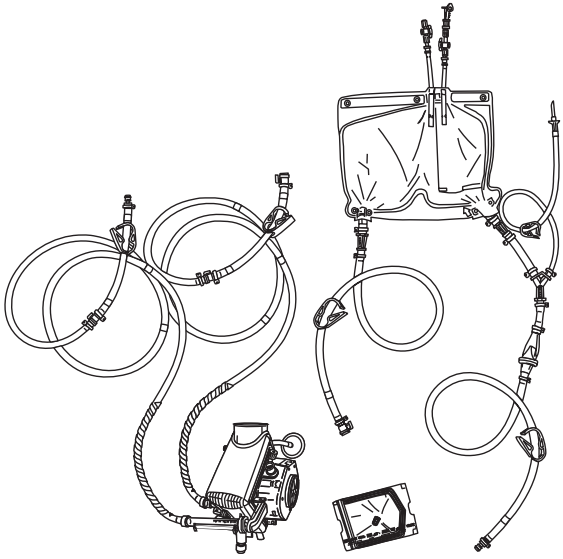

INSTRUCTIONS FOR USE

HLS Set Advanced 5.0 / 7.0

G-660
70106.9386

MAQUET
GETINGE GROUP

Table of Contents

Catalogue number

Batch code

Use-by date

Date of manufacture

Caution

Consult instructions for use

Follow instructions for use

Manufacturer

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

Packaging unit

Sterilized using ethylene oxide

Do not resterilize

Do not re-use

Do not use if package is damaged

Non-pyrogenic

Contains or presence of phthalates (DEHP)

Do not stack

Keep away from sunlight

Keep dry

Fragile, handle with care

Temperature limit

This way up

Protection against vertically falling water drops

Defibrillation-proof Type CF applied part

Clamp symbol

HLS Set Advanced 5.0 / 7.0

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1 Description

The HLS Set Advanced is used for cardiopulmonary bypass.
The HLS Set Advanced is a preconnected set and comprises the following components:

- HLS Module Advanced
- BIOLINE Coating
- Tube connections
- Priming set

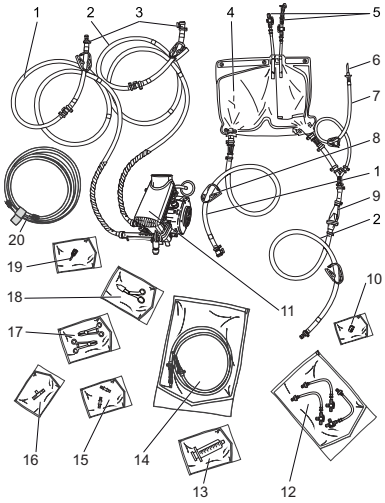
The HLS Module Advanced is a hollow fiber membrane oxygenator with diffusion membrane, heat exchanger and integrated centrifugal pump.
The centrifugal pump pumps the blood into the oxygenator. The oxygenator essentially consists of two membrane packages. The first chamber contains the plastic fibers of the heat exchanger and the oxygenation fibers arranged in crosswise mats. The second chamber contains solely mats made of oxygenation fibers.
The blood can be cooled or warmed, as required, by means of the integral heat exchanger.
The gas transfer rates are designed for treating patients within this blood flow range. If treating patients of smaller sizes, always take into account the relatively higher hemodilution due to the priming volume.
Three pressure sensors and a temperature sensor are integrated in the HLS Module Advanced. The venous measuring cell can be used to measure venous oxygen saturation, hemoglobin, hematocrit and venous temperature.
The designation HLS Set Advanced refers to all available versions, unless stated otherwise.

Version	REF	Coating	Blood flow
HLS Set Advanced 5.0	BEQ-HLS 5050-USA	BIOLINE Coating	0.5 – 5 l/min
HLS Set Advanced 7.0	BEQ-HLS 7050-USA	BIOLINE Coating	0.5 – 7 l/min

These Instructions for Use must only be used in conjunction with the following Instructions for Use:

- CARDIOHELP System
- BIOLINE Coating

The device may only be operated by trained medical staff experienced in the use of cardiopulmonary bypass.
The device is intended to be used in a surgical environment.
In emergency situations the HLS Set Advanced can be used for intra-hospital patient transport within surgical environment.
Within the specified flow rate, the device can be used for all patients irrespective of age, body weight and gender.



HLS Set Advanced

1 Blue tube line
2 Red tube line
3 Quick-action coupling
4 Priming bag
5 Luer lock line with 2-way stopcock
6 Filling spike
7 Priming line
8 Integrated tube clamps
9 One-way valve
10 Yellow protective cap (2 pcs)
11 HLS Module Advanced
12 Sampling lines with 3-way stopcock
13 Syringe
14 Emergency Priming Line
15 3/8" connectors
16 3/8" connector with Luer lock
17 Blue plastic clamps (2 pcs)
18 Scissors
19 Long protective cap for venous sampling
20 Gas tube

Not shown: Cable ties

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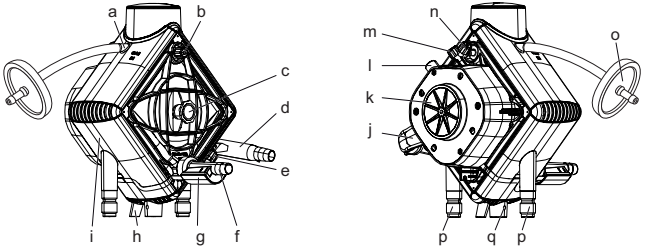

HLS Module Advanced

a Gas inlet
b "Quick Vent" Luer lock connector
c Dialysis lock with valve
d "Blood inlet" 3/8" connector with venous measuring cell
e Luer lock connector "Arterial sampling"
f "Blood outlet" 3/8" connector
g Pressure sensor (p_{Art}) and temperature sensor
h Gas outlet
i Oxygenator
j Venous blood inlet with pressure sensor (P_{Ven})
k Centrifugal pump
l Connection for integrated sensors
m "Venous sampling" Luer lock connector
n De-airing membrane with yellow protective cap
o Gas filter
p Water connector
q Safety opening

2 Indications for use

The HLS Set Advanced is a set of disposable devices (used with the CARDIOHELP System) that includes an oxygenator that provides physiologic gas exchange, a heat exchanger that allows regulation of blood temperature, and a centrifugal pump that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

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

3 Contraindication

The benefits of cardiopulmonary bypass must be weighed against the risks of systemic anticoagulation. In patients who are at risk of severe bleeding or serious coagulopathies, the risks of systemic anticoagulation may represent a contraindication.

Hemodilution caused by the priming liquid in the system must also be taken into account. The choice of priming liquid and drugs used should also take into account possible allergic reactions of patients.

Contraindications:

- The targeted use for an unlimited period of time for cardiac support ("destination therapy").
- Depending on the cannulation options and area of perfusion, vascular dissections may represent a contraindication.
- Severe aortic valve insufficiency in the case of veno-arterial circulation.

The device with BIOLINE Coating (heparin-albumin coating) must not be used with:

- Patients with known hypersensitivity to heparin (heparin allergy).

- Patients currently suffering from, or with a history of, type II antibody-related heparin-induced thrombocytopenia (HIT).

4 Warnings and Precautions

4.1 Basic Safety Instructions

- Failure to comply with the indications for use can result in serious injuries or death.
  - Only use the device in accordance with these Instructions for Use.
  - Read the Instructions for Use completely before using the device.
  - Observe all information on the device.
  - Also follow the Instructions for Use for additional components used.
- A lack of knowledge on use of the device can result in serious injuries to or death of the patient.
  - The device may only be operated and monitored by qualified medical staff.
  - The device may only be operated by staff specially trained in the field of cardiopulmonary bypass.
  - The physician in charge of treatment is responsible for the procedure and correct use of the device.
- Modifications to the device can result in serious injuries to or death of the patient.
  - Do not modify the device.
- Resterilization can damage the device. In addition, electrical safety can be compromised due to insufficient insulation. This can lead to inadequate patient support, an electric shock, an undesired increase in the device's temperature and infection of the patient, user and third parties.
  - Do not resterilize the device.
  - Do not use resterilized devices.
- Stacking the HLS Set Advanced in its primary packaging can damage the sterile barrier.
  - Do not stack sets on top of each other in their primary packaging.
- Missing protective caps can result in loss of device sterility. This can lead to infections in the patient.
  - Immediately after opening the sterile packaging, check that all connectors have protective caps.
  - Do not use the device unless all connectors are protected by protective caps.
  - Only remove the protective caps immediately before use.
- Note for use on children and expectant or breastfeeding mothers: The device or parts of the device which come into contact with blood or tissue contain DEHP. Based on the current state of knowledge, the risk to patients from DEHP is negligible as the device is intended for short-term use and, as a rule, the patient is only treated once.
- Contact with solvents such as alcohol, ether, acetone, and liquid inhalation anesthetics (e.g. isoflurane, Ethrane, enflurane) can damage the device. Its functionality is no longer guaranteed and the manufacturer will not accept liability under any circumstances.
  - Do not allow solvents to come into contact with the interior or exterior of the device.

4.2 Safety Instructions for the Cardiopulmonary Bypass

- Implementing a cardiopulmonary bypass can cause the associated side effects in the patient, such as infections, hemolysis, embolisms, post-perfusion syndrome and organ damage.
  - Monitor the patient regularly for possible side effects.
- Either insufficient anticoagulation or lack of anticoagulation may cause thrombus formation within the cardiopulmonary bypass circuit which can lead to inadequate patient support, hemolysis, thrombus formation in the patient, and/or ischemia.
  - Consider the risk and the benefits of cardiopulmonary bypass against the risks of systemic anticoagulation.
  - Use anticoagulants; e.g., heparin or argatroban.

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  - Check the effect of anticoagulants at regular intervals by measuring the ACT (activated clotting time). Ensure that the ACT value does not fall below the value which is appropriate for the application.
  - Check the coagulation status of the patient's blood regularly. The protocol for coagulation management is the responsibility of the user in charge.
- The partial thromboplastin time (PTT) should be in the range from 60 to 90 seconds. An antithrombin III (AT III) value in the normal range is required for reliable anticoagulant therapy with heparin.
- Mechanical forces may act on the components during the application. Unsecured tube connections can come loose. This can lead to blood loss, embolisms and inadequate patient support.
  - Attach the tube connections correctly and securely.
  - Secure all tube connections in the tube system with two cable ties rotated 180°.
  - Secure all connections.
  - Avoid excessive tension and check the integrity and leak-tightness of the components immediately.
- If the gas pressure or the ambient pressure is higher than in the cardiopulmonary bypass circuit, gas may enter the blood. This can lead to an air embolism in the patient.
  - During perfusion and recirculation, always maintain positive pressure on the blood side.
- If possible, avoid high negative pressures in excess of -75 mmHg during perfusion in order to prevent cavitation and hemolysis. In addition, a rapid transition from a low to a high negative pressure in the venous line should be avoided.
- The administration of protamine and pro-coagulants (e.g., Factor VII, cryoprecipitate, FFP, platelets) may cause thrombus formation in the cardiopulmonary bypass circuit which can lead to inadequate patient support, hemolysis, thrombus formation in the patient, and/or ischemia.
  - Do not administer protamine and/or pro-coagulants via the cardiopulmonary bypass circuit.
  - Do not administer protamine and/or pro-coagulants until cardiopulmonary bypass has been discontinued.
- The cardiopulmonary bypass circuit must be clamped in the event of leakage and air embolisms to prevent infections, blood loss and embolisms in the patient.
  - Always keep 4 metal clamps at the ready.
  - Make sure that the metal clamps have no sharp edges.
- Do not administer cytostatic agents before or during perfusion.
- Exposure of the venous circulation to ambient air during cardiopulmonary bypass may result in air entrainment into the venous circulation (and therefore, the cardiopulmonary bypass circuit) due to the negative pressure applied by the centrifugal pump. Examples of such situations where air entrainment may occur during cardiopulmonary bypass are inadvertent opening of the venous circulation during creation of a tracheotomy, opening of a central (e.g. right atrial) access line to air, structural/vascular perforation or loose ligatures around the cannula(e).

4.3 Safety Instructions for the HLS Set Advanced

- Pump start is not possible if the flow/bubble sensor is not properly connected. This can lead to air embolisms or insufficient blood flow to the patient.
  - Note the correct direction of flow, taking the arrow into account.
  - Position the flow/bubble sensor on the arterial side.
  - Ensure that the locking device of the flow/bubble sensor has clicked into place.
- An insufficient supply of power and oxygen can lead to inadequate patient support.
  - Ensure there is a sufficient supply of medical oxygen.
  - Ensure that the batteries of the drive are fully charged.
- Centrifugal pumps are non-occlusive blood pumps. Backflow can occur if the pump stops. This can lead to inadequate patient support.
  - Avoid excessively low pump speeds.

  - If the pump stops, clamp the arterial line to prevent backflow.
- Check that the set is complete.
- Use a medical gas supply with dry air and oxygen. Do not use an air humidifier in the gas supply.
- Do not allow stasis to occur in any part of the set in order to prevent thrombus formation.
- Kinking, clamping or blockage on the blood inlet side of the HLS Module Advanced can lead to cavitation, particularly at high pump speeds. This can lead to an air embolism in the patient.
  - Avoid kinking, clamping and blockage on the blood inlet side of the HLS Module Advanced.
  - If clamping is necessary, reduce the blood flow to below 0.6 l/min.
  - If possible, deactivate the LPM mode on the CARDIOHELP-i before clamping.
  - Always clamp the arterial and venous line at the same time.

4.3.1 Safety Instructions for the Oxygenator

- Deposits on the membrane can lead to inadequate patient support.
  - Do not administer medications, substances, drugs, and/or anesthetics through the oxygenator.
  - Do not use methylene blue immediately before or during perfusion.
- Exceeding the permissible maximum values damages the oxygenator. This can lead to embolisms and inadequate patient support.
  - Observe the permissible maximum values for blood flow and gas flow as well as pressure on the blood side and on the gas side.
- The structure of the diffusion membrane is such that there is limited permeability for anesthetic gas molecules.
  - Do not use the oxygenator for the administration of volatile anesthetic gases.
- A pressure drop on the HLS Module Advanced can be a sign of reduced performance. This can lead to inadequate patient support.
  - Monitor the pressure drop by measuring the pressure upstream and downstream of the oxygenator.
  - Consider replacing the HLS Set Advanced if the pressure drop is significant.
  - Check the gas exchange rate using blood gas analyses.
  - Prepare to replace the HLS Set Advanced.
- Due to a temperature gradient between the water and the gas supply as well as the ambient conditions, condensation could form in the HLS Module Advanced during the water leak test which could lead to steam permeation.
  - Perform the water leak test before you start the gas flow with an untempered medical gas/oxygen supply.
  - Make sure that the temperature gradient between the environment and the water circuit is as small as possible.
  - Monitor the HLS Module Advanced for signs of leakage.
  - Do not use the HLS Module Advanced if there are signs of condensation.
- In the event of decrease oxygenator performance, condensate may have accumulated in the oxygenator.
  - Please check if flushing the oxygenator resolves the situation. As a note, *flushing* the oxygenator is considered momentarily increasing, then decreasing the gas flow to the previous level in an effort to evacuate any accumulated condensate.
  - Carry out oxygenator flushing only when the patient's blood gas levels permit.
  - Monitor the patient's blood gas parameters carefully during the flushing process.
  - Discontinue flushing the gas fibers if signs of hypocapnia occur.
- Avoid releasing an occlusive clamp placed on the blood outlet side of the HLS Module Advanced when the pump is operating at high speed, because sudden acceleration of the blood flow may cause negative pressure on the blood side.

- The oxygenator performance is restricted if the oxygenator operating position is incorrect or if the gas flow is obstructed. This can lead to inadequate patient support or air embolisms in the patient.
  - Only operate the oxygenator with the gas inlet at the top.
  - Do not occlude or block the gas outlet or the safety opening.
- Incorrect CARDIOHELP-i positioning can cause air permeation on the blood side of the HLS Module Advanced. This can lead to air embolisms in the patient.
  - The CARDIOHELP-i must be positioned at a level lower than the patient.
  - Secure the CARDIOHELP-i as close to the patient as possible.
- Incorrect installation of the HLS Module Advanced can lead to a device malfunction. This can endanger the patient.
  - Use the device only together with the device CARDIOHELP-i.
  - Install or remove the device only when the pump of the CARDIOHELP-i is at a standstill (0 rpm).
  - Ensure that the device is fitted onto the drive correctly and securely fixed, to eliminate the risk of magnetic decoupling between the drive and the centrifugal pump.
- Only use the Luer lock connector "Quick Vent" in emergencies. Make sure that the Luer lock connector "Quick Vent" is closed during priming and during perfusion.
- The de-airing membrane must be open throughout priming to ensure safe de-airing of the oxygenator.
  - To effectively de-air the oxygenator, remove the yellow protective cap and keep the yellow protective cap using aseptic technique.
- Negative pressure excursion inside the oxygenator can result in air entrainment through the de-airing membrane. This can lead to air embolisms in the patient.
  - Ensure that the de-airing membrane of the oxygenator is closed with the yellow protective cap during application.
- Soiled sensing surfaces can lead to incorrect measurements and, as a result, to unsuitable measures being taken. This can endanger the patient.
  - Keep the measuring cell for the venous probe on the HLS Module Advanced clean.
- Improper rinsing of the Luer lock connectors for sampling may result in coagulation and air penetration.
- To prevent hemostasis during application, regularly check the HLS Module Advanced for signs of coagulation.
- Always ensure that the patient has a sufficiently high hematocrit and volume. Substitute any losses as clinically indicated by administering red blood cell concentrates and, if necessary, physiological volume replacement solutions.

Heat exchanger

- Using hydrogen peroxide in the water circuit may affect the integrity of the heat-exchanger of the HLS Module Advanced.
  - Do not use hydrogen peroxide in the circulating water path during procedures.
- Soiled water or water with additives in the heater-cooler unit can block the fibers of the heat exchanger and reduce its performance. There is a risk of the patient overheating or suffering hypothermia.
  - Only use clean water in the water circuit.
  - Check regularly that the water used in the water circuit contains neither dirt nor particles.
  - After cleaning the heater-cooler unit, remove the cleaning agent and disinfectant used from the water circuit.
- If the water pressure at the heat exchanger inlet is too high, it may damage the oxygenator and result in water entering the blood. There is a risk of patient infection.
  - Do not exceed the water pressure of 1 bar (750 mmHg).

- High water temperatures in the heat exchanger can cause blood or neurological damage in the patient.
  - Make sure that the water temperature at the heat exchanger inlet does not exceed 37.9°C (100.2°F).
  - Make sure that the temperature gradient between the water and the blood inlet of the heat exchanger does not exceed 8°C (14.4°F).
- Temperature sensors that have not been tested and approved can lead to incorrect measured values. This can lead to arrhythmia, coagulation problems or blood damage in the patient.
  - Test the functioning of the temperature sensors before each use.
  - Only use tested and approved temperature sensors.
  - Note that the ambient temperature may lead to inaccuracies of the temperature sensor at the arterial outlet of the HLS Module Advance. (⇒ *Technical data*, page 14).
- An unnoticed change in the blood temperature can lead to cooling of the patient. This can cause hemodynamic instability, cardiac arrhythmias and/or coagulation disorders.
  - Monitor the blood temperature in accordance with your clinical protocol.
  - Regularly check the temperature setting of the heater cooler unit, the delivered water temperature and the HLS Module Advanced heat transfer.

4.3.2 Safety Instructions for Centrifugal Pump

- Leaks or scratching noises in the centrifugal pump can be a sign that it is malfunctioning. Malfunctioning can lead to inadequate patient support.
  - Always keep a replacement HLS Set Advanced at the ready.
  - Listen for scratching noises when priming the system.
  - Replace the HLS Set Advanced if you hear scratching noises.
- The centrifugal pump can create a high negative pressure on the venous side. This can lead to gas bubbles forming and increased hemolysis in the patient.
  - Avoid high speed coupled with minimal flow.
  - Monitor the negative pressure on the venous side.
- Operating the centrifugal pump without liquid may damage the rotor bearing and lead to malperformance of the pump, thereby endangering the patient.
  - Operate the centrifugal pump only when it has been primed.
- If the CARDIOHELP-i experiences a pump failure, the blood flow to the patient can be reduced or interrupted. This can lead to inadequate patient support, hemolysis, and/or thrombus formation in the patient.
  - If the CARDIOHELP-i experiences a pump failure, use the CARDIOHELP Emergency Drive.
  - Position the CARDIOHELP Emergency Drive close to the CARDIOHELP-i so that it can be switched to manual operation at any time.
  - The CARDIOHELP-i must be positioned in such a way that the hand crank of the CARDIOHELP Emergency Drive can be used at any time.
  - Always keep the CARDIOHELP Emergency Drive clean.
- Do not use the HLS Module Advanced for aspiration.
- Do not use this device in the vicinity of MRI devices.
- Exceeding the outlet pressure above the maximum operating range may compromise hemocompatibility.

4.4 Safety Instructions for Intra-hospital Patient Transport

- If the patient is repositioned or transported, there is a risk of decannulation caused by strain on the tubing and mechanical damage. This can lead to inadequate patient support.
  - Use the recommended holders and secure them close to the patient.
  - Do not carry the system in your hand during application. Use the recommended accessories to secure it to the bed.
  - Do not allow tubes or cables to hang down.

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- Ensure that there is no strain on tubes or cables.
- Avoid mechanical impacts and knocks, particularly in confined spaces, such as doorways and elevators.
- Avoid kinking tubes or cables.

- During intra-hospital patient transport, environmental influences and supply sources for the system change. This can lead to infections and inadequate patient support.
  - Take the CARDIOHELP Emergency Drive and the power supply cable for the CARDIOHELP-i with you.
  - Make sure that there is sufficient oxygen in the gas bottle and that the batteries of the CARDIOHELP-i are charged.
  - Connect a pressure reducer when using gas bottles.
  - Protect the patient, devices and system from environmental influences such as dust.

5 Product Information

5.1 Technical data

Device version	HLS Set Advanced 5.0	HLS Set Advanced 7.0
Blood flow	0.5 – 5 l/min	0.5 – 7 l/min
Gas flow	max. 10 l/min	max. 14 l/min
Recommended ratio of gas flow to blood flow	0.5:1 – 2:1	0.5:1 – 2:1
Tube size (inside diameter x wall thickness)	3/8" x 3/32" (9.53 mm x 2.38 mm)	3/8" x 3/32" (9.53 mm x 2.38 mm)
Centrifugal pump speed	0 – 5000 rpm	0 – 5000 rpm
Oxygenation membrane surface area	1.3 m^2	1.8 m^2
Heat exchanger surface area	0.3 m^2	0.4 m^2
Priming volume of the HLS Set Advanced with 2 x 2.2 m tube length	570 ml	600 ml
Priming volume of the HLS Module Advanced	240 ml	273 ml
Residual blood volume of the HLS Module Advanced	130 ml	175 ml
Sterilization method	Ethylene oxide	Ethylene oxide

Maximum permissible values	HLS Set Advanced 5.0	HLS Set Advanced 7.0
Pressure on blood side	max. 0.533 bar (400 mmHg)	max. 0.533 bar (400 mmHg)
Pressure on gas side	max. 12 mbar (9 mmHg)	max. 15 mbar (11.25 mmHg)
Water/blood temperature difference	Max. 8°C (14.4°F)	max. 8°C (14.4°F)
Water pressure (heat exchanger inlet)	max. 1 bar (750 mmHg)	max. 1 bar (750 mmHg)
Water temperature (heat exchanger inlet)	max. 41°C (105.8°F)	max. 41°C (105.8°F)

Pressure	Accuracy	Drift
Pressure range -500 ... -151 mmHg	± 7% of the measured value	
Pressure range -150 ... +249 mmHg	± 10 mmHg	
Pressure range +250 ... +900 mmHg	± 7% of the measured value	
Offset drift in the range -100 ... 400 mmHg		■ Max. ±15 mmHg in 6 hours

Temperature	
Sensor measuring range +15 ... +40°C	

Temperature		
Ambient temperature	**Blood temperature**	**Accuracy**
+20 ... +24°C	+32 ... +40°C	± 0.7°C
+15 ... +40°C	+32 ... +37°C	± 1.0°C

Connectors		**Connectors**	
Blood inlet	3/8" (9.53 mm)	Dialysis lock with valve	Pos lock
Blood outlet	3/8" (9.53 mm)	Sampling port	Luer lock
Gas inlet	1/4" (6.35 mm)	Quick Vent	Luer lock
Gas outlet	3/8" (9.53 mm)	De-airing membrane	Luer lock
Venous measuring cell	Venous probe of the CARDIOHELP-i		
Water connector	1/2" Hansen coupling		

Materials	
HLS Module Advanced:	
■ Housing	Polycarbonate (PC)
■ Oxygenation fibers	Polymethylpentene (PMP)
■ Heat exchanger fibers	Polyurethane (TPU)
■ Potting material	Polyurethane (PU)
■ Protective caps	Polyethylene (PE) Polypropylene (PP)
■ Step bearing	Polyethylene (PE)
■ Bearing ball of the centrifugal pump	Aluminium oxide
■ Integrated pressure sensors	Silicone gel / polysulfone
■ O-ring	Silicone
Tubing set:	
■ Tubing	DEHP-free polyvinyl chloride (PVC)
■ Priming bag	DEHP-containing polyvinyl chloride (PVC) Polyethylene terephthalate (PET)
■ Connectors	Polycarbonate (PC)
Packaging:	
■ Tray	Polystyrene (PS), Tyvek
■ Table set bowl	Acrylonitrile butadiene styrene (ABS)
■ Multi-unit box	Cardboard, corrugated cardboard

Further information	
The following details are given in the chapter ⇒ *Performance Data*, page 23	
O_2 transfer rates	[O2 Transfer]
CO_2 transfer rates	[CO2 Transfer]
Hydraulic performance	[Hydraulic Performance]
Pressure drop in the blood-carrying line	[Pressure Drop]
Heat exchanger performance	[Heat Exchanger Performance]
The following details are available on request:	

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Further information

- Information on possible blood cell damage
- Information about the sterilization procedure
- Information about pressure drops in the gas-carrying line
- Information about pressure drops in the blood-carrying line
- Information about materials of the blood-carrying line
- Information about material properties of the tubes and test results
- Information about test methods for determining covering and leaching

5.2 Accessories

Permitted accessories	
Holder for priming bag	HKH 8870

5.3 Packaging and Storage

The device is delivered sterile and pyrogen-free. Sterility remains assured as long as the packaging is not opened or damaged and the use-by date has not expired. Before use, the device must be kept in a cool, dark and dry place at a thermostatically maintained storage temperature of +15°C ... +25°C (+59°F ... +77°F). Deviations of up to +30°C (+86°F) which can occur in pharmacies, hospitals or storage facilities are permitted. Transient temperature peaks of up to +40°C (+104°F) are permitted, as long as the average kinetic temperature does not exceed +25°C (+77°F) and the peaks do not last longer than 24 hours.
If you have any questions regarding the storage temperature conditions of our devices or the calculation of the average kinetic temperature, please contact Getinge directly.

6 Application

6.1 Preparation and Installation

⚠ **WARNING!**
Damage to the device or packaging.
A non-sterile or defective device can lead to blood loss or to embolisms or infections in the patient.

- Perform a careful visual inspection of the sterile packaging before use. Pay particular attention to moisture, openings and soiling.
- Perform a careful visual inspection of the device before use. In particular, ensure there is no damage to the material, cracks, burrs or fractures.
- Only use a sterilized device.
- Do not use the device if the device itself or the sterile packaging show any signs of damage.
- Observe the use-by date on the packaging.
- Adhere to strict asepsis during setup, priming and application.

For detailed information on the handling and use of the CARDIOHELP-i, refer to the "CARDIOHELP System" Instructions for Use.

1. Carry out a function check on the CARDIOHELP-i as well as a battery check.
2. Switch the CARDIOHELP-i off.
3. Open the safety bar of the CARDIOHELP-i.
4. Plug the connectors of the pressure cable and the flow/bubble sensor into the respective slots on the CARDIOHELP-i.
5. Fix the venous probe in the stand-by position on the safety bar of the CARDIOHELP-i and connect the short connection cable to the CARDIOHELP-i.
6. Open the sterile packaging and remove the set.
7. Install the HLS Module Advanced [11] on the drive of the CARDIOHELP-i. Ensure that the HLS Module Advanced is correctly secured.
8. Check that all Luer lock connections are secure.

9 Leave the de-airing membrane [n] open.

10 Plug the cable for the integrated sensors into the connector of the HLS Module Advanced [l]. Bear in mind that the connection can only be made in one position.

11 Close the safety bar.

12 Place the table set bowl on the CARDIOHELP-i horizontally.

WARNING! The flow/bubble sensor must always be affixed on the arterial side of the set if you are using the CARDIOHELP-i with the software version 3.4.0.0 or higher. With an activated intervention, the detection of bubbles by the flow/bubble sensor triggers a pump stop.

CAUTION! Fix the flow/bubble sensor so that the arrow on the sensor points in the direction of flow.

13 Fit the 3/8" flow/bubble sensor between the white marks on the red line.

14 Connect the gas tube to the gas filter [o]. Adjust the length of the gas tube to suit the individual working conditions. Use either a gas blender or the gas supply unit of the SPRINTER CART as the gas supply.

15 Hang the priming bag on an infusion pole.

16 Close the two-way stopcocks of the two Luer lock lines [5] on the priming bag.

17 Close the clamp [8] on the blue line [1] of the priming set.

18 Fill the priming bag [4] with physiological solution via the spike [6] of the priming line [7]. Use a capacity of more than 1.5 l, but not more than 2 l.

19 Close the clamp on the priming line of the priming set.

20 Make sure there is sufficient distance in height (at least 60 cm) between the upper protective frame of the CARDIOHELP-i and the lower edge of the priming bag [4].

21 Remove the sterile protection from the ends of the lines of the table set bowl and the ends of the lines of the priming set. Connect the blue line [1] of the priming set with the blue line [1] of the table set bowl. Repeat this step for the red lines.

22 Make sure that all the integrated tube clamps in the red line [2] are open.

23 Switch on the CARDIOHELP-i.

WARNING! Only use thApp “Cardiopulmonary Support”. The thApp “Circulatory Support”, “Pulmonary Support”, and “CO2 Removal” are not to be used with the current indications for use as there is not sufficient data to support the safety and effectiveness of these applications with the CARDIOHELP System. The thApp “MECC” is not to be used as there is currently no compatible disposable product available in the United States for use with the thApp “MECC”.

24 Check the charge state of both batteries.

25 Select the thApp "Cardiopulmonary Support".

26 Activate the "Global Override" mode.

27 In the menu of one of the blood parameters, check whether the venous probe has been initialized and the mounted set has been recognized.

28 Carry out the calibration for each pressure parameter of the integrated sensors. To do this, the system must be free of liquids. For this reason, carry out the calibration before priming the set.

29 Connect the water circulation of the heater-cooler unit to the water connectors [p] on the HLS Module Advanced.

6.2 Priming the System

⚠ WARNING!

A set that is filled too early (pre-priming) can lead to widening of tubes, formation of air bubbles in the set, and air embolism in the patient.

- Only prime the set shortly before use and in accordance with the priming instructions.
- Calibration values are lost when the drive unit is switched off.

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⚠ WARNING!

Leaks and damage on the device.

Can lead to infections, blood loss and embolisms in the patient.

- Check the device for leaks during priming.
- Do not use the device if there are any leaks.
- Do not use the device if the surface of the measuring cell is damaged.

⚠ WARNING!

Missing yellow protective cap

A missing yellow protective cap during clinical application can result in leakage, infection to patient, users or third parties. Air entrainment may result and lead to air embolism.

- Close the de-airing membrane with the yellow protective cap following priming and de-airing.
- Ensure that the de-airing membrane of the oxygenator is closed with the yellow protective cap during operation.

1 Before priming the set, run water through the heat exchanger of the HLS Module Advanced [11] and check for leaks.

2 Completely open the integrated tube clamps [8] on the blue line. Wait until the set is passively primed and the flow has stopped. Ensure that the lines are not pinched or kinked.

3 Set a speed of 3000 rpm for 2 minutes.

4 Reduce the speed to 0 rpm for at least 5 seconds and reset the flow/bubble sensor.

WARNING! Do not use hard objects, as they may damage the components. This can lead to embolisms and infections in the patient.

5 Tap the tube system and the HLS Module Advanced [11] with your hand to remove any gas bubbles still present in the system.

6 Set the speed to 4000 rpm for 1 minute.

7 Reduce the speed to 0 rpm.

8 De-air all of the Luer lock connectors of the HLS Module Advanced [11].

9 If a further bubble was detected during step 6, reset the flow/bubble sensor and repeat steps 3 to 7.

10 Close the de-airing membrane with the yellow protective cap [n].

11 Clamp the red line [2] on the clamp symbol on the blood outlet side using a metal clamp.

12 Clamp the blue line [1] on the clamp symbol on the blood inlet side using a metal clamp.

13 Clamp the red line [2] downstream of the flow/bubble sensor.

14 Calibrate the flow/bubble sensor in the flow sensor menu.

15 Remove the clamp downstream of the flow/bubble sensor.

16 Deactivate the "Global Override" mode.

17 Open all of the metal clamps on the red [2] and blue [1] lines.

18 Heat up the priming solution before commencing cardiopulmonary bypass in order to avoid cardiac arrhythmias and other health risks.

19 Close all of the integrated tube clamps on the red [2] and blue [1] lines.

20 Separate the priming set from the table set bowl by disconnecting the quick-action couplings. Connect the red [2] and blue [1] lines of the table set.

6.3 Connecting to the patient

1 Open the table set bowl. The person working under sterile conditions clamps the red [2] and blue [1] tubes close to the clamp symbol using the clamps in the bowl and connects the red [2] and blue [1] lines of the table set by disconnecting the quick-action couplings. The sterile table set can now be removed from the table set bowl.

2 Cut off the quick-action couplings [3].

3 Connect the set to the cannulae air-free. Make sure that the cannulae are connected to the correct tube ends.

4 Secure the tube connections between the set and cannulae using cable ties.

6.4 Starting Perfusion

⚠ WARNING!
Cardiopulmonary bypass circuit which has not been completely de-aired.
Risk of embolisms in the patient.

- Ensure that the cardiopulmonary bypass circuit has been completely de-aired before starting the perfusion.
- Ensure that all connections, Luer lock openings and the de-airing membrane are secured and closed before you start the perfusion.
- Ensure that the components used and the corresponding system are functioning correctly before you start the perfusion.

⚠WARNING!
The priming set is only intended for priming the system in order to achieve rapid and sufficient de-airing of the HLS Set Advanced.

- Remove all of the quick-action couplings before you start perfusion. The quick-action couplings are intended exclusively for priming the set.
- Remove the priming bag and priming line before you start perfusion.

Ensure an adequate gas flow and gas-to-blood flow ratio.

- Start perfusion with a gas-to-blood flow ratio of 1:2 and an oxygen content of at least 80%.

Getinge recommends using a double purse-string suture on the venous cannula in order to prevent any air penetrating the venous line. Connect the venous catheter without any air inclusions. All ancillary components connected to the blue line must be closed to the outside air and completely air free.

WARNING! Note the correct direction of flow.

1 Connect the set, free of air, to the cannulae.

WARNING! It must not be possible for air bubbles to enter the HLS Module Advanced.

2 After the set has been connected to the patient, attach the venous bubble sensor to the blue line [1] as near to the patient as possible. Only then can the sensor be plugged into the CARDIOHELP-i.
If you plug the connector of the venous bubble sensor into the CARDIOHELP-i without having fitted the sensor to the blue tube beforehand, a bubble alarm is immediately emitted and automatic backflow prevention may be triggered. This can only be reset after the venous bubble sensor has been attached to the filled tube. Use of the bubble sensor is the responsibility of the user.

3 By means of ACT, determine whether adequate anticoagulation has been achieved.

WARNING! A temperature drop may lead to complications ranging from cardiac arrhythmias to cardiac arrest.

4 Ensure that the temperature of the heater-cooler unit is set appropriately.

5 Ensure an adequate gas mix and gas flow. At the beginning of the perfusion, Getinge recommends setting the gas-to-blood flow ratio to 1:2 and an oxygen content of at least 80%.

6 During cardiopulmonary bypass, open the clamp on the red line [2]. Note the arterial pressure value (P_{Art}). Clamp the red line [2] again. Open all clamps on the blue line [1]. Increase the speed until you reach a pressure of 10-20 mmHg above the previously noted arterial pressure (P_{Art}). Open the clamp on the red line [2]. Set the desired blood flow.

7 At the beginning of the perfusion, make sure that the resistance of the patient is overcome by using an adequate speed for the CARDIOHELP-i and avoiding a backflow.

8 Attach the venous probe, which has been successfully initialized on the safety bar, to the venous measuring cell [d]. Then check that the venous probe has been successfully calibrated and that the set used has been correctly recognized.

9 During cardiopulmonary bypass, always ensure that there is sufficient venous return and the patient's volume status is physiologically correct. The assessment of patient volume and venous return depends on the specific situation and must be carried out by the physician responsible.

10 Carry out a blood gas analysis (BGA) to test the gas transfer of the oxygenator and thereby ensure an adequate oxygen supply to the patient.

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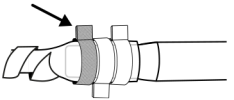
11 Negative pressure in the venous system could cause the formation of gas bubbles. If possible, avoid negative pressures below -75 mmHg.
12 Check the gas flow settings shortly after beginning of cardiopulmonary bypass. Adjust the oxygen content and the blood flow to gas flow ratio according to the measured values.
13 In the interim immediately check the gas exchange based on the color difference between the red line [2] and the blue line [1].
14 Regularly check the effect of the anticoagulant medication (e.g., by measuring the ACT or PTT).
15 If the blood flow is between 0.5 and 2.5 l/min, carry out a visual inspection for signs of coagulation in the tube system at shorter intervals. If necessary, increase the ACT or PTT values.
16 Before putting the tube clamps in place, set a blood flow of less than 0.8 l/min and always firstly clamp the red line [2] before clamping the blue line [1].
17 Deactivate the LPM mode before you place a clamp.

If cardiopulmonary bypass is temporarily interrupted, recirculation should be maintained at a minimum flow rate of 200–250 ml/min.

6.5 Performing Perfusion

Checking tube connections on the HLS Module Advanced for leaks

- If a leak occurs at the blood inlet connector [d] or the blood outlet connector [f], secure the tube connection with a third cable tie.



Blood gas analysis

⚠ **WARNING!**

Incorrect blood sampling site for blood gas analysis.

Incorrect treatment measures based on incorrect blood levels can harm the patient.

- Only use the "Sampling" connector on the "Blood outlet" connector for arterial blood gas analysis.
- Do not use the dialysis lock or the "Quick Vent" connector for blood sampling.

Possible measures based on completed blood gas analysis:	
pO_2 high	Reduce FiO_2
pO_2 low	Increase FiO_2
pCO_2 high	Increase gas flow
pCO_2 low	Reduce gas flow

1 During perfusion, regularly perform blood gas analyses.
2 Recalibrate the venous probe on the CARDIOHELP-i based on the checked venous blood gas values.
3 Increase the test intervals for the blood gas analysis in the case of significant nonconformities.

6.6 Ending Perfusion

1 Reduce the blood flow to 200 - 250 ml/min or the speed to less than 1000 rpm. Clamp the red [2] and then the blue [1] line. The blood flow, or speed, indicated depends heavily on the afterload, and may vary.
2 Adjust the gas flow and the temperature to the situation and the reduced blood flow.
3 Stop the centrifugal pump.
4 Switch off the heater-cooler unit.
5 Close the gas flow.

6.6.1 Emptying the HLS Set Advanced

- Connect an empty blood bag to the Luer lock connector of the arterial outlet [e]. The blood flows out of the HLS Module Advanced and the tube system by gravity.

7 Emergency Procedures

7.1 Using dialysis lock

⚠ **WARNING!**

If a tube is connected to the dialysis lock with valve during ongoing perfusion, air may enter the oxygenator.

This can lead to an air embolism in the patient.

- Screw the tube to the dialysis lock with a swift turn-and-press movement.
- Make sure that the tube is not clamped and the air in the tube is displaced by the blood flowing out, to prevent a pulsating backflow of air into the oxygenator.
- Make sure that the pressure in the oxygenator is higher than the ambient pressure.

7.2 Using the Emergency Priming Line

Air in the blue line [1] which has not yet reached the HLS Module Advanced can be removed retrogradely with the emergency priming line.

1. Reduce the blood flow to 0.8 l/min or the pump speed to less than 1500 rpm.
2. Clamp the red tube line [2].
3. Clamp the blue line [1] and the venous cannula in the designated clamping section proximal of the wire reinforcement.
4. Prime the emergency priming line with the help of an infusion bag or a plastic bottle.
5. Disconnect the blue tube line [1] from the venous cannula.
6. Connect the emergency priming line to the dialysis lock [c] of the HLS Module Advanced. Ensure that the connection is free of air.
7. Remove the air from the blue tube line [1] by compressing the bag of the emergency priming line. To do this, remove the clamp on the blue line [1].
   - Ensure that no air enters the patient.
   - After having displaced the air, clamp the emergency de-airing line. This prevents air from penetrating the HLS Module Advanced.
8. Now reconnect the de-aired blue line [1] to the venous cannula so that there are no longer any bubbles in the venous limb.
9. As soon as the system is free of air and the cause of the air penetration has been remedied, the clamps on the blue line [1], on the cannula and on the red line [2] can be released and cardiopulmonary bypass can be restarted.
10. Reset the venous bubble sensor if applicable.
11. Remove the emergency priming line immediately after removing the air retrogradely. To reduce the contact between metal and blood to a minimum, the emergency priming line should be removed directly after de-airing is completed.

Blood-air contact and hemostasis encourage coagulation in the tube system. Before restarting the cardiopulmonary bypass, ensure that there has been no system area thrombosis in order to prevent air embolization and thromboembolization.

7.3 Indications for Replacing the Set

Replacement of the set can be indicated in the following cases:

- Leakage
- Penetration of air
- Visible deposits in the set
- Increase in pressure drop
- Insufficient oxygenation or carbon dioxide elimination at maximum gas flow or 100% FiO_2.

As far as gas transfer and pressure increase are concerned, the decision to replace the set depends on the particular situation. The indication for replacing the HLS Set Advanced is detailed below by way of example.

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- An increased pressure drop can be tolerated within the limits stated above if the gas transfer and arterial blood gas analysis values are still good. If an increase in pressure drop is coupled with deteriorating gas transfer and there are indications that this development is set to continue, a replacement should be carried out as quickly as possible.
- Replacement is necessary if the pressure difference (ΔP) increases and the gas exchange capacity is significantly impaired.

Assessment of the situation and the decision whether or not to replace the set is the responsibility of the physician in charge of treatment.

7.4 Replacing the Set

Recommended procedure for replacing the set.

1. Prepare the replacement set.
2. Stop the water supply to the HLS Module Advanced and disconnect the water tubes.
3. Activate the "Global Override" mode.
4. Remove the venous probe and the integrated sensors from the set currently being used.
5. To perform cardiopulmonary bypass, proceed as follows:
   - If necessary, switch to RPM mode and set a flow rate of 0.6 l/min.
   - Clamp the red [2] and then the blue [1] line of the set.
   - Set the CARDIOHELP-i to 0 rpm and place the HLS Module Advanced [11] in the CARDIOHELP Emergency Drive. This pushes in the protective film on the upper latch.
   - Ensure that the HLS Module Advanced is securely fixed in the CARDIOHELP Emergency Drive.
   - Remove the venous clamp. Operate the CARDIOHELP Emergency Drive at 1500 rpm and open the arterial clamp.
   - Resume the cardiopulmonary bypass manually at the speed last used. The speed is indicated on the LED of the CARDIOHELP Emergency Drive.
   - Adjust the speed to suit the pressure and blood flow requirements of the patient.
6. Prepare the replacement set and prime it as described in the sections ⇒ *Preparation and Installation*, page 16 and ⇒ *Priming the System*, page 17.
7. When the replacement set is ready to use, stop the running set and place 2 clamps each on the red [2] and blue [1] tubes respectively, approx. 10 cm apart, near to the patient. Connect the gas supply [a] to the new set.
8. If you use the original cannulae, place an absorbent, sterile material underneath the tubes. Spray the tubes with disinfectant and cut the tubes with a sterile pair of scissors or a sterile scalpel. Watch out for escaping blood and avoid any contamination of the open tubes.
9. Attach connectors to the open tubes. Connect the red [2] and the blue [1] tube lines to the correct cannulae using the connectors. Check the direction of flow.
10. Deactivate the "Global Override" mode.
11. Start the cardiopulmonary bypass. Continue here according to the procedure described in section ⇒ *Starting Perfusion*, page 19.

8 Disposal and Service

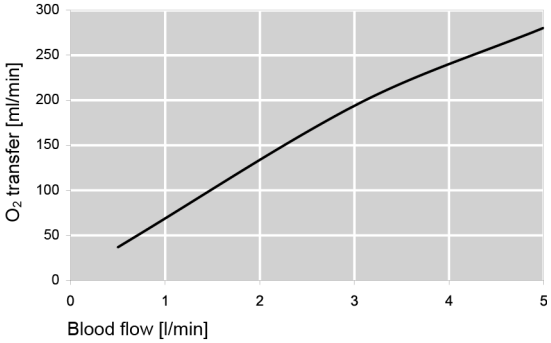
- Dispose of the device according to the applicable regulations for contaminated devices and the packaging as per the national regulations.
- If you have any questions or problems, or if you experience any malfunctions, please consult your local Getinge representative or contact Maquet Cardiopulmonary GmbH directly.

Performance Data

HLS Set Advanced 5.0

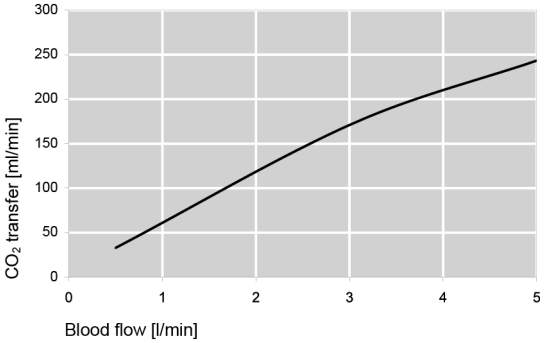
O_2 Transfer

37 °C
Gas-blood flow ratio 1:1

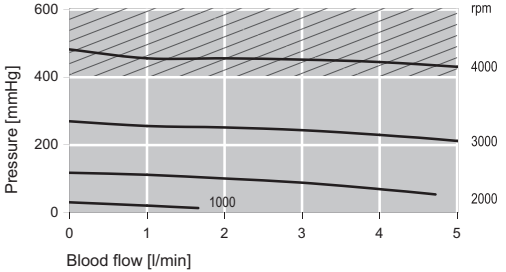


CO_2 Transfer

37 °C
Gas-blood flow ratio 1:1

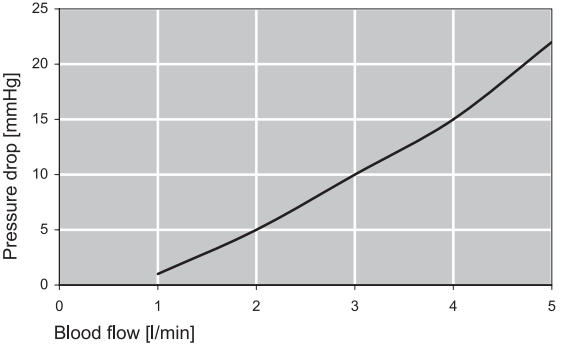


Hydraulic Performance



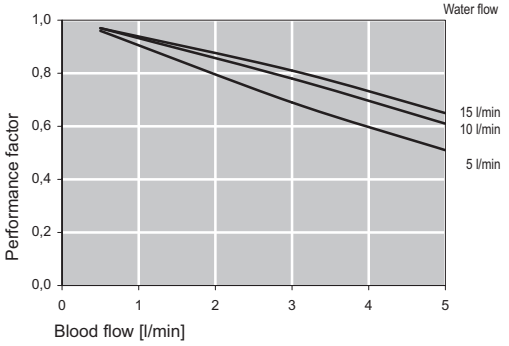
Note: The maximum permissible value is 400 mmHg (see Product Information).

Pressure Drop Oxygenator



Heat Exchanger Performance

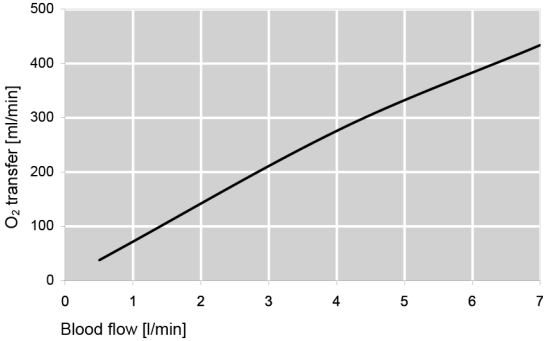
ISO 7199 Standard, 37 °C



HLS Set Advanced 7.0

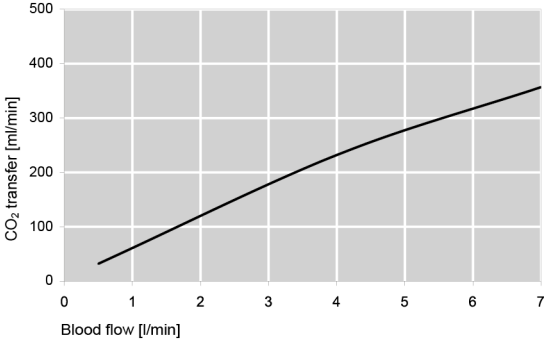
O_2 Transfer

37 °C
Gas-blood flow ratio 1:1

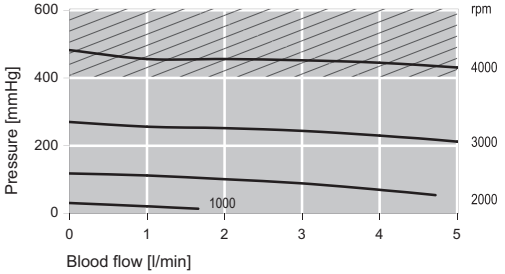


CO_2 Transfer

37 °C
Gas-blood flow ratio 1:1

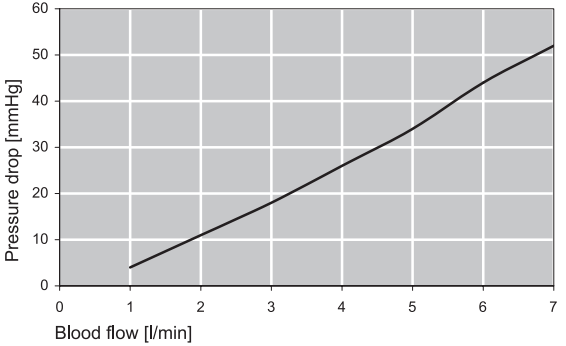


Hydraulic Performance



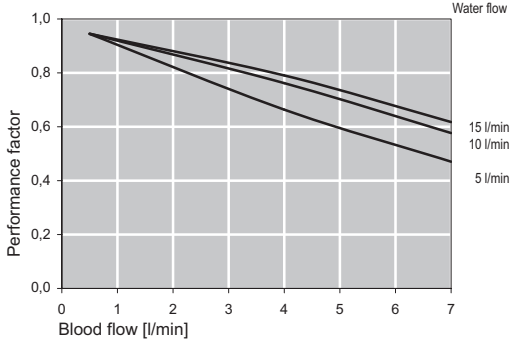
Note: The maximum permissible value is 400 mmHg (see Product Information).

Pressure Drop Oxygenator



Heat Exchanger Performance

ISO 7199 Standard, 37 °C



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