Chalice Medical Ltd.

Instructions for Use

Paragon Oxygenators

English

Read entire contents prior to using this device

Contents

1 Products Covered by this Instructions For Use

This document covers all instructions required for the safe use of the Chalice Medical Ltd. products listed below.

Model	Description	Product Type
XCMOPI300MN	Paragon Adult Maxi Integrated Oxygenator with MicroNet Filter	Integrated Oxygenator
XCMOPI300PP	Paragon Adult Maxi Integrated Oxygenator	Integrated Oxygenator
XCMOPI260MN	Paragon Adult Midi Integrated Oxygenator with MicroNet Filter	Integrated Oxygenator
XCMOPI260PP	Paragon Adult Midi Integrated Oxygenator	Integrated Oxygenator
XCMOP305PMP	Paragon Adult Maxi PMP Oxygenator	Oxygenator
XCMOP265PMP	Paragon Adult Midi PMP Oxygenator	Oxygenator
XCMOPI140MN	Paragon Infant Integrated Oxygenator with MicroNet Filter	Integrated Oxygenator
XCMOPI140PP	Paragon Infant Integrated Oxygenator	Integrated Oxygenator
XCMOP145PMP	Paragon Infant PMP Oxygenator	Oxygenator
XCMOP43PMP	Paragon Neonatal PMP Oxygenator	Oxygenator

2 MicroNet, PP, PMP Oxygenators & Cardiotomy / Venous Reservoirs

2.1 Product Description

The Paragon Adult Maxi, Midi, Infant and Neonatal Oxygenators (hereafter referred to as Paragon Oxygenator(s)) are hollow fibre membrane oxygenators with integrated heat exchangers. Paragon Oxygenators facilitate 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 can also be supplied with three different gas exchanger membrane fibre variations: polymethylpentene (PMP), polypropylene (PP), and polypropylene with an internal MicroNet (MN) filter. 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 PP and MN Oxygenators are formed from microporus hollow fibre membranes. The gas exchange section of the Paragon 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.

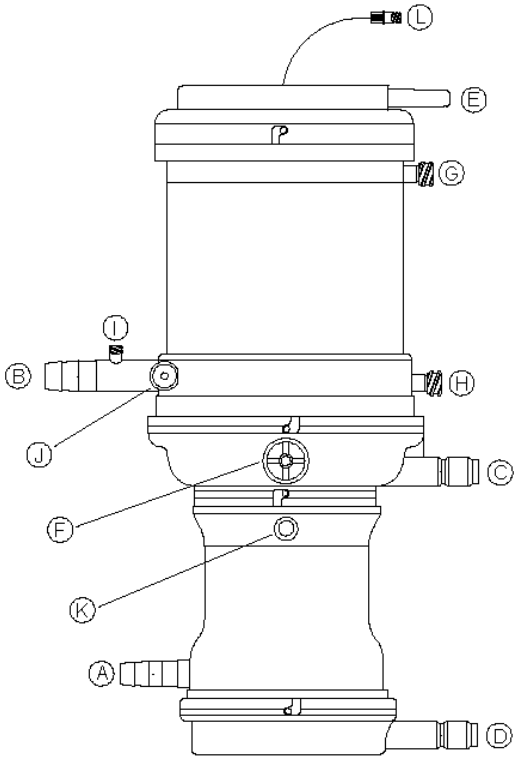
The heat exchanging part of the oxygenator is made of non-porous hollow fibre membranes. Water flows through the inner lumen of the fibres, so that blood temperature flowing outside is regulated. In the Paragon Neonatal, water flows through the outside of the fibres, so blood flowing through the internal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

The size of the oxygenator should be chosen based on the flow rates that are detailed within the specifications (Section 2.3). The flow rates are dependent on the patient's weight and size.

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

2.2 Ports & Path Flows

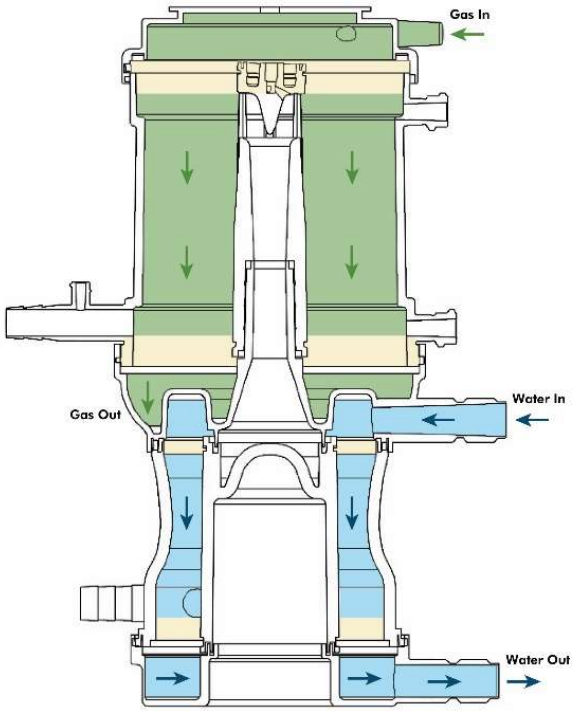
Maxi & Midi Ports



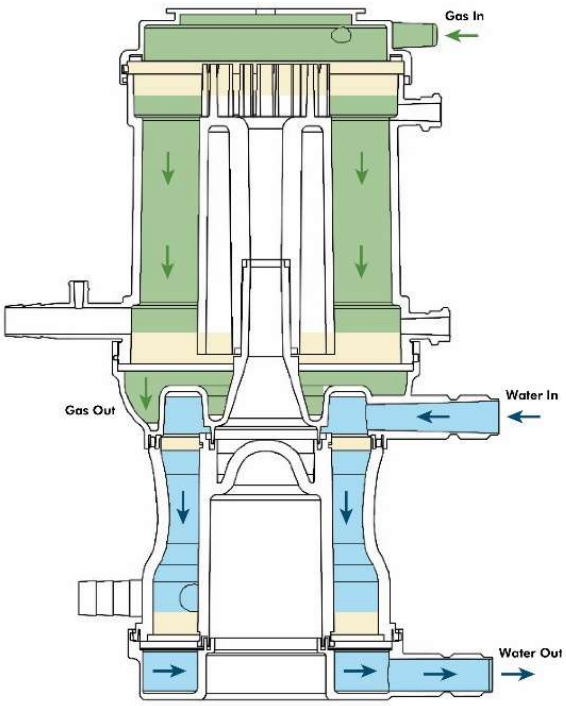
Item	Connector
A	Blood inlet
B	Blood outlet
C	Water inlet
D	Water outlet
E	Gas inlet
F	Gas outlet
G	Post gas exchanger vent
H	Re-circulation / cardioplegia
I	Luer lock arterial sample / post-membrane pressure
J	Temperature adaptor
K	Heat exchanger vent / pre-membrane pressure
L	Pre gas exchanger vent (PMP models only)

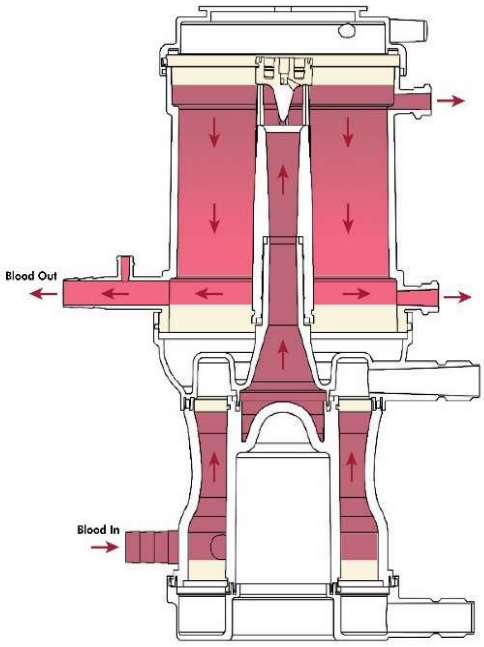
Blood, Gas, Water Flow

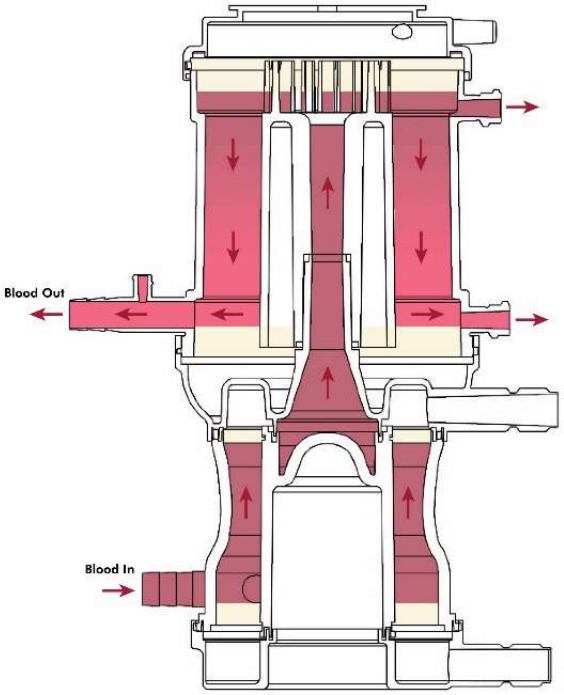
Adult Maxi



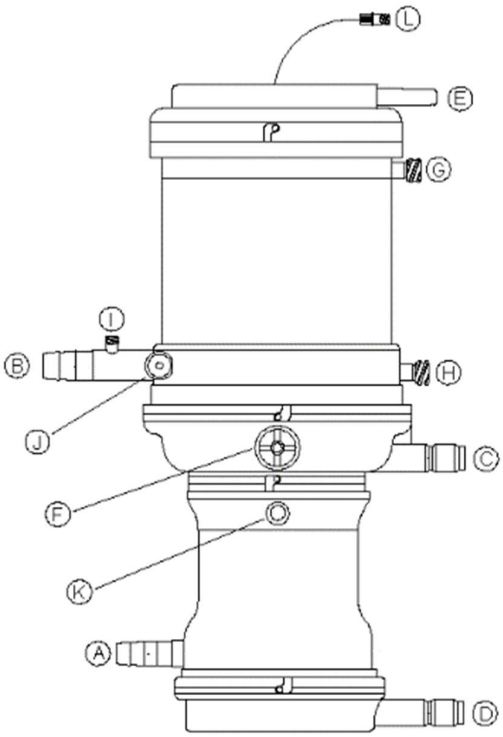
Adult Midi





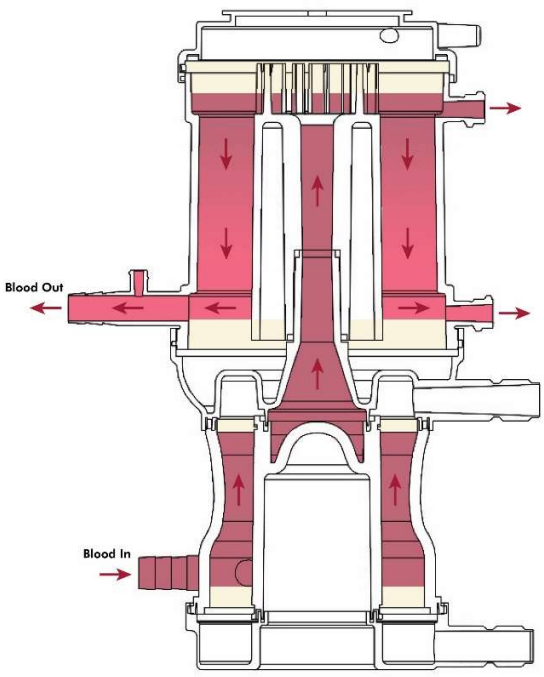


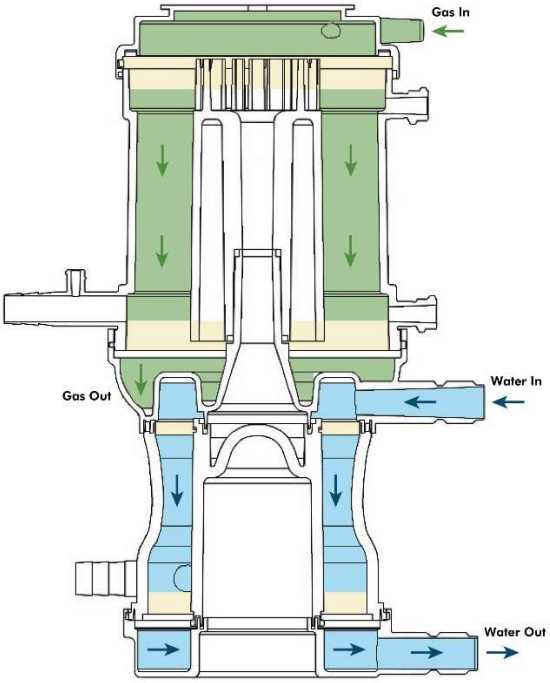
Infant Ports



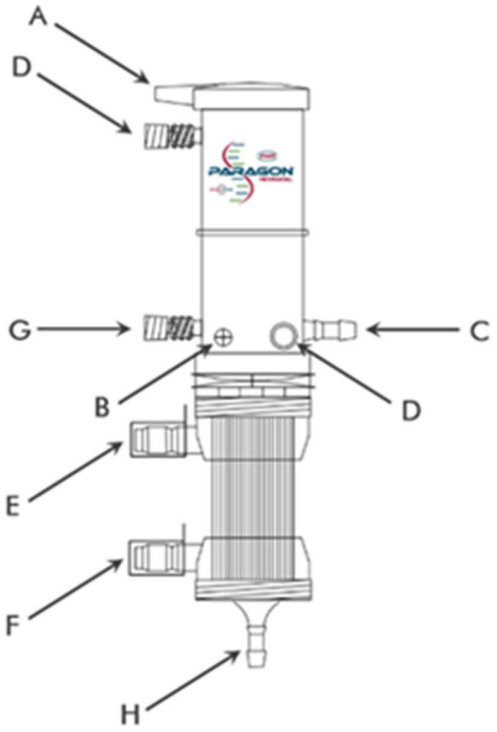
Item	Connector
A	Blood inlet
B	Blood outlet
C	Water inlet
D	Water outlet
E	Gas inlet
F	Gas outlet
G	Post gas exchanger vent
H	Re-circulation / cardioplegia
I	Luer lock arterial sample / post-membrane pressure
J	Temperature adaptor
K	Heat exchanger vent / pre-membrane pressure
L	Pre-gas exchanger vent (PMP models only)

Blood, Gas and Water flow



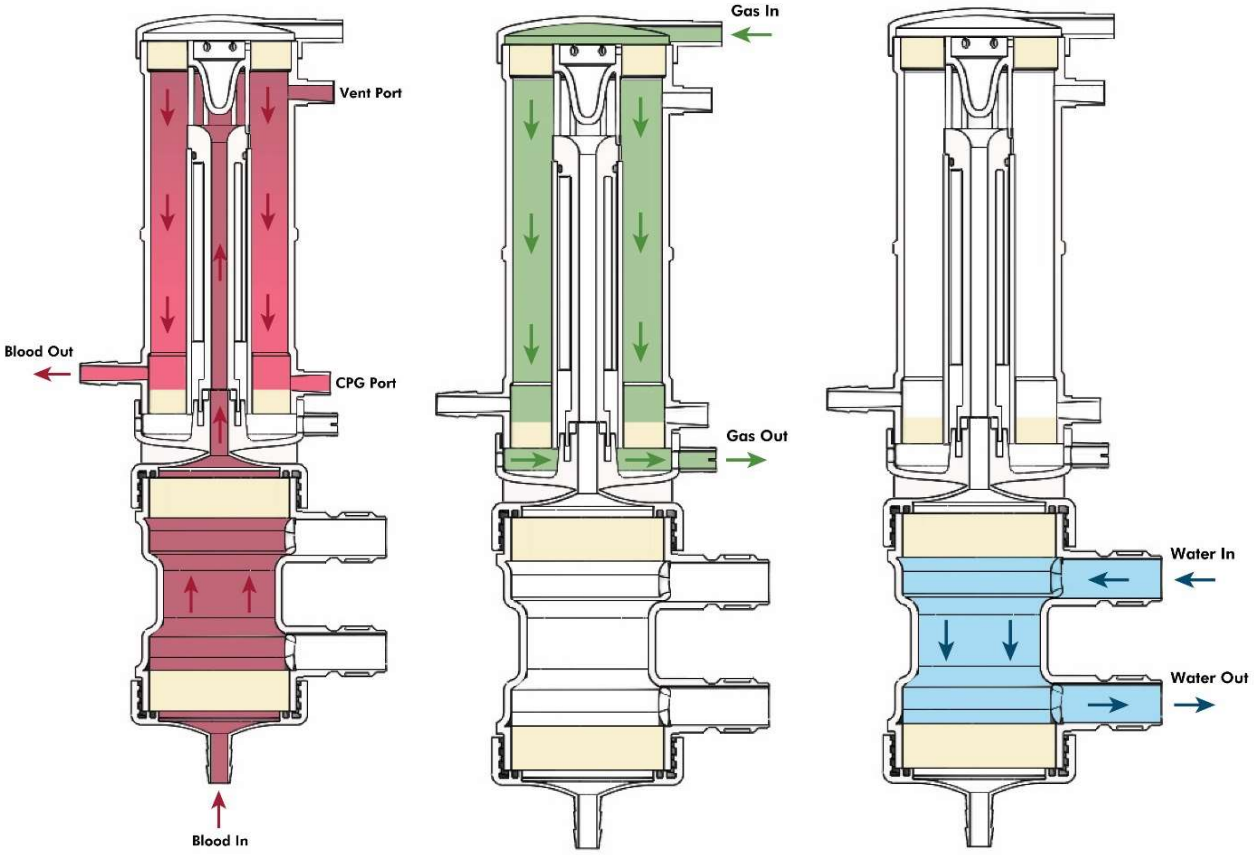


Neonatal Ports



Item	Connector
A	Gas inlet
B	Temperature adaptor
C	Blood outlet
D	Air removal / samples
E	Water inlet
F	Water outlet
G	Re-circulation / cardioplegia
H	Blood inlet

Blood, Gas and Water Flow



2.3 Specifications

	Adult Midi PMP Oxygenator	Adult Maxi PMP Oxygenator	Infant PMP Oxygenator	Neonatal PMP Oxygenator
Blood Flow Rate	1 – 7 L/min	1 – 8 L/min	0.5 – 3 L/min	0.1 – 1.4 L/min
Static Priming Volume	260 mL	300 mL	151 mL	65 mL
Residual Priming Volume	175 mL	195 mL	65 mL	23 mL
Gas Prime Volume	0.5 – 14 L/min	0.5 – 16 L/min	0.25 – 6 L/min	0.05 – 2.8 L/min
Gas Exchanger				
Material	Polymethylpentene			
Type	Plasma-tight hollow fibre			
Surface Area	1.89 m^2	2.47 m^2	0.86 m^2	0.46 m^2
Burst Pressure of Fibre	≥ 200 kPa			
Heat Exchanger				
Material	Polyester			
Type	Non-porous hollow fibre			
Surface Area	0.38 m^2		0.20 m^2	0.13 m^2
Burst Pressure of Fibre	≥ 600 kPa			
Port Configurations				
Blood Inlet, Outlet	Barbed 3/8″		Barded 1/4″	Barbed 3/16″
Gas Inlet	Non-barbed 1/4″			
Water Inlet, Outlet	3/8 Hansen type coupler (ISO 8637-1)			
Recirculation / Cardioplegia	DIN luer lock female BS EN ISO 80369-7			
Blood Sample, Arterial	DIN luer lock female BS EN ISO 80369-7			
Temperature, Arterial	Glued			
Post Gas Exchanger Vent	Non-barbed connection			
Heat Exchanger Vent	Luer lock female BS EN ISO 80369-7			
Pre Gas Exchanger Vent	Luer lock female BS EN ISO 80369-7			

	Adult Midi PP Oxygenator	Adult Maxi PP Oxygenator	Infant PP Oxygenator
Blood Flow Rate	1 – 7 L/min	1 – 8 L/min	0.5 – 3 L/min
Static Priming Volume	260 mL	300 mL	150 mL
Gas Flow Rate	0.5 – 14 L/min	0.5 – 16 L/min	0.25 – 6 L/min
Gas Exchanger			
Material	Polypropylene		
Type	Microporous hollow fibre		
Surface Area	1.54 m^2	2.07 m^2	0.66 m^2
Burst Pressure of Fibre	≥ 300 kPa		
Heat Exchanger			
Material	Polyester		
Type	Non-porous hollow fibres		
Surface Area	0.38 m^2		0.20 m^2
Burst Pressure of Fibre	≥ 600 kPa		
Port Configurations			
Blood Inlet, Outlet	Barbed 3/8″		Barbed 1/4″
Gas Inlet	Non-barbed 1/4″		
Water Inlet, Outlet	3/8″ Hansen type coupler (ISO 8637-1)		
Recirculation / Cardioplegia	DIN luer lock female BS EN ISO 80369-7		
Blood Sample, Arterial	DIN luer lock female BS EN ISO 80369-7		
Temperature, Arterial	Glued		
Post Gas Exchanger Vent	Non-barbed connection		
Heat Exchanger Vent	Luer lock female BS EN ISO 80369-7		

	Adult Midi MicroNet Oxygenator	Adult Maxi MicroNet Oxygenator	Infant MicroNet Oxygenator
Blood Flow Rate	1 – 7 L/min	1 – 8 L/min	0.5 – 3L/min
Static Priming Volume	260 mL	295 mL	150 mL
Residual Priming Volume		206 mL	76 mL
Gas Flow Rate	0.5 – 14 L/min	0.5 – 16 L/min	0.25 – 6 L/min
Gas Exchanger			
Material	Polypropylene		
Type	Microporous hollow fibres		
Surface Area	1.54 m^2	2.07 m^2	0.66 m^2
Burst Pressure of Fibre	≥ 300 kPa		
Heat Exchanger			
Material	Polyester		
Type	Non-porous hollow fibres		
Surface Area	0.38 m^2		0.20 m^2
Burst Pressure of Fibre	≥ 600 kPa		
Port Configurations			
Blood Inlet, Outlet	Barbed 3/8"		Barbed 1/4"
Gas Inlet	Non-barbed 1/4"		
Water Inlet, Outlet	3/8" Hansen type coupler (ISO 8637-1)		
Recirculation / Cardioplegia	DIN luer lock female BS EN ISO 80369-7		
Blood Sample, Arterial	DIN luer lock female BS EN ISO 80369-7		
Temperature, Arterial	Glued		
Post Gas Exchanger Vent	Non-barbed connection		
Heat Exchanger Vent	Luer lock female BS EN ISO 80369-7		
MicroNet Filter			
Filtration Surface Area	210 cm^2		162 cm
Filtration Material	40 μm polyester		

2.4 Indications

Paragon PMP, Paragon PP, and Paragon MN are hollow fibre membrane oxygenators 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, so that the oxygenator serves both in achieving hypothermia or maintaining normothermia.

2.5 Contraindications

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 the ECLS support of patients undergoing heparin mediated anticoagulation.

2.6 Duration of Use

The Paragon **PP, and MicroNet** Oxygenators 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.

The Paragon **Midi, Infant and Neonatal PMP** Oxygenators are intended for clinical use of up to 24 hours, provided the product is used in accordance with standard operational practices for these devices and especially with respect to maintaining adequate anticoagulation.

The Paragon **Maxi PMP** Oxygenators are intended for clinical use of up to 15 days, provided the product is used in accordance with standard operational practices for these devices and especially with respect to maintaining adequate anticoagulation.

2.7 Clinical Benefit

The benefit of the Paragon Oxygenator is to oxygenate a patient's blood and remove carbon dioxide, thereby providing life support until the affected organ can recover, or so that cardiac surgery can be performed. The device also allows for heating, cooling, or maintenance of blood temperature through an incorporated heat exchanger.

2.8 Combination Products

Compatibility, performance, connection and requirements of devices to be used in combination with the Paragon Oxygenators are given in the following tables. All devices listed must be CE or UKCA marked.

Maxi & Midi Oxygenators

Device	Performance Requirements	Connection to the Oxygenator Requirements	Connection from the Oxygenator Requirements
Continuous flow blood pumps - centrifugal	Blood flow rate range: Maxi 0 – 8 L/min Midi 0 – 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	Blood flow rate range: Maxi 0 – 8 L/min Midi 0 – 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 rate range: Maxi 0 - 16 L/min Midi 0 - 14 L/min	Green gas tubing	N/A
	Oxygen 21% – 100% air		
Heater / cooler	Water flow rate 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			
Venous & cardiotomy reservoir	Blood flow rate range: Maxi 0 – 8 L/min Midi 0 – 7 L/min	Connection with tubing with internal diameter of 3/8″	Connection with tubing with internal diameter of 3/8″
Holder	Standalone Paragon Oxygenator compatible with CMEH047		
	Integrated Paragon Oxygenator compatible with CMEH012		

Infant Oxygenators

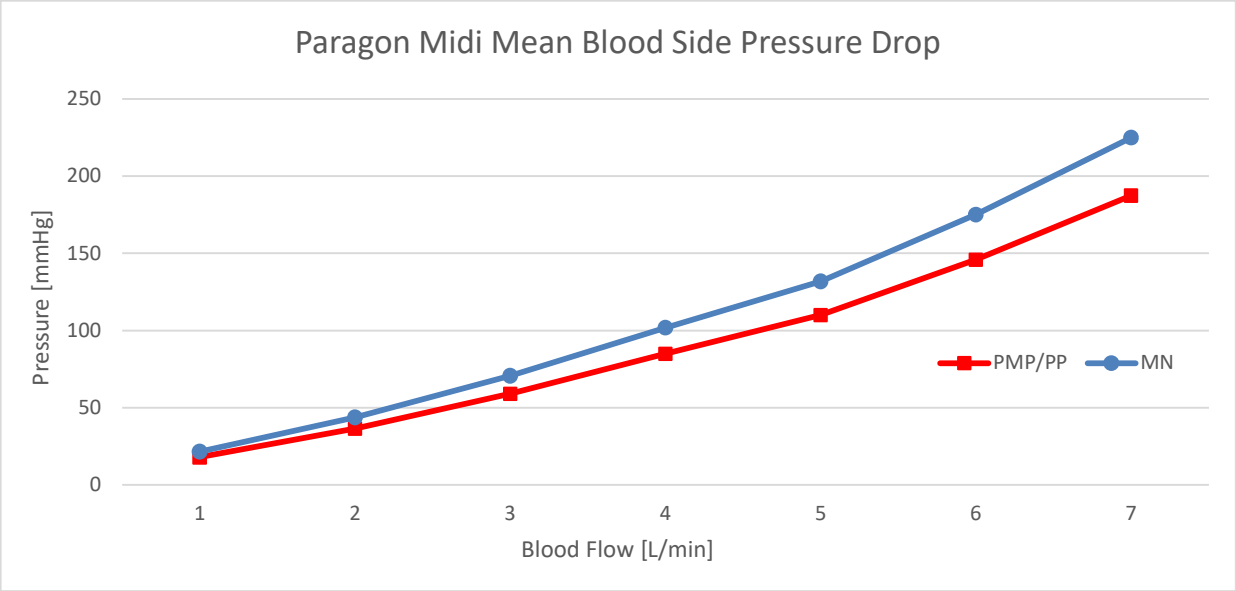
Device	Performance Requirements	Connection to the Oxygenator Requirements	Connection from the Oxygenator Requirements
Continuous flow blood pumps - centrifugal	Blood flow rate range: 0 – 3 L/min	Connection of tubing from the blood pump to the oxygenator must have tubing with an internal diameter of 1/4″	Connection of tubing from the outlet of the oxygenator must have an internal diameter of 1/4″
Continuous flow blood pumps - roller	Blood flow rate range: 0 – 3 L/min	Connection of tubing from the blood pump to the oxygenator must have tubing with an internal diameter of 1/4″ or 3/8″	Connection of tubing from the oxygenator must have an internal diameter of 1/4″
Air / oxygen blender	Gas flow rate range: 0 – 6 L/min	Green gas tubing	N/A
	Oxygen 21% – 100% air		
Heater / cooler	Water flow rate range: 1 – 15 L/min	3/8″ Hansen type coupler	3/8″ Hansen type coupler
PVC tubing	Phthalate free	With internal diameter tubing of 1/4″	With internal diameter tubing of 1/4″
Silicone tubing			
Venous & cardiotomy reservoir	Blood flow rate range: 0 – 3 L/min	Connection tubing with internal diameter of 1/4″	Connection tubing with internal diameter of 1/4″
Holder	Standalone Paragon Oxygenator compatible with CMEH047		
	Integrated Paragon Oxygenator compatible with CMEH042		

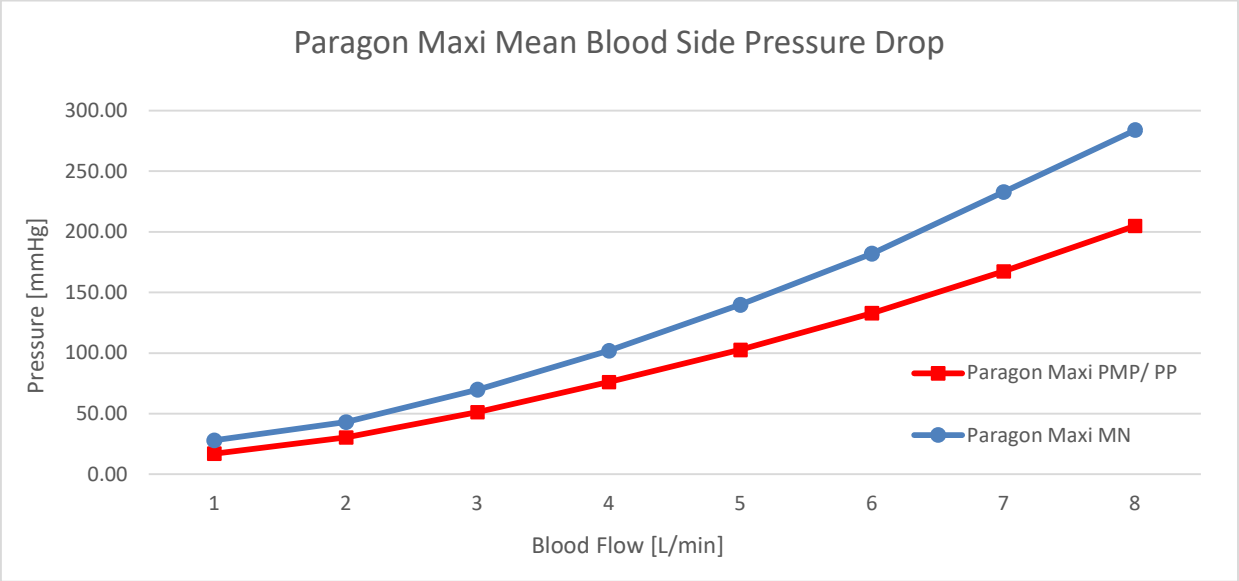
Neonatal Oxygenators

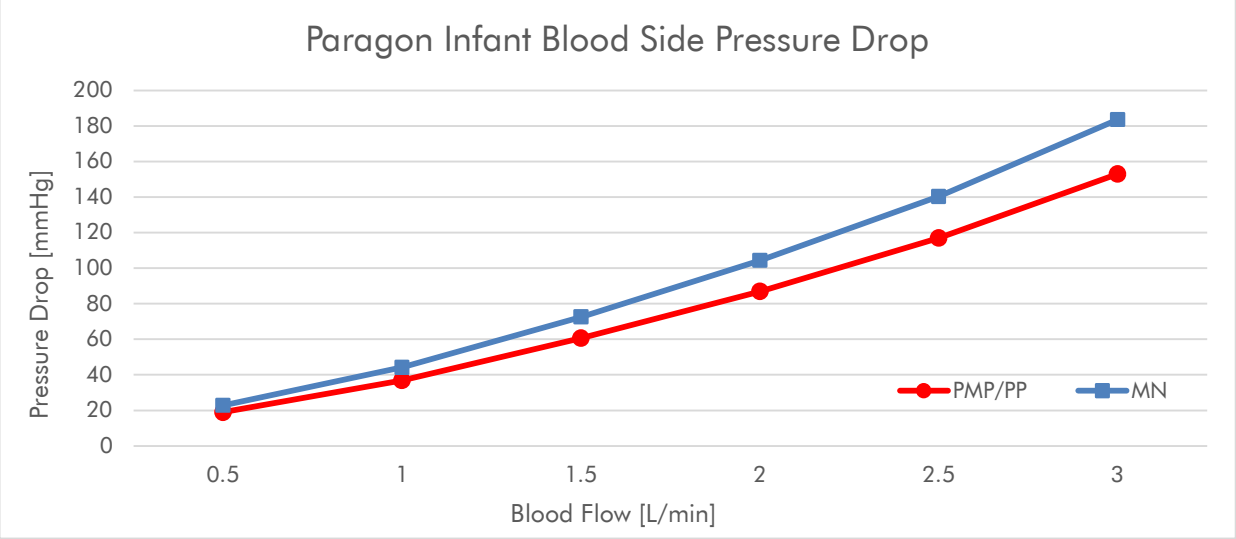
Device	Performance Requirements	Connection to the Oxygenator Requirements	Connection from the Oxygenator Requirements
Continuous flow blood pumps - centrifugal	Blood flow rate range: 0 - 1.4 L/min	Connection of tubing from the blood pump to the oxygenator must have tubing with an internal diameter 3/16" or 1/4"	Connection of tubing from the outlet of the oxygenator must have an internal diameter of 3/16" or 1/4"
Continuous flow blood pumps - roller	Blood flow rate range: 0 - 1.4 L/min	Connection of tubing from the blood pump to the oxygenator must have tubing with an internal diameter of 3/16" or 1/4"	Connection of tubing from the oxygenator must have an internal diameter of 3/16" or 1/4"
Air / oxygen blender	Gas flow rate range: 0 – 2.8 L/min Oxygen 21% – 100% Air	Green gas tubing	N/A
Heater / cooler	Water flow rate range: 1 – 10 L/min	3/8" Hansen Type Coupler	3/8" Hansen Type Coupler
PVC tubing Silicone tubing	Phthalate free	With internal diameter tubing of to 3/16"	With internal diameter tubing of 3/16"
Venous & cardiotomy reservoir	Blood flow rate range: 0 - 1.4 L/min	Connection tubing with internal diameter of 3/16"	Connection tubing with internal diameter of 3/16"
Holder	Standalone Paragon Oxygenator compatible with CMEH049		

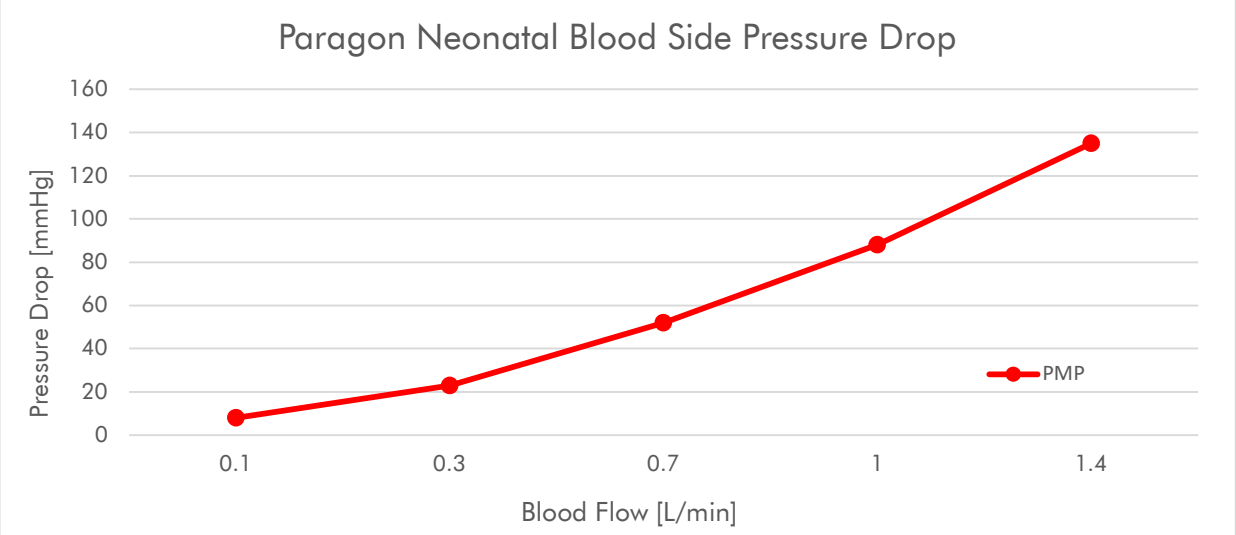
2.9 Performance Data

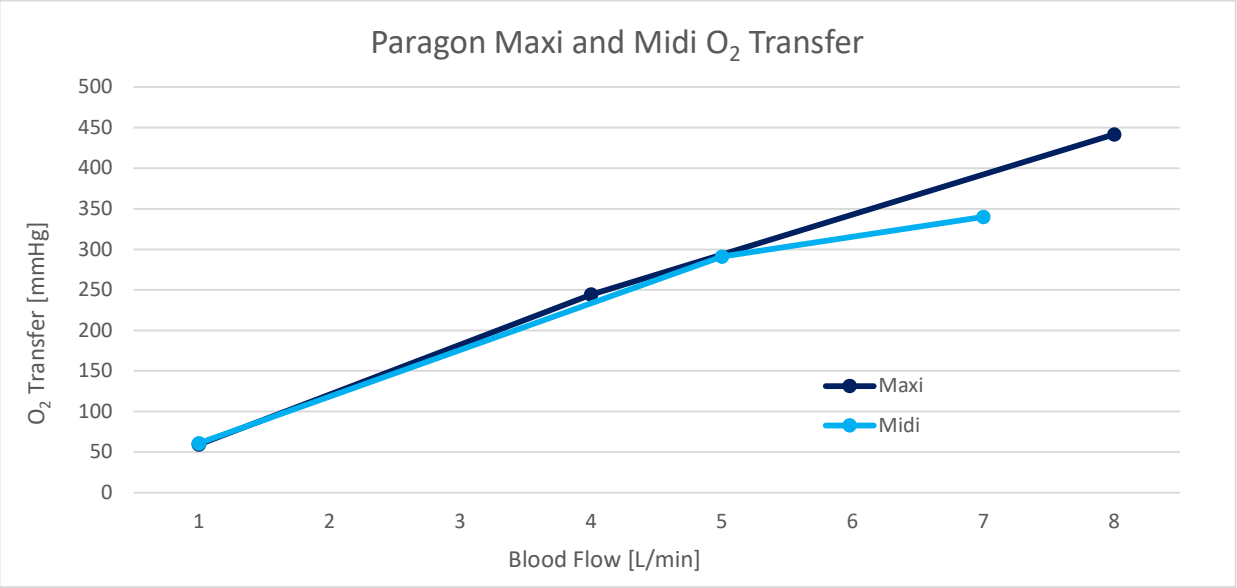
All tests have been carried out according to the BS EN ISO 7199 standard.

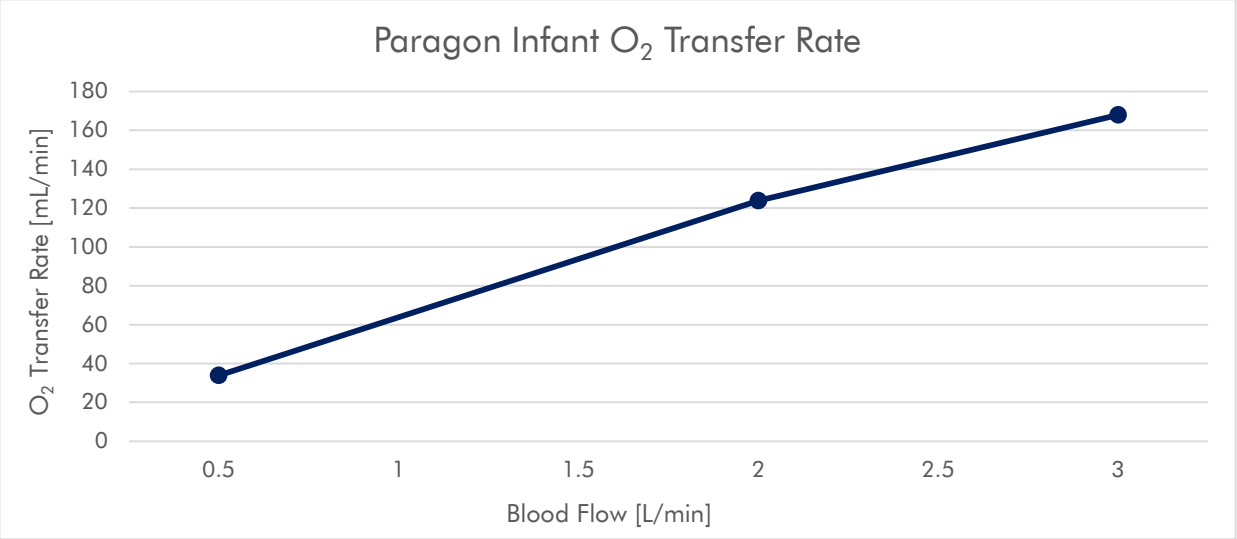


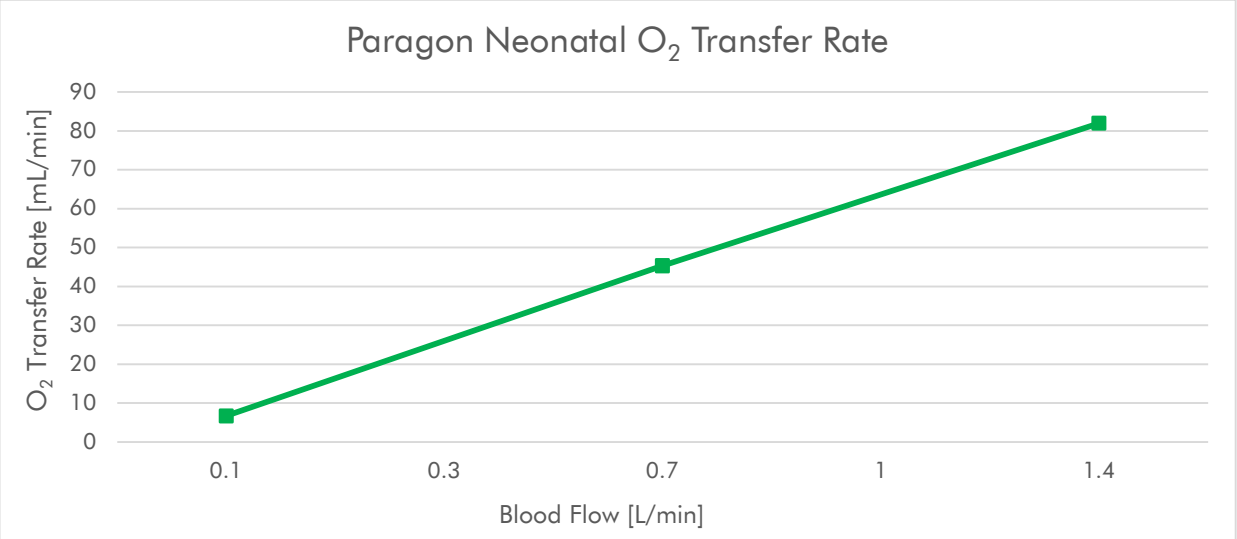

Paragon Maxi Mean Blood Side Pressure Drop
300.00
250.00
200.00
150.00
100.00
50.00
0.00
Pressure [mmHg]
1
2
3
4
5
6
7
8
Blood Flow [L/min]
Paragon Maxi PMP/ PP
Paragon Maxi MN

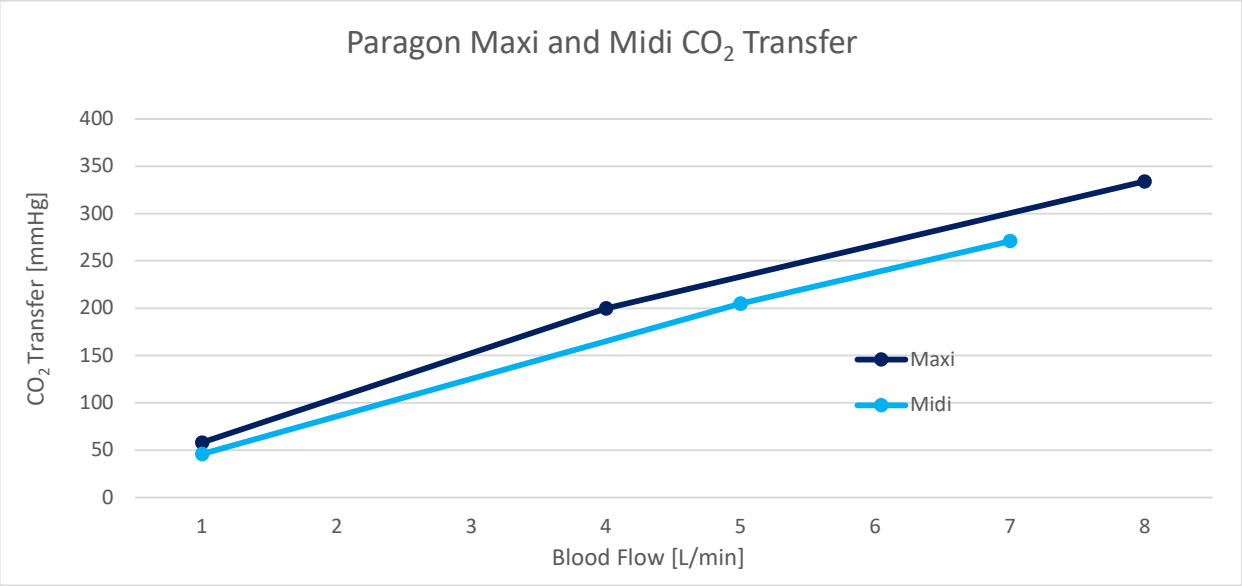

Paragon Infant Blood Side Pressure Drop
200
180
160
140
120
100
80
60
40
20
0
Pressure Drop [mmHg]
0.5
1
1.5
2
2.5
3
Blood Flow [L/min]
PMP/PP
MN

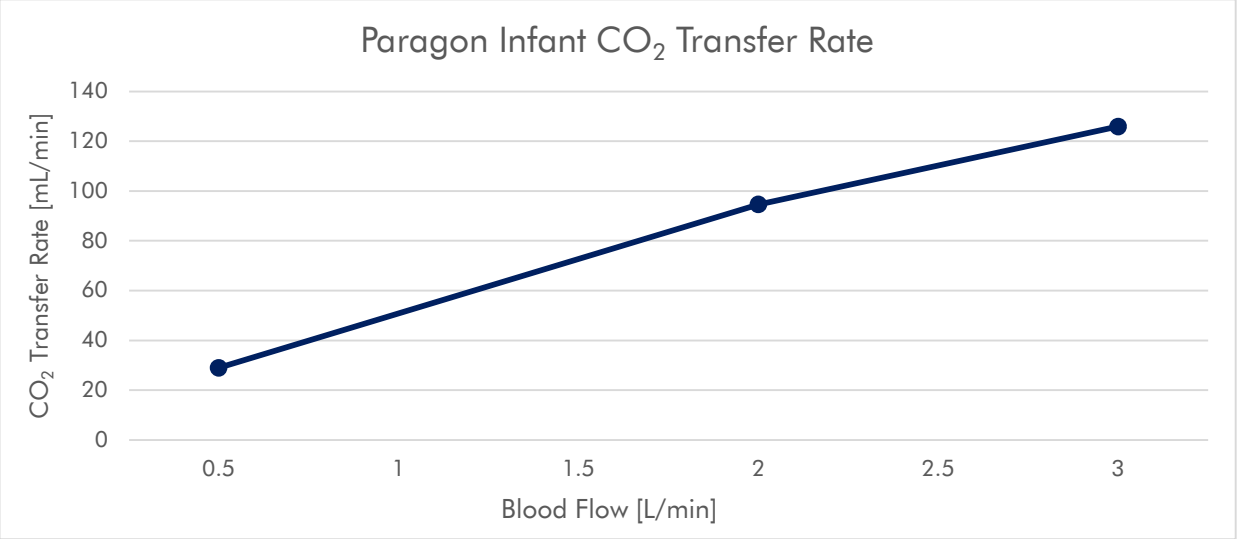

Paragon Neonatal Blood Side Pressure Drop
160
140
120
100
80
60
40
20
0
Pressure Drop [mmHg]
0.1
0.3
0.7
1
1.4
Blood Flow [L/min]
PMP

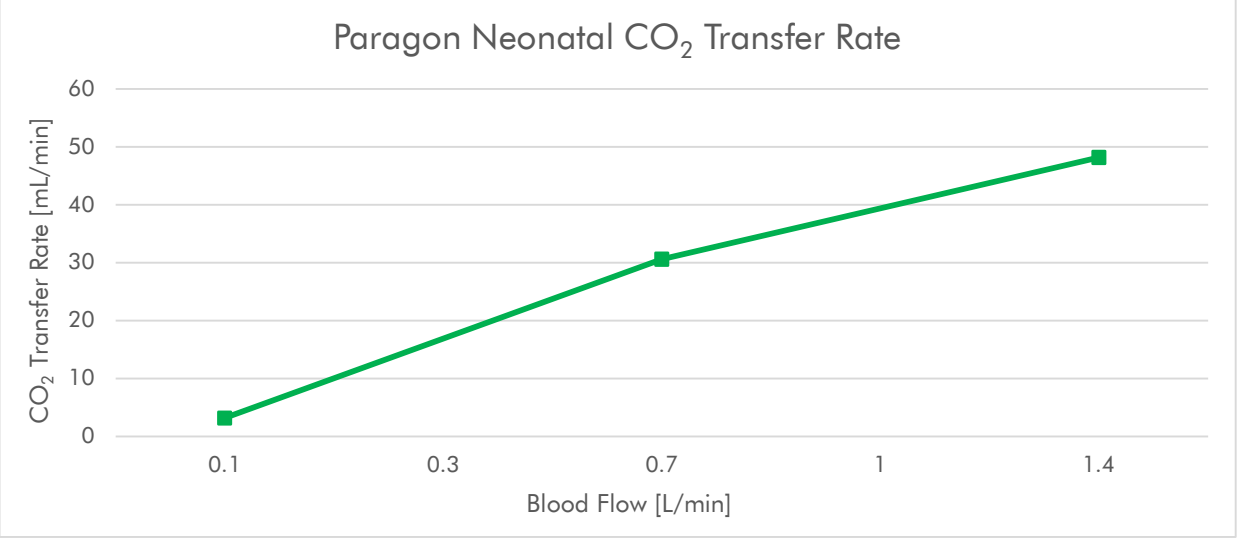

Paragon Maxi and Midi O_2 Transfer
O_2 Transfer [mmHg]
500
450
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
Blood Flow [L/min]
Maxi
Midi

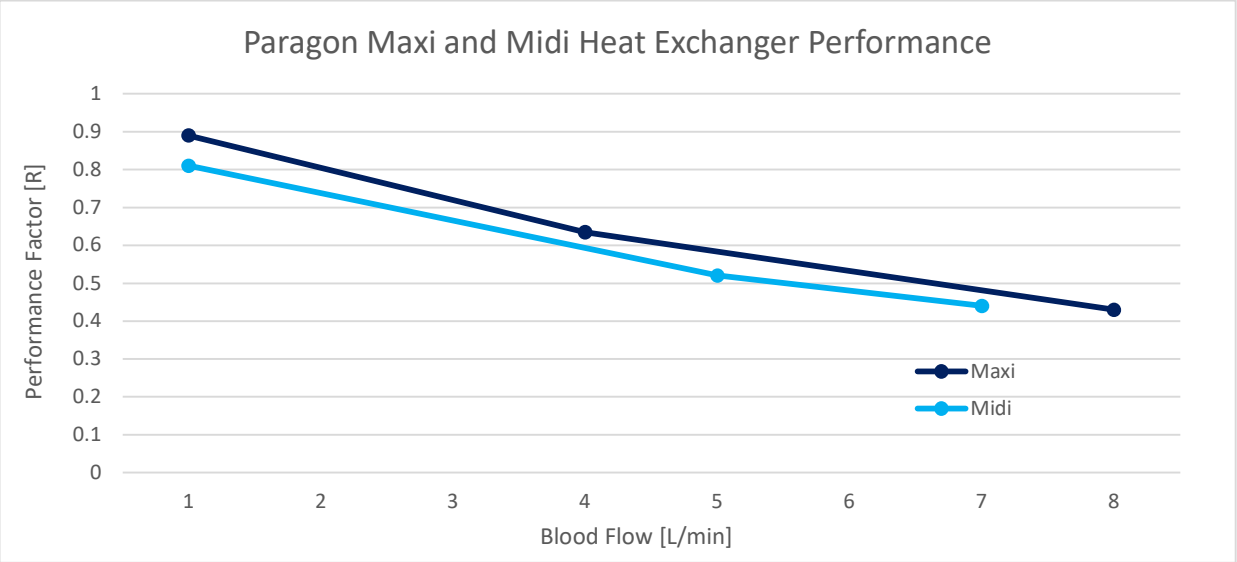

Paragon Infant O_2 Transfer Rate
O_2 Transfer Rate [mL/min]
180
160
140
120
100
80
60
40
20
0
0.5
1
1.5
2
2.5
3
Blood Flow [L/min]

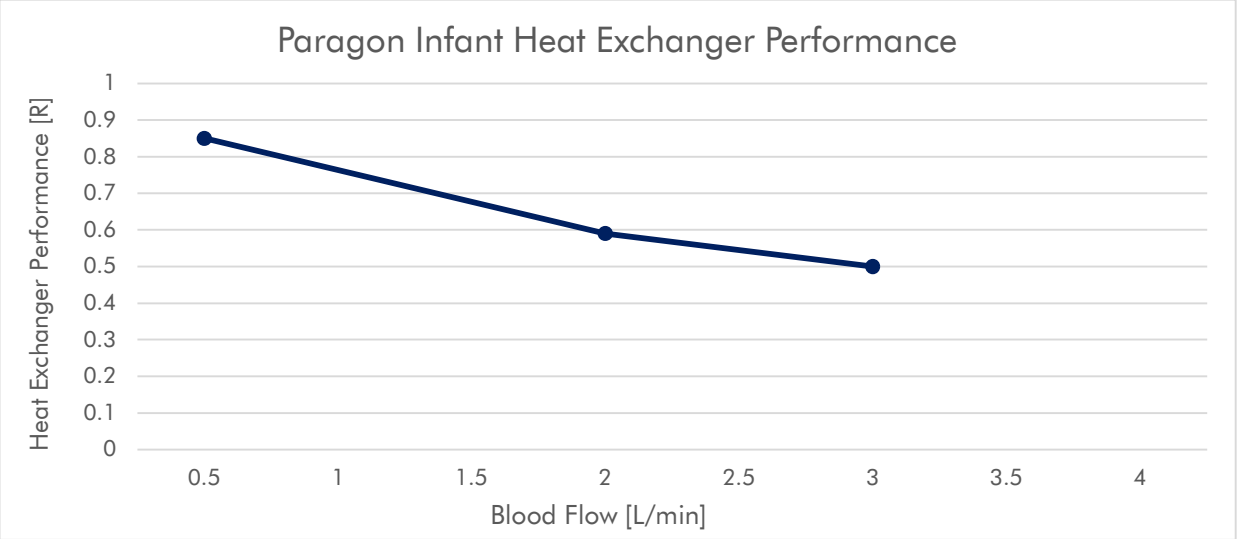

Paragon Neonatal O_2 Transfer Rate
O_2 Transfer Rate [mL/min]
90
80
70
60
50
40
30
20
10
0
0.1
0.3
0.7
1
1.4
Blood Flow [L/min]

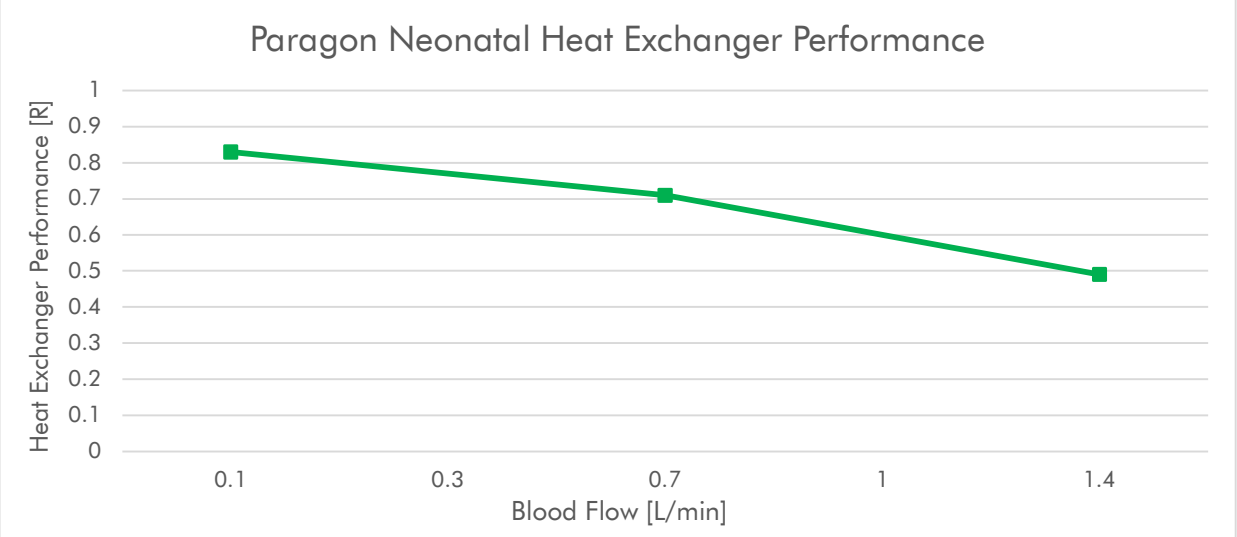

Paragon Maxi and Midi CO_2 Transfer
CO_2 Transfer [mmHg]
400
350
300
250
200
150
100
50
0
1
2
3
4
5
6
7
8
Blood Flow [L/min]
Maxi
Midi


Paragon Infant CO_2 Transfer Rate
CO_2 Transfer Rate [mL/min]
140
120
100
80
60
40
20
0
0.5
1
1.5
2
2.5
3
Blood Flow [L/min]


Paragon Neonatal CO_2 Transfer Rate
CO_2 Transfer Rate [mL/min]
60
50
40
30
20
10
0
0.1
0.3
0.7
1
1.4
Blood Flow [L/min]


Paragon Maxi and Midi Heat Exchanger Performance
Performance Factor [R]
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1
2
3
4
5
6
7
8
Blood Flow [L/min]
Maxi
Midi


Paragon Infant Heat Exchanger Performance
Heat Exchanger Performance [R]
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0.5
1
1.5
2
2.5
3
3.5
4
Blood Flow [L/min]


Paragon Neonatal Heat Exchanger Performance
Heat Exchanger Performance [R]
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0.1
0.3
0.7
1
1.4
Blood Flow [L/min]

2.10 Cardiotomy / Venous Reservoir

2.10.1 Product Description

The cardiotomy / venous reservoir is a sealed polycarbonate blood storage and filtering device for extra corporeal perfusion.

2.10.2 Specifications

	Adult V&C Reservoir	Infant V&C Reservoir
Maximum Volume	4000 mL	1800 mL
Minimum Operating Volume	300 mL	100 mL
Maximum Blood Flow Rates		
Venous Section	1-7 L/min	0.3 – 3 L/min
Cardiotomy Section	4 L/min	3 L/min
Maximum total flow	7 L/min	3 L/min
Cardiotomy Filtration	38 μm	38 μm
Venous Port Configuration		
Venous inlet	1/2", 360° swivelling	3/8" , 360° swivelling
Luer ports	3 x female	3 x female
Cardiotomy Port Configuration		
Suction	6 x 1/4" with 3/8"- transition	
Vertical Ports	1 x 3/8", 1x 1/4"	
Luer Ports	4 x female	
Recirculation	1 x 1/4", 1 x BS EN ISO 80369-7	
Non Filtered / Non Defoamed Ports		
Vent Port	1/4"	
Luer Port	1 x female	
Venous Outlet	3/8"	1/4"
Temperature Port	Optional, via screwable temperature sensor at female Luer port of venous inlet connector	
Vacuum Relief Valve		
Negative Pressure	Opening pressure: about -150 mbar negative pressure	
Positive Pressure	Opening pressure: about 2 mbar	Opening pressure: about <2 mbar
Dynamic Prime Volumes		
500 mL/min	N/A	232 mL
800 mL/min	N/A	255 mL
1000 mL/min	300 mL	N/A
1500 mL/min	N/A	273 mL
4000 mL/min	359 mL	N/A
7000 mL/min	401 mL	N/A

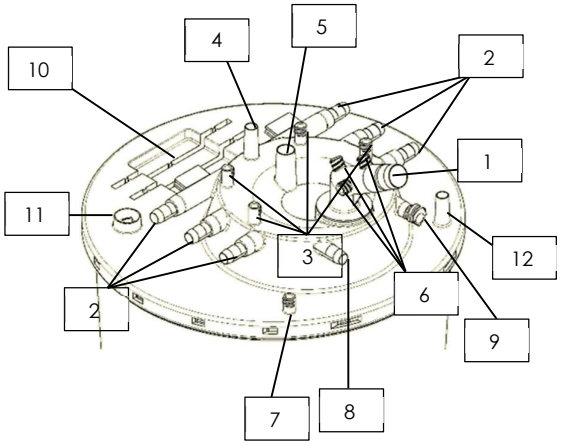
Tolerance of Scales used for blood measurement – Maxi & Midi

At the maximum volume marker of 4000 mL, the volume of the fluid added is within 0.2% of the stated value. At the marker volume of 2000 mL, the volume of fluid added is within 0.3% of the stated value. At the volume marker of 300 mL, the volume of fluid added is within 2% of the stated value.

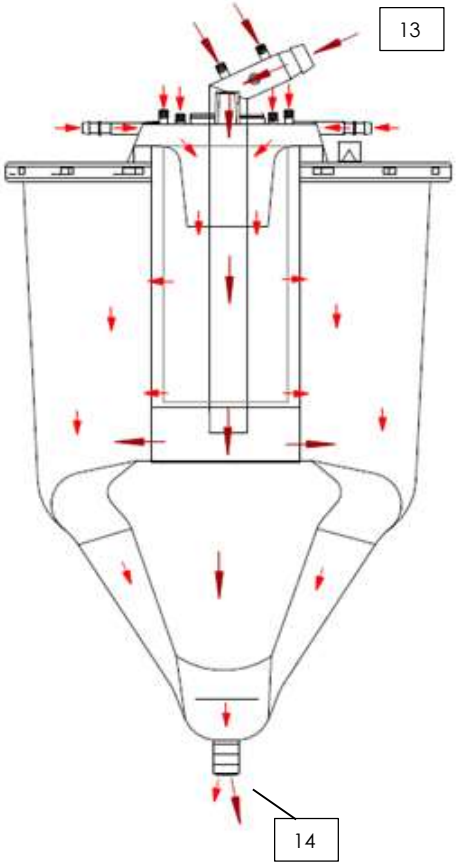
Tolerance of Scales used for blood measurement – Infant & Neonatal

Infant Reservoir: At the maximum volume marker of 1800 mL, the volume of the fluid added is within 0.77% of the stated value. At the marker volume of 800 mL, the volume of fluid added is within 0.625% of the stated value. At the volume marker of 200 mL, the volume of fluid added is within 1% of the stated value.

2.10.3 Ports / Blood Path Connections



Number	Description	Details
1 & 13	Venous inlet 1/2" for 4000 mL reservoir, 3/8" for 2500 mL & 1800 mL reservoir	Can be rotated up to 360°
2	Filtered and defoamed suction ports, 6 x 1/4" (with 3/8" transition)	Sucker blood is directed through the ports and a filter.
3	Filtered and defoamed luer ports, 4 x female	
4	Filtered and defoamed vertical port 1/4"	Port provided for the administration of unfiltered solutions.
5	Filtered and defoamed vertical port 3/8"	Port provided for the administration of unfiltered solutions.
6	Cardiotomy filter-bypass-port, defoamed, unfiltered, 3 x luer female	Connect temperature probe to one of these ports. Ports can also serve as drug ports (medication should only be added to the venous section of the reservoir).
7	Unfiltered, non-defoamed port, luer females	Port bypasses filtered and defoamed sections of the reservoir.
8	Recirculation port, 1/4"	
9	Recirculation BS EN ISO 80369-7	
10	Holder for sample manifold	Section to add a manifold for sampling.
11	Positive-, negative release valve	Safety valve for negative pressure.
12	Vent port	Check cap is vented
14	Venous outlet	



2.10.4 Indications

The reservoir is intended to store and filter blood during extracorporeal life support.

2.10.5 Contraindications

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 the ECLS support of patients undergoing heparin mediated anticoagulation.

2.10.6 Duration of Use

The reservoir is intended for clinical use 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.**

2.10.7 Combination Products

Compatibility, performance, connection and requirements of devices to be used in combination with the Paragon Reservoir, are given in the table below. All devices listed must be CE or UKCA marked.

Device	Connection Requirements	Reservoir Compatibility
Adult oxygenator	Connection with tubing with internal diameter of 3/8"	Adult V&C reservoir
Infant oxygenator	Connection with tubing with internal diameter of 1/4".	Infant V&C Reservoir
Continuous flow blood pumps – roller (heart lung machine)	The tubing within the blood pump raceway must have tubing with an internal diameter of either 3/8" or 1/2"	All reservoirs
PVC tubing Silicone tubing	With internal diameter tubing of 3/8". Tubing to be phthalate free.	
Cannula (size patient dependant)	Connection with tubing with internal diameter of 3/8" which may require an adaptor (patient dependant)	

2.10.8 Precaution

The minimum operating volume in the reservoir is stated in Section 2.10.2 (Specifications). However, to ensure an adequate response time in case of a venous flow obstruction, it is recommended that an adequate volume in addition to the minimum level is maintained in the venous cardiotomy reservoir. Do not exceed the maximum operating volume in the reservoir. The effect of smaller filter surfaces on the filter performance due to higher reservoir filling level has to be taken into consideration.

2.11 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.
- Correct heparinization and exact monitoring of the anticoagulation status before, during and after bypass has to be observed.
- Before and during extracorporeal circulation adequate anticoagulation must be maintained. The ACT (activated clotting time) must be maintained above 480 seconds for PP oxygenators.
- In the case of prolonged extracorporeal use with PMP oxygenators ACT levels can be reduced.
- In accordance with ELSO guidelines, once an ACT level of 300 seconds is recorded, an infusion of unfractionated heparin (UNFR) should be started, maintaining the ACT in a range of 180-220 seconds. The ACT must be adjusted based on factors such as circuit clotting, patient bleeding issues, and other measurements of clotting such as Xa level and thromboelastographs (TEG)[1] (References Section 10).
- 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 the device.
- 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.
- 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 CO_2 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.
- 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 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 narcotic gas is administered to the blood 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 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 °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.

- Blood flow through the venous filter must not exceed the recommended product specifications. The blood flow through the cardiotomy filter must not exceed the recommended product specifications.
- The filter element should be carefully monitored at high flow rates, as drug administration, high blood and air volume can lead to extensive foaming of the blood which may affect the performance of the filter.
- Initial priming of the reservoir should be performed via a filtered cardiotomy port in order to moisten the filter. The priming fluid should be re-circulated using an appropriate filter.
- The flow and defoaming of the reservoir should be observed and adjusted according to performance efficiency.
- The vent port must not be covered with non-venting caps or tubing. An adequate connective negative pressure has to be controlled.
- When introducing additional blood products, ensure that a filtered luer port or a vertical filtered port of the reservoir is used. Sufficient anticoagulation has to be assured.
- Medication should not be added through the cardiotomy part of the reservoir, these should be added to the venous section of the reservoir to ensure that they are mixed properly.
- To ensure an adequate response time in case of a venous flow obstruction, it is recommended that an adequate volume in addition to the recommended minimum level is maintained in the reservoir. The application of a level sensor is recommended.
- Sufficient venous drainage can only be achieved in an air free venous line. The user has to ensure that no air enters the venous line, otherwise the venous backflow will be stopped.
- To remove air the manifold should be purge and prefilled to avoid penetration of air.
- Negative pressure in the reservoir must not exceed -150 mmHg, this should be carefully controlled by the user.
- The reservoir must only be used with an appropriate holder.
- **The Paragon PP, MicroNet or 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.

2.12 Handling

- 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 unintentionally opened before use or exposed to conditions outside of those specified should not be used.
- Fasten the product to the appropriate holder, taking account of the following precaution:

Precaution: Only use the holders that are listed in Section 6, 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.

- When using an open system with the reservoir in the adapter, which connects the reservoir and oxygenator, the reservoir can be rotated opposite to the oxygenator.
- It is recommended to rinse the oxygenator with CO_2 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 CO_2, the blood side of the oxygenator should be closed from the atmosphere until priming.
- Remove the caps from the water connections on the heat exchanger and the cap of the gas inlet connector.
- Connect the water lines with Hansen couplings to the quick locks on the oxygenator.
- **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.**
- 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.
- Connect the arterial line to the arterial outlet of the oxygenator.
- Connect the re-circulation port of the oxygenator with a free port on the cardiotomy reservoir (sucker port or re-circulation port).
- 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.
- Connect the tubing of the arterial pump between the outlet connector of the venous reservoir and the 3/8" inlet connector of the oxygenator.

- Connect the gas supply line with the gas inlet connector. Check, that the gas supply comes from a compatible air/oxygen mixer.

Warning: If zip ties are not secured correctly, a leak can occur. All zip ties must be secured tightly such that the connection does not move.

- 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.
- Insert a suitable temperature probe into the temperature measuring point of the oxygenator and connect it to the monitoring system.
- A suitable pressure monitoring system must be used during clinical use (for suitable connection points, see Section 2.10.3 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.

2.13 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/cardiotomy 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 cardiotomy reservoir so that the fluid flows into the venous reservoir. Then vent the flexible venous reservoir by slowly opening the vent line.
10. Remove the pump segment from the arterial pump. Fill the pump segment 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 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 for the Maxi & Midi or 200-500 mL/min for the Infant and Neonatal – re-circulating via an AV loop (consisting of a pre- bypass filter or a connecting line).
12. Increase the pump flow up to and advised maximum range (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 for the Maxi & Midi or 100 – 300 mL for the Infant & Neonatal. 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.

2.14 Application of the Oxygenator System.

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. 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 2:1 gas flow rate: blood flow rate ratio.

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.

This also applies to the Paragon PMP Oxygenator. 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

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 mL should take place for the Maxi & Midi oxygenators, or 150 – 200 mL for the Infant & Neonatal oxygenators.

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.

2.15 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.

2.16 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 protamine must be administered.

6. Open the re-circulation line.
7. Increase the blood flow rate up to 400 - 800 mL/min for the Maxi & Midi or 100 – 300 mL for the Infant & Neonatal.

> Warning: During re-circulation the blood flow rate must never exceed 800 mL/min for the Maxi & Midi or 300 mL for the Infant & Neonatal.

2.17 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 for the Maxi & Midi or 300 mL/min for the Infant & Neonatal.
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.

2.18 Replacement of an Oxygenator

Procedure:

1. Stop the water supply to the old oxygenator and remove the water lines.
2. Disconnect any connections to the old oxygenator that are no longer necessary.
3. Remove the old oxygenator from the holder and replace with a new oxygenator.
4. Stop the blood pump.
5. Clamp the venous line at the venous reservoir.
6. Clamp the venous and arterial lines at the oxygenator.
7. Fill up the cardiotomy reservoir with sufficient fluid to be able to fill the second oxygenator.
8. If using a soft reservoir, ventilate the same.
9. Disconnect the gas and monitoring lines.
10. Connect the water lines to the new oxygenator and open the water supply. Check the oxygenator for any leaks.
11. Aseptically disconnect the blood inlet, outlet and re-circulation lines on the old oxygenator.
12. Connect all lines on the new oxygenator aseptically ensuring it is free from bubbles, fix all the connections.
13. Open the re-circulation and venous oxygenator inlet line. The venous back flow and arterial line have to remain clamped.
14. Switch on the blood pump and slowly fill up the oxygenator.
15. Re-circulate the blood through the re-circulation line.
16. As soon as the complete system is air-free and no leaks have been highlighted, open the venous and arterial lines. Bypass can now be re-started.

Close the re-circulation line.

3 Storage & Handling

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

4 Fittings

The following products can be ordered from the manufacturer.

Product	Order Code
Holder for Integrates Paragon Oxygenator with 4000 mL Reservoir	CMEH012
Holder for integrate Paragon Oxygenator with 1800 mL Reservoir	CMEH042
Holder for Standalone Paragon Adult and Infant Holder	CMEH047
Holder for Standalone Paragon Neonatal Oxygenator	CMEH049
Straight Hansen Connectors	U-CME90058
90° Hansen Connectors	U-CME90059

5 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 not use if packaging is damaged		Keep away from sunlight	
Temperature limitation		Non-pyrogenic: Indicates a medical device which is non-pyrogenic	
Keep dry		EC authorised representative	
Sterilised using ethylene oxide		Importer	
Single sterile barrier system with protective packaging outside		Language symbol – assigned as required	
Single sterile barrier system		Medical device	
CE Mark		UKCA mark	
Single sterile barrier system with protective packaging inside		Serial number	
Lot number/ batch code		Catalogue Number	

6 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.
- Data on particle release from the oxygenator according to the manufacturer's quality control management system.
- Relevant tolerances for data presented.
- Sterilisation method
- 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.

7 Warranty and Liability Statement

The manufacturer guarantees that the products have been manufactured, sterilised, and packaged according to the MDD Regulations 93/42/EEC and the Medical Devices Regulations 2002, including the 2023 amendment numbered 627.

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.

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

9 Economic operator Contacts

Importer

HSC-Medical GmbH
Rugenranzel 4
25373 Ellerhoop
Deutschland

T.: + 49 (0) 04120-70679-0

EC Authorised Representative

EC REP

Chalice Medical Europe GmbH
Alter Landweg 11
32584 Löhne
Deutschland

Email: EUregulatoryaffairs@chalicemedical.com

10 References

1. Extracorporeal Life Support: The ELSO Red Book. 5th Edition pub. 2017. Editors T.V. Brogan, L. Lequier, R. Lorusso, G. MacLaren, G. Peek.

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