AMG PMP Adult Oxygenator

PRODUCT HIGHLIGHTS

Hollow-fiber oxygenator 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
Adult Oxygenator

PRODUCT SPECIFICATIONS

PART NUMBER	DESCRIPTION
US5062	**AMG PMP Adult Oxygenator** Box of 4
US2257	**Oxygenator Holder** Articulating arm and holder for AMG PMP Adult Oxygenator. Clamps onto vertical posts such as IV poles

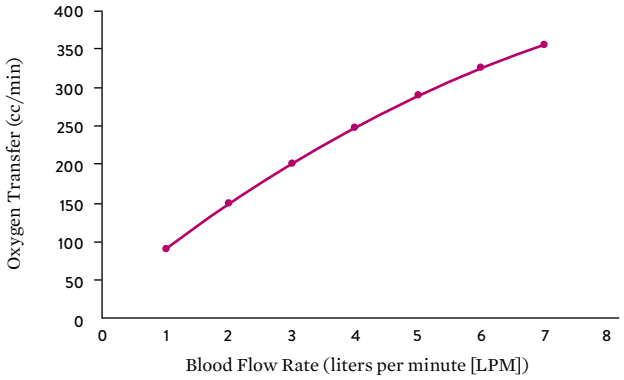
TECHNICAL SPECIFICATIONS

TECHNICAL SPECIFICATION	AMG PMP ADULT OXYGENATOR
Maximum Blood Flow Rate	7.0 L/min
Priming Volume	220 mL
Gas Exchange Membrane Surface Area	1.81 m^2
Heat Exchanger Surface Area	0.08 m^2
Gas Exchange Material (Membrane Type)	Polymethylpentene (PMP)
Heat Exchange Material	Stainless Steel
Surface Coating	Phosphorylcholine (PC)
Inlet and Outlet	3/8″ Barbed Connectors

PRESSURE, HEAT EXCHANGE AND GAS EXCHANGE CURVES

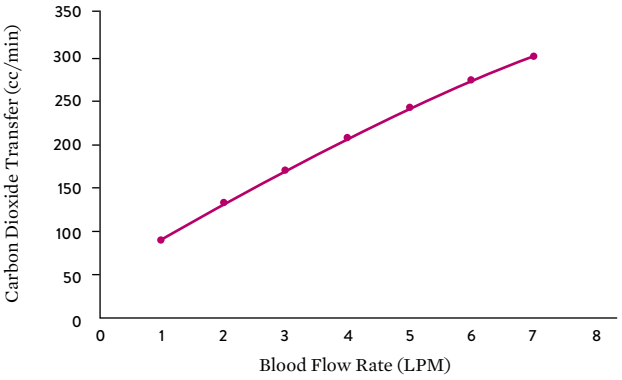
O_2 TRANSFER

Efficiency of blood oxygenation



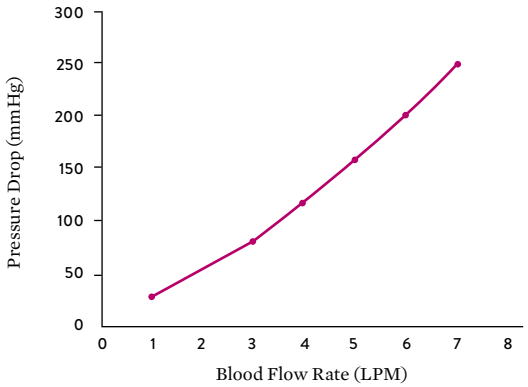
CO_2 TRANSFER

Efficiency of blood carbon dioxide removal



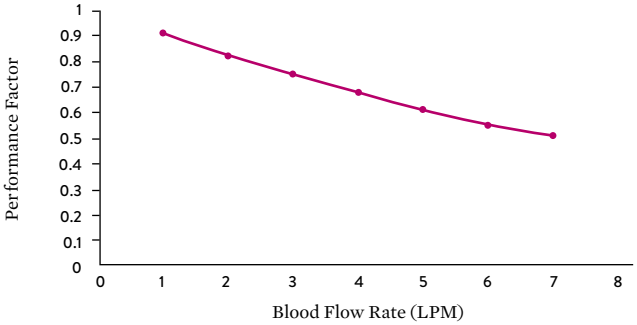
PRESSURE DROP

Difference in blood pressure before and after the oxygenator



HEAT EXCHANGE

Efficiency of heat exchange



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

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Cardiovascular.Abbott/CentriMag

Rx Only
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 Adult Oxygenator Temporary Expanded Indication: A.M.G. MODULE PMP NO T.P. STERILE is indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency.

AMG PMP Adult Oxygenator Indications [510(k) Clearance; 6-hour use]: The AMG MODULE PMP NO T.P. STERILE is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The AMG MODULE PMP NO T.P. STERILE 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 routine cardiopulmonary bypass procedures up to 6 hours in duration. Contact with blood for a longer period of time is unadvisable. AMG MODULE PMP NO T.P. STERILE is an adult oxygenator. The AMG MODULE PMP NO T.P. STERILE should be used in combination with medical devices listed in section "Medical devices for use with the AMG MODULE PMP NO T.P. STERILE."

AMG PMP Adult Oxygenator Contraindications [510(k) Clearance; 6-hour use]: This device used for any other purposes than for the indicated intended use is the responsibility of the user. See Instructions for Use.

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 cardiotomy 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™ Circulatory Support System Adverse Events [PMA Approval; 30-day use]: Adverse events that may be associated with mechanical circulatory support can include, but are not limited to, the following: bleeding on device support, hemolysis, infection, renal failure/dysfunction/complication, respiratory dysfunction, hepatic dysfunction, cardia arrhythmias (atrial or ventricular), thromboembolism (venous and arterial non-CNS), hypotension, hypertension, device malfunction or failure, psychiatric events, right heart failure, and death.

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 cardiotomy 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™ Acute Circulatory Support System Temporary Expanded Indication: The FDA issued an enforcement policy guidance document in April 2020 allowing for FDA-cleared or approved cardiopulmonary bypass devices to be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency. The CentriMag™ System including the CentriMag™ Blood Pump and PediMag™ Blood Pump are indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure.

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 cardiotomy 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.

MAT-2001000 v2.0 | Item approved for U.S. use only

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