



AMG PMP Pediatric Oxygenator

PRODUCT HIGHLIGHTS

Hollow-fiber oxygenator with integrated heat exchanger able to oxygenate the blood, remove carbon dioxide from the blood and regulate blood temperature in pediatric patients. It is designed for hemocompatibility for use in extracorporeal circuits.

Key Features

- Polymethylpentene (PMP) fibers
- Phosphorylcholine (PC) coating
- Integrated arterial and venous luer ports
- Compatible with any circuit with 3/8" tubing
- Holder connects to the CentriMag™ System Cart or IV pole



AMG PMP
Pediatric Oxygenator

PRODUCT SPECIFICATIONS

PART NUMBER	DESCRIPTION
US5087	AMG PMP Pediatric Oxygenator Box of 4
US2257	Oxygenator Holder Articulating arm and holder for AMG PMP Oxygenators. Clamps onto vertical posts such as IV poles
210-50142	CentriMag™ System Transporter Oxygenator Bracket, Medium Fixes AMG PMP Pediatric Oxygenator to CentriMag™ System Transporter

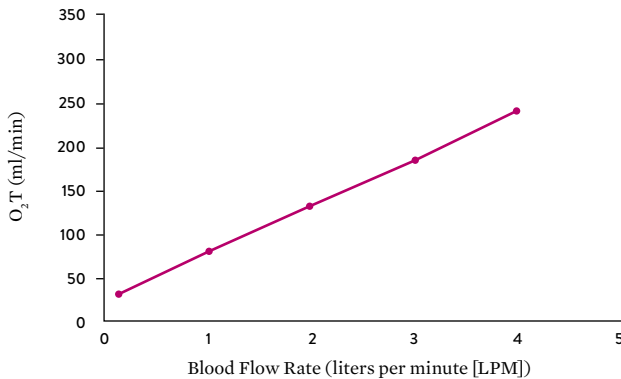
TECHNICAL SPECIFICATIONS

OXYGENATOR SPECIFICATIONS	
Membrane Material	Polymethylpentene (PMP) with phosphorylcholine (PC) coating
Maximum Blood Flow Rate	4 L/min
Priming Volume	190 mL
Residual Blood Volume	100 mL
Membrane Surface Area	1.35 m ²
Heat Exchanger Type	Stainless steel
Heat Exchanger Surface Area	0.08 m ²
Heat Exchanger Performance Factor	0.64 at 4 L/min
Max Water Pathway Pressure	29 PSI (1,500 mmHg)
Max Gas Pathway Pressure	0.14 PSI (7 mmHg)
Max Blood Pathway Pressure	14.5 PSI (750 mmHg)
Venous Inlet and Arterial Outlet	3/8" barbed connectors
Water Inlet and Outlet	1/2" Hansen™ quick couplings
Gas Inlet	1/4"

PRESSURE, HEAT EXCHANGE AND GAS EXCHANGE CURVES*

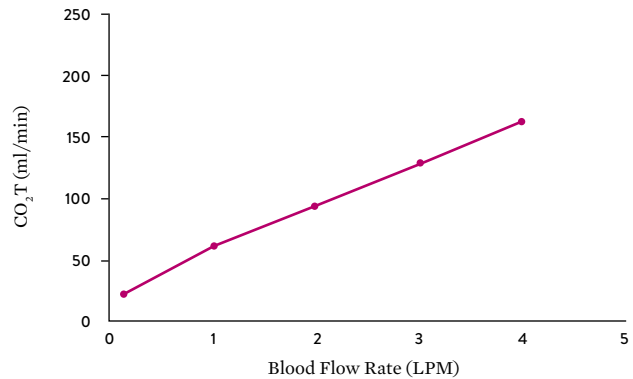
O₂ TRANSFER

Efficiency of blood oxygenation



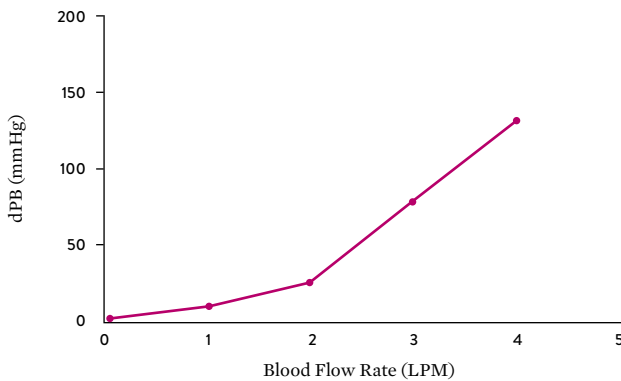
CO₂ TRANSFER

Efficiency of blood carbon dioxide removal



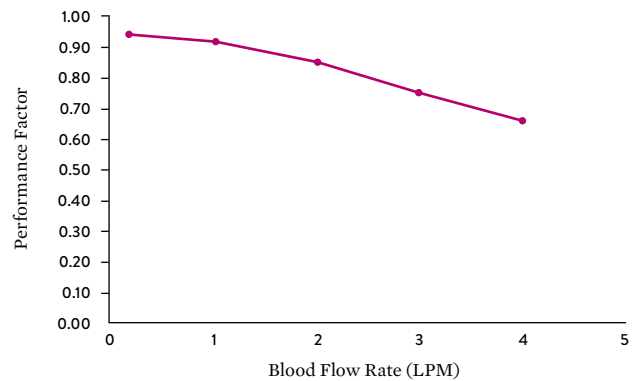
PRESSURE DROP

Difference in blood pressure before and after the oxygenator



HEAT EXCHANGE

Efficiency of heat exchange



*ISO 7199 Condition

AMG PMP Oxygenators and Oxygenator Holder are manufactured by Eurosets s.r.l. and distributed by Abbott.

Abbott

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Rx Only

Important Safety Information

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

AMG PMP Pediatric Oxygenator Indications [510(k) Clearance; 6-hour use]:

The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for 6 hours or less with a maximum blood flow rate of 4 liters/minute.

AMG PMP Pediatric Oxygenator Contraindications [510(k) Clearance; 6-hour use]: No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions. Do not use the device for any purpose other than indicated.

CentriMag™ Circulatory Support System Indications [PMA Approval; 30-day use]:

Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy.

CentriMag Circulatory Support System Contraindications [PMA Approval; 30-day use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

Humanitarian Device Statement: Caution: Humanitarian Device. The CentriMag Circulatory Support System is authorized by Federal Law for temporary circulatory support for up to 30 days for patients in cardiogenic shock due to right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

CentriMag™ RVAS Indications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is intended to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.

CentriMag RVAS Contraindications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

CentriMag™ Blood Pump Indications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

CentriMag Blood Pump Contraindications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

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