

Abiomed Breethe **OXY-1 System™**



Instructions for Use
& Reference Manual

USER RESPONSIBILITY

The OXY-1 System will perform in conformity with the description thereof contained in this manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. The OXY-1 System must be checked and serviced periodically. A defective system should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. Should such repair or replacement become necessary, Abiomed recommends that a telephone or written request for service advice be made to your sales rep or directly to Abiomed's service line. The OXY-1 System or any of its parts should not be repaired other than in accordance with written instructions provided by Abiomed and performed by Abiomed authorized service personnel. The OXY-1 System must not be altered without Abiomed's prior written approval. The operator of the OXY-1 System shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Abiomed.

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ABOUT THIS MANUAL

INSTRUCTIONS FOR USE

Read the entire operating manual completely before use. This manual contains special notifications:



WARNING!

This instruction must be observed to avoid injury to the patient, operator or other persons.



CAUTION!

This instruction must be observed to avoid damage to the equipment.



NOTE

Additional detail for explanation.

INDICATIONS & INTENDED USERS

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 OXY-1 System requires clinical judgement 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.






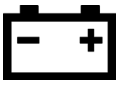
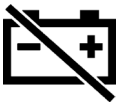



CONTRAINDICATIONS

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

SYMBOLS

Symbol	Title	Reference	Standard Title	Explanatory Text
	Refer to instruction manual/booklet	IEC 60601-1, Reference no. Table D.2, Safety sign 10 (ISO 7010-M002)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	To signify that the instruction manual/ booklet must be read
	Consult instructions for use	ISO 15223-1:2016 and ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates the need for the user to consult the instructions for use.
	Class II equipment	IEC 60417 Reference no. Table D.1, Symbol 9 (IEC 60417- 5172)	Graphic symbols for use on electrical equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140
	Defibrillation-proof Type CF applied part	IEC 60601-1 Reference no. Table D.1, Symbol 21 (IEC 60417-5336)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance.	To identify a defibrillation-proof Type CF applied part complying with IEC 60601-1
	Use-by date	ISO 15223-1:2021 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates the date after which the medical device is not to be used.
	Prescription only	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109 (b)(1)	Labeling-Medical devices; prominence of required label statements. Labeling-Prescription devices	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Manufacturer	ISO 15223-1:2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates the medical device manufacturer
	Date of manufacture	ISO 15223-1:2021 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates the date when the medical device was manufactured.
	Unique Device Identifier	ISO 15223-1:2021, Reference no. 5.7.10	Medical devices Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a carrier that contains unique device identified information.
	Catalog Number	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Indicates the manufacturer's catalog number so that the medical device can be identified
	General Warning	ISO 7010 Reference # W001	Graphical symbols - Safety colours and safety signs - Registered safety signs	Signifies a general warning
	Caution	ISO 15223-1:2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences

Symbol	Title	Reference	Standard Title	Explanatory Text
	Humidity limitation	ISO 15223-1: 2021 Reference no. 5.3.8. (ISO 7000-2620)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Indicates the range of humidity to which the medical device can be safely exposed
	Keep away from sunlight	ISO 15223-1:2021 Reference no. 5.3.2. (ISO 7000-0624)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates a medical device that needs protection from light sources.
	Non-Pyrogenic	ISO 15223-1: 2021 Reference no. 5.6.3. (ISO 7000-2724)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Indicates a medical device that is non-pyrogenic
	Sterilized Using Ethylene Oxide	ISO 15223-1:2021 Reference no. 5.2.4. (ISO 7000-2501)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates a medical device that has been sterilized using ethylene oxide.
	Batch code	ISO 15223-1:2021 ISO 7000-2492	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Serial Number	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Mass; weight	ISO 7000-1321B	Graphical symbols for use on equipment	To indicate mass. To identify a function related to mass.
	Input: entrance	IEC-TR-60878 Reference no. (ISO 7000-0794)	Graphical symbols for electrical equipment in medical practice	To identify an entrance, for example exhaust gas entry for measurement (for example of CO- value)
	Fuse	IEC 60417-1 Reference no. ISO 7000-5016	Graphical symbols for use on equipment	To identify fuse boxes or their location
	Do not reuse	ISO 15223-1:2021 Reference no. 5.4.2. (ISO 7000- 1051)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Keep dry	ISO 15223-1:2021 Reference no. 5.3.4. (ISO 7000-0626)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates a medical device that needs to be protected from moisture.
	Temperature Limit	ISO 15223-1:2021 Reference no. 5.3.7 (ISO 7000-0632)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if package is damaged	ISO 15223-1:2021 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Indicates a medical device that should not be used if the package has been damaged or opened.

Symbol	Title	Reference	Standard Title	Explanatory Text
	Collect separately	DIRECTIVE 2012/19/ EU (WEEE)	N/A	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required.
	Non-Sterile	ISO 15223-1:2021 Reference no. 5.2.7 (ISO 7000-2609)	Medical devices -- Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements.	To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized.
	MET Certification Mark	N/A	N/A	The MET mark indicate that the product has met the minimum requirements of the applicable safety standards. The Eurofins MET Mark indicates national compliance by virtue of Eurofins' equivalent accreditations to UL and CSA. The Eurofins MET mark clearly indicates compliance to US requirements.
IPX1	Degree of protection	IEC 60601-1 (IEC 60529) Reference no. 6.3; Table D.3; Code 2	Medical electrical equipment – Part 1: General requirements. for basic safety and essential performance	IPX1: N1=X, protection from particulates is not required; N2=1, Protection against vertically falling water drops
	Standby	IEC 60417-5009	Graphical symbols for use on equipment	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicated using a corresponding color.
	Quantity	N/A	N/A	To indicate quantity
	Battery charging condition	ISO 7000-0247	Graphical symbols for use on equipment	To indicate whether the battery is charging
	Battery disconnect; battery shut-off	ISO 7000-2063	Graphical symbols for use on equipment	To identify the control that disconnects the battery from the electrical system. To indicate that the battery has been disconnected.
	Oxygen Gas	N/A	N/A	N/A
	Cable Interface 1	N/A	N/A	N/A
	Tubing Interface 1	N/A	N/A	N/A







Symbol	Title	Reference	Standard Title	Explanatory Text
	Tubing Interface 2	N/A	N/A	N/A
	Pole Mount Bracket Orientation	N/A	N/A	N/A
 UN3481	Lithium ion batteries contained in equipment	IATA Dangerous Goods Regulations Figure 7.1.C	IATA Dangerous Goods Regulations	To indicate Lithium batteries contained in equipment
	This way up	ISO 7000-0623	Graphical symbols for use on equipment	To indicate correct upright position of the transport package
	Write and read data into and from store	ISO 7000-1107	Graphical symbols for use on equipment - Registered symbols	To identify the control or the indicator for writing or reading (retrieving) data to/from a storage device.
	Country of manufacture	ISO 15223- 1:2021 Reference no. 5.1.11. (IEC 60417-6049)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	To identify the country of manufacture of products

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WARNINGS & CAUTIONS



WARNING! GENERAL USE

- Read all instructions prior to use. Improper use could result in death or injury to the patient or user, or damage to the OXY-1 System.
- No modification of this equipment is allowed.
- The OXY-1 System must be operated and monitored by trained individuals under the direction and prescription of a physician.
- The administration of oxygen sweep gas in patients receiving full Cardiopulmonary Bypass (Veno-arterial Cannulation) is critical because the lungs are by-passed.
- Cardiopulmonary Bypass requires the use and monitoring of anticoagulants to prevent clotting.
- Patients receiving therapy require hemodynamic monitoring to assess circulatory performance and arterial blood gas monitoring to evaluate adequacy of gas exchange. Patients should also have continuous SpO₂ to monitor blood oxygenation.
- Operate the OXY-1 System in accordance with this manual over the specified range.
- Use of this device at an altitude above 7000 ft above sea level or outside a temperature of 10-30C or a relative humidity above 90% Rh is expected to adversely affect the flowrate and the percentage of oxygen and consequently, quality of therapy.
- Do not operate the pump without closing the latching mechanism on the Pump Driver. This can be verified through inspection. Improper or partially closing the latch will result in improper blood flow reporting.
- Do not use grease or oils to lubricate the oxygen inlet and outlet ports to avoid the risk of fire and burns.
- The OXY-1 System is not intended for use in a medical transport (e.g., by ambulance, helicopter or fixed-wing aircraft) environment.
- The OXY-1 System is MR Unsafe. The device presents a projectile hazard in the presence of a MR environment.
- Thermal Management – The OXY-1 System is not fitted with a heater/warmer system. Patients receiving therapy require routine core temperature monitoring. Rewarm hypothermic patients per institution protocol.



WARNING! CONSOLE BATTERIES

- The OXY-1 System Console batteries must be enabled prior to device use.
- See Section 5 - Initial Equipment Set-Up



WARNING! BLOOD/FLUID MANAGEMENT

- Avoid clamping the blood tubing to halt blood flow while the pump is operating to minimize damage to the blood (hemolysis).
- Do not insert or remove the Disposable while the motor is running to avoid pump damage.
- Do not operate the pump without priming the PLU Disposable with fluid prior to starting.
- Frequently inspect for leaks throughout the entire Disposable circuit.
- Ensure all blood connection points (tubing connectors) are firmly inserted and securely attached. The use of tie bands is recommended on all blood connection points.
- Excessive positive or negative pump pressure can result in hemolysis, cavitation, collapse of the vessels surrounding the cannula and/or greater vessels causing interruption of therapy.



WARNING! EXTERNAL O₂ MODE

- Only use medical grade oxygen source fitted with a flowmeter that meters flow between 0-15 LPM



WARNING! INTERNAL GAS MODE

- The oxygen transfer capacity is reduced in backup Internal Gas mode. Closely monitor the patient's SpO₂ when transitioning to backup Internal Gas mode to ensure adequate support. Patients with a high oxygen deficit may not be adequately supported and require an external oxygen source. External oxygen source includes portable oxygen tanks when mobilizing or transport of the patient
- Sweep gas flow rate setting may be different between External O₂ mode and backup Internal Gas mode. Backup Internal Gas mode uses an oxygen and air combination and may require higher sweep gas (total flow) to achieve equivalent CO₂ elimination when compared to External O₂ Mode.
- When operating in backup Internal Gas mode, access to a backup oxygen supply source is required in the event of system failure or higher oxygenation support is need.



WARNING! EQUIPMENT SET UP AND POSITIONING

- Position the Pump Lung Unit (PLU Disposable) below the level of the patient's heart.
- Always have tubing clamps available to halt blood flow or prevent retrograde flow.
- Do NOT operate the OXY-1 System in the presence of flammable gases. An explosion hazard exists under these conditions.
- DO NOT operate the device in an enclosed space, such as a closet.
- DO NOT block the air inlet or the exhaust vents located on the front and side of the device.
- DO NOT cover the device with a towel, blanket, etc.
- Have a backup OXY-1 System available in the unlikely event of a device failure.
- Do not connect the Pump Driver to the Console while the Console is powered on. A Pump Control Failure alarm may occur.
- Do not cycle the Power Button on the Console while the pump motor is spinning. A Pump Control Failure alarm may occur.
- Confirm the pump motor has stopped spinning before turning the Console off. A Pump Control Failure alarm may occur when the Console is turned back on.
- Keep Condensation Tray in the protective packaging and store in a dry place prior to patient use. Install just prior to patient use. Surfaces may become damp and/or contaminated if stored in the Pump Driver for extended periods prior to application to the patient.



WARNING! PLU DISPOSABLE

- Inspect PLU Disposable sterile package for damage prior to opening. Do not use if there is damage or breach of the sterile barrier, as this could result in contamination and severe infection.
- Verify the PLU Disposable kit expiration date has not been exceeded prior to use.
- Thoroughly prime and de-air the PLU Disposable blood circuit prior to use.
- DO NOT reuse or re-sterilize single-use PLU Disposable.
- Have a backup primed PLU Disposable available in the unlikely event of a circuit failure.



WARNING! EQUIPMENT DISPOSAL AT END OF EQUIPMENT LIFE

- Do not dispose of electronic equipment or batteries as unsorted municipal waste. Observe local ordinances for proper disposal.



CAUTION!

- A fully discharged battery will take no less than 180 minutes to return to a fully charged state. Allow adequate time for the batteries to fully recharge before placing in service.
- Batteries will discharge slowly in storage (without AC power attached). Maintain AC power source when not in use to maintain a maximum charge.
- Do not operate the Pump Driver with the PLU Disposable removed.
- Do not operate the Pump Driver without priming the PLU Disposable with fluid prior to starting.
- Do not remove the PLU Disposable while in operation or attempt to install or reinstall the PLU Disposable while the Pump Driver is in operation. This may cause damage to the pump.
- Lock the four castors before operating the OXY-1 System.
- Verify the PLU Disposable and Pump Driver are securely fitted to each other and properly attached to the Pole Mount.
- Remove the OXY-1 System from service if it has been exposed to mechanical shocks and once removed, inspect for damage.
- If the Console touchscreen malfunctions, remove it from service.
- Confirm the E-Drive is available and securely attached.
- Confirm E-Drive is accessible and can be operated without interference.
- Do not block the air intake duct on the Console. Poor air flow will reduce performance and potentially cause the OXY-1 System to malfunction.



NOTE:

- Hemolysis is often precipitated by excessive pump speed, the presence of thrombosis and the entrapment of air bubbles in the blood circuit and pump. Noise emanating from the pump is often an indicator of air bubbles in the pump impeller. Frequent and routine visual and audio inspection of the blood circuit is necessary. Immediate removal of air bubbles and clots is recommended to minimize blood damage.
- Only use the components described within this manual with the OXY-1 System.
- Additional data not included in this manual is made available upon request. This may include but is not limited to:
 - sterilization method
 - list of materials of the blood pathway
 - data related to blood cell damage (hemolysis)
 - particle release from the oxygenator
 - gas pathway pressure drops at the maximum blood and gas flow rates specified for intended use
 - blood pathway pressure drops at the range of blood flow rates specified for intended clinical use
 - relevant tolerances for data presented

TECHNICAL SPECIFICATIONS

*Items noted with an asterisk indicate essential performance.

MODEL	
Breathe OXY-1 System	
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 Surface Area	2.4 m ²
Oxygenator Priming Volume	310 ml
O ₂ Transfer	Full Range > 95% Blood Oxygen Saturation*
TUBING	
Size	3/8" ID x 12.5 ft. (9.5 mm ID x 3.7 m); 3/32" thickness
Blood Tubing Priming Vol (uncut)	540 ml -Drainage & Return Tube Full Length (12.5 ft.)
PUMP DRIVER	
Driver Dimensions (L x W x H)	10.8 x 6.3 x 5.6 inches (275x160x144 mm)
Driver Weight/ Mass (w/o PLU Disposable)	3.5 lbs. (1.6 kg)
Flow & Bubble Detection Sensors	Ultrasonic flow and bubble detection
Mount	25-40mm Dia. Pole Mount
CONSOLE / PUMP CONTROLLER	
Pump RPM range	0-4500 RPM in 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 / INTERNAL GAS SUPPLY	
External O ₂ mode; Flow Meter	Flow rate < 15 LPM from external flow meter Pressure - 10 psi [69 kPa] MAX O ₂ barb tubing connector
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*
Internal Gas mode Warm-up Time	4 minutes @ 0.5 LPM
Sigh Function	(Available in backup Internal Gas mode only)
POWER	
AC Mains	5.0 A, 100-240 VAC, 50/60 Hz
Battery Type	Lithium Ion
Battery Run Time	200 minutes (see Section 14)
Battery Charge Time (from zero state)	< 180 minutes on Standby or < 6.5 hours on Run Mode

CONSOLE	
Graphical Display	Touch Screen Control / Capacitive
Console Dimensions (H x W x D)	26 x 14 x 9 Inches (66 x 36 x 23 cm)
Console Weight/ Mass	48.5 lbs. (22.5 kg)
Wheels	Locking Castors
Handle	Foldable Handle
System Alarm Sound Pressure Level	> 60 dBA
E-DRIVE	
RPM Range	0-5000 RPM
Power	Manual Hand Crank
ENVIRONMENTAL CONDITIONS	
Storage Conditions:	
Durable (Console & Pump Driver)	0-38° C and 5-85% RH noncondensing
PLU Disposable Kit	10-30° C < 85% RH noncondensing
Operating Conditions	10-30° C and 15-90% RH noncondensing
Altitude	Sea level to 7,000 feet
Atmospheric Pressure	101-78 kPa
Air Quality	Free of smoke, pollutants, and fumes.
COMPLIANCE STANDARDS	See Appendix C
EQUIPMENT CLASSIFICATION	
Protection against electric shock	POWER SOURCE: Class II, Externally Powered and Internally Powered (Battery) APPLIED PART: Type CF, Defibrillation Proof Mains isolation provided by disconnect-able power cord
Protection against harmful ingress of water or particulate matter	IPX-1: Dripping water with vertically falling drops
Method of sterilization	PLU Disposable is supplied sterilized by Ethylene Oxide
Suitability for use in oxygen rich environment	Yes
Mode of Operation	Continuous

GLOSSARY OF TERMS

Blood Circuit – the disposable blood circuit including the PLU Disposable, blood tubing and accessories that are in contact with the blood.

Clot/Thrombus – a coagulated blood mass formed within the vascular system of the body or blood circuit that impedes blood flow or gas exchange.

Condensate Tray – a single use disposable intended to trap condensation generated by the sweep gas exhaust to prevent excessive water leakage.

Console – the controller subsystem that allows the user to control the pump speed and manage sweep gas, power, and therapy delivered.

Drainage Line – blood circuit tubing (blue stripe) carrying the unoxygenated blood from the patient to the pump and membrane oxygenator (outflow).

De-air – the process of removing air and air bubbles from the blood circuit.

Device Performance Data – data that is accessible by the User to review the OXY-1 System setting and output data over time.

Durable Components – the Console, Pump Driver assembly, pole mounting interfaces and E-Drive components declared reusable after cleaning and disinfection.

Hemodynamic Monitoring – the measurement of pressure, flow, and oxygenation of blood within the cardiovascular system.

PLU – (Pump Lung Unit) the disposable assembly that contains the pump and oxygenator assembly.

PLU Cable Guard – a protective sheath and strain relief used to protect the PLU electrical cable and gas tubes between the Pump Driver and Console.

PLU Disposable – a single use disposable that contains the pump and oxygenator assembly, Air and O₂ tubing, Luer blood extension tubes, caps, priming kit and corresponding packaging.

PLU Mounting Bracket – a mounting bracket used to secure the Pump Driver to the IV pole in either a vertical or horizontal position.

Pre-Use Checkout – procedures required to confirm OXY-1 System readiness just prior to patient use.

Priming Volume – the volume of priming fluid required to fill and de-air the blood circuit.

Recirculation – recirculating fluid through the blood circuit.

Recirculation (Venovenous) – a phenomenon where oxygenated blood returned by the system is drawn back through the drainage circuit and recirculated. This often occurs when the drainage and supply cannula are positioned too closely, blood flow settings are too high causing recirculation, and/or a combination of these factors.

Return Line – the blood tubing (red stripe) carrying the oxygenated blood from the membrane oxygenator to the patient (inflow).

Sigh – the process of driving gas through the gas exchange membrane at a high flow rate to remove condensation that accumulates in the gas path.

Stopcock – a three-way valve placed in series with a blood access port used for accessing blood in the circuit.

Sweep Gas – gas (oxygen, or oxygen and air) that passes through the oxygenator membrane where oxygen diffuses into the blood and carbon dioxide (CO₂) diffuses into the gas flow for CO₂ elimination. The rate of the sweep gas flow controls the quantity of oxygen saturation and the rate of CO₂ elimination from the blood that passes through the oxygenator.

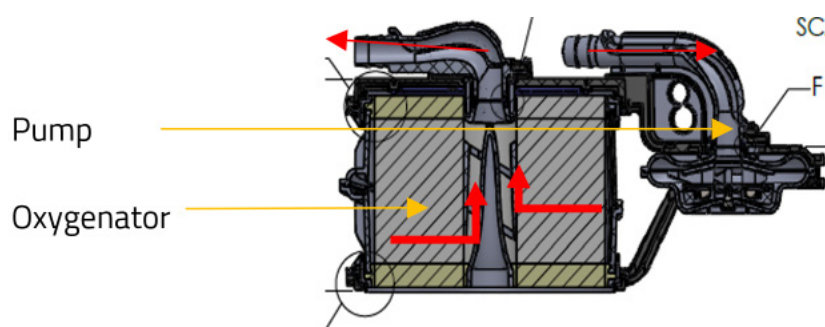
V-A – Venoarterial cannulation – cannulation of the patient's greater vessels where the drainage cannula is placed into the venous side of the body and the return is in the arterial side of the body.

V-V – Venovenous cannulation - cannulation of the patient's greater vessels where the drainage cannula is placed into the venous side of the body upstream of the right side of the heart and the return cannula is placed in the venous side downstream of the drainage cannula.

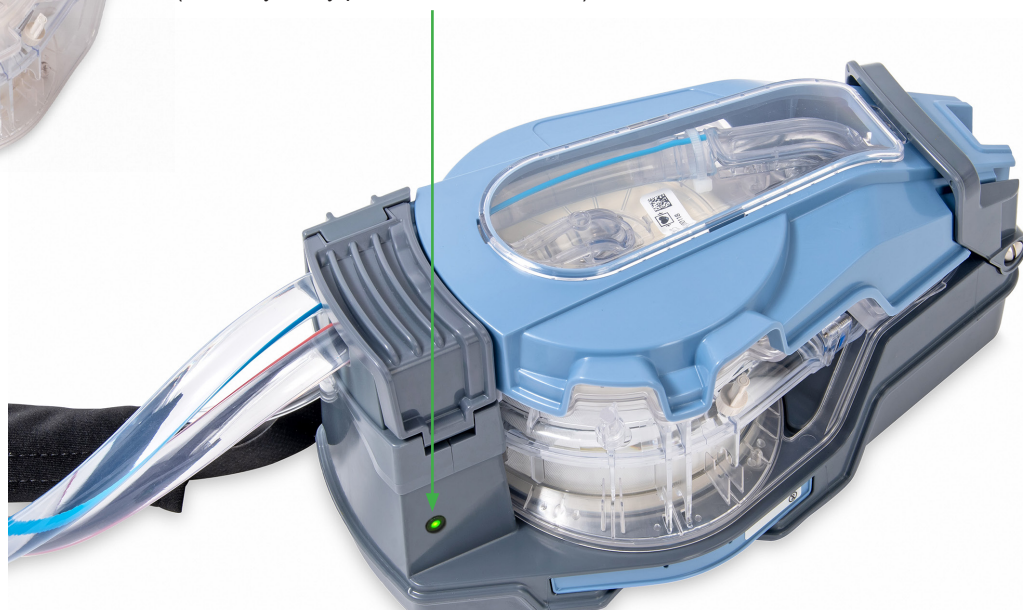
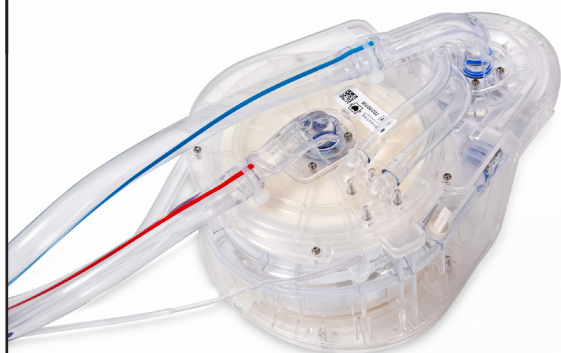
1. OXY-1 SYSTEM DESCRIPTION

The OXY-1 System provides extracorporeal circulation for cardiopulmonary bypass support for up to six hours. The OXY-1 System includes a Disposable pump and oxygenator, blood tubing, a Pump Driver (blood pump), and Console for controlling the pump and managing gas flow. These components are designed to operate together, simplify operation, and reduce the overall equipment footprint at the bedside.

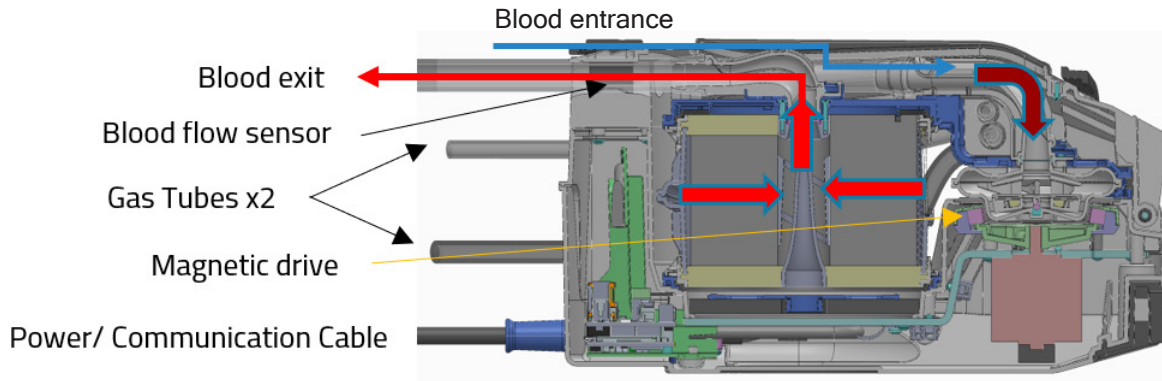
The Pump and Oxygenator – An oxygenator and a centrifugal pump form a single use, permanently assembled Disposable called the Pump Lung Unit (PLU). The oxygenator has a polycarbonate exterior housing that encloses a polymethylpentene (PMP) hollow fiber membrane. A sweep gas passes through the interior lumens of the hollow fibers and gases exchange across the membrane with the blood in contact with the fibers. The centrifugal pump moves blood across the hollow fibers. The blood exits the PLU Disposable outlet and is delivered back to the patient.



Pump Driver – The Pump Driver encases the PLU Disposable, provides energy to the centrifugal pump and houses a flow sensor that monitors blood flow through the PLU Disposable. Energy and communication are provided to the Pump Driver via a 2-meter communication cable that is connected to the Console. The cable allows the Pump Driver to be mounted proximal to the patient on an IV Pole. The Pump Driver contains a **GREEN LED** to indicate the pump motor is rotating. (Clinically verify presence of blood flow)



Blood Tubing – 3/8" inner diameter, 3/32" thick PVC tubing (Drainage and Return flow) with a maximum working pressure of 650 mmHg are attached to the PLU Disposable to provide a conduit for blood to circulate to and from the patient. The 12.5 ft. length tubes are marked to indicate Drainage (outflow- blue) and Return (inflow- red) flow and cut to length by the physician depending on the physician's preference and cannulation method.



Console – The Console is an electromechanical, software-driven component that contains a computer and touch screen User Interface (UI) to enable 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. The Console contains a set of alarms for monitoring and alerting the Operator when the OXY-1 System operates outside of its preset range or Operator defined alarm limits. The Console contains an integrated back-up battery system and gas supply (oxygen concentrator and blower) to provide a source of power and sweep gas when external sources are not available.

OXY-1 CONSOLE



The Console is fitted with a cable interface for connecting to the Pump Driver (C1) and a tubing interface for circulating sweep gas to the oxygenator in the PLU Disposable (T1 & T2). This interface is located on the rear left side of the Console, adjacent to the handle.

The Console is fitted with a standard tubing connector located on the left side of the Console for receiving oxygen from an external source. This interface allows the operator to control the sweep gas flow from an external source such as a wall O₂ flowmeter or a portable oxygen flowmeter.



The OXY-1 System can operate in two modes: External O₂ mode, where oxygen is supplied by an external metered gas source; or, as a backup Internal Gas mode, where sweep gas is supplied by an internal gas source. The backup Internal Gas mode is activated when external gas flow is no longer detected and either internal gas flow settings are greater than 0 LPM.

When transitioning from External O₂ to backup Internal Gas mode, the onboard oxygen concentrator requires a warm-up period to achieve optimal performance prior to switching (removal of the external gas source). See section 1.2.1 for instructions on the O₂ Concentrator Warm-up.

1.1 THEORY OF OPERATION

1.1.1 OXYGENATOR GAS EXCHANGE

The PLU Disposable is an integrated pump and oxygenator. The oxygenator contains a polymethylpentene (PMP) hollow fiber membrane mesh. The hollow fiber membrane is a straw tube-like structure with a gas permeable wall. Approximately 30,000 fibers (each 380 microns in diameter) are woven into an array, restraining and aligning the fibers in an axial direction. These fibers are wound into the cylinder shape. Urethane restrains the fibers in place at both ends of the oxygenator housing. Blood is pumped through the oxygenator from the outside perimeter of the fiber cylinder, passes through the fiber bundle in a radial direction until it reaches the center, then exits in an axial direction at the top. Sweep gas is directed towards the end of the cylinder bundle and through the center of the hollow fibers, entering one end and exiting (exhausting) the opposite end. The cylindrical geometry is designed to provide uniform blood flow across the membrane with minimal opportunity for stagnation. As blood passes through the bundle, it contacts the surface of the membrane fibers where oxygen and carbon dioxide diffuse across the membrane, into and out of the blood respectively. The flow rates of the sweep gas affect blood oxygen saturation and carbon dioxide elimination.

1.1.2 PUMP

The PLU Disposable is an integrated (combined) pump and oxygenator. The pump design uses a centrifugal pump containing a single pivot bearing. The design has been optimized to reduce hemolysis and provide the hydraulic power for both V-V and V-A applications. Pump speed is controlled by RPM setting only.

1.1.3. OXYGENATOR SWEEP GAS DIVIDER

Sweep gas provides oxygen for blood saturation and carbon dioxide elimination from the blood to the gas stream. The oxygenator sweep gas pathway is divided to enable independent gas delivery to each segment, without blending. This division in the gas path separates the gas that passes through the surface area of the oxygenator's inner core from an outer surface area (see figure below). In External O₂ mode, oxygen supplied to the OXY-1 System is delivered to the inner and outer portions of the oxygenator membrane (entire surface area) like typical oxygenators on the market. In backup Internal Gas mode, oxygen from the concentrator is delivered to the center 75% of the surface area for oxygen saturation, and the remaining 25% of the outer ring is supplied with air for CO₂ removal. The divider allows for a lower flow of oxygen from the oxygen concentrator (1-3 lpm) to fully oxygenate the blood without mixing with the air blower. The air blower uses a separate gas path to supplement sweep for CO₂ elimination for patients that require a higher sweep rate above the O₂ concentrator maximum of 3 LPM. In backup Internal Gas mode, and as a backup only, air and oxygen flow can be adjusted separately through the graphical user interface.

1.1.4. BACKUP INTERNAL GAS MODE

The Console is fitted with an oxygen concentrator and air blower as a backup for External O₂ mode. The sweep gases are divided into two separate gas paths. The oxygen concentrator uses room air and separates nitrogen from the air to produce oxygen at a concentration of approximately 93% and has a maximum flow rate of 3 lpm. In backup Internal Gas mode, the oxygen is supplied by the concentrator and an air blower takes filtered room air into a second gas path and delivers it to the outer segment of the oxygenator. This is to supplement CO₂ elimination when a sweep flow rate greater than 3 LPM from the concentrator is required to match the patient demand. See Section 12 for performance data graphs.

The oxygen transfer capacity is reduced in backup Internal Gas mode. Closely monitor the patient's SpO₂ when transitioning to internal gas mode to ensure adequate support. Patients with a high oxygen deficit may not be adequately supported and require an external oxygen source. External oxygen source includes portable oxygen tanks when mobilizing or transport of the patient.

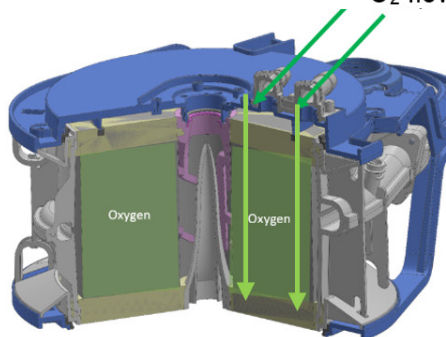


NOTE

- The oxygen transfer capacity is reduced in backup Internal Gas mode. Patients with a high oxygen deficit may NOT be adequately supported and require an external oxygen source. The use of an external oxygen source includes portable oxygen tanks when mobilizing or transport of the patient.
- In backup Internal Gas mode, the Oxy-1 System delivers both oxygen and air through the membrane via a divided gas path to prevent blending. Approximately 75% of the oxygenator membrane receives oxygen for oxygen transfer and 25% receives air for CO₂ removal. Patients that have a severe oxygen deficit or an oxygenator with compromised performance that are marginally saturated on External O₂ mode, may not be adequately supported in backup Internal Gas mode and require an external gas source.

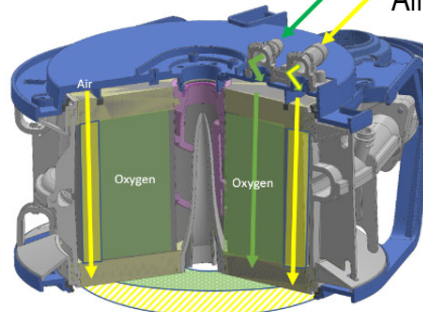
External O₂ Gas Mode

O₂ flow < 15 LPM



Internal Gas Mode

Oxygen ≤ 3 LPM
Air ≤ 15 LPM



1.1.5. CONSOLE PNEUMATIC CIRCUIT

The OXY-1 System is designed to deliver sweep gas using an external oxygen metered gas source or an internal gas source. The Console is fitted with a pneumatic circuit to manage gas flow from either source to the PLU Disposable containing the oxygenator. The pneumatic circuit contains a sensor that detects the presence of gas from external gas port (located on the left side the Console). When external flow is present, the pneumatic circuit divides the flow into two gas paths and exits the Console at two terminal tubing port connectors located on the top left rear side of the Console. The tubing connectors are different sizes to match the two gas tubes supplied with the PLU Disposable. The gas circuit tubes attach to the Console for the gas path from the Console to the PLU Disposable.

When gas flow from the external gas port is no longer detected, the OXY-1 System activates the onboard oxygen concentrator and blower to deliver the flow preset by the user. When the activation occurs, the pneumatic circuit closes a valve that separates the gas path so that the oxygen and air travel down the separate gas pathways to the oxygenator as described in above section 1.1.3.

It is recommended that a gas circuit integrity test be performed before connecting to a patient. This is to ensure gas lines are properly connected and devoid of leaks that may lead to reduced oxygenation/CO₂ removal, delays in therapy and potential harm to the patient. See section 7.2.4 for procedure.

1.1.6. CONDENSATION MANAGEMENT

The exhaust gas from the oxygenator is typically 100% saturated with water vapor that can condense and collect on surfaces. The Pump Driver is fitted with a disposable absorbent disk and condensation tray that is placed directly beneath the PLU Disposable. The absorbent disk will capture condensation exiting the oxygenator either during normal use or the sighing function. Monitor the disk periodically for saturation. If saturated, replace the entire tray assembly.

1.2 SPECIAL FUNCTIONS



1.2.1. O₂ CONCENTRATOR WARM-UP

The OXY-1 System has an integrated O₂ Concentrator that provides O₂ gas flow when operating in backup Internal Gas mode. The O₂ Concentrator has a warm-up period before full oxygen concentration output is achieved. The OXY-1 System's User Interface features a warm-up function that should be performed prior to transitioning from External O₂ mode to backup Internal Gas mode.

Before the O₂ Concentrator Warm-up can be enabled, the OXY-1 System must be in External O₂ mode and the Internal Gas flow settings must be greater than zero. After the O₂ Concentrator Warm-up has been enabled, a white progress bar on the User Interface will indicate the warm-up status. Once complete, a message will appear on the touch screen indicating "Warm-Up Complete." When in backup Internal Gas mode, the O₂ Concentrator outputs the user's O₂ flow setting.



1.2.2. SIGH FUNCTION (BACKUP INTERNAL GAS MODE ONLY)

Select this icon on the User Interface to initiate the sigh function to void condensate from the oxygenator. This is achieved by generating a series of oxygen pulses and increasing the air blower's flow. The sigh function is a two-minute process and will return to normal operation after the process is completed. The sigh function can be aborted if pressed again. See Section 9.2 for instructions.

In External O₂ mode, the sigh function is controlled manually by increasing flow of the flowmeter from the external oxygen source.



1.2.3. BATTERY POWER MODE

The Console operates on AC power or an internal lithium ion battery system. Battery mode is activated when AC power is removed. The onboard battery requires 180 minutes to completely charge from a fully discharged state while the device is off, and 6.5 hours while the device is running. From a fully charged state, the OXY-1 System will operate for minimum of 200 minutes in nominal operating conditions and will alarm when 20 minutes of operational battery capacity remain.

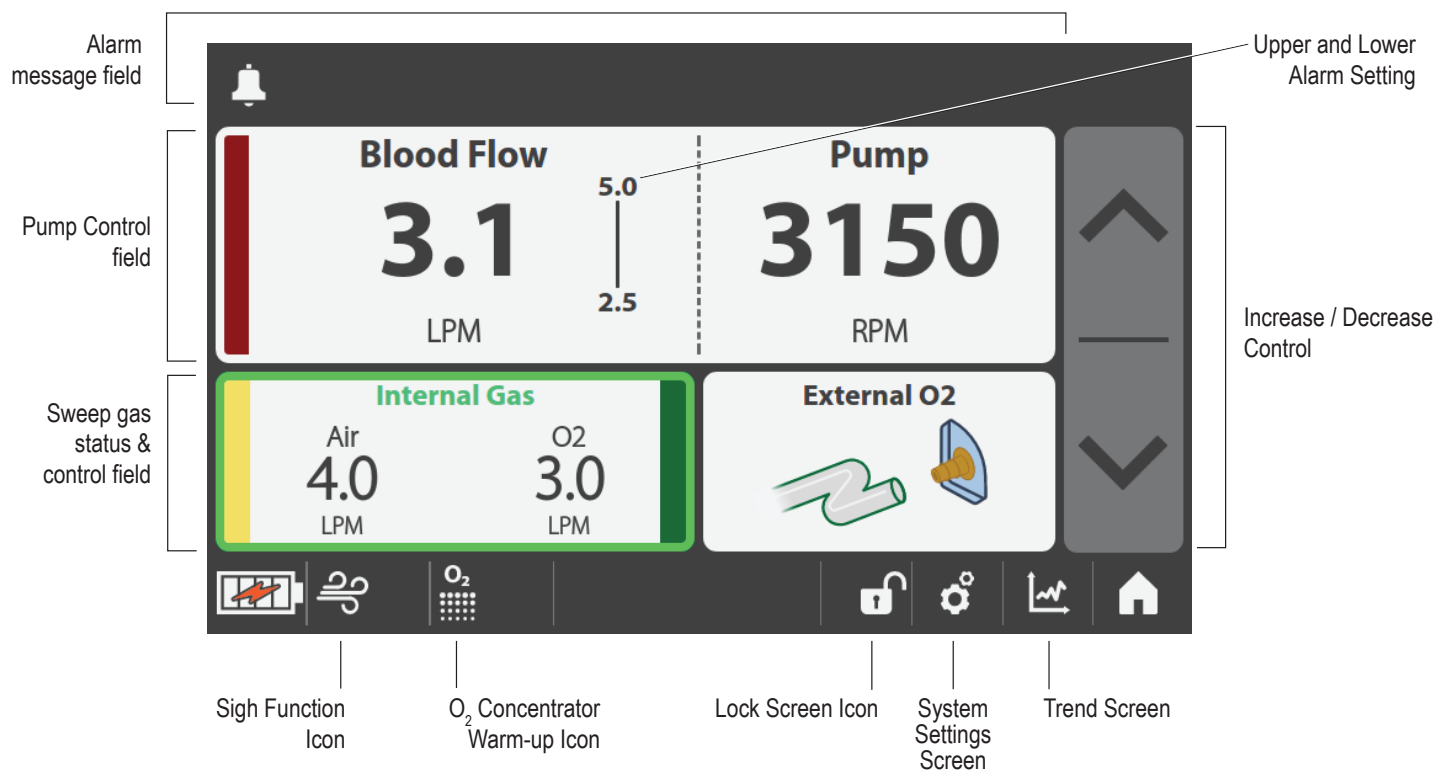
2. OXY-1 SYSTEM OPERATING INSTRUCTIONS

2.1 ADJUSTING PARAMETERS

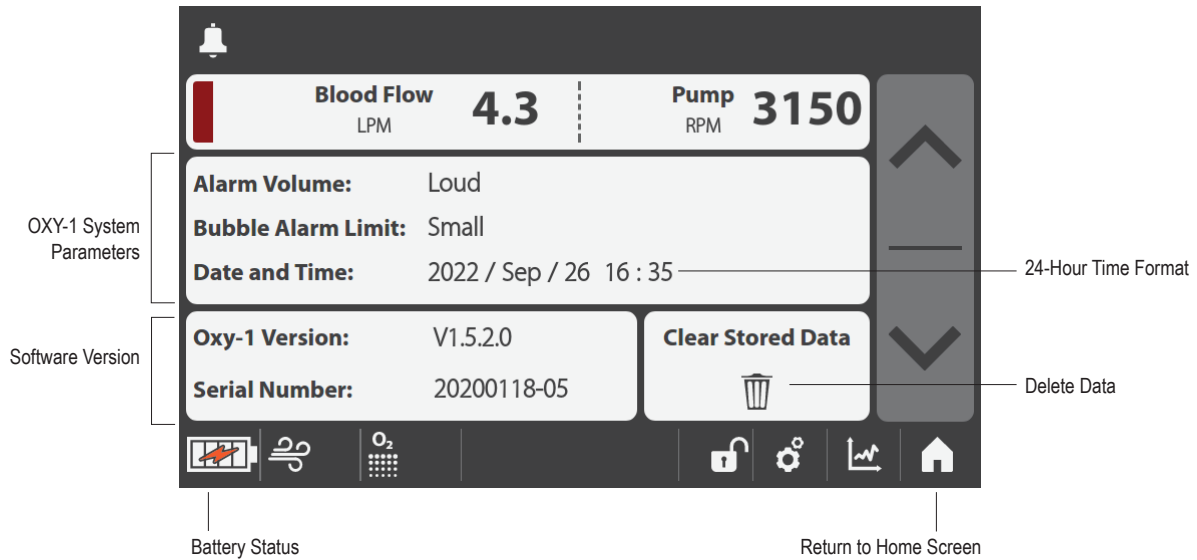
2.1.1 Touch Screen Display

Select a parameter by touching the field or parameter directly. The selected parameter will transition from display mode to adjustment mode. The arrows located to the right side of the screen are used to increase or decrease parameter settings. The parameter will immediately change as the arrow fields are adjusted. After 10 seconds the display will return to the unselected state.

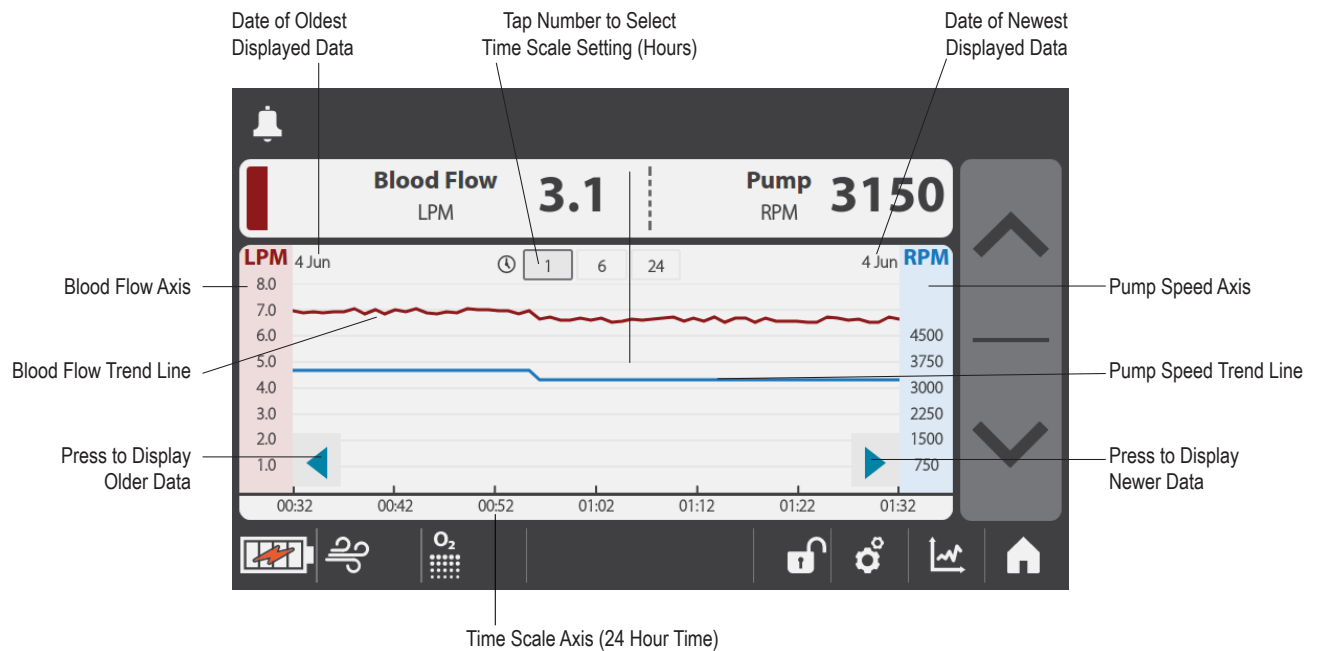
Home Screen




Settings Screen

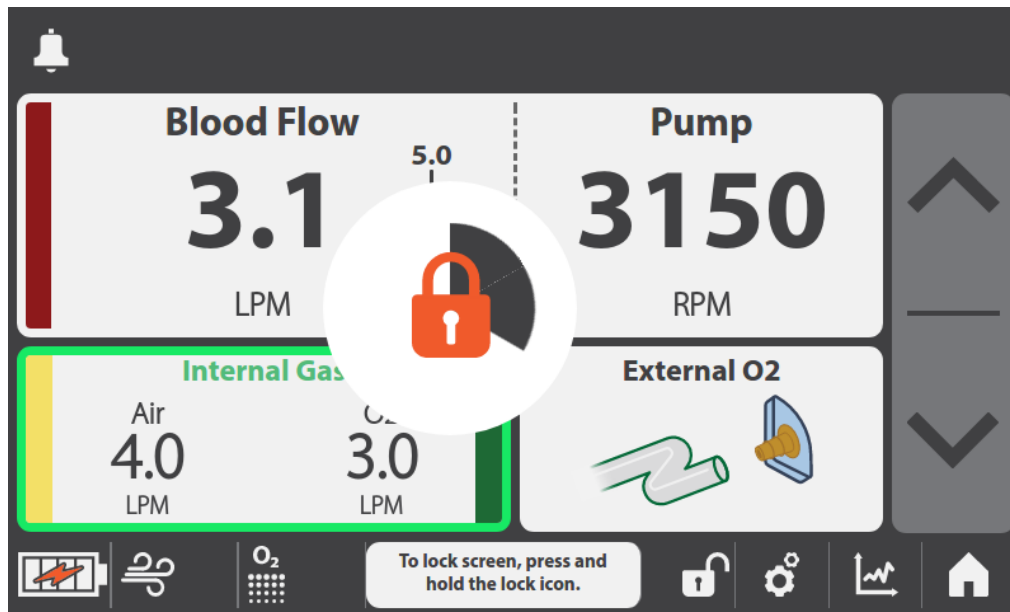


Trends Screen



2.1.2 Lock Screen

1. Touch small "Lock" icon. 
2. Touch and hold big "Lock" icon
3. Screen is now locked.
4. To unlock- touch anywhere on screen
5. Touch and Hold big "Lock" icon



2.1.3 Blood Flow Parameters

1. Blood Flow
 - a. Blood Flow is controlled by adjusting the pump RPM setting. The displayed value is measured blood flow detected by the flow sensor.
2. Blood Flow Alarm Limits
 - a. Touch the upper or lower value to enable adjustment.
 - b. Tap the up/down arrows to adjust the Alarm Limit setting.
 - c. Upper Limit range: 1.0 to 6.0 LPM or Off; Default: 5.0 LPM.
 - d. Lower Limit range 0.0 to 5.0 LPM; Default: 2.5 LPM.
3. Pump RPM (Adjusting Blood Flow)
 - a. Touch the Pump RPM field to enable adjustment.
 - b. Tap the up/down arrows to adjust the Pump speed setting – changes take effect immediately.
 - c. Pump speed range: 0-4500 RPM; Touch Increment: 50 RPM.

2.1.4 Sweep Gas Flow Parameters



NOTE:

- When operating in backup Internal Gas mode, access to a backup oxygen supply source is required in the event of a system failure.
- When transitioning to backup Internal Gas mode, always perform O₂ Concentrator warm-up to avoid transient reduction in oxygen delivery to the oxygenator.
- Sweep rates in backup Internal Gas mode settings may need to be higher to achieve equivalent CO₂ elimination when compared to External O₂ mode. See Data Performance Section 12 for CO₂ elimination curves.

External O₂ mode

1. External O₂ gas source is activated when an oxygen source is connected to the Console O₂ inlet and flow is detected (> 0.5 LPM). The OXY-1 System will automatically switch to External O₂ mode.
2. Gas flow rate is controlled by the source O₂ flow meter. The OXY-1 System does not control or measure the gas flow rate of the External O₂ source.
3. Oxygen is delivered to the entire oxygenator during External O₂ mode. (per section 1.1)

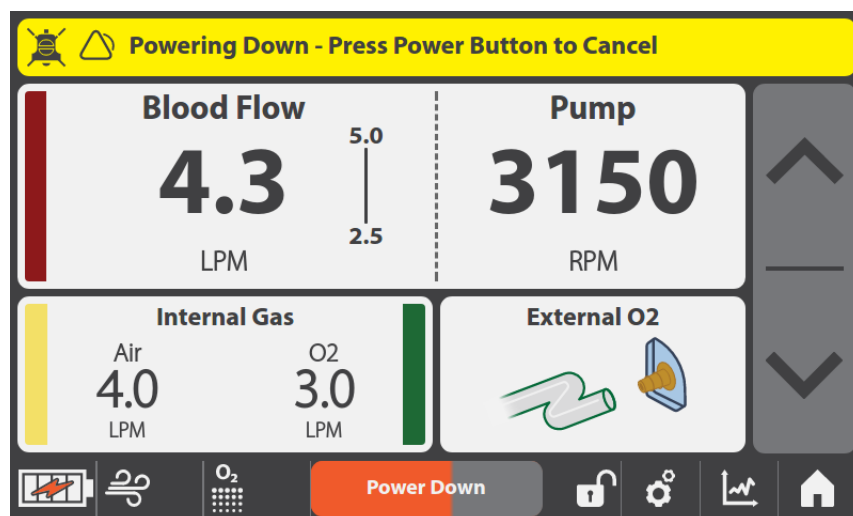
Backup Internal Gas mode

1. Backup Internal Gas mode, which serves as a backup operational mode, is automatically activated when the external gas source flow is no longer detected or has been removed (< 0.5 LPM).
2. Gas flow delivery is adjusted by using the Console User Interface for oxygen and air separately.
3. Oxygen Setting
 - a. Touch the O₂ flow field to enable adjustment.
 - b. Tap the up/down arrows to adjust the O₂ flow setting. The changes will take effect immediately. Note that there is a warm-up period for the Internal O₂ source (see section 1.2.1)
 - c. O₂ flow range: 0.0-3.0 LPM; Touch Increment: 0.5 LPM
4. Air Setting
 - a. Touch the Air flow field to enable adjustment. The field will highlight indicating it is ready.
 - b. Tap the up/down arrows to adjust the Air flow setting. The change will take effect immediately.
 - c. Air flow range: 1.0-15.0 LPM; Touch Increment: 0.5 LPM


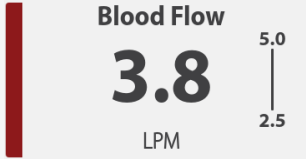
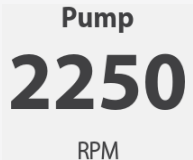




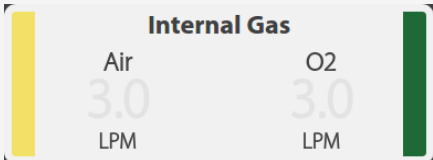
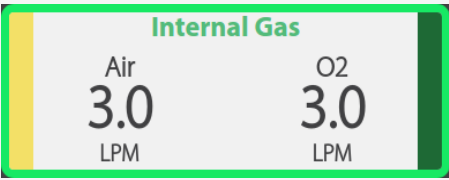
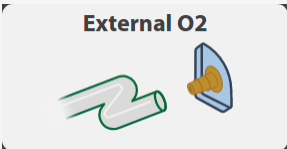
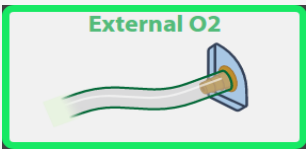
2.1.5 POWER OFF PROCESS
























The Oxy-1 System has a power off process that will delay shut down **8 seconds** after deactivating the Power Button. The system will assert an alarm to notify the user that a power down process has been initiated and the display interface will show the count down. If the power button is depressed prior to shut down, the power off process is aborted and the system will continue at the last settings.




1. Initiate the power off process by depressing the Power Button.
2. The system will alarm indicating the power down is in process.
3. The display interface will show time to shut down.
4. To abort the power off process, depress the power button again.



2.2 DISPLAY ICONS & DESCRIPTION

DISPLAY ICONS		DESCRIPTION
		Alarm Indicator – If an alarm condition is detected, a flashing notification will be displayed. See Section 3.2 for additional information.
		Blood Flow – Measured blood flow in liters per minute (LPM). Range: -10 to +10, Resolution 0.1 LPM. Blood Flow Alarm Limits – If the measured blood flow is outside this set range, then an alarm is activated. The limits are Operator adjustable. High blood flow alarm preset is 5.0 LPM. Low blood flow alarm preset is 2.5 LPM.
		Pump Setting – Operator controlled blood pump speed setting in revolutions per minute (RPM). Range: 0 to 4500 in 50 RPM increments.
		Up Arrow – When enabled, touch control to increase a selected value. Hold to rapidly increase selected value.
Disabled	Enabled	
		Down Arrow – When enabled, touch control to decrease a selected value. Hold to rapidly decrease selected value.
Disabled	Enabled	
		Internal Gas Disabled – Whenever External Gas is detected, OR both Air and O ₂ settings are 0.
		Internal Gas Enabled – When External Gas is not detected, AND either Air or O ₂ settings are > 0. Operator controlled Air flow setting: 1.0 to 15.0 LPM in 0.5 LPM increments. Operator controlled O₂ flow setting: 0.0 to 3.0 LPM in 0.5 LPM increments.
		External O₂ Not Detected – External gas source is not connected OR no flow is detected (< 0.5 LPM). backup Internal Gas mode is activated.
		External O₂ Detected – Flow from an external gas source is detected (> 0.5 LPM). Internal Gas Source will automatically deactivate.

DISPLAY ICONS			DESCRIPTION
			Touch to return to Home screen.
			Touch to access the Settings screen.
			Touch to access the Trends screen.
			Indicates the touch screen is unlocked. Touch the icon to start the screen lock process.
			Indicates the screen is locking/unlocking. Touch and hold the icon until the inner circle fills to complete either process.
			Orange lock indicates the touch screen is locked.
			If the lightning bolt is present, then the OXY-1 System is powered by AC power. Otherwise the OXY-1 System is powered by Battery.
			Sigh control. Press icon to select, Press radio button to activate the sigh process. Sigh process is only available in backup Internal Gas mode. See “Sighing” for additional information.
Off	Selected	Enabled	
			Sigh status. White progress status bar will increase until complete.
			O₂ Concentrator Warm-up control. Press icon to select, press radio button to activate the warm-up process. See “O ₂ Concentrator” for additional information.
Off	Selected	Enabled	
			O₂ Concentrator Warm-up status. White progress status bar will increase until complete.
 Warm-up complete			O₂ Concentrator Warm-up completion notification. The system is ready to have external gas disconnected.
 Set O2 flow rate before initiating warm-up			O₂ Concentrator Warm-up error message. Set internal O ₂ flow rate and initiate sequence.
 Warm-up unavailable, set desired O2 flow rate			O₂ Concentrator Warm-up error message. Reconnect external gas, set internal O ₂ flow rate and initiate sequence.
 Warm-up unavailable, O2 is flowing			O₂ Concentrator Warm-up error message. External gas has been disconnected and internal O ₂ flow has been detected. Check settings.

DISPLAY ICONS DESCRIPTION	
	The Battery icons indicate the current battery capacity. The OXY-1 System will alarm when there is 20 minutes of battery remaining.
Alarm Volume:	Alarm Volume setting: Soft, Moderate or Loud. Default setting is Loud. Sample alarm will play with each volume change.
Bubble Alarm Limit:	Bubble Alarm Limit setting: Off, Small, Medium, or Large sensitivity. Default setting is Small.
Date and Time: 	Date and Time setting: Select each date and time item to adjust using arrows. Touch orange clock icon to save changes.
Clear Stored Data 	Clear Stored Data: When touched, the instructions and control mechanism to clear the OXY-1 System data are visible.
Oxy-1 Version Vx.x.x.x	Software Version

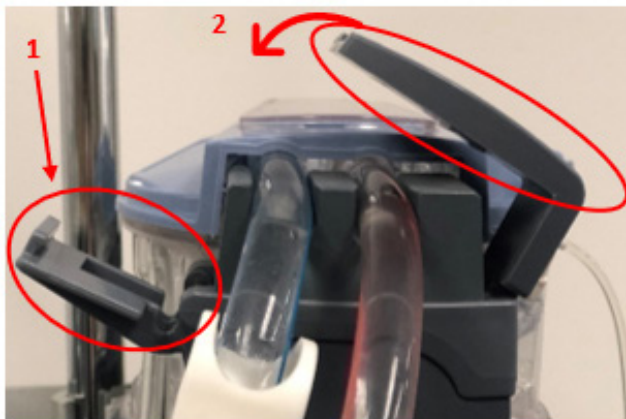
2.3 INSTALLING PLU DISPOSABLE INTO PUMP DRIVER



WARNING!

- Never install or remove the PLU Disposable while the Pump Driver is running (RPM > 0). This could cause pump damage or pump malfunction.

1. Open Pump Driver lid by raising the left latch lever and releasing the latch arm from the latch plate.
2. Open the top latch plate.
3. Open the lid far enough to engage hinge detents.
4. Align the PLU Disposable with the pump socket and seat the PLU Disposable into the Pump Driver.
5. Route Air and O₂ tubing below latch lever.
6. Press Return line (red) tube into sensor channel firmly.
7. Press Drainage line (blue) tube into channel groove in the Pump Driver.
8. Close large lid (#1) and close top latch plate (#2) over the lid.
9. Engage latch arm to top latch plate (#3).
10. Lower latch lever to clamp the tubing in place (#4)



2.4 PUMP MOTOR ON INDICATOR



NOTE

- The Oxy-1 PUMP DRIVER is contains a **GREEN LED** to indicate the pump motor is rotating. When the LED is OFF, it is an indication pump motor is not rotating. (Clinically verify presence of blood flow).



3. ALARMS & TROUBLESHOOTING

3.1 ALARM DEFINITIONS, CONDITIONS AND ACTIONS

The OXY-1 System alarms are divided into two (2) classes: therapy and technical. Therapy alarms are designed to alert the operator to a life-threatening change in patient therapy to include: no detectable blood flow, high flow rate, low flow rate and bubbles detected. Technical alarms indicate status of the mechanical and software elements of the OXY-1 System and can include battery status, O₂ concentrator status, air flow, sigh function and pump status. Any alarm message preceded with "System Failure" should alert the operator to initiate use of the E-Drive.



CAUTION!

- Setting extreme alarm values may render the OXY-1 alarm system effectively useless.
- Access to the system should always remain unobstructed to allow for prompt and effective alarm message response and solution.










WARNING!


- Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions.
- A Hazard can exist if different Alarm Presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or operating theatre.

3.1.1 ALARM PRIORITY LEVELS & SOUND


Alarm priority is indicated by the color of the flashing notification in the alarm bar at the top of the User Interface. A red color indicates a high priority alarm and a yellow color indicates a medium or low priority alarm. Once an alarm message is acknowledged, audio is paused for about 120 seconds before resetting. The Operator's position for responding to an alarm is dependent on the specific message displayed.

	High Priority Alarm
	Medium Priority Alarm
	Low Priority Alarm
	Disabled Alarm – Appears next to the alarm parameter that has been disabled.
	No Alarm - bell symbol with no additional symbols or text.
	Active Alarm – Audio will sound and alarm text displayed
	Silenced/Acknowledged Alarm - The alarm audio has been silenced, but the underlying issue has not yet been resolved.

3.1.2 Alarm Volume / Date and Time

1. Tap the **Settings** icon to enter settings screen. 
2. Touch the Alarm Volume value to enable adjustment.
3. Tap the up/down arrows to adjust the setting: **Soft**, **Moderate** and **Loud**.
4. A sample alarm sound will play once with each new volume setting.
5. Touch any Date and Time value to enable adjustment.
6. Tap the up/down arrows to adjust the setting.
7. Touch orange clock to save settings.
8. Tap the Home icon to return to the home screen



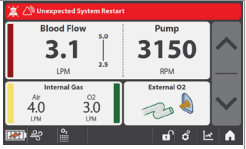
3.1.3 Bubble Alarm Settings

1. Tap the **Settings** icon to enter settings screen.
2. Touch the Bubble Alarm Setting to highlight the field and enable adjustment.
3. Tap the up/down arrows to adjust the bubble size setting.
4. Tap the **Home** icon to return to the home screen. 

3.2 SYSTEM FAILURE AND RESTART

If a system failure occurs that causes the Console processor to stop running, the system will attempt to reboot, continue therapy, and recover previous settings.

RESTART PROCESS:

State	User Interface	Alarm	Blood Pump	Gas Delivery	Console Display
1. Initial	Blank Screen	Buzzer Beeping	Check Green LED on Pump Driver	Ext: Not Affected Int: Check Flow	
If unable to Restart, the system will remain in the initial state. If Green LED is off, initiate use of the E-Drive immediately.					
2. Reboot in Progress	Breeth Logo	Buzzer Beeping	Check Green LED on Pump Driver	Ext: Not Affected Int: Check Flow	
3. Reboot Complete	Main Screen	Buzzer Stops Alarm Tone Sounds Alarm Message Displayed (refer to Section 3.3)	Check Blood Flow on Main Screen	Ext: Not Affected Int: Check Settings	
Replace Console at earliest convenience.					



NOTE

- The **GREEN LED** on the Pump Driver is an indicator that the pump is continuing to rotate. (Clinically verify presence of blood flow)



WARNING!

- Immediately evaluate the patient condition and switch to the Emergency Drive if therapy is inadequate. A major power system failure will interrupt therapy and the manual Emergency Drive is required. Replace Console immediately!

3.3 ALARM TROUBLESHOOTING

3.3.1. HIGH PRIORITY ALARMS

HIGH PRIORITY ALARMS	ALARM TEXT	CONDITIONS FOR ALARM	SOLUTION
	Air Flow Out of Range	<ul style="list-style-type: none"> Air flow sensor detects flow not at setpoint for backup Internal Gas mode. Alarm Limit: within +/- 1.0 LPM of Air Flow setpoint Loss of internal gas operating mode. Alarm Delay: None 	<ul style="list-style-type: none"> Verify gas tubing is properly connected on rear of Console T1 & T2. Check for blocked or kinked air tubing Switch to External O₂ mode and replace Console promptly
	Alarm System Disabled	<ul style="list-style-type: none"> Alarm System not functioning; no other alarms will be reported. Alarm Delay: None, issued upon detection. 	<ul style="list-style-type: none"> Verify therapy is being delivered and replace Console promptly
	Battery Failure 1	<ul style="list-style-type: none"> Two or more batteries fail to charge or discharge Alarm Limit: Fails to charge or discharge when between 10% and 90% state of charge Alarm Delay: 3 minutes 	<ul style="list-style-type: none"> Restore AC power Replace Console
	Battery Failure 2 - Battery Runtime Unknown	<ul style="list-style-type: none"> Two or more batteries fail to communicate Alarm Delay: 1 minute 	<ul style="list-style-type: none"> Restore AC power Replace Console
	Battery Over Temperature	<ul style="list-style-type: none"> One or more batteries report operating temperature above operating limit Alarm Limit: >70°C Alarm Delay: 15 seconds 	<ul style="list-style-type: none"> Check console filters for blockages Replace Console Check inlet and exhaust ports for blockages
	Blood Flow < 0 LPM	<ul style="list-style-type: none"> Blood flow sensor detects negative flow Alarm Limit: < -0.1 LPM Alarm Delay: None 	<ul style="list-style-type: none"> Set Pump RPM > 0
	Blood Flow Sensor Failure	<ul style="list-style-type: none"> Flow sensor communication failure Blood flow and blood bubble detection and alarms will not be triggered Alarm Delay: None 	<ul style="list-style-type: none"> Check Pump Driver's electrical cable for connection Replace Console and Pump Driver If failure persists, use a 3rd party flow sensor; Pump RPM will still indicate pump function
	Bubbles Detected	<ul style="list-style-type: none"> Blood Bubble Sensor detects bubble size equal to or greater than the Bubble Alarm Limit Settings Alarm Preset: Small Alarm Delay: None 	<ul style="list-style-type: none"> Check for bubbles and purge as needed
	High Blood Flow	<ul style="list-style-type: none"> Blood flow sensor detects blood flow equal to or greater than the Blood Flow Upper Limit setting Alarm Preset: 5.0 LPM Alarm Delay: None 	<ul style="list-style-type: none"> Check Circuit Adjust Pump RPM Adjust Alarm Limits

HIGH PRIORITY ALARMS




ALARM TEXT	CONDITIONS FOR ALARM	SOLUTION
Lost External Gas - No Internal Oxygen Set	<ul style="list-style-type: none"> External gas source was lost & Internal O₂ flow is set to 0.0 LPM Alarm Delay: None 	<ul style="list-style-type: none"> Adjust O₂ flow setting to continue therapy OR Acknowledge alarm by touching screen
Lost External Gas - Confirm Internal Settings	<ul style="list-style-type: none"> Low priority lost external gas - confirm internal settings alarm has been present for at least 30 seconds Alarm Delay: None 	<ul style="list-style-type: none"> Acknowledge alarm by touching screen Reconnect to external gas OR Adjust Internal Gas Settings to continue therapy
Low Battery Power	<ul style="list-style-type: none"> Medium priority low battery power alarm has been present for at least 10 minutes OR AC Power lost with remaining battery runtime less than 20 minutes Alarm Delay: None 	<ul style="list-style-type: none"> Restore AC Power
Low Blood Flow	<ul style="list-style-type: none"> Blood flow sensor detects blood flow equal to or less than the Blood Flow Lower Limit setting Alarm Preset: 2.5 LPM Alarm Delay: None 	<ul style="list-style-type: none"> Check Circuit Adjust Pump RPM Adjust Alarm Limits
No Internal Oxygen Set	<ul style="list-style-type: none"> Medium priority no internal oxygen set alarm has been present for at least 1 minute Alarm Delay: None 	<ul style="list-style-type: none"> Adjust O₂ flow setting to continue therapy OR Acknowledge alarm by touching screen
Oxygen Concentrator Failure 1	<ul style="list-style-type: none"> Internal temperatures reported out of range External gas source not present Alarm Limit: >70°C Alarm Delay: None 	<ul style="list-style-type: none"> Check for blocked air inlet Replace Console
Oxygen Concentrator Failure 2	<ul style="list-style-type: none"> O₂ Concentrator communication failure External gas source not present Alarm Delay: None 	<ul style="list-style-type: none"> Replace Console
Oxygen Concentrator FiO₂ < 72%	<ul style="list-style-type: none"> O₂ Concentrator detects internal source O₂ concentration is < 72% Loss of Internal Gas Mode Alarm Delay: 7 minutes from Oxygen Concentrator Start; after warm-up no alarm delay 	<ul style="list-style-type: none"> Switch to External Gas Mode Replace Console
Oxygen Concentrator Flow Out of Range	<ul style="list-style-type: none"> O₂ Concentrator detects internal source O₂ flow not at setpoint for backup Internal Gas mode. Alarm Limit: within +/- 0.5 LPM of O₂ flow setpoint Loss of internal gas operating mode. Alarm Delay: None 	<ul style="list-style-type: none"> Switch to External Gas Mode Replace Console

HIGH PRIORITY ALARMS




ALARM TEXT	CONDITIONS FOR ALARM	SOLUTION
Pneumatics Failure	<ul style="list-style-type: none"> External gas pressure sensor communications failure Alarm Limit: External gas pressure source is not between -2.5 PSI and 20 PSI Alarm Delay: None 	<ul style="list-style-type: none"> Verify blood flow rate Replace Pump Driver
Pump Control Failure 2	<ul style="list-style-type: none"> Pump Driver encoder failure Pump Driver is attempting to run in block commutation mode without using encoder Alarm Delay: None 	<ul style="list-style-type: none"> Verify blood flow rate Replace Pump Driver
Sigh Function Failure	<ul style="list-style-type: none"> Sigh process detected insufficient O₂ pressure while sigh valve closed (when sigh is activated) Loss of internal gas operating mode Alarm Limit: Oxygen concentrator outlet pressure less than 5 PSI when concentrator running with sigh valve closed Alarm Delay: None 	<ul style="list-style-type: none"> Switch to External O₂ mode Replace Console
System Failure: Internal Power 1	<ul style="list-style-type: none"> Pump Driver power is in over-current condition Pump Driver motor and blood flow and bubble sensors are not functioning. Alarm Limit: 2.5A Alarm Delay: None 	<ul style="list-style-type: none"> Initiate E-Drive Replace Console and Pump Driver
System Failure: Internal Power 2	<ul style="list-style-type: none"> One or more power rails within the Console is in over-current condition Faulted power rails turned off and will affect vital system functionality Alarm Delay: None 	<ul style="list-style-type: none"> Initiate E-Drive Replace Console and Pump Driver
System Failure: No External Power	<ul style="list-style-type: none"> Two or more batteries report discharging while console is connected to external power Alarm Delay: 3 minutes 	<ul style="list-style-type: none"> Remove and replace console Replace batteries
System Failure: Pump Control 1	<ul style="list-style-type: none"> Pump Driver communications failure Pump will not be spinning Alarm Delay: None 	<ul style="list-style-type: none"> Check Pump Driver's electrical cable for connection Initiate E-Drive Replace Console and Pump Driver
System Failure: Pump Drive	<ul style="list-style-type: none"> Pump-reported RPM is not at setpoint Alarm Limit: Pump-reported RPM is not within +/- 100 RPM of setpoint Alarm Delay: None 	<ul style="list-style-type: none"> Initiate E-Drive Replace Console and Pump Driver
Unexpected System Restart	<ul style="list-style-type: none"> System Failure and Restart with settings recovered Alarm Delay: None 	<ul style="list-style-type: none"> Replace Console
Unexpected System Restart - Unable to Recover Settings	<ul style="list-style-type: none"> System Failure and Restart; System fails to recover parameter settings Alarm Delay: None 	<ul style="list-style-type: none"> Set therapy settings Replace console

3.3.2. MEDIUM PRIORITY ALARMS

MEDIUM PRIORITY ALARMS	ALARM TEXT	CONDITIONS FOR ALARM	SOLUTION
	Battery Failure 1	<ul style="list-style-type: none"> One battery fails to charge or discharge Alarm Delay: 1 minute 	<ul style="list-style-type: none"> Restore AC power Replace Console
	Battery Failure 2	<ul style="list-style-type: none"> One battery fails to communicate Alarm Delay: 1 minute 	<ul style="list-style-type: none"> Restore AC power Replace Console
	Low Battery Power	<ul style="list-style-type: none"> Remaining battery runtime less than 20 minutes First battery power alert Alarm Delay: None 	<ul style="list-style-type: none"> Restore AC power
	No Internal Oxygen Set	<ul style="list-style-type: none"> Internal O₂ flow is set to 0.0 LPM. Air flow is changed to > 0.0 LPM. Alarm Delay: None 	<ul style="list-style-type: none"> Adjust O₂ flow setting to continue therapy OR Acknowledge alarm by touching screen
	Oxygen Concentrator FiO ₂ < 85%	<ul style="list-style-type: none"> Alarm Limit: O₂ Concentrator detects internal source O₂ concentration is < 85% Loss of backup Internal Gas mode Alarm Delay: 7 minutes from Oxygen Concentrator Start; after warm-up no alarm delay 	<ul style="list-style-type: none"> Switch to External O₂ mode Replace Console
	System Failure: No External Power	<ul style="list-style-type: none"> One battery reports discharging while console is connected to external power Alarm Delay: 3 minutes 	<ul style="list-style-type: none"> Self-clearing Replace batteries

3.3.3. LOW PRIORITY ALARMS

 LOW PRIORITY ALARMS	ALARM TEXT	CONDITIONS FOR ALARM	SOLUTION
	Lost External Gas - Confirm Internal Settings	<ul style="list-style-type: none"> External gas source was lost; Internal O₂ setting is > 0.0 LPM Alarm Delay: None 	<ul style="list-style-type: none"> Acknowledge alarm by touching screen Reconnect to external gas OR Adjust Internal Gas Settings to continue therapy
	Oxygen Concentrator Failure 1	<ul style="list-style-type: none"> Internal temperatures reported out of range External gas source present Alarm Limit: >70°C Alarm Delay: None 	<ul style="list-style-type: none"> Check for blocked air inlet Replace Console
	Oxygen Concentrator Failure 2	<ul style="list-style-type: none"> O₂ Concentrator communication failure External gas source present Alarm Delay: None 	<ul style="list-style-type: none"> Replace Console
	Powering Down - Press Power Button to Cancel	<ul style="list-style-type: none"> Power Button deactivated Alarm Delay: None 	<ul style="list-style-type: none"> If shutdown not intended, activate Power Button
	Running on Battery	<ul style="list-style-type: none"> Console has previously been removed from external power source Alarm Delay: 5 seconds 	<ul style="list-style-type: none"> Acknowledge alarm by touching screen Monitor battery life icon

4. OPERATING THE EMERGENCY PUMP DRIVE (E-DRIVE)



WARNING!

- Placing the Pump Driver above the level of the patient's heart is not recommended. In the event of a System Failure, static negative pressure caused by retrograde blood flow into the Pump Lung Unit may create negative static pressure in the blood circuit and cause air to ingress across the oxygenator membrane.
- Verify the operator can install the PLU Disposable and operate the hand crank unobstructed. Inability to access will interrupt therapy when the E-Drive is needed in the event of an emergency.



CAUTION!

- Placing the Pump Driver higher than 21 inches from the floor can cause a tip hazard that may cause damage to the OXY-1 System and compromise performance.
- Misaligning the PLU Disposable can result in therapeutic disruption.
- Verify the Pump Driver is properly mated to the mounting bracket. Improper attachment can cause the pump to detach and fall, causing damage to the OXY-1 System and compromising performance.
- Take caution when moving or transferring the PLU Disposable- dropping can result in blood pump damage, circuit damage and/or patient blood loss.

4.1 EMERGENCY DRIVE INITIAL SET-UP

The E-Drive is a manual Pump Driver used in the event of pump function failure. Always ensure the crank handle path for the E-Drive is unobstructed to manually power the PLU Disposable when necessary. Consider all factors required to transfer the PLU Disposable from the Pump Driver to the E-Drive, including blood tubing orientation, gas tubing, cables, etc.

4.2 TRANSFERRING PLU DISPOSABLE TO E-DRIVE

1. Unzip Cable Guard to expose the gas tubing and cable.
2. Clamp blood tubing to prevent retrograde flow.
3. If the pump is not already stopped, set Pump RPM to 0.
4. Remove PLU Disposable from Pump Driver.
5. Align and latch PLU Disposable to E-Drive.
6. Maintain gas tubes connections between the PLU Disposable to Console.
7. Verify gas flow from either internal or external gas source.

4.3 MANUALLY POWERING THE E-DRIVE

1. Unfold E-Drive handle.
2. Crank handle clockwise to initiate blood flow. Unclamp blood tubing.
3. Adjust cranking rate to achieve desired blood pump RPM as shown on the LED display.

4.4 TRANSFERRING PLU DISPOSABLE FROM E-DRIVE TO NEW PUMP DRIVER

1. Power up the new OXY-1 System Console.
2. Clamp blood tubing to prevent retrograde flow.
3. Stop cranking E-Drive handle.
4. Wait for the E-Drive to stop.
5. Press & hold E-Drive release button.
6. Unlatch the PLU Disposable from E-Drive.
7. Attach the PLU Disposable to the new Pump Driver.
8. Gradually increase Blood Pump RPM. Unclamp blood tubing.
9. Move tubing from external oxygen source (wall or tank) to new Console oxygen inlet.
10. Move Air and O₂ tubing from the old Console to the new Console.
11. Reattach the Cable Guard.



5. INITIAL EQUIPMENT SET-UP



WARNING!

- Complete the installation checkout procedure section of this manual before putting the OXY-1 System into operation. If the OXY-1 System fails any portion of the checkout procedure, it must be removed from use and repaired.



NOTE

- Before any assembly, test, or checkout procedures can be performed on the OXY-1 System, the Battery Enable Procedure must be completed.
- Do not plug the Console into AC power until after the batteries have been enabled.
- A hospital supplied IV pole is required for the OXY-1 System configuration. The IV Pole must meet the following minimum requirements: 25-40mm diameter pole, 20 kg load capacity, 24-inch base with 5-legs and castors. Locking castors are recommended.

5.1 INITIAL EQUIPMENT SET UP / CONTENTS

The OXY-1 System's durable components are packaged separately from the PLU Disposable. The durable portion of the OXY-1 System is shipped in a package containing the following:

- Console (with power cord)
- Pump Driver
- Pole Mount
- E-Drive
- System Operator's Manual
- 4 Wheel Casters
- 17 mm wrench to attach wheels

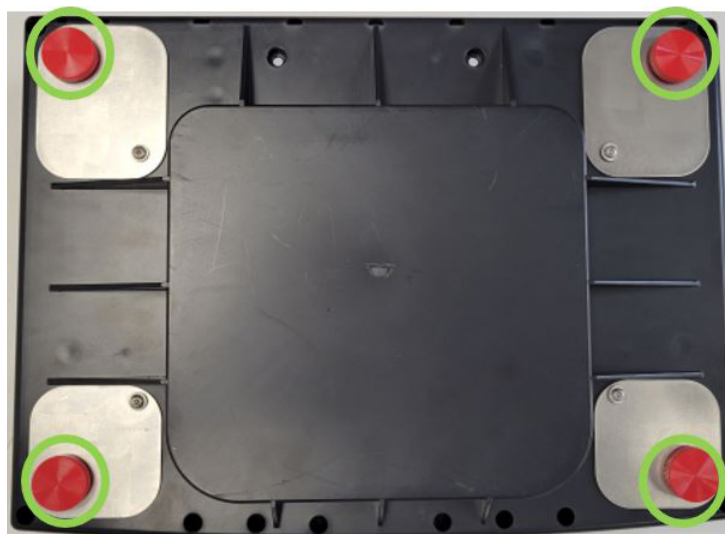


5.1.1 BATTERY ENABLE

1. The Battery Enable Procedure must be performed prior to assembly, test, and checkout procedures. See Appendix D

5.1.2 INSTALL WHEEL CASTERS

1. Remove the 4 wheel casters located in the packaging under the user manual.
2. Locate and remove the 17 mm wrench (see image)
3. Locate a clean surface and gently place Console on the rear panel to examine the base.
4. Locate and remove the four 17 mm thumb screws located in the corners of the base (see image). These thumb screws are used for transport only and may be disposed after removal.
5. Insert the caster bolt into the socket and rotate bolt to engage the threads.
6. Using the supplied wrench, firmly tighten the casters to the base.
7. Repeat with all four casters.
8. Return the console to the upright position.



5.1.2 MECHANICAL INSPECTION

1. Examine each item for any damage or missing parts.
2. Examine the power cord and cord retainer for any signs of damage. Replace if damaged.
3. Check all castors are in firm contact with the floor and the OXY-1 System is stable.
4. Lock castor brakes and verify the OXY-1 System remains in place and unlocks and moves smoothly.
5. Verify the Console handle can be raised/lowered and locked securely in both positions.
Handle operation instructions:
 - a. Press hinge button to unlock handle.
 - b. Rotate handle and release hinge button.
 - c. Handle will re-lock once rotated fully in the raised or lowered position.

5.1.3 ASSEMBLY

1. Securely mount the Pole Mount to the IV Pole approximately 21 inches from floor. The arrow on the label of the bracket should point upwards. Apply downward pressure to the Pole Mount to verify it will not move.
2. Latch the Pump Driver into the Pole Mount. There will be an audible click. Lift up on the Pump Driver to ensure the latch is properly engaged.
3. Place the E-Drive onto the Pole Mount.
4. Mate the Pump Driver electrical cable to the Console connector labeled C1 located on the rear top of the Console. Lift the dust cover, align the red dots and fully mate the connector.

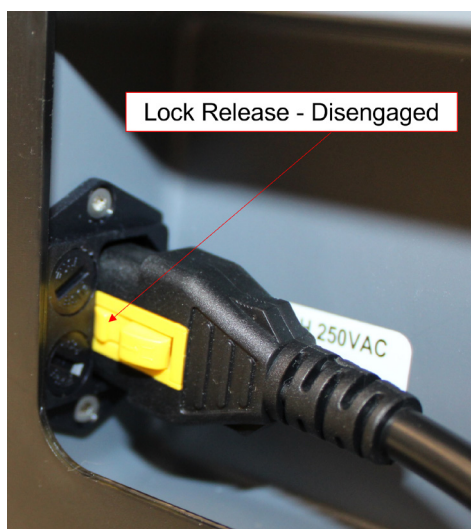
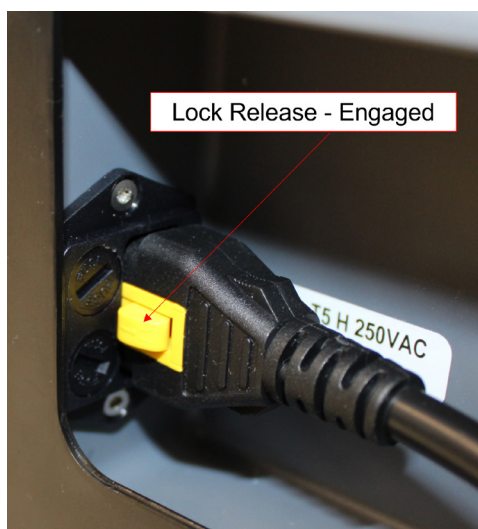


CAUTION!

- Verify the Pump Driver is properly attached (locked in place). Improper attachment can cause the pump to detach and fall, causing damage to the OXY-1 System and compromising performance.

5.1.4 AC POWER CORD

1. The AC Power cord will either be pre-installed to the Console or included separately in the packaging.
2. The AC Power Cord mates to the AC inlet located on the rear of the Console inside the cord pocket. Ensure that the AC Power Cord is fully inserted and locked into the AC inlet.
3. Once inserted, gently pull on the cord to test that the cord lock is engaged.
4. To remove the AC Power Cord, depress the yellow lock release and pull cord from the AC Inlet. (See images)

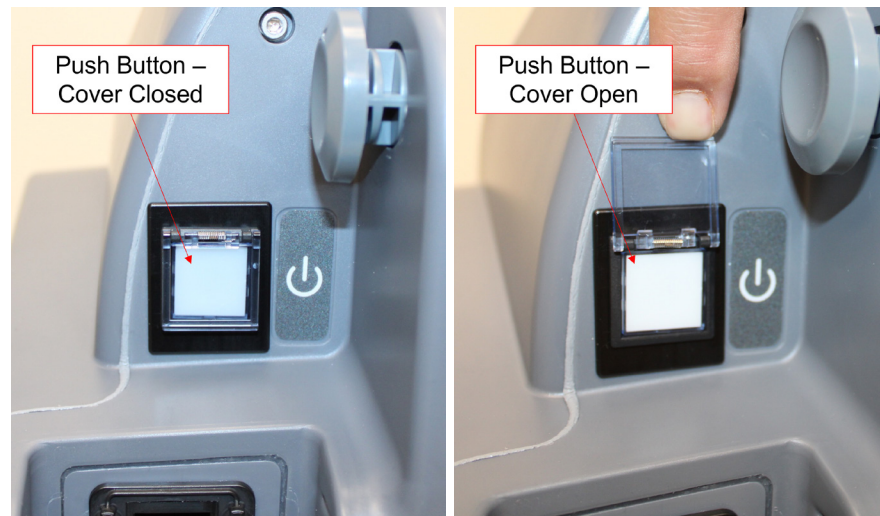


5.1.5 CORD STRAP

- Included with the AC Power cord is a cord strap to be used to secure the cord during storage, transport, or ambulating. The cord strap is mounted to the rear of the cord pocket.

5.1.6 POWER BUTTON

- The Power Button can be found on the rear of the Console. It is an On-Standby type of push button switch. The push button version has a protective cover that must be raised to access the push button switch actuator. The Power Button will be illuminated when the switch is in the ON state.



5.2 INSTALLATION CHECKOUT PROCEDURES

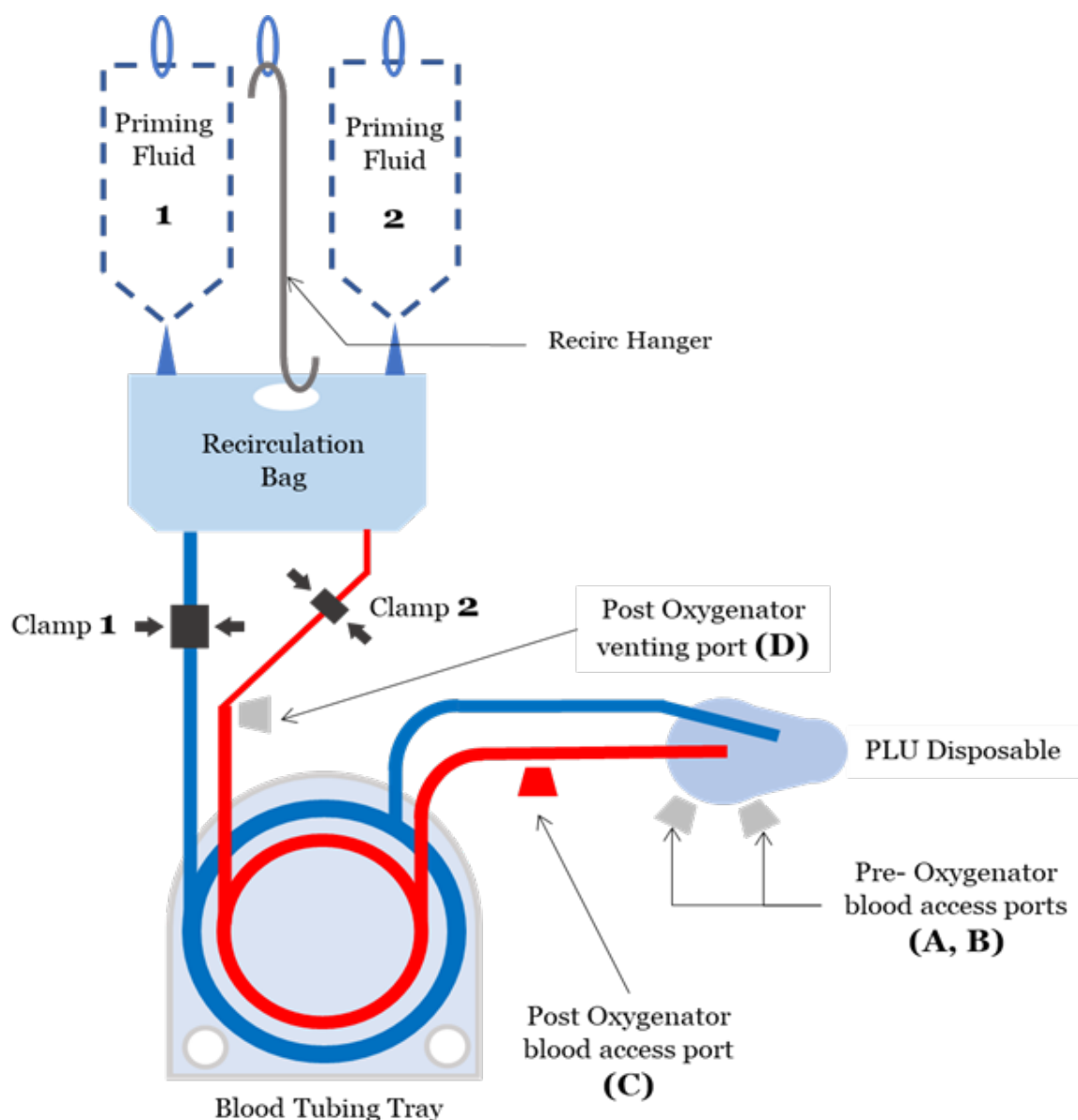
5.2.1 FUNCTIONAL CHECK

1. Connect the AC power cord to a wall outlet. The blue battery charging LED is on.
2. Switch the Power Button to the ON position (located on the back of the Console.)
3. Verify the following as the OXY-1 System boots up:
 - a. The screen is on and displaying the Breethe logo and OXY-1 System name.
 - b. An audible alarm beep is heard.
4. Verify no alarms exist after OXY-1 System boot completes and the home page is displayed.
5. Switch the Power Button to the OFF position.
6. Keep the OXY-1 System plugged in to fully charge the battery. Solid blue light indicates AC power is present.
7. Verify E-Drive is operational by manually cranking the handle clockwise. Increase RPM and LED display will indicate RPM from 1500 to 5000.

5.2.2 ELECTRICAL SAFETY CHECKS

All OXY-1 Systems should be tested by the facility's biomedical engineering team for safety prior to patient use. See Appendix B for recommended methods.

6. PLU DISPOSABLE SET-UP & PRIMING PROCEDURE



WARNING!

- Do not operate pump before the PLU Disposable has been properly primed. Operating the pump without fluid can cause damage to the pump.
- Inspect for leaks throughout the entire circuit during the priming process. Verify connectors and access ports are closed. Minor leaks can cause major blood loss- do not use if leaks cannot be corrected.



NOTE

- The PLU Disposable items must remain sealed until the contents are ready to be primed to maintain sterility. The tubing tray is labeled to notate proper orientation for opening during patient connection.
- The maximum working pressure of the blood circuit tubing is 650mmHg.

6.1 REQUIRED EQUIPMENT

- (1) Configured OXY-1 System
- (1) PLU Disposable kit
- (3) 1-Liter IV bags (Priming Fluid)

6.2 PLU DISPOSABLE KIT CONTENTS


- **(1) Sterile Pump Lung Unit (PLU) Disposable**
 - Coiled Air and O₂ tubing
 - 3/8", 500 mL coiled blood tubing pre-attached in a dust cover tray
 - Priming circuit with recirculation bag and hanger
 - (2) Luer caps on PLU Disposable access ports
 - (1) 1/4" x 3/8" Hose Barb with Luer access port (white, non-vented cap)
 - (1) 3/8" x 3/8" Hose Barb with Luer access port (red, vented cap)
- **(1) Condensate Tray**
- **(1) Cable Guard**
- **(4) Luer lock extension tubes with 3-way stopcocks**
- **(1) PLU Disposable Priming instructions**
- **(1) 3/8" x 3/8" Hose barb with Luer access port (white, non-vented cap)**
- **(1) Luer cap**
- **(4) Cable Ties**

6.3 PRIMING KIT SET-UP



WARNING!

- Inspect all sterile packaging for signs of damage. Discard and replace any items showing signs of damage. Sterility cannot be assured if packaging has been damaged or previously opened.
- Verify the PLU Disposable kit expiration date has not been exceeded prior to use.
- Aseptic technique should be maintained when setting up the PLU Disposable to prevent contamination of the circuit. The setup and priming process should be performed in a clean environment.
- The Blood Tubing Tray should not be opened until the surgical team is ready to place the tubing into the sterile field.
- Verify the blood port access connectors and caps are firmly attached (tight) and stopcocks are closed to prevent leaks. Leaks through blood access ports are a major source for circuit leaks.
- Do not install the spare access port on the low-pressure side of the blood circuit due to increased risk of air entrainment.

1. Inspect the kit cover for signs of damage and check expiration date located on the package label next to the "use by" symbol: 
2. Peel off the top cover of the PLU Disposable Kit tub.
3. Remove all pouched accessories and set aside. Do not open pouches.
4. Move the clear Air and O₂ tubing coil connected to the PLU Disposable and set outside the plastic tub, leaving the paper bands in place.
5. Remove bands from the priming circuit and hang the recirculation bag on the bag hook and IV pole as shown.
6. Unfasten the hook-and-loop straps holding the Blood Tubing Tray and PLU Disposable. Remove and set aside for later use.
7. Place the PLU Disposable into the Pump Driver, leaving the Pump Driver lid open.
8. Remove and replace the red vented Luer cap in position (C) with a non-vented male Luer cap (white) OR with an extension tube and stopcock provided in the accessory pouches.
9. Remove and replace one OR both PLU Disposable access port caps (A & B) with an extension tube and stopcock as desired.
10. Confirm all Luer port connections are secure and stopcocks are closed.

6.4 PRIMING PROCESS (BLOOD TUBING)

1. Close all clamps, large clamp (#1) and small clamp (#2).
2. Hang two (2) 1-liter IV priming fluid bags on the IV Pole.
3. Remove caps and insert priming bag spike ports into the IV bags as shown and allow the recirculation bag to fill with priming fluid. Periodically squeeze the recirculation bag to displace air bubbles back into the IV bags.
4. Position the Blood Tubing Tray on a horizontal flat surface below the priming bag to aid in purging bubbles.
5. Open the large clamp (#1) and allow the fluid to enter the circuit.
6. Remove the Luer cap (D) to vent air out of the circuit and position the Luer port over the PLU Disposable Kit tub to catch priming fluid.
7. Allow air to escape the Luer port (D) until fluid expels into the tub and close after the major air bubbles are voided.
8. Open the small clamp (#2) to purge the remaining air into the recirculation bag.
9. Squeeze the recirculation bag to displace air bubbles into the IV bags.
10. Replace one of the IV Bags if empty and air is present in recirculation bag.

6.5 PLU DISPOSABLE DE-AIRING



WARNING!

- Removing bubbles from the blood circuit is critical to preventing air embolism. Frequently inspect the circuit and take actions to remove bubbles from the circuit when bubbles are observed at the blood access port locations.
- Do not operate the pump without closing the latching mechanism on the Pump Driver. This can be verified by inspection. Improper or partially closing the latch will result in improper blood flow reporting.

1. Remove PLU Disposable from the Pump Driver and inspect for trapped air bubbles.
2. Manipulate the PLU Disposable to ensure air that may be trapped in the pump and oxygenator housing is dislodged and collects near the access port. This may require tapping the side of the PLU Disposable to migrate bubbles to the access port location.
3. Open the stopcock on blood access ports A or B to expel the air from the circuit.
4. Repeat steps 1 through 3 until no air bubbles are present.
5. Purge the air from all Luer ports and extension tubes. Verify all ports are firmly tightened.
6. Return the PLU Disposable back to the Pump Driver. Secure the tubing and close the lid using the 4-step latch process (see section 2.3)

6.6 PUMP CIRCULATION DE-AIRING

1. Hang the Blood Tubing Tray on the IV pole using the Velcro strap, and adjust the height to prevent any kinks in the tubing.
2. Set the pump to 2000 RPM (an approximate flow rate of 2.0 LPM) and run for three (3) minutes. Allow priming fluid to purge air bubbles from the circuit. Squeeze the recirculation bag to displace air bubbles into the IV bags.
3. Increase the pump to 4500 RPM (an approximate flow rate of 6 LPM) and run for thirty (30) minutes to purge any remaining bubbles. Inspect the tubing for any restrictions if flow is significantly lower.
4. Inspect the entire blood circuit and tap on connectors to remove air bubbles while pump is running.
5. Stop the pump for final inspection of entire blood circuit.
6. If necessary, repeat the de-airing process as described in Section 6.5.

7. PRE-USE CHECKOUT PRIOR TO PATIENT USE

7.1 CONNECTING GAS TUBING



NOTE

- When attaching the Cable Guard, start zipper at the Console end and draw towards the Pump Driver.

1. Remove the green and white caps from the ends of the gas tubing.
2. Connect the 3/16" ID O₂ tube to 3/16" barbed fitting, T1, at the Console.
3. Connect the 1/4" ID Air tube to a 1/4" barbed fitting, T2, at the Console.
4. Open the zipper on the Cable Guard. Attach tab to Console button.
5. Starting at the Console, wrap the PLU Cable Guard around gas tubes and electrical cables and zip up the entire length.
6. Attach the Cable Guard tab to Pump Driver button.
7. Attach the hook/loop strap to the Cable Guard on the Console.



7.2 PRE-USE CHECKS (BEFORE PLACING ON PATIENT)

7.2.1 CONSOLE

1. Confirm the following:
 - a. Installation Checkout Procedure (Section 5.2) is completed.
 - b. OXY-1 System is positioned near the patient in a well-ventilated area free of pollutants and high humidity.
 - c. The Console air intake and exhaust ports are not obstructed.
 - d. Console castors and IV pole castors (if equipped) are locked.
 - e. Power cord is connected directly to an outlet. See Technical Specifications or rating label on back of Console.
 - f. The blue battery charging LED is on.
2. Switch the Power Button to the ON position.
3. Confirm the following during power up:
 - a. The screen is on and displaying the Breathe logo and OXY-1 System name.
 - b. An audible alarm beep is heard.
 - c. The blue battery charging LED is on.
4. After boot completes and the home page is displayed, confirm no alarms exist.

7.2.2 PUMP DRIVER

1. Confirm the Pump Driver is securely latched onto the Pole Mount.
2. Verify that the primed PLU Disposable is properly seated in the Pump Driver.
3. Check that the blood tubing is properly seated into the channels of the Pump Driver flow sensor.
4. Check that the lid is closed beneath the latch and the latch is fully engaged on the Pump Driver.
5. Check the blood circuit access ports for leaks. Tighten caps or adjust stopcocks as needed.
6. The gas tubing between the PLU Disposable and Console is properly connected.
7. The Cable Guard is zipped over the gas tubing and electrical cable and buttoned at both ends.
8. Check that the Condensate Tray is installed. The Condensate Tray is installed into the Pump Driver as shown in the photo below.



7.2.3 BLOOD CIRCUIT CHECK

1. Increase the Pump RPM until the Blood Flow is 3 LPM.
2. Inspect the entire blood circuit and blood pump for bubbles.
3. If bubbles are present, stop the blood pump and eliminate bubbles (see section 6.5 & 6.6)
4. Confirm the **GREEN LED** indicator light comes on when the motor is rotating.
5. Set the Pump RPM to 0.

7.2.4 GAS CIRCUIT INTEGRITY TEST



WARNING!

- Verify the integrity of all gas tubing connections and that the gas tubing is not obstructed. Loss in gas flow can result in insufficient O₂ and CO₂ transfer



NOTE

- A false-positive test result is triggered when the Air and O₂ tubing are not completely occluded during the test.

1. Remove external gas source (if connected).
2. Set Internal Gas, Air Flow to 15 LPM.
3. Set Internal Gas, O₂ Flow to 3 LPM.
4. Wait 60 seconds for internal gas sources to reach max flow settings.
5. Clamp both the Air and O₂ tubing.
6. Wait 60 seconds for the Console to detect flow errors:
 - a. High Priority Alarm "Air Flow Out of Range"
 - b. High Priority Alarm "Oxygen Concentrator Flow Out of Range"
7. If either flow error was NOT detected, this indicates there is a leak in the gas circuit.
8. Verify both gas tubing lines are firmly attached to the Console and repeat the test.
9. If either flow error was still NOT detected, the OXY-1 System should be removed from use.
10. Otherwise, release clamps on Air and O₂ tubing.
11. Wait for the Console to clear the flow errors.
12. Set Internal Gas, Air Flow to 0 LPM.
13. Set Internal Gas, O₂ Flow to 0 LPM.
14. Reconnect to external gas source.

8. CONNECTING TO PATIENT & INITIATION OF THERAPY

Verify Pre-Use check is completed prior to initiating therapy (Chapter 7)



WARNING!

- Always position the PLU Disposable and Pump Driver below the level of the patient's heart.
- Confirm the Drainage (Blue) and Return (Red) line are correctly set-up for the respective cannula. Incorrect tubing connection will result in reverse flow and potentially harm the patient.
- If blood pump failure occurs, clamp the blood tubing to prevent retrograde flow.
- Always set pump RPM to ensure sufficient blood flow and prevent retrograde flow before removing blood circuit clamps.
- Excessive negative pressure and restriction on the Drainage line can result in cavitation and hemolysis. Excessive positive pressure and restriction on the Return line can result in cavitation and hemolysis.

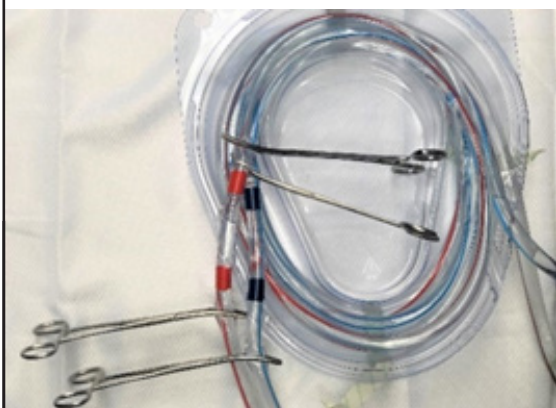


NOTE

- Monitor the patient's SpO₂ for effectiveness during therapy.

8.1 PRESENTING PRIMED PLU DISPOSABLE TO SURGICAL TEAM IN STERILE FIELD

1. Clamp the Return (red) and Drainage (blue) on the priming side of the circuit near the Blood Tubing Tray.
2. Open the Blood Tubing Tray with the label oriented “This Side Up” and present sterile tubing to a surgical team member in the sterile field.
3. A team member in the sterile field will:



- a. Clamp both tubes inside the sterile border of the Blood Tubing Tray.
 - b. Cut the tubing between the clamps to separate the blood tubing from the priming circuit outside the sterile field.
 - c. Remove blood tubing from Blood Tubing Tray and place into the sterile field.
 - d. Cut tubing to the desired length. Be sure to clamp tubing near the cut to maintain the priming fluid in the circuit.
 - e. Place the tubing ends of the primed circuit near the ends of the cannulas.
 - f. De-air the tubing and connector by continuously flushing saline while both ends are mated.
 - g. Confirm the correct drainage and return lines are connected to the appropriate cannula.
 - h. Unclamp the blood drainage/return lines on the PLU Disposable tubing and cannula.
 - i. A surgical team member will indicate patient readiness to initiate therapy.
4. Initiate blood flow by increasing the RPM setpoint on the main screen.
 5. Inspect the circuit for blood movement and absence of leaks or bubbles.
 6. Increase the flow rate gradually to prevent back flow of blood. Allow the blood to completely fill the circuit before increasing incrementally.

8.2 ADJUST BLOOD FLOW TO TARGET FLOW SET POINT

1. Begin sweep gas flow once blood flow starts and set to the desired set point.
2. Inspect the inflow and outflow tubing for color changes in the blood exiting the oxygenator. The outflow should be bright red in color.
3. Confirm that the parameter settings have been reached.
4. Providers may confirm the blood flow rate with an external flow sensor.
5. Verify and set alarms are set to their values according to the hospital policy.

9. MONITORING & ONGOING MAINTENANCE



WARNING!

- Patients receiving therapy require continuous monitoring to ensure gas delivery and transfer performance is adequate. This includes the use of SpO₂ monitors, arterial blood gas monitoring and frequent inspection of the blood circuit.
- Patients receiving therapy require the use and monitoring of anticoagulants to prevent thrombin formation and clotting.
- The use of extracorporeal circuits for cardiopulmonary bypass can cause hemolysis and other changes in blood properties. Frequently monitoring the patient's blood properties for evidence of elevated plasma free hemoglobin (PFHb) is recommended.

9.1 ONGOING MONITORING DURING THERAPY

Changes in patient condition and device performance require continuous monitoring of the patient and the OXY-1 system. Perform periodic inspections to ensure optimal delivery of therapy. The following are recommended actions related to the OXY-1 System delivery performance.

9.1.1 BLOOD FLOW CIRCULATION

Monitor blood flow rate changes for a given RPM settings. Changes in blood flow may be an indication of several factors, including changes in the patient condition and flow restrictions in the circuit.

9.1.2 BLOOD CIRCUIT INSPECTION

Begin by inspecting from one cannula, through the entire blood circuit, to the opposite cannula. Note that inspection may require the use of a flashlight to illuminate the circuit. If an anomaly is detected, action should be taken to remedy the issue. Inspect for the following:

1. Blood tubing is positioned and routed in a manner to prevent entanglement or accidental forces from being applied to the circuit that will strain the circuit, cause detachment and/or damage.
2. Migration or movement of the cannula from the location it was originally anchored and secured to on the patient.
3. Indications of blood loss.
4. Kinking or sharp bend radii in the blood tubing or cannula that may restrict blood flow.
5. Presence of clot formation throughout the entire blood path.
6. Presence or accumulation of air bubbles in the circuit.

7. Presence of air bubbles in the pump head. This is often identified by a rattling noise at the pump.
8. Verify connectors are secure and reinforced with tie bands and/or tape.
9. Verify stopcocks and extension tubing are closed to prevent leakage and are secure from accidental breakage.
10. Inspect the PLU Disposable and connectors for evidence of cracking caused by inadvertent trauma.
11. Inspect gas tubing for proper connection to the Console and evidence of occlusion that may restrict gas flow.
12. Inspect for changes in blood flow and consider measuring transmembrane pressure.

9.1.3 GAS TRANSFER RATE

The gas transfer of the oxygen into the blood should be measured on a periodic basis to monitor changes in the membrane. This can be performed by taking blood gas measurements pre and post oxygenator and calculating the gas transfer rate for a given blood flow rate. Significant changes in the gas transfer rate require additional evaluation. This should also include changes in the patient's arterial and venous blood gas levels.

1. Verify gas tubing between the Console and external source gas, and tubing between the console and the PLU Disposable are firmly attached to the console (T1&T2)
2. Sigh the oxygenator membrane on a periodic basis. Excess condensation can reduce gas transfer.
3. Monitor pre and post oxygenator blood gases for changes in performance.
4. Confirm the gas delivery and set points are as expected.
5. Visually inspect the condensation trap by removing from the Pump Driver and replace as needed.

9.1.4 OXY-1 SYSTEM

Routinely confirm that the OXY-1 System operating at the set points for blood flow and sweep gas flow rate and that the patient is responding to the therapy.

1. Confirm set points are as expected. Consider locking screen to prevent inadvertent changes to set parameters.
2. Monitor for the presence of alarms and troubleshoot as needed.
3. Verify the OXY-1 System is always plugged into an AC outlet to maintain optimal battery charge.
4. Verify the OXY-1 System is positioned and unobstructed for monitoring and access.
5. Verify the E-Drive is near, unobstructed, and accessible in the event of an emergency.

6. Verify the four castors are locked to prevent movement.



CAUTION!

- Regularly check the cleanliness of the air inlet filter located on the front of the Console.
- Failing to replace a dirty air inlet filter, or operating the Console without a filter, may cause serious damage to the Console.
- The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.

7. The air inlet filter condition should be visually checked before each use. Any significant amount of lint and debris covering filter surface will require the air filter replacement.
To replace the air filter, grab the filter foam strip with forceps, or similar tool, and pull it out.

To install the air filter, thread the foam strip narrow side in behind the panel tab. So, tab will be at the middle of the foam strip, as shown on the picture. Use forceps, or similar tool to aid with the task. Tack the filter into the Console filter cavity.



9.1.5 TRENDS SCREEN

The OXY-1 System Trends Screen has the following features:

- Ability to view blood flow and pump speed over time
- The blood flow is trended on a scale from 0 to 8 LPM
- The pump speed is trended on a scale of 0 to 4500 RPM
- The visible trend window can show 1, 6, or 24 hours of trend data
- Arrows allow moving the visible trend window along the entire trend time-period
- The maximum trend time-period is the most recent 7 days of continuous runtime

The Trends Screen will only display the trend data that has been recorded since power on. If the device is powered off and powered back on, all previous trend data is removed from the Trends Screen display. All trend data (from the last 30 days) is included in the log file and available to extract from the Console. (See Section 13 - Exporting Data)

To access the Trends Screen, press the icon on the bottom of the display:



9.2 SIGHING FUNCTION



WARNING!

- Hypocarbica (hypocapnia) is a state of reduced carbon dioxide in the blood. This may occur when sweep gas flow is set too high or if sighing is performed too often or for too long a duration.



NOTE







- Periodic Sighing prevents disruptions in oxygenation and CO₂ removal due to condensation build-up

Water vapor can condense in the membrane oxygenator, reducing gas permeability and resulting in poor oxygenation and CO₂ clearance. It may be cleared by periodically increasing sweep gas flow to a high flow to force vapor out of the membrane. Sighing should be performed at regular intervals. One of two sighing methods is required based on the gas mode source: External or Internal.

External Gas: When in External (wall/tank) gas mode, increase the sweep gas flow by manually increasing the flow rate via the control valve at the wall gas or tank output. The duration and level of increased sweep gas flow is determined by the Operator.

Internal Gas: Internal gas sighing is a function of the Console and controlled by the Operator via the User Interface.

1. Initiate Sighing by touching the Sigh icon.
2. Switch the function to the ON state. When enabled, the Sigh icon color will change from white to orange and the background will show a white progress bar.
3. The Sighing function may be terminated at any time during the 2 minutes by touching the Sigh icon and switching the function to the OFF state.

USER INTERFACE INDICATION		SIGHING PROGRESS
		Indicates normal therapeutic delivery. Press to initiate the Sighing process.
		Indicates that sighing is selected and ready to initiate.
		Sighing process started.
		Indicates that the sighing process is starting.
		Sighing is about 75% complete.
		Sighing is complete.

9.3 PLU DISPOSABLE CHANGE-OUT PROCEDURE



WARNING!

- Pump left running with tubing clamped can lead to hemolysis and therapeutic disruption.
- Inspect circuit for bubbles before initiating therapy



CAUTION!

- Clamping tubes too tightly can cause tears and leaks in circuit.

In the event of oxygenator membrane failure, change out the PLU Disposable with the following procedure. See Troubleshooting table for more details.

1. Set up all necessary equipment to change out PLU Disposable:
 - a. Sterile drapes and sterile scissors
 - b. Minimum of 6 tubing clamps
 - c. Disinfectant solution and applicators
 - d. New, primed PLU Disposable with blood tubing cut to desired length and clamped
 - e. Large syringe with saline solution for de-airing connector interface
 - f. 3/8" sterile hose barb connectors
2. Install 3/8" hose barbs into replacement PLU Disposable blood tubes.
3. Position replacement PLU Disposable adjacent to the PLU Disposable being changed.

4. Use aseptic technique to create a sterile field and disinfect blood tube surfaces that will be cut for implantation of the replacement PLU Disposable.
5. Clamp Return and Drainage blood lines on both sides of the tube transected locations. Set Pump RPM to 0.
6. Cut blood tube between each pair of clamps.
7. De-air and connect replacement PLU Disposable with corresponding patient line. Verify the correct line matches the corresponding blood flow direction.
8. Repeat steps 6 & 7 for other set of blood tubing.
9. Remove failed PLU Disposable from Pump Driver and insert replacement PLU Disposable.
10. Remove Cable Guard.
11. Unclamp blood tubing and increase pump speed to return blood flow to desired set point.
12. Inspect for presence of air bubbles as flow is restored.
13. At Console, change out failed PLU Disposable gas tubing with replacement PLU Disposable gas tubing.
14. Verify sweep gas flow is restored to the PLU Disposable.
15. Reattach Cable Guard.

9.3.1 LEAK IN BLOOD TUBING OR CONNECTION

1. Clamp tubing above and below location of leak.
2. Set Pump RPM to 0.
3. Repair leak, correct issue or replace defective component.
4. Remove clamps.
5. Slowly increase Pump RPM to achieve desired flow.
6. Re-inspect repaired area.



WARNING!

- Removing bubbles from the blood circuit is critical to preventing air embolism. Frequently inspect the circuit and take actions to remove bubbles from the circuit when bubbles are observed at the blood access port locations.

9.3.2 AIR IN THE BLOOD CIRCUIT

Air can be entrained in the blood circuit and pose a serious risk to the patient. Bubbles can enter the circuit during OXY-1 System assembly, priming or when a connection is inadvertently dislodged. The bubble detector in the Pump Driver will activate the alarm in accordance with the preset bubble alarm limits, and the UI will display a “Bubbles Detected” message with an audible sound. Periodic visual inspections can also detect entrained bubbles. To remove bubbles: shake, tap or otherwise manipulate the tubing or PLU Disposable to move the bubble to an access port for expulsion.

9.4 TRANSFERRING TO A NEW OXY-1 SYSTEM DURING USE

A backup OXY-1 System (Console and Pump Driver) should be available at all times when a patient is on support. In the event that the device fails, follow the steps below to transfer the PLU Disposable to a new Console and Pump Driver. **Note:** See sections 4.2 - 4.4 if transferring the PLU Disposable to the E-Drive.

1. Confirm that the backup OXY-1 System is powered on and ready.
2. Unzip and disconnect Cable Guard from the old Console and Pump Driver.
3. Clamp blood tubing to prevent retrograde flow.
4. If the pump is not already stopped, set Pump RPM to 0.
5. Remove PLU Disposable from old Pump Driver.
6. Attach the PLU Disposable to the new Pump Driver.
7. Gradually increase Blood Pump RPM on the new Console. Unclamp blood tubing.
8. Move tubing from external oxygen source (wall or tank) to new Console oxygen inlet.
9. Move Air and O₂ tubing from the old Console to the new Console.
10. Attach the Cable Guard to the new Console and Pump Driver.

9.5 TROUBLESHOOTING COMMON PROBLEMS DURING THERAPY

PROBLEM/ ISSUE	CAUSE	POTENTIAL CORRECTIVE ACTION
Oxygen Concentrator Warm-up does not initiate	<ol style="list-style-type: none"> 1. External gas is connected, and Internal O₂ levels are set to 0 2. Device is operating in backup Internal Gas mode, but Internal O₂ levels are set to 0 3. Warm-Up is unavailable because Internal O₂ flow is detected 	<ol style="list-style-type: none"> 1. Adjust Internal O₂ flow rate setting before initiating warm-up 2. Reconnect external O₂ & set Internal O₂ flow rate above zero before initiating warm-up 3. Leave Internal O₂ running, or reconnect external gas & initiate warm-up
Tubing “chugging”- rapid oscillations in blood flow	Excess negative pump pressure causing collapse of the cannula or vessels. This can result in pump cavitation.	<ol style="list-style-type: none"> 1. Correct flow restrictions in the blood circuit on the drainage side. 2. Decrease pump speed to reduce negative pressure 3. Evaluate patient hemodynamics i.e., fluid level
Reduction in blood flow at constant RPM	<p>Restriction in blood flow resulting in higher back pressure on the circuit.</p> <ol style="list-style-type: none"> 1. Change in patient condition 2. Blood circuit restrictions 3. Increase transmembrane pressure (clotting) 	<ol style="list-style-type: none"> 1. Evaluate patient hemodynamics and cannula position. 2. Correct flow restrictions in the blood circuit (drainage & return) side. 3. Confirm transmembrane pressure & replace PLU Disposable
Decreased gas transfer (oxygen or CO₂ elimination) across the oxygenator	<p>Reduction in gas diffusion across the membrane</p> <ol style="list-style-type: none"> 1. Change sweep gas flow 2. Compromised gas circuit 3. Condensation accumulation in the air circuit 4. Change in blood flow conditions (demand) 5. Changes in the blood properties (bleeding) 6. Impaired membrane function caused by deposition or formation of clots 	<ol style="list-style-type: none"> 1. Verify sweep gas source and flow 2. Verify gas tubing connectors are firmly attached at all the console connection points and at the external source (if running in External O₂ mode) 3. Sigh membrane by increasing flow to 15 LPM for 30 seconds to void condensation 4. Increasing blood flow may increase oxygen/ CO₂ demand 5. Evaluate blood properties and address underlying cause 6. Consider monitoring the transmembrane pressure with an external pressure transducers pre- and post- membrane 7. Replace PLU Disposable
Pump chatter/ rattle	Accumulation of air bubbles in the centrifugal pump. Excessive churn of air bubbles will increase hemolysis.	Stop pump, clamp tubing, isolate and migrate bubbles to a blood Luer port and evacuate bubbles with a syringe.
Excessive air in blood circuit	<p>Breach in the blood circuit on the negative / drainage side of the circuit.</p> <ul style="list-style-type: none"> • Open or broken stopcock, Luer cap and blood port connection. 	Verify and tighten connectors; replace if broken; insert and secure blood tubing connectors

10. DISCONTINUATION/TERMINATION OF THERAPY

10.1 TERMINATING THERAPY

1. Reduce RPM and double clamp Return and Drainage blood lines near patient.
 - a. Check that clamps are fully engaged to prevent leaks.
2. Set Pump RPM to 0.
3. Cut the tubing between each pair of clamps.
4. Decannulate patient per your institutional protocol.
5. Discontinue sweep gas.
6. Turn the Power Button to OFF.
7. Remove Cable Guard from Console.
8. Remove PLU Disposable from Pump Driver.
9. Dispose of PLU Disposable per hospital policy.

10.2 DISPOSAL OF SINGLE USE PLU



NOTE: OSHA REGULATION [29 CFR 1910.1030(D)(4)(III)(C)]

The final disposal of all regulated waste must be in accordance with applicable regulations of the United States, State and Territories, and political subdivisions of State and Territories.

Dispose of all waste per hospital/facility regulations for blood contaminated components. Improper disposal could result in personal injury and environmental impact.

11. CLEANING & DISINFECTION



WARNING!

Always wear personal protective equipment while cleaning and disinfecting the OXY-1 System.



CAUTION!

- Switch the OXY-1 System OFF and disconnect the power cord before cleaning and disinfecting. Remove from service if there is evidence of damage to the housing, blood tubes and/or cables.
- Do not use bleach to disinfect the DATA connector located at the rear of the console. Damage may occur.
- Do not spray cleaning or disinfecting solution directly on the OXY-1 System. Use a soft cloth moistened with solution..
- Do not clean the OXY-1 System with acetone, organic solvents, scouring compounds, strong acids, or strong bases. These compounds may damage the OXY-1 System.
- If the Console's touch screen display requires cleaning during use, verify the display is locked before wiping it with a cloth. Failure to lock screen can result in changes to OXY-1 System settings.
- Clean the blood flow sensor after each use.

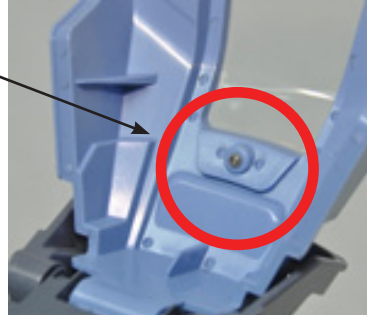
While the OXY-1 System is in clinical use, wipe down any contamination or soil from the OXY-1 System surfaces as soon as possible. The OXY-1 System must be cleaned and disinfected after each use.

11.1 CLEANING TOUCHSCREEN

1. Place OXY-1 System in "Lock Screen" by following instructions in section 2.1.2.
2. Obtain recommended cleaning solution.
3. Wipe touchscreen with a soft, lint free cloth dampened with recommended cleaning solution.
4. Allow cleaning solution to completely dry or dry with a lint free cloth.
5. Unlock screen to continue normal use.

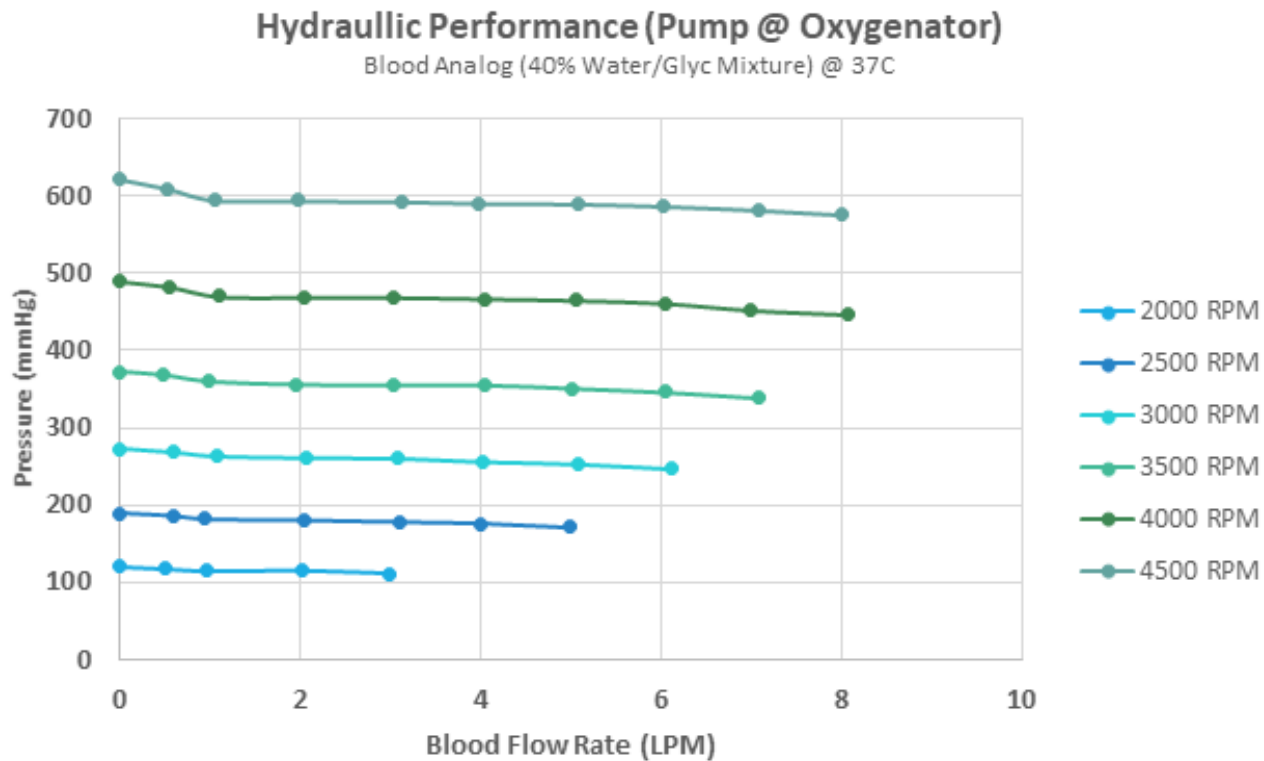
11.2 CLEANING AND DISINFECTION AFTER EACH USE

1. Clean the Pump Driver, Console and other accessories (pole mount), including the cables, by wiping them with a soft cloth moistened with the enzymatic detergent solution, like ENZOL®, until OXY-1 System is visibly clean. Use a small brush or similar tool moistened in detergent solution to clean small areas or crevices.
2. The Pump Driver cover has a clear window. The clear window can be disassembled for cleaning and disinfection if the joint between this window and the cover become soiled. Use a small Phillips tip screwdriver to remove the screw holding the window and disconnect the window from the cover.
3. If the Console foam intake filter is soiled or dirty, it must be replaced.
4. Wipe the OXY-1 System with a soft cloth moistened with water only to rinse all surfaces. Wipe dry after cleaning.
5. Disinfect the Pump Driver, Console and other accessories (pole mounts), including the cables, by first wiping them with a soft cloth moistened with a 1:10 aqueous solution of 5.25%–6.15% sodium hypochlorite (i.e., household bleach) to remove residual contamination.
6. Use a small brush or similar tool moistened in bleach solution to disinfect small areas or crevices.
7. Wet the OXY-1 System surfaces for at least 5 minutes with bleach solution using a soft moistened cloth.
8. Wipe the OXY-1 System with a soft cloth moistened with water only to rinse all surfaces. Wipe dry after disinfecting.
9. Reattach the Pump Driver cover window if it was removed for cleaning and disinfection.

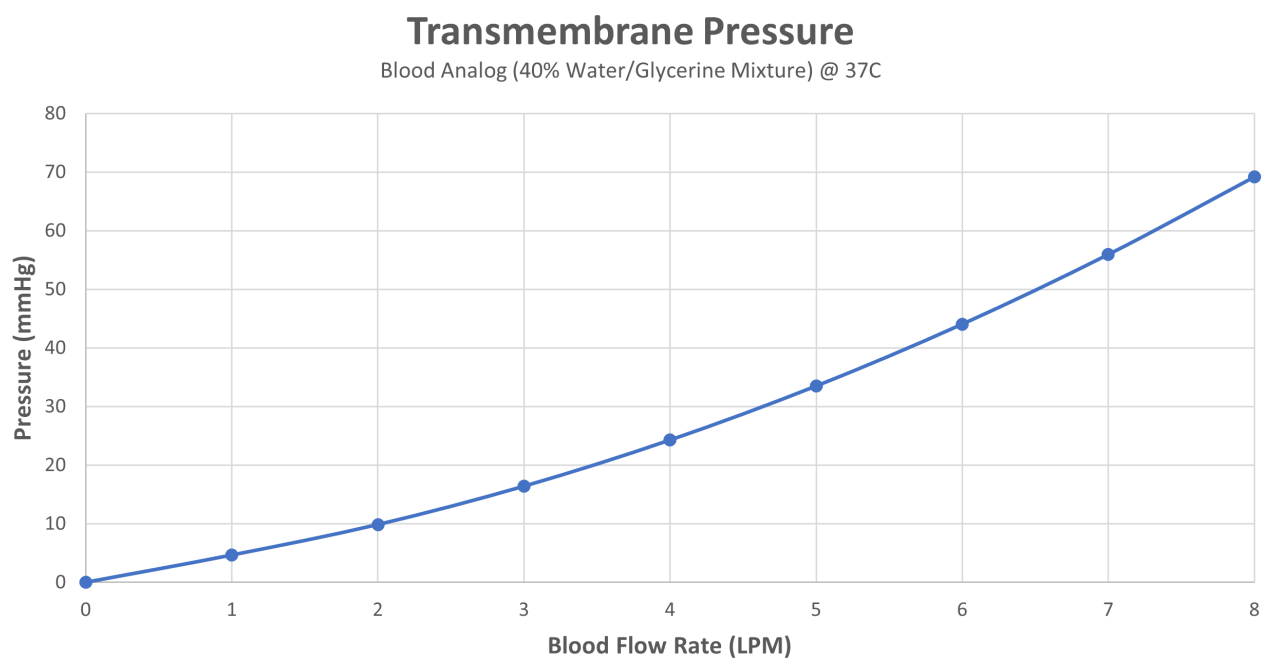


12. PUMP & OXYGENATOR PERFORMANCE DATA

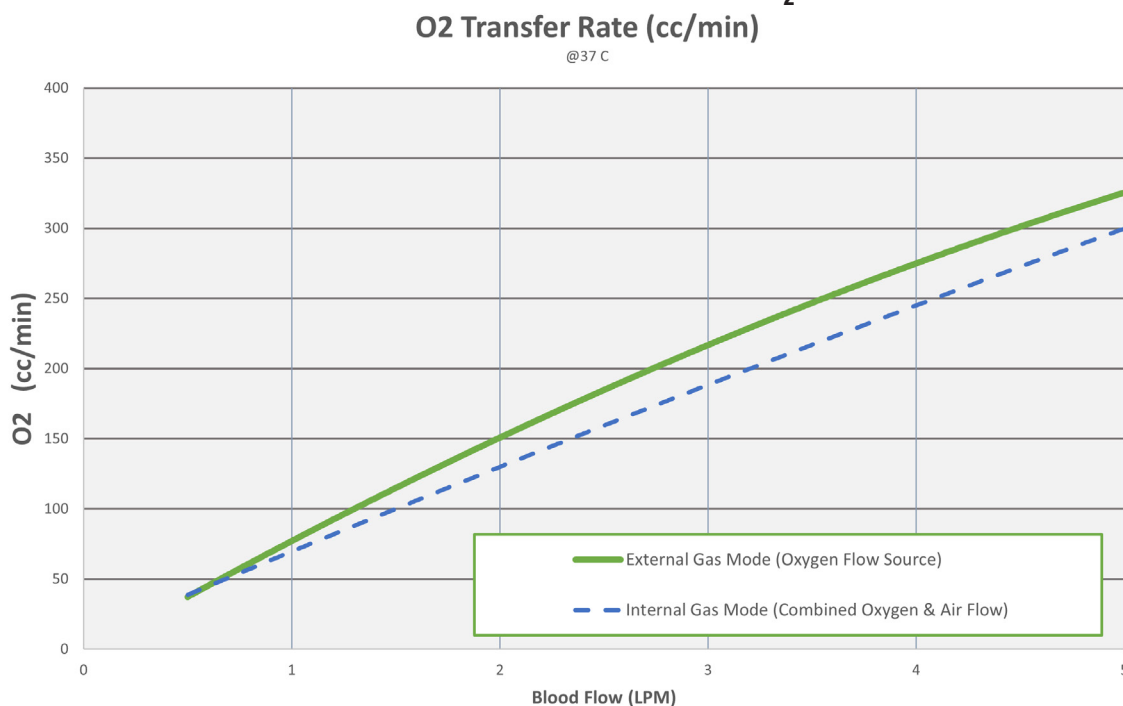
12.1 PUMP HYDRAULIC PERFORMANCE



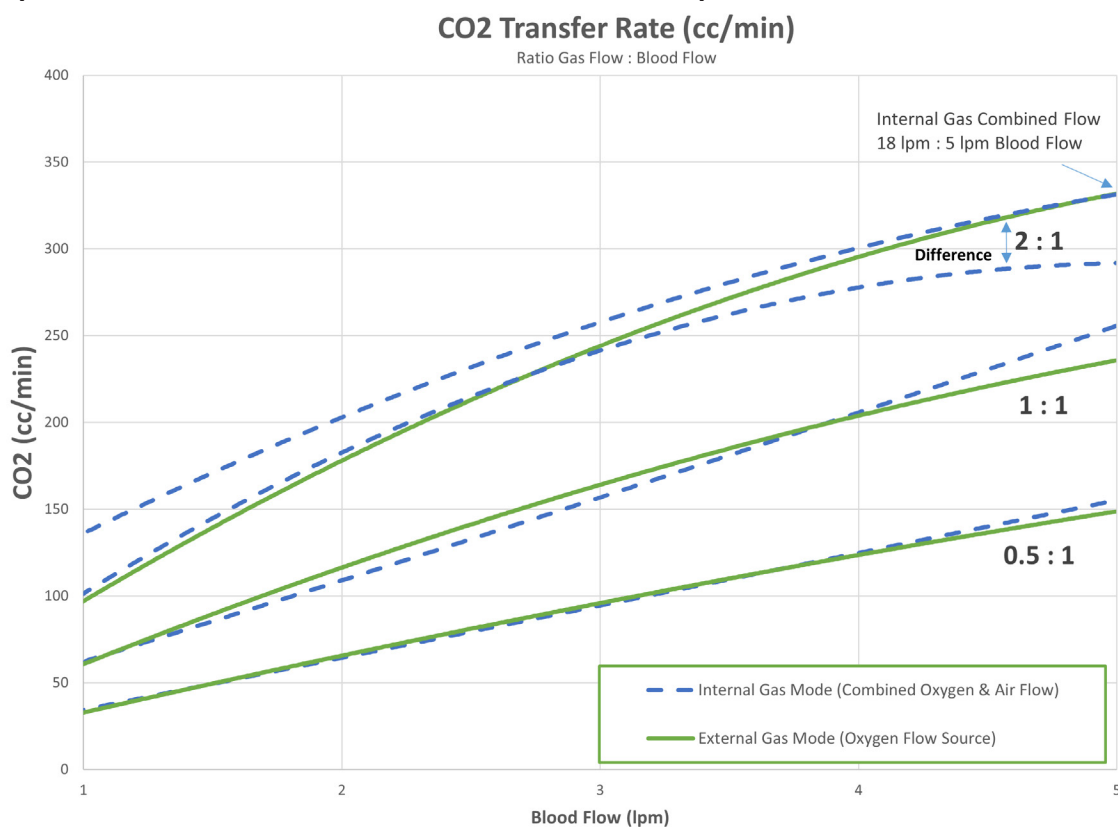
12.2 TRANSMEMBRANE PRESSURE



12.3 OXYGEN TRANSFER (INTERNAL & EXTERNAL O₂ MODE, 1:1)



12.4 CO₂ TRANSFER (INTERNAL & EXTERNAL O₂ MODE)



NOTE

backup Internal Gas mode flow is total gas flow of oxygen and air. Oxygen is increased from 0.5 to 3 LPM and then air is increased to create a total flow. For example: 5 LPM = 3 LPM of O₂ + 2 LPM of Air.


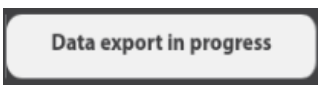

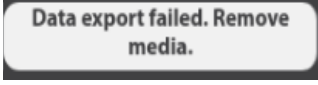
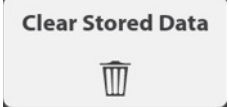
13. EXPORTING DATA

OXY-1 System parameters settings, time stamped data, alarms and system power down information are stored once every 5 seconds on a non-volatile, solid-state drive for a maximum of 30 days. As data “ages out” (over 30 days), it will be replaced by new information. Therefore, space is always available for current information. Logged information can be exported as a file. The Operator can also clear data in the log by clicking on the trash can icon in the “Settings” menu.

To extract the data, insert the proprietary media into the media port on the left side of the rear of the Console.

1. Information regarding alarms and other functions will download to the drive regardless of other Console actions.
2. Observe the content of the screen notifications to determine the progress of data transfer. See table below for the steps for exporting data.



UI INDICATION	STATUS OF DATA EXPORT
	Normal Operation prior to Export, irrespective of screen in use.
	Indicates that data export is in progress.
	Indicates that all information has been transferred to the removable media.
	Extract the media device and evaluate cause of transfer failure.
	Click on this region of the UI to clear information currently stored within the Console memory.

To transfer data from the proprietary media to a computer, plug the media into the included adapter, then plug the adapter into the computer's USB port. The operating system will then recognize it as a USB flash drive.



14. SERVICE & PERIODIC MAINTENANCE



WARNING!

- Any service, repair or maintenance task should only be conducted by authorized service personnel. Unauthorized service or maintenance tasks may result in harm to patient and/or operator, damage to the OXY-1 System, and may void or terminate OXY-1 System warranty.
- The OXY-1 System should be disconnected from patient use before performing service/maintenance tasks.

14.1 SERVICE & REPAIR - GUIDANCE

The OXY-1 System has an expected service life of three years.

Contact Abiomed for service in case of the following:

- Unexplained service interruption
- A sharp and/or unexpected impact to the Console
- Exposure to smoke or fire damage
- Discharge of a fire extinguisher in the direction of the OXY-1 System

PM AREA	REQUIREMENT
Batteries	The batteries will charge when the Console is plugged in.
	Do not attempt to open the Console after the batteries are enabled; there are no Operator serviceable parts.
Storage	Request an annual service check. Contact Abiomed for additional information or to schedule an appointment.
Blood Flow Sensor	The Pump Driver's blood flow sensor should be inspected annually to avoid incorrect flow readings and improper device use. Contact Abiomed to schedule an appointment.

Contact Abiomed to schedule periodic maintenance every 12 months. At end of equipment life, do not dispose of electronic equipment or batteries as unsorted municipal waste. Observe local ordinances for proper disposal.

Battery Run Time Parameters - Nominal Conditions, 50% Duty Cycle:

PARAMETER	VALUE
Blood Flow Rate	3 LPM at 3000 RPM
Internal O ₂ Flow	2 LPM
Internal Air Flow	5 LPM

APPENDIX A: ELECTROMAGNETIC RISKS

Safety Standards: IEC 60601-1, Edition 3.1

EMC Standards: IEC 60601-1-2, 4th Edition



WARNING!

- Medical Electrical Equipment requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the User Manual or the service manual.
- Portable RF communications equipment (including Cellular Technologies, and peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- This equipment/system is intended for use by clinically trained professionals only. It may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment system or shielding the location. Verify equipment adjacent to the OXY-1 System operates as intended.
- The use of cables, power supplies, and/or accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



NOTE: ESSENTIAL PERFORMANCE

- Essential performance includes gas flow and blood flow. Electro-magnetic interference can result in partial or total loss of gas transfer and/or blood circulation. In this event, use the emergency Pump Driver with external oxygen.

The OXY-1 System is intended for use in the electromagnetic environment specified below. The customer or the operator of the above listed model is responsible for monitoring and maintaining these environmental conditions.

Immunity Test	IEC 60601-1-2 4th Edition Test Level		Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) According to IEC 61000-4-2	±8 kV contact			Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±2 kV, ±4 kV, ±8 kV, ±15 kV air			
Radiated RF according to IEC 61000-4-3	Professional	Home Healthcare	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz		
Proximity Field from Wireless Transmitters according to IEC 61000-4-3	The following individual frequencies and test levels are for the separation distance of 0.3 m from each wireless device.			Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
	27 V/m @ 385 MHz Pulse modulation 18 Hz			
	28 V/m @ 450 MHz FM, ± 5 kHz deviation, 1 kHz sine			
	9 V/m @ 710 MHz, 745 MHz, 780 MHz Pulse modulation 217 Hz			
	28 V/m @ 810 MHz, 870 MHz, 950 MHz Pulse modulation 18 Hz			
	28 V/m @ 1720 MHz, 1845MHz, 1970 MHz Pulse modulation 217 Hz			
	28 V/m @ 2450 MHz Pulse modulation 217Hz			
	9 V/m @ 5240 MHz, 5500 MHz, 5785 MHz Pulse modulation 217 Hz			
Fast Transients / Bursts according to IEC 61000-4-4	±2 kV power supply lines 100 kHz repetition frequency			Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
	±1 kV signal lines 100 kHz repetition frequency			
Surge Immunity according to IEC 61000-4-5	AC / DC Power Lines: ±0.5, ±1, ±2 kV Line-to-Ground		±2 kV Line-to-Ground	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
	Differential mode: ±0.5, ±1 kV Line-to-Line		±1 kV Line-to-Line	

Immunity Test	IEC 60601-1-2 4th Edition Test Level		Compliance Level	Electromagnetic Environment – Guidance
Conducted RF according to IEC 61000-4-6	Professional	Home healthcare	3 VRMS 150 kHz to 80 MHz 6 VRMS at ISM and Amateur bands 80 % AM at 1 kHz	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
	3 VRMS 150 kHz to 80 MHz 6 VRMS at ISM bands (a, b) + additional modulations conditions upon the RM 80 % AM at 1 kHz	3 VRMS 150 kHz to 80 MHz 6 VRMS at ISM and Amateur bands (a, b) + additional modulations conditions based upon RM 80 % AM at 1 kHz		
Rated power frequency magnetic fields according to IEC 61000-4-8	30 A/m 50 Hz or 60 Hz			Minimum distance from sources of power frequency magnetic field at least 15 cm. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment and home healthcare environment.
Voltage Dips according to IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle Single phase: at 0° 70 % UT; 25/30 cycles Single phase: at 0°			Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
Voltage Interruptions according to IEC 61000-4-11	0 % UT; 250/300 cycle			Built-in batteries allow OXY-1 System to operate during mains interruption.
Known sources of EMI: RFID Readers, Electrosurgical & Electrocautery devices, Diathermy, EM security systems,WPT and 5G Cellular AIM 7351731 Rev. 3.00 (2021-06-04).	RFID Readers: 5 - 65 V/m RMS; 134.2 kHz - 2.4 GHz Electrosurgical devices: 500 V/m pulsed; 1.7 MHz Electrocautery devices: 400 V/m pulsed; 1.7 MHz Diathermy: 50 V/m; 1.7 - 2.3 MHz X-Ray: 10 V/m; 30 kHz NFC: 81.5 dBuA/m; 13.56 MHz Electronic Article Surveillance: 40 V/m; 7.7 - 8.7 MHz Wireless power transfers: 30 dBm; 113 kHz, 126 kHz 5G Cellular bands (c)			Min distance from RF communications equipment should be at least 30 cm. RF frequencies and amplitudes should be at levels characteristic of a typical location in a typical commercial or hospital environment and home healthcare environment.
Comment				
a. ISM bands: 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283; MHz; 40,66 MHz to 40,70 MHz; b. Amateur bands: 1,8 MHz to 2,0 MHz; 3,5 MHz to 4,0 MHz; 5,3 MHz to 5,4 MHz; 7 MHz to 7,3 MHz; 10,1 MHz to 10,15 MHz; 14 MHz to 14,2 MHz; 18,07 MHz to 18,17 MHz; 21,0 MHz to 21,4 MHz; 24,89 MHz to 24,99 MHz; 28,0 MHz to 29,7 MHz; 50,0 MHz to 54,0 MHz; c. 5G Cellular bands: 40 dBm - 742 MHz, 842 MHz, 1909.9 MHz, 1923.264 MHz; 22 dBm - 24.5 GHz; 26 dBm - 25.75 GHz; 13 dBm - 27.25 GHz; 20 dBm - 28.15 GHz, 29.0 GHz; 30dBm - 38.05 GHz; 28 dBm - 39.5 GHz				

APPENDIX B: ELECTRICAL SAFETY TESTS

Leakage current testing as defined in IEC 60601-1 recommended to be performed annually. Use of the direct method of leakage current test as defined in IEC 62353 is an acceptable substitution.

Wait until the OXY-1 System has powered up and completed all self tests before taking readings.

Measurement of insulation resistance is not recommended. Long term effects of repeated exposure of high voltage on the electrical insulation system may damage the OXY-1 System.

Use an approved electrical safety analyzer to perform leakage current tests. Follow the operating instructions supplied by the manufacturer of the electrical safety analyzer to verify the following:

Leakage Current

1. Touch current (Equipment leakage)
 - a. The touch current shall be less than 100 microamperes.
 - b. In a single fault condition, the touch current shall be less than 500 microamperes.
2. Patient leakage current (Applied part leakage)

The Pump Driver is defined as the "Applied part in the OXY-1 System." The PLU Disposable is held by the Pump Driver. Leakage current can be tested by wrapping the Pump Driver tightly in aluminum foil in close contact with the inside of the Pump Driver. The flow sensor channel, the condensation tray and pump cradle should be covered. See figure below for an example of set-up. The measurement shall be taken from the aluminum foil.

AC Leakage Current

- In normal condition, in all possible operating modes, the patient lead leakage current shall be less than 10 microamperes.
- In single fault condition, in all possible operating modes, the patient leakage current shall be less than 50 microamperes.

DC Leakage Current

- In normal condition, in all possible operating modes, the patient lead leakage current shall be less than 10 microamperes.
- In single fault conditions, in all possible operating modes, the patient lead leakage current shall be less than 50 microamperes.

APPENDIX C: COMPLIANCE TESTING & STANDARDS

The OXY-1 System is intended for use in the electromagnetic environment specified below. The customer or the operators of the above listed model are responsible for abiding by these conditions.

EMISSIONS TEST		COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF Radiated Emissions CISPR 11		Group 1, Class A	The above listed model uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Conducted Emissions CISPR 11		Group 1, Class A	The above listed model is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2		Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3		Complies	
Group 1	All ISM equipment in which there is intentionally generated or used conductively-coupled Radio Frequency (RF) energy that is necessary for the internal functioning of the equipment itself.		
Class A	Equipment suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Cyber Security Statement

At Abiomed, products are designed to be safe, effective and secure. Security considerations apply throughout the entire product lifecycle. During the premarket phase, threat modeling, security risk assessment, security controls, and security testing activities are all represented. During post market up through end of life, vulnerability management activities are performed in association with software maintenance. Abiomed's Breethe OXY-1 is a non-networked device and, as such, is not at risk from any class of network-based attack. Abiomed field service representatives apply updates via a proprietary port on the device, which has been configured to accept only validated OXY-1 software.

If you believe you have identified a potential vulnerability in the Breethe OXY-1, please submit information related to the potential vulnerability using the MedISAO vulnerability reporting form, which can be found at https://members.medisao.com/vulnerability_disclosure/. Further information on product security at Abiomed can be found at <https://www.abiomed.com/product-security>.

Additional information can be found in the Manufacturer Disclosure Statement for Medical Device Security (MDS2) for the Breethe OXY-1.

The OXY-1 System has been tested and found compliant with the following standards:

COMPLIANCE STANDARD	SCOPE
AAMI ES 60601-1:2005/ (R)2012 + A1:2012	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010 +A1:2013	Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:2006 +A1:2012	Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2: 2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 7199: 2016	Cardiovascular Implants and Artificial Organs - Blood-gas Exchangers
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
ISO 11135:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
AIM 7351731 Rev. 3.00 (2021-06-04)	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

APPENDIX D: BATTERY ENABLE PROCEDURE



Before starting:

- Verify the AC plug of the Console is NOT plugged into an AC power outlet.
- Verify the Power Switch located on the rear of the Console is in the Standby position (not illuminated).

D.1.0 REQUIRED TOOLS

- 3 mm Hex Driver

D.2.0 BATTERY ENABLE PROCEDURE

- D.2.1** Using a 3 mm Hex Driver, loosen the 4 screws on the cover plate on the rear of the Console. Remove the cover plate.
- D.2.2** To enable the batteries, slide the triple switch actuator fully upward to turn on the three switches. Ensure the actuator is horizontal and all switches are in the same position.
- D.2.3** Re-install the cover plate. Be sure all 4 screws are installed and tightened using a 3 mm Hex Driver.



D.3.0 CHECK OUT PROCEDURE

- D.3.1 Verify the AC cord is fully inserted into the socket located in the rear lower recess of the Console.
- D.3.2 Insert the AC plug of the Console into an AC power outlet. Verify the blue LED on the bottom left of User Interface is on. This indicates that AC power is present and the batteries are being charged.
- D.3.3 Turn-on the Console and wait 90 seconds for any possible battery alarms to occur. If the batteries are not enabled properly, either of the following alarms will occur:



If no alarms occur after 90 seconds, then the batteries have been enabled properly.

D.4.0 BATTERY DISABLE PROCEDURE

If the OXY-1 System Console requires shipment via an air carrier, then the batteries are required to be disabled. Follow the reverse of the procedure described above to properly disable the batteries prior to shipment.

APPENDIX E: OXY-1 PART NUMBERS

DESCRIPTION	PART NUMBER
OXY-1 System (Console, Pump Driver, E Drive, and Pole Mount)	001-0500-001
OXY-1 PLU Disposable	001-0400-100
Consumables:	
OXY-1 Condensate Tray (Qty 5)	001-0403-006
OXY-1 Cable Guard (Qty 1)	001-0403-007
Console Intake Filter (Qty 5)	001-3300-039
AC Power Cord, 3 m (Qty 1)	001-0403-008
Service Replacement:	
OXY-1 Console	001-3300-040
OXY-1 Pump Driver	001-0301-003
OXY-1 E-Drive	001-0901-007
OXY-1 Pole Mount	001-0390-007

APPENDIX F: OPERATOR ASSISTANCE

CLINICAL SUPPORT: 1-800-422-8666

SERVICE: 1-978-646-1400

SALES: 1-978-646-1400

COMPLAINTS/COMMENTS: 1-978-646-1400

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