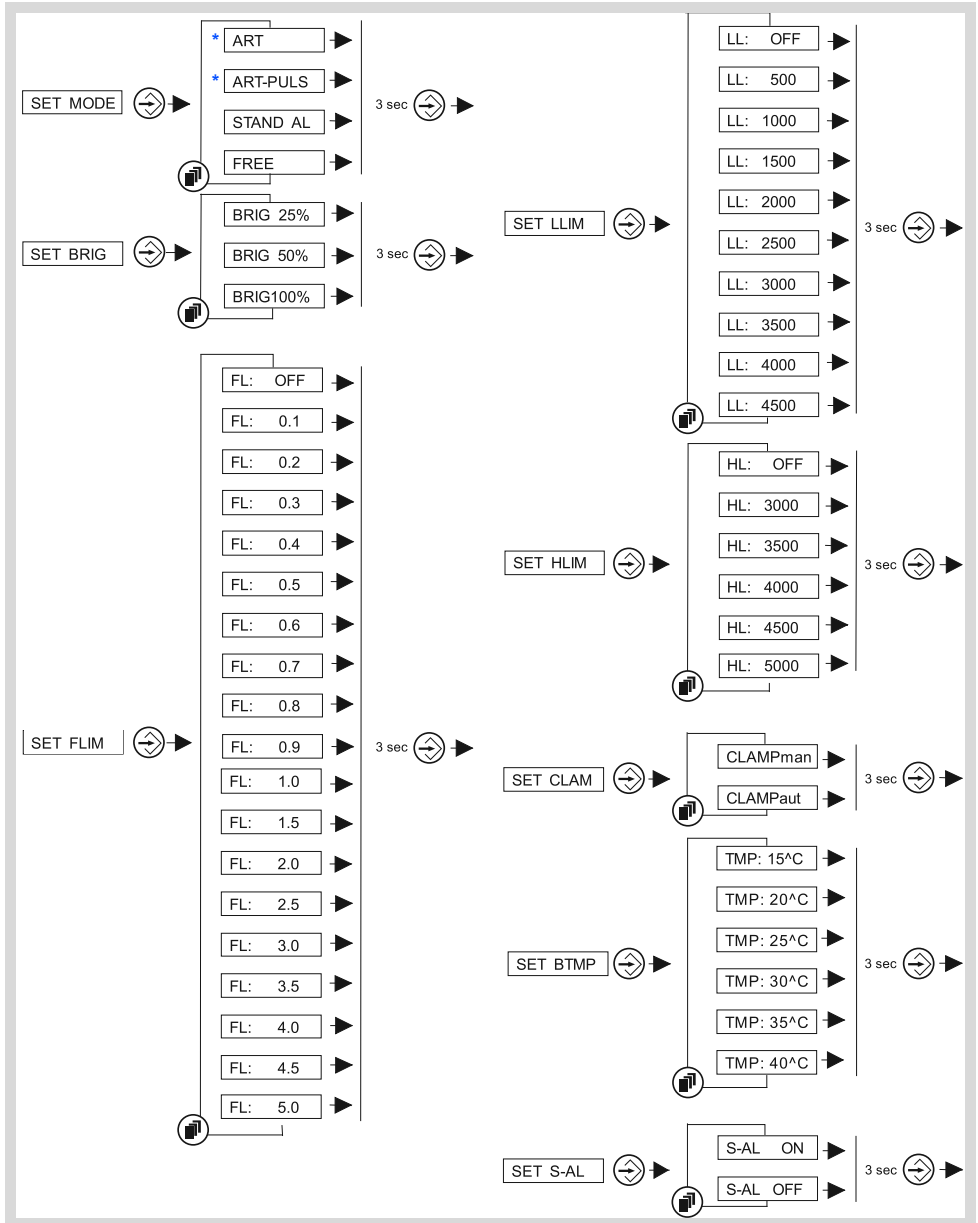
Reset bubble sensor before starting “STAND AL” mode

You must reset the bubble sensor after a bubble intervention. This also applies to bubble interventions prior to the actual application (e.g., during priming). To do so, press the “Bubble override” button briefly (less than 3 seconds).

4.2 SELECTING SETTINGS

Changing settings with a flow of 0 rpm

Settings can only be changed at a flow of 0 rpm. It is therefore advisable to establish all settings before starting the application.



* Modes "ART" and "ART PULS" only with operation on a heart-lung machine

- 1 Press the select button repeatedly until the status display shows the setting you wish to change.
 - [SET MODE]: Mode (⇒ 4.1 “Modes”, page 31).
 - [SET BRIG]: Brightness of display
 - [SET FLIM]: Lower flow limit
 - [SET LLIM]: Lower speed limit
 - [SET HLIM]: Upper speed limit
 - [SET CLAM]: Not used
 - [SET BTMP]: Blood temperature (to optimize flow measurement)
 - [SET S-AL]: Soft alarm (⇒ User’s Manual for heart-lung machine).
- 2 Confirm selection with the set button.
- 3 Press the select button repeatedly until the status display shows the value you require.

Modes “ART” and “ART PULS” can only be selected with operation on a heart-lung machine.
- 4 To accept the changes, press the set button for 3 seconds.

If you wish to reject the changes, press any other button.

An acoustic signal is emitted and the status display shows the mode.

Note

If the lower flow limit (FLIM), lower speed limit (LLIM) or upper speed limit (HLIM) is exceeded, the ROTAFLOW Console emits an acoustic alarm and an error message flashes (⇒ 9.2.2 “In speed and flow displays”, page 49).

4.3 PRIMING AND ZERO CALIBRATION

ATTENTION!

Prime before use to prevent the bearings of the ROTAFLOW Centrifugal Pump from being damaged.

- 1 Prime with an isotonic electrolyte or a saline solution (⇒ User’s Manual for ROTAFLOW Centrifugal Pump).
- 2 Clamp the tube beyond the ROTAFLOW Centrifugal Pump and turn the flow regulator to zero.

- 3 When the ROTAFLOW Centrifugal Pump stops, and a flow within ± 1 l/min is displayed, press the “Zero adjustment” button for three seconds to calibrate flow measurement to zero.

4.3.1 BUBBLE MONITORING: PERFORMANCE TEST

Check that the ROTAFLOW System stops, an acoustic alarm is emitted and the status display shows [STOP BUB] when a bubble passes the bubble sensor.

You must reset the bubble sensor after a bubble intervention. To do so, press the “Bubble override” button briefly (less than 3 seconds).

4.3.2 LEVEL MONITORING: PERFORMANCE TEST

Check that the ROTAFLOW System stops, an acoustic alarm is emitted, and the status display shows [STOP LEV] when the level of liquid in the reservoir is lower than the arrow of the level sensor pad.

WARNING!

Repeat the performance test whenever the level sensor pad is moved. If there is a malfunction, try a new level sensor pad.

4.4 CHECKS BEFORE USAGE

- Check that the ROTAFLOW System is functioning.
 - Check that the speed display matches the speed set on the flow regulator.
 - Check that the correct mode has been set for the ROTAFLOW Console (\Rightarrow 4.1 “Modes”, page 31).
 - Check that the patient-specific lower flow limit (FLIM) is set correctly (\Rightarrow 4.2 “Selecting settings”, page 33). If the flow is too low, this may be dangerous and harm the patient.
 - Check every intervention selected by simulating an alarm condition:
 - “STAND AL” mode:
 - Bubble monitoring: Performance test (\Rightarrow 4.3.1, page 35)
 - Level monitoring: Performance test (\Rightarrow 4.3.2, page 35)
 - Modes “ART” and “ART PULS”.
- Monitoring via monitoring systems of heart-lung machine (\Rightarrow User’s Manual for heart-lung machine).

4.5 FLOW REGULATION

WARNING!

- If a bubble, level or pressure intervention occurs during flow regulation, the ROTAFLOW System will aim for a flow of 0 l/min. This does not however necessarily correspond to a speed of 0 rpm.
- Never clamp a tube during flow regulation (⇒ 1.2.1 “Clamping the tube”, page 10). With a clamped tube, the ROTAFLOW Centrifugal Pump can still reach a maximum speed of 5000 rpm even when the system is aiming for a flow of 0 l/min.
- The ROTAFLOW System should only be used with a valve or other adequate systems or methods (e.g., two tube clamps) preventing a reverse flow.
- Set the patient-specific upper speed limit (HLIM) correctly (⇒ 4.2 “Selecting settings”, page 33). If the speed is too high, this may be dangerous and harm the patient.

Recommendation: Use speed regulation in aircraft:

Extreme electromagnetic radiation may occur during transportation in aircraft – possibly impairing flow regulation.

It is therefore recommended to use speed regulation during transportation in aircraft and not flow regulation.

The flow is kept constant with flow regulation.

- 1 Set a flow above 0.5 l/min.
- 2 Press the “LPM Mode” button for at least 3 seconds.

The current flow is allocated to the current speed scale position.

The “LPM Mode” button lights up.
- 3 You can now adjust the flow (instead of the speed) using the flow regulator.

Press the “LPM Mode” button again to return to speed regulation. The “LPM Mode” button is extinguished.

4.6 “STAND AL” MODE: INTERVENTIONS

In “STAND AL” mode the following interventions can be used:

- Stop when bubbles are detected
- Stop when the level of liquid in the reservoir is low

Monitoring is performed by the internal bubble sensor of the ROTAFLOW Drive and a level sensor, which is connected to the ROTAFLOW Console.

The status display indicates whether the ROTAFLOW System was stopped by an intervention. The ROTAFLOW Console emits an acoustic signal.

STOP BUB	Stopped by bubble monitoring
STOP LEV	Stopped by level monitoring

4.6.1 “STAND AL” MODE: BUBBLE MONITORING

Note

Microbubbles are sometimes generated in bubble oxygenators, but should not appear in membrane oxygenators.

The pump is stopped immediately if bubbles exceed 5 mm in size.

You must reset the bubble sensor after a bubble intervention. To do so, press the “Bubble override” button briefly (less than 3 seconds).

4.6.2 “STAND AL” MODE: LEVEL MONITORING

WARNING!

- Use the level monitoring system to prevent the liquid level in the reservoir from becoming too low.
- Only use a fully functional level monitoring system with each operation. Always perform a function test before use.
- Only use the capacitive level sensor with a polycarbonate reservoir (Makrolon).
- Protect the level sensor from mechanical wear and tear (knocks, hanging down loose, etc.). For example, attach a level sensor pad to a safe place on the heart-lung machine where the level sensor can be kept when not in use.
- If other electronic equipment causes interference to the level sensor, continuously check the level in the reservoir visually until the source of interference is identified and removed.
- Only use the “Level override” button in exceptional circumstances (e.g., while filling or emptying the reservoir).
- The pump is not stopped at a low level in “Override”. Continuously check the level in the reservoir visually in this case.

4.7 MODES “ART” AND “ART PULS”: INTERVENTIONS

In the modes “ART” and “ART PULS” the following interventions can be used. Selection is made on the heart-lung machine.

- Stop when upper pressure limit is exceeded
- Stop when bubbles are detected
- Stop when the level of liquid in the reservoir is low

Monitoring is performed via the monitoring systems of the heart-lung machine (⇒ User’s Manual for heart-lung machine).

The status display indicates whether the ROTAFLOW System was stopped by an intervention. The heart-lung machine emits an acoustic signal.

STOP BUB	Stopped by bubble monitoring
STOP LEV	Stopped by level monitoring
STOP PRx	Stopped by pressure monitoring x (x = 1 to 4).

WARNING! Pump stop with communication error with heart-lung machine

If the monitoring system of the heart-lung machine is switched off during operation or a communication error occurs, the ROTAFLOW System will stop, and the relevant intervention LED will flash. An acoustic alarm is emitted and the status display flashes [\[NO COMM.\]](#). Please take note of ⇒ 5.1 “Modes “ART” and “ART PULS”: Communication error with heart-lung machine”, page 39.

5 SAFETY

The ROTAFLOW System is continuously monitored during operation. If an error possibly causing a malfunction occurs, the ROTAFLOW System emits an acoustic alarm, shows messages on the displays and may stop (⇒ 9 “Messages”, page 49).

WARNING!

- In an emergency or with a stop, close the arterial and venous tube clamp (to prevent reverse flow) until pumping can be safely resumed.
- If the pump stops, 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 promptly.

5.1 MODES “ART” AND “ART PULS”: COMMUNICATION ERROR WITH HEART-LUNG MACHINE

WARNING!

- In “FREE” mode no intervention is made by the monitoring system.
- The ROTAFLOW System remains in “FREE” mode, also when the monitoring system is switched back on.

If the monitoring system of the heart-lung machine is switched off during operation, or a communication error occurs, the ROTAFLOW System stops and the relevant intervention LED flashes. An acoustic alarm is emitted and the status display flashes **[NO COMM.]**.

To continue the operation, select “FREE” mode as described in Section ⇒ 4.2 “Selecting settings”, page 33. See below for a more simple method:

- 1 Turn the flow regulator to zero (the acoustic alarm is switched off).
- 2 The status display flashes **[SET FREE]**. Press the set button to confirm the selection of “FREE” mode.
- 3 Turn the flow regulator to the required flow rate.

To use the internal bubble sensor and the connected level sensor, please note ⇒ 5.4 “Disconnection from a heart-lung machine during operation”, page 43.

5.2 BATTERY OPERATION

The ROTAFLOW System automatically switches to battery operation on any interruption in the external power supply (mains voltage or heart-lung machine console). Once power returns, the ROTAFLOW System will automatically switch back to the external power supply.

The batteries are automatically charged when the ROTAFLOW System is connected to the external power supply. For power to be supplied from mains, the mains power switch at the rear of the ROTAFLOW Console has to be switched on.

5.2.1 POTENTIAL OPERATING TIME

Conditions	Load	Potential operating time
■ New, fully charged batteries	Normal	min. 1.5 hours
■ 5 l/min		

WARNING! Reduced period of use with battery operation

The period of use depends on the battery capacity and power consumption. If the batteries used are not fully charged or old, or if the power consumption is high, the period of use will be reduced and the system will switch itself off more quickly.

5.2.2 BATTERY VOLTAGE DURING BATTERY OPERATION

WARNING!

If the voltage drops to 20 V, there is only power left for a very short time.

During battery operation, the ROTAFLOW Console emits an acoustic alarm and shows messages on the displays:

Battery voltage	Displays	Acoustic alarm
27.4 (fully charged) ... 20.0 V	Status display: [BAT XX.X] XX.X corresponds to the current battery voltage.	Can be switched off with the “Audio off” button.
20.0 ... 19.0 V	Speed and flow display: [LOW BAT.]	Cannot be switched off.
19.0 V	The system switches off!	

ATTENTION!

When the ROTAFLOW Console is stored or not in use, it should be left connected to an external power source to keep the batteries fully charged.

- Leave the mains power switch at the rear of the ROTAFLOW Console switched on. Otherwise the batteries will not be charged.
- Check that the “Battery charging” lamp lights up during charging. It extinguishes once the battery is fully charged.

5.3 REPLACING ULTRASONIC CONTACT CREAM

WARNING! Risk of serious injury or death with failure to observe this procedure.

During this procedure, the blood flow will be interrupted and supply to the patient will cease.

- This procedure should therefore be performed as quickly as possible.
- This procedure may only be performed by qualified staff.
- Only use ultrasonic contact cream, which is listed as an accessory.
(⇒ 8 “Accessories”, page 47).

During longer procedures, it is possible that the ultrasonic contact cream might dry out, which can impair the results of the flow meter. For this reason, the ultrasonic contact cream must be renewed every 48 hours or as soon as the error message **[SIG!]** appears.

Note

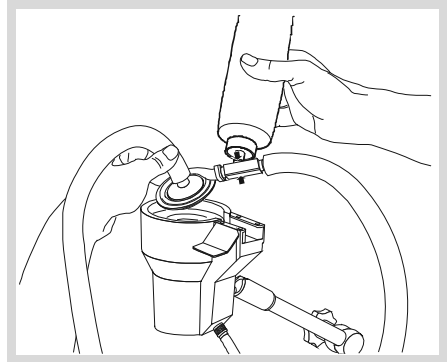
The error message **[SIG!]** indicates an error in flow measurement. The ROTAFLOW Centrifugal Pump continues to function nevertheless.

Ensure that this procedure is performed in less than 60 seconds.

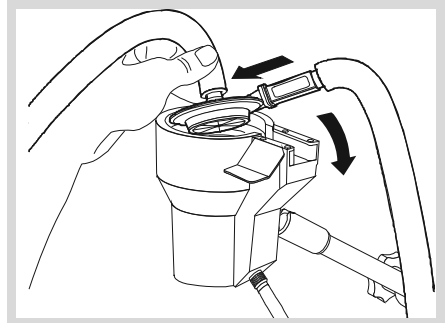
- 1 Reduce the speed to the minimum (1500 rpm) to prevent a reverse flow (drainage) of the patient's blood. The minimum speed is the speed at which the patient and line pressure are exceeded.
- 2 Clamp the outlet tube of the ROTAFLOW Centrifugal Pump to prevent a reverse flow.
- 3 Reduce the speed to 0 rpm.
- 4 Open the lock on the ROTAFLOW Drive.
- 5 Remove the ROTAFLOW Centrifugal Pump from the ROTAFLOW Drive.

6 Remove the ultrasonic contact cream from the ROTAFLOW Centrifugal Pump with a lint-free cloth.

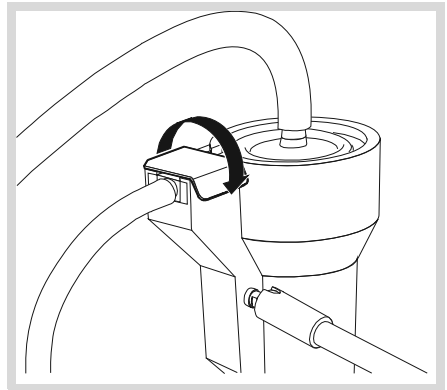
7 Apply ultrasonic contact cream to both sides (left and right) around the outlet of the ROTAFLOW Centrifugal Pump. Both sides must be completely covered with the ultrasonic contact cream.



8 Insert the ROTAFLOW Centrifugal Pump into the ROTAFLOW Drive. Check that the ROTAFLOW Centrifugal Pump is positioned under the holder of the ROTAFLOW Drive.



9 Close the lock.



10 Calibrate the flow measurement to zero:

- Make sure that a speed of 0 rpm is selected.
- Press the “Zero adjustment” button for three seconds to calibrate flow measurement to zero.

11 Set the speed to 1500 rpm to overcome the patient and line pressure.

12 Open the tube clamp.

13 Set the required flow.

If the error message [SIG!] is still displayed afterwards, follow the safety procedures and use the ROTAFLOW Emergency Drive (⇒ 5.5 “Using Emergency Drive”, page 44).

5.4

DISCONNECTION FROM A HEART-LUNG MACHINE DURING OPERATION

You can proceed as follows in an emergency:

Disconnection	Steps to be performed
Monitoring system	1 – 6
Monitoring system and power supply	1 – 8
Monitoring system, power supply and physical	1 – 11

- 1 If level monitoring is selected for the ROTAFLOW System, override it on the heart-lung machine.
- 2 Connect the level sensor to the “CLS” socket on the ROTAFLOW Console.
- 3 Switch off the pump switch on the console of the heart-lung machine.
The ROTAFLOW System automatically switches to battery operation.
- 4 Select “STAND AL” mode for the ROTAFLOW-System (⇒ 4.1 “Modes”, page 31 and ⇒ 4.2 “Selecting settings”, page 33).
The ROTAFLOW System may stop.
- 5 Press the “Bubble override” button to reset the bubble sensor (briefly, not so as to override the function).
- 6 If no level sensor is connected, press the “Level override” button for three seconds. The button flashes.
The ROTAFLOW System starts again.
- 7 Connect the power cord to the power socket of the ROTAFLOW Console.
- 8 Switch on the mains power switch at the rear of the ROTAFLOW Console.
- 9 Remove the ROTAFLOW Console.
- 10 Release the securing mechanism of the protective plug cap on the underside of the ROTAFLOW Console and close the protective plug cap.

- 11 Fit the protective cap to the connection socket of the heart lung machine.

Bubble and level monitoring in “STAND AL” mode

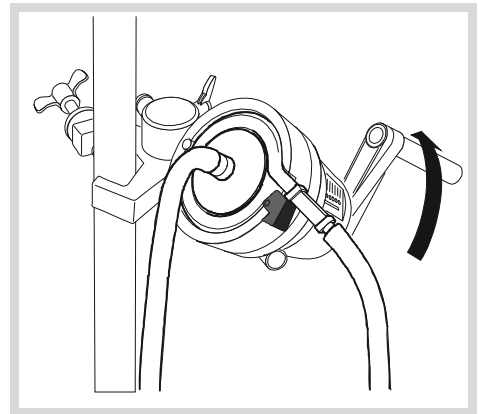
Monitoring is performed by the internal bubble sensor of the ROTAFLOW Drive and a level sensor, which is connected to the ROTAFLOW Console.

In “STAND AL” mode the pressure is not monitored.

5.5 USING EMERGENCY DRIVE

A ROTAFLOW System can be easily replaced with a spare ROTAFLOW System. In emergencies, the ROTAFLOW Centrifugal Pump can be operated manually with the ROTAFLOW Emergency Drive.

- 1 Close the arterial and the venous tube clamp.
- 2 Remove the ROTAFLOW Centrifugal Pump from the ROTAFLOW Drive. Insert it in the ROTAFLOW Emergency Drive.
- 3 Lift the handle and turn clockwise. The speed display shows the speed from 1500 rpm to 5000 rpm in steps of 500 rpm. Above 5000 rpm, all LEDs are lit.
- 4 When the speed is sufficiently high, open both tube clamps.



Note

Turning counterclockwise is not possible.

6 CLEANING AND DISINFECTION AFTER EACH USE

ATTENTION! Risk of damage to equipment

- Make sure that no liquids enter the ventilation slit of the ROTAFLOW Drive.
- Never flush the system with large amounts of water.
- Do not use chemical solvents (e.g., alcohol, ether or acetone).
- Do not spill anesthetics (e.g., Foram (isoflurane)).

Clean the surface of the whole system to remove any spilt blood.

If necessary, use a scrubbing sponge suitable for stainless steel and aluminum surfaces.

Standard liquid household cleaners can generally be used to clean the foils on the front panel. In case of doubt, please consult a MAQUET representative.

Open the lock on the ROTAFLOW Drive and remove all the ultrasonic contact cream with a lint-free cloth.

7 MAINTENANCE AND SERVICE

7.1 MAINTENANCE

WARNING!

Check battery capacity at least every six months.

Batteries should be replaced by MAQUET-authorized personnel:

- Every two years
- If they cannot be fully charged within 8.5 hours
- If fully charged batteries fail to operate the system for at least 30 minutes.

Disposal of batteries

Return batteries to MAQUET for environmentally friendly disposal.

Remove the ventilation slot collar of the ROTAFLOW Drive and clean the ventilation holes regularly.

Maintenance and repairs may only be performed by personnel authorized by MAQUET.

7.2 SERVICE

The device must be serviced at least every 1000 hours of operation or every 12 months by MAQUET or MAQUET-authorized service personnel.

Make sure that devices are returned suitably packaged to protect them from damage during transportation. Enclose a description of the problem together with the name, address and telephone number of a contact person.

8

ACCESSORIES

WARNING!

To ensure patient safety, only use tested and approved equipment, parts, accessories and disposables.

- ROTAFLOW Console
 - including ultrasonic contact cream
- ROTAFLOW Drive
- ROTAFLOW Emergency Drive
- Ultrasonic contact cream (Order no. 102 27 54)
- Capacitive level sensor
- Level sensor pads, 100 pcs.

9 MESSAGES

9.1 MESSAGES DURING SELF-TEST

Speed display	Flow display	Status display	Meaning
	EX.X		[X.X]: Software version
		RFC XXXX	[XXXX]: Operating hours since the ROTAFLOW Console's last servicing
		RFDXXXXX	[XXXX]: Operating hours since the master ROTAFLOW Drive's last servicing
		RFDS- - - -	Slave ROTAFLOW Drive not connected
-OK-	EX.X	PUMP OK	Self-test completed without errors.

9.2 ERROR MESSAGES

9.2.1 IN SPEED DISPLAY

Message	Acoustic alarm	Pump stop	Cause/Error source
←←	-	-	Recommendation to turn flow regulator to zero.
↑↑↑↑	Yes	No	Speed > upper speed limit (HLIM)
↓↓↓↓	Yes	No	Speed < lower speed limit (LLIM)
!!!!	Yes	Yes	More than one [RUN AWAY] within 20 seconds Switch off pump to clear error.

9.2.2 IN SPEED AND FLOW DISPLAYS

Message	Acoustic alarm	Pump stop	Cause/Error source
ERR OR	-	-	Error: The status display shows a further message.
LOW BAT.	Yes	No	The batteries are almost depleted. ⇒ 5.2.2 "Battery voltage during battery operation", page 40
NO SEL	Yes	Yes	Console control module in the heart-lung machine

Message	Acoustic alarm	Pump stop	Cause/Error source
RUN AWAY	Yes	Yes	Speed is more than 20% faster than the set value (above 1000 rpm). Turn the flow regulator to zero to clear the error. With continuous pumping, the reaction time is approx. 5 seconds. With pulsatile pumping, the reaction time is approx. 15 seconds (1.5 seconds above 6000 rpm).
VALVE?	-	-	Confirmation required that suitable systems or methods are available to prevent a reverse flow (⇒ 3.7 “Switch on ROTAFLOW Console, Self-test”, page 29).

9.2.3 IN FLOW DISPLAY

Message	Acoustic alarm	Pump stop	Cause/Error source
- * -			Flow meter not connected.
----	Yes	No	Invalid flow value
↑↑↑↑	–	–	Flow > 10 l/min The ROTAFLOW Console stops the pump at 12 l/min and an acoustic alarm is emitted.
↓↓↓↓	Yes	No	Flow < lower flow limit (FLIM)
????	Yes	Yes	Flow meter
DEL	Yes	Yes	Delay line of flow meter
ERR			Error: Flashes together with a further message.
RAM	Yes	Yes	Flow meter memory
SIG!	Yes	No	Error in flow measurement Replacing ultrasonic contact cream (⇒ 5.3, page 41) During longer procedures, it is possible that the ultrasonic contact cream might dry out, which can impair the results of the flow meter. The ROTAFLOW Centrifugal Pump continues to function nevertheless.
STAT	Yes	Yes	Flow meter status
TEMP	Yes	Yes	Flow meter temperature
TXRX	Yes	Yes	Transmission receiver of flow meter.

9.2.4

IN STATUS DISPLAY

Message	Acoustic alarm	Pump stop	Cause/Error source
-12VTEST	Yes	Yes	-12 V supply is out of range by more than $\pm 10\%$.
+12VTEST	Yes	Yes	+12 V supply is out of range by more than $\pm 10\%$.
+5VTEST	Yes	Yes	+5 V supply is out of range by more than $\pm 5\%$
AD-CONV	Yes	Yes	A/D converter
ARITHMET	Yes	Yes	Microcontroller
B TEMP	Yes	Yes	Temperature of battery > 60°C
BAT ERR	Yes	No	Battery charger
BAT XX.X	Yes	No	Battery operation (\Rightarrow 5.2, page 39) [XX.X]: Current battery voltage
BLOCKED	No	No	Mode occupied (during selection).
C TEMP	Yes	Yes	Temperature of electronics > 70°C
EEPROM	Yes	Yes	EPROM (programmable memory)
FATAL	Yes	Yes	Software
FAULTBUB	Yes	Yes	Bubble monitoring
FAULTLEV	Yes	Yes	Level monitoring
HEAD	Yes	Yes	Tachometer
ILL.ERR	Yes	Yes	Other error
ILL.MODE	Yes	Yes	Memory for mode
KEYSTUCK	Yes	No	Button pressed for longer than 15 seconds.
LAMPTTEST	Yes	Yes	Display
M TEMP	Yes	Yes	Temperature of ROTAFLOW Drive > 70°C
MODEBLO	Yes	Yes	Selection of mode
MODELIN	Yes	Yes	Reprogramming
MODEUSED	No	No	Mode occupied (during selection).
NO COMM.	Yes	Yes	Modes "ART" and "ART PULS": Communication error with heart-lung machine (\Rightarrow 5.1, page 39)
NOSELECT	Yes	Yes	Selection of mode
OFFSET	Yes	Yes	Offset voltage too high
RAM	Yes	Yes	Internal data memory
REFERENC	Yes	Yes	Internal voltage reference is out of range by more than $\pm 5\%$.
ROM	Yes	Yes	Internal program memory
SEL-LINE	Yes	Yes	Reprogramming

Message	Acoustic alarm	Pump stop	Cause/Error source
STOP ???	Yes	Yes	Stopped by an intervention not yet identified. Possible causes: <ul style="list-style-type: none"> ■ Communication error if monitoring system has been switched off ■ Immediately after reprogramming of ROTAFLOW Console
STOP BUB	Yes	Yes	Stopped by bubble monitoring
STOP LEV	Yes	Yes	Stopped by level monitoring
STOP PRX	Yes	Yes	Stopped by pressure monitoring [X]: Pressure monitoring 1 to 4
STOP-INP	Yes	Yes	Monitoring intervention
TEMP B↑↑↑	No	No	Temperature of battery > 50°C
TEMP C↑↑↑	No	No	Temperature of electronics > 60°C
TEMP M↑↑↑	No	No	Temperature of ROTAFLOW Drive > 50°C
UNEXPECT	Yes	Yes	Software

Notes: Temperatures

- If the temperature of the electronics exceeds 45°C, the ventilator switches to full speed.
- If the ROTAFLOW System stops because the temperature is too high, it cannot be started again until the temperature has fallen.
- No temperature messages should appear under normal operating conditions. However, if this does happen, contact MAQUET Service.

10 TECHNICAL DATA

10.1 GENERAL

10.1.1 SPEED

Range	0 ... 5000 rpm
Display resolution	1 rpm
Display accuracy	±20 rpm

10.1.2 FLOW

Range	0 ... 9.99 l/min
Display resolution	0.01 l/min
Display accuracy	<div>■ From 0 to 1 l/min: 0.07 l/min + offset drift</div> <div>■ From 1 to 9.99 l/min: 7% of current value + offset drift</div>
Offset drift	Max. 0.05 l/min
Maximum flow deviation with an error	+20%

10.1.3 AMBIENT CONDITIONS

	Operation	Storage	Transport
Temperature	+10 ... +40°C	-18 ... +45°C	-18 ... +55°C
Relative humidity (non-condensing)	15 ... 95%	10 ... 96%	10 ... 96%
Air pressure	66 ... 106 kPa	66 ... 106 kPa	66 ... 106 kPa

Note

If storage and transportation exceed 15 weeks, comply with the ambient conditions for operation.

10.2 ROTAFLOW CONSOLE

Power supply		
■ Stand-alone operation	Mains power supply	
	Line voltage (factory-set)	100/115/230/240 V AC
	Fuse	■ For 100/115 V: 2 A ■ For 230/240 V: 1 A
	Frequency	50/60 Hz
■ Operation on heart-lung machine	Power supply via heart-lung machine	
	Voltage	+24 V
	Current	Max. 8 A
Batteries	Type	NiCd
	Voltage	24 V
	Capacity	5 Ah
	Charge/discharge cycles	Min. 500
	Shelf life	Max. 6 months (under storage conditions)
Serial output interface	Transfer rate	9600 Baud
	Protocol	8 N 1
Measurements and weight	Dimensions (length × width × height)	179 × 385 × 243 mm
	Weight	Approx. 14.4 kg

10.2.1 POSSIBLE SETTINGS

Status display	Meaning	Possible values
SET MODE	Mode	ART, ART PULS, STAND AL, FREE (⇒ 4.1 “Modes”, page 31).
SET BRIG	Brightness of display	25%, 50%, 100%
SET FLIM	Lower flow limit	Off, 0.1 ... 0.9 l/min (resolution 0.1 l/min), 1.0 ... 5.0 l/min (resolution 0.5 l/min)
SET LLIM	Upper speed limit	Off, 500 ... 4500 rpm (resolution 500 rpm)
SET HLIM	Upper speed limit	Off, 3000 ... 5000 rpm (resolution 500 rpm)
SET CLAM	Not used: Automatic or manual tube clamp	

Status display	Meaning	Possible values
SET BTMP	Blood temperature (to optimize flow measurement)	15 ... 40°C (resolution 5°C)
SET S-AL	Soft alarm	On, Off (⇒ User's Manual for heart-lung machine)

10.3 ROTAFLOW DRIVE

Coupling	Magnetic
Speed	0 ... 5000 rpm
Pressure	Max. 750 mmHg
Flow meter	Ultrasonic
Bubble sensor	Ultrasonic
Pump stop	Air bubbles > 5 mm (0.065 cm ³)
Motor	Brushless, DC
Voltage	+24 V
Dimensions without holder (diameter × length)	102 × 150 mm
Holder radius of action	Approx. 470 mm
Weight	Approx. 3.2 kg

10.4 ROTAFLOW EMERGENCY DRIVE

Coupling		Magnetic
Gear		1:39
Speed display	Range	1500 ... 5000 rpm
	Resolution	500 rpm
	Accuracy	±250 rpm
Dimensions without holder	Diameter × length	102 × 270 mm
	Length (handle folded in)	185 mm
Holder radius of action		Approx. 210 mm
Weight		Approx. 2.2 kg

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