LIFE-SAVING TECHNOLOGIES

Instructions for Use

Membrane Oxygenator

BRCoating

2024-02 Rev.0

SUMMARY

READ INSTRUCTIONS BEFORE USE

Code	Description
622375	Membrane Oxygenator Adult BRCoating
622266	Membrane Oxygenator Pediatric BRCoating
622257	Membrane Oxygenator Infant BRCoating
622261	Membrane Oxygenator Infant 1500 BRCoating
622271	Membrane Oxygenator Newborn BRCoating

1. DESCRIPTION

The Membrane Oxygenator BRCoating consists of two coupled chambers (Gas Exchanger and Heat Exchanger), being indicated for cardiopulmonary bypass procedures lasting up to 6 hours.

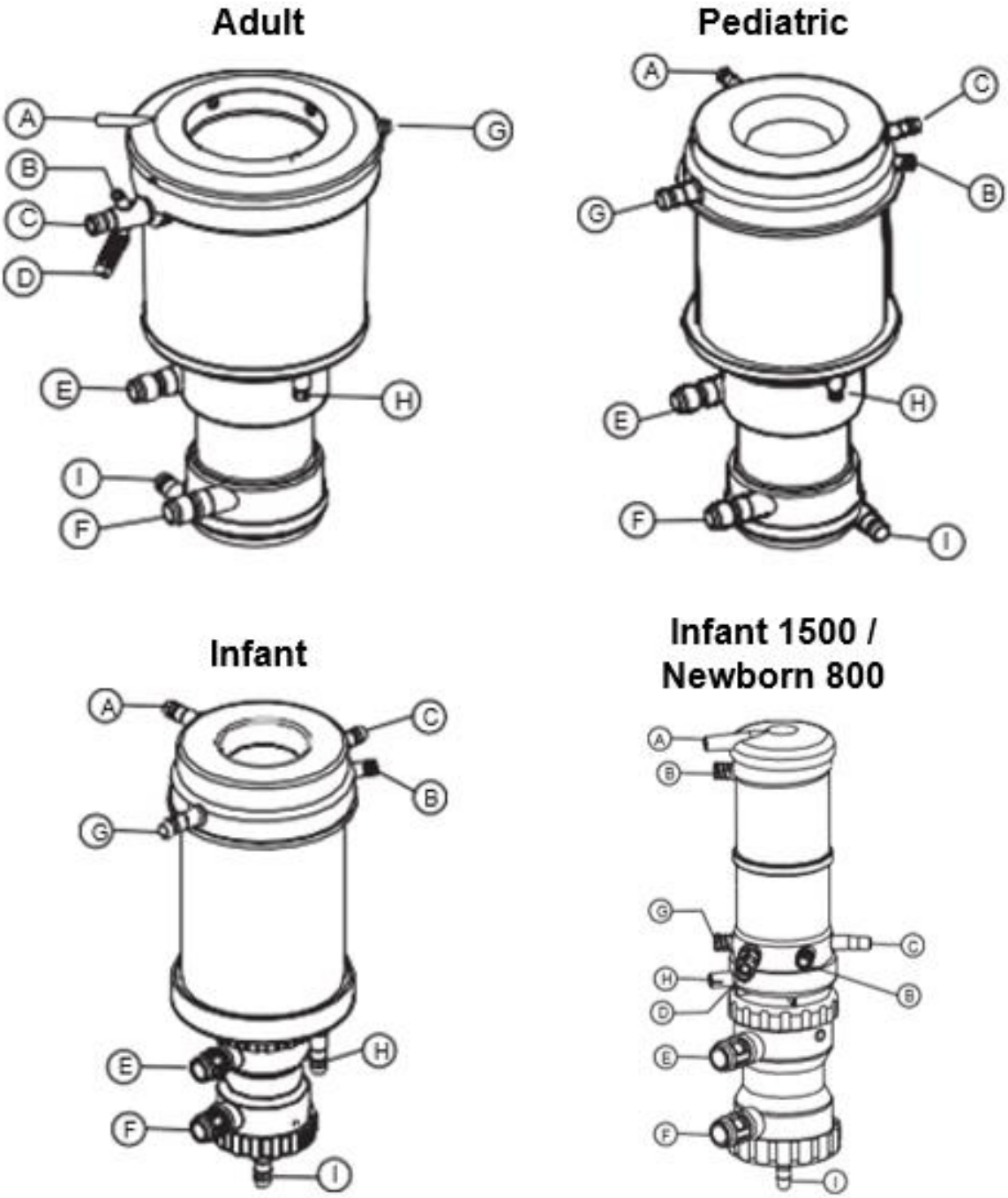
The internal space of the gas exchanger is filled with a hydrophobic Polypropylene (PP) membrane, formed by capillaries (fibers) with a highly porous surface. The high porosity of the capillaries, associated with a uniform distribution of pores, provides the membrane with high gas transfer (diffusion) performance, desirable to meet the fundamental principle of an oxygenator: efficiency in transferring O_2 to the blood and in removing carbon dioxide (CO_2).

The internal space of the heat exchanger is filled with thermoplastic polymer (polyester) capillaries. This thermoplastic composition, combined with the characteristics of the production process, results in non-porous capillaries, totally impermeable to blood and water, and with a high thermal transfer capacity.

All the Oxygenator surfaces in contact with blood are treated with the biocompatible coating, named BRCoating, composed of water produced by reverse osmosis, Polyethylene glycol 300 and recombinant human albumin*. This solution coats the inner surface of the product, reducing the interaction of the blood with it.

*Recombinant human albumin it is not derived from Animal or Human sources.

1.1. Graphic images



A	Gas inlet	D	Temperature Probe	G	Recirculation
B	Air removal / Samples	E	Water inlet	H	Gas outlet
C	Blood outlet	F	Water outlet	I	Blood inlet

Figure 1 - Components description

Table 1 - Compatibility table between membrane oxygenators and supports (Sold Separately)

Membrane Oxygenator Description / Code	Support (Holder)	Support Description	Support Code
Membrane Oxygenator Adult BRCoating (622375)		Membrane Oxygenator Adult Support	232496
Membrane Oxygenator Pediatric BRCoating (622266)		Membrane Oxygenator Pediatric Support	49999
Membrane Oxygenator Infant BRCoating (622257)		Membrane Oxygenator Infant Support	30537
Membrane Oxygenator Infant 1500 BRCoating (622261) Membrane Oxygenator Newborn 800 BRCoating (622271)		Support for CPB mod IV	215220

1.2. Technical Specifications

Table 2 - Technical Specifications

Model	Adult	Pediatric	Infant	Infant 1500	Newborn 800
Material					
Housing/connector Material	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate
Protective covers	Polyethylene	Polyethylene	Polyethylene	Polyethylene	Polyethylene
Coating	BRCoating	BRCoating	BRCoating	BRCoating	BRCoating
Performance					
Maximum Blood flow rate	7.0 L/min	3.0 L/min	2.0 L/min	1.5 L/min	0.8 L/min
Blood inlet maximum pressure	100 kPa (760 mmHg)	100 kPa (760 mmHg)	100 kPa (760 mmHg)	100 kPa (760 mmHg)	100 kPa (760 mmHg)
Priming volume (Static)	390ml	280ml	190ml	65ml	43ml
Gas flow: blood flow ratio	0.5:1 - 1:1 - 2:1	0.5:1 - 1:1 - 2:1	0.5:1 - 1:1 - 2:1	0.5:1 - 1:1 - 2:1	0.5:1 - 1:1 - 2:1

Gas Exchanger					
Fiber Material	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Surface Area	2.2 m²	1.6 m²	0.7 m²	0.5 m²	0.37 m²
Temperature connector	YSI	YSI	YSI	YSI	YSI
Blood outlet Direction: Right Side	3/8” (9.5 mm)	3/8” (9.5 mm)	1/4" (6.4 mm)	3/16” (4.76 mm)	3/16” (4.76 mm)
Gas inlet Connector	1/4" (6.4 mm)	1/4" (6.4 mm)	1/4" (6.4 mm)	1/4" (6.4 mm)	1/4" (6.4 mm)
Recirculation Connector	1/4" (6.4 mm)	1/4" (6.4 mm)	1/4" (6.4 mm)	Luer lock	Luer lock
Arterial Sample Connector	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock
Removal air connector	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock
Heat Exchanger					
Fiber material	Polyester	Polyester	Polyester	Polyester	Polyester
Surface Area	0.68 m²	0.35 m²	0.10 m²	0.10 m²	0.05 m²
Water Maximum temperature	42ºC	42ºC	42ºC	42ºC	42ºC
Water maximum pressure	32 PSI (1660 mmHg)	32 PSI (1660 mmHg)	32 PSI (1660 mmHg)	32 PSI (1660 mmHg)	32 PSI (1660 mmHg)
Blood inlet	3/8" (9.5 mm)	3/8" (9.5 mm)	1/4" (6.4 mm)	3/16” (4.76 mm)	3/16” (4.76 mm)
Water connector	1/2” (12.7 mm) Hansen quick connect fittings	1/2” (12.7 mm) Hansen quick connect fittings	1/2” (12.7 mm) Hansen quick connect fittings	1/2” (12.7 mm) Hansen quick connect fittings	1/2” (12.7 mm) Hansen quick connect fittings

Disclosable information: Information on blood cell damage, data tolerances and Leaching.

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

2. PRESENTATION

The Membrane Oxygenator BRCoating is sterile (sterilized by Ethylene Oxide - ETO) and non-pyrogenic. In its primary packaging, the product is packed in Tyvek paper envelope and polyethylene film. In its secondary packaging, the Membrane Oxygenator BRCoating is packed in a cardboard box. The instruction manual accompanies the product, in the secondary packaging.

3. INTENDED PURPOSE

The Membrane Oxygenator BRCoating is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

4. INDICATION FOR USE

The Membrane Oxygenator Adult BRCoating is intended to be used for patients who need surgical procedures requiring cardiopulmonary bypass (CPB). The Membrane Oxygenator is for use with patients when required blood flow rate (cardiac output) will not exceed:

Membrane Oxygenator Adult BRCoating:	7 L/min
Membrane Oxygenator Pediatric BRCoating:	3 L/min
Membrane Oxygenator infant BRCoating:	2 L/min
Membrane Oxygenator infant 1500 BRCoating:	1.5 L/min
Membrane Oxygenator Newborn 800 BRCoating:	0.8 L/min

This device shall only be used by properly trained and qualified personnel.

5. CONTRAINDICATIONS

The product is contraindicated to perform other functions that are not determined by the indication for use, or when, in the opinion of the medical team, its use is contrary to the best benefits for the patient.

6. CLINICAL BENEFITS

Enabling surgical procedures that require cardiopulmonary bypass by using blood circuits including this device.

7. ADVERSE EFFECTS

Use of this medical device may cause: Pressure drop, Hemolysis, Blood Loss, Inflammatory reaction, Embolism, Hypoxia, Infection Organ and tissue failure; Septic Shock, Kidney Failure, Heart attack, cell death, Permanent damage; Death.

8. INSTRUCTION FOR USE

It is recommended to use the Membrane Oxygenator BRCoating with devices

from the Braile Biomédica brand, listed in Table 3.

Table 3 - Compatible devices (sold separately)

Membrane Oxygenator Adult BRCoating (622375)	
Description	**Code**
Tubing Set Adult BRCoating	622286
Blood Reservoir Venous 4000 BRCoating	622258
Blood Reservoir Cardiotomy 4000 BRCoating	622272
Centrifugal Pump Safira Centriflux with BRCoating	616322
Membrane Oxygenator Pediatric BRCoating (622266)	
Tubing Set Pediatric BRCoating	622298
Blood Reservoir Venous 4000 BRCoating	622258
Blood Reservoir Cardiotomy 4000 BRCoating	622272
Blood Reservoir Venous 2000 BRCoating	622262
Blood Reservoir Cardiotomy 2000 BRCoating	622277
Centrifugal Pump Safira Centriflux with BRCoating	616322
Membrane Oxygenator Infant BRCoating (622257)	
Tubing Set infant BRCoating	622290
Blood Reservoir Venous 2000 BRCoating	622262
Blood Reservoir Cardiotomy 2000 BRCoating	622277
Centrifugal Pump Safira Centriflux with BRCoating	616322
Membrane Oxygenator Infant 1500 BRCoating (622261)	
Tubing Set Infant 1500 BRCoating	622294
Blood Reservoir Venous 500 BRCoating	622267
Blood Reservoir Cardiotomy 500 BRCoating	622279
Centrifugal Pump Safira Centriflux with BRCoating	616322
Membrane Oxygenator Newborn (622271)	
Tubing Set Newborn BRCoating	622302
Blood Reservoir Venous 5000 BRCoating	622267
Blood Reservoir Cardiotomy 500 BRCoating	622279
Centrifugal Pump Safira Centriflux with BRCoating	616322

***** Braile Biomédica cannot guarantee the compatibility between products from other manufacturers and, consequently, their safety and effectiveness.

8.1 Set-Up

a. **Support (holder):** turn the knob counterclockwise to free the support Fixing clamp to be able to position it on the rod freely. Set the holder at the appropriate height to prevent the lines from kinking, and turn the handle clockwise to lock the support. The oxygenator support must always be fixed below the blood venous reservoir support.

b. Check that the support is properly locked and secure.

c. **Oxygenator:** Open the sterile packaging using aseptic techniques.

d. **Adult, Pediatric and Infant Models:** Fit the lower part of the oxygenator (heat exchanger) into the lower clamp/fitting of the support. Subsequently, fit the upper part (Gas exchanger) into the upper claw of the support. Check that the oxygenator is properly locked and secure.

e. **Infant 1500 and Newborn 800 Models:** Fit the upper part (Gas exchanger) into the claw of the support. Check that the oxygenator is properly locked and secure.

8.2 Installation of Blood Lines (Figure 2)

a. Connect the cava line (venous) (1) of the Tubing set to the venous inlet connector (2) of the Blood Venous Reservoir and clamp it.

Note 1: Refer to the instructions for use of the Tubing set and Blood Venous Reservoir before initiation of the circuit assembly.

Note 2: The Blood Venous Reservoir should always be positioned above the Oxygenator.

b. Connect the recirculation line (3) to the connectors for recirculation of the Oxygenator and Blood Venous Reservoir and clamp it.

c. Connect the pump line (4) to the Blood Venous Reservoir blood outlet connector and to the venous inlet connector of the Oxygenator heat exchanger and clamp it.

d. Connect the arterial line (5) to the Oxygenator blood outlet connector and clamp it.

Note 3: It is recommended the use of an Arterial Blood Filter (E) in the arterial line of the Tubing set, in order to prevent blood clots. The Filter blood inlet should be connected to the arterial outlet of the Oxygenator, and the blood outlet of the Filter to the arterial line, which will be later connected to the Arterial Cannula, as instructions in the product's instructions manual.

e. Place three-way stop cocks in the venous and arterial sample connectors of the Oxygenator and Blood Venous Reservoir making sure they are closed.

f. Connect the suction lines (6) to inlet connectors for suction of the Blood Venous Reservoir.

g. Check all connections, and for security, use the clamps that come with the Tubing set to hold them.

8.3 Installation of Gas and Water Lines (Figure 2)

a. Connect the outlet of the Gas Mixer/Flowmeter (7) to the Gas Filter.

Note 4: Refer to the instructions for use of the Gas Mixer/Flowmeter before using it and use the inlet gas pressure recommended by the manufacturer.

Note 5: Make sure that the outlet gas connector of the Oxygenator is clear.

b. Connect the gas line (8) to the Gas Filter and to the Oxygenator gas inlet connector.

c. Connect the Water Circulator to the inlet/outlet water connectors (9) of the Oxygenator heat exchanger.

Note 6: Refer to the instructions for use of the Water Circulator unit before initiating the circuit assembly.

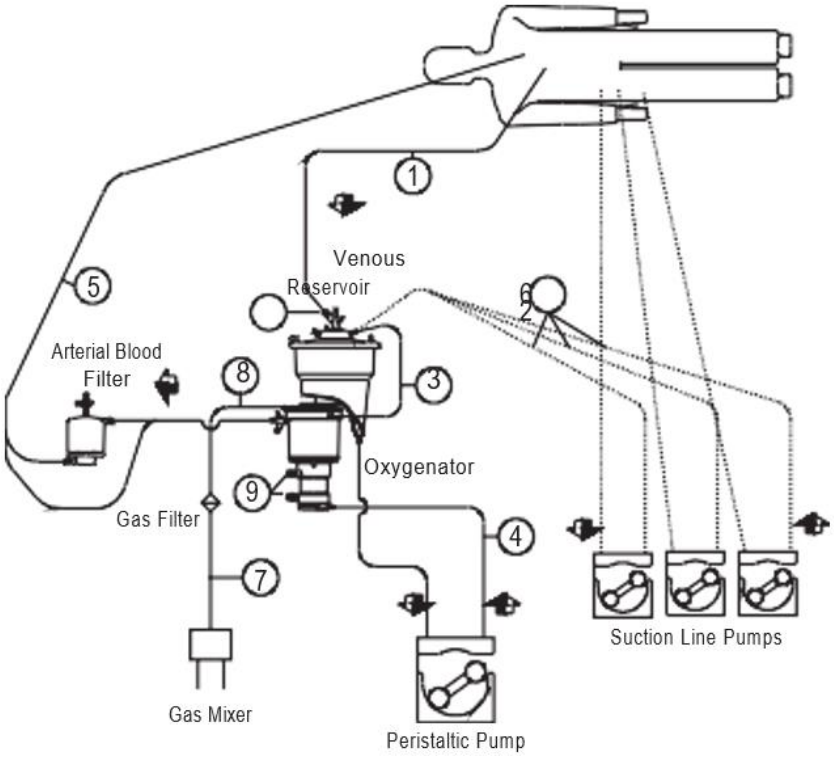


Figure 2 - Scheme of the CPB circuit assembling

8.4 Priming procedure (Figure 3):

a. Make sure that all lines of the CPB circuit are not clamped.

b. Clamp the pump line (1) and the Oxygenator arterial blood outlet (2).

c. Infuse the priming solution through the connectors on the Blood Venous Reservoir cap intended for application of drugs, so that the solution passes through the reservoir filter.

d. With the pump line outside of the Arterial Roller Pump, slowly loosen the clamp of the pump line (1) so that the priming solution drains by gravity and fills the entire line and the Oxygenator.

e. Place the tube of the pump line in the Arterial Roller Pump and circulate the priming solution slowly for a period of about 5 minutes or until the complete trapping of air bubbles in the Oxygenator.

Note 7: The adjustment of the occlusion of the Arterial Roller Pumps should be performed before the assembly of the CPB circuit, following the instructions in the instructions for use of the Pump.

f. Stop the Arterial Pump, clamp the Oxygenator recirculation line (3) and connect the arterial line (7) to the venous drainage line (9).

Note 8: It is recommended to use a Recirculation Filter (or Pre-Bypass Filter) between the lines (7) and (9).

g. Put an Extensor Tube (6) between the Blood Filter and the Blood Venous Reservoir, by keeping the three-way stopcock closed.

h. Clamp the inlet (4) and outlet (5) of the Blood Filter, loosen the arterial blood outlet clamp (2) of the Oxygenator; turn on the Arterial Pump and circulate the priming solution through the circuit with high flow and for a period of approximately 5 minutes.

i. Adjust the Pump to a low flow rate, open the three-way stopcock and loosen the clamp (5) of the Blood Filter outlet, allowing retrograde filling with the priming solution.

j. Remove air bubbles from the Blood Filter, loosen the inlet clamp (4), and make sure that all units and tubes from CPB circuit are free of air bubbles and leakage points.

k. To start the cardiopulmonary bypass procedure, connect lines (9) and (7) to the arterial and venous cannulas, respectively, ensuring the total absence of air bubbles in the connecting points, and adjust the perfusion parameters as standard protocol of the surgical team.

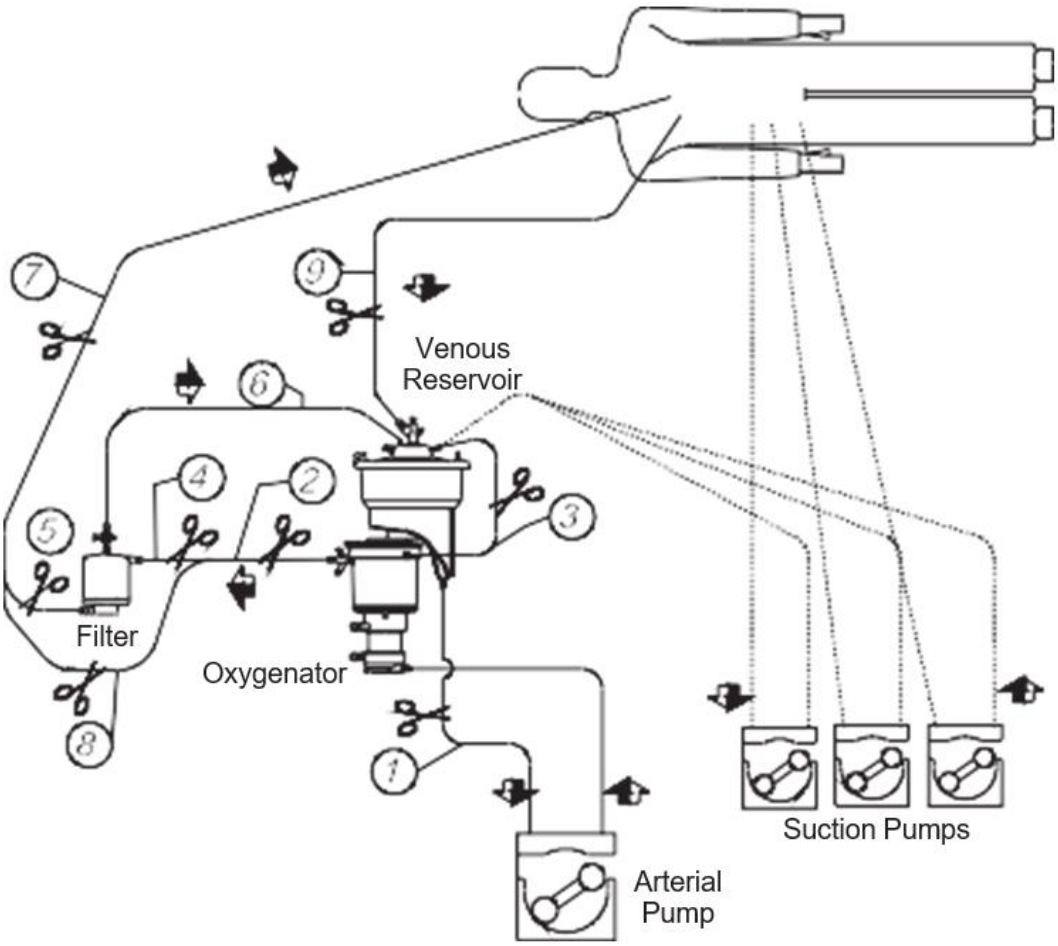


Figure 3 - Circuit for priming procedure

8.5 Perfusion Control

Oxygenation and CO_2 removal controls during perfusion are independent. By varying the gradients of partial pressure of oxygen (pO_2) and partial pressure of carbon dioxide (pCO_2) between blood and gas mixture, oxygenation and CO_2 removal are altered, respectively.

To change (increase or decrease) the blood oxygenation level, the oxygen concentration (FiO_2) in the Gas Mixer must be varied. To change (increase or decrease) the carbon dioxide removal capacity, you must vary the flow of the gas mixture in the Oxygenator, that is, change the gas flow/blood flow ratio.

Blood temperature is controlled by regulating the temperature of the water that circulates through the Oxygenator heat exchanger.

Note 4: The connection for the Temperature Sensor is the place destined for the coupling of a Temperature Sensor, whose purpose is to monitor the blood in the arterial outlet.

8.6 Emergency Oxygenator Replacement

In case of failures or leaks in the Oxygenator, the procedure below must be followed to replace the unit:

a. Remove the reserve Oxygenator from the packaging and check its integrity.

b. Clamp the arterial and venous lines.

c. Stop rotation and water flow in the heart-lung machine.

d. Close gas flow.

e. Place tube clamps close to the oxygenator blood outlet and blood inlet connectors, close the recirculation line.

f. Remove the oxygenator to be replaced from the holder and replace with the new one.

g. Remove the arterial line from the oxygenator to be replaced and connect it to the new one.

h. Remove the venous line from the oxygenator to be replaced and connect to the new one.

i. Remove the pump line from the oxygenator to be replaced and connect to the new one.

j. Place the recirculation line in the new oxygenator and keep it open.

k. Open the clamp next to the blood inlet connector and allow the solution to flow until it is completely filled, through the prime inlet connector.

l. Do the step describe in 8.4.

m. Make sure there are no bubbles in the circuit.

n. Remove all other clamps (venous, arterial and water lines).

o. Turn on the pump, the gas flow and the water circulator and restart the perfusion.

8.7 Common Problems and Possible Solutions

Table 4 - Common Problems and solutions

Problems and solutions	
low pO_2	Increase O_2%
high pO_2	Reduce O_2%
low pCO_2	Decrease gas flow
high pCO_2	Increase gas flow

9. WARNINGS

- Read the instructions before use;
- Single use product. Therefore, do not re-sterilize or reuse the product. There are no data to support the sterility, pyrogenicity and functionality of devices after reprocessing;
- Reprocessing prohibited. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device (leaks, low performance, membrane rupture);
- Do not use non-sterile products - they must be sterile before use;
- Do not use the product after the expiry date;
- Do not use the product if it is damaged or the packaging is broken;
- Before use, the product must be checked for proper operation and to ensure the model is suitable for its intended purpose;
- Product intended exclusively for medical use;
- The product should only be used by people specially trained on cardiopulmonary bypass (CPB) techniques;
- The procedure and the correct application of the product are the responsibility of the doctor who performs the treatment;
- The product must not be used under conditions that contradict its technical specifications, under penalty of loss of performance or accidents. It is up to the person responsible for using the product to check in advance whether the technical specifications meet the needs of the procedure to be performed;
- Always use aseptic techniques when handling the product after opening;
- Avoid any impacts during transport or use;
- Do not use the product in case of doubt;
- The product should be used immediately after opening the package. After use, dispose of safely as medical waste according to health institution policies. The product is biohazardous as it is contaminated with blood;
- Pressure at the blood inlet of the oxygenator should not exceed 100kPa (760 mmHg). Pressure greater than 100kPa (760 mmHg) may cause leaks or damage to the device;
- Water pressure at the heat exchanger inlet should not exceed 220Kpa (32 PSI or 1660mmHg). Pressure greater than 220kPa may cause leaks or damage to the device;
- When using the centrifugal pump on the arterial line, clamp the arterial line distal to the oxygenator (the patient's side) before stopping the pump. Improper clamping may causa back-flow or migration of gaseous emboli into the blood side;

10. PRECAUTIONS

- It is recommended that you check the product carefully before use. The operation of the product packaging may be affected by transport. It is not possible to guarantee full operation of the product when transport damage occurs. If the product has been dropped or crushed, it cannot be used and must be replaced with a new product;
- Always keep a spare unit of the product during the procedure;
- The manufacturer is not responsible for damage resulting from lack of experience, misuse or failure to follow the instructions for use;
- During the procedure, blood anticoagulation protocol should be adopted;
- Protamine should not be used in patients before or during extracorporeal circulation;
- It is necessary to provide correct heparinization and accurate monitoring of the anticoagulation status before, during or after extracorporeal circulation;
- Check all circuit connections in advance to prevent any leaks;
- Remove all air from the extracorporeal circuit before the start of CPB using the circuit prime procedure;
- Do not make changes to the product;
- Do not use the product if not all connectors are protected with a protective cover. The protective covers must be retained immediately before use;
- Regularly monitor the patient to identify side effects of cardiopulmonary bypass (e.g., infections, hemolysis, post-perfusion syndrome and organ damage);
- Regularly monitor the patient clotting status (e.g., activated clotting time and partial thromboplastin time). The anticoagulation control protocol is the responsibility of the responsible user;
- Broken and / or leaking connectors must be replaced;
- Tube metal clamps should be available;
- During transport of patient, avoid leaving the tubes hanging, excessive forces, bumps and kinks;
- To collect samples, avoid creating bubbles in the circuit;
- Monitor collection and recirculation lines to prevent clots;
- To ensure optimal operation of the oxygenator, additional devices or connections are required. Read the instructions for use carefully before using the device, ensuring that all necessary parts are available before use;
- Avoid bumping into the oxygenator during the prime procedure;
- During infusion, the blood pressure in the oxygenator gas exchanger must always be kept higher than the gas pressure to prevent formation of micro-bubbles in blood (gas embolism);

- The gas outlets of the oxygenator must never be blocked, as this causes an increase in gas pressure in the gas exchanger, which can cause gas embolism;
- The maximum blood flow of the oxygenator model used must not be exceeded;
- Blood flow should never be reduced suddenly. The sudden reduction or sudden stop of blood flow causes a decrease in blood pressure in the gas exchanger, which can cause gas embolism. The reduction or stop of blood flow must always be done gradually and accompanied by reduction in gas flow, with continuous monitoring of gas and blood pressures in the gas exchanger;
- Whenever the Arterial Pump is stopped (zero flow), the gas flow must be closed (zero flow), under the risk of gas embolism;
- Monitor oxygenation and carbon dioxide removal throughout the procedure through periodic gas analysis;
- Monitor the suction pressure in the venous line, check if luer connections and 3-way valves are closed to avoid embolism in the line;
- Monitor oxygenator pressure gradient (pressure before and after the oxygenator);
- Monitor gas exchange performance in gas analysis;
- Always position the oxygenator below the patient level;
- Never infuse drugs directly into the oxygenator connectors;
- Do not use solvents such as alcohol, ether, acetone, liquid anesthetics by inhalation (for example: Halothane, Enflurane, etc.), as these can damage the product;
- In case of need to replace the Oxygenator during procedure, proceed according to related instructions contained in the Product Replacement Instructions.

11. STORAGE AND TRANSPORT

The product in its original packaging must be stored in a clean, dry, weather-free environment and at temperatures above -10ºC and below 40ºC. For its transportation, it should never be refrigerated, frozen or exposed to temperatures above 40ºC.

12. PRODUCT DISPOSAL

After use, follow the **safe disposal procedure, item 12.1,** to safely dispose of the device. Product and packaging disposal must comply with the hospital and / or local government policy. The product must be disposed of only in hospital / infectious waste. The product is biohazardous as it is contaminated with blood.

12.1 Safe Disposal Procedure

Warning: Wear gloves to carry out this process, there is a risk of contamination.

Note 5: It is not necessary to disconnect the bloodlines tubes.

Note 6: This safe disposal procedure serves the cardiopulmonary bypass circuit and its main components (Tubing Set, Oxygenator, Blood Reservoir Venous/Cardiotomy and centrifugal pump). For specific components, follow instructions that come with the device in question.

a. Remove the aspirators lines from the roller of the heart-lung machine and set them aside on a secure surface.

b. Remove the pump line from the roller of the heart-lung machine or, if using a centrifugal pump, detach it and set aside on a secure surface.

c. Position a surgical field below the oxygenator to avoid wetting the floor, clamp the water lines near the oxygenator's water inlet/outlet connectors, and, disconnect the lines, set the pipes aside on a safe surface.

Note 7: For the next steps, use the disposal waste for contaminated products.

Note 8: Always handle the Venous Reservoir and the Cardiotomy Reservoir in an upright position to avoid blood overflow through the top cover.

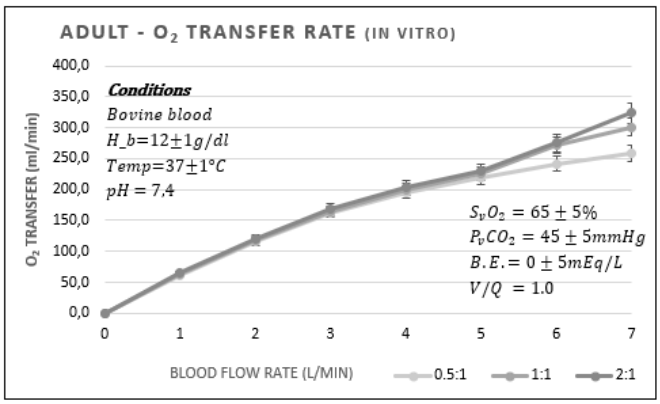
d. Remove the oxygenator and venous reservoir from their respective holders and discard it carefully.

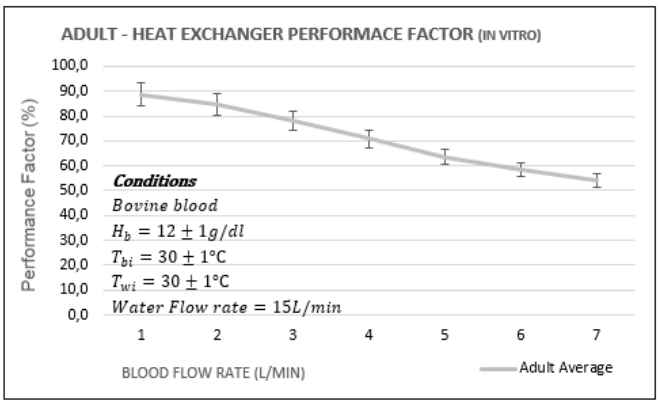
e. Remove the Cardiotomy reservoir from the holder and discard it carefully.

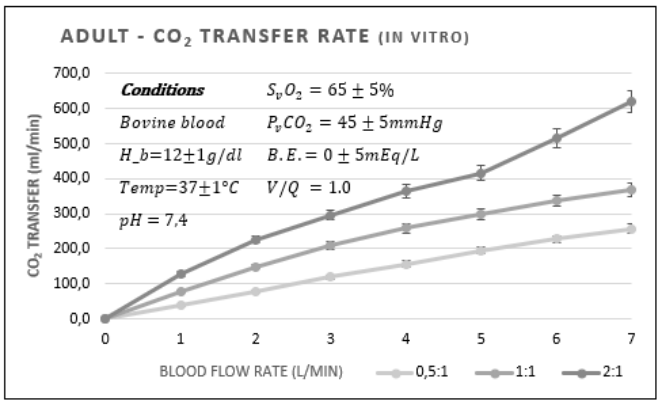
f. Discard the remaining lines, including the centrifugal pump line if used.

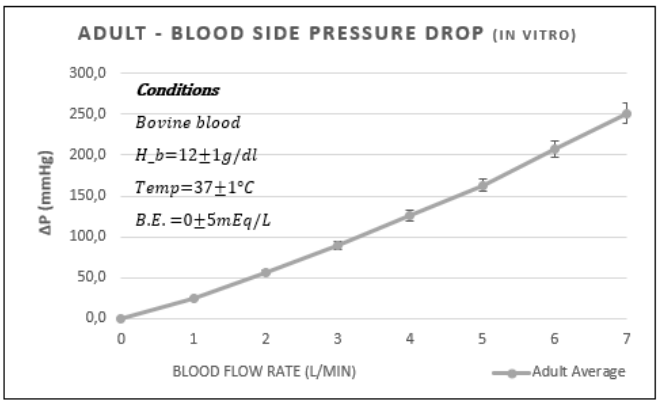
13. PERFORMANCE DATA

Membrane Oxygenator Adult BRCoating

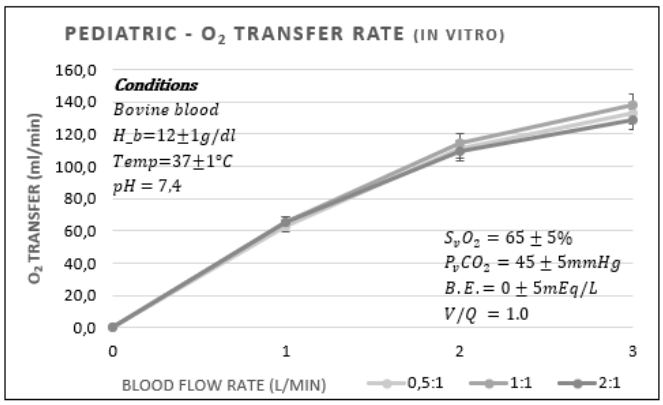


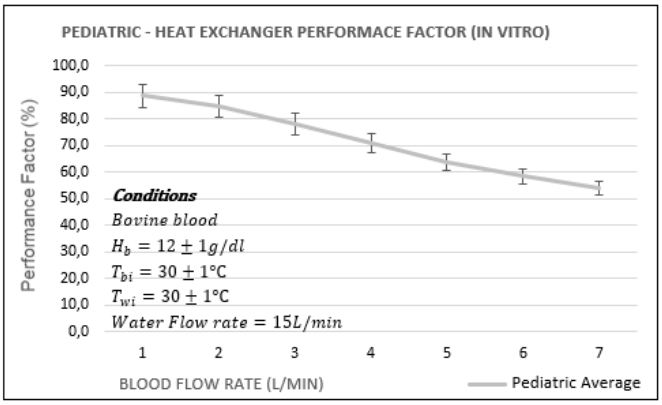


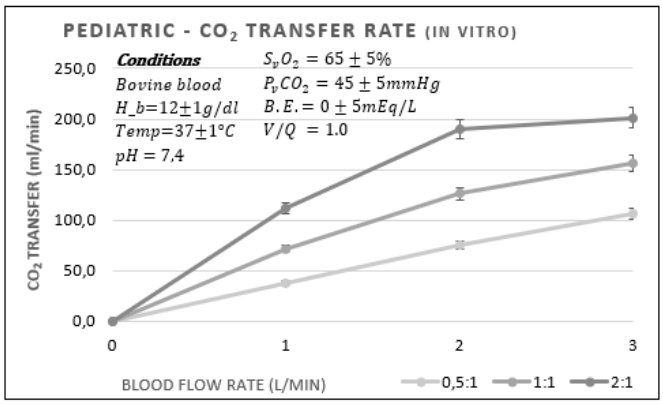


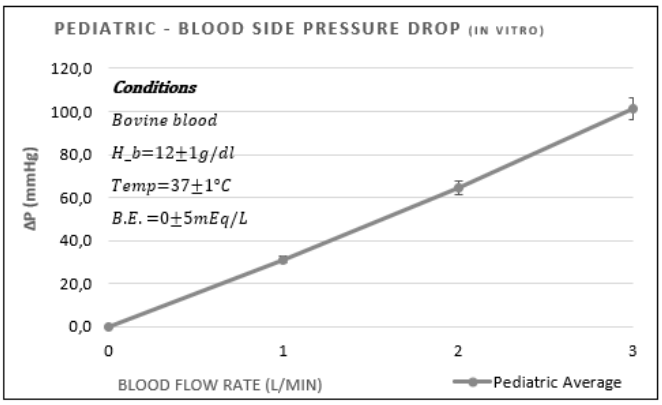


Membrane Oxygenator Pediatric BRCoating

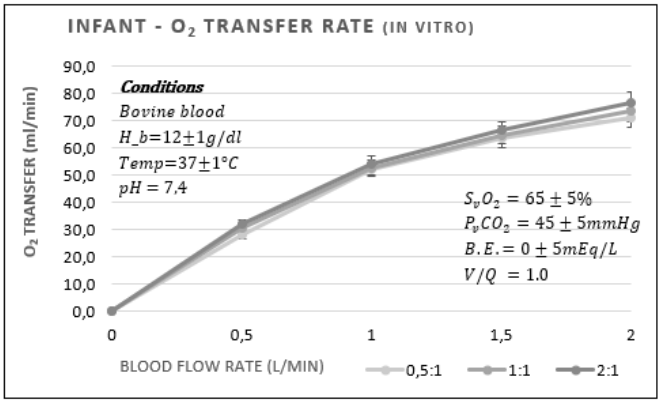


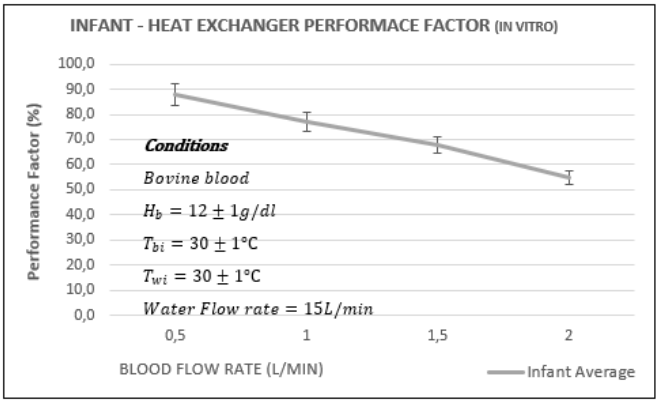


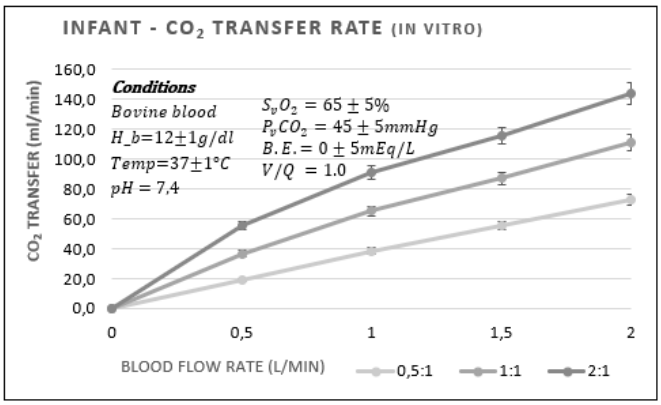


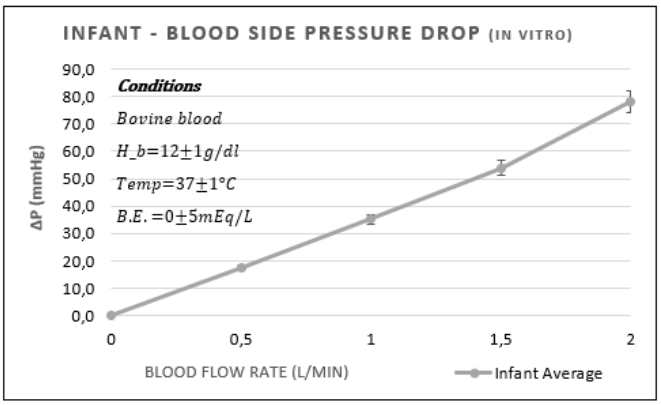


Membrane Oxygenator Infant BRCoating

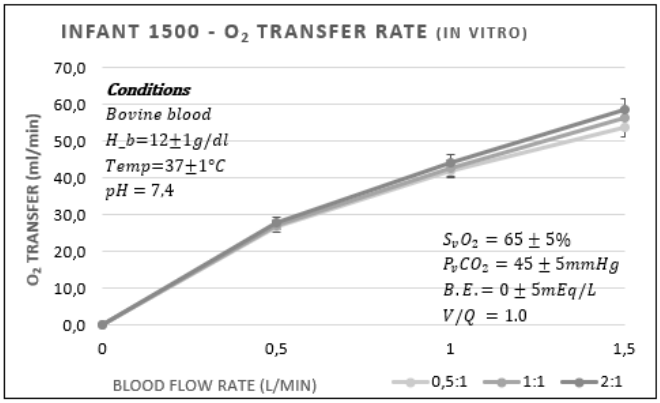


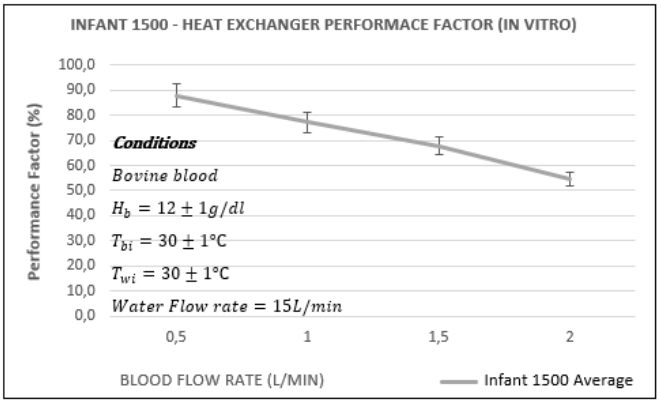


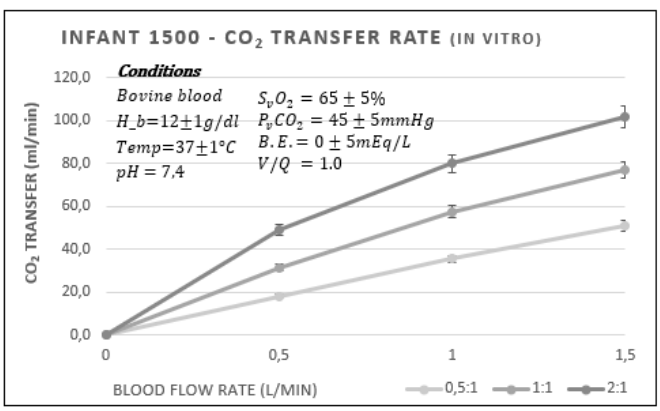


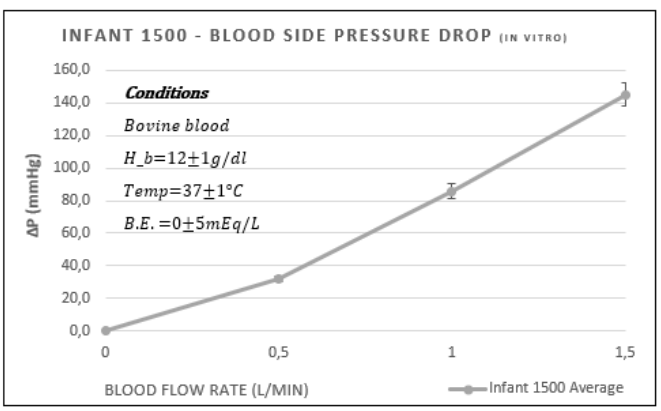


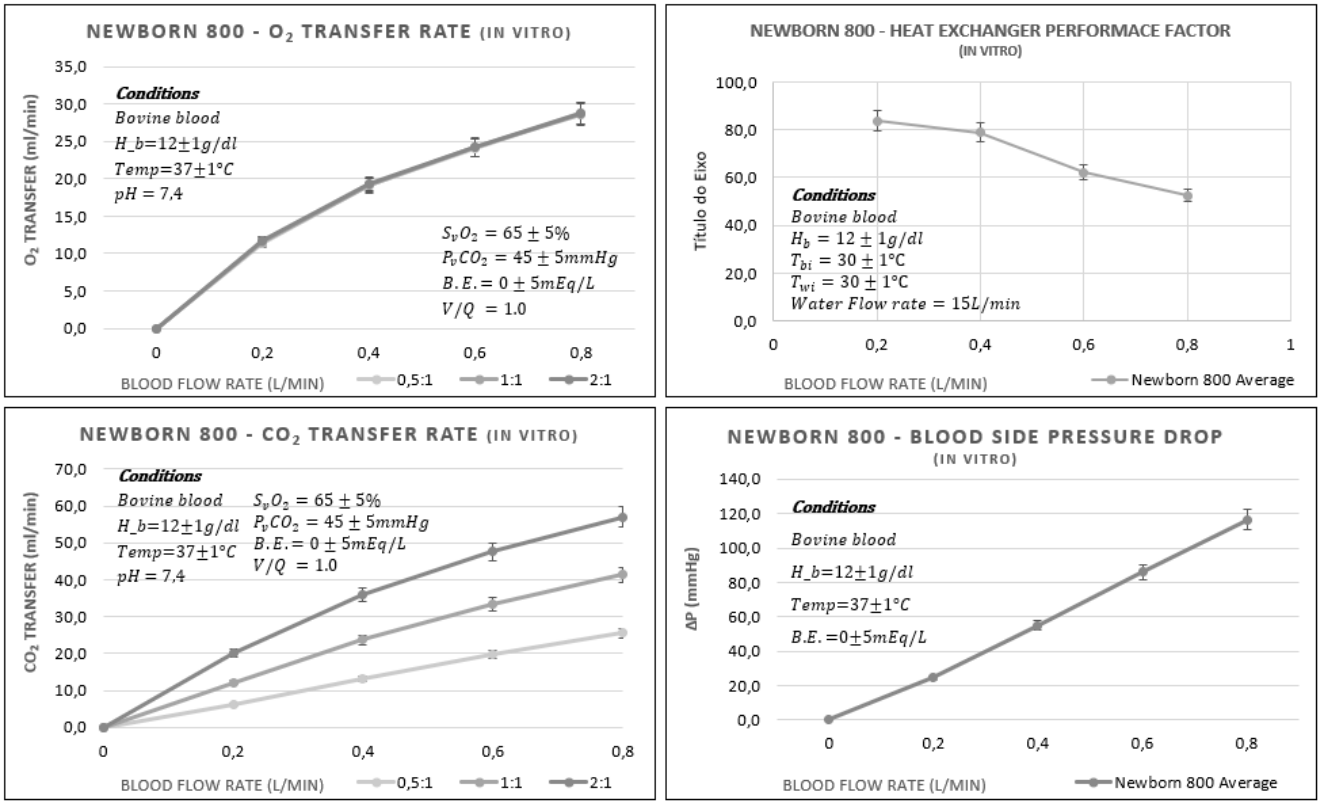
Membrane Oxygenator Infant 1500 BRCoating











14. SHELF-LIFE

The Membrane Oxygenator BRCoating is valid for 3 years after the sterilization date, considered sterile only if the package has not been violated. Check the validity date on the label of the product package.

15. WARRANTY

Braile Biomédica Indústria, Comércio e Representações Ltda, certifies that the product has been manufactured with due care, with good quality materials, and is warranted for manufacturing defects pursuant to the Brazilian Consumer Protection Code. It further clarifies that if the product is violated by unauthorized or unqualified personnel, the warranty will be void. The manufacturer states that any other warranty expressly or implicitly granted by others shall not be valid. The use of the product is restricted to doctors or qualified and trained technicians under the supervision of the responsible physician, who are familiar with the procedures for using the product, being their responsibility said use. The manufacturer will not be responsible for any damage resulting from product misuse.

Braile Biomédica Ltda also states that the right to complain about the product will be governed by the provisions contained in Article 26 of the Brazilian Consumer

Protection Code (Law 8.078 / 90). No agent, employee, representative, or distributor of the Braile Biomédica Ltda has the authority to change or amend what is described herein, assume or bind the Braile Biomédica Ltda to any other liability or warranty in connection with this product.

This product was developed and manufactured based on legal and regulatory requirements, and under strict quality control, aiming at managing potential risks of its use, in order to minimize them within safe limits. However, Braile Biomédica cannot ensure that the product is totally free from the likelihood of failure, so that its use must respect all precautions, restrictions, warnings, special care and relative instructions for use, as well as must be constantly and carefully monitored.

16. MANUFACTOR INFORMATION

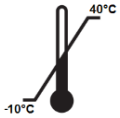
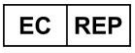
Manufactured by:

Braile Biomédica Indústria Comércio e Representações Ltda
CNPJ N°: 52.828.936/0001-09
Av. Presidente Juscelino Kubitschek de Oliveira, 1505 – Jardim Tarraf I
CEP: 15091-450
São José do Rio Preto – São Paulo

Imported and distributed by:

Mars Medical
Landhausstrasse 46
70190, Stuttgart – Germany
Tel: +49 1751938653
E-Mail: info@marsmedical.de

17. SYMBOLS DESCRIPTION

	Manufacturer		Use-by date
	Catalog Number		Sterile
	Serial Number		Sterilized using ethylene oxide
	Batch Code		Do not use if packaging is damaged
	Date/ Country Manufacture		Fragile, handle with care
	Non-pyrogenic		This way up
	Consult Instructions for Use or electronic instructions for use		Stacking limit
	Temperature limit		Recyclable
	Keep dry		Medical Device
	Keep away from sunlight		Do not re-use
	Unique Device Identifier		Do not resterilize
	CE Mark		Authorized representative in the European Union

18. LABEL TEMPLATE

Braile Biomédica Indústria Comércio e Representações Ltda.
Av. Presidente Juscelino Kubitschek de Oliveira, 1505 - Jardim Tarraf I
CEP 15091-450 - São José do Rio Preto - SP - Brasil
Fone: +55 17 2136-7000 SAC: 0800 707 20 50
CNPJ: 52.828.936/0001-09 www.braile.com.br

CE 2797

EC REP

Mars Medical
Landhausstrasse 46
70190, Stuttgart – Germany
Tel: +49 1751938653
E-Mail: info@marsmedical.de

MEMBRANE OXYGENATOR BRCOATING

Description (Model): XXXXXX
Package Content: 01 unit of Membrane Oxygenator **#model** BRCoating / 01 Instruction for Use
Contains 1 unit destined to medical application

ANVISA Registration nº: XXXXX
Technical Name: Oxygenator
Technician in Charge: Vladimir D. A. Ramirez – CRF-SP 09010

Read instructions before use
Single use product / Prohibited reprocessing

Indications, Precautions, Warnings, Instructions of Use, Preservation Cares*.
* Please refer to leaflet insert "INSTRUCTIONS OF USE".

REF XXXXXX SN XXXXXX LOT XXXXXX

BR YYYY/MM/DD UDI

YYYY/MM/DD

STERILE STERILE EO

braile.com.br/en/produtos/cemark products

MD

The external package has the following informations

The product must be stored and transported in its original packaging, in a clean, dry, weather-free environment and at a controlled temperature.