



CMO8 PMP Oxygenator

Instructions for Use

Adult



USA

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Read entire contents prior to using this device

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CMO8 Oxygenator

1.1 Product Description

The CMO8 Oxygenators are hollow fibre membrane oxygenators with integrated heat exchangers. The CMO8 Oxygenator facilitates the gas exchange and the regulation of blood temperature during Extracorporeal Life Support. CMO8 Oxygenators are a single use disposable product, which is non-toxic and non-pyrogenic. Pyrogen and Bioburden testing has been carried out to assess acceptable limits of biological contaminants. CMO8 Oxygenators are supplied with a Rheopak surface coating that reduces platelet adhesion to coated surfaces. CMO8 Oxygenators are supplied sterile.

The gas exchange section of the CMO8 PMP Oxygenators are formed from plasma tight hollow fibre membranes. Gas flow takes places through the internal lumen of the fibres. Blood in contact with the outside of the fibres allows oxygen to diffuse into the venous blood and carbon dioxide to be removed.

The heat exchanging part of the oxygenator is made of non-porous hollow fibre membranes. Water flows through the inner lumen of the fibres, so that blood temperature flowing outside is regulated.

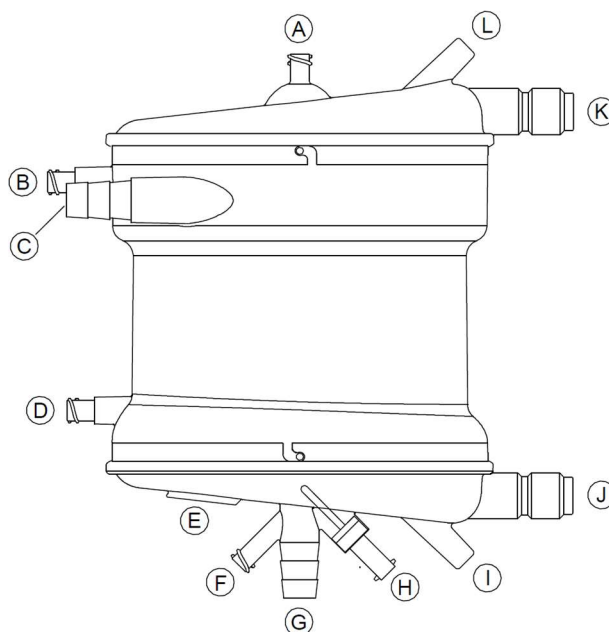
Information relating to the specifications including maximum pressure and flow rate limitations for the device is to be made available at point of use.

CAUTION:

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

2 Technical Specifications

2.1 CMO8 Oxygenator Ports



Item	Connector
A	Recirculation / Arterial Sample / Post Gas Exchanger Vent
B	Heat Exchanger Vent / Pre-Membrane Pressure
C	Blood Inlet
D	Pre-Gas Exchanger Vent
E	Pressure Relief Exhaust
F	Post Membrane Pressure / Cardioplegia Port
G	Blood Outlet
H	Temperature Adaptor
I	Gas Outlet
J	Water In
K	Water Out
L	Gas Inlet

Figure 1: CMO8 Oxygenator Port Configuration

2.2 CMO8 Oxygenator Blood, Gas and Water Flow Paths

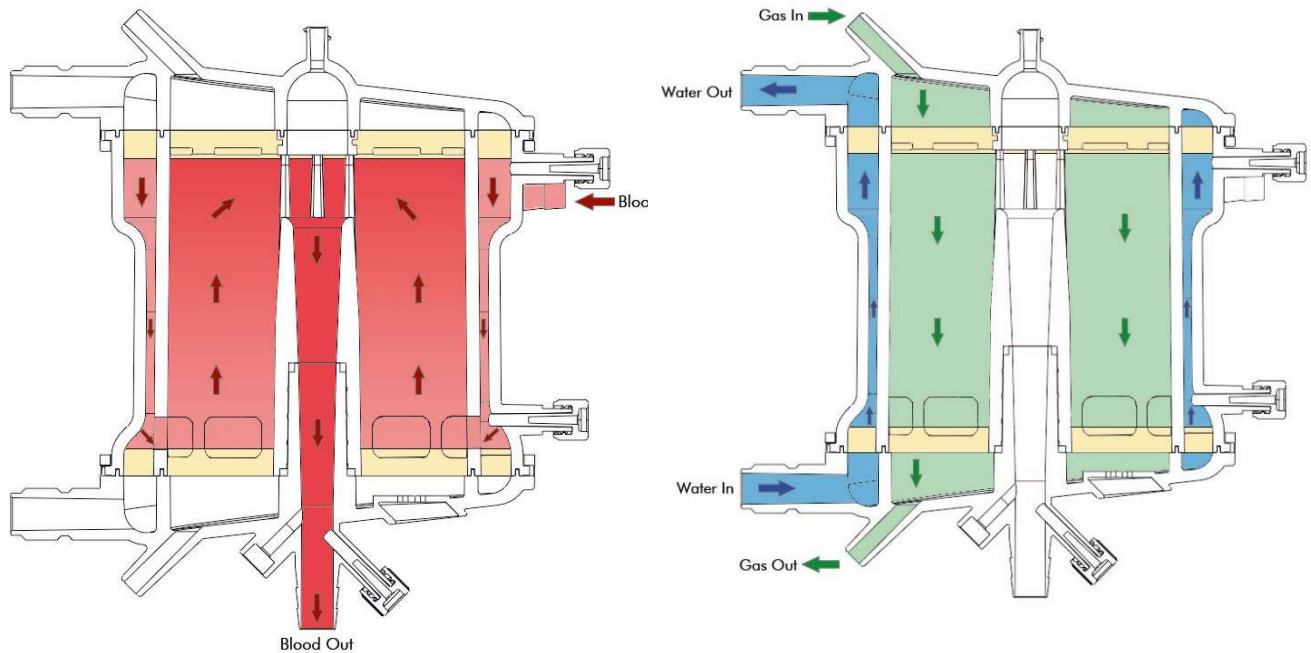


Figure 2: CMO8 Oxygenator Blood, Water and Gas Pathway

2.3 CMO8 Oxygenator Specification

CMO8 PMP Oxygenator	
Blood Flow Rate	1 – 7 l/min
Static Priming Volume	301 ml
Residual Priming Volume	93.6 ml
Gas Exchanger	
Material	Polymethylpentene
Type	Plasma Tight Hollow Fibres
Surface Area	2.47 m ²
Burst Pressure of Fibre	≥ 200kPa
Heat Exchanger	
Material	Polyester
Type	Non-Porous Hollow Fibres
Surface Area	0.27 m ²
Burst Pressure of Fibre	≥ 600kPa
Port Configurations	
Blood Inlet / Outlet	Barbed 3/8"
Gas Inlet	Non-Barbed 1/4"
Water Inlet / Outlet	3/8 Hansen Type Coupler – ISO 8637-1
Cardioplegia	Luer Lock Female – ISO 80369-7
Recirculation	Luer Lock Female – ISO 80369-7
Blood Sample (Arterial)	Luer Lock Female – ISO 80369-7
Temperature (Arterial)	Glued bayonet fitting – YSI Compatible
Pre & Post Gas Exchanger Vent	Luer Lock Female – ISO 80369-7
Heat Exchanger Vent	Luer Lock Female BS EN ISO 80369-7
Pre & Post Membrane Pressure	Luer Lock Female BS EN ISO 80369-7

2.4 CMO8 Oxygenator Performance Data

All tests have been carried out in accordance with the ISO 7199:2016+A1:2021 standard. The following data (Figures 3-6) are for information purposes only.

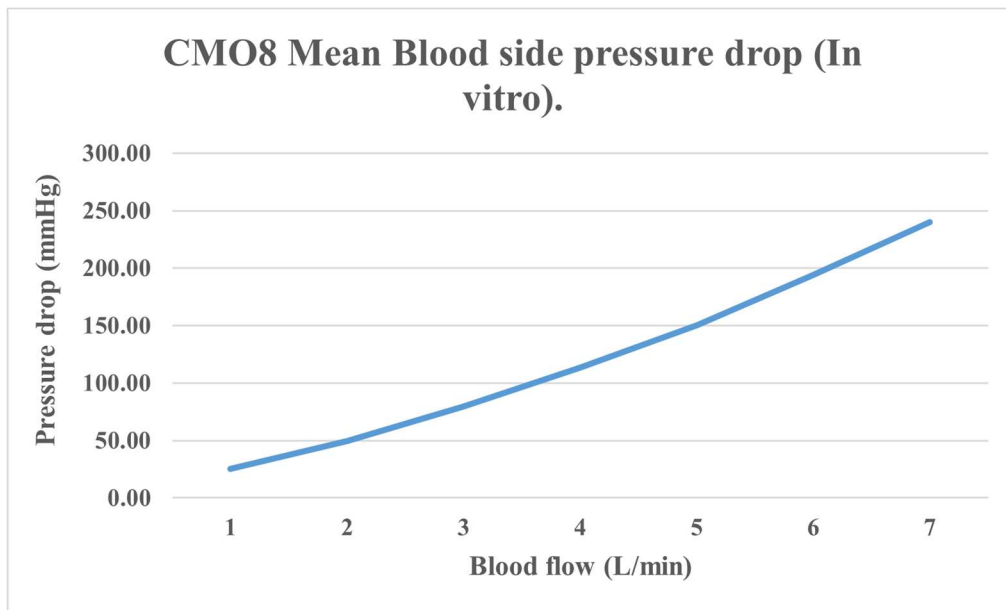


Figure 3: CMO8 Oxygenator Mean Blood Side Pressure Drop

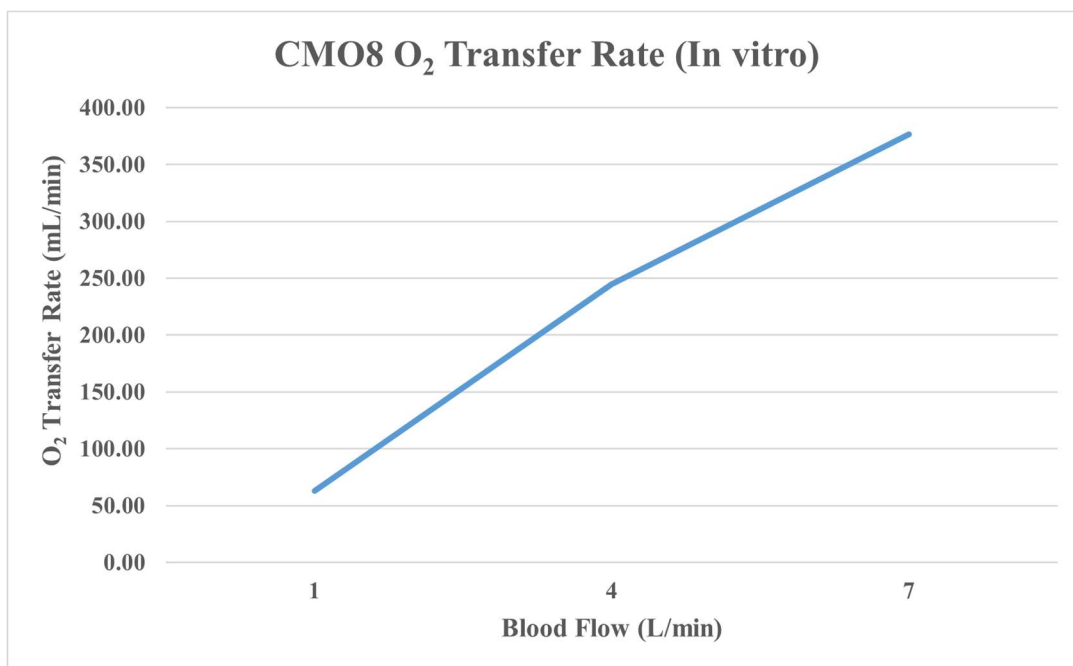


Figure 4: CMO8 Oxygenator O₂ Transfer Rate

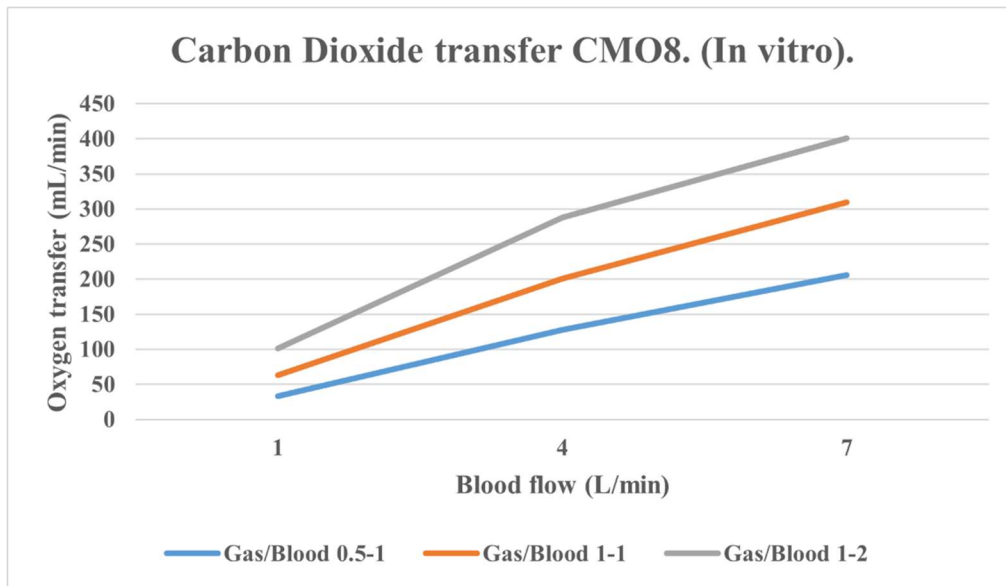


Figure 5: CMO8 CO₂ Transfer Rate

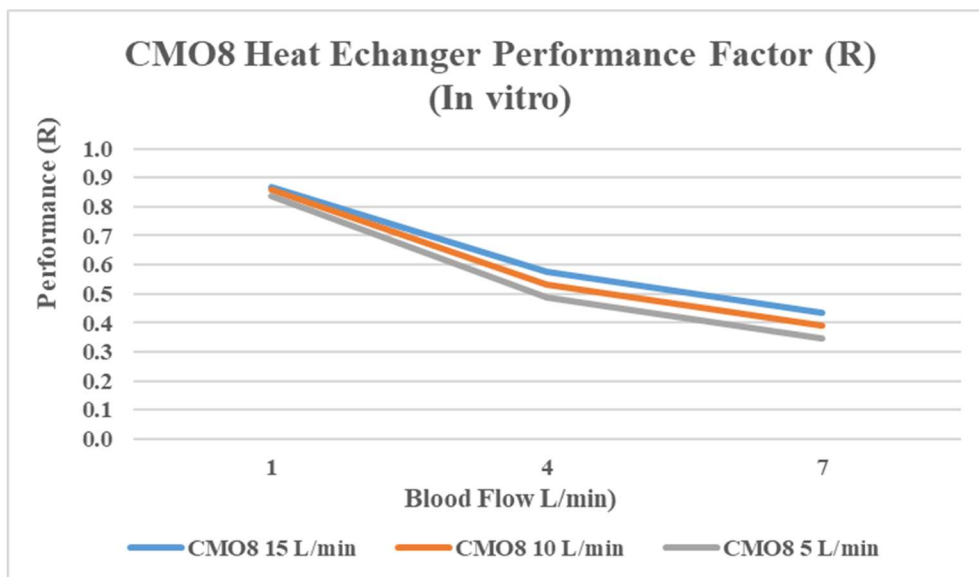


Figure 6: CMO8 Heat Exchanger Performance Factor

3 Product Information

3.1 Intended Use

The CMO8 Oxygenator is intended for use in the extracorporeal circuit during Extracorporeal Life Support procedures, lasting 6 hours or less. The CMO8 Oxygenator is a hollow fibre membrane oxygenator for application during Extracorporeal Life Support where extracorporeal oxygenation and carbon dioxide elimination is required. The integrated heat exchanger makes it possible to regulate the blood temperature.

3.2 Contra-indications

No contraindications have been raised to the present date with use as directed and by observing all indications and precautionary measures. Do not use protamine before or during extracorporeal circulation.

3.3 Duration of Use

The CMO8 Oxygenator are intended for clinical use of up to 6 hours, provided the product is used in accordance with standard operational practices for these devices and especially with respect to maintaining adequate anticoagulation.

3.4 Clinical Benefit

The CMO8 Oxygenator is designed to either provide partial support or full support for patients who require oxygenation and carbon dioxide removal from their blood that conventional ventilation or mechanical ventilation can no longer provide. The device allows for maintenance of blood temperature through the incorporated heat exchange component.

3.5 Combination Products

Compatibility, performance, connection and requirements of devices to be used in combination with the CMO8 Oxygenators with tubing pack.

Device	Performance Requirements	Connection to the Oxygenator Requirements	Connection from the Oxygenator Requirements
Continuous Flow Blood Pumps. Centrifugal	To provide blood flow range 1 – 7 l/min	Connection of tubing from the blood pump to the inlet of the Oxygenator must have tubing with an internal diameter of 3/8"	Connection of tubing from the outlet of the Oxygenator must have an internal diameter of 3/8"
Continuous Flow Blood Pumps. Roller.	To provide blood flow range 1 - 7 l/min	Connection of tubing from the blood pump to the inlet of the Oxygenator must have an internal diameter of 3/8" or 1/2"	Connection of tubing from the outlet of the Oxygenator must have an internal diameter of 3/8"
Air / Oxygen Blender	Gas flow range 2:1 blood flow	Green gas tubing	N/A
	Oxygen 21% – 100% Air		
Heater / Cooler	Water flow range 1 – 15 l/min	3/8" Hansen Type Coupler	3/8" Hansen Type Coupler
PVC Tubing	Phthalate free	With internal diameter tubing of 3/8"	With internal diameter tubing of 3/8"
Silicone Tubing			

Device	Performance Requirements	Connection to the Oxygenator Requirements	Connection from the Oxygenator Requirements
Venous & Cardiotomy Reservoir	To allow blood flow 0 – 7 L/min	Connection with tubing with internal diameter of 3/8"	Connection with tubing with internal diameter of 3/8"
Holder	Standalone CMO8 Oxygenator Holder		

3.6 Storage

The products are single packed.

Even with correct storage the oxygenator has a limited shelf life. Please pay attention to the expiry date on the oxygenator packaging. The device has to be stored in a dry, frost-free area and protected from direct solar or UV Light. Storage temperatures are detailed on the product label.

4 Warnings

Read all warnings, precautions and instructions carefully prior to use.

- Protamine must not be used on patients before or during extracorporeal circulation. This also has to be observed when restarting the Heart Lung Machine (HLM).
- Correct heparinization and exact monitoring of the anticoagulation status before, during and after bypass must be observed.
- Before and during extracorporeal circulation adequate anticoagulation must be maintained.
- Sterility of sterile oxygenators is only guaranteed if the packaging is undamaged.
- Check the expiry date prior to use (do not use if date has expired). The data and the device unique serial number should be recorded on the Perfusion Pump Chart.
- Products supplied sterile are sterilised with Ethylene Oxide.
- Do not re-sterilise the product.
- Sterile product must not be used for further production.
- Avoid any strong shocks whilst carrying or using.
- Products are for single use on one patient only (to avoid cross contamination).
- The product has to be considered a biological risk after use. Dispose of the product according to clinical and local regulations.
- It is recommended to carefully check the product before use. Function and packaging of the products could be affected during transportation. The full function of the product cannot be guaranteed when transport damage occurs. If the product has been dropped or crushed it must not be used and should be replaced with a new product. Damaged products must be notified to the manufacturer.
- The product must be used directly after the protective caps have been removed.
- All products are to be used under aseptic conditions.
- It is recommended that the device is CO₂ flushed before priming on the blood side.
- Before priming the blood phase of the unit, leave the water to re-circulate inside the heat exchanger for a minimum of 5 minutes to check that the structure of the heat exchanger is leak free and that there are no leaks from the water area. This test is necessary although the oxygenator left the manufacturing facilities in a faultless state, because the manner with which the device will be handled after despatch, cannot be known.

If any water leaks are noticed, the device must not be used clinically. The device must be replaced immediately. The manufacturer should be notified.

- Before clinical use, the device must be primed and de-aired in accordance with the departmental medical drug policy.
- Do not tap the oxygenator with tools during the priming procedure.
- The oxygenator and matching system have to be vented before starting extracorporeal circulation.
- For reasons of patient safety this product has to be continuously monitored by qualified personnel during use.
- To avoid mix-ups, all connections have to be checked before using the device.
- The products must only be used by appropriately trained and qualified personnel during clinical use.
- The manufacturer holds no responsibility for damages due to lack of experience, improper use or neglect of instructions for use.
- To assure optimal function of the oxygenator, additional devices or connections are required. Carefully read the instructions for use before using the device, ensuring that all required fittings are at hand before application.
- Do not use solvents such as alcohol, ether, acetone, liquid inhalation anaesthesia (e.g. halothan, enfluran etc) as these can damage the products.
- If the narcotic gas administration of the blood is performed through the gas exchange membrane of the oxygenator, take account of all necessary safety instructions (e.g. pay careful attention to the dosage, inlet procedure only with a suitable vapour, aspirate narcotic gas at oxygenator outlet, no contact of liquid anaesthesia within the inner and outer structure of the oxygenator etc.)
- Inhalation anaesthesia permeability through the gas exchange membrane of the CMO8 PMP oxygenator is strongly impeded when compared with oxygenators with micro porous fibres (this indication has to be considered with narcotic procedures).
- Tubes and luer lock connections must only be fixed by hand to avoid damaging the connectors. The luer lock connectors will loosen during the sterilisation process and therefore must be tightened again by hand before application.
- To avoid product damage, do not use lubricants or disinfectants etc. for tube connection.
- Measure the pressure drop across the oxygenator during the clinical use of the oxygenator.
- **Pressure on the blood side must not be higher than 750 mmHg (10^5 Pa).**
- **The water pressure at the inlet of the heat exchanger must not exceed 750 mmHg (10^5 Pa).**
- **To avoid air embolism the pressure inside the blood chamber has to be kept higher than the pressure inside the gas chamber at all times.**
- The gas outlet of the oxygenator has to be fully passable, otherwise a dangerous positive pressure may be created in the gas chamber allowing air bubbles to pass from the gas phase to the blood phase.
- To assure a permanent positive pressure onto the membrane, the outlet of the reservoir has to be placed higher than the oxygenator.
- The water temperature at the inlet of the heat exchanger must not exceed $+42^{\circ}\text{C}$.
- The maximum blood flow rate must not be exceeded.
- Once the product has been primed it should be used within hours to minimise the danger of microbiological contamination, precipitation of priming fluid etc.
- In order to avoid air bubbles entering into the blood chamber during the re-circulation process, the re-circulation line of the oxygenator must never be removed or exchanged.
- Spare products should be available at all times.

- The CMO8 PMP Oxygenator must never be positioned higher than the patient.

Note: - Any serious incident that has occurred in relation to the device, should be reported by the user to the manufacturer and the competent authority with jurisdiction in the locale in which the user is established.

5 Handling / Set up

1. Remove the products from the outer packaging and visually inspect the packaging (sterile barrier) for damage and check the expiry date. After opening, the sterility of the product is only ensured by the caps on the inlet and outlets. Carefully remove the product from the sterile packaging and check for any damages. If the packaging or product seems to be damaged, do not use. Sterile Medical Devices unintendedly opened before use or exposed to conditions outside of those specified should not be used.
- A. Hang the A.V Loop Tray at an appropriate height and secure the CMO8 Oxygenator to the holder using steps B to E.

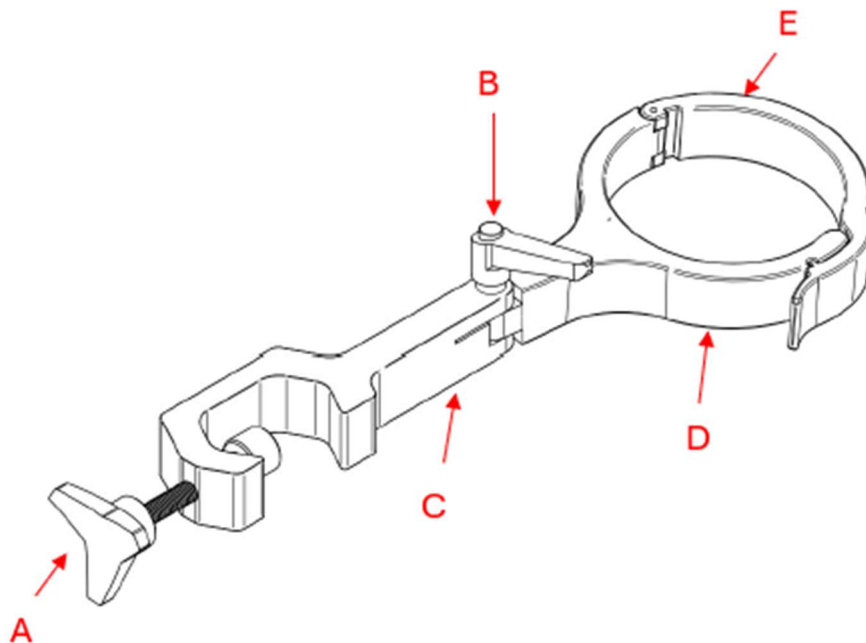


Figure 4: CMEH054: Diagram of the CMO8 Oxygenator Holder in its "open" position

- B. The star knob at the end (part A) can be rotated to move the G-Clamp in or out to accommodate the size of the pole it is to be attached to. This holder can be used on poles with a diameter from 23mm to 40mm.
- C. The lever handles (part B) can be turned to release the mechanism that joins part C & D. This will allow parts C and D to pivot to the desired position. Once the desired position has been achieved, the lever handles (part B) can be tightened to lock the position.
- D. With part E in the open position the CMO8 Oxygenator is pushed into part D.
- E. Once the Oxygenator is in position, part E is fixed into place.
- F. The process is reversed to remove the CMO8 Oxygenator from the holder.

Precaution: Only use the holders that are listed in section 8, as the holders relate

to an integral part of the system. Ensure that the device is securely fastened in the holder to assure a stable position during use. Check the holder for damages before each use.

2. It is recommended to rinse the oxygenator with CO₂ before priming. A bacterial gas filter has to be used with this application to avoid contamination of the sterile blood path with germs.
After rinsing with CO₂, the blood side of the oxygenator should be closed from the atmosphere until priming.
3. Remove the caps from the water connections on the heat exchanger, and the cap of the gas inlet connector.
4. Connect the water lines with Hansen couplings to the quick locks on the oxygenator.
5. **The water must be left to re-circulate inside the heat exchanger for a minimum of 5 minutes to check that the structure of the heat exchanger is leak free and that there are no leaks from the water area. This test is necessary even though the oxygenator left the manufacturing facility in a faultless state, because the manner with which the device will be handled after despatch, cannot be known. Leaky oxygenators must not be used and should be replaced. The manufacturer should be notified.**
6. After removing the caps, connect the venous line to the venous inlet of the venous reservoir or if using a closed system with the venous soft reservoir.
7. Connect the arterial line to the 3/8" arterial outlet of the oxygenator.
8. Connect the re-circulation port of the oxygenator with a free port on the cardiectomy reservoir (sucker port or re-circulation port).
9. Connect the cardiectomy outlet port with the inlet port of the venous soft reservoir and clamp the connection. Connect the cardiectomy suction lines to the suction ports of the reservoir.
10. Connect the tubing of the arterial pump between the outlet connector of the venous reservoir and the 3/8" inlet connector of the oxygenator.
11. Connect the gas supply line with the 1/4" gas inlet connector. Check, that the gas supply comes from a compatible air/oxygen mixer.

Warning - All connections are to be secured with suitable ties.

12. The gas outlet port ensures gas escape. The gas outlet port has a horizontal connector, which provides connection to a capnograph. The gas outlet must not be obstructed in any way.
13. Insert a suitable temperature probe into the temperature measuring point of the oxygenator and connect it to the monitoring system.
14. A suitable pressure monitoring system must be used during clinical use (for suitable connection points, see Section 2.1 Ports).

Warning - The use of a bubble trap or a filter as a bubble trap is recommended in the arterial line to avoid the risk of transmitting an air embolism to the patient.

6 Filling Procedure

1. The gas supply has to be switched off.
2. Clamp the re-circulation line.
3. Clamp the venous line with a throttle clamp.
4. Clamp the arterial line.
5. Clamp the outflow tubing just behind the outlet connector of the reservoir to minimise

- the development of air bubbles while filling with the priming solution.
6. Clamp the outlet of the venous soft reservoir.
 7. **Check again the water tubing circulation and the heat exchanger for signs of any water leaks.**
 8. Fill up the venous hardshell/cardiectomy reservoir with the priming solution through a filtered connection according to the individual hospital procedure. The filter material should then be moistened.

Indication: As soon as the priming procedure has been completed, the unfiltered luer lock for adding additional solutions can be used.

9. With a closed system remove the clamp from the outlet tube of the cardiectomy reservoir so that the fluid flows into the venous reservoir. Then vent the flexible venous reservoir by slowly opening the vent line.
10. If using a roller pump, remove the arterial pump boot from its raceway. If using a centrifugal pump, remove the pump head from the drive unit.
11. Fill the pump segment or centrifugal pump head by holding it at the same level as the venous reservoir and by slowly opening the clamp with which it is closed. The air inside the tube or the centrifugal pump head will be guided into the oxygenator by slowly bending the tube part downwards to be filled. The oxygenator will be filled by gravity.
12. Insert the pump element into the arterial pump or re-insert the centrifugal pump head into its drive unit. Remove the clamps from the arterial and venous lines, then start the arterial pump with a speed of approximately 400-800 ml/min – re-circulating via an AV loop (consisting of a pre- bypass filter or a connecting line).
13. Increase the pump flow to 4-5 l/m (please be aware of the instructions for use of the pre-bypass filter). Tap the complete AV system during this period to ease the removal of micro bubbles. Remove air from the oxygenator by using the vent line. 3-5 minutes re-circulation at a high flow rate will remove the rest of the air.
14. Make sure the vent tubing from the Oxygenator to the Reservoir is open, working and free from air.
15. Make sure the Oxygenator vent tubing is clamped off before stopping the Pump.
16. Stop the arterial pump and close the venous as well as arterial line with clamps. Remove the pre-bypass filter (if used). Re-circulate the fluid through the oxygenator after filling at a flow rate of 200-500 ml/min. Once the product has been primed it should be used within hours to minimise the danger e.g. of microbiological contamination.

Warning – The machine should only be switched on/off when the pump speed is zero. For control of the pump activity the servo speed or pressure control should be used.

7 Application of the Oxygenator System

7.1 Start of Bypass

1. Ensure that the extracorporeal system is air-free.
2. Set FiO₂ ratio to 80-100%
3. Start bypass by removing the clamp on the arterial line and slowly open the clamp on the venous line. Set the gas-to-blood flow ratio of 1:1.
4. Open the Oxygenator Vent line to the reservoir. This should remain open during the

bypass procedure in case of air emboli into the Oxygenator.

5. Carefully observe blood is returning to the venous reservoir and that the minimum operating level is maintained.

Warning - Always start the blood flow before the gas flow to the oxygenator. Never exceed a proportion of 2:1 for the gas blood flow rate.

Air may enter through the membrane into the blood chamber during abnormal conditions. This only happens when the gas pressure exceeds the blood pressure. The pressure on the blood side always has to be kept higher than on the gas side.

After a few minutes the blood gas control starts by online monitoring or by taking blood samples. Adjust the gas mixer on the basis of these values as follows: -

- * High pO_2 —————> decrease FiO_2
- * Low pO_2 —————> increase FiO_2
- * High pCO_2 —————> increase gas flow rate
- * Low pCO_2 —————> decrease gas flow rate

7.2 During Bypass

Should a higher venous backflow become necessary please observe the following instructions: -

- a) Lower the level of the reservoir
- b) Open the throttle clamp further for venous backflow.
- c) Increase the backflow via an active venous drainage (AVD).

During a temporary pause in bypass, re-circulation at a minimum flow of 200 – 250 mls should take place.

With a closed system, the level in the cardiotomy reservoir must almost be the same as or higher than the venous bag level. With the open system the level in the venous reservoir has to be at least as high as in the oxygenator at all times.

Warning - If the pulsative flow is used, it is recommended to maintain a sufficient level inside the venous reservoir.

Warning - The ACT (Activated Clotting Time) has to be 480 seconds or more at all times in order to guarantee the systemic anticoagulation in the extracorporeal circuit.

Arterial Blood Probe:

The arterial blood sample is taken through the luer connection at the blood outlet port of the oxygenator.

Venous Blood Probe (Reservoir):

The venous blood sample is taken through the venous sample port or from the port on the venous line. The application of a level sensor is recommended.

7.3 Re-circulation at a low flow rate (hypothermia at circulatory arrest)

1. Lower the gas flow rate down to an adequate level.
2. Open the re-circulation line and clamp the venous line carefully.
3. Decrease the arterial flow rate to an adequate level.

4. Clamp the arterial line.
5. During patient circulatory arrest, re-circulate at an adequate level.
6. Open the arterial and venous line to re-start normal perfusion and slowly increase the blood flow.
7. Close the re-circulation line.
8. Re-adjust the gas flow rate.

7.4 Termination of Bypass

1. Switch off the gas flow.
2. Switch off the water circulation inside the heat exchanger.
3. Slowly reduce the arterial pump flow and occlude the venous backflow.
4. Clamp off the oxygenator vent line
5. Clamp the arterial line.

Note: A minimum blood flow inside the oxygenator has to be maintained in order to re-start extracorporeal circulation. No protamine must be administered.

6. Open the re-circulation line.
7. Increase the blood flow rate up to 400—800 ml/min.

Warning - During re-circulation the blood flow rate must never exceed 800 ml/min through the vent line alone.

7.5 Air Removal from the Oxygenator

To remove air in the oxygenator, please perform the following: -

1. Switch off the gas flow.
2. Switch off the arterial pump.
3. Clamp the arterial line.
4. Clamp the venous line.
5. Vent the oxygenator into a sufficiently filled reservoir via the re-circulation line for one minute at approximately 800 ml/min.
6. Remove air from the oxygenator by opening the vent port.
7. All air has to be removed through the vent line.
8. Remove the clamps at the arterial and venous line and re-start bypass, close the re-circulation and venous vent line of the oxygenator.

7.6 Replacement of an Oxygenator

A. Preparation of the replacement Oxygenator

1. Make sure the replacement Oxygenator packaging is intact and has a current expiry date.
2. Remove the replacement Oxygenator from its packaging and inspect the replacement Oxygenator for any signs of damage. If damaged, do not use and obtain another Oxygenator.
3. Connect the replacement Oxygenator to a suitable priming circuit, ensuring all connections are secure.
4. Connect water lines from a suitable heater cooler and test the integrity of the heat exchanger.
5. Prime and de-air the replacement Oxygenator.
6. Once the replacement Oxygenator is fully de-aired, place a clamp 10cm away from the oxygenator on both the blood outlet line and the blood inlet line.

7. Place a second clamp 20cm away from the oxygenator on both the blood outlet line and the blood inlet line.
8. Cut the tubing between the two clamps on both lines, freeing the oxygenator from the priming set

B. Removal of existing Oxygenator from the cardiopulmonary bypass circuit

1. Turn off the heater cooler and remove the water lines.
2. Stop gas flow and disconnect the gas line to the Oxygenator.
3. Remove temperature probe(s).
4. Clamp off any recirculating lines and turn off the pump, stopping the blood flow to the Oxygenator.
5. Place a clamp on the arterial line to the patient approximately 50cm from the oxygenator. Place a clamp on the venous line from the patient approximately 50cm from the venous inlet to the reservoir. (Clamps referred to as Clamps A & B in steps 6 & 9 below).
6. Place a clamp on the oxygenator's blood outlet line and blood inlet line 5cm away from the oxygenator.
7. Place a second clamp on the oxygenator's blood outlet line and blood inlet line 10cm away from the oxygenator.
8. Cut the tubing between the two clamps and remove the Oxygenator from within the cardiopulmonary bypass circuit.

C. Insertion of the new Oxygenator into the circuit

1. Place the replacement Oxygenator on to the oxygenator holder and connect the gas line to the replacement Oxygenator.
2. Connect the arterial line to the patient to the blood outlet line on the oxygenator with a 3/8 x 3/8" connector.
3. Connect the venous line from the pump to the inlet line on the oxygenator with a 3/8 x 3/8" connector. Once the venous line is connected, remove both clamps from the line.
4. Check fluid level within the venous reservoir and if required add volume to bring fluid level above minimum operating level.
5. Add and reconnect all recirculating lines. Once connected, open to take blood from the blood outlet line from the oxygenator back to the venous reservoir.
6. Remove both clamps from the blood outlet of the oxygenator. **Do not remove clamps A & B on the arterial and venous lines to and from the patient.**
7. Turn the pump on and recirculate through the recirculating line(s).
8. Check the circuit including the venous and arterial lines are free of air.
9. Once checks have been made and the replacement oxygenator is free of air, remove clamps A & B on the arterial line and venous line and clamp the recirculation lines.
10. Adjust blood flow rate and the gas flow rate as required.
11. Reconnect temperature probe(s) to temperature port(s).
12. Reconnect the water lines to the heat exchanger of the replacement oxygenator and make sure that the water is circulating within the heat exchanger.

8 Fittings

These can be ordered from the manufacturer.

Product

CMO8 Standalone Oxygenator Holder

Order Code

CMEH054

9 Explanation of Symbols

Do Not Re-Use		Use By	
Date of Manufacture		Fragile handle with care	
Manufacturer		Consult Instructions for Use	
Do Not Re-Sterilise		Addition of number to determine how many products are in the packaging.	
Do No Use if Packaging is Damaged		Keep away from sunlight	
Temperature limitation		Non- Pyrogenic: Indicates a medical device which is non-pyrogenic.	
Keep dry		Serial Number	
Sterilised Using Ethylene Oxide		Catalogue Number	
Language Symbol – assigned as required		Medical Device	
Single Sterile Barrier System with Protective Packaging Outside		Lot Number/ Batch Code	
Single Sterile Barrier System		Single sterile barrier system with protective packaging inside	
Caution: Federal Law restricts this device to sale by or on the order of a licensed health care practitioner			

10 Information Available Upon Request

The following information can be supplied upon request.

- List of materials of the blood pathway
- Data related to blood cell damage and a summary of the protocol used
- Data on particle release from the oxygenator according to the manufacturer's

- quality control management system
- Relevant tolerances for data presented
- Sterilization Method
- An electronic version of this IFU in a PDF format
- Gas pathway pressure drop at the maximum blood and gas flow rates specified by the manufacturer for intended use
- Blood pathway pressure drop at the range of blood flow rates specified by the manufacturer for intended use

11 Warranty and Liability Statement

The manufacturer guarantees that the products have been manufactured, sterilised, and packaged according to Article 21 of the Code of Federal Regulations.

The manufacturer's obligation is to replace any products, which it determines were defective at the time of shipment. Faulty products must be returned for investigation. Because of factors that are out of the manufacturers control i.e. shipping, storage and handling by the user, the manufacturer cannot guarantee that a product is without faults. The manufacturer can therefore not be made liable for damages, resulting from use or misuse of the product other than as intended. The manufacturer is not liable for any damages caused by re-sterilisation or re-use of the product.

12 Further Information

All serious incidents relating to this product should be reported to Chalice Medical Ltd or Sales Representative and the Competent Authority of the Member State in which the User and/or patient is established. The report can be made by email to quality@chalicemedical.com.

A product associated with an incident must not be disposed immediately after use. If the product is to be returned for any reason, please seek prior approval from Chalice Medical Ltd. If the product is contaminated, it is the responsibility of the User to adequately prepare and label the product for return shipment. The shipping address for returns is the Manufacturer's address.

It is encouraged to electronically record the Unique Device Identifier (UDI) of products that are supplied.

Along with a physical copy of the IFU, a QR code is provided on the product packaging to allow users to obtain a PDF version of the IFU.

For further information or additional copies of the IFU, they can be obtained from enquiries@chalicemedical.com.

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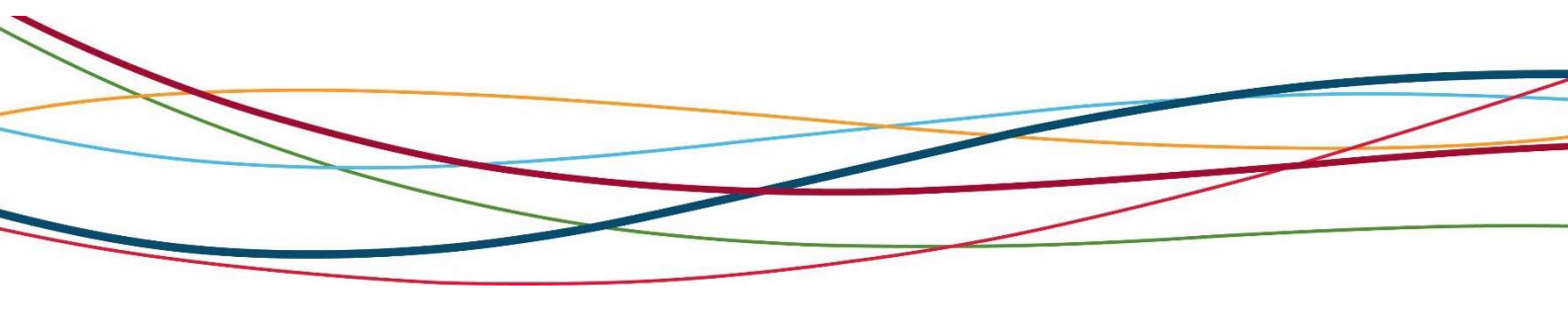


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A series of overlapping, wavy lines in various colors (red, blue, green, orange, yellow) that sweep across the bottom of the page, creating a dynamic, abstract design.