

Abiomed Breathe OXY-1 System™

Cardiopulmonary Support System

Easy-to-use, compact cardiopulmonary support system, with an integrated oxygen concentrator and pump that provides an independent oxygen source to promote mobility. The Abiomed Breathe OXY-1 System pumps, oxygenates and removes carbon dioxide from blood.

▲ Designed for Mobility

All-in-one compact design with built-in oxygen concentrator

▲ Integrated Pump Lung Unit

Volute spiral technology designed for uniform blood flow to minimize stagnation and thrombosis

▲ Advanced Gas Exchange Technology

Innovative gas path enables full therapy with reduced O₂ demand

▲ Easy and Intuitive

Simple for health care providers to set up, manage, and monitor

▲ Tailored Patient Strategy with Abiomed Support

24/7 on-call and on-site support for Impella® and extracorporeal MCS



OVERVIEW

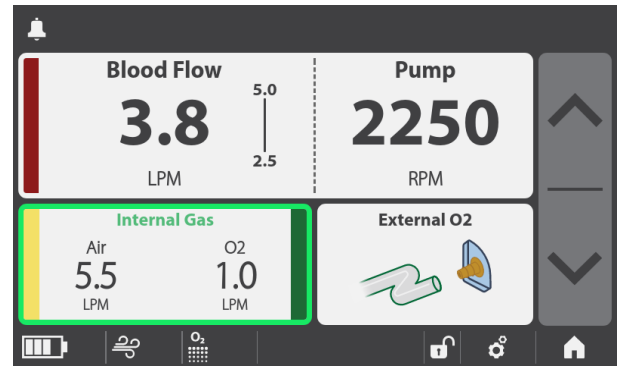
▲ Console

The console touch screen enables the operator to set pump speed, monitor blood flow and set sweep gas flow rate. The gas can be provided by an external flow metered gas source or from an internal oxygen concentrator and blower when external gas source is interrupted or not available.

- A set of alarms monitors and alerts the operator when the system operates outside operator defined alarm limits or system defined limits.
- The integrated back-up battery system provides up to 3 hours of power.

▲ Pump Driver Unit

1. Pump Lung Unit (PLU)
2. Blood Tubing
3. Condensation Tray
4. Cable Guard
5. Pump Driver Lid
6. Ultrasonic Flow Sensor & Bubble Detection



▲ Pump Lung Unit Disposable (PLU)

The OXY-1 PLU Disposable is an integrated pump and oxygenator containing a polymethylpentene (PMP) hollow fiber membrane mesh. The oxygenator is cylindrical in shape and the blood uniformly enters the oxygenator membrane from the outside perimeter in a radial direction until it reaches the center and exits at the top.

- This unique geometry and uniform blood flow reduces the opportunity for stagnation by eliminating corners and dead flow zone as you will find in other oxygenators.
- As blood passes through and contacts the surface of the membrane, oxygen diffuses into the blood and carbon dioxide diffuses out of the blood into the sweep gas.
- The OXY-1 contains a unique sweep gas interface that reduces the need for high-flow oxygen supply.

TECHNICAL SPECIFICATIONS

Pump & Oxygenator Pump Lung Unit:

Blood Flow Rate: 0.5 – 5 LPM @ 500 mmHg*

Nominal Transmembrane Pressure: 35 mmHg @ 5 LPM

Pump Priming Volume: 34 mL

Oxygenator Priming Volume: 285 mL

O₂ Transfer: > 95% Saturation*

Blood Tubing:

Size: 3/8" ID x 12 ft. (9.5 mm ID x 3.7 m); 3/32" thickness

Console/Pump Controller:

Graphical Display: Touch Screen Control / Capacitive

Pump RPM range: 0-4500 RPM (50 RPM Increments)

Blood Flow Accuracy: +/- 0.3 LPM 0-2 LPM, ±15% > 2 LPM

Bubble Detection: Detectable bubble size > 4 mm diameter

Sweep Gas Modes:

External Oxygen: Flow rate < 15 LPM from external O₂ flow meter

Internal Gas Mode: Sweep Gas (setting): Oxygen: 0.5 – 3 LPM greater of ± 10% LPM or ± 0.2 LPM, 91% ± 6% Oxygen concentration* Air: 1.0 – 15 LPM greater of ± 10% or 0.5 LPM Air*

*Items noted with an asterisk indicate essential performance

Power:

AC Mains: 5.0 A, 100-240 VAC, 50/60 Hz

Battery / Runtime: Lithium Ion; 200 min from a full charge

Battery Charge Time (from zero): < 180 minutes on Standby or < 6.5 hours on Run Mode

System Alarm Sound Pressure Level: > 60 dBA

Console:

Console Dimensions: (H x W x D) 26 x 14 x 9 Inches (66 x 36 x 23 cm)

Console Weight/Mass: 47 lbs./ 21.5 Kg

Wheels: Locking Wheel Castors

Handle: Foldable Handle

Pump Driver:

Driver Dimensions (L x W x H): 10.8 x 6.3 x 5.6 inches (275x160x144 mm)

Weight / Mass (w/o PLU Disposable): 2.9 lbs. (1.3 kg)

Sensors: Ultrasonic flow and bubble detection

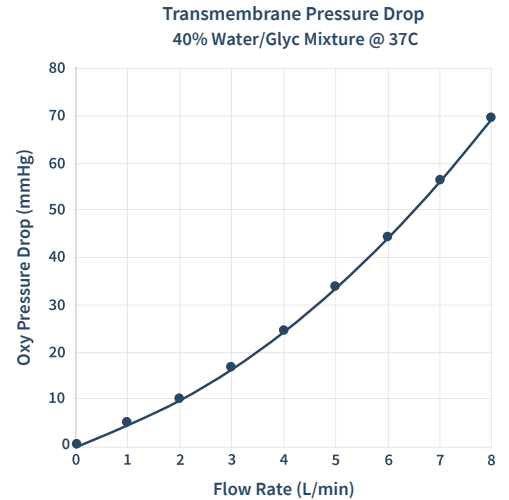
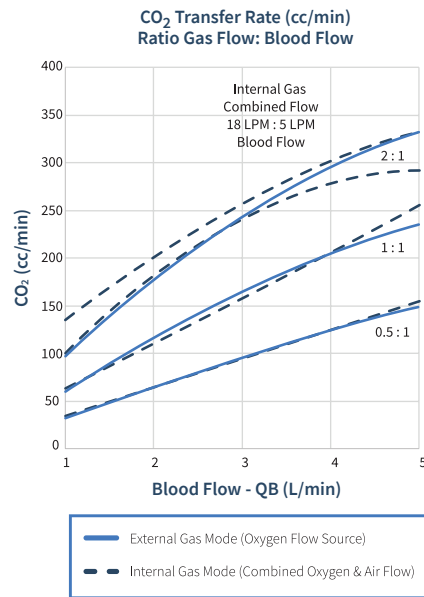
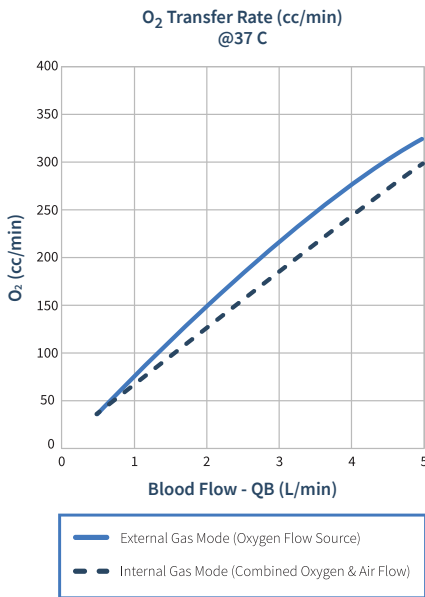
Mount: 25-40mm Dia. IV Pole Mount (Included)

E-Drive:

Power: Manual Hand Crank

RPM Range: 0-5000 RPM

OXYGENATOR PERFORMANCE



INDICATIONS FOR USE

The OXY-1 System is intended to be used for extracorporeal circulation. The OXY-1 System pumps, oxygenates and removes carbon dioxide from blood during cardiopulmonary bypass up to 6 hours in duration.

INTENDED USERS

The OXY-1 System must be operated and/or monitored by users with specialized training in extracorporeal circulation therapy. These users include perfusionists, extracorporeal circulation specialists, ICU nurses with specialized extracorporeal circulation training, cardiothoracic surgeons, intensivists, and others with specialized training and experience. Users are required to be knowledgeable and experienced in methods that require cardiopulmonary bypass and mechanical circulatory support.

Utilization of the Abiomed Breathe OXY-1 System requires clinical judgment for patient risks vs benefits in all circumstances and requires specialized training in the use of cardiopulmonary bypass systems for safe operation under the direct supervision of a qualified physician. This is a prescription-only device.

Important Risk Information for Abiomed Breathe OXY-1 System

CONTRAINDICATIONS

This device used for any other purposes than for the indicated intended use is the responsibility of the user.

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with the Abiomed Breathe OXY-1 System.

Visit <http://www.abiomed.com/important-safety-information> to learn more

TEMPORARY ECMO INDICATION MODIFICATION DURING COVID-19 EMERGENCY

Under guidance issued by FDA, on April 6, 2020, the Abiomed Breathe OXY-1 System is now permitted to be used temporarily in the U.S. for ECMO therapy greater than six hours. Therefore, it now has a limited indication modification for use longer than six hours in an extracorporeal membrane oxygenation (ECMO) circuit to treat patients who are experiencing acute temporary respiratory or acute cardiopulmonary failure. This limited indication modification for ECMO therapy greater than six hours has not been cleared or approved by FDA and is in effect only for the duration of the public health emergency related to COVID-19 as declared by the U.S. Department of Health and Human Services (HHS).