TransMedics® Organ Care System™

Clinical User Guide: OCS™ Lung System

Software Version 3.1.2
PN 100004071 Rev 6
REF 2102

CE 0086

TransMedics®
Bringing new life to organ transplant

Manufacturer's Address:

TransMedics, Inc.
200 Minuteman Rd., Suite 302 Andover, MA 01810, USA
Tel: +1 978 552 0999
Fax: +1 978 552 0978
Website: www.transmedics.com

CE 0086
This device complies with the Medical Device Directive 93/42 EEC.

Authorized EU Representative:

EC REP

Healthlink Europe BV
De Tweeling 20-22
5215 MC's Hertogenbosch
The Netherlands
Tel: +31-(0) 13-5479316

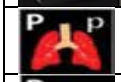
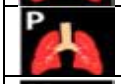
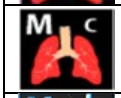
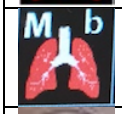
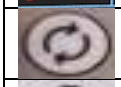
Patents:
U.S. Patents 6,046,046, 6,100,082; International Patents EU, UK, FR, ES, IT, BE, DK, FI, IE, LU, MC, NL, PT, CH, SE 1017274, DE 69819759.3-08, AU728233, ATE253819; Additional Patents Pending.

Manual PN & Rev
PN 100004071, Rev 6

CAUTION: United States federal law restricts this device to sale by or on the order of a physician.

Table of Contents

LIST OF SYMBOLS IN THIS GUIDE

Symbol	Meaning
	Run/Standby button on Wireless Monitor
	Wireless Bluetooth link between the Wireless Monitor and the OCS™ Lung Console
	ON position for OCS™ Lung Console
	Pause Preservation mode icon on the Wireless Monitor screen
	Preservation mode icon on the Wireless Monitor screen
	Continuous Monitoring mode icon on the Wireless Monitor screen
	Bronchoscope Monitoring mode icon on the Wireless Monitor screen
	Pump Adjust button on Wireless Monitor
	Main configuration button on Wireless Monitor

GLOSSARY OF TERMS

Term	Meaning
ABG	Arterial Blood Gas
BPM	Breaths/minute
Bronchoscope Mode	Ventilation of the lungs with ambient air, to allow endoscopic examination of lung's airways
Bronchoscope Port	Port on the Lung Perfusion Module through which a Bronchoscope probe may be inserted to inspect the interior of the lung
Circuit	Refers to the perfusate loop in the Lung Perfusion Module
Continuous Monitoring Mode	The Ventilator Mode in which the OCS™ Lung System continuously deoxygenates the perfusate by supplying Lung Monitoring Gas into the gas exchanger. At the same time, ambient air is used to ventilate the lung. Medical professionals may evaluate the capabilities of the lungs according to their clinical judgment by comparing the base O_2 saturation of the deoxygenated perfusate to the O_2 saturation of the perfusate exiting the lung.
Cuvette	An adapter on the perfusion module used for an oxygen saturation measurement probe.
Data Card	A removable SD Data card used to store perfusion, ventilation, and monitoring parameters from the current session, which can be downloaded and analyzed on a personal computer
FiO_2	Fraction of inspired oxygen
HCT%	Hematocrit, expressed as a percentage by volume
LA	Left atrial
LGRSAE	Lung graft-related serious adverse event
L/min	Liters/minute
LPM	Lung Perfusion Module
MDI Port	Metered Dose Inhaler port on the Lung Perfusion Module through which MDI drugs may be injected into the lungs
mL/hr	Milliliters per hour
mL/min	Milliliters per minute
mmHg	Millimeters of mercury
Mobile Base	The removable Mobile Base has four wheels, with brakes on the front wheels. The Mobile Base can be installed as needed during system use. During transport, raise the two-position handle to push the system. With the Mobile Base removed, you can set the system flat or carry it with the lift handles.
Organ Care System	The Organ Care System (OCS™) houses the removable Wireless Monitor, circulatory pump driver, multi- mode Ventilator, drive and control, batteries, data card, gas delivery subsystem, and reusable flow and pulse oximeter probes. When in active use, it houses the disposable Lung Perfusion Module.
PA	Pulmonary artery
PaO_2	Partial pressure of oxygen in mmHg in arterial (oxygenated) perfusate.
PAP	Pulmonary Artery Pressure. The perfusate pressure in mmHg at the Pulmonary Artery cannula as the perfusate flows into the lungs.

Glossary of Terms

Term	Meaning
Pause Preservation Mode	A Ventilator mode in which the bellows remain stationary and the OCS™ Lung System achieves a static level of lung inflation. Pause Preservation enables oxygenation of perfusate prior to lung instrumentation using the Lung Preservation Gas.
PAWP	Peak Air Way Pressure. The peak pressure in the lungs at the end of the inspiration. When the measured PAWP reaches the user-set PAWP limit, the Ventilator will stop. PAWP corresponds to Peak Inspiratory Pressure on mechanical Ventilators.
PEEP	Positive End Expiratory Pressure. The pressure maintained in the lungs by the Ventilator at the end of the expiration phase
Perfusate	The fluid pumped through the lung that delivers dissolved gases and nutrients.
Power-cycle	To power-cycle the lung system, use the On/Off switch on the side of the OCS™ Lung Console to turn the system OFF, wait 10 seconds, and then turn it ON.
Preservation Mode	A Ventilator mode in which the OCS™ Lung System operates with the lung rebreathing the same captive breath. A small percentage of fresh Lung Preservation Gas is injected into the ventilation circuit to maintain the required gas concentration and to maintain Positive End Expiratory Pressure (PEEP).
Priming Inlet Port	Port on the Lung Perfusion Module through which priming solution and other large-volume perfusate components flow into the reservoir
Priming Solution	The sterile OCS™ Lung Solution added to the reservoir through the priming inlet port to preserve the lungs supplemented with other perfusate components.
Pump Compliance Chamber	It is located between the circulatory pump and the perfusate warmer. Its main function is to dampen the pulsatile flow from the Pump.
Pump Flow Probe	A probe that you attach to the Lung Perfusion Module. It is used to measure OCS™ Lung System Pump flow.
PvO_2	Partial pressure of oxygen gas in mmHg in venous (deoxygenated) perfusate.
RR	Respiration Rate. Number of respiration cycles per minute in units of breaths/minute
Run Mode	Power mode where the system is on, the Wireless Monitor is active, and the Pump and Ventilator can operate
SaO_2	Oxygen saturation of arterial (oxygenated) perfusate, expressed as a percentage and measured at the outflow of the lung at the LA drain
SaO_2/Hematocrit Probe	An OCS™ Lung System probe that you attach to the Lung Perfusion Module. It is used to measure the arterial oxygen saturation and the hematocrit of the perfusate leaving the lung through the LA.
Session	A session is created in internal system memory when the system is set to Run Mode. Every time Run Mode is entered, you can choose whether to continue using the last session file or create a new one. In ordinary circumstances, data from all procedures associated with an organ should be documented in only one session. The system logs all system error events, all alarm events, trend data for each parameter at 2-minute intervals, and all system operating events that occur in each session.
Standby-Cycle	To Standby-cycle the system, press the Standby button to switch from Run Mode to Standby Mode and then back to Run Mode. The system will automatically run the Self Test.
Standby Mode	A power mode where the system is on but the Wireless Monitor is off and no ventilation or perfusion may be performed. Standby Mode is the mode used during OCS™ Lung System storage; organs cannot be preserved in this mode. The OCS™ must be plugged in to AC power to avoid battery depletion when storing the lung system in this mode.

Glossary of Terms

Term	Meaning
SvO_2	Oxygen saturation of venous (deoxygenated) perfusate, expressed as a percentage and measured at the inflow to the lung on the PA line
SvO_2/Hematocrit Probe	An OCS™ Lung System probe that you attach to the Lung Perfusion Module. It is used to measure the venous oxygen saturation and hematocrit of the perfusate entering the lung through the pulmonary artery cannula.
Temp	Temperature of perfusate supplied to the lung, displayed on the Wireless Monitor in degrees Celsius
TV	Tidal Volume. The volume of air breathed in and out of the lungs during a respiration cycle.
VR	Vascular Resistance. This is a measure of the resistance to flow that must be overcome to push perfusate through the vasculature of the lungs. It is calculated as (80* mean PAP)/(Pump Flow) and displayed in units of (dyne*sec)/cm^5.
Waveform	Real-time waveforms display continuously updated data. The waveforms are drawn from left to right with the most current data. An update bar displays the oldest data first. If more than one graphic frame is configured to show real-time waveforms, the update bars are automatically synchronized. The airway pressure waveform is always displayed in the top-most frame on the Wireless Monitor. Use the Configuration Menu to configure which of the following waveforms are displayed in the middle and bottom frames on the Wireless Monitor.
Wireless Monitor	A small, dockable monitoring system with an LCD screen and controls for configuring system functions and screen displays, and for adjusting system settings during preservation. When removed from its docking station on the OCS™ Lung Console, the Wireless Monitor operates wirelessly, powered by its own battery.

1. CHAPTER 1: READ THIS FIRST

This chapter contains important information about the documentation for your TransMedics® Organ Care System (OCS™) and about contacting TransMedics.

1.1. Directions to User

This manual provides detailed instructions regarding clinical use of the OCS™ Lung System. For a system overview, how to set up the system, and understanding the Wireless Monitor controls and functions, see the *TransMedics Technical User Guide: OCS™ Lung System.* Both guides are to be reviewed prior to using the system, noting the Warnings and Cautions throughout the guides.

The OCS™ Lung System can only be purchased upon order of a physician. A TransMedics representative must install and activate each newly purchased system before a qualified health care professional can use it.

1.2. User Training Requirements

The OCS™ Lung System enables medical professionals to monitor key parameters that may be useful in assessing organ condition and function according to their clinical judgment. The system is intended for use only by qualified healthcare professionals specializing in lung transplants and trained in the use of the OCS™ Lung System.

Completion of the TransMedics training program is required for every new lung transplant center prior to starting an OCS™ Lung System program at their institution. All team members who will be using the OCS™ Lung System at an institution must be trained. The training consists of initial hands-on training and periodic refresher training as needed.

1.3. Indications for Use

The TransMedics Organ Care System (OCS) Lung is a portable normothermic organ perfusion, ventilation and monitoring medical device indicated for preservation of standard criteria donor lung pairs and for preservation of donor lung pairs initially deemed unacceptable for procurement and transplantation based on the limitations of cold static preservation. The device allows for ex vivo assessment of donor lungs prior to transplantation.

1.4. Contraindications

Moderate to severe traumatic donor lung injury with air leak (as seen on radiological studies, bronchial examination or final visual assessment in donor's chest) to avoid:

- Perfusate leakage from injury site into the airways and potential edema formation
- Inability to recruit donor lungs due to air leak.

1.5. Precautions

The safety and effectiveness of the OCS™ Lung System is based upon clinical evaluations ≤ 5 years after organ preservation and transplantation. The impact of OCS™ Lung System organ preservation on longer-term clinical outcomes (e.g., incidence of bronchiolitis obliterans syndrome (BOS) and longer-term post-transplantation survival) is unknown. Users are advised to carefully review the available clinical data in Appendix A and Appendix B when considering use of the OCS™ Lung System for any donor organs and recipients.

Safety and effectiveness of the OCS™ Lung System for the preservation of isolated single-lung donor organs has not been evaluated. This Clinical User Guide only includes instructions intended for the preservation of en-bloc double-lung donor organs.

The safety and effectiveness of the OCS™ Lung System has not been studied in recipients with the following:

- Single lung transplant
- Prior solid organ or bone marrow transplant
- Multi-organ transplants
- Chronic use of hemodialysis or diagnosis of chronic renal failure requiring dialysis.

Safety and effectiveness of the OCS™ Lung System has not been studied for donor organs with:

- Hepatitis B and Hepatitis C
- Presence of confirmed active pneumonia or persistent purulent secretions on repeated bronchoscopy evaluation or endotracheal (ET) suction.

A device malfunction or user error could lead to a potential loss of a donor organ.

Only trained users are allowed to use the OCS™ Lung System.

1.6. Patient Counseling

It is important to adequately inform patients about the risks and benefits of the OCS™ Lung System. The patient should be provided with the OCS™ Lung System patient brochure that describes the device, the benefits and risks and provides an overall summary of the clinical experience with the OCS™ Lung System.

The patient should be instructed to review the Patient Brochures and discuss the warnings, precautions, and complications. At the end of the Patient Brochure for recipients of standard criteria donor lungs, there is a patient decision checklist for the patient's review and signature.

1.7. Conventions

The system, OCS™ Lung System, the lung system, and OCS™ are used interchangeably throughout this manual to refer to the TransMedics OCS™ Lung System.

The system uses consistent conventions throughout the interface and accompanying documentation to make it easy for you to learn and use.

WARNING—A Warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in loss of organ, death, or serious injury.

CAUTION—A Caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly a risk of more serious injury.

NOTE—A Note brings your attention to important information that will help you operate the system more effectively.

1.8. Supplies

The components, accessories, and supplies required when using the OCS™ Lung System must be used in accordance with this user manual, associated documents, and accepted medical standards.

CAUTION—Only accessories and supplies purchased from or recommended by TransMedics, Inc. are to be used with the TransMedics OCS™ Lung System. Use of accessories and supplies other than those supplied by or recommended by TransMedics may cause system malfunction and invalidate the TransMedics warranty.

For details on what is included with your OCS™ Lung System, see the *TransMedics Technical User Guide: OCS™ Lung System*.

To order additional parts and supplies, see Section 10 of the *TransMedics Technical User Guide: OCS™ Lung System.* Other materials, not supplied by TransMedics, are required to operate the OCS™ Lung System. See Section 3.

1.9. Contacting TransMedics

1—For Customer Clinical Support:
Please contact TransMedics prior to departure to donor site on one of the following numbers:
US/AUS/Canada: +1 978-222-3733
EUR: +31(0) 20-7084561

2—For Customer Service:
Please contact TransMedics at Tel: +1 978-552-0999
You can also contact one of the following offices for referral to a customer service representative, or visit the TransMedics website: www.transmedics.com.

Corporate and North American Headquarters
TransMedics, Inc.
200 Minuteman Road, Suite 302
Andover, MA 01810, USA
Tel: +1 978-552-0999
Fax: +1 978-552-0978

Authorized EU Representative
Healthlink Europe
De Tweeling 20-22
5215 MC's Hertogenbosch
The Netherlands
Telephone: +31(0) 13 547 9316

2. CHAPTER 2: OVERVIEW OF OCS™ LUNG SYSTEM

The TransMedics® Organ Care System (OCS™) Lung System is a portable organ perfusion, ventilation and monitoring medical device intended to preserve donated lungs in a near physiologic, ventilated, and perfused state for transplantation. The OCS™ Lung System enables medical professionals to continuously monitor key parameters that may be useful in assessing organ condition and function according to their clinical judgment.

2.1. System Components

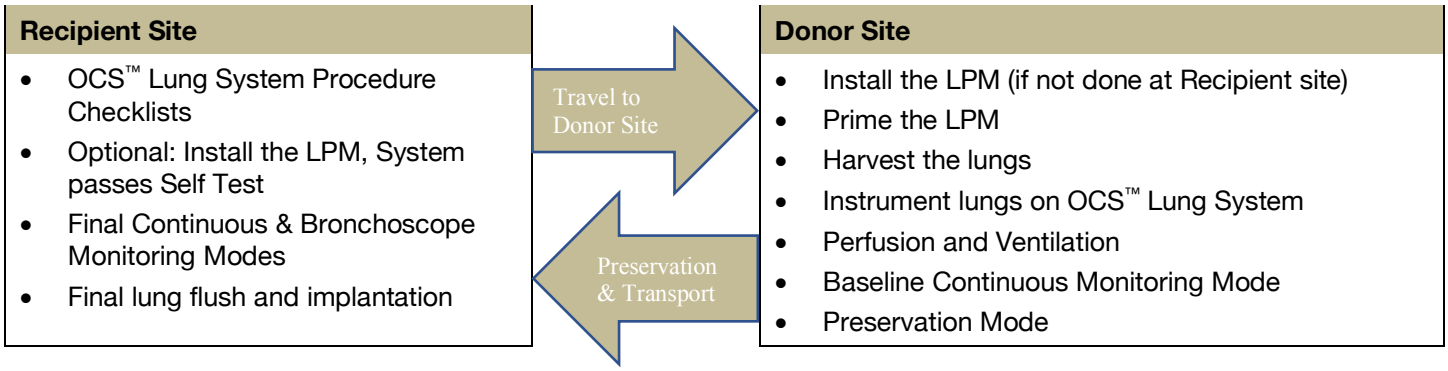
The system consists of the following major components:

1. **Lung Console:** The Lung Console is a non-sterile, reusable, portable enclosure that houses an electronic display and non-sterile mechanical and electrical elements required to warm, pump, ventilate, and manage gas content of the perfusate.
2. **Lung Perfusion Set**: The Lung Perfusion Set (LPS) includes a sterile, single-use perfusion module (Lung Perfusion Module or LPM) and various accessories. The perfusion module consists of an organ chamber and a circulatory system to perfuse and ventilate the lung. The supplied accessories connect the lung to the organ chamber and facilitate the management of fluids within the perfusion module.
3. **OCS™ Lung Solution:** This is the high oncotic solution used for ex-vivo flush and perfusion of donor lungs when combined with pRBCs.

2.2. Overview of OCS™ Lung System Preservation Process

Figure 1 illustrates the various activities performed at the donor site during preservation and at the recipient hospital.

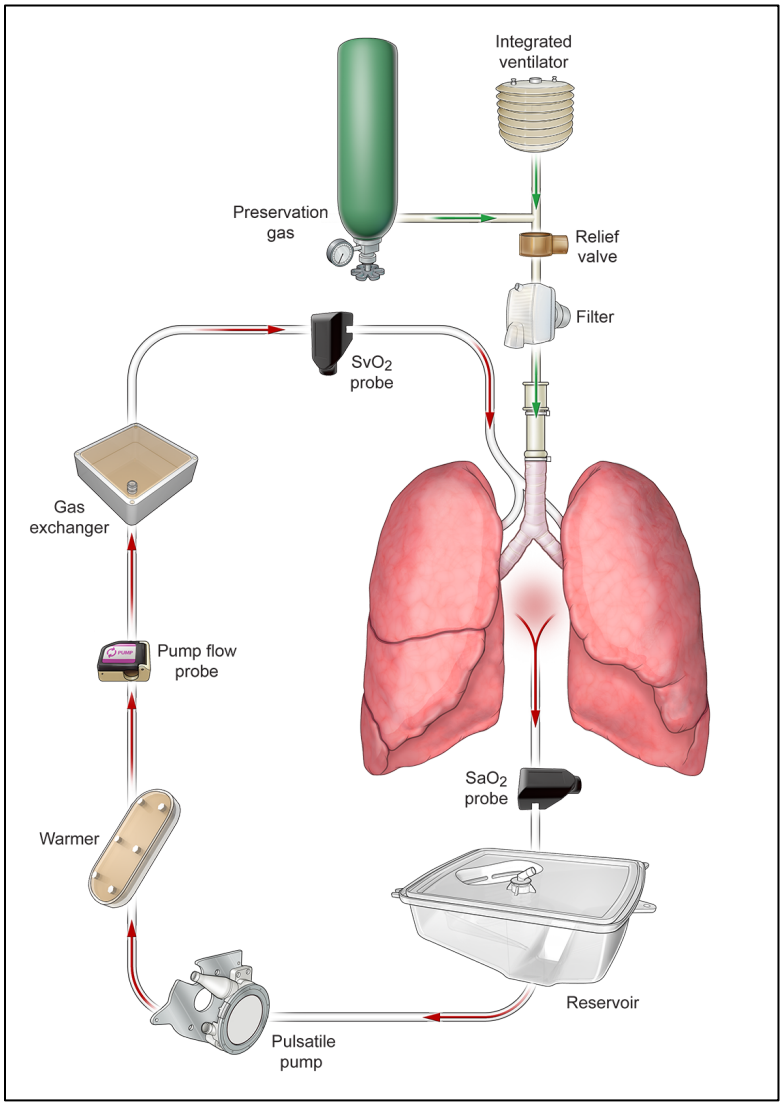
Figure 1: OCS™ Lung System Preservation Process Overview



2.3. Overview of Perfusion and Ventilation

The OCS™ Lung System preserves ventilated lungs using warm oxygenated cellular perfusate. The system supports several Ventilator modes to ensure both preservation and assessment of lung function during retrieval. Ventilator modes of the lung system include the following: Pause Preservation; Preservation; Continuous Monitoring; Bronchoscope Monitoring; and OFF Mode. Figure 2 shows an overview of the circulation and ventilation.

Figure 2: Circulation and Ventilation Overview



2.4. Clinical Study of the OCS™ Lung System

The safety and effectiveness of the OCS™ Lung System was studied in two international pivotal clinical studies. The INSPIRE trial was a randomized controlled trial of the OCS™ Lung System for the preservation of standard criteria donor lungs compared to standard of care cold storage. The EXPAND trial was a single arm study of the OCS™ Lung System to preserve donor lungs initially deemed unacceptable for procurement and transplantation based on the limitations of cold static preservation. These type of donors are also being studied in a second study, the EXPAND II trial. Summaries of the studies, and the results are provided in Appendix A (INSPIRE) and Appendix B (EXPAND and EXPAND II) of this document. Data are being collected in a post-market registry study of the OCS™ Lung System for standard criteria donor lungs and for donor lungs initially deemed unacceptable for procurement and transplantation based on the limitations of cold static preservation.

NOTE— It is essential that you carefully review the study results in Appendix A (INSPIRE) and Appendix B (EXPAND). These appendices provide clinical results that are important to know when considering the risks and benefits of preserving donor lungs with the OCS™ Lung System. If you have any questions about these results, please contact TransMedics.

3. CHAPTER 3: ACTIVITIES PERFORMED BEFORE DEPARTURE TO DONOR SITE

Adequate preparation ensures the smoothest possible organ retrieval run with the OCS™ Lung System. This chapter provides information on the checklists and tasks that are performed at the recipient site prior departure to the donor site.

3.1. Procedure Overview Checklist

3.1.1. General Checklist

1. OCS™ Lung Console, removable cover, and 3 fully charged OCS™ Lung System batteries.
2. Lung Preservation Gas cylinder (>30% full) and Lung Monitoring Gas cylinder (>50% full). For less gas, replace, or take a spare cylinder.
3. 2 L of OCS™ Lung Solution, medications, and additives needed for priming. Refer to Section 3.3.
4. OCS™ Lung Solution for donor lung flush with buffering additives.
5. 3 units of leukocyte reduced packed red blood cells (pRBCs) – ABO type-matched/compatible to transplant recipient.
6. OCS™ Lung Perfusion Module (LPM) and Accessory Sets
   a. OCS™ Lung Instrumentation Tool Set
   b. OCS™ Lung Perfusion Initiation Set
   c. OCS™ Lung Perfusion Termination Set.
7. OCS™ Run Bag and contents.

3.1.2. OCS™ Lung Console Checklist

1. Ensure the OCS™ Lung System passes Self Test and is set to Run Mode.
2. With the OCS™ Wireless Monitor correctly docked on the lung system and in Standby mode, press the  button on the Monitor to set the OCS™ Lung System to Run Mode.
3. Ensure Bluetooth is enabled on the Wireless Monitor  .
4. Check the date and time, and adjust as needed.
5. The OCS™ Lung Preservation Gas cylinder is installed properly inside the gas compartment. Open the cylinder to check the status of the Lung Preservation Gas on the Wireless Monitor.
6. Check the status of the 3 fully charged OCS™ Lung System batteries as follows:
   a. Press the test button (located on the front of each battery) to check battery charge.
   b. Battery status will be displayed on the Wireless Monitor once the Lung System is set to Run Mode.

c. For detailed instructions on checking the battery status and charging the batteries, see the *TransMedics Technical User Guide: OCS™ Lung System*.

NOTE— Each fully charged battery provides a minimum of 80 minutes of power, totaling four hours of power with three fully charged batteries under normal operating conditions. Additional batteries can be ordered from TransMedics® as needed.

7. The OCS™ Lung System has a TransMedics approved Data Card.

8. After OCS™ Lung Console check, switch back to Standby Mode by pressing  on the Wireless Monitor until the LPM is installed.

3.2. Checklists for OCS™ Lung Gas Cylinders

3.2.1. Lung Preservation Gas Cylinder

The Lung Preservation Gas is composed of 12% Oxygen, 5.5 % CO_2, and 82.5 % Nitrogen balance. The Lung Preservation Gas is used by the system during Priming in the Pause Preservation Mode to oxygenate the perfusate, as well as throughout transportation to ventilate the lungs in the Preservation Mode. The Lung Preservation Gas cylinder needs to be installed inside the gas compartment of the OCS™ Lung Console before using the system.

A full Lung Preservation Gas cylinder contains 3000 psi.

Lung Preservation Gas Cylinder checklist:

1. Ensure the Lung Preservation Gas cylinder is ≥ 30% full (at least 900 psi); otherwise, replace or take a spare full cylinder and store in the Run Bag.
   - Open the Lung Preservation Gas cylinder valve with the gas cylinder wrench, located in the front of the gas compartment, and check the level on the gas gauge. To open the valve, turn it in counter-clockwise direction.
   - The Lung Preservation Gas level will be reflected, as well on the gas status icon, on the Wireless Monitor screen after opening the cylinder's valve and switching the Lung System to Run Mode.
2. Close the cylinder's valve (turn in clockwise direction) after check and until priming the LPM at the donor's site.

NOTE— For more information, see "Estimating the Remaining Preservation Gas Supply" in the *TransMedics Technical User Guide: OCS™ Lung System*. Replace the cylinder if necessary. Close the gas valve after check and after use.

3.2.2. Lung Monitoring Gas Cylinder

The Lung Monitoring Gas is composed of 6% CO_2 and 94% Nitrogen balance. Lung Monitoring Gas is needed to assess oxygenation capacity of lungs preserved on the OCS™ Lung System in Continuous Monitoring Mode. To use the Lung Monitoring Gas, the cylinder needs to be connected to the lung system using the Monitoring Gas Regulator Kit.

A full Lung Monitoring Gas Cylinder contains 3000 psi.

Lung Monitoring Gas Cylinder checklist:

1. Ensure the Lung Monitoring cylinder is ≥ 50% full (At least 1500 psi) before departure to donor site. Otherwise, replace or take a spare.
2. Regulator and green line (Monitoring Regulator Kit) are attached to the cylinder before usage.
3. Connect the Lung Monitoring cylinder to the Monitoring port on the OCS™ Lung Console and open its valve by turning it in counterclockwise position. Check the gauge reading on the Regulator Kit.
4. Close the Monitoring Gas cylinder's valve (turn in clockwise direction) and store the cylinder in the retrieval Run Bag.

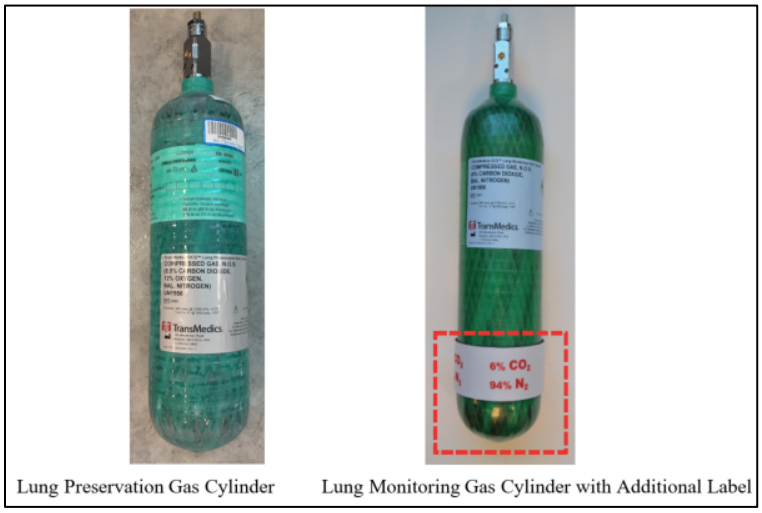
WARNINGS—

Please note the different colors of the labels on the Lung Monitoring and the Lung Preservation Gas cylinders, to ensure installing the correct cylinder inside the OCS™ Lung Console.

To avoid the inadvertent insertion of the Lung Monitoring Gas cylinder into the OCS™ Lung Console, an additional label is placed around the Lung Monitoring Gas Cylinder to prevent it from fitting into the Lung Console's Preservation Gas compartment.

NO attempts should be taken to remove this additional label at any time. See Figure 3.

Figure 3: Lung Monitoring Cylinder with Additional Differentiating Labels from Lung Preservation Cylinder



Lung Preservation Gas Cylinder Lung Monitoring Gas Cylinder with Additional Label

3.3. OCS™ Lung Solution & Additives Checklists

3.3.1. Donor Lung Flush

- Use at least 3-5 L of cold buffered* OCS™ Lung Solution for antegrade flush supplemented with 50 mg of nitroglycerin in the first flush bag.
- Use at least 1-2 L of cold buffered* OCS™ Lung Solution for retrograde flush.
- Deliver flush by gravity.

**Use 10 mEq of $NaHCO_3$ or 1 mmol of THAM/L (tromethamine) to buffer the OCS™ Lung Solution immediately before usage.*

3.3.2. OCS™ Lung Perfusate & Additives

- 1.5-2 L of buffered* OCS™ Lung Solution is the only recommended solution for priming the LPM in preparation for Lung perfusion on the OCS™ Lung System

** Use 10 mEq of $NaHCO_3$ or 1 mmol of THAM/L to buffer the OCS™ Lung Solution immediately before usage.*

- 3 units of leukocyte reduced, CMV negative, ABO-typed/compatible pRBCs to the transplant recipient ABO type

Table 1: OCS™ Lung Solution Composition

Component	Concentration (g/L)
Dextran 40	50
Glucose Monohydrate	2
Magnesium Sulfate Heptahydrate	.201
Potassium Chloride	0.4
Sodium Chloride	8
Dibasic Sodium Phosphate Dihydrate	0.058
Monopotassium Phosphate	0.063
Water for Injection To 1000 mL	
Hydrochloric Acid pH adjustment	

CAUTION—The OCS™ Lung Solution is ONLY intended for use with the OCS™ Lung System. The OCS™ Lung Solution is NOT intended for intravenous injection.

Table 2: Perfusate Additives (added once at time of Priming)

Medication	Dose
Multivitamins	1 unit
Methylprednisolone	500 mg
Insulin	20 IU
Milrinone (Primacor®)	4 mg
$NaHCO_3$	40 mEq

Table 3: Perfusate Prophylactic Medications (added once at time of Priming)

Medication	Dose
Cefazolin (or equivalent gram positive antibiotics in prophylactic dose)	1 g
Ciprofloxacin (or equivalent gram negative antibiotics in prophylactic dose)	200 mg
Voriconazole (or equivalent antimycotic in prophylactic dose) e.g., Caspofungin	200 mg (or 70 mg of Caspofungin)

3.3.3. Perfusate Corrective Medications Checklist– (As needed & after every blood sample check)

1. $NaHCO_3$ for low bicarbonate (< 22 mmol/L)
2. Dextrose for low glucose (< 120 mg/dL)
3. Nitroglycerin for high pulmonary artery pressure (PAP) (Mean PAP >20 mmHg).

3.4. Leukocyte Reduced Packed Red Blood Cells (pRBCs) Checklist

1. 3 units are required to use with the OCS™ Lung System
2. ABO compatible (to transplant recipient)
3. Tested Cytomegalo Virus (CMV) Negative
4. Leukocyte reduced
5. Stored in a cooler during transport.

3.5. OCS™ Lung Perfusion Set Checklists

1. Check the expiration date and check for any obvious shipping damage on the Lung Perfusion Set (LPS).
2. If the date has expired or if any damage is found to a packaged LPS, do not use this LPS.
3. Installing the Lung Perfusion Module (LPM) prior departure to donor site is optional. For details of installing the LPM, refer to Section 4.
4. If the LPM is installed before departure to donor site, Accessory Sets shipped with the corresponding LPS should be stored in the OCS™ Run Bag to be used at the donor site.
5. Accessory Set packages should not be opened until just before use at the donor site.
6. Once the LPM is installed, switch the OCS™ Lung System to Run Mode and verify that the lung system passes the Self Test.
   a. If displayed errors indicate problems, refer to the Troubleshooting chapter in the *TransMedics Technical User Guide: OCS™ Lung System*.
7. If no errors display, select “New Session File” and confirm the following:
   a. Ventilator Mode is defaulted to Pause Preservation

b. NO **(+++)** OR **(- - -)** values are displayed on the Monitor for Pulmonary Artery Pressure (PAP) or the airway pressure readings.

WARNING— Abnormal values of either **(+++) or (- - -)** displayed on the Wireless Monitor as Mean PAP or if airway pressure measurements indicate readings above or below (respectively) preset ranges as read by the sensors in the installed LPM. If this abnormality is detected, DO NOT use the installed Module, and replace it with a new one to ensure proper management of perfusion and ventilation parameters during lung preservation.

8. Switch back to Standby Mode until the module is ready for Priming at the donor site.

WARNING— Without a Sterile OCS™ Lung Perfusion Set (LPM and Accessory Sets), the OCS® Lung System cannot be used.

3.6. Run Bag Checklist and Contents

1. 2 L of OCS™ Lung Solution with buffering agents (THAM/$NaHCO_3$) for LPM priming at donor site
2. Perfusate additives and medications (prophylactic and corrective) listed in Section 3.3.
3. OCS™ Lung Monitoring Gas cylinder (≥ 50% full) & Monitoring Gas Regulator Kit
4. Sterile syringes, needles, gloves, alcohol wipes and petroleum jelly/Vaseline®
5. OCS™ Lung Accessory Sets (if the LPM is installed before departure to donor site):
   a. OCS™ Lung Instrumentation Tool Set
   b. OCS™ Lung Perfusion Initiation Set
   c. OCS™ Lung Perfusion Termination Set
6. A sterile OCS™ Lung Manual Inflation Set/Ambu Bag
7. Spare gas wrench and tie-downs to secure the OCS™ Lung Console during transport

NOTE— When transporting the system prior to and during a preservation session, if necessary, bring along extra charged batteries, extra gas cylinder(s), and country-specific power cords as required.

3.7. Transport Considerations

When selecting a transport vehicle, consider the following:

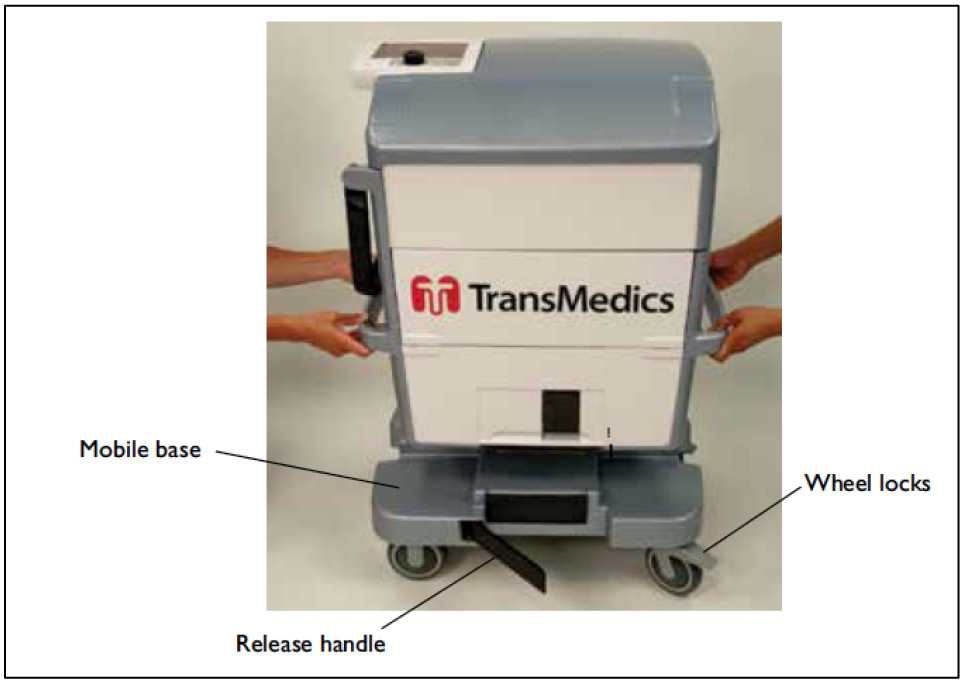
1. Identify a level area large enough to accommodate the OCS™ Lung Console (with its mobile base removed), approximately 29” x 19” x 29” (72 cm x 46 cm x 72 cm).
2. Position the OCS™ Lung System for access to its gas and batteries, if possible.
3. Secure the OCS™ Lung Console to the vehicle to immobilize it during transport, using tie-downs.
4. Install the OCS™ Lung Console cover to avoid heat loss (particularly returning to the recipient site).
5. Ensure the ambient temperature of the OCS™ in the vehicle is consistent with normal passenger comfort, e.g. 20°C.

3.7.1. Preparing the OCS™ Lung System for Travel to Donor Site

1. Press the Run/Standby button on the docked Monitor to set the lung system back to Standby Mode.
2. Unplug the OCS™ Lung Console from the AC receptacle and wind the power cord around the power cord wrap.
3. With the Mobile Base installed, press the push handle release buttons, raise the handle and push the Lung Console to the loading area.
4. Lock the Mobile Base wheels by pressing each wheel break down.
5. Disconnect the Mobile Base from the OCS™ Lung Console by pulling the release handle outwards to release the Mobile base grips.
6. With two people using the right and left lift handles, lift the OCS™ Lung System into the transport vehicle.
7. Position the OCS™ Lung Console level in the vehicle and secure it using tie-downs.
8. Remember to take the Mobile Base with you for use at the donor site.

For additional information on safely transporting the OCS™ Lung System, including temperature and humidity limits, see the *TransMedics Technical User Guide: OCS™ Lung System.*

Figure 4: Lifting the OCS™ Lung Console off the Mobile Base



4. CHAPTER 4: ACTIVITIES PERFORMED AT DONOR SITE

This chapter provides instructions for the tasks that are performed at the donor site to retrieve, preserve, monitor and assess the lungs' function throughout transport.

NOTE—The LPM may be installed in the OCS™ Lung System before going to the donor site. At the donor site, allow at least 30 minutes to prepare medications and prime the LPM with the perfusate before the lungs are instrumented on the lung system.

CAUTION—Keep the OCS™ Lung System connected to a live AC power at all times when available to ensure continuously charging its batteries.

4.1. Unpacking, Installation, and OCS™ Lung System Setup

This section provides instructions for unpacking the Lung Perfusion Set, installing the LPM, attaching the probes, and running the system Self Test.

4.1.1. Unpacking and Inspecting the Lung Perfusion Set (LPS)

Accessories packaged and shipped with the LPS should be unpacked immediately before use.

For illustrations and descriptions of the components included in the LPS, see the *TransMedics Technical User Guide: OCS™ Lung System*.

4.1.2. Unpacking and Inspecting the Sterile Components

1. Inspect the packaging of each sterilized component for tears or breaks in the seal that might compromise sterility. If any tears or damage are found, do not use the damaged item.

   CAUTION—Check the expiration date on each package. If the date has expired, do not use the item.

2. Unpack each sterilized component immediately before use.
3. Open the Lung Instrumentation Tool Set components in a sterile field, using a sterile technique.

4.1.3. Opening the LPM Packaging

1. Check the expiration date and inspect for any obvious shipping damage. If the date has expired or if any damage is found, do not use the LPM.
2. Partially lift the bagged LPM out of the box, supporting the bottom of the module on the foam insert.
3. Open the bag by locating the blue notch at the bag's corner and tearing straight across until you reach the other notched corner.
4. Carefully remove the LPM from the bag and discard the bag.

5. Supporting the bottom of the LPM on the foam insert inside the box, grasp the corner of the foam wrapped around the LPM and tear off the foam.
6. Remove the foam block from the rear of the LPM.
7. After removing the LPM from its box, regardless of whether the module is still in its sterile bag or not, lay the LPM on its right side and on a flat surface. Laying the LPM on its back or front may damage it.

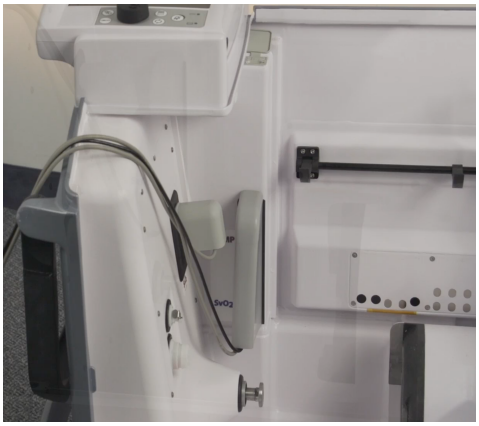
WARNING— Inspect the bellows plate prior installing the LPM. If it is disengaged from all or some of the holding clips, refer to the Troubleshooting chapter of the *TransMedics Technical User Guide: OCS™ Lung System* before installing the module in the OCS™ Lung Console.

4.2. Installing the LPM on the OCS™ Lung System

For photos of the back and front of the LPM and its location inside the OCS™ Lung System, see the *TransMedics Technical User Guide: OCS™ Lung System.*

1. Stabilize the OCS™ Lung Console by pressing the wheel brakes on the mobile base down.
2. Remove the OCS™ Lung Console cover and lower the front panel of the system.
3. Keep the system in STANDBY mode to ensure full retraction of the Ventilator's Actuator (arm) and thus facilitates installing and engaging the module to the OCS™ Lung Console.
4. Pull the saturation and flow probes cables to the left to avoid getting them in the user's way while engaging the module to the Ventilator's arm. See Figure 5.

Figure 5: OCS™ Lung System Probes Pulled to the Side of the LPM



CAUTION— Do not uninstall the LPM while the Pump or Ventilator is ON as doing so may cause the Pump or Ventilator to jam. If this occurs, reset the system as described in the *TransMedics Technical User Guide: OCS™ Lung System*.

5. Hold the LPM from the front and back holding grips and tilt the module for 30 degrees to align Pump head and Ventilator Actuator in the OCS™ Lung Console to engage with the Pump dome interface and the Bellows plate hook of the module respectively. See Figure 6.

Figure 6: Pump Head, Ventilator Actuator of the OCS™ Lung Console (A) and the Bellows Plate of the LPM (B)

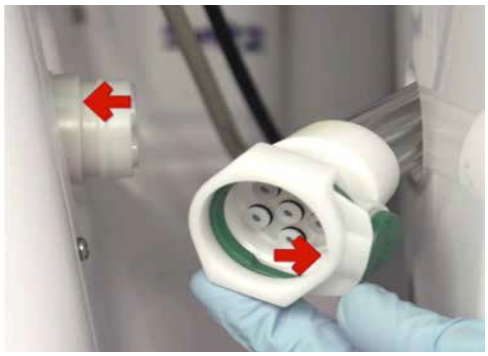
6. Push the LPM backwards after ensuring proper alignment of the OCS™ Lung System holding clips with the LPM's recesses to keep it in place. See Figure 7. Press the release metal handle of the OCS™ Lung Console DOWN to ensure the LPM is well seated and held by the holding clips.

NOTE— If a resistance is faced or misalignment is detected need during installation of the LPM with the OCS™ Lung Console, DO NOT proceed to avoid damaging the LPM. Disconnect the LPM by pushing the release handle up and start all over again with Steps 5 and 6.

Figure 7: Holding Clips Engaging with the LPM (A) and Ventilator Actuator Engaged with the Bellows Plate of the LPM (B)

7. Confirm proper engagement of the Ventilator Actuator with the hook on the Bellows plate as seen in Figure 7B above.
8. Hold the Ventilator lines connector of the LPM and align its inner recessed notch with the raised tab on the Ventilator lines connection port on the OCS™ Lung Console. Once aligned, avoid pressing the green release button on the connector while pushing it to the port until a click is heard, which indicates a proper and secured connection. See Figure 8.

Figure 8: Ventilator Lines Connection Port

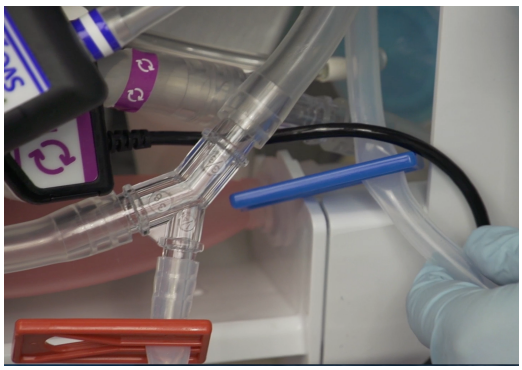


WARNING—When connecting the Ventilator lines, ensure that the recessed notch on the LPM Ventilator lines connector aligns with the corresponding raised tab on the OCS™ Lung Console Ventilator lines connection port in the Lung Console (Figure 8). Malconnected Ventilator lines to the connection port should be avoided to ensure proper operation of all different Ventilator Modes (Figure 9).

Figure 9: Proper Connection vs. Wrong Correction of Ventilator Lines

9. Expose the Oxygenator recirculation line of the module and release its clamps to be opened. Push the blue and the red clamps all the way up on the recirculation line and store in clamped on position. See Figure 10.

Figure 10: Clamp onto the Oxygenator Recirculation Line



10. Close the pulmonary artery flush port as seen in Figure 11.

Figure 11: Closing the PA Flush Port

4.3. Attaching the Probes

This section provides detailed instructions on attaching the Pump flow probe, the SaO_2/Hematocrit probe, and the SvO_2/Hematocrit sensor/probe to the tubing on the LPM.

4.3.1. Attaching the Pump Flow Probe

The Pump flow probe is installed between the purple bands (between the perfusate warmer and the gas exchanger).

1. Apply a small amount of petroleum jelly to the inside of the probe.
2. Locate the color-coded bands on the LPM that match the color of the probe label.

CAUTION— Apply ONLY petroleum jelly/Vaseline® to the inside of the flow probe. Using any other coupling gel, such as silicone grease or ultrasound gel, may damage the Pump flow probe.

3. Align the probe between the bands so that the double lines on the probe label are next to the band with double lines on the tubing (Figure 12).
4. Insert the tubing into the sensing cavity and close the lid.
5. Make sure the lid is completely closed and the latch is secure. The fit should be tight, with the full tubing cross-section contacting all inner surfaces of the sensing window. The tubing will be slightly compressed into a rectangular shape.
6. Once fluid is flowing through the tubing during priming, check the Wireless Monitor display to make sure that the desired flow parameters are being displayed.

Figure 12: Pump Flow Position

4.3.2. Attaching the SaO_2/Hematocrit and SvO_2/Hematocrit Probes

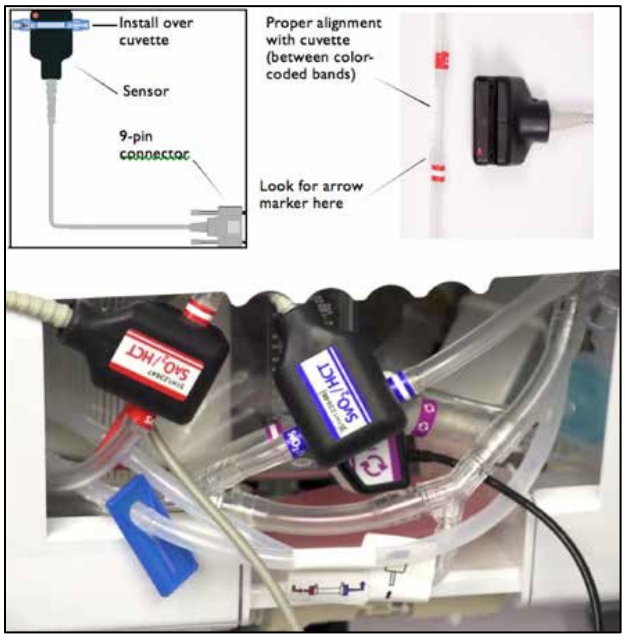
The SaO_2/Hematocrit and SvO_2/Hematocrit optical probes are designed to be clipped onto cuvettes that are incorporated into the LPM's tubing. The cuvette is marked with colored bands at each end. The color of the bands should match the color of the label on the corresponding probe. Align the probe between the bands so that the double lines on the probe label are next to the band with double lines on the tubing.

The probes are attached to the following locations:

1. Clip the SvO_2/Hematocrit probe to the cuvette between the blue bands on the line between the gas exchanger and the pulmonary artery (PA) inflow.
2. Clip the SaO_2/Hematocrit probe to the cuvette between the red bands between the left atrial (LA) drain and the reservoir.

Figure 13 shows the SvO_2/Hematocrit and SaO_2/Hematocrit probe components and the probes attached to the tubing.

Figure 13: SaO2/HCT and SvO2/HCT Probes



CAUTION—Ensure the saturation probes are securely connected to the cuvette.

4.4. Running the OCS™ Lung System Self Test

After the LPM is fully installed, run the system Self Test again to make sure that the system is operating properly.

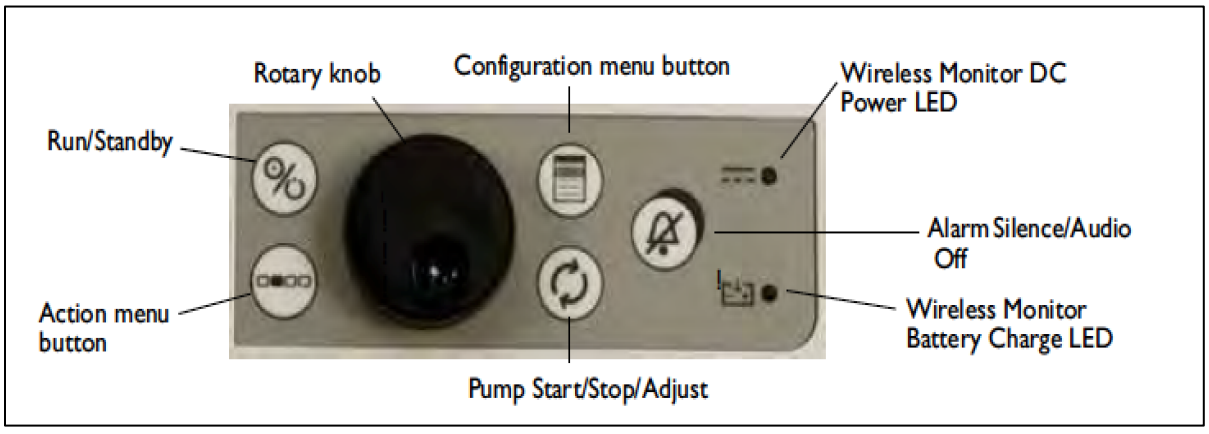
CAUTION—To ensure proper system operation, install the LPM in the OCS™ Lung Console before running the Self Test.

To run the system Self Test:

1. Make sure the Wireless Monitor is docked to the OCS™ Lung Console and the lung system is in Standby Mode. Figure 14 shows the controls of the Wireless Monitor.
2. Make sure the ON/OFF switch on the OCS™ Lung Console is in the 'ON'  position.
3. Press the  button on the Wireless Monitor. The system performs a Self Test and displays system transitional status messages. If errors are encountered, error messages are displayed.
4. If displayed errors indicate problems, refer to the Troubleshooting chapter in the *TransMedics Technical User Guide: OCS™ Lung System*.
5. If no errors display, select "New Session File" to proceed.
6. Start a "New Session File" and confirm the following:
   - Ventilator Mode is defaulted to Pause Preservation. 
   - NO **(+++)** OR **(- - -)** are displayed on the Wireless Monitor for Mean PAP or airway pressure readings.

CAUTION—If the system detects an issue during the Self Test, a message is displayed with information about the issue until it is resolved. To resolve the issue, follow the steps in the troubleshooting section of the *TransMedics Technical User Guide: OCS™ Lung System*.

Figure 14: Wireless Monitor Controls



NOTES—

The Run/Standby button on the Wireless Monitor will NOT FUNCTION unless the Wireless Monitor is DOCKED on the OCS™ Lung System.

At the beginning of the session, the system may display messages and sound alarms related to sensor probes. These messages and alarms can be disregarded. For details of system initialization and messages, see the *TransMedics Technical User Guide: OCS™ Lung System*.

4.5. Preparing the OCS™ Lung System for Lung Instrumentation

This section provides instructions for preparing the lung system for lung instrumentation.

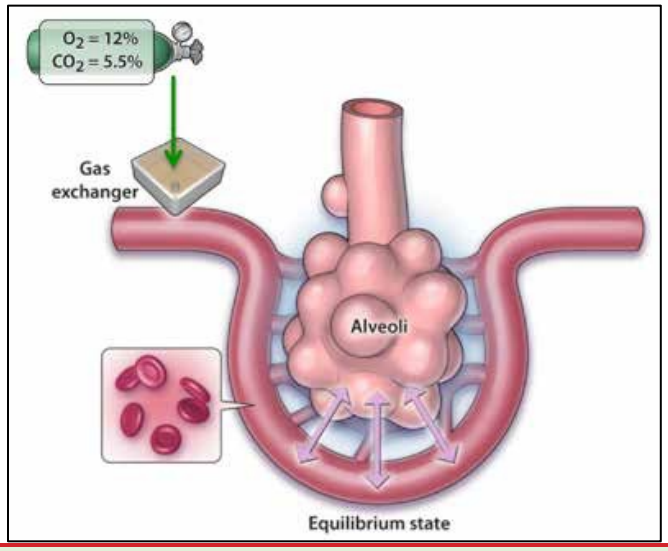
4.5.1. Priming the OCS™ LPM

Priming overview settings are listed in Table 4. After the LPM and the probes are installed and the Self Test is complete, the lung system will default to Pause Preservation Ventilation Mode, and the module will be ready to be primed.

4.5.2. Pause Preservation Mode

In Pause Preservation Mode, the bellows remain stationary and the OCS™ Lung System achieves a static level of lung inflation. Pause Preservation enables oxygenation of the perfusate prior to lung instrumentation using the Lung Preservation Gas. As the lung is perfused, the dissolved gas in the perfusate is exchanged across the alveoli (Figure 15) with the gas in the static breath. The Wireless Monitor icon for Pause Preservation Mode is shown here at the right:

Figure 15: Pause Preservation Mode



NOTE— Use aseptic technique when performing the following priming procedure.

Table 4: Priming Overview

Settings	OCS™ Lung System Recommendations	
Priming	• 1.5-2 L of buffered* OCS™ Lung Solution • +3 units of pRBCs • Medications (additives & prophylactic medications) **Use 10 mEq of $NaHCO_3$ or 1 mmol of THAM/L (tromethamine) to buffer the OCS™ Lung Solution immediately before usage.*	
Temperature	• Set to 32°C in Preservation settings	
Pump Flow	• Increase to 3 L/min to de-air & mix perfusate • After de-airing, lower to 1 L/min until temperature reaches 32°C • Lower Pump flow to 0.5 L/min before lungs are instrumented	
Preservation Gas Flow	Open the Lung Preservation Gas cylinder & set flow to 300 ml/min	
Ventilation	Pause Preservation	
Recommended Ventilation Settings	**Preservation Mode**	**Monitoring Mode**
Tidal Volume (TV)	6 ml/kg (ideal body weight) #	
Positive End Expiratory Pressure (PEEP)	7 cmH_2O	5 cmH_2O
Respiratory Rate (RR)	12 BPM	
# Devine's Ideal Body Weight Formula (see Appendix C).		

#NOTE—For a suggested ideal body weight formula, see Appendix C: Body Weight Formula (Devine's Formula for donor's height above 150 cm (5 feet)).

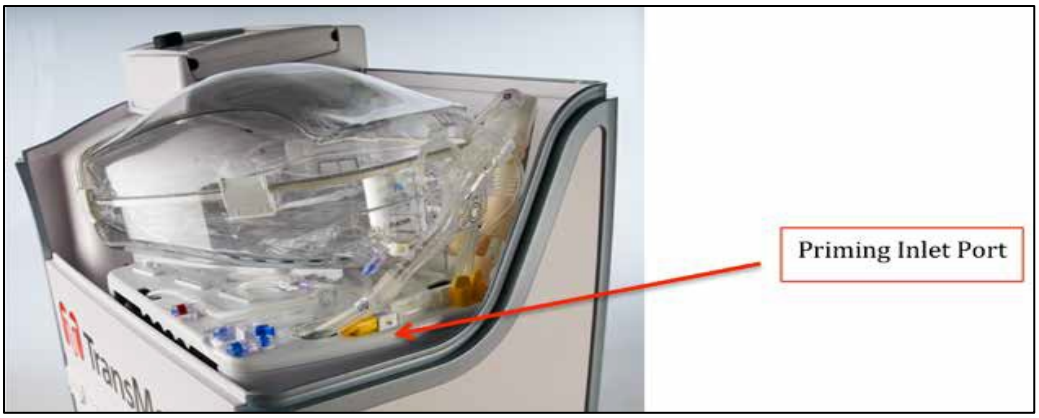
4.5.3. Priming the LPM

For priming the LPM, the Lung Perfusion Initiation Set needs to be used to deliver the lung perfusate (OCS™ Lung Solution and RBCs) to the LPM as follows:

1. Open one of the packaged Dual Vented Prime Lines in the Lung Perfusion Initiation Set.
2. Close the clamps on the Dual Vented Prime Line.
3. Insert the piercing spike of the Dual Vented prime line into the buffered OCS™ Lung Solution bags, using a twisting motion until the set is firmly seated.
4. Remove the yellow protective cap from the LPM's Priming Inlet Port (Figure 16).
5. Uncover and connect the outlet from the Dual Vented Prime line to the Priming Inlet Port.
6. When ready to prime the LPM, open the Dual Vented Prime Line's clamp and add 1.5-2 L of buffered OCS™ Lung Solution to the reservoir.
7. Add the 3 units of ABO-compatible (to the recipient) leukocyte-reduced pRBCs after adding the OCS™ Lung Solution using a set of the Dual Vented Prime Lines.
8. Clamp and cover the Priming Inlet Port of the LPM with one of the provided spare covers on the modules. Reposition the covered Priming Inlet Port back in its recess.

9. Turn on the Pump to start circulating, mixing, and warming the perfusate.

Figure 16: LPM Priming Inlet Port



4.5.4. Start of Perfusate Circulation

1. Make sure the gas exchanger vent on the LPM remains open.
2. Ensure that the Termination Flush Stopcock is closed.
3. Open the Preservation Gas cylinder by turning its valve 180 degrees in a counter-clockwise direction.
4. Always keep the OCS™ Lung System connected to AC power while at the donor site and during system priming.

CAUTION— Ensure that the Flush stopcock is closed before turning the Pump on to avoid pumping the perfusate out of the module if the cap on the Termination Flush Port is removed.

5. Start circulation with the following settings:
   a. Press the Pump adjust button  on the Wireless Monitor and adjust Pump flow to 3.0 L/min for few minutes to de-air the module, mix and warm the perfusate.
   b. Press the Configuration menu button  , highlight and select the Preservation tab using the rotary knob. Adjust the settings as follows for the Preservation settings:
      - Ensure that the temperature is set to 32°C.
      - Ensure that the gas flow rate is set to 300 mL/min (Lung Preservation Gas flow rate).
      - Set the ventilation setting, as listed in Table 4, using the rotary knob to highlight, select, and adjust all settings.
      - Ensure that you confirm your settings by highlighting and pressing “accept” displayed at the bottom of each menu using the rotary knob.
   c. Press the Configuration menu button  , highlight and select the Monitoring tab using the rotary knob. Adjust the settings as follows for the Monitoring settings:

- Ensure that the temperature is set to 37°C (factory default setting).
- Set ventilation, as listed in Table 4, using the rotary knob to highlight, select, and adjust all settings.
- Confirm settings by highlighting and pressing “accept” displayed at the bottom of each menu using the rotary knob.

d. Confirm that the OCS™ Lung System defaults to Pause Preservation Mode on the Wireless Monitor. 

e. If Pause Preservation Mode was not configured, please refer to the *TransMedics Technical User Guide: OCS™ Lung System*.

f. Ensure that the PA stopcock (blue) stays open as seen in Figure 17 to de-air the PA flow. If necessary, use a syringe to initiate flow through the purge line.

Figure 17: Pulmonary Artery Stopcock in Open Position

4.5.5. Injecting Additives into the Perfusate and Preparing for Use

Table 5 below describes the additives and prophylactic medications to be injected into the perfusate before use. Additives, syringes, and medium gauge needles must be available at the donor site.

Table 5: Additives for Perfusate Injections

Recommended Additives	Recommended Dosage
Methylprednisolone	500 mg
Multivitamins	1 unit
Insulin	20 IU
Milrinone	4 mg
Sodium Bicarbonate ($NaHCO_3$)	40 mEq
Cefazolin (or equivalent gram positive antibiotics)	1 g
Ciprofloxacin (or equivalent gram negative antibiotics)	200 mg

Recommended Additives	Recommended Dosage
Voriconazole or Caspofungin (or equivalent antimycotic)	200 mg 70 mg (for Caspofungin)

To inject additives into the perfusate:

1. Inject the additives listed in Table 5 through the reservoir injection port (Figure 18) using an aseptic technique.

Figure 18: Additive Injections

2. Let the fluids circulate for few minutes at a flow rate of 3 L/min initially.
3. During priming:
   - Check for air bubbles in the perfusate. If present, tap the lines as vigorously as necessary to dislodge the trapped air for removal by the system defoamer.
   - Once de-airing is completed, lower the Pump flow to 1 L/min until the preset temperature is reached (32°C).

CAUTION— Air tends to collect in the LA line leaving the Lung Organ Chamber and the Compliance Chamber during system priming. More attention to these areas is needed while deairing. If air lock occurs manually apply some pressure to the chamber (squeeze) to push any trapped air into the reservoir while increasing Pump flow initially.

   - Make sure there are no leaks in the LPM's tubing or connections.
   - Check the Wireless Monitor to make sure it is displaying all system parameters.
   - Verify that the perfusate temperature begins to increase toward the Temp Set Point.
4. With the hematocrit (HCT) of the perfusate above 15%, look for SvO_2 and SaO_2 readings that are rising to stabilize between 90% and 99%.
5. Obtain a priming blood sample from the arterial sample port once preset temperature (32°C) is reached.
6. Lower the Pump flow rate to approximately 500 ml/min until the lungs are instrumented.

4.5.6. Evaluating Hematocrit and Reservoir Volume Level

After components of the perfusate have been added to the reservoir and have been circulating for approximately 2-3 minutes during priming, evaluate the HCT. TransMedics recommends the perfusate's HCT to be between 15-25% for optimal lung evaluation.

WARNING— Maintain a volume of at least 500 mL in the reservoir at all times and at different Pump flow rates (Figure 19). Lower volumes may result in air being introduced into the organ.

Figure 19: Reservoir of the LPM

4.5.7. Obtaining a Priming (Pre-Instrumentation) Blood Sample

Using aseptic technique, take a perfusate sample from the arterial sample port (wipe port with alcohol before perfusate withdrawal). Enter the results into the OCS™ Lung Session File as needed after each sample using the Record Blood Sample function on the Action menu. For details, see *TransMedics Technical User Guide: OCS™ Lung System.*

Timing:

- After system priming and before lungs are instrumented on the OCS™ Lung System
- At Temp: 32°C

Purpose:

- Correct HCO_3 to be (22-28 mmol/L) by adding 1.5 mEq of $NaHCO_3$ to every 1-ve Base Excess
- Correct glucose if it is < 120 mg/dL, by adding 1-2 grams of dextrose

4.6. Harvesting Donor Lungs

This section provides detailed instructions on harvesting, cannulating, and connecting the lungs to the OCS™ Lung System.

NOTE— Use standard procedures to prepare the donor for organ explantation.

4.6.1. Administering Heparin

Per standard retrieval procedure, the donor receives heparin (around 300 IU/Kg), and adequate time for heparinization is allowed before explanting the lung.

4.6.2. Donor Lung Flush, Clamping Trachea, and Stopping Ventilation

1. Donor Lung Flush
    - Use at least 3-5 L of cold buffered* OCS™ Lung Solution + 50 mg of nitroglycerin for antegrade flush.

- Use at least 1-2 L of cold buffered* OCS™ Lung Solution for retrograde flush.
- Deliver flush by gravity.

**Use 10 mEq of $NaHCO_3$ or 1 mmol of THAM/L (tromethamine) to buffer the OCS™ Lung Solution immediately before usage.*

2. Clamp the trachea while pulling the endotracheal tube out to stop ventilation. Explant the lung according to standard protocol.
3. Once the lungs are removed, they must be prepared for instrumentation on the lung system.

4.6.3. Preparing the Lung for the OCS™ Lung System (Cannulation & Instrumentation)

A sterile operator performs back table lung preparation while a non-sterile operator primes and prepares the lung system for instrumenting the lungs.

4.6.4. Securing TransMedics® Cannulae to the Donor Lung

These procedures require supplies from the Lung Instrumentation Tool Set. You will need to supply and use the following:

- Silk tie
- Surgical clamp

Table 6 lists and describes the components in the Lung Instrumentation Tool Set.

Table 6: Lung Instrumentation Tool Set

Item	Description and Size
Cable Tie Tool and Cable Ties	Use the cable tie tool and cable ties for securing the lung trachea to the trachea connector
Tube Cutter	For sizing selected PA Cannula
Tubing Clamps (2)	For clamping the cannula
Trachea Cannulae	0.70 in/17.8 mm 0.80 in/20.3 mm 0.90 in/22.9 mm
PA Cannula	For PA cannulation when connecting the lung to the LPM
Banded Bags (sterile covers)	Place around Lung Organ Chamber prior to transport: 26 in/66.0 cm 40 in/101.6 cm

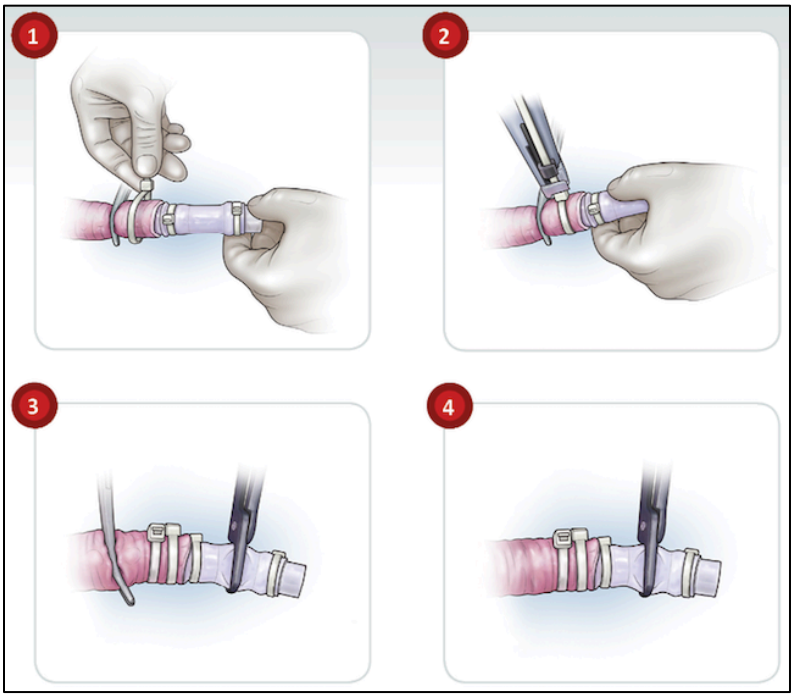
CAUTION— Save the sterile covers (part of the Lung Instrumentation Tool Set) to be used later after lungs are ventilated and wrapped on the OCS™ Lung System. Covers will be applied over the closed Lung Organ Chamber cover.

4.6.5. Connecting and Securing the Trachea Cannula

To connect and secure the trachea cannula:

1. Apply second surgical clamp at least 1.5 in. (3.8 cm) distal to the first surgical clamp (applied to the endotracheal tube during organ removal) and then remove first clamp.
2. Trim the trachea at the level of the lung apex, leaving at least 1” (2.5 cm) of trachea proximal to the clamp.
3. Select the appropriate size trachea cannula, insert the largest cannula that fits into the trachea, and connect it by using the TransMedics cable ties (1 or 2 ties) and cable tie tool (Figure 20).
4. Clamp the flexible portion of the trachea cannula with the TransMedics tubing clamp.
5. Remove the surgical clamp from the trachea.

Figure 20: Tracheal Cannula Procedure

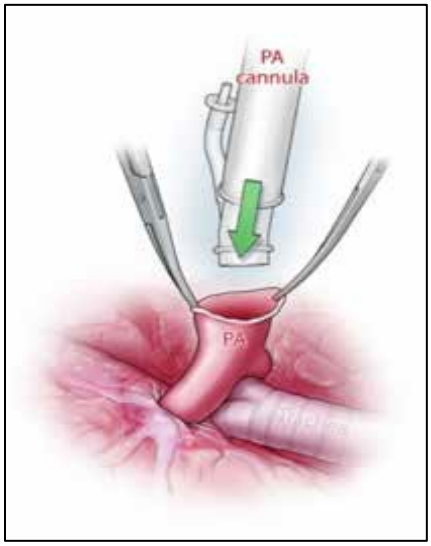


4.6.6. Pulmonary Artery (PA) Cannulation

To cannulate the PA with a single cannula:

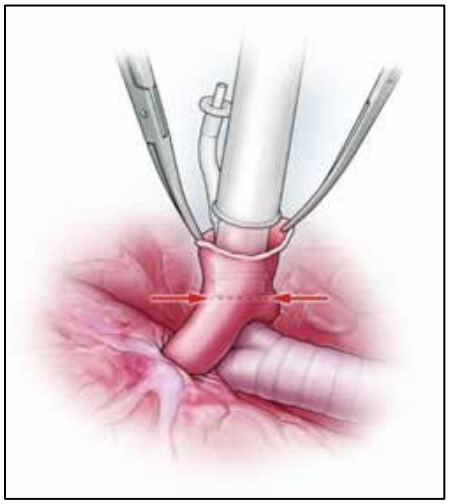
1. A main pulmonary artery stump of at least 1 inch (2.5 cm) is needed to cannulate the PA.
2. Align PA Cannula in the midline with the pressure line pointing up (Figure 21).

Figure 21: PA Cannula Alignment



3. Position cannula tip in the main PA to ensure equal and homogeneous perfusion to both lungs (Figure 22).

Figure 22: PA Cannula Tip Positioning



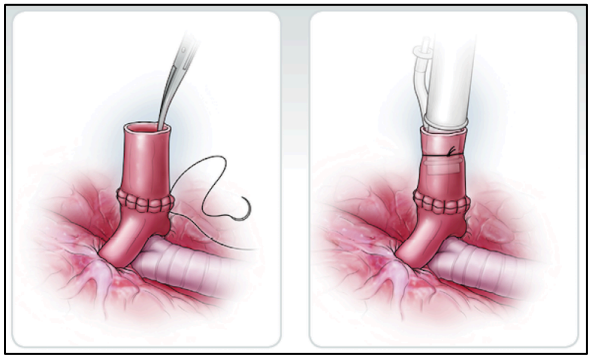
4. Secure the cannula using a silk tie or a purse string suture and a silk tie above the ridge at the tip of the PA Cannula.
5. Pull on the cannula to make sure its tip is not pushed against the PA wall.

4.6.7. PA Reconstruction and Cannulation

The instructions for PA reconstruction and cannulation are as follows:

1. If the lung has a short PA, use a piece of descending aorta to reconstruct the main PA (Figure 23).
2. Secure the PA Cannula into the reconstructed PA conduit as previously described.

Figure 23: Reconstructed PA



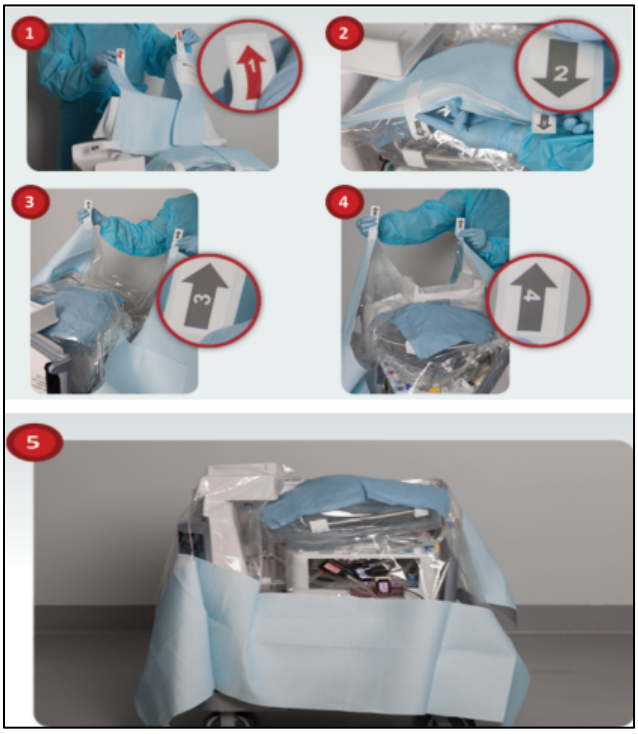
4.7. Draping the Work Area in Preparation for Instrumentation

As the PA and trachea are being cannulated and after taking the priming blood sample from the perfusate, drape the lung system in preparation for instrumenting the lungs by a sterile surgeon.

Steps:

1. A non-sterile operator may remove the Wireless Monitor from its docking cradle.
2. Remove the strap on the sterile drape attached to the Lung Organ Chamber of the LPM (Figure 24).
3. Grasp the drape at the arrow marking on the top of the drape and pull it backward away from the chamber.
4. Continue unfolding following the arrow markings printed on the drape in order and until the whole drape is extended.

Figure 24: Sterile Drape (Unfolding and Draping)



If the Wireless Monitor is to be left in its docking cradle during lung instrumentation:

- Assure that the clear film covers the Wireless Monitor so that the controls and screen can be easily seen and accessed by the user.
- Use the rest of the drape to cover the system and other system surfaces outside the Lung Organ Chamber.

4.8. Instrumenting Lungs on the OCS™ Lung System

4.8.1. Before Instrumentation

1. Dry the Trachea Cannula with a dry sterile gauze before connecting the lungs to the lung system in the sequence shown in Figure 25.
2. Press the Pump adjust button  and decrease the flow to 500 mL/min if not done earlier. This will ensure gradual warming of the cold lungs once connected to the lung system.
3. Confirm that the Ventilator Mode is set to Pause Preservation and that the  icon is displayed on the lower left corner of the Wireless Monitor's screen. If not, press the main configuration button  on the Wireless Monitor and set the Ventilator Mode to Pause Preservation.

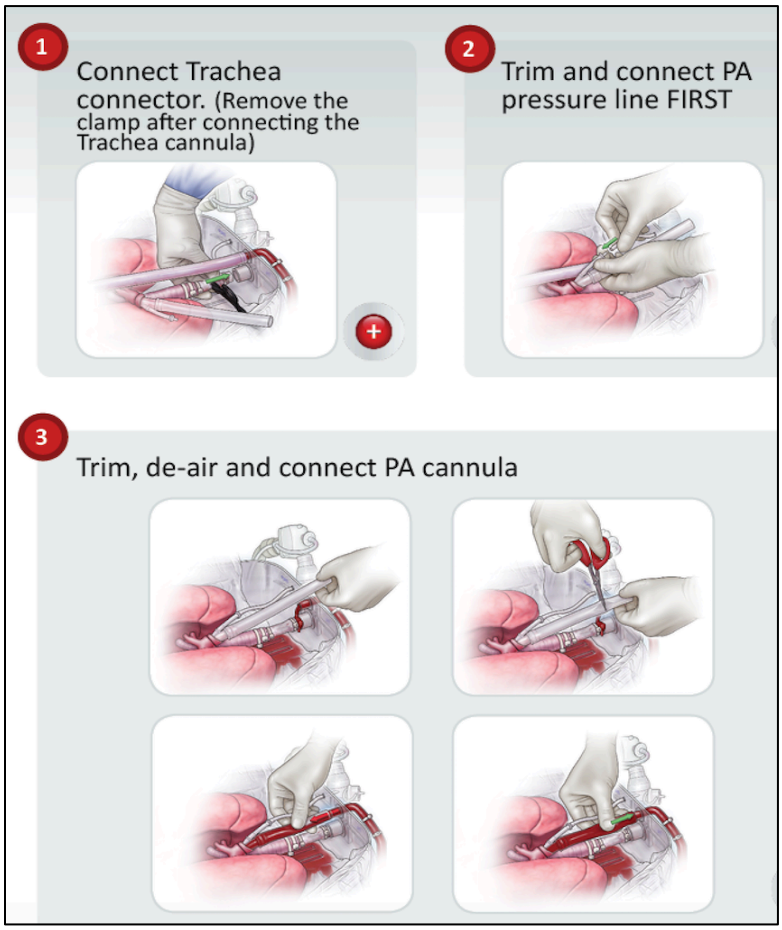
CAUTION— DO NOT set VENTILATOR MODE to OFF at any time during the retrieval

4. Reset the perfusate temperature under the Preservation settings to 37°C. Immediately before instrumentation, press the main configuration button  on the Wireless Monitor and set the perfusate Temp to 37°C under the Preservation menu. Confirm the new setting by acknowledging the "accept" command using the rotary knob.
5. Open the Lung Organ Chamber and fully unfold the enclosed folds of the OCS™ Lung Wrap.
6. Keep the Prime Tube attached in place inside the Lung Organ Chamber until the trachea connection is secured.
7. Place the lungs in the Lung Organ Chamber with the cannulae directed toward the connection ports inside the Lung Organ Chamber with anterior aspect of the lungs are facing the operator.
8. Follow the instrumentation sequence as seen below in Figure 25.

4.8.2. Instrumentation Sequence Overview

Figure 25 illustrates the sequence of instrumentation.

Figure 25: Sequence of Instrumentation



4.8.3. Connecting Trachea Cannula and PA Cannula to OCS™ Lung System

1. Connect the Trachea Cannula to the Lung Organ Chamber's Trachea Connector.
2. Unclamp the Trachea Tubing Clamp.
3. Trim and connect the PA pressure line before connecting the PA Cannula.
4. Connect the PA pressure port on the PA Cannula to the PA pressure line inside the Lung Organ Chamber.
5. Remove the Priming Tube in preparation to connect the PA Cannula.
6. Trim the PA Cannula (see diagram Connecting Trachea Cannula and PA Cannula to the OCS™ Lung System).
7. Fill the PA Cannula with blood to de-air it.
8. When the PA Cannula is fully de-aired, make the connection between the PA Cannula and the PA connector on the Lung Organ Chamber.

4.8.4. Initial Stabilization Overview

Table 7 provides recommended settings for initial stabilization.

Table 7: Initial Stabilization Settings

Settings	OCS™ Lung System Preservation Settings
Instrumentation Temperature	• Reset to 37°C in Preservation settings
Pump Flow	• Gradually increase to 1.5-2 L/min over approximately 15 min
Mean PA Pressure	• Maintain mean PAP < 20 mmHg while gradually increasing the Pump flow rates
Start of Ventilation	• At temperature ≥ 34°C and Pump flow ≥ 1 L/min, switch the Ventilator to Bronchoscope Mode for 5 min • Switch to Preservation Mode after 5 min in Bronchoscope Mode • Wrap the lungs after PEEP and TV are fully delivered • Close the Lung Organ Chamber cover and continue targeting the recommended Pump flow
Preservation Gas Flow	• 300 ml/min
Peak Airway Pressure (PAWP)	• Maintain < 25 cmH_2O

4.8.5. Warming the Lungs

The lungs must be warmed and fully perfused before transport. However, a rapid increase in Pump flow rate may potentially injure the lung and should be avoided.

Refrain from ventilation until a brief equilibrium period had been established, with a perfusate temperature of 34°C and Pump flow of at least 1 L/min.

1. After instrumenting the lungs on the OCS™ Lung System, press the main configuration button  on the Wireless Monitor and reset the perfusate temperature to 37°C under the Preservation menu. Confirm the new setting by acknowledging the “accept” command using the rotary knob.
2. Gradually increase the Pump flow rate using the rotary knob and after pressing the Pump adjust button  on the Wireless Monitor.
3. Maintain a target flow rate of 1.5-2 L/min over the course of 15 minutes to ensure gradual rewarming of cold lungs.

CAUTIONS—

To avoid potential lung injury, ensure that the mean PAP does not exceed 20 mmHg at any time during retrieval and particularly at times where the Pump flow is increased.

For mildly injured lungs, maintain the Pump flow rate throughout the preservation session, including Monitoring Modes not higher than 1.5 L/min, to minimize perfusate leakage in injured segments.

While gradually warming the lungs, press the main Configuration menu button  and set the ventilation settings to match settings in Table 7 under both Preservation and Monitoring Menu tabs (if not performed during priming).

4.8.6. Ventilation Start on the OCS™ Lung System

The start of ventilation takes place after the perfusate temperature reaches 34°C and the Pump flow rate reaches at least 1 L/min. It is recommended to start ventilation in Bronchoscope Mode for the first 5 minutes while continuing to achieve a target flow rate of 1.5-2 L/min. Bronchoscope Mode is intended at this phase to help to lower FiO_2 in the donor's lungs to 21%. During Bronchoscope Mode, the lungs are ventilated with room air (FiO_2 21%).

Steps:

1. Once perfusate temp reaches 34°C (around 10 minutes from instrumentation) and Pump flow rate reaches at least 1 L/min, press the Configuration menu button (at right). 
2. Highlight the Ventilator Mode tab using the rotary knob of the Wireless Monitor.
3. Switch to Bronchoscope Mode to initiate Ventilation using room air for 5 minutes.
4. Ensure absence of blood or air leak (bubbles) from the lung tissue or around the trachea and PA Cannulae.
5. Fix source as needed before wrapping the lungs and closing the Lung Organ Chamber.

4.8.7. Bronchoscope Monitoring Mode (Overview)

Based on a clinical decision, the user can perform a Bronchoscopic examination on the OCS™ Lung System without deflating the lungs. During Bronchoscope Mode, the lungs are ventilated with room air (FiO_2 21%).

4.8.8. Wrapping the Lung

Wrapping the lungs with the OCS™ Lung Wrap is intended to avoid over-distension of the lungs during ventilation. The wrap should comfortably envelop the lungs in an anatomical position while maintaining inflation volume and without adding any additional pressure or tension on the lungs.

Timing:

Apply the OCS™ Lung Wrap at peak inspiration after ensuring the following:

- The lungs have maintained the preset PEEP and TV under the Monitoring settings (in Bronchoscope Mode).
- There is no evidence of blood or air leak around the cannulae that needs to be fixed before closing the Lung Organ Chamber.

4.8.9. Steps of Lung Wrapping

Figure 26 illustrates the steps for applying the OCS™ Lung Wrap.

Figure 26: Steps of Lung Wrapping

1. Approximate both lungs to mid line (Anatomical position).
2. Wrap both lungs with one fold of the OCS™ Lung Wrap at peak inspiration.
3. Apply the second fold of the OCS™ Lung Wrap to overlap the first one.
4. Ensure PAWP is < 25 cmH_2O and a good LA blood flow (Pulmonary veins drainage) through the hilum area towards the lower left drain of the Lung Organ Chamber.
5. Close the Lung Organ Chamber cover.

CAUTIONS—

When wrapping the lungs, make sure the wrap is applied at the peak of inspiration.

Avoid restricting the LA blood at the lung hilum during wrapping and ensure good free flow of LA blood to the lower left drain of the Lung Organ Chamber. Neglecting this step might result in backpressure on pulmonary vasculature and development of lung edema.

Wrapping the lung too tightly will restrict ventilation and can cause an elevation in PAWP.

Monitor PAWP after wrapping. If PAWP is ≥ 25 cmH_2O, check that the wrap is not too tight and adjust before closing the Lung Organ Chamber.

4.8.10. Applying Banded Bags/Sterile Covers

Apply two sterile banded bags to a closed Lung Organ Chamber prior leaving the donor's OR to provide additional protection to the organ from external environmental contamination during transport.

Both banded bags need to stay in place throughout the preservation period on the OCS™ Lung System. These sterile covers are to be removed in the recipient operating room at time of final physical assessment after OCS™ lung preservation of the lung (i.e., at time of disconnecting the lung from the OCS™ Lung System).

CAUTION— When applying the banded bags over the Lung Organ Chamber cover, avoid pushing the release handle on the OCS™ Lung Console to avoid disconnecting the LPM from the OCS™ Lung System.

1. Using aseptic technique, perform the following steps to apply the smaller (26 in, 66.04 cm) banded bag while the sterile drape is still in place around the Lung Organ Chamber (Figure 27):
    a. Remove the 26 in. (66.04 cm) bag from its sterile package.
    b. Stretch the bag around the front of the Lung Organ Chamber and secure it while avoiding touching the inner surface of the bag.
    c. Pull the bag over the top and around the left side, underneath the Wireless Monitor.
    d. Pull the elastic over the rear hinges of the cover of the Lung Organ Chamber.
    e. Carefully pull the elastic band around the right side making sure not to cover the Metered Dose Inhaler (MDI) or bronchoscope ports.
    f. Make sure the elastic band is below the seam of the Lung Organ Chamber cover.
2. Remove and properly dispose of the sterile drape.
3. Repeat Step 1 to apply the larger (40 in., 101.6 cm) banded bag over the smaller one and note the following:
    a. Ensure the larger bag's elastic band is well below the smaller bag's band without covering the MDI or Bronchoscope ports.
    b. Make sure the bag does not cover the two filters that protrude from the rear of the Lung Organ Chamber.
    c. Pull any excess bag material away from the sampling and injection manifold and tuck it under the cradle of the Wireless Monitor.

4.8.11. End of the Initial Stabilization Phase

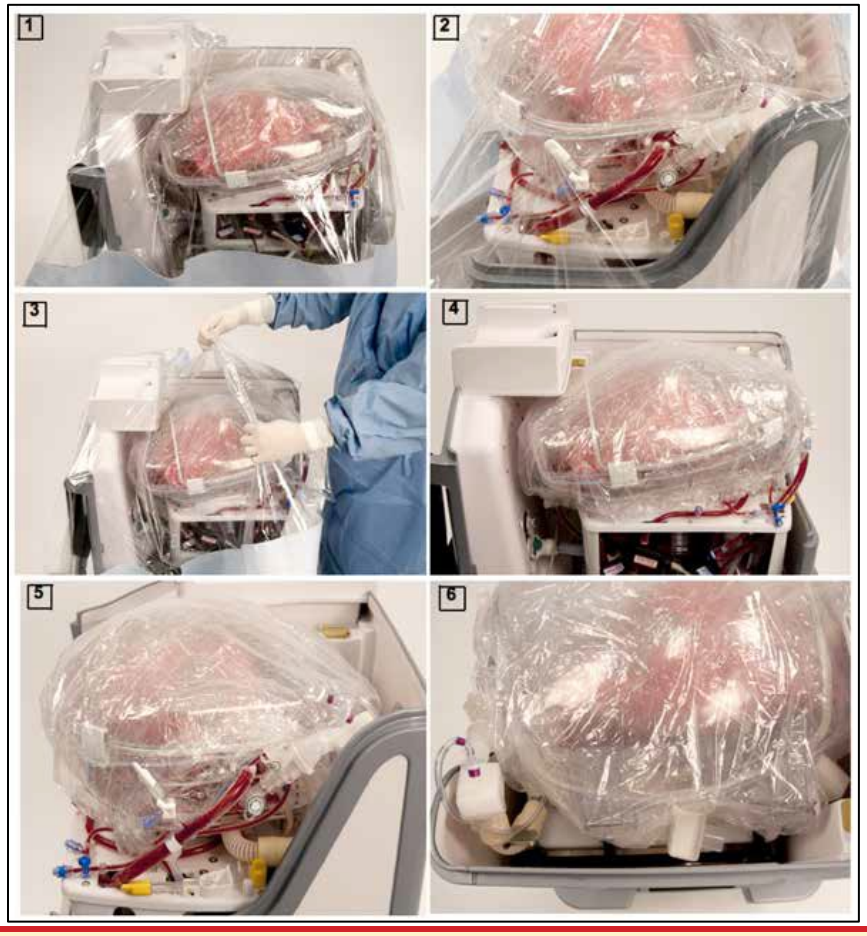
Initial stabilization phase is considered complete after the perfusate's temperature reaches 37°C, lung ventilation has started, and all target ventilation and perfusion parameters are fully met.

Before proceeding to the initial/baseline monitoring of the lungs, confirm the following are shown on the Wireless Monitor:

- Mean PA pressure is stabilized below 20 mmHg
- PAWP is stabilized below 25 cmH_2O
- Perfusate temperature has reached 37°C
- PA flow rate is 1.5-2 L/min

- PEEP and TV are fully delivered and maintained in Preservation Mode.

Figure 27: Applying the Sterile Covers/Banded Bags



CAUTION—Do not disconnect the OCS™ Lung System from AC power until you are ready to leave the donor site.

4.9. Initial (Baseline) Monitoring Overview

4.9.1. Assessing Lungs at Donor Site Prior to Transport

1. If needed, perform an initial assessment of lung oxygenation capacity using Continuous Monitoring Mode.
2. If needed, a Bronchoscopic examination can be performed on the OCS™ Lung System (at donor site). For detailed steps of performing a physical Bronchoscopic examination, refer to Section 6.2.2. The Bronchoscope port must always be closed if a Bronchoscopic examination is not performed to avoid air leakage and lung deflation during Preservation Mode.

CAUTION—Bronchoscope port must always be closed throughout preservation to avoid air leakage and lung deflation.

4.9.2. Continuous Monitoring Mode Timing and Settings

PA (Pump) Flow Recommendation for Continuous Monitoring Mode:

- 2-3 L/min

WARNING— For mildly injured or hemorrhagic lungs, perform Continuous Monitoring Mode at a Pump flow of 1.5 L/min to avoid additional fluid leakage into the alveolar space with a higher Pump flow.

Ventilators' Settings (under Monitor Settings Tab):

- PEEP = 5 cmH_2O
- TV = 6 mL/kg ideal donor body weight*
- RR = 12 breaths per minute (BPM)
- During Continuous Monitoring Mode, FiO_2 = 21% (room air)

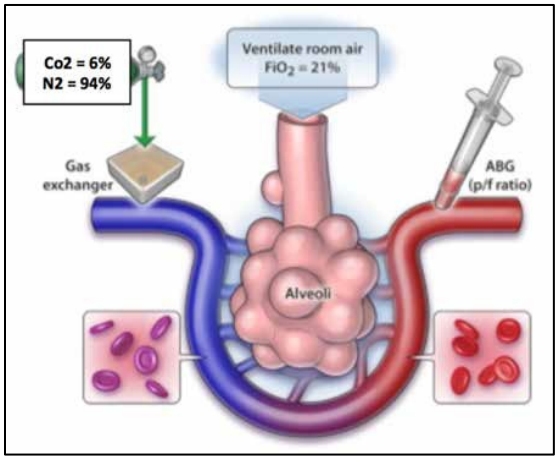
***NOTE—** For a suggested ideal body weight formula, see Appendix C: Body Weight Formula (Devine's Formula for donor's height above 150 cm (5 feet)).

4.10. Continuous Monitoring Mode

The OCS™ Lung System continuously deoxygenates the perfusate by supplying Lung Monitoring Gas into the gas exchanger. At the same time, ambient air is used to ventilate the lung. This mode simulates a near physiologic perfusion of the lung to assess its capacity to oxygenate venous (PA) blood to a systemic arterial (LA) blood.

The Wireless Monitor icon for Continuous Monitoring Mode is shown here: 

Figure 28: Continuous Monitoring Mode



4.10.1. Steps of Performing Continuous Monitoring Mode (baseline at donor site)

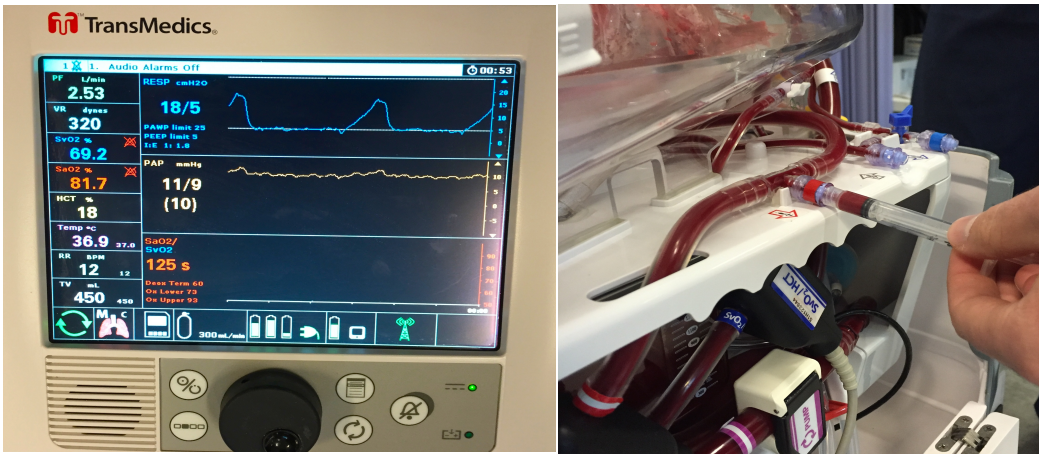
1. Connect the Lung Monitoring Gas cylinder to the Monitoring port of the OCS™ Lung Console and open its valve (turn in a counter-clockwise direction) as seen in Figure 29.

Figure 29: Connecting Lung Monitoring Gas Cylinder to the Monitoring Port of OCS™ Lung System

2. Increase the Pump flow gradually to 2-3 L/min (unless the lungs are mildly injured).
   a. Press the Pump adjust button and gradually increase the Pump flow to 2-3 L/min while maintaining a mean PA pressure below 20 mmHg.
   b. For mildly injured or hemorrhagic lungs, Continuous Monitoring Mode needs to be performed at 1.5 L/min to avoid additional fluid leakage into the alveolar space.
3. Set Ventilator Mode to Continuous Monitoring Mode.
   a. On the Wireless Monitor, press the Configuration menu button to display the Ventilator Mode tab.
   b. Select Continuous Monitoring and accept the selection using the rotary knob.
   c. Once Continuous Monitoring is accepted, the icon will be displayed in the lower left corner of the Monitor's screen
4. Take a baseline monitoring/assessment ABG from the arterial sampling port (LA blood) at 120-180 sec (displayed on bottom graphic display on Monitor) to calculate baseline PaO_2/FiO_2 ($PaO_2/0.21$) (Figure 30).
5. Press the Pump adjust button and lower the flow rate back to 1.5-2 L/min using the rotary knob.
6. Upon completion of Continuous Monitoring Mode (180 sec) the system will automatically revert to Preservation Mode and the icon will be displayed as the PaO_2 Ventilation Mode on the Monitor.
7. Close the Lung Monitoring Gas cylinder valve using the Cylinder Wrench (turn all the way in a clockwise direction) and disconnect it from the lung system.
8. Store the Monitoring Gas cylinder back in the run bag and store the Cylinder Wrench back inside the gas compartment of the OCS™ Lung Console.
9. Check the baseline ABG is to assess the following:
   a. PaO_2 to calculate the baseline PaO_2/FiO_2 ($PaO_2/0.21$)

b. HCO_3 to adjust its level between 22-28 mmol/L. To correct low HCO_3, add 1.5 mEq of $NaHCO_3$ to every 1-ve Base Excess (BE).
c. Glucose level to ensure it is ≥ 120 mg/dL. For low glucose (≤ 120 mg/dL), add 1-2 grams of dextrose.

Figure 30: Sampling from the Arterial Sampling Port between 120-180 sec in Continuous Monitoring Mode

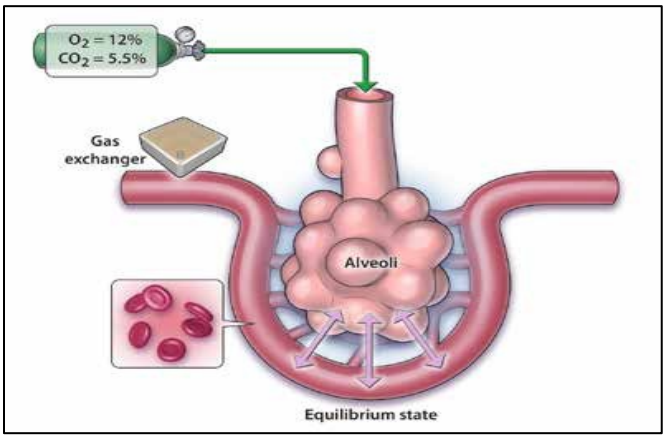


4.11. Preservation Mode

The OCS™ Lung System operates with the lung rebreathing the same captive breath (Figure 31). This helps the system conserve battery power and Lung Preservation Gas while helping the lungs to conserve heat and humidity. A small percentage of fresh Lung Preservation Gas is injected into the ventilation circuit to maintain the required gas concentration and to maintain Positive End Expiratory Pressure (PEEP).

The Wireless Monitor icon for Preservation Mode is shown here:

Figure 31: Preservation Mode



After baseline Continuous Monitoring Mode and prior to leaving the donor site, confirm the alarm limits are set to the recommended ranges below (see Table 8). For instructions on how to set alarms, please refer to the *TransMedics Technical User Guide: OCS™ Lung System.*

Table 8: Setting Alarms

Configuration (Unit)	Preservation		Monitoring Mode	
	Low	High	Low	High
PF (L/min)	1.4	2.1	1.4	3.1
PAP mmHg	N/A	20	N/A	20
VR (dyne*s)/cm^5	200	600	200	600
Temp °C	36.5	37.5	36.5	37.5
SaO_2 %	90	N/A	90	N/A
SvO_2 %	90	N/A	60	N/A
HCT %	16	N/A	16	N/A
PAWP cmH_2O	10	25	10	25
PEEP cmH_2O	5	9	5	9
RR % change from set point	0	0	0	0
TV % change from set point	0	0	0	0

During Preservation Mode and throughout transport, ensure the following:

- PEEP is maintained to ensure absence of air leak.
- PAWP trend is stable or trending down at the same Pump flow and Ventilator settings (<25 cmH_2O).
- Mean PAP is stable or trending down at the same Pump flow and Ventilator settings (<20 cmH_2O).
- Vascular Resistance (VR) is stable or trending down at the same Pump flow and Ventilator settings.

It is recommended to always display PAWP trend versus VR trend on the bottom graphic display of the Monitor's screen during Preservation Mode.

Real time display of these parameters will help the OCS™ Lung System users to manage the lungs as needed during transport. For instructions on how to set or change the lower graphic display on the Monitor's screen, please refer to the *TransMedics Technical User Guide: OCS™ Lung System.*

NOTE— Vascular Resistance (VR). This is a measure of the resistance to flow that must be overcome to push the perfusate through the vasculature of the lungs. It is calculated as (80* mean PAP)/(Pump Flow) and displayed in units of dyne*sec/cm^5.

5. CHAPTER 5: ACTIVITIES PERFORMED DURING PRESERVATION AND TRANSPORT

The OCS™ Lung System enables medical professionals to perfuse and ventilate the lungs and monitor key parameters during transport between the Donor site and the Recipient site. The instructions for transporting and caring for the lungs found in this chapter are designed to optimize the condition of the organ in preparation for transplant.

5.1. Preparing for Transport

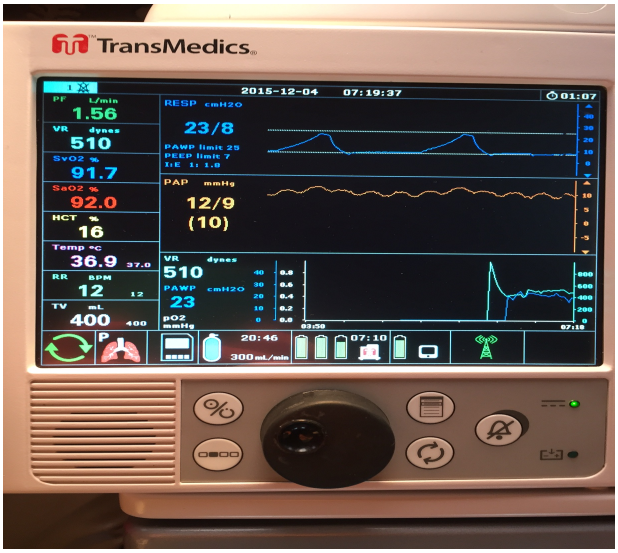
CAUTIONS—

Avoid leaving the OCS™ Lung System in an uncontrolled temperature environment for longer than a few minutes. During such periods, monitor the perfusate temperature and take remedial action if the temperature registers more than one or two degrees over or under the desired setting.

If the Wireless Monitor is taken out of its range of 3 meters (9 feet), verify upon return to range that all parameters are as expected (to detect the rare instance in which a system event occurred while out of range).

1. It is recommended that you set the bottom graphic frame of the Wireless Monitor's screen to display PAWP trend versus VR trend on during Preservation Mode. Real time display of these parameters will help OCS™ Lung System users to manage the lungs as needed during transport (see detailed settings in Figure 32). For more information, please refer to the *TransMedics Technical User Guide: OCS™ Lung System.*

Figure 32: Monitor Picture with Bottom Graphic Frame Set in Preservation Mode to Display VR Trend vs. PAWP Trend



2. Close the front panel and reinstall the cover of the OCS™ Lung Console.
3. Unplug the system from AC power and wind the power cord around the power cord wrap.

4. Have all supplies needed for transport to the recipient site (e.g., Lung Preservation Termination Set, gas wrench, Mobile base, Corrective Medications, Cooler and all other routine retrieval items).
5. Press the release buttons on the push handle, lock in the upright position, and push the system to the vehicle loading area.
6. At the vehicle, set the wheel locks, open the Mobile Base release handle, and lift the system off the base using the lift handles.

NOTE— Always use two people to lift and carry the system. Do not lift the system when it is mounted on to the Mobile Base.

WARNING— Tilting the system to an angle greater than 15 degrees during transport may disrupt fluid paths in the LPM and lead to system malfunction.

7. Position the OCS™ Lung Console in the vehicle and secure it using tie downs. Remember to bring the Mobile Base for use at the recipient site.
8. For remote monitoring, remove the Wireless Monitor from its docking station and keep within approximately 3 meters of the OCS™ Lung Console.

5.2. Managing the Lung and OCS™ Lung System During Preservation and Transport

Periodically check and monitor the following lung parameters on the Wireless Monitor:

- PEEP (ensure it is maintained in Preservation Mode)
- At the same Pump flow and ventilation setting, make sure that the following parameters are stable or trending down:
  - Mean PA pressure < 20 mmHg
  - PAWP < 25 cmH_2O
  - VR
- TV is fully delivered per settings
- Preservation Gas levels
- OCS™ and Wireless Monitor battery charge status
- SaO_2
- Pump flow

NOTE— If the SaO_2 on the Wireless Monitor drops below 90%, switch the Ventilator Mode to Bronchoscope Mode for 2 minutes (FiO_2 21%) then back to Preservation Mode (FiO_2 12%).

Maintain Pump Flow: 1.5-2 L/min during Preservation Mode

Gas Flow: 300 ml/min. Refer to Section 7 for when the Lung Preservation Gas flow rate is recommended to be set higher.

Ventilator Settings:

- PEEP = keep at 7 cmH_2O throughout preservation except during flights, reduce PEEP to 5 cmH_2O
- TV = 6 ml/kg ideal donor body weight
- RR = 12 BPM

NOTES—

PEEP can be dropped to 5 cmH_2O earlier if the lungs are suspected to have mild injury in the donor's chest with evidence of air leak on the OCS™ Lung System.

To recruit lungs with severe atelectasis, PEEP can be set to 7 cmH_2O for greater periods as long as transporting the lungs by car, and both PAWP trend and VR trend are not rising at the same Pump flow and ventilation settings.

CAUTION—OCS™ Lung System during flights – DO NOT set PEEP > 5 cmH_2O.

6. CHAPTER 6: ACTIVITIES PERFORMED AT RECIPIENT SITE

This chapter provides instructions for the tasks that are performed upon returning to the recipient site.

6.1. Final Recruitment in Preservation Mode

Timing:

- If recruitment of the donor lungs is clinically required, we recommend that you initiate it at least 30 to 60 minutes before performing final assessment on the OCS™ Lung System.

Ventilator Settings for Recruitment:

- PEEP = 7-9 cmH_2O (NOT during flights) in Preservation Mode settings.
- TV = 6 ml/kg ideal donor body weight
- RR = 12 BPM

Actions:

Upon arrival at the recipient site:

1. Plug the OCS™ Lung System into an active wall AC outlet.
2. Take a final recruitment ABG to:
    - Correct HCO_3 to be 22-28 mmol/L by adding 1.5 mEq of $NaHCO_3$ to every 1-ve (mmol/L) Base Excess.
    - Ensure Glucose ≥ 120 mg/dL. If glucose < 120 mg/dL, add 1-2 grams of dextrose.

6.2. Final Monitoring/Overview

Perform final Continuous Monitoring and Bronchoscopic examination for the lungs at the end of the preservation session.

6.2.1. Continuous Monitoring Mode Timing and Settings

PA (Pump) Flow:

- 2-3 L/min (set to the same Pump flow rate at which the initial/baseline Continuous Monitoring Mode was performed)

WARNING—For mildly injured or hemorrhagic lungs, Continuous Monitoring Mode needs to be performed at a Pump flow as low as 1.5 L/min to avoid additional fluid leakage into the alveolar space.

Ventilator Settings:

- PEEP = 5 cmH_2O
- TV = 6 ml/kg ideal donor body weight

- RR = 12 BPM
- During Continuous Monitoring Mode, FiO_2 = 21% (room air)

Performing Continuous Monitoring Mode (Final):

1. Connect the Lung Monitoring Gas cylinder to the Monitoring port on the OCS™ Lung Console and open its valve (turn in a counter-clockwise direction).
2. Increase the Pump flow gradually to 2-3 L/min (unless mildly injured lungs).
   a. Press the Pump adjust button  and gradually increase the Pump flow to 2-3 L/min while maintaining the mean PA pressure below 20 mmHg.
   b. For mildly injured or hemorrhagic lungs, Continuous Monitoring needs to be performed at 1.5 L/min to avoid additional fluid leakage into the alveolar space.
3. Set the Ventilator Mode to Continuous Monitoring Mode.
   a. On the Wireless Monitor, press the Configuration menu button  to display the Ventilator Mode tab.
   b. Select Continuous Monitoring and accept the selection using the rotary knob.
   c. Once Continuous Monitoring is accepted,  will be displayed in the lower left corner of the Monitor's screen.
4. Take a final Monitoring ABG from the arterial sampling port (LA blood) at 120-180 sec (displayed on bottom graphic display on Wireless Monitor) to calculate baseline PaO_2/FiO_2 (PaO_2/0.21). See Figure 30.
5. Press the Pump adjust button  and lower the flow rate back to 1.5-2 L/min using the rotary knob.

NOTE—To ensure an accurate judgment of VR, mean PAP, and PAWP trends at final monitoring, it is important to assess the lung's oxygenation capacity at the same Pump flow rate and ventilation setting at which the baseline monitoring was performed.

6. Upon completion of Continuous Monitoring Mode (180 sec), the lung system will automatically revert to Preservation Mode and  will be displayed as the ventilation Mode icon on the Wireless Monitor's screen.
7. Close the Lung Monitoring cylinder valve using the Cylinder Wrench (turn all the way in a clockwise direction) and disconnect it from the lung system.
8. Store the Lung Monitoring Gas cylinder back in the run bag and store the Cylinder Wrench back inside the gas compartment of the OCS™ Lung Console.
9. Check the ABG to assess the following:
   - PaO_2 to calculate the baseline PaO_2/FiO_2 (PO_2/0.21).
   - HCO_3 to adjust its level between 22-28 mmol/L. To correct for low HCO_3, add 1.5 mEq of $NaHCO_3$ to every 1-ve Base Excess.

- Glucose level to ensure it is ≥ 120 mg/dL. For low glucose (≤ 120 mg/dL), add 1-2 grams of dextrose.

6.2.2. Physical Bronchoscope Monitoring

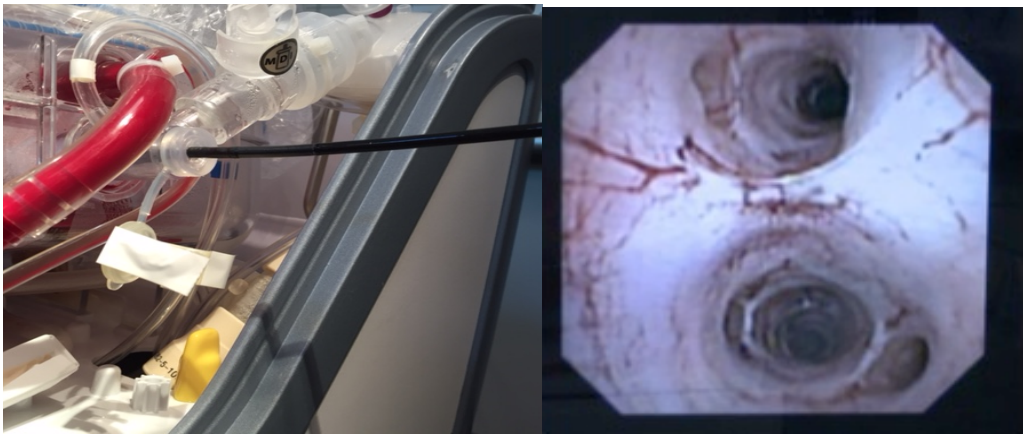
The OCS™ Lung System has the capability of conducting a Bronchoscopic examination while the lungs are inflated on the device.

To perform a Bronchoscopic examination:

1. Keep the Pump flow at 1.5-2 L/min (same Preservation Mode Pump flow).
2. Ensure that the OCS™ Lung System is stationary by locking the Mobile base brakes.
3. Remove the OCS™ Lung Console top cover.
4. Lower the front panel.
5. Switch Ventilator to Bronchoscope Mode first and before opening the Bronchoscope port as follows:
   a. Press  to display the Configuration Menu and select the Ventilator Mode tab.
   b. Using the rotary knob, highlight and select Bronchoscope Monitoring and press the rotary knob again.
   c. Confirm switching to Bronchoscope Mode by highlighting the “Accept” option and acknowledge the selection using the rotary knob.
   d. A successful switch to Bronchoscope Mode can be confirmed by seeing the 

icon displayed on the lower left corner of the Wireless Monitor screen.
6. Insert the fiber-optic Bronchoscope via the Bronchoscope port to perform a Bronchoscopic examination as seen in Figure 33.

Figure 33: Bronchoscopic Examination on the OCS™ Lung System through a Bronchoscope Port)



7. After the Bronchoscopic examination is completed, tightly secure the cap to the Bronchoscope port before changing the Ventilator mode.
8. Switch back to Preservation Mode following the steps below:
   a. Press  to display the Configuration Menu and select the Ventilator Settings tab.

b. Using the rotary knob, highlight and select Preservation and press the knob again.
c. Confirm switching to Preservation Mode by highlighting the "Accept" option and acknowledge the selection using the rotary knob.
d. A successful switch to Preservation Mode can be confirmed by seeing the  icon displayed on the lower left corner of the Monitor screen.

6.2.3. Physical Assessment in Lung Organ Chamber

It is recommended to perform visual and physical assessments at the recipient's OR prior to preservation termination.

Steps of Performing Physical Assessment and Palpation of the Lungs:

1. Remove the outer banded bag.
2. Create a sterile field around the Lung Organ Chamber before opening its cover.
3. Remove the inner banded bag and open the Lung Organ Chamber cover only at the recipient's OR.
4. Unwrap the lungs for adequate palpation and physical assessment of different lung segments.
5. Adequately rewrap after inspecting all lung segments.
6. Keep the Lung Organ Chamber cover closed until the lungs are ready to be disconnected from the lung system.
7. Reset PEEP back to 5 cmH_2O in Preservation Mode if no additional recruitment is needed and until the final lung flush.

6.3. Implantation Decision

The implantation decision should be made by the transplantation team after considering all of the following:

1. Stability of the lung perfusion and ventilation parameters (VR, PAWP, and mean PAP trends) at same ventilation parameters and Pump flow rate.
2. PaO_2/FiO_2 ratio ≥ 300 at time of final Continuous Monitoring on the OCS™ Lung System.
3. Clinically acceptable lungs based on visual, physical and, if needed, a Bronchoscopic examination.

6.4. Lung Preservation Termination

General Considerations:

When disconnecting the lung from the OCS™ Lung System, a sterile operator(s) performs all actions that involve the inside of the Lung Organ Chamber. Non-sterile operator(s) may perform other actions.

NOTE—To maintain warmth and humidity, keep the Lung Organ Chamber cover closed throughout the procedure until the lung is ready to be disconnected from the OCS™ Lung System.

When the surgical team is ready to accept and receive the lung for transplant, perform either one of following options in Section 6.4.1 or Section 6.4.2.

6.4.1. Double Lung Flush Technique

Double Lung Flush Using Cold Buffered OCS™ Lung Solution:

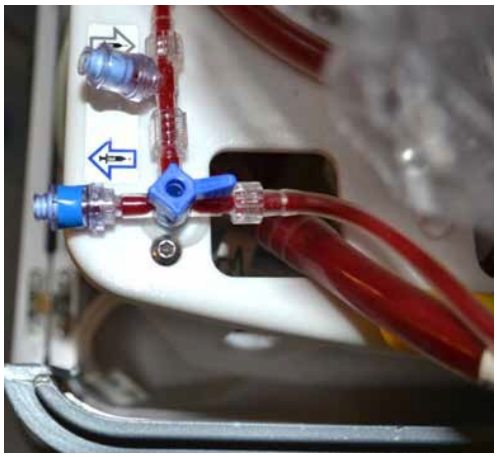
- Use at least 3-5 L of cold and buffered* OCS™ Lung Solution for antegrade flush of the lungs at the end of the perfusion session on the OCS™ Lung System.
- Additional OCS™ Lung Solution can be used if needed for additional antegrade flush on the lung system or retrograde flush at the back table after the lungs are disconnected.

**Use 10 mEq of $NaHCO_3$ or 1 mmol of THAM/L (tromethamine) to buffer the OCS™ Lung Solution immediately before usage.*

Steps of Double Lung Final Flush:

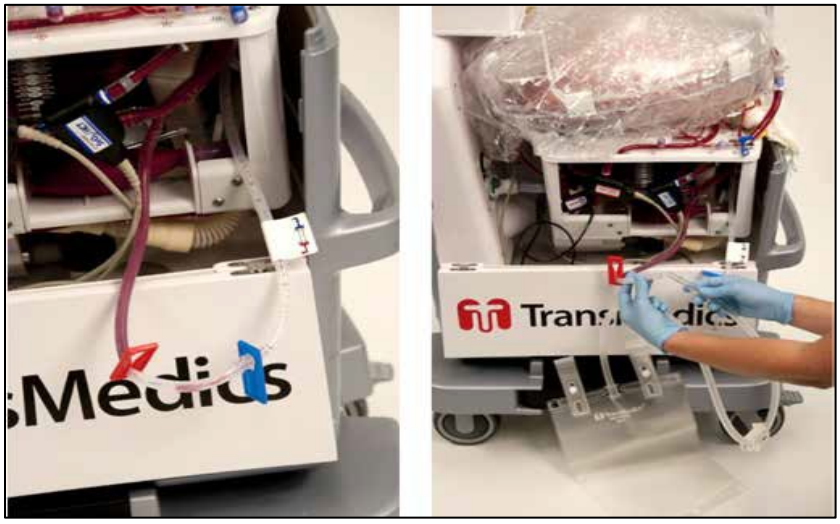
1. Close the PA vent line stopcock (Figure 34) to ensure all cold solution reaches the pulmonary artery and none gets to the reservoir.

Figure 34: PA Vent Line in Close Position



2. Switch the Ventilator to Bronchoscope Monitoring Mode to increase FIO_2 to 21%.
3. Connect the Lung Flush Collection Bag to the red side of the Oxygenator Recirculation loop while keeping the red clamp over the tubing securely clamped off. Place the bag on the floor (Figure 35).

Figure 35: Connecting the Lung Flush Collection Bag to the Oxygenator Recirculation Line



4. Hang at least 3 L of cold buffered OCS™ Lung Solution from an IV pole. Attach one bag of solution at a time to the Termination Flush Line.
5. Open the clamp of the flush line to de-air the Termination Flush line, then clamp the de-aired flush line.
6. De-air the Termination Flush Port on the OCS™ LPM using a sterile syringe after removing the cap on the Flush Port and keep the flush stopcock closed (Figure 36).

Figure 36: De-airing the Termination Flush Port

7. Uncap the end of the Termination Flush Line and the Termination Flush Port on the OCS™ LPM. Make a wet-to-wet connection between the Flush Line and the Termination Flush Port (Figure 37).
8. Once the connection is made, leave the Termination Flush line clamp open and keep the flush stopcock closed until you are ready to flush both lungs.

Figure 37: Making a Wet-to-Wet Connection

9. To deliver flush solution to the lung, open the LPM Termination flush stopcock (Figure 38).

Figure 38: Delivering Flush Solution

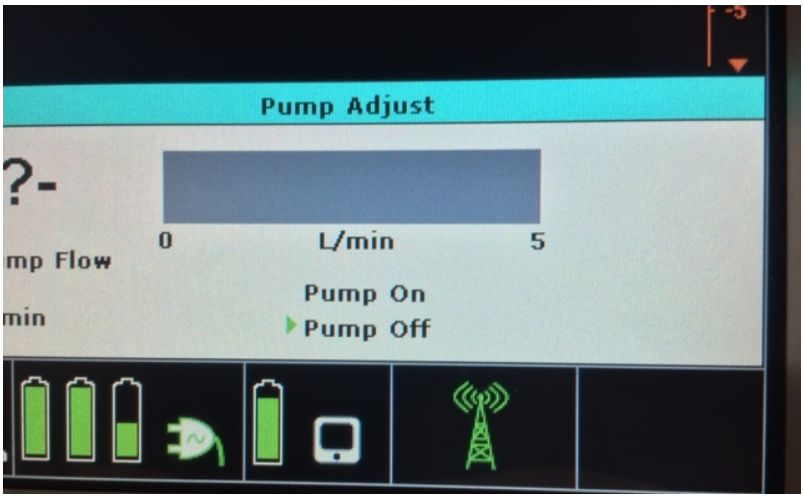
10. Immediately after starting delivery of the cold flush solution, clamp the PA line of the LPM below the level of the flush port using a hemostat or other surgical clamping instrument (Figure 39).

Figure 39: Clamping the PA Line

11. Once the inflow line to the lung (PA line) is clamped, turn off the Pump as follows:

a. Press the Pump adjust button on the Wireless Monitor 
b. Turn the rotary knob all the way to the left (counter-clockwise) until the Pump is turned off and the Wireless Monitor displays the icon on the screen indicating the Pump is off (Figure 40).

Figure 40: Monitor Screen Showing Pump is Turned Off in the Pump Adjust Menu (see green arrow left of "Pump Off")



12. Open the red clamp on the Oxygenation Recirculation line to drain the reservoir while flushing the lungs.
13. Once the first flush bag is delivered, clamp off the flush line and reuse it to spike the next bag of cold buffered OCS™ Lung Solution, and then open the flush line clamp to continue flushing with the second bag of solution.
14. Repeat step 13 until at least 3-5 L of cold buffered OCS™ Lung Solution are delivered antegradely to the lungs.
15. Monitor the perfusate temperature on the Wireless Monitor screen. Once the temperature drops to 32°C, switch the Ventilator Mode to "Pause Preservation" and continue delivering the remaining antegrade flush.
    a. Press  to display the Configuration Menu and select the Ventilator Mode tab.
    b. Using the rotary knob, highlight and select Pause Preservation and press the rotary knob again.
    c. Confirm the switch to Pause Preservation Mode by highlighting the "Accept" option and knowledge the selection using the rotary knob.
    d. A successful switch to Pause Preservation Mode can be confirmed by seeing the  icon displayed on the lower left corner of the Wireless Monitor screen.
16. Once the antegrade flush is completed, undock the Wireless Monitor, if not performed earlier, and remove the outer banded bag.
17. Create a standard sterile field using sterile surgical drapes around the cover of the Lung Organ Chamber before opening it.

18. Remove the inner banded bag from the top of the Lung Organ Chamber cover and open the Organ Chamber for the surgeon.
19. Disconnect both lungs from the LPM as follows (performed by a sterile surgeon):
    a. Unwrap both lungs.
    b. Clamp the Trachea Cannula.
    c. Disconnect the PA and Trachea Cannulae from the OCS™ Lung System.
    d. Remove the lungs from the lung system.
20. Retrograde flush (1-2 L) can be performed as needed using cold buffered OCS™ Lung Solution at the back table.

CAUTION— While one lung is implanted, the second lung must be maintained cold until it is reperfused in the recipient's chest

6.4.2. Separating and Cooling One Lung While Perfusing and Ventilating the Second Lung until Implantation

WARNING— Safety and effectiveness of the OCS™ Lung System for the preservation of isolated single-lung donor organs has not been evaluated.

The OCS™ Lung System may be configured to (50% of Pump flow rate and ventilation settings) to continue perfusing and ventilating the second lung while the first lung is being implanted into the recipient

Prior to considering this termination option, please consider the following**:**

- Full exploration of both the left and the right pulmonary arteries of the donor's lungs at the time of harvest is recommended to easily split and separate one lung at a time on the OCS™ Lung System.
- The lowest TV that can be configured on the lung system is 200 ml.
- The lowest recommended Pump flow rate setting is 500ml/min.
- One (First) lung needs to be disconnected from the OCS™ Lung System while maintaining perfusion to the remaining (second) lung (Pump should be running all the time).
- The first separated lung needs to be flushed with cold and buffered OCS ™ Lung Solution at the back table but not on the OCS™ Lung System. As the same perfusate will continue to perfuse the second lung on the lung system until ready to be disconnected from the lung system.
- The remaining (second) lung on the OCS™ Lung System must be adequately wrapped while being ventilated (Preservation Mode) and perfused.

Sequence of Steps:

1. Undock the Wireless Monitor and remove the outer banded bag.
2. Create a standard sterile field using sterile surgical drapes around the LPM before opening the Organ Chamber.
3. Remove the inner banded bag from the top of the organ chamber cover.
4. Open the Organ Chamber.
5. Unwrap both lungs.
6. Lower the Pump flow to not less than 500 ml/min to allow better visibility to the surgical field while one lung is being separated from on the OCS™ Lung System.
7. Set the Ventilator to Pause Preservation Mode until one lung is separated.

> **CAUTION—**If lowering the Pump is needed below 750 ml/min for better visualization of the LA cuff during splitting the lungs, **never** lower the Pump below 500 ml/min. Once splitting is completed, restore Pump flow rate back to 750-1000 ml/min) to adequately perfuse the remaining lung on the system.

8. Configure TV under Preservation and Monitoring settings to 50% of the TV set to ventilate both lungs. (The lowest TV that can be configured on the OCS™ Lung System is 200 ml)
9. Keep PEEP set to 5 cmH_2O under Preservation and Monitoring settings.
10. Separate one lung following standard surgical procedure.
11. Flush the separated lung on back table (both antegradely and retrogradely) using cold buffered OCS™ Lung Solution as needed (2-3L)
12. Maintain the second lung's airway and perfusion connection to the organ chamber to ensure its perfusion and ventilation by the OCS™ Lung System.
13. Adjust Pump flow rate to half flow used to perfuse both lungs in Preservation Mode (750 - 1000 ml/min).
14. Set Ventilator to Preservation Mode to start ventilating the remaining lung connected to the lung system.
15. Apply both folds of the lung wrap around the remaining lung perfused by the lung system during peak inspiration and per the use model.
16. Close the Organ chamber and continue to manage the lung until its final flush and disconnection from the OCS™ Lung System.
17. Once ready to flush the second lung, follow the same flushing steps in Section 6.4.1 with 2-3 L of cold and buffered OCS™ Lung Solution antegradely. Additional retrograde flush can be performed at the back table as needed.

6.5. Performing the Shut-Down Protocol

This section provides instructions for terminating the preservation session and shutting down the OCS™ Lung System.

Perform the following steps after the organ has been disconnected from the system:

1. Remove sterile drapes around the Lung Organ Chamber.
2. Clamp the red side of the Oxygenator Recirculation loop and disconnect the Lung Flush Collection Bag.
3. Dispose of all materials according to the standard site procedure for disposal of blood contaminated materials.

6.6. Preparing the OCS™ Lung System for Shutdown

1. Once the organ has been removed press the  button while the Wireless Monitor is docked to the OCS™ Lung Console.
2. Set the lung system to Standby Mode.
3. If no data card is present, the software will provide on-screen instructions.
   a. Follow the on-screen instructions to ensure that all data are downloaded to the data card.
   b. Remove the data card from the slot to the right of the Wireless Monitor-docking cradle.

6.7. Removing the Probes from Tubing

The probes are reusable and do not require sterilization since they do not directly contact perfusate. After the lung has been removed, detach the Flow, SaO_2/Hematocrit, and SvO_2/Hematocrit probes from the tubing, clean the probes as described in **Chapter 8** of the *TransMedics Technical User Guide: OCS™ Lung System*, and store them inside the OCS™ Lung System.

To remove the Flow probe from the tubing:

1. Press the latch on the side of the probe down until the probe lid opens.
2. Carefully remove the flow probe from the tubing on the LPM, but leave it connected to the OCS™ Lung Console.

To remove the SvO_2/Hematocrit and SaO_2/Hematocrit probes from the tubing:

1. Firmly grasp the probe with one hand.
2. Use the other hand to gently remove the cuvette from the probe.
3. Carefully remove the SaO_2/Hematocrit probe and the SvO_2/Hematocrit probe from the tubing on the LPM, but leave them connected to the OCS™ Lung Console.

6.8. Disconnecting the Ventilator Lines

NOTE— Before disconnecting the Ventilator lines, make sure the OCS™ Lung System is in Standby Mode or switch the Ventilator to OFF.

1. To turn the Ventilator to OFF Mode, press the  button to set the system to Standby Mode, or configure the Ventilator Mode to OFF.

2. Disconnect the Ventilator lines after the system is set to Standby Mode. Disconnect the Ventilator lines by pressing down the green button on the Ventilator lines to release the connector and disconnect from the OCS™ Lung Console.

6.9. Turning Off the Lung Preservation Gas

CAUTIONS—

Do not over-tighten the gas valve with the cylinder wrench. Excessive tightening may damage the valve.

Always ensure that the gas cylinders are shut OFF after the preservation session is complete.

1. Use the Cylinder Wrench to shut off the Lung Preservation Gas by slowly turning the shut-off valve clockwise.
2. If the Lung Monitoring Gas cylinder is connected to the OCS™ Lung Console, close its valve and disconnect it from the Lung Console.

6.10. Removing and Disposing of the LPM

1. Facing the OCS™ Lung System, perform the following:
   a. Press the LPM release lever to disengage the clips that hold it in place.
   b. Hold the LPM with your left hand and disengage it with your right hand.
   c. Angle the LPM 30° toward you to disengage it from the Pump slot.
   d. Lift the LPM up and out of the OCS™ Lung Console.
2. Dispose of the entire LPM using your institution's protocol for handling and disposing of blood-contaminated materials.

6.11. Preparing the OCS™ Lung System for Storage

1. Disconnect the system from AC power.
2. Clean the system by following the instructions in the *TransMedics Technical User Guide: OCS™ Lung System*.
3. Reinstall the top cover.
4. Transport the system to the storage area and connect it to an AC outlet with the Wireless Monitor docked in its cradle, ensuring the power switch remains in the ON position and that the system is stored in Standby Mode.

6.12. Steps of Resetting the OCS™ Lung System

1. Set the power switch to the OFF position and wait for 10 seconds.
2. Set the power switch back to ON to restart the system. Within 60 seconds, the system will return to the last mode of operation prior the reset.
3. Switch the system back to Standby Mode using the Wireless Monitor while docked to the OCS™ Lung Console, by pressing the  button on the Wireless Monitor and following the instructions on the screen.

7. CHAPTER 7: CRITICAL SCENARIOS AND TROUBLESHOOTING

If any of the problems described in this chapter or other problems present themselves, please contact TransMedics at:

- US/AUS/Canada: +1 978-222-3733
- EUR: +31(0) 20-7084561

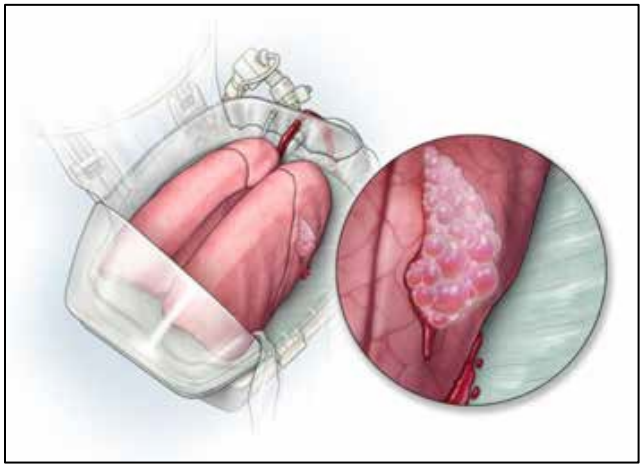
7.1. If PEEP Can Not Be Maintained During Preservation Mode

Refer to the screen shot in Figure 41.

Figure 41: Wireless Monitor Showing Unmaintained PEEP in Preservation Mode

1. Check for external air leaks and fix (e.g., opened Bronchoscope or MDI ports).
   a. Close and secure the cover on the Bronchoscope and MDI ports if were opened.
2. Check for tracheal leaks, including at the cannulation site, and correct as needed.
3. If source of air leak cannot be identified or corrected, suspect an internal air leak that could be seen as a bloody froth accumulating in the Lung Organ Chamber (Figure 42). Manage lungs as follows:
   a. Adjust PEEP to 5 cmH_2O if it was higher.
   b. Increase the Lung Preservation Gas flow rate to 500-700 ml/min and check for the delivered PEEP and the remaining gas time as displayed on the Monitor.
   c. Maintain Pump flow rate throughout the preservation session, including Monitoring Modes not higher than 1.5 L/min, to minimize perfusate leakage.
   d. Perform Continuous Monitoring at 1.5 L/min and not higher.

Figure 42: Lung Injury with Blood Froth



7.2. If Mean PAP, VR, and/or PAWP is Rising at Same Ventilation and Perfusion Settings, Manage as Follows:

- Ensure correct drainage of pulmonary veins.
- Look for a missed lung injury, fix, and manage accordingly.
- Lower the Pump flow rate to 1.5 L/min if it was higher.

8. APPENDIX A: SUMMARY OF OCS™ LUNG SYSTEM INSPIRE STUDY

8.1. Background

Lung transplantation is the mainstay of therapy for a variety of end-stage lung diseases such as pulmonary fibrosis, cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and primary pulmonary hypertension (PPH). Lung transplantation has seen significant advancements and innovation in all aspects of the surgical procedure and in pre- and post-operative clinical management of lung transplant recipients; however, donor lung preservation for transplantation has been limited to cold static storage. Cold storage of donor lungs for transplantation has many limitations that may negatively impact lung transplantation and its outcomes and limit the utilization of donor lungs. These limitations include: (1) severe time-dependent injury, which may increase the risk of primary graft dysfunction (PGD) and long-term morbidity/mortality; (2) the inability to assess organ viability; and (3) the inability to modulate organ condition.

The OCS™ Lung System is a portable organ perfusion, ventilation, and monitoring medical device intended to preserve donor lungs in a near physiologic, ventilated, and perfused state prior to transplantation. The OCS™ Lung System accomplishes this by performing 3 key functions:

- Reducing ischemic time through the use of warm, oxygenated blood-based perfusion.
- Modulating the lung condition by allowing ventilatory recruitment maneuvers and by perfusing the organ with high-oncotic perfusion solution supplemented with nutrients.
- Allowing for ex-vivo functional assessment of the donor lung during preservation and prior to transplant.

The safety and effectiveness of the OCS™ Lung System was evaluated in the INSPIRE Trial, the first prospective, randomized, controlled trial (RCT) to evaluate the potential impact of this ex-vivo lung perfusion (EVLP) technology on post-transplant clinical outcomes in standard criteria double lung transplantation.

The INSPIRE Trial was guided by an Investigator Steering Committee of academic international lung transplant surgeons, it incorporated an independent Data Safety Monitoring Board (DSMB), and it utilized an independent academic thoracic transplant expert as medical monitor for adjudication of adverse events and PGD grading.

The outcomes of the INSPIRE Trial demonstrated reasonable assurance of the safety and effectiveness of the OCS™ Lung System.

8.2. INSPIRE Trial Objectives and Design

The primary objective of the INSPIRE Trial was to compare the safety and effectiveness of the OCS™ Lung System with the current cold storage standard of care for the preservation of standard criteria donor lungs. The INSPIRE Trial was conducted in 21 academic lung transplant centers in the U.S., Europe, Australia, and Canada. The study was conducted over a 3-year period and follow-up data were collected from patients for 2 years post-lung transplantation with minimal missed follow-up.

The INSPIRE Trial was designed as a non-inferiority study and included a test for superiority only if non-inferiority was met.

Subjects were randomized to either the standard cold static organ preservation (Control) or to the OCS™ Lung System (OCS™).

8.3. Primary Effectiveness Endpoint

PGD[1] is a form of acute lung injury that is a known serious complication of lung transplantation. The most severe form (PGD3) has been shown to be correlated with poor short and long-term outcomes, including reduced survival and increased incidence of Bronchiolitis Obliterans Syndrome (BOS) (Huang, et al., 2008[2] and Daud, et al., 2007[3]).

The amended primary endpoint is a composite of patient survival at day 30 post-transplantation and PGD3 within 72 hours post-transplantation (i.e., T0, T24, T48, and T72). The initial primary endpoint was a composite of patient survival at day 30 post-transplantation and absence of PGD3 at 72 hours post-transplantation.

Evaluation of PGD3 within the entire initial 72 hours post-transplant allows for the assessment of the impact of the OCS™ Lung System in reducing donor lung preservation injury throughout the initial 72 hours after lung transplantation (i.e., T0, T24, T48 and T72). Evaluation of PGD3 at T72 provides an assessment of the impact of the OCS™ Lung System in reducing donor lung preservation injury at a single late timepoint after transplantation (i.e., T72).

8.4. Secondary Effectiveness Endpoints and Other Clinical Endpoints

The secondary effectiveness endpoints were:

- Incidence of ISHLT PGD3 at T72 hours post-lung transplantation
- Incidence of ISHLT PGD2 or 3 at T72 hours post-lung transplantation
- Patient survival at day 30.

Other clinical endpoints were:

- Duration of mechanical ventilation
- Duration of ICU and hospital stay
- Incidence of clinical diagnosis of BOS at 6, 12, and 24 months.

8.5. Safety Endpoint

The primary safety endpoint was the mean number of lung graft-related serious adverse events (LGRSAEs) through the 30 days post-transplantation per subject. A LGRSAE is defined as the occurrence of any of the following four categories of adverse events that are also serious. In calculating the primary safety endpoint, multiple occurrences of SAE of the same category on the same subject within 30 days is counted as one LGRSAE.

- Biopsy proven moderate to severe acute rejection
- Respiratory failure

[1] PGD was graded according to the ISHLT 2005 consensus statement (Christie, J.D., et al., J. Heart Lung Transplant., 24(10):1454-1459, 2015). See Appendix D for the details of the ISHLT Consensus Statement grading used in the INSPIRE Trial.
[2] Huang, et al., Am J. Transplant.; Vol. 8: pp.2454-2462, 2008.
[3] Daud, et al., Am. J. Respir. Crit. Care Med. Vol 175, pp.507-513, 2007.

- Bronchial anastomotic complication
- Major pulmonary-related infection.

8.6. Adjunct Effectiveness Analyses

- **Composite of in-hospital and 30-day survival and freedom from PGD3 within the initial 72 hours:** Although the primary endpoint composite included survival at day 30, the evaluation of survival at initial hospital discharge post-transplantation (if longer than 30 days) was also collected. Assessing survival through initial transplant hospital discharge, even if longer than 30 days, captures patients who never recovered following their transplantation surgery and died in hospital. TransMedics performed a post-hoc adjunct composite effectiveness endpoint analysis that evaluated survival throughout 30 days and initial hospital discharge and absence of PGD3 within the first 72 hours post-transplantation.
- **Composite of in-hospital and 30-day survival and freedom from PGD3 at 72 hours:** TransMedics performed an additional post-hoc adjunct composite effectiveness endpoint analysis that evaluated survival throughout 30 days and initial hospital discharge and absence of PGD3 at a single timepoint, 72 hours post-transplantation.
- **OCS Solution Subgroup Analysis:** The initial INSPIRE Trial IDE permitted the use of either OCS™ Lung Solution or a commercially available solution, and the OCS Arm includes data from subjects perfused with both solutions. However, only the OCS™ Lung Solution is approved for use with its OCS™ Lung System. The data from the OCS Solution Subgroup (i.e., only subjects perfused with the OCS™ Lung Solution) are presented as an adjunct post-hoc analysis.

8.7. Study Population

Subjects were lung transplant recipients who met inclusion/exclusion criteria as outlined below. Inclusion/exclusion criteria were also defined for the donor organs as described below.

8.7.1. Inclusion Criteria

- Donor Inclusion Criteria
  - Age < 65 years old
  - Normal gas exchange, i.e., $PaO_2/FiO_2 \geq 300$, at the time of final acceptance of donor lungs
  - No active primary pulmonary disease
  - Donor lungs suitable for preservation with either OCS™ or Standard of Care.
- Recipient Inclusion Criteria:
  - Registered male or female primary double-lung transplant candidate
  - Age ≥ 18 years old
  - Signed: 1) written informed consent document and 2) authorization to use and disclose protected health information.

8.7.2. Exclusion Criteria

- Donor Exclusion Criteria
  - Positive serology for Hepatitis B, Hepatitis C, or HIV
  - Presence of moderate to severe traumatic lung injury presenting as moderate or massive pneumothorax, hemothorax or lung contusion as evidenced by chest X-ray, CT-Scan, visual inspection or bronchoscopy
  - Presence of confirmed active pneumonia.
- Recipient Exclusion Criteria
  - Prior solid organ or bone marrow transplant
  - Single lung recipient
  - Multiple organ transplant recipient
  - Chronic use of hemodialysis or diagnosis of chronic renal insufficiency.

8.8. Study Treatments

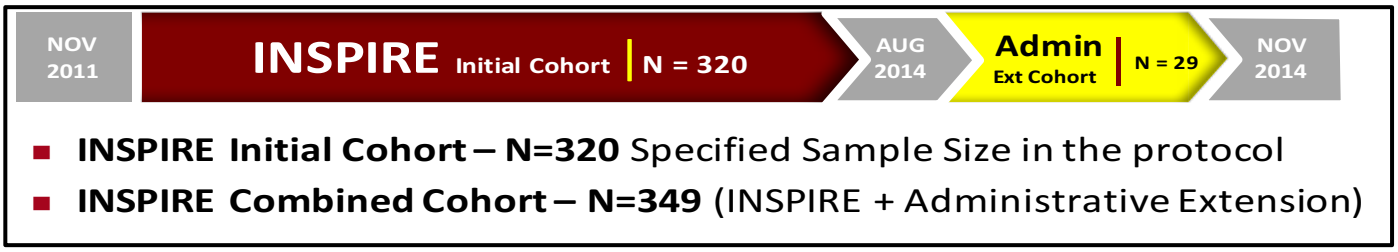
The donor organs in the OCS Arm were perfused with the OCS™ Lung System. The Control Arm utilized an FDA-cleared, commercially available low potassium dextran (LPD) solution for lung flushing and preservation in cold storage. The LPD solution was used according to its instructions for use.

Follow-up data collection was conducted through the initial 7 days, hospital discharge, 30 days, and 6 months post-transplant, with additional long-term data collection at 12 and 24 months.

8.9. Trial Enrollment and Analysis Populations

The OCS™ Lung System requires the use of a high-oncotic perfusion solution supplemented with matched packed red blood cells (pRBCs) as part of the perfusate. The initial INSPIRE Trial IDE was approved to allow for either OCS™ Lung Solution or a commercially available LPD solution. However, during the course of the INSPIRE Trial, TransMedics experienced a shortage of the OCS™ Lung Solution as it was transitioning from one contract manufacturer to another. During this time, many of the INSPIRE investigational sites used LPD solution for OCS™ Lung System perfusion. TransMedics requested an administrative extension to enroll additional patients beyond the pre-specified total sample size for the INSPIRE Trial to avoid trial stoppage. FDA granted the extension, and an additional N=29 subjects were transplanted in an “Administrative Extension.” The INSPIRE Initial trial Cohort plus the Administrative Extension comprises the INSPIRE Combined Cohort (N=349). Figure 43 below shows the timeline for the two cohorts of the INSPIRE Trial patients. For simplicity, the data are presented for the INSPIRE Combined Cohort. Data for the OCS Solution subgroup are an important adjunctive analysis to consider, since it is the product approved by FDA. Results for the OCS Solution subgroup (only subjects perfused with the OCS™ Lung Solution that is approved for use with the OCS™ Lung System) are presented in Section 8.22. Results for the INSPIRE Initial Cohort (N=320), i.e. the first 320 subjects enrolled in the study, are presented in Section 8.23.

Figure 43: INSPIRE Enrollment Timeline & Trial Cohorts Definitions



There were 3 key analysis populations pre-specified in the INSPIRE Trial as described below.

- **Per-Protocol (PP)**: This population consists of all randomized patients who are transplanted and have no major protocol violations and for whom the eligible donor lung received the complete preservation procedure as per the randomization assignment.
- **Modified Intention-to-Treat (mITT):** This population consists of all randomized patients for whom a matching donor lung has been harvested and determined to be eligible for preservation with either OCS or Control before any attempt has been made to preserve the lung with either OCS or Control.
- **Safety Population (SP)**: This population consists of all patients who were transplanted in the trial with an eligible donor lung that had been preserved with OCS or Control, except for patients randomized to OCS who, due to a decision of the treatment team, were switched to standard therapy (cold storage) before OCS treatment was initiated. The SP is the primary analysis population for safety in the INSPIRE Trial.

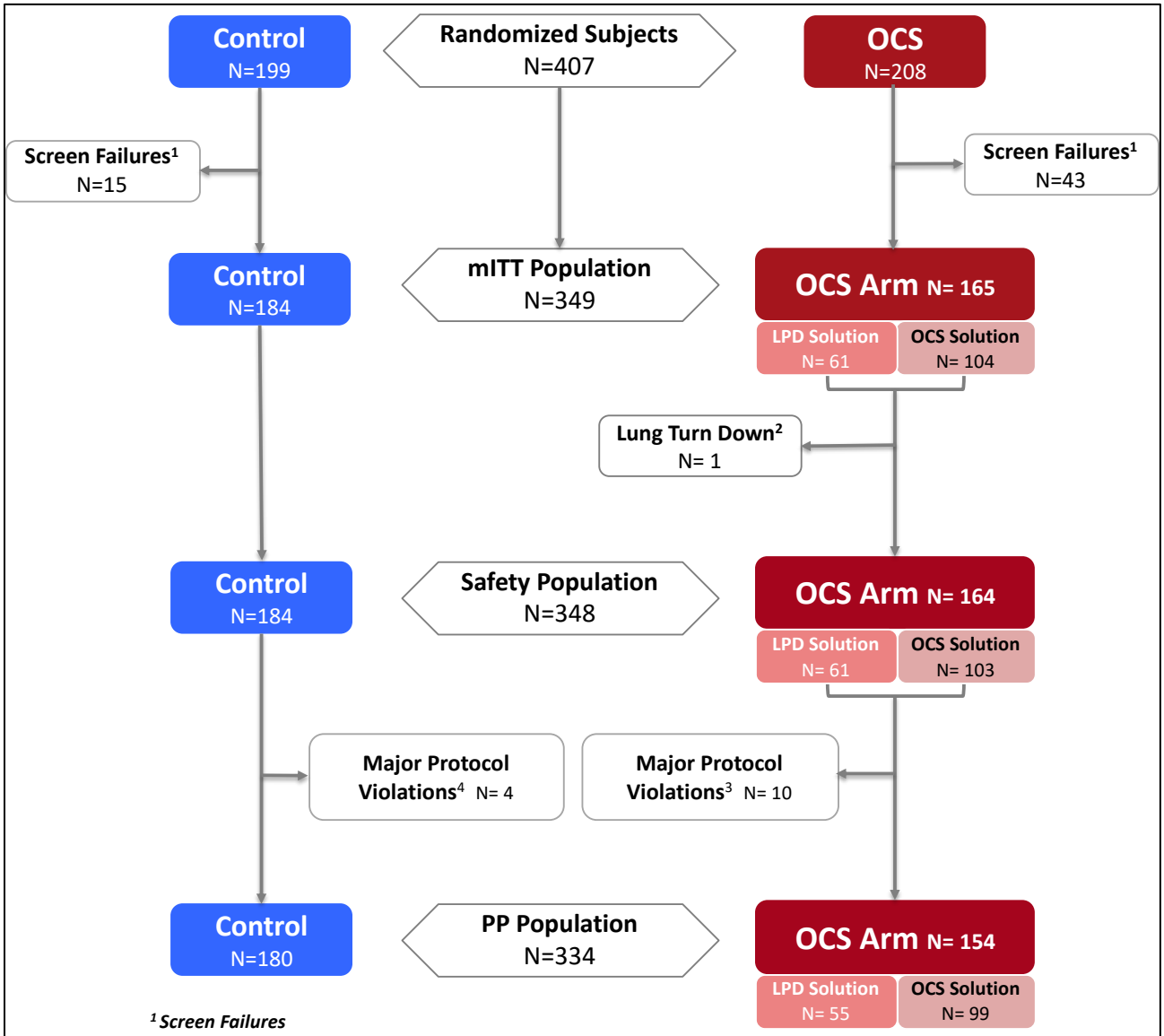
Table 9 below summarizes the number of patients in each analysis population for the INSPIRE Combined Cohort, INSPIRE Initial Cohort, and OCS Solution subgroup.

Table 9: Number of Patients per Analysis Population

	mITT Population	Safety Population	PP Population
INSPIRE Combined Cohort	349	348	334
INSPIRE Initial Cohort	320	319	306
OCS Lung Solution Subgroup	104	103	99

The subject consort diagram is shown in Figure 44 below.

Figure 44: INSPIRE Trial Enrollment Detailed Consort Diagram



[1] ***Screen Failures***
Donor screen failure = 41 (31 OCS, 10 Control)
Recipient screen failure = 6 (2 OCS, 4 Control)
Logistics screen failure =11 (10 OCS, 1 Control)

[2] ***Turn down N=1 (OCS Solution):*** Pump flow was set higher than recommended by user and the filter assembly in OCS reservoir was not able to clear the fluid at high flow resulting in compromised flow to PA. Donor lungs were turned down due to clinical concern of potential air embolism and warm ischemia.

[3] ***Major Protocol Violations*** N=14 (10 OCS, 4 Control)

8.10. Demographic and Baseline Information

Recipient characteristics are shown in Table 10 below. The two groups were similar in all categories and where small differences were observed, the recipients tended to have more risk factors in the OCS Arm than Control; e.g., the mean LAS Score was 51 in the OCS Arm compared to 48 in Control, the prevalence of secondary pulmonary hypertension was 40% in OCS compared to 32% in Control, and the OCS Arm also had 8.5% of patients who were diagnosed with idiopathic pulmonary arterial hypertension compared to 4.3% for Control.

Table 10: Recipient Demographic and Baseline Characteristics (mITT Population, N=349. INSPIRE Combined Cohort)

Parameter	Control (N=184)	OCS Arm (N=165)	OCS Solution Subgroup (N=104)
Age (years)			
N	184	165	104
Mean ± SD	50.34 ± 13.43	50.45 ± 12.82	49.63 ± 13.21
Median	55.0	54.0	52.5
Minimum - Maximum	18.0 - 72.0	18.0 - 72.0	18.0 - 71.0
Gender			
Female	35.9% (66/184)	47.9% (79/165)	51.0% (53/104)
Male	64.1% (118/184)	52.1% (86/165)	49.0% (51/104)
Ethnicity			
Hispanic or Latino	9.2% (17/184)	13.3% (22/165)	12.5% (13/104)
Not Hispanic or Latino	70.7% (130/184)	66.7% (110/165)	68.3% (71/104)
Not Applicable	20.1% (37/184)	20.0% (33/165)	19.2% (20/104)
Race			
American Indian or Alaskan Native	0.0% (0/183)	0.0% (0/162)	0.0% (0/102)
Asian	1.6% (3/183)	1.9% (3/162)	1.0% (1/102)
Black or African American	2.7% (5/183)	4.3% (7/162)	4.9% (5/102)
Hispanic	3.3% (6/183)	7.4% (12/162)	5.9% (6/102)
Native Hawaiian or Other Pacific Islander	0.5% (1/183)	0.0% (0/162)	0.0% (0/102)
White	88.0% (161/183)	84.6% (137/162)	87.3% (89/102)
Other	3.8% (7/183)	1.9% (3/162)	1.0% (1/102)
Weight (kg)			
N	184	165	104
Mean ± SD	68.78 ± 15.30	67.13 ± 16.65	65.20 ± 17.35
Median	68.0	66.0	63.0
Minimum - Maximum	37.0 - 112.5	32.0 - 128.0	32.0 - 128.0

Parameter	Control (N=184)	OCS Arm (N=165)	OCS Solution Subgroup (N=104)
Type of Status			
Urgent	84.3% (43/51)	82.7% (43/52)	82.4% (28/34)
High-Urgent	15.7% (8/51)	17.3% (9/52)	17.6% (6/34)
Lung Allocation Score			
N	125	107	66
Mean ± SD	47.57 ± 18.34	50.54 ± 20.10	48.32 ± 17.75
Median	40.0	41.0	40.0
Minimum - Maximum	29.095.0	29.0 - 95.0	31.0 - 94.0
Primary Cause of Lung Failure			
Chronic Obstructive Pulmonary Disease	28.8% (53/184)	28.5% (47/165)	29.8% (31/104)
Cystic Fibrosis	23.4% (43/184)	20.6% (34/165)	23.1% (24/104)
Idiopathic Pulmonary Arterial Hypertension	4.3% (8/184)	8.5% (14/165)	9.6% (10/104)
Bronchiectasis	4.9% (9/184)	4.8% (8/165)	4.8% (5/104)
Idiopathic Pulmonary Fibrosis	34.8% (64/184)	35.2% (58/165)	32.7% (34/104)
Sarcoidosis	4.9% (9/184)	2.4% (4/165)	1.9% (2/104)
Other	3.3% (6/184)	4.8% (8/165)	2.9% (3/104)
Additional Risk Factors			
Diagnosis of Secondary Pulmonary Hypertension	32.2% (59/183)	40.2% (66/164)	39.8% (41/103)
Diagnosis of Heart Failure	7.2% (13/180)	8.5% (14/164)	11.7% (12/103)

Donor demographic baseline characteristics and risk factors are shown in Table 11 below. The donor characteristics were generally similar between the arms, although there was a trend towards slightly more males than females in the Control group. Also, the OCS group had a higher percentage of abnormal findings on final physical examination of the donor lungs prior to retrieval and a higher percentage of surgical complications during retrieval prior to preservation (e.g., adhesions tears, COPD blebs resections).

Table 11: Donor Demographic and Baseline Characteristics (mITT Population, N =349, INSPIRE Combined Cohort)

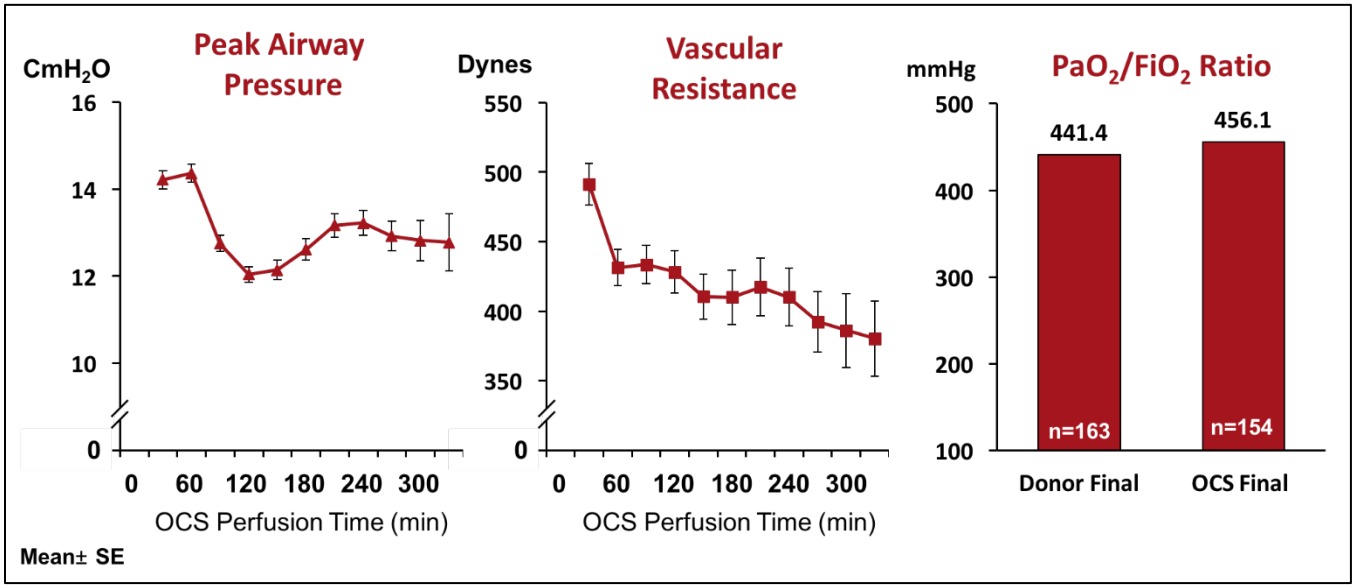
Parameter	Control (N=184)	OCS Arm (N=165)	OCS Solution Subgroup (N=104)
Donor Age (years)	n=183	n=163	n=103
Mean ± SD	40.15 ± 13.70	41.52 ± 14.40	41.00 ± 14.53
Median	42.0	44.0	43.0
Min.-Max.	14.0 - 63.0	13.0 - 64.0	13.0 - 63.0
Gender	n=184	N=165	N=104
Female	39.7% (73/184)	47.3% (78/165)	51.0% (53/104)
Male	60.3% (111/184)	52.7% (87/165)	49.0% (51/104)
Donor Final PaO_2/FiO_2 Ratio	n=184	n=163	n=103
Mean ± SD	431.73 ± 73.34	441.37 ± 78.89	445.83 ± 78.61
Median	427.1	435.0	443.1
Min.-Max.	301.0 - 642.0	304.0 - 689.0	315.0 - 689.0
Abnormal Findings on Physical Examination of Donor Lungs Prior to Retrieval	25.5% (47/184)	36.4% (60/165)	41.3% (43/104)
Any Surgical Complications/Tears during Retrieval?	1.4% (2/148)	6.0% (9/151)	6.3% (6/95)
Cigarette use (>20 pack years) Continued in Last 6 months	n=183	n=165	n=104
Yes	17.5% (32/183)	18.3%(30/164)	18.3% (19/104)
No	71.6% (131/183)	69.5% (114/164)	71.2% (74/104)
Unknown	10.9% (20/183)	12.2% (20/164)	10.6% (11/104)

8.11. Donor Lung Preservation Characteristics

8.11.1. Donor Lung Preservation Characteristics on OCS™ Lung System

During OCS™ lung perfusion, vascular resistance and airway pressures are monitored to assess the stability of perfusion conditions. In addition, the OCS™ Lung System enables assessment of lung oxygenation capacity during preservation using blood gas measurement through an external blood gas analyzer. Figure 45 below demonstrates the OCS™ lung perfusion parameters and oxygenation capacity measured by the standard PaO_2/FiO_2 ratio at end of OCS™ preservation and compared to final PaO_2/FiO_2 ratio at time of retrieval for donor lungs preserved using OCS™.

Figure 45: OCS™ Lung Perfusion Parameters and PF Ratio for OCS Arm



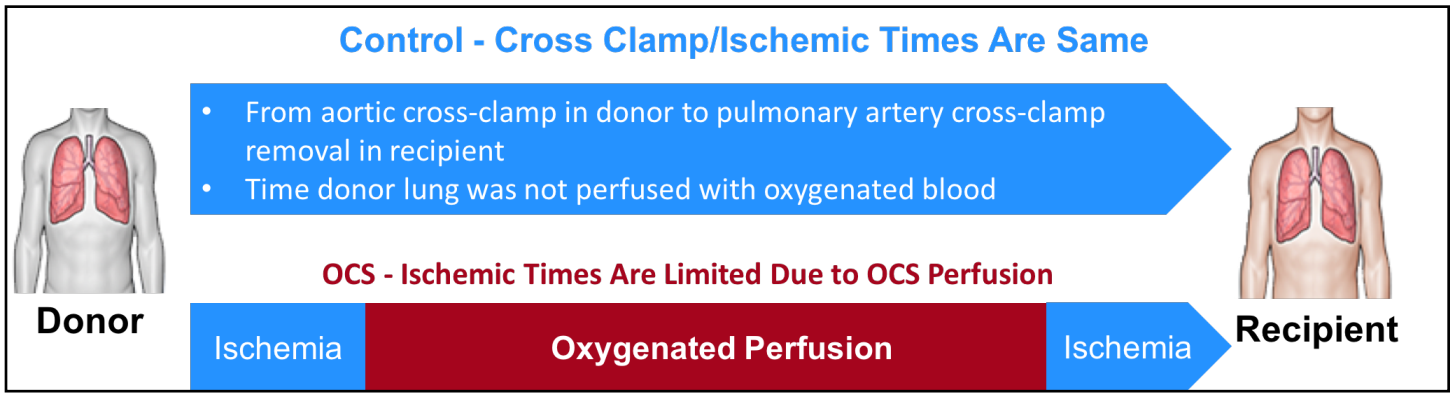
8.11.2. Total Cross Clamp and Ischemic Times

In the Control cold storage preservation arm, the donor lungs are ischemic from the time they are removed from the donor body until the release of the cross clamp in the recipient. Thus, the total cross clamp time and ischemic times are identical.

In the OCS Arm, the donor lung is perfused with oxygenated blood perfusate and ischemic times are limited to small windows of time during donor procurement and during surgical re-implantation into the recipient. Thus, the ischemic time is different from the total cross clamp time in the OCS Arm.

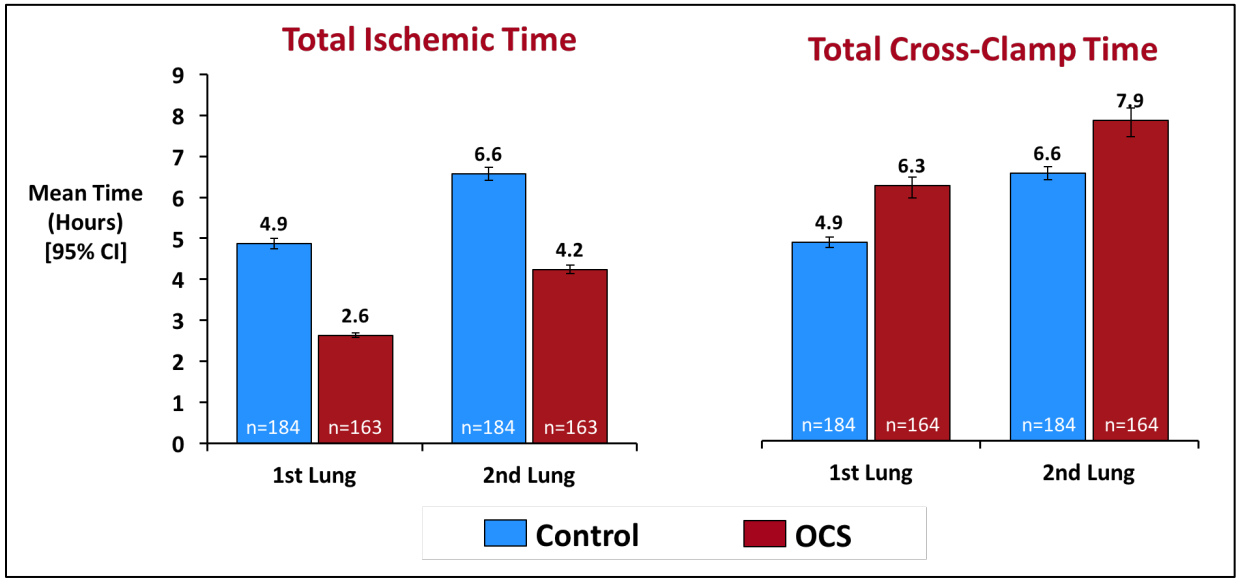
See Figure 46 below.

Figure 46: OCS™ Lung Perfusion Impact on Ischemia Time During Lung Transplantation



The OCS™ Lung System reduced ischemic time for the donor lungs by an average of 2+ hours compared to Cold Storage, despite longer cross-clamp time. See Figure 47 below.

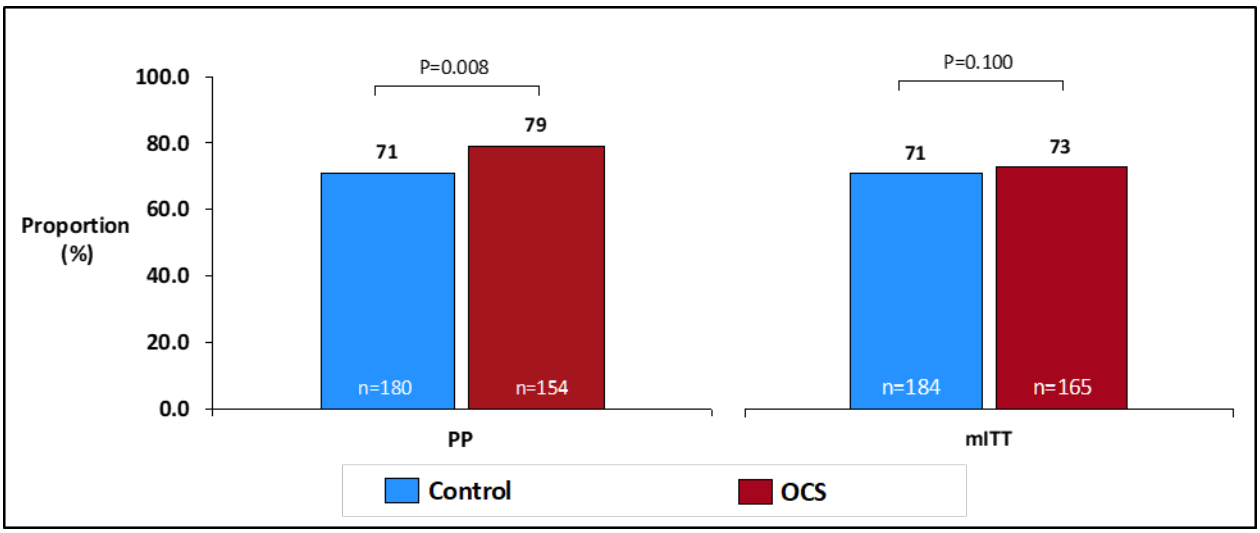
Figure 47: Total Cross Clamp and Ischemic Times on Transplanted Lungs (mITT Population)



8.12. Primary Effectiveness Endpoint

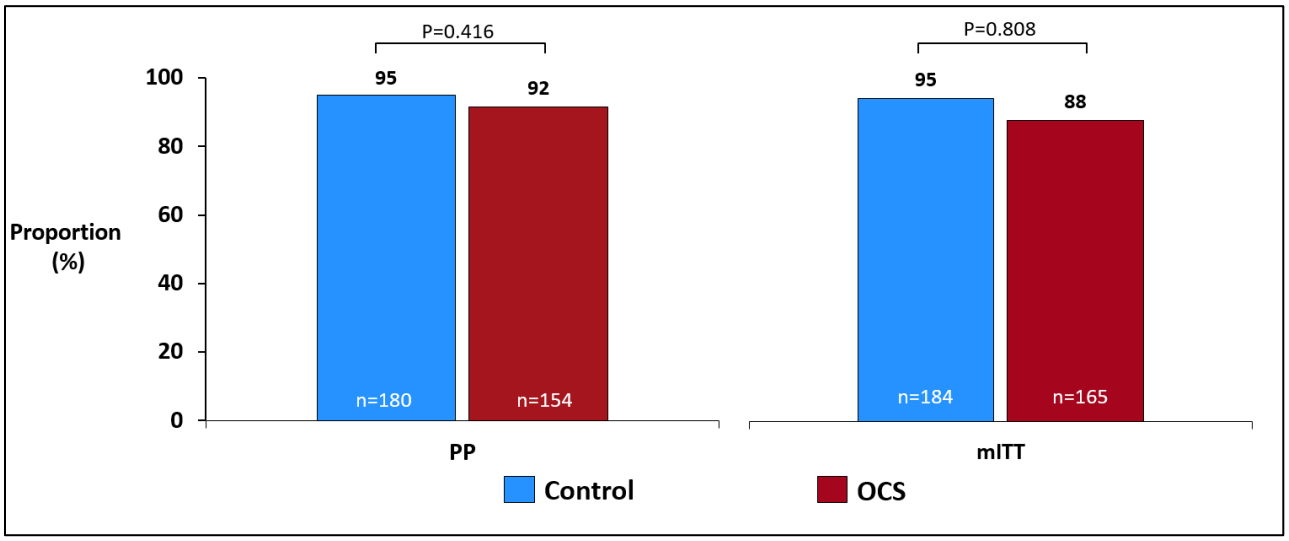
The INSPIRE Trial amended primary effectiveness endpoint assessed the impact of the OCS™ Lung System on 30-day patient survival and incidence of PGD3 within 72 hours post-transplantation. Based on the 4% non-inferiority margin, the primary endpoint was met in the PP population but was not met in the mITT population, despite the OCS Arm showing higher point estimates. See Figure 48 below.

Figure 48: Results for INSPIRE Trial Amended Primary Effectiveness Endpoint (Survival at 30 Days and Freedom from PGD3 Within 72 Hours Post-Transplant), INSPIRE Combined Cohort



The results for the initial primary effectiveness endpoint of survival at day 30 and freedom from PGD3 at the last timepoint of T72 hours are shown in Figure 49 below. Non-inferiority was not shown in the mITT or PP populations.

Figure 49: Results for INSPIRE Trial Initial Primary Effectiveness Endpoint: Survival at Day 30 Post-Transplantation and Absence of ISHLT PGD3 at 72 Hours, INSPIRE Combined Cohort



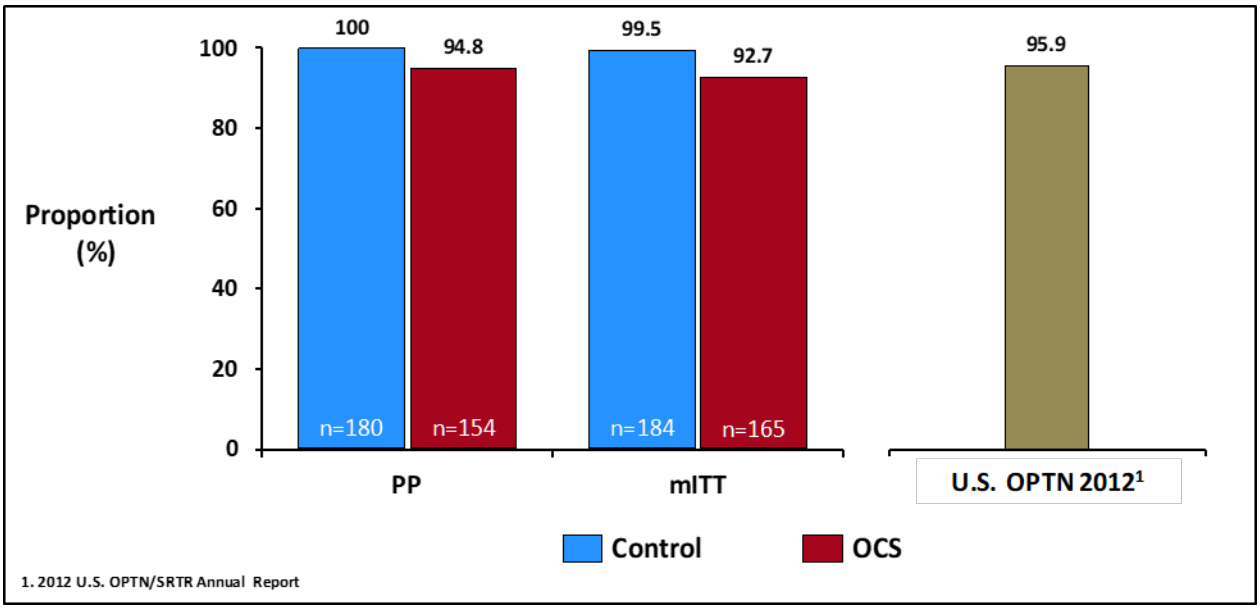
8.13. Survival Component of Primary Composite Endpoint- Survival at Day 30

Figure 50 below shows the results for a component of the composite primary endpoint, i.e., patient survival at day 30 post-transplantation. Patient survival at day 30 was lower in the OCS Arm in comparison to Control. There were 11 deaths in the OCS group and 1 death in the Control group within 30 days in the Combined Cohort. Of the 11 deaths in the OCS Arm, 6 were due to cardiac or vascular causes adjudicated as unrelated to the lung graft, 4 were lung graft failure or infection, and one was due to generalized sepsis adjud1icated as unrelated to the lung graft. The death in the Control group was due to metabolic coma. Note that the U.S. average 30-day all-cause mortality reported for lung transplant recipients in the 2012 OPTN/SRTR annual report was 4.1% [OPTN/SRTR 2014[4]].

The survival throughout transplant hospital admission, even if longer than 30 days, was similar between the two groups. Please see Section 8.21.1 for an adjunctive analysis on survival through initial hospital stay.

[4] OPTN/SRTR 2012 Annual Report. Am. J. Transplant. 2014 15(51):1-192.

Figure 50: 30-Day Patient Survival, INSPIRE Combined Cohort

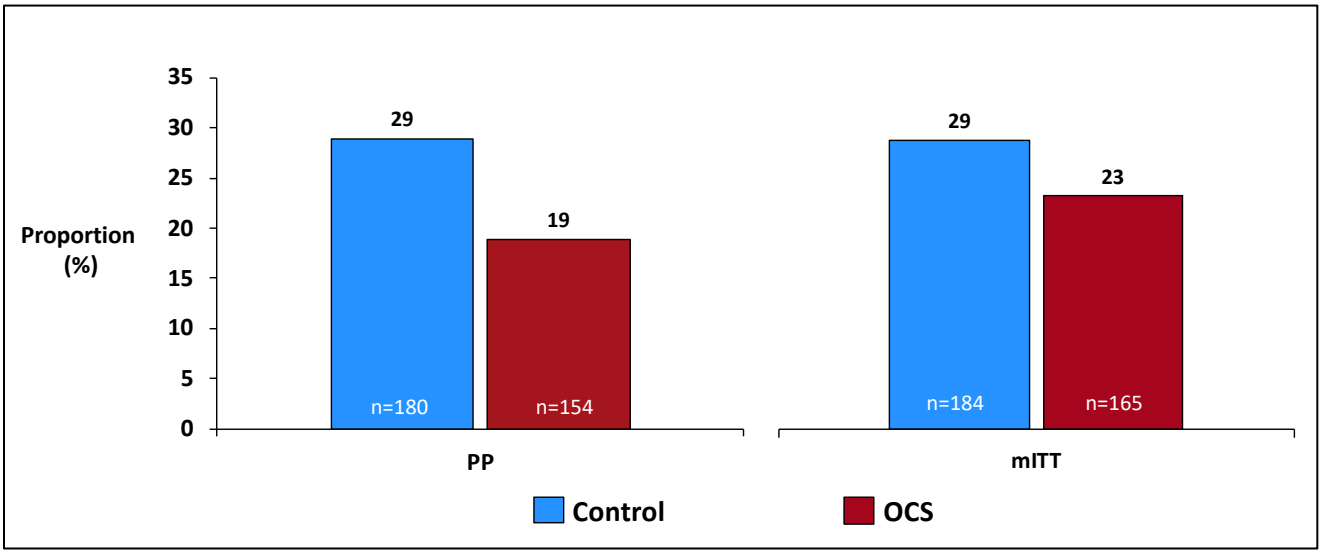


8.14. PGD3 Component of The Primary Composite Endpoint – PGD3 within 72 Hours and PGD3 at T72:

Figure 51 below provides the results for the other component of the amended composite primary endpoint, i.e., the incidence of PGD3 within the initial 72 hours post-transplantation.

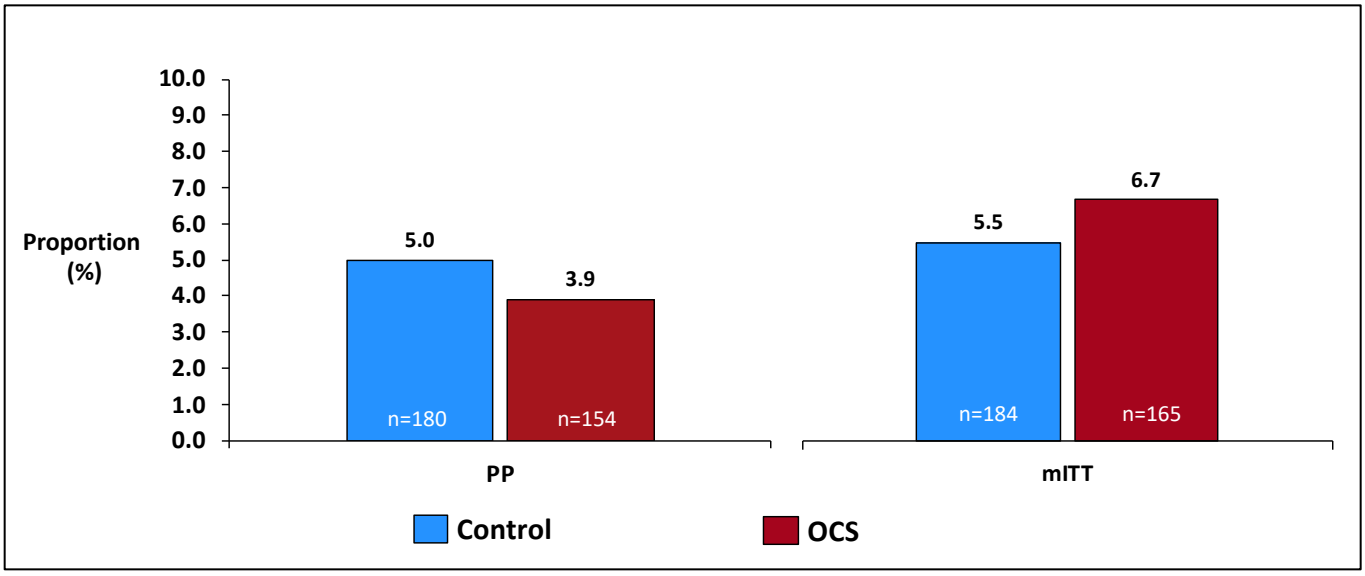
The OCS Arm was shown to reduce the incidence of PGD3 within the initial 72 hours as compared to the Control Arm in the PP population and mITT populations. The highest reduction in PGD3 occurred at T0 and that there was no difference in PGD3 at the latest timepoint of T72 between the OCS and Control groups.

Figure 51: Incidence of PGD3 within 72 hours (INSPIRE Combined Cohort - PP Population and mITT population)



The results for the other component of the initial primary composite endpoint, PGD3 at T72, are shown in Figure 52 below. The incidence of PGD3 at T72 hours was similar between both groups and was low overall.

Figure 52: Incidence of PGD3 at T72 hours (INSPIRE Combined Cohort - PP Population and mITT population)



8.15. Secondary Endpoints

The results for the secondary endpoints for the PP and mITT populations are shown in Table 12 and Table 13, respectively. The analysis of the secondary endpoints was performed using the fixed sequence testing procedure with endpoints tested in order. Statistical testing for non-inferiority was performed for a given secondary endpoint only if non-inferiority was demonstrated for the previous secondary endpoints.

The incidence of PGD2 or PGD3 at T72 hours was similar between both groups. The non-inferiority test was not achieved in either the PP or the mITT analyses for this parameter. Survival at 30 days and PGD3 at T72 were also secondary endpoints; these results have been previously presented and are also listed below.

Table 12: Secondary Effectiveness Endpoints, PP Population, INSPIRE Combined Cohort

Parameter	Control (N=180)	OCS Arm (N=154)
Incidence of PGD3 at 72 hours post-transplantation		
Proportion (π) (%) (n/N)[1]	5.0% (9/179)	3.9% (6/154)
95% CI for Proportion[2]	(2.3%, 9.3%)	(1.4%, 8.3%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		-1.1% (-∞, 2.6%)
p-value of non-Inferiority test[4]		0.0033
Incidence of PGD2 or PGD3 at 72 hours post-transplantation		
Proportion (π) (%) (n/N)[1]	10.6% (19/179)	13.0% (20/154)
95% CI for Proportion[2]	(6.5%, 16.1%)	(8.1%, 19.3%)

Parameter	Control (N=180)	OCS Arm (N=154)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		2.4% (-∞, 8.2%)
p-value of non-Inferiority test[4]		0.0746
Patient survival at day 30 post-transplantation		
Proportion (π) (%) (n/N)[1]	100.0% (180/180)	94.8% (146/154)
	(98.0%, 100.0%)	(90.0%, 97.7%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		5.2% (-∞, 8.1%)
p-value of non-Inferiority test[4]		N/A

[1]π = n/N *100% = simple proportion. [2]The 95% confidence interval was calculated based on the Clopper-Pearson method. [3]The 95% upper confidence limit is for the difference between the two population proportions (π_{ocs}-$\pi_{Control}$) for secondary endpoints 1 and 2. [4]The p-value is based on Wald Method. The non-inferiority margin is 5%, 7.5% and 4% for secondary endpoint 1, 2, and 3, respectively. N/A – Not applicable.

Table 13: Secondary Effectiveness Endpoints, mITT Population, INSPIRE Combined Cohort

Parameter	Control (N=184)	OCS Arm (N=165)
Incidence of PGD3 at 72 hours post-transplantation		
Proportion (π) (%) (n/N)[1]	5.5% (10/183)	6.7% (11/164)
95% CI for Proportion[2]	(2.7%, 9.8%)	(3.4%, 11.7%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		1.2% (-∞, 5.5%)
p-value of non-Inferiority test[4]		0.0724
Incidence of ISHLT PGD2 or PGD3 at 72 hours post-transplantation		
Proportion (π) (%) (n/N)[1]	10.9% (20/183)	16.5% (27/164)
95% CI for Proportion[2]	(6.8%, 16.4%)	(11.1%, 23.0%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		5.5% (-∞, 11.6%)
p-value of non-Inferiority test[4]		N/A
Patient survival at day 30 post-transplantation		
Proportion (π) (%) (n/N)[1]	99.5% (183/184)	92.7% (153/165)
95% CI for Proportion[2]	(97.0%, 100.0%)	(87.6%, 96.2%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		6.7% (-∞, 10.2%)
p-value of non-Inferiority test[4]		N/A

[1]π = n/N *100% = simple proportion. [2]The 95% confidence interval was calculated based on the Clopper-Pearson method. [3]The 95% upper confidence limit is for the difference between the two population proportions (π_{ocs}-$\pi_{Control}$) for secondary endpoints 1 and 2. [4]The p-value is based on Wald Method. The non-inferiority margin is 5%, 7.5% and 4% for secondary endpoint 1, 2, and 3, respectively. N/A – Not applicable.

8.16. Safety Endpoint

The results for the safety endpoint (i.e., the average number of LGRSAEs through 30 days post-transplant) for the Combined Cohort Safety Population are shown in Table 14 below. The safety endpoint was met, providing evidence for the safety of the OCS™ Lung System for the proposed use.

Table 14: Safety Endpoint Analysis – (Average Number of LGRSAEs through the 30 days post-transplantation per patient) in INSPIRE Combined Cohort Safety Population

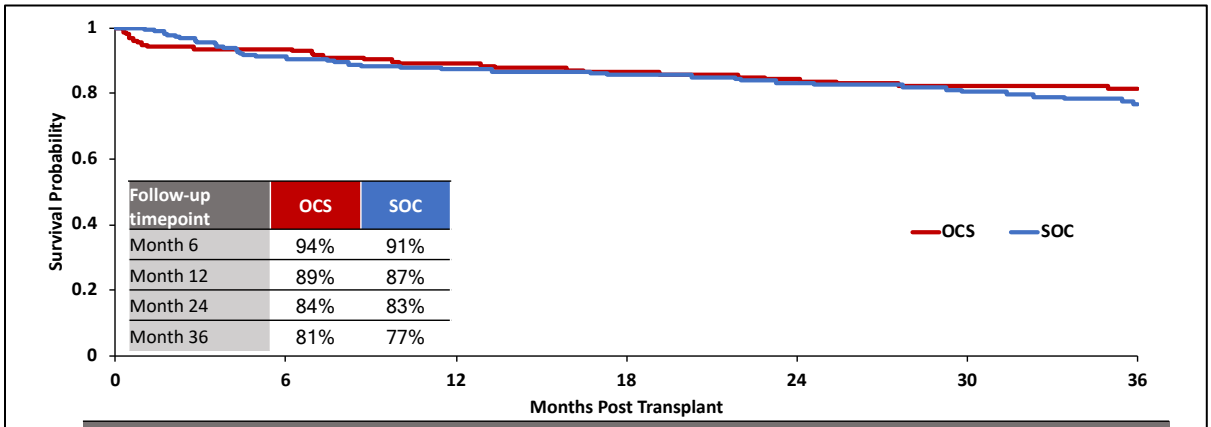
INSPIRE Combined Cohort (n=349)	Control N=184	OCS N=164
Lung-graft related SAEs, n (%)	45 (24.5)	40 (24.4)
Mean ± SD	0.29 ± 0.54	0.26 ± 0.48
Non-Inferiority p-value		0.042
Type of Lung-graft related SAEs, n (%)		
Acute Rejection	4 (2)	2 (1)
Respiratory Failure*	16 (9)	23 (14)
Bronchial Anastomotic Complication	4 (2)	0
Major Pulmonary-Related Infection	29 (16)	18 (11)

* Need for re-intubation, tracheostomy or the inability to discontinue ventilator support within 4 days post-transplant

8.17. Long-Term Survival

Figure 53 and Figure 54 below demonstrate the results of the Kaplan-Meier (K-M) survival analyses through 36 months for the PP and mITT populations, respectively. The long-term survival of the OCS and Control Arms was similar at 36 months of follow-up.

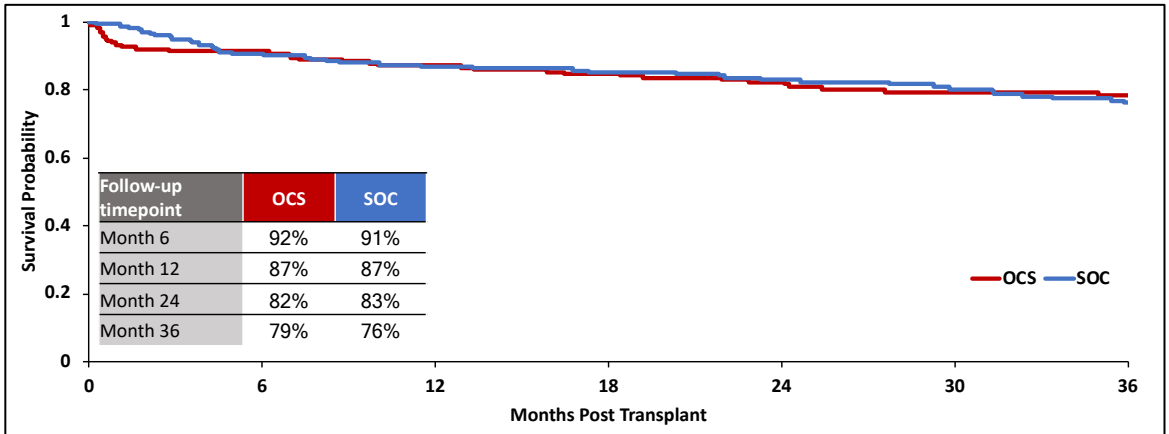
Figure 53: K-M Survival for OCS and Control Groups at 36 Months (INSPIRE Combined Cohort PP)



Follow-up timepoint	OCS	SOC
Month 6	94%	91%
Month 12	89%	87%
Month 24	84%	83%
Month 36	81%	77%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
OCS – Patients at Risk	154	144	137	129	97
Patients Censored **Patients Died**	--	0 10	0 17	1 24	29 28
Control – Standard of Care (SOC) – Patients at Risk	180	164	157	150	105
Patients Censored **Patients Died**	--	0 16	0 23	0 30	36 39

Figure 54: K-M Survival for OCS and Control Groups at 36 Months (INSPIRE Combined Cohort mITT)



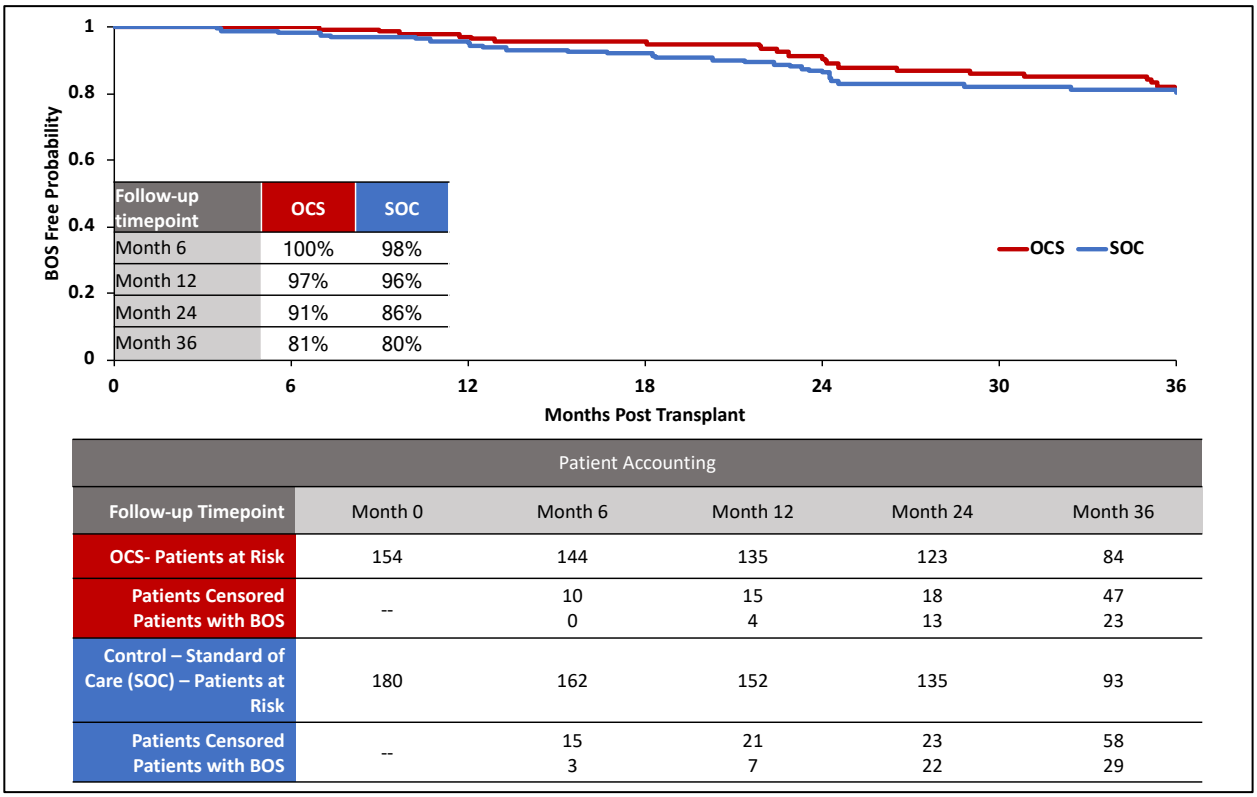
Follow-up timepoint	OCS	SOC
Month 6	92%	91%
Month 12	87%	87%
Month 24	82%	83%
Month 36	79%	76%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
OCS – Patients at Risk	165	151	144	135	100
Patients Censored **Patients Died**	--	0 14	0 21	1 29	31 34
Control – Standard of Care (SOC) – Patients at Risk	184	167	160	153	107
Patients Censored **Patients Died**	--	0 17	0 24	0 31	36 41

8.18. Freedom from BOS through 36 months

The results for patients who were free from BOS were generally similar for both groups. The point estimates for the OCS™ Lung System showed slightly higher freedom from BOS at 36 months after transplantation compared to the cold storage standard of care. These results are shown in Figure 55 and Figure 56 below for the PP and mITT populations, respectively. BOS is a chronic condition that develops between 2 and 5 years following lung transplantation. TransMedics will continue to evaluate this trend for 5 years post-transplant in our post-market study.

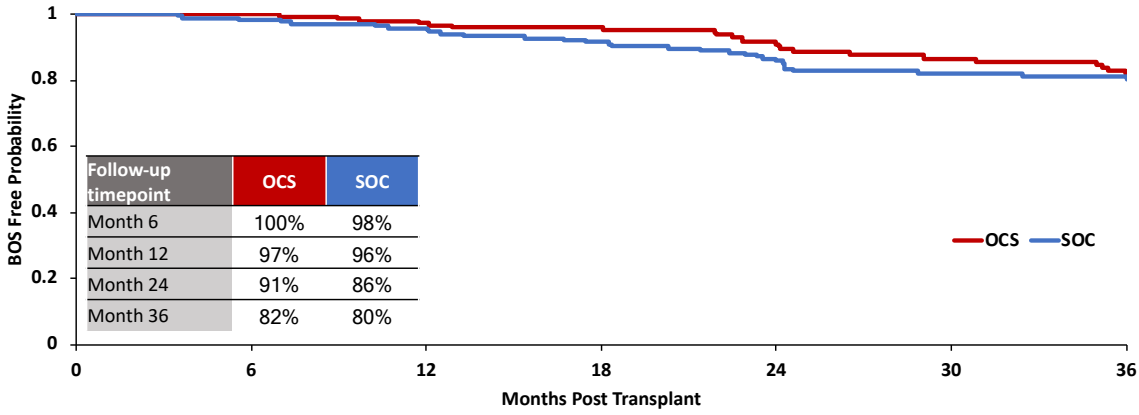
Figure 55: BOS Free Probability through 24 Months (INSPIRE Combined Cohort PP)



Follow-up timepoint	OCS	SOC
Month 6	100%	98%
Month 12	97%	96%
Month 24	91%	86%
Month 36	81%	80%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
OCS- Patients at Risk	154	144	135	123	84
Patients Censored **Patients with BOS**	--	10 0	15 4	18 13	47 23
Control – Standard of Care (SOC) – Patients at Risk	180	162	152	135	93
Patients Censored **Patients with BOS**	--	15 3	21 7	23 22	58 29

Figure 56: BOS Free Probability through 36 Months (INSPIRE Combined Cohort mITT)



Follow-up timepoint	OCS	SOC
Month 6	100%	98%
Month 12	97%	96%
Month 24	91%	86%
Month 36	82%	80%

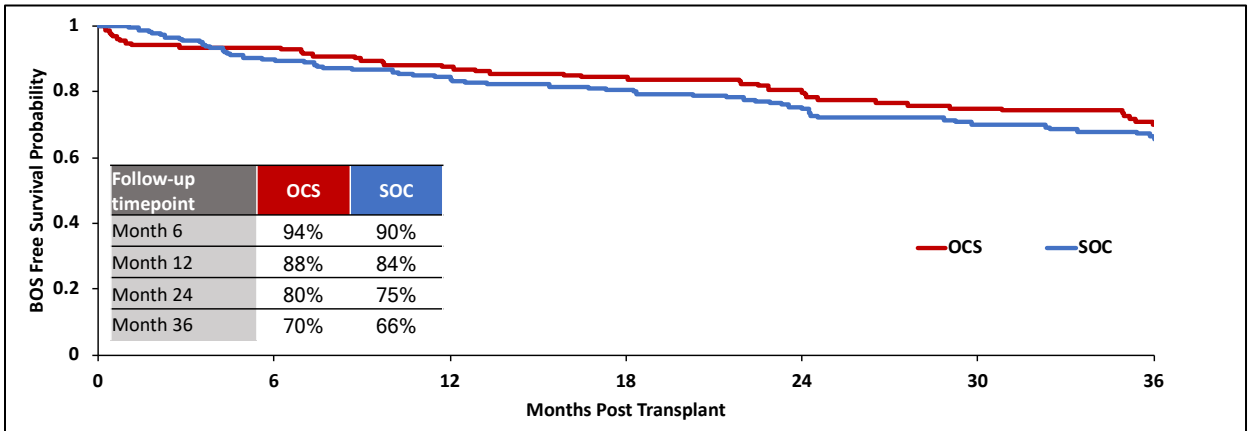
Patient Accounting

Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
OCS – Patients at Risk	165	151	142	129	87
Patients Censored Patients with BOS	--	14 0	19 4	23 13	55 23
Control – Standard of Care (SOC) – Patients at Risk	184	165	155	137	95
Patients Censored Patients with BOS	--	16 3	22 7	24 23	59 30

8.19. BOS-free Survival through 36 Months

BOS is the most common long-term complication after lung transplantation and is the leading cause of long-term graft failure. The results for patients who survived and were free from BOS were generally similar for both groups. The point estimates for the OCS™ Lung System showed slightly higher BOS-free survival at 36 months after transplantation compared to the cold storage standard of care. These results for the PP and mITT populations are shown in Figure 57 and Figure 58, respectively. BOS is a chronic condition that develops between 2 and 5 years following lung transplantation. TransMedics will continue to evaluate this trend for 5 years post-transplant in our post-market study.

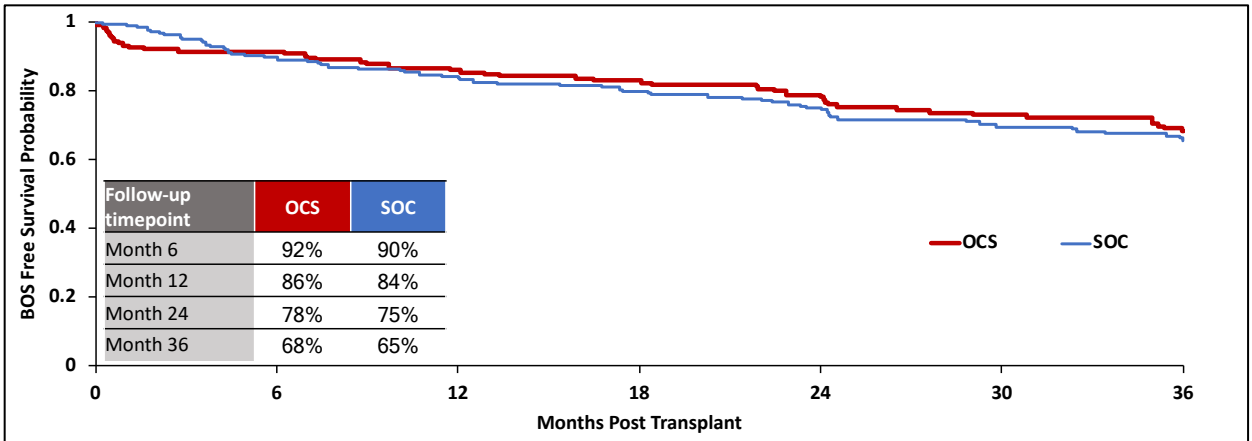
Figure 57: BOS-Free Survival Probability through 36 Months (INSPIRE Combined Cohort PP)



Follow-up timepoint	OCS	SOC
Month 6	94%	90%
Month 12	88%	84%
Month 24	80%	75%
Month 36	70%	66%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
OCS – Patients at Risk	154	144	135	123	84
Patients Censored Patients with BOS or Died	--	0 10	0 19	0 31	27 43
Control – Standard of Care (SOC)- Patients at Risk	180	162	152	135	93
Patients Censored Patients with BOS or Died	--	0 18	0 28	0 45	29 58

Figure 58: BOS-Free Survival Probability through 24 Months (INSPIRE Combined Cohort mITT)



Follow-up timepoint	OCS	SOC
Month 6	92%	90%
Month 12	86%	84%
Month 24	78%	75%
Month 36	68%	65%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
OCS – Patients at Risk	165	151	142	129	87
Patients Censored Patients with BOS or Died	--	0 14	0 23	0 36	29 49
Control – Standard of Care (SOC) – Patients at Risk	184	165	155	137	95
Patients Censored Patients with BOS or Died	--	0 19	0 29	0 47	29 60

8.20. Reduction in Mechanical Ventilation, ICU Stay, and Hospital Stay

Although not statistically significant, the OCS Arm showed a reduction of time on ventilator and a reduction in ICU time and hospital stay post-lung transplantation. See Figure 59 and Figure 60 below.

Figure 59: Improvements in Ventilation Time, ICU Time, and Hospitalization (INSPIRE Combined Cohort PP)

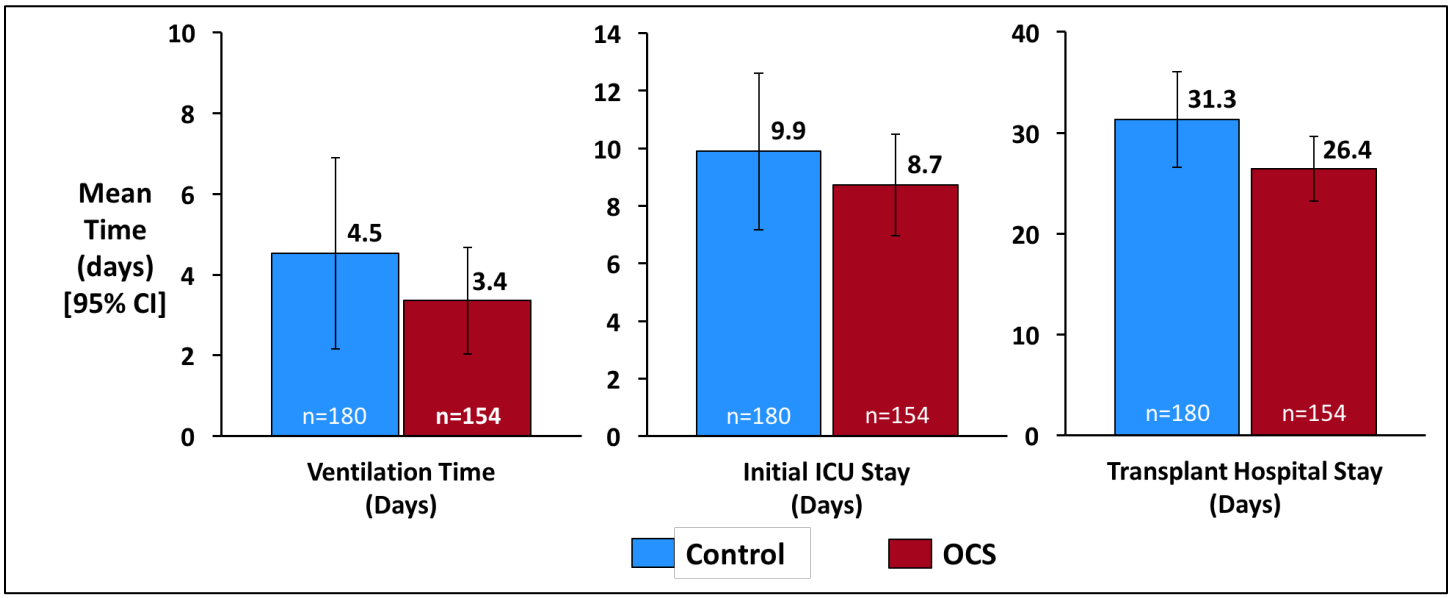
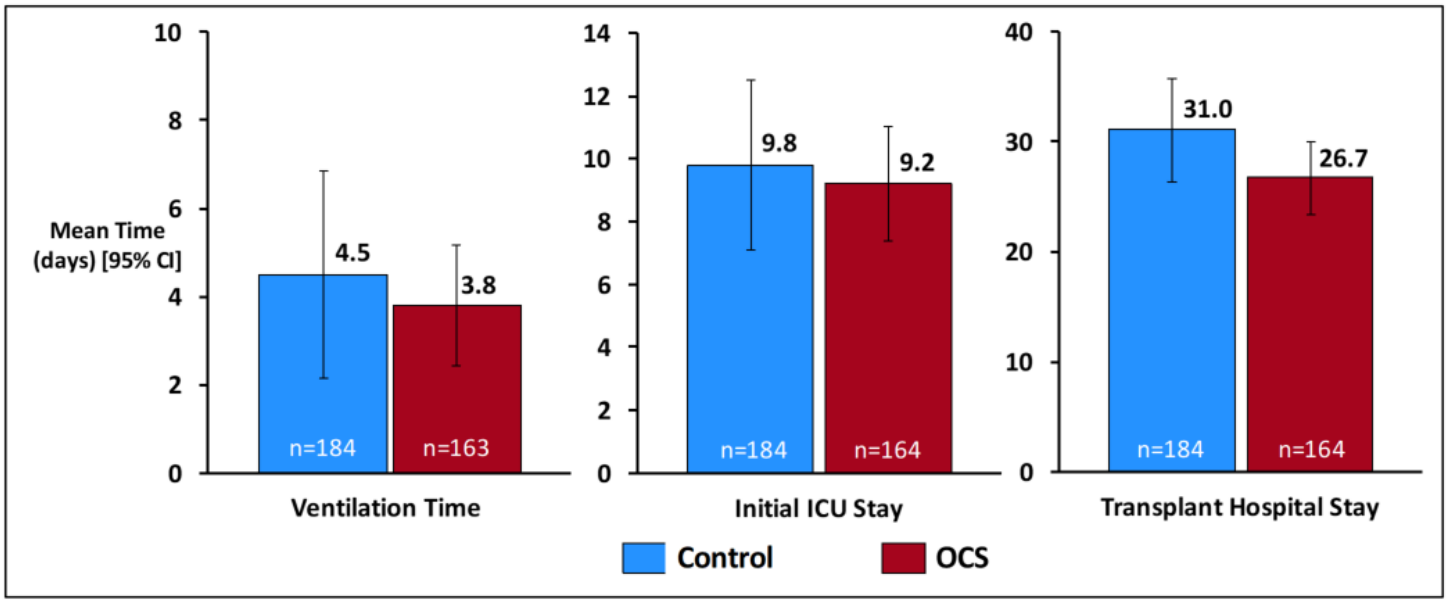


Figure 60: Improvements in Ventilation Time, ICU Time, and Hospitalization (INSPIRE Combined Cohort mITT)

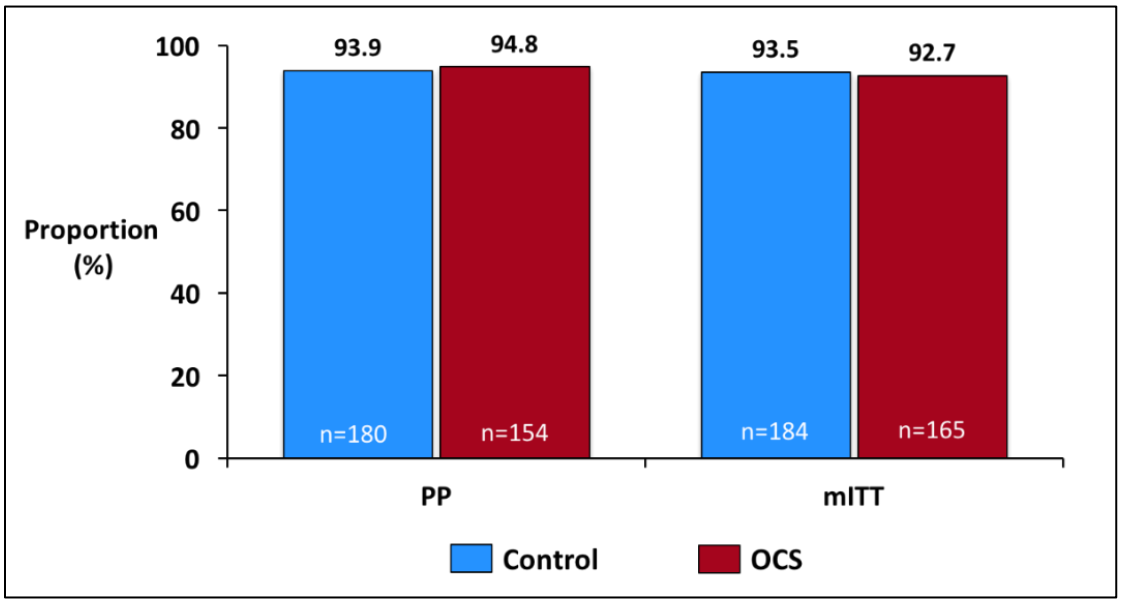


8.21. Adjunct Effectiveness Post-hoc Analyses

8.21.1. Survival at Initial Hospital Discharge

While 30 days patient survival is the historical timepoint for assessing post-transplant mortality, contemporary assessment of mortality includes in-hospital mortality if longer than 30 days. Assessing survival through initial transplant hospital discharge, even if longer than 30 days, captures patients who did not recover following their transplantation surgery and died in hospital (surgical mortality). Survival throughout transplant hospital admission, even if longer than 30 days, was similar between the two groups (see Figure 61).

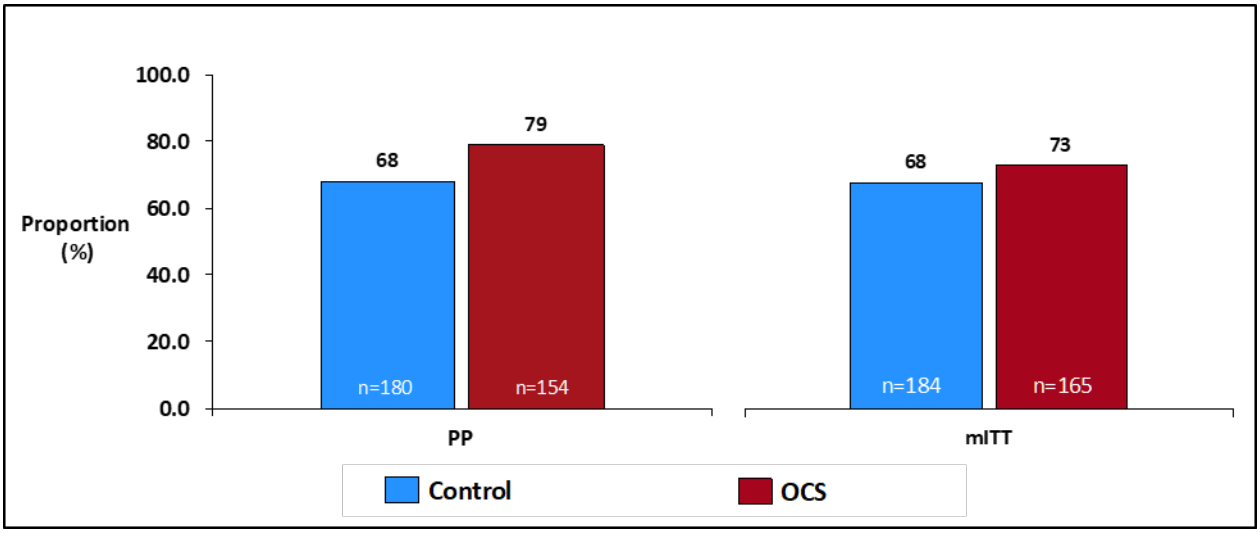
Figure 61: 30-Day and In-Hospital Survival (INSPIRE Combined Cohort)



8.21.2. Adjunct Effectiveness Analysis: Survival at Day 30 and at Initial Hospital Discharge and Freedom from PGD3 within 72 Hours

TransMedics performed a post-hoc adjunct composite effectiveness endpoint analysis that evaluated the same components of the primary effectiveness endpoint (short term survival and freedom of PGD3 in the first 72 hours); however, it assessed survival throughout 30 days and initial hospital discharge instead of limiting it to 30 days post-transplant (see Figure 62 below). In this analysis, the OCS Arm was lower than control in both the PP and mITT cohorts.

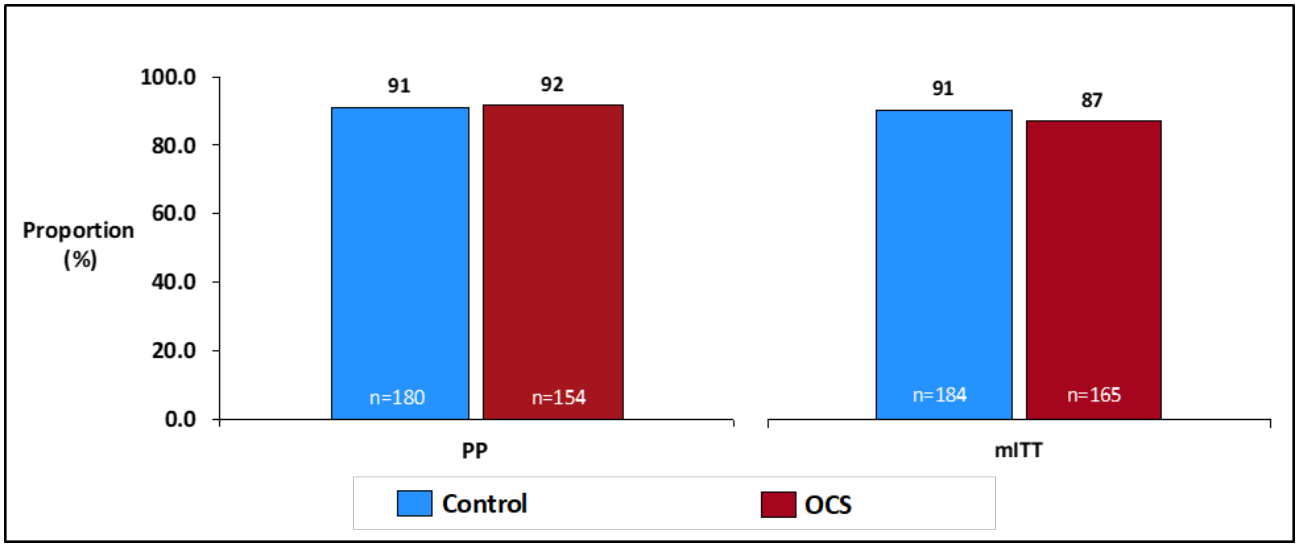
Figure 62: Adjunct Effectiveness Composite Analysis of Survival Through Initial Hospital Discharge and Freedom from PGD3 Within 72 Hours Post-transplant (INSPIRE Combined Cohort – PP & mITT)



8.21.3. Adjunct Effectiveness Analysis: Survival at Day 30 and at Initial Hospital Discharge and Freedom from PGD3 at 72 Hours

An additional post-hoc adjunct analysis was performed that evaluated the composite of PGD3 at T72 and survival throughout 30 days and initial hospital discharge. See Figure 63 below.

Figure 63: Adjunct Effectiveness Composite Analysis of Survival Through Initial Hospital Discharge and Freedom from PGD3 at 72 Hours Post-transplant (INSPIRE Combined Cohort – PP & mITT)



8.22. OCS Solution Subgroup

The OCS Solution subgroup consists of patients in the OCS Arm who received donor lungs perfused only with OCS™ Lung Solution (instead of commercially available LPD solution). Only the OCS™ Lung Solution is approved by FDA for use with the OCS™ Lung System.

The results for the amended Primary Endpoint are shown in Figure 64 below, and the results for the initial composite primary endpoint are shown in Figure 65 below. The results for one component of the amended primary endpoint (i.e., PGD within 72 hours) are shown in Figure 66, and the results for one component of the initial primary endpoint, PGD3 at T72 are provided in Figure 67. Results for the Secondary Endpoints, including survival at 30 days, are shown in Table 15 and Table 16 below for the PP and mITT populations, respectively.

In summary, the results for the OCS Solution subgroup are consistent with those shown for the overall OCS Arm.

Figure 64: Results for Amended Primary Effectiveness Endpoint: Survival at Day 30 Post-Transplantation and Absence of PGD3 *within* 72 Hours, OCS Solution Subgroup, OCS Arm, and Control, INSPIRE Combined Cohort

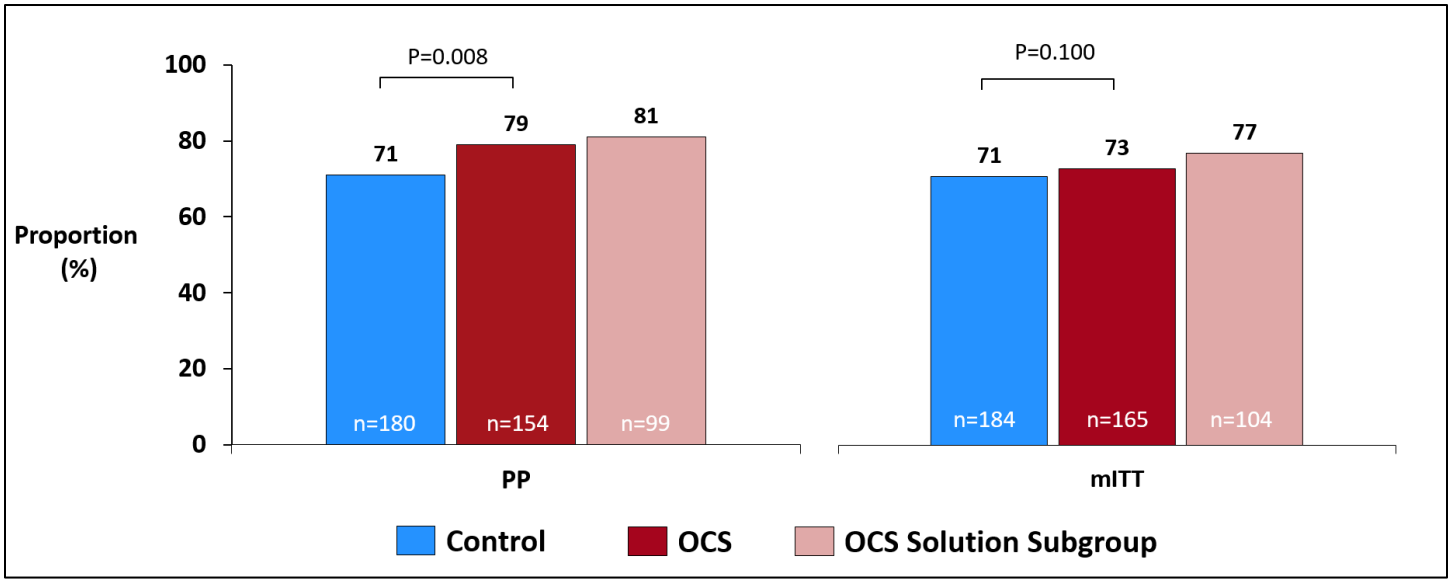


Figure 65: Results for Initial Primary Effectiveness Endpoint: Survival at Day 30 Post-Transplantation and Absence of PGD3 at 72 Hours, OCS Solution Subgroup, OCS Arm and Control, INSPIRE Combined Cohort

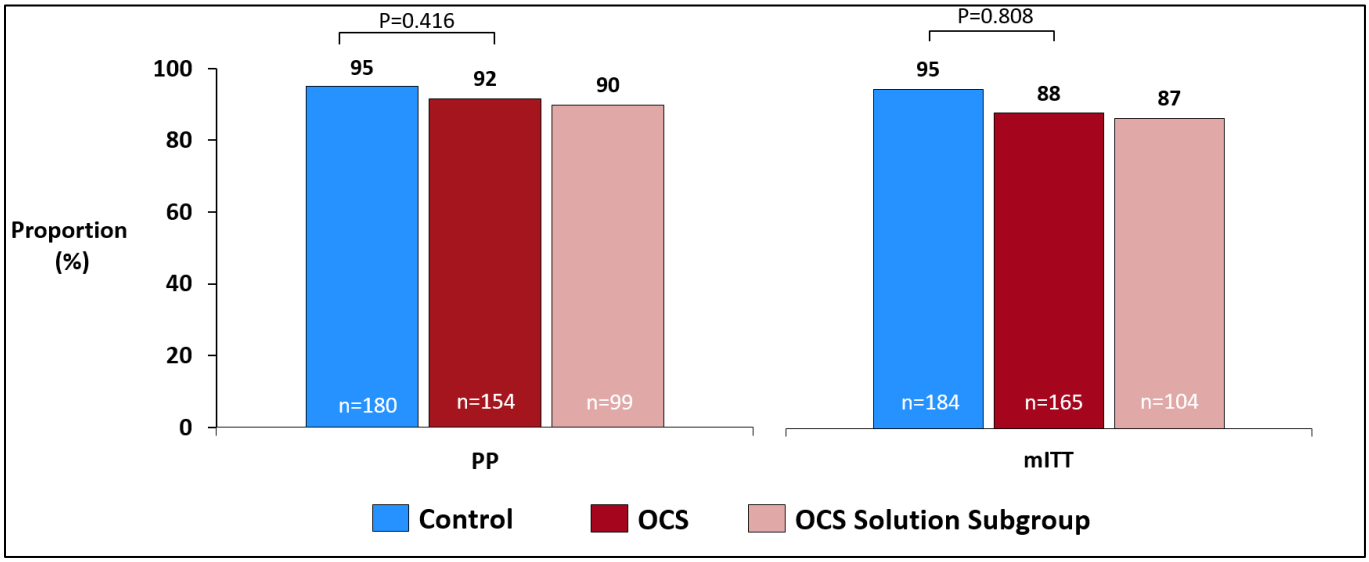


Figure 66: Results for Incidence of PGD3 within 72 Hours: OCS Solution Subgroup, OCS Arm, and Control, INSPIRE Combined Cohort

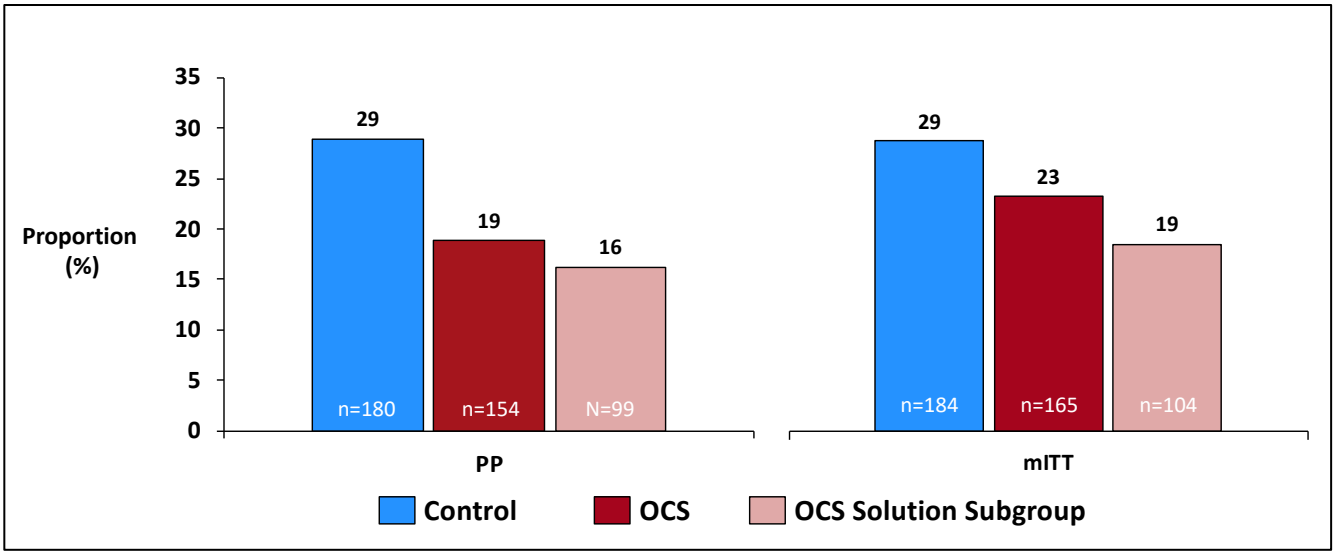


Figure 67: Results for Incidence of PGD3 at 72 Hours: OCS Solution Subgroup, OCS Arm, and Control, INSPIRE Combined Cohort

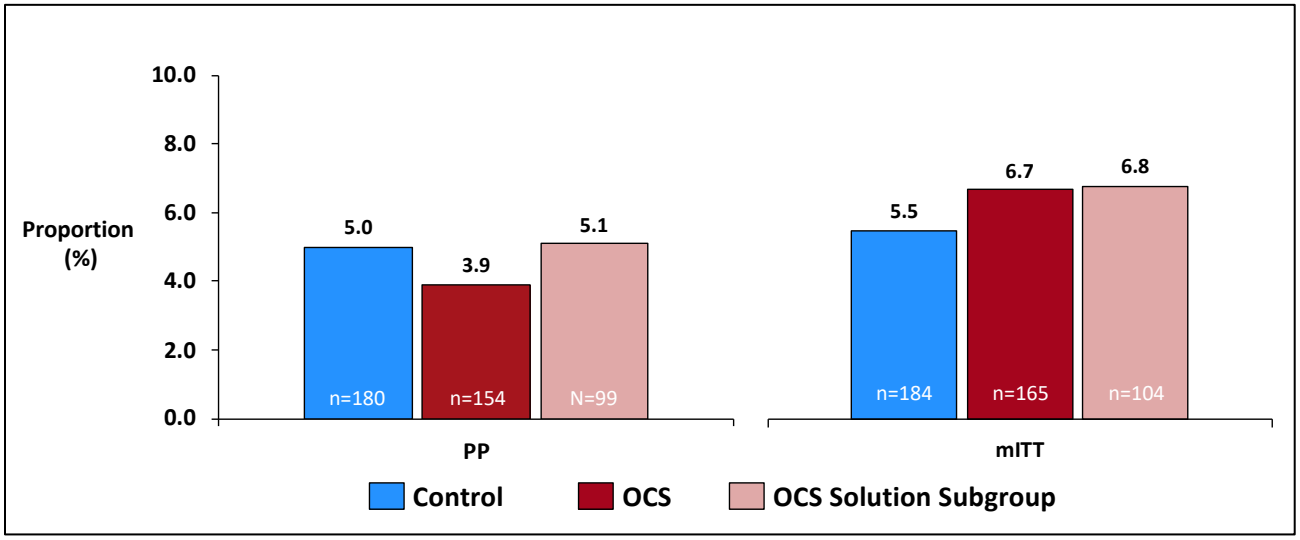


Table 15: Secondary Endpoints: OCS Solution Subgroup compared to OCS Arm and Control group, PP Population, INSPIRE Combined Cohort

Parameter	Control (N=180)	OCS Arm (N=154)	OCS Solution (N=99)
Incidence of PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	5.0% (9/179)	3.9% (6/154)	5.1% (5/99)
95% CI for Proportion[2]	(2.3%, 9.3%)	(1.4%, 8.3%)	(1.7%, 11.4%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		-1.1% (-∞, 2.6%)	0.0% (-∞, 4.5%)
p-value of non-Inferiority test[4]		0.0033	--
Incidence of ISHLT PGD grade 2 or 3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	10.6% (19/179)	13.0% (20/154)	10.1% (10/99)
95% CI for Proportion[2]	(6.5%, 16.1%)	(8.1%, 19.3%)	(5.0%, 17.8%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		2.4% (-∞, 8.2%)	-0.5% (-∞, 5.7%)
p-value of non-Inferiority test[4]		0.0746	--
Patient survival at day 30 post-transplantation			
Proportion (π) (%) (n/N)[1]	100.0% (180/180)	94.8% (146/154)	93.9% (93/99)
95% CI for Proportion[2]	(98.0%, 100.0%)	(90.0%, 97.7%)	(87.3%, 97.7%)
$\pi_{Control}$ - π_{ocs} (%) (one-sided 95% CI)[3]		5.2% (-∞, 8.1%)	6.1% (-∞, 10.0%)
p-value of non-Inferiority test[4]		N/A	---
[1] π = n/N *100% = simple proportion. [2] The 95% confidence interval was calculated based on the Clopper-Pearson method.			

Parameter	Control (N=180)	OCS Arm (N=154)	OCS Solution (N=99)
[3]The 95% upper confidence limit is for the difference between the two population proportions (π_{ocs}-$\pi_{Control}$ for secondary endpoints 1 and 2. $\pi_{Control}$-π_{ocs} for secondary endpoint 3) and was calculated based on the normal approximation.			
[4]The p-value is based on Wald Method. The non-inferiority margin is 5%, 7.5% and 4% for secondary endpoint 1, 2, and 3, respectively. N/A – Not applicable.			

Table 16: Secondary Effectiveness Endpoints: OCS Solution Subgroup compared to OCS Arm and Control group, mITT Population, INSPIRE Combined Cohort

Parameter	Control (N=184)	OCS Arm (N=165)	OCS Solution (N=104)
Incidence of PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	5.5% (10/183)	6.7% (11/164)	6.8% (7/103)
95% CI for Proportion[2]	(2.7%, 9.8%)	(3.4%, 11.7%)	(2.8%, 13.5%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		1.2% (-∞, 5.5%)	1.3% (-∞, 6.3%)
p-value of non-Inferiority test[4]		0.0724	--
Incidence of PGD2 or PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	10.9% (20/183)	16.5% (27/164)	11.7% (12/103)
95% CI for Proportion[2]	(6.8%, 16.4%)	(11.1%, 23.0%)	(6.2%, 19.5%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		5.5% (-∞, 11.6%)	0.7% (-∞, 7.2%)
p-value of non-Inferiority test[4]		N/A	--
Patient survival at day 30 post-transplantation			
Proportion (π) (%) (n/N)[1]	99.5% (183/184)	92.7% (153/165)	91.3% (95/104)
95% CI for Proportion[2]	(97.0%, 100.0%)	(87.6%, 96.2%)	(84.2%, 96.0%)
$\pi_{Control}$ - π_{ocs} (%) (one-sided 95% CI)[3]		6.7% (-∞, 10.2%)	8.1% (-∞, 12.7%)
p-value of non-Inferiority test[4]		N/A	--
[1]π = n/N *100% = simple proportion. [2]The 95% confidence interval was calculated based on the Clopper-Pearson method.			
[3]The 95% upper confidence limit is for the difference between the two population proportions (π_{ocs}-$\pi_{Control}$ for secondary endpoints 1 and 2. $\pi_{Control}$-π_{ocs} for secondary endpoint 3) and was calculated based on the normal approximation.			
[4]The p-value is based on Wald Method. The non-inferiority margin is 5%, 7.5% and 4% for secondary endpoint 1, 2, and 3, respectively. N/A = Not applicable.			

8.23. INSPIRE Initial Cohort

The INSPIRE Initial Cohort represents the first 320 subjects enrolled in the INSPIRE Trial and is the specified sample size for the study.

The results for the amended Primary Endpoint for the INSPIRE Initial Cohort are shown in Figure 68 below, and the results for the initial primary endpoint are shown in Figure 69 below. The results for both analyses are similar.

The results for PGD within 72 hours are shown in Figure 70, and the results for PGD3 at 72 hours are shown in Figure 71. The results for the Secondary Endpoints, including survival at 30 days, are provided in Table 17 and Table 18 below for the PP and mITT populations, respectively.

In summary, the results for the INSPIRE Initial Cohort are consistent with those shown for the INSPIRE Combined Cohort.

Figure 68: Results for Amended Primary Endpoint (30-Day Survival and Freedom from PGD3 within 72 Hours) for the INSPIRE Initial Cohort (N=320)

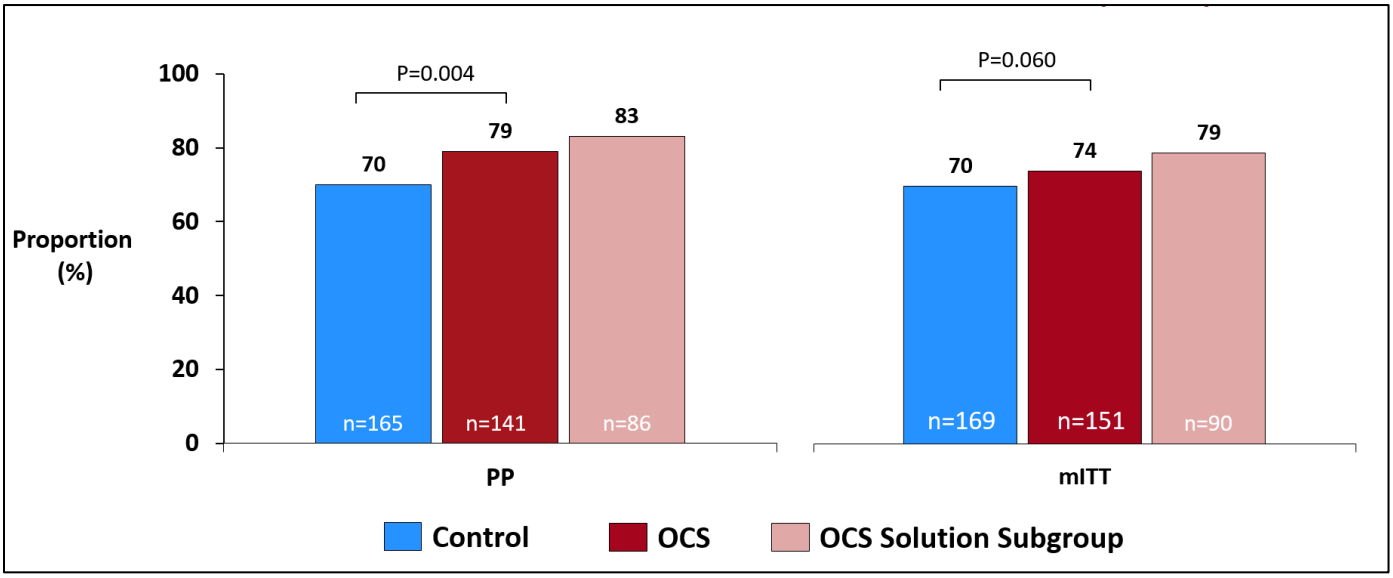


Figure 69: Results for Initial Composite Primary Endpoint (30-Day Survival and Freedom from PGD3 at 72 Hours) for the INSPIRE Initial Cohort (N=320)

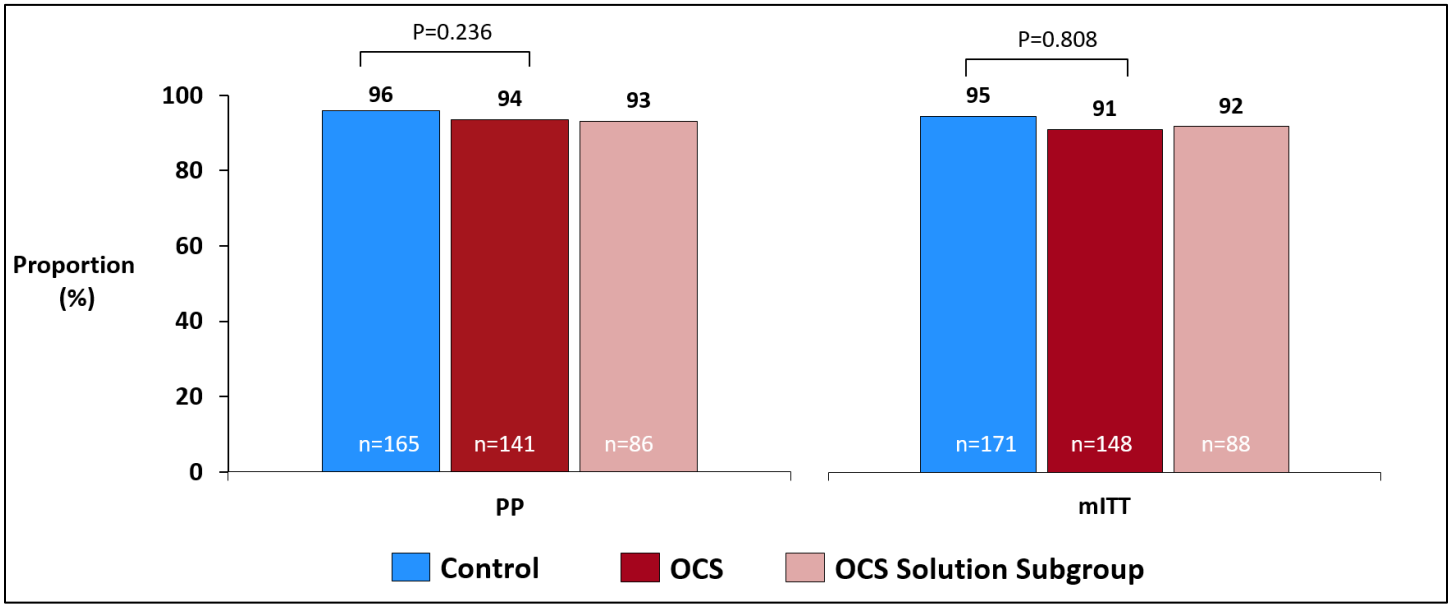


Figure 70: Incidence of PGD3 within 72 hours, PP and mITT Populations, INSPIRE Initial Cohort (N=320)

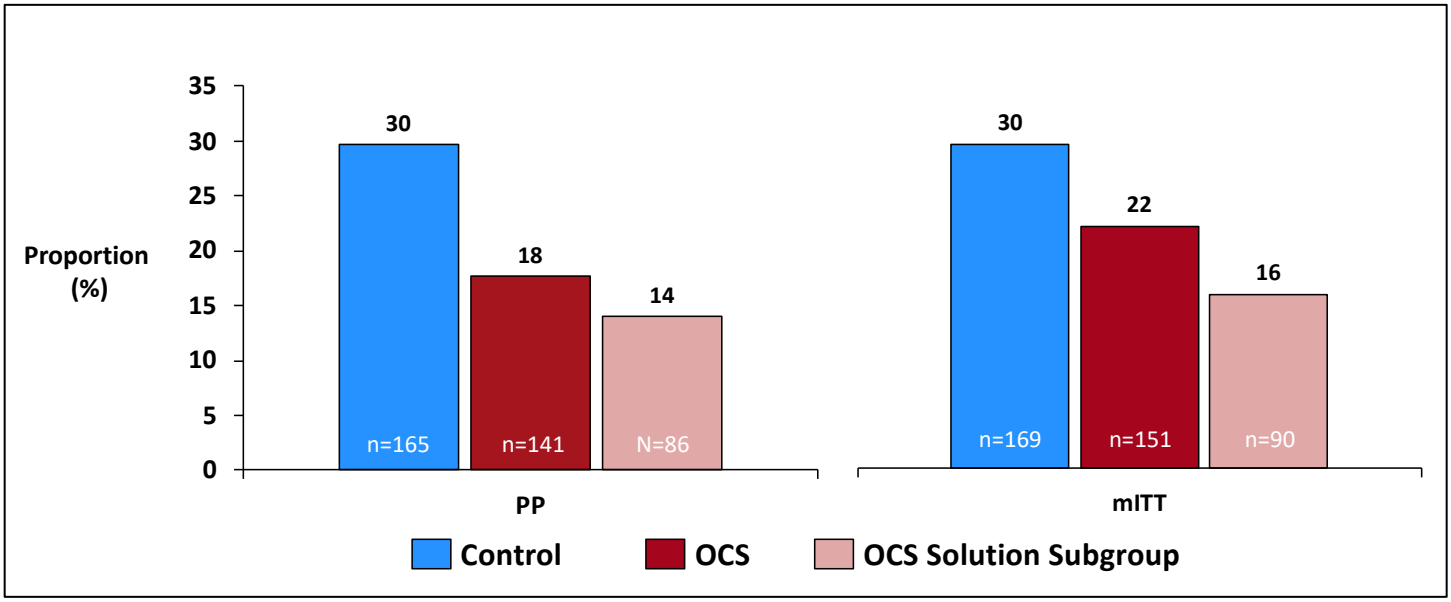


Figure 71: Incidence of PGD3 at T72 hours, PP and mITT Populations, INSPIRE Initial Cohort (N=320)

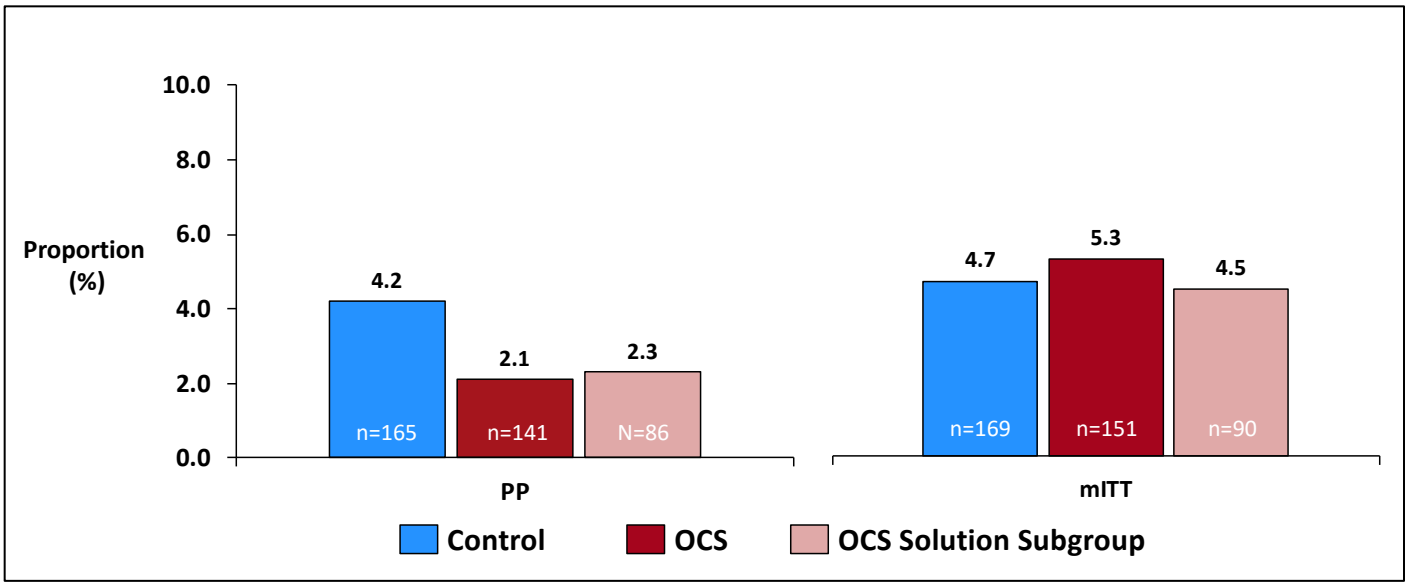


Table 17: Secondary Endpoints: INSPIRE Initial Cohort, PP Population

Parameter	Control (N=165)	OCS Arm (N=141)	OCS Solution (N=86)
Incidence of PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	4.2% (7/165)	2.1% (3/141)	2.3% (2/86)
95% CI for Proportion[2]	(1.7%, 8.5%)	(0.4%, 6.1%)	(0.3%, 8.1%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		-2.1% (-∞, 1.1%)	-1.9% (-∞, 1.8%)
p-value of non-Inferiority test[4]		0.0002	--
Incidence of PGD2 or PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	8.5% (14/165)	11.3% (16/141)	7.0% (6/86)
95% CI for Proportion[2]	(4.7%, 13.8%)	(6.6%, 17.8%)	(2.6%, 14.6%)
π_{ocs} - $\pi_{Control}$ (%) (one-sided 95% CI)[3]		2.9% (-∞, 8.5%)	-1.5% (-∞, 4.2%)
p-value of non-Inferiority test[4]		0.0889	--
Patient survival at day 30 post-transplantation			
Proportion (π) (%) (n/N)[1]	100.0% (165/165)	95.7% (135/141)	95.3% (82/86)
95% CI for Proportion[2]	(97.8%, 100.0%)	(91.0%, 98.4%)	(88.5%, 98.7%)
$\pi_{Control}$ - π_{ocs} (%) (one-sided 95% CI)[3]		4.3% (-∞, 7.1%)	4.7% (-∞, 8,4%)
p-value of non-Inferiority test[4]		N/A	--

[1] π = n/N *100% = simple proportion. [2] The 95% confidence interval was calculated based on the Clopper-Pearson method.

[3] The 95% upper confidence limit is for the difference between the two population proportions (π_{ocs}-$\pi_{control}$ for secondary endpoints 1 and 2. $\pi_{control}$-π_{ocs} for secondary endpoint 3) and was calculated based on the normal approximation.

[4] The p-value is based on Wald Method. The non-inferiority margin is 5%, 7.5% and 4% for secondary endpoint 1, 2, and 3, respectively. N/A – Not applicable.

Table 18: Secondary Effectiveness Endpoints: INSPIRE Initial Cohort, mITT Population

Parameter	Control (N=169)	OCS Arm (N=151)	OCS Solution (N=90)
Incidence of PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	4.7% (8/169)	5.3% (8/150)	4.5% (4/89)
95% CI for Proportion[2]	(2.1%, 9.1%)	(2.3%, 10.2%)	(1.2%, 11.1%)
πocs - πControl (%) (one-sided 95% CI)[3]		0.6% (-∞, 4.6%)	-0.2% (-∞, 4.3%)
p-value of non-Inferiority test[4]		0.0366	--
Incidence of PGD2 or PGD3 at 72 hours post-transplantation			
Proportion (π) (%) (n/N)[1]	8.9% (15/169)	15.3% (23/150)	9.0% (8/89)

Parameter	Control (N=169)	OCS Arm (N=151)	OCS Solution (N=90)
95% CI for Proportion[2]	(5.1%, 14.2%)	(10.0%, 22.1%)	(4.0%, 16.9%)
πocs - πControl (%) (one-sided 95% CI)[3]		6.5% (-∞, 12.5%)	0.1% (-∞, 6.3%)
p-value of non-Inferiority test[4]		0.3881	--
Patient survival at day 30 post-transplantation			
Proportion (π) (%) (n/N)[1]	99.4% (168/169)	94.0% (142/151)	93.3% (84/90)
95% CI for Proportion[2]	(96.7%, 100.0%)	(89.0%, 97.2%)	(86.1%, 97.5%)
πControl - πocs (%) (one-sided 95% CI)[3]		5.4% (-∞, 8.7%)	6.1% (-∞, 10.5%)
p-value of non-Inferiority test[4]		N/A	--

[1] π = n/N *100% = simple proportion. [2] The 95% confidence interval was calculated based on the Clopper-Pearson method. [3] The 95% upper confidence limit is for the difference between the two population proportions (π_{ocs}-$\pi_{Control}$ for secondary endpoints 1 and 2. $\pi_{Control}$-π_{ocs} for secondary endpoint 3) and was calculated based on the normal approximation. [4] The p-value is based on Wald Method. The non-inferiority margin is 5%, 7.5% and 4% for secondary endpoint 1, 2, and 3, respectively. N/A – Not applicable.

8.24. Device Malfunctions

A summary of the device malfunctions that occurred during the INSPIRE Trial is provided in Table 19 below. Twelve (12) malfunctions occurred. In 2 subjects, the malfunction occurred prior to donor organ retrieval, and the subjects were transplanted off study using cold storage. The other 10 patients were analyzed in the study. One malfunction (reduced reservoir volume at high flow rate) led to loss of a donor organ. This patient later received an organ preserved with cold storage.

Table 19: Summary of Device Malfunctions and User Errors

Malfunctions/User Errors & Learning Curve	Total N (12)	Loss of Lung	Treated off Study - Screen Failure	Treated and Analyzed in INSPIRE
Reduced reservoir volume at high pump flow	4	1	0	3
User Errors • Premature unlocking of LPM • Failure to secure port cover during bronchoscopy • Failure to install LPM properly (2)	4	0	0	4
Battery failure	1	0	0	1
Broken gas port	1	0	0	1
Perfusate leak from LPM Prior to Lung Retrieval or Instrumentation on OCS™ Lung System	1	0	1	0
Unable to power up device Prior to Lung Retrieval or Instrumentation on OCS™ Lung System	1	0	1	0
TOTAL	12	1	2	9

TransMedics has addressed the observed malfunctions with design and manufacturing improvements that were implemented and used during the INSPIRE Trial to minimize the potential for recurrence as described below:

- The filter assembly components of the LPM were modified to improve the efficiency and capacity of these sub-components, thereby improving perfusate flow from the organ chamber to the reservoir.
- The LPM was modified to improve the engagement with the OCS™ Lung Console. This design change mitigated against the user inadvertently disconnecting the LPM from the OCS™ Lung Console.
- The port on the gas regulator was changed to resist breakage.
- The reservoir vent design and the manufacturing method of the LPM frame were improved to reduce the likelihood of leaks at the tubing connection points to the frame.
- The failure of the OCS battery to deliver charge was addressed by a strict battery shelf life requirement and preventive maintenance.

8.25. Summary of Adverse Events

An overall summary of adverse events is presented in Table 20 below, and the serious adverse events (SAEs) are shown in Table 21 below, presented by MEDRA preferred term. Both analyses are for the safety population (N=348). There were no differences noted between Control and OCS subjects.

Table 20: Adverse Events by Type of Event; Safety Population (N=348)

Parameter	Control (N=184)	OCS Arm (N=164)	OCS Solution (N=103)
Patients with Any Type of Adverse Events	152 (82.6%)	136 (82.9%)	86 (83.5%)
Patients with Adverse Events Definitely Related to OCS or Control	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patients with Adverse Events Probably Related to OCS or Control	0 (0.0%)	1 (0.6%)	1 (1.0%)
Patients with Adverse Events Possibly Related to OCS or Control	5 (2.7%)	5 (3.0%)	2 (1.9%)
Patients with Adverse Events Unlikely Related to OCS or Control	57 (31.0%)	59 (36.0%)	35 (34.0%)
Patients with Adverse Events Unrelated to OCS or Control	131 (71.2%)	113 (68.9%)	70 (68.0%)
Patients with Adverse Events Unanticipated	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patients with Any Serious Adverse Events	116 (63.0%)	92 (56.1%)	58 (56.3%)
Patients with Any Severe Adverse Events	54 (29.3%)	51 (31.1%)	31 (30.1%)
Deaths up to 24 months[1]	31 (16.8%)	28 (17.1%)	19 (18.4%)

[1] OCS Arm death count includes Subject 31-030 who was withdrawn from study first, then followed by re-transplantation and died afterwards. All Adverse Events were up to 30 days post-transplantation or initial hospital discharge, LGR SAEs were up to 6 months post-transplantation.

Potential AEs that may occur but that were not observed in the INSPIRE Trial include: anemia; cough; gastroesophageal reflux disease; malignancy (post-transplant lymph proliferative disorder (PTLD)); mucus plug; neurological dysfunction; pleural bleeding; and pulmonary infarction.

Table 21: Adjudicated Serious Adverse Events by Preferred Term that occurred in ≥ 1% of Subjects; Safety Population (N=348)

System Organ Class and Preferred Term		Control n (%)		OCS Arm n (%)		OCS Solution n (%)	
		Patients (N=184)	Events (N=247)	Patients (N=164)	Events (N=192)	Patients (N=103)	Events (N=118)
Total		116 (63.0)	247 (100.0)	92 (56.1)	192 (100.0)	58 (56.3)	118 (100.0)
Respiratory, thoracic and mediastinal disorders		57 (31.0)	74 (30.0)	47 (28.7)	59 (30.7)	29 (28.2)	37 (31.4)
	Respiratory failure	17 (9.2)	18 (7.3)	20 (12.2)	22 (11.5)	13 (12.6)	15 (12.7)
	Pleural effusion	12 (6.5)	12 (4.9)	6 (3.7)	7 (3.6)	3 (2.9)	4 (3.4)
	Pneumothorax	12 (6.5)	12 (4.9)	5 (3.0)	6 (3.1)	3 (2.9)	4 (3.4)
	Haemothorax	9 (4.9)	9 (3.6)	7 (4.3)	8 (4.2)	2 (1.9)	3 (2.5)
	Bronchostenosis	4 (2.2)	5 (2.0)	5 (3.0)	5 (2.6)	3 (2.9)	3 (2.5)
	Pulmonary embolism	4 (2.2)	4 (1.6)	3 (1.8)	3 (1.6)	2 (1.9)	2 (1.7)
	Bronchial disorder	3 (1.6)	4 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Bronchial secretion retention	2 (1.1)	2 (0.8)	2 (1.2)	2 (1.0)	0 (0.0)	0 (0.0)
	Acute respiratory failure	1 (0.5)	1 (0.4)	2 (1.2)	2 (1.0)	2 (1.9)	2 (1.7)
	Chylothorax	2 (1.1)	2 (0.8)	1 (0.6)	1 (0.5)	1 (1.0)	1 (0.8)
	Bronchopleural fistula	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infections and infestations		56 (30.4)	72 (29.1)	38 (23.2)	43 (22.4)	26 (25.2)	29 (24.6)
	Pneumonia	20 (10.9)	20 (8.1)	14 (8.5)	15 (7.8)	10 (9.7)	11 (9.3)
	Lung infection	7 (3.8)	8 (3.2)	3 (1.8)	3 (1.6)	2 (1.9)	2 (1.7)
	Bronchopneumonia	3 (1.6)	3 (1.2)	5 (3.0)	5 (2.6)	3 (2.9)	3 (2.5)
	Infection	5 (2.7)	5 (2.0)	3 (1.8)	3 (1.6)	1 (1.0)	1 (0.8)
	Bronchitis	4 (2.2)	4 (1.6)	1 (0.6)	1 (0.5)	0 (0.0)	0 (0.0)
	Bronchopulmonary aspergillosis	4 (2.2)	4 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Lung infection pseudomonal	1 (0.5)	1 (0.4)	3 (1.8)	3 (1.6)	2 (1.9)	2 (1.7)
	Respiratory tract infection	2 (1.1)	2 (0.8)	2 (1.2)	2 (1.0)	2 (1.9)	2 (1.7)

System Organ Class and Preferred Term		Control n (%)		OCS Arm n (%)		OCS Solution n (%)	
		Patients (N=184)	Events (N=247)	Patients (N=164)	Events (N=192)	Patients (N=103)	Events (N=118)
	Sepsis	4 (2.2)	4 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Staphylococcal infection	3 (1.6)	3 (1.2)	1 (0.6)	1 (0.5)	1 (1.0)	1 (0.8)
	Wound infection	4 (2.2)	4 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Diverticulitis	2 (1.1)	2 (0.8)	1 (0.6)	1 (0.5)	1 (1.0)	1 (0.8)
	Aspergillosis	0 (0.0)	0 (0.0)	2 (1.2)	2 (1.0)	1 (1.0)	1 (0.8)
	Clostridium difficile colitis	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Cytomegalovirus infection	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Pseudomonas infection	0 (0.0)	0 (0.0)	2 (1.2)	2 (1.0)	2 (1.9)	2 (1.7)
	Septic shock	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders		16 (8.7)	17 (6.9)	15 (9.1)	20 (10.4)	11 (10.7)	13 (11.0)
	Atrial fibrillation	6 (3.3)	7 (2.8)	7 (4.3)	7 (3.6)	5 (4.9)	5 (4.2)
	Cardiac arrest	0 (0.0)	0 (0.0)	5 (3.0)	6 (3.1)	4 (3.9)	4 (3.4)
	Arrhythmia	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Atrial flutter	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Cardiac failure congestive	0 (0.0)	0 (0.0)	2 (1.2)	2 (1.0)	1 (1.0)	1 (0.8)
	Cardiac tamponade	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders		13 (7.1)	13 (5.3)	13 (7.9)	13 (6.8)	7 (6.8)	7 (5.9)
	Renal failure acute	6 (3.3)	6 (2.4)	11 (6.7)	11 (5.7)	7 (6.8)	7 (5.9)
	Renal failure	7 (3.8)	7 (2.8)	2 (1.2)	2 (1.0)	0 (0.0)	0 (0.0)
Vascular disorders		9 (4.9)	10 (4.0)	11 (6.7)	14 (7.3)	6 (5.8)	7 (5.9)
	Haemorrhage	5 (2.7)	5 (2.0)	5 (3.0)	5 (2.6)	3 (2.9)	3 (2.5)
	Deep vein thrombosis	1 (0.5)	1 (0.4)	4 (2.4)	4 (2.1)	2 (1.9)	2 (1.7)
	Ischaemia	0 (0.0)	0 (0.0)	2 (1.2)	2 (1.0)	1 (1.0)	1 (0.8)

System Organ Class and Preferred Term		Control n (%)		OCS Arm n (%)		OCS Solution n (%)	
		Patients (N=184)	Events (N=247)	Patients (N=164)	Events (N=192)	Patients (N=103)	Events (N=118)
Injury, poisoning and procedural complications		10 (5.4)	10 (4.0)	11 (6.7)	11 (5.7)	7 (6.8)	7 (5.9)
	Post-procedural haemorrhage	1 (0.5)	1 (0.4)	6 (3.7)	6 (3.1)	3 (2.9)	3 (2.5)
	Wound dehiscence	2 (1.1)	2 (0.8)	3 (1.8)	3 (1.6)	3 (2.9)	3 (2.5)
	Procedural complication	2 (1.1)	2 (0.8)	1 (0.6)	1 (0.5)	0 (0.0)	0 (0.0)
Gastrointestinal disorders		13 (7.1)	17 (6.9)	2 (1.2)	2 (1.0)	1 (1.0)	1 (0.8)
	Impaired gastric emptying	2 (1.1)	2 (0.8)	1 (0.6)	1 (0.5)	1 (1.0)	1 (0.8)
	Diarrhoea	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Gastrointestinal haemorrhage	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Large intestine perforation	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Immune system disorders		12 (6.5)	12 (4.9)	6 (3.7)	6 (3.1)	5 (4.9)	5 (4.2)
	Lung transplant rejection	12 (6.5)	12 (4.9)	5 (3.0)	5 (2.6)	4 (3.9)	4 (3.4)
Nervous system disorders		8 (4.3)	8 (3.2)	8 (4.9)	9 (4.7)	4 (3.9)	4 (3.4)
	Cerebrovascular accident	0 (0.0)	0 (0.0)	4 (2.4)	4 (2.1)	1 (1.0)	1 (0.8)
	Encephalopathy	2 (1.1)	2 (0.8)	1 (0.6)	1 (0.5)	0 (0.0)	0 (0.0)
	Brain oedema	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Convulsion	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
General disorders and administration site conditions		5 (2.7)	5 (2.0)	3 (1.8)	3 (1.6)	3 (2.9)	3 (2.5)
Blood and lymphatic system disorders		1 (0.5)	1 (0.4)	3 (1.8)	3 (1.6)	1 (1.0)	1 (0.8)
Psychiatric disorders		4 (2.2)	4 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Delirium	2 (1.1)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders		2 (1.1)	2 (0.8)	1 (0.6)	1 (0.5)	1 (1.0)	1 (0.8)
Musculoskeletal and connective tissue disorders		0 (0.0)	0 (0.0)	2 (1.2)	2 (1.0)	1 (1.0)	1 (0.8)
Surgical and medical procedures		0 (0.0)	0 (0.0)	2 (1.2)	2 (1.0)	1 (1.0)	1 (0.8)

8.26. Summary of INSPIRE Clinical Study

The INSPIRE Trial met its amended primary effectiveness endpoint in the PP population and its safety endpoint and the data provide reasonable assurance of the safety and effectiveness of the OCS™ Lung System and supports its favorable benefit-risk. In addition, there are several other findings from the INSPIRE Trial that show a favorable clinical benefit profile.

- The OCS™ Lung System reduces the incidence of PGD3 in the initial 72-hour period following lung transplantation.
- The OCS™ Lung System reduces ischemic time on donor lungs compared to the standard of care cold storage, despite the fact that the cross-clamp time was longer.
- Although the mortality at 30 days is higher in the OCS group, patients treated with the OCS™ Lung System demonstrate similar mortality in the initial post-transplant hospitalization period and at 12, 24, and 36 months compared to cold storage standard of care.
- The OCS™ Lung System may be associated with reductions in mechanical ventilation, ICU stay, and hospital stay.
- The OCS Arm in the INSPIRE Trial has shown numerically lower incidence of BOS through 36 months after transplant compared to cold storage. BOS is a chronic condition that develops between 2 and 5 years following lung transplantation. TransMedics will continue to evaluate this trend in our post-market registry study.

As with any new technology, there are risks posed by the introduction of the OCS™ Lung System into standard clinical practice for transplantation. A device malfunction or user error could lead to a potential loss in an organ. This risk has been mitigated by careful product design and testing as well as incorporation of an extensive, hands on training program which was implemented and utilized during the conduct of the INSPIRE Trial.

In conclusion, the INSPIRE Trial data provide evidence for the safety, effectiveness, and clinical benefit of the OCS™ Lung System for use in standard criteria lung preservation for double lung transplantation.

9. APPENDIX B: OCS™ LUNG SYSTEM EXPAND STUDY

9.1. EXPAND Study Objective and Design

The objective of the EXPAND trial was to evaluate the safety and effectiveness of the OCS™ Lung System to preserve and allow for clinician assessment ex vivo of harvested donor double lungs with one or more of the following characteristics:

- Donor $PaO_2/FiO_2 \leq 300$ mmHg; or
- Expected ischemic time > 6 hours; or
- Donor after Cardiac Death (DCD donor); or
- Donor age ≥ 55 years old.

The above criteria have been reported in published scientific literature to define offered donor lungs that are seldom accepted for lung transplantation in the U.S.:

- OPTN/SRTR reports that the primary reason donor lungs are not utilized is low PaO_2/FiO_2 ratio (Valapour, et al., 2018[5]).
- Less than 20% of U.S. lung transplants are performed with donor lungs with 6 hours or more of total ischemic time (Grimm, et al., 2015[6]).
- In 2016 only 4% of lung transplants were from DCD donors in the U.S. (Valapour, et al., 2018[5]).
- Less than 10% of the U.S. lung transplants were from donors of 55 years or older in age (Bittle, et al., 2013[7]).

The EXPAND trial was a prospective, international single-arm trial of extended criteria donor lungs and double lung transplant recipients. This trial was conducted at 8 institutions in the U.S. and Europe and included 79 recipients who received donor organs preserved with the OCS™ Lung System (55 in the U.S. and 24 in Europe). Follow-up data collection was conducted through the initial 7 days, hospital discharge, 30 days and 6 months post-transplant, with additional long term data collection at 12 and 24 months.

9.2. Primary Effectiveness Endpoint

Primary Graft Dysfunction (PGD)[1] is a form of acute lung injury that is a known serious complication of lung transplantation. The most severe form, PGD Grade 3, has been shown to be correlated with poor short and long-term outcomes, including reduced survival and increased incidence of Bronchiolitis Obliterans Syndrome (BOS) (Huang, et al., 2008[2] and Daud, et al., 2007[3]). PGD Grade 2

[5] Valapour, et al. OPTN/SRTR 2016 Annual Data Report: Lung. *Am. J. Transplant.* 18(S1): 363-433, January 2018.

[6] Grimm, et al. Association between Prolonged Graft Ischemia and Primary Graft Failure or Survival following Lung Transplantation. *JAMA Surg.* 2015.; 150(6): 547-553.

[7] Bittle, et al. The Use of Lung Donors Older than 55 Years: A Review of the United Network of Organ Sharing Database. *J. Heart Lung Transplant.* 2013; 32:760-768.

is also correlated with worse clinical outcomes, though to a lesser degree than PGD Grade 3. The effectiveness endpoints evaluated the rates of PGD and survival.

The primary effectiveness endpoint was a composite of patient survival at Day 30 post-transplant and absence of PGD3 at all timepoints up to 72 hours post-transplant (T0-T72 hours), with a Performance Goal of 65%. PGD in this study was graded according the ISHLT 2005 consensus statement.[1] The primary hypothesis for this trial was that the true proportion of transplanted recipients with composite patient survival at Day 30 post transplantation and freedom of PGD3 at any timepoint up to 72 hours post-transplant is greater than 65%. The EXPAND trial Performance Goal was based on published data available for PGD3 within the initial 72 hours post-transplant in mostly standard criteria donor lungs (Diamond, et al., 2013[8]).

The primary statistical hypotheses were as follows:

H_0: $\pi \leq 65\%$

H_1: $\pi > 65\%$,

where π is the true proportion of transplanted recipients with patient survival at Day 30 and freedom from PGD Grade 3 at any timepoint up to 72 hours post-transplant.

To claim success on this endpoint, the lower bound of the 95% confidence interval must be > 65%.

PGD grading, serious adverse events and cause of death were adjudicated by a Medical Monitor. PGD adjudication utilized the ISHLT criteria as outlined in Appendix D.

9.3. Secondary Effectiveness Endpoints

The secondary effectiveness endpoints were:

- Incidence of PGD2 or 3 at T72 hours post-lung transplantation
- Incidence of PGD3 at T72 hours post-lung transplantation.

9.4. Other Endpoints

- Duration of initial post-transplant invasive mechanical ventilation
- Length of initial post-transplant ICU stay
- Length of initial post-transplant hospital stay
- PGD Scores at T0, T24, T48, and T72
- Incidence of BOS at 6 and 12 months post-transplantation.

9.5. Adjunct Effectiveness Analyses

- Patient survival for up to 24 months post-transplant.
- Donor lung utilization rate.

[8] Diamond et al., Clinical Risk Factors for Primary Graft Dysfunction After Lung Transplantation. *American Journal of Respiratory and Critical Care Medicine*; 2013: vol 187(5) 527-534.

9.6. Safety Endpoint

The safety endpoint was the number of lung-graft-related serious adverse events (LGRSAE) through the 30 days post-transplantation per subject. A LGRSAE is defined as the occurrence of any of the following four categories of adverse events that are also serious. Reporting of the safety endpoint included the average number of LGRSAEs per patient, with multiple occurrences of SAE of the same category on the same subject within 30 days counted as one LGRSAE.

- Acute rejection (biopsy-proven)
- Respiratory failure
- Bronchial anastomotic complication
- Major pulmonary-related infection.

9.7. Post-hoc Subgroup Analyses

Additional post-hoc clinical analyses were performed on various post-hoc subgroups of EXPAND transplanted recipients, as well as comparing Lung EXPAND results to the results for the INSPIRE control group, who received standard criteria lungs preserved using standard of care cold storage.

9.8. Study Population

Subjects were double lung transplant recipients and donors who met inclusion/exclusion criteria.

9.8.1. Donor Inclusion Criteria

At least one of the following:

- Donor $PaO_2/FiO_2 \leq 300$ mmHg; or
- Expected ischemic time > 6 hours; or
- Donor after Cardiac Death (DCD donor); or
- Donor age ≥ 55 years old.

9.8.2. Recipient Inclusion Criteria - Day of Transplant

- Registered male or female primary double lung transplant candidate
- Age ≥ 18 years old
- Signed: (1) written informed consent document and (2) authorization to use and disclose protected health information.

9.8.3. Donor Exclusion Criteria

- Presence of moderate to severe traumatic lung injury with air and/or blood leak
- Presence of confirmed active pneumonia or persistent purulent secretions on repeated bronchoscopy evaluation or ET suction
- Previous history of pulmonary disease
- Multiple transfusions of >10 pRBCs units

- ABO incompatibility
- Tobacco history of >20 packs per year.

9.8.4. Recipient Exclusion Criteria - Day of Transplant

- Prior solid organ or bone marrow transplant
- Single lung recipient
- Chronic use of hemodialysis or diagnosis of chronic renal insufficiency.

9.8.5. Donor Lung Acceptance for Transplantation after Preservation on OCS™ Lung System

- All donor lungs preserved on OCS™ Lung must meet the following standard clinical criteria for transplantation at final assessment on the OCS™ Lung System:
  - PaO_2/FiO_2 ratio of ≥ 300 mmHg
  - Stable perfusion parameters (PAP, PVR, & PAWP): defined as stable or < 20% worsening of each of these parameters from beginning to end of OCS perfusion
  - Clinically acceptable by the center's trial PI
- Any decision to turn down lungs after the lungs have been retrieved, preserved and assessed on OCS™ Lung should be done with notification to the Site PI.

9.9. Donor Lung Disposition

In the EXPAND trial, ninety-three (93) donor lungs were preserved and assessed on the OCS™ Lung System. Of those, 12 donor lungs (13%) were turned down for transplantation due to failing to meet the clinical transplantability criteria while on the OCS™ Lung System. The clinical reasons for discarding the perfused lungs were:

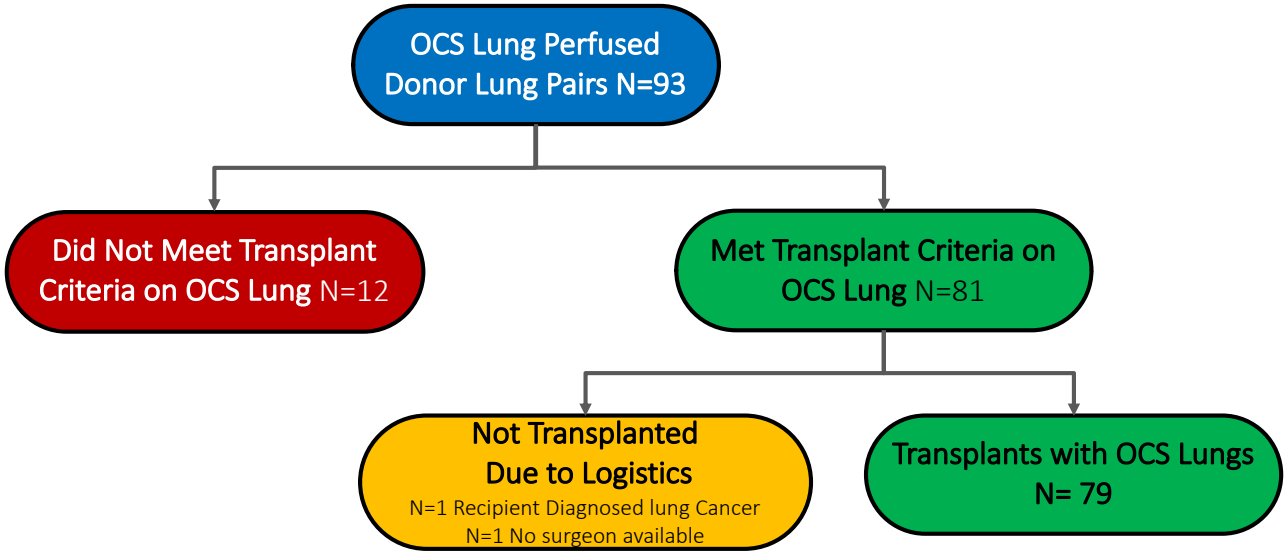
- N= 6 – Donor lung contusion and open lung injury resulting in air and perfusate leakage into the bronchoalveolar space
- N= 4 – Unstable OCS™ Lung perfusion parameters and persistent low P/F ratio
- N=1 – Persistent lung edema
- N=1 – Persistent purulent secretions.

Eight-one (81) donor lungs (87%) met the clinical transplantability criteria on OCS™ Lung System. Two (2) of the donor lungs that met transplantability criteria were not transplanted:

- N=1 – Recipient was determined to have lung cancer on day of transplantation.
- N=1 – Surgical team was not available to perform the transplant due to surgical emergency.

This resulted in 79 transplants in the EXPAND trial. The donor lung disposition is presented in Figure 72 below. Donor lung utilization is discussed in Section 9.20.2.

Figure 72: Donor Lung Disposition in the EXPAND Trial



9.10. Demographic and Baseline Characteristics

Donor demographic baseline characteristics and risk factors for donor lungs transplanted in EXPAND are shown in Table 22 below. The retrieved donor lungs met several eligibility criteria including donor age ≥ 55 years (39%), expected cross clamp time > 6 hours for the second lung (32%), PaO_2/FiO_2 ≤ 300 mmHg at final offer (25%) and Donation after Circulatory Death (DCD) (33%). Twenty-one (21) of the 79 donors (26.6%) had more than one donor inclusion criterion met. Table 23 shows the donor demographic baseline characteristics and risks factors for donors in EXPAND with one donor inclusion criteria met. Note that in the sections that follow, the overall transplanted recipient population (N=79) includes recipients who received donor lungs with multiple inclusion criteria met (N=21) and recipients of donors with a single inclusion criterion met (N=58).

Table 22: Donor Demographics by Inclusion Criteria – ALL Donors (N=79)

	PaO_2/FiO_2 Ratio ≤ 300 mmHg (N=20) mean ± SD Median Range	Expected Cross Clamp Time > 6 hours (N=25) mean ± SD Median Range	DCD Donor (N=26) mean ± SD Median Range	Donor Age ≥ 55 (N= 31) mean ± SD Median Range	All Donors (N=79) mean ± SD Median Range
PaO_2/FiO_2 Ratio (mmHg)	239 ± 47 254 (135-295)	378 ± 122 376 (190 – 624)	407 ± 81 416 (250 – 624)	398 ± 106 400 (144 – 663)	378 ± 110 383 (135 – 663)
Observed Cross Clamp Time (min)	603 ± 88 593 (452 – 800)	643 ± 124 608 (432 – 864)	608 ± 146 599 (359 – 899)	604 ± 134 581 (353 – 1047)	609 ± 127 590 (353 – 1047)
Donor Age (Years)	42 ± 16 45	38 ± 14 40	40 ± 14 41	63 ± 6 62	47 ± 16 50

	PaO_2/FiO_2 Ratio ≤ 300 mmHg (N=20) mean ± SD Median Range	Expected Cross Clamp Time > 6 hours (N=25) mean ± SD Median Range	DCD Donor (N=26) mean ± SD Median Range	Donor Age ≥ 55 (N= 31) mean ± SD Median Range	All Donors (N=79) mean ± SD Median Range
	(17 – 68)	(17 – 62)	(17 – 69)	(55 – 76)	(17 – 76)
Additional Demographics & Risk Factors					
Female gender: % (n/N)	25.0% (5/20)	28.0% (7/25)	34.6% (9/26)	54.8% (17/31)	41.8% (33/79)
Abnormal Findings on Inspection and Palpation % (n/N)	30.0% (6/20)	12.0% (3/25)	26.9% (7/26)	50.0% (15/30)	32.1% (25/78)
Abnormal Imaging Findings % (n/N)	75.0% (15/20)	75.0% (18/24)	57.7% (15/26)	67.7% (21/31)	65.4% (51/78)

Table 23: Donor Demographics by Inclusion Criteria for Donors with a Single Inclusion Criteria met (N=58)

Parameter	Donor PaO2/FiO2 ratio ≤ 300 mmHg (N=9) mean ± SD Median Range	Expected total ischemic time > 6 hours (N=11) mean ± SD Median Range	Donor experienced cardiac death (DCD donor) (N=16) mean ± SD Median Range	Donor ≥ 55 years old (N=22) mean ± SD Median Range	All Donors (N=58) mean ± SD Median Range
PaO_2/FiO_2 Ratio (mmHg)	240.6 ± 48.6 245.4 135.0 - 295.0	426.70 ± 85.0 399.7 307.0 - 559.0	407.6 ± 51.4 426.7 312.0 - 492.0	442.5 ± 84.0 429.5 305.0 - 663.0	398.4 ± 99.4 401.0 135.0 - 663.0
Observed Cross Clamp Time (min)	610.6 ± 92.0 588.0 524 - 761	637.1 ± 106.9 640.0 432 - 821	565.1 ± 140.9 513.5 359 - 899	606.7 ± 147.0 581.0 353 - 1047	601.6 ± 130.5 584.5 353 - 1047
Donor Age (Years)	34.7 ± 12.5 34.0 17.0 - 53.5	36.3 ± 11.8 40.2 17.5 - 52.7	41.8 ± 10.3 43.8 25.1 - 54.0	63.7 ± 6.5 62.5 55.1 - 76.0	48.0 ± 15.8 49.9 17.0 - 76.0
Additional Demographics & Risk Factors					
Female gender % (n/N)	22.2% (2/9)	54.5% (6/11)	50.0% (8/16)	59.1% (13/22)	50.0% (29/58)
Abnormal Findings on	33.3% (3/9)	18.2% (2/11)	18.8% (3/16)	52.4% (11/21)	33.3% (19/57)

Parameter	Donor PaO2/FiO2 ratio ≤ 300 mmHg (N=9) mean ± SD Median Range	Expected total ischemic time > 6 hours (N=11) mean ± SD Median Range	Donor experienced cardiac death (DCD donor) (N=16) mean ± SD Median Range	Donor ≥ 55 years old (N=22) mean ± SD Median Range	All Donors (N=58) mean ± SD Median Range
Inspection and Palpation % (n/N)					
Abnormal Imaging Findings % (n/N)	66.7% (6/9)	80.0% (8/10)	50.0% (8/16)	59.1%(13/22)	61.4% (35/57)

As shown in Table 24 below, the EXPAND trial enrolled a representative mix of standard lung transplant recipients including high-risk factors and characteristics. This was evident by the mean LAS score of 42 and median 37. There were 22.8% (18/79) recipients diagnosed with IPF and 27.8% (22/79) diagnosed with secondary pulmonary hypertension.

Table 24: Recipient Demographic and Baseline Characteristics

	OCS EXPAND Lung Recipients (n=79)
Age (Years): Mean ± SD	55.56 ± 10.58
Gender (% Female)	41.8
BMI (kg/m^2) Mean ± SD	24.49 ± 4.57
LAS Score (n=70) Mean ± SD Median	42.0 ± 13.49 37.0
Primary Diagnosis	
• Chronic obstructive pulmonary disease/Emphysema	34.2% (27/79)
• Idiopathic pulmonary fibrosis (IPF)	22.8% (18/79)
• Cystic Fibrosis	15.2% (12/79)
• Nonspecific interstitial pneumonia	6.3% (5/79)
• Bronchiectasis	5.1% (4/79)
• Sarcoidosis	2.5% (2/79)
• Other	13.9% (11/79)
Secondary Pulmonary Hypertension	27.8% (22/79)

9.11. UNOS U.S. Donor Lungs Match Run Data

TransMedics obtained match run data from the UNOS/OPTN database on the number of donor offers that were turned down by other transplant centers, prior to the organ being accepted into the EXPAND trial and being instrumented on the OCS™ Lung System.

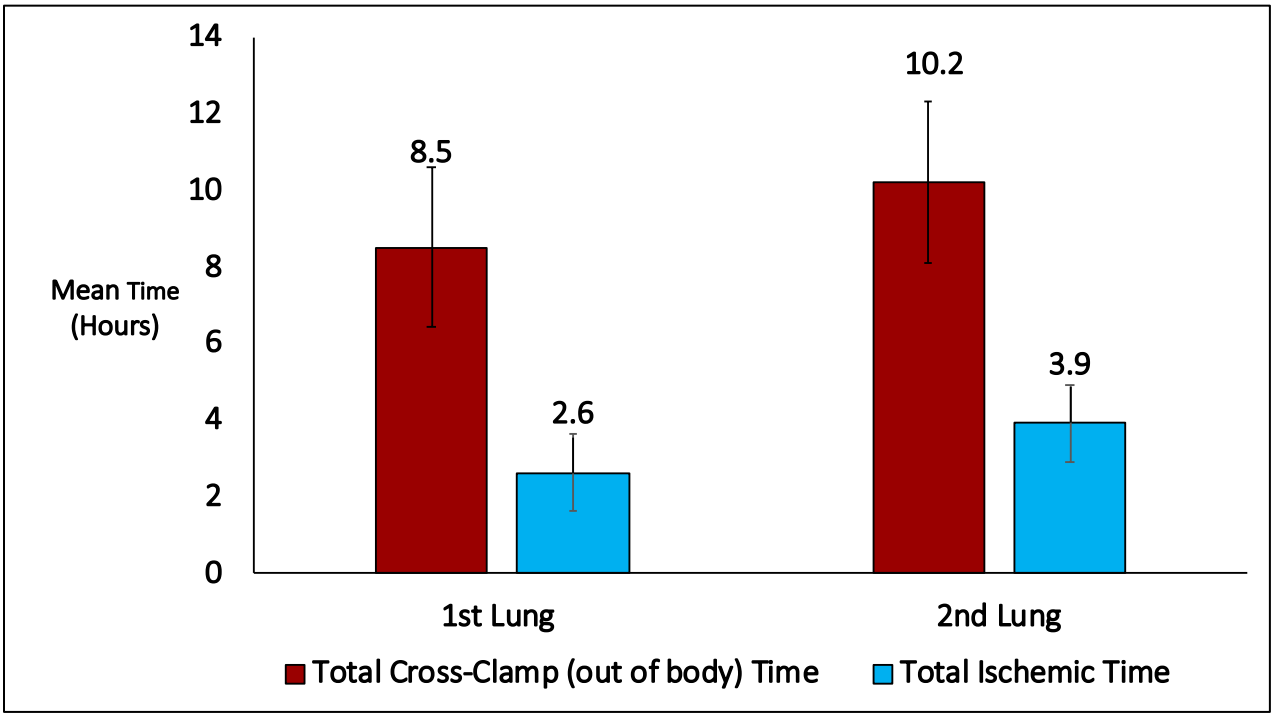
Of the 93 lungs instrumented on OCS, 67 were in the U.S. and UNOS/OPTN data are available on 66 of these 67 U.S. donor lungs. No match run data is available on OUS donor lungs. The 66 donor lungs were refused by other centers an average of 35.3 times (median 21, 25% percentile 6.25 times and 75% percentile 49.7 times), with a range of 0 to 197 rejections prior to the donor lung acceptance in the EXPAND trial and instrumentation on the OCS™ Lung System.

9.12. Donor Lung Preservation Characteristics on OCS™ Lung System

Donor Lung preservation characteristics are shown in Figure 73 below. Note that total out of body time (also referred to as cross-clamp time) is the time from aortic cross clamp application in the donor to the pulmonary artery (PA) cross-clamp removal in the recipient. During OCS™ perfusion, the donor lung is perfused with oxygenated blood perfusate and ischemic times are limited to small windows of time during donor procurement and during surgical re-implantation into the recipient. Thus, the ischemic time is different from the total cross clamp time.

The total out of body time averaged 8.5 and 10.2 hours for the first and second lung respectively, while the average ischemic times for the first and second donor lungs was 2.6 and 3.9 hours, respectively.

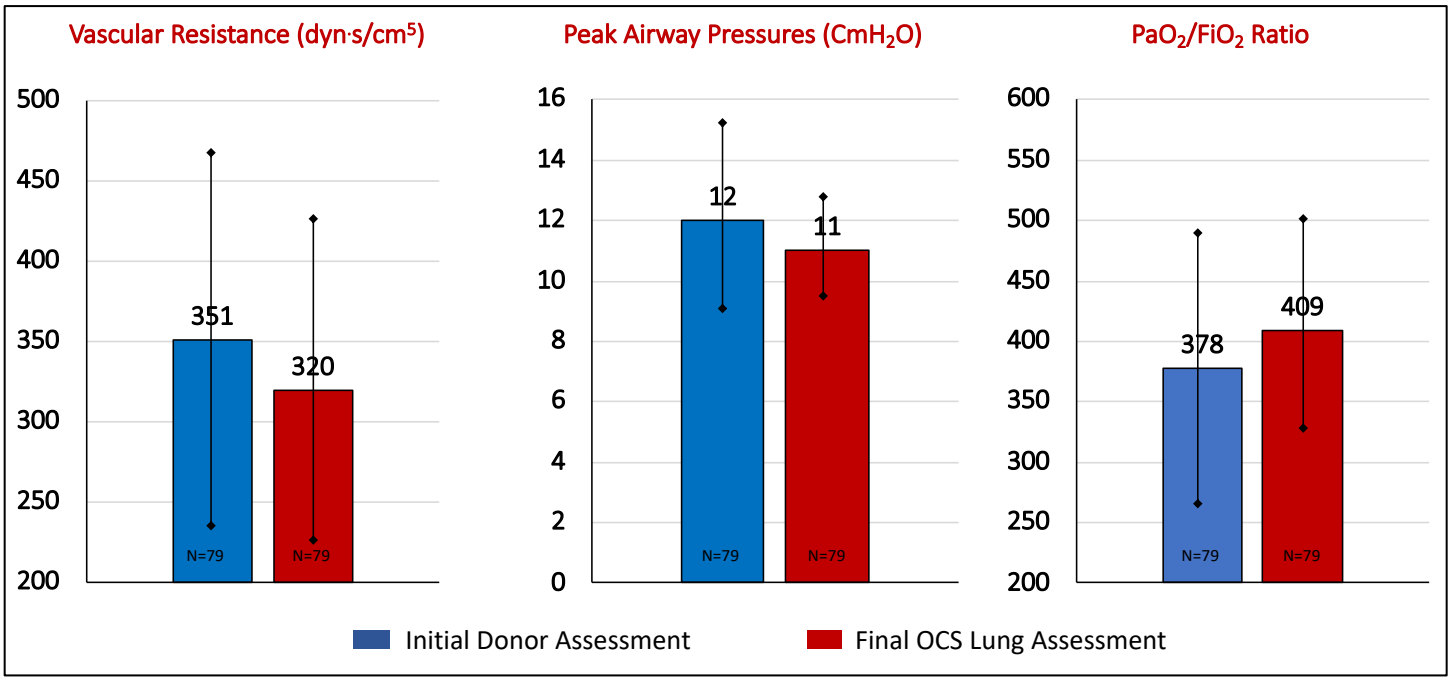
Figure 73: Total Out of Body Time and Ischemic Time for First and Second Lung in EXPAND Trial



9.13. OCS™ Lung System Perfusion and Ventilation Parameters

A comparison of the perfusion and ventilation parameters at initial and final assessments on the OCS™ Lung System are shown in Figure 74 below for Vascular Resistance and Peak Airway Pressure. A comparison between the average final PaO_2/FiO_2 ratio in donor chest and PaO_2/FiO_2 ratio at final assessment on the OCS™ Lung System on room air is also shown. Note that the timepoint of "initial" PaO_2/FiO_2 ratio differs from that of "initial" perfusion and ventilation parameters, with the former occurring prior to donor organ and the latter occurring after the resected organ has been stabilized on the device.

Figure 74: Comparison of Initial and Final Mean OCS Assessments for EXPAND Donor Lungs



9.14. Primary Effectiveness Endpoint

Table 25 below shows the results of the primary effectiveness endpoint for the EXPAND trial. The primary effectiveness endpoint of patient survival at day 30 post-transplant and freedom from PGD3 within initial 72 hours for the EXPAND trial did not meet the pre-specified Performance Goal of 65%, as the 95% lower confidence interval was 42.8%.

A comparison of the primary endpoint results stratified by donor inclusion criteria is provided in Section 9.21, and a comparison of survival and PGD3 results for the overall EXPAND population compared to INSPIRE control is shown in Section 9.24.

Table 25: Results for Primary Effectiveness Endpoint for the EXPAND Trial

Results for Primary Effectiveness Endpoint	Transplanted Recipients (N= 79)
Patient survival at day 30 post-transplantation and absence of ISHLT PGD grade 3 in the first 72 hours post-transplantation	
Number (n)	43
Proportion (%) (n/N)	54.4% (43/79)
95% CI (%) for Proportion[1]	(42.8%, 65.7%)[2]
p-value[3]	0.9663

[1] Clopper-Pearson exact confidence interval for a binomial proportion.

[2] The primary effectiveness endpoint is not met since the lower bound of the 95% confidence interval is 42.8%, which is lower than the Performance Goal of 65%.

[3]The p-value is based on a one-sided exact binomial test, testing the null hypothesis that the true proportion is less than or equal to 65% versus the alternative hypothesis that the true proportion is greater than 65% (Performance Goal).

9.15. Survival Component of the Primary Effectiveness Endpoint - Survival at Day 30 Post-Transplant

The results for the patient survival at day 30 post-transplantation component of the primary effectiveness endpoint for the EXPAND trial are shown in Table 26 below.

Table 26: Results for Components of Primary Effectiveness Endpoint for the EXPAND trial: Patient Survival at Day 30 Post-Transplant

	Transplanted Recipients (N= 79)
Patient survival at day 30 post-transplantation	
Number (n)	78
Proportion [1] (%) (n/N)	98.7% (78/79)
95% CI (%) for Proportion[2]	(93.1%, 100%)

[1] Observed proportion = n/N *100%. [2] Clopper-Pearson exact confidence interval for a binomial proportion.

9.16. PGD3 Component of the Primary Effectiveness Endpoint – PGD3 within 72 Hours

The results for the PGD3 within 72 hours (i.e., at T0, T24, T48, or T72) component of the primary effectiveness endpoint for the EXPAND trial are shown in Table 27 below.

Table 27: Results for Components of Primary Effectiveness Endpoint for the EXPAND trial: Absence of PGD3 within the first 72 hours post-transplant

	Transplanted Recipients (N= 79)
Absence of ISHLT PGD grade 3 in the first 72 hours post-transplantation (i.e., T0, T24, T48 or T72)	
Number (n)	44
Proportion [1] (%) (n/N)	55.7% (44/79)
95% CI (%) for Proportion[2]	(44.1%, 66.9%)
[1] Observed proportion = n/N *100%. [2] Clopper-Pearson exact confidence interval for a binomial proportion.	

9.17. Secondary Effectiveness Endpoints

The results for the secondary endpoints are shown in Table 28 below. One patient was ungradable at T48 and T72 due to missing arterial blood gas (ABG) and/or chest X-ray (CXR). A comparison of the Secondary Endpoint results stratified by donor inclusion criteria are provided in Section 9.20. A comparison of the secondary endpoint results for the overall population compared to INSPIRE control are shown in Section 9.23.

Table 28: Results for Secondary Effectiveness Endpoints in EXPAND Trial

	Transplanted Recipients (N= 79)
Incidence of PGD2 or PGD3 at T72 hours post-transplantation	
Number (n)	13
Proportion [1] (%) (n/N)	16.7% (13/78)
95% CI (%) for Proportion[2]	(9.2%, 26.8%)
Incidence of PGD3 at T72 hours post-transplantation	
Number (n)	5
Proportion [1] (%) (n/N)	6.4% (5/78)
95% CI (%) for Proportion[2]	(2.1%, 14.3%)
[1] Observed proportion = n/N *100%. [2] Clopper-Pearson exact confidence interval for a binomial proportion.	

9.18. Other Clinical Endpoints

9.18.1. ICU, Ventilation, and Hospitalization Times

The duration of initial post-transplant ventilation, the length of initial post-transplant ICU time and length of initial post-transplant hospital stay are shown in Table 29 below.

Table 29: ICU, Ventilation, and Hospitalization Times

	Transplanted Recipients (N=79)
Duration of Initial Post-Transplant Mechanical Ventilation (Hours)	
Mean ± SD	180.6 ± 397.2
Median	37.0
Min.-Max.	5.2 – 2620.5
Length of Initial Post-Transplant ICU Stay (Hours)	
Mean ± SD	266.8 ± 292.0
Median	155.7
Min.-Max.	32.3 – 1370.5
Length of Initial Post-Transplant Hospital Stay (Days)	
Mean ± SD	30.9 ± 26.1
Median	23.0
Min.-Max.	10-151

9.18.2. ISHLT PGD Grades at T0, T24, T48, and T72 Hours Post-transplant

The PGD grades at T0, T24, T48 and T72 post-transplant for EXPAND recipients are listed in Table 30 below. Note that one patient was ungradable at T48 and T72 due to missing ABG and/or CXR. A comparison of the results for EXPAND recipients compared to the INSPIRE control group is provided in Section 9.23.

Table 30: Listing of ISHLT PGD Grades at T0, T24, T48, and T72 Hours for Transplanted Recipients in EXPAND Trial

PGD Grade	Transplanted OCS Recipients (N=79)
T0 hour	
0	17.7% (14/79)
1	16.5% (13/79)
2	25.3% (20/79)
3	40.5% (32/79)
T24 hour	
0	26.6% (21/79)
1	38.0% (30/79)
2	19.0% (15/79)

PGD Grade	Transplanted OCS Recipients (N=79)
3	16.5% (13/79)
T48 hour	
0	29.5% (23/78)
1	50.0% (39/78)
2	11.5% (9/78)
3	9.0% (7/78*)
T72 hour	
0	35.9% (28/78)
1	47.4% (37/78)
2	10.3% (8/78)
3	6.4% (5/78*)
*One patient was ungradable at T48 and T72 due to missing ABG and/or CXR	

9.18.3. Incidence of BOS at 6 and 12 Months

BOS is the most common long-term complication after lung transplantation and is the leading cause of long-term graft failure. As shown in Table 31 below, the incidence of BOS diagnosis for the EXPAND trial was 0% (0/78) and 1.4% (1/74) at 6- and 12-months follow-up timepoints, respectively. Longer-term Freedom from BOS for EXPAND subjects is shown in Section 9.21 and a comparison of Freedom from BOS for EXPAND recipients and INSPIRE control group is provided in Section 9.23.

Table 31: BOS through 12 Months for EXPAND Transplanted Recipients

	EXPAND Transplanted Recipient Population (N=79)
BOS by 6 months	
Incidence of BOS, n/N (%)	0/78[1] (0.0%)
95% CI*	(0.0%, 4.6%)
BOS by 12 months	
Incidence of BOS, n/N (%)	1/74[2] (1.4%)
95% CI*	(0.0%, 7.3%)
*Clopper-Pearson exact confidence interval for a binomial proportion [1]Excludes one patient who died before 6 months [2]Excludes five patients who died before 12 months	

9.19. Safety Endpoint

The EXPAND trial safety endpoint was defined as the number of LGRSAEs up to 30 days follow-up after lung transplantation, consisting of the following (at least one per type): acute rejection (biopsy proven); respiratory failure; bronchial anastomotic complications; and major pulmonary-related infection. Reporting of the safety endpoint included the average number of LGRSAEs per patient, with multiple occurrences of SAE of the same category on the same subject within 30 days counted as one LGRSAE. The results are shown in Table 32. The safety endpoint's average for the EXPAND subjects was 0.3 ± 0.47. which is comparable to the results observed for the INSPIRE Control group (see Section 9.23).

Table 32: Safety Endpoint for Lung EXPAND Trial and Listing of LGRSAEs

Number of lung-graft-related serious adverse events (LGRSAEs) up to the 30-day follow-up after transplantation (at most one per type)[1]	**OCS EXPAND (N= 79)**
Mean ± SD	0.3 ± 0.47
Median	0.0
Min.-Max.	0.0 - 2.0
95% Confidence Interval of mean[2]	(0.1, 0.4)
Type of LGRSAEs n(%)	**OCS EXPAND (N= 79)**
Acute Rejection	0 (0%)
Respiratory Failure[3]	12 (15.2%)
Bronchial Anastomotic Complication	0 (0%)
Major Pulmonary-Related Infection	7 (8.9%)

[1]Multiple occurrences of the same category of events on one patient are counted once only.

[2]Confidence interval calculated based on the t-distribution.

[3]Need for re-intubation, tracheostomy or the inability to discontinue ventilator support within 4 days post-transplant.

There were 12 patients in the EXPAND trial who had the LGRSAE of respiratory failure. Six (6) of these 12 patients (50%) with respiratory failure had DCD donors. Eight (8) of the 12 patients had PGD3 within 72 hours, but only 2 of these had PGD3 that persisted through 72 hours (one patient did not have PGD results available at T72). None of the patients developed BOS. One of these patients died at Day 352 post-transplant and another patient died at Day 393 post-transplant.

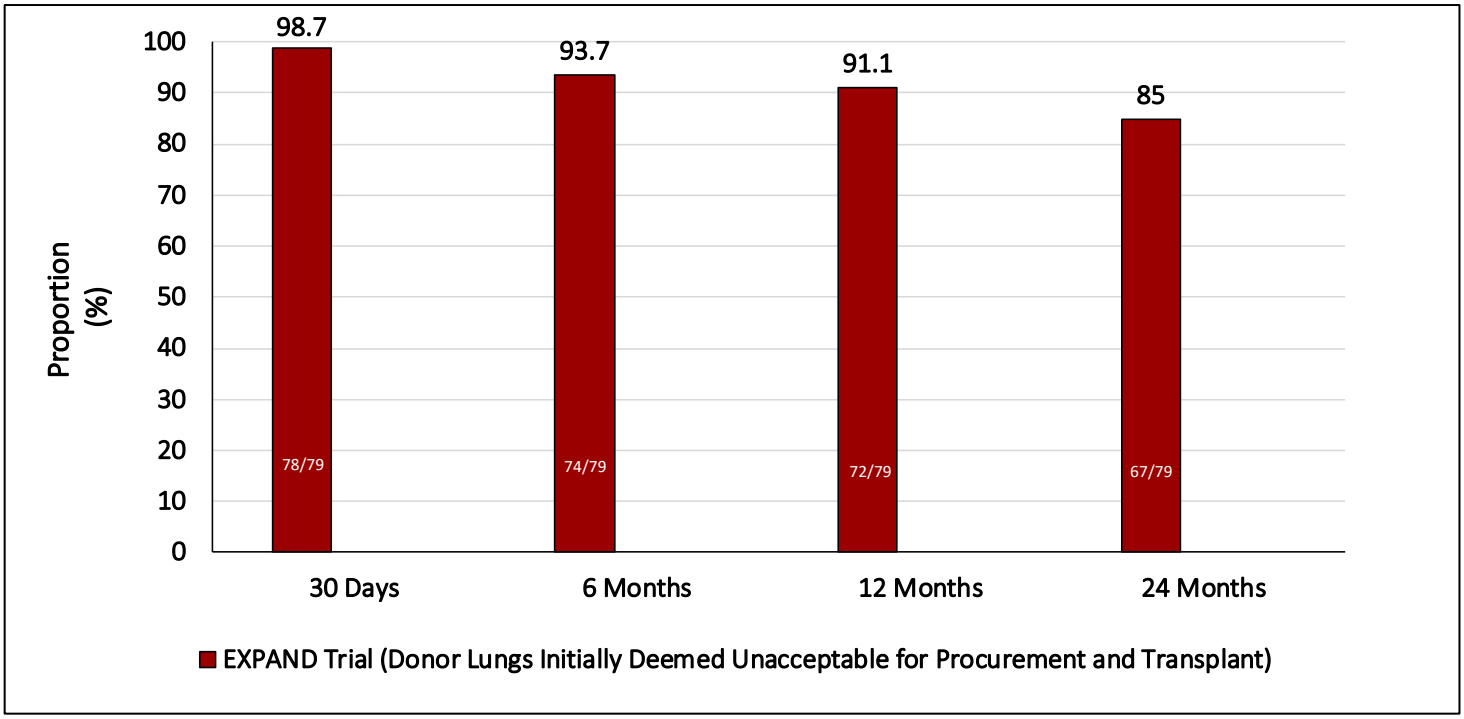
The LGRSAE of respiratory failure for both EXPAND and INSPIRE was defined as: impairment of respiratory function requiring re-intubation, tracheostomy or the inability to discontinue invasive ventilatory support within 4 days (96 hours) post-transplant. Reintubation does not necessarily mean the transplanted lung is functioning poorly.

9.20. Adjunct Effectiveness Analyses

9.20.1. Patient Survival

The results for patient survival at 30 days, 6 months, 12 months, and 24 months in the EXPAND study are shown in Figure 75. The OPTN/SRTR national averages for the same time periods are 96.2%, 90.2%, 85% and 76%, respectively (Valapour, et al., 2018[5]). Longer-term survival of EXPAND subjects compared to survival of INSPIRE control subjects and UNOS National averages is described in Section 9.23.

Figure 75: Patient Survival for All EXPAND Recipients (N=79) through 24 Months Post-transplant



9.20.2. Utilization Rate

In the EXPAND trial, 93 donated lungs were instrumented and assessed on the OCS™ Lung System. Twelve (13%) donor lungs failed to meet the trial's transplantation criteria on OCS™ Lung System, resulting in 81 (87%) donor lungs designated as appropriate for transplantation. Two (2) (2.2%) donor lungs were not transplanted due to recipient and logistics screen failures. Utilization rate for the Lung EXPAND study is shown in Table 33 below.

Table 33: Donor Lung Utilization in the EXPAND trial

Donor Lung Utilization in the EXPAND Trial	Number of Donor Lungs
OCS Perfused Lungs	93
Did not meet transplant criteria after OCS perfusion	12
Met transplant criteria after OCS perfusion	81
Recipients transplanted with the OCS lungs	79
OCS perfused lungs not transplanted	2

Donor Lung Utilization in the EXPAND Trial	Number of Donor Lungs
	Rate % (n/N)
Rate of transplanted lungs among OCS perfused lungs % (n/N) 95% Confidence Interval	85% (79/93) (76.0%, 91.5%)
Rate of utilizable lungs after OCS perfusion, % (n/N) 95% Confidence Interval	87% (81/93) (78.6%, 93.2%)

9.21. Post-Hoc Subgroup Analyses of EXPAND Results Stratified by Donor Inclusion Criteria

Post-hoc subgroup results for the primary effectiveness endpoint are displayed in Table 34 below for recipients of donors with a single criterion met (N=58), recipients of donors with multiple criteria met (N=21) and all recipients (all donors, N=79), stratified by donor inclusion criteria. Analogous results for the components of the primary effectiveness endpoint (patient survival at day 30 post-transplant and freedom from PGD3 within 72 hours post-transplant are shown in Table 35 and Table 36, respectively.

Table 34: Post-hoc subgroup analyses of Primary Effectiveness Endpoint stratified by donor inclusion criteria for recipients of donors with a single criterion met (N=58), recipients of donors with multiple inclusion criteria met (N=21) and for all transplanted recipients (all donors, N=79)

	Primary Effectiveness Endpoint: Survival at Day 30 Post-Transplant and Freedom from PGD3 within 72 hours post-transplant
Recipients of Donors with a Single Criterion Met (N=58)	**58.6% (34/58)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=9)	55.6% (5/9)
• Donor Age $\geq$ 55 (N=22)	63.6% (14/22)
• Expected Cross-Clamp Time > 6 hr (N=11)	63.6% (7/11)
• DCD (N=16)	50.0% (8/16)
Recipients of Donors with Multiple Criteria Met (N=21)	**42.9% (9/21)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=11)	63.6% (7/11)
• Donor Age $\geq$ 55 (N=9)	44.4% (4/9)
• Expected Cross-Clamp Time > 6 hr (N=14)	35.7% (5/14)
• DCD (N=10)	20.0% (2/10)
All Recipients – All Donor Inclusion Criteria (N=79)	**54.4% (43/79)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=20)	60% (12/20)
• Donor Age $\geq$ 55 (N=31)	58.1% (18/31)
• Expected Cross-Clamp Time > 6 hr (N=25)	48% (12/25)
• DCD (N=26)	38.5% (10/26)

Table 35: Post-hoc subgroup analyses of component of Primary Effectiveness Endpoint: Patient Survival at Day 30 Post-Transplant stratified by donor inclusion criteria for recipients of donors with a single criterion met (N=58), recipients of donors with multiple inclusion criteria met (N=21) and for all transplanted recipients (all donors, N=79)

	Component of Primary Effectiveness Endpoint: Patient Survival at Day 30 Post-Transplant
Recipients of Donors with a Single Criterion Met (N=58)	**98.3% (57/58)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=9)	100% (9/9)
• Donor Age $\geq$ 55 (N=22)	100% (22/22)
• Expected Cross-Clamp Time > 6 hr (N=11)	90.9% (10/11)
• DCD (N=16)	100.0% (16/16)
Recipients of Donors with Multiple Criteria Met (N=21)	**100% (21/21)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=11)	100% (11/11)
• Donor Age $\geq$ 55 (N=9)	100% (9/9)
• Expected Cross-Clamp Time > 6 hr (N=14)	100% (14/14)
• DCD (N=10)	100% (10/10)
All Recipients – All Donor Inclusion Criteria (N=79)	**98.7% (78/79)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=20)	100% (20/20)
• Donor Age $\geq$ 55 (N=31)	100% (31/31)
• Expected Cross-Clamp Time > 6 hr (N=25)	96.0% (24/25)
• DCD (N=26)	100% (26/26)

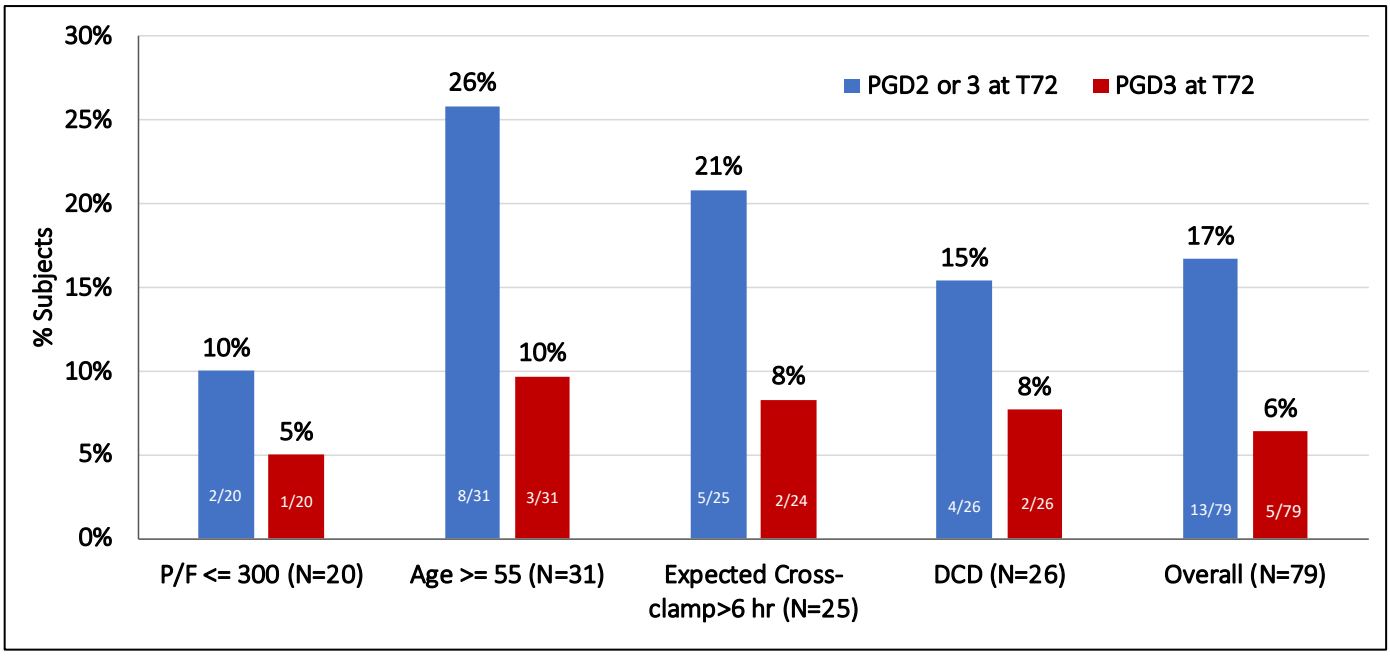
Table 36: Post-hoc subgroup analyses of Component of Primary Effectiveness Endpoint: Freedom from PGD3 within 72 hours post-transplant, stratified by donor inclusion criteria for recipients of donors with a single criterion met (N=58), recipients of donors with multiple inclusion criteria met (N=21) and for all transplanted recipients (all donors, N=79)

	Component of Primary Effectiveness Endpoint: Freedom from PGD3 within 72 hours post-transplant
Recipients of Donors with a Single Criterion Met (N=58)	**60.3% (35/58)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=9)	55.6% (5/9)
• Donor Age $\geq$ 55 (N=22)	63.6% (14/22)
• Expected Cross-Clamp Time > 6 hr (N=11)	72.7% (8/11)
• DCD (N=16)	50.0% (8/16)
Recipients of Donors with Multiple Criteria Met (N=21)	**42.9% (9/21)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=11)	63.6% (7/11)
• Donor Age $\geq$ 55 (N=9)	44.4% (4/9)

	Component of Primary Effectiveness Endpoint: Freedom from PGD3 within 72 hours post-transplant
• Expected Cross-Clamp Time > 6 hr (N=14)	35.7% (5/14)
• DCD (N=10)	20.0% (2/10)
All Recipients – all Donor Inclusion Criteria (N=79)	**55.7% (44/79)**
• $PaO_2/FiO_2 \leq 300$ mm Hg (N=20)	60.0% (12/20)
• Donor Age ≥ 55 (N=31)	58.1% (18/31)
• Expected Cross-Clamp Time > 6 hr (N=25)	52.0% (13/25)
• DCD (N=26)	38.5% (10/26)

The results for the secondary endpoints (PGD2 or 3 at T72 post-transplant and PGD3 at T72 post-transplant) are shown in Figure 76 below, stratified by donor inclusion criteria.

Figure 76: Secondary Endpoint Results (PGD2 or PGD3 at T72 post-transplant and PGD3 at T72 post-transplant) for EXPAND Trial Overall Population (N=79) and Stratified by Donor Inclusion Criteria

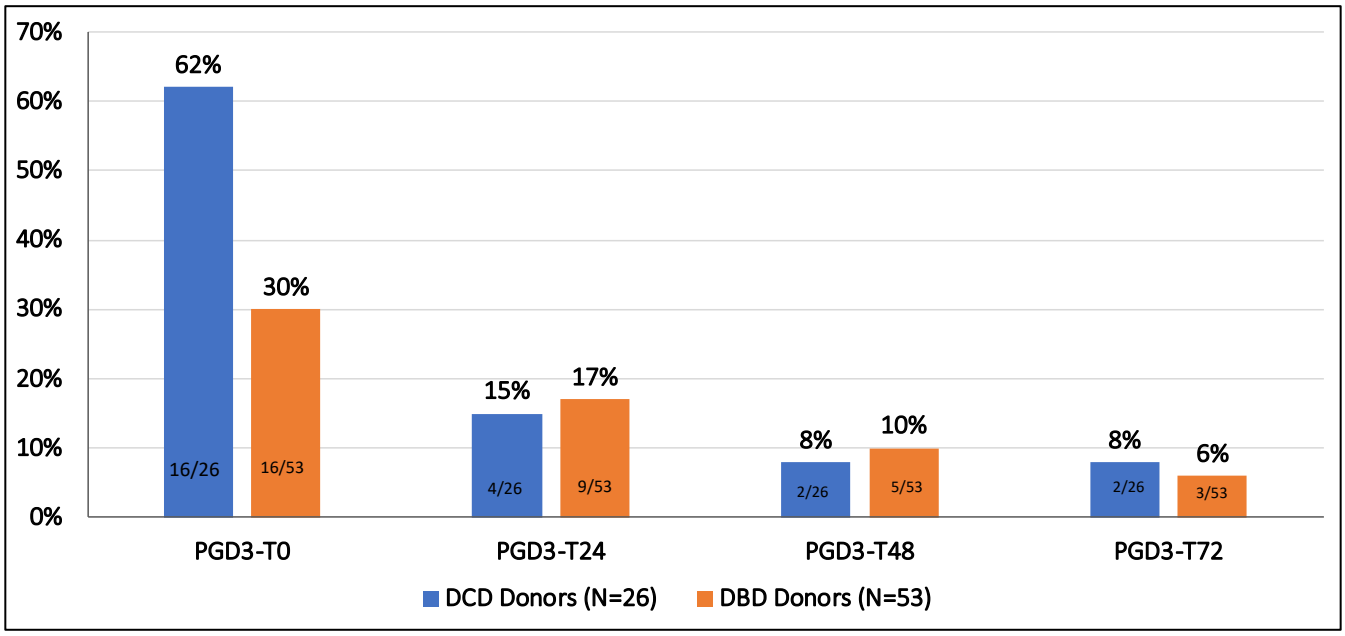


9.21.1. Post-hoc Subgroup Analysis of DCD and DBD Donors

In the EXPAND trial, the incidence of PGD3 at T0 for DCD Transplants was 62% (16/26) compared to the incidence of PGD3 at T0 for DBD Transplants which was 30% (16/53) (see Figure 77). The finding of elevated rates of PGD3 post-transplant in DCD lungs in the EXPAND trial is consistent with

recent reports for other technologies for ex vivo lung preservation (Whitson, et al., 2018[9] and Fisher, et al., 2016[10]).

Figure 77: Incidence of PGD3 at each timepoint for EXPAND Recipients stratified by DCD vs DBD Donor lungs



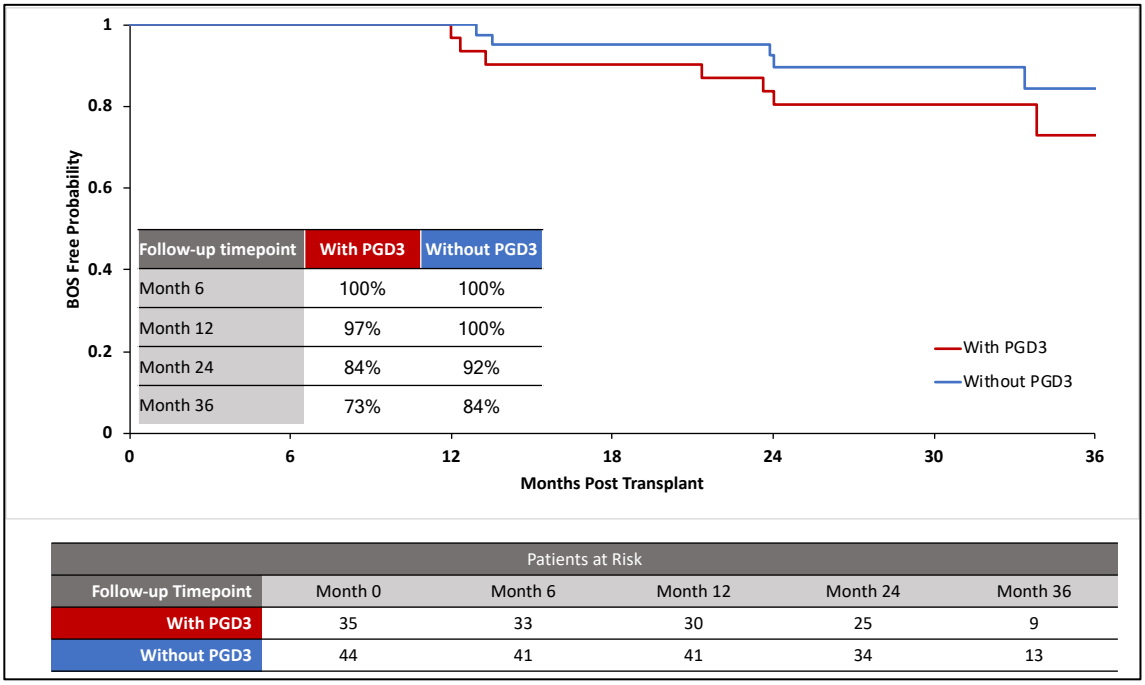
9.22. Post-hoc Subgroup Analyses of BOS

In the EXPAND trial, there were 35 subjects with PGD3 and 44 subjects without PGD3 in the first 72 hours post-transplant. The results for Kaplan-Meier (K-M) Analysis of Freedom from BOS for EXPAND subjects with and without PGD3 in the first 72 hours post-transplant are shown in Figure 78. As expected, subjects with PGD3 showed a higher incidence of BOS compared to subjects without PGD3. Note that data at 36 months post-transplant are available for 57% of EXPAND subjects since follow-up is on-going.

[9] Whitson, et al. Ex-Vivo Lung Perfusion in Donation after Circulatory Death in Lung Transplantation increases Donor Utilization: Analysis of the NOVEL Extension Trial. *J. Heart Lung Transplant.* 2018; 37(4)S147-S148

[10] Fisher, et al. An Observational Study of Donor Ex Vivo Lung Perfusion in UK Lung Transplantation: DEVELOP-UK. *Health Tech. Assess.* 2016; 20(85).

Figure 78: K-M Analysis of BOS for EXPAND Recipients with PGD3 vs. without PGD3 within 72 Hours Post-Transplant

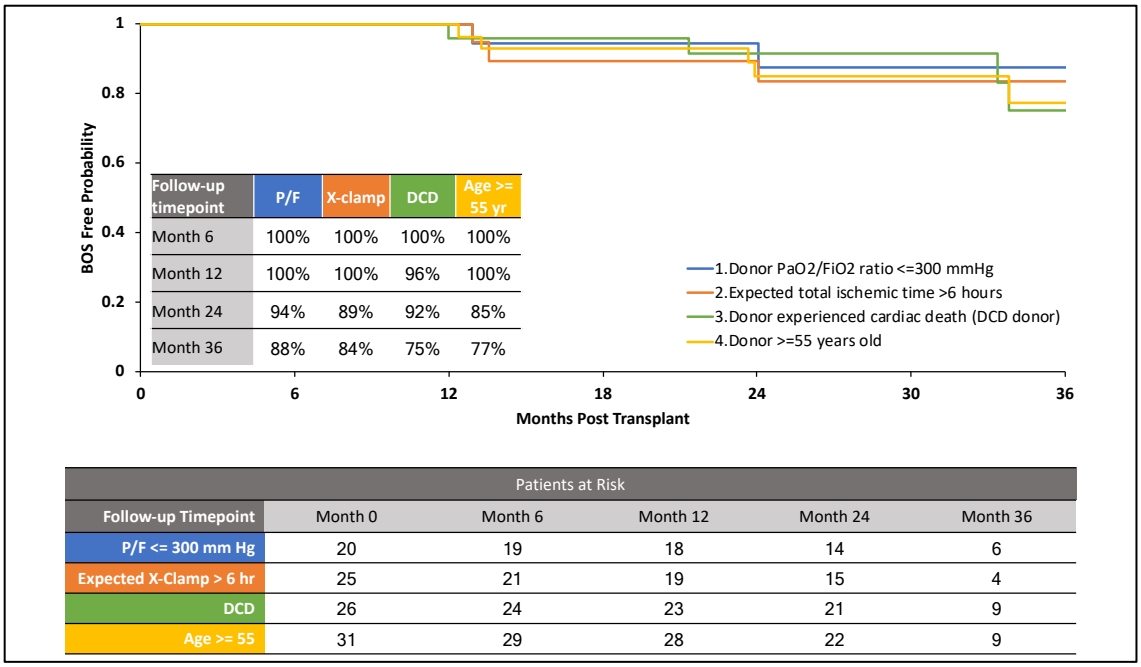


Follow-up timepoint	With PGD3	Without PGD3
Month 6	100%	100%
Month 12	97%	100%
Month 24	84%	92%
Month 36	73%	84%

Patients at Risk					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
With PGD3	35	33	30	25	9
Without PGD3	44	41	41	34	13

The results for the K-M analyses of BOS through 36 months, stratified by donor inclusion criteria are shown in Figure 79 and Figure 80 below for the overall EXPAND transplanted recipients (N=79) and for recipients of donor lungs with a single donor criterion met (N=58), respectively. Note that data at 36 months post-transplant is available for 57% of EXPAND subjects since follow-up is on-going.

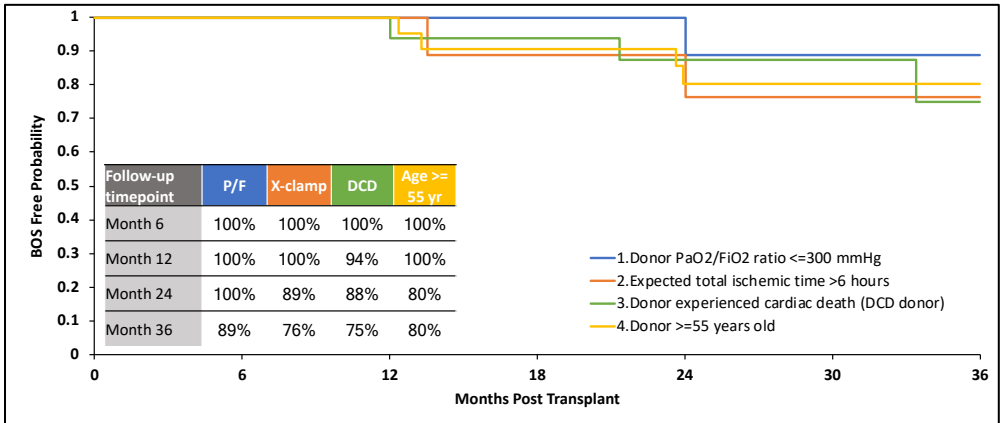
Figure 79: K-M Analysis of Freedom from BOS for EXPAND Stratified by Donor Inclusion Criteria for All Transplanted Recipients (N=79)



Follow-up timepoint	P/F	X-clamp	DCD	Age >= 55 yr
Month 6	100%	100%	100%	100%
Month 12	100%	100%	96%	100%
Month 24	94%	89%	92%	85%
Month 36	88%	84%	75%	77%

Patients at Risk					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
P/F <= 300 mm Hg	20	19	18	14	6
Expected X-Clamp > 6 hr	25	21	19	15	4
DCD	26	24	23	21	9
Age >= 55	31	29	28	22	9

Figure 80: K-M Analysis of Freedom from BOS for EXPAND Stratified by Donor Inclusion Criteria for Recipients with Single Donor Inclusion Criterion Met (N=58)



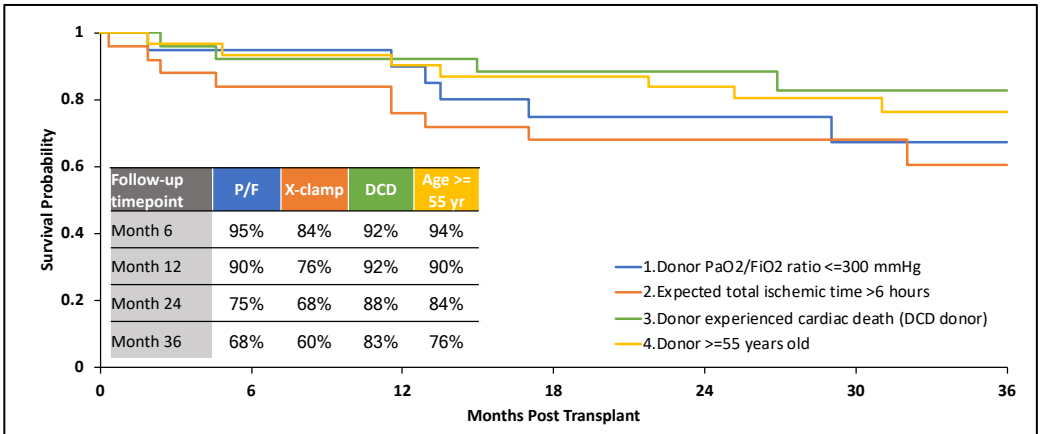
Follow-up timepoint	P/F	X-clamp	DCD	Age >= 55 yr
Month 6	100%	100%	100%	100%
Month 12	100%	100%	94%	100%
Month 24	100%	89%	88%	80%
Month 36	89%	76%	75%	80%

Patients at Risk					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
P/F <= 300 mm Hg	9	9	9	9	3
Expected X-Clamp > 6 hr	11	10	9	7	1
DCD	16	16	15	14	6
Age >= 55	22	21	21	16	6

9.23. Post-hoc Subgroup Analyses of Patient Survival

The results for the K-M analyses of patient survival through 36 months, stratified by donor inclusion criteria are shown in Figure 81 and Figure 82 below for the overall EXPAND transplanted recipients (N=79) and for recipients of donor lungs with a single donor criterion met (N=58), respectively. Note that data at 36 months post-transplant is available for 57% of EXPAND subjects since follow-up is on-going.

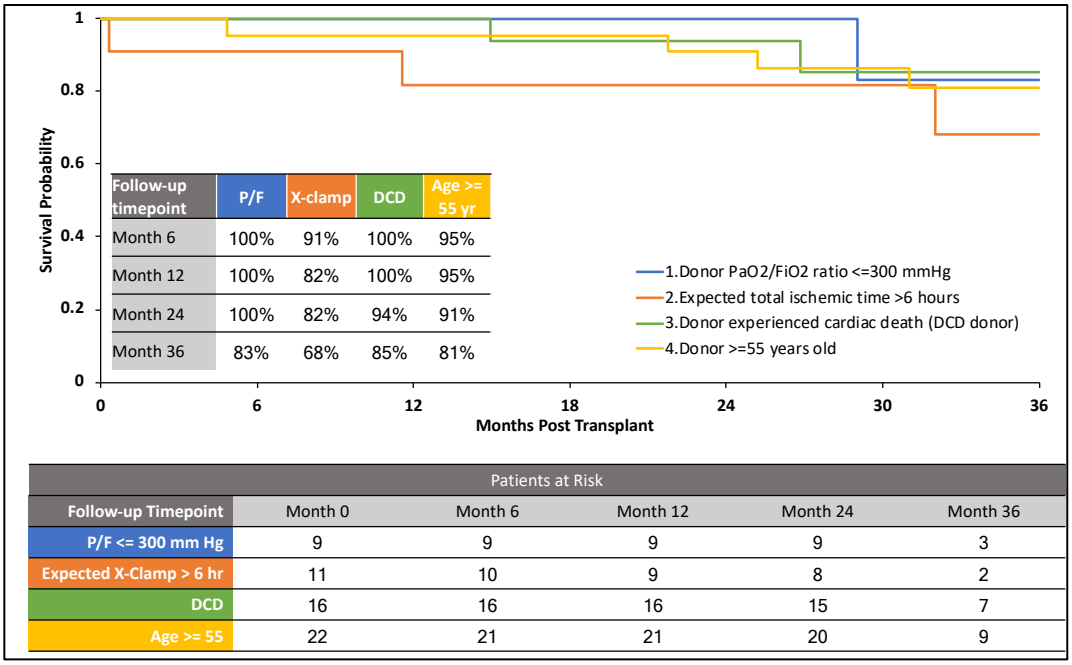
Figure 81: K-M Analysis of Survival of EXPAND Subjects Stratified by Inclusion Criteria for All Transplanted Recipients (N=79)



Follow-up timepoint	P/F	X-clamp	DCD	Age >= 55 yr
Month 6	95%	84%	92%	94%
Month 12	90%	76%	92%	90%
Month 24	75%	68%	88%	84%
Month 36	68%	60%	83%	76%

Patients at Risk					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
P/F <= 300 mm Hg	20	19	18	14	6
Expected X-Clamp > 6 hr	25	21	19	16	5
DCD	26	24	24	22	11
Age >= 55	31	29	28	26	13

Figure 82: K-M Analysis of Survival of EXPAND Subjects Stratified by Donor Inclusion Criteria for Transplanted Recipients who had a Single Donor Inclusion Criterion (N=58)



Follow-up timepoint	P/F	X-clamp	DCD	Age >= 55 yr
Month 6	100%	91%	100%	95%
Month 12	100%	82%	100%	95%
Month 24	100%	82%	94%	91%
Month 36	83%	68%	85%	81%

Patients at Risk

Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
P/F <= 300 mm Hg	9	9	9	9	3
Expected X-Clamp > 6 hr	11	10	9	8	2
DCD	16	16	16	15	7
Age >= 55	22	21	21	20	9

9.24. Post-hoc Comparison of Lung EXPAND Results with INSPIRE Control Group

Table 37 below compares the demographic data for donors and recipients in the EXPAND trial and the INSPIRE control group, who received standard criteria donor lungs preserved on cold storage, including various donor and recipient factors as identified in Diamond, et al. (2013).Enrollment criteria for recipients in INSPIRE and EXPAND were the same and although the donor inclusion/exclusion criteria differed, there was some overlap in donor organ characteristics as described below.

Although the recipient inclusion/exclusion criteria were the same for the two trials, some differences were observed. The percentage of recipients with BMI > 25 was 50.6% (40/79) for EXPAND compared to 34.2% (63/184) for INSPIRE control. The mean LAS Score was 42 for the EXPAND recipients and 48 for the INSPIRE Control group. The prevalence of secondary pulmonary hypertension was 28% (22/79) in the EXPAND recipients compared to 32% (59/184) in the INSPIRE control group.

For donor risk factors, 23.0% (42/184) of INSPIRE donors had a history of smoking > 20 pack-years compared to 1.3% (1/79) of donors for EXPAND (Smoking > 20 pack-years was an exclusion criterion in EXPAND, but not INSPIRE). In addition, 39.2% (31/79) EXPAND donors had age ≥ 55 years compared to 17.5% (32/184) for INSPIRE control, 25.3% (20/79) EXPAND Donors had $PaO_2/FiO_2 \leq 300$ mmHg compared to 0% (0/0) for INSPIRE control and 65.4% (51/79) EXPAND donors had abnormal findings on chest X-ray compared to 48.3% (85/184) for INSPIRE control.

Table 37: Comparison of Recipient and Donor Demographics for EXPAND Trial Recipients and INSPIRE Control Recipients (Standard criteria donors, preserved on cold storage)

	EXPAND Transplanted Recipients N=79	INSPIRE Control Recipients N=184
Donor Characteristics		
Donor Age ≥ 55 years, n (%)	31 (39.2%)	32 (17.5%)
Female Gender, n (%)	33 (41.8%)	73 (39.7%)
Smoking > 20 pack years, n (%)	1 (1.3%)	42 (23.0%)
PaO_2/FiO_2 ratio ≤ 300 mmHg, n (%)	20 (25.3%)	0 (0.0%)
History of Aspiration, n (%)	3 (3.8%)	19 (10.4%)
Head trauma as cause of death, n (%)	8 (10.1%)	50 (27.2%)
Abnormal findings on chest X-ray, n (%)	51 (65.4%)	85 (48.3%)
Recipient Characteristics		
Cardiopulmonary bypass, n (%)	38 (48.1%)	70 (38.0%)
BMI > 25, n (%)	40 (50.6%)	63 (34.2%)
Diagnosis of COPD, n (%)	27 (34.2%)	53 (28.8%)
Diagnosis of sarcoidosis, n (%)	2 (2.5%)	9 (4.9%)
Diagnosis of cystic fibrosis, n (%)	12 (15.2%)	43 (23.4%)
Diagnosis of idiopathic pulmonary fibrosis (IPF), n (%)	18 (22.8%)	64 (34.8%)
Diagnosis of secondary pulmonary hypertension, n (%)	22 (27.8%)	59 (32.2%)
Use of pre-transplant ECMO, n (%)	1 (1.3%)	10 (5.5%)
Use of pre-transplant mechanical ventilation, n (%)	3 (3.8%)	10 (5.5%)
History of heart failure, n (%)	1 (1.3%)	13 (7.2%)
History of insulin dependent diabetes, n (%)	19 (24.1%)	40 (21.7%)
LAS – Mean ± SD (n/N)	42 ± 14 (70/79)	48 ± 18 (125/184)

9.24.1. Post-hoc Comparison of PGD for EXPAND and INSPIRE Control Recipients

The results for PGD3 within 72 hours post-transplant in the EXPAND transplanted recipient population are higher than the INSPIRE control population, but the results for PGD3 at T72 are comparable to those observed for the INSPIRE Control group. Similarly, results for PGD2 or PGD3 at T72 post-transplant were higher in the EXPAND recipients compared to the INSPIRE control recipients (see Table 38).

Table 38: Comparison of PGD post-transplant for EXPAND trial recipients and INSPIRE control group (standard criteria donor lungs preserved on cold storage)

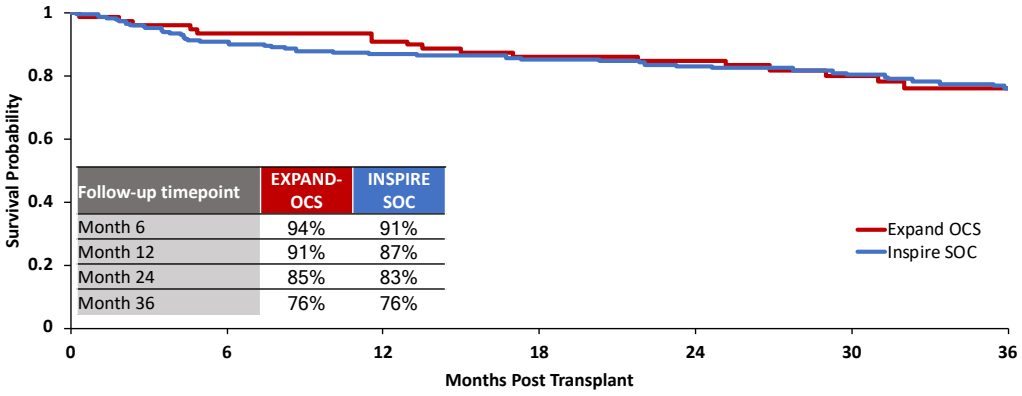
	EXPAND Trial Transplanted Recipients N=79	INSPIRE Trial Control Group N=184
PGD3 within T72 post-transplant (T0, T24, T48 and T72)	35/79 (44.3%)	53/184 (28.8%)
PGD3 at T0 post-transplant	32/79 (40.5%)	38/184 (20.7%)
PGD3 at T24 post-transplant	13/79 (16.5%)	20/184 (10.9%)
PGD3 at T48 post-transplant	7/78 (9.0%)	12/183 (6.6%)
PGD3 at T72 post-transplant	5/78 (6.4%)	10/183 (5.5%)
PGD2 or PGD3 at T72 post-transplant	13/78 (16.7%)	20/183 (10.9%)

A post-hoc analysis of PGD3 within the initial 72 hours was performed using logistic regression to adjust for the identified differences. Terms were included for treatment, donor age ≥ 55 years, donor smoking > 20 pack years, donor P/F ratio ≤ 300 mmHg, donor head trauma as cause of death, donor abnormal findings on chest X-ray, and recipient BMI > 25. Regarding PGD3, the adjusted rates are higher in the EXPAND group when compared to the INSPIRE control group regardless of the other variables.

9.24.2. Post-Hoc Subgroup Analyses of Patient Survival through 36 Months

Figure 83 below shows the K-M post-transplant patient survival results through 36 months in the EXPAND trial compared to the recipients of standard donor lungs preserved on cold storage in the Control arm of the INSPIRE trial. Analyses at 36 months are based on available data. Figure 84 below compares the results for the EXPAND trial to the results of the OPTN/SRTR national average statistics for patient survival post-lung transplantation through 24 months post-transplant.

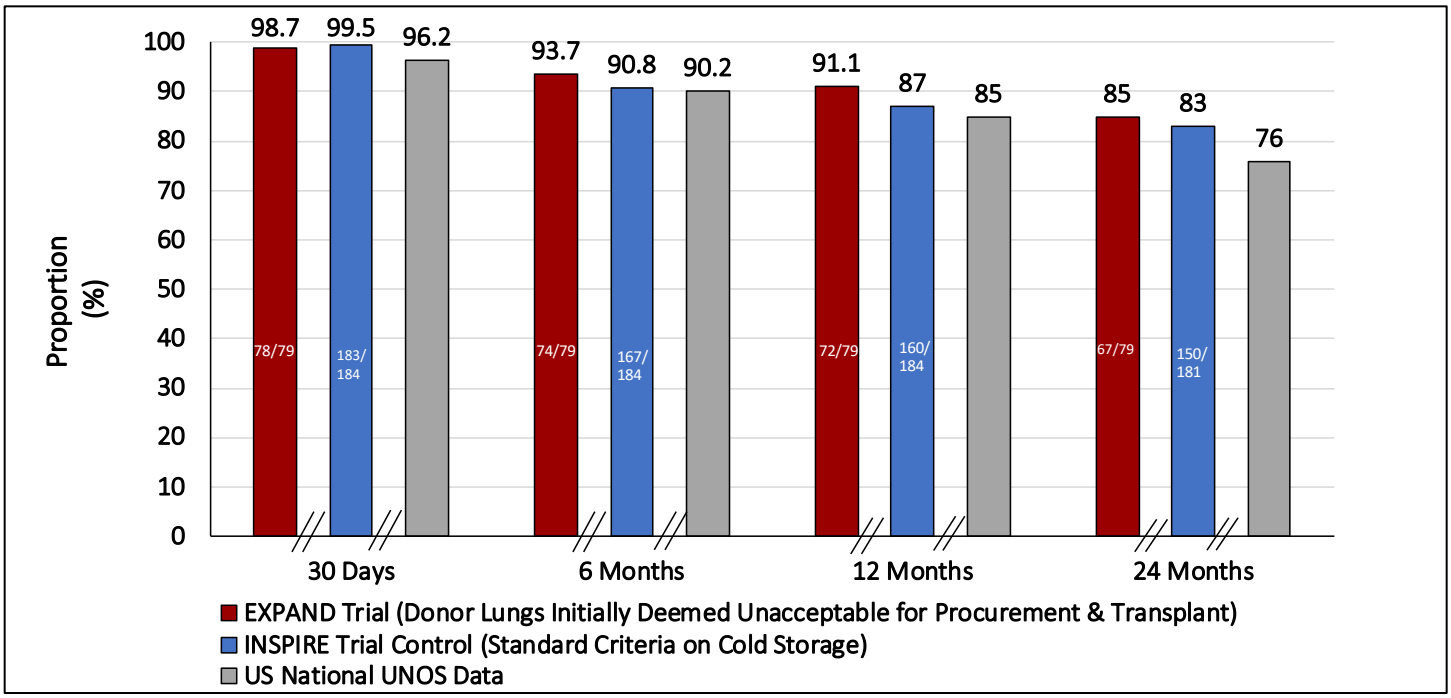
Figure 83: K-M Overall Survival through 36 Months Post-transplant for EXPAND Subjects Compared to INSPIRE Control



Follow-up timepoint	EXPAND-OCS	INSPIRE SOC
Month 6	94%	91%
Month 12	91%	87%
Month 24	85%	83%
Month 36	76%	76%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
EXPAND-OCS- Patients at Risk	79	74	72	65	28
Patient Censored	--	0	0	2	34
Patient Died		5	7	12	17
INSPIRE – Standard of Care (SOC)- Patients at Risk	184	167	160	153	107
Patient Censored	--	0	0	0	36
Patient Died		17	24	31	41

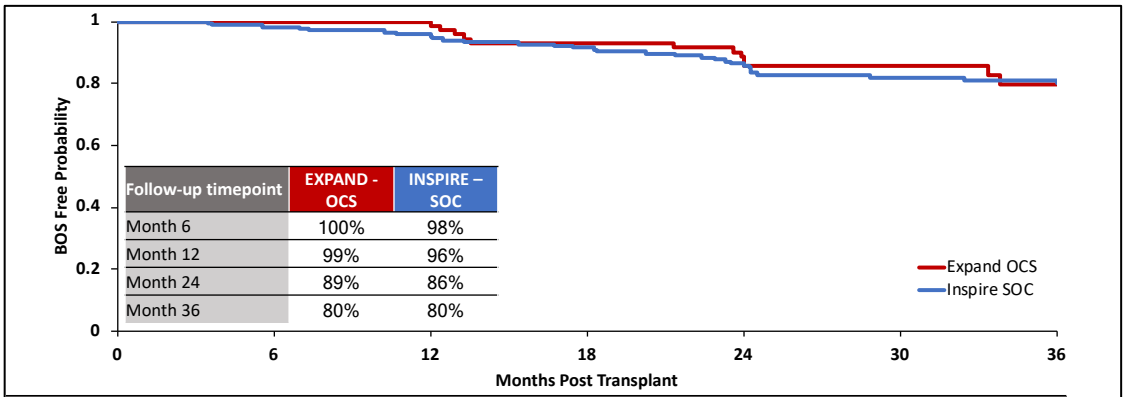
Figure 84: Comparison of Patient survival in the EXPAND trial overall population (N=79) to INSPIRE Control Group (N=184) and to U.S. National Average post-lung transplantation (Valapour, et al., 2018)



9.24.3. Freedom from Bronchiolitis Obliterans Syndrome (BOS) through 36 Months Post-transplant: Lung EXPAND and INSPIRE Control

The results for K-M analyses for Freedom from BOS for EXPAND recipients compared to INSPIRE control group through 36 months post-transplant are shown in Figure 85. The comparative K-M analysis for BOS-free survival (Survival and Freedom from BOS) through 36 months is shown in Figure 86. The analyses at 36 months are based on available data. TransMedics will continue to evaluate this trend for 5 years post-transplant in a post-market study of EXPAND subjects.

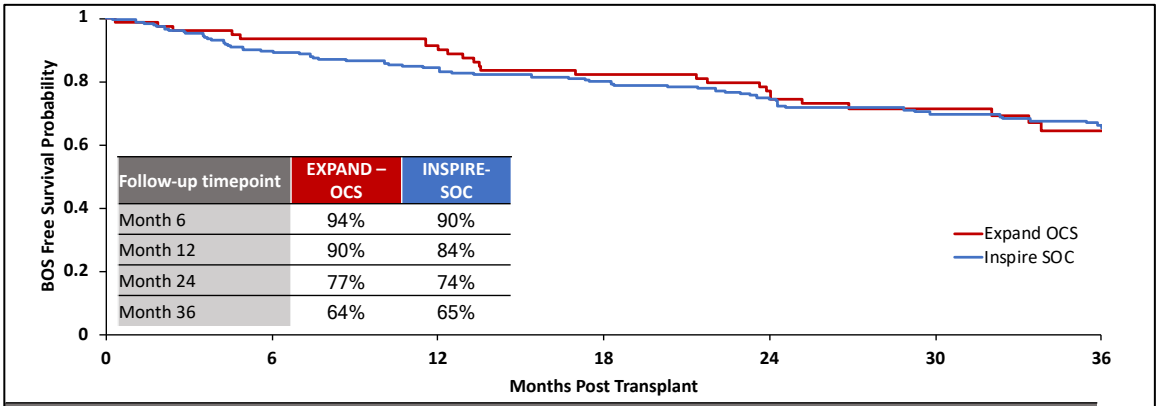
Figure 85: K-M Analysis of Freedom from BOS through 36 Months Post-transplant, EXPAND Recipients Compared to INSPIRE Control



Follow-up timepoint	EXPAND - OCS	INSPIRE – SOC
Month 6	100%	98%
Month 12	99%	96%
Month 24	89%	86%
Month 36	80%	80%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
EXPAND –OCS – Patients at Risk	79	74	71	59	22
Patient Censored	--	5	7	12	45
Patient with BOS		0	1	8	12
INSPIRE –Standard of Care (SOC) – Patients at Risk	184	165	155	137	95
Patient Censored	--	16	22	24	59
Patient with BOS		3	7	23	30

Figure 86: K-M Analysis of BOS-free Survival through 36 Months Post-transplant, EXPAND Recipients Compared to INSPIRE control



Follow-up timepoint	EXPAND – OCS	INSPIRE-SOC
Month 6	94%	90%
Month 12	90%	84%
Month 24	77%	74%
Month 36	64%	65%

Patient Accounting					
Follow-up Timepoint	Month 0	Month 6	Month 12	Month 24	Month 36
EXPAND – OCS – Patients at Risk	79	74	71	59	22
Patient Censored	--	0	0	2	32
Patient with BOS or Died		5	8	18	25
INSPIRE – Standard of Care (SOC) – Patients at Risk	184	165	155	137	95
Patient Censored	--	0	0	0	29
Patient with BOS or Died		19	29	47	60

9.24.4. Additional Post-hoc Subgroup Analyses

Table 39 through Table 42 below provide post-hoc subgroup analyses comparing various subgroups in the Lung EXPAND trial with similar post-hoc subgroups in the INSPIRE control group.

Table 39: Post-hoc Subgroup comparisons of EXPAND trial transplanted recipients and INSPIRE control group (standard criteria donor lungs preserved using cold storage): LAS ≥ 50

	OCS EXPAND (Donor Lungs Initially Deemed Unacceptable for Procurement and Transplant) (N= 79)	**INSPIRE Control (Standard Criteria Lungs, Cold Storage) (N = 184)**
Recipient LAS Score ≥ 50	**N=11**	**N=37**
LAS Score, Mean + SD	67.5 ± 16.6	71.3 ± 16.5
Primary Effectiveness Endpoint, n/N (%)	3/11 (27.3%)	21/37 (56.8%)
• Survival at Day 30 post-transplant, n/N (%)	10/11 (90.9%)	37/37 (100%)
• Freedom from PGD3 within 72 hours post-transplant, n/N (%)	4/11 (36.4%)	21/37 (56.8%)
Incidence of PGD2 or PGD3 at T72, n/N (%)	4/10 (40%)	5/37 (13.5%)
Incidence of PGD3 at T72, n/N (%)	2/10 (20%)	2/37 (5.4%)

Table 40: Post-hoc Subgroup comparisons of EXPAND trial transplanted recipients and INSPIRE control group (standard criteria donor lungs preserved using cold storage): LAS <50

	OCS EXPAND (Donor Lungs Initially Deemed Unacceptable for Procurement and Transplant) (N= 79)	INSPIRE Control (Standard Criteria Lungs, Cold Storage) (N = 184)
Recipient LAS Score < 50	**N=59**	**N = 88**
LAS Score, Mean + SD	37.3 ± 4.9	37.6 ± 5.2
Primary Effectiveness Endpoint, n/N (%)	35/39 (59.3%)	69/88 (78.4%)
• Survival at Day 30 post-transplant, n/N (%)	59/59 (100%)	88/88 (100%)
• Freedom from PGD3 within 72 hours post-transplant, n/N (%)	35/39 (59.3%)	69/88 (78.4%)
Incidence of PGD2 or PGD3 at T72, n/N (%)	7/59 (11.9%)	6/87 (6.9%)
Incidence of PGD3 at T72, n/N (%)	3/59 (5.1%)	4/87 (4.6%)

Table 41: Post-hoc Subgroup comparisons of EXPAND trial transplanted recipients and INSPIRE control group (standard criteria donor lungs preserved using cold storage): Donor Age ≥ 55

	OCS EXPAND (Donor Lungs Initially Deemed Unacceptable for Procurement and Transplant)	OCS EXPAND (Donor Lungs Initially Deemed Unacceptable for Procurement and Transplant)	INSPIRE Control (Standard Criteria Lungs, Cold Storage)
Donor Age ≥ 55 years	**Donors enrolled with single criterion Age ≥ 55 N=22**	**All Donors enrolled with criterion Age ≥ 55 N=31**	**All Donors with Age ≥ 55[1] N=32**
Donor Age, mean ± SD	63.7 ± 6.5	62.9 ±6.1	58.1 ± 2.4
Primary Effectiveness Endpoint, n/N (%)	14/22 (63.6%)	18/31 (58.1%)	22/32 (68.8%)
• Survival at Day 30 post-transplant, n/N (%)	22/22 (100%)	31/31 (100%)	32/32 (100%)
• Freedom from PGD3 within 72 hours post-transplant, n/N (%)	14/22 (63.6%)	18/31 (58.1%)	22/32 (68.8%)
Incidence of PGD2 or PGD3 at T72, n/N (%)	5/22 (22.7%)	8/31 (25.8%)	5/32 (15.6%)
Incidence of PGD3 at T72, n/N (%)	2/22 (9.1%)	3/31 (9.7%)	3/32 (9.4%)
[1]Donor Age ≥ 55 was not an enrollment criterion for INSPIRE			

Table 42: Post-hoc Subgroup comparisons of EXPAND trial transplanted recipients and INSPIRE control group (standard criteria donor lungs preserved using cold storage): Expected and Observed Cross-Clamp Time > 6 hours

	OCS EXPAND (Donor Lungs Initially Deemed Unacceptable for Procurement and Transplant)	OCS EXPAND (Donor Lungs Initially Deemed Unacceptable for Procurement and Transplant)	INSPIRE Control (Standard Criteria Lungs, Cold Storage)
Cross-Clamp Time > 6 hr	**Donors with single criterion of expected cross-clamp time > 6 hr N = 11**	**All donors enrolled with expected cross-clamp Time > 6 hr N=25**	**All donors with observed cross-clamp time > 6 hr N=99**
Observed Cross-Clamp Time (min), Mean ± SD	637.1 ± 106.9	642.5 ± 124.2	488.1 ± 103.9
Primary Effectiveness Endpoint, n/N (%)	7/11 (63.6%)	12/25 (48%)	76/99 (76.8%)
• Survival at Day 30 post-transplant, n/N (%)	10/11 (90.9%)	24/25 (96.0%)	99/99 (100%)
• Freedom from PGD3 within 72 hours post-transplant, n/N (%)	8/11 (72.7%)	13/25 (52.0%)	76/99 (76.8%)
Incidence of PGD2 or PGD3 at T72, n/N (%)	2/10 (20.0%)	5/25 (21%)	10/98 (10.2%)
Incidence of PGD3 at T72, n/N (%)	0/10 (0.0%)	2/25 (8%)	5/98 (5.1%)

9.24.5. Comparison of Safety Endpoint

The EXPAND trial and the INSPIRE trial utilized the same safety endpoint, as defined in Section 9.6. The results for EXPAND recipients for this endpoint compared to INSPIRE control group are shown in Table 43 below. The mean number of LGRSAEs and the type of LGRSAEs are similar for the two studies.

Table 43: Number of LGRSAEs during the first 30 days post-transplantation in the EXPAND Trial, with Comparison to INSPIRE Control group as a Benchmark

Number of lung-graft-related serious adverse events up to the 30-day follow-up after transplantation (at most one per type)[1]	OCS EXPAND (Extended Criteria Lungs) (N= 79)	INSPIRE Control (Standard Criteria Lungs, Cold Storage) (N = 184)
Mean ± SD	0.3 ± 0.47	0.3 ± 0.54
Median	0.0	0.0
Min.-Max.	0.0 - 2.0	0.0 – 2.0
95% Confidence Interval of mean[2]	(0.1, 0.4)	(0.21, 0.37)
Type of LGRSAEs n(%)		
Acute Rejection	0 (0%)	4 (2.2%)
Respiratory Failure[3]	12 (15.2%)	16 (8.7%)

Number of lung-graft-related serious adverse events up to the 30-day follow-up after transplantation (at most one per type)[1]	OCS EXPAND (Extended Criteria Lungs) (N= 79)	INSPIRE Control (Standard Criteria Lungs, Cold Storage) (N = 184)
Bronchial Anastomotic Complication	0 (0%)	4 (2.2%)
Major Pulmonary-Related Infection	7 (8.9%)	29 (15.8%)

[1]Multiple occurrences of the same category of events on one patient are counted once only. [2]Confidence interval calculated based on the t-distribution. [3] Need for re-intubation, tracheostomy or the inability to discontinue ventilator support within 4 days post-transplant.

9.25. EXPAND Trial Serious Adverse Events (SAEs)

Table 44 below provides a summary of the Adverse Events by Type in the EXPAND trial, while Table 45 below shows the adjudicated SAEs by System Organ Class for EXPAND recipients. SAEs were collected for 30 days post-transplant or through hospital discharge, if longer than 30 days.

Table 44: Adverse Events by Type in EXPAND Trial

Parameter	OCS Expand N = 79
Subjects with Any Type of Adverse Events	67 (84.8%)
Subjects with Adverse Events Probably or Definitely Related to OCS[1]	0 (0.0%)
Subjects with Unanticipated Adverse Device Effect (UADE)	0 (0.0%)
Subjects with at least one Serious Adverse Event	61 (77.2%)
Deaths up to 12 months	7 (8.9%)

[1]Relatedness determined by site investigators.

Table 45: List of Serious Adverse Events by System Organ Class and Preferred Term through 30 days of follow-up in EXPAND Trial –Transplanted Recipient Population

	OCS (N=79)	
System Organ Class/Preferred Term	Subjects n (%)	Events n (%)
Total	61 (77.2%)	121 (100.0%)
Cardiac disorders	9 (11.4%)	9 (7.4%)
Arrhythmia supraventricular	1 (1.3%)	1 (0.8%)
Atrial fibrillation	5 (6.3%)	5 (4.1%)
Atrial flutter	1 (1.3%)	1 (0.8%)
Supraventricular tachycardia	2 (2.5%)	2 (1.7%)
Gastrointestinal disorders	1 (1.3%)	1 (0.8%)
Pancreatitis	1 (1.3%)	1 (0.8%)

	OCS (N=79)	
System Organ Class/Preferred Term	**Subjects n (%)**	**Events n (%)**
General disorders and administration site conditions	1 (1.3%)	1 (0.8%)
Multi-organ failure	1 (1.3%)	1 (0.8%)
Hepatobiliary disorders	1 (1.3%)	1 (0.8%)
Haemobilia	1 (1.3%)	1 (0.8%)
Immune system disorders	2 (2.5%)	2 (1.7%)
Anaphylactic shock	1 (1.3%)	1 (0.8%)
Lung transplant rejection	1 (1.3%)	1 (0.8%)
Infections and infestations	27 (34.2%)	38 (31.4%)
Bronchitis	1 (1.3%)	1 (0.8%)
Bronchopneumonia	1 (1.3%)	1 (0.8%)
Bronchopulmonary aspergillosis	2 (2.5%)	2 (1.7%)
Candida pneumonia	1 (1.3%)	1 (0.8%)
Clostridial infection	2 (2.5%)	2 (1.7%)
Cytomegalovirus infection	1 (1.3%)	1 (0.8%)
Device related infection	1 (1.3%)	1 (0.8%)
Enterobacter tracheobronchitis	1 (1.3%)	1 (0.8%)
Fungal infection	1 (1.3%)	1 (0.8%)
Infection	3 (3.8%)	3 (2.5%)
Lung infection pseudomonal	2 (2.5%)	2 (1.7%)
Oesophageal infection	1 (1.3%)	1 (0.8%)
Pneumonia	8 (10.1%)	8 (6.6%)
Pneumonia bacterial	1 (1.3%)	2 (1.7%)
Pneumonia klebsiella	2 (2.5%)	3 (2.5%)
Pneumonia staphylococcal	2 (2.5%)	2 (1.7%)
Pseudomonas infection	3 (3.8%)	3 (2.5%)
Pulmonary tuberculosis	1 (1.3%)	1 (0.8%)
Respiratory syncytial virus infection	1 (1.3%)	1 (0.8%)
Respiratory tract infection	1 (1.3%)	1 (0.8%)
Injury, poisoning and procedural complications	16 (20.3%)	18 (14.9%)
Arterial injury	2 (2.5%)	2 (1.7%)
Bronchial anastomosis complication	1 (1.3%)	1 (0.8%)
Deep vein thrombosis postoperative	1 (1.3%)	1 (0.8%)

	OCS (N=79)	
System Organ Class/Preferred Term	**Subjects n (%)**	**Events n (%)**
Endotracheal intubation complication	1 (1.3%)	1 (0.8%)
Nerve injury	1 (1.3%)	1 (0.8%)
Operative haemorrhage	2 (2.5%)	2 (1.7%)
Post procedural haemorrhage	6 (7.6%)	6 (5.0%)
Post procedural pulmonary embolism	1 (1.3%)	1 (0.8%)
Postoperative thoracic procedure complication	1 (1.3%)	1 (0.8%)
Procedural complication	1 (1.3%)	1 (0.8%)
Wound dehiscence	1 (1.3%)	1 (0.8%)
Investigations	1 (1.3%)	1 (0.8%)
Clostridium test positive	1 (1.3%)	1 (0.8%)
Metabolism and nutrition disorders	2 (2.5%)	2 (1.7%)
Hypernatraemia	2 (2.5%)	2 (1.7%)
Musculoskeletal and connective tissue disorders	2 (2.5%)	2 (1.7%)
Compartment syndrome	1 (1.3%)	1 (0.8%)
Osteopenia	1 (1.3%)	1 (0.8%)
Nervous system disorders	1 (1.3%)	1 (0.8%)
Horner's syndrome	1 (1.3%)	1 (0.8%)
Psychiatric disorders	6 (7.6%)	6 (5.0%)
Delirium	6 (7.6%)	6 (5.0%)
Renal and urinary disorders	4 (5.1%)	4 (3.3%)
Renal failure	3 (3.8%)	3 (2.5%)
Renal failure acute	1 (1.3%)	1 (0.8%)
Respiratory, thoracic and mediastinal disorders	28 (35.4%)	31 (25.6%)
Acute respiratory failure	1 (1.3%)	1 (0.8%)
Bronchial secretion retention	2 (2.5%)	2 (1.7%)
Chylothorax	2 (2.5%)	2 (1.7%)
Haemothorax	2 (2.5%)	2 (1.7%)
Hypercapnia	1 (1.3%)	1 (0.8%)
Hypoxia	2 (2.5%)	2 (1.7%)
Pleural effusion	2 (2.5%)	2 (1.7%)
Pneumonia aspiration	2 (2.5%)	2 (1.7%)

	OCS (N=79)	
System Organ Class/Preferred Term	**Subjects n (%)**	**Events n (%)**
Pneumothorax	3 (3.8%)	3 (2.5%)
Respiratory failure	12 (15.2%)	14 (11.6%)
Vascular disorders	4 (5.1%)	4 (3.3%)
Deep vein thrombosis	2 (2.5%)	2 (1.7%)
Iliac artery occlusion	1 (1.3%)	1 (0.8%)
Lymphocele	1 (1.3%)	1 (0.8%)
Notes: Number of subjects refers to the number of subjects with at least one serious adverse event of the indicated type. Number of events refers to all events of the indicated type. Percentages are calculated based on the total number of subjects in the Transplanted Recipient Population, or the total number of events, as appropriate. For number of subjects, subjects experiencing multiple events under the same system organ class/preferred term are counted only once for that system organ class/preferred term.		

9.26. Device Malfunctions

A summary of the device malfunctions that occurred during the EXPAND Trial is provided in Table 46. Four (4) malfunctions occurred. Three (3) of the 4 malfunctions occurred prior to initiation of preservation. All four patients who experienced the device malfunctions were transplanted with the OCS-preserved lungs and were analyzed in the study. None of the malfunctions led to a loss of a donor organ.

Table 46: Summary of Device Malfunctions and User Errors

Malfunctions/User Error	Total N (4)	Loss of Lung	Treated and Analyzed in EXPAND
Ventilator subsystem failure	2	0	2
LPM with out-of-range values for PAP prior to preservation	1	0	1
Pump failure prior to preservation	1	0	1
TOTAL	4	0	4

TransMedics has addressed the observed malfunctions with design and/or manufacturing process improvements, in accordance with our Quality System.

9.27. Additional Clinical Evidence: Lung EXPAND II Trial

The EXPAND II study is an ongoing, follow-up study of the OCS™ Lung System with the same inclusion and exclusion criteria for donor lungs that were enrolled in the Lung EXPAND study. The EXPAND II trial was designed with two co-primary endpoints: utilization rate and patient survival at Day 30 or at hospital discharge if longer than 30 days.

Data are currently available on 40 transplanted recipients. Donor characteristics are shown in Table 47 below. Thirty (30) of the 40 subjects (75%) received donor lungs with a single donor criterion met:

- 6 patients – Donor $PaO_2/FiO_2 \leq 300$ mm Hg

- 7 patients – Expected Cross-Clamp Time > 6 hours
- 13 patients – DCD
- 4 patients – Donor Age ≥ 55.

Ten (10) of the 40 subjects (25%) received donor lungs with multiple donor inclusion criteria met:

- 3 patients - Donor Age ≥ 55 and Donor PaO_2/FiO_2 ≤ 300 mm Hg
- 3 patients - DCD and Donors with Expected Cross-Clamp time > 6 hours
- 1 patient - Donor with Expected Cross-Clamp time > 6 hours and Donor PaO_2/FiO_2 ≤ 300 mm Hg
- 1 patient - DCD and Donor PaO_2/FiO_2 ≤ 300 mm Hg
- 1 patient - Donor with Expected Cross-Clamp time > 6 hours and Donor Age ≥ 55
- 1 patient – DCD and Donor PaO_2/FiO_2 ≤ 300 mm Hg and Donor Age ≥ 55.

Table 47: Donor Demographics by Inclusion Criteria for EXPAND II transplanted donors to date (N=40)

	PaO_2/FiO_2 Ratio ≤ 300 mmHg (N=12) Mean ± SD Median (Range)	**Expected Cross Clamp Time > 6 hours (N=12) Mean ± SD Median (Range)**	**DCD Donor (N=18) Mean ± SD Median (Range)**	**Donor Age ≥ 55 (N= 9) Mean ± SD Median (Range)**	**All Donors (N=40) Mean ± SD Median (Range)**
PaO_2/FiO_2 Ratio (mmHg)	254 ± 32 262 (201-296)	414 ± 77 402 (288 – 553)	399 ± 82 386 (253 – 602)	360 ± 124 382 (201 – 520)	375 ± 100 381 (201 – 602)
Observed Cross Clamp Time (min)	624 ± 150 583 (411 – 927)	725 ± 94 695 (617-919)	609 ± 157 614 (330 – 851)	571± 123 546 (411 –762)	631 ± 145 617 (330 – 927)
Donor Age (Years)	47 ± 12 50 (27 – 61)	41 ± 13.0 43 (23 – 65)	40 ± 12 43 (15 – 61)	60 ± 3 61 (56 – 65)	44 ± 13 44 (15 – 65)
Additional Demographics & Risk Factors					
Female gender: % (n/N)					40.0% (16/40)
Abnormal Findings on Inspection and Palpation % (n/N)					59.0% (23/39)
Abnormal Imaging Findings % (n/N)					77.5% (31/40)

The EXPAND II trial enrolled typical lung transplant recipients including those with high-risk factors and characteristics, as shown in Table 48 below.

Table 48: Recipient Demographic and Baseline Characteristics for EXPAND II subjects to date (N=40)

	OCS EXPAND II (n=40)
Age (Years): Mean ± SD	55 ± 14
Gender (% Female)	40.0
BMI (kg/m^2) Mean ± SD	25 ± 4
LAS Score	43 ± 9 (39/40)
Primary Diagnosis	
• Chronic obstructive pulmonary disease/Emphysema	13% (5/40)
• Idiopathic pulmonary fibrosis	38% (15/40)
• Cystic Fibrosis	13% (5/40)
• Bronchiectasis	0% (0/40)
• Sarcoidosis	5% (2/40)
• Interstitial Lung Disease other than IPF	25% (10/40)
• Other	8% (3/40)
Secondary Pulmonary Hypertension	30% (12/40)

9.27.1. EXPAND II Results to Date

The study is on-going and preliminary results are available. A total of 46 eligible lungs were preserved on OCS to date and of these, 40 were transplanted, giving a utilization rate, defined as the number of donated lungs instrumented on OCS™ that meet inclusion/exclusion criteria for the trial and acceptance criteria for transplantation after OCS™ Lung assessment divided by the total eligible donor lungs instrumented on the OCS™ Lung System, of 87.0%. Patient survival at 30 days was 95% while patient survival at 30 days and hospital discharge (if longer than 30 days) was 84%.

The results for the co-primary and secondary endpoints for EXPAND II subjects to date are shown in Table 49 below.

Table 49: Co-primary and Secondary Endpoints for Lung EXPAND II trial based on available adjudicated data (N=40)

Lung EXPAND II Primary and Secondary Endpoints	**n/N (%) (range)**
Co-primary Endpoint 1: Patient survival at Day 30 or Post-transplant Hospital Discharge (whichever is later)	31/37 (84%)
• Patient Survival at Day 30 post-transplant	37/39 (95%)
Co-primary Endpoint 2: Utilization rate	40/46 (87%)

Lung EXPAND II Primary and Secondary Endpoints	n/N (%) (range)
Secondary Endpoints	
Incidence of Primary Graft Dysfunction (PGD) Grade 3 at T72 hours	5/37 (13.5%) (4.5%, 28.8%)
Incidence of PGD Grade 3 within the initial 72 hours post-transplantation.	22/35 (62.9%) (44.9%, 78.5%)
Incidence of Primary Graft Dysfunction (PGD) Grades 2 or 3 at T72 hours	6/37 (16.2%) (6.2%, 32.0%)
Incidence of PGD Grades 2 or 3 within the initial 72 hours post-transplantation	27/35 (77.1%) (59.9%, 89.6%)

9.28. Summary Conclusions

The OCS™ Lung EXPAND trial data provide evidence for the safety, effectiveness and clinical benefit of the OCS™ Lung System for the preservation of donor lungs initially deemed unacceptable for procurement and transplantation due to the limitations of cold static preservation.

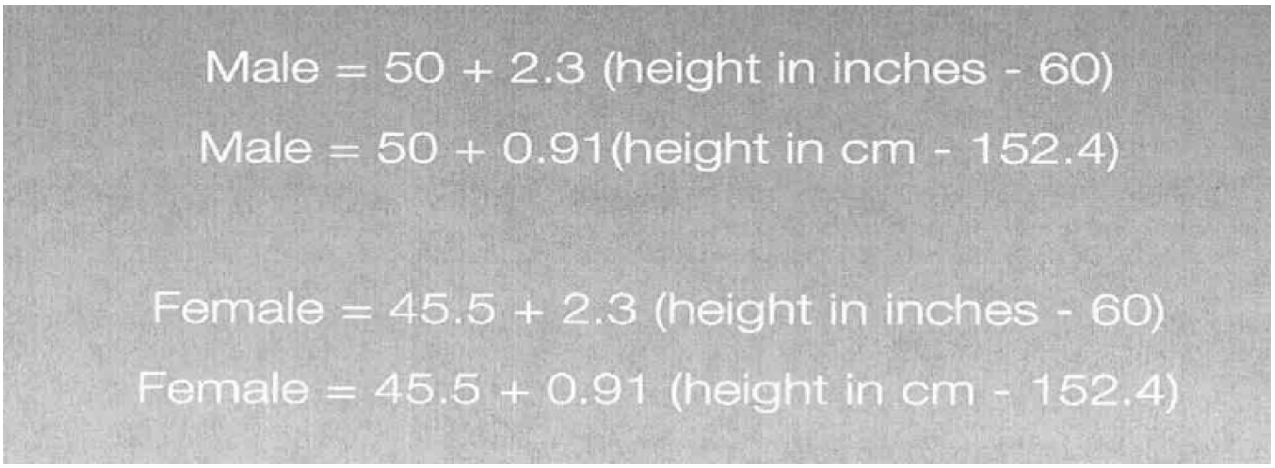
- The primary effectiveness endpoint was a composite of survival at 30 days and incidence of PGD3 within the first 72 hours post-transplant. The primary effectiveness endpoint was not met (observed rate 54.4%, lower confidence interval 42.8%), which was lower than the performance goal of 65%.
- The incidence of PGD3 at T72 post-transplant was 6.4% (5/78) and the incidence of PGD3 or PGD2 at T72 post-transplant was 16.7% (13/78). These aggregate secondary effectiveness endpoint results are similar to those observed for patients in the INSPIRE Control group who received standard criteria donor lungs preserved on cold storage, i.e., 5.5% (10/183) for PGD3 at T72 post-transplant and 10.9% (20/183) for PGD2 or PGD3 at T72 post-transplant.
- The incidence of PGD3 within 72 hours was highest at the T0 timepoint (40.5%, 32/79), and the DCD lung transplants were associated with a higher rate of PGD3 (60% at T0, 16/26) and 33% (26/79) donors in the EXPAND trial were DCD.
- Patient survival through 24 months was 85% and Kaplan-Meier analysis for survival through 36 months was 76% (based on available data on 57% of EXPAND patients).
- Subjects who received donor organs with a single inclusion criterion of age ≥ 55 years or expected ischemic time > 6 hours accounted for 42% of the EXPAND population. These subjects experienced better clinical outcomes (primary and secondary effectiveness endpoints) than other subgroups in EXPAND or the EXPAND population as a whole. Comparison of these single inclusion criterion subgroups to similar subgroup results from INSPIRE Control patients demonstrated somewhat different clinical outcomes (primary and secondary effectiveness endpoints) in INSPIRE Control.
- The Freedom from BOS observed for the EXPAND recipients was 99%, 89% and 80% for 12, 24 and 36 months, respectively, based on available data at 36 months (57% of

EXPAND recipients). These results are similar to the Freedom from BOS results that was observed for standard criteria donor lungs preserved using cold storage in the INSPIRE trial, which was 96%, 86% and 80% for the same timepoints. Given the time course of BOS development, this result is preliminary, and the rate will continue to be updated over time in post-approval studies.

- The rate of transplanted lungs among OCS perfused lungs in the EXPAND trial (i.e., utilization rate) was 85% (79/93).
- The safety profile, i.e., occurrence of lung graft related SAEs in the first 30 days post-transplant, was similar to that observed for patients who received standard criteria donor lungs in the INSPIRE trial. Rates of the defined LGRSAE respiratory failure are higher in subjects receiving OCS-preserved lungs in EXPAND as compared to Control subjects in INSPIRE who received standard criteria donor lungs preserved with cold storage.

10. APPENDIX C: BODY WEIGHT FORMULA

*Devine's formula for a suggested ideal body weight calculation for person's height over 5 feet (150 cm) is provided below:



* Paul L. Marino. (1998). *The ICU Book. (Second edition)*. Maryland: Lippincott Williams & Wilkins. p 872

*Devine, Ben J (1974). "Gentamicin therapy". Drug Intell Clin Pharm 8 (11): 650–5.

11. APPENDIX D: PRIMARY GRAFT DYSFUNCTION CLASSIFICATION USED IN INSPIRE AND EXPAND TRIALS

International Society for Heart and Lung Transplantation Primary Graft Dysfunction

GRADING SCHEMA: (Christie, 2005)

Grade	PaO_2/FiO_2	Radiographic Infiltrates Consistent with Pulmonary Edema
0	>300	Absent
1	>300	Present
2	200–300	Present
3	<200	Present

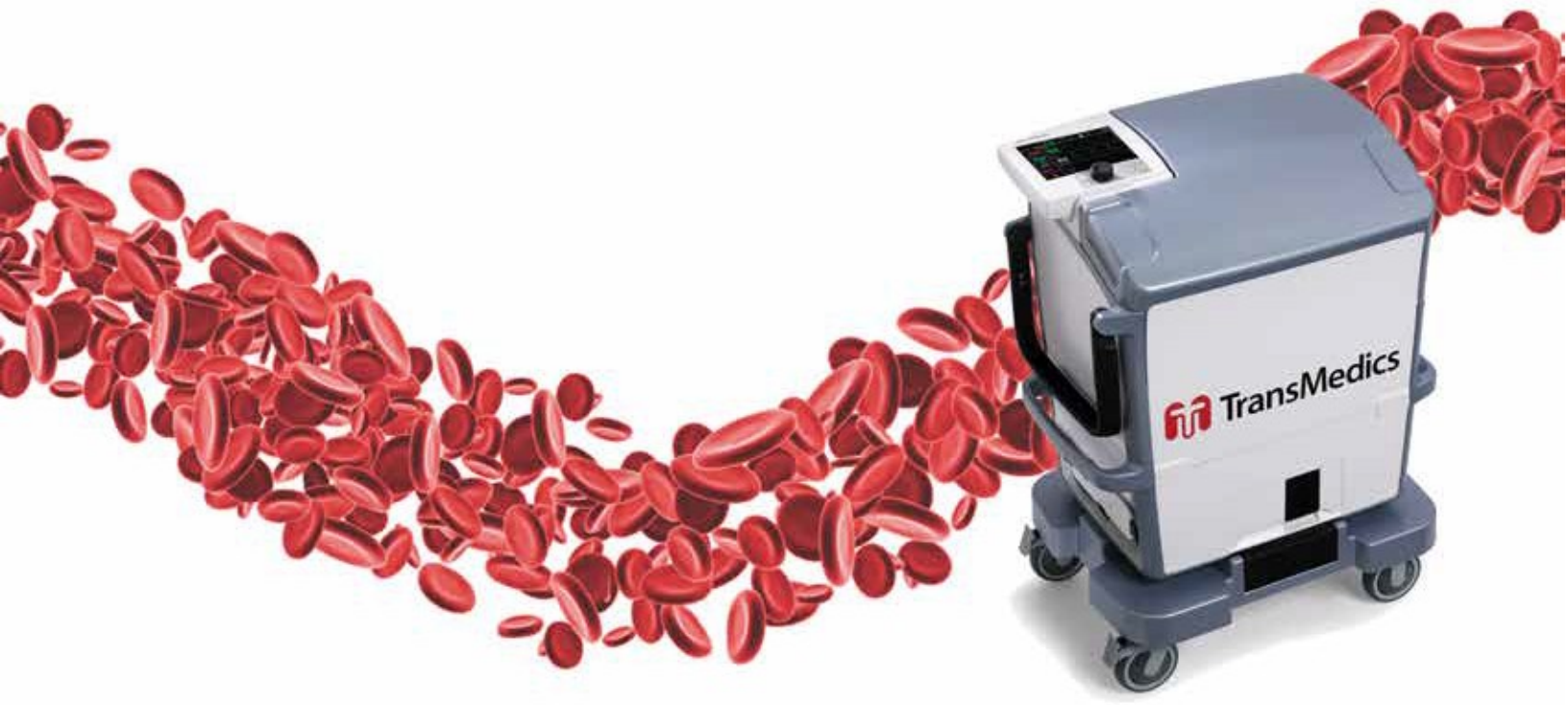
The INSPIRE Trial used the Consensus Statement for assessment of PGD that was published by the ISHLT in 2005 as listed above. The clinical implementation of the caveats was defined by the INSPIRE Senior Investigator Steering Committee as follows:

- If a patient is intubated, PGD will be assessed primarily based on the PaO_2/FiO_2 ratio and chest radiograph (CXR) read out according to the ISHLT consensus statement.
- If the patient is extubated, the PGD will be assessed as either 0 or 1 based on the absences or presence of infiltrates or edema on CXR, respectively.
- If the patient is on post-transplant ECMO for oxygenation support, PGD will be graded as 3 automatically, except for center specific prophylactic ECMO support for patients with pulmonary hypertension or hemodynamic support and not for oxygenation.

TransMedics®
Bringing new life to organ transplant

200 Minuteman Rd., Suite 302, Andover, MA 01810, USA
Tel: +1 978 552 0900
Service: +1 978 552 0999
Fax: +1 978 552 0978
Website: www.transmedics.com

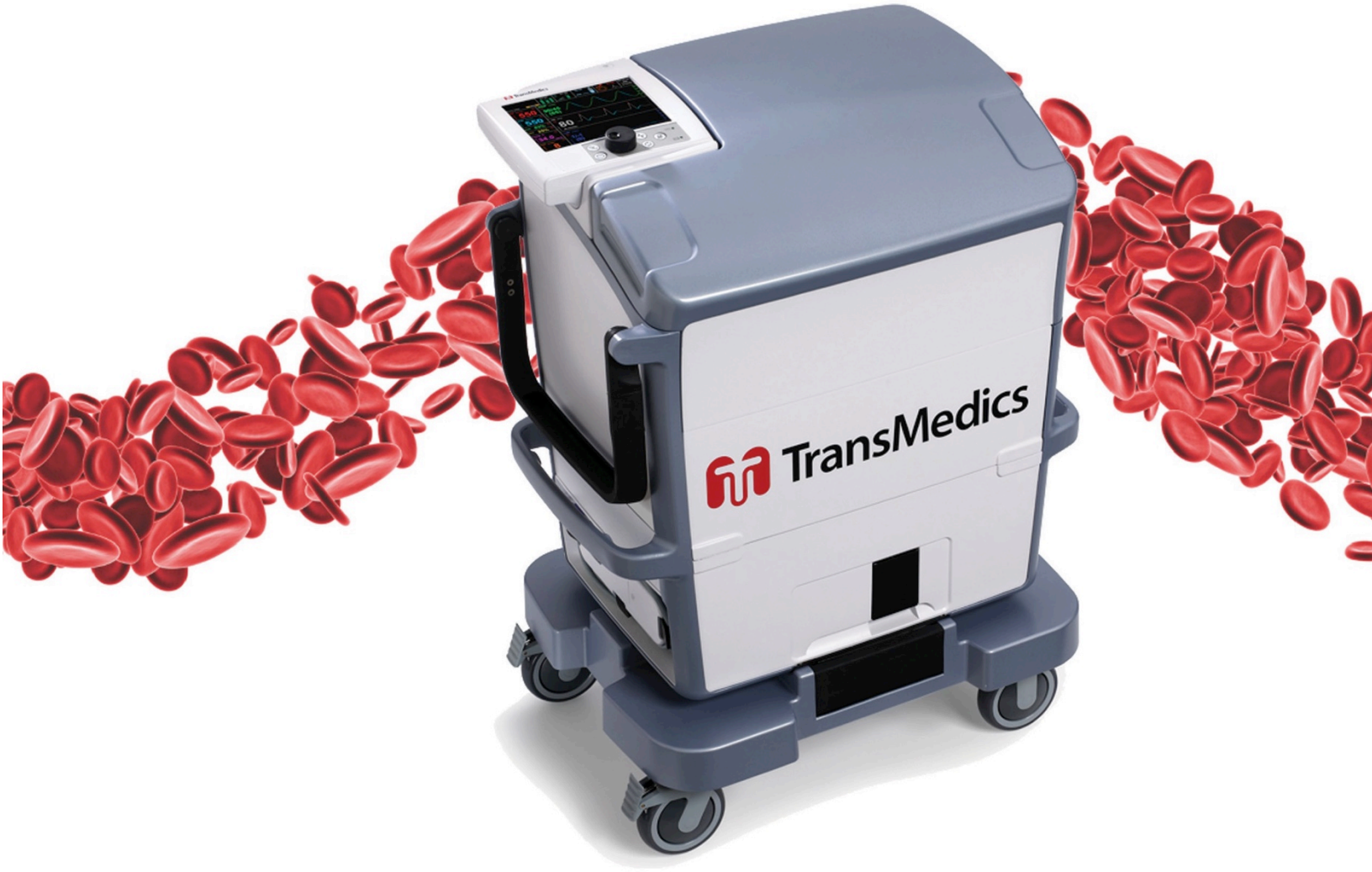
Software Version 3.1.2
PN 100004071, Rev 6
REF 2102



TransMedics® Organ Care System™

Technical User Guide: OCS™ Lung System

Software Version 3.1.2
PN 100004070 Rev 6
REF 2103



CE 0086

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Manufacturer's Address:

TransMedics, Inc.
200 Minuteman Rd., Suite 302 Andover, MA 01810, USA
Tel: +1 978 552 0999
Fax: +1 978 552 0978
Website: www.transmedics.com

CE 0086
This device complies with the Medical Device Directive 93/42 EEC.

Authorized EU Representative:

EC REP
Healthlink Europe BV De Tweeling 20-22
5215 MC's Hertogenbosch, The Netherlands
Tel: +31-(0)13-5479316

Patents:

U.S. Patents 6,046,046, 6,100,082; International Patents EU, UK, FR, ES, IT, BE, DK, FI, IE, LU, MC, NL, PT, CH, SE 1017274, DE 69819759.3-08, AU728233, ATE253819; Additional Patents Pending.

Manual PN & Rev
PN 100004070 REV 6

CAUTION: United States federal law restricts this device to sale by or on the order of a physician.

Table of Contents

GLOSSARY OF TERMS

Term	Meaning
ABG	Arterial Blood Gas
Annotations	Notes or comments entered through the Wireless Monitor during the session that are automatically stamped with the time of entry and saved in the session file.
BPM	Breaths/minute
Bronchoscope Mode	Ventilation of the lungs with ambient air, to allow examination of the interior of the lungs with a Bronchoscope.
Bronchoscope port	Port on the Lung Perfusion Module through which a Bronchoscope probe may be inserted to inspect the interior of the lung.
Circuit	Refers to the perfusate loop in the Lung Perfusion Module.
Continuous Monitoring Mode	The Ventilator Mode in which the OCS™ Lung System continuously deoxygenates the perfusate by supplying Lung Monitoring Gas into the gas exchanger. At the same time, ambient air is used to ventilate the lung. Medical professionals may evaluate the capabilities of the lungs according to their clinical judgment by comparing the base O_2 saturation of the deoxygenated perfusate to the O_2 saturation of the perfusate exiting the lung.
Cuvette	An adapter on the Lung Perfusion Module used for an oxygen saturation measurement probe.
Data Card	A removable SD Data card used to store perfusion, ventilation, and monitoring parameters from the current session, which can be downloaded and analyzed on a personal computer.
Expiratory Time	The time during the respiration cycle between the end of the plateau time and the beginning of the next inspiration. This includes the time that the lungs are exhaling, and the rest time until the start of the next inspiration.
FiO_2	Fraction of inspired oxygen.
Gas Intake Port	Ventilation inlet port on the Lung Perfusion Module through which room air enters the ventilation circuit during Monitoring Modes.
HCT%	Hematocrit, expressed as a percentage by volume.
IE Ratio	Inspiration / Expiration Time Ratio
Inspiratory Time	The time during the respiration cycle when gas flows into the lungs.
LA	Left Atrial
LPM	Lung Perfusion Module
LPS	Lung Perfusion Set
L/min	Liters/minute
MDI Port	Metered Dose Inhaler port on the Lung Perfusion Module through which MDI drugs may be injected into the lungs
mL/hr	Milliliters per hour
mL/min	Milliliters per minute
mmHg	Millimeters of mercury.
Mobile Base	The removable Mobile Base has four wheels, with brakes on the front wheels. The Mobile Base can be installed as needed during system use. During transport, raise the two-position handle to

Term	Meaning
	push the system. With the Mobile Base removed, you can set the system flat or carry it with the lift handles.
Organ Care System	The Organ Care System (OCS™) houses the removable Wireless Monitor, circulatory pump driver, multi-mode Ventilator drive and control, batteries, data card, gas delivery subsystem, and reusable flow and pulse oximeter probes. When in active use, it houses the disposable Lung Perfusion Module.
PA	Pulmonary artery
PaO_2	Partial pressure of oxygen in mmHg in arterial (oxygenated) perfusate.
PAP	Pulmonary Artery Pressure. The perfusate pressure in mmHg at the Pulmonary Artery going into the lungs.
Pause Preservation Mode	A Ventilator mode in which the bellows remain stationary and the OCS™ Lung System achieves a static level of lung inflation. Pause Preservation enables oxygenation of perfusate prior to lung instrumentation using the Lung Preservation Gas.
PAWP	Peak Air Way Pressure. The peak pressure in the lungs at the end of the inspiration. When the measured PAWP reaches the user-set PAWP limit, the Ventilator will stop. PAWP corresponds to Peak Inspiratory Pressure on mechanical Ventilators.
PEEP	Positive End Expiratory Pressure. The pressure maintained in the lungs by the Ventilator at the end of the expiration phase.
Perfusate	The fluid pumped through the lung that delivers dissolved gases and nutrients
Plateau Time	The time between the end of inspiration and the start of expiration.
Power-cycle	To *Power-cycle* the system, use the On/Off switch on the side of the OCS™ Lung Console to turn the system OFF, wait 10 seconds, and then turn it ON.
Preservation Mode	A Ventilator mode in which the OCS™ Lung System operates with the lung rebreathing the same captive breath. A small percentage of fresh Lung Preservation Gas is injected into the ventilation circuit to maintain the required gas concentration and to maintain Positive End Expiratory Pressure (PEEP).
Priming Inlet Port	Port on the Lung Perfusion Module through which priming solution and other large-volume perfusate components flow into the reservoir.
Priming Solution	The sterile OCS™ Lung solution added to the reservoir through the priming inlet port to preserve the lung and to supplement the volume of other perfusate components. Priming solution is circulated through the Lung Perfusion Module circuit along with other perfusate components prior to organ connection and during organ preservation
Pump Compliance Chamber	Located between the circulatory pump and the perfusate warmer, the red-colored pump flow compliance chamber smooths out the pulsatile flow from the pump.
Pump Flow Probe	A probe that you attach to the Lung Perfusion Module. It is used to measure OCS™ pump flow.
PvO_2	Partial pressure of oxygen gas in mmHg in venous (deoxygenated) perfusate.
Relief Port	Port on the Lung Perfusion Module through which lung exhalation gas is output.
RR	Respiration Rate. Number of respiration cycles per minute in units of breaths/minute.
RESP	Name of the airway pressure/respiration pressure, waveform displayed on the Wireless Monitor
Run Mode	Power mode where the system is on, the Wireless Monitor is active, and the pump and Ventilator can operate.

Term	Meaning
SaO_2	Oxygen saturation of arterial (oxygenated) perfusate, expressed as a percentage and measured at the output of the lung at the LA drain.
SaO_2 Hematocrit Probe	An OCS™ Lung Console probe that you attach to the Lung Perfusion Module. It is used to measure the arterial oxygen saturation and the hematocrit of the perfusate leaving the lung through the LA.
Session	A session is created in internal system memory when the system is set to Run Mode. Every time Run Mode is entered, you can choose whether to continue using the last session file or create a new one. In ordinary circumstances, data from all procedures associated with an organ should be documented in only one session. The system logs all system error events, all alarm events, trend data for each parameter at 2-minute intervals, and all system operating events that occur in each session.
Standby-cycle	To *Standby-cycle* the system, press the Standby button to switch from Run Mode to Standby Mode and then back to Run Mode. The system will automatically run the Self Test.
Standby Mode	A power mode where the system is on but the Wireless Monitor is off and no ventilation or perfusion may be performed. Standby Mode is the mode used during OCS™ storage; organs cannot be preserved in this mode. The OCS™ must be plugged in to AC power to avoid battery depletion when storing the OCS™ in this mode.
SvO_2	Oxygen saturation of venous (deoxygenated) perfusate, expressed as a percentage and measured at the input to the lung on the PA line.
SvO_2 Hematocrit Probe	An OCS™ Lung Console probe that you attach to the Lung Perfusion Module. It is used to measure the venous oxygen saturation and hematocrit of the perfusate entering the lung through the pulmonary artery cannula.
Temp	Temperature of perfusate supplied to the lung, displayed on the Wireless Monitor in degrees Celsius.
Trend	A trend contains the most recent 24 hours of data, updated every two minutes. Each data point represents the average value calculated over the previous two minutes. You can configure trend data to display on the middle and bottom frames on the Wireless Monitor.
TV	Tidal Volume. The volume of air breathed in and out of the lungs during a respiration cycle.
Update Bar	A vertical line displayed on the waveform. Newest data is displayed to the immediate left of the update bar. The bar is aligned with other update bars displayed at the same time.
Ventilator Lines connector	Integrated pneumatic connector that conveys ventilation and control gas between the OCS™ Lung Console and the Lung Perfusion Module.
VR	Vascular Resistance. This is a measure of the resistance to flow that must be overcome to push perfusate through the vasculature of the lungs. It is calculated as (80* mean PAP)/(Pump Flow) and displayed in units of (dyne*sec)/cm^5.
Waveform	Real-time waveforms display continuously updated data. The waveforms are drawn from left to right with the most current data. An update bar displays the oldest data first. If more than one graphic frame is configured to show real-time waveforms, the update bars are automatically synchronized. The airway pressure waveform is always displayed in the top-most frame on the Wireless Monitor. Use the Configuration Menu to configure which waveforms are displayed in the middle and bottom frames on the Wireless Monitor.
Wireless Monitor	A small, dockable monitoring system with an LCD screen and controls for configuring system functions and screen displays, and for adjusting system settings during preservation. When removed from its docking station on the OCS™ Lung Console, the Monitor operates wirelessly, powered by its own battery.

1. CHAPTER 1: READ THIS FIRST

This chapter contains important information about the documentation for your TransMedics® Organ Care System (OCS™) Lung System and about contacting TransMedics.

1.1. Directions to User

This manual provides detailed instructions about using the OCS™ Lung System, including an overview of the system, how to set up the system, understanding the Wireless Monitor and its controls and functions, troubleshooting, and cleaning and maintaining the system. For step-by-step instructions for using the system before, during, and after organ collection, preservation, and transport, as well as a summary of the clinical results, see the *TransMedics Clinical User Guide: OCS™ Lung System.* Both guides are to be reviewed prior to using the system, noting the Warnings and Cautions throughout the guides.

The OCS™ Lung System can only be purchased upon order of a physician. A TransMedics representative must install and activate each newly purchased system before a qualified health care professional can use it.

1.2. User Training Requirements

The OCS™ Lung System enables medical professionals to monitor key parameters that may be useful in assessing organ condition and function according to their clinical judgment. The system is intended for use only by qualified healthcare professionals specializing in lung transplants and trained in the use of the OCS™ Lung System.

Completion of the TransMedics training program is required for every new lung transplant center prior to starting an OCS™ Lung System program at their institution. All team members at an institution must be trained. The training consists of initial hands-on training and periodic refresher training as needed.

1.3. Indications for Use

The indications for use are as follows:

> The TransMedics Organ Care System (OCS) Lung is a portable normothermic organ perfusion, ventilation and monitoring medical device indicated for preservation of standard criteria donor lung pairs and for preservation of donor lung pairs initially deemed unacceptable for procurement and transplantation based on the limitations of cold static preservation. The device allows for ex vivo assessment of donor lungs prior to transplantation.

For contraindications, warnings, and cautions specific to clinical use, as well as a summary of the INSPIRE Study and EXPAND Study clinical results, refer to the *TransMedics Clinical User Guide: OCS™ Lung System.*

1.4. Conventions

The terms *OCS™ Lung System*, *OCS™*, and *system* are used interchangeably throughout this manual to refer to the TransMedics OCS™ Lung System. The system uses consistent conventions

throughout the interface and accompanying documentation to make it easy for you to learn and use. The documentation follows these conventions:

- All step-by-step procedures are numbered, and all sub-procedures are lettered. You must complete steps in the sequence they are presented to ensure success.
- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- The term Press means to press the push button or the rotary knob on the Wireless Monitor.
- Highlight means to turn the rotary knob to move a highlight to a screen element.
- Select and Enter means to highlight the selection and press the rotary knob on the Wireless Monitor to confirm selection of a highlighted item.
- Controls, labels, and selectable menu items are shown in bold type and are capitalized exactly as they appear. For example, Return, Cancel.
- The terms Standby Mode, Preservation Mode, and Monitoring Mode are capitalized so you can easily determine the mode.
- The terms Donor, Donor Site, Recipient, and Recipient Site are capitalized.
- The term circuit refers to the Lung Perfusion Module with the perfusate running through it.
- Warnings, Cautions, and Notes are set apart from other text. See below for definitions.
- The left side of the system is to your left as you stand in front of the system, facing the system. The front of the system is nearest you with the push handle on the left side.
- The Glossary lists terms used throughout this manual and their definitions.

Warnings, Cautions, and Notes

The Warnings, Cautions, and Notes in this user manual are specific to the controls and functions of the OCS™ Lung System.

WARNING—A Warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in loss of organ, death, or serious injury.

CAUTION—A Caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly a risk of more serious injury.

NOTE—A Note brings your attention to important information that will help you operate the system more effectively.

1.5. Upgrades and Updates

TransMedics is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated documentation will accompany those system upgrades.

1.6. Supplies

The components, accessories, and supplies required when using the OCS™ Lung System must be used in accordance with this user manual, associated documents, and accepted medical standards.

CAUTION—Only accessories and supplies purchased from or recommended by TransMedics, Inc. are to be used with the OCS™ Lung System. Use of accessories and supplies other than those supplied by or recommended by TransMedics may cause system malfunction and invalidate the TransMedics warranty.

For details on what is included with your OCS™ Lung System and Lung Perfusion Set, see Chapter 3: Overview. To order additional parts and supplies, see Section 10. Other materials, not supplied by TransMedics, are required to operate the OCS™. See the *TransMedics Clinical User Guide: OCS™ Lung System* for details.

1.7. Contacting TransMedics

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact TransMedics for assistance at +1 978-552-0999.

You can also contact one of the following offices for referral to a customer service representative, or visit the TransMedics website: www.transmedics.com.

Corporate and North American Headquarters
TransMedics, Inc.
200 Minuteman Road, Suite 302
Andover, MA 01810, USA
Tel: +1 978-552-0999
Fax: +1 978-552-0978

Authorized EU Representative
Healthlink Europe BV
De Tweeling 20-22
5215 MC's Hertogenbosch
The Netherlands
Telephone: +31(0) 13 547 9316

2. CHAPTER 2: SAFETY INFORMATION

The TransMedics® OCS™ Lung System can be purchased only upon order of a physician and is intended for use by qualified medical personnel who have received TransMedics training. Only a trained operator can use the system.

This chapter provides information about safety issues that may arise. Read this section before you use the OCS™ Lung System or any of its components. Be sure to read all applicable usage, patient-safety, operator-safety, and electrical safety guidelines in this manual.

If you have any comments or questions about safety, contact your TransMedics representative. For precautions for handling and disposing of blood-contaminated equipment and materials, see Chapter 7: Cleaning and Maintaining the OCS™.

2.1. Electrical Safety

This section provides warnings and cautions related to electrical safety.

WARNINGS—

No modification of this equipment is allowed.

Failure to abide by the precautions detailed in this section may cause the system and its use to be out of compliance with regulations and places personnel and any people near the system at risk of injury or death.

Connect the system AC power cord only to a properly grounded 100V to 240V, 50/ 60 Hz Hospital Grade AC outlet.

To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

If you have any doubt about the integrity or suitability of the external power or of the cable, plug, or connector, do not connect the power cord. To avoid potential electrical hazards, allow the system to function on OCS™ battery power only, until appropriate external power is available or any problems have been resolved.

Never use a converter adapter to plug the three-pronged AC plug into a two-pronged ungrounded wall outlet. Doing so may result in electric shock to the operator and damage to the equipment.

To avoid electrical shock, use only the power cords supplied by TransMedics for the OCS™, and connect only to properly grounded wall outlets.

Do not use additional cables or extension cords with the TransMedics system.

Do not remove any system covers except those necessary to access the system for use, as described elsewhere in this manual. Any other covers are to be removed by qualified TransMedics service personnel only. Accidentally contacting the electrical circuits inside the housings may result in electric shock to the operator and damage to the equipment.

Internal fuses are not field serviceable.

Before cleaning or servicing the system, disconnect all external power sources.

To completely disconnect AC power, you must unplug the system from the AC power receptacle and turn off the power switch. Neither the  button nor the On/Off switch completely disconnects power.

To fully de-power the system, you must unplug the system from the AC power receptacle and either fully deplete the OCS™ batteries, or remove them completely from the system.

CAUTION— Use the system only at the temperatures, relative humidities, and altitudes specified in Table 8-2, "OCS™: Electrical and Physical Specifications."

2.2. Mechanical and System Safety

Shipment Inspection. Inspect TransMedics packaging to ensure there has been no shipping damage.

Periodic Visual Inspection. Before and after each use, inspect the system for any physical damage that might require service or replacement of an individual component in time for the next use.

Regular Cleaning and Disinfection. Keep surfaces and cables clean, cleaning all surfaces and cables before and after each use. Clean and disinfect any bodily fluid or blood-contaminated areas of non-sterile parts of the system immediately after removing and properly disposing of the Lung Perfusion Module. Clean and disinfect only as described in Chapter 7: Cleaning and Maintaining the OCS™.

Preventative Maintenance. The OCS™ Lung Console should be tested by a qualified TransMedics representative at least once per year. At this time, the following components should be serviced: ventilation filters. The use life of the OCS™ Lung Console is expected to be at least five years with a rate of use of 50 preservation sessions per year.

WARNINGS— Do not immerse an OCS™ battery in water, and do not allow liquids to enter the slot or the electrical contacts at the back of the battery during cleaning. Lithium may react violently when mixed with water, leading to possible battery leakage, smoke, and fire.

CAUTIONS—

Use only accessories and supplies purchased from or recommended by TransMedics. Use of accessories and supplies other than those supplied by or recommended by TransMedics may cause organ damage and will invalidate the TransMedics warranty. (This manual details approved accessories and supplies as relevant to system operation.)

Do not attempt to sterilize the OCS™ or any of its non-sterile components. Doing so may damage the system.

Do not use any cleaning or disinfection agents other than those prescribed in this manual.

Doing so may lead to component damage, or interference with proper system operation.

2.3. Operator Safety

Intended Users: The OCS™ is intended for use only by qualified health care professionals specializing in organ transplants and trained in use of the OCS™.

Before Using the System: Each user should carefully review the manual, noting especially the Warnings and Cautions throughout and the information in this chapter.

Careful Cable Routing: Carefully route system power cables and other cables to reduce the possibility of tripping or disrupting operation during system use or transport.

Disposal of Blood-Contaminated Materials: Always follow your institutional protocols for handling and disposal of blood-contaminated materials.

Not Serviceable by User: There are no user-serviceable parts in the system. Service can only be provided by a trained TransMedics Service Representative. Any attempt to open any covers other than the covers intended to be opened during system use can expose the user to potential physical or electrical hazards.

WARNINGS—

Opening the covers reserved for access by TransMedics service personnel could expose the user to electrical or physical hazards that could cause serious injury or shock.

The OCS™ is intended for use only by qualified health care professionals who specialize in organ transplants and are trained in the use of the OCS™.

Always follow your institutional procedures for use of aseptic procedures, for working inside a surgical field, and for handling and disposing of blood-contaminated materials. Failure to do so can lead to biocontamination of the organ, the operating room environment and personnel.

Do not use the system and accessories in the presence of explosive anesthetics.

Only a qualified TransMedics Service representative may service the system or any of its accessories. Any attempt by the user to disassemble the OCS™ or any of its accessories may result in shock or serious injury and will void the warranty.

Cleaning and disinfection must be performed in a well-ventilated area to prevent inhalation of toxic fumes.

Failure to use personal protective equipment while cleaning and disinfecting may result in exposure to blood borne pathogens or other potentially infective materials.

CAUTIONS—

Always use two people to lift or carry the system, which may weigh up to 45 kg (100 lb) without the organ, fluids, or the mobile base.

Users should avoid contact with the bellows in the Lung Perfusion Module while the OCS™ Lung Console is powered.

Wheel brakes are only meant to stop forward movement of the OCS™ Lung Console but the device can move backwards with the brakes engaged.

Use only the black push handle to push the system, as using other surfaces could result in instability.

Do not use the push handle to lift the system. The handle is not designed to support the system weight. System damage or personal injury may result if the push handle is used improperly.

2.4. Patient and Organ Safety

No System Contact with Patients: The system is intended only for preservation of an explanted organ. It is not intended for direct contact with any patient.

WARNINGS—

The OCS™ Lung Console, the Lung Perfusion Module components and accessories, and the OCS™ Lung Solutions are not intended for direct contact with any patient.

Always follow your institutional procedures for use of aseptic procedures, for working inside a surgical field and for handling and disposing of blood-contaminated materials. Failure to do so can lead to biocontamination of the organ, the operating room environment and personnel.

All parts of the Lung Perfusion Module and its sterile accessories are intended for single use only. To avoid the risk of biocontamination, do not attempt to sterilize and reuse the Lung Perfusion Module or any of the sterile accessories.

CAUTIONS—

Avoid leaving the system in an uncontrolled temperature environment for longer than a few minutes. During such periods closely monitor perfusate temperature and take remedial action if the temperature registers more than one degree over or under the desired range. If necessary, adjust fluid temperature accordingly to accommodate external temperatures.

Use only accessories and supplies purchased from or recommended by TransMedics. Use of accessories and supplies other than those supplied by or recommended by TransMedics may cause organ damage and will invalidate the TransMedics warranty. (This manual details approved accessories and supplies as relevant to OCS™ operation.)

2.5. Component Safety

Inspection of sterile components before Use. Before use, aseptically open and inspect each component, checking for any cracks, leaks, or other damage that might impact use.

Non Sterilizable. Do not attempt to sterilize the TransMedics system or any of its non-sterile components. The Lung Perfusion Module and its sterile accessories are intended for single use only. Do not attempt to re-sterilize any of these single use components.

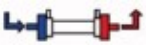
TransMedics-Approved Accessories and Supplies Only. Use only accessories and supplies purchased from or recommended by TransMedics. Use of accessories and supplies other than those supplied by or recommended by TransMedics may invalidate the TransMedics warranty and may cause a safety hazard. (This manual details approved accessories and supplies as relevant to system operation.)

Check Expiration Dates on Packaging. Always check the expiration date on each package. If the date has expired, do not use the item.

2.6. Symbols Used on the System

Appendix A (Symbol Glossary) at the end of this document describes the symbols on the OCS™ Lung System packaging. Table 2-1 below shows and describes the symbols used on the Lung Perfusion Module and Console.

Table 2-1: Symbols Used on the Lung Perfusion Module and Lung Console

Symbol	Meaning	Symbol	Meaning
	Indicates On (only for a part of the equipment)		Indicates Off (only for a part of the equipment)
	Run/Standby		Non-ionizing, electromagnetic radiation
	Direct current		Alternating current
	Bronchoscope Port		Level 1 ingress protection
	Trachea Connector		Blood and Prime Solution Port
	PA Connector		LA Return Line
	Venous Sampling Port		Pulmonary Artery Pressure Port
	Reservoir Injection Port		Oxygenator Recirculation Line Connections
	Venous Injection Port		Venous Oxygen Saturation/ Hematocrit Probe
	Arterial Sampling Port		Arterial Oxygen Saturation/ Hematocrit Probe
	Gas Intake Port		Venous Oxygen Saturation/ Hematocrit Probe (on OCS™ Lung Console)
	Metered Dose Inhaler Port		Arterial Oxygen Saturation/ Hematocrit Probe (on OCS™ Lung Console)
	Venous Oxygen Saturation/ Hematocrit Cuvette		Pump Flow Probe (on OCS™ Lung Console)
	Arterial Oxygen Saturation/ Hematocrit Cuvette		Pump Flow Probe
	Follow instructions for use		Pump Flow probe location (on LPM)
	Drainage Bag Connection		Gas exchanger vent stopcock

NOTE—For detailed information on system status icons that appear on the Wireless Monitor and its display, see Chapter 5: Wireless Monitor Overview.

2.7. Using Aseptic Technique

When using the OCS™ Lung System, you must use aseptic technique when performing any procedures that involve the following:

- Touching the organ.
- Opening the organ chamber.
- Opening the sterile drape.
- Accessing the docked Wireless Monitor's controls through the clear film of the TransMedics sterile drape.
- Manipulating the lung inner wrap.
- Preparing and connecting solutions for use in the circuit.
- Collecting and filtering blood and transferring it to the reservoir.
- Making injections into the circuit.
- Sampling fluids from the circuit.

NOTE—Steps in which the sterile drape is opened, or in which the organ is touched, require use of surgical attire and strict adherence to normal operating room procedure inside a sterile field.

Tasks that do not require aseptic technique include:

- Installing and removing batteries, gas cylinders, the Wireless Monitor, and probes.
- Other routine tasks that involve only the non-sterile components of the OCS™ or non-sterile components outside the surgical field.

NOTE—After use, the entire Lung Perfusion Module and its one-time use accessories must be disposed of in accordance with institutional procedures for disposal of blood-contaminated materials.

2.8. Moving the System

Read the following warnings and cautions before moving the system.

WARNINGS—

Failure to follow any of these precautions may result in injury and/or damage to the TransMedics OCS™ and its contents.

Disconnect the system power cord from the wall outlet and wind it snugly around the power cord wrap before moving the system.

When moving the system without installing the Mobile Base, use two people, one holding the right lift handle and one holding the left lift handle.

Before transporting the OCS™ in a vehicle, strap it securely in place.

During transport, position the OCS™ Lung Console so that it never sits at an angle of greater than 15 degrees from vertical.

CAUTIONS—

Angles greater than 15 degrees may disrupt fluid paths in the Lung Perfusion Module and lead to system malfunction.

Never use the push handle to lift the system during a move, with or without the Mobile Base attached.

Only use the black push handle to roll the OCS™ Lung Console as using other surfaces could result in instability.

Wheel brakes are only meant to stop forward movement of the OCS™ Lung Console but the device can move backwards with brakes engaged.

TransMedics recommends attention to outside temperature; low temperatures can accelerate battery depletion. When moving the system outside, be sure to keep the OCS™ top cover in place to conserve energy.

During transport, do not subject the OCS™ to vibration levels higher than those to which a patient can be safely exposed. Excessive vibration may disrupt fluid paths in the Lung Perfusion Module and lead to system malfunction.

During transport, avoid sudden stops, turns, and reversals in direction that might subject the OCS™ to high lateral acceleration.

When moving the system with the Mobile Base attached:

- Make sure the system is properly mounted and latched on the Mobile Base.
- Make sure the system wheel locks are disengaged and that the wheels are free to rotate prior to moving the system.
- If you must move the system up or down ramps with an incline of more than 5 degrees, use two people to move the system.
- Do not use the push handle to lift the system.

2.9. Storing the System Between Uses

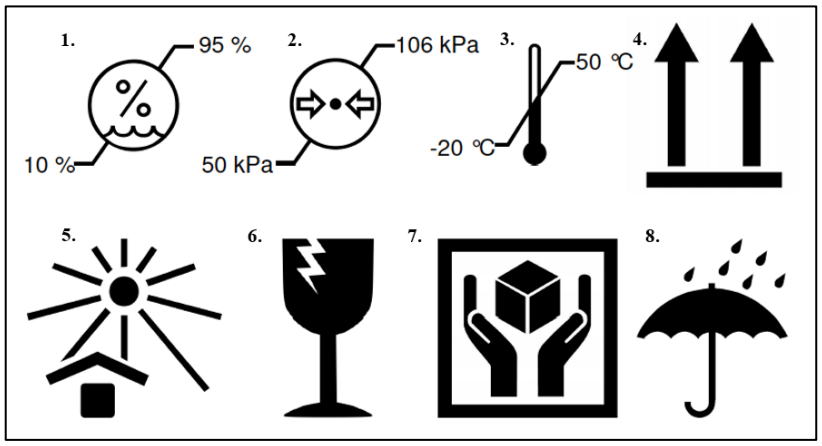
Follow these guidelines to store your system between uses:

- Before storing, clean the system and probes as described in Chapter 7: Cleaning and Maintaining the OCS™.
- Store the system in a clean, dry area away from traffic.
- Press  to set the system to Standby Mode.
- Connect the OCS™ power cord to an active AC power source and ensure the On/Off switch remains in the On position to recharge the batteries.
- Wrap the excess power cord to eliminate interference with traffic in the area.
- Store only in areas that meet the temperature and humidity conditions specified in Table 8-2, “OCS™: Electrical and Physical Specifications.”
- Store the flow and SO_2/Hematocrit sensors within the Console, connected to the system.

- Set the wheel locks.

2.10. Shipping, Handling and Storage Requirements

Figure 2-1: Shipping, Handling, and Storage Requirements Symbols



Unless otherwise noted the OCS™ and its accessories have the following shipping, handling and storage requirements:

1. 10% to 95% Humidity Limitation
2. 50 to 106 kPa Atmospheric Pressure Limitation
3. -20 to 50°C Ambient Temperature
4. If so marked the package must only be oriented the indicated side up
5. Keep away from sunlight
6. Fragile, handle with care
7. Handle with care
8. Keep away from rain

2.11. Periodic Safety Tests

Table 2-2 is provided for institutions that require periodic safety checks to assure that systems continue to be safe. The table lists the maximum allowed values.

Table 2-2: Safety Test Guidelines

Test	Maximum Allowed (IEC 60601-1)
Earth Leakage Current	300 µA Normal Condition (IEC 60601-1 Fig 16) 1000 µA Single Fault Condition (IEC 60601-1 Fig 16)
Enclosure Leakage Current	100 µA Normal Condition (IEC 60601-1 Fig 18) 300 µA Single Fault Condition (IEC 60601-1 Fig 18)
Earth Continuity	0.1 ohms (excluding supply cord)

CAUTION—The OCS™ relies on a proper earth ground to provide safe operation when operating on AC power. The ground integrity should be checked, at a minimum, annually to assure that proper grounding exists.

2.12. Explosion Hazard

WARNING—Do not use the system and accessories in the presence of explosive anesthetics.

2.13. Electromagnetic Compatibility

The OCS™ meets the following electromagnetic compatibility standards:

- IEC 60601-1-2 (International and U.S.)
- EN 60601-1-2 (Europe)

For more information on electromagnetic compatibility, see Chapter 8: System Specifications.

2.14. Electromagnetic Interference (EMI)

Though the OCS™ has been designed to resist electromagnetic interference, the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health care environment may result in disruption of performance. EMI interference is indicated by erratic readings, cessation of operation or other operational problems. If these symptoms occur, the site of operation should be surveyed to determine the source of disruption and action taken to eliminate the source. If assistance is required, contact TransMedics.

To help identify the source of electromagnetic interference, ask the following questions:

- Is the interference intermittent or constant?
- Does the interference occur with one sensor only, or with several sensors?
- Is the interference present if the system is moved to a different location in the facility? For example, moving the cable or other medical equipment away from the system can reduce electromagnetic interference.

Please answer these questions before contacting your service representative. The answers will help a service representative determine if the problem is in the system or in the environment.

2.15. Handling Batteries

Your system contains three user-replaceable system batteries in the OCS™ Lung Console and one non-user replaceable battery in the Wireless Monitor.

NOTE—The Wireless Monitor battery can be serviced and replaced only by qualified TransMedics Service Personnel.

To use the OCS™ Lung Console to recharge the system and Wireless Monitor batteries, the system must be connected to AC power and the On/Off switch must be in the On position. The OCS™ Lung Console cannot recharge the Wireless Monitor battery unless the Wireless Monitor is docked.

CAUTION— Each battery includes rechargeable lithium ion cells. Lithium is a highly reactive element which reacts violently when mixed with water, leading to possible battery leakage, smoke, and fire. Batteries must be handled, stored and disposed of with care to prevent physical damage to the battery and to meet the environmental requirements specified.

WARNINGS—

Failure to adhere to these procedures may cause bodily injury, and environmental and equipment damage.

Use only OCS™ batteries supplied by TransMedics.

Do not attempt to recharge the batteries by methods other than within the OCS™ Lung Console. Doing so may cause a fire or damage equipment.

For long-term storage, store extra OCS™ batteries in the original shipping containers from TransMedics.

Lithium batteries must be packaged for shipment by qualified personnel and shipped according to applicable transportation laws in the original packaging or replacements supplied by TransMedics.

Do not dispose of OCS™ batteries in an incinerator or other fire. The cells may explode.

Check with local codes for special disposal instructions.

Do not open, pierce, or crush the batteries. Doing so may result in a fire. In addition, released electrolyte is corrosive, may cause damage to the eyes or skin, and may be toxic if swallowed.

If a fire occurs, use institutional procedures for putting out a lithium fire. Do not use water.

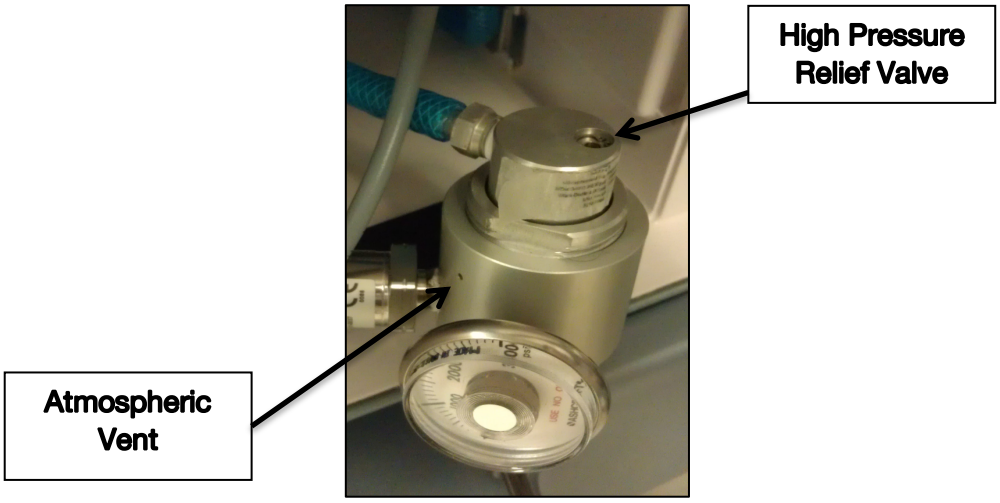
To prevent risk of fire, store batteries within the temperature and humidity limitations specified in Chapter 8: System Specifications.

2.16. Handling Pressurized Gas Cylinders

Your system contains a Lung Preservation Gas cylinder and a Lung Monitoring Gas cylinder. These gas cylinders connect to the OCS™ Lung Console with the supplied regulators.

In the event of an internal failure of the pressure regulator, a pressure relief valve will automatically activate to maintain regulated system pressure. In this event, high-pressure gas may exhaust from the high-pressure relief valve and/or atmospheric vent and can cause eye injury.

Figure 2-2: Atmospheric Vent and High Pressure Relieve Valve



WARNINGS—

Do not look into the high-pressure exhaust sources while connecting the gas cylinder to the regulator.

In the event of a regulator failure, do not look into the high-pressure exhaust sources.

Failure to follow the precautions for the gas cylinders may cause severe bodily injury, even death, and may cause equipment damage.

Each gas cylinder used with the OCS™, when full, contains approximately 400 L at 3000 psi (21000 kPa) of pressurized gas. If a pressurized cylinder falls over, the valve on the top of the cylinder might break off. If this occurs, high-pressure gas will rapidly escape, which may cause the cylinder to move in an uncontrolled manner, possibly causing property damage or personal injury.

To avoid this hazard, always make sure that cylinders are secured to a stable cart, or place them horizontally on the floor or other stable flat surface where they cannot roll or fall.

For more information on conditions for storing gas tanks, see Table 8-2.

For details on removing empty gas cylinders see Section 4.4.2, “Removing and Installing a Lung Preservation Gas Cylinder.” For details on returning empty gas cylinders to TransMedics, see Section 4.6 “Returning an EMPTY Gas Cylinder to TransMedics.”

CAUTION— Use ONLY this packaging or a replacement supplied by TransMedics. Other containers may not sufficiently protect the cylinder from potential damage during shipment and may not meet regulatory requirements.

2.17. Disposal of the System and Components

After the system and its components have exhausted their use life, as determined by TransMedics, they must be disposed of appropriately. Before disposing of any system component contact TransMedics. See Section 10.1, “Contacting TransMedics.”

3. CHAPTER 3: OVERVIEW

The TransMedics® OCS™ Lung System is a portable organ perfusion, ventilation and monitoring medical device intended to preserve donated lungs in a near physiologic, ventilated, and perfused state for transplantation. The OCS™ Lung System enables medical professionals to continuously monitor key parameters that may be useful in assessing organ condition and function according to their clinical judgment.

The OCS™ Lung System is designed to maintain the lungs in a normothermic state through continuous pulsatile perfusion of warm, oxygenated, substrate-enriched, leukocyte-depleted perfusate while ventilating the lungs in an equilibrium state that maintains the physiologic Oxygen, CO_2, and pH balance. The system enables medical professionals to monitor key parameters that may be useful in assessing organ status and evaluating lung function according to their clinical judgment. Controls on the system allow clinicians to adjust the preservation environment, and access ports enable medical treatment of the organ.

3.1. System Components

The system consists of the following major components:

1. **Lung Console:** The Lung Console is a non-sterile, reusable, portable enclosure that houses an electronic display and non-sterile mechanical and electrical elements required to warm, pump, ventilate, and manage gas content of the perfusate.
2. **Lung Perfusion Set**: The Lung Perfusion Set (LPS) includes a sterile, single-use perfusion module (Lung Perfusion Module or LPM) and various accessories. The perfusion module consists of an organ chamber and a circulatory system to perfuse and ventilate the lung. The supplied accessories connect the lung to the organ chamber and facilitate the management of fluids within the perfusion module.
3. **OCS Lung Solution:** This is the high oncotic solution used for ex-vivo flush and perfusion of donor lungs when combined with pRBCs.

This section lists the components included with your OCS™ Lung Console and Lung Perfusion Sets. For information about ordering additional supplies, see Section 10, “Parts and Supplies.”

CAUTION—The components, accessories, and supplies required when using the OCS™ must be used in accordance with this user manual, associated documents, and accepted medical standards. Only accessories and supplies purchased from or recommended by TransMedics are to be used with the OCS™. Use of accessories and supplies other than those supplied by or recommended by TransMedics may cause system malfunction and invalidate the TransMedics warranty.

3.1.1. Items Included with the OCS™ Lung System

Each OCS™ Lung Console is shipped with the following components:

- Mobile base
- Universal Wireless Monitor
- Data cards

- Rechargeable OCS™ batteries (3)
- Power cords (Country-specific)
- Gas Cylinders
  - Lung Preservation Gas Cylinders
  - Lung Monitoring Gas Cylinders
- Flow probe (Pump)
- SvO_2/Hematocrit Probe
- SaO_2/Hematocrit Probe
- Lung Monitoring Gas Regulator Kit

3.1.2. Items Included with the Lung Perfusion Set

Each Lung Perfusion Set is shipped with the necessary sterile components required during a lung preservation session. Each Lung Perfusion Set includes the following components:

- Lung Perfusion Module
- Lung Instrumentation Tool Set
- Lung Perfusion Initiation Set
- Lung Perfusion Termination Set

3.2. OCS™ Lung System

Figure 3-1 shows the OCS™ Lung System and identifies the components with the top cover on and the front panel in the up position. For detailed instructions on setting up and using the OCS™, see the chapters that follow throughout this manual. Figure 3-2 shows the OCS™ with the covers removed:

CAUTION— Use the OCS™ Lung System only at the temperatures, relative humidities, and altitudes specified in Table 8-2, “OCS™: Electrical and Physical Specifications.”

Figure 3-1: OCS™ Lung System (with Covers)

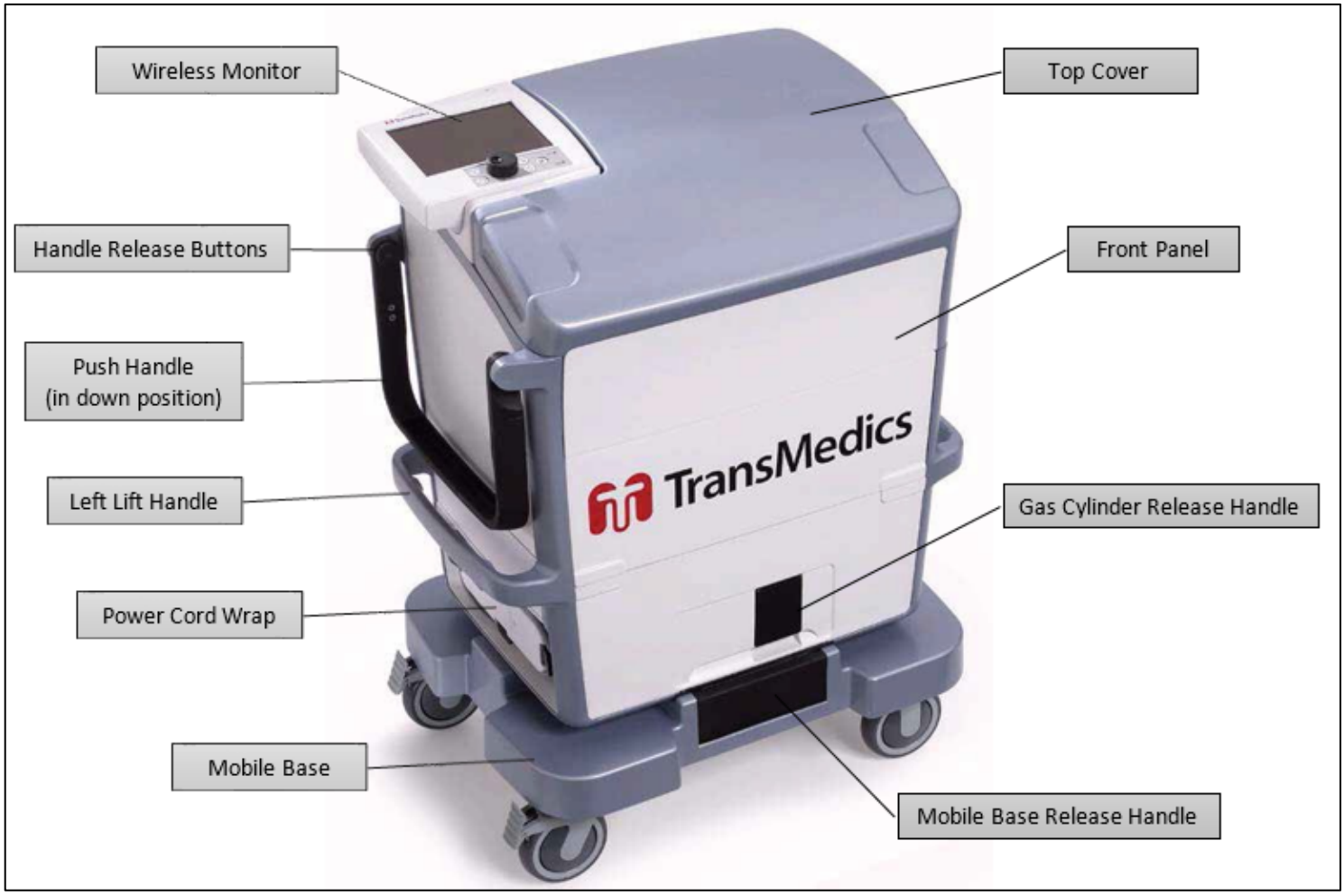
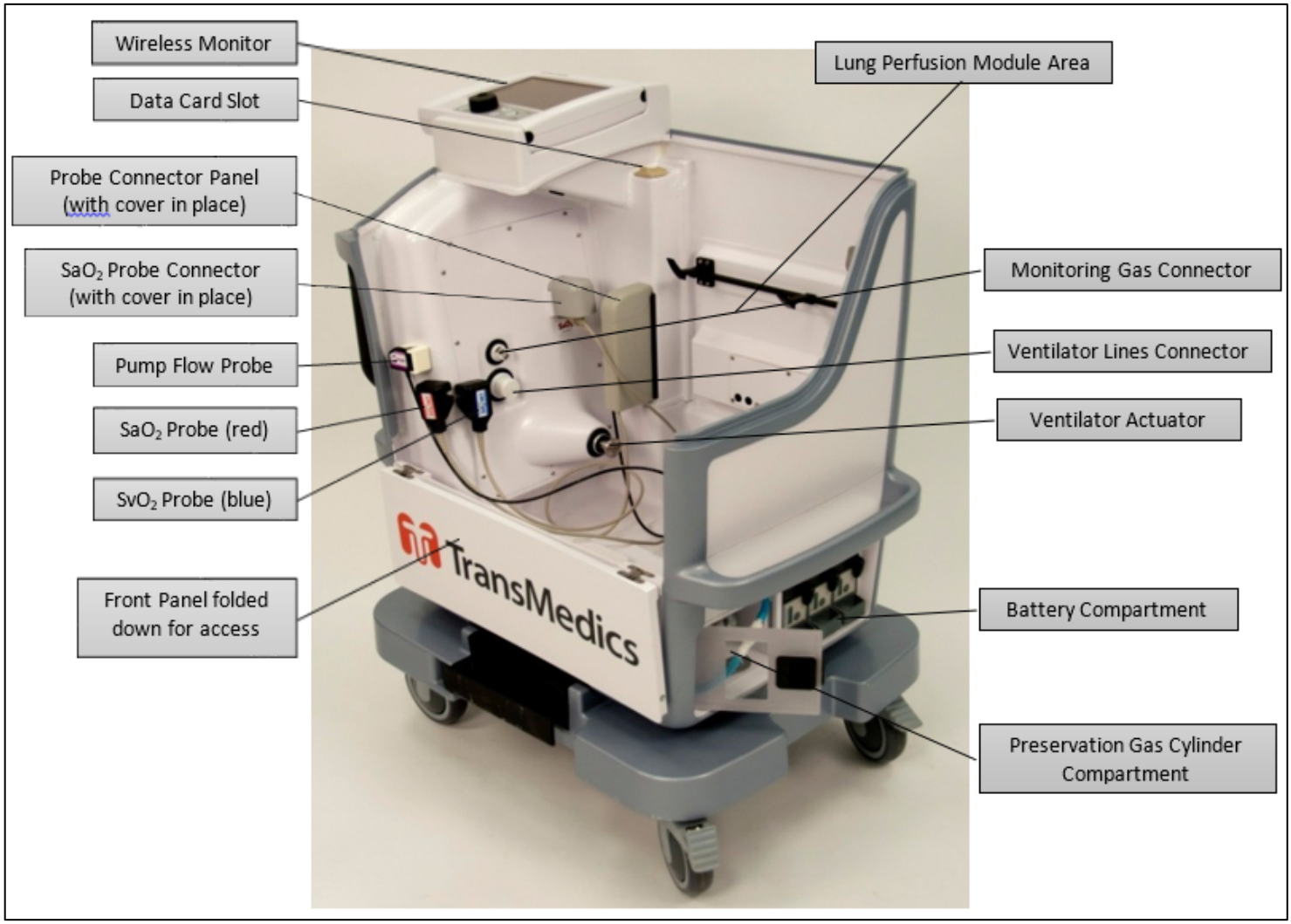


Figure 3-2: OCS™ (with Covers Removed)



3.2.1. Wireless Monitor

The Wireless Monitor (as shown in Figure 3-1) tracks the vital functions of an organ perfused with the OCS™ and displays organ- and system-functional parameters. You can use the Wireless Monitor while it is docked on the OCS™ Lung Console, or you can remove it (undock it) and use it remotely, such as when transporting the organ.

The Wireless Monitor's screen displays various system and organ parameters as well as messages to visually and audibly indicate out-of-range alarms and system fault conditions.

For more information about the Wireless Monitor, see Chapter 5: Wireless Monitor Overview.

NOTE— Only Wireless Monitors for the OCS™ Lung System can be used with the OCS™ Lung System.

3.2.2. Probes

The OCS™ contains several probes that provide information about the perfusate supplied to and collected from the organ.

The probes are reusable and do not require sterilization since they touch only the exterior of the tubing and never contact the perfusate flowing through the circuit. Each probe is sized to match the tubing to which it connects. When not in use on a Lung Perfusion Module, probes are cleaned and stored inside the Console.

Figure 3-3: OCS™ Probes

The pump flow probe measures the flow rate of perfusate within the Lung Perfusion Module circuit.

The TransMedics non-invasive SvO_2/Hematocrit probe monitors both blood hematocrit (percentage of red blood corpuscles to whole blood volume) and blood oxygen saturation (percentage of oxyhemoglobin to total hemoglobin). The SaO_2/Hematocrit probe is used to measure the arterial oxygen saturation in the perfusate leaving the lung through the LA.

3.2.3. Lung Preservation Gas Cylinders

A continuous gas supply is vital to organ preservation. Each Lung Preservation Gas cylinder (Figure 3-4) holds 408 L at 3000 psi (21000 kPa), enough gas to last approximately 12 hours in Preservation Mode under ordinary operating conditions. The Lung Preservation Gas cylinder compartment, shown in Figure 3-2, is located on the right side of the OCS™ Lung Console behind a clear plastic access door, directly above the Mobile Base's front wheels when the Mobile Base is installed.

Figure 3-4: Lung Preservation Gas Cylinder

For safety information on handling gas cylinders, see Section 2.16, "Handling Pressurized Gas Cylinders."

For more information on installing and removing gas cylinders, see Section 4.4, “Using the Lung Preservation Gas Cylinders.” For details on gas monitoring and system response to low gas supply, see Section 5.3.4, “System Status Icons on the Wireless Monitor.”

3.2.4. Lung Monitoring Gas Cylinders

Figure 3-5: Lung Monitoring Gas Cylinder

Lung Monitoring Gas is used during Monitoring Modes (described in Section 3.4.1, “OCS™ Lung System Perfusion and Ventilation Circuit.”). Each cylinder holds 408 L at 3000 psi (21000 kPa). For details on estimating the remaining Lung Monitoring Gas, see Table 4-2. The Lung Monitoring Gas cylinder is connected using the supplied regulator.

For safety information on handling gas cylinders, see Section 2.16, “Handling Pressurized Gas Cylinders.”

3.2.5. System and Wireless Monitor Batteries

One lithium-ion battery is incorporated into the Wireless Monitor and three lithium-ion batteries are installed in the OCS™ Lung Console. At the end of service life, the battery in the Wireless Monitor is NOT user- replaceable, but you can replace the OCS™ batteries as needed. When transporting the system, be sure to have sufficient quantities of charged batteries to allow for the time you expect the system to be dependent on battery power.

The Wireless Monitor’s lithium-ion battery supplies power to the Wireless Monitor when it is undocked from the OCS™ Lung Console. If the Wireless Monitor battery fully discharges, the monitoring functions are disabled. However, system information is retained and the session continues at existing conditions. If the Wireless Monitor battery is fully discharged, you can dock the Wireless Monitor on the OCS™ Lung Console to restore its operation.

Figure 3-6: OCS™ Batteries

The OCS™ batteries (Figure 3-6) are installed in the battery compartment on the right side of the OCS™ Lung Console, next to the gas cylinder compartment, as shown in Figure 3-2. When the OCS™ is connected to AC power, the batteries automatically charge.

Under normal operating conditions, each OCS™ battery has sufficient charge to last a little more than one hour, for a minimum of four hours of total power without replacing or recharging the batteries. A fully charged undocked Wireless Monitor battery lasts at least six hours. When the system is connected to AC power, and the Wireless Monitor is docked on the system, the Wireless Monitor's battery and the OCS™ batteries are automatically recharged as needed.

NOTES—

When the OCS™ is in Standby mode and not connected to AC power, the batteries will deplete. TransMedics recommends connecting the OCS™ to AC power whenever possible.

When the OCS™ is connected to AC power and not operational, it can take up to 12 hours to fully recharge all three discharged OCS™ batteries and the Wireless Monitor's battery.

CAUTION—Environmental conditions impact the amount of power actually used by the system. System operation at colder temperatures will cause higher power usage and faster battery depletion. When the system is in operation, you can extend the battery life by placing the OCS™ top cover over the perfusion module whenever practical.

For details on low battery power indicators, see Figure 5-1 and Table 6-9, "Types of Alarms."

3.3. Lung Perfusion Set Components

The Lung Perfusion Set provides a sterile, protective environment for storage of the lung and facilitates delivery of perfusate and gases to the organ.

The Perfusion Set ships with a Lung Perfusion Module and all the sterilized accessories required for connection to an organ and for use during a preservation session. This chapter shows and describes the sterile TransMedics accessories that you use to connect and monitor the organ within the Lung Perfusion Module.

In addition to the materials supplied by TransMedics, other equipment and accessories are expected to be supplied at the Donor and Recipient Sites.

The TransMedics Perfusion Set contains all the components and mechanisms that directly contact perfusate or the organ during organ preservation. The entire Perfusion Set with all integrated and enclosed components has been sterilized using ethylene oxide (ETO). It is intended for single use only.

The entire Lung Perfusion Module (with user-installed probes disconnected) and all sterile accessories must be properly disposed of at the end of the organ preservation session according to the institution's protocol for disposing of blood-contaminated materials.

3.3.1. Lung Perfusion Module

The Lung Perfusion Module (Figure 3-7 through Figure 3-12) provides the sterile perfusate and ventilation circuit and protected environment for an organ within the OCS™. It is designed as a

single use module that mounts into the OCS™ Lung Console. Use the Wireless Monitor to observe measurements made within the Lung Perfusion Module. The lung is instrumented within the lung chamber of the Lung Perfusion Module. The inner dimensions of the lung chamber are 16.5 in (41.9 cm) long, 12.5 in (31.8 cm) wide, 7 in (17.8 cm) high. The Lung Perfusion Module includes:

- Integrated and easily accessible sampling and de-airing ports
- Integrated pulsatile pump dome interface
- Integrated low shear titanium perfusate warmer
- Integrated gas exchanger
- Integrated ventilator interface
- Integrated sensors (pressure and temperature) and communication circuitry.

Figure 3-7 shows the front view of the Lung Perfusion Module and its components.

Figure 3-7: Lung Perfusion Module - Front View

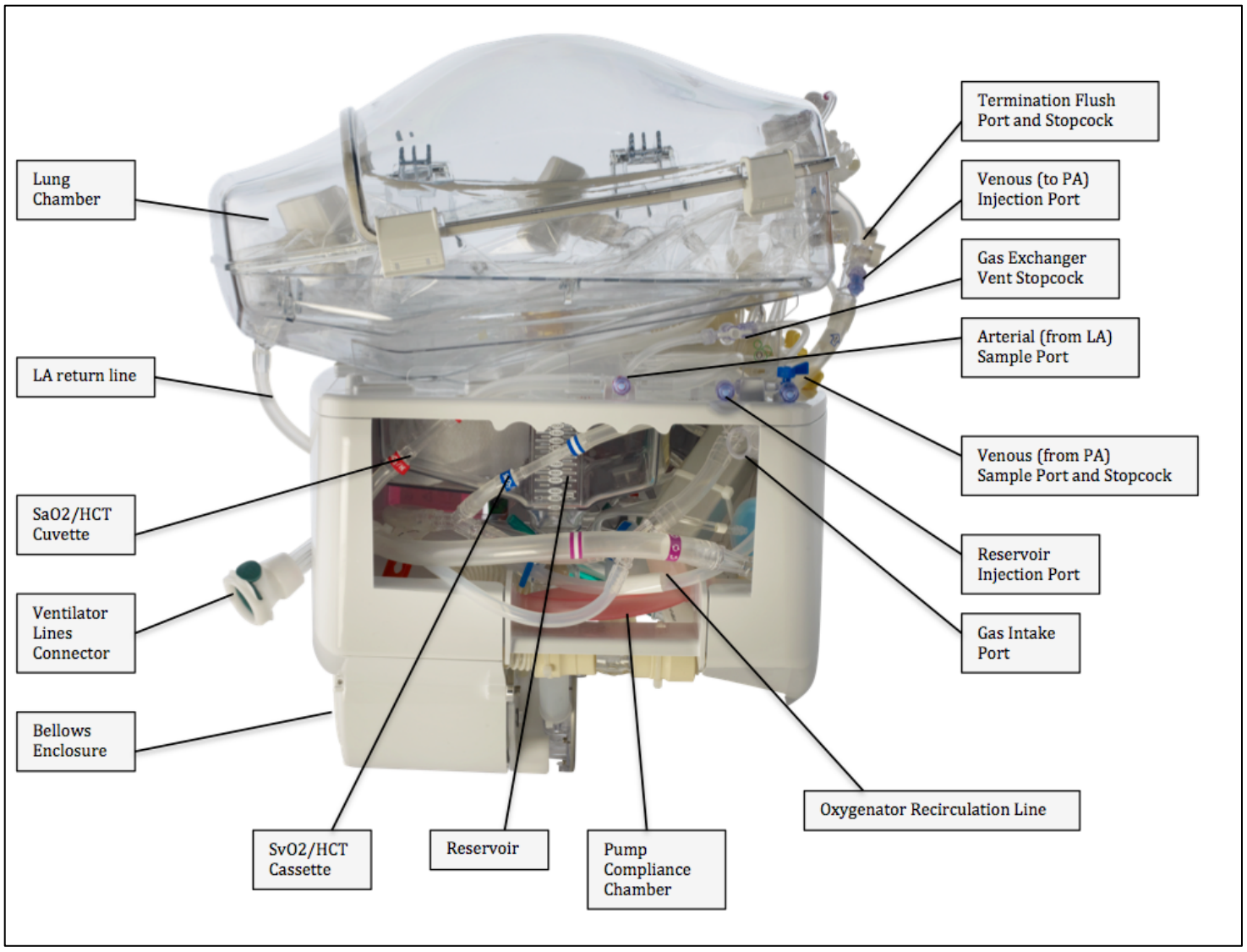


Figure 3-8 shows the left side of the Lung Perfusion Module.

Figure 3-8: Lung Perfusion Module - Left Side View

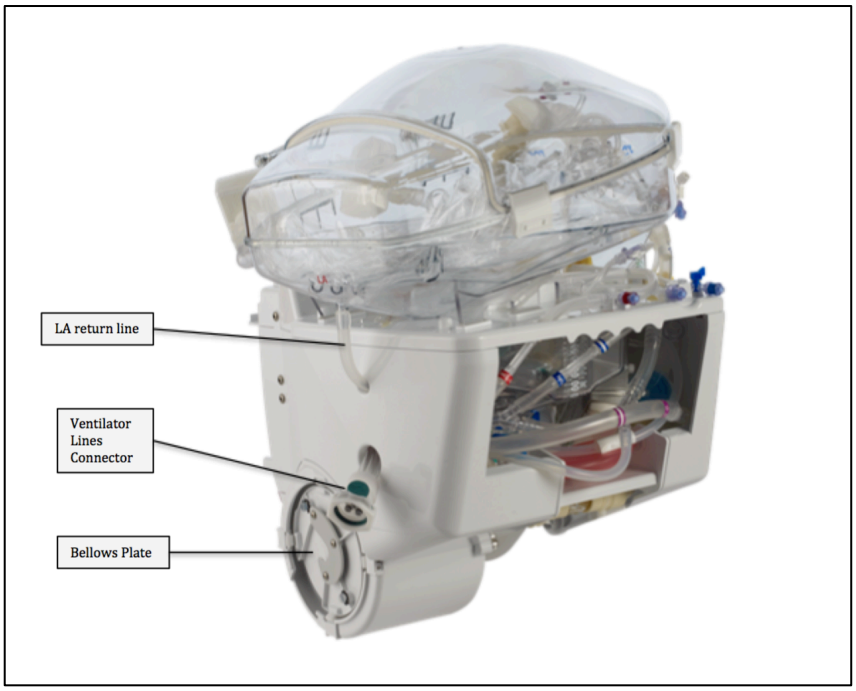


Figure 3.9 shows the back view of the Lung Perfusion Module and its components.

Figure 3.9: Lung Perfusion Module - Back View

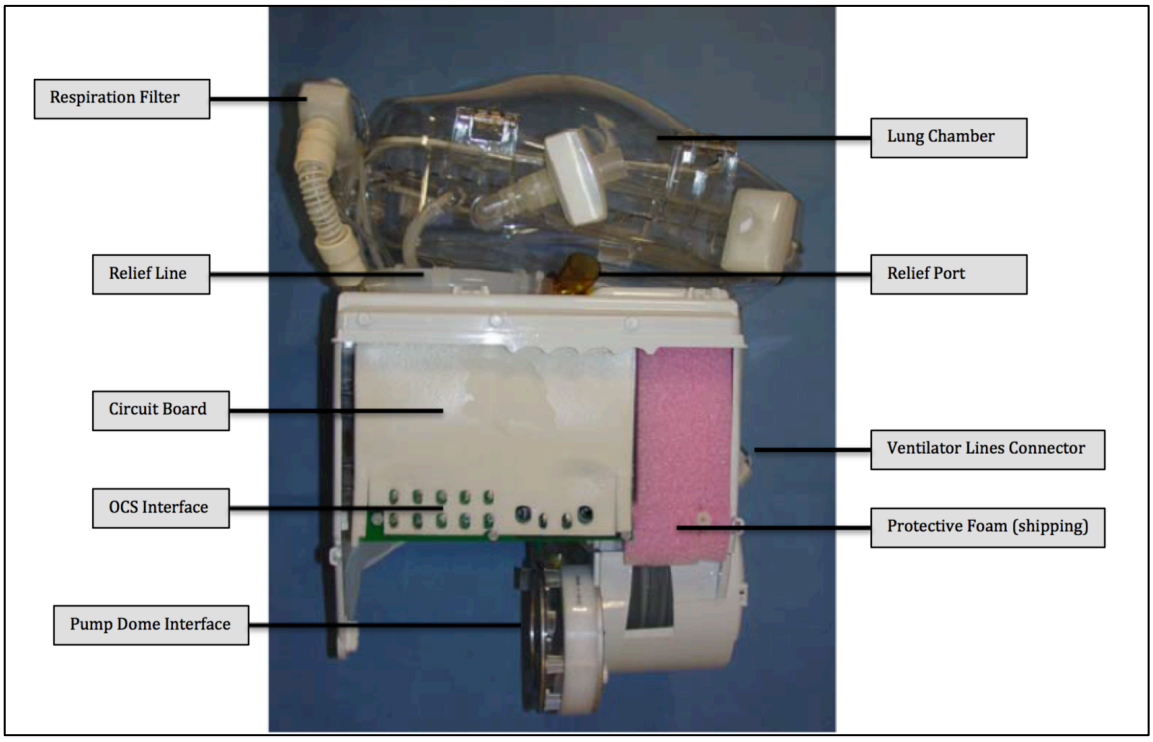


Figure 3-10 shows the top view of the Lung Perfusion Module.

Figure 3-10: Lung Perfusion Module Top View (with chamber cover open)

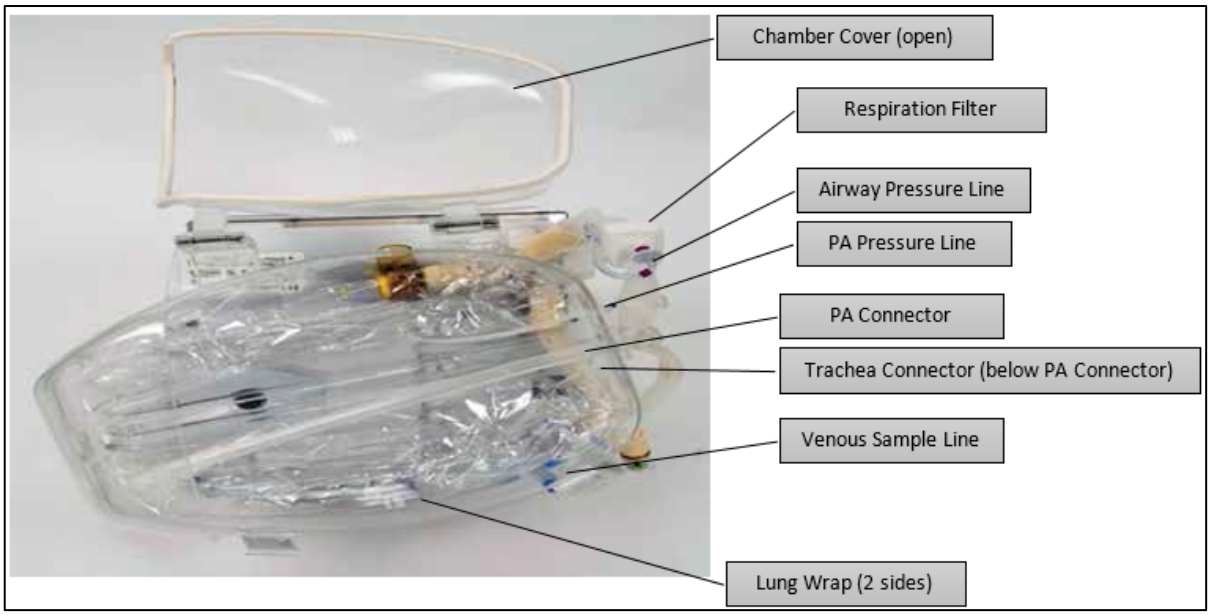


Figure 3-11 shows the right-side view of the Lung Perfusion Module.

Figure 3-11: Lung Perfusion Module Right Side View

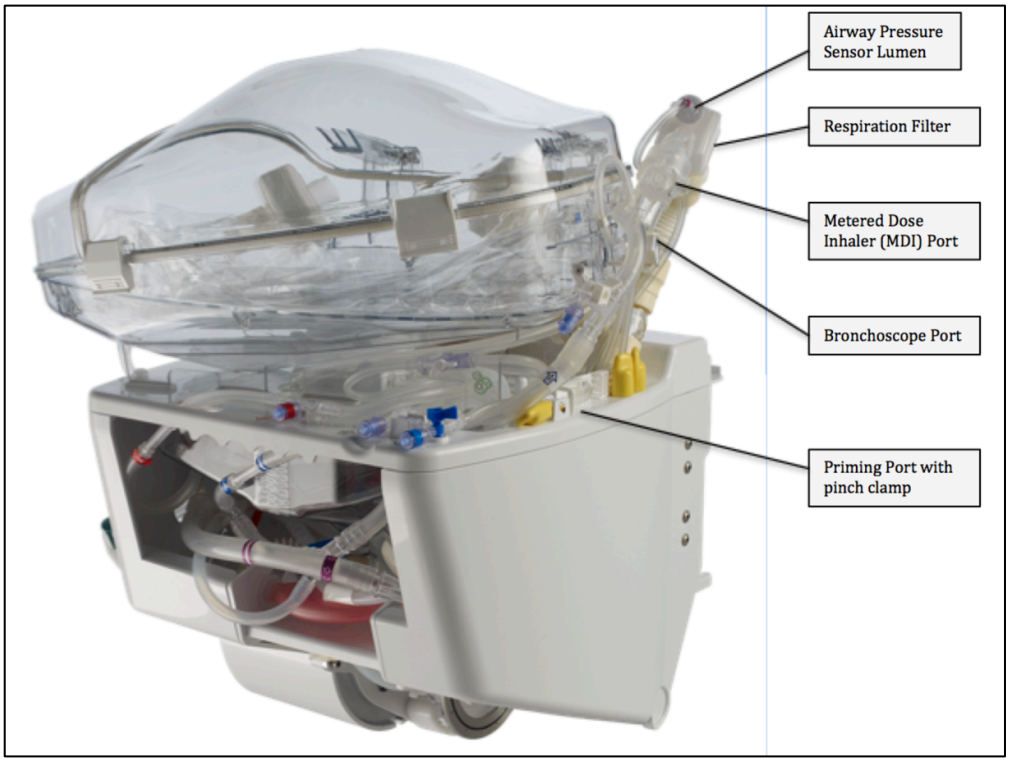


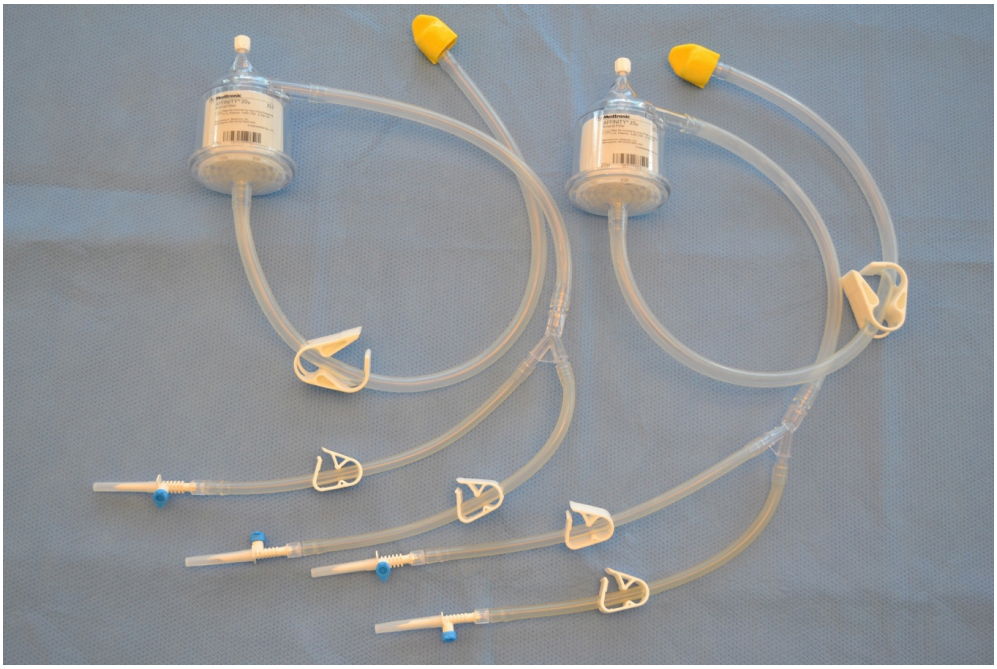
Figure 3-12 shows where the Lung Perfusion Module is mounted in detail.

Figure 3-12: OCS™ Lung Console with Lung Perfusion Module Area Detail

3.3.2. Lung Perfusion Initiation Set

Use the TransMedics Lung Perfusion Initiation Set (Figure 3-13) at the beginning of the perfusion procedure. The set includes two Dual-Vented Prime Lines for adding bagged or bottled solutions. The prime lines include a filter to remove particulate matter from pooled packed red blood cell units (pRBCs) that may be used to prime the circuit.

Figure 3-13: Lung Perfusion Initiation Set



3.3.3. Lung Instrumentation Tool Set

The Lung Instrumentation Tool Set (Figure 3-14) includes sterilized accessories for instrumenting the lung to the OCS™. Select the accessory size most appropriate for the Donor lung. For details about the use of each item in the set and specific sizes and styles available, see Table 3-1.

Figure 3-14: Lung Instrumentation Tool Set

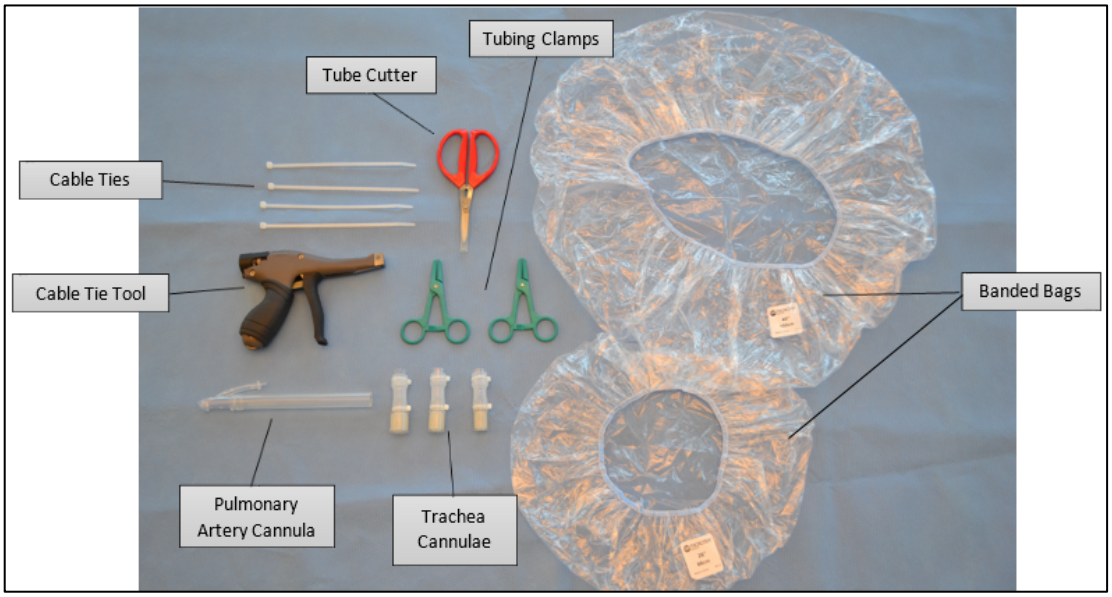


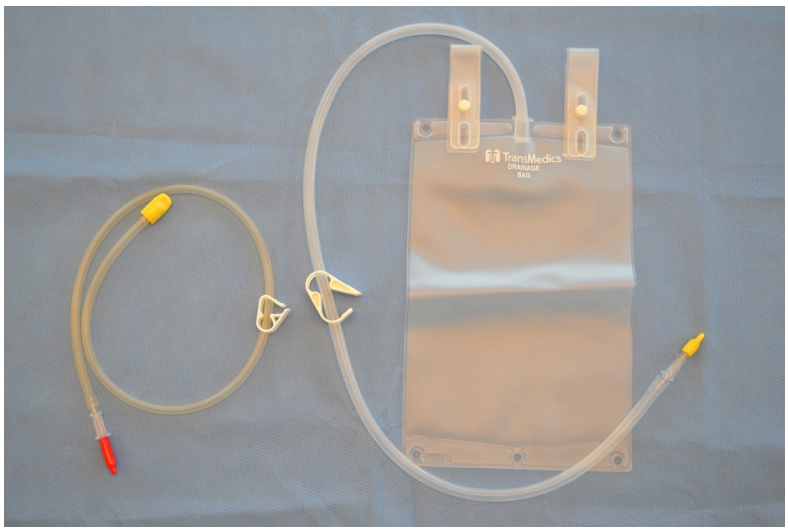
Table 3-1: Lung Instrumentation Tool Set

Accessory	Quantity	Description
Cable Ties	8	For securing the lung trachea to the Trachea Cannulae. (Note that photo includes only 4 of the 8 cable ties.)
Cable Tie Tool	1	For securing the lung trachea to the Trachea Cannula.
Pulmonary Artery Cannula	1	For PA Cannulation when connecting the lungs to the Lung Perfusion Module.
Tube Cutter	1	For sizing PA cannula.
Tubing Clamps	2	For clamping the Trachea Cannula.
Trachea Cannulae	3 (one of each size)	For Trachea cannulation when connecting the lung to the Lung Perfusion Module. There are three sizes to correspond to varying trachea sizes: 0.70 in / 17.8 mm 0.80 in / 20.3 mm 0.90 in / 22.9 mm
Banded Bags	2 (one of each size)	Place around organ chamber prior to transport. 26 in / 66.0 cm 40 in / 101.6 cm

3.3.4. Lung Perfusion Termination Set

Use the TransMedics Lung Perfusion Termination Set at the end of the perfusion procedure. The set includes a drainage bag for removing solution from the OCS™. TransMedics recommends using a single 3 Liter bag of termination flush solution for the final flush. The user must supply a sterile drape(s) for the termination procedure.

Figure 3-15: Lung Perfusion Termination Set



3.4. Overview of Use

The OCS™ maintains lung viability by supplying warm perfusate to the lung and ventilating the lung under controlled conditions. Controls on the system allow clinicians to adjust the preservation environment, and access ports enable medical treatment of the organ.

The system also enables medical professionals to monitor key parameters that may be useful in evaluating lung function according to their clinical judgment.

This section provides general information about the following:

- Overview information about the Preservation Mode and Monitoring Modes
- Valves and ports used to monitor, sample, and intervene during a preservation session.

3.4.1. OCS™ Lung System Perfusion and Ventilation Circuit

Figure 3-16 illustrates the perfusion and ventilation circuits. The OCS™ circulates perfusate by pumping it from the reservoir through the warmer, into the gas exchanger and into the lung's Pulmonary Artery. The perfusate travels through the lung and then drains out of the Left Atrium, back into the reservoir.

The OCS™ circulates ventilation gas from the gas cylinders into the ventilation line. The bellows expand and contract to exchange gas with the lungs. In certain ventilation modes, the gas from the cylinder is also directed to the gas exchanger to change the diffused gas composition of the perfusate.

3.4.2. Ventilation Modes

The OCS™ supports two main ventilation modes.

3.4.2.1. Preservation Mode

In **Preservation Mode**, the lung re-breathes Lung Preservation Gas. Lung Preservation Gas contains a mixture of nitrogen, CO_2 and Oxygen to maintain the metabolic activity of the lung tissue. The OCS™ ventilates the lung in Preservation Mode by breathing Lung Preservation Gas into the lung, withdrawing the gas out again, then re-breathing it back into the lung. This is done to establish an equilibrium between the gas composition in the breath and the perfusate. In addition, this re-breathing conserves heat and moisture.

Preservation Mode is the mode that is typically used for organ transport.

The **Pause Preservation** mode has no active mechanical ventilation. In this mode, the ventilation circuit maintains a closed system to prevent the lungs from deflating.

3.4.2.2. Monitoring Mode

In Monitoring Mode, medical professionals can evaluate the gas transfer capability of the lung. The OCS™ supports two main modes of monitoring, *Continuous Monitoring* and *Bronchoscope Monitoring*.

In **Continuous Monitoring Mode**, the organ is monitored for its gas transfer capabilities using a method where the perfusate volume is continuously deoxygenated externally. The lung is then used to oxygenate the perfusate by breathing air. Medical professionals can assess the gas transfer capabilities of the lung according to their clinical judgment measuring the O_2 saturation of the perfusate exiting the lung.

The **Bronchoscope Monitoring** Mode ventilates the lungs with room air. This mode supports insertion of a bronchoscope into the trachea.

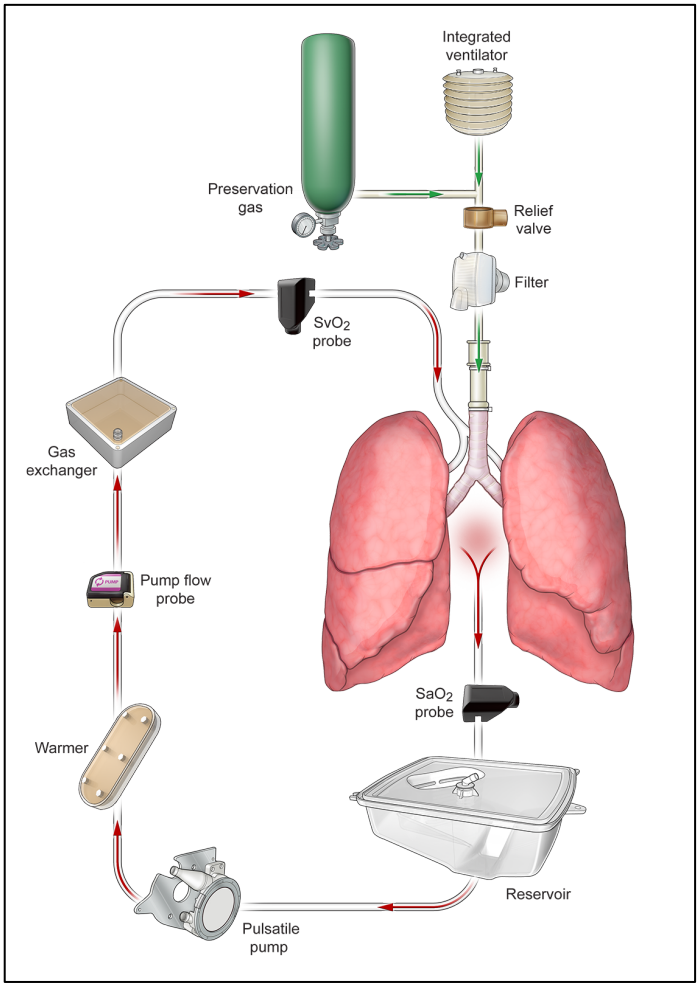
The following table identifies the type of gas used in each Ventilator Mode.

Table 3-2: Ventilation Gas by Ventilator Mode

Ventilator Mode	Ventilated Gas	Destination
Preservation	Lung Preservation Gas	Lung
Pause Preservation	Lung Preservation Gas	Gas Exchanger
Monitoring - Continuous	Lung Monitoring Gas	Gas Exchanger
Monitoring - Bronchoscope	Room Air	Lung

For more details about the usage of Preservation and Monitoring Modes, see the *TransMedics Clinical User Guide: OCS™ Lung System*.

Figure 3-16: Circulation and Ventilation



3.4.3. Valves and Ports

The Lung Perfusion Module includes manual valves and ports (refer to Figure 3-7) for various interventions that may be required when managing the organ throughout the phases of preservation.

NOTE—While using these Lung Perfusion Module ports and valves to adjust pulmonary performance, pay attention to the readings from the user-installed flow and SO_2/Hematocrit probes. Adjust or reinstall probes if readings seem inaccurate.

- A reservoir injection port lets you inject solutions into the reservoir.
- A venous injection port allows injection of solutions directly to the lung.
- A Priming Inlet port lets you add priming solution and perfusate to the reservoir.
- Two sample ports (Arterial and Venous) permit withdrawal of perfusate for testing from the Arterial or Venous line
- A four-way stopcock on the line lets you purge air from the PA flow lines, routing it to the reservoir.

- The Gas Exchanger vent is used to expel excess air from the gas exchanger into the reservoir.
- A Termination Flush port lets you flush the lung before removing it from the OCS™.
- A Bronchoscope port lets the user insert a bronchoscope into the lung airway through the trachea connection. The port cap includes resealable peel-away adhesive fasteners to ensure the port cap is secured when not in use.

3.4.4. Opening and Closing Stopcocks

- All stopcocks are left open during sterilization (before packaging and shipment to customers) and must be adjusted throughout the use of the Lung Perfusion Module. This section describes the stopcocks and how to open and close them.
- The Lung Perfusion Module includes three stopcocks.
- The Gas Exchanger Vent stopcock allows flow in one direction. It is open when the stopcock is parallel (180°) to the line and is closed when the handle is perpendicular (90°) to the line. Use the gas exchanger one-way stopcock (refer to Figure 3-7) to purge air from the gas exchanger (when open).
- The Venous Sample stopcock is open in three directions and closed in the direction of the OFF handle. Use the Venous Sample four-way stopcock (refer to Figure 3-7) to control the purging and sampling from the PA vent and when injecting into the perfusate.
- The Flush stopcock is open in three directions and closed in the direction of the OFF handle. Use the Flush stopcock to flush the lung before removing it from the OCS™.

4. CHAPTER 4: SYSTEM SETUP AND CONNECTIONS

This chapter describes how to set up the OCS™ Lung System for each use, prior to installing the Lung Perfusion Module for a preservation session.

4.1. Connecting the System to AC Power

The OCS™ Lung System can be powered by connecting it to an acceptable external AC power source or, when disconnected from external power, it can be powered by the OCS™ batteries. When connected to AC power with the ON/OFF switch set to ON, the OCS™ batteries and the Wireless Monitor battery (if the Wireless Monitor is docked) are automatically charged as needed, and battery power is not expended.

NOTE—When using and storing the OCS™ Lung System where an acceptable AC power receptacle is accessible, TransMedics recommends ALWAYS connecting the system power cord to the AC source, rather than running the system on battery power.

WARNINGS—

If it is necessary to disconnect the unit from the AC power, you must unplug the unit from the AC power receptacle. Neither the  button nor the system On/Off switch will completely disconnect power.

Do not use the OCS™ and accessories in the presence of explosive anesthetics.

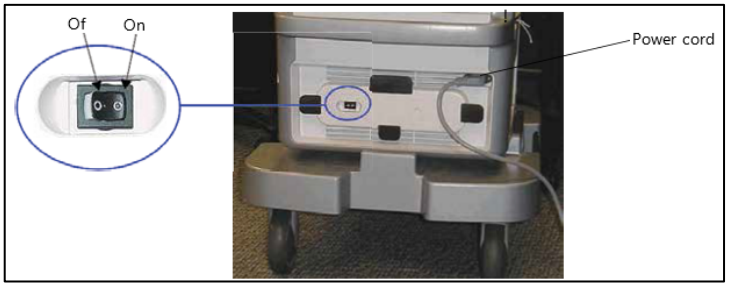
To avoid electrical shock, use only the power cords supplied by TransMedics for the OCS™, and connect only to properly grounded wall outlets.

If you have any doubt about the integrity or suitability of the external power or of the cable, plug, or connector, do not connect the power cord. To avoid potential electrical hazards, allow the system to function on OCS™ battery power only, until appropriate external power is available or any problems have been resolved.

Never use a converter adapter to plug the three-pronged AC plug into a two-pronged, ungrounded wall outlet, and do not use additional cables, extension cords, or outlets with the system. Doing so may result in electric shock to the operator and damage to the equipment.

NOTE—Batteries will not charge if the ON/OFF switch is set to the OFF position. TransMedics recommends leaving the ON/OFF switch set to the ON position at all times except when the device must be powered down for service or cleaning.

Figure 4-1: On/Off Switch and Power Cord



4.1.1. To connect the system to AC power

1. Connect the power cord to the recessed power inlet receptacle located above the power cord wrap (Figure 4-1).
2. If necessary, unwind the power cord from the power cord wrap.
3. Connect the plug into a properly grounded 100 to 240V, 50/60Hz Hospital Grade AC outlet only.
4. Position the power cord so that it does not interfere with traffic, using the power cord wrap to take up any excess cord, or positioning and securing the power cord so that it is out of the way.
5. Ensure the ON/OFF switch is set to the ON position (Figure 4-1).

NOTE—When the system is connected to AC power, the LED above the Wireless Monitor docking area illuminates (Figure 4-2).

4.2. Checking Battery Power

This section provides instructions for making sure the system and Wireless Monitor have adequate battery power for the preservation session. This section also provides instructions for charging the batteries.

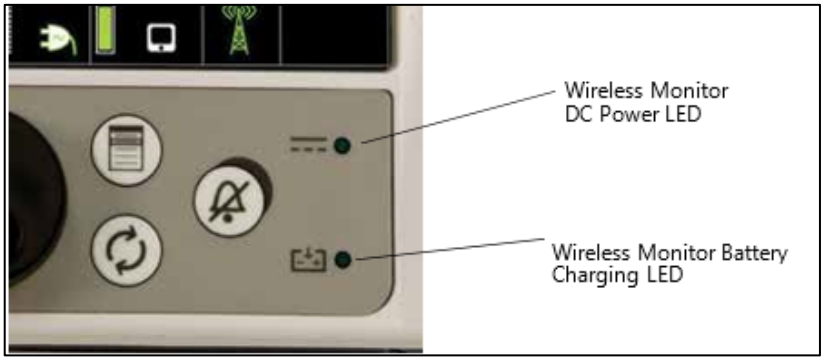
4.2.1. Checking Wireless Monitor Power

When the Wireless Monitor is docked on the OCS™, it automatically uses power from the power source supplying the OCS™, and, if the system is connected to AC power, the Wireless Monitor battery is recharged as needed. When you undock the Wireless Monitor and use it remotely, it uses power from its own battery.

The two LED lights on the Wireless Monitor's control panel provide information about Wireless Monitor power status (Figure 4-2):

- When the Wireless Monitor is receiving power from the system, the DC Power LED (⎓) is lit.
- When the Wireless Monitor is fully charged, the Battery Charging LED ( ) is solidly lit. When it is charging the light blinks. Otherwise, the LED is off.

Figure 4-2: Wireless Monitor Power LEDs



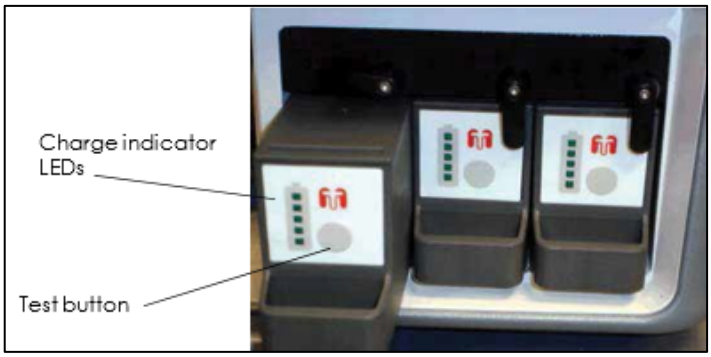
4.2.2. Checking System Battery Power

You can determine the charge status of each battery by viewing the battery status icons on the Wireless Monitor. For more information, see Table 5-3. If you do not have access to the Wireless Monitor display, perform the following steps to manually check the charge level of each battery.

4.2.2.1. To check the OCS™ battery charge LED

1. Press the test button on the front of each battery (Figure 4-3). The battery charge LEDs indicate charge level.
2. Determine the charge level and take the appropriate action:
   - If all five indicator LEDs light, the battery is fully charged.
   - If the lower LED flashes and the remaining four LEDs are not illuminated, it indicates that the battery is fully discharged. Replace the battery with a fully charged battery or connect the OCS™ to AC power.
   - If no LEDs light, do not use the battery and contact TransMedics service (+1-978- 552-0999).

Figure 4-3: OCS™ Batteries



4.2.3. Duration of OCS Battery Powered Operation

When transporting the OCS Lung, be sure to have sufficient quantities of charged batteries to allow for the time you expect the system to be dependent on battery power. Under normal operating conditions, the set of three OCS™ batteries has sufficient charge to last a minimum of four hours of operation. Each additional battery will supply at least 1.3 hours of operation.

WARNING— To avoid loss of battery power during transport, especially due to unanticipated transportation delays, connect the system to AC power whenever available.

The OCS™ batteries are automatically recharged when the system is connected to AC power. Note that the system will charge, in order, the Wireless Monitor, then the OCS Batteries, one at a time.

4.2.4. Removing and Installing System Batteries

When one or more OCS™ batteries are discharged, the Wireless Monitor display indicates which batteries are discharged. You can hot swap the batteries one at a time with a fully charged replacement battery while the system continues to operate normally. You cannot remove more than one OCS™ battery at a time.

WARNING—If powered by the OCS™ batteries, the system will cease to function when the batteries are fully discharged. To avoid loss of power, regularly monitor the battery status icons and audible alarms on the Wireless Monitor display and replace OCS™ batteries as needed, or connect the system to AC power. (For details on battery capacity alarms that appear on the Wireless Monitor screen, see Table 6-9).

For details on low battery power indicators, see Figure 5-1 and Table 5-3, “System Status Icons.”

WARNING—Each TransMedics OCS™ battery includes rechargeable lithium ion battery cells. Lithium is a highly reactive element that can react violently when mixed with water, leading to possible battery leakage, smoke, and fire. Batteries must be handled, stored and disposed of with great care. Failure to adhere to proper lithium handling procedures may cause bodily injury and environmental and equipment damage. Carefully review safety information in Section 2.15, “Handling Batteries.”

CAUTION—Before removing an OCS™ battery, make sure you are removing the intended battery. Although the system prevents you from removing more than one battery at a time, it is possible to remove any single battery, potentially leaving the system with NO charged batteries in place and shutting down system operation.

4.2.4.1. To remove a discharged battery and install a fully charged battery

1. To test the battery before replacing it, press the battery test button (Figure 4-3). For instructions on testing battery charge status, see Section 4.2.2, “Checking System Battery Power.”
2. Move the battery’s retaining lever up and out of the way.

   CAUTION—Once you have removed an OCS™ battery, no other battery can be removed until you install a battery in the open slot and close the retaining lever. Do not try to forcefully remove a battery. Doing so may damage the system and the battery.

3. Firmly grasp the battery handle, pull the discharged battery straight out, and set it aside.
4. Slide the new battery into the open slot and move the retaining lever back in place, making sure the battery is secure.

CAUTION— Ensure that the battery is oriented correctly (See Figure 4-3) prior to inserting it in the OCS™ Lung Console. Push in gently. Excessive force may damage the battery, resulting in bodily injury and environmental and equipment damage.

5. Verify battery function by checking the battery status icon on the Wireless Monitor. For more information on viewing battery status, see Table 5-3.

NOTES—

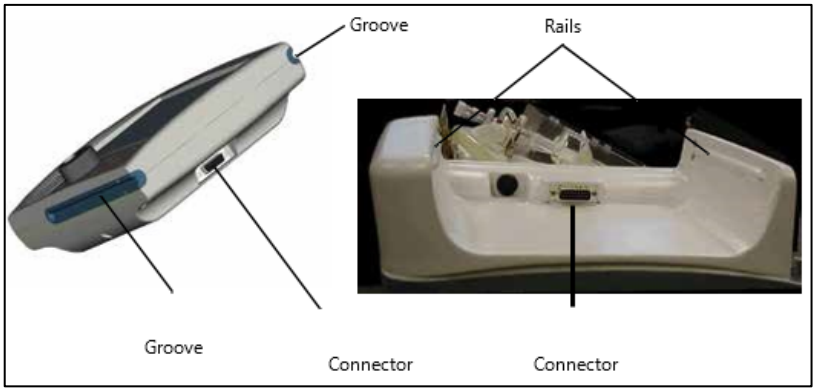
If you will not be immediately recharging the removed battery, return it to the original TransMedics shipping container for storage. For details on storing batteries, see Chapter 8: System Specifications.

If you need to ship OCS™ batteries, they must be packaged for shipment by qualified personnel and shipped according to applicable transportation laws in the original shipping packages or replacements supplied by TransMedics.

4.3. Docking and Undocking the Wireless Monitor

The Wireless Monitor (Figure 4-4) has side grooves that slide over matching rails on the top of the OCS™ Lung Console. A connector on the side of the Wireless Monitor inserts into a connector on the system.

Figure 4-4: Docking the Wireless Monitor



4.3.1. To dock the Wireless Monitor

1. Position the Wireless Monitor so that its grooves line up with the rails on the system (Figure 4-4).
2. Slide the Wireless Monitor all the way into the Monitor docking cradle, until the receptacle on the Monitor locks into the connector on the system. For reliable operation, make sure that the Monitor is fully inserted into the OCS™ Lung Console so that the electrical contacts are fully connected. The DC Power LED (⎓) should be lit indicating the Wireless Monitor is receiving power from the system.

4.3.2. To Undock the Wireless Monitor

To undock the Wireless Monitor, use both hands to pull it straight along the rails until the Wireless Monitor clears the OCS™ Lung Console.

4.3.3. Using the Wireless Monitor Remotely

When removed from the system, the Wireless Monitor operates from its own battery.

CAUTIONS—

Before undocking the Wireless Monitor, check the Wireless Communication status icon to make sure it is safe to undock the Monitor (). If the Wireless Fault icon () is displayed, DO NOT undock the Wireless Monitor. Doing so may result in data loss.

Keep the Wireless Monitor within an unobstructed range of approximately 3 meters at all times and as close as possible to the system to facilitate quick response to alarms and other conditions that require intervention. If there is an obstruction between the Wireless Monitor and the system, the effective range may be reduced.

If the Wireless Monitor is out of range of the OCS™ Lung Console for 10 minutes, it turns itself off. While the Wireless Monitor is off, the rest of the system continues to function. Once the Wireless Monitor is docked on the OCS™ Lung Console, it turns itself back on and full monitoring functionality is restored.

When the Wireless Monitor is back in range, verify all parameters are as expected in the rare instance that a system event occurred while out of range.

If the Wireless Monitor unexpectedly generates an Out of Range alarm, verify that the OCS™ pump and ventilator are still functioning and check the status of the organ.

During remote operation, all controls operate normally except the Run/Standby button () which functions only when the Wireless Monitor is docked to the system. The Run/Standby button lets you transition the OCS™ from an inactive state (Standby) to an active state (Run).

If the Wireless Monitor is moved out of range of the system, a warning tone emits and continues until the connection is re-established. Refer to the Cautions above for more information. In addition to the warning tone, the Wireless Fault icon blinks and is displayed in red (as shown at right).

If the Wireless Monitor battery fails, the screen goes blank and the Wireless Monitor does not function until it is docked on the system.

NOTE—Even though the Wireless Monitor screen is blank when no power is available, the OCS™ continues working at the current settings, unless the OCS™ loses power. When the Wireless Monitor returns to normal operation, you can view the messages.

4.4. Using the Lung Preservation Gas Cylinders

To assure that a sufficient supply of Lung Preservation Gas is continuously circulated with the perfusate, carefully monitor the gas status frame and the SvO_2 and SaO_2 parameters on the Wireless Monitor Display. Chapter 5: Wireless Monitor Overview provides details of where gas-related

parameters appear on the Wireless Monitor during a preservation session. If the system is in Standby Mode or the pump has not been turned on yet, open the gas valve and check the pressure gauge on the gas regulator in the OCS™ Lung Console.

CAUTIONS—

It is vital to keep careful track of gas status before and during organ preservation. Insufficient gas supply may lead to tissue hypoxia.

If a regulator failure occurs, monitor blood chemistry and gas cylinder pressure closely as the cylinder will expire more quickly than under normal conditions. If any unexpected changes in blood chemistry occur, turn gas flow rate to 0 L/min, close the valve on the gas cylinder and discontinue its use.

Bring a spare gas cylinder if you anticipate that the amount of gas remaining in the gas cylinder will not last for the projected duration of preservation or if you anticipate any possible delays.

4.4.1. Estimating the Remaining Lung Preservation Gas Supply

When the system is in Run Mode, the Wireless Monitor provides continuously updated information about remaining Lung Preservation Gas cylinder capacity. However, when the system is in Standby Mode, you can only estimate the remaining Lung Preservation Gas supply (without turning on the Wireless Monitor) by viewing the pressure gauge on the gas cylinder. Table 4-1 indicates the hours of gas supply left at various pressure readings and flow rates.

Table 4-1: Hours of Lung Preservation Gas Supply Remaining at Various Flow Rates and Cylinder Pressures

Pressure (psi)	Flow Rate (ml/min)								
	200	300	400	500	600	700	800	900	1000
	Hours Remaining Based on Pressure (psi) and Flow Rate								
3000	32.3	21.5	16.2	12.9	10.8	9.2	8.1	7.2	6.5
2500	26.6	17.8	13.3	10.7	8.9	7.6	6.7	5.9	5.3
2000	21.0	14.0	10.5	8.4	7.0	6.0	5.2	4.7	4.2
1500	15.3	10.2	7.7	6.1	5.1	4.4	3.8	3.4	3.1
1000	9.6	6.4	4.8	3.9	3.2	2.8	2.4	2.1	1.9
500	4.0	2.6	2.0	1.6	1.3	1.1	1.0	0.9	0.8

4.4.2. Removing and Installing a Lung Preservation Gas Cylinder

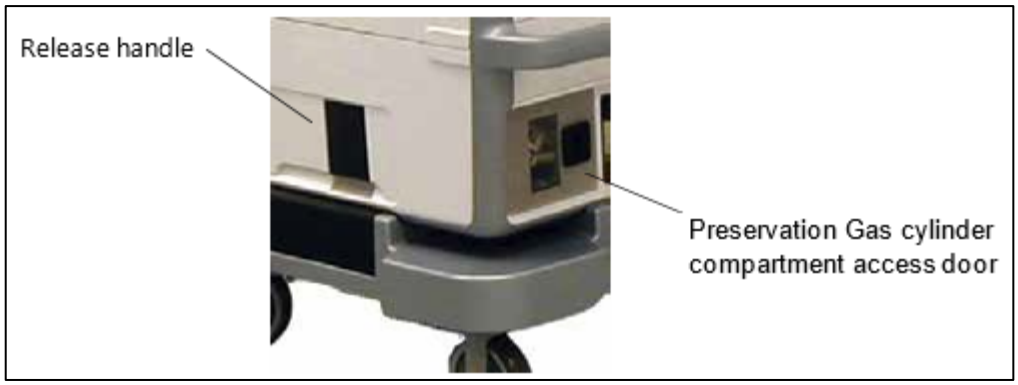
This section provides instructions for removing an empty Lung Preservation Gas cylinder and installing a new gas cylinder. It also provides details on how to determine if the regulator's yoke gasket is intact, and if necessary, how to replace it.

CAUTION—To minimize the time without Lung Preservation Gas supply to the organ, work as quickly as possible when removing and replacing gas cylinders during preservation.

4.4.2.1. To remove an empty Lung Preservation Gas cylinder

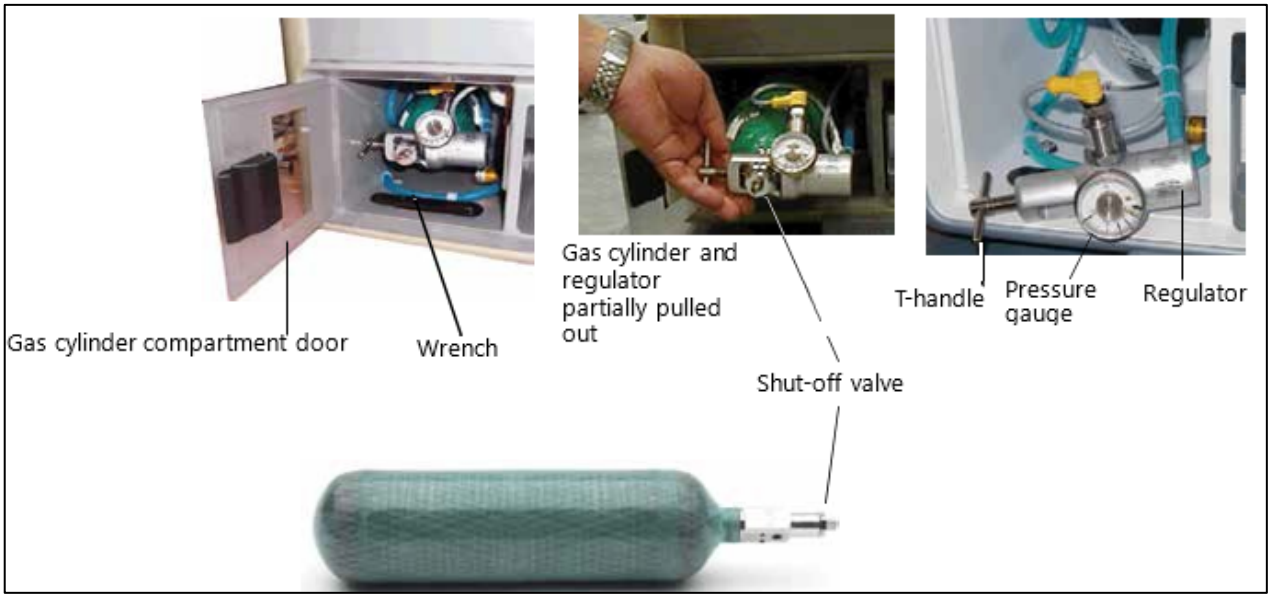
1. Lift the cylinder release handle on the front of the OCS™ Lung Console (Figure 4-5).

Figure 4-5: Removing an Empty Gas Cylinder



2. Open the access door to the Lung Preservation Gas cylinder compartment (Figure 4-6).
3. Remove the cylinder wrench mounted inside the door at the front of the compartment on a velcro® mounting strip.
4. Slide the Lung Preservation Gas cylinder partially out of the compartment so that you can access the regulator fitting.

Figure 4-6: Lung Preservation Gas Cylinder and Regulator

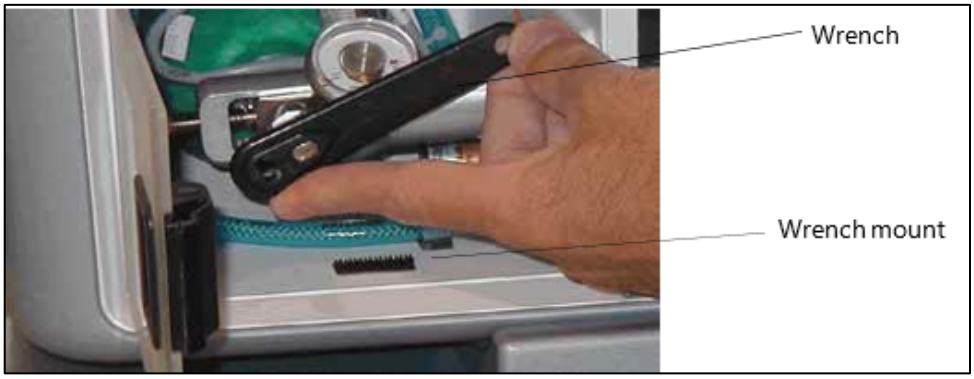


NOTE— You cannot remove the cylinder at this point because the regulator fittings and gauge are attached to the cylinder and are permanently connected inside the compartment.

5. Use the cylinder wrench to shut off the gas by slowly turning the shut-off valve clockwise (Figure 4-7).

CAUTION— Do not overtighten the T-handle or valve. Tightening too much may damage the valve.

Figure 4-7: Gas Cylinder Compartment Wrench



6. Using your fingers, loosen the T-handle (shown in Figure 4-6) that holds the cylinder in the regulator by turning the handle counterclockwise. Swing the regulator out of the way.

NOTE— You may hear a hissing sound from some residual gas venting as you disconnect the regulator. If the cylinder continues to vent, then the valve is not completely shut. To correct, immediately close the valve as described in step 5.

7. Gently slide out the empty cylinder. Use caution as the regulator is now hanging by tubing and cabling. Make sure the cylinder is completely detached before pulling it all the way out.

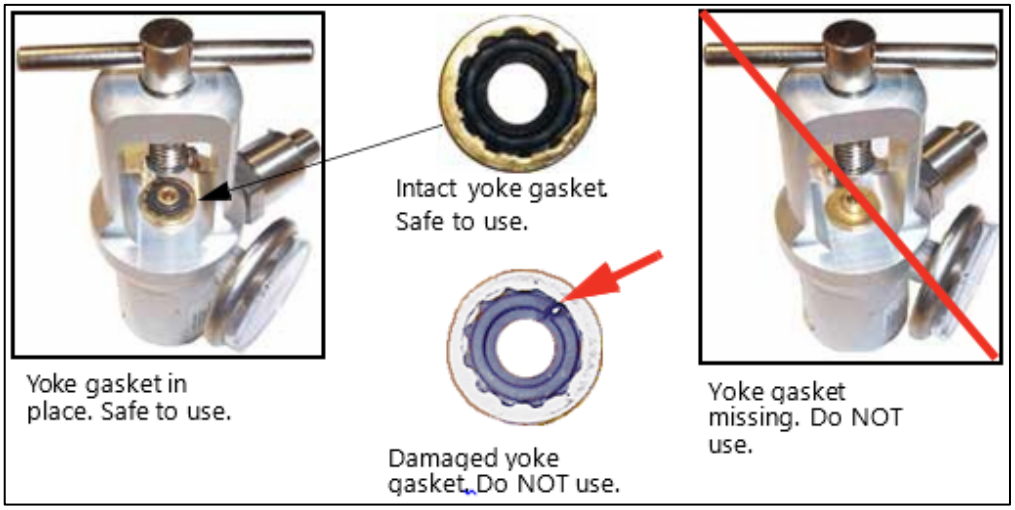
4.4.2.2. To install a new Lung Preservation Gas cylinder

1. Remove the Lung Preservation Gas cylinder from the packaging, and remove the shrink-wrap packed around the valve, and then remove the white plastic plug.

NOTE— Discard the shrink-wrap and plastic plug, but be sure to KEEP the other packaging to use when returning empty cylinders for refill.

2. Partially insert the new cylinder, with the bottom of the cylinder toward the OCS™ Lung Console and the cylinder valve toward you.
3. Make sure that the regulator's yoke gasket is in place and undamaged (Figure 4-8). If the gasket appears to be damaged, remove it and replace it as described in Section 4.7, "Replacing a Yoke Gasket."

Figure 4-8: Gas Cylinder-Regulator Yoke Gasket



WARNING— Do not look into the high-pressure exhaust sources while connecting the gas cylinder to the regulator. Using a cylinder without a yoke gasket or with a damaged yoke gasket may cause the cylinder to leak high pressure gas, possibly resulting in injury.

4. Place the regulator on the valve stem and line up the pins on the regulator with the holes on the valve stem.

NOTE— If the cylinder is not properly mounted, gas will vent when the cylinder's valve is opened. To correct, immediately close the valve and remount the regulator.

5. Hand-tighten the T-handle by turning the handle clockwise.
6. If you are ready to use the system, to test the gas valve, or to read the pressure level, use the gas cylinder wrench to open the valve **slowly**, turning it counterclockwise.
7. When the valve is open, ensure that the gauge indicates a high enough reading to meet the projected gas needs (see Table 4-1). If not, replace the cylinder with a full cylinder.
8. Push the cylinder all the way into the cylinder compartment.
9. Return the wrench to its location on the wrench mount in the gas cylinder compartment, so that it will be available for the next use (see Figure 4-7).
10. Lock the cylinder in place by pressing the cylinder release handle on the front of the system.
11. Close the access door to the gas cylinder compartment.

4.5. Using the Lung Monitoring Gas Cylinder

The Lung Monitoring Gas is used during Monitoring Mode only. The Lung Monitoring Gas cylinder is placed outside of the OCS™ Lung Console and connects via the Lung Monitoring Gas Regulator Kit.

4.5.1. Estimating the Remaining Lung Monitoring Gas Supply

To estimate the remaining Lung Monitoring Gas supply, view the pressure gauge on the Lung Monitoring Gas cylinder and use Table 4-2 to determine the approximate number of Monitoring Mode observations that can be performed at various pressure readings and flow rates.

CAUTIONS—

If the Lung Monitoring Gas regulator fails, discontinue use immediately and return the system to Preservation Mode.

The OCS™ does not provide an alarm if the Lung Monitoring Gas capacity is low, and the Wireless Monitor does not provide icons or indicators for the Lung Monitoring Gas supply. You need to estimate the amount of remaining Lung Monitoring Gas based on the table below.

Table 4-2: Estimated Number of Continuous Monitoring Observations Remaining at Various Flow Rates and Cylinder Pressures (Based on Average Use)

Pressure (psi)	Number of Observations
3000	10
2500	8
2000	6
1500	5
1000	3
500	1

4.5.2. Connecting and Disconnecting a Lung Monitoring Gas Cylinder

This section provides instructions for connecting and disconnecting a Lung Monitoring Gas cylinder to the OCS™ Lung Console.

4.5.2.1. To connect a Lung Monitoring Gas cylinder

1. Remove the Lung Monitoring Gas cylinder from the packaging, remove the shrink-wrap packed around the valve, and then remove the white plastic plug.

   NOTE— Discard the shrink-wrap and plastic plug, but be sure to KEEP the other packaging to use when returning empty cylinders for refill.

2. Make sure that the regulator's yoke gasket is in place and undamaged (Figure 4-8). If the gasket appears to be damaged, remove it and replace it as described in Section 4.7, "Replacing a Yoke Gasket."

   WARNINGS—

   When setting up the Lung Monitoring Gas regulator, always point the high-pressure exhaust ports away from yourself and others.

Do not look into the high-pressure exhaust sources while connecting the gas cylinder to the regulator. In the event of a regulator failure, do not look into the high-pressure exhaust sources

Using a cylinder without a yoke gasket or with a damaged yoke gasket may cause the cylinder to leak high pressure gas, possibly resulting in injury.

3. Place the cylinder on the ground next to the OCS™ Lung Console or in a portable cylinder cart.
4. Place the regulator from the Lung Monitoring Gas Regulator Kit on the valve stem and line up the pins on the regulator with the holes on the valve stem.

NOTE— If the regulator is not properly mounted, gas will vent when the cylinder's valve is opened. To correct, immediately close the valve and remount the regulator.

5. Hand-tighten the T-handle by turning the handle clockwise.

CAUTION— Do not overtighten the T-handle. Excessive tightening may damage the valve.

6. Connect the fitting at the free end of the tubing to the Lung Monitoring Gas connector inside the OCS™ Lung Console, directly above the Ventilator Lines connector (Figure 4-9). Ensure that the tubing is not pinched or kinked.

Figure 4-9: Connecting the Monitoring Gas to the OCS™

7. Remove the cylinder wrench mounted inside the door at the front of the Lung Preservation Gas compartment on a velcro mounting strip.
8. If you are ready to use the Lung Monitoring Gas cylinder or to read the pressure level, use the gas cylinder wrench to open the valve slowly, turning it counterclockwise.
9. When the valve is open, ensure that the gauge indicates a high enough reading to meet the projected gas needs (see Table 4-2). If not, replace the cylinder with a full cylinder.
10. Return the cylinder wrench to its location on the wrench mount in the Lung Preservation Gas cylinder compartment, so that it will be available for the next use (see Figure 4-7).

4.5.2.2. To disconnect the Lung Monitoring Gas cylinder

1. Remove the cylinder wrench mounted inside the door at the front of the Lung Preservation Gas compartment on a velcro mounting strip.
2. Use the cylinder wrench to shut off the gas by slowly turning the shut-off valve clockwise.

CAUTION— Do not over-tighten the valve. Excessive tightening may damage the valve.

3. Disconnect the fitting at the end of the Lung Monitoring Gas tubing from the connector on the OCS™.

NOTE— You may hear a brief hissing sound from some residual gas venting as you disconnect the fitting. If the cylinder continues to vent, then the cylinder valve was not shut completely. To correct, immediately close the valve as described in step 2.

4. Using your fingers, loosen the T-handle that holds the regulator on the cylinder by turning the handle counterclockwise. Slide the regulator off the valve stem.

4.6. Returning an EMPTY Gas Cylinder to TransMedics

This section provides instructions for returning Preservation and Monitoring Gas cylinders to TransMedics. For safety reasons, a depleted gas cylinder must be fully emptied prior to shipping.

CAUTIONS—

Avoid contact with the gas stream. Gas under pressure can cause bodily injury and property damage.

Open the valve slowly. Opening it quickly or any further than 1/4 turn may cause the gas cylinder to move rapidly from its current location, which may result in bodily injury and property damage.

Use ONLY packaging or a replacement packaging supplied by TransMedics. Other containers may not sufficiently protect the cylinder from potential damage during shipment, and may not meet regulatory requirements.

4.6.1. To prepare a gas cylinder for shipping

1. Move the partially empty cylinder to a well ventilated, open area and strap it to a stable cart, or place it on a stable flat surface where it cannot roll or fall.
2. Position the cylinder with the valve outlet face down, away from people and loose objects.
3. Slowly open the valve 1/4 turn.
4. After the cylinder is empty, leave the valve open.
5. Label the cylinder EMPTY, and pack it in the inner packaging in which the cylinder was originally shipped, and return it for replacement.

4.7. Replacing a Yoke Gasket

The yoke gasket is a gasket that seals the regulator to the gas valve. If it is damaged or missing (see example in Figure 4-8), it must be replaced.

4.7.1. To replace a damaged yoke gasket

1. Wearing gloves, remove the damaged yoke gasket from the base and discard it.
2. Remove the new gasket from its packaging.
3. Clean the gasket and the brass post with an alcohol wipe and allow the alcohol to air dry prior to installing the gasket.
4. Press the gasket down to the base, making sure that it is fully seated.

NOTE—The gasket is the same on both sides so may be positioned either way.

4.8. Using the TransMedics Data Cards

Transitioning from Standby Mode to Run Mode initiates an active period of OCS™ use known as a session. When the system is in Run Mode, system information is automatically stored internally. The system logs the following data:

- All system error events
- All system operating alarm events
- Trend data

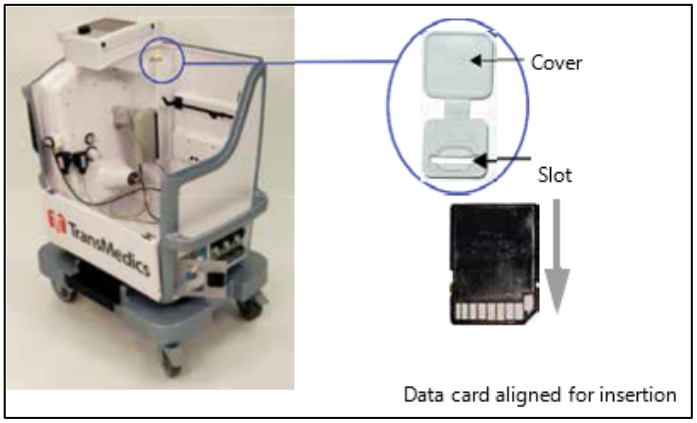
The OCS™ is shipped with data cards. Each card can hold data from multiple preservation sessions. TransMedics recommends installing the card prior to transitioning from Standby Mode to Run Mode, removing the card to retrieve data during the system shutdown protocol after the organ is removed, and then reinstalling it to prepare for the next session.

CAUTION—Use only data cards supplied by TransMedics. Other data cards will not function properly with the OCS™ and may cause a disruption of OCS™ operation.

NOTE—For instructions on transferring data from the OCS™ to the data card, see Section 6.1.3, “Managing Session Files.”

After you install a data card, the system automatically transfers all preservation session data to the data card. The system then updates it at 15-minute intervals. (See Chapter 6: Managing the System for details on data-related messages and status icons you may see when using a data card.)

Figure 4-10: Data Card and Installation Slot



4.8.1. To install a data card

1. With the system top cover removed, locate the data card slot at the back of the system at the top right of the Wireless Monitor docking area (Figure 4-10).
2. Open the slot cover.
3. Align the card vertically as shown in Figure 4-10, and gently push it into the slot.
4. Close the slot cover.

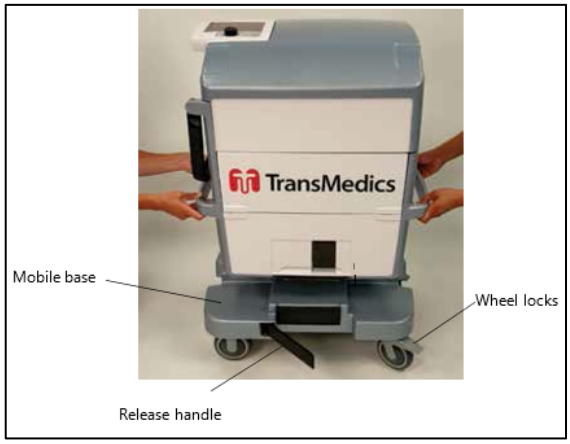
4.8.2. To remove a data card

1. Open the slot cover.
2. Push the edge of the card down until the card releases and partially ejects.
3. Remove the card by pulling it straight up and out of the card slot.
4. Close the slot cover.

4.9. Using the Mobile Base

You can install and remove the OCS™ Mobile Base (Figure 4-11) at any time during use, as needed. Use the wheel locks on the front wheels to lock the system for stability; unlock the wheels to move and position the system. With the Mobile Base installed, the organ chamber is at bedside level. During transport, the push handle can be set to the up position and used to push the system. With the Mobile Base removed, the OCS™ Lung Console can be set flat or carried by two people with the lift handles.

Figure 4-11: Mobile Base



CAUTIONS—

Always use two people to lift or carry the OCS™, which may weigh up to 45 kg (100 lb) without organ, fluids, or the mobile base.

Do not use the push handle to lift the OCS™. The handle is not designed to support the system weight. System damage or personal injury may result if the push handle is used improperly.

4.9.1. To remove the Mobile Base

1. Close the front panel and install the top cover on the OCS™ Lung Console.
2. Press each wheel lock downward to lock the Mobile Base in place (Figure 4-11).
3. Pull the Mobile Base release handle outward to release the Mobile Base grips (Figure 4-11).
4. Using two people, lift the OCS™ with the right and left lift handles.

4.9.2. To mount the OCS™ Lung Console to the Mobile Base and move the system

1. Close the front panel and install the top cover on the OCS™ Lung Console.
2. Orient the Mobile Base so that the rotating wheels face the right of the OCS™ Lung Console and press each wheel lock downward to lock the Mobile Base into position (Figure 4-11).
3. Pull the Mobile Base release handle outward to release the Mobile Base grips (Figure 4-11).
4. Using two people, lift the OCS™ with the right and left lift handles and position it on the Mobile Base.
5. Adjust the OCS™ Lung Console until the Mobile Base is in place.
6. Push in the Mobile Base release handle to activate the Mobile Base grips.
7. When ready to move the system, lift the wheel locks to unlock the wheels, and set the push handle to the up position.

4.10. Lung Perfusion Module Preparation

For details about installation and priming of the Lung Perfusion Module, see the *TransMedics Clinical User Guide: OCS™ Lung System.*

5. CHAPTER 5: WIRELESS MONITOR OVERVIEW

The Wireless Monitor tracks the vital functions of an organ preserved with the OCS™ Lung System and displays organ and system parameters. You can use the Wireless Monitor while it is docked on the OCS™ Lung System or you can remove it (undock it) and use it remotely, such as when transporting the organ.

5.1. Wireless Monitor Components

The Wireless Monitor's screen (Figure 5-1) displays various system and organ parameters as well as messages to visually and audibly indicate out-of-range alarms and system fault conditions. This chapter describes the display features.

Figure 5-1: Wireless Monitor Components

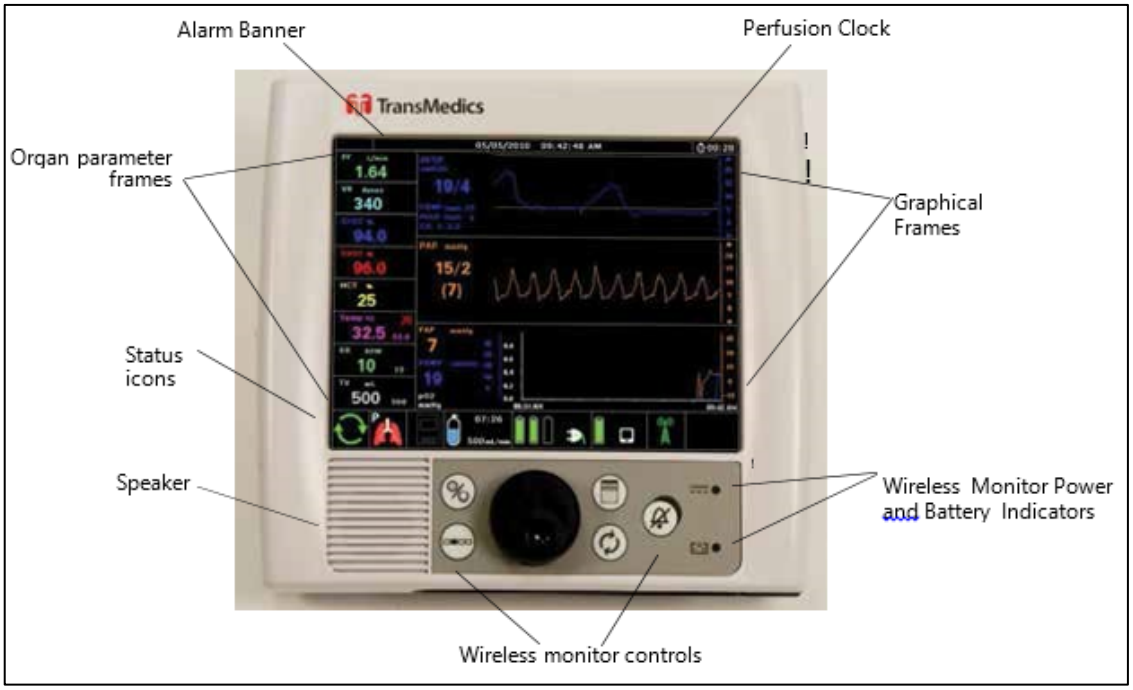


Table 5-1 lists and describes the Wireless Monitor components.

Table 5-1: Wireless Monitor Components

Wireless Monitor Component	Description	For more information, see:
Alarm Banner	The Alarm Banner displays at the top of the Wireless Monitor screen to let you quickly determine when physiological parameters are extended above or below their limits, when gas or battery capacity is running low, and when there is an issue with the system.	"Alarm Banner," Section 5.3.1
Organ Parameter Frames	Parameter values are displayed on the left of the screen in real time. Each organ parameter frame includes the name,	"Organ Parameter Frames," Section 5.3.2

Wireless Monitor Component	Description	For more information, see:
	units of measurement, the value, and whether the alarm is disabled.	
Status Icons	The status icons that appear along the bottom row of the Wireless Monitor screen help you quickly determine information about the system and preservation session.	"System Status Icons on the Wireless Monitor," Section 5.3.4
Speaker	The speaker sounds audible alerts when parameters go out-of-range, when system faults are detected, or when you press a key that is currently unavailable.	
Perfusion Clock	The  icon is displayed in the upper right corner of the Wireless Monitor, along with the elapsed perfusion time.	"Starting and Resetting the Perfusion Clock," Section 6.10
Graphical Frames (Waveforms and Trends)	The graphical frames area in the center of the screen can be configured to show waveforms and trend data.	"Managing Real-Time Waveforms," Section 6.8
Wireless Monitor Power and Battery Indicators	At the bottom right of the Wireless Monitor, two LED lights provide information about Wireless Monitor power status.	"Checking Wireless Monitor Power," Section 4.2.1
Wireless Monitor Controls	Use the rotary knob and push button controls to set the system to Run or Standby Mode, to silence alarms, to display and navigate the Action and Configuration menus, to control the pump and to display menus for configuring the system and performing tasks.	"Wireless Monitor Controls," Section 5.2

5.2. Wireless Monitor Controls

Use the rotary knob and push buttons (Figure 5-2) on the Wireless Monitor to control the OCS™. Except for the Run/Standby button, these controls are functional when the Wireless Monitor is both docked and undocked. Table 5-2 below lists and describes the controls.

Figure 5-2: Wireless Monitor Controls

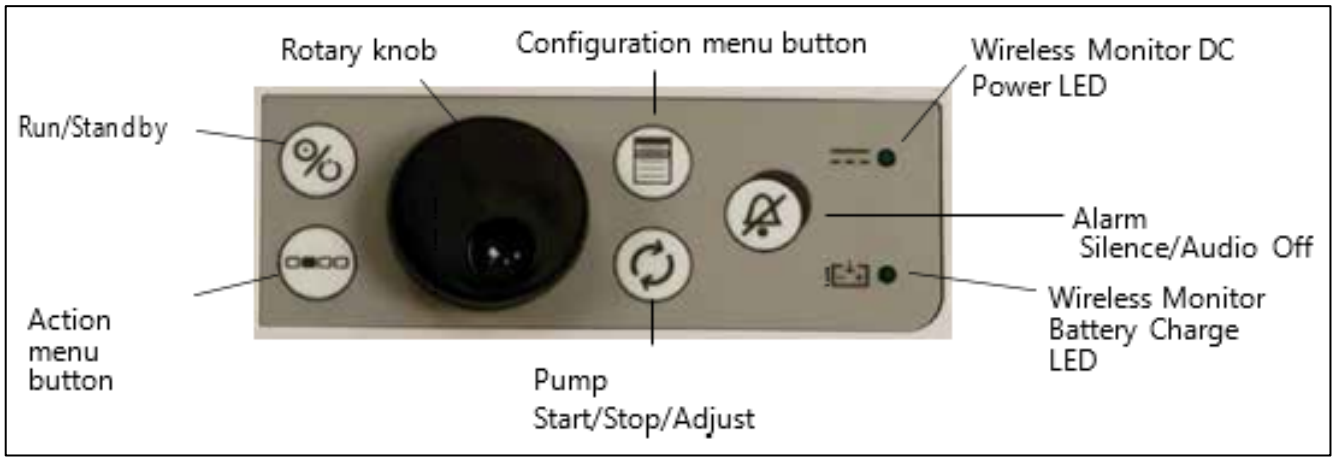


Table 5-2: Wireless Monitor Controls

Control	Name	Description
	Run/Standby Button	Press this button to transition between Run Mode and Standby Mode. Note: This button can only be used when the Wireless Monitor is docked on the OCS™ Lung Console. If the Wireless Monitor is not docked, pressing this button has no effect.
	Action	Press this button to display the Action menu in the lower part of the Wireless Monitor to perform tasks such as displaying system status, copying session files, changing waveform scaling, and so on. For a list of Action menu functions, see Table 6-2, “Action Menu Functions.”
	Configuration	Press this button to display and close the Configuration Menu. The Configuration Menu is used to select ventilator modes, to set specific parameters associated with each ventilator mode, and to configure global system settings.
	Alarm Silence	Press this button to silence alarms. Press and hold this button to enable and disable the Audio Off function.
	Pump Start/ Stop/ Adjust	Press this button to enable and disable the pump adjust function.
	Rotary knob	Turn this knob to highlight selections and press the knob to select highlighted items. Use this knob to adjust pump flow.

5.3. Wireless Monitor Display Overview

This section provides general information about the components on the Wireless Monitor display.

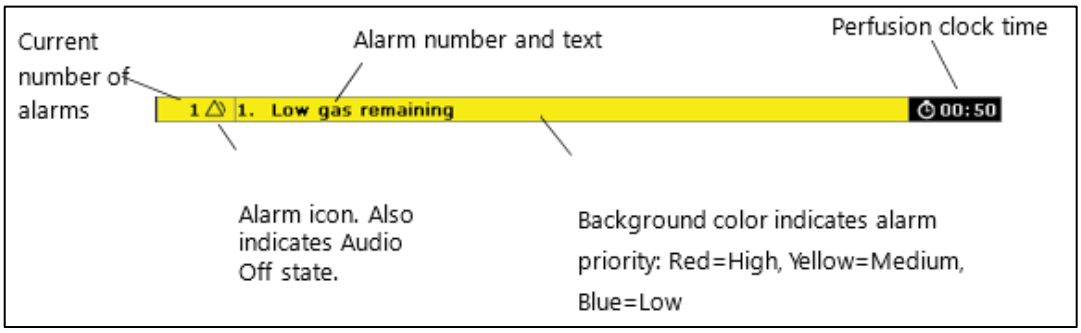
CAUTION—The user should remain in close proximity to the OCS™ while in use such that they can read the Monitor display at all times, or undock the Monitor such that they can view it at all times.

5.3.1. Alarm Banner

The system produces both visual and audible indicators of various alarm conditions to alert you when there is an important physiological or system condition that requires attention. The Alarm Banner (Figure 5-3) is displayed at the top of the Wireless Monitor screen. The background color on the left side of the Alarm Banner is that of the highest priority alarm in the banner.

For more information, see Section 6.7, “Managing Alarms.”

Figure 5-3: Alarm Banner



5.3.2. Organ Parameter Frames

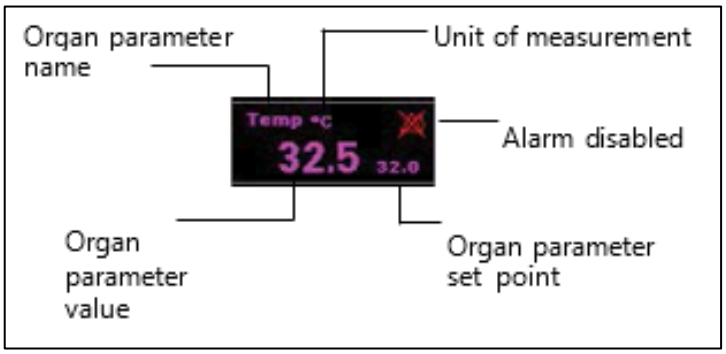
Organ parameter values are displayed in the frames on the left side of the Wireless Monitor, as shown in Figure 5-1. Organ parameter values include:

- **PF:** Pump Flow in L/min
- **VR:** Vascular Resistance in (dyne*s)/cm^5
- **SvO_2**: mixed venous hemoglobin saturation percentage
- **SaO_2**: mixed arterial hemoglobin saturation percentage
- **HCT**: Hematocrit percentage
- **TEMP**: Temperature of perfusate supplied to the organ in degrees Celsius
- **RR**: Respiration Rate in breaths/minute (BPM)
- **TV**: Tidal Volume in mL.

NOTE— The software displays “dynes” as an abbreviation for the VR units which are (dyne*s)/cm^5.

Figure 5-4 shows the components that are displayed in the organ parameter frame.

Figure 5-4: Organ Parameter Frame Components



The system displays the following symbols to indicate when values are above the range, below the range, and when data is not available:

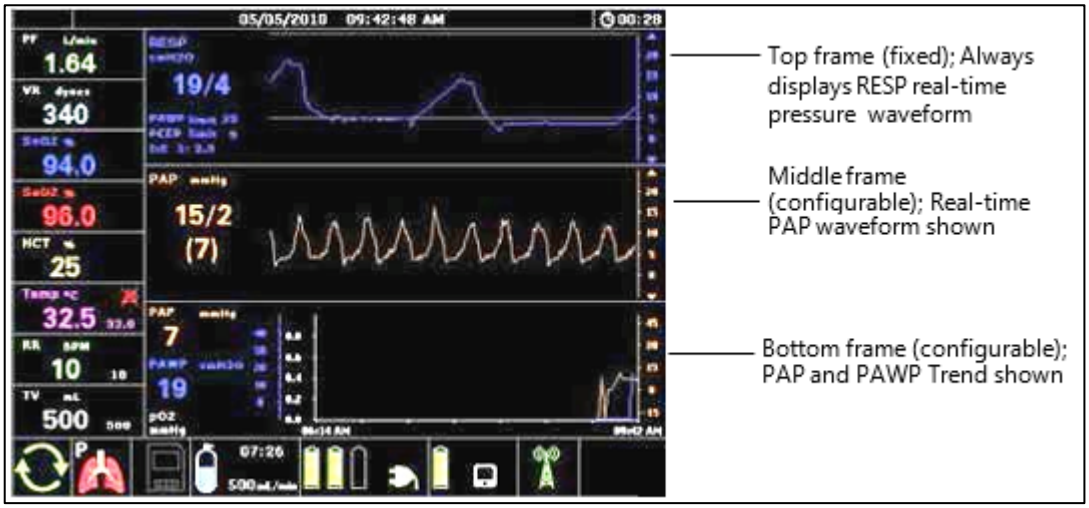
- – – – (three dashes) indicate the current value is below the minimum of the measurable range (under-range)
- + + + (three plus signs) indicate the value is above the maximum value of the measurable range (over-range)
- – ? – (dash-question mark-dash) indicates the data is not available

For instructions on setting organ parameter values, see Section 6.3, “Configuring Session Settings.”

5.3.3. Graphical Frames

The main center section of the Wireless Monitor (Figure 5-5) displays up to three graphical frames to help you quickly determine parameter information and to view trend data.

Figure 5-5: Graphical Frames



Each time you change modes during the session, the graphical frames that you configure for that mode are automatically displayed on the Wireless Monitor. For detailed instructions, see Section 6.3, “Configuring Session Settings.”

5.3.4. System Status Icons on the Wireless Monitor

The status icons that appear on the Wireless Monitor help you quickly determine information about the system and preservation session. Table 5-3 lists and describes the system status icons that appear on the Wireless Monitor.

Table 5-3: System Status Icons

Icons	Description
Pump Status	
	Pump On
	Pump Off
	Pump Fault Alarm
Preservation Gas Cylinder Status	
	Lung Preservation Gas On: Bottle icon shows relative amount of Lung Preservation Gas remaining in hours and minutes (hh:mm) and the current flow rate in milliliters/minute.
	Lung Preservation Gas Off

Icons	Description
	Lung Preservation Gas Capacity Alarm: Activates with 60 minutes of estimated remaining gas consumption time and displays estimated gas remaining time as gas depletes.
	Lung Preservation Gas Fault Alarm
Organ Icons	
	**Preservation Mode** A “p” in the upper right corner indicates the mode is Paused.
	**Monitoring Mode** Submodes are indicated by the letter in the upper right corner: • **b**=Bronchoscope • **c**=Continuous
	No Flow
Battery Status	
	Battery Active, indicates Wireless Monitor (single battery) or OCS™ (three batteries) and displays the time remaining for each battery.
	Battery Removed
	Battery Capacity Alarm: Activates with 30 minutes of estimated remaining battery life and displays estimated remaining time as the battery depletes.
	Battery Fault Alarm
Data Card Status	
	Data card inserted
	Data card transfer in progress
	No data card inserted
	Data card fault
Wireless Communication	
	Wireless communication between the docked or undocked Wireless Monitor and OCS™ is functioning properly.

Icons	Description
	Wireless Fault
Generic System Fault	
	Generic system fault. This icon appears on the lower right corner of the Wireless Monitor display. Refer to the Alarm Banner at the top of the display for further information about the issue and instructions.

6. CHAPTER 6: MANAGING THE SYSTEM

This chapter provides information and instructions for managing the system.

6.1. Managing Sessions

A session is a period of time during which the OCS™ Lung System is in active use. During a session, users can perform such tasks as priming the Lung Perfusion Module circuit and preserving and monitoring the lung. This section provides information and instructions for managing each session. It includes how to switch the system from Standby Mode to Run Mode, and how to manage session files.

6.1.1. Using Standby Mode and Run Mode

When the OCS™ power switch is turned ON, you can select one of two power modes: Standby Mode and Run Mode. Standby Mode is intended for when the OCS™ is not in active use. To initiate a session and begin active use of the OCS™, transition to Run Mode. In Run Mode, the OCS™ and Wireless Monitor are fully functional, with monitoring capabilities enabled.

6.1.2. Using Standby Mode

Use Standby Mode to conserve power and to recharge the batteries during storage. In Standby Mode:

- The Wireless Monitor display is blank (off).
- The circulatory pump is turned off.
- The ventilator is turned off.
- The perfusate warmer is turned off
- Gas flow is turned off.

Standby Mode is the recommended power mode for storage of the OCS™. While in Standby Mode, the batteries in the Wireless Monitor and OCS™ can be charged if the OCS™ is connected to an appropriate power supply and the On/Off button is set to the On position.

NOTES—

When the OCS™ is in Standby mode and not connected to AC power, the batteries will deplete. TransMedics recommends connecting the OCS™ to AC power whenever possible.

Batteries will not charge if the On/Off button is set to the Off position. TransMedics recommends leaving the On/Off button set to the On position at all times except when the device must be powered down for service or cleaning.

CAUTION—Standby Mode should be used only when an organ is not being preserved.

6.1.2.1. To enter Standby Mode

Press  to switch the system between Standby Mode and Run Mode.

CAUTION—The  button on the Wireless Monitor functions only when the Wireless Monitor is docked on the OCS™ Lung Console.

To completely disconnect power from the system, toggle the power switch to the "Off" position (located on the lower left side of the system), and unplug the system.

6.1.2.2. To enter Run Mode from Standby Mode:

1. Press  . The system automatically performs a Self Test and displays system messages. The system prompts you to either create a new session file or to continue the previous session.
2. Do one of the following:
   - To create a new session, select **New Session File**. The system configuration reverts to the saved session defaults.
   - To continue adding data to the previous session, select **Continue Prior Session**. The system configuration retains its latest settings.

NOTE—If the system detects an issue during the Self Test, a message is displayed with information about the issue until it is resolved. For more information about system messages, see Chapter 9: Troubleshooting.

6.1.3. Managing Session Files

This section provides information about the type of data that is collected during each session, and how to copy the session data to a data card.

A session is created in internal system memory when the system is set to Run Mode. Every time Run Mode is entered, you can choose whether to continue using the last session file or create a new one.

When you insert the data card, the latest state of the session files for the current session is copied to the card.

TransMedics recommends that you insert a data card at the beginning of each session.

NOTE—Under ordinary circumstances, data from all procedures associated with an organ should be documented in only one session.

Data is continuously saved in internal memory. The OCS™ will log critical data regardless of the state of the Alarm System and regardless of whether a data card has been inserted by the user. The OCS™ will retain logged data after a total loss of power.

All session data from internal memory is automatically transferred to the user accessible card when the user inserts a data card. If the card is left in this external slot, data from the current session is updated every 15 minutes and upon entering Standby.

The data saved on the SD data card is in .xls or .txt file format. Table 6-1 describes the contents of the session files.

Table 6-1: Session Data Files

File Name	Data Logged
events.txt	Includes the following text that is associated with the current session: Alarms, annotations, configuration settings, and other changes to system setup and operation, logged by date and time.
trends.xls	Includes trend data associated with the current session for all parameters sampled at two-minute intervals and logged by date and time. The trend data saved on the data card is tab-delimited and the column data format is general.
blood-sample.xls	Includes blood sample data entered by the user associated with the current session for all parameters sampled including the time and type (Arterial or Venous).
lungmon.xls	The Lung Monitoring results file contains one-second samples of the arterial and venous saturation measurements during a Monitoring session.
system-errors.txt	This text file contains the system's cumulative error history, logged by date and time.

6.1.3.1. To copy sessions to the data card

CAUTIONS—

To avoid possible operational problems, use only data cards supplied by TransMedics.

While a data transfer is in progress, the data card status icon is displayed with a green arrow. To avoid data loss or corruption, do not remove the card while the transfer is in progress.

1. Insert the TransMedics data card into the card slot. All available data from the current session is automatically transferred to the card.
2. To obtain data from previous sessions, press  and do one of the following:
   - To copy the last five sessions, select **Copy Last Five Sessions**.
   - To copy all the sessions that are currently stored in the OCS™'s internal memory, select **Copy All Sessions.**

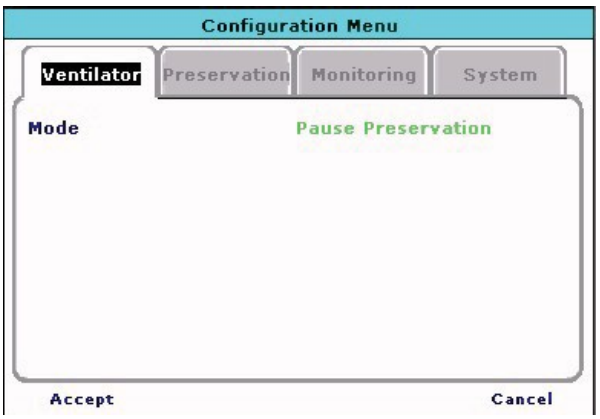
NOTE—You can perform other tasks while the session data is being transferred to the card. However, do not remove the card until the data transfer is complete.

6.2. Using the Configuration and Action Menus

To display the Configuration Menu shown in Figure 6-1, press  . The **Configuration Menu** is organized by tabs: **Ventilator, Preservation, Monitoring**, and **System**. Use the Ventilator tab to select the ventilator mode. Use the Preservation and Monitoring tabs to configure parameters that

are associated with each organ mode. Use the System tab to configure global system settings such as the time and the date.

Figure 6-1: Configuration Menu Resting Tab



6.2.1. To display and use the Configuration Menu

1. Press to display the **Configuration Menu.**
2. To select a tab, turn the rotary knob to highlight one of the tabs.
3. To select the highlighted tab, press the knob. The menu associated with the selected tab is activated. Turn the knob to scroll through the fields on the selected menu.
4. To select an item, highlight it and press the knob. The selected item blinks.
5. To change a set-point, turn the knob to the value you want and press the knob again. The knob returns to its item-selection function.
6. When you complete configuration changes, do any of the following to exit the **Configuration Menu**:
   - To apply and save the changes, select **Accept**.
   - To cancel the changes, select **Cancel**.
   - To select another tab on the **Configuration Menu**, turn the knob.

To display the Action menu shown in Table 6-2, press Use the Action menu to perform the tasks below.

Table 6-2: Action Menu Functions

Action	Description
Display Status	Displays technical information about the OCS™ and the Lung Perfusion Module.
Display Alarm Summary	Displays a summary of the current alarms.
Halt Monitoring Mode	Terminates the current Monitoring function and returns to Preservation Mode.
Restart Perfusion Clock	Resets the Perfusion Clock to zero, or if the Perfusion Clock is not currently running, starts the Perfusion Clock.

Action	Description
Add Annotation	Lets you enter text strings that are added to the session event file.
Add Blood Sample Data	Lets you enter blood gas sample data for display as a trend and for inclusion in the session file.
Edit Blood Sample Data	Lets you edit blood gas sample data that has been entered into the session file.
Copy Current Session	Copies the current session folder to the external SD card.
Copy Last Five Sessions	Copies only the most recent five session folders to the external SD card.
Copy All Sessions	Copies all session folders to the external SD card.
Scale RESP	Lets you switch between fixed waveform scales (airway pressure and PA pressure) or use auto-scaling.
Scale PAP	
Toggle Trend Scroll	Toggles the trend graph scrolling method between scrolling by each sample (with a cursor) and scrolling by 30-minute pages.
Calibrate SaO_2/HCT Probe	Initiates the calibration of the SaO_2 probe. This function was performed before system installation. It should be performed on the rare occasion when prompted by the system.

Figure 6-2: Action Menu

6.2.2. To display and use the Action Menu

1. Press  to display the Action menu shown in Figure 6-2.
2. To scroll through the available menu items, turn the rotary knob to highlight the items.
3. To select the highlighted item, press the knob.
4. If the selected item has a menu associated with it, the menu is activated. Turn the knob to scroll through the fields on the selected menu.
5. To select an item, highlight it and press the knob. If the selected item has a menu associated with it, the menu is activated. The selected item blinks.
6. To change a set-point, turn the knob to the value you want and press the knob again. The knob returns to its item-selection function.

6.3. Configuring Session Settings

Transitioning from Standby to Run initiates a session of active OCS™ operation during which you can perform such tasks as preserving and monitoring the organ. The following sections describe how to configure selected session parameters.

6.3.1. Selecting Ventilator Modes

The OCS™ Lung System contains a volume-controlled ventilation circuit with overpressure protection. This system has multiple modes to support the recruitment, preservation and

assessment of lungs. Use the Ventilator tab on the Configuration Menu to select from among the following ventilator modes:

- The **Pause Preservation** mode has no active mechanical ventilation. In this mode, the ventilation circuit maintains a closed system to prevent the lungs from deflating.
- The **Preservation** mode functions as a re-breather of Lung Preservation Gas to support the lungs during the session. The bellows are used to deliver tidal volume to the lungs.
- The **Bronchoscope Monitoring** mode ventilates the lungs with room air. This mode supports insertion of a bronchoscope into the trachea.
- The **Continuous Monitoring** mode deoxygenates the circulating blood with Lung Monitoring Gas and ventilates the lungs with room air to facilitate assessment of lung function using the clinically relevant PaO_2/FiO_2 ratio.
- The **Ventilator Off** mode retracts the Ventilator Actuator so that the Lung Perfusion Module can be removed from the system.

6.3.2. Configuring Preservation Mode and Monitoring Mode Settings

Use the Preservation and Monitoring tabs on the Configuration menu to set parameters for these modes. Menu selections include

- Tidal Volume – the volume for the lungs to inspire, in milliliters
- Inspiration Time – the length of time in seconds to inspire the Tidal Volume
- Plateau Time – the length of time to hold the Tidal Volume
- Respiration Rate – the number of breaths in one minute
- PEEP limit – the pressure, in cmH_2O, at which to hold the residual volume
- PAWP limit – the maximum pressure, in cmH_2O, allowed during inspiration. In addition, the Monitoring Mode tab also provides the selections as described in Table 6-6.

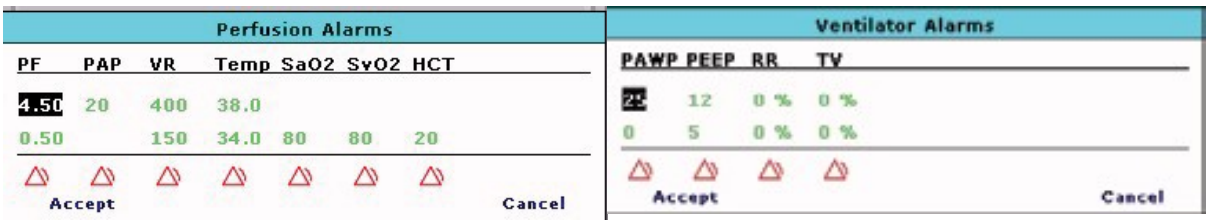
NOTE— The default values for these parameters have been established for clinical use. Configuration values should only be set per TransMedics clinical training.

6.3.3. Configuring Alarms

Use the **Perfusion Alarms** and **Ventilator Alarms** windows (Figure 6-3) to set the alarm limits on the perfusion and ventilation parameters in the Preservation Mode and Monitoring Modes. You can configure Perfusion and Ventilator-specific alarms by using the knob to select and modify the desired field. Each time you place the system in a different mode, the alarms that you configure for that mode are automatically in effect. A icon indicates that an alarm is on and will display on the Wireless Monitor if the value rises above or falls below the settings. A icon indicates that the alarm is off; the alarm will not emit a tone and alarm-related messages will not appear in the Alarm Banner.

Alarm system settings are restored automatically after a power loss of any duration. For more information about alarms, see Section 6.7, “Managing Alarms.”

Figure 6-3: Alarms



NOTE— Table 6-3 and Table 6-4 list the Alarm Limit Configurations for Preservation and Monitoring Modes. Most parameters listed have a high and low limit. However, TV and RR work slightly differently. The limits are not hard numbers, but are percentages of the set-point. For example, if the parameter is set to 0%, then the actual read value must exactly match the set-point, otherwise an alarm will sound. If the parameter is set to 5%, the actual read value can be off as much as 5% from the set point before an alarm sounds. You can configure the high and low percentages independently.

CAUTION— Do not set alarm limits to extreme values that can render the Alarm System useless.

Table 6-3 lists the Perfusion and Ventilator alarm limit configurations for Preservation Mode.

Table 6-3: Preservation Mode: Alarm Limits Configurations

Configuration		Min	Max	Factory Default	Step	Units
Perfusion Alarms						
PF	High Alarm Limit	0.10	5.00	4.50	0.1	L/min
	Low Alarm Limit	0.00	4.90	0.50	0.1	L/min
PAP	High Alarm Limit	0	45	20	1	mmHg
	Low Alarm Limit	--	--	--	--	--
VR	High Alarm Limit	110	1350	1070	10	$(dyne*s)/cm^5$ a
	Low Alarm Limit	100	1340	150	10	$(dyne*s)/cm^5$ a
Temp	High Alarm Limit	31.5	38.0	38.0	0.5	°C
	Low Alarm Limit	31.0	37.5	33.5	0.5	°C
SaO_2	High Alarm Limit	--	--	--	--	--
	Low Alarm Limit	55	95	80	1	%
SvO_2	High Alarm Limit	--	--	--	--	--
	Low Alarm Limit	55	95	80	1	%
HCT	High Alarm Limit	--	--	--	--	--
	Low Alarm Limit	16	30	20	1	%

Configuration		Min	Max	Factory Default	Step	Units
Ventilator Alarms						
PAWP	High Alarm Limit	1	60	25	1	cmH_2O
	Low Alarm Limit	0	59	5	1	cmH_2O
PEEP	High Alarm Limit	1	15	12	1	cmH_2O
	Low Alarm Limit	0	14	5	1	cmH_2O
RR	High Alarm Limit	0	95	0	5	%b
	Low Alarm Limit	0	95	0	5	%b
TV	High Alarm Limit	0	98	0	2	%c
	Low Alarm Limit	0	98	0	2	%c

a. The software displays “dynes” as an abbreviation for the VR units which are (dyne*s)/cm^5.
b. Percentage of the configured set point in BPM.
c. Percentage of the configured set point in mL.

Table 6-4 lists the Perfusion and Ventilator alarm limit configurations for Monitoring Mode.

Table 6-4: Monitoring Mode: Alarm Limits Configurations

Configuration		Min	Max	Factory Default	Step	Units
Perfusion Alarms						
PF	High Alarm Limit	0.10	5.00	4.50	0.1	L/min
	Low Alarm Limit	0.00	4.90	0.50	0.1	L/min
PAP	High Alarm Limit	0	45	25	1	mmHg
	Low Alarm Limit	--	--	--	--	--
VR	High Alarm Limit	110	1350	1070	10	(dyne*s)/cm^5 a
	Low Alarm Limit	100	1340	150	10	(dyne*s)/cm^5 a
Temp	High Alarm Limit	31.5	38.0	38.0	0.5	°C
	Low Alarm Limit	31.0	37.5	34.0	0.5	°C
SaO_2	High Alarm Limit	--	--	--	--	--
	Low Alarm Limit	55	95	60	1	%
SvO_2	High Alarm Limit	--	--	--	--	--
	Low Alarm Limit	55	95	60	1	%
HCT	High Alarm Limit	--	--	--	--	--
	Low Alarm Limit	16	30	20	1	%
Ventilator Alarms						

Configuration		Min	Max	Factory Default	Step	Units
PAWP	High Alarm Limit	1	60	25	1	cmH_2O
	Low Alarm Limit	0	59	5	1	cmH_2O
PEEP	High Alarm Limit	1	15	12	1	cmH_2O
	Low Alarm Limit	0	14	5	1	cmH_2O
RR	High Alarm Limit	0	95	0	5	%b
	Low Alarm Limit	0	95	0	5	%b
TV	High Alarm Limit	0	98	0	2	%c
	Low Alarm Limit	0	98	0	2	%c

a. The software displays “dynes” as an abbreviation for the VR units which are (dyne*s)/cm^5.
b. Percentage of the configured set point in BPM.
c. Percentage of the configured set point in mL.

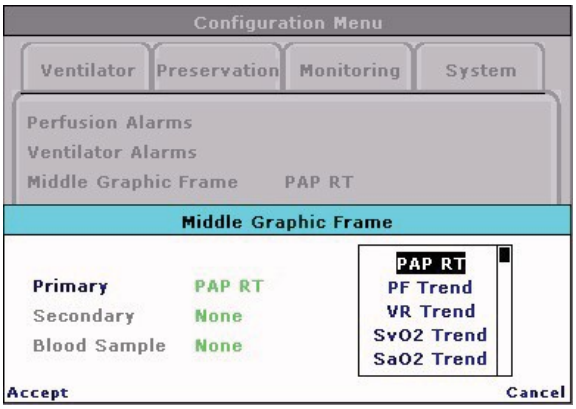
6.3.4. Setting the Lung Preservation Gas Flow Rate

Use the **Gas Flow Rate** field of the **Configuration Menu** to configure the amount of Lung Preservation Gas that is delivered to the perfusate through either the gas exchanger during Preservation Pause Mode, or directly to the lungs in Preservation Mode. Each time you place the system in Preservation or Preservation Pause Mode, the Lung Preservation Gas flow rate that you configure for that mode is automatically in effect.

6.3.5. Configuring Graphic Frames

Use the **Middle Graphic Frame** and **Bottom Graphic Frame** menu options (Figure 6-4) to configure which graphic frames are displayed in the middle and bottom sections of the Wireless Monitor during Preservation or Monitoring Mode. Each time you place the system in Preservation or Monitoring Mode during the session, the graphical frames that you configure for that mode are automatically displayed.

Figure 6-4: Configuring Middle and Bottom Graphic Frames



You can configure the middle and bottom graphical frames to display different combinations of real-time, trend, and blood sample graphs. For each graphical frame, a primary, secondary and blood sample graph may be configured, according to the following rules:

- The **Primary** value may either be a real-time pressure waveform or trend.
- The **Secondary** value and the **Blood Sample** value are only available for configuration if you selected a Trend as the **Primary** value.
- When configuring **Secondary or Blood Sample values**, you can specify **None** as the selection.

For more information on entering blood and perfusate sample data, see Section 6.11.1, “Adding Blood and Perfusate Sample Data.”

6.3.6. Setting the Temperature Set Point

Use the **Temp Set Point** field of the **Configuration Menu** to specify the temperature set point for Preservation or Monitoring Mode. The **Temp Set Point** is the temperature at which you want the perfusate warmer to maintain the fluids that are perfusing the organ. Each time you place the system in Preservation or Monitoring Mode, the temperature set point that you configure for that mode is automatically in effect.

6.3.7. Configuring Continuous Auto Exit

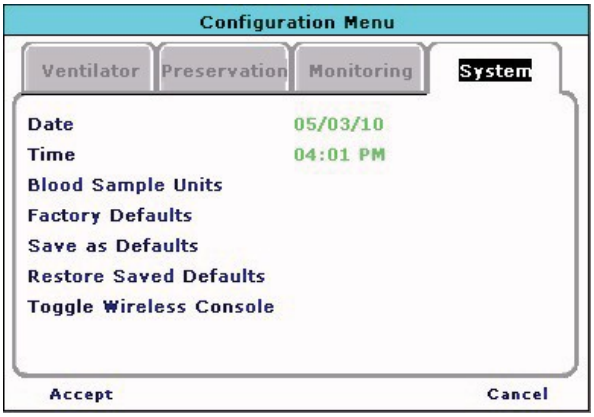
Use the **Configuration Menu** to configure the **Continuous Auto Exit** feature in Continuous Monitoring Mode. When enabled, the Continuous Monitoring Mode automatically exits after three minutes and enters Preservation Mode.

6.4. Configuring System Settings

The following sections describe how to configure the system settings to include setting the time and the date. Figure 6-5 shows the **System** tab on the **Configuration Menu**.

When you finish changing system settings, select **Accept** to save your changes.

Figure 6-5: Configuration Menu: System Tab



CAUTION—The system does not automatically adjust for Daylight Saving Time. If your area uses Daylight Saving Time, you need to manually reset the time to adjust to Daylight Saving Time.

NOTE—Set the system time and date before starting the perfusion clock. Once the perfusion clock is running, you cannot set the system time and date until you start a new session.

6.4.1. Setting the Blood Sample Units

Use the **System** tab of the **Configuration Menu** (Figure 6-5) to set blood sample units for parameters that can have multiple types of units.

For details on adding, editing, and deleting blood and perfusate sample data, see Section 6.11, “Managing Blood and Perfusate Sample Data.”

NOTES—

You cannot change the blood sample units once a blood sample has been added for the current session.

The Toggle wireless console menu item in the System tab is a TransMedics service function and is not user-accessible.

6.5. Managing Default Configuration Settings

This section provides information and instructions for saving default settings and restoring system settings. It also lists the system parameters, ranges, and factory default values.

6.5.1. Saving Default Settings

Use the **Save as Defaults** field of the **System** tab of the **Configuration Menu** to save the current Preservation Mode, Monitoring Mode, and system settings as the session default. The session default settings are applied automatically when a new session starts.

6.5.2. Restoring Session and System Defaults

Use the **System** tab of the **Configuration Menu** to restore the saved defaults and to restore the factory defaults. Restoring to the saved settings reverts most settings to the last saved session and system defaults. Restoring to the factory settings reverts most settings to the factory default settings.

- To restore the saved system defaults, select Restore Saved Defaults.
- To restore the factory defaults, select Restore Factory Defaults.

CAUTION—Before saving your selections by selecting **Accept** or **Save as Defaults**, be sure to review the displayed settings to make sure you have set these parameters for adequate organ preservation.

NOTE— Restoring defaults does not change how the Date, Time, pump state, ventilation mode, or Continuous Monitoring Auto Exit settings are configured.

6.5.3. Preservation Mode Defaults

Table 6-5 lists the session parameters, ranges of user-configurable defaults, and factory default values for Preservation Mode. When you restore the system to its factory default settings, all parameters are changed to the factory default values shown in Table 6-5. For factory default alarm settings in Preservation Mode, see Table 6-3.

Table 6-5: Preservation Mode: Session Parameters, Default Ranges, and Factory Defaults

Parameter	Range of User-Configurable Defaults	Factory Default
Gas Flow Rate	0, 200 to 1000 mL/min	300 mL/min
Temp Set Point	Off, 32°C to 37°C	32° C
PAWP Limit	15 to 30 cmH2O	25 cmH_2O
PEEP Limit	4 to 13 cmH2O	5 cmH_2O
RR Set Point	8 to 16 BPM	10 BPM
TV Set Point	200 to 1000 mL	500 mL
Inspiratory Time Set Point	1.3 to 2.0 seconds	1.5 seconds
Plateau Time Set Point	0.3 to 2.0 seconds	0.3 seconds
Top Graphic Frame	Always airway pressure real-time waveform	Not configurable
Middle Graphic Frame		
Primary Parameter	Real-time waveform options: PAP Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP, Monitoring	PAP Real-Time
Secondary Parameter	Generic option: none Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP	None
Blood Sample	Generic option: none Blood Samples (See Table 6-8, “Blood and Perfusate Sample Analyte Data”)	None
Bottom Graphic Frame		
Primary Parameter	Real-time waveform options: PAP Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP, Monitoring	PAP Trend
Secondary Parameter	Generic option: none Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP	PAWP Trend
Blood Sample	Generic options: none	PO_2

Parameter	Range of User-Configurable Defaults	Factory Default
	Blood Samples (See Table 6-8, “Blood and Perfusate Sample Analyte Data”)	

CAUTION— Do not attempt to set the PAWP limit above 25 cmH_2O.

6.5.4. Monitoring Mode Defaults

Table 6-6 lists the session parameters, ranges of user-configurable defaults, and factory default values for Monitoring Mode. When you restore the system to its factory default settings, all parameters are changed to the factory default values shown in Table 6-6. For factory default alarm settings in Monitoring Mode, see Table 6-4.

Table 6-6: Monitoring Mode: Session Parameters, Default Ranges, and Factory Defaults

Parameter	Range of User-Configurable Defaults	Factory Default
Temp Set Point	Off, 32°C to 37°C	37°C
PAWP Limit	15 to 30 cmH_2O	25 cmH_2O
PEEP Limit	4 to 13 cmH_2O	5 cmH_2O
RR Set Point	8 to 16 BPM	12 BPM
TV Set Point	200 to 1000 mL	700 mL
Inspiratory Time Set Point	1.3 to 2.0 seconds	1.5 seconds
Plateau Time Set Point	0.3 to 2.0 seconds	0.3 seconds
Top Graphic Frame	Always airway pressure real-time waveform	Not configurable
Middle Graphic Frame		
Primary Parameter	Real-time waveform options: PAP Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP, Monitoring	PAP Real-Time
Secondary Parameter	Generic option: none Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP	None
Blood Sample	Generic options: none Blood Samples (See Table 6-8, “Blood and Perfusate Sample Analyte Data”)	None
Bottom Graphic Frame		
Primary Parameter	Real-time waveform options: PAP	Monitoring

Parameter	Range of User-Configurable Defaults	Factory Default
	Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP, Monitoring	
Secondary Parameter	Generic option: none Trend graphic waveform options: PF, VR, SvO_2, SaO_2, HCT, Temp, RR, TV, PAWP, PEEP, PAP	None
Blood Sample	Generic options: none Blood Samples (See Table 6-8, "Blood and Perfusate Sample Analyte Data")	None

CAUTION— Do not attempt to set the PAWP limit above 25 cmH_2O.

6.5.5. System Defaults

Table 6-7 lists the system parameters and ranges of user-configurable defaults.

Table 6-7: System Defaults

Parameter	Range of User-Configurable Defaults	Factory Default
Time of Day	Hours: 0-23; Minutes: 0-59	Not applicable
Date	Months: 1-12 Days - 1-31 Year - 04-99	Not applicable

6.5.6. Blood and Perfusate Sample Analyte Data

Table 6-8 lists the parameters, range, and units for the blood and perfusate analyte data that can be entered into the system.

Table 6-8: Blood and Perfusate Sample Analyte Data

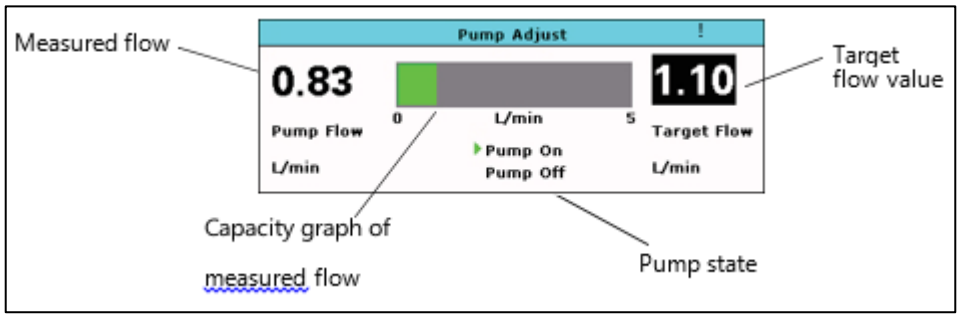
Parameter	Range
Lactate	0 to 20.0 mmol/L 0 to 180.2 mg/dL
pH	6.50 to 8.20
PCO_2	5.0 to 130.0 mmHg 0.67 to 17.33 kPa
PO_2	5 to 800 mmHg 0.7 to 106.6 kPa
BEecf	-30 to 30 mmol/L
HCO_3	1.0 to 85.0 mmol/L
TCO_2	1 to 85 mmol/L

Parameter	Range
SO_2	0 to 100%
Sodium	100 to 180 mmol/L
Potassium	2.0 to 9.0 mmol/L
Ionized Calcium	0.25 to 2.50 mmol/L 1.0 to 10.0 mg/dL
Glucose	20 to 700 mg/dL 1.1 to 38.9 mmol/L
Hematocrit	10-75 %PVC 0.10 to 0.75 Fraction
Hb	3.4 to 25.5 g/dL; 34 to 255 g/L 2.1 to 15.8 mmol/L

6.6. Adjusting the Pump

Use the Pump Adjust window (Figure 6-6) to adjust the flow (liters per minute).

Figure 6-6: Pump Adjust Window



CAUTION— Perfusate warming and gas flow are enabled only when the pump is on (or faulted). Setting the pump to OFF turns off the pump, the gas, the ventilator, and the perfusate warmer. When the pump flow is off, physiological parameter alarm monitoring is disabled.

6.6.1. To adjust the pump

1. Press  to open the **Pump Adjust** window (Figure 6-6).
2. Do one of the following:
   - To increase pump flow, turn the knob clockwise.
   - To decrease pump flow, turn the knob counterclockwise.
   - To turn the pump off, turn the knob all the way counterclockwise until the Pump Status icon (Table 5-3) indicates that the pump state is off.

- As you turn the knob, a target flow value displays on the right side of the window, indicating the estimated pump flow that will be produced by your adjustments. The value shown on the left side of the window shows the currently measured pump flow.

NOTES—

Invalid adjustments generate an error tone.

The displayed target flow value is an estimate based on the initial flow and the dialed-in adjustments.

3. Five seconds after you stop adjusting the target pump flow, the target flow display is removed. Subsequent knob rotation reopens the pump flow display for further adjustment.
4. To close the **Pump Adjust** window, press the knob or press  .

NOTE—After 90 seconds of knob inactivity, the Wireless Monitor automatically exits the Pump Adjust window.

6.7. Managing Alarms

This section provides information about the visual and audible alarms, and how to manage them.

6.7.1. Overview of Alarms

The Alarm Banner, located at the top of the Wireless Monitor screen, provides summary information about the current alarms. For more information, see Section 5.3.1, “Alarm Banner.”

Critical alarms require you to acknowledge them and appear with a red background in the Alarm Banner; the text blinks red and gray and the Alarm Banner freezes on that alarm until it is acknowledged. Press  to acknowledge the alarm.

Non-critical alarms rotate through the Alarm Banner and will disappear without user acknowledgement if the condition is resolved. Non-critical alarms can be one of the following three types:

- High priority alarms (red) are system faults (such as a broken probe)
- Medium priority alarms (yellow) are physiologic (such as limit violations), or capacity-related (such as battery/gas low)
- Low priority alarms (blue) are system-related (such as redundant sensor failure)

The **Low gas remaining** alarm is an example of a medium (yellow) alarm message. It appears on the Alarm Banner and is dismissed when the condition is resolved. For example, when you turn off the gas, or replace the gas cylinder with a full tank of gas, the low gas alarm condition is resolved.

For more information on configuring alarms, see Section 6.3.3, “Configuring Alarms.” When alarm settings for parameters are disabled, the  icon is displayed with that parameter on the Wireless Monitor.

CAUTION—Operators should remain in close proximity to the OCS™ while in use such that they can read the Monitor display at all times, or undock the Monitor such that they can view it at all times.

Table 6-9 summarizes the indicators that may occur during system operation. System faults that may require TransMedics service are listed in Chapter 9: Troubleshooting.

Table 6-9: Types of Alarms

Alarm Type	Example	Visual Indicator	Action Required
Physiological	Parameter value exceeds high or low alarm limit or goes from in-range to out-of-range	Parameter value border blinks and a message is also displayed in the Alarm Banner.	• Investigate the physiological cause of the alarm • Change the control settings that affect the parameter • Change the alarm limit • Press to silence the alarm for one minute • Press and hold to disable all audible alarm indications
Capacity	Low system batteries, low Wireless Monitor battery, low gas level	Capacity level alarm is displayed (as shown in Table 5-3) and a message is displayed in the Alarm Banner	• Replace the battery or gas in response to the capacity alarm • Connect the system to AC power • Dock the Wireless Monitor to recharge the battery • Press to silence the alarm for five minutes • Press and hold to disable all audible alarm indications
System Fault	Wireless Monitor wireless link is lost	Associated system icon blinks with a red background and a message is displayed in the Alarm Banner	• Refer to the Alarm Banner message for details in response to the system fault alarm • Press to silence the alarm until the condition recurs • Press and hold to disable all audible alarm indications
Critical System Fault	Reset occurred, Self Test bypassed	Parameter value border blinks and a message is displayed in the Alarm Banner until the fault is acknowledged	Must be acknowledged. Press to acknowledge and dismiss the alarm. The message continues to display in the Alarm Banner until the alarm is acknowledged.

CAUTION—The OCS™ does not provide an alarm if the Lung Monitoring Gas capacity is low. You need to estimate the amount of remaining Lung Monitoring Gas based on the information in Table 4-2.

6.7.2. Visual Alarm Indicators

Alarm messages are displayed in the Alarm Banner in different colors to indicate the priority: High Priority alarms appear in red, Medium in yellow, and Low priority/informational alarms appear in blue. The item associated with the alarm flashes on the Wireless Monitor to help you quickly identify the issue and respond accordingly. If multiple alarms exist, the alarm text and priority of the current alarms display repeatedly in the Alarm Banner. The number on the left side of the Alarm Banner

indicates the current number of alarms, and the color on the left side of the Alarm Banner is that of the highest priority alarm in the banner.

6.7.3. Audible Alarm Indicators

Audible alarm indicators consist of various alarm sounds associated with the type of fault detected. For example, pressing an incorrect key generates an error tone, sounded at the time of the key press; an out-of-range parameter beeps until the condition is changed or until the alarm is silenced.

The auditory alarm signal sound pressure is approximately 84 dB.

NOTES—

A parameter is expected to fluctuate at the beginning of monitoring, so an alarm will not sound until the value settles into the configured limit range. This alarm state is referred to as “initial suspend.” Once a parameter’s values are within the limits, alarm processing is enabled, and any time the parameter is out of the preset alarm range, an alarm will sound.

When the condition that caused an alarm is rectified, the associated visual and audible indicators return to normal. Alarms associated with an out-of-range Wireless Monitor do not affect data collection; all data will continue to be collected, even though the Wireless Monitor is not displaying the data. Once the Wireless Monitor is brought within range, data will display again, and all the data acquired during the out-of-range period will be available for scrolling.

6.7.4. Displaying the Summary of Alarm Messages

The **Display Alarm Summary** item in the **Actions Menu** lets you quickly review the list of current alarm messages.

NOTE—The **Display Alarm Summary** is a snapshot. It does not update in real-time with the changing contents of the Alarm Banner.

6.7.5. Responding to Alarms

The Alarm Silence  button lets you silence (acknowledge) active alarms temporarily, or lets you enable and disable audible alarm alerts indefinitely.

6.7.5.1. To temporarily silence (acknowledge) an alarm

Press  briefly to silence an alarm.

When you silence an alarm:

- The visual flashing of a physiological parameter alarm stops but the border remains highlighted to match the priority as long as the alarm is active.
- There is no icon to represent a silenced alarm in the parameter box.
- Capacity alarms are silenced for five minutes; physiological alarms are only silenced for one minute; system fault alarms are silenced indefinitely.

6.7.5.2. To disable alarm tones

Press and hold to disable all audible alarm tones indefinitely. Visual alarm indications continue to display. If the pump is on, the Wireless Monitor also emits a beep every 2 minutes and a message is displayed in blue on the Alarm Banner to remind you that the audio alarm is off.

The icon is displayed at the left of the Alarm Banner to indicate audio alarm tones are disabled.

6.7.5.3. To enable alarm tones

Press and hold the for two seconds. The icon is displayed in the Alarm Banner to indicate visual and audio alarm tones are enabled.

6.8. Managing Real-Time Waveforms

The main center section of the Wireless Monitor displays real-time waveforms or historical trends, depending on the configuration. The top most graphic frame on the main monitoring screen always displays the airway respiration pressure (RESP) real-time waveform. You can configure the middle and bottom frames to display either real-time waveforms or trend graphs. For detailed instructions, see Section 6.3.5, “Configuring Graphic Frames.”

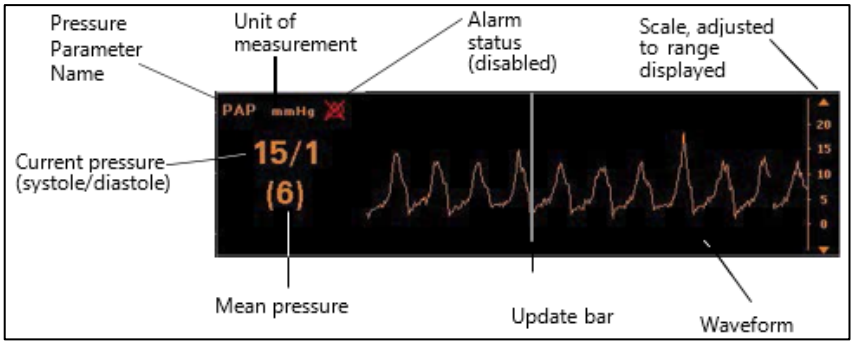
Real-time waveforms are time synchronized and display continuously updated data. The waveforms are redrawn from left to right with the most current data. The oldest data is displayed just to the right of the update bar as it sweeps across the screen, and the newest data is just to the left. If more than one graphic frame is configured to show real-time waveforms, the update bars are automatically synchronized.

6.8.1. Pressure Waveforms

The system supports the display of the following real-time pressure waveforms: RESP and PAP. By default, real-time pressure waveforms are automatically scaled within a set of fixed ranges that automatically change as the pressure range changes. You can also manually scale the pressure waveforms using the **Actions Menu**. If no pressure data is detected, the parameter value displays as (-?-) and a flat line displays at the bottom of the frame.

Figure 6-7 shows the contents of a real-time pressure waveform display. For detailed instructions on configuring a pressure waveform to display on the Wireless Monitor, see Section 6.3.5, “Configuring Graphic Frames.”

Figure 6-7: Real-Time Pressure Waveforms



6.8.2. Pressure Waveform Data Scaling Methods

Real-time pressure waveforms may be scaled automatically or manually.

6.8.3. Auto-Scaled Pressure Waveform Data

The OCS™ supports auto-scaling of pressure waveforms. When auto-scaling is enabled, the y-axis range changes automatically as the displayed pressure data changes. Arrow icons are displayed at the top and bottom of the y-axis scale when this mode is active (Figure 6-8).

Figure 6-8: Auto-Scaled Waveform

When the scale of a waveform changes, only that graphical frame is affected. The y-axis scale of the graphical frame is erased and then redrawn with the new scale values. The entire waveform is erased and then drawn forward of the current update bar location using the new scale values. For instructions on auto-scaling pressure waveforms, see Section 6.8.5, “Scaling Real-Time Waveforms.”

6.8.4. Manually Scaled Pressure Waveform Data

When manually scaled, the graph remains at one of the fixed y-axis scales that you configured. When this mode is active, no arrow icons are displayed at the top and bottom of the y-axis scale. You can only manually scale the currently displayed waveforms.

To help you quickly determine if the waveform is in Auto- or Manual-scaling mode, look at the right side of the waveform. Arrows indicate Auto-scaling, and no arrows indicate Manual-scaling (Figure 6-9).

Figure 6-9: Manually-Scaled Waveform

6.8.5. Scaling Real-Time Waveforms

Use the Action menu to access scaling options for each waveform. To scale a waveform automatically, enable auto-scaling. To scale a waveform manually, select a y-axis range from among the preset options available for that particular parameter.

6.8.5.1. To scale a waveform automatically or manually

1. Make sure the waveform to be scaled is displayed in one of the graphical frames. For details, see Section 6.3.5, “Configuring Graphic Frames.”
2. Press  and select one of the following, depending on which pressure waveform you want to scale:
   - Scale RESP
   - Scale PAP
3. With the selected scale flashing, do any of the following:
   - To select the next larger scale limit for that waveform, turn the knob clockwise.
   - To select the next lower scale limit, turn the knob counterclockwise.
   - To turn on auto-scaling, turn the knob all the way clockwise until the scaling arrows on the y-axis are visible.
4. Press the knob to confirm the settings.

NOTES—

If the knob is idle for 90 seconds or if you press any other button (other than Alarm Silence) the current scale value is selected.

In Auto-Scale mode, when the graphical frame setting is changed to a different real-time pressure graph, the scaling mode setting is reset to the default.

6.9. Managing Historical Trend Graphs

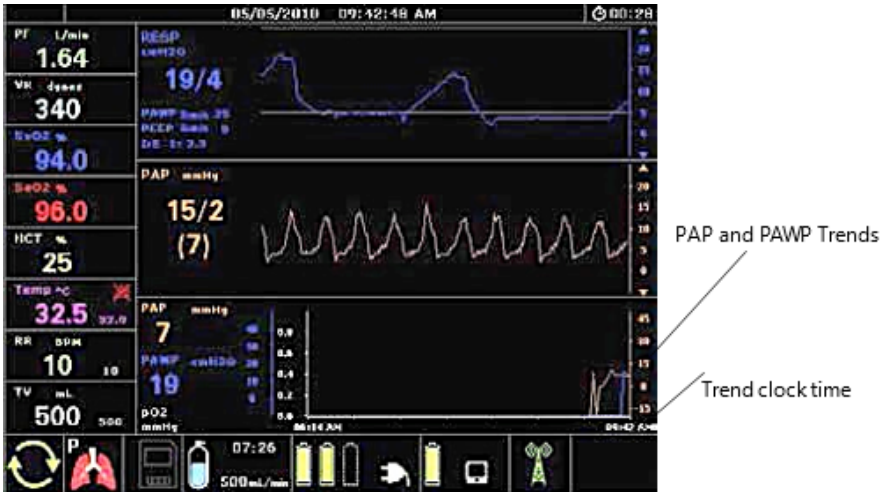
As an alternative to real-time waveforms, you can configure one or both of the bottom two graphical frames to display a constantly updated historical trend graph. For more information, see Section 6.3.5, “Configuring Graphic Frames.” You can configure one or two of the physiological parameters, and a single blood sample parameter:

A trend graph can display the most recent 24 hours of data, updated every two minutes. Each data point represents the average value calculated over the previous two minutes. You can view 3 1/2 hours of historical data at once and use the rotary knob to scroll back and forth to review all the saved data.

CAUTION—If the time or date is changed through the **Configuration Menu** before starting the Perfusion Clock, the date and time of the previously saved trend data does not change. The dates and times prior to the change reflect the time and date settings at the time the trend was drawn.

Each trend has an individual scale range and display, but each has the same components as those shown in Figure 6-10. The most recent data is shown to the right of the screen and the oldest data to the left.

Figure 6-10: Sample Trend



All available trend data is saved with the session file.

For detailed instructions on configuring trend graphs to display on the Wireless Monitor, see Section 6.3.5, “Configuring Graphic Frames.”

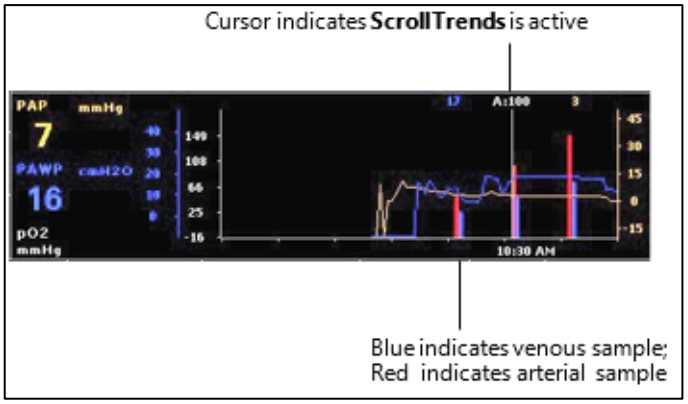
6.9.1. Using Scrolling and Cursor Mode

When scrolling through a trend, each click of the knob represents approximately 30 minutes of data, with the screen showing about 3½ hours of data at a time. In **Scroll Trends** mode, you can position a cursor to view specific trend data at specific times. In addition to historical parameter data, results of blood and perfusate samples entered into the system can also be viewed. The values and their associated colors and labels are displayed in the trends window. The color blue and the label **V:** indicates the values of samples taken from the venous site. The color red and the label **A:** indicates the values of samples taken from the arterial site.

Use the **Scroll Trends** command in the Action menu to scroll through the current trends displayed in the lower two graphic frames.

NOTE—To quickly determine if you are viewing trended data or live data, the bottom axis (x-axis) blinks when Scroll Trends is active. If the sample time displayed on the right of the x-axis is the current time, the trend data continues to update with the latest data.

Figure 6-11: Scroll Trends



6.9.1.1. To scroll trend data

1. Press  .
2. Blue indicates venous sample; Red indicates arterial sample.
3. Select **Toggle Trend Scroll**. The x-axis of the trend frame blinks to indicate scroll mode.
4. Turn the knob clockwise to view the most recent time; turn counterclockwise to view the previous data in half-hour increments. Trend values are displayed with labels and colors to indicate the data.
5. Press the knob to switch from cursor mode to scroll mode.
6. Press the knob and turn it clockwise or counterclockwise to scroll through the history of trend data. A vertical cursor line is displayed in the trend window.
7. Press the knob to return to scroll mode.
8. To exit, press and hold the rotary knob for 2 seconds.

6.10. Starting and Resetting the Perfusion Clock

The perfusion clock tracks how long the lung has been perfused on the OCS™. This section provides information about the perfusion clock and instructions for starting and resetting the clock.

CAUTION—When a new session is started, the perfusion clock is reset to zero and turned off.

NOTE—Set the system time and date before starting the perfusion clock. Once the perfusion clock is running, you cannot set the system time and date until the next session.

The perfusion clock starts automatically when all three of the following conditions are met:

- The pump is on
- The ventilator is in Pause Preservation mode

- The mean PAP is at least 4 mmHg

6.10.1. To manually start or restart the perfusion clock

Press and select **Restart Perfusion Clock**.

NOTE—To display trend data on the Wireless Monitor, and to capture it in a session, the perfusion clock must be turned on.

6.11. Managing Blood and Perfusate Sample Data

You can manually enter time-stamped blood and perfusate sample data into the system from a blood chemistry analyzer. This data is recorded, included in the session data set, and can be graphed with other OCS™ parameters.

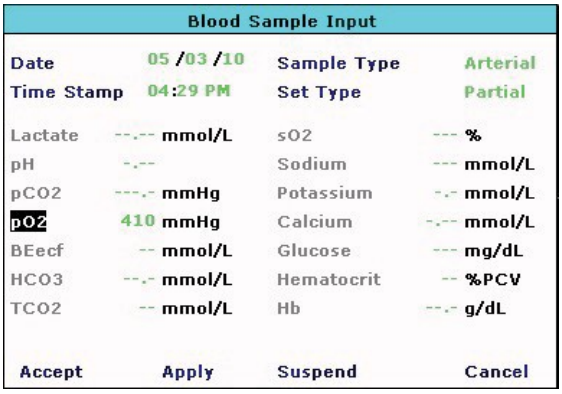
Use the **Action Menu** to add, edit, and delete the blood and perfusate analytes shown in Figure 6-12. You can specify the **Sample Type** (**Arterial** or **Venous**), and the **Date**. You must enter a time in the **Time Stamp** field. This information is used in the Trending data and is saved to the data card for the session.

NOTE—For details on configuring the units of measure for each analyte, see Section 6.5, “Managing Default Configuration Settings.“

6.11.1. Adding Blood and Perfusate Sample Data

Use the Action Menu to add blood and perfusate sample data taken during the session. On the OCS™ Lung System, pO_2 is the default sample analyte.

Figure 6-12: Blood Sample Input Window



6.11.1.1. To add blood and perfusate sample data

1. Press
2. Rotate the knob to highlight **Add Blood Sample** and press the knob. The **Blood Sample Input** window is displayed (Figure 6-12). The last values entered for each analyte are listed.

NOTE— Be sure to always enter the date and time as displayed on the OCS™ rather than the local date and time. This will ensure that blood and perfusate sample data will appear within the historical trends in correct chronological order relative to other data collected by the OCS™. This is particularly important when transporting organs across time zones.

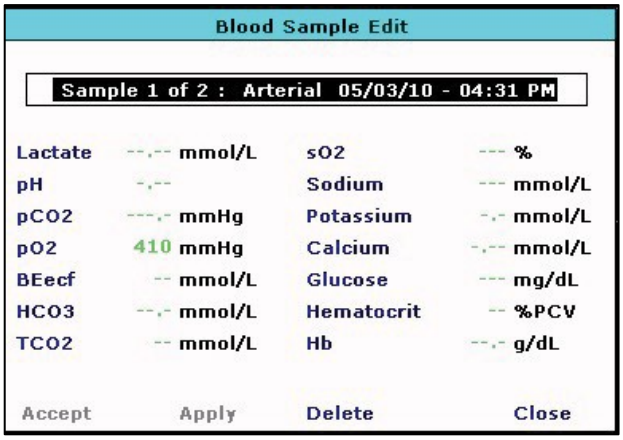
3. Enter the date indicated by the OCS™ in the **Date** field.
4. Enter the time indicated by the OCS™ of the sample in the **Time Stamp** field.
5. Select the **Sample Type: Arterial** or **Venous**.
6. Enter the **pO_2** value. Highlight and select **pO_2**, then turn the knob to increase or decrease the value. Press the knob to enter the highlighted value.
7. If you need to enter additional analyte values, turn the knob to highlight **Set Type** and select **Full** to activate the complete set of analyte data fields. Press the knob and turn it to highlight the next analyte and enter the value.
8. Do one of the following:
   - To accept the values and close the Blood Sample Input window, select Accept.
   - To apply the values without closing the window, select Apply.
   - To hold the values and close the window, select Suspend. When you reopen the Blood Sample Input window, the last values you entered are displayed.
   - To discard the values and close the window, select Cancel.
9. If you applied or accepted the values, a message is displayed prompting you to confirm that you updated the required fields. Make sure the time, date, and type are entered correctly and select **Accept**, or select Cancel and enter the time in the **Time Stamp** field.

6.11.2. Editing and Deleting Blood Sample Data

Use the **Action Menu** to edit and delete blood and perfusate sample entries taken during the session. You can scroll through the sample entries by the time stamp entered for each entry.

NOTE— You can only edit and delete analyte results. You cannot change the data in the **Date**, **Time Stamp**, or **Type** fields.

Figure 6-13: Blood Sample Edit Window



6.11.2.1. To edit or delete blood and perfusate sample data

1. Press 
2. Rotate the knob to highlight **Edit Blood Sample** and press the knob. The **Blood Sample Edit** window is displayed (Figure 6-13). The last values entered for each analyte type are listed.
3. To view blood and perfusate sample data, press the knob and do one of the following:
   - To scroll through the samples, select the field with the sample number and time stamp.
   - To scroll from the current sample toward earlier samples by time stamp, turn the knob counterclockwise.
   - To scroll from the current sample toward more recent samples by time stamp, turn the knob clockwise.
4. To edit or delete a specific sample entry, press the knob when the entry is displayed.
5. To delete a sample entry, turn the knob and select **Delete**.
6. To edit the values in the sample entry, turn the knob and press it to change the values. You cannot edit the **Date**, **Time Stamp**, or **Type** values.
7. Do one of the following:
   - To accept the changes and close the **Blood Sample Edit** window, select **Accept**.
   - To apply the changes without closing the window, select **Apply**.
   - To discard the changes and close the window, select **Cancel**.

6.12. Using Annotations

You can add notes and comments during the preservation session as Annotations. You can also use the **Annotation Menu** through the **Action Menu** to enter an organ identifier to be included in the session files. Annotations are automatically stamped with the time of entry and saved in the session

file. You can enter up to 60 characters at a time on two lines. Characters can be a combination of individually input characters and selections from a list of default key words and phrases.

NOTES—

If you attempt to enter more keywords or characters than permitted, an error tone sounds and the highlight is automatically shifted to the **Accept** button. If you are in process of adding a keyword when the 60-character limit is reached, the entry is truncated to fit.

The Wireless Monitor will present a reminder if the user has not entered an Organ ID within 35 minutes of the start of a new session.

6.12.1. Entering Key Words

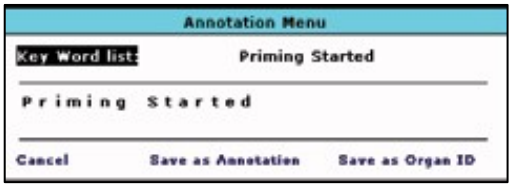
Table 6-10 lists the commonly used key words that are provided with the system.

Table 6-10: Key Words Available

Event Indicated
Priming Started
Lungs Wrapped
Injection: Flolan
Injection: Glucose
Injection: Insulin
Injection: Milrinone
Injection: Other
Injection: HCO_3
Injection: Tham

Figure 6-14 shows the **Annotation Menu** window.

Figure 6-14: Adding Annotations



6.12.1.1. To enter keywords during a preservation session

1. Press  .
2. Turn the knob to highlight **Add Annotation**. Press the knob. The **Annotation Menu** window (Figure 6-14) displays, with the highlight on **Key Word lists**.

3. Press the knob. The first available key word appears to the right of **Key Word List** and temporarily between the two thick lines.
4. Turn the knob to display each available word or phrase.
5. When the highlight is on a word or phrase you want to enter, press the knob. The keyword is entered as an annotation, and the highlight shifts to Cancel. Each new keyword is entered one space after the last keyword entered, separated by a comma.
6. Do one of the following:
   - To save the entry as the ID for this preservation session, replace any previously entered ID, and clear the annotation field, select **Save as Organ ID**.
   - To save the current entry as the annotation, select **Save as Annotation**.
   - To discard any annotations, select **Cancel**.

6.12.2. Entering Freeform Annotations

You can select letters and numbers to enter freeform text during a preservation session.

6.12.2.1. To enter letters and numbers

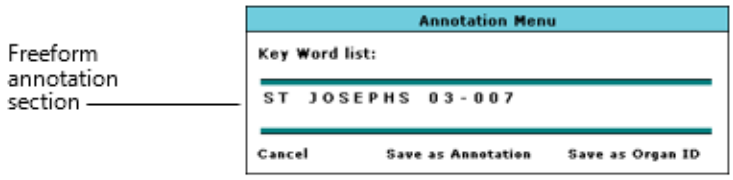
1. Press  .
2. Turn the knob to highlight **Add Annotation** and press the knob. The **Annotation Menu** window (Figure 6-14) displays.
3. Rotate the knob to move the highlight to the area beneath the first heavy line and press the knob (Figure 6-15).
4. Move the cursor to the place where you want the first character to appear and press the knob.
5. Rotate the knob one click at a time to move through the available symbols, letters, and numbers. Clockwise rotation moves forward through the choices; counterclockwise rotation moves backward.
6. When a character you want to select is highlighted, press the knob to enter it, then press the knob again to begin selecting another character to enter in the next space, or move the highlight to another location on the line.

   Do one of the following

   - To save the entry in a session file as the Organ Identifier, and to clear the current annotation field, select **Save as Organ ID**.
   - To save the annotation and clear the annotation field, select **Save as Annotation**.

You must press the knob before and after each entry to continue entering characters. To make a menu choice, rotate the knob until the desired choice is highlighted, and press the knob.

Figure 6-15: Freeform Annotations



6.12.3. Editing and Extending an Annotation

You can alternate between entering keywords and freeform annotations. These rules apply:

- A new keyword entry is added one space after the last freeform entry.
- You can begin a freeform entry anywhere on the line by moving the cursor to the location and entering characters as described in Section 6.12.2, “Entering Freeform Annotations.”
- You can edit a freeform entry by selecting the character you want to change, pressing the knob, then entering characters as described in Section 6.12.2, “Entering Freeform Annotations.”
- You cannot insert new text between two previously entered adjacent letters. The text editor overwrites the previously entered text.

6.13. Calibrating the SaO_2/HCT Probe

The SaO_2 and SvO_2 probes have been calibrated at the factory before the OCS™ was installed. If directed by TransMedics to recalibrate the probes, follow these steps.

6.13.1. To calibrate the SaO_2/HCT probe

1. Press  .
2. Press and select **Calibrate SaO_2/HCT Probe**.
3. When you are ready to begin the calibration, select **Accept**.
4. Within a few seconds, the system displays a message stating the calibration is successful.
5. If you receive a message that the calibration failed, refer to Table 6-11 for details on the alarm messages that may appear, and their meanings.

Table 6-11: SaO_2/HCT Calibration Failure Messages and Meanings

Message	Meaning
SaO_2/HCT probe calibration failed: SvO_2/SaO_2/HCT unavailable	There is currently no SvO_2, SaO_2, or HCT reading available.
SaO_2/HCT probe calibration failed: SvO_2 or SaO_2 saturated	The SvO_2 or SaO_2 reading is currently saturated (99.9%).
SaO_2/HCT probe calibration failed: SAT probes not warmed up	The difference between the SaO_2 reading and the SvO_2 reading is out of tolerance (is greater than 10%).

6.14. Displaying System Status

The **Display Status** item in the **Actions** tab of the **Configuration Menu** lets you quickly review the current status of system components and settings. This function is also useful when communicating system information to TransMedics.

7. CHAPTER 7: CLEANING AND MAINTAINING THE OCS™

This chapter describes how to inspect, clean, and disinfect the TransMedics® OCS™ Lung System. It also provides routine cleaning and maintenance procedures to ensure system performance and reliability.

CAUTION— Do not sterilize the OCS™ Lung System, or any component of the system. Sterilization, by any means, will damage the system and void the warranty.

Full preventive maintenance includes the routine, operator-performed procedures described here as well as periodic visual inspections and electrical safety testing. If equipment problems cannot be solved using the instructions in this manual, you should contact a qualified TransMedics Service representative.

WARNING— Only a qualified TransMedics Service representative may service the TransMedics OCS™ Lung System or any of its accessories. Any attempt by the user to disassemble the system or any of its accessories may result in shock or serious injury and will void the warranty.

7.1. Routine Inspection Before and After Use

Before and after each use, inspect the OCS™ Lung Console for any damage that might require service or replacement of an individual component in time for the next use, and for possible biocontamination that might require special attention. Check for:

- Damage to probe cables and housings.
- Damage to the Lung Perfusion Module holding area.
- Damage to the circulatory pump.
- Damage to the ventilator shaft or coupling.
- Damage to the Lung Monitoring Gas connector.
- Damage to the Ventilator Lines connector.
- Proper functioning of system covers, access doors, OCS™ battery restraints, and push handle.
- Damage to the system AC power cord and connectors.
- Damage to the Wireless Monitor screen.
- Damage to OCS™ batteries.
- Damage to the data card housing.
- Batteries that do not charge completely.
- Proper functioning of the Mobile Base, including the wheel-lock mechanism.
- Proper functioning of the Lung Perfusion Module latching mechanisms.
- Damage to the Wireless Monitor docking area.

- Proper operation of the Wireless Monitor controls.

If you find any damage, contact TransMedics Service.

7.2. Infection Control

For protection of both staff and patients, always follow institutional infection control procedures when setting up, using, and cleaning the OCS™.

7.3. Handling Blood-Contaminated Components

After one use, dispose of the entire Lung Perfusion Module, including the attached PC board and all sterile accessories in accordance with institutional protocols for disposing of blood-contaminated materials.

CAUTION—All parts of the Lung Perfusion Module and its sterile accessories are intended for single-use only. Do not attempt to sterilize and reuse the Lung Perfusion Module or any of the sterile accessories.

NOTE—The flow probe, the SvO_2/Hematocrit probe, and the SaO_2/Hematocrit probe are NOT sterile and should be cleaned as described later in this section.

7.4. Cleaning and Disinfecting the System after Use

After the OCS™ has been used and after you have removed and properly disposed of the Lung Perfusion Module and accessories, clean the system to remove gross contamination, and then disinfect the system to prevent the transmission of blood borne pathogens. The precautions taken during the cleaning and disinfection of the OCS™ Lung Console are similar to those for any medical equipment that may come in contact with human blood or other bodily fluids.

7.4.1. Personal Protective Equipment

You must wear proper personal protective equipment and clothing during cleaning and disinfection.

NOTE—Personal protective equipment is not supplied by TransMedics.

You will need:

- Gloves
- Protective mask
- Eye protection with side shields
- Protective clothing

Refer to your institution's procedures for additional institutional requirements.

7.4.2. Required Cleaning and Disinfecting Agents and Supplies

Prior to cleaning and disinfecting the system, assemble the following agents and supplies:

- 10% bleach (0.52% sodium hypochlorite) wipes
- 70% isopropyl alcohol wipes
- 70% isopropyl alcohol swabs
- Tongue depressors
- Soft lint-free cloths
- Lint-free swabs
- Disposable soft brushes (e.g., 3/8" horse hair brush from Tanis, part number 02001)
- Paper towel
- Water

7.4.3. Exposure Times

To assure proper disinfection, you must allow adequate exposure time for each agent used. Exposure time is the length of time the disinfectant must be left undisturbed on the system or component surface to ensure proper disinfection.

7.4.4. Removing Excess Disinfectant and Drying

After the prescribed exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water. Dry the surface using soft lint-free cloths.

7.4.5. Cleaning and Disinfection Process

Use Table 7-1 below to guide you through the proper cleaning and disinfecting procedures. Begin with General Cleaning, the first item in the **Area** column, and then treat each system area or component in the order presented. After properly cleaning and disinfecting the system, properly dispose of all materials and used personal protective equipment according to institutional procedures.

NOTES—

Where "5 minutes (twice)" appears in the Exposure time column in Table 7-1, it indicates to perform the task two times, allowing a 5-minute exposure time during each procedure

For cleaning and disinfection instructions for the probes, see Section 7.5, "Cleaning and Disinfecting the Probes."

Table 7-1: Cleaning and Disinfecting the OCS™ Lung Console

Area	Supplies	Exposure time	Cleaning Procedure
GENERAL CLEANING			
Pre-disinfection cleanup	Soft brushes Soft lint-free cloths Lint-free swabs	As required	1. Prior to cleaning, disconnect the system from the AC wall outlet.

Area	Supplies	Exposure time	Cleaning Procedure
	Water		2. Wipe up any blood, wet or dry, with a soft lint-free cloth or lint-free swab dampened with water from the external surfaces. 3. If necessary, use a soft brush to remove dry residues. 4. Remove excess water with a clean, dry soft lint-free cloth. 5. Remove the OCS™ Lung Console's top cover and open the front panel (Figure 3-1). 6. Remove and dispose of the LPM and accessories. 7. Repeat steps 2-4 on the OCS™ Lung Console's internal surfaces (Lung Perfusion Module Area, Figure 3-2).
DISINFECTION OF INTERIOR OF SYSTEM WITH COVERS OPEN (LPM ALREADY REMOVED)			
White painted surfaces with exception of connector block	Bleach wipes Tongue depressors Soft lint-free cloths Lint-free swabs Water	10 minutes	1. Wipe with bleach wipes. Wrap the bleach wipe around a tongue depressor to access smaller areas as needed. 2. Pay particular attention to the floor of the system, where fluids and spills may accumulate, making sure no fluids are left in the unit. 3. Avoid getting any bleach on the gas line connectors when wiping the surrounding painted areas. 4. After exposure time, remove the excess of disinfectant with a soft lint-free cloth or lint-free swab moistened with water and then dry.
Probe Connector Panel Cover(s)	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	For details, see Section 7.5, "Cleaning and Disinfecting the Probes" 1. Remove probe connector panel cover(s). 2. Wipe with alcohol wipes and swabs. 3. Repeat after first 5-minute exposure time has elapsed. 4. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry. 5. Replace probe connector panel cover.
Metal components (Latching mechanism, circulatory pump mechanism, gas line connectors, ventilator shaft and coupling, front panel hinges)	Alcohol wipes Alcohol swabs Tongue depressors Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Circuit board connector block (includes the silver-	Alcohol wipes Soft lint-free cloths	5 minutes (twice)	1. Wipe with alcohol wipes. 2. Repeat after first 5-minute exposure time has elapsed.

Area	Supplies	Exposure time	Cleaning Procedure
colored buttons, the three dark IR transmission windows, and the immediately surrounding white panel, which extends to the rectangular seal.)	Water Paper towel Metal Cleaner		3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry. 4. Thoroughly scrub each silver contact button with an alcohol wipe to remove any soluble materials. 5. Scrub each button with a dry paper towel, rubbing briskly to remove any surface oxidation. 6. If the surface oxidation still exists, thoroughly scrub the silver button with Diamond Paste Metal Cleaner supplied by TransMedics (REF 1460) for 10 seconds using a lint-free wipe. Wipe the silver button and Circuit Board Connector Block clean with alcohol wipes and lint-free wipes. 7. Inspect the strip of gold tape below the silver buttons for signs of peeling.
Data card slot cover	Alcohol wipes Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Inside of front panel	Bleach wipes Soft lint-free cloths Water	10 minutes	1. Wipe surfaces with bleach wipes, supporting the panel to avoid breaking it. 2. After exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry. 3. Raise the panel.
Inside of system top cover	Bleach wipes Soft lint-free cloths Water	10 minutes	1. Wipe surfaces with bleach wipes. 2. After exposure time, remove the excess of disinfectant with a cloth moistened with water and then dry. 3. Install on system.
DISINFECTION OF EXTERIOR OF SYSTEM WITH WIRELESS MONITOR UNDOCKED			
White, silver/blue, and red/ black (logo) painted surfaces	Bleach wipes Tongue depressors Soft lint-free cloths Lint-free swabs Water	10 minutes	1. Wipe surfaces with bleach wipes. Wrap the bleach wipe around a tongue depressor to access smaller areas as needed. 2. After exposure time, remove the excess of disinfectant with a soft lint-free cloth or lint-free swab moistened with water and then dry.
Push handle	Alcohol wipes Alcohol swabs Tongue depressors	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed. 2. Repeat after first 5-minute exposure time has elapsed.

Area	Supplies	Exposure time	Cleaning Procedure
	Soft lint-free cloths Water		3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Gas cylinder access door	Alcohol wipes Alcohol swabs Tongue depressors Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Gas cylinder release handle	Alcohol wipes Alcohol swabs Tongue depressors Soft lint-free cloths Water	5 minutes (twice	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Wireless Monitor docking connector	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	**DO NOT ALLOW CONNECTOR PINS TO GET WET.** 1. Wipe with alcohol wipes and swabs. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Power cord wrap	Alcohol wipes Alcohol swabs Tongue depressors Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed. 2. Repeat after first 5-minute exposure time has elapsed. **3.** After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
System On/Off switch	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
OCS™ battery and battery compartment	Alcohol wipes Alcohol swabs Tongue depressors	5 minutes (twice)	**DO NOT ALLOW CONNECTORS TO GET WET.** 1. Remove one battery pack at a time to disinfect. 2. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed.

Area	Supplies	Exposure time	Cleaning Procedure
	Soft lint-free cloths Water		3. Repeat after first 5-minute exposure time has elapsed. 4. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
DISINFECTION OF WIRELESS MONITOR			
White painted surfaces	Bleach wipes Tongue depressors Soft lint-free cloths Lint-free swabs Water	10 minutes	1. Wipe surfaces with bleach wipes. 2. Pay particular attention to the speaker grill, using a wipe on a tongue depressor to access smaller areas as necessary. 3. After exposure time, remove the excess of disinfectant with a soft lint-free cloth or lint-free swab moistened with water and then dry.
Connector	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	**DO NOT ALLOW CONNECTOR PINS TO GET WET.** 1. Wipe with alcohol wipes and swabs. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Screen, rotary knob, keypad, black side rails	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry. 4. Dock Wireless Monitor.
DISINFECTION OF MOBILE BASE WITH OCS™ REMOVED			
Silver/blue painted surfaces	Bleach wipes Tongue depressors Soft lint-free cloths Water	10 minutes	1. Wipe surfaces with bleach wipes. Wrap the bleach wipe around a tongue depressor to access smaller areas as needed. 2. After exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Metal parts and casters	Alcohol wipes Alcohol swabs Tongue depressors Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry. 4. Place OCS™ Lung Console back on Mobile Base.

7.4.6. Warnings and Cautions

To avoid injury to personnel or damage to equipment, observe the following warnings and cautions when cleaning and disinfecting the system.

WARNINGS—

To prevent the inhalation of toxic fumes, only clean and disinfect the system in a well-ventilated area.

Failure to use personal protective equipment while cleaning and disinfecting may result in exposure to blood borne pathogens or other potentially infective materials.

Failure to disconnect the system from AC power can cause electrical shock when cleaning or disinfecting.

Failure to use the prescribed disinfection agents, to allow sufficient disinfection exposure times, or to perform two applications with the alcohol wipes may result in insufficient disinfection and an increased possibility of blood borne pathogen transmission.

Do not immerse a battery in water, and do not allow liquids to enter the slot or the electrical contacts at the back of the battery during cleaning or disinfecting. Lithium may react violently when mixed with water, leading to possible battery leakage, smoke, and fire.

CAUTIONS—

Sterilization (by any means) is not allowed for any component of the OCS™.

Do not use any disinfection agents other than those prescribed in this manual. Doing so may lead to component damage, interfering with proper system operation.

Do not allow liquids to get into the Lung Monitoring Gas connector or the Ventilator Lines connector.

Do not attempt to manually extend the ventilator shaft.

Do not spray cleaning solutions onto the system's housings or immerse any component in water, cleaning solutions, or other liquids.

Do not allow fluids to get into electrical connectors (for example, the batteries or the probe connectors.)

Do not use pressurized air.

Do not use sharp or metallic tools to remove residues.

7.5. Cleaning and Disinfecting the Probes

Flow probes and the SvO_2/Hematocrit probes require special handling and cleaning after use.

CAUTION— Do not sterilize the OCS™, or any component of the OCS™. Sterilization, by any means, will damage the system and void the warranty.

7.5.1. To clean and disinfect the Flow Probes

1. Use a soft lint-free cloth to remove petroleum jelly.

2. Open each flow probe and remove any visible foreign material with a soft-bristled brush.
3. Clean each probe, cable, and connector body with alcohol wipes.
4. Use alcohol swabs to clean hard-to-access areas.
5. Allow a 5-minute exposure time to elapse.
6. Repeat the alcohol application and allow a second 5-minute exposure time to elapse.
7. Remove the excess of disinfectant with a soft lint-free cloth moistened with water.
8. Dry with a soft lint-free cloth and store inside the OCS™ Lung Console.

7.5.2. To clean and disinfect the SvO_2/Hematocrit Probe and the SaO_2/Hematocrit Probe

1. Using a soft lint-free cloth or swab, thoroughly clean the channel that fits over the cuvette in the Lung Perfusion Module.

CAUTION— Do NOT use a brush to clean the SvO_2/Hematocrit probe, or the SaO_2/Hematocrit probe. Brushing can damage the optical surfaces.

2. Clean the probe, cable, and connector body with alcohol wipes.
3. Use alcohol swabs to clean hard-to-access areas.
4. Allow a 5-minute exposure time to elapse.
5. Repeat the alcohol application and allow a second 5-minute exposure time to elapse.
6. Remove the excess of disinfectant with a soft lint-free cloth moistened with water.
7. Dry with a soft lint-free cloth and store inside the OCS™ Lung Console.

7.6. Cleaning and Maintenance Task Checklist

Table 7-2 provides a checklist for cleaning and maintaining the system and its components.

NOTES—

The OCS™ does not require periodic calibration.

The OCS™ shall not be serviced or maintenance activities performed while preserving a donor lung.

Table 7-2: Cleaning and Maintenance Checklist

Activity	Frequency	Comment
Shipment inspection	Upon receipt of TransMedics System or individually purchased TransMedics components and supplies, and prior to and after each use and at least once a month during storage.	Visual inspection
Routine cleaning	As needed during storage and prior to each use	Visual inspection

Activity	Frequency	Comment
Post-use inspection, cleaning, and disinfection.	After each use	Visual inspection. If soil remains visible, repeat the cleaning and disinfection process described in Section 7.4 until the OCS™ Lung Console is visually clean.
Gas cylinder inspection	Prior to each use	Visual inspection
Gas cylinder replacement	Prior to use, and as needed while in use	When pressure gauge on gas cylinder or readout on Wireless Monitor shows remaining gas less than sufficient for a preservation session.
Battery check - System and Wireless Monitor	Prior to each use	Verify that the OCS™ and Wireless Monitor batteries are fully charged. Refer to Section 5.3.4, “System Status Icons on the Wireless Monitor,” to ascertain battery status.
Battery replacement - System	When an OCS™ battery cannot be fully charged, when remaining battery run time is less than 1.3 hours after fully charging the battery, when the labeled manufacture date exceeds 5 years, or when the number of clinical uses exceeds 100.	Order new OCS™ batteries from TransMedics as needed.
Battery replacement - Wireless Monitor	When a Wireless Monitor battery cannot be charged, when remaining battery run time is less than 6 hours after fully recharging the battery, when the labeled manufacture date exceeds 8 years, or when the number of clinical uses exceeds 100.	Contact TransMedics; Wireless Monitor battery is not serviceable or replaceable by customer.
Circuit Board Connector Block cleaning	After each use and at least once a month if system has not been used.	Follow procedure in Table 7-1.
Leakage current test	Once a year or as required by the institution.	By institutional biomedical engineer according to institution’s procedures. (Table 2-2 lists the safety test guidelines.)
Ground integrity test	Once a year or as required by the institution.	By institutional biomedical engineer according to institution’s procedures. (Table 2-2 lists the safety test guidelines.)
Preventive Maintenance	Once a year	By TransMedics Service

8. CHAPTER 8: SYSTEM SPECIFICATIONS

This chapter lists and describes the following specifications for the TransMedics® OCS™ Lung System.

- Safety and Regulatory Specifications
- Electrical and Physical Specifications
- Electromagnetic Emissions: Guidance and Manufacturer's Declaration
- Recommended Separation Distances from Portable and Mobile RF Communications Equipment

8.1. Safety & Regulatory Specifications

Table 8-1 lists the Safety and Regulatory specifications.

Table 8-1: OCS™ Safety & Regulatory Specifications

Category	Specifications
Regulatory specifications	European Communities Council Directive 93/42/EEC, as amended, concerning medical devices
Safety standards system meets	IEC 60601-1:2005 CORR. 1 (2005) + CORR. 2 (2007) + A1:2012 Medical Electrical Equipment Part 1: General Requirements for basic safety and essential requirements
	IEC 60601-1-2:2007 / AC 2010 and IEC 60601-1-2 Ed 3.0 and IEC 60601-1-2 Ed 4.0 Electromagnetic emissions and immunity requirements for medical electrical equipment - Group 1 Equipment, Class A for non-life supporting
Electromagnetic compatibility (EMC)	Refer to the following tables: Table 8-3 through Table 8-5.
Bluetooth Devices	R&TTE 1999/5/EC – Radio and Telecommunications Terminal Equipment Directive FCC/CFR 47 Part 15
Classifications:	
Type of protection, shock	Class 1
Degree of protection, ingress	System: IPX1
Flammable mixtures	Not for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous
Leakage & Auxiliary Currents:	
Maximum allowable chassis leakage current	100 µA rms normal condition 300 µA rms single-fault condition

8.2. Electrical and Physical Specifications

Table 8-2 lists and describes the electrical and physical specifications of the OCS™.

Table 8-2: OCS™: Electrical and Physical Specifications

Parameter	Specification
System Power Input - AC Line input voltage:	IEC power inlet receptacle 100 to 240V, 50-60Hz, 375VA
OCS™ Battery Wireless Monitor Battery	14.8 V 15 Ah 7.2 V 12 Ah
Operating Conditions Temp Range: Relative Humidity (non-condensing, steady state):	15°C to 35°C (59°F to 95°F) 20% to 90%
Altitude	up to 3000 meters
Storage Conditions (OCS™ Lung Console) Ambient Temperature: Relative Humidity (non- condensing, steady state):	 -20°C to +50° C (-4° F to +122°F) 10% to 95%
Storage Conditions (Sterile Components) Ambient Temperature: Relative Humidity (non-condensing, steady state):	 -20°C to +50° C (-4°F to +122°F) 10% to 95%
Weight System (without organ or fluids or base): Mobile Base:	 <45.4 kg (<100 lbs) <13.6 kg (<30 lbs)

8.3. Electromagnetic Emissions

The OCS™ is intended for use in the electromagnetic environment specified in Table 8-3 through Table 8-6. The customer or user of the OCS™ should assure that they are used in such an environment.

Table 8-3: OCS™ - Guidance and Manufacturer's Declaration Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The OCS™ uses RF energy only for internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electrical equipment.
RF emissions CISPR 11	Class A	The OCS™ 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.
RF Emissions CIPSR 25 (Automotive)	Class 1	

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions ISO 7137 / RTCA DO-160G (Aircraft)	Category M	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Medical electrical equipment needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in this document.

WARNINGS—

Use of accessories and cables other than those specified, with the exception of cables sold by TransMedics, Inc., as replacement parts for internal components may result in increased emissions or decreased immunity of the OCS™.

The OCS™ should not be used adjacent to other equipment. If such use is necessary, the OCS™ should be observed to verify normal operation.

Table 8-4 lists the guidance and manufacturer's declaration of electromagnetic immunity for the OCS™.

Table 8-4: Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	100% drop for 0.5 cycles 100% dip for 1 cycle 30% dip for 25/30 cycles 100% drop for 5 seconds	100% drop for 0.5 cycles 100% dip for 1 cycle 30% dip for 25/30 cycles 100% drop for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OCS™ requires continued operation during power mains interruptions, it is recommended that the OCS™ be powered from an

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance	
			uninterruptible power supply or a battery.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz 80 % AM at 1kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz 80 % AM at 1kHz	Portable and mobile communications equipment should be separated from the OCS™ by no less than the distances calculated/listed below. **Recommended separation distance** *D* $D = [\frac{3.5}{3}]\sqrt{P}$	
Radiated RF IEC 61000-4-3	3 V/m 80 kHz to 2.7 GHz 80 % AM at 1kHz	3 V/m 80 kHz to 2.7 GHz 80 % AM at 1kHz	$D = [\frac{3.5}{3}]\sqrt{P}$	80 MHz to 800 MHz
			$D = [\frac{7}{3}]\sqrt{P}$	800 MHz to 2.7 GHz
			where *P* is the maximum power in watts. *D* is the recommend separation distance in meters.	
			Field strengths from fixed transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance levels (V1 and E1).[b] Interference may occur in the vicinity of equipment containing a transmitter.	

a. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OCS™ is used exceeds the applicable RF compliance level, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OCS™.

b. Over the frequency range of 150 kHz to 80 mHz, field strengths should be less than 3 V/m.

WARNING—The OCS™ incorporates an RF transceiver for short-range communication between the base unit and the undocked Wireless Monitor. Consequently, the OCS™ may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

The OCS contains a wireless Bluetooth 2.1+EDR transmitter which operates between 2.400 GHz and 2.485 GHz. The Bluetooth module has FCC ID PVH0946 and IC 5325A-0946. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference; and (2) this device must accept any interference received, including interference that may cause undesired operation. The maximum output power is 11 dBm (0.01W). The unobstructed wireless range between the OCS Lung Console and its Wireless Monitor is a minimum of 3 meters.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. Table 8-5 lists the recommended separation distances between portable and mobile RF communications equipment for the OCS™.

Table 8-5: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the OCS™

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter in meters for V =3Vrms and E =3 V/m**		
W	150 kHz to 80 MHz $D = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz [1] $D = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $D = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.1166	0.1166	0.2333
For transmitters rated at a maximum output power not listed above, the recommended separation distance (D) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. [1] At 80 MHz and 800 MHz, the higher frequency range applies.			

NOTE—The guidelines in Table 8-5 may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

8.4. Essential Performance

- Pump warmed oxygenated perfusate to the lung
- Ventilate the lung
- Monitor and display pressure, flow and temperature
- Allow the user to control the functions of the OCS

8.5. Accuracy of Displayed Values

The accuracy of the values displayed by the system are as tabulated:

Table 8-6: Accuracy of Displayed Values

Value	Range	Accuracy
Hematocrit (HCT)	15 to 50%	±5%
Saturation (SvO_2, SaO_2)	50.0 to 99.9%	±5%
Flow (Pump)	0 to 5 L/min	±12% at ≥ 1 L/min, ±(2% + 0.1 L/min) at 0 to 1 L/min
Temperature (Temp)	5 to 45 °C	±1°C
Pressure (PAP)	-10 to 50 mmHg	Greater of ±5% or ±2 mmHg
Pressure (PEEP, PAWP)	-5 to 60 cmH_20	Greater of ±5% or ±1 cmH_2O
Tidal Volume	200 ml to 1000 ml	±10%
Vascular Resistance (VR)	0 to 1700 (dyne*s)/cm^5	±19%

9. CHAPTER 9: TROUBLESHOOTING

This chapter lists and describes troubleshooting tips, system messages, and related Technical Service information.

9.1. Emergency Support

If a situation arises that threatens the safe perfusion of a donor organ, TransMedics® support is available to complement the recommended actions in this section. A TransMedics emergency response representative can be reached at any time by calling +1 978 552 0999, ext 1.

9.2. Technical Service Follow-Up

If an issue is observed during the operation of the OCS™ Lung System, this may indicate the need for follow-up Technical Service to be performed on the equipment after the perfusion run is completed. Technical Service is available via email at service@transmedics.com, or by calling +1 978 552 0999, ext 2. Depending on the cause of the issue, different Technical Service response may be indicated:

- **LPM Service:** These issues are resolved with the installation of another LPM and as a result OCS™ Service is not required.
- **OCS™ Service:** Depending on the nature of the issue, you may be directed to not use the OCS™ until it has been serviced.
- **Component Service:** The issue is specific to a user-replaceable component of the OCS™. Contact TransMedics for follow-up service on a user replaceable part.

9.3. Troubleshooting the OCS™

This section lists and describes the OCS™ Lung System messages and the recommended actions to resolve issues.

Note the following:

- Attempt to resolve the issue one step at a time by performing the recommended actions in the order that they appear in the tables in this section. After each step, assess whether the issue has been resolved and only proceed to the next step if additional troubleshooting is needed. Based on the outcome of the troubleshooting process, follow-up with TransMedics Technical Service.
- For an alphabetical list of all troubleshooting messages, see the Messages entry in the Index.

9.4. Standby-Cycling the System

Standby-cycle the system means to press  (with the Wireless Monitor docked) once to switch from Run Mode to Standby Mode and a second time to switch back to Run Mode. The system

automatically runs the Self Test when entering Run Mode. This sequence shuts off the pump and the ventilator.

9.5. Power-Cycling the System

Power-cycle the system means to use the On/Off switch on the side of the OCS™ Lung Console to turn the system OFF, wait 10 seconds, and then turn it ON. This sequence temporarily shuts off the pump and the ventilator. When the OCS™ powers on, it will continue operating at the same settings that were present when it was shut off.

9.6. Unlatching and Latching the Lung Perfusion Module

Unlatch and latch LPM means to unlatch the LPM, tilt it forward, and wait 30 seconds until the alarm message indicates the LPM has been removed. Tilt the LPM back to latch it.

NOTE—The ventilator is in a ready position as long as the Lung Perfusion Module is inserted. The ventilator mode must be set to Off before attempting to physically remove the Lung Perfusion Module.

9.7. Early Termination Procedure

1. Remove the OCS™ top cover.
2. Lower the front panel.
3. Using sterile technique, open the organ chamber and unwrap the lungs.
4. Disconnect the tracheal connector from its corresponding port in the organ chamber and then connect the sterile inflation bag from the TransMedics Manual Inflation Set to the tracheal connector.
5. Manually inflate the lungs, keeping the airway pressure below 20 cmH_2O.
6. After ensuring adequate inflation, apply a sterile clamp to the tracheal cannula and disconnect the manual inflation bag. Keep the trachea clamped inside the organ chamber until the final flush.
7. Perform the final lung flush procedure as described in the *TransMedics Clinical User Guide: OCS™ Lung System*.
8. Disconnect the lung from the OCS™ as described in the *TransMedics Clinical User Guide: OCS™ Lung System*.
9. Follow cold storage protocol.

Users should keep an OCS™ Lung Manual Inflation Set in the run bag and bring the OCS™ Lung Perfusion Termination Set with them to the Donor hospital to support the Early Termination Procedure. Manual Inflation Sets are separately orderable from TransMedics. (REF 2404)

Table 9-1: Troubleshooting Pumping

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Pump Failure	1. Remove and reinsert LPM. Standby-cycle the system.	1. Turn pump off and attempt to restart. 2. Turn the ventilator off, remove and reinsert LPM, and then attempt to restart pump. 3. Perform Standby-cycle and then attempt to restart pump.	1. Perform Early Termination Procedure. Then follow-up with OCS™ Service.

Table 9-2: Troubleshooting Ventilation

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Ventilator failure	1. Connect the LPM's Ventilator Lines connector to the OCS™ Lung Console and Standby-cycle the system. 2. Turn ventilator to Off, remove and reinsert LPM, and Standby-cycle the system.	1. Verify the Ventilator Lines connection to the OCS™ Lung Console. 2. Turn pump and ventilator off, remove and reinsert LPM and perform Standby-cycle. 3. Power-cycle the system and Standby-cycle the system.	1. Verify the Ventilator Lines connection to the OCS™ Lung Console. 2. Perform Early Termination Procedure. Then follow-up with OCS™ Service.
Check ventilator pneumatic connector	1. Connect the LPM's Ventilator Lines connector to the OCS™ Lung Console. 2. Standby-cycle the system.	1. Connect the LPM's Ventilator Lines connector to the OCS™ Lung Console. 2. Standby-cycle the system.	1. Connect the LPM's Ventilator Lines connector to the OCS™ Lung Console. 2. Perform Early Termination Procedure. Then follow-up with OCS™ Service.

Table 9-3: Troubleshooting Heating

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Blood temperature sensor failure Blood warmer sensor failure; blood warming disabled	1. Turn the ventilator off and unlatch and latch the LPM. 2. Standby-cycle the system. 3. Replace the LPM and follow-up with LPM Service.	1. Turn the ventilator off, turn the pump off, and unlatch and latch the LPM. 2. Standby-cycle the system.	1. Perform Early Termination Procedure. Then follow-up with OCS™ Service.
Blood warmer too hot Blood too hot	1. Standby-cycle the system. 2. Replace the LPM	1. This is usually a transient event. Wait one minute for the message to clear with the pump running and fluid in the LPM. 2. Standby-cycle the system.	1. This is usually a transient event. Wait one minute for the message to clear. 2. Perform Early Termination Procedure. Then follow-up with LPM Service.
Blood warmer failure	1. Turn off the pump and ventilator, remove the LPM, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, and reinstall the LPM. 2. Standby-cycle the system. 3. Replace the LPM.	1. Turn off the pump and ventilator, remove the LPM, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, and reinstall the LPM. 2. Standby-cycle the system.	1. Perform Early Termination Procedure. Then follow-up with OCS™ Service.
Single blood temperature sensor failure Single blood warmer sensor failure	1. Turn off the ventilator, unlatch and latch the LPM. 2. Standby-cycle the system. 3. Replace the LPM. (If a replacement LPM is not available, contact TransMedics for instructions on how to proceed with organ perfusion.)	N/A	N/A
Single blood warmer element failure	1. Turn off the ventilator, remove the LPM, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, and reinstall the LPM. 2. Standby-cycle the system. 3. Replace the LPM and follow-up with LPM Service.	1. Turn off the pump and ventilator, remove the LPM, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, and reinstall the LPM. 2. Standby-cycle the system.	1. Proceed with use if necessary but be aware that perfusate warming capacity is reduced. Keep the OCS™ covers closed as much as possible and keep the OCS™ in a warm environment. 2. If you are not able to maintain the desired perfusate temperature,

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
	4. Proceed with use if necessary but be aware that perfusate warming capacity is reduced. Keep the OCS™ covers closed as much as possible and keep the OCS™ in a warm environment. Then follow- up with OCS™ Service.	3. Proceed with use if necessary but be aware that perfusate warming capacity is reduced. Keep the OCS™ covers closed as much as possible and keep the OCS™ in a warm environment. Then follow- up with OCS™ Service.	perform Early Termination Procedure. Then follow-up with OCS™ Service.

Table 9-4: Troubleshooting Lung Preservation Gas

Message	Recommended Action(s)		
	If Detected During Self Test/ LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Lung Preservation Gas tank sensor failure	1. Check, and if necessary, tighten the electrical connector on the pressure sensor of the gas regulator by turning the metal collar clockwise. 2. Standby-cycle the system. 3. Proceed by using the gauge on the gas tank to determine the amount of gas remaining, and follow-up with OCS™ Service.		1. Check, and if necessary, tighten the electrical connector on the pressure sensor of the gas regulator by turning the metal collar clockwise. 2. Proceed by using the gauge on the gas tank to determine the amount of gas remaining, and follow-up with OCS™ Service.

Table 9-5: Troubleshooting the Pressure Probes

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Pressure probe failure: Dual PAP Pressure probe failure: Dual Airway	1. Turn off the ventilator, and unlatch and latch the LPM. 2. Standby-cycle the system. 3. Replace the LPM. (If a replacement LPM is not available, contact TransMedics for instructions on how to proceed with organ perfusion.)	1. Turn off the ventilator and pump, and unlatch and latch the LPM. 2. Standby-cycle the system.	1. If the lung has stabilized, proceed without the functioning probe. If the lung has not stabilized, proceed to step 2. 2. Perform Early Termination Procedure. Then follow-up with OCS™ Service.
Pressure probe failure: Single PAP Pressure probe failure: Single Airway	1. Turn off the ventilator, and unlatch and latch the LPM. 2. Power-cycle the system. 3. Replace the LPM. (If a replacement LPM is not available, contact TransMedics for instructions on how to proceed with organ perfusion.)	N/A	N/A
"+++" or "---" value displayed for PAP or RESP	1. Replace the LPM. (If a replacement LPM is not available, contact TransMedics for instructions on how to proceed with organ perfusion.)	1. Check the circuit for kink or blockage. 2. Replace the LPM.	1. Check the circuit for kink or blockage. 2. Perform Early Termination Procedure. Then follow-up with OCS™ Service.

Table 9-6: Troubleshooting the Lung Perfusion Module

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Lung Perfusion Module failure	1. Turn off the pump and ventilator, remove the LPM, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, and reinstall the LPM. 2. Standby-cycle the system. 3. Replace the LPM.	N/A	N/A
Lung Perfusion Module not present	1. Turn off the ventilator, remove the LPM, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, and reinstall the LPM. 2. Standby-cycle the system. 3. Replace the LPM.	1. Remove the LPM, unlatch the LPM, tilt the LPM forward, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, latch the LPM. 2. Standby-cycle the system.	1. Perform Early Termination Procedure. Then follow-up with PM Service.
Pump disabled when Lung Perfusion Module removed Pump disabled due to Lung Perfusion Module failure	N/A	1. Acknowledge the alarm. Then unlatch the PM, tilt the PM forward, vigorously scrub the silver contact buttons on the circuit board connector block with alcohol wipes, latch the PM. Then attempt to restart the pump and restore to the previous settings.	1. Acknowledge alarm and attempt to set pump to desired flow rate. 2. Perform Early Termination Procedure. Then follow-up with OCS™ Service.

Table 9-7: Troubleshooting the Flow Probes

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Check flow probe: Pump	1. Check for air in the line. 2. Check that the flow probe cover is latched. 3. Reinstall probe with coupling gel. 4. Check for kinked/bent tubing. 5. Ensure probe is properly connected to OCS™ Lung Console and is in the proper position on the Lung Perfusion Module. 6. Standby-cycle the system.	1. Check for air in the line. 2. Check that the flow probe cover is latched. 3. Reinstall probe with coupling gel. 4. Check for kinked/bent tubing. 5. Ensure probe is properly connected to OCS™ Lung Console and is in the proper position on the Lung Perfusion Module. 6. Standby-cycle the system.	1. Check for air in the line. 2. Check that the flow probe cover is latched. 3. Reinstall probe with coupling gel.
Missing probe: Pump	1. Connect the Pump flow probe to OCS™ Lung Console. 2. Standby-cycle the system.	N/A	N/A

Table 9-8: Troubleshooting the SvO_2/HCT and SaO_2/HCT Probes

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Check SvO_2/HCT probe Check SaO_2/HCT probe	1. Ensure probe is properly connected to OCS™ Lung Console. 2. Standby-cycle the system	1. Ignore this message if there are no red blood cells in the SvO2/ HCT cuvette and if the circuit is not properly de-aired. 2. Ensure probe is properly seated to cuvette on PM. Then ensure probe is properly connected to OCS™ Lung Console. 3. Standby-cycle the system. 4. Place the system into Standby mode to replace the probe.	1. Ensure probe is properly seated to cuvette on PM. Then ensure probe is properly connected to OCS™ Lung Console. Follow up with Component Service. 2. Proceed without the functioning probe by monitoring blood gases and hematocrit using a blood gas analyzer. Then follow-up with OCS™ Service.

Table 9-9: Troubleshooting SaO_2/HCT Probe Calibration Issues

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
SaO_2/HCT probe calibration required	1. Ignore this message until priming.	1. After red blood cells have been added to the system and the SvO_2, SaO_2, and HCT values are stable, calibrate SaO_2/HCT probe. For instructions, see Section 6.13, "Calibrating the SaO_2/HCT Probe."	1. Calibrate SaO_2/HCT probe. For instructions, see Section 6.13, "Calibrating the SaO_2/HCT Probe."
SaO_2/HCT probe calibration failed: SvO_2/SaO_2/HCT unavailable	N/A	1. Ensure probes are properly seated to cuvettes on PM and properly connected to OCS™ Lung Console. When the SvO_2, SaO_2, and HCT values are stable, then retry calibration. 2. Standby-cycle the system.	1. Ensure probes are properly seated to cuvettes on PM and ensure probes are properly connected to OCS™ Lung Console. When the SvO_2 and SaO_2 values are stable, then retry calibration. 2. Monitor oxygen saturation and hematocrit during Continuous Mode using a blood gas analyzer. Do not rely on the SaO_2 and SvO_2 values displayed on the screen.
SaO_2/HCT probe calibration failed: SvO_2 or SaO_2 saturated	N/A	1. Monitor oxygen saturation and hematocrit during Continuous Mode using a blood gas analyzer. Do not rely on the SaO_2 and SvO_2 values displayed on the screen.	
SaO_2/HCT Probe calibration failed: SAT probes not warmed up	N/A	1. After red blood cells have been added to the system and the SvO_2, SaO_2, and HCT values are stable, ensure that the probes have had at least ten minutes to warm up, then retry calibration.	1. Ensure that the probes have had at least ten minutes to warm up, then retry calibration. 2. Monitor oxygen saturation and hematocrit during in Continuous Mode using a blood gas analyzer. Do not rely on the SaO_2 and SvO_2 values displayed on the screen.

Table 9-10: Troubleshooting the Wireless Monitor Communications

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Loss of wireless communication. Monitor is out of range from the OCS™ or OCS™ is not functioning. The Monitor will shut down in 10 minutes.	N/A	1. Return the Wireless Monitor in range of the OCS™ Lung Console. 2. Dock the Wireless Monitor and- wait 60 seconds for the OCS™ to recover. 3. Dock the Wireless Monitor and power-cycle the system. 4. Dock a spare Wireless Monitor to establish the communications link with the OCS™.	1. Return the Wireless Monitor in range of the OCS™ Lung Console and immediately verify if the system is still functioning. 2. If the pump and ventilator are still functioning, dock the Wireless Monitor and wait 60 seconds for the OCS™ to recover. -or- If the pump and ventilator are no longer functioning, proceed to step 4. 3. Dock a spare Wireless Monitor to establish the communications link with the OCS™. Then follow-up with Component Service for the primary Wireless Monitor. 4. Perform Early Termination Procedure. Then follow-up with OCS™ Service.
Radio communications failure	1. Power-cycle the system. 2. Dock a spare Wireless Monitor to establish the communications link with the OCS™. 3. Proceed with operating the system with the Wireless Monitor docked on the OCS™ Lung Console.	1. Power-cycle the system. 2. Dock a spare Wireless Monitor to establish the communications link with the OCS™. 3. Proceed with operating the system with the Wireless Monitor docked on the OCS™ Lung Console.	1. Dock a spare Wireless Monitor to establish the communications link with the OCS™. 2. Operate the system with the Wireless Monitor docked.
Monitor external power failure	1. Undock and dock the Wireless Monitor. 2. Power-cycle the system. 3. Dock a spare Wireless Monitor to establish the communications link with the OCS™	1. Undock and dock the Wireless Monitor. 2. Power-cycle the system. 3. Dock a spare Wireless Monitor to establish the communications link with the OCS™.	1. Undock and dock the Wireless Monitor. 2. Dock a spare Wireless Monitor to establish the communications link with the OCS™.
Downloading Monitor Software	1. Wait approximately 5 minutes for the Wireless Monitor to complete the software download. During the software download, critical functions of ventilation, heating, pumping, and gas delivery continue at the last settings made by the user.		

Table 9-11: Troubleshooting the Power

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Power system failure (AC Line Power Supply)	N/A	1. Power-cycle the system. 2. Operate the OCS™ on battery power only	1. Operate the OCS™ on battery power only
Power failure on channel 1	N/A	1. Remove and reinsert battery 1 (Left OCS™ battery). 2. Replace battery 1 with a spare battery. 3. Power-cycle the system. 4. As soon as battery 2 or 3 is depleted, replace it with a charged battery,	1. As soon as battery 2 or 3 is depleted, replace it with a charged battery.
Power failure on channel 2	N/A	1. Remove and reinsert battery 2 (middle OCS™ battery). 2. Replace battery 2 with a spare battery. 3. Power-cycle the system. 4. As soon as battery 1 or 3 is depleted, replace it with a charged battery.	1. As soon as battery 1 or 3 is depleted, replace it with a charged battery.
Power failure on channel 3	N/A	1. Remove and reinsert battery 3 (Right OCS™ battery). 2. Replace battery 3 with a spare battery. 3. Power-cycle the system. 4. As soon as battery 1 or 2 is depleted, replace it with a charged battery.	1. As soon as battery 1 or 2 is depleted, replace it with a charged battery.
Battery failure, remove battery 1	1. Remove left battery from use, replace battery with a spare battery. Use AC power whenever available.		1. Remove battery from use. Replace battery with a spare battery. Use AC power whenever available. 2. As soon as battery 2 or 3 is depleted, replace it with a charged battery
Battery failure, remove battery 2	1. Remove middle battery from service, replace battery with a spare battery		1. Remove battery from use. Replace battery with a spare battery. Use AC power whenever available.

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
			2. As soon as battery 1 or 3 is depleted, replace it with a charged battery.
Battery failure, remove battery 3	1. Remove right battery from service, replace battery with a spare battery		1. Remove battery from use, Replace battery with a spare battery. Use AC power whenever available. 2. As soon as battery 1 or 2 is depleted, replace it with a charged battery.
Monitor battery failure	N/A	1. Undock the Wireless Monitor and then dock the Wireless Monitor. 2. Dock the spare Wireless Monitor to establish the communications link with the OCS™. Proceed with the Wireless Monitor docked.	
Battery 1 charging failure. Battery may be used.	N/A	1. Proceed with use of the OCS™ and allow the battery to cool. This message indicates a fault only if it persists for more than one hour. It may occur normally when the OCS™ battery is warm from being recently charged. 2. Remove battery and reinsert. 3. Replace battery with a spare.	
Battery 2 charging failure. Battery may be used.			
Battery 3 charging failure. Battery may be used.			
Monitor battery charging failure. Monitor may be used.	N/A	1. Proceed with use of the OCS™ and allow the battery to cool. This message indicates a fault only if it persists for more than one hour. It may occur normally when the Wireless Monitor battery is warm from being recently charged. 2. Dock the spare Wireless Monitor to establish the communications link with the OCS™. 3. Proceed with the Wireless Monitor docked.	

Table 9-12: Troubleshooting the External SD Card

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Data card is full.	N/A	1. Use an alternate TransMedics-supplied SD card. 2. Remove the SD card from the OCS™ Lung Console and delete files to create capacity. 3. At the end of the run, access trend graphs on the Wireless Monitor	
Data card incorrectly formatted. Reinsert card.	N/A	1. Remove and reinsert the SD card. 2. Use an alternate TransMedics-supplied SD card. 3. At the end of the run, access trend graphs on the Wireless Monitor	
Data card transfer error. Reinsert card.	N/A	1. Remove and reinsert the SD card to retry the transfer. 2. Use an alternate TransMedics-supplied SD card. 3. At the end of the run, access trend graphs on the Wireless Monitor	
Data card write protected.	N/A	1. Remove the SD card, ensure write-protection switch is not enabled, and reinsert card. 2. Use an alternate TransMedics-supplied SD card. 3. At the end of the run, access trend graphs on the Wireless Monitor and contact OCS™ Service.	
Data card corrupted. Data card not recognized.	1. Remove and reinsert the SD card. 2. Use an alternate TransMedics-supplied SD card. 3. At the end of the run, access trend graphs on the Wireless Monitor		

Table 9-13: Troubleshooting the System

Message	Recommended Action(s)		
	If Detected During Self Test/LPM Insertion:	**If Detected During Priming:**	**If Detected After Organ is Instrumented:**
Internal error. Please inform TransMedics Customer Support.	N/A	1. In the event of a software reset, the system will continue critical functions including ventilation, heating, pumping, and gas delivery at the last settings made by the user. Note the error code displayed in the Alarm Summary, acknowledge the alarm and proceed. Follow-up with OCS™ Service.	
Communications failure to OCS™	N/A	1. Undock and dock the Wireless Monitor. 2. Power-cycle the system. 3. Dock the spare Wireless Monitor to establish the communications link with the OCS™. 4. Proceed with the Wireless Monitor undocked	1. Undock and dock the Wireless Monitor. 2. Dock a spare Wireless Monitor to establish the communications link with the OCS™. 3. Proceed with the Wireless Monitor undocked
(A dark Wireless Monitor)	1. Check power switch is in the ON position. 2. Undock and dock the Wireless Monitor. 3. Dock a spare Wireless Monitor 4. Power-cycle the system and Standby-cycle the system.	1. Check power switch is in the ON position. 2. Undock and dock the Wireless Monitor. 3. Dock the spare Wireless Monitor. 4. Power-cycle and Standby-cycle the system.	1. Check power switch is in the ON position. 2. Undock and dock the Wireless Monitor. 3. If the pump and ventilator are still functioning, dock the spare Wireless Monitor. -or- If the pump and ventilator are no longer functioning, proceed to step 4. 4. Perform Early Termination Procedure. Then follow-up with OCS™ Service.

9.8. Resetting the System

Use the system's On/Off switch under the following conditions to reset the system:

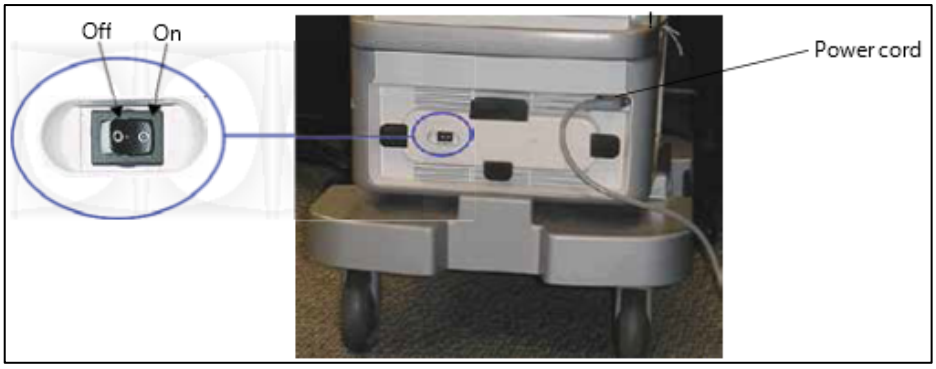
- If the system appears to be inoperative or is not responding to commands
- If a disabling system failure occurs
- If instructed by TransMedics Service personnel

If the system appears to be inoperative, setting the switch to Off and then On may restart the system and return it to the previous system status and previous settings for perfusate temperature, pump flow rate, ventilator mode, and gas flow.

WARNING— The On/Off switch should be in the ON position (Figure 9-1) while the system is in Run or Standby Mode. If the system is disconnected from AC power for extended periods, the On/Off switch should be placed in the Off position to shut off all battery-powered circuits.

NOTE— Restarting the system with the system On/Off switch takes longer than when setting the system to Run Mode with the button. When the system is resetting, you cannot use any controls and the Wireless Monitor's screen is blank for approximately one minute.

Figure 9-1: System On/Off Switch



9.8.1. To reset the system

1. Set the switch to the Off position (Figure 9-1).
2. Wait 10 seconds, then set the switch back to On to restart the system.

9.9. Wireless Monitor Failures

If the Wireless Monitor fails for any reason, the OCS™ will continue to function. Critical functions of ventilation, heating, pumping, and gas delivery continue at the last settings made by the user. In the event of such a failure, you can restore full functionality of the OCS™ by docking a spare Wireless Monitor.

9.10. Shipping Equipment for Service

In some situations, you may need to send equipment to TransMedics for service or replacement. For contact information, see Section 10.1, “Contacting TransMedics.”

NOTE— Before returning equipment to TransMedics, please contact TransMedics Service regarding the return.

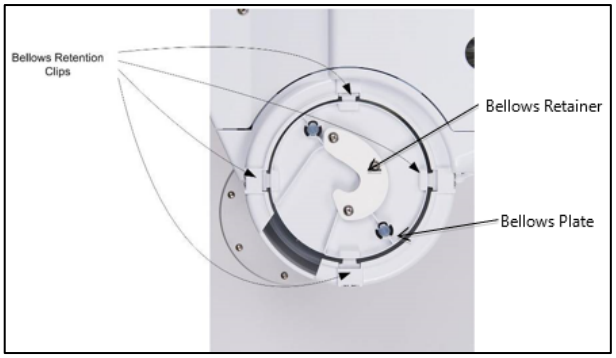
When possible, use the original shipping containers to return system components. Using the original packaging will minimize delays and shipping damage. The OCS™ batteries MUST be shipped by qualified personnel according to applicable transportation laws in the original shipping packages, which are especially designed for safe, legal shipment of these lithium-containing units. TransMedics is not responsible for shipping damage to customer-shipped units.

9.11. Aligning the Bellows Plate

As show below, the user should find the Bellows Plate of the Lung Perfusion Module held in place by the Bellows Retention Clips when the Lung Perfusion Module is removed from its packaging. For a successful installation, the Bellows Plate should be seated flush and held in place by the clips as shown in the figure below. If the Bellows Plate is not in this position, please follow the procedure described below.

WARNING— The Bellows Retainer must be hooked to the Ventilator Actuator to deliver the configured tidal volume to the lungs. Failure to install correctly may result in loss of PEEP.

Figure 9-2: Bellows Alignment



9.12. Bellows Alignment Procedure

Materials required: Manual Inflation Bag

1. Locate the Gas Intake Port of the Lung Perfusion Module (labeled with ).
2. Connect the Manual Inflation Bag to the Gas Intake Port.
3. Gently squeeze the Manual Inflation Bag to expand the bellows.
4. While squeezing the Manual Inflation Bag, pull the Bellows Plate into position until the four clips engage the Bellows Plate.

5. Remove the Manual Inflation Bag.
6. Install the Lung Perfusion Module into the OCS™ Lung Console.

After installation of the Lung Perfusion Module into the OCS™ Lung Console, observe that the Ventilator Actuator is engaged by the Bellows Retainer, as shown in the figure below.

Figure 9-3: Correct Bellows Engagement

9.13. Known Limitations of the OCS™ 3.1.2-C Software

The following table lists the known limitations that users of OCS™ Software 3.1.2-C may encounter and the steps TransMedics recommends to mitigate each situation.

Table 9-14: Known Limitations of the OCS™ 3.1.2-C Software

Behavior	Recommended Action
Changes to the Peak Airway Pressure (PAWP) limit may require several respiratory cycles to take effect	**Issue:** Under certain conditions (e.g. short inspiration times, high pulmonary resistance) the Peak Airway Pressure (PAWP) limit may be exceeded by up to 2 cmH_2O for up to two respiratory cycles before the Peak Airway Pressure is constrained to the PAWP limit ± 1 cmH_2O. **Mitigation:** Wait two complete respiratory cycles, and then confirm the Peak Airway Pressure is constrained to the PAWP limit ± 1 cmH_2O. If the Peak Airway Pressure continues to exceed the PAWP limit by more than 1 cmH_2O, contact OCS™ Service.

10. PARTS AND SUPPLIES

This chapter lists the parts and supplies that you can order directly from TransMedics, Inc.

10.1. Contacting TransMedics

Customer service representatives are available to answer questions and to provide maintenance and service. Please contact TransMedics for assistance at +1 978-552-0999.

For more information, see Section 1.7, “Contacting TransMedics.”

10.2. Ordering Parts and Supplies

Table 10-1 lists the part numbers, names, and descriptions for parts and supplies you can order directly from TransMedics.

Table 10-1: Parts and Supplies

Part Number	Name	Description
2000	OCS™ Lung System	A robust platform that integrates all elements required for warm perfusion and ventilation of donor lungs. The TransMedics Lung Perfusion Module securely mounts within the OCS™ Lung Console. Housed within the OCS™ Lung Console are the necessary pulsatile pump, ventilator subsystem, flow and pulse oximeter probes, Lung Preservation Gas supply, and system batteries. The system’s Wireless Monitor provides operator control for the system as well as monitoring and management for the instrumented organ. The Wireless Monitor can be used docked or remotely during organ transport. Preservation session data and trend information is stored on a removable secure digital (SD) card. The OCS™ Lung System includes: • Wireless Monitor • Data Card • Lung Preservation Gas Cylinders • Lung Monitoring Gas Cylinders • Lung Monitoring Gas Regulator kit • Mobile Base • Batteries (qty. 3) • System Power Cord • Installation • 1-Year Factory Warranty **Lung Application Package** The Lung Application software provides control of the OCS™ Lung System perfusion and displays calculated parameters such as PEEP, PAWP, Respiration Rate, SvO_2, SaO_2, Pump Flow, Pulmonary Arterial Pressure, Vascular Resistance, Perfusate Temperature, hematocrit and Tidal Volume. This application package supports Preservation Mode as well as Monitoring Mode. It provides user-configurable alarms and other settings, the display of parameters, and the display of waveforms and

Part Number	Name	Description
		trended data. The package also allows session trend data and event logs to be copied to an external SD card for external analysis. The application package also includes necessary lung-specific accessories, including: • Lung Application Software • *Technical User Guide: OCS™ Lung System* • *Clinical User Guide: OCS™ Lung System* • Breathing Lung Transplant Training at TransMedics' Andover MA (USA) Training and Development Facility • On-Call 24/7 Expert Run Support. A trained TransMedics clinical representative is available 24/7 for real-time telephone clinical support of in-process organ procurements. Contact your TransMedics representative for more information.
1404	Data Card	A removable SD data card used to store perfusion parameters from the preservation session, which can be downloaded and analyzed on a personal computer.
1408	OCS™ Battery	OCS™ Battery (Quantity 1) Note: The OCS™ Lung System requires 3 rechargeable batteries
1411	Mobile Base	Includes four wheels, with brakes on the front wheels. With the base installed, the organ chamber is at bedside level. With the mobile base removed, the system can be set flat or safely carried by two people with the lift handles.
1423	Regulator Yoke Gasket	A custom fit washer that must be in place on the regulator when replacing a gas cylinder. A missing gasket may cause the cylinder to leak high-pressure gas, possibly resulting in injury.
1426	Pump Flow Probe	A probe that you attach to the Lung Perfusion Module. It is used to measure OCS™ pump flow.
1432	OCS™ Power Cord: United States	This power cord allows the OCS™ to be connected to grounded AC power in the United States.
1460	Metal cleaner	For maintenance of the silver buttons on the Circuit Board Connector Block
2103	Documentation Set US	The OCS™ Lung System Documentation Set includes the Technical User Guide and the Clinical User Guide and other pertinent documentation for users in the US.
2200	Lung Perfusion Set	Contains single use sterile components required for lung instrumentation and management within the OCS™. (All components are provided in sterile packaging.) Includes: **Lung Perfusion Module** The Lung Perfusion Module provides the sterile perfusion circuit and protected environment for lungs within the OCS™. It is designed as a single, easily mounted module that joins with the OCS™ and through embedded sensors and proprietary integrated circuit, communicates with the OCS™ and its Wireless Monitor. The lung is instrumented within the organ chamber of the Lung Perfusion Module. It includes: • Lung-specific organ chamber with special purpose lung wrap, to provide expansion support to the organ while breathing

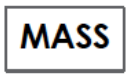
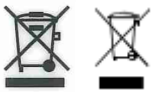
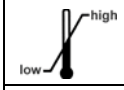
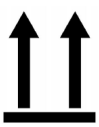
Part Number	Name	Description
		• Integrated and easily accessible perfusate sampling and de-airing manifold • Integrated pulsatile pump head • Integrated low shear titanium perfusate warmer • Integrated gas exchanger • Integrated ventilation bellows • Integrated sensors (perfusate pressure, airway pressure, temperature) and communication circuitry
		Lung Instrumentation Tool Set Kitted sterile packaging contains: • Trachea connectors (3 sizes: .70 in (17.8 mm), .80 in (20.3 mm), .90 in (22.9 mm)) • Cable tie tool • Cable ties (Quantity 8) • Tube cutter • PA cannula • Tubing clamps (Quantity 2) • Banded Bags (2 sizes: 26 in (66.0 cm), 40 in (101.6 cm))
		Lung Perfusion Initiation Set Kitted sterile package contains: • Dual vented prime line (Quantity 2)
		Lung Perfusion Termination Set Kitted sterile package contains: • Lung flush collection bag and line
2300	OCS™ Lung Solution Set	Contains four 1 Liter bags of OCS™ Lung Solution
2401	Lung Instrumentation Tool Set	**Lung Instrumentation Tool Set** Kitted sterile packaging contains: • Trachea connectors (3 sizes: 0.70 in (17.8 mm); 0.80 in (20.3 mm); 0.90 in (22.9 mm)) • Cable tie tool • Cable ties • Tube cutter • PA cannula • Tubing clamps (Quantity 2) • Banded Bags (2 sizes: 26 in (66.0 cm); 40 in (101.6 cm))
2402	Lung Perfusion Initiation Set	**Lung Perfusion Initiation Set** Kitted sterile package contains: • Dual vented prime line (2)
2403	Lung Perfusion Termination Set	**Lung Perfusion Termination Set** Kitted sterile package contains:

Part Number	Name	Description
		• Lung flush collection bag and line
2404	Lung Manual Inflation Set	Manual Inflation Bag
2460	Lung Preservation Gas Cylinders	(Quantity 2) These ultra-lightweight cylinders contain a gas mixture that has been optimized for lungs supported on the OCS™, when operating in Preservation Mode.
2461	Lung Monitoring Gas Cylinders	(Quantity 2) These ultra-lightweight cylinders contain a gas mixture that has been optimized for lungs supported on the OCS™, when operating in Monitoring Mode.
2450	Lung Wireless Monitor	A small monitoring system with an LCD screen and controls for configuring system functions and screen displays, and for adjusting system settings during use. When removed from its docking station on the OCS™ Lung Console, the Wireless Monitor operates wirelessly, powered by its own battery.
2451	SaO_2/Hematocrit Probe	A probe that attaches to the Lung Perfusion Module in order to measure the arterial oxygen saturation and hematocrit in the perfusate leaving the lung through the left atrium.
2452	SvO_2/Hematocrit Probe	A probe that attaches to the Lung Perfusion Module in order to measure the venous oxygen saturation and hematocrit in the perfusate entering the lung through the pulmonary artery.

APPENDIX A. SYMBOL GLOSSARY

This glossary describes the symbols used on the packaging for the OCS™ Lung System.

Symbol	Standard and Symbol Reference	Standard Title	Symbol Definition
	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.	Prescription only
	ISO 7000-2497	Graphical symbols for use on equipment.	Date of manufacture
	ISO 7000-3082	Graphical symbols for use on equipment.	Manufacturer
	ISO 7000-2493	Graphical symbols for use on equipment.	Catalog Number
	ISO 7000-2498	Graphical symbols for use on equipment.	Serial Number
	ISO 7000-2492	Graphical symbols for use on equipment.	Batch code
	ISO 7000-2501	Graphical symbols for use on equipment.	Sterilized using ethylene oxide treatment
	ISO 7000-2503	Graphical symbols for use on equipment.	Sterilized using steam or dry heat
	ISO 7000-2606	Graphical symbols for use on equipment.	Do not use if package is damaged
	ISO 7000-0434A	Graphical symbols for use on equipment.	Attention: Read all warnings and precautions in instructions for use
	ISO 7000-2607	Graphical symbols for use on equipment.	Use-by date; Expiration date is identified to the right of this hour glass symbol
	ISO 7010-M002	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use
	ISO 7010-M002	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use
	ISO 7000-1641	Graphical symbols for use on equipment.	Consult instructions for use
	ISO 7000-1051	Graphical symbols for use on equipment.	Do not reuse

Symbol	Standard and Symbol Reference	Standard Title	Symbol Definition
	ISO 7000-2608	Graphical symbols for use on equipment.	Do not resterilize
	-	-	Proof of product compliance to North American safety standards, per Intertek
	IEC 60417-5140	Graphical symbols for use on equipment.	Non-ionizing, electromagnetic radiation
	-	-	The weight of the OCS and perfusion module
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	WEEE—Subject to waste electrical and electronic equipment regulations, i.e. not for general waste
	IEC 60529	Degrees of Protection provided by enclosures (IP Code).	Level 1 ingress protection
	ISO 7000-0632	Graphical symbols for use on equipment.	Temperature limit
	ISO 7000-0626	Graphical symbols for use on equipment.	Keep dry
	ISO 7000-2724	Graphical symbols for use on equipment.	Non-pyrogenic
	ISO 7000-0624	Graphical symbols for use on equipment.	Keep away from sunlight
	ISO 7000-2621	Graphical symbols for use on equipment.	Atmospheric Pressure Limitation
	ISO 7000-2620	Graphical symbols for use on equipment.	Humidity limitation
	ISO 7000-0623	Graphical symbols for use on equipment.	This way up
	—	—	Handle with Care

Symbol	Standard and Symbol Reference	Standard Title	Symbol Definition
	ISO 7000-0621	Graphical symbols for use on equipment.	Fragile, handle with care
CE	Directive 93/42/EEC	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)	CE marking indicates product conformance with the applicable European Union Directives
EC REP	ISO 15223-1: 2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	EC REP—Authorized Representative in the European Community
	CFR 49 Section 172.446	Code of Federal Regulations, Transportation	Miscellaneous hazardous materials, class 9

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200 Minuteman Rd., Suite 302 Andover, MA 01810, USA
Tel: +1 978 552 0900
Service: +1 978 552 0999
Fax: +1 978 552 0978
Website: www.transmedics.com

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