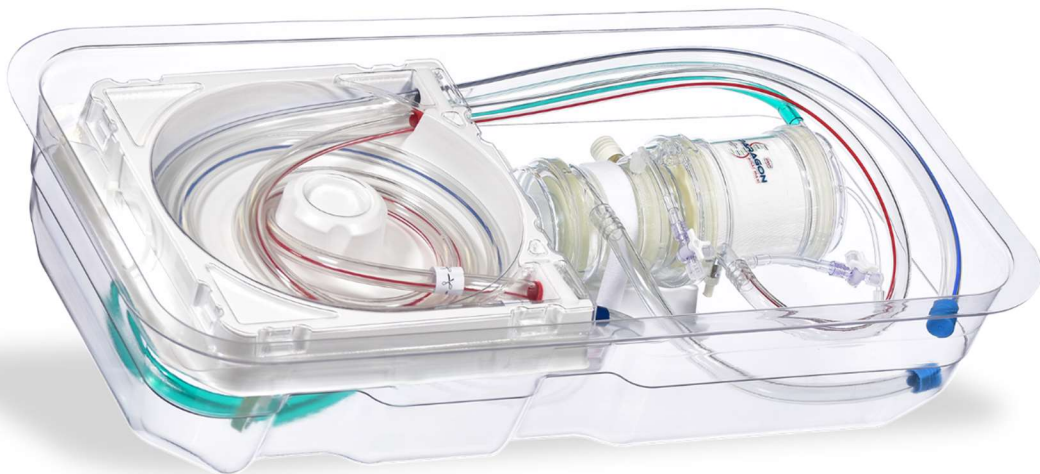




Paragon Adult Maxi PMP Oxygenator with Tubing Pack

Instructions for Use



Read entire contents prior to using this device

1	Product Description	3
1.1	Tubing Pack Product Description	3
1.2	Oxygenator Product Description	3
2	Technical Specifications	3
2.1	Paragon Oxygenator Ports	3
2.2	Paragon Oxygenator Blood, Gas, and Water Flow	4
2.3	Paragon Oxygenator Specifications	4
2.4	Paragon Oxygenator Performance Data.....	5
2.5	Tubing Specifications	7
3	Product Information	7
3.1	Adult Tubing Pack Intended Use.....	7
3.2	Patient Target Group(s).....	7
3.3	Intended Users	7
3.4	Indications for Use	7
3.5	Contra-indications	8
3.6	Duration of Use.....	8
3.7	Clinical Benefit.....	8
3.8	Combination Products.....	8
3.9	Storage.....	8
4	Warnings	8
5	Handling / Setup.....	10
6	Filling Procedure	11
7	Application of the Oxygenator System	12
7.1	Start of Bypass:.....	12
7.2	During Bypass:	12
7.3	Re-circulation at a low flow rate (hypothermia at circulatory arrest)	13
7.4	Termination of Bypass	13
7.5	Air Removal from the Oxygenator	13
7.6	Replacement of an Oxygenator	13
8	Accessories.....	14
9	Explanation of Symbols.....	14
10	Information available upon request	15
11	Warranty and Liability Statement	15
12	Further Information.....	16

1 Product Description

1.1 Tubing Pack Product Description

The Adult Tubing Pack with Paragon Adult Maxi PMP Oxygenator (hereafter referred to as “ECLS Tubing Pack”) is a component of a cardiopulmonary bypass procedure that facilitates extracorporeal circulatory support for a term of up to 6 hours.

The Adult Tubing Pack with Paragon Adult PMP Oxygenator is supplied sterile as a single use disposable product. It is non-toxic and non-pyrogenic. Pyrogen and Bioburden testing has been carried out to assess acceptable limits of biological contaminants.

1.2 Oxygenator Product Description

The Paragon Adult Maxi PMP Oxygenator (hereafter referred to as the Paragon Oxygenator(s)) is a hollow fibre membrane oxygenator with an integrated heat exchanger. The Paragon Oxygenator facilitates the gas exchange and the regulation of blood temperature during extracorporeal life support (ECLS). Paragon Oxygenators are a single use disposable product, which are non-toxic and non-pyrogenic. Pyrogen and bioburden testing has been carried out to assess acceptable limits of biological contaminants. Paragon Oxygenators are supplied with a Rheopak surface coating that reduces platelet adhesion to coated surfaces. Paragon Oxygenators are supplied sterile.

The gas exchange section of the Paragon Oxygenator is 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.

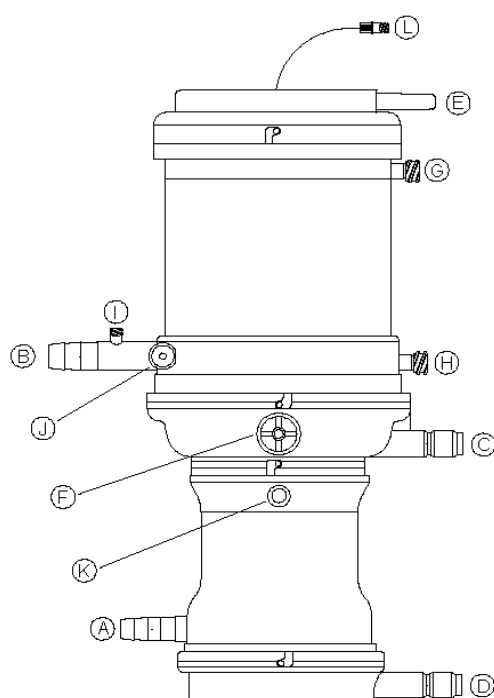
The heat exchanging component of the oxygenator is made of non-porous hollow fibre membranes. Water flows through the inner lumen of the fibres, so that blood temperature flowing outside is regulated.

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

Caution: This device must be used in conjunction with a venous reservoir (not provided in this pack)

2 Technical Specifications

2.1 Paragon Oxygenator Ports



Item	Connector
A	Blood Inlet
B	Blood Outlet
C	Water Inlet
D	Water Outlet
E	Gas Inlet
F	Gas Outlet
G	Post Gas Exchanger Vent
H	Re-Circulation / Cardioplegia
I	Arterial Sample / Post-membrane Pressure
J	Temperature Monitoring Adaptor
K	Heat Exchanger Vent / Pre-membrane Pressure
L	Pre-Gas Exchanger Vent

Figure 1: Paragon Adult Maxi PMP Oxygenator Port Configuration

2.2 Paragon Oxygenator Blood, Gas, and Water Flow

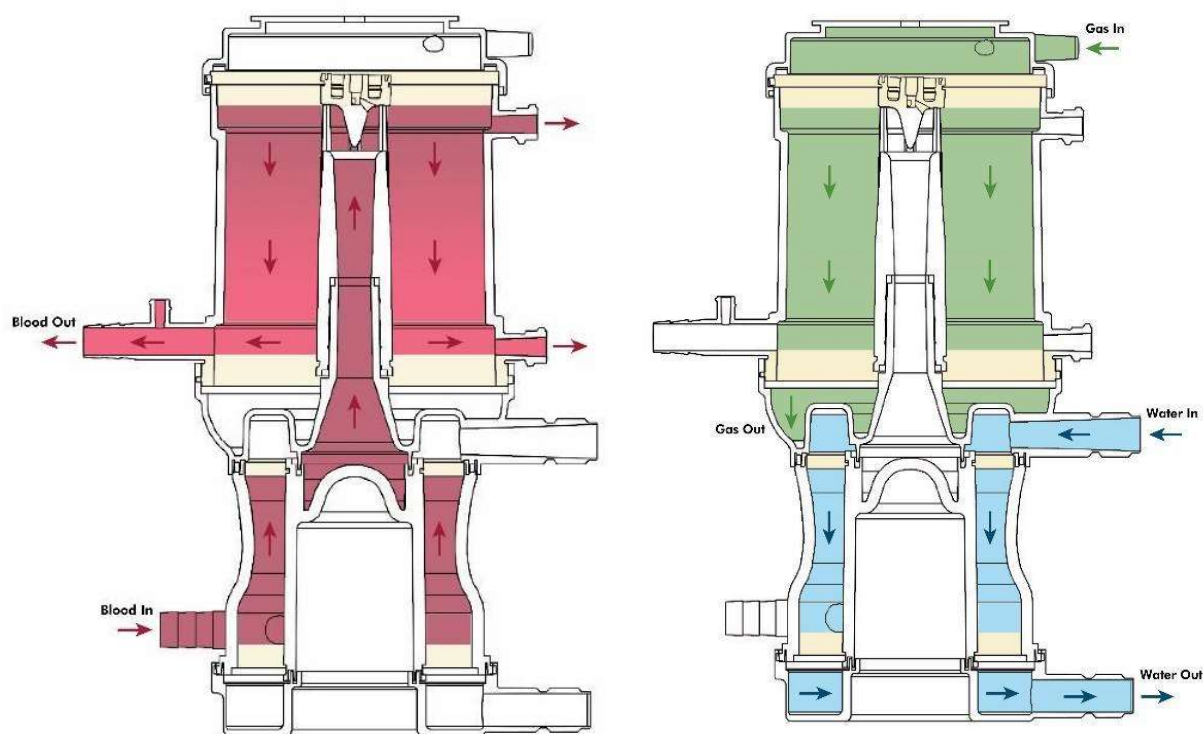


Figure 2: Paragon Adult Maxi PMP Oxygenator Blood, Water and Gas Flow

2.3 Paragon Oxygenator Specifications

Adult Maxi PMP Oxygenator	
Blood Flow Rate	2 – 8 L/min
Static Priming Volume	300 mL
Residual Priming Volume	194 mL
Gas Exchanger	
Material	Polymethylpentene
Type	Plasma-Tight Hollow Fibres
Surface Area	2.47 m ²
Burst Pressure of Fibre	≥ 200 kPa
Heat Exchanger	
Material	Polyester
Type	Non-porous Hollow Fibres
Surface Area	0.38 m ²
Burst Pressure of Fibre	≥ 600 kPa
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
Recirculation / Cardioplegia	DIN Luer Lock Female – ISO 80369-7
Blood Sample (Arterial)	Luer Lock Female – ISO 80369-7
Temperature (Arterial)	Glued
Post Gas Exchanger Vent Port	DIN Luer Lock Female – ISO 80369-7
Gas Vent / Outlet (diameter)	Non-Barbed Connection (16 mm inner, 18 mm outer)
Heat Exchanger Vent	Luer Lock Female BS EN ISO 80369-7
Pre-Gas Exchanger Vent Port	Luer Lock Female BS EN ISO 80369-7

2.4 Paragon Oxygenator Performance Data

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

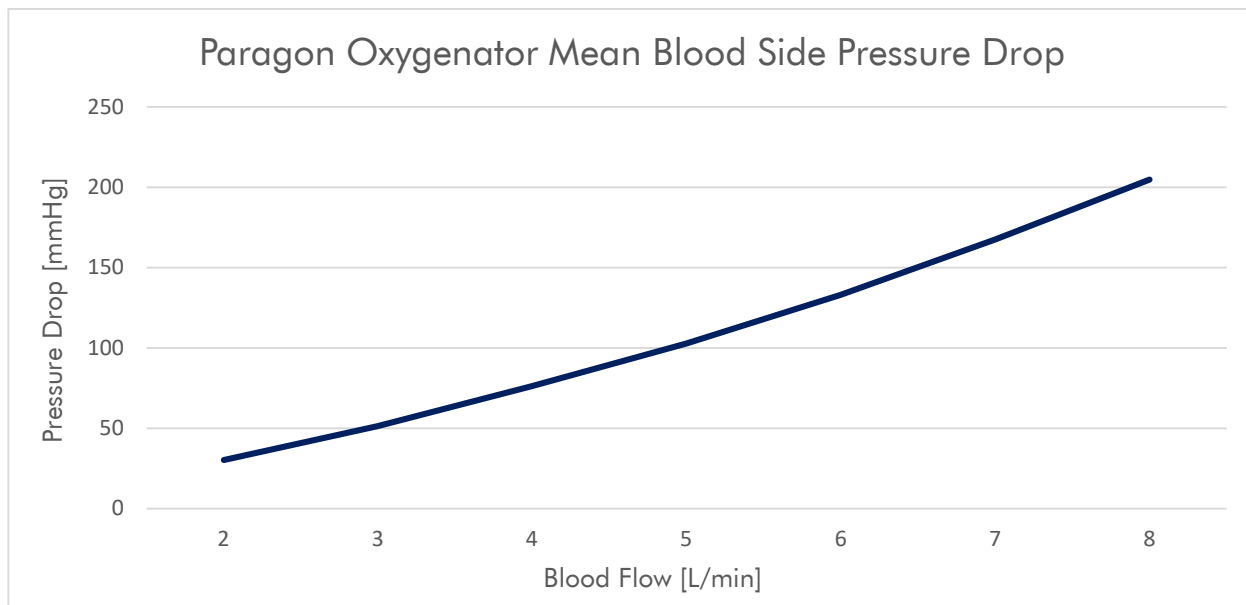


Figure 3: Paragon Oxygenator Mean Blood Side Pressure Drop

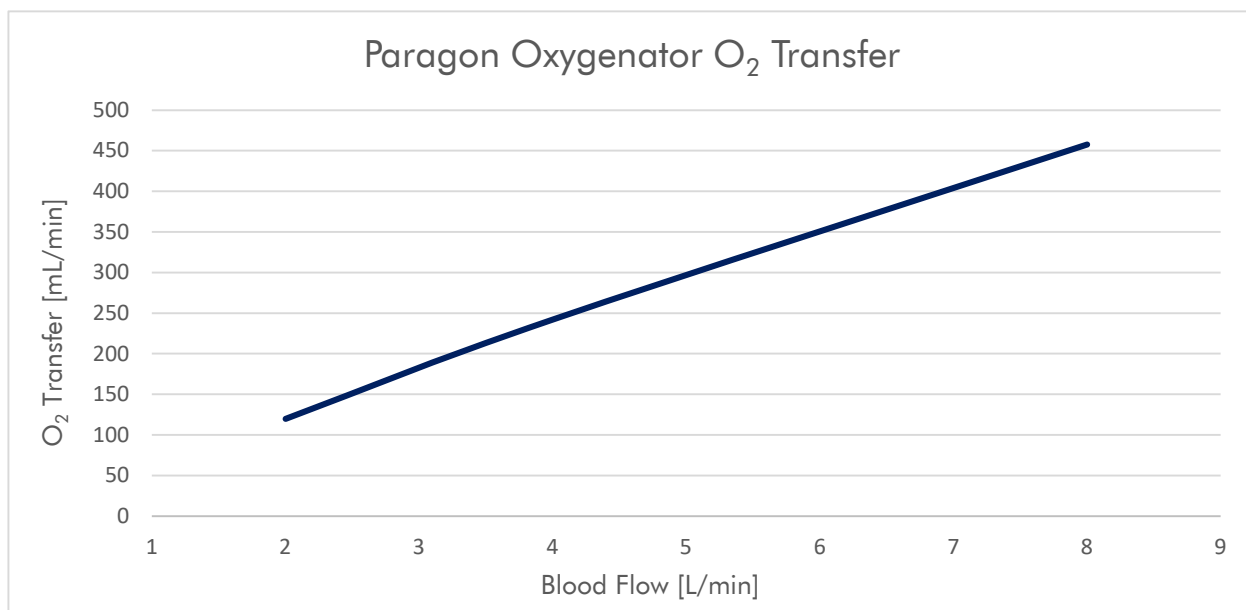


Figure 4: Paragon Oxygenator O₂ Transfer Rate

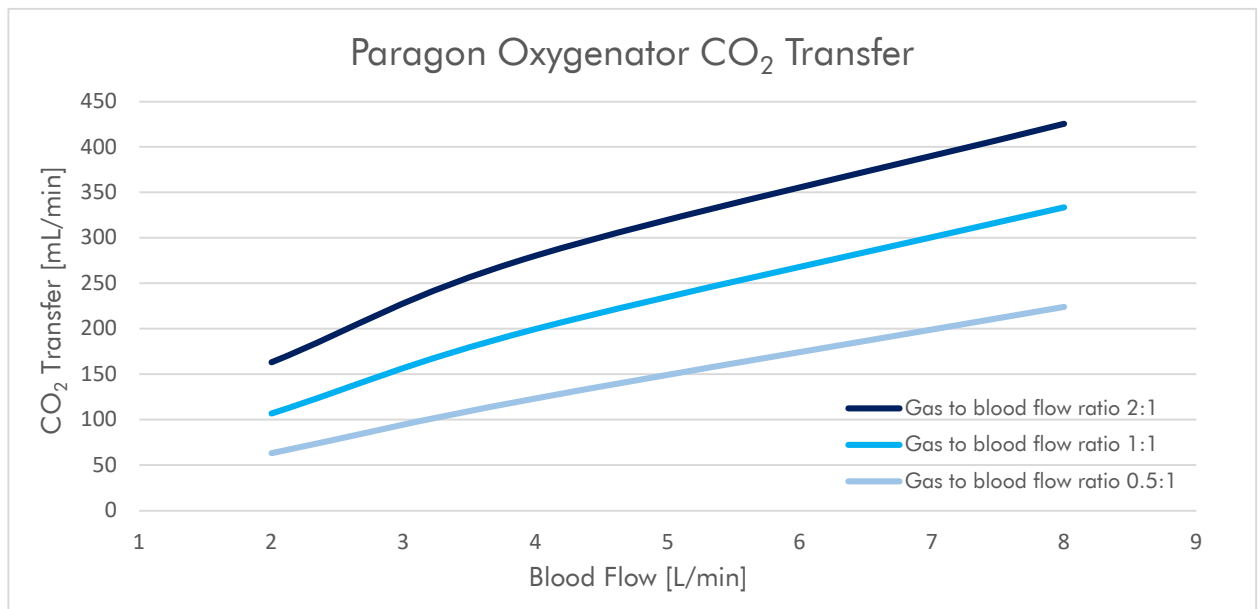


Figure 5: Paragon Maxi CO₂ Transfer Rate

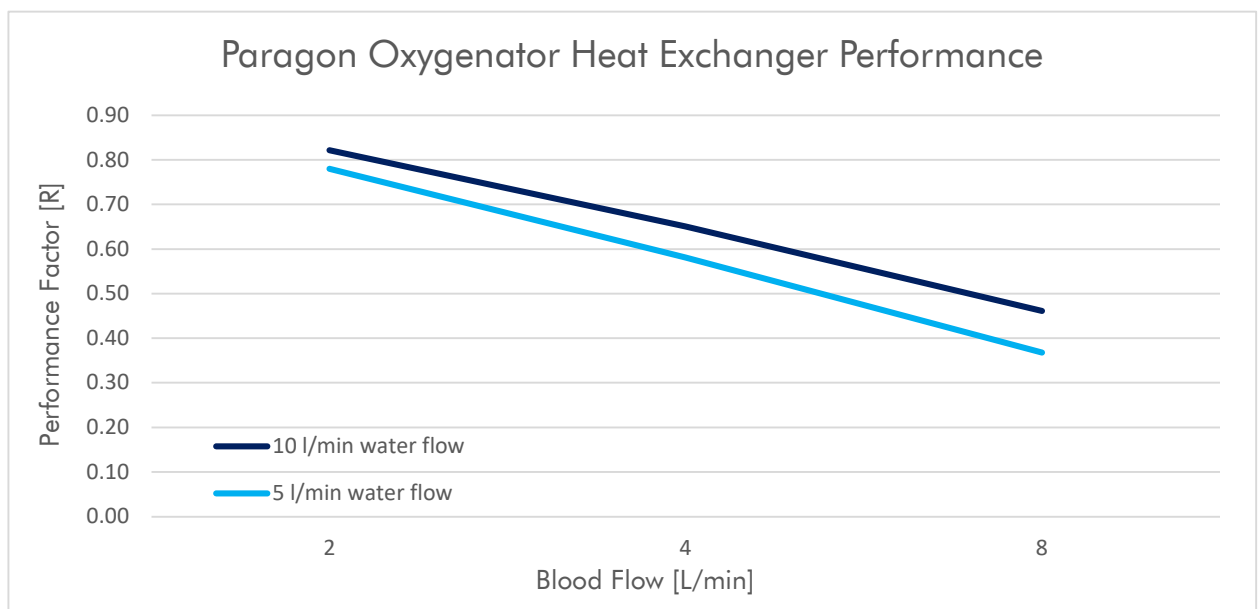


Figure 6: Paragon Maxi Heat Exchanger Performance Factor

The adult tubing pack contains the following components:

Quantity	Description
1	Red stripe PVC arterial line 215 cm
1	Blue stripe PVC venous line 205 cm
1	Green PVC Gas line with filter 200 cm
1	Paragon Adult Maxi PMP Oxygenator
1	Tubing Organiser
2	Female Luer adaptors
1	3-way tap
1	20 mL syringe
6	5 cm Sample lines
1	O ₂ cylinder connector line 10 cm

Figure 7: Adult tubing pack contents

2.5 Tubing Specifications

Tubing Specifications						
Product Code	Priming/ Blood Volume (ml)	Duration of Use/ Lifetime (Hours)	Max Pressure (mmHg)	Clinical Flow Rate Limits (L/min)	All Components Flow Rate Limits (L/min)	All Components Priming Flow Rate Limits (L/min)
CME40004	673.7452	6	750	0-8.0	0-1.4	0-1.4

Information relating to the tubing specifications detailed above is to be made available at the point of use.

3 Product Information

3.1 Adult Tubing Pack Intended Use

The Tubing Pack with Paragon Adult Maxi PMP Oxygenator is intended for use in an extracorporeal circuit during ECLS procedures lasting 6 hours or less. The Paragon Maxi is a hollow fibre membrane oxygenator intended for use in the support of adults and small adults, where extracorporeal oxygenation and carbon dioxide removal is required. The integrated heat exchanger makes it possible to regulate the blood temperature.

3.2 Patient Target Group(s)

The Paragon Adult Maxi PMP Oxygenators are intended for adult patients.

3.3 Intended Users

The Paragon Adult Maxi PMP Oxygenators are to be used by qualified, skilled personnel.

3.4 Indications for Use

The Paragon Adult Maxi PMP Oxygenator is indicated for adult patients undergoing surgical procedures requiring cardiopulmonary bypass.

3.5 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 ECLS support of patients undergoing heparin mediated anticoagulation.

3.6 Duration of Use

The ECMO Tubing Pack with Paragon Oxygenator is 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 of 450 seconds or more.

3.7 Clinical Benefit

The PMP Oxygenator is designed to provide partial or full support for patients requiring 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.

3.8 Combination Products

The ECMO Tubing Pack and Paragon Oxygenator can be used in combination with compatible heart-lung machines, heater/coolers, and their compatible tubing sets and reservoirs.

3.9 Storage

The products are single packed. Even with correct storage, the tubing pack and oxygenator have a limited shelf life. Please pay attention to the expiry date on the oxygenator packaging (YYYY-MM-DD). 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 must also 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 sterilized with ethylene oxide.
- Do not re-sterilize 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 must 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.
- 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 free from leaks. 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 must be vented before starting extracorporeal circulation.
- This instruction for use explains how to check the parts of the oxygenator and how to use them.
- For reasons of patient safety this product must be continuously monitored by qualified personnel during use.
- To avoid mix-ups, all connections must 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 may be 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., halothane, enflurane 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 Paragon PMP oxygenator is strongly impeded when compared with oxygenators with microporous fibres (this indication must 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 sterilization 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 (10⁵ Pa).**
- **The water pressure at the inlet of the heat exchanger must not exceed 750 mmHg (10⁵ Pa).**
- **To avoid air embolism the pressure inside the blood chamber must be always kept higher than the pressure inside the gas chamber.**
- The gas outlet of the oxygenator must 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 must be placed higher than the oxygenator.
- The water temperature at the inlet of the heat exchanger must not exceed +42 °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.
- To avoid air bubbles entering 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 Paragon 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 / Setup

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 caps on the inlet and outlet of tubing and connectors. 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 unintentionally opened before use or exposed to conditions outside of those specified should not be used.
2. Hang the A.V Loop Tray at an appropriate height and secure the Paragon Oxygenator to the holder (Figure 8) using steps A-D below.

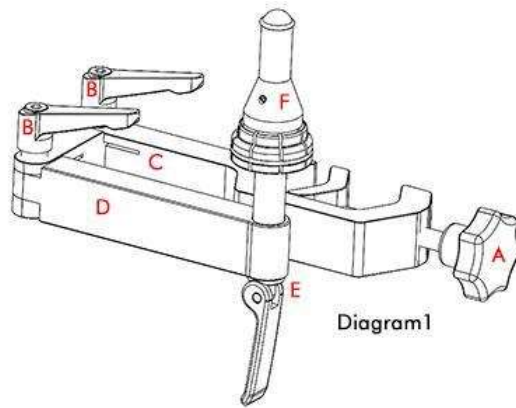


Figure 8: CMEH047: Diagram of the Paragon Oxygenator Holder in its “open” position

- A. 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 23 mm to 40 mm.
- B. The lever handles (part B) can be turned to release the mechanism that joins part C & D. This will allow parts C & D to pivot to the desired position. Once the desired position has been achieved, the lever handle (part C) can be tightened to lock the position.
- C. The lever (part E) is disengaged when it is in the position shown in Figure 8. This will allow a Paragon Oxygenator to be placed over the acetal spike (part F) and rotated to the desired orientation. Once the desired position has been achieved, the lever (part E) can be pushed up towards the main body of the holder (part D), locking the Paragon Maxi and its position to the acetal spike (part F).
- D. The process is reversed to remove the Paragon Maxi from the holder.

Precaution: Only use holders that are listed in Section 8, as the holders are 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.

3. It is recommended to rinse the oxygenator with CO₂ before priming. A bacterial gas filter must 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.
4. Remove the caps from the water connections on the heat exchanger and connect the water lines with Hansen couplings to the water inlet and outlet ports 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 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 cardiotomy reservoir (sucker port or re-circulation port).
9. Connect the cardiotomy outlet port with the inlet port of the venous soft reservoir and clamp the connection. Connect the cardiotomy 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" tubing pre-connected to the blood inlet of the Paragon Maxi.
11. Remove the protective cap on the gas line pre-connected to the oxygenator and connect to the gas supply 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 allows the 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 Paragon 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 Paragon Maxi 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 off the venous line with a throttle clamp.
4. Clamp off 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 to 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/cardiotomy reservoir with suitable priming solution through a filtered connection according to the individual hospital procedure. The filter material should then be moistened.
9. With a closed system remove the clamp from the outlet tube of the cardiotomy reservoir so that the fluid flows into the venous reservoir. Then vent the flexible venous reservoir by slowly opening the vent line. 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.
10. 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 will be guided into the oxygenator by slowly bending the tube part downwards to be filled. The oxygenator will be filled by gravity.
11. Insert the pump element into the arterial pump. 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).
12. Increase the pump flow to 4-5 L/min (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.
13. Make sure the vent tubing from the Oxygenator to the reservoir is open, working and free from air.
14. Make sure the Oxygenator vent tubing is clamped off before stopping the pump.
15. 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 FiO_2 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. 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 400-800 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 pulsatile flow is used, it is recommended to maintain a sufficient level inside the venous reservoir.

Warning - The ACT (Activated Clotting Time) has to be 450 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 the venous 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 must 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 Paragon Maxi packing is intact and has a current expiry date.
2. Remove the replacement Paragon Maxi from its packaging and inspect the replacement Paragon Maxi for any signs of damage. If damaged, do not use and obtain another Paragon Maxi.
3. Connect the replacement Paragon Maxi into 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 Paragon Maxi.
6. Once the replacement Paragon Maxi 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 the existing Paragon Maxi 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 Paragon Maxi.
3. Remove temperature probe(s).
4. Clamp off any recirculating lines and turn off the pump, stopping the blood flow to the Paragon Maxi.
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 Paragon Oxygenator from within the cardiopulmonary bypass circuit.

C. Insertion of the new Oxygenator in to the circuit

1. Place the replacement Paragon Oxygenator on to the oxygenator holder and connect the gas line to the replacement Paragon 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 Paragon Maxi oxygenator back to the venous reservoir.
6. Remove both clamps from the blood outlet of the Paragon Maxi 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 Paragon Maxi 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 Paragon Maxi heat exchanger.

8 Accessories

These can be ordered from the manufacturer.

Product

Paragon Stand Alone Oxygenator Holder

Product Code

CMEH047

9 Explanation of Symbols

Do Not Re-Use	
Date of Manufacture	
Manufacturer	
Do Not Re-Sterilise	

Use By Date: YYYY-MM-DD	
Fragile handle with care	
Consult Instructions for Use	
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		Sterilised Using Ethylene Oxide	
Keep dry		Non- Pyrogenic: Indicates a medical device which is non-pyrogenic.	
Single Sterile Barrier System with Protective Packaging Outside		Language Symbol – assigned as required	
Single Sterile Barrier System		Catalogue Number	
Single sterile barrier system with protective packaging inside		Lot Number/ Batch Code	
Medical Device		Serial Number	
Caution: Federal Law Restricts this device to sale by or on the order of a licensed health care practitioner		E-IFU Symbol	

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.
- Data on plasma leakage across any semi-permeable membrane, if applicable;
- Air-handling capability of the soft venous reservoir and summary of the protocol used.
- Antifoam characteristics of the soft venous reservoir and a summary of the protocol used;
- Break-through volume of the soft venous reservoir
- Filtration efficiency of the soft venous reservoir
- Sterilization Method.
- An electronic version of the 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 a 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. Reports can also be made to our US agent, Emergo at usagent@ul.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.

[illegible]

[illegible]

[illegible]



Chalice Medical Ltd
Manton Wood Enterprise Park,
Worksop, Nottinghamshire,
S80 2RS, United Kingdom

Telephone: +44 (0) 1909 470 777
Email: enquiries@chalicemedical.com
Website: www.chalicemedical.com

CD1102A Rev: 2 (2025/05)