TransMedics®
Organ Care System™
OCS Heart User Guide

Software Version 3.3.7

PN 100005602 Rev 1

REF 1502

2797

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2797
This device complies with the Medical Device Directive 93/42 EEC.

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Patents:
For U.S. and international patents, refer to www.transmedics.com/patents.

Manual PN & Rev
PN 100005602, Rev 1

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

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SYMBOLS USED IN THIS GUIDE AND ON THE HPM AND HEART CONSOLE

Symbol	Meaning	Symbol	Meaning
	Direct current		Pump Flow
	Indicates On (only for a part of the equipment)		Prime Solution and Blood Infusion Port
	Indicates Off (only for a part of the equipment)		Defibrillator Connector
	Pulmonary Artery		Oxygenator Vent
	Aorta		Solution #1 Infusion Line Connection Location
	Coronary Flow		Solution #2 Infusion Line Connection Location
	Oxygen Saturation/Hematocrit		Solution #3 Infusion Line Connection Location
	Aortic Flow		Solution #4 Infusion Line Connection Location
	Stopcock Flow Position		Injection Port
	Pump On; ECG Synchronization Off		Arterial Blood Sampling Port
	Pump On; ECG Synchronization On		Venous Blood Sampling Port
	Pump Off		Battery Active, indicates Monitor (single battery), or OCS (three batteries) and displays the time remaining for each battery
	Pump Fault Alarm		Battery Removed
	Gas On: Bottle icon shows relative amount of gas remaining in hours and minutes (hh:mm) and the current flow rate in milliliters/minute		Battery Capacity Alarm, displays remaining time
	Gas Off		Battery Fault Alarm
	Gas Capacity Alarm		No cassette is inserted
	Data Card is inserted		The cassette is inserted and that the channel is in Auto or Manual Mode

Symbols Used in this Guide and on the HPM and Heart Console

Symbol	Meaning	Symbol	Meaning
	Data Card is transferring		The cassette is inserted but the channel is not infusing
	Data Card Fault		The channel requires attention
	Data Card is not inserted		Wireless Connected
	Gas Fault Alarm		Wireless Fault Alarm

GLOSSARY OF TERMS

Term	Meaning
Annotations	Notes or comments entered during the preservation session which are automatically stamped with the time of entry and saved in the session file. Annotations are automatically transferred with the file to a data card. User can enter up to 60 characters at a time on two lines. Annotations can be a combination of individually input characters or selections from a list of default key words and phrases.
ABG	Arterial Blood Gas
AO	Aorta
AOF	Aortic Flow. The Aortic flow is displayed on the Wireless Monitor in liters/minute.
Aortic Flow Probe	A probe that the user attaches to the Heart Perfusion Module. It is used to measure the aortic blood flow into the heart.
AOP	Aortic Pressure. Aortic pressure is displayed on the Wireless Monitor in millimeters of mercury (mmHg).
CF	Coronary Flow. During perfusion, the Coronary Flow is displayed on the Monitor in liters/minute.
Circuit	Refers to the Heart Perfusion Module with the solutions running through it.
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.
ECG	Electrocardiogram
Erase bar	A vertical line displayed on the waveform. Newest data is displayed to the immediate left of the erase bar. The bar is aligned with other eraser bars displayed at the same time.
HCT	Hematocrit percentage
Heart Perfusion Set	A sterile, single-use Heart Perfusion Module and accessories. The Heart Perfusion Module consists of an organ chamber, tubing, connectors, blood reservoir, oxygenator, pump head (dome) for interface with the OCS circulatory pump, blood warmer, user-controlled valves, integrated pressure and temperature sensors, ECG/ defibrillation electrodes, and the electronics that permit communication between the Heart Perfusion Module and the OCS. Essentially, it provides a closed circuit to perfuse an adult-sized heart with warmed oxygenated, blood supplemented with the Heart Solution Set, and to monitor the organ and preservation conditions. The Heart Perfusion Set also includes the sterile accessories necessary to collect and filter the donor blood, connect the heart to the device, and administer and drain cardioplegic solutions.
Heart Solution Set	The proprietary, sterile TransMedics Priming and Maintenance Solutions.
HR	Heart Rate measured in beats per minute (bpm)
Lactate Venous-Arterial Differential	The venous lactate concentration minus arterial lactate concentration.
L/min	Liters per minute
Maintenance Solution	The proprietary, sterile TransMedics Maintenance Solution, included in the Heart Solution Set, is designed to ensure an appropriate nutritional environment for the organ during preservation.
mL/min	Milliliters per minute
mm/sec	Millimeters per second
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. With the Base installed, the organ chamber is at bedside level. During

Term	Meaning
	transport, raise the two-position handle to push the system. With the Mobile Base removed, user can set the system flat or carry it with the lift handles.
Organ Care System	The Organ Care System (OCS) houses the permanent circulatory pump, the batteries, a data card, the gas delivery subsystem, and the reusable flow and SvO_2/HCT Probes. During preservation it houses the single-use Heart Perfusion Module. The OCS also provides a docking station for the portable Wireless Monitor, and storage for the TransMedics Maintenance Solution. The multi-channel Solution Delivery Subsystem incorporated into the OCS is used to set up and monitor the infusion of TransMedics Maintenance Solution during organ preservation.
PA	Pulmonary artery
PAP	Pulmonary artery pressure. Displayed on the Wireless Monitor in millimeters of mercury (mmHg).
Power-cycle	Power-cycle the system means use the On/Off switch on the side of the OCS to turn the system OFF, wait 5 seconds, and then turn it ON.
Priming Solution	The proprietary, sterile TransMedics Priming Solution, included in the Heart Solution Set, is circulated through the Heart Perfusion Module along with donor blood, prior to organ connection and during organ preservation.
Pump Compliance Chamber	Located between the circulatory pump and the oxygenator, the red-colored pump compliance chamber affects flow to the aorta.
Pump Flow Probe	A probe that user attaches to the Heart Perfusion Module. It is used to measure OCS pump flow.
Session	A session is created in internal system memory when the system is set to Run Mode. 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	Standby-cycle the system means to enter in Standby mode and then to exit Standby. The system automatically runs the Self Test.
SvO_2	Mixed venous oxygen saturation percentage
SvO_2/HCT Probe	A probe that user attaches to the Heart Perfusion Module. It is used to measure the venous oxygen saturation and hematocrit in the blood leaving the heart through the pulmonary artery cannula.
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, 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™ Heart System, as well as a system overview, how to set up the system, understanding the Wireless Monitor controls and functions, troubleshooting, cleaning, and maintaining the system. This guide is to be reviewed prior to using the system, noting the Warnings, Cautions, and Notes throughout the guide.

A TransMedics representative must install and activate each system before a qualified health care professional can use it.

1.2. User Training Requirements

The OCS™ Heart System is intended for use only by qualified healthcare professionals trained in the use of the OCS™ Heart System.

Completion of the TransMedics training program is required prior to use of the OCS™ Heart System. 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) Heart is indicated for the preservation of donation-after-brain-death (DBD) hearts initially deemed unsuitable for procurement and transplantation at initial evaluation due to limitations of prolonged cold static cardioplegic preservation (e.g., > 4 hours of cross-clamp time). The OCS Heart System is also indicated for the *ex vivo* reanimation, functional monitoring, and beating-heart preservation of donation-after-circulatory-death (DCD) hearts.

1.4. Contraindications

Do not use the OCS™ Heart System if any of the following conditions exist:

- Moderate to severe aortic valve incompetence in donor heart
- Observed myocardial contusion on donor heart
- Known unrepaired interatrial or interventricular defects including patent foramen ovale.

1.5. Warnings

- **The OCS Heart System is not intended for the preservation of donor hearts deemed suitable for procurement and transplantation using cold static cardioplegic preservation techniques (e.g., ≤4 hours of cross-clamp time). In the PROCEED II randomized controlled trial, survival was lower in patients transplanted with DBD donor hearts preserved with the OCS Heart System compared to patients transplanted with donor hearts preserved with cold static preservation.**
- Pathological evidence of myocardial injury has been observed in some turned-down DBD hearts preserved with the OCS Heart System. It is unknown whether the injury was due to the use of the OCS

Heart System. The transplant turn-down rate of post-preservation donor hearts is higher after OCS Heart System preservation than after cold static preservation

1.6. Precautions

- A device malfunction or user error could lead to a potential loss of a donor organ.
- Only trained users should use the OCS™ Heart System.
- The impact of OCS Heart System on long-term clinical outcomes is unknown. In studies supporting safety and effectiveness, the mean follow-up was 37.6 $\pm$ 9.1 months.

1.7. Patient Counseling

Physicians should review the following information when counseling patients about the TransMedics Organ Care System (OCS) Heart System:

- Proceeding with heart transplantation is an individual decision between a candidate patient and their transplant team and involves a number factors including:
    - The patient's clinical status (e.g., stable out-patients on medical therapy, stable outpatients requiring mechanical circulatory support devices, critically ill in-patients requiring life support).
    - The availability of a potentially suitable donor heart.

- An important factor in determining the suitability of a potential DBD donor heart is the expected cross-clamp time duration from donor to recipient.

- The OCS Heart is indicated for the preservation of DBD hearts deemed unsuitable for transplantation at initial evaluation due to the limitations of prolonged cold static cardioplegic preservation (e.g., > 4 hours of cross-clamp time) and is also indicated for the ex vivo reanimation, functional monitoring and beating heart preservation of DCD hearts.

- Physicians and patients should be aware that in the historical PROCEED II randomized controlled trial conducted between 2008-2013 with an earlier design iteration of the OCS Heart System, which studied standard donor hearts *suitable for cold static cardioplegic preservation*, overall survival was lower in patients transplanted with DBD hearts preserved with the OCS Heart System compared to patients transplanted with donor hearts preserved with cold static preservation (see Appendix C for additional details). PROCEED II was the only randomized controlled trial comparing the safety and effectiveness of DBD heart preservation using the OCS Heart System to that using cold static storage.

- The OCS Heart System was studied between 2015 and 2020 in the single-arm Heart EXPAND and associated Continued Access Protocol (CAP) studies that enrolled non-standard DBD donor hearts, which showed a 94.6% patient survival at 30 days post-transplant and 89.3% freedom from severe PGD (left or right ventricle) in the first 24 hours post-transplant (see Appendix B for additional details). Patients should review the OCS Heart System Patient Brochure that describes the device, the benefits and risks, and provides an overall summary of the clinical experience with the OCS Heart System.

- In cases in which transplantation with an available DBD donor heart would require prolonged cold static cardioplegic preservation, patients and physicians should consider the benefits and risks of proceeding with heart transplantation using the OCS Heart vs. the risks associated with waiting for a DBD donor heart that would not require prolonged cold static cardioplegic preservation.

1.8. Conventions

The terms *system*, *OCS™ Heart System*, the *system* are used interchangeably throughout this manual to refer to the OCS™ Heart 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.

1.9. Supplies

The components, accessories, and supplies required when using the OCS™ Heart System must be used in accordance with this user manual, associated documents, and accepted medical standards. To order additional parts and supplies, see Chapter 10.

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

1.10. Contacting TransMedics

1—For Customer Clinical Support:

Please contact TransMedics prior to departure to donor site using one of the following numbers:

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

2—For Customer 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.

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TransMedics, Inc.
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Prinsessegracht 20
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The Netherlands
Tel: +31 70 345 8570

2. CHAPTER 2: SAFETY INFORMATION

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

2.1. Before Using the OCS™ Heart System

The following conditions may negatively impact perfusion:

- Donor hematocrit < 25%. Low donor hematocrit should be managed by transfusing packed red cells prior to donor blood collection.
- Confirmed bolus doses of inotropic medications immediately prior to donor blood collection. Advise donor OR anesthetist of the blood collection process in advance.
- Unable to collect ≥ 1100 mL donor blood. If unable to collect 1100 mL of donor blood, do not use the OCS™.

2.2. General Warnings and Cautions

WARNINGS—

Failure to abide by the precautions detailed in this document 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.

No modification of this equipment is allowed.

Not to be used for children or pregnant or nursing women.

CAUTIONS—

Always check the expiration date on each package, including the Heart Perfusion Set and the OCS™ Heart Solution Set. If the date has expired, do not use the item.

Always follow your institutional protocols for handling and disposal of blood-contaminated materials.

All donors must be properly screened for infectious diseases as part of the standard of care for heart transplants. User exposure to donor blood from leakage at connection sites during the blood collection process may occur. Follow Universal Precautions.

2.3. Electrical Safety

This section provides warnings and cautions related to electrical safety.

WARNINGS—

Never use a converter adapter to plug the 3-pronged AC plug into a 2-pronged ungrounded wall outlet. Doing so may result in electric shock to the operator and damage to the equipment.

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

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. 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 could expose the user to electrical or physical hazards that could cause serious injury or shock and will void the warranty. Accidentally contacting the electrical circuits inside the housings may result in electric shock to the operator and damage to the equipment.

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.

Do not dispose of OCS™ battery packs in an incinerator or other fire. The cells may explode. Check with local codes for special disposal instructions. If a fire occurs, use institutional procedures for putting out a lithium fire. Do NOT use water.

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

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.

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. 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.

To avoid a possible shock, stand clear of the HPM during defibrillation.

CAUTIONS—

Use the system only at the temperatures, relative humidities, and altitudes specified in the System Specifications section of this manual.

Carefully wrap the OCS™ power cord around the power cord wrap tabs when the device is not plugged into AC power.

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

To fully de-power the system, the user must unplug the system from the AC power receptacle and either fully deplete the OCS™ batteries, or remove them completely from the system. See Section 4.4.2.1 for details.

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.

2.4. Mechanical and System Safety

This section provides warnings and cautions related to mechanical and system safety.

WARNINGS—

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

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.

Do not to look into the high-pressure exhaust sources while connecting the gas cylinder to the regulator. 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 high-pressure relief valve and/or atmospheric vent and can result in an eye injury (Figure 1).

Figure 1: Left: CPI Regulator (note smooth body); Right: PI Regulator (note threaded body)

CAUTIONS—

Inspect TransMedics shipments to ensure all items are included and that there has been no shipping damage.

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.

Before use, aseptically open and inspect each component, checking for any cracks, leaks, or other damage that might impact use. If either the HPM, the accessories or their packaging is damaged, do not use the components and contact TransMedics.

Keep the Heart Console surfaces and cables clean, cleaning all surfaces and cables before and after each use. Dispose of the HPM, then clean and disinfect any bodily fluid or blood-contaminated areas of non-sterile parts of the system according to the instructions in Chapter 7. Do not remove the SDS from the OCS™ except as required for cleaning. 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.

Do not attempt to sterilize the OCS™ or any of its non-sterile components. Doing so may damage the system. The HPM and its sterile accessories are intended for single use only. Do not attempt to re-sterilize any of these single use components.

During transport, position the OCS™ so that it never sits at an angle of greater than 15 degrees from vertical. Operating the OCS™ at angles greater than 15 degrees may disrupt fluid paths in the HPM and lead to system malfunction.

If a regulator failure occurs, monitor arterial blood gas and gas cylinder pressure closely as the cylinder will expire more quickly than under normal conditions. If any unexpected changes in arterial blood gas occur, turn gas flow rate to 0 ml/min, close the valve on the gas cylinder and discontinue its use.

Carefully route system power cords and defibrillator cords to reduce the possibility of tripping or disrupting operation during system use or transport.

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. 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.

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.

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

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

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

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 HPM and lead to system malfunction.

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

Use only accessories and supplies 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.)

2.5. Patient and Organ Safety

This section provides warnings and cautions related to patient and organ safety.

WARNINGS—

The OCS™ Heart Solution Set is intended for use only with the OCS™ Heart System for heart transplantation. It should not be administered in any way directly to a patient.

The OCS™ Heart System is intended only for preservation of an explanted heart. It is not intended for direct contact with any patient.

Always follow your institutional guidelines for performing 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. Use aseptic technique when:

- Opening the sterile drape or the heart chamber's inner sterile membrane
- Accessing the docked Wireless Monitor's controls through the clear film of the TransMedics sterile drape
- Accessing the heart and electrodes through a sterile membrane attached to the inner organ chamber cover
- Preparing and connecting solutions for use in the module
- Collecting, filtering, and transferring blood to the reservoir
- Making injections into the module
- Sampling fluids from the module.

All parts of the HPM and its sterile accessories are sterilized by Ethylene Oxide and intended for single-use only. Do not attempt to re-sterilize or reuse the HPM or any of the sterile accessories. Reuse or re-sterilization may compromise the structural integrity of the sterile components, thus creating a potential risk to patient safety.

CAUTION—TransMedics-approved solutions have been tested on the TransMedics OCS™ Heart System. Non-TransMedics-approved solutions have not been tested, and TransMedics cannot assure their compatibility. If non-TransMedics solutions are used with the OCS™ Heart System, the physician must ensure their compatibility as part of the overall fluid mix. Potential hazards include interactions, inaccurate delivery rates, inaccurate pressure alarms, and nuisance alarms.

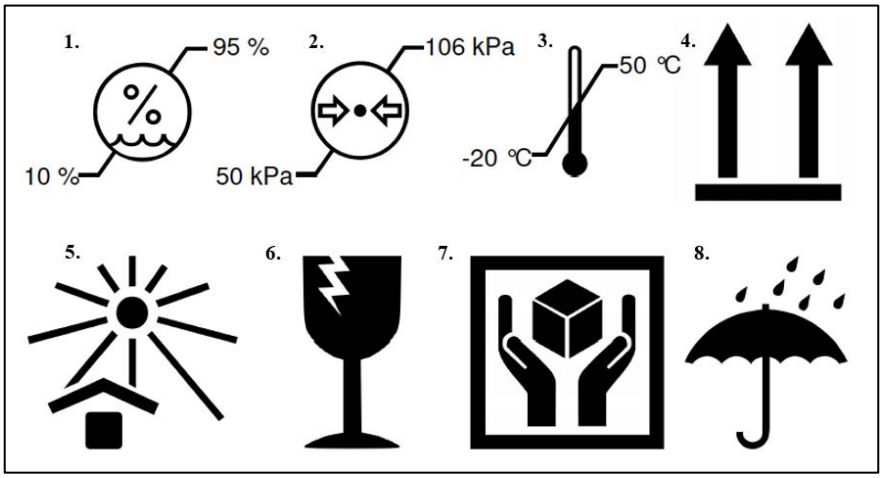
2.6. Potential Adverse Effects

Below is a list of the potential adverse effects (e.g., complications) associated with receiving a donor heart preserved using the OCS Heart System, which are typical of the heart transplant procedure:

- Death
- Acute rejection
- Airway anastomotic complications
- Arrhythmia
- Aspiration
- Bleeding (major)
- Emphysema
- Fever
- Focal or systemic major infection
- Gastro esophageal reflux disease
- Graft failure
- Hemodynamic instability
- Hemothorax
- Hepatic dysfunction
- Hyperammonaemia
- Malignancy (post-transplant lymphoproliferative disorder (PTLD)
- Multiple organ failure
- Myocardial infarction
- Neurological dysfunction
- Pancreatitis, peptic ulceration
- Pleural bleeding
- Pleural effusion
- Pneumothorax
- Primary Graft Dysfunction (PGD)
- Pulmonary embolism (PE)
- Pulmonary infarction
- Renal dysfunction
- Respiratory failure
- Sepsis
- Tracheobronchitis/pneumonitis/pneumonia
- Venous thromboembolism (deep venous thrombosis [DVT])
- Wound dehiscence.

2.7. Shipping, Handling, and Storage Requirements

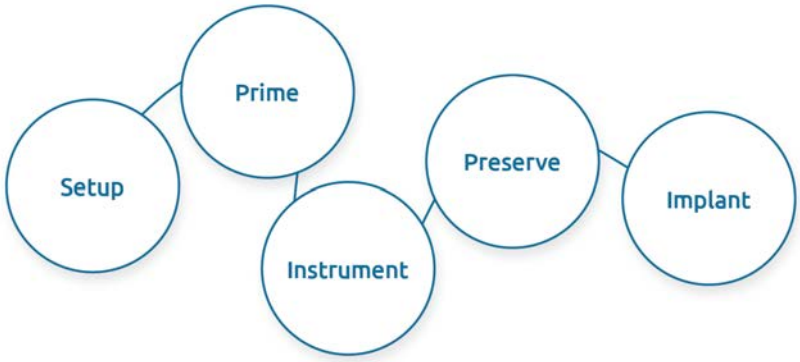
Figure 2: Shipping, Handling, and Storage Requirements Symbols



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. 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.

3. CHAPTER 3: OVERVIEW OF OCS™ HEART SYSTEM



The TransMedics® OCS™ Heart System preserves the heart in a near-physiologic beating state immediately after explant from a donor and connection to the system, during transportation and until disconnection from the system for transplant. The heart is perfused with a warmed, donor blood-based perfusate that is supplemented with nutrients and oxygen in a controlled and protected environment. The user manages important physiological and system parameters with the Wireless Monitor and a portable blood analyzer, and intervenes, as necessary, by adjusting Wireless Monitor settings and using manual controls and ports.

The system maintains heart viability by providing a near-physiologic controlled environment for the organ. Blood is collected from the organ donor and filtered with the TransMedics Blood Collection Set. The heart is continuously perfused with warmed, oxygenated blood, supplemented with the TransMedics proprietary Maintenance and Priming Solutions (i.e., the OCS Heart Solution Set).

This chapter describes how to identify physiologic information, to determine the state of the OCS™ Heart System and how to operate the system through the user interface.

3.1. OCS™ Heart System Components

The OCS™ Heart System is composed of 3 major components:

1. **OCS™ Heart Console (Heart Console):** This is a compact electromechanical device that contains an integrated pulsatile perfusion pump, batteries, perfusate warmer, and pressure, flow and SvO_2/HCT probes. In addition, it has an integrated Wireless Monitor that allows the operator to control and display critical perfusion parameters.
2. **OCS™ Heart Perfusion Set (HPS):** The HPS consists of the Heart Perfusion Module (HPM) and HPS Accessories. The HPM is a sterile, single use perfusion module that contains embedded sensors (pressure, temperature), perfusion circuits, and perfusate sampling ports. The HPS Accessories are sterile, disposable accessories necessary to instrument the heart and manage the perfusate.
3. **OCS™ Heart Solution Set (OCS Heart Solution Set):** The set consists of two proprietary heart preservation solutions, the OCS Priming Solution and the OCS Maintenance Solution, to replenish the nutrients and hormones (adenosine) that the metabolically active donor heart requires.

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 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.

The figures below show the OCS™ Heart System and identifies the components.

Figure 3: OCS™ Heart System (with Cover)

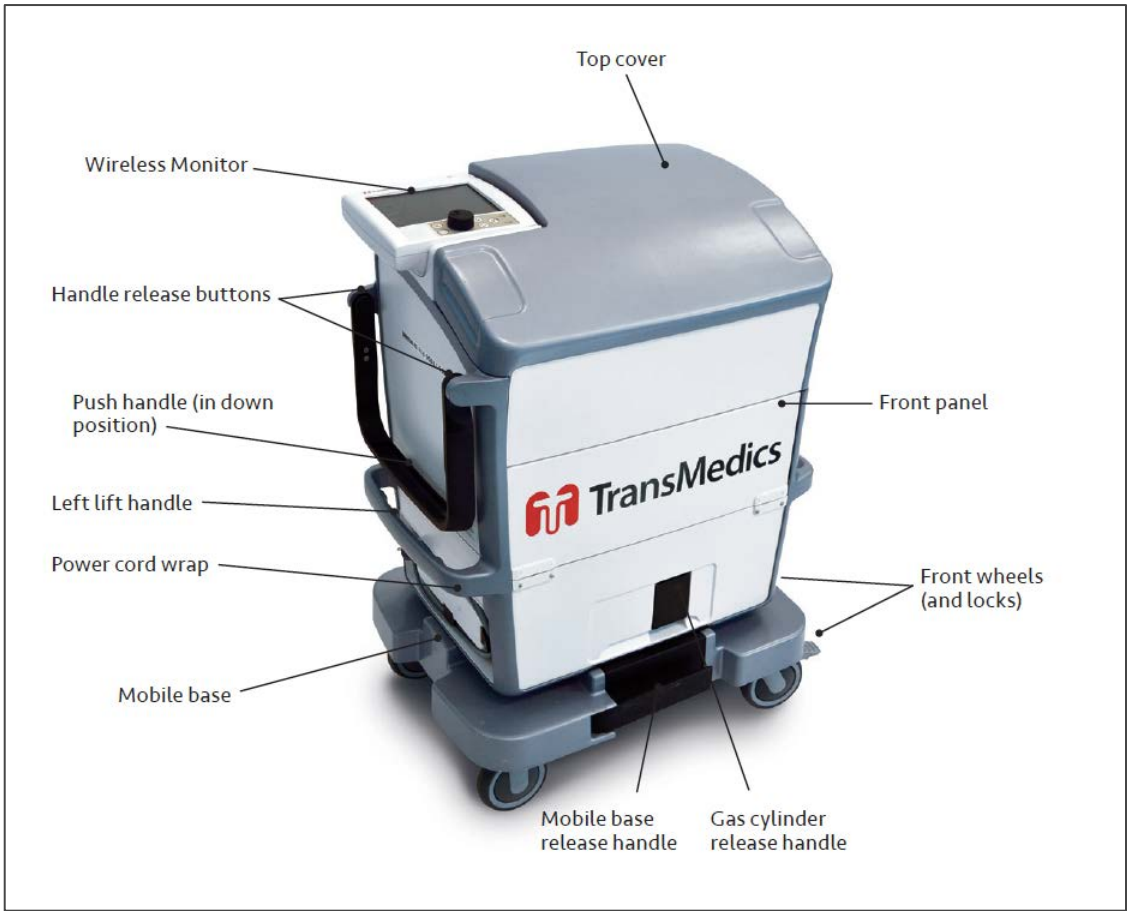
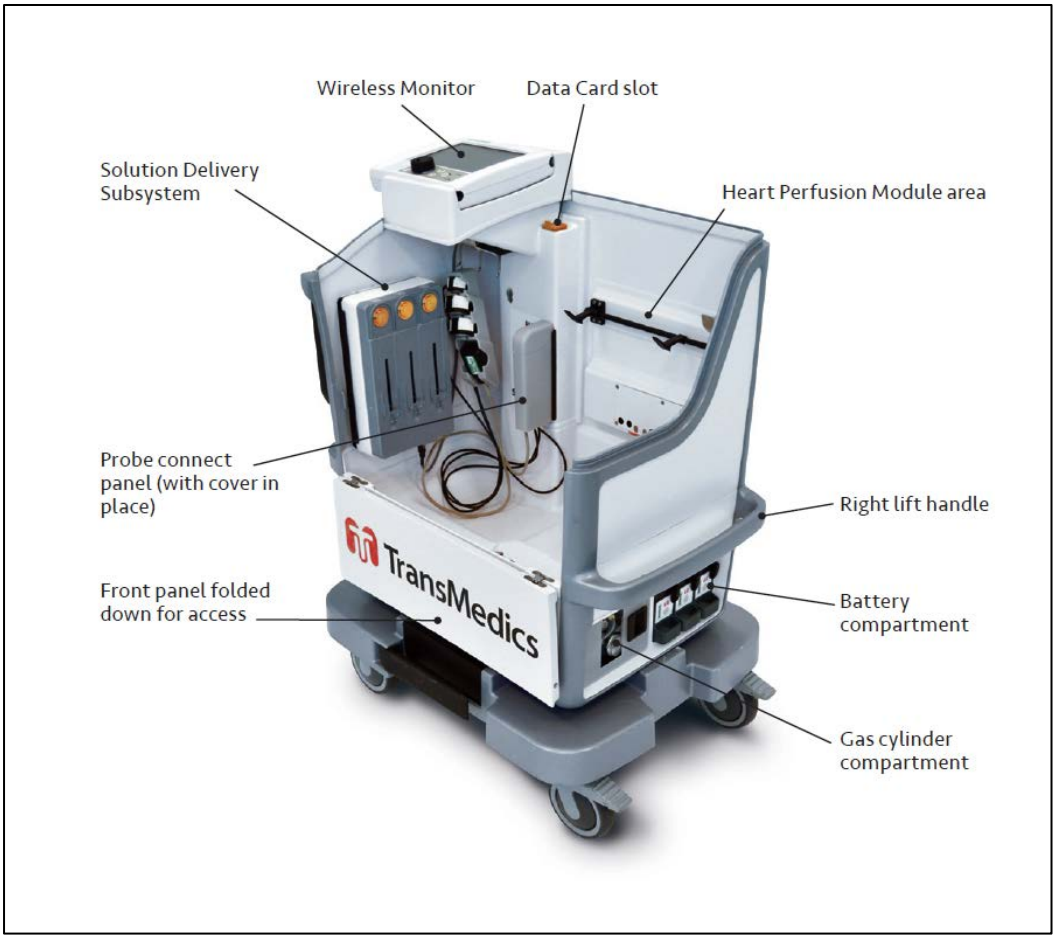


Figure 4: OCS™ Heart System (without Cover)



3.2. Heart Console

3.2.1. Wireless Monitor

The Wireless Monitor tracks the vital functions of a heart preserved with the OCS™ Heart System and displays organ and system parameters (Figure 5). The Wireless Monitor can be used while it is docked on the Heart Console, or it can be removed (undocked) and used remotely, such as when transporting the organ.

CAUTION—Before undocking the Wireless Monitor, check for an alarm to make sure it is safe to undock the Wireless Monitor. If a Wireless Monitor related alarm is present, 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. If connection is lost, verify all parameters are as expected once connection is restored.

Figure 5: Wireless Monitor

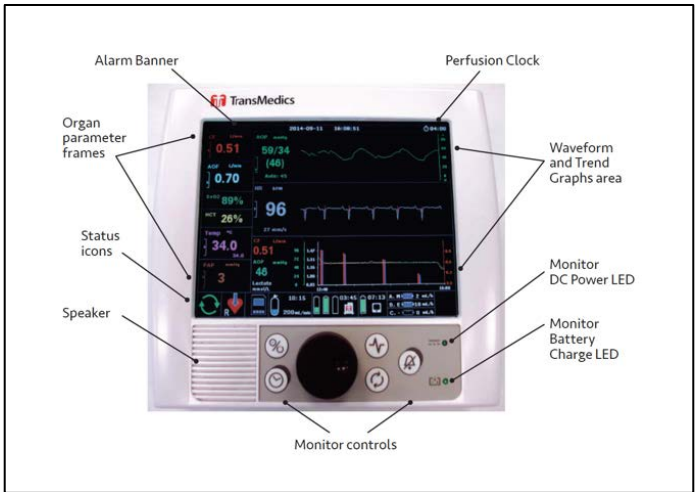


Figure 6: Wireless Monitor Buttons

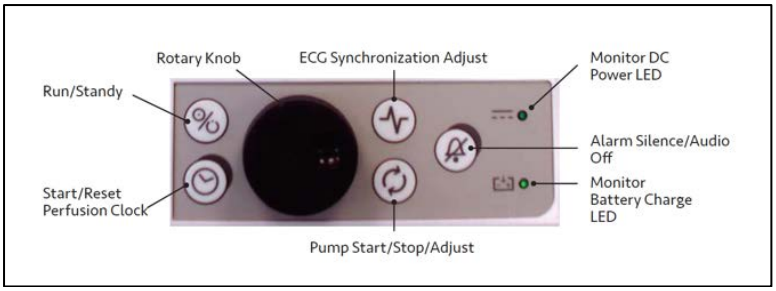


Table 1: Wireless Monitor Components

Monitor Component	Description
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.
Organ Parameters	Parameter values are displayed in real time. Each organ parameter frame includes the name, units of measurement, the value, the range relative to the configured alarm setting, and whether the alarm is disabled.
Status Icons	The status icons that appear along the bottom row of the Wireless Monitor help you quickly determine information about the system and preservation session.
Perfusion Clock	The clock icon is displayed in the upper right corner of the Wireless Monitor, along with the elapsed time when the Perfusion Clock is running.
Graphical Frames (Waveforms and Trends)	The graphical frames area can be configured to show waveforms and trend data.
Power and Battery Indicators	The two LED lights on the Wireless Monitor's control panel provide information about Wireless Monitor power status.

NOTE—The middle and bottom graphical frame can be configured to display either real-time pressure waveforms, the ECG waveform, or trend data.

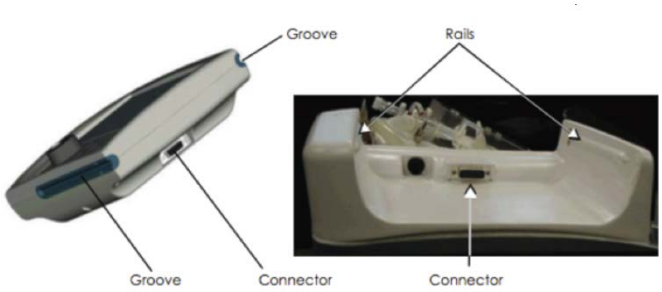
Table 2: Wireless Monitor Buttons

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™. If the Wireless Monitor is not docked, pressing this button has no effect.
	Perfusion Clock	Press this button to start or hold to reset the Perfusion Clock. The clock is displayed in hours and minutes.
	ECG Synchronization/ Adjust	Press this button to turn ECG Synchronization on and off. Press and hold this button for two seconds to display the Synchronization Adjust Menu.
	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 display or remove the pump adjust menu.
	Rotary Knob	Turn this knob to highlight selections. Press this knob to select highlighted items and to display the Configuration Menu.

3.2.1.1. Docking and Undocking the Wireless Monitor

The Wireless Monitor has side grooves which slide over matching rails on the top of the OCS™. A connector on the side of the Wireless Monitor inserts into a connector on the system.

Figure 7: Wireless Monitor Docking



<u>To Dock the Wireless Monitor</u>:

Position the Wireless Monitor so that its grooves line up with the rails on the system (Figure 7). Slide the Wireless Monitor all the way into the system Wireless Monitor cradle until the receptacle on the Wireless Monitor locks into the connector on the system. For reliable operation, make sure that the Wireless Monitor is fully inserted into the OCS™ 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.

<u>To Undock the Wireless Monitor</u>:

To undock the Wireless Monitor, use both hands to pull it straight along the rails until the Wireless Monitor clears the OCS™.

3.2.1.2. Using the Wireless Monitor Remotely

When undocked from the system, the Wireless Monitor operates from its own battery pack.

During remote operation, all controls operate normally except the Run/Standby button ( ) which functions only when the Wireless Monitor is docked to the system. If the Wireless Monitor is moved out of range of the system, a warning tone emits and continues until the connection is re-established. If the Wireless Monitor battery fails, the screen blanks, and you cannot use the Wireless Monitor until it is docked on the system. 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.

NOTE—Even if the remote Wireless Monitor screen is blank when no power is available, unless the OCS™ loses power, the OCS™ continues working at the current settings. When the Wireless Monitor is reconnected, the screen will display all previous settings and parameters.

If the Wireless Monitor is out of range of the OCS™ for 10 minutes, it turns itself off. While the Wireless Monitor is off, the rest of the system continues to function at the existing settings. Once the Wireless Monitor is re-docked on the OCS™, it turns itself back on and full monitoring functionality is restored. When the Wireless Monitor is returned in range, verify all parameters are as expected. If the OCS™ has stopped functioning, the Wireless Monitor generates an Out of Range alarm. If this occurs, immediately check the OCS™ to verify that the pump is still functioning.

3.2.1.3. Monitor Controls

The Rotary Knob is the main control of the Wireless Monitor (Figure 6). To open the Configuration Menu, press the Rotary Knob. To select different tabs and functions, rotate the knob left and right. The buttons on the Wireless Monitor are either single or dual function. Buttons with a shaded background (Start/Reset Perfusion Clock and Alarm Silence/Audio Off) function by being pressed once or pressed and held. The Run/Standby and Pump buttons can only be pressed to initiate their function (Table 2).

3.2.1.3.1. Using the Configuration Menu

Press the rotary knob to display the Configuration Menu. The Configuration Menu is organized by tabs: Use the System tab to configure global system settings such as the time and date. Use the Resting tab to configure parameters such as alarm ranges, gas flow rate or blood temperature. Use the Actions tab to perform immediate tasks such as to display system status or display the alarm summary.

Menu selections are effected using the rotary knob. As the knob is rotated, menu items are highlighted. When the user presses the knob on a highlighted item, the item becomes selected. Depending on the menu item, it may be immediately acted on, such as Accept, or it may lead to another menu, such as Alarms, or it may enable configuration of a value, such as Gas Flow Rate.

Configuration changes are only committed when the Configuration Menu is exited using the Accept selection. If the Configuration menu is exited using the Cancel selection, the system configuration remains unchanged.

The system does not automatically adjust for Daylight Saving Time. If your area uses Daylight Saving Time, the user needs to manually reset the time to adjust to Daylight Saving Time. Set the system time before starting the perfusion clock. Once the perfusion clock is running, the user cannot set the system time until the user starts a new session.

3.2.1.4. Adjusting the Pump

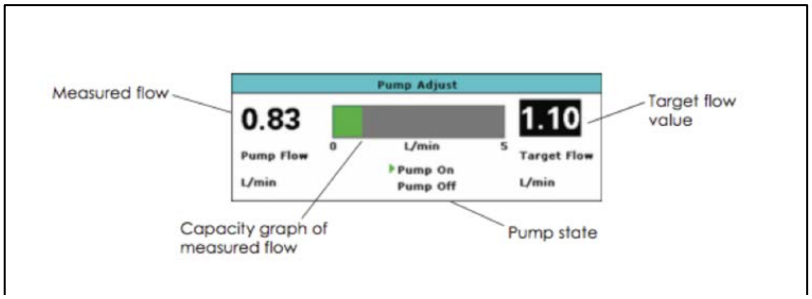
Use the Pump Adjust window to adjust the flow between 0-5 L/min (Figure 8).

3.2.1.4.1. To Adjust the Pump

Press  to open the Pump Adjust window.

- To increase pump flow, turn the Rotary knob clockwise.
- To decrease pump flow, turn the Rotary knob counterclockwise.
- To turn the pump off, turn the Rotary knob all the way counterclockwise until the green arrow in the status icon indicates that the pump state is off.

Figure 8: Wireless Monitor Pump Adjust Window



As you turn the Rotary 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.

To close the Pump Adjust window, press the Rotary knob or  .

CAUTION—Blood warming and gas flow are enabled only when the pump is on. Setting the pump to OFF turns off the pump, the gas, and the blood warmer. When the pump flow is off, physiological parameter alarm monitoring is disabled.

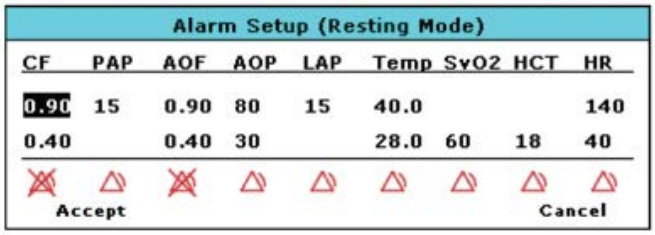
3.2.1.5. Session Settings

Use the Alarm Setup window to configure the alarm ranges and settings for Resting Mode. The user can also configure each physiologic alarm's enable/disable setting individually (Figure 9).

In the Alarm Setup window, rotate the knob to highlight the value the user wants to change and press the knob to activate the selection. Rotate the knob to the desired value and press the knob to set the value. Then exit the menu using the Accept or Cancel selections. Then Accept or Cancel on the Configuration Menu to complete the process.

A icon indicates that an alarm is on and will display on the Wireless Monitor if the parameter changes to a value outside these 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.

Figure 9: Wireless Monitor Alarm Setup Window



CAUTIONS—

The OCS™ will log critical data regardless of the state of the Alarm System.

Set alarm limits to bracket target ranges for early warning of shifts in the perfusion parameters.

NOTE—The OCS™ has factory default ranges for all alarms. Unless new defaults are saved, starting a new session will revert all ranges to the default.

Use the Configuration Menu to specify the amount of gas flow in milliliters per minute. Each time the user begins a new session, the Gas Flow Rate that the user configures is automatically in effect.

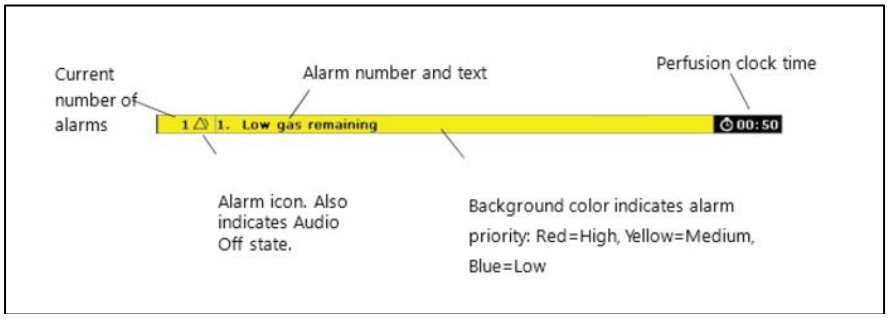
Use the Configuration Menu to specify the temperature set point. The Temp Set Point is the temperature at which the user wants the blood warmer to maintain the blood and other fluids that are perfusing the organ.

The OCS™ is capable of displaying blood gas samples as entered by the user in a trend graph. Use the System tab of the Configuration Menu to configure blood sample units for parameters that can have multiple types of units.

3.2.1.6. Alarm Banner

The system produces both visual and audible indicators of various alarm conditions to alert the user when there is an important physiological or system condition that requires attention. Auditory Alarm Signal sound pressure is approximately 84 dB. The Alarm Banner is displayed at the top of the Wireless Monitor screen. The color of the Alarm Icon area is that of the highest priority alarm in the banner.

Figure 10: Wireless Monitor Banner



The Alarm Banner displays the following types of alarms:

- Physiological alarm (Yellow): Indicates that a measured physiological parameter is extended above or below its alarm limits

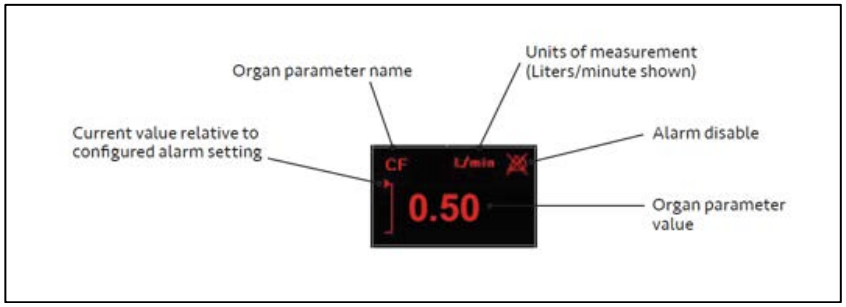
- Capacity alarm (Yellow): Indicates a low battery capacity or a low gas cylinder capacity
- System Fault alarm (Red): Indicates an equipment failure.

3.2.1.7. Organ Parameters

Organ parameter values are displayed in the frames on the left side of the Wireless Monitor and within the graphical frames in the center of the screen, as shown in Figure 11 below. Organ parameter values include:

- CF: Coronary Flow in liters/minute
- AOF: Aortic Flow in liters/minute
- SvO_2: The mixed venous saturation percentage
- HCT: The Hematocrit percentage
- TEMP: Blood Temperature in degrees Celsius
- PAP: Pulmonary Artery Pressure, in millimeters of mercury
- AOP: Aortic Pressure, in millimeters of mercury
- HR: Heart Rate, in beats per minute.

Figure 11: Wireless Monitor Parameter Window



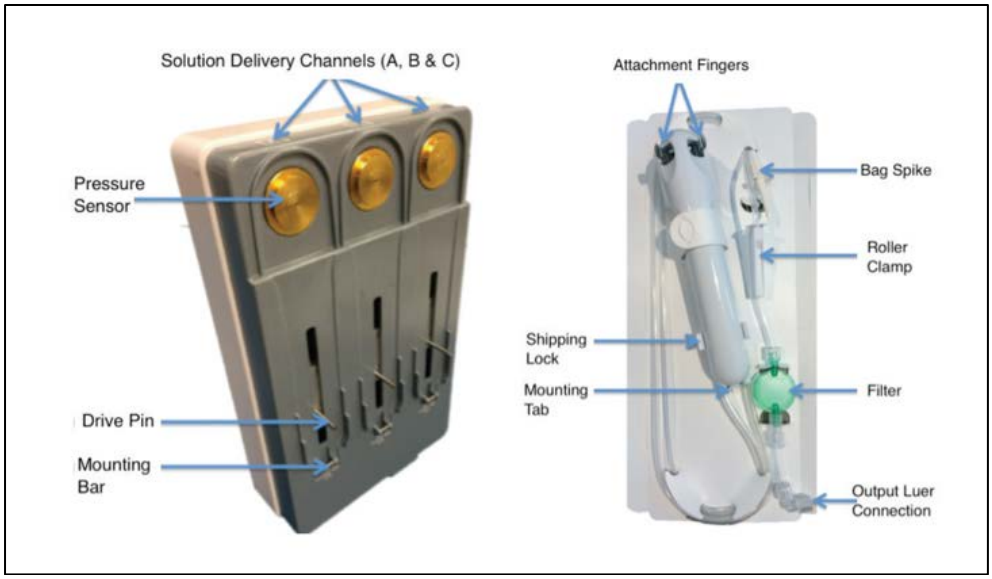
The system displays the following symbols to indicate when values are above the range, below the range, and when data is not available:

- --- (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 system is unable to provide a measured value, e.g. a disconnected probe or no fluid in the circuit.

3.2.2. Solution Delivery Subsystem (SDS)

The SDS in the OCS™ Heart System is used to administer solutions to the HPM throughout organ preservation. This subsystem is comprised of the non-disposable SDS Console and disposable line sets (Figure 12). The SDS Console is incorporated into the OCS™ Heart Console. The disposable line sets are included with the Heart Perfusion Set.

Figure 12: SDS Console and SDS Line Set Components

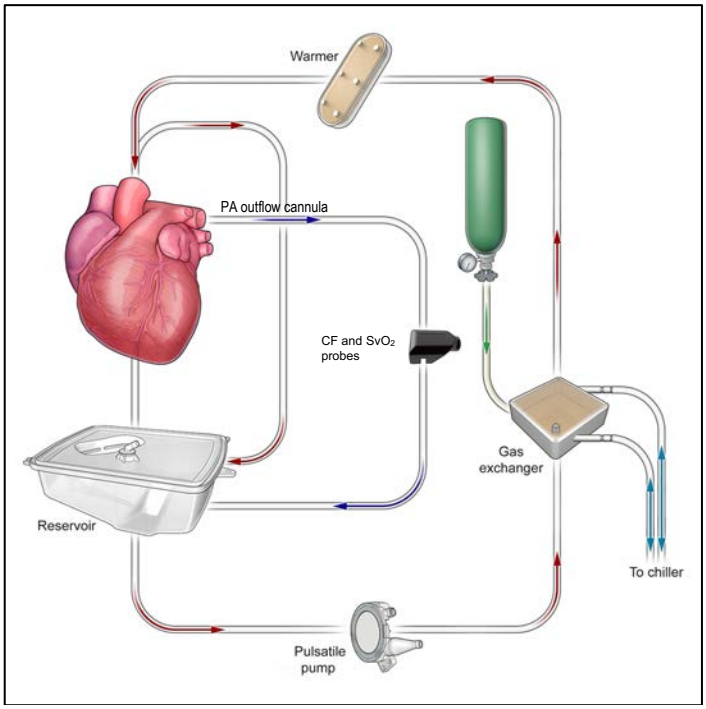


3.2.2.1. Resting Mode Flow

The OCS™ delivers warmed perfusate through the HPM circuit to the heart. Blood supplemented with the TransMedics solutions is pumped from the reservoir by the circulatory pump through an oxygenator and blood warmer. The warm, oxygenated blood is directed to the aorta to perfuse the coronaries. This perfusate flow design is called Resting Mode.

Deoxygenated blood from the coronary arteries then enters the right atrium and passes through the tricuspid valve to the right ventricle. The blood is then ejected through the pulmonary artery to the blood reservoir, where it repeats the process. Figure 13 below illustrates the direction of perfusate flow in the HPM circuit.

Figure 13: OCS™ Heart Resting Mode Flow



3.3. Heart Perfusion Set (HPS)

3.3.1. Heart Perfusion Module (HPM)

The HPM provides the sterile blood circuit and protective environment for a heart within the OCS™. It is designed as a single-use module. The heart is instrumented within the heart chamber of the HPM. The HPM includes:

- Dual-lid heart-specific protective chamber with integrated ECG/defibrillator electrodes
- Integrated and easily accessible blood sampling and de-airing manifold
- Integrated pulsatile pump head
- Integrated low-shear titanium blood warmer
- Integrated blood oxygenator with Hansen quick connect fittings
- Integrated sensors (pressure and temperature) and communication circuitry.

CAUTION—The safe minimum operating volume in the reservoir of the HPM is 300 ml and the safe maximum operating volume is 2000 ml.

Figure 14: HPM Back View

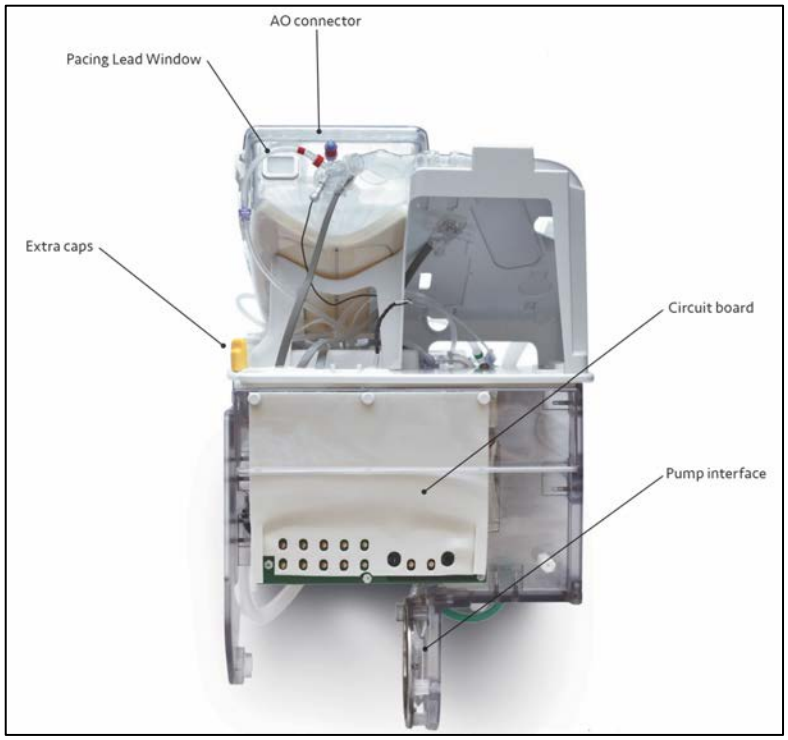


Figure 15: HPM Front View

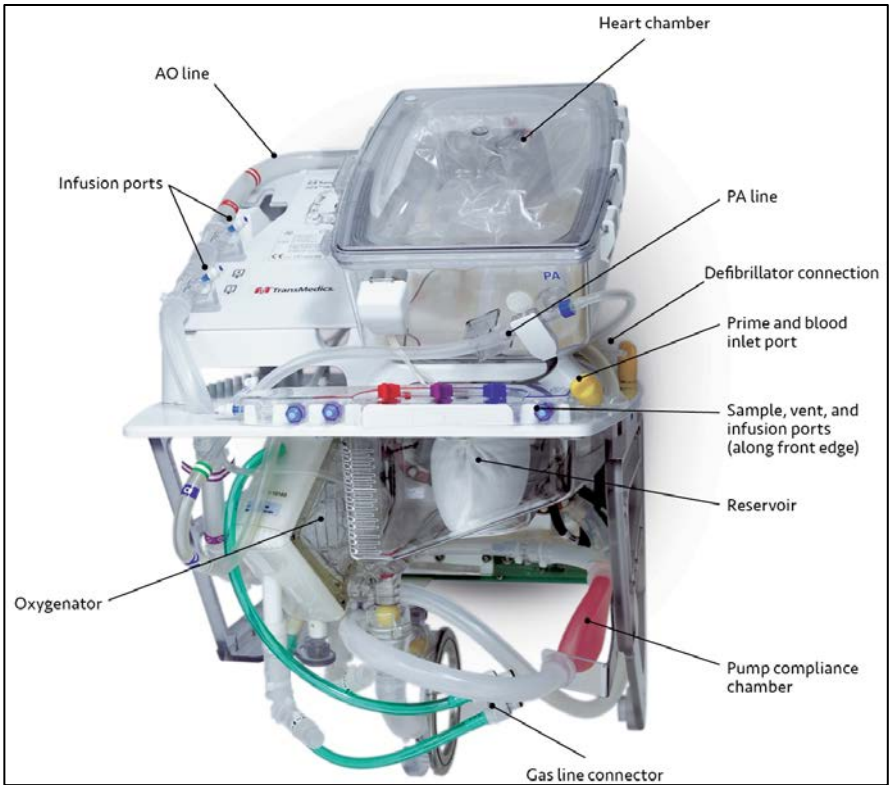


Figure 16: HPM Side View

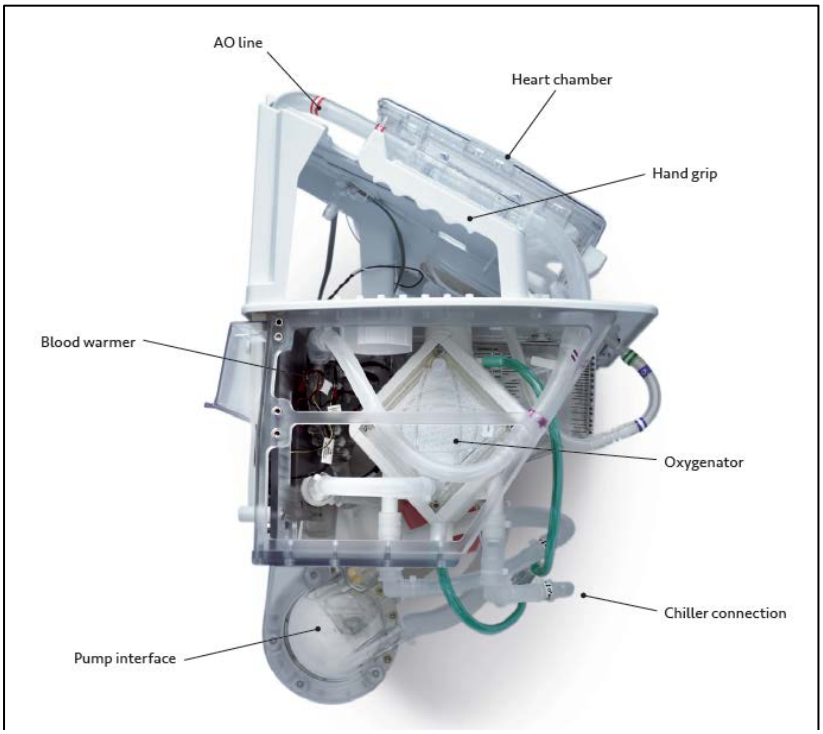
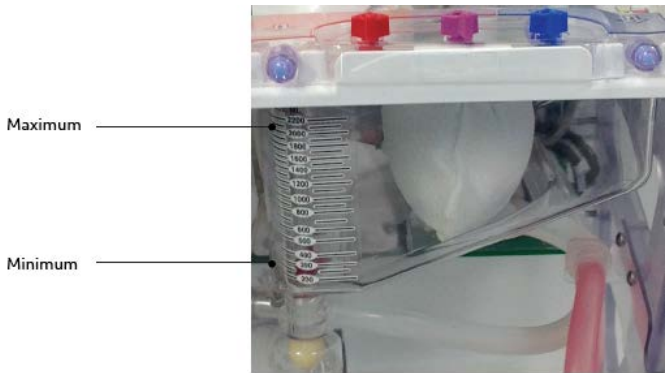


Figure 17: HPM Reservoir Detail



3.3.1.1. Defibrillator

The OCS Heart System can be used with an off-the-shelf defibrillator. Before using the defibrillator with the OCS, perform a Self Test as provided in the instructions for the off-the-shelf defibrillator.

The HPM contains a connector to allow for defibrillation via sterile electrodes located inside of the Organ Chamber. This connector, located next to the Prime and blood inlet port, is for the off-the-shelf defibrillator. The heart may be defibrillated by:

- Connect defibrillator to the HPM defibrillator connector.
- Turn defibrillator selector switch to DEFIB.
- Select energy setting using the down arrow (begin at 10 joules).
- Press CHARGE.
- Once charged, announce CLEAR and ensure that all users are clear of heart and HPM.
- Deliver shock by pressing SHOCK.
- Repeat defibrillation as needed. Higher energy settings may be selected, not exceeding 50 joules.
- Pad location may need to be adjusted if SHOCK not delivered.

The defibrillator should be returned to AC power when not in use. When in use, the defibrillator should not be plugged into AC power.

CAUTION—Be certain that the off-the-shelf defibrillator can connect to the HPM defibrillator connector. If it cannot connect, then you will need to use external paddles.

3.3.1.2. Blood Gas Analyzer

A blood gas analyzer is utilized to check blood gases, electrolytes, and lactate throughout perfusion. Arterial and venous blood lactate samples are measured to ensure adequate myocardial perfusion of the donor organ. Be sure to bring sufficient cartridges for transport and synchronize the date and time before leaving the donor hospital.

NOTE—The user should set and maintain the Heart Console clock and blood gas analyzer clock to be synchronized with each other and in the recipient hospital time zone.

3.3.1.3. Monitoring and Intervening Controls

While using the HPM ports and controls to adjust perfusion parameters, pay attention to the readings from the user-installed flow probes, SvO_2/HCT Probe, and lactate V-A differential. Adjust or reinstall probes if readings seem inaccurate.

The HPM includes the following manual controls and ports for various interventions that the user may need to make when monitoring the heart throughout the phases of heart preservation (Figure 15).

- An injection port lets the user inject solutions into the reservoir.
- Two infusion ports (Solution 1 and Solution 4) allow infusion of solutions directly into the aortic flow line.
- An additional infusion port (Solution 2) allows infusion of an additional solution into the blood reservoir.
- Two sample ports permit withdrawal of perfusate for testing from the Arterial (AO), or venous (PA) line.
- The 4-way stopcocks on the AO, and PA lines allow the user to purge air from selected flow lines, routing it to the reservoir.
- The Oxygenator vent is used to expel purged air from the oxygenator into the reservoir and remain open during perfusion.
- The AO access port is also used for perfusion conclusion as described in “Final Arrest” in Chapter 5.
- External access port on the AO line also permits insertion of catheters, probes, and other monitoring instruments with diameters of 9 FR or less into the AO, after installing the Tuohy-Borst valves in the Monitoring Accessories Set.
- Pacing leads passed through Pacer Lead Window to the pacer.

CAUTION—The AO connectors and lines accommodate only instruments of 9 FR or smaller. Attempting to use larger instruments may damage the connectors and lines.

3.3.2. HPS Accessory Sets

This section shows and describes the sterile TransMedics accessories that are included as part of each Heart Perfusion Set. Inspect each set before use to ensure all parts are present and in good condition.

The HPS Accessories include:

- OCS™ Blood Collection Set - intended to collect and process the donor blood
- OCS™ Heart Instrumentation Tool Set - intended to connect the heart to the HPM circuit
- OCS™ Cardioplegic Arrest Set - intended to infuse cardioplegia to terminate the preservation, directly prior to transplantation
- OCS™ Heart Solution Line Set - intended to transfer OCS™ Priming Solution and infuse the OCS™ Maintenance Solution to the HPM
- OCS™ Monitoring Accessories Set - intended to facilitate monitoring of the heart function.

3.3.2.1. Blood Collection Set

The Blood Collection Set is used to collect donor blood and then to pass the blood through a leukocyte filter line into the HPM reservoir. Donor blood is drained into the blood collection bag. The blood collection line is then disconnected from the blood collection cannula and connected to the filter line, which is then connected to the HPM's Prime port. Blood is then drained by gravity from the blood collection line bag through the leukocyte-depleting filter and into the HPM's reservoir.

The operating volume for the OCS™ Heart System is determined by the total amount of Priming Solution and the amount of donor blood collected. A minimum total operating volume of 1500 mL is required to achieve pump flow rates of up to 1000 mL/min. To achieve this minimal volume the user must collect a minimum of 1100 mL of blood from the donor. It is anticipated that a small volume of the collected blood will remain in the leukocyte filter line when transferring blood from the blood collection bag into the module.

Figure 18: Blood Collection Set Components

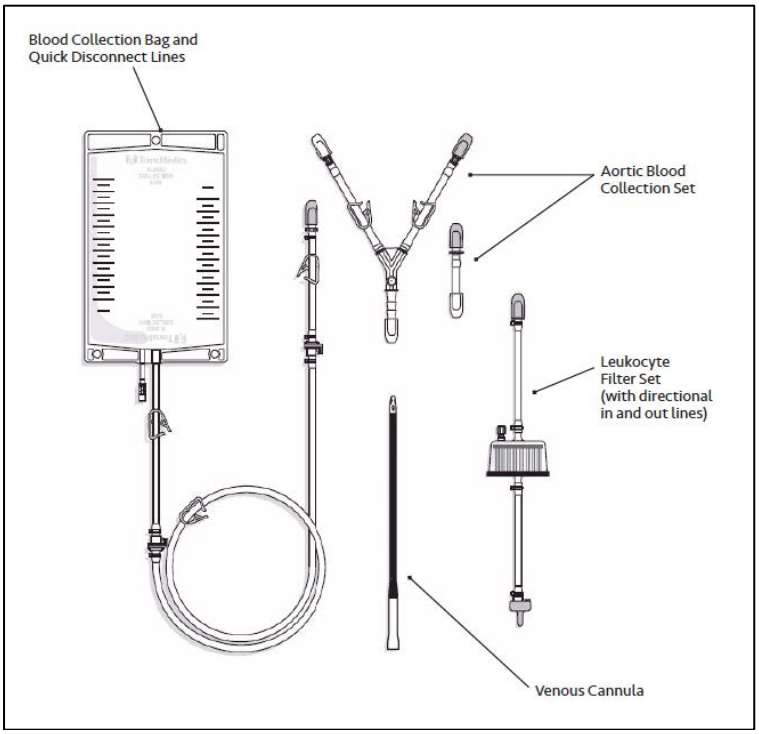


Table 3: Blood Collection Set Components

Items	Description
Blood Collection Bag, Line and Clamp	A blood collection line with a 2000 mL collection bag and clamp for collecting blood from the donor.
Venous Cannula (34 F)	Used for collecting blood from a venous site.
Aortic Blood Collection Set	Includes an aortic blood collection line. A reducing connector line adapts a user-supplied 9.5 mm (3/8 in) aortic cannula to the 6.4 mm (1/4 in) aortic line. The Y-shaped aorta line also includes a line which can be used for administration of donor cardioplegia.
Leukocyte Filter Line	The filter includes directional in and out lines.

3.3.2.2. Heart Instrumentation Tool Set

The Heart Instrumentation Tool Set includes sterilized accessories for instrumenting the heart to the OCS™ Heart System.

Figure 19: Heart Instrumentation Tool Set Components

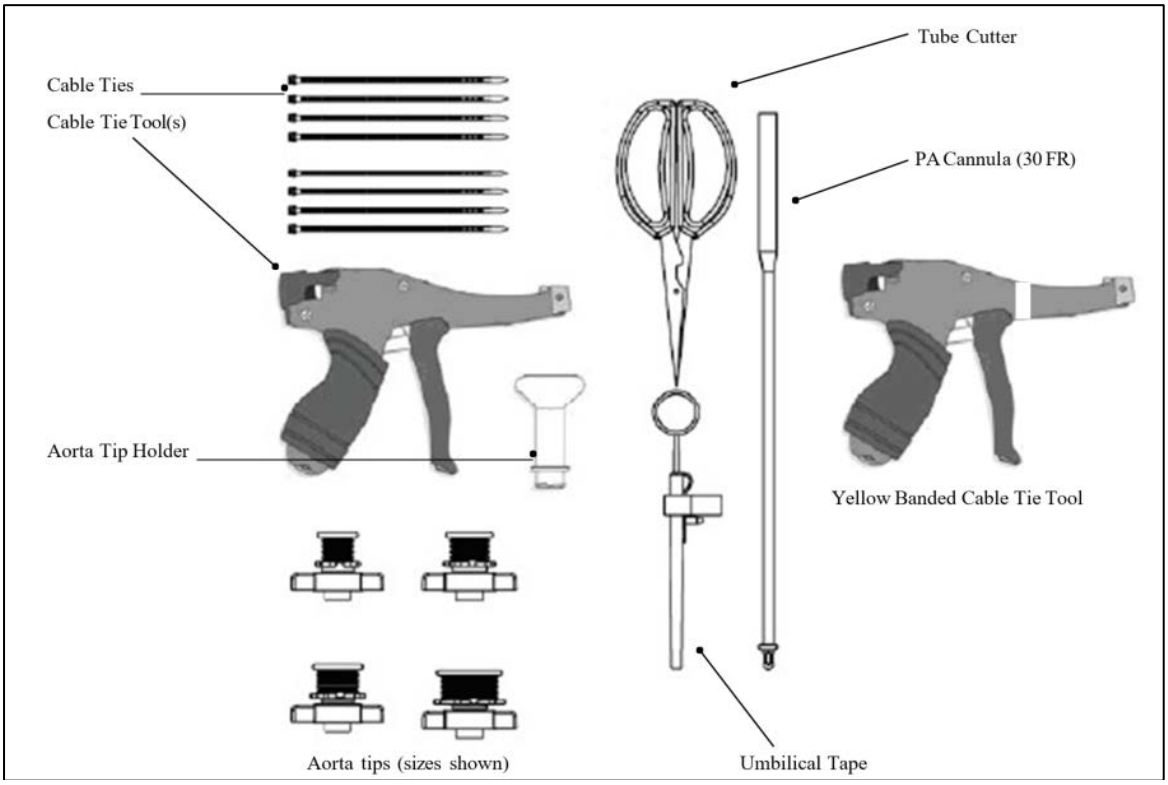


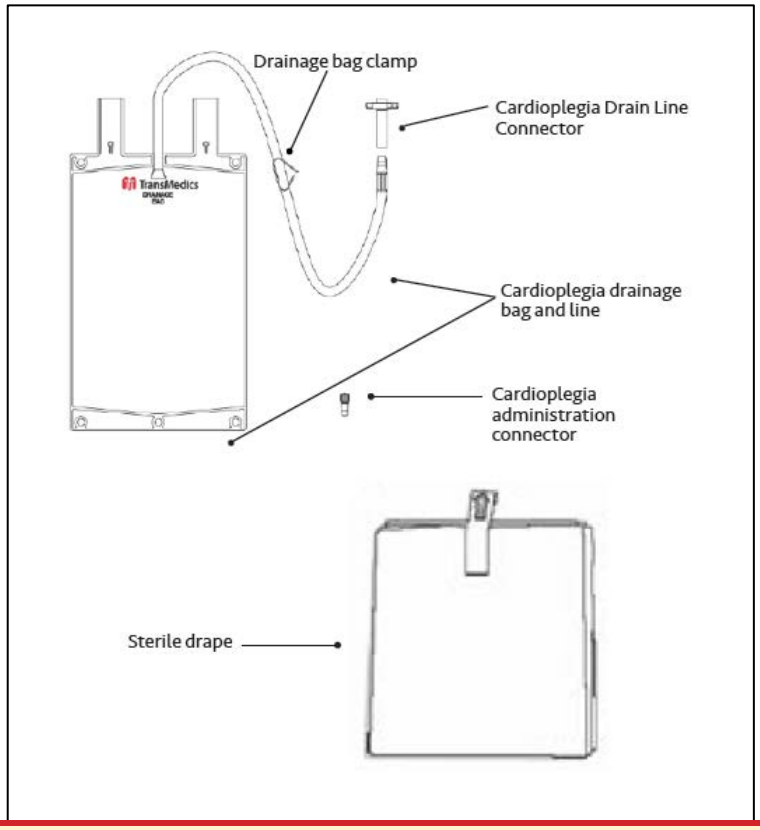
Table 4: Heart Instrumentation Tool Set Components

Items	Description
PA Cannula (30 F)	For PA cannulation when connecting heart to system; one cannula.
Aorta Tips	4 sizes (from 19.1 mm (3/4 in) to 31.8 mm (1 ¼ in)) to select from when connecting aorta to system.
Aorta Tip Holder	Holds aorta tip temporarily during the heart cannulation procedure.
Cable Tie Tool and Cable Ties	The cable tie tool provided with this set is meant for the largest cannula tip. Another cable tie tool with a yellow stripe is provided separately and is to be used with the three smaller tips. The set includes eight cable ties. Use the appropriate cable tie tool for securing the corresponding aorta tip to the aorta tissue.
Tube Cutter	For sizing the PA cannula.
Umbilical Tape	Use the umbilical tape to help stabilize the PA cannula.

3.3.2.3. Cardioplegic Arrest Set

When the recipient heart has been explanted, the donor heart is mechanically cooled and then arrested with cold cardioplegia and disconnected from the OCS™. Use the Cardioplegic Arrest Set to facilitate this process. The set includes a connector for use in administering cardioplegia to the heart (it connects the cardioplegia line to the AO Access port on organ chamber), and a drainage bag for removing excess cardioplegia from the module.

Figure 20: Cardioplegic Arrest Set Components



CAUTIONS—

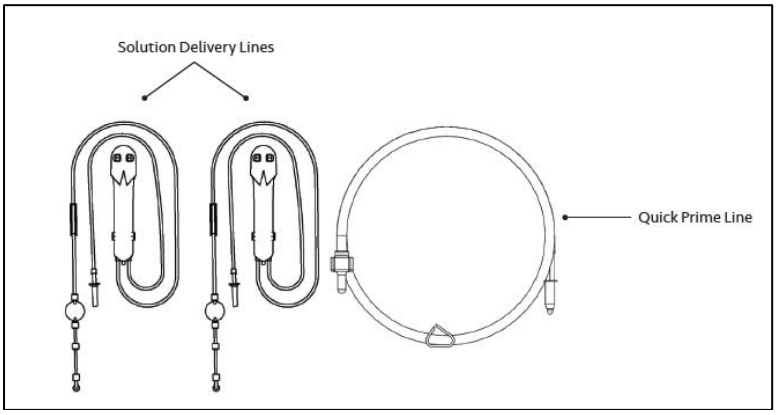
The pressure bag and any associated sterile components are not provided by TransMedics.

Always release the drainage bag clamp before connecting to the system.

3.3.2.4. Heart Solution Line Set

The solution line set contains two Solution Delivery Lines and a Quick Prime Line for Priming Solution administration.

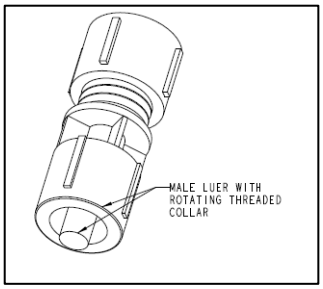
Figure 21: Heart Solution Line Set Components



3.3.2.5. Monitoring Accessories Set

The Monitoring Accessories Set is a single Tuohy-Borst Valve. This valve can be connected to the AO connector of the HPM to facilitate instrument access through the aorta for examination of the heart.

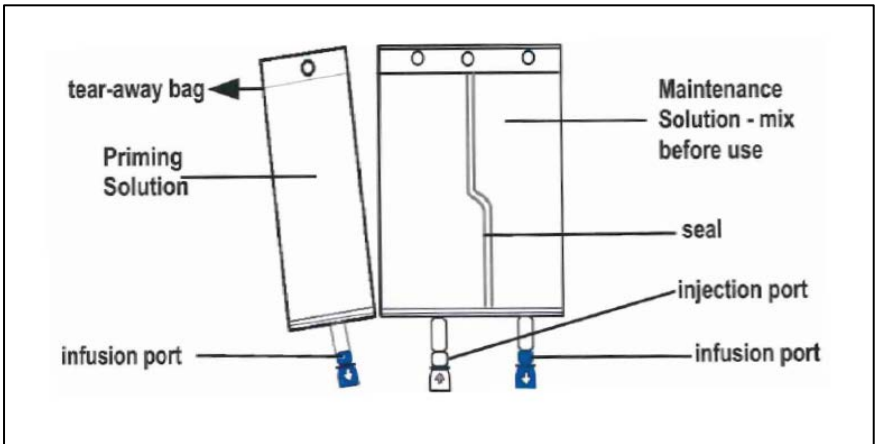
Figure 22: Tuohy-Borst Valve



3.4. OCS Heart Solution Set

The OCS Heart Solution Set box contains one set of the proprietary, sterile TransMedics solutions.

Figure 23: OCS Heart Solution Set Components



The TransMedics Priming Solution and the TransMedics Maintenance Solution are packaged together in a 3-chamber bag and steam sterilized. The Priming Solution is provided in a 1-chamber tear-away bag and must be removed before preparation and use. Priming Solution is circulated through the HPM along with the blood and additives prior to heart connection. After heart connection, the system circulates this perfusate while the Maintenance Solution is continuously infused to the module.

The TransMedics Maintenance Solution components are manufactured in two separate chambers and must be mixed immediately before use. Combination of the two chambers produces 1000 mL of solution.

The table below provides the purpose for the components of the OCS™ Heart Solution Set.

Table 5: OCS Heart Solution Set Components

Substance	Purpose
OCS Priming Solution[1]	
Mannitol	Osmotic pressure
Sodium Chloride	Electrolyte balance
Sodium Glycerophosphate	Phosphate Source for metabolic balance
Potassium Chloride	Electrolyte balance
Magnesium sulfate heptahydrate	Electrolyte balance
Hydrochloric Acid	pH adjustment during manufacturing
Water for Injection	Fluid
OCS Maintenance Solution[2]	
Calcium Chloride (g)	Electrolyte to support metabolism
Magnesium Sulfate (g)	Electrolyte to support metabolism
Potassium Chloride (g)	Electrolyte to support metabolism
Sodium Chloride (g)	Electrolyte to support metabolism
Adenosine (g)	Nutrient to support metabolism
Dextrose (g)	Energy Source
Amino Acids	Nutrients to support metabolism

[1] OCS Priming Solution of 500 mL to prime the OCS circuit.

[2] This is the composition after the two separate OCS Maintenance Solution chambers are mixed.

Part 1:
Clinical GUIDE

4. CHAPTER 4: SYSTEM SETUP AND TRANSPORTATION

4.1. Routine Inspection

Before and after each use, inspect the OCS™ 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. Refer to Section 7.5 for specific details.

NOTES—

Ensure all OCS™ equipment and supplies have been checked before leaving for the run: Heart Console, Heart Perfusion Set, Heart Solution Set, Defibrillator, and fully stocked Run Bag.

The presence of a data card is optional in order to operate the system. However, if any data card is used, ensure it is a TransMedics approved card.

4.2. Test System Operation

1. Set the OCS™ to Run Mode by pressing the button and ensure it passes the Self Test.
2. Ensure there are three fully charged OCS™ batteries.
3. Ensure the OCS™ Gas Cylinder is at least ½ full. Otherwise bring a spare full OCS™ Gas Cylinder.
4. Ensure the OCS™ has a TransMedics approved data card.
5. Confirm that the tamper evident seal on the back of the OCS is intact across the seam of the rear panel and the Console (see Figure 24).

Figure 24: Photograph of Tamper Evident Seal on Console

4.3. Checking Date and Time

Due to changes in time because of time drift or Daylight Saving Time, the OCS™ date and time should be checked before each use. Similarly, the date and time of the portable blood gas analyzer should be changed to match the OCS™. With the OCS™ in Run mode:

1. Press the Rotary Knob to open the Configuration Menu.
2. Rotate the Knob to the System Tab.
3. Press the Rotary Knob to select the System tab.
4. Scroll down to Date and press the knob to modify.
5. After accepting the changes, repeat the process for the Time.

NOTE—Adjust OCS™ clock and blood gas analyzer clock before each run and every time there is a local time change.

4.4. OCS™ and Wireless Monitor Batteries

One lithium-ion battery is incorporated into the Wireless Monitor and three lithium-ion batteries are installed in the Heart Console (i.e., OCS™ batteries). 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 Heart 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 Heart Console to restore its operation.

The OCS™ batteries (Figure 25) are installed in the battery compartment on the right side of the Heart Console. When the system is connected to AC power, the batteries automatically charge.

Under normal operating conditions, a fully charged, undocked Wireless Monitor battery lasts at least six hours. In addition, each fully-charged OCS™ battery has sufficient charge to last a little more than an hour, for a minimum of four hours of total power without replacing or recharging the batteries. When the system is connected to AC power (see Section 4.4.4) and the Wireless Monitor is docked on the system, the Wireless Monitor's battery is automatically recharged as needed, and then 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 at all times when available to ensure charging of the Heart Console and Wireless Monitor batteries.**

The Wireless Monitor battery can be serviced and replaced only by qualified TransMedics Service Personnel.

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 Monitors battery.

WARNING—Do not immerse or splash an OCS™ battery pack in water, and do not allow liquids to enter the slot or the electrical contacts at the back of the battery pack during cleaning. Lithium may react violently when mixed with water, leading to possible battery leakage, smoke, and fire. Do not open, pierce, or crush the battery packs. Doing so may result in a fire. In addition, released electrolyte is corrosive, may cause damage to eyes or skin, and may be toxic of swallowed. To prevent risk of fire, store batteries within the temperature and humidity limitations specified. Failure to adhere to these procedures may cause bodily injury, and environmental and equipment damage.

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.

4.4.1. Checking System Battery Power

1. Press the test button on the front of each battery pack. The battery pack charge LEDs indicate charge status.
2. Determine the charge status and take the appropriate action:
   - If all five indicator LEDs light, the battery pack is fully charged.
   - If the lower LED flashes it indicates that the battery is fully discharged. Replace the battery with a fully charged battery or connect the OCS™ to AC power to charge any discharged batteries.
   - If no LEDs light, do not use the battery and contact TransMedics Service.

4.4.2. Removing and Installing OCS™ Battery Packs

When one or more OCS™ battery packs are discharged, the Wireless Monitor display indicates which packs are discharged. The user can hot swap the packs one at a time with a fully charged replacement pack, while the system continues to operate normally.

CAUTION—Before removing an OCS™ battery pack, make sure you are removing the intended battery pack. Although the system prevents the user from removing more than one battery pack at a time, inadvertently removing a charged battery could potentially leave the system with NO charged battery packs in place and shut down system operation.

To remove a discharged battery pack and install a fully charged battery pack:

1. Determine the battery charge level before replacing it.
2. Move the battery pack's retaining lever up and out of the way.
3. Firmly grasp the battery pack handle, pull the discharged battery pack straight out, and set it aside.

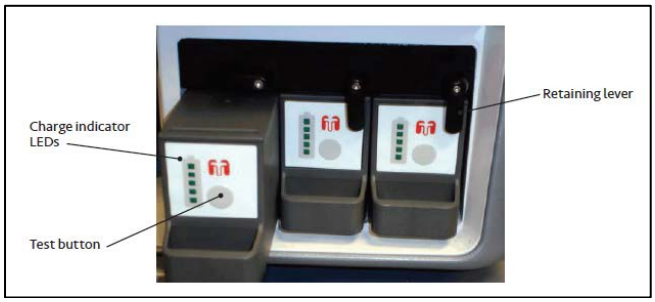
   CAUTION—Once you have removed an OCS™ battery pack, the system prevents the user from removing another battery pack until you install a battery in the open slot and close the retaining lever. Do not try to forcefully remove a battery. Doing so may damage the system and the battery pack.

4. Slide the new battery pack into the open slot and move the retaining lever back in place, making sure the battery pack is secure.

   CAUTION—When inserting a battery pack into the system, push gently as excessive force may damage the battery pack, resulting in bodily injury and environmental and equipment damage.

5. Verify battery function by checking the battery status icon on the Wireless Monitor.

Figure 25: Removal of Discharged OCS™ Battery Pack



4.4.2.1. To fully de-power the Heart Console for Service

1. Turn the power switch to the Off position.
2. Unplug the AC cord from the power source.
3. Remove the first battery pack using steps 1 through 3 provided above.
4. Locate the metal tab below the retaining lever of the open slot. See Figure 26.
5. While pressing the metal tab, rotate the retaining lever of the open slot down, into its vertical position. Then release the metal tab.

6. Repeat these steps to remove each of the next two OCS™ Battery Packs.

Figure 26: Removal of All OCS™ Battery Packs

4.4.3. Checking the Wireless Monitor Battery

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 pack is recharged as needed. When the Wireless Monitor is undocked and used remotely, it uses power from its own battery pack. The two LED lights on the Wireless Monitor's control panel provide information about Wireless Monitor power status

- 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.

4.4.4. Connecting the System to AC Power

The OCS™ Heart 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.

When using and storing the OCS™ 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.

See Section 2.3 for electrical safety warnings and cautions.

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 27).

Figure 27: On/Off Switch and Power Cord

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. When the system is connected to AC power, the LED above the Wireless Monitor docking area illuminates.
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 27).

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.

CAUTIONS—

Do NOT use additional cables, extension cords, or outlets with the TransMedics system.

If it is necessary to disconnect the unit from the AC power, the user must unplug the unit from the AC power receptacle. Neither the standby button nor the system On/Off switch will completely disconnect power.

4.5. Gas Cylinders

A continuous oxygen supply is vital to heart preservation. Each cylinder holds 408 L at 3000 psi (21000 kPa), enough gas to last over 24 hours under ordinary operating conditions. The gas cylinder compartment is located at the side of the OCS™ behind a clear plastic access door, adjacent to the battery packs.

When the system is in Run Mode, during circulation the Wireless Monitor provides continuously updated information about remaining gas cylinder capacity. However, when the system is in Standby mode, the user can only estimate the remaining gas supply (without turning on the Wireless Monitor) by viewing the pressure gauge on the gas cylinder. Table 6 below indicates the hours of gas supply left at various pressure readings and flow rates. The range for the OCS™ Heart Gas Flow Rate is 0, 150-500 mL/min with a default of 150 mL/min.

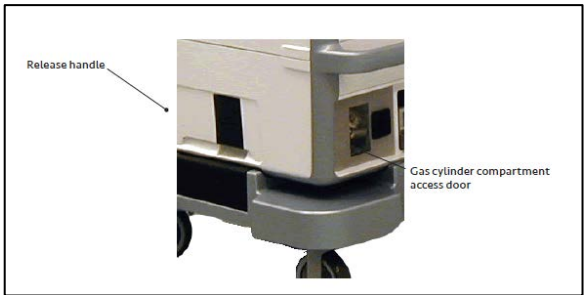
Table 6: Gas Supply in Hours

Pressure (PSI)	Flow Rate (mL/min)							
	150	200	250	300	350	400	450	500
3000	43.1	32.3	25.8	21.5	18.5	16.2	14.4	12.9
2500	35.5	26.6	21.3	17.8	15.2	13.3	11.8	10.7
2000	28.0	21.0	16.8	14.0	12.0	10.5	9.3	8.4
1500	20.4	15.3	12.2	10.2	8.7	7.7	6.8	6.1
1000	12.8	9.6	7.7	6.4	5.5	4.8	4.3	3.9
500	5.3	4.0	3.2	2.6	2.3	2.0	1.8	1.6

4.5.1. To Remove an Empty Gas Cylinder

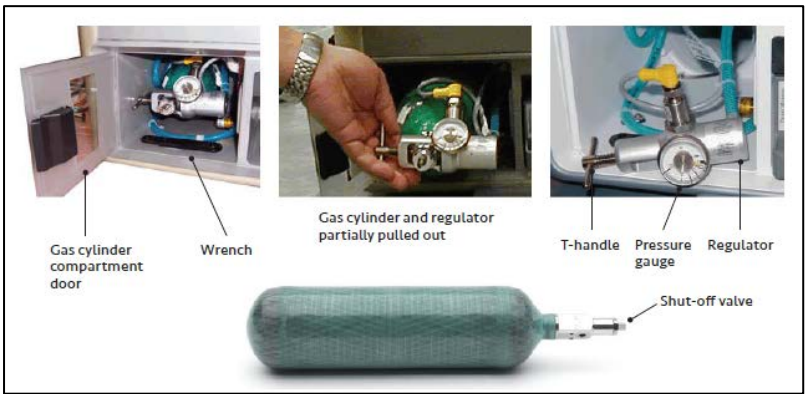
1. Lift the cylinder release handle on the front of the OCS™.

Figure 28: Heart Console Gas Cylinder Release Handle



2. Open the access door to the gas cylinder compartment.
3. Remove the cylinder wrench mounted inside the door at the front of the compartment on a mounting strip.
4. Slide the gas cylinder partially out of the compartment so that the user can access the regulator fitting. The user cannot completely remove the cylinder at this point, because it is still attached to the regulator.

Figure 29: Exchanging Gas Cylinders



5. Use the cylinder wrench to shut off the gas by slowly turning the shut-off valve clockwise.
6. Using your fingers, loosen the T-handle that holds the cylinder in the regulator by turning the handle counterclockwise. Swing the regulator out of the way.
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.

CAUTIONS—

Initially, open valve slowly. Opening it quickly or any further than ¼ turn may cause the gas cylinder to move rapidly from its current location, which may result in bodily injury and property damage.

Avoid contact with the gas stream. Gas under pressure can cause bodily injury and property damage.

NOTES—

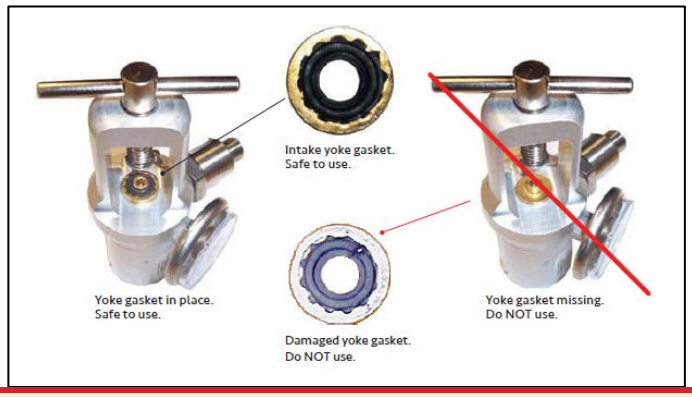
If the regulator is not properly mounted, gas will vent when the cylinder's valve is opened. To correct, immediately close the valve and remount the regulator.

The user may hear a hissing sound from some residual gas venting as user disconnects the regulator. If the cylinder continues to vent, then the user did not shut off the valve completely. To correct, immediately close the valve as described in step 5.

4.5.2. To Install a New Gas Cylinder

1. Remove the new gas cylinder from the cardboard box, and discard the shrink-wrap packed around the valve, and the white plastic plug. Keep the other cardboard packaging to use when returning empty cylinders for refill.
2. Partially insert the new cylinder, with the bottom of the cylinder toward the OCS™ and the cylinder valve toward the user.
3. Make sure that the regulator's yoke gasket is in place and undamaged. If the gasket appears to be damaged, remove it and replace it as described below in "To Replace a Damaged Yoke Gasket."

Figure 30: Yoke Gasket Installation



CAUTION—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.

NOTE—TransMedics provides appropriate packaging for gas cylinder return. Other containers may not sufficiently protect the cylinder from potential damage during shipment and may not meet regulatory requirements.

4. Place the regulator on the valve stem and line up the pins on the regulator with the holes on the valve stem.
5. Hand-tighten the T-handle by turning the handle clockwise.

CAUTION—Do not over-tighten the T-handle or valve. Tightening too much may damage the valve.

6. If the user is ready to use the system or to test the gas valve or 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 (Table 4). 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. Lock the cylinder in place by pressing the cylinder release handle on the front of the system.
10. Close the access door to the gas cylinder compartment.

4.5.3. To Replace a Damaged Yoke Gasket

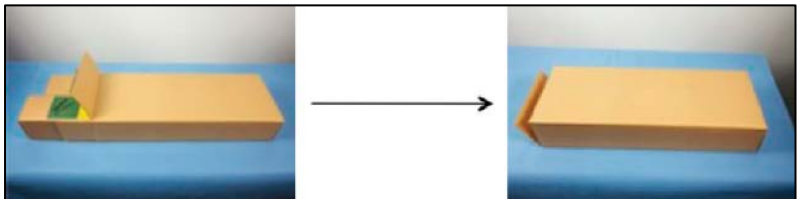
1. Wearing gloves, remove the damaged yoke gasket from the base and discard it.
2. Remove the new gasket from its packaging.
3. Clean the gasket and the brass post with an alcohol wipe and allow the alcohol to air dry prior to installing the gasket.
4. Press the gasket down to the base, making sure that it is fully seated.

NOTE—The gasket is the same on both sides so it may be positioned either way.

4.5.4. To Return an Empty Gas Cylinder to TransMedics

1. Using the provided gas cylinder wrench, close the cylinder valve.
2. Unscrew the T-handle on the regulator to disconnect it from the cylinder.
3. Move the cylinder to a well-ventilated, open area.
4. Position the valve outlet face down, away from people and loose objects and secure the cylinder.
5. Slowly open the valve ¼ turn and allow contents to drain fully. (After the cylinder is empty, leave the valve open.)
6. Label the cylinder's box EMPTY with a permanent marker.
7. Repack it, first in its individual cylinder box, then repack the 2 individual cylinder boxes in the supplied middle unlabeled box.
8. Contact TransMedics Customer Service for instructions regarding shipment customerservice@transmedics.com.

Figure 31: Gas Cylinder Packaging



4.6. TransMedics Data Cards

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 for each parameter at 2-minute intervals
- Blood gas sample values as entered by the user.

The OCS™ is shipped with data cards. Each card can hold data from multiple preservation sessions. TransMedics recommends installing the card prior to system use in a preservation session, removing the card to retrieve data immediately after the end of the session, 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—The system can perform without a Data Card present.

4.7. Pack Accessories

The HPM may be installed prior to departing for the donor site or upon arrival. When the HPM is unpacked, ensure that all accessories are packed in the Run Bag.

4.7.1. Run Bag List

4.7.1.1. Recommended Medications Per Use

- Sodium Bicarbonate (2 x 20 mEq)
- Methylprednisolone (250 mg)
- Multi-vitamin (1 Unit)
- Regular Insulin (80 IU)
- Epinephrine (0.25 mg)
- 5% Dextrose in water (500 mL)
- Heparin (10,000 IU)
- Ciprofloxacin (100 mg)
- Cefazolin (1 g)
- 25% Human Albumin (100 mL)
- Sterile Water (as needed)

- Calcium Gluconate (as needed)
- Dextrose 40-50% (as needed)
- Potassium Chloride (as needed)
- Syringes and needles (as needed).

NOTE—The recommended medications and quantities may be substituted based on availability and at the discretion of the clinician.

4.7.1.2. Sampling Items

- Blood Gas Analyzer
- Blood Gas Analyzer cartridges
- Syringes
- Alcohol Wipes
- Gloves
- Disposal Bag.

4.7.1.3. Spare and Supplemental Items

- 9V batteries
- Spare SDS cassettes
- LV vent
- Spare leukocyte filter line
- Tie downs
- External pacemaker and pacing leads
- Yellow Banded Cable Tie Tool.

4.7.2. Accessory List

- Heart Perfusion Set
  - OCS Blood Collection Set
  - OCS Heart Instrumentation Tool Set
  - OCS Cardioplegic Arrest Set
  - OCS Solution Line Set
  - OCS Monitoring Accessories Set
- OCS Heart Solution Set
  - TransMedics Priming Solution

- TransMedics Maintenance Solution

- 2 x 1 L Heart Flush Solution.

4.8. OCS Heart Solution Set

4.8.1. Priming Solution

After tearing the Priming Solution bag away from the Maintenance Solution bags, snap off the blue port cap, and inject sodium bicarbonate as described in Table 7. Lay the 2-chambered Maintenance Solution bag on a flat surface. Beginning at the hanger end, carefully roll up the bag to break the seal between the chambers. Once the seal is broken, gently pull both sides of the bag to fully open the seal. Rotate the bag back and forth several times to mix. Inject insulin as described in Table 7.

4.8.2. Solution Preparation

Solution preparation can take up to 30 minutes, so it is important to make time for these steps.

Table 7: OCS Heart Solution Set, Infusions, and Additives

Solutions	Additives	OCS™ Administration
TransMedics Priming Solution	20 mEq Sodium Bicarbonate	Use Quick Prime Line connected to the Priming port on the HPM to administer at system priming.
TransMedics Maintenance Solution	50 IU Regular Insulin	Connect SDS line to Solution Port 1. Maintenance Solution may be infused during preservation to optimize perfusion and only after the heart is beating
Epinephrine Drip	0.25 mg of Epinephrine in 500 mL of 5% Dextrose in water 30 IU Regular Insulin	Connect SDS line to Solution Port 4. Start infusion at 10 mL/hr at system priming.
Additives	100 mL 25% Human Albumin 100 mg of Ciprofloxacin 1 g of Cefazolin 250 mg of Methylprednisolone 1 Unit of Adult Multivitamin	Inject directly to reservoir at system priming through the HPM injection port

4.9. Set Up Activities

The following steps should take place before proceeding with OCS™ instrumentation and perfusion initiation:

- Find a suitable location for the Heart Console
- Lock the wheels
- Plug the Heart Console into AC power
- Install the HPM (described in Section 4.10 below)
- Transition from Standby Mode to Run Mode.

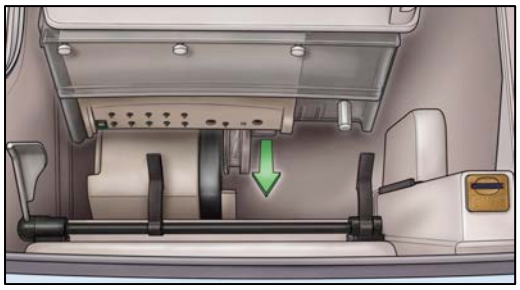
4.10. Install Heart Perfusion Module (HPM)

This section provides the steps to install the HPM. Ensure OCS™ is in Standby Mode before installing the HPM.

CAUTION—To ensure proper system operation, include the HPM in the system's Self Test by installing the HPM in the Heart Console while the system is in Standby Mode.

1. Inspect package for rips or tears before removing plastic and then remove foam wrap.
2. Remove the pink foam block from the back of the HPM.
3. Hold and tilt the module at 30° angle to align with pump head.

Figure 32: HPM Alignment Guide



4. Insert and push backwards until the module clicks into the support clips.
5. Connect the gas lines.

Figure 33: HPM Gas Lines Connections

6. Orient the flow probes so that the double line on the probe's label is adjacent to the double line label on the module's tubing (Figure 35).
7. Apply petroleum gel to flow probes and connect to color matched labels on module lines.
8. Connect SvO_2/HCT Probe to green coded cuvette in PA line (Figure 38).
9. Set aortic vent line stopcock (red) to open position. Close purple and blue stopcocks (Figure 34).

Figure 34: HPM Stopcock Manifold Configuration

NOTE—After the initial installation, the probes remain connected to the OCS.

4.10.1. Connecting Probes to the OCS™

This section provides instructions for connecting flow probes and the SvO_2/HCT Probe to the OCS™. The probe cables are connected to the OCS™ as part of the setup process. Once connected, you can attach the probes to the tubing.

Figure 35: HPM Flow Probes

CAUTION—Use only petroleum jelly. Using any other coupling gel, such as silicone grease or ultrasound gel, may damage the probe.

4.10.2. Attaching Probes to the HPM

This section provides detailed instructions on attaching the flow probes and SvO_2/HCT Probe to the tubing in the HPM. At this point, the probe cables should already be connected to the OCS™.

4.10.2.1. Attaching a Flow Probe

Flow probes are installed in the following blood circuit locations in the HPM. Directionality is indicated by aligning the striped side of the probe to the striped sticker on the HPM:

- The AO probe is installed between the red bands in the upper left corner of the HPM (see Figure 36).
- The PUMP flow probe is installed between the purple bands (see Figure 35).
- The CF probe is installed between the blue bands (see Figure 35).
- After the initial installation, the probes remain connected to the OCS™.

Figure 36: AO Flow Probe

4.10.2.2. To attach a flow probe to the tubing

Apply a thin layer of petroleum jelly to the black windows of the probe to enable ultrasonic transmission between the tube and sensor (Figure 37).

Figure 37: Open Flow Probe

1. Open the hinged lid by pressing the latch and separating the top and bottom parts of the probe around the hinge.
2. Locate the color-coded bands that match the color of the probe label.
3. Align the probe between the bands so that the cable side of the probe is next to the double band, which marks outflow.
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 with the system in Run Mode, check the Wireless Monitor display to make sure that the desired flow parameters are being detected.

4.10.2.3. To remove a flow probe from tubing

1. Press the latch on the side of the probe until the probe lid opens.
2. Carefully remove the probe from the tubing.

After use in a preservation session, leave the probe cable connected to the system, clean as described in Chapter 7 “Cleaning and Maintaining the System,” mount in the probe hanger, and store in the system until next use.

4.10.2.4. Attaching the SvO_2/HCT Probe

The SvO_2/HCT Probe is designed to be clipped onto a cuvette incorporated into the HPM’s tubing between the pulmonary artery outflow (PA) and the reservoir. The cuvette is marked with green bands at each end. Flow direction is marked with a small arrow on the cuvette itself. This directional icon should be aligned with the red dot on the probe. The probe is reusable and does not require sterilization, since it never directly contacts blood. When not in use, the probe is detached from the tubing, cleaned, and stored on the probe hanger inside the system.

NOTE—Ensure the probe is securely connected to the cuvette.

4.10.2.5. To attach the SvO_2/HCT Probe to the tubing

1. Locate the cuvette (between the PA connector and the reservoir) in the HPM.
2. Align the probe so that the straight section of the tubing is centered in the probe opening (marked with green bands on each end) and the red dot on the probe is aligned with the small arrow on the tubing (Figure 38).
3. Snap the probe into place around the cuvette, with the opening downward over the tubing and the top of the probe facing up.

Figure 38: SvO_2/HCT Connection

4.10.2.6. To remove the SvO_2/HCT Probe

1. Firmly grasp the probe with one hand.
2. Use the other hand to gently remove the cuvette from the probe.

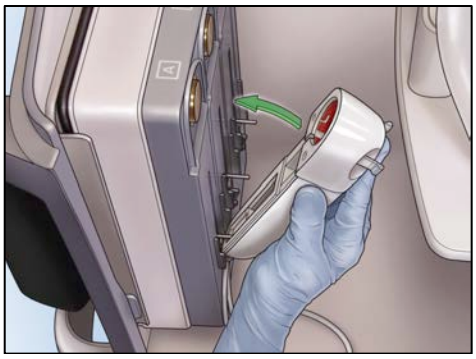
After use in a preservation session, leave the probe cable connected to the system, clean as described in Chapter 7 “Cleaning and Maintaining the System,” and store it in the system until next use.

4.11. SDS Setup

After solutions are connected to the SDS, configure each channel to control solution flow.

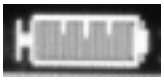
1. Spike the solution with the SDS Line Set.
2. Hang the infusion bag on the hanger provided in the Heart Console.
3. By squeezing the attachment fingers, remove the shipping lock and protective cover on the pressure sensor dome.
4. Insert the mounting tab behind the mounting bar on the SDS Console. Ensure that the drive pin on the SDS Console is inserted into the receiving socket on the cassette.

Figure 39: SDS Cassette Connections



5. While fully squeezing the cassette's attachment fingers, firmly press the cassette onto the SDS Console's pressure sensor. Release attachment fingers to secure.
   - Connect the cassette attached to the Maintenance Solution in the channel marked "A."
   - Connect the cassette attached to the Epinephrine in the channel marked "B."
6. Connect the line to an infusion port on the HPM.
   - Connect the Maintenance Solution to the port on the HPM labeled "Solution Port 1."
   - Connect the Epinephrine to the "Solution Port 4".
7. In the Configuration Menu (accessed by pressing the rotary knob), under the Resting tab, select SDS A Settings. Set Solution Type to Maintenance. Set Mode to OFF. Set AOP AUTO mode value and Volume Remaining to 1000 mL.
8. In the Configuration Menu, under the Resting tab, select SDS B Settings. Set Solution Type to Epinephrine. Set Mode to Off. Set Rate to 10 mL/hr and Volume Remaining to 500 mL.
9. With channels set to OFF, in the Configuration Menu, under the Actions Tab, select De-Air SDS.
   - Select SDS A, scroll to De-air, and press the rotary knob multiple times until line is fully de-aired.
   - Repeat for SDS B.

Table 8: SDS Monitor Icon Descriptions

Icon	Description
	The icon with a dashed outline indicates that no cassette is inserted.
	The icon with a solid outline and blue fill indicates that the cassette is inserted and that the channel is in Auto or Manual Mode. The amount of blue fill in the icon is proportional to the estimated percentage of solution volume remaining.
	The icon with a solid outline and gray fill indicates that the cassette is inserted but the channel is not infusing. This generally occurs when the blood pump is Off. The amount of gray fill in the icon is proportional to the estimated percent of solution volume remaining.
	The icon with a colored background and a yellow triangle with an exclamation point indicate that the channel requires attention. The background color identifies the priority.

4.12. Using the Mobile Base

The user can install and remove the Mobile Base 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 removed, the OCS™ can be set flat or be carried by two people with the lift handles.

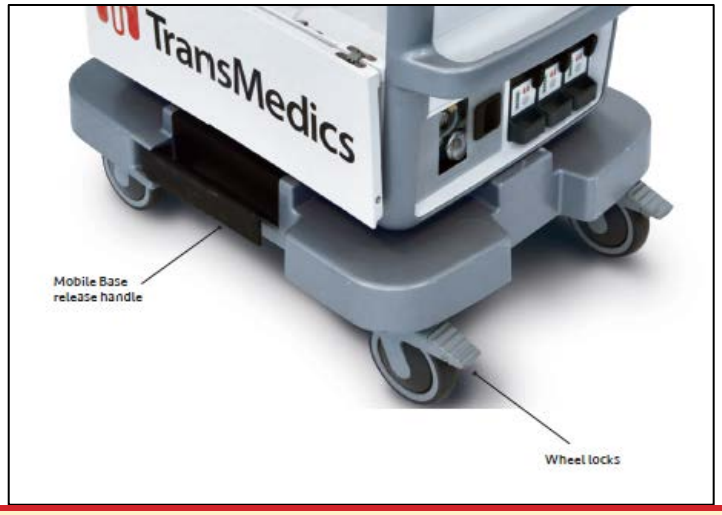
CAUTION—ALWAYS bring the Mobile Base and Cover with the OCS™.

4.12.1. Mobile Base

When moving the system with the Mobile Base attached (Figure 40):

- 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.
- To eliminate the potential danger of system tip over, avoid ramps that are steeper than 5°.
- If you must move the system up or down ramps with an incline of more than 5°, use two people to move the system.
- Do NOT lift the system to move it over uneven elevator entrances or other steps and barriers taller than 2 inches (5 cm). Instead, remove the Mobile Base and move the system manually, or find a route that avoids such problems.

Figure 40: Mobile Base and Wheel Detail



CAUTIONS—

During transport, position the OCS™ so that it never sits at an angle of greater than 15° from vertical. Angles greater than 15° may disrupt fluid paths in the HPM and lead to system malfunction.

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

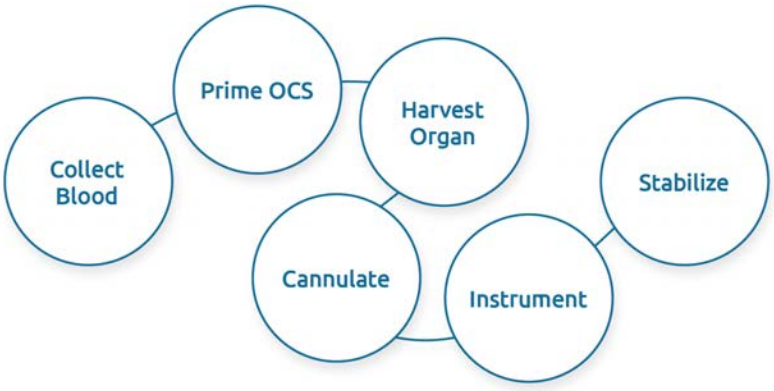
4.12.2. To Remove the Mobile Base

1. Press each wheel lock downward to lock the Mobile Base in place.
2. Pull the Mobile Base release handle by hand into the disengaged position.
3. Using two people, lift the OCS™ with the right and left lift handles.

4.12.3. To Mount the OCS™ to the Mobile Base and Move the System

1. Position the Mobile Base and press each wheel lock downward to lock the Mobile Base into position.
2. Pull the Mobile Base release handle outward to release the Mobile Base grips.
3. Using two people, lift the OCS™ with the right and left lift handles and position it on the Mobile Base, with the Mobile Base release handle on the same side as the front of the Heart Console.
4. Adjust the OCS™ until the Mobile Base is in place.
5. Push in the Mobile Base release handle by hand to lock the Heart Console to the Mobile Base.

5. CHAPTER 5: MAINTAINING A HEART IN A BEATING STATE



5.1. Prime System with Blood, Additives, and Solutions

The system must be primed before instrumentation. These steps may be carried out in parallel to cannulation.

5.1.1. Collect and Filter Donor Blood

Blood should be collected from the heparinized donor immediately prior to cross clamp. Donor should be heparinized per standard protocol. It is important to ensure adequate donor hematocrit of at least 25% prior to collection of donor blood and procurement of the heart.

Once enough blood is collected, the aortic cross clamp is applied and cardioplegia is administered to temporarily preserve the organ (see Instrumentation section for more details).

Targets:

- Donor Hematocrit ≥ 25%
- Optimal Amount = 1200-1500 mL.

CAUTIONS—

If less than 1100 mL of blood is collected, DO NOT use the OCS™.

Use packed RBCs in place of crystalloids to optimize hemodynamic targets and volume status in the donor.

Gradually wean off inotropes/ vasopressors prior to blood collection, if appropriate

DO NOT add boluses of inotropes/vasopressors within 15 minutes of blood collection.

DO NOT infuse any preservation solution or cardioplegia until blood collection to the donor is complete.

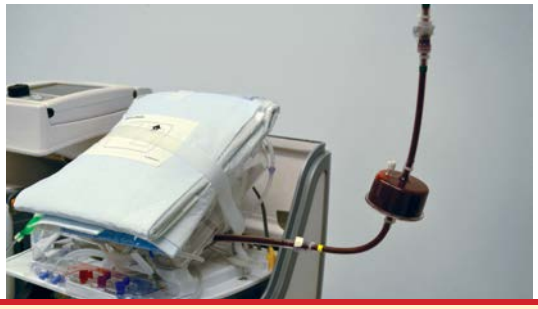
Immediately prior to cross clamp:

1. Donor should be heparinized according to standard protocol.
2. Add 10,000 IU of heparin to the blood collection bag.
3. Collect blood from RA/SVC using the provided 34 Fr single stage venous cannula.
4. Apply cross clamp.

5. Infuse up to 1 L of cold cardioplegia.

The donor blood is passed through a leukocyte filter line and into the reservoir of the HPM (Figure 41). This donor blood will be used with the OCS™ to serve as the primary component of the fluid circulated through the HPM to the heart.

Figure 41: Leukocyte Filter Connection



CAUTION—Always filter the blood through the TransMedics leukocyte-depleting filter. Using unfiltered blood may result in clots, thrombi or emboli in the heart.

5.1.2. Initial Cardioplegia

Administer 500-1000 mL of cardioplegia immediately after blood collection and donor cross clamp. Follow standard hospital procedures during administration to avoid excessively high cardioplegia delivery pressure. Explant the organ and place in a cold bowl containing cardioplegia or saline.

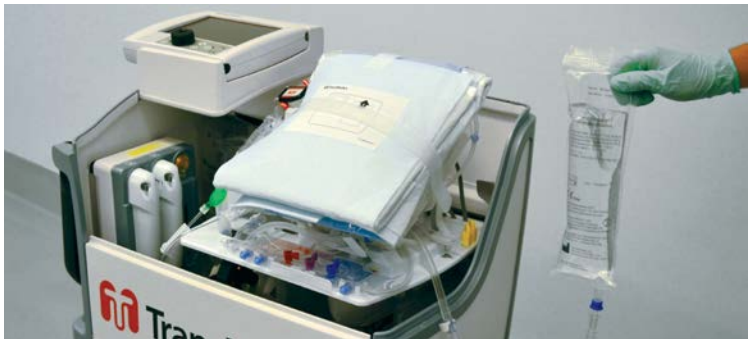
CAUTION—Place cardioplegia cannula as high as possible in the ascending aorta of the donor's heart.

WARNING—Start heart flush immediately after completion of blood collection and cross clamp of aorta.

5.1.3. Prime System

To prime the system, 500 mL of the OCS™ Priming Solution is added to the OCS™ using the Quick Prime Line connected to the priming port on the HPM. Next, the recommended 1200-1500 mL of donor blood is added to the HPM through the leukocyte filter line. Starting the OCS™ pump provides adequate circulation and flow to mix the perfusate and de-air the module.

Figure 42: Priming Solution Connection



Check Priming Settings:

- Pump Flow: 1-1.5 L/min
- Gas Flow: 150 mL/min
- Temperature: 37°C.

Starting the OCS™ pump will automatically activate gas flow and blood warming. The blood warmer is set to increase the temperature of the blood to 37°C. Fully de-air Solution Ports 1 and 4 by re-entering the Actions Tab of the Configuration menu, selecting de-air and pressing de-air. Begin the infusion of Epinephrine solution at a flow rate of 10 mL/hr. Ensure that the SDS channel for the TransMedics Maintenance Solution is set to AUTO Mode at the specified value.

Two broad spectrum antibiotics (gram-positive and gram-negative), Adult Multivitamin, and Methylprednisolone are added to the circulating perfusate at this time through the injection port.

Figure 43: Injecting Additives through Stopcock Manifold

To add injectable medications to the HPM, use aseptic technique and utilize the Injection Port on the Sampling Manifold.

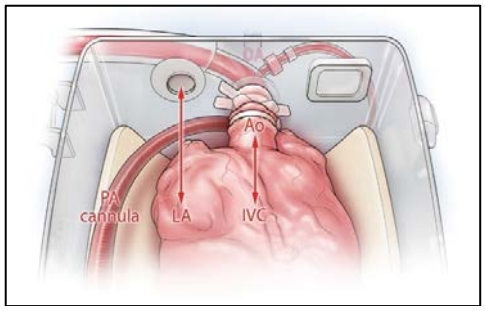
5.2. Instrumentation of Donor Heart

This section provides information related to the preparation and instrumentation of the donor heart.

5.2.1. Heart Alignment

The donor heart is instrumented on the OCS™ with the posterior facing the user. The superior vena cava is tied off. The inferior vena cava is left open as a vent until the heart is reanimated, at which point it is tied off. A left ventricle vent is placed to assist with de-airing and prevent distension. The temperature of the heart is gradually increased as the organ is perfused with the warm, oxygenated blood supplemented with OCS™ TransMedics Maintenance and Priming Solutions.

Figure 44: Heart Alignment Reference Points



CAUTION—Never fully disconnect the aortic tip from the port if heart need to be re-aligned: (1) loosen collar; (2) rotate heart; and (3) re-secure collar.

5.2.2. Prepare for Cannulation

The physician explants the heart in accordance with their institution's standard procedures. Trim the aorta below the cardioplegic cannula site (or secure with a suture if it is near aortic root). Then tie/oversew the Superior Vena Cava (SVC) and leave open the Right atrial cuff and Inferior Vena Cava (IVC).

5.2.3. Back Table Preparation

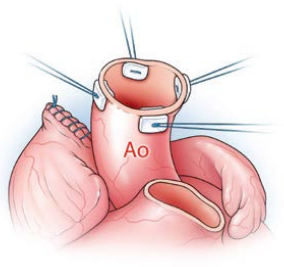
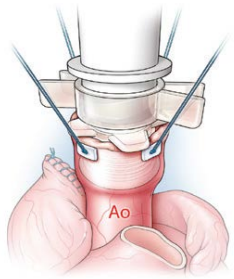
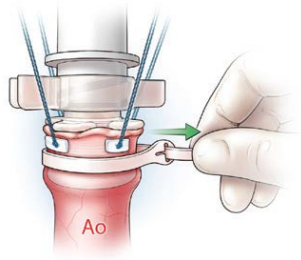
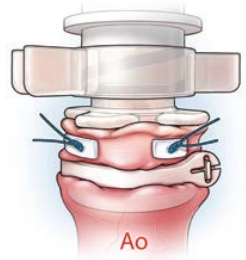
To minimize ischemic time, have the back table prepared for cannulation in advance. Items which need to be prepared in a sterile fashion are:

- Blood Collection Set (Retrieve Leukocyte Filter line for OCS™ Priming)
- Instrumentation Tool Set
- Small Diameter Cable Tie Tool
- Pledgets
- LV Vent
- Pacing Wires.

5.2.4. Aortic Cannulation

1. Apply four hard double-pledgeted sutures at 12, 3, 6, and 9 o'clock positions.
   - Use TFE firm pledgeted 3-0 prolene (or equivalent), supplemented with free TFE firm polymer pledgets.
   - Tie all four sutures to secure the double pledgets in place.
2. Attach the aortic tip holder to the appropriate size aortic tip.
   - Insert the appropriate size aortic tip connected to the aortic tip holder inside the aorta.
   - Use the pledgets to pull the aortic tissue edges upwards to the stops on the cannula to cover the entire collar of the aortic tip.
3. Apply a single cable tie above the lower ridge of the cannula and below the 4 pledgets and use a cable tie tool to secure the cable tie.
4. Apply extra knots to the external pledgets and trim the excess suture material leaving the pledgets in place.

Figure 45: Aortic Cannulation

Aorta Pledget Locations	Aortic Cannulation	Cable Tie Tightening	Suture Trimming
			

CAUTIONS—

DO NOT cannulate the aortic arch of the donor heart.

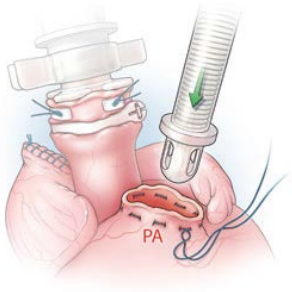
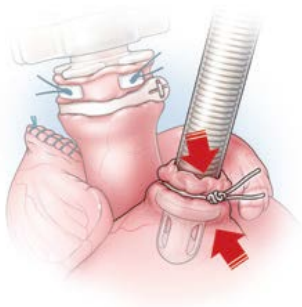
Ensure adequate tissue remains above cable tie before securing with appropriate cable tie tool.

NOTE—Use Cable Tie Tool with yellow band for the Aortic Cannula sizes ¾", 7/8", and 1". Use unmarked Cable Tie Tool for Aortic Cannula size 1.25".

5.2.5. Pulmonary Artery Cannulation

1. Use prolene purse string suture for PA cannulation. Secure suture above cannula ridge. Avoid interference with the PA valve, when possible.
   - The PA cannula should be inserted at a depth that does not interfere with the PA valve.
2. Apply and secure a piece of umbilical tape above the cannula ridge.

Figure 46: Pulmonary Artery Cannulation

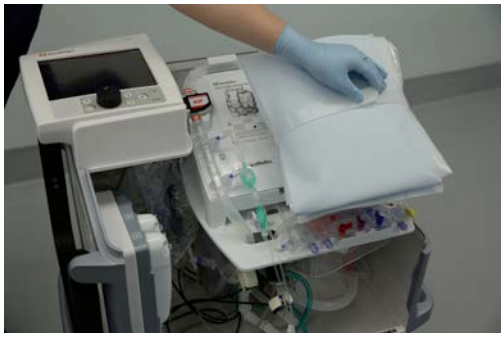
PA Cannula Purse String	PA Cannula Umbilical Tape
	

5.3. Drape the System

To prepare for Instrumentation, the sterile drape must be opened. The drape is attached to the Organ Chamber via a Velcro Belt. Four numbered directional tabs are provided to open the drape. Pull the tabs in

numerical order in the direction corresponding to the arrow. Two tabs (front and back) are provided for the 3rd and 4th steps.

Figure 47: Sterile Drape Opening



5.4. Instrumentation on OCS™

1. Open Sterile Drape to cover the OCS™.
2. Set pump flow to 1 L/min.
3. Open Organ Chamber and remove the Prime Line.
4. Remove aortic tip holder and drain cardioplegia from the heart.
5. Hold aortic tip collar with one hand.
6. Fill the aorta with blood before attaching the aortic tip to the organ chamber.
7. Push cannula tip into the aortic port and rotate the flange of the aortic tip in a clockwise direction using the other hand to secure the aortic tip in place.
8. Start the perfusion clock by pressing the  button.

CAUTION—Check Pump flow value after instrumentation and if flow has decreased to less than 1 L/min, restore to 1 L/min immediately after instrumentation.

5.5. Heart Reanimation

1. Set the temperature to 34°C.
2. Massage the heart once connected to de-air and avoid distention.
3. Insert an LV vent and secure to the open LA tissue.
4. Place defibrillator/electrode pads at RA and LV positions.
5. If the heart does not reanimate spontaneously after reaching 34°C:
   - Connect defibrillator to HPM defibrillator connector.
   - Turn defibrillator selector switch to DEFIB.
   - Select energy setting using the down arrow (begin at 10 joules).
   - Press CHARGE.

- Once charged, announce CLEAR, ensure that all users are clear of heart and HPM.
- Deliver shock by pressing SHOCK.
- Repeat defibrillation as needed until sinus rhythm. Higher energy settings may be selected, not exceeding 50 joules.

CAUTION—When placing the LV Vent, secure its location with a stay stitch to ensure it does not dislodge.

NOTE—Check and reposition electrode pads if shock does not appear to deliver.

5.6. After Heart Reanimation

1. Confirm SDS Maintenance channel is in AUTO AOP or Manual Mode.
2. Connect PA cannula to PA port.
3. Tie/oversew the IVC.
4. Fix a pacemaker lead to each ventricle in case pacing is needed.
   - Pass pacing wires through the Pacer Lead Window located in the top right corner of the organ chamber.

5.7. Preservation and Sampling

Pump flow and solution infusion rates should be set to optimize mean Aortic Pressure (AOP), Coronary Flow (CF), and Heart Rate (HR). Once stable, the heart is ready for transport. Lactate values are measured from arterial and venous blood samples to confirm adequacy of perfusion of the organ. The effect of any adjustments of the perfusion parameters should always be assessed based on comparison of arterial and venous lactates and its trend.

Table 9: Initial Recommended Perfusion Parameters

Starting Use Model	Settings
Maintenance Solution Rate	AUTO AOP Mode or Manual AOP Mode*
Epinephrine Drip Rate	10 mL/hr
OCS™ Coronary Flow	700-800 mL/min
Temperature	34°C
Gas Flow Rate	150 mL/min
Pump Flow Rate	1000 mL/min
* An initial target mean AOP of approximately 75 mmHg is recommended (80 mmHg for hearts with left ventricular hypertrophy or coronary narrowing). Over the course of perfusion, the optimal mean AOP required will vary between hearts and should be validated based on the metabolic state of the organ as determined by the lactate profile.	

NOTE—Use of Auto AOP mode with a set point of 75-80 mmHg is recommended; however, use of Manual Mode with a target mean AOP of 75-80 mmHg can be used.

5.8. Perfusion Parameters

5.8.1. Primary Controls

5.8.1.1. Pump Flow

Manipulation of the Pump Flow has a direct correlation to the Coronary Flow (CF) and Mean Aortic Pressure (AOP). An increase in Pump Flow increases both CF and AOP. A decrease in Pump Flow decreases both CF and AOP. Each incremental Pump Flow adjustment corresponds to approximately 50 mL/hr of flow.

5.8.1.2. Maintenance Solution

In combination with buffered electrolytes, amino acids, and glucose, the Maintenance Solution includes Adenosine, a potent vasodilator. An increase of the Maintenance Solution rate will increase delivery of Adenosine resulting in increased CF and a decrease of mean AOP. A decrease of Maintenance Solution rate will decrease delivery of Adenosine resulting in decreased CF and increased mean AOP.

5.8.1.3. Auto AOP Mode

This setting allows automatic AOP control by adjusting the delivery rate of the Maintenance Solution to achieve a preset target value. The mode will adjust the Maintenance Solution delivery rate over the range from 0 mL/hr up to 30 mL/hr. If a delivery rate of greater than 30 mL/hr is desired due to an unachievable AOP set point, Manual Mode must be used.

5.8.1.4. Manual Mode

This mode is recommended when the required Maintenance Solution delivery rate exceeds 30 mL/hr. If AUTO AOP Mode is not achieving the desired AOP set point or stable perfusion parameters, the user should switch to Manual Mode and control the delivery rate manually. Maintenance Solution delivery rate can be adjusted from 1 mL/hr up to 99 mL/hr.

5.8.2. Secondary Controls

5.8.2.1. Gas Flow

The OCS™ Heart gas mixture is 85% Oxygen, 1% Carbon Dioxide, and a Nitrogen balance. In addition to oxygenating the circulating perfusate, the gas flow rate impacts arterial pCO_2 levels as follows: An increase in gas flow rate results in an additional sweep of pCO_2 leading to an elevated pH. A decrease in gas flow rate results in a reduced sweep of pCO_2 leading to a lowered pH.

5.8.2.2. Epinephrine Solution

The purpose of the epinephrine solution is to replace catecholamines throughout perfusion. Pacing is recommended for correction of bradycardia on the OCS™ Heart System. In the absence of pacing, the Epinephrine solution rate may be adjusted to increase heart rate.

5.8.2.3. Pacing

Pacing in the range of 80-90 bpm is recommended for any heart with a heart rate below 80 bpm. From time to time, pacing may be withdrawn to determine if the heart can maintain an adequate heart rate on its own.

5.9. Sampling

A blood gas analyzer is utilized to check blood gasses, electrolytes, and lactate throughout perfusion. Arterial and venous blood lactate samples are measured to ensure adequate myocardial perfusion of the donor organ. A venous lactate value lower than an arterial value within a sampling set indicates adequate perfusion as does a stable or downward trending lactate over time. Adjustments may be made to perfusion controls in order to optimize perfusion at any time during the retrieval.

5.9.1. Sampling Procedures

- Arterial samples are taken from the arterial port on the HPM sampling manifold.
- Venous samples are taken from the venous port on the HPM sampling manifold. Ensure port is flushed at least twice before taking final blood sample for analysis.

5.9.2. Recommended Sampling Scheme

- Donor lactate within 30 minutes prior to blood collection.
- Baseline OCS™ lactate sample with blood gases and electrolytes during priming.
- Approximate hourly arterial and venous lactates throughout preservation. Multiple samples may be performed during stabilization to optimize perfusion.
- Periodic arterial blood gas and electrolyte samples throughout perfusion.

5.9.3. Electrolytes May Need Replenishment

- Treat low ionized calcium levels to achieve a minimum concentration of 0.8 mmol/L.
- Treat low glucose levels to achieve a minimum concentration of 100 mg/dL (5.5 mmol/L).

As a reminder, Maintenance Solution contains electrolytes and glucose, and will replenish some perfusate components during infusion.

5.10. Organ Management

The guidance ranges for mean aortic pressure (AOP) and coronary flow (CF) are 40-100 mmHg and 400-900 mL/min, respectively. Management of parameters outside of these ranges may be required to optimize perfusion.

Two scenarios may commonly occur initially when using OCS™ Heart System. Below are these examples and possible mitigations.

5.10.1. Low mean AOP with adequate CF (AOP < 70 mmHg and CF ≥ 700 mL/min)

Goal: Develop higher mean AOP and maintain adequate CF to achieve adequate perfusion based on lactate determinations.

5.10.1.1. Auto AOP Control Mode

- Confirm AUTO AOP set point is not less than the target mean AOP in order to minimize delivery of Maintenance Solution. Increase set point, if necessary.
- If mean AOP increases, reassess perfusion parameters and adequate AOP by checking arterial and venous lactate samples.

5.10.1.2. Manual Control Mode

- Reduce Maintenance Solution rate manually by increments of up to 5 mL/hr to achieve target mean AOP.
- If mean AOP increases, reassess perfusion parameters and adequate AOP by checking arterial and venous lactate samples.

5.10.1.3. Pump Flow Control

- If adequate mean AOP is not achieved by adjusting Maintenance Solution rate, as determined by arterial and venous lactate levels, increase Pump Flow as necessary.
- Reassess perfusion parameters and adequate AOP by checking arterial and venous lactate samples.

5.10.2. High mean AOP with low CF (AOP > 90 mmHg and CF ≤ 700 mL/min)

Goal: Enhance vasodilation to decrease mean AOP and increase CF to achieve adequate perfusion based on lactate determinations.

5.10.2.1. Auto AOP Control Mode

- Allow SDS to infuse Maintenance Solution to the maximum AUTO AOP infusion rate (30 mL/hr).
- If more than 30 mL/hr of Maintenance Solution is needed in AUTO AOP mode, switch to Manual Mode.
- Increase Maintenance Solution rate manually until adequate mean AOP is achieved as determined by arterial and venous lactate samples.
- Monitor decrease in AOP over time, and reduce Maintenance Solution rate manually as needed to maintain stable adequate AOP. Return to AUTO AOP Mode once mean AOP reaches the desired set point and the Maintenance Solution rate is ≤ 30 mL/hr.

5.10.2.2. Manual Control Mode

- Start Maintenance Solution rate at 5 mL/hr.
- Increase rate in increments of up to 5 mL/hr until AOP stabilizes and/or begins to decrease.
- Monitor decrease in AOP over time until adequate, stable AOP is achieved as determined by arterial and venous lactate samples.

Selection of the strategy may be based on donor information such as age, cause of death, and know medical risk factors such as the presence of left ventricular hypertrophy (LVH).

5.11. Organ Management Strategy

Figure 48: Organ Management Strategy

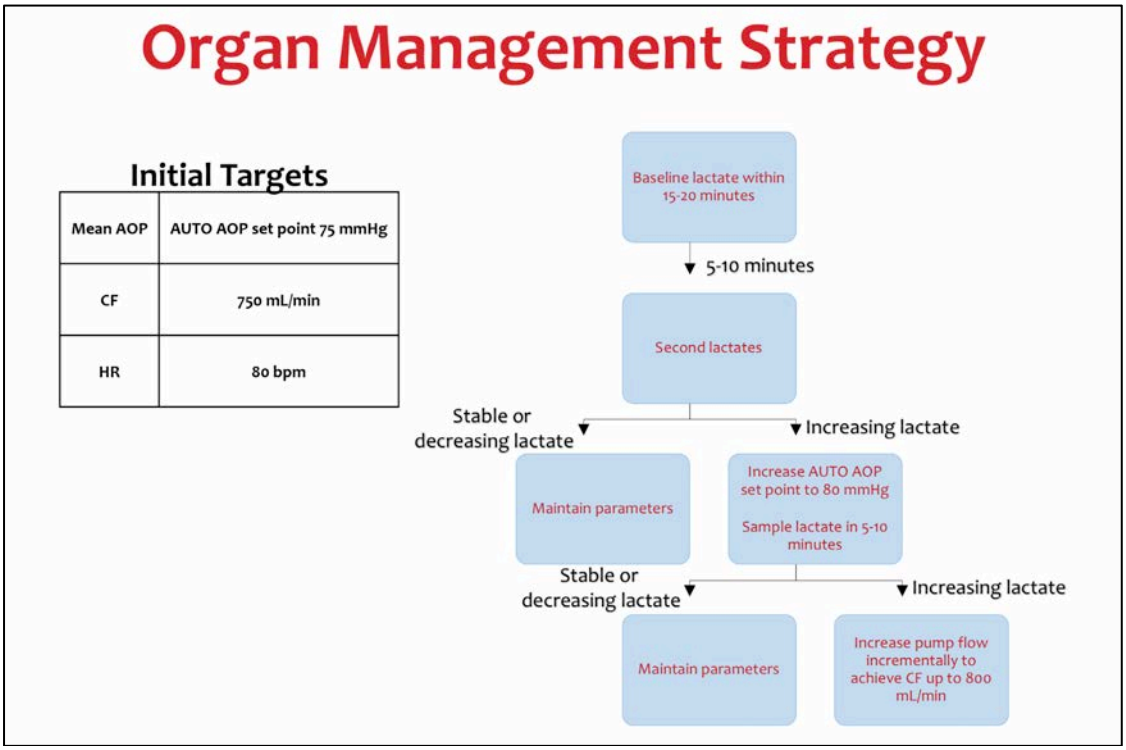
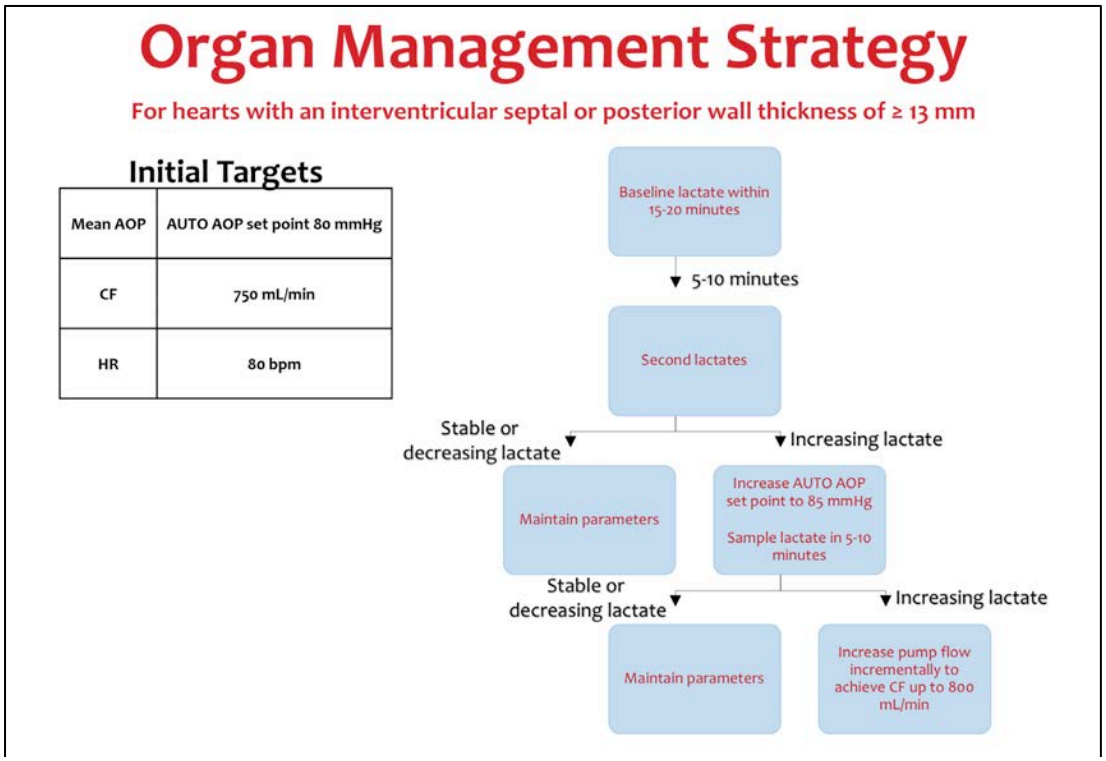


Figure 49: Organ Management Strategy for Hypertrophic Hearts



5.11.1. ECG Synchronization

In ECG synchronization mode, the circulatory pump is synchronized with the ECG R-wave. The system begins each pump cycle at an offset (delay) from the R-wave that you specify using the ECG Synchronization Adjust (Figure 50) menu. To assist the user with setting and monitoring the delay, the ECG and pressure waveforms are marked with a yellow highlight, illustrating the time in the pump cycle when the flow to the heart is being maximized at the current delay (Figure 51). Any change in perfusion parameters should always be assessed based on comparison of arterial and venous lactates and its trend within 5-10 minutes of making the change. While in ECG Synchronization mode, lactates should be checked periodically.

Figure 50: ECG Synchronization Adjust Window

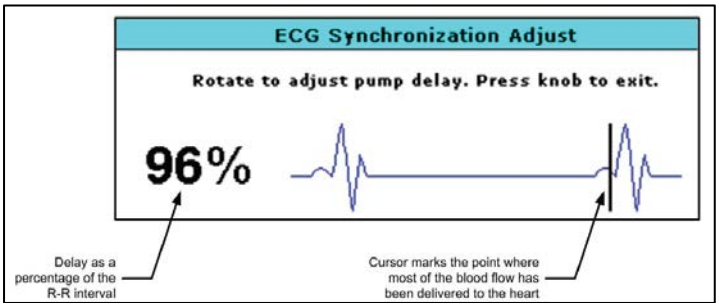
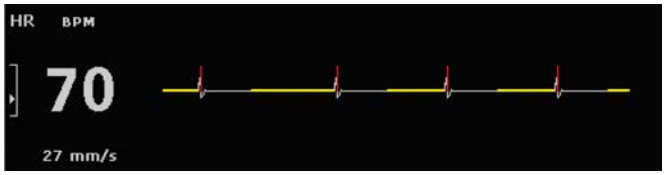


Figure 51: ECG Synchronization Heart Rate Waveform Highlights



5.11.2. Availability of the ECG Synchronization Function

The ECG Synchronization function is not available, and cannot be enabled if any of the following conditions occur:

- If the perfusion clock is off
- If there is no R-wave signal or if the ECG signal is lost
- If HR is less than 30 BPM
- If HR is greater than 120 BPM.

A critical system fault alarm is displayed if the system exits ECG synchronization. The system does not automatically restart ECG synchronization when the condition is resolved. You must manually re-enable synchronization.

5.11.3. To Enable ECG Synchronization

ECG synchronization mode turns on if the  button is pressed.

The Pump icon  is displayed in the lower left corner of the Wireless Monitor and a yellow highlight appears on the ECG and pressure waveforms.

NOTE—Prior to activating ECG synchronization, ensure that the heart is contracting at a regular rhythm and the Coronary Flow (CF) level is appropriate for asynchronous operation. This is the flow level that will be established when ECG Synchronization mode is terminated.

5.11.4. To Disable ECG Synchronization

Press  to exit ECG synchronization mode.

5.11.5. To Adjust the ECG Synchronization Delay

Adjust the ECG synchronization delay to properly synchronize the pump's action to the heart rate to optimize cardiac perfusion. Entering ECG synchronization adjust mode automatically enables the ECG synchronization.

1. Press and hold  to display the ECG Synchronization Adjust window and adjust the synchronization delay.
2. The Pump icon  is displayed in the lower left corner of the Wireless Monitor and a yellow highlight appears on the ECG and pressure waveforms. Establish CF per clinical training.
3. Rotate the knob clockwise to increase or counterclockwise to decrease the time delay between the ECG R-wave and the initiation of the pump stroke. As you rotate the knob, the cursor moves and the pump immediately adjusts to the new setting.
4. Adjust the synchronization delay until you see the highlight end just before the R-wave on the ECG waveform. This denotes that the majority of the perfusate flow arrives during diastole of the cardiac cycle.
5. When the heart and pump are synchronized, press the knob to exit from ECG Synchronization Adjust mode.

CAUTION—Sustained periods of cardiac arrhythmias or excessive vibration may introduce instability in the timing of pump flow when using ECG Synchronization. While using ECG Synchronization it is important to monitor the ECG waveform to ensure that the red markers are centered on the actual R-waves and that the heart is contracting at a regular rhythm. If these conditions are not met, then ECG Synchronization mode should be terminated.

5.12. Removal of Donor Heart from System

5.12.1. Cooling Heart on System

NOTE—Before cooling on OCS™, return to Asynchronous mode. This action will prevent the OCS™ from canceling Synchronous mode automatically during cooling.

1. De-air the AO access port and attach heart flush infusion line.
2. Set and achieve temperature on heater/cooler to 34°C prior to connection and attach the Hansen Quick Connects between the HPM oxygenator and the inflow/outflow lines of the heater/cooler.
3. Once heater/cooler temperature reaches 34°C, open the circulation loop.
4. Undock the Wireless Monitor.

5. Apply the Sterile Drape to the work area.
6. Open the outer hard cover.
7. Turn the OCS™ temperature to OFF in Resting tab of Configuration Menu.
8. Reduce the heater/cooler temperature by 10°C and pump flow by 100 mL/min.
9. Repeat Step 8 when the Wireless Monitor displayed blood temperature is within 2°C of cooler temperature.
10. Cool until the Wireless Monitor temperature is within 2°C of 14°C.

NOTE—Prior to activating ECG synchronization, ensure that the heart is contracting at a regular rhythm and the Coronary Flow (CF) level is appropriate for asynchronous operation. This is the flow level that will be established when ECG Synchronization mode is terminated.

5.12.2. Final Arrest

1. Using 1 L of a Heart Flush Solution.
2. Close the AO vent.
3. Detach PA cannula through the inner lid sterile membrane.
4. Begin infusion of 1 L of cold cardioplegia (via a pressure bag maintain a mean pressure 45-65 mmHg).
5. Clamp the aortic blood line.
6. Turn the OCS™ pump off.

CAUTION—Once the aortic blood line is clamped, ensure OCS™ pump is off by confirming pump has fully stopped.

5.12.3. Transplant into Recipient

The donor heart is then removed from the OCS™ after establishing a standard sterile field on the OCS™ and placed in a sterile bowl filled with cold saline. In addition, topical cooling or other preservation methods may be used for further protection of the heart during implantation. The OCS™ cannulae are removed and the donor organ prepared for implant in accordance with standard surgical procedure.

5.13. Shutting Down the System

5.13.1. Preparing the OCS™ Heart System for Shutdown

To prepare the OCS™ Heart System for shutdown after the organ has been removed from the system:

1. Press the  button to place the system in Standby Mode.
2. Follow the on-screen directions to ensure that all data is downloaded to the data card.
3. If no data card is present, the system will store the data internally and the data can be retrieved later.

5.13.2. Removing the Probes from Tubing

The probes are reusable and do not require sterilization since they do not directly contact perfusate. After the heart has been removed, detach the AO Flow, Pump Flow, Coronary Flow, and SvO_2/HCT Probes from the tubing, clean the probes as described in Cleaning of the TransMedics IFU, and store them inside the Heart Console.

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 HPM, but leave it connected to the Heart Console.

To remove the SvO_2/HCT Probe 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 SvO_2/HCT Probe from the tubing on the HPM, but leave it connected to the Heart Console.

5.13.3. Turning Off the Gas Cylinder

1. Use the cylinder wrench to shut off the gas by slowly turning the shut-off valve clockwise.

CAUTIONS—

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

Always ensure that the gas cylinder is OFF after the preservation session is complete.

2. Disconnect the gas lines connecting the HPM to the Heart Console.

5.13.4. Disposing of the HPM and Preparing the System for Cleaning

After one use, dispose of the entire HPM, including the attached PC board and all sterile accessories in accordance with institutional protocols for disposing of blood-contaminated materials.

To remove the HPM, face the system so that Wireless Monitor is on your left, do the following:

1. Press the HPM release lever to disengage the Holding Clamps that hold it in place.
2. Hold the HPM with your left hand and disengage it with your right hand.
3. Angle the HPM 30° toward you to disengage it from the pump slots.
4. Lift the HPM up and out of the system.
5. Dispose of the entire HPM using your institution's protocol for handling and disposing of blood-contaminated materials.

CAUTIONS—

Do not sterilize the Heart Console or any component of the system. Sterilization, by any means, will damage the system and void the warranty.

Do not attempt to sterilize and reuse the HPM or any of the sterile accessories.

NOTE—The probes require specialized cleaning and disinfection instructions. See the "Cleaning and Disinfecting the Probes" section for more details.

Disposal Regulations: The OCS™ Heart System contains components that may require special considerations for disposal as a result of local, national, or EU regulations. Dispose of all single use products per standard hospital procedures. Contact your local TransMedics service representative for disposal instructions for products that are at their end of service life.

The use life of the Heart Console is expected to be at least five years with a rate of use of 50 preservation sessions per year.

NOTE—See Chapter 7, "Cleaning and Maintaining the System" for information on how to clean and disinfect the system after use.

Part 2:
TECHNICAL GUIDE

6. CHAPTER 6: ADVANCED

6.1. Configurations

6.1.1. Managing Alarms

Critical alarms that require the user to acknowledge them (such as loss of ECG) display 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. Momentarily press  to acknowledge the alarm. This will dismiss the alarm. Press and hold to mute all audible alarm indications indefinitely. Press and hold again to restore audible alarms.

The messages that rotate through the Alarm Banner can be one of the following three types of non-critical alarms. Non-critical alarms can be high, medium, or low priority. These types of alarms remain displayed until their condition is resolved.

- 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) alarms are system-related (such as perfusion clock not started, 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 the user turns on the gas, or replaces the gas cylinder with a full tank of gas, the low gas alarm condition is resolved.

The Display Alarm Summary item in the Actions tab of the Configuration Menu lets the user quickly review the list of current alarm messages with a time stamp of when the list was acquired.

6.1.2. Starting and Resetting the Perfusion Clock

Until the perfusion clock is started, the system does not generate a valid heart rate and will not declare a loss of heart rate system fault alarm. The heart rate frame displays --- (HR Too Low) in the heart rate frame on the Wireless Monitor until the perfusion clock is started.

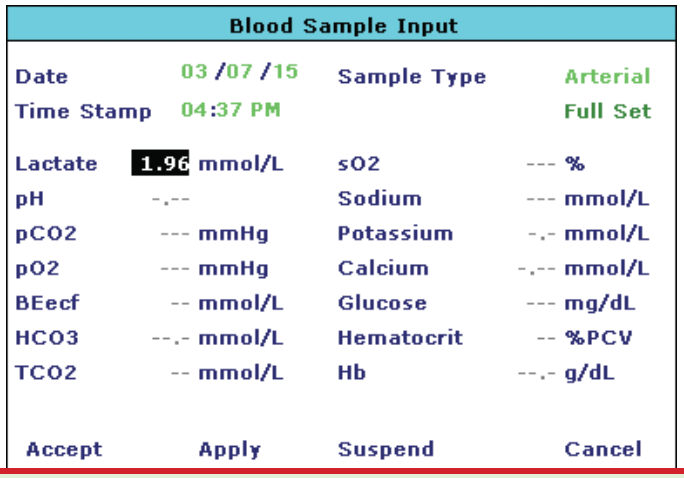
Press  to start, or press and hold to reset the clock.

6.1.3. Sample Data - Setting the Blood Sample Units

The OCS™ is capable of displaying blood gas samples as entered by the user in a trend graph. Use the System tab of the Configuration Menu to configure blood sample units for parameters that can have multiple types of units.

Select Add Blood Sample in the Actions tab of the Configuration Menu to add blood sample data taken during the preservation session. Lactate is the default blood sample. If the user needs to enter other blood sample types, the user can select Full Set and turn the knob to highlight other blood sample types.

Figure 52: Recording a Blood Sample



NOTE—You cannot change the blood sample units once blood samples have been entered.

6.2. Using Annotations

The user can add notes and comments during the preservation session as annotations to the digital session file. The user can also use the Annotation 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. The user 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. Annotations should not contain any information that needs to be protected from unauthorized disclosure.

Select **Add Annotation** in the Actions tab of the Configuration Menu to display the Annotation Menu. The user can enter annotations as free form text, as predefined text, or a combination. By selecting Key Word List, the user can scroll through and select from a predefined set of Keywords. By rotating the knob to beneath the first heavy line in the menu and pressing the knob, the user can enter free form text one character at a time. Available characters include letters, numbers and symbols. The character is selected by pressing the knob.

To save the annotation as the ID for this preservation session, select Save as Organ ID. To save the current entry as the annotation, select Save as Annotation. To discard any annotations, select Cancel. If no Organ ID is saved, an alarm will occur approximately thirty minutes after transitioning out of Standby Mode.

6.3. Installing Pacing Leads

If necessary, the user can install user-supplied pacing leads and connect them to an external pulse generator through the Pacer Lead Window in the heart chamber. If pacing leads are installed, the Wireless Monitor may display pacer markers on the monitored waveforms (depending on the magnitude of the pace energy).

CAUTIONS—

When using an external pacemaker, it is possible that pacer energy may be detected by the OCS™ as R-waves. If this occurs then the Heart Rate displayed on the Wireless Monitor screen may be inaccurate which would also affect heart rate alarms. It is important to set the pulse amplitude high enough to stimulate contractions but not so high as to induce inappropriate R-wave counting. Adjust the placement of the RA electrode if necessary to reduce the pacer interference with the R wave detection.

When using an external pacer, it is important to verify that the heart is contracting at a regular rhythm. If the rhythm is not regular or at the configured pace rate, then the blood will not always be delivered to the heart at the desired point in the cardiac cycle. ECG Synchronization should be turned off immediately.

6.4. Inserting a Monitoring Instrument

1. Wipe the Aortic Connector port with an alcohol swab.
2. Remove the Tuohy-Borst Valve from the sterile packaging.
3. Insert the monitoring instrument halfway into the valve.
4. Turn the Tuohy-Borst Valve clockwise to tighten on the instrument.
5. Screw the Valve into the Aortic Connector port.
6. Loosen the Tuohy-Borst Valve opening by turning counterclockwise, sufficient to pass the instrument into the desired position within the organ.
7. Retighten the Tuohy-Borst Valve on the instrument until there is no blood leakage.
8. When finished, loosen the valve sufficient to withdraw the instrument, so that it is halfway in the valve. Remove the valve completely from the Aortic Connector.

6.5. Session Files

Data are continuously saved in internal memory. Once a data card is inserted, all saved data is automatically transferred to the card, and then updated in 15-minute increments. TransMedics recommends that the user inserts a data card at the beginning of each session. Under ordinary circumstances, data from all of the procedures associated with an organ should be documented in a single session.

The system logs the following information for each session:

- All system operating and error events
- All physiological, capacity, and system fault alarm events
- Trend data for each parameter at two-minute intervals.

The data saved on the SD data card are in text file format. The trend data saved on the data card is tab-delimited and the column data format is general to be compatible with Microsoft Excel software. The table below shows the contents of the files created and transferred as part of the session file.

Table 10: Session File Folder Contents

File Name	Data Logged
events.txt	Includes the following data that is associated with the current session: Alarms, configuration settings, and other changes to system setup and operation, transitions between Run and Standby modes, annotations, errors detected, and the user responses logged by date and time.
trends.xls	Includes the following data that is associated with the current session: Trend data for all parameters sampled at two-minute intervals and logged by date and time.
blood-sample.xls	Includes the following data that is associated with the current session:

File Name	Data Logged
	Blood sample data entered by the user for all parameters sampled including the time and type (Arterial or Venous).
system-errors.txt	It contains the system's cumulative error history logged by date and time.

6.6. Managing Configuration Settings

6.6.1. Saving Default Settings

Use the System tab of the Configuration Menu to save the current settings as the session default. The session default settings are applied automatically when a new session starts.

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 theses parameters for adequate organ preservation.

6.6.2. Restoring System Settings

Use the System Tab of the Configuration Menu to restore previously Saved Defaults or to revert all settings to Factory Defaults.

7. CHAPTER 7: CLEANING AND MAINTAINING THE SYSTEM

This chapter describes how to clean, disinfect, and inspect the OCS™ Heart System. It also provides routine cleaning and maintenance procedures to ensure system performance and reliability.

Maintenance activities includes the routine, operator-performed procedures described here and periodic visual inspections. 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 OCS™ Heart 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. Cleaning and Disinfecting the System after Use

After the OCS™ Heart System has been used and after you have removed and properly disposed of the HPM 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 Heart Console are similar to those for any medical equipment that may come in contact with human blood or other bodily fluids.

7.1.1. 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, and protective clothing.

Refer to your institution's procedures for additional institutional requirements.

7.1.2. 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, PN 02001)
- Paper towels
- Water.

7.1.3. 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.

7.1.4. 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.

7.1.5. Cleaning and Disinfection Process

Use Table 11 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 11, 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 7.2, "Cleaning and Disinfecting the Probes."

Table 11: Cleaning and Disinfecting the Heart Console

Area	Supplies	Exposure Time	Cleaning Procedure
General Cleaning			
Pre-disinfection cleanup	Soft brushes Soft lint-free cloths Lint-free swabs Water	As required	1. Prior to cleaning, disconnect the system from the AC wall outlet. 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 Heart Console's top cover and open the front panel. 6. Remove and dispose of the HPM and accessories. 7. Repeat steps 2-4 on the Heart Console's internal surfaces.
Disinfection of Interior of System with Covers Open (HPM Already Removed)			
Painted surfaces (white) with exception of Circuit Board Connector Block	Bleach wipes Tongue depressors Soft lint-free cloths Lint-free swabs	10 minutes	1. Wipe with bleach wipes. Wrap the bleach wipe around a tongue depressor to access smaller areas as needed.

Area	Supplies	Exposure Time	Cleaning Procedure
	Water		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	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	For details, see Section 7.2, "Cleaning and Disinfecting the Probes" 1. Remove probe connector panel cover. 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, SDS sensors, 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-colored buttons, the three dark IR transmission windows, and the immediately surrounding white panel, which extends to the rectangular seal)	Alcohol wipes Soft lint-free cloths Water Paper towel Metal Cleaner	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. 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 each silver button with Diamond Paste Metal Cleaner supplied by TransMedics (REF 1460) for 10 seconds using a lint-free wipe. Wipe each silver button and the 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	5 minutes (twice)	1. Wipe with alcohol wipes.

Area	Supplies	Exposure Time	Cleaning Procedure
	Soft lint-free cloths Water		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			
Painted (white, silver/blue, and red/ black (logo)) 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 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 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.

Area	Supplies	Exposure Time	Cleaning Procedure
			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 Soft lint-free cloths Water	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. 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			
Painted (white) 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	5 minutes (twice)	DO NOT ALLOW CONNECTOR PINS TO GET WET. 1. Wipe with alcohol wipes and swabs.

Area	Supplies	Exposure Time	Cleaning Procedure
	Soft lint-free cloths Water		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			
Painted (silver/blue) 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 Heart Console back on Mobile Base.

To avoid injury to personnel or damage to equipment, observe the warnings and cautions below 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 splash or 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—

Do not sterilize the OCS™, or any component of the OCS™. Sterilization, by any means, will damage the system and void the warranty.

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 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 gas or electrical connectors (e.g., the batteries or probe connectors).

Do not use pressurized air.

Do not use sharp or metallic tools to remove residues.

Probes require special handling and cleaning after use.

7.2. Cleaning and Disinfecting the Probes

The 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.

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 Heart Console.

To clean and disinfect the SvO_2/HCT Probe and the SaO_2/HCT Probe:

1. Using a soft lint-free cloth or swab, thoroughly clean the channel that fits over the cuvette in the HPM.

> **CAUTION**—Do NOT use a brush to clean the SvO_2/HCT Probe or the SaO_2/HCT 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 Heart Console.

7.3. Storing the System Between Uses

1. Transport the system to a safe, secure, and access-controlled storage area. Store the system in a clean, dry area away from traffic that meet the temperature and humidity conditions specified in Section 9.2, “Electrical and Physical Specifications.”
2. Store the probes within the Heart Console, connected to the system.
3. Check the gas cylinder and the need to replace it.
4. Store the gas cylinder in the OCS™ gas compartment with its valve closed.
5. Reinstall the top cover.
6. Set the wheel locks and wrap the excess power cord to eliminate interference with traffic in the area.
7. Connect the OCS™ power cord to an active AC power source and ensure the On/Off switch remains in the On position while the system is in Standby Mode to ensure charging the Heart Console and Wireless Monitor batteries.
8. Put the OCS™ in Standby Mode with the Wireless Monitor docked in its cradle.
9. Plug the defibrillator into AC power.

7.4. Cleaning and Maintenance Task Checklist

Table 12 below provides a checklist for cleaning and maintaining the system and its components.

Table 12: Cleaning and Maintenance Checklist

Activity	Frequency	Comment
Product inspection	Upon receipt of TransMedics System or individually TransMedics components and supplies, and prior to and after each use and at least once a month during storage.	Visual inspection

Activity	Frequency	Comment
Routine cleaning	As needed during storage and prior to each use	Visual inspection
Post-use inspection, cleaning, and disinfection.	After each use	Visual inspection. If soil remains visible, repeat the cleaning and disinfection process until the Heart 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 "Symbols Used in this Guide and on the HPM and Heart Console" 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 11.
Preventive Maintenance	Once a year	By TransMedics Service
Leakage current test	Once a year	By TransMedics Service
Ground integrity test	Once a year	By TransMedics Service

7.5. Routine Inspection Before and After Use

Before and after each use, inspect the Heart 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 the probe cables and housings
- Damage to the SDS Console housing or damage to the HPM holding area
- Damage to the circulatory pump
- 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 the Wireless Monitor docking area

- Proper operation of the Wireless Monitor controls
- Damage to OCS™ battery packs
- 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 HPM latching mechanism
- Evidence that the tamper evident seal in no longer intact across the seam of the rear panel and the Console
- Ensure the buttons/contacts on the front end interface of the Console are clean.

If you find any damage, contact TransMedics Service.

8. CHAPTER 8: TROUBLESHOOTING

8.1. 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 the table below. A TransMedics emergency response representative can be reached at any time by calling the U.S. at +1-978-222-3733 or the EU at +31(0) 20-7084561.

8.2. Technical Service Follow-Up

If an issue is observed during the operation of the OCS™, 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.

8.3. Troubleshooting the OCS™ Heart System

Try to resolve the issue one step at a time by performing the recommended actions in the order that they appear in Table 13 below. Based on the outcome of the troubleshooting process, follow up with TransMedics Technical Service.

Note the following:

- **Standby-cycle** the system means to press  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 blood pump.
- **Power-cycle** the system means use the On/Off switch on the side of the Heart Console to turn the system OFF, wait 5 seconds, and then turn it ON. This sequence shuts off the blood pump. When the OCS™ powers on, it will continue operating at the same settings that were present when it was shut off.
- **Unlatch and re-latch** HPM means to shut the blood pump off, unlatch the HPM, tilt it forward and wait at least 30 seconds until the alarm message indicates the HPM module has been removed, and then tilt it back to re-latch it. Then restart the pump.

CAUTION—If the blood pump is temporarily shut off as part of the fault recovery process, the user must check for air in the Aorta line and take appropriate action to remove the air before resuming the blood pump.

NOTE—If the Wireless Monitor fails for any reason, the OCS™ will continue to function. Critical functions of SDS infusion, heating, pumping, and gas delivery continue at the last settings made by the user.

Table 13: Troubleshooting the OCS™ Heart System

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	During Priming	During Preservation
Pumping			
Pump Failure	1. Remove and reinsert HPM. 2. Power-cycle the system.		1. Arrest heart with cold cardioplegia.
Heating			
Blood temperature sensor failure	1. Unlatch and re-latch the HPM. 2. Standby-cycle the system.		1. Continue the preservation session. The system maintains the blood warmer plates to a constant temperature per the set point.
Blood warmer sensor failure; blood warming disabled	1. Unlatch and latch the HPM. 2. Standby-cycle the system.		1. Arrest heart with cold cardioplegia.
Blood warmer too hot; Blood too hot	1. Wait one minute for the message to clear with the pump running and fluid in the HPM. 2. Standby-cycle the system.	1. This is usually a transient event. Wait one minute for the message to clear with the pump running and fluid in the HPM. 2. Standby-cycle the system.	1. With the pump running at flow rate > 300 mL/min, wait one minute for the message to clear. 2. Arrest the heart with cold cardioplegia.
Blood warmer failure	1. Turn off the pump, remove the HPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 11 or vigorously scrub them with alcohol wipes, then reinstall the HPM. 2. Standby-cycle the system.		1. Arrest heart with cold cardioplegia.
Single blood warmer element failure	1. Turn off the pump, remove the HPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 11 or vigorously scrub them with alcohol wipes, and then reinstall the HPM. 2. Standby-cycle the system. 3. Proceed with use if necessary but be aware that blood warming capacity is reduced. Keep the Console covers closed as much as possible and keep the system in a warm environment.		1. Proceed with use if necessary but be aware that blood warming capacity is reduced. Keep the Console covers closed as much as possible and keep the system in a warm environment.
Gas			
Gas tank sensor failure	1. If it's loose, 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.		1. If it's loose, 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.
Gas flow control failure	1. Standby-cycle the system.		1. To clear the fault, configure the gas flow rate to 0 mL/min

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	During Priming	During Preservation
			and accept the change. Then set the gas flow rate to the desired value. 2. If restarting the gas does not correct the problem, monitor the blood gases. 3. Arrest the heart with cold cardioplegia if the blood gas levels fall outside of the optimal ranges.
Pressure Probes			
Pressure probe failure: Dual AOP	1. Unlatch and latch the HPM. 2. Standby-cycle the system. 3. Replace the HPM. 4.	1. Unlatch and latch the HPM. 2. Standby-cycle the system.	1. Proceed with perfusion and monitor coronary flow, heart rate, and lactate. If perfusion parameters become unstable and fall outside of the recommended range, arrest the heart with cold cardioplegia.
Pressure probe failure: Dual PAP			1. Proceed with perfusion and monitor the right ventricle for signs of distension. If RV shows signs of distension, detach the PA cannula from the PA port or arrest the heart with cold cardioplegia.
HPM			
Perfusion Module failure	1. Turn off the pump, remove the HPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 11 or vigorously scrub them with alcohol wipes, and then reinstall the HPM. 2. Standby-cycle the system. 3. Replace the HPM.	1. Turn off the pump, remove the HPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 11 or vigorously scrub them with alcohol wipes, and then reinstall the HPM. 2. Standby-cycle the system.	1. Unlatch and re-latch the HPM after vigorously scrubbing the silver contact buttons with alcohol wipes. 2. Arrest the heart with cold cardioplegia.
Perfusion Module not present	N/A	1. Remove the PM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 11 or vigorously scrub them with alcohol wipes, and then reinstall the PM. 2. Standby-cycle the system.	1. Unlatch and re-latch the HPM after vigorously scrubbing the silver contact buttons with alcohol wipes. 2. Arrest the heart with cold cardioplegia.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	**During Priming**	**During Preservation**
		3. Follow-up with OCS™ Service.	
Loss of Heart Rate	N/A	N/A	1. Check ECG electrode pad placement and orientation. 2. Monitor HR by visually monitoring the heart.
Flow Probes			
Check flow probe: Pump	1. Check for air in the line. Follow de-airing instructions. 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 Console. 6. Standby-cycle the system.		1. Check for air in the line. 2. Check that the flow probe cover is latched. 3. Reinstall the probe with coupling gel. 4. Proceed with heart perfusion. Refer to AOF value instead of Pump Flow.
Check flow probe: AOF			1. Check for air in the line. 2. Check that the flow probe cover is latched. 3. Reinstall the probe with coupling gel. 4. Proceed with heart perfusion. Refer to Pump Flow value instead of AOF.
Check flow probe: CF			1. Check for air in the line. 2. Check that the flow probe cover is latched. 3. Reinstall the probe with coupling gel.
Missing probe: AOF Missing probe: CF Missing probe: Pump	1. Connect each probe to its proper location on the Console. 2. Standby-cycle the system.	N/A	N/A
SvO_2/HCT Probe			
Check SvO_2/HCT Probe	1. Ensure the probe is properly connected to the Console. 2. Standby-cycle the system.	1. Ignore this message if there is no blood in the SvO_2/HCT cuvette. 2. Ensure the probe is properly seated to cuvette on HPM. 3. Ensure the probe is properly connected to Console. 4. Standby-cycle the system.	1. Ensure probe is properly seated to cuvette on HPM. 2. Ensure probe is properly connected to the Console. 3. Proceed without the functioning probe by monitoring blood gases and hematocrit using the portable blood gas analyzer.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	During Priming	During Preservation
Wireless Monitor Communications			
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 Console. 2. Dock the Wireless Monitor and wait 60 seconds for the Console to recover. 3. Dock the Wireless Monitor and power-cycle the system.	1. Return the Wireless Monitor in range of the Console and immediately verify if the system is still functioning. 2. If the pump is still functioning, Dock the Wireless Monitor and wait 60 seconds for the Console to recover. 3. If the pump is no longer functioning, power-cycle the system. 4. Arrest the heart with cold cardioplegia.
Radio communications failure	1. Power-cycle the system. 2. Proceed with operating the system with the Wireless Monitor docked on the Console.		1. Operate the system with the Wireless Monitor docked. 2. Replace the Wireless Monitor with a spare.
Power			
Power system failure (AC Line Power Supply)	N/A	1. Power-cycle the system. 2. Operate the Console on battery power only.	1. Operate the Console on battery power only.
Power failure on channel 1 [or channel 2 or channel 3]	N/A	1. Remove and reinsert the battery. [Channel 1 is left, 2 is middle and 3 is right-hand side.] 2. Replace battery with a spare battery. 3. Power-cycle the system.	1. As soon as the battery is depleted, replace it with a charged battery.
Battery failure, remove battery 1 [or battery 2 or battery 3]	1. Remove the battery from the Console [channel 1 is left, 2 is middle and 3 is right-hand side.] 2. Replace the battery with a spare battery.		1. Remove the battery from the Console [channel 1 is left, 2 is middle and 3 is right-hand side.] 2. Replace the battery with a spare battery. 3. As soon as battery [battery 2 or 3 is depleted], replace it with a charged battery or plug the Console into an AC supply.
Wireless Monitor battery failure	N/A	1. Undock the Wireless Monitor and then dock the Wireless Monitor. 2. Proceed with the Wireless Monitor docked.	
Battery 1, 2 or 3 charging failure.	1. Proceed with use and allow time for the battery to cool. This message indicates a fault only if it persists for more than one		1. Proceed with use and allow time for the battery to cool.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	During Priming	During Preservation
Battery may be used.	hour. It may occur normally when the OCS™ battery is warm from being recently charged. 2. Remove the battery and reinsert. 3. Replace the battery with a spare. 4. Power-cycle the system.		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.
ECG Synchronization			
ECG Synchronization canceled, ECG signal lost, HR > 120 bpm or HR < 30 bpm	N/A	N/A	1. Press the Alarm Silence button to acknowledge the alarm. 2. Check organ function. 3. Check ECG electrode pad placement and orientation. The shiny metal side should be facing up.
External SD Card			
Data card is full	1. Use an alternate TransMedics-supplied SD card. 2. Remove the SD card from the Console and delete files to create capacity. 3. At the end of the run, view trend data on the Wireless Monitor as needed.		
Data card incorrectly formatted. Reinsert card.	1. Remove and reinsert the 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.	1. Remove and reinsert the SD card to retry the transfer. 2. Use an alternate TransMedics-supplied SD card.	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	1. Remove the SD card. Slide the tab on the card to the unlocked position. Reinsert the card.		
Data card corrupted	1. Remove and reinsert the SD card to retry the transfer. 2. Use an alternate TransMedics supplied SD card.		
Internal SD Card			
Incorrect Internal Memory Device Format or Internal Memory Device Error	1. Power-cycle the system then Standby-cycle the system.		1. Proceed with use of the OCS™.
SDS			
Solution Side Occlusion	N/A	1. Check for depleted solution and replace as necessary.	

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	During Priming	During Preservation
		2. Check and correct for kinks in the tubing between the cassette and solution bag. Restart solution delivery by setting channel to Manual Mode or AUTO Mode.	
Organ Side Occlusion	N/A	1. Verify the roller clamp is open. 2. Check and correct for kinks in the tubing between the cassette and HPM. Restart solution delivery by setting channel to Manual Mode or AUTO Mode.	
Channel Failure	1. Remove cassette and manually retract the receiving socket all the way down. Reinsert the cassette to the SDS Console, ensuring the drive pin is aligned into the receiving socket on the cassette. Restart the solution delivery by setting the channel mode to Manual or AUTO Mode. 2. Move the cassette to another SDS channel.		
Cassette Failure	1. Remove and reinsert the cassette to the SDS Console, ensuring the drive pin is aligned into the receiving socket on the cassette. Restart the solution delivery by setting the channel mode to Manual Mode or AUTO Mode. 2. Replace the cassette and restart solution delivery.		
Cassette Removed	N/A	1. Manually retract the receiving socket all the way down. Reinsert the cassette ensuring that the drive pin is aligned into the receiving socket on the cassette. Restart the solution delivery by setting the channel mode to Manual mode or AUTO Mode.	
Communications Error to SDS	1. Check that the cable between the SDS and the Console is connected.	1. Check that the cable between the SDS and the Console is connected. 2. Note that while the SDS has power, it will infuse at factory default rates for all channels that are delivering solutions (Maintenance at 10 mL/hr; other channels at 5 mL/hr).	
System			
Internal error. Please inform TransMedics Customer Support.	N/A	1. Note the error code displayed in the Alarm Summary. 2. Acknowledge the alarm and proceed.	
Communications failure to OCS	N/A	1. Undock and dock the Wireless Monitor. 2. Power-cycle the system.	1. Undock and dock the Wireless Monitor. 2. Proceed with the Wireless Monitor undocked.
Reset occurred – self test bypassed	1. This message will be displayed if the system power switch was turned on or in the case of a system/ software reset. 2. The system will return to its previous operating state. Subsystems such as pumping and heating will continue during the reboot process from a software error and the system will return to full operation within 60 seconds. 3. Press the Alarm Silence button to acknowledge/dismiss the message. 4. If desired, Standby-cycle to perform the Self Test.		1. This message will be displayed if the system power switch was turned on or in the case of a system/ software reset. 2. The system will return to its previous operating state. Subsystems such as pumping and heating will continue during the reboot process from a software error and the system will return to full operation within 60 seconds.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/HPM Insertion	During Priming	During Preservation
			3. Press the Alarm Silence button to acknowledge/ dismiss the message.
A dark screen and no message in response to the exit from Standby	1. Confirm the power switch is in the On position. 2. Undock and dock the Wireless Monitor. 3. Power-cycle the system.	N/A	N/A
A dark screen, but Wireless Monitor buttons respond with a tone	1. Dock the Wireless Monitor and power-cycle the system.		1. Undock the Wireless Monitor. 2. Reboot the Wireless Monitor by pressing and holding both the Pump Adjust button and Alarm Silence button at the same time for at least 5 seconds. 3. Dock the Wireless Monitor.

8.4. Troubleshooting Heart Rate Counting Issues

The OCS™ relies upon the ECG electrodes to determine the heart rate. The Heart Rate displayed on the Wireless Monitor is calculated (by the OCS™ software) by counting the QRS complexes detected in the ECG signal.

There are conditions in which the display of the Heart Rate become unreliable. For example, the ECG can be distorted if the RA ECG electrode is not making good contact with the heart.

If the displayed Heart Rate becomes unreliable:

- Check that the RA electrode is properly positioned. Only the RA electrode (rightmost) is needed by the OCS™ to determine the Heart Rate. Make sure the RA electrode is placed underneath the Right Atrium at a location where the electrode is covered by heart tissue even when the heart beats.
- Make small adjustments in the position of the electrode to facilitate electrical conductivity and check to see if the Heart Rate counting improves. The electrode can be repositioned without opening the inner sterile membrane and maintaining the sterility of the heart chamber.
- After this sort of adjustment, wait 10-15 seconds for the software to notice the adjustment and display a new rate. Note that small adjustments in the position of the electrode can make a big difference in the morphology of the ECG waveform.

NOTE—The sterility of the heart can be maintained while interacting with the heart by use of the sterile membrane.

8.5. 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.

To reset the system, dock the Wireless Monitor, set the On/Off switch to Off, wait 5 seconds and switch to the On position.

CAUTION—The On/Off switch should be in the ON position 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.

8.6. Shipping Equipment for Service

In some situations, including end of OCS™ service life, you may need to send equipment to TransMedics for service or replacement. For contact information, see Section 1.10, "Contacting TransMedics."

NOTES—

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™ battery packs 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. CHAPTER 9: SYSTEM SPECIFICATIONS

This chapter describes the select specifications for the OCS™ Heart System.

9.1. Safety and Regulatory Specifications

The table below lists the safety and regulatory specifications for the OCS™ Heart System.

Table 14: Safety and 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 (2006) + CORR. 2 (2007) + A1:2012 Medical Electrical Equipment Part 1: General Requirements for basic safety and essential requirements
Electromagnetic Compatibility (EMC)	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 Refer to Table 16 and Table 17
Bluetooth Devices	RED 2014/53/EU - Radio 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

9.2. Electrical and Physical Specifications

The table below lists the electrical and physical specifications for the OCS™ Heart System.

Table 15: Electrical and Physical Specifications

Parameter	Specifications
System Power Input - AC	IEC power inlet receptacle
Line input voltage:	100 to 240V, 50-60Hz, 375VA
OCS™ Battery	14.8 V 15 Ah
Wireless Monitor Battery	7.2 V 12 Ah
Operating Conditions	
Temp Range:	10°C to 35°C (50°F to 95°F)
Relative Humidity (non-condensing, steady state):	20% to 90%
Altitude	Up to 3000 meters
Storage Conditions (Heart Console and Sterile Components)	

Parameter	Specifications
Ambient Temperature:	-20°C to +50°C (-4°F to +122°F)
Relative Humidity (non-condensing, steady state)	10% to 95%
Weight	
System (without organ or fluids or base):	< 45.4 kg (< 100 lbs)
Mobile Base:	< 13.6 kg (< 30 lbs)
Gas Blend	85% O_2, 1% CO_2, balance N_2

9.3. Electromagnetic Emissions and Immunity

The OCS™ Heart System is intended for use in the electromagnetic environment specified in Table 16 and Table 17. The customer or user of the OCS™ should assure that they are used in such an environment.

Table 16: 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 emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
RF emissions CISPR 25	Class 1	
RF emissions ISO 7137 / RTCA DO 160G	Category M	
Harmonic IEC 61000-3-2	Class A	
Flicker 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 17 below lists the guidance and manufacturer's declaration of electromagnetic immunity for the OCS™ Heart System.

Table 17: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ±4, ±8 and ±15 kV air	Passed	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±0.5 kV, ±1 kV and ± 2 kV	Passed	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	Passed	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips/dropout IEC 61000-4-11	0% UT 0.5 cycles at 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o and 315^o 0% UT 1 cycle 70% UT 25 cycles, 50 Hz single phase at 0^o 0% UT 250 cycles, 50 Hz single phase at 0^o	Passed	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 its battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m at 50/60 Hz	Passed	Power frequency magnetic fields should that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms AC Mains 6 Vrms AC Mains (ISM Bands)	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
Immunity to proximity fields from RF wireless communications equipment 61000-4-3	9 V/m at 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz and 5785 MHz 27 V/m at 385 MHz 28 V/m at 450 MHz 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Passed	
Radiated Immunity for Airborne Equipment ISO 7137 / RTCA DO-160G	Category R	Passed	

WARNINGS—

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) can affect Medical Electrical Equipment and should be used no closer than 30 cm (12 inches) to any part of the OCS™. Otherwise degradation of the performance of this equipment could result.

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 Heart Console and its Wireless Monitor is a minimum of 3 meters.

9.4. Essential Performance

- Pump warmed oxygenated perfusate to the heart
- Infuse Maintenance solution
- Monitor and display pressure, flow, and temperature
- Allow the user to control the functions of the OCS™.

9.5. Accuracy of Displayed Values

Table 18 below provides the accuracy of the values displayed by the OCS™ Heart System.

Table 18: Accuracy of Displayed Values

Value	Measurable Range	Accuracy
Hematocrit (HCT)	15% to 50%	±5%
Saturation (SvO_2)	50% to 99%	±5%
Flow (Pump, AOF)	0 L/m to 6.5 L/m	±(12% +0.14 L/min)
Flow (CF)	0 L/m to 2.0 L/m	±(12% +0.14 L/min)
Temperature (Temp)	0°C to 45.0°C	±1.0°C
Pressure (AOP, PAP)	-25 mmHg to 225 mmHg	Greater of ±7% or ±10 mmHg
Heart Rate	20 BPM to 250 BPM	1 BPM

9.6. System Configuration Limits

Table 19 below provides the configuration limits and default values for the OCS™ Heart System. Alarm limit defaults are listed in the table as Lower, Upper.

Table 19: System Configuration Settings

Parameter	Range	Default	Units
Gas Flow Rate Set Point	0, 150 – 500	150	mL/min
ECG Sync Delay	0 - 98	92	Percent
Blood Temperature Set Point	Off, 34.0 – 37.0	37.0	°C
Manual Solution Delivery Rate	1-99	10	mL/hr
Initial Solution Volume	250-1000	1000	mL
AO Pressure Regulation Set Point	40-100	75	mmHg
Blood Temperature Alarm Range	33.0 – 38.0	33.5, 37.5	°C
Coronary Flow Alarm Range	0.1 – 1.5	0.6, 0.9	L/min
Aortic Flow Alarm Range	0.1 – 1.5	0.8, 1.2	L/min
Aortic Mean Pressure Alarm Range	20 – 120	60, 100	mmHg
Pulmonary Artery Mean Pressure Alarm Range	0 – 50	n/a, 15	mmHg
SvO_2 Alarm Range	55 - 70	60, n/a	Percent
Hematocrit Alarm Range	16 - 30	18, n/a	Percent
Heart Rate Alarm Range	20 - 190	40, 140	BPM

10. CHAPTER 10: PARTS AND SUPPLIES

Table 20 below lists the parts and supplies that the user can order directly from TransMedics, Inc.

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 "Contacting TransMedics" in Chapter 1.

Table 20: Part and Supplies

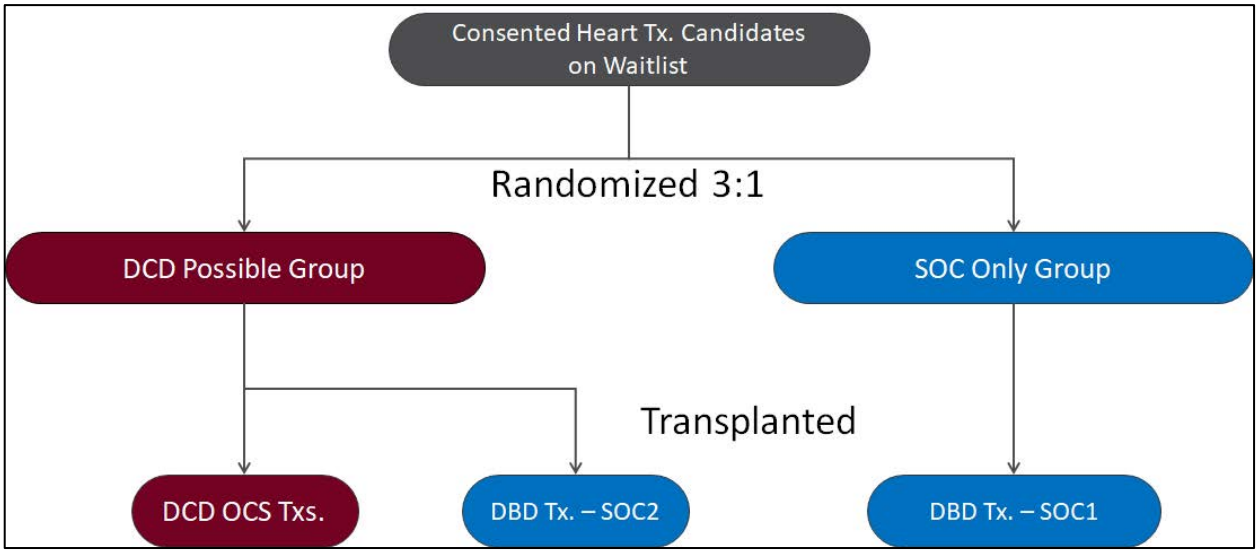
Part Number	Name	Description
1000	OCS Heart Console	As described in Chapter 3.
1200	OCS Heart Perfusion Set	As described in Chapter 3.
1300	OCS Heart Solution Set	As described in Chapter 3.
OCS Heart Console subcomponents that can be ordered separately		
1404	OCS Data Card	As described in Chapter 3.
1406	OCS Gas Cylinder	As described in Chapter 3.
1408	OCS Battery	As described in Chapter 3.
1411	OCS Mobile Base	As described in Chapter 4.
1423	OCS Regulator Yoke Gasket	A custom fit washer that must be in place on the regulator when replacing a gas cylinder.
1432	OCS Power Cord: North America	This power cord allows the OCS™ to be connected to grounded AC power in North America.
OCS Heart Perfusion Set subcomponents that can be ordered separately		
1400	OCS Blood Collection Set	As described in Chapter 3.
1401	OCS Heart Instrumentation Tool Set	As described in Chapter 3.
1421	OCS Cardioplegic Arrest Set	As described in Chapter 3.
1457	OCS Heart Solution Line Set	As described in Chapter 3.
1461	OCS Small Cable Tie Tool	For securing the three smaller aortic tips.
1466	Leukocyte Filter, 2-pack	One component from OCS Blood Collection Set, as described in Section 3. Serves as spare parts.
1467	Solution Delivery Cassettes, 3-pack	One component from OCS Heart Solution Line Set, as described in Section 3. Serves as spare parts.
Other		
1502	OCS Heart Documentation Set	The labeling documentation set (US).
1460	OCS Console Contact Button Cleaner	For maintenance of the silver buttons on the Circuit Board Connector Block.

11. APPENDIX A: OCS DCD HEART TRIAL

11.1. Summary Overview of DCD Heart Trial Design and Objectives

The OCS DCD Heart Trial was a prospective, two-arm, multicenter study, as illustrated in Figure 53. Eligible patients were randomized (3:1) into two groups: DCD Heart Possible and Standard-of-Care (SOC) Heart Only (SOC1). Patients randomized to the DCD Heart Possible group could receive a DCD heart preserved with the OCS Heart System or a DBD heart preserved with cold static preservation, whichever is available first. In contrast, patients randomized to the SOC1 group could only receive a DBD heart preserved with cold static preservation. In the DCD Heart Possible group, patients who received a DBD heart formed a second SOC heart group (SOC2). The trial compared the outcomes of donor heart recipients who received a DCD heart with those of donor heart recipients who received a DBD heart (SOC1 + SOC2).

Figure 53: OCS DCD Heart Trial Overview



11.1.1. Primary Endpoint

A non-inferiority comparison of patient survival at 6 months post-transplant between recipients of DCD hearts preserved on the OCS Heart System (*DCD Heart Transplanted Recipient Population)* and recipients of standard criteria donor hearts preserved using cold storage (*SOC1 + SOC2, SOC Heart Transplanted Recipient Population*), adjusting for risk factors.

11.1.2. Secondary Endpoint

Utilization Rate is defined as the number of eligible DCD donor hearts that met the warm ischemic time limit and were instrumented on the OCS Heart System that met the acceptance criteria for transplantation after OCS Heart preservation divided by the total number of eligible DCD donor hearts that met the warm ischemic time limit above and were instrumented on the OCS Heart System.

11.1.3. Other Clinical Endpoints

Other endpoints include:

- Patient and graft survival at 30 days post-transplant

- Patient and graft survival at 30 days and initial hospital discharge, if later than 30 days
- Severe PGD (left or right ventricle) (not including rejection or cardiac tamponade) according to ISHLT consensus manuscript (as defined in the study protocol)
- Use of post-transplant mechanical circulatory support for > 72 hours immediately post-transplant.
- The incidence of Heart Graft-related Serious Adverse Events (HGRSAEs) in the first 30 days post-heart transplantation in the DCD Heart Transplanted Recipient Population, defined as the following adverse events (at most one per type):
  - Moderate or Severe heart PGD (left or right ventricle) (not including rejection or cardiac tamponade) according to ISHLT consensus manuscript (as defined in the study protocol).
  - Primary graft failure requiring re-transplantation.
- Patient survival at 1 year after transplant; comparison of *DCD Heart Transplanted Recipients* and *SOC Heart Transplant Recipients* (*SOC1 + SOC2*) through UNOS/OPTN database.

11.1.4. Analysis Populations

The primary analysis population was pre-specified as the Per Protocol (PP) Population which consists of all randomized patients who were transplanted and have no major protocol violations. This includes the DCD Heart Transplanted Recipient Population and the SOC Heart Transplanted Recipient Population (SOC1 + SOC2). The primary analysis of the primary and secondary effectiveness endpoints, and of other endpoints are based on the PP Population.

The Modified Intent-to-Treat (mITT) population consists of all randomized patients who were transplanted in the trial. This includes the DCD modified Intent-to-Treat (DCD-mITT) Heart Transplanted Recipient Population and the SOC modified Intent-to-Treat (SOC-mITT) Heart Transplanted Recipient Population (SOC1 + SOC2). The mITT analyses are the secondary analyses of effectiveness.

The primary analysis of utilization rate is based on the OCS Heart Population. The OCS Heart Population consists of all DCD donor hearts that were instrumented on the OCS Heart System without protocol deviations. Donor hearts with warm ischemic time > 30 mins or from pediatric donors are excluded.

11.2. Trial Enrollment

Randomized patients were enrolled at 13 U.S. sites between December 1, 2019 and November 11, 2020. At the time of database lock, a total of 101 DCD donor hearts were preserved using the OCS Heart System and 303 patients enrolled in the study. The disposition of the donor hearts is summarized in Figure 54.

Out of the 303 patients, 297 were randomized, including 226 to the DCD Heart Possible group and 71 to the SOC Only group. Within the DCD Heart Possible group, 90 patients received a DCD heart preserved using the OCS Heart System and 62 received an SOC heart. Of the 71 patients randomized to SOC Only group, 28 were transplanted. In all, 90 patients each received a DCD heart and an SOC heart. The recipient enrollment consort diagram is shown in Figure 55.

Figure 54: OCS Heart DCD Trial – Utilization Rate

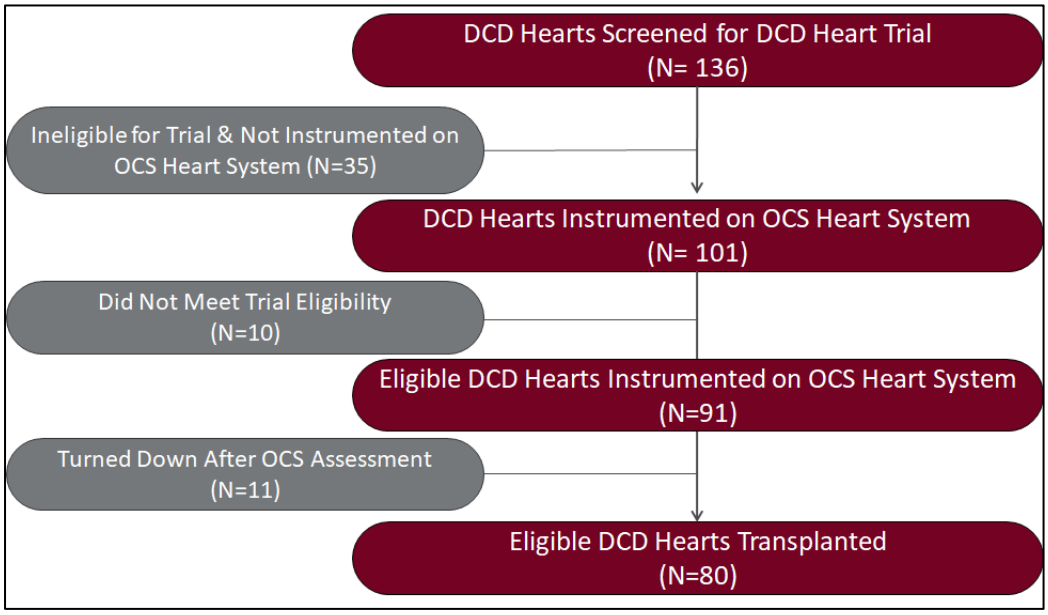
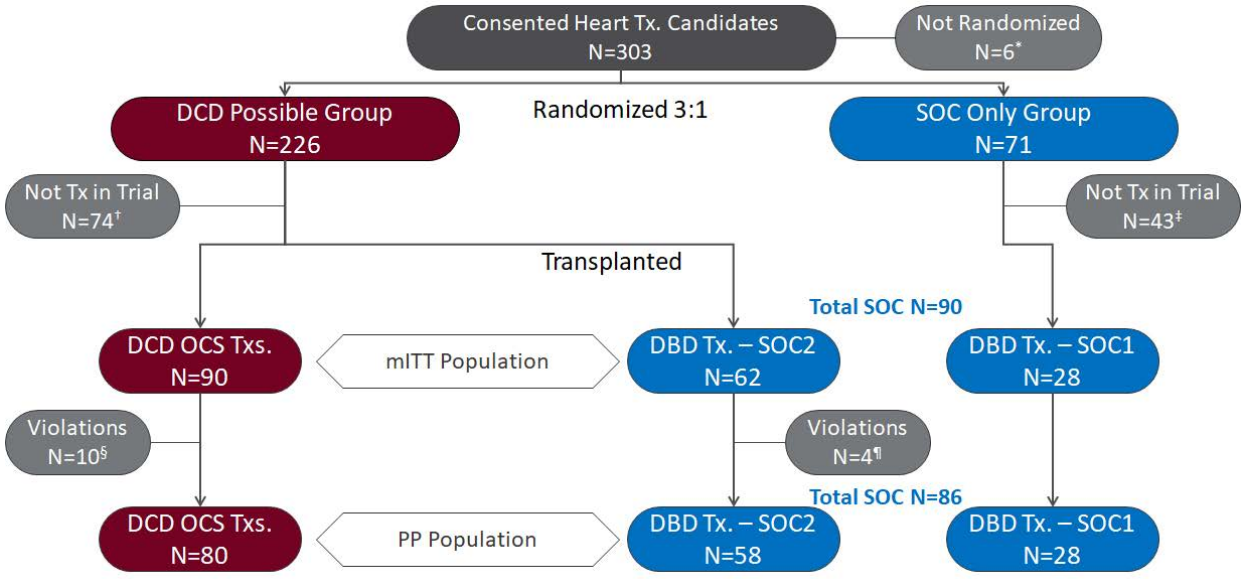


Figure 55: Recipient Enrollment Consort Diagram



*Enrolled after the randomization was stopped.
†Including 59 patients still on waitlist at the end of the trial, 6 patients withdrawn and transplanted in another trial, 3 patients who became ineligible prior to transplant, 3 patients who died on the waitlist, and 3 patients who withdrew consent.
‡Including 32 patients still on waitlist at the end of the trial, 7 patients withdrawn and transplanted in another clinical trial, 1 patient who became ineligible prior to transplant, 1 patient died on the wait list, and 2 patients delisted for transplant.
§Including 3 with donor age <18 years, 6 with warm ischemic time >30 mins, and 1 with continuously increasing lactate.
¶Including 4 donor age < 18 years.

The main analysis populations included the Per Protocol (PP) Population and the Modified Intent-to-Treat (mITT) Population, as defined in Table 21. The PP Population was the prespecified primary analysis population.

Table 21: Analysis Populations

Population	Definition	OCS DCD Group	SOC Group (SOC1+SOC2)
Modified Intent-to-Treat (mITT) population	All randomized patients who were transplanted	90	90
Per Protocol (PP) population	All randomized patients who were transplanted and had no major protocol violations	80	86

11.2.1. Donor Demographic and Baseline Characteristics

The donor demographics and baseline characteristics are shown in Table 22. The DCD heart donors were slightly younger than the SOC (DBD) heart donors, and there were more males and more that died from "anoxia-other" in the DCD heart donors than those in the SOC heart donors.

Table 22: Donor Demographics for OCS-DCD and SOC-DBD groups in OCS DCD Heart Trial (mITT)

Parameter	OCS-DCD (N=90)	SOC-DBD (N=90)	p-value [2]
Age (years) [1]			0.0076
Mean ± SD	29.30 ± 7.50	33.18 ± 11.37	
Median	28.95	31.20	
Minimum - Maximum	15.7 - 47.0	12.3 - 65.3	
Age >= 55 Years			0.2458
n (%)	0 (0.0)	3 (3.3)	
Gender			0.0029
Female - n (%)	6 (6.7)	21 (23.3)	
Male - n (%)	84 (93.3)	69 (76.7)	
BMI (kg/m^2)			0.1824
Mean ± SD	27.27 ± 6.15	28.54 ± 6.53	
Median	26.20	26.95	
Minimum - Maximum	17.9 - 49.7	16.9 - 47.6	
Cause of Death			0.0094
Cerebrovascular Hemorrhage - n (%)	4 (4.4)	12 (13.3)	
Head Trauma - n (%)	38 (42.2)	40 (44.4)	
Anoxia-Drug Overdose - n (%)	17 (18.9)	21 (23.3)	
Anoxia-Other [(3)] - n (%)	30 (33.3)	13 (14.4)	
Other [4] - n (%)	1 (1.1)	4 (4.4)	
Did the donor experience cardiac arrest?			0.8805

Parameter	OCS-DCD (N=90)	SOC-DBD (N=90)	p-value [2]
Yes - n (%)	51 (57.3)	50 (55.6)	
No - n (%)	38 (42.7)	40 (44.4)	
Estimated duration of cardiac arrest (mins)			0.2040
n	29	22	
Mean ± SD	21.4 ± 14.55	27.5 ± 19.43	
Median	18.0	26.0	
Minimum - Maximum	0 - 60	1 - 61	

Note: Percentages are calculated based on the number of donors with non-missing data in the given population.

(1) Age = (Date of donor acceptance - date of birth)/365.25

(2) p-value from a two-sided, two-sample t-test for continuous variables or from a two-sided Fisher's Exact test for categorical variables, testing for a difference between the OCS and SOC

(3) Anoxia other includes suicides by hanging, drownings, seizures, etc.

(4) Other cause of death for OCS: Cardiac arrest, and for SOC: Traumatic cardiac arrest, Cerebrovascular accident (stroke), Trauma, Trauma – electrical

11.2.2. Recipient Demographic and Baseline Characteristics

The recipient demographics and baseline characteristics are summarized in Table 23 for the mITT population, which are typical for a heart transplant study performed in the U.S. The OCS DCD and the SOC groups were similar in all parameters except for age, UNOS allocation status at time of transplant, the presence of mechanical circulatory support pre-transplant. Patients in the OCS DCD group were slightly younger than those in the SOC group. The OCS DCD group had more Status 4 patients, while the SOC group had more Status 2 patients at the time of transplant. In addition, more patients in the OCS DCD group had a left ventricular assist device (LVAD) pre-transplant, while more patients in the SOC group had an intra-aortic balloon pump (IABP) placed pre-transplant.

Table 23: Recipient Demographic and Baseline Characteristics (mITT)

Parameter	Summary Statistics		p-value*
	OCS DCD Group (N=90)	SOC Group (N=90)	
Age (years)†			0.0409
Mean ± SD	51.31 ± 12.58	54.99 ± 11.39	
Median	53.95	57.60	
Minimum - maximum	20.0 - 73.1	22.3 - 73.9	
Age ≥ 65 years			0.5491
n (%)	13 (14.4)	17 (18.9)	
Gender			1.0000
Female - n (%)	24 (26.7)	24 (26.7)	
Male - n (%)	66 (73.3)	66 (73.3)	
Female donor to male recipient			0.1177
n (%)	1 (1.1)	6 (6.7)	
Body mass index (kg/m^2)			0.9402
Mean ± SD	29.63 ± 5.08	29.57 ± 5.25	

Parameter	Summary Statistics		p-value*
	OCS DCD Group (N=90)	SOC Group (N=90)	
Median	29.30	29.20	
Minimum - maximum	19.2 - 40.6	15.9 - 43.5	
Baseline panel reactive antibody (%)			0.7467
Mean ± SD	8.3 ± 20.16	9.3 ± 22.19	
Median	0.0	0.0	
Minimum - maximum	0 - 87	0 - 91	
Primary etiology of heart failure diagnosis, n (%)			0.9694
Ischemic cardiomyopathy	21 (23.3)	22 (24.4)	
Congenital heart disease	8 (8.9)	5 (5.6)	
Restrictive cardiomyopathy	2 (2.2)	3 (3.3)	
Dilated cardiomyopathy	17 (18.9)	16 (17.8)	
Non-ischemic Cardiomyopathy	40 (44.4)	42 (46.7)	
Other‡	2 (2.2)	2 (2.2)	
Presence of mechanical circulatory support pre-transplant, n (%)	58 (64.4)	64 (71.1)	0.4253
Left ventricular assist device (LVAD)	44 (48.9)	27 (30.0)	0.0144
Right ventricular assist device (RVAD)	0 (0.0)	2 (2.2)	
Bi-ventricular assist device (BiVAD)	0 (0.0)	2 (2.2)	
Extracorporeal membrane oxygenation (ECMO)	0 (0.0)	4 (4.4)	
Intra-aortic balloon pump (IABP)	14 (15.6)	38 (42.2)	0.0001
Artificial Heart	0 (0.0)	0 (0.0)	
UNOS heart allocation status on day of transplant, n (%)			<0.0001
Status 1	1 (1.1)	5 (5.6)	
Status 2	18 (20.0)	47 (52.2)	
Status 3	16 (17.8)	15 (16.7)	
Status 4	43 (47.8)	14 (15.6)	
Status 5	0 (0.0)	0 (0.0)	
Status 6	12 (13.3)	9 (10.0)	
Presence of mechanical ventilation on the day of transplant, n (%)	0 (0.0)	0 (0.0)	-
History of diabetes	31 (34.4)	28 (31.1)	
History of renal dysfunction	3 (3.3)	2 (2.2)	

*p-value from a two-sided, two-sample t-test for continuous variables or from a two-sided Fisher's Exact test for categorical variables, testing for a difference between the DCD and SOC.

†Age = (Date of transplant - date of birth)/365.25.

‡Other includes: muscular dystrophy and post-partum cardiomyopathy for the DCD group; cardiogenic shock and arrhythmogenic right ventricular cardiomyopathy for the SOC group.

11.3. Primary Effectiveness Endpoint

The analysis of the primary endpoint is summarized in Table 24 for the PP population and mITT population. The adjusted patient survival rate at 6 months post-transplant in the PP Population (the prespecified primary analysis population) was 93.7% in the DCD group and 90.4% in the SOC group, with a difference of -3.2% (90% CI: -9.8%, 3.4%). Since the upper bound of the 90% confidence interval of the difference was less than the non-inferiority margin of 20%, the primary endpoint was met, which was further corroborated by the mITT analysis. The results of the primary endpoint are shown in Figure 56 below.

Table 24: Analyses of the Primary Endpoint

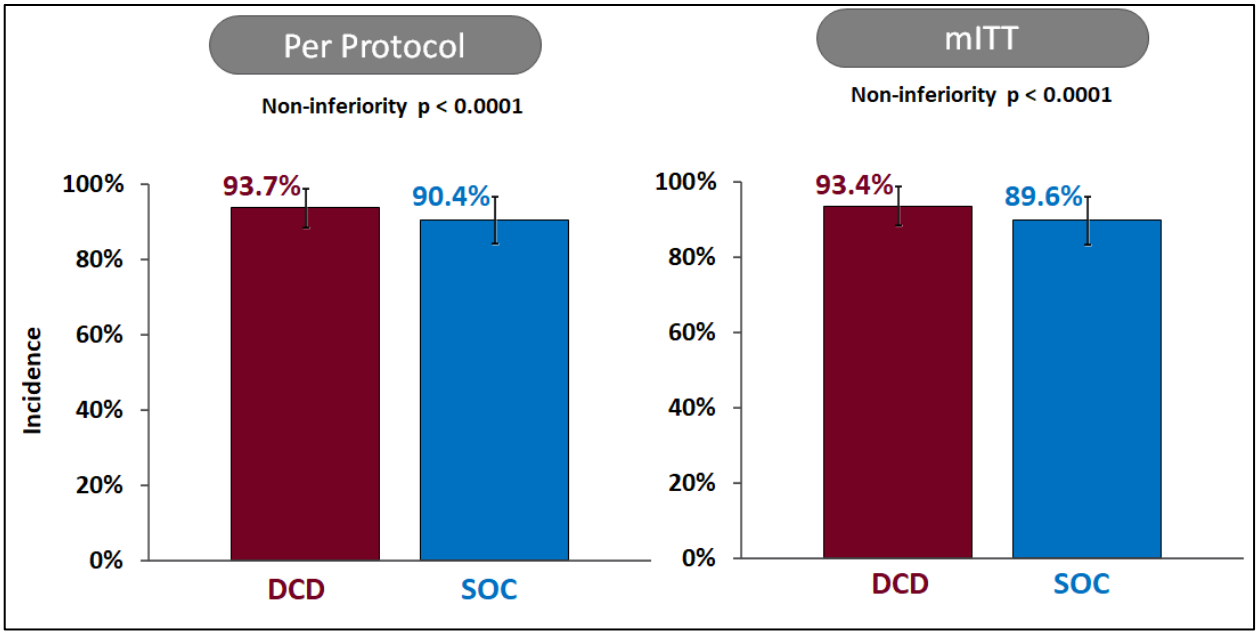
Variable	PP Analysis		mITT Analysis	
	OCS DCD	SOC	OCS DCD	SOC
Total # of patients	80	86	90	90
Total # of patients included in the analysis*	80	84	90	88
Patient survival at 6 months post-transplant	76	75	85	78
Success rate at 6 months (unadjusted)	95.0%	89.3%	94.4%	88.6%
Success rate at 6 months (adjusted‡)	93.7%	90.4%	93.4%	89.6%
Difference (SOC-DCD): adjusted	-3.2%		-3.9%	
90% confidence interval	[-9.8%, 3.4%]		[-10.9%, 3.2%]	
Non-inferiority limit	20%		20%	
p-value§	<0.0001		<0.0001	
Non-inferiority test	Passed		Passed	

*Two patients in the SOC group were retransplanted on day 5 and day 7, respectively, after the first transplant and were excluded from the analysis.

‡Adjusted percentages are based on a linear probability model, with the following terms in the model: treatment, ischemic time >= 4 hours (Y/N) and mechanical circulatory support pre-transplant (Y/N).

§The one-sided p-value for the test of the null hypothesis was obtained based on a statistic for the difference (SOC-DCD) in least squares means for each treatment minus the non-inferiority margin of 0.20, divided by the standard error of the difference in the least squares means, assuming an approximate normal distribution.

Figure 56: Primary Effectiveness Endpoint - (PP and mITT Populations), Adjusted for Risk Factors

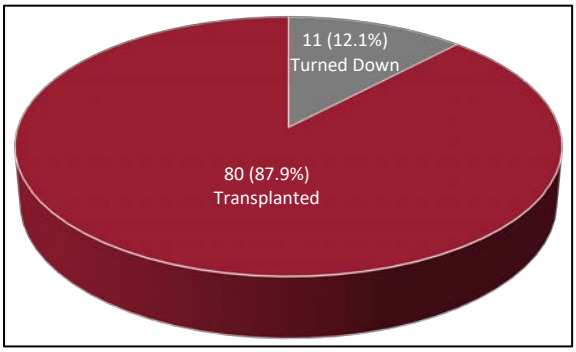


The unadjusted primary endpoint results were similar, with 95% survival for the OCS DCD patients compared to 89% survival for the SOC DBD patients in the PP population and 94% survival in the OCS DCD patients compared to 89% survival in the SOC DBD patients in the mITT population.

11.4. Secondary Endpoint - DCD Heart Utilization

Of the DCD donor hearts instrumented and preserved on the OCS Heart System, 91 met the trial eligibility, 80 of which were transplanted. Thus, the DCD heart utilization rate was 87.9% (80/91), as illustrated in Figure 57.

Figure 57: Utilization Rate of Eligible DCD Donor Hearts

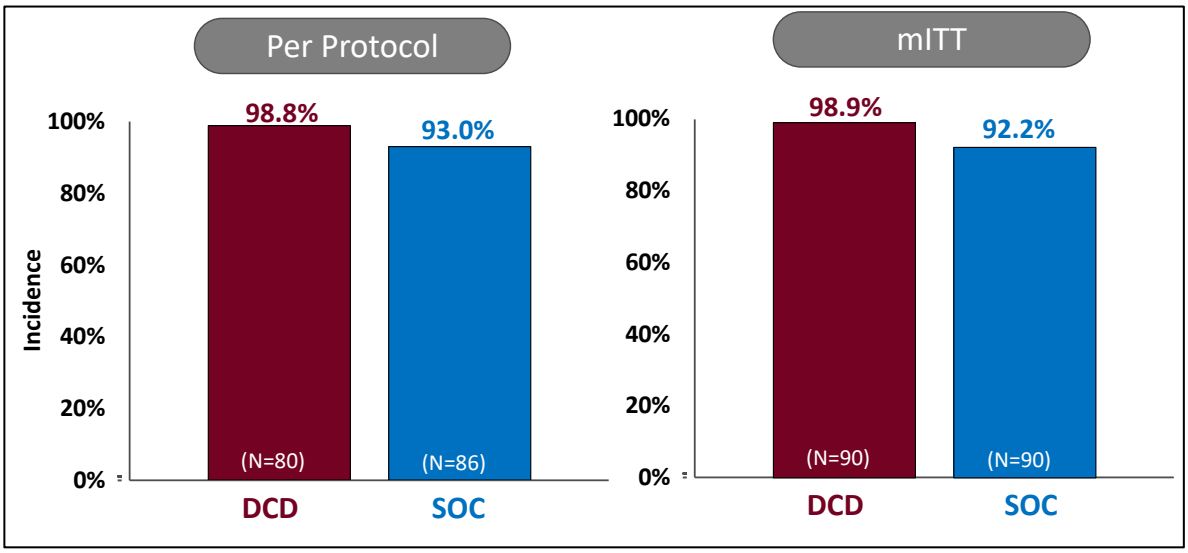


11.5. Other Endpoints

11.5.1. Patient and graft survival at 30 days post-transplant

Patient and graft survival at 30 days post-transplant is shown in Figure 58 below. In the PP population, the patient and graft survival rate at 30 days was 98.8% in the OCS DCD group compared to 93.0% in the SOC group. The result for the mITT population was similar (98.9% vs. 92.2%).

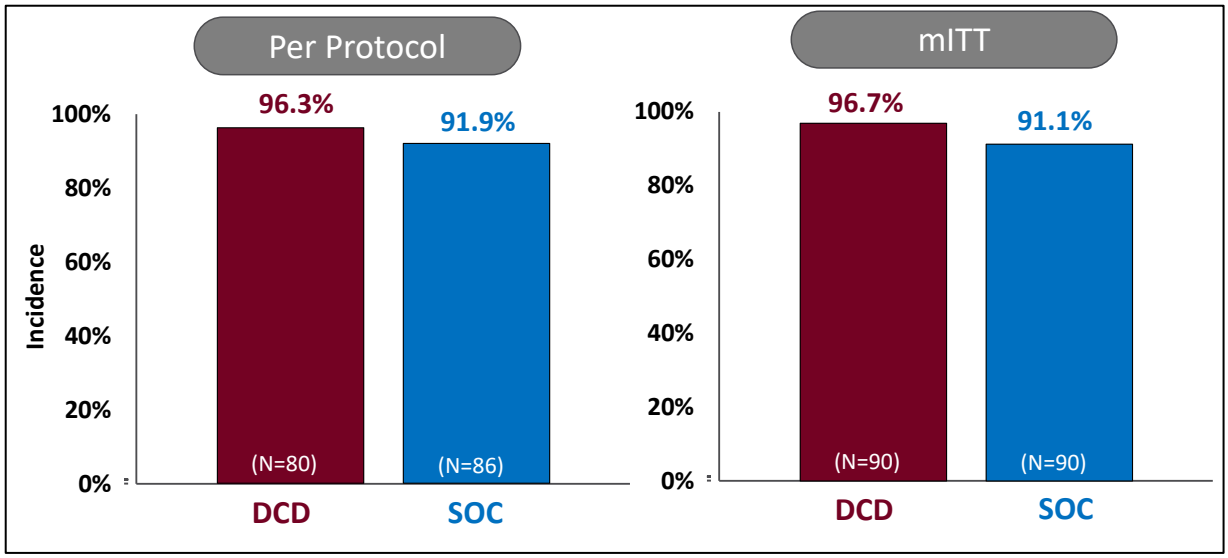
Figure 58: Patient & Graft Survival at 30 days for PP and mITT populations



11.5.2. Patient and graft survival at 30 days post-transplant and initial hospital discharge, if later than 30 days

Patient and graft survivals at day 30 or initial hospital discharge (if later than 30 days) were 96.3% in the OCS DCD group and 91.9% in the SOC group in the PP population, as summarized in Figure 59. The results were similar in the mITT population (96.7% vs. 91.1%).

Figure 59: Patient and Graft Survival at 30 Days or Initial Hospital Discharge, if Later Than 30 Days



11.5.3. Severe Primary Graft Dysfunction (PGD)

In the PP population, the incidences of severe PGD as defined by the ISHLT consensus criteria were 16.3% and 4.8% in the in the OCS DCD group and SOC group, respectively; in the mITT population, the incidences were 14.4% and 4.5%, respectively, as summarized in Table 25.

Table 25: Severe PGD Within 24 Hours

Severe PGD	Summary Statistics*	
	OCS DCD Group	SOC Group
PP population	13/80 (16.3)	4/84 (4.8)
mITT population	13/90 (14.4)	4/88† (4.5)

*n/N (%)

†One study site did not provide the data on 2 patients in the SOC group.

11.5.4. Use of post-transplant mechanical circulatory support for > 72 hours immediately post-transplant.

In the PP population, 13.8% of patients in the OCS DCD group had MCS for greater than 72 hours immediately post-transplant, while in the mITT population, the proportion was 13.3%, as summarized in Table 26.

Table 26: Use of MCS for > 72 Hours Immediately Post-transplant- OCS DCD Group Only

Use of MCS for > 72 hours immediately post-transplant	Summary Statistics*
PP population	11/80 (13.8)
mITT population	12/90† (13.3)

*n/N (%)

†Of the 12 patients, 7 had severe PGD adjudicated by the CEC and 5 did not have severe PGD but had IABPs placed: 3 for center specific protocol (prophylactic) and 2 for cardiac support (graft dysfunctions not meeting the PGD criteria).

11.5.5. Incidence of HGRSAEs

The average number of HGRSAEs per patient within the first 30 days post-transplantation, was 0.2 for the OCS DCD patients compared to 0.1 for the SOC DBD patients. More patients in the OCS DCD group experienced moderate or severe PGD (20.0%) compared to the SOC group (9.1%). However, more patients in the SOC group had primary graft failure (2.2%) than those in the OCS DCD group (0.0%). (Table 27).

Table 27: HGRSAEs within 30 Days (mITT)

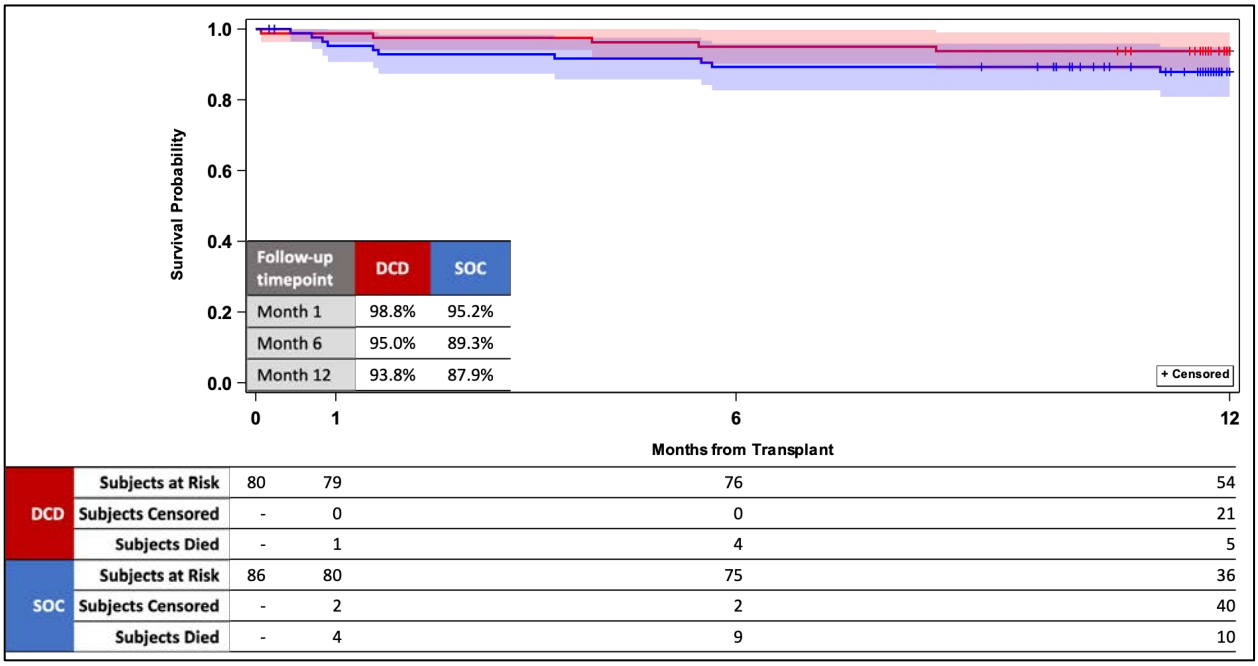
Parameter	OCS-DCD (N=90)	SOC-DBD (N=88[2])
Number of HGRSAEs in the First 30 Days Post-transplantation per Subject[1]		
• Mean	0.2	0.1
• Median	0.0	0.0
• SD	0.40	0.38
• Minimum - Maximum	0 - 1	0 - 2
• 95% CI for Mean	(0.12 - 0.28)	(0.03 - 0.20)
HGRSAEs by Type n/N (%)		
• Moderate or Severe PGD (LV or RV)	18/90 (20.0)	8/88 (9.1)
○ LV Moderate PGD	5/90 (5.6)	4/88 (4.5)
○ LV Severe PGD	12/90 (13.3)	4/88 (4.5)
○ RV PGD	1/90 (1.1)	0/88 (0.0)
• Primary Graft Failure Requiring Re-transplantation	0/90 (0.0)	2/90 (2.2)

[1] For number of HGRSAEs, patients with both LV moderate or severe PGD and RV PGD will be counted as having one event.
[2] One study site did not provide the data on 2 SOC subjects

11.5.6. Patient survival at 1 year after transplant

The Kaplan-Meier (KM) analysis of patient survival through 1 year post-transplant are shown in Figure 60. The patient survival rate was 93.8% in the OCS DCD group and 87.9% in the SOC group.

Figure 60: Patient Survival through 1 year after transplant (PP Population)

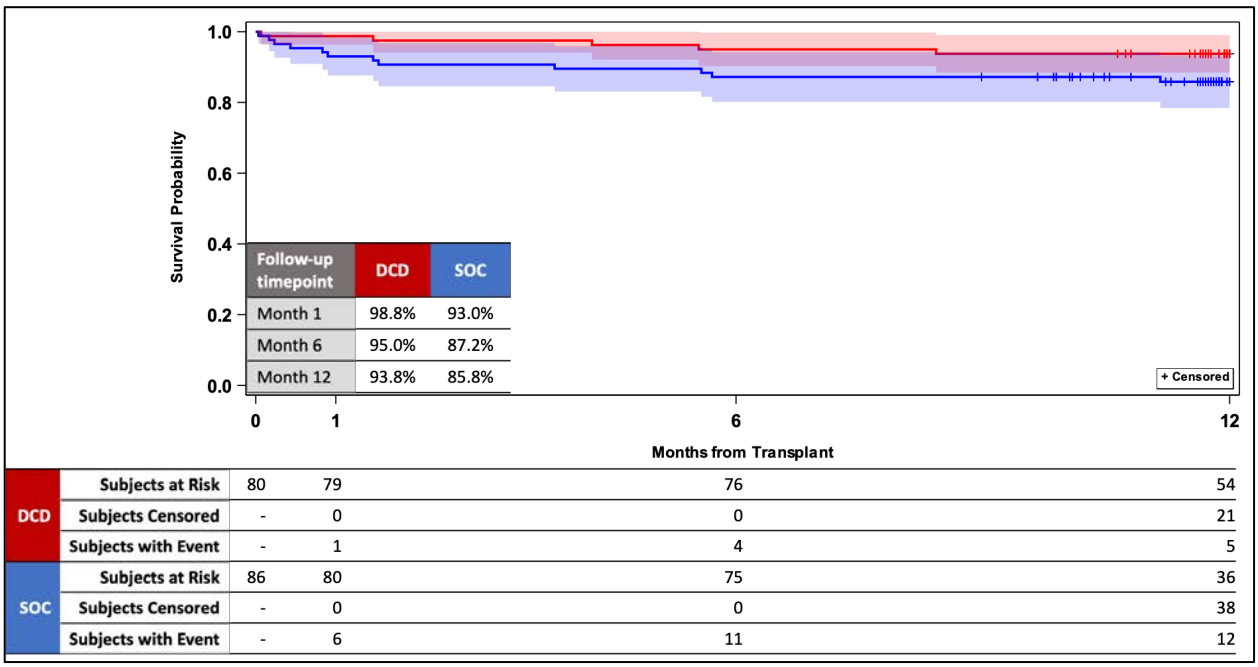


DCD	Subjects at Risk	80	79	76	54
	Subjects Censored	-	0	0	21
	Subjects Died	-	1	4	5
SOC	Subjects at Risk	86	80	75	36
	Subjects Censored	-	2	2	40
	Subjects Died	-	4	9	10

11.5.7. Patient and Graft Survival at 1 year post-transplant

The Kaplan-Meier analysis of patient and graft survival through 1 year post-transplant is shown in Figure 61 below. At 12 months post-transplant, the patient and graft survival rate was 93.8% in the OCS-DCD group compared to 85.8% in the SOC group.

Figure 61: Patient and Graft survival through 1 year post-transplant (PP Population)



DCD	Subjects at Risk	80	79	76	54
	Subjects Censored	-	0	0	21
	Subjects with Event	-	1	4	5
SOC	Subjects at Risk	86	80	75	36
	Subjects Censored	-	0	0	38
	Subjects with Event	-	6	11	12

11.5.8. Serious Adverse Events

The comprehensive list of all CEC-adjudicated serious adverse events (SAEs) observed through 30 days post-transplant in the OCS DCD group is shown in Table 28.

Table 28: CEC-adjudicated SAEs Observed Through 30 Days in the OCS DCD Group – (mITT)

SAEs by System Organ Class/Preferred Term	Summary Statistics*	
	Patients	Events
Any SAEs	67 (74.4)	133 (100.0)
Blood and lymphatic system disorders	3 (3.3)	3 (2.3)
Anemia	1 (1.1)	1 (0.8)
Coagulopathy	2 (2.2)	2 (1.5)
Cardiac disorders	34 (37.8)	38 (28.6)
Arrhythmia supraventricular	1 (1.1)	1 (0.8)
Atrial fibrillation	1 (1.1)	1 (0.8)
Atrial flutter	2 (2.2)	2 (1.5)
Cardiac arrest	1 (1.1)	1 (0.8)
Cardiac tamponade	2 (2.2)	2 (1.5)
Cardiogenic shock	2 (2.2)	2 (1.5)
Left ventricular dysfunction	16 (17.8)	16 (12.0)
Pericardial effusion	4 (4.4)	4 (3.0)
Pericardial hemorrhage	1 (1.1)	1 (0.8)
Right ventricular dysfunction	6 (6.7)	6 (4.5)
Supraventricular tachycardia	1 (1.1)	1 (0.8)
Tricuspid valve incompetence	1 (1.1)	1 (0.8)
Gastrointestinal disorders	4 (4.4)	5 (3.8)
Diarrhea	1 (1.1)	1 (0.8)
Gastrointestinal necrosis	2 (2.2)	2 (1.5)
Intestinal ischemia	1 (1.1)	1 (0.8)
Volvulus	1 (1.1)	1 (0.8)
Immune system disorders	18 (20.0)	19 (14.3)
Transplant rejection	18 (20.0)	19 (14.3)
Infections and infestations	12 (13.3)	12 (9.0)
Bacteremia	2 (2.2)	2 (1.5)
Endocarditis	1 (1.1)	1 (0.8)
Fungal infection	1 (1.1)	1 (0.8)
Nasopharyngitis	1 (1.1)	1 (0.8)
Pneumonia	5 (5.6)	5 (3.8)
Sepsis	2 (2.2)	2 (1.5)
Injury, poisoning and procedural complications	3 (3.3)	3 (2.3)
Iatrogenic injury	1 (1.1)	1 (0.8)
Traumatic hemothorax	2 (2.2)	2 (1.5)
Metabolism and nutrition disorders	1 (1.1)	1 (0.8)
Hyperkalemia	1 (1.1)	1 (0.8)
Musculoskeletal and connective tissue disorders	1 (1.1)	1 (0.8)
Flank pain	1 (1.1)	1 (0.8)
Nervous system disorders	6 (6.7)	6 (4.5)
Brain hypoxia	1 (1.1)	1 (0.8)

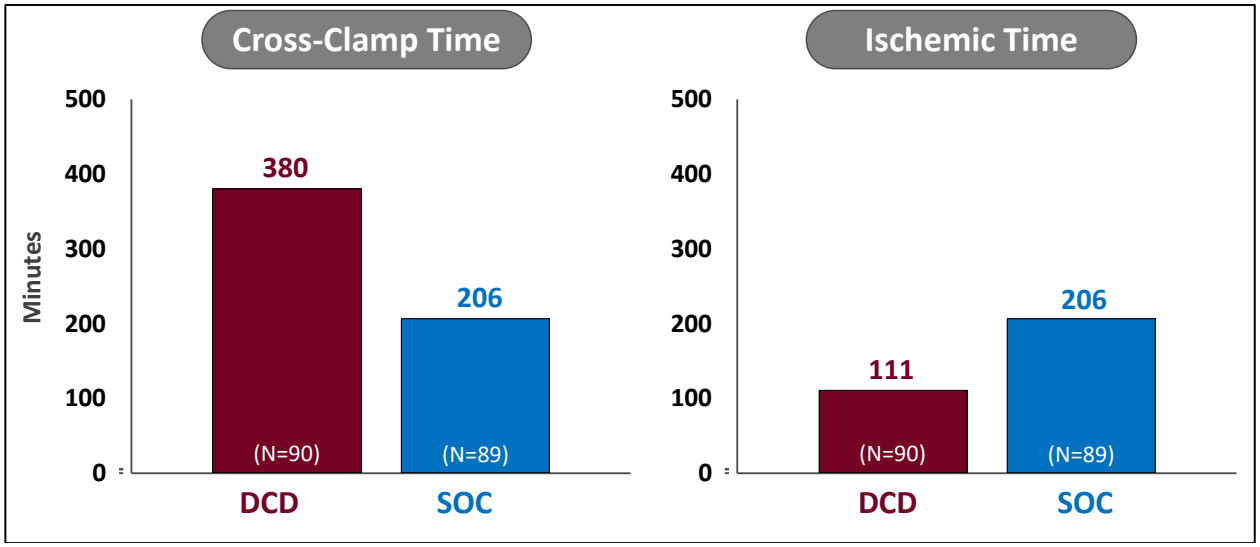
SAEs by System Organ Class/Preferred Term	Summary Statistics*	
	Patients	Events
Ischemic stroke	1 (1.1)	1 (0.8)
Migraine	1 (1.1)	1 (0.8)
Seizure	2 (2.2)	2 (1.5)
Spinal stroke	1 (1.1)	1 (0.8)
Psychiatric disorders	2 (2.2)	2 (1.5)
Delirium	2 (2.2)	2 (1.5)
Renal and urinary disorders	19 (21.1)	19 (14.3)
Acute kidney injury	15 (16.7)	15 (11.3)
Renal failure	4 (4.4)	4 (3.0)
Respiratory, thoracic and mediastinal disorders	11 (12.2)	11 (8.3)
Bronchial secretion retention	1 (1.1)	1 (0.8)
Hypoxia	1 (1.1)	1 (0.8)
Pleural effusion	3 (3.3)	3 (2.3)
Respiratory failure	6 (6.7)	6 (4.5)
Vascular disorders	13 (14.4)	13 (9.8)
Deep vein thrombosis	2 (2.2)	2 (1.5)
Hemodynamic instability	1 (1.1)	1 (0.8)
Hemorrhage	10 (11.1)	10 (7.5)

*n (%). Number of patients refers to the number of patients with at least one SAE of the indicated type. Number of events refers to all events of the indicated type. Patients experiencing multiple events under the same system organ class/preferred term are counted only once for that system organ class/preferred term. Percentages are calculated based on the total number of patients in the given population or the total number of events, as appropriate.

11.5.9. Total Cross-clamp Time and Ischemic Time

The mean cross-clamp time (time from cross-clamp application in the donor to the cross-clamp removal in the recipient) and ischemic time (time that a donor heart is ischemic without any oxygenated perfusion) for the donor hearts are shown in Figure 62. The mean cross-clamp time was longer in the DCD group than in the SOC group (380 vs. 206 minutes), while the mean ischemic time was shorter in the DCD group than in the SOC group (111 vs. 206 minutes).

Figure 62: Mean Cross Clamp Time and Ischemic Time for Donor Hearts



11.5.10. OCS Heart System Perfusion Parameters for Transplanted DCD Hearts

The OCS Heart System perfusion parameters for the transplanted DCD donor hearts are summarized in Table 29. The donor hearts were maintained within the recommended parameters on the OCS Heart System.

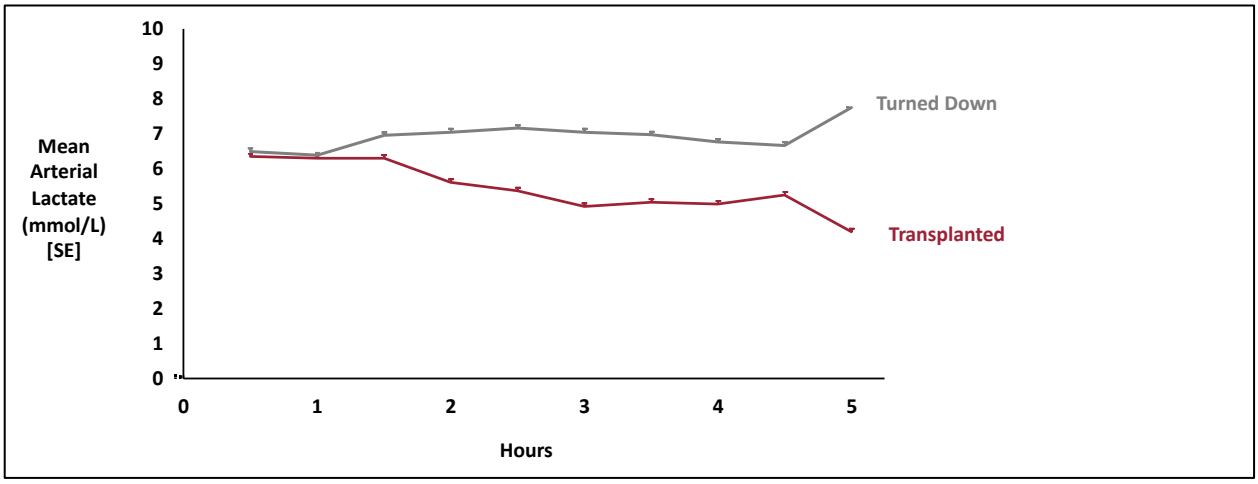
Table 29: OCS Heart System Perfusion Parameters

Parameter	Summary Statistics (N=90)
Perfusion time (mins)	
Mean ± SD	270.0 ± 65.01
Median	263.0
Minimum - maximum	104 - 472
Pump flow (L/min)	
Mean ± SD	1.086 ± 0.108
Median	1.065
Minimum - maximum	0.90 - 1.47
Coronary flow (L/min)	
Mean ± SD	0.714 ± 0.117
Median	0.720
Minimum - maximum	0.15 - 0.98
Aortic flow (L/min)	
Mean ± SD	1.105 ± 0.094
Median	1.095
Minimum - maximum	0.91 - 1.47
Aortic pressure (mmHg)	
Mean ± SD	72.0 ± 8.79
Median	74.0
Minimum - maximum	46 - 88

11.5.11. Donor Heart Turndowns following OCS Preservation

Eleven (11) DCD donor hearts were turned down for transplantation following preservation on the OCS Heart System. The reasons for the turndowns were primarily rising lactate and/or other clinical factors related to the organ performance or condition as determined by the surgeons. The mean arterial lactate levels in the turned-down hearts were generally higher than those that were transplanted, as shown in Figure 63. Additionally, a decreasing arterial lactate trend was not achieved in the turned-down hearts as was the general case for the transplanted hearts.

Figure 63: Mean arterial lactate trend in DCD hearts on OCS



11.6. Summary Clinical Conclusions Supporting the Safety and Effectiveness of the OCS Heart System for DCD hearts

The OCS DCD Heart trial is a novel, multi-center, randomized, controlled trial in the U.S. that was conducted to evaluate the effectiveness of the OCS Heart for the *ex vivo* reanimation, functional monitoring and beating-heart preservation of DCD hearts. The results of OCS DCD Heart Trial provide evidence of the effectiveness, safety and favorable benefit/risk profile of the OCS™ Heart System for the DCD indication:

Effectiveness Conclusions:

- In the OCS DCD Heart Trial, the 6-month survival rate in recipients of a DCD donor heart preserved on the OCS Heart System was 93.7% (PP population), which was statistically non-inferior to that (90.4%, $p<0.0001$) in recipients of a DBD donor heart preserved using SOC cold storage, after adjusting for risk factors.
- The 30-day patient and graft survival rate was 98.8% in the OCS DCD heart recipients and 93.0% in the SOC DBD heart recipients (PP population).
- Patient survival at 1 year post-transplant was 93.8% in the OCS DCD group compared to 87.9% in the SOC group (PP population).
- At 1 year post-transplant, the KM rates of patient and graft survival were 93.8% and 85.8% in the OCS DCD and SOC heart recipients, respectively (PP population).

- The utilization rate of the DCD hearts preserved on the OCS Heart System was 87.9%, which demonstrated the potential of the OCS Heart System to make more DCD hearts available for transplantation.

Safety Conclusions

- In the OCS DCD Heart Trial, the safety of the device was primarily assessed through the endpoint of HGRSAEs. In all the transplant recipients, the average number of HGRSAEs per patient was 0.2 in the first 30 days in the DCD group compared to 0.1 in the SOC group.
- Although more patients in the OCS DCD group experienced moderate or severe PGD (20.0%) than in the SOC group (9.1%), more patients in the SOC group had primary graft failure requiring re-transplantation (2.2%) than in the OCS DCD group (0.0%).
- **Benefit/Risk Determination:**

  Heart transplantation is universally accepted as the only curative treatment option for end-stage heart disease. However, the availability of donor heart allografts has not kept pace with the demand. The study data indicated that 88% of the DCD donor hearts procured using the OCS Heart System were utilized for transplantation and the graft and patient survival was statistically non-inferior to DBD cold storage transplantation. Utilization of DCD hearts that otherwise would mostly not have been utilized due to the limitations of the cold storage increases the donor pool and allows more heart transplants to be performed for patients on the waitlist. Providing heart transplant candidates additional transplant options with DCD organs is a substantial public health benefit.

  The probable risks of preservation of DCD donor hearts using the OCS Heart System include HGRSAEs, including PGD and graft failure. The data from the OCS DCD Heart Trial support that the probable benefits of preservation of DCD hearts using the OCS Heart System outweigh the probable risks and provide clinical benefit to heart transplantation patients.

12. APPENDIX B: OCS HEART EXPAND AND OCS HEART EXPAND CONTINUED ACCESS PROTOCOL (CAP) STUDIES

12.1. Introduction

The primary clinical data sets supporting FDA approval of the OCS Heart System is the OCS Heart EXPAND study. Supporting evidence comes from the OCS Heart EXPAND Continued Access Protocol (CAP). The following sections describe the OCS Heart EXPAND study and results, followed by results of the OCS Heart EXPAND CAP study.

The purpose of the OCS Heart EXPAND study was to evaluate the effectiveness of the OCS Heart System to resuscitate, preserve and assess donor hearts that may not meet current standard donor heart acceptance criteria for transplantation. In addition to assessing the impact of the OCS Heart System on expanding donor heart utilization from extended criteria donors, given that the OCS Heart EXPAND was the first of its kind study, it also provided important short and long term clinical outcome data for these types of donor heart transplants in a prospective fashion.

12.2. Primary Effectiveness Endpoint

The primary effectiveness endpoint is a composite of patient survival at Day 30 post-transplant and freedom from severe ISHLT Primary Graft Dysfunction (PGD) at 24 hours post-transplant (as defined in Appendix 2 of the protocol according to ISHLT consensus manuscript (Kobashigawa, et al., 2014)). The primary hypothesis for the study was that the true proportion of transplanted recipients with the composite of patient survival at Day 30 post-transplantation and freedom from severe PGD in the first 24 hours post-transplantation was greater than the performance goal value of 0.65 (65%). Given the lack of published literature on post-transplant clinical outcomes from these types of donor hearts at the time OCS Heart EXPAND was being designed, TransMedics established this OPG based on published literature for standard criteria heart transplantation incidence of severe PGD of ~30% and on published OPTN/SRTR reports of 30-day patient mortality of ~5%.

12.3. Secondary Endpoints

- Patient survival at Day-30 post-transplantation.
- Incidence of severe primary heart graft dysfunction (PGD) (left or right ventricle) in the first 24 hours post-transplantation (as defined according to ISHLT consensus manuscript).
- Rate of donor heart utilization, i.e., the percentage of donor hearts successfully transplanted after preservation and assessment on the OCS™ Heart System.
- Patient survival at Day 30 and hospital discharge if longer than 30 days.
- Patient survival at 6 and 12 months post-transplant.
- Incidence of heart graft-related Serious Adverse Events (HGRSAEs) in the first 30 days post heart transplantation, defined as:
  - Moderate or Severe primary heart graft dysfunction (PGD) (left or right ventricle) (not including rejection or cardiac tamponade), as defined according to ISHLT consensus manuscript.
  - Primary graft failure requiring retransplantation.

12.4. Study Population

Patients were heart transplant recipients and donors who met inclusion and exclusion criteria.

12.4.1. Inclusion Criteria

Donor: At least one of the following:

- Expected total cross-clamp time of ≥ 4 hours
- Expected total cross-clamp time of ≥ 2 hours **PLUS** one or more of the following risk factors:
  - Donor age 45-55 years old with no coronary catheterization data; or
  - Donor age ≥ 55 years old; or
  - Left ventricular septal or posterior wall thickness of > 12 ≤ 16 mm; or
  - Reported down time of ≥ 20 min, with stable hemodynamics at time of final assessment; or
  - Left heart ejection fraction (EF) ≥ 40 ≤ 50%; or
  - Donor angiogram with luminal irregularities with no significant CAD; or
  - History of Carbon monoxide poisoning with good cardiac function at time of donor assessment; or
  - Social history of alcoholism with good cardiac function at time of donor assessment; or
  - History of diabetes combined with negative coronary angiogram for coronary artery disease (CAD).

Recipient - Day of Transplant

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

12.4.2. Exclusion Criteria

Donor

- Angiogram proven CAD with > 50% stenosis; or
- Cardiogenic shock or myocardial infarction; or
- Sustained terminal EF of < 40%; or
- Significant valve disease except for competent bicuspid aortic valve.

Recipient - Day of Transplant

- Prior solid organ or bone marrow transplant; or
- Chronic use of hemodialysis or diagnosis of chronic renal insufficiency; or
- Multi-organ transplant.

12.4.3. Donor Heart on OCS Acceptance Criteria

All donor hearts preserved on the OCS™ Heart System should meet the following clinical criteria for transplantation at final assessment on the OCS™ Heart System:

- Final total arterial circulating perfusate lactate level < 5 mmol/L with stable lactate trend.
- Stable CF, AOP trends within ranges after stabilization (certain expanded criteria organs, e.g., LVH hearts, may require higher CF and/or AOP to achieve adequate perfusion)
  - Aortic Pressure (mean AOP): 40-100 mmHg
  - Coronary Flow (CF): 400-900 mL/min.

In addition, to clinical judgment of the transplanting surgeon, arterial lactate trend on OCS was used to determine acceptance criteria of donor hearts perfused on OCS (Hamed, et. al. 2009).

12.5. OCS Heart EXPAND Study Cohort

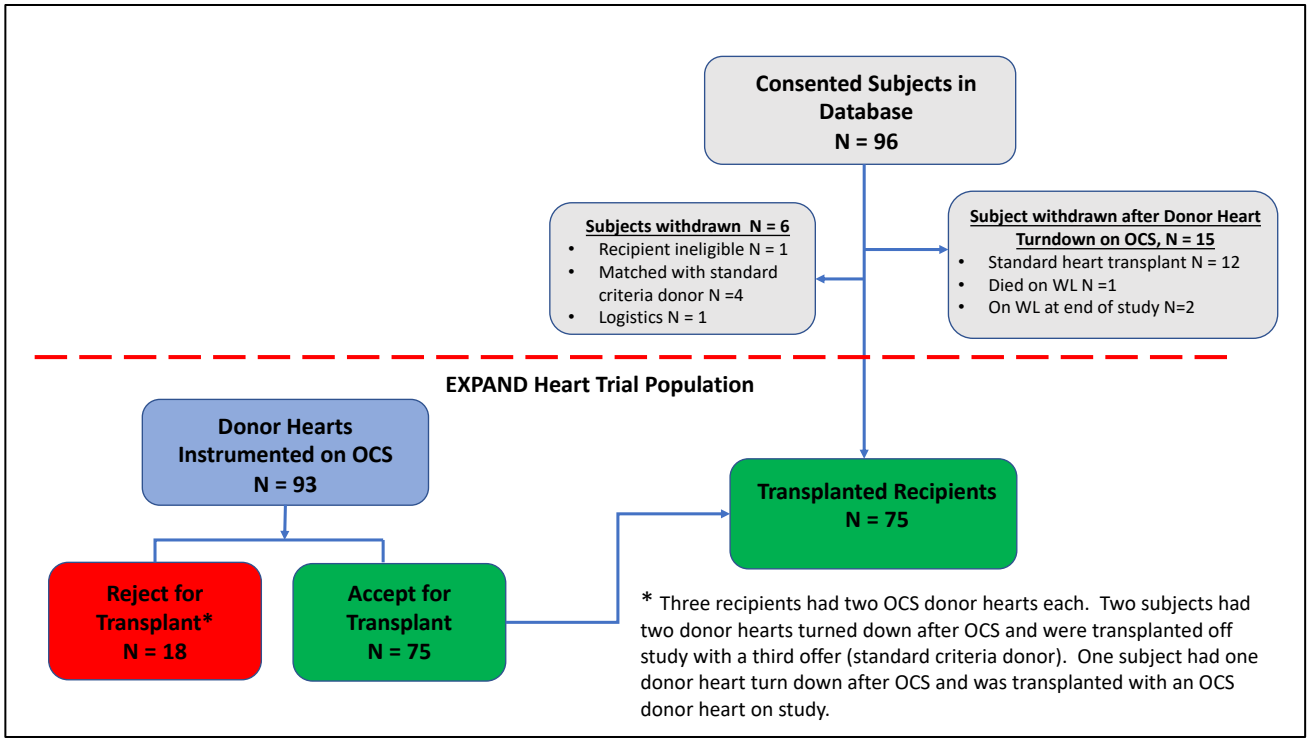
There were 96 patients who signed informed consent with data in the database. Of these, 6 patients were not matched with a donor heart that was instrumented on the OCS: 4 of the patients were matched with a standard criteria donor heart, 1 patient became ineligible (delisted for transplant) and 1 patient was withdrawn and transplanted with a donor heart preserved on cold storage due to logistics.

Sixteen (16) patients experienced donor heart turndown following OCS preservation. The disposition of these 16 patients was as follows:

- 10 patients were transplanted outside of the study with a subsequent standard criteria donor offer preserved on cold storage after one OCS turndown.
- 2 patients were transplanted outside of the study with a subsequent standard criteria donor offer preserved on cold storage after two OCS turndowns.
- 3 patients remained on the waiting list after OCS turndown. Two of these patients were alive and one patient had died by the end of the study.
- 1 patient was transplanted in the OCS Heart EXPAND study with a second donor offer preserved on OCS after one OCS turndown.

Therefore, the transplanted recipient population consists of 75 subjects who were transplanted with donor hearts preserved on the OCS™ Heart System. The analyses of all effectiveness and safety endpoints were based on the transplanted recipient population. The OCS Heart EXPAND transplanted recipient population is illustrated in Figure 64 below.

Figure 64: OCS Heart EXPAND Heart Study Population



12.5.1. Study Population Demographics and Baseline Parameters

The OCS Heart EXPAND study enrolled a complex group of donor hearts with many exhibiting multiple inclusion criteria. As shown in Table 30, 35 of the 75 transplanted donor hearts (47%) met more than one inclusion criterion.

Table 30: Donor Inclusion Criteria Met for Transplanted Donor Hearts in OCS Heart EXPAND

Inclusion Criteria Met	Summary Statistics* (N=75)
Expected cross-clamp time ≥ 4hr	28 (37.3%)
Donor age ≥ 55	10 (13.3%)
LVH	17 (22.7%)
Downtime ≥ 20 min	23 (30.7%)
LVEF 40% -50%	21 (28.0%)
Luminal irregularities	7 (9.3%)
Alcoholism	9 (12.0%)
Carbon monoxide as cause of death	1 (1.3%)
Diabetes	2 (2.7%)
Donor age 45-55 with no coronary catheterization data	1 (1.3%)
Donor hearts met single criterion	40 (53.3%)
Donor hearts met multiple criteria	35 (46.7%)
*Categorical measures – no. (%)	

The recipient demographics for the 75 transplanted recipients are shown in Table 31 below. The majority of recipients (69%) were UNOS status 1A and were on mechanical circulatory support at the time of transplant (64%).

Table 31: Recipient Demographics in OCS Heart EXPAND

Recipient Characteristics	OCS Transplanted Recipients N=75
Age (years) mean ± SD	55.5 ± 12.6
Age > 65	18 (24.0%)
Gender – male n (%)	61 (81.3 %)
BMI (kg/m^2) – mean ± SD	27.7 ± 4.7
Race	
• Asian	2 (2.7%)
• Black or African American	12 (16.0%)
• White	58 (77.3%)
• Other	2 (2.7%)
• Not Provided	1 (1.3%)
History of Mechanical Circulatory Support	48 (64.0%)
• LVAD	47 (62.7%)
• RVAD	0 (0%)
• BiVAD	1 (1.3%)
• ECMO	0 (0%)
Status n (%):	
• Status IA	52 (69.3%)
• Status IB	22 (29.3%)
• Status II	1 (1.3%)
Primary Etiology of Heart Failure Diagnosis	
• Ischemic Cardiomyopathy	26 (34.7%)
• Congenital Heart Disease	2 (2.7%)
• Restrictive Cardiomyopathy	7 (9.3%)
• Non-ischemic Cardiomyopathy	24 (32.0%)
• Dilated Cardiomyopathy	9 (12.0%)
• Other	7 (9.3%)
Female donor to male recipient mismatch	12 (16.0%)

Recipient Characteristics	OCS Transplanted Recipients N=75
Renal dysfunction	11 (14.7%)
PRA (%) mean (range)	7.9 (0-81)

12.6. Primary Composite Effectiveness Endpoint

Table 32 shows the results of the composite primary effectiveness endpoint. The primary effectiveness endpoint met the pre-specified objective performance goal of 65% (p <0.0001).

Table 32: Primary Endpoint Result – OCS Heart EXPAND

Patient survival at 30 days post-transplant and absence of severe PGD (left or right ventricle) in the first 24 hours post-transplant (N=75)	
Proportion - % (n/N)[*]	88.0% (66/75)
95% CI for proportion[†]	(78.4%, 94.4%)
Performance goal	65%
p-value[‡]	<0.0001
[*]Simple proportion. [†]Clopper-Pearson exact confidence interval for a binomial proportion. [‡]One-sided exact binomial test.	

12.7. Secondary Effectiveness Endpoints

The secondary endpoints were the components of the composite primary endpoint.

12.7.1. Patient Survival at Day 30 Post-transplant

The result of patient survival at 30 days post-transplant is summarized in Table 33. One of the 75 recipients of a donor heart preserved on the OCS Heart System experienced a graft failure and underwent re-transplantation using cold storage on post-operative day (POD) 6. This patient was terminated from the study. Seventy (70) of the remaining 74 recipients were alive at 30 days post-implant, which led to a patient survival rate of 94.6% at 30 days post-transplant.

Table 33: Patient Survival at 30 Days Post-transplant – OCS Heart EXPAND

Patient survival at 30 days post-transplant (N=75)	
Proportion - % (n/N)	94.6% (70/74)[*]
95% CI for proportion[†]	(86.7%, 98.5%)
[*]One recipient with graft failure and re-transplant during the first 30 days was excluded. [†]Clopper-Pearson exact confidence interval for a binomial proportion.	

12.7.2. Incidence of Severe ISHLT PGD in the first 24 hours post-transplant

The OCS Heart EXPAND protocol utilized the ISHLT consensus statement definition for severe PGD and the results were adjudicated by an independent medical monitor. As shown in Table 34 below, the incidence of severe PGD in the first 24 hours post-transplantation was 10.7%.

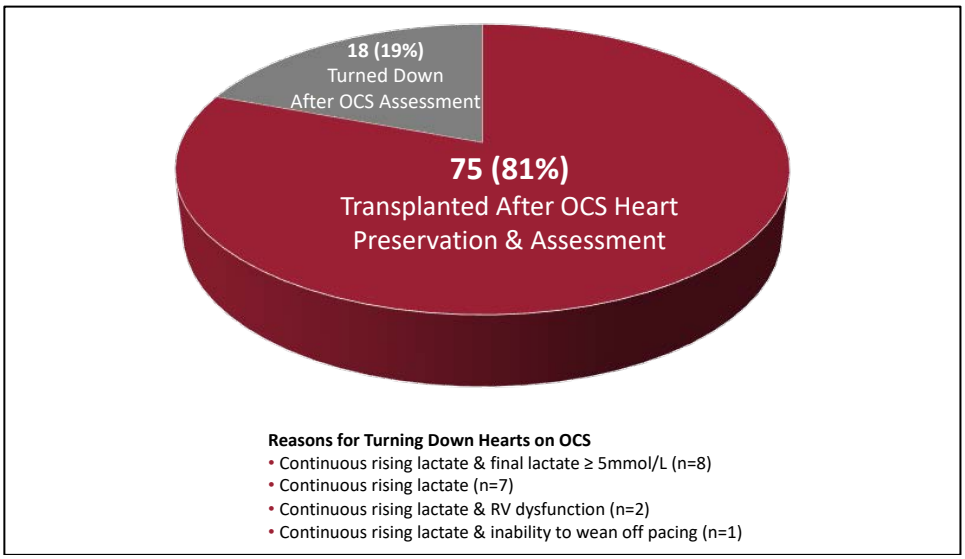
Table 34: Incidence of Severe ISHLT PGD in OCS Heart EXPAND

Incidence of severe ISHLT PGD (left or right ventricle) in the first 24 hours post-transplant (N=75)	
Proportion - % (n/N)	10.7% (8/75)
95% CI for proportion*	(4.7%, 19.9%)
*Clopper-Pearson exact confidence interval for a binomial proportion.	

12.7.3. Donor Heart Utilization

In OCS Heart EXPAND, a total of 93 donor hearts were preserved and assessed on OCS and of these, 75 were transplanted, giving a utilization rate of 81% (see Figure 65).

Figure 65: OCS Heart EXPAND Donor Utilization



12.8. Incidence of HGRSAEs in the First 30 Days Post-transplant

The HGRSAEs in the first 30 days post-transplantation are summarized in Table 35. The incidence of moderate or severe PGD (LV or RV) was 14.7%, and one patient had primary graft failure requiring re-transplantation. The mean number of HGRSAEs per patient was 0.16

Table 35: Primary Safety Endpoint – HGRSAEs in the First 30 Days Post-Transplant – OCS Heart EXPAND

HGRSAEs in the first 30 days post-transplant (N=75)	
Number of HGRSAEs	12*
Moderate or severe PGD (LV or RV)	11

HGRSAEs in the first 30 days post-transplant (N=75)	
Severe LV PGD	6
Moderate LV PGD	3
RV PGD	2
Primary graft failure requiring re-transplantation	1
Incidence of HGRSAEs	0.16 (12/75)
95% CI[†]	(0.1, 0.2)
[*]One recipient developed two HGRSAEs (severe LV PGD + re-transplantation). [†]Confidence interval calculated based on the t-distribution.	

12.9. Serious Adverse Events (SAEs)

Table 36 below shows the adjudicated SAEs by System Organ Class for OCS Heart EXPAND subjects. All SAEs were reviewed and adjudicated by the Medical Monitor.

Table 36: List of Adjudicated SAEs By System Organ Class and Preferred Term – OCS Heart EXPAND Transplanted Recipient Population through 30 Days of Follow-up

System Organ Class	Preferred Term	Subjects N=75	Events
Total		56 (74.7%)	105
Cardiac disorders		31 (41.3%)	38
	Arrhythmia	4 (5.3%)	4
	Arrhythmia supraventricular	1 (1.3%)	1
	Atrial fibrillation	5 (6.7%)	5
	Atrial flutter	1 (1.3%)	1
	Atrial tachycardia	1 (1.3%)	1
	Atrioventricular block	1 (1.3%)	1
	Bradycardia	1 (1.3%)	1
	Cardiac failure congestive	4 (5.3%)	4
	Cor pulmonale	2 (2.7%)	2
	Electromechanical dissociation	1 (1.3%)	1
	Left ventricular dysfunction	5 (6.7%)	5-
`	Left ventricular failure	1 (1.3%)	1
	Nodal rhythm	1 (1.3%)	1
	Pericardial effusion	5 (6.7%)	5
	Right ventricular dysfunction	4 (5.3%)	4
	Right ventricular failure	1 (1.3%)	1

System Organ Class	Preferred Term	Subjects N=75	Events
General disorders and administration site conditions		1 (1.3%)	1
	Multi-organ failure	1 (1.3%)	1
Hepatobiliary disorders		1 (1.3%)	1
	Hepatic failure	1 (1.3%)	1
Immune system disorders		12 (16.0%)	12
	Heart transplant rejection	12 (16.0%)	12
Infections and infestations		4 (5.3%)	4
	Clostridial infection	1 (1.3%)	1
	H1N1 influenza	1 (1.3%)	1
	Pneumonia	1 (1.3%)	1
	Sepsis	1 (1.3%)	1
Injury, poisoning and procedural complications		9 (12.0%)	10
	Cardiac procedure complication	3 (4.0%)	3
	Heart injury	1 (1.3%)	1
	Operative haemorrhage	1 (1.3%)	1
	Post-operative thoracic procedure complication	1 (1.3%)	1
	Procedural complication – Non-cardiac	2 (2.7%)	2
	Rectal laceration post-operative	1 (1.3%)	1
	Vascular pseudoaneurysm	1 (1.3%)	1
Metabolism and nutrition disorders		1 (1.3%)	1
	Fluid overload	1 (1.3%)	1
Nervous system disorders		6 (8.0%)	6
	Cerebrovascular accident	3 (4.0%)	3
	Convulsion	2 (2.7%)	2
	Vocal cord paralysis	1 (1.3%)	1
Psychiatric disorders		3 (4.0%)	3
	Delirium	3 (4.0%)	3
Renal and urinary disorders		12 (16.0%)	12

System Organ Class	Preferred Term	Subjects N=75	Events
	Renal failure acute	10 (13.3%)	10
	Renal impairment	2 (2.7%)	2
Respiratory, thoracic and mediastinal disorders		14 (18.7%)	15
	Acute respiratory distress syndrome	1 (1.3%)	1
	Acute respiratory failure	2 (2.7%)	2
	Hydrothorax	1 (1.3%)	1
	Hypoxia	1 (1.3%)	1
	Pleural effusion	3 (4.0%)	3
	Respiratory distress	1 (1.3%)	1
	Respiratory failure	6 (8.0%)	6
Vascular disorders		2 (2.7%)	2
	Hemorrhage	1 (1.3%)	1
	Subclavian vein thrombosis	1 (1.3%)	1
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. 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.			

12.10. Other Study Observations

12.10.1. Donor Heart Match Run Refusals Prior to Acceptance into the Study

Table 37 below shows the donor match run data available from UNOS for the 93 donor hearts preserved on the OCS™ Heart System for OCS Heart EXPAND. UNOS manages the national system for matching patients on the waiting list with available donor hearts. Using the combination of donor and patient information, the UNOS computer system generates a “match run,” a rank-order list of patients to be offered each donor organ. When a donor organ is turned down for a matched patient, it will be offered to the next matched patient on the list. Table 37 summarizes the donor match run data available from UNOS for the 93 donor hearts preserved on the OCS Heart System.

These 93 hearts were refused for transplant by other centers an average of 66 times (median 29) before being offered to an EXPAND Heart study patient and accepted. For reference, from 2007-2014, the median number of refusals for heart transplants in the U.S. was 2 (Baran, et al., 2019), which suggests that the donor hearts transplanted in OCS Heart EXPAND would likely have gone unutilized outside of the study.

Table 37: Donor Heart Offers Refusals Prior to Acceptance in OCS Heart EXPAND

	Donor Heart Refusals from UNOS Donor Match Run Data (N = 93)
Mean number of Refusals per donor heart (Mean ± SD)	66 ± 90
Median number of Refusals per donor heart	29
Minimum - Maximum	0 - 379

12.11. Transplanted Donor Heart Preservation Characteristics

Donor heart preservation characteristics are shown in Table 38 below. Note that total cross-clamp time (total out-of-body time) is the time from aortic cross-clamp application in the donor to the pulmonary artery (PA) cross-clamp removal in the recipient, while the total ischemic time is the time that donor hearts were ischemic without any oxygenated perfusion. Despite the total cross-clamp time that averaged over 6 hours (380.7 minutes), the OCS™ Heart System significantly reduced the injurious ischemic time for the hearts to less than 2 hours (102.1 minutes).

Table 38: Donor Heart Preservation Characteristics

Parameter	OCS Heart EXPAND (N=75)
Cross-clamp Time (mins)[1]	N=75
Mean ± SD	380.7 ± 93.2
Median	369.0
Min.- Max.	173 - 682
Total Ischemic Time (mins)[2]	N = 75
Mean ± SD	102.1 ± 22.6
Median	98.0
Min.- Max.	65 - 168
OCS Perfusion Time (mins)	N = 75
Mean ± SD	278.6 ± 83.3
Median	276.0
Min.- Max.	100 - 532

[1] Cross-clamp time is the time from aortic cross-clamp application time in the donor to the PA cross-clamp removal time in the recipient (Out of body time).

[2] Total ischemic time for hearts preserved by OCS is the cross-clamp time minus OCS perfusion time.

12.12. OCS Heart System Perfusion Parameters

The OCS™ Heart System perfusion parameters are summarized in Table 39 below. The donor hearts were maintained within the recommended parameters on the OCS™ Heart System.

Donor arterial baseline lactate level is a function of many different aspects of the donor demographics and retrieval environment and the lactate level in the donor is not optimized or controlled. Once the organ is placed on the OCS™ Heart System, the user has the ability to adjust the AOP and/or coronary flow to adequately perfuse the donor heart, resulting in a stable lactate profile. Further adjustments may then be made to maintain the lactate at acceptable levels.

Lactate trend was considered a clinical indicator for adequacy of perfusion, after adjustment and optimization of OCS Heart perfusion parameters and hemodynamics. The stability of perfusion parameters, heart hemodynamics, as well as clinical judgement of heart contractility/rhythm on OCS also played a role in deciding whether to accept or reject a donor heart on the OCS™ Heart System. For many experienced OCS Heart clinical users, unstable and rising lactate trend despite multiple attempts to stabilize the perfusion parameters (CF and AOP) is a sign of compromised clinical condition of the donor heart which would lead them to turn down the heart for transplantation.

Table 39: OCS™ Heart System Perfusion Parameters

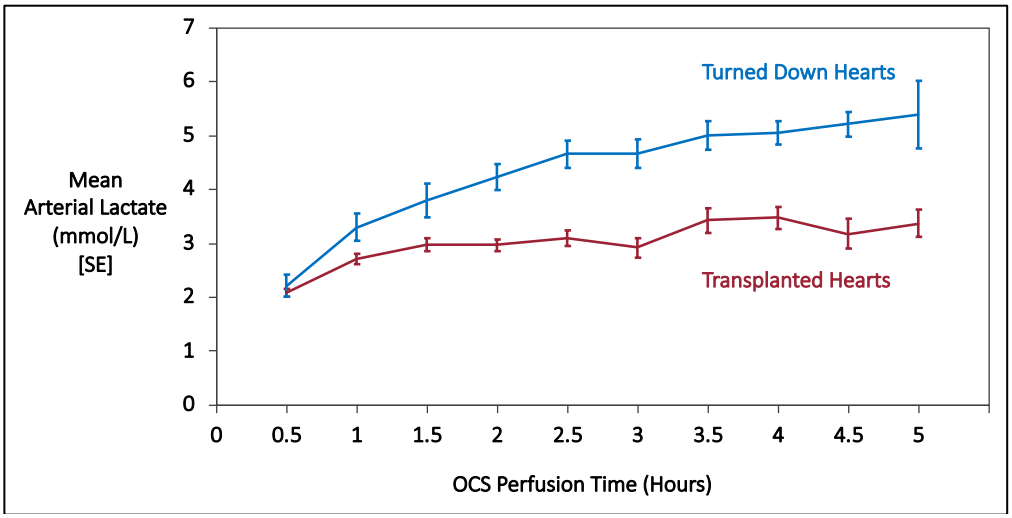
Parameter	OCS (N=75)
AOP Mean (mmHg)	N = 75
Mean ± SD	81.2 ± 7.8
Median	81.4
Min.- Max.	48 - 102
Coronary Flow (CF) (L/min)	N = 75
Mean ± SD	0.74 ± 0.13
Median	0.756
Min.- Max.	0.05 - 0.93
Arterial Lactate (mmol/L) – Initial OCS Instrumentation	N = 75
Mean ± SD	1.9 ± 0.63
Median	1.750
Min.- Max.	0.93 - 3.80
Arterial Lactate (mmol/L) – Final OCS Instrumentation	N = 75
Mean ± SD	3.08 ± 0.95
Median	3.01
Min.- Max.	0.55 - 4.97
Pump Flow (L/min)	N = 75
Mean ± SD	1.13 ± 0.12

Parameter	OCS (N=75)
Median	1.12
Min.- Max.	0.93 - 1.76
Heart Rate (BPM)	N = 75
Mean ± SD	78.8 ± 2.5
Median	78.6
Min.- Max.	74 - 87
Hematocrit (%)	N = 74
Mean ± SD	21.1 ± 3.6
Median	20.7
Min.- Max.	16 – 33.0

12.12.1. Analysis of Donor Hearts Turned Down following OCS Preservation

Of the 93 donor hearts instrumented on OCS, 18 donor hearts (matched to 16 subjects) did not meet transplantability criteria following preservation on OCS™ Heart System as determined by the transplant surgeons due to unstable and rising lactate trends as well as other clinical reasons (e.g., right ventricular disfunction and inability to regain sinus rhythm) and were not transplanted. 75 of 93 donor hearts were successfully transplanted after OCS™ Heart System preservation and assessment (81% utilization rate as defined in the protocol). The mean UNOS donor match run refusals for the turned down hearts was 80.7, indicating that they most likely would not have been utilized outside of the OCS Heart EXPAND study. Figure 66 below illustrates the mean lactate values for the 18 hearts that were turned down after OCS Heart System assessment as compared to the OCS Heart System lactate profile for the donor hearts that were transplanted.

Figure 66: Mean Arterial Lactate Trend on the OCS Heart System for All Turned Down Donor Hearts Compared to Hearts that were Transplanted in OCS Heart EXPAND



12.12.2. Mechanical Circulatory Support Post-Transplant

The use of MCS postoperatively in the OCS Heart EXPAND study is summarized in Table 40. Twenty (20) of the 75 (26.7%) recipients required MCS postoperatively.

Table 40: Post-operative MCS Support – OCS Heart EXPAND

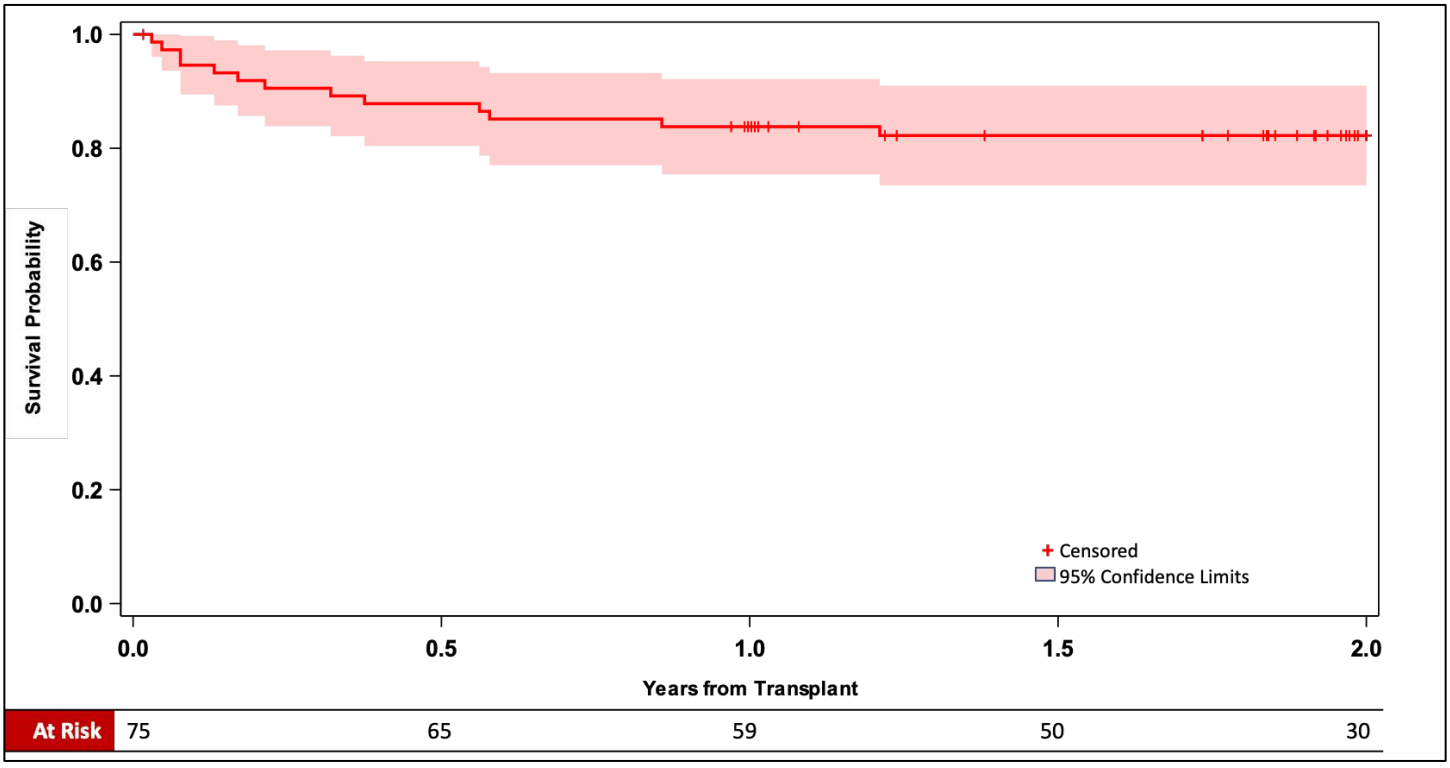
	Percentage of Patients* (n/N)	Duration of Support† (hours)
Mechanical circulatory support	26.7% (20/75)	
RVAD	2.7% (2/75)	219.12 ± 31.35
LVAD	2.7% (2/75)	139.0 ± 93.34
IABP	18.7% (14/75)	80.0 ± 63.20
ECMO	12.0% (9/75)	132.04 ± 97.09
BiVAD	0% (0/75)	-

*Percentages are calculated based on the number of transplanted recipients without missing data. A recipient may have more than one type of post-transplant support.
†The duration of support is the sum of the durations of all periods of support.

12.12.3. Patient Longer-Term Survival

All transplanted recipients in OCS Heart EXPAND have been followed through 24 months post-transplant by March 2020. The Kaplan-Meier Analysis of overall survival for OCS Heart EXPAND subjects is shown in Figure 67 below. Four (4) of 13 deaths in OCS Heart EXPAND through 2 years were cardiac-related.

Figure 67: Kaplan-Meier Analysis of Overall Survival for OCS Heart EXPAND Subjects



In addition, 4 of 13 deaths in OCS Heart EXPAND through 24 months (representing 5% of the overall mortality) were due to recipient factors and were not related to the transplanted heart, in general, or the use of the OCS Heart System:

- 1 patient died on Day 29 due to pre-existing chronic liver cirrhosis.
- 1 patient died on Day 80 and the subject likely had undiagnosed parenchymal lung disease leading to post-op acute respiratory distress disease.
- 1 patient died on Day 212 due to reoccurrence of pre-existing amyloidosis with refractory GI bleed.
- 1 patient died 14 months post-transplant due to motor vehicle accident that is unlikely to be related the transplant procedure or the transplanted heart.

These deaths were related to the recipients' comorbidities or other factors and are not attributable to the heart transplant or the use of the OCS™ Heart System.

12.13. OCS Heart EXPAND Continued Access Protocol (CAP) Study

FDA approved a CAP for OCS Heart EXPAND for an additional 75 patients. As of the date of database closure, in the OCS Heart EXPAND CAP, 49 donor hearts had been perfused on OCS, 45 patients have been transplanted and 41 of 45 of these transplanted recipients had a minimum of 30 days follow-up post-transplant with source data verified. Therefore, the analysis of transplanted recipients is based on these 41 patients and utilization rate is also based on these 41 patients.

12.13.1. Donor Characteristics and Risk Factors

Donor inclusion criteria/risk factors are provided in Table 41. Among these 41 transplanted recipients, 17 (41.5%) received donor hearts that met multiple donor inclusion criteria.

Table 41: Donor Inclusion Criteria Met by Transplanted Donor Hearts for OCS Heart EXPAND CAP

Inclusion Criteria Met	Summary Statistics (N=41)
Expected cross-clamp time ≥ 4hr	25 (61.0%)
Donor age ≥ 55	2 (4.9%)
LVH	5 (12.2%)
Downtime ≥ 20 min	10 (24.4%)
LVEF 40% -50%	6 (14.6%)
Luminal irregularities	3 (7.3%)
Alcoholism	7 (17.1%)
History of carbon monoxide poisoning	0 (0.0%)
Diabetes	1 (2.4%)
Donor age 45-55 with no coronary catheterization data	0 (0.0%)
Donor hearts met single criterion	24 (58.5%)
Donor hearts met multiple criteria	17 (41.5%)
*Categorical measures – no. (%)	

12.13.2. Recipients Demographics and Baseline Characteristics

The recipient demographics are shown in Table 42 below. The majority of recipients (61%) were UNOS Urgency Status 1A and were on mechanical circulatory support at the time of transplant (68%, 28/41).

Table 42: Summary of Recipient Demographics and Baseline Characteristics for OCS Heart EXPAND CAP

Demographics and Baseline Characteristics	Summary Statistics* (N=41)
Age (years)	52.1 ± 14.2
Age > 65	7 (17.1%)
Gender – male	32 (78.0 %)
BMI (kg/m^2)	29.4 ± 4.7
Race	
Asian	0 (0.0%)
Black or African American	12 (29.3%)
White	28 (68.3%)
Other	1 (2.4%)
Not provided	0 (0.0%)
History of mechanical circulatory support	28 (68.3%)
IABP	16 (39.0%)
LVAD	11 (26.8%)
RVAD	1 (2.4%)
BiVAD	0 (0.0%)
ECMO	2 (4.9%)
UNOS status	
Status IA (Status 1-3)	25 (61.0%)
Status IB (Status 4)	12 (29.3%)
Status II (Status 5 & 6)	4 (9.8%)
Primary etiology of heart failure diagnosis	
Ischemic cardiomyopathy	14 (34.1%)
Congenital heart disease	3 (7.3%)
Restrictive cardiomyopathy	0 (0.0%)
Non-ischemic cardiomyopathy	15 (36.6%)
Dilated cardiomyopathy	7 (17.1%)
Other	2 (4.9%)
Renal dysfunction	1 (2.4%)
Percent PRA - mean (range)	6.6% (0-79%)
*Continuous measures - Mean ± SD; categorical measures – no. (%)	

12.13.3. Primary Endpoint Results

Table 43 below shows the results of the composite primary effectiveness endpoint for OCS Heart EXPAND CAP. 91% of the subjects achieved success on the composite endpoint of patient survival at Day 30 post-

transplantation and absence of severe ISHLT PGD in the first 24 hours post-transplantation. All 41 recipients were alive at 30 days post-transplant, and 1 patient had severe PGD (left or right ventricle) in the first 24 hours post-transplant.

Table 43: Primary Effectiveness Endpoint for OCS Heart EXPAND CAP

Patient survival at 30 days post-transplant and absence of severe PGD (left or right ventricle) in the first 24 hours post-transplant (N=41)	
Proportion - % (n/N)[*]	97.6% (40/41)
95% CI for proportion[†]	(87.1%, 99.9%)
[*]Simple proportion. [†]Clopper-Pearson exact confidence interval for a binomial proportion.	

12.13.4. Secondary Endpoint Results

The secondary endpoints are shown in Table 44 and Table 45 below. The 30-day survival was 100%. The incidence of severe ISHLT PGD was 2.4%.

Table 44: Patient/Graft Survival at 30 Days Post-transplant – OCS Heart EXPAND CAP

Patient survival at 30 days post-transplant (N=41)	
Proportion - % (n/N)	100% (41/41)
95% CI for proportion[*]	(91.4%, 100%)
[*]Clopper-Pearson exact confidence interval for a binomial proportion.	

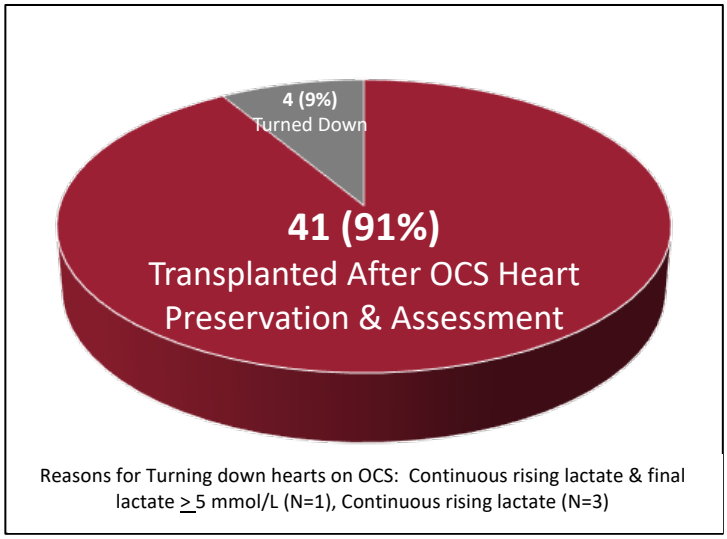
Table 45: Incidence of Severe ISHLT PGD (Left or Right Ventricle) in the First 24 Hours Post-transplant – OCS Heart EXPAND CAP

Incidence of severe ISHLT PGD (left or right ventricle) in the first 24 hours post-transplant (N=41)	
Proportion - % (n/N)	2.4% (1/41)
95% CI for proportion[*]	(0.1%, 12.9%)
[*]Clopper-Pearson exact confidence interval for a binomial proportion.	

12.13.5. Donor Heart Utilization

Forty-one (41) of the 45 donor hearts instrumented on the OCS Heart System were transplanted, giving a utilization rate of 91%, as shown in Figure 68.

Figure 68: Donor Heart Utilization Rate – OCS Heart EXPAND CAP



12.13.6. Incidence of HGRSAEs in the first 30 days post-transplant

The results of the HGRSAEs in the first 30 days are summarized in Table 46. Seven (7) recipients experienced a total of 7 HGRSAEs. The incidence of HGRSAEs in the first 30 days was 0.17, which is very similar to that observed in OCS Heart EXPAND.

Table 46: HGRSAEs in the First 30 days post-transplant - OCS Heart EXPAND CAP

HGRSAEs in the first 30 days post-transplant (N=41)	
Number of HGRSAEs	7
Moderate or severe PGD (LV or RV)	7
Severe LV PGD	1
Moderate LV PGD	6
RV PGD	0
Primary graft failure requiring re-transplantation	0
Incidence of HGRSAEs	0.17 (7/41)
95% CI*	(0.1, 0.3)
*Confidence interval calculated based on the t-distribution.	

12.13.7. Serious Adverse Events (SAEs)

Table 47 below shows the adjudicated SAEs by System Organ Class and Preferred term for OCS Heart EXPAND CAP. The SAEs are typical of those experienced by heart transplant recipients and there are no signals of concern. No SAEs were adjudicated as having been device-related.

Table 47: List of Adjudicated SAEs by System Organ Class and Preferred Term –Transplanted Recipient Population through 30 Days of Follow-up in OCS Heart EXPAND CAP

System Organ Class	Preferred Term	Summary Statistic*	
		Recipients (N=41)	Events
Total		27 (65.9%)	54
Blood and lymphatic system disorders		1 (2.4%)	1
	Anemia	1 (2.4%)	1
Cardiac disorders		13 (31.7%)	16
	Atrial fibrillation	3 (7.3%)	3
	Atrioventricular block	2 (4.9%)	2
	Intrapericardial thrombosis	1 (2.4%)	1
	Left ventricular dysfunction	3 (7.3%)	3
	Pericardial hemorrhage	1 (2.4%)	1
	Right ventricular dysfunction	3 (7.3%)	3
	Sinus bradycardia	1 (2.4%)	1
	Ventricular dysfunction	2 (4.9%)	2
Immune system disorders		4 (9.8%)	4
	Heart transplant rejection	4 (9.8%)	4
Infections and infestations		3 (7.3%)	3
	Bacteremia	1 (2.4%)	1
	Pneumonia	2 (4.9%)	2
Injury, poisoning and procedural complications		1 (2.4%)	1
	Vena cava injury	1 (2.4%)	1
Metabolism and nutrition disorders		2 (4.9%)	2
	Dehydration	1 (2.4%)	1
	Fluid overload	1 (2.4%)	1
Nervous system disorders		3 (7.3%)	3
	Cerebrovascular accident	1 (2.4%)	1
	Hemorrhagic stroke	1 (2.4%)	1
	Neuralgia	1 (2.4%)	1
Psychiatric disorders		2 (4.9%)	2
	Delirium	2 (4.9%)	2
Renal and urinary disorders		10 (24.4%)	10
	Renal failure acute	9 (22.0%)	9
	Renal impairment	1 (2.4%)	1

System Organ Class	Preferred Term	Summary Statistic*	
		Recipients (N=41)	Events
Respiratory, thoracic and mediastinal disorders		4 (9.8%)	6
	Bronchial secretion retention	1 (2.4%)	1
	Pleural effusion	3 (7.3%)	3
	Pulmonary oedema	1 (2.4%)	1
	Respiratory failure	1 (2.4%)	1
Vascular disorders		5 (12.2%)	6
	Aortic dissection	1 (2.4%)	1
	Hematoma	1 (2.4%)	1
	Hemorrhage	1 (2.4%)	1
	Hypotension	1 (2.4%)	1
	Orthostatic hypotension	2 (4.9%)	2

*Number of recipients refers to the number of recipients with at least one SAE of the indicated type. Number of events refers to all events of the indicated type. Percentages are calculated based on the total number of recipients. For number of recipients, recipients experiencing multiple events under the same system organ class/preferred term are counted only once for that system organ class/preferred term.

12.13.8. UNOS Donor Match Run Refusals prior to acceptance into study

Table 48 below shows the donor match run data available from UNOS/SRTR for the OCS Heart EXPAND CAP donor hearts which shows that these donor hearts were refused by other centers a mean of 48 times.

Table 48: UNOS Donor Match Run Donor Heart Offers Refusals Prior to Acceptance in OCS Heart EXPAND CAP

Donor Heart Offer Refusals by Other Centers	Summary Statistics (N = 45)
Number of refusals per donor heart - Mean ± SD	48 ± 93
Median number of refusals per donor heart	12
Range	0 - 480

12.13.9. Transplanted Donor Heart Preservation Characteristics

OCS perfusion time, total ischemic time and cross-clamp time are listed in Table 49 below for the 41 transplanted recipients in OCS Heart EXPAND CAP. The mean cross-clamp time, OCS Heart System perfusion time, and total ischemic time were 382.3 ± 87.9, 278.3 ± 77.2, and 104.0 ± 22.2 minutes, respectively.

Table 49: Preservation Characteristics for Donor Hearts for OCS Heart EXPAND CAP

Parameter	Summary Statistics (N=41)
Cross-clamp time (mins)*	
Mean ± SD	382.3 ± 87.9

Parameter	Summary Statistics (N=41)
Median	385
Range	253 - 585
OCS Heart System perfusion time (mins)	
Mean ± SD	278.3 ± 77.2
Median	278
Range	158 - 440
Total ischemic time (mins)[†]	
Mean ± SD	104.0 ± 22.2
Median	98
Range	69 - 189

[*] Cross-clamp time (i.e., out of body time) is the time from aortic cross-clamp application in the donor to the pulmonary artery cross-clamp removal in the recipient.
[†] Total ischemic time for hearts preserved by OCS Heart System is the cross-clamp time minus OCS Heart System perfusion time.

12.13.10. OCS Heart System Perfusion Parameters

The OCS perfusion parameters are summarized in Table 50 below for both transplanted and turned down donor hearts.

Table 50: OCS Heart System Perfusion Parameters for OCS Heart EXPAND CAP

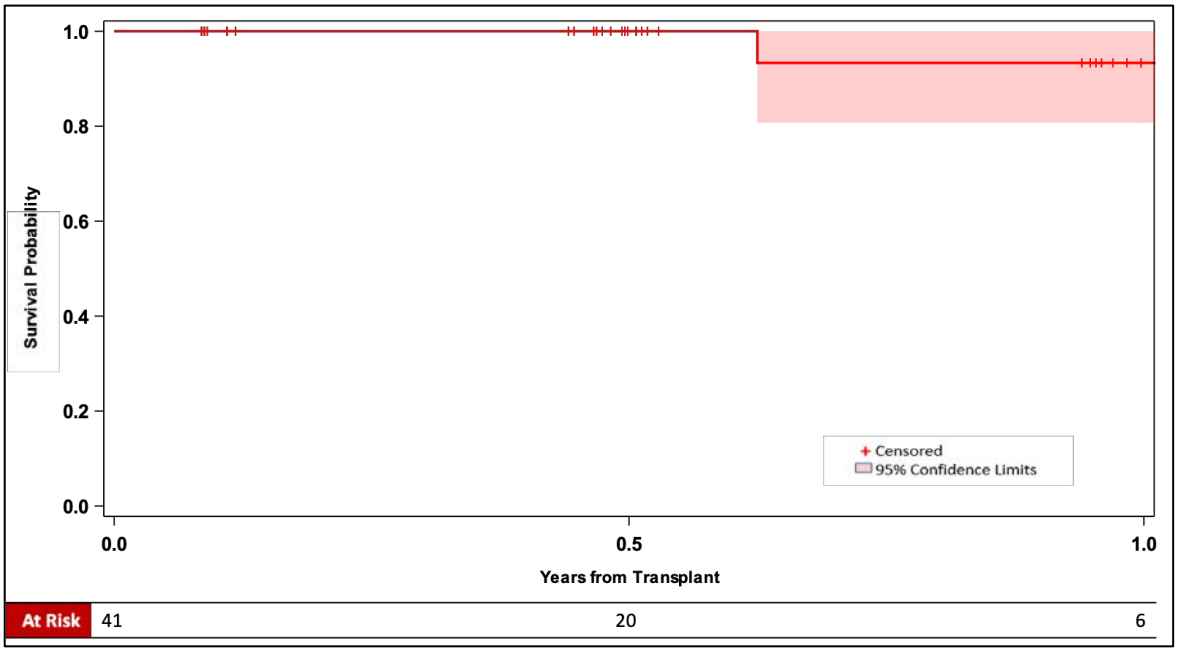
Parameter	Summary Statistics (N=41)
AOP (mmHg)	
Mean ± SD	77.4 ± 8.5
Median	79.3
Range	52 – 96
Coronary flow (L/min)	
Mean ± SD	0.73 ± 0.11
Median	0.75
Range	0.32 - 0.92
Arterial lactate (mmol/L) – Initial OCS instrumentation	
Mean ± SD	1.8 ± 0.85
Median	1.7
Range	0.67 – 5.70
Arterial lactate (mmol/L) – Final OCS instrumentation	
Mean ± SD	2.9 ± 1.26
Median	2.6
Range	1.28 – 7.59
Pump flow (L/min)	
Mean ± SD	1.10 ± 0.11

Parameter	Summary Statistics (N=41)
Median	1.10
Range	0.89 - 1.42
Heart Rate (BPM)	
Mean ± SD	78.7 ± 1.4
Median	78.5
Range	77 - 85
Hematocrit (%)	
Mean ± SD	20.0 ± 3.4
Median	19.1
Range	15 – 32

12.13.11. Patient Survival

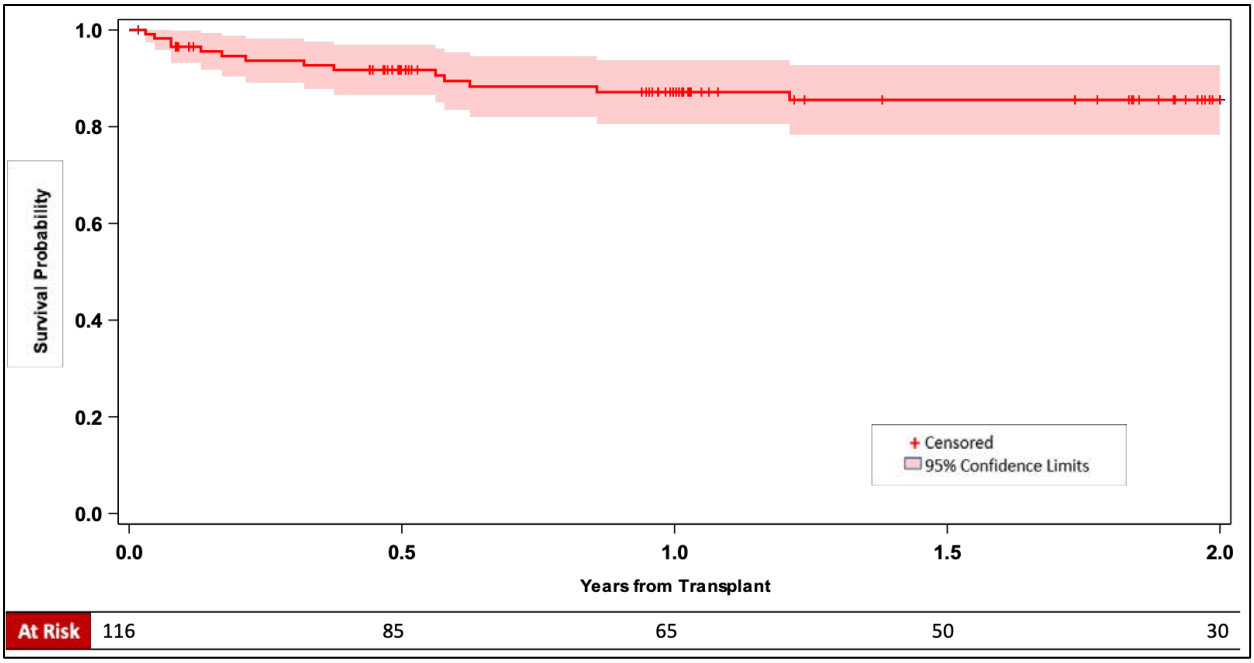
Kaplan-Meier analysis of overall patient survival is shown in Figure 69 below. The Kaplan-Meier estimates of the overall survival rates were 100% at 6 months and 93.3% at 1 year.

Figure 69: Overall Patient Survival for OCS Heart EXPAND CAP Patients



A *post hoc* Kaplan-Meier analysis of the overall survival for the pooled OCS Heart EXPAND Heart and OCS Heart EXPAND CAP recipients is shown in Figure 70. The Kaplan-Meier estimates of the overall survival rates were 91.7% at 6 months and 87.2% at 1 year.

Figure 70: Kaplan-Meier Analysis of Overall Survival EXPAND Heart + EXPAND Heart CAP (N=116)



12.14. Conclusions of OCS Heart EXPAND and OCS Heart EXPAND CAP

The results of OCS Heart EXPAND provide evidence of the effectiveness, safety and favorable benefit/risk profile of the OCS™ Heart System:

- OCS Heart EXPAND met its primary effectiveness composite endpoint of 30-day patient survival and freedom from severe ISHLT PGD with an 88% success rate on the primary effectiveness composite endpoint ($p<0.0001$).
- The 30-day patient survival was of 95% and 100% in OCS Heart EXPAND and CAP, respectively.
- The incidence of severe ISHLT PGD post-transplant was 10.7% in OCS Heart EXPAND and 2.4% in OCS Heart EXPAND CAP.
- OCS Heart EXPAND long-term patient survival at 12 and 24 months post-transplant was 84% and 82%, respectively, while survival for OCS Heart EXPAND CAP patients at 12 months was 93%
- The mean number of HGRSAEs per patient was 0.16 in OCS Heart EXPAND and 0.17 in OCS Heart EXPAND CAP, with an overall safety profile that was consistent with routine heart transplantation.
- Serious Adverse Events were typical for patients undergoing heart transplantation.
- 81-91% of donor hearts perfused on OCS Heart System were successfully transplanted in EXPAND and CAP, respectively, despite having factors that make them seldom transplanted due to the limitations of cold storage.

13. APPENDIX C: OCS HEART PROCEED II TRIAL

Historical clinical data includes the PROCEED II trial. PROCEED II was a randomized, prospective, non-inferiority, open-label, multi-center clinical trial that evaluated whether the clinical outcomes of patients undergoing heart transplantation with standard donor hearts preserved on the OCS™ Heart System were non-inferior to the outcomes of heart transplant recipients whose donor hearts were preserved using standard-of-care cold storage. PROCEED II was designed in 2006 and was the first trial of *ex-vivo* donor organ perfusion in the world and the first of the OCS™ Heart System. This study provided important learnings for the OCS Heart EXPAND trial. The results have been published in the Lancet (Ardehali, et al., 2015).

13.1. PROCEED II Study Design

13.1.1. Primary Study Endpoint

The primary study endpoint was 30-day patient survival following transplantation with the originally transplanted heart and no mechanical circulatory assist device at Day 30.

13.1.2. Secondary Study Endpoints

The secondary study endpoints were:

- Incidence of serious cardiac (graft)-related adverse events, defined as those which are attributed to preservation injury of the donor heart in the first 30 days post-transplant: e.g., right ventricular dysfunction; left ventricular dysfunction; graft failure and myocardial infarction.
- Incidence of biopsy proven ISHLT (International Society for Heart and Lung Transplant) grade 2R (moderate) or 3R (severe) acute rejection on any of the surveillance endomyocardial biopsies as determined by the core pathology laboratory or clinically symptomatic rejection requiring augmentation of immunosuppressive therapy during the 30-day follow-up period.
- Length of intensive care unit (ICU) stay.

13.1.3. Study Populations for Analysis

The Per Protocol (PP) Population consisted of all patients randomized to their original group who were transplanted and had no major protocol violations. This was the primary analysis population for the study.

The ITT population included all randomized patients for whom it was determined at the donor site that there was a matching and eligible heart. In analyses based on the ITT population, patients were analyzed as randomized. The As-Treated (AT) Population consisted of all randomized recipients who received a donor heart preserved by either the OCS or standard cold storage technique, subsequent to randomization, and regardless of whether or not the subject received a donor heart according to the randomization assignment.

Analysis of the primary study effectiveness endpoint was based on the Per Protocol population and was also analyzed for all study populations. All secondary endpoints were analyzed using the AT population.

13.2. Subject Disposition

Of the 143 initially screened and randomized patients, 13 patients failed secondary screening/eligibility. Thus, 130 patients comprised the ITT Population, with 67 patients randomly assigned to the OCS Group and 63 patients randomly assigned to the standard cold storage group (Control Group). The As-Treated Population consisted of 128 randomized patients who received an OCS or Control donor heart, regardless of whether or not there was conformance with the randomization assignment, with 62 in the OCS Group and 66 in the Control group. The Per-Protocol Population comprised 121 randomized subjects who received a donor heart in conformance with the randomization assignment and had no major protocol violations, with 60 in the OCS Group and 61 in the Control Group.

Figure 71: PROCEED II Trial Populations

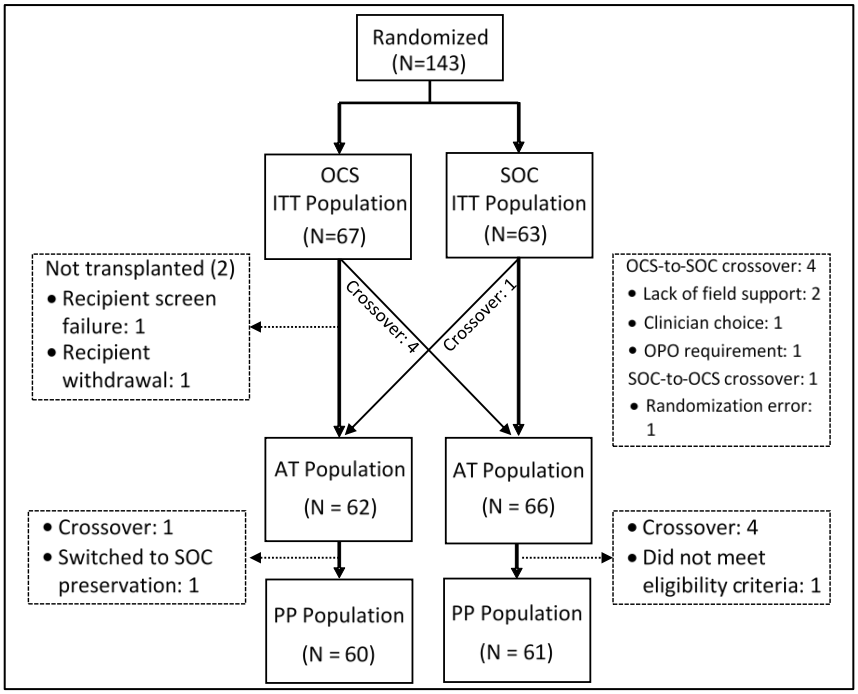


Table 51: PROCEED II Analysis Populations

Analysis Population	Definition	Number of Patients	
		OCS	SOC
Intention-To-Treat (ITT)	All randomized patients for whom it was determined at the donor site that there was a matching and eligible heart.	67	63
As Treated (AT)	All ITT patients who received a donor heart preserved by either the OCS or SOC technique, regardless of whether or not the patient received a donor heart according to the randomization assignment.	62	66
Per Protocol (PP)	All AT patients who were transplanted according to their randomization assignments and had no major protocol deviations.	60	61

13.3. Donor and Recipient Baseline Characteristics and Risk Factors

Donor and recipient demographics and risk factors for the OCS and control groups are shown in Table 52 below. The groups were generally well balanced for donor and recipient characteristics.

Table 52: Donor and Recipient Characteristics (As Treated Populations)

Donor Characteristics	**OCS Group (N=62)**	**Control Group (N=66)**
Age (yr)	36.2 (18-58)	34.0 (13-60)
Age ≥ 55 years	2 (3.2%)	3 (4.5%)
Male Sex	42 (67.7%)	47 (71.2%)
BMI (kg/m^2)	27.7 (18-44)	26.0 (15-45)
LVEF % Mean (range)	60.6 (50-70)	62.0 (45-75)
Cause of Death		
• Anoxia	14 (22.6%)	14 (21.2%)
• Stroke/CVA	17 (27.4%)	18 (27.3%)
• Head Trauma	26 (41.9%)	28 (42.4%)
• Other	5 (8.1%)	6 (9.1%)
Recipient Characteristics	**OCS Group (N=62)**	**Control Group (N=66)**
Age (yr)	53.0 (20-71)	54.7 (20-76)
Age > 65	11 (17.4%)	18 (27.3%)
Male Sex	52 (83.9%)	48 (72.7%)
BMI (kg/m^2)	26.3 (17-41)	24.2 (16-38)
Clinical History of Diabetes	17 (27.4%)	17 (25.8%)
On VAD	18 (29%)	15 (22.7%)
Female Donor to Male Recipient	12 (19.4%)	12 (18.2%)
Diagnosis of Cardiomyopathy		
• Ischemic	23 (37.1%)	20 (30.3%)
• Idiopathic	7 (11.3%)	10 (15.5%)
• Dilated Cardiomyopathy	21 (33.9%)	23 (34.8%)
• Congenital Heart Disease	1 (1.6%)	1(1.5%)
• Restrictive	2 (3.2%)	4 (6.1%)
• Other	7 (11.3%)	9 (13.6%)
UNOS Status		

• IA • IB • II	44 (71.0%) 8 (12.9%) 10 (16.1%)	51 (77.3%) 6 (9.1%) 9 (13.6%)
Data are mean (range) or number (%), P-values are from the two-sample t-test for continuous variables, testing for a difference in means between treatments, or from Fisher's Exact Test for categorical variables, testing for a difference between treatments in the proportions in each category.		

13.4. Primary Endpoint Results

The study met its primary endpoint for all study populations, demonstrating that the OCS™ Heart System was non-inferior to Control preservation at the pre-specified 10% margin (Table 53).

Table 53: Primary Endpoint (30-Day Patient and Graft Survival and Absence of a Mechanical Assist Device at Day 30) for Various Study Populations

Study Populations	OCS Group	Control Group	Between Group Difference in % (SOC-OCS)	95% Upper Confidence Bound for Difference in %	Non-inferiority criterion*
Per Protocol	56/60 (93.3)	59/61 (96.7)	3.4	9.9	pass
As Treated	58/62 (93.5)	64/66 (97.0)	3.5	9.6	pass
Intent to Treat[1]	63/67 (94.0)	61/63 (96.8)	2.8	8.8	pass

Data are number (%).
*The non-inferiority hypothesis was demonstrated for all three analysis populations as the 95% UCB for the difference between the two trial groups was < 10% for all populations.
[1] Missing values were imputed with multiple imputation. The logistic regression method of imputation was used with terms for treatment, age, and gender.

13.5. Secondary Endpoint Results

13.5.1. Cardiac Graft-related Serious Adverse Events

The study met the secondary endpoint of cardiac graft-related serious adverse events, demonstrating the safety of the OCS for donor heart preservation (non-inferiority of OCS compared with Control). Eight (8) OCS patients and 9 Control patients experienced one or more cardiac graft-related serious adverse events (Table 54).

Table 54: Secondary Endpoint – Patients Experiencing At Least One Cardiac Graft-related Serious Adverse Event (CEC-adjudicated)

Statistic	OCS (N=62)	SOC (N=66)
Number of cardiac graft-related SAEs	8	9
Incidence of cardiac graft-related SAEs	12.9% (8/62)	13.6% (9/66)
Difference in incidence between arms	-0.7%	
95% upper confidence bound of difference*	9.1%	
Non-inferiority margin	10%	
Non-inferiority criterion	Pass	

Statistic	OCS (N=62)	SOC (N=66)
*Calculated based on the normal approximation		

13.5.2. Graft Rejection at 30 Days Post-transplant

The incidences of graft rejections during the 30-day follow-up period are summarized in Table 55. Eleven (11; 17.7%) patients in the OCS arm and 9 (13.6%) in the SOC arm experienced moderate acute graft rejection requiring augmentation of immunosuppressive therapy. Statistical non-inferiority was not demonstrated for this endpoint.

Table 55: Graft Rejection at 30 Days Post-Transplant (AT Population)

Statistic	OCS (N=62)	SOC (N=66)
Number of rejections	11	9
Grade 3R rejection	0	0
Grade 2R rejection	11	9
Clinically symptomatic rejection	0	0
Incidence of rejections	17.7% (11/62)	13.6% (9/66)
Difference between arms	4.1%	
95% upper confidence bound of difference	14.7%	
Non-inferiority margin	10%	
Non-inferiority criterion	Failed	

13.5.3. Median Length of ICU Stay

The length of initial ICU stay data are summarized in Table 56. The median length of the initial ICU stay was 147.1 hours for the OCS arm and 137.1 hours for the SOC arm. Statistical non-inferiority was not observed in this endpoint.

Table 56: Median Length of ICU Stay (AT Population)

Statistic (hours)	OCS (N=62)	SOC (N=66)
Mean (SD)	234.2 (349.0)	161. 3 (92.1)
Median	147.1	137.1
Difference in median between arms	10.0	
95% upper confidence bound of difference*	37.7	
Non-inferiority margin	12	
Non-inferiority criterion	Failed	
*Calculated based on the normal approximation to the Wilcoxon rank sum test statistic.		

13.6. Serious Adverse Events

The SAEs at 30 days post-transplant observed during the PROCEED II trial are summarized in Table 57. A total of 46.8% (29/62) of the recipients in the OCS arm and 34.8% (23/66) in the SOC arm experienced an SAE.

Table 57: Summary of SAEs at 30 Days – PROCEED II (AT Population)

System Organ Class	Preferred Term	Summary Statistic*	
		OCS (N=62)	SOC (N=66)
Total		29 (46.8%)	23 (34.8%)
Blood and lymphatic system disorders		3 (4.8%)	1 (1.5%)
	Coagulopathy	3 (4.8%)	0 (0.0%)
	Thrombocytopenia	0 (0.0%)	1 (1.5%)
Cardiac disorders		13 (21.0%)	9 (13.6%)
	Cardiac arrest	1 (1.6%)	1 (1.5%)
	Intrapericardial thrombosis	0 (0.0%)	1 (1.5%)
	Left ventricular dysfunction	0 (0.0%)	2 (3.0%)
	Pericardial effusion	3 (4.8%)	0 (0.0%)
	Right ventricular dysfunction	2 (3.2%)	6 (9.1%)
	Tricuspid valve incompetence	3 (4.8%)	0 (0.0%)
	Ventricular dysfunction	4 (6.5%)	1 (1.5%)
Gastrointestinal disorders		0 (0.0%)	1 (1.5%)
	Pancreatitis acute	0 (0.0%)	1 (1.5%)
General disorders and administration site conditions		1 (1.6%)	1 (1.5%)
	Catheter site inflammation	1 (1.6%)	0 (0.0%)
	Influenza like illness	0 (0.0%)	1 (1.5%)
Hepatobiliary disorders		1 (1.6%)	0 (0.0%)
	Cholecystitis	1 (1.6%)	0 (0.0%)
Immune system disorders		1 (1.6%)	1 (1.5%)
	Heart transplant rejection	1 (1.6%)	1 (1.5%)
Infections and infestations		4 (6.5%)	1 (1.5%)
	Adenoviral upper respiratory infection	1 (1.6%)	0 (0.0%)
	Lobar pneumonia	1 (1.6%)	0 (0.0%)
	Perirectal abscess	0 (0.0%)	1 (1.5%)
	Septic shock	1 (1.6%)	0 (0.0%)
	Urosepsis	1 (1.6%)	0 (0.0%)

System Organ Class	Preferred Term	Summary Statistic*	
		OCS (N=62)	SOC (N=66)
Injury, poisoning and procedural complications		7 (11.3%)	7 (10.6%)
	Deep vein thrombosis Postoperative	1 (1.6%)	0 (0.0%)
	Operative hemorrhage	1 (1.6%)	1 (1.5%)
	Post procedural hemorrhage	6 (9.7%)	6 (9.1%)
Investigations		1 (1.6%)	1 (1.5%)
	Cardiac Output Decreased	0 (0.0%)	1 (1.5%)
	Pulmonary Arterial Wedge Pressure Increased	1 (1.6%)	0 (0.0%)
Metabolism and nutrition disorders		1 (1.6%)	0 (0.0%)
	Hypovolemia	1 (1.6%)	0 (0.0%)
Nervous system disorders		1 (1.6%)	3 (4.5%)
	Cerebral hematoma	0 (0.0%)	1 (1.5%)
	Dizziness	1 (1.6%)	0 (0.0%)
	Paresis	0 (0.0%)	1 (1.5%)
	Subarachnoid hemorrhage	0 (0.0%)	1 (1.5%)
Renal and urinary disorders		4 (6.5%)	3 (4.5%)
	Oliguria	0 (0.0%)	1 (1.5%)
	Renal failure	2 (3.2%)	0 (0.0%)
	Renal failure acute	2 (3.2%)	2 (3.0%)
Respiratory, thoracic and mediastinal disorders		7 (11.3%)	3 (4.5%)
	Pleural effusion	0 (0.0%)	1 (1.5%)
	Pneumothorax	0 (0.0%)	1 (1.5%)
	Pulmonary oedema	1 (1.6%)	0 (0.0%)
	Respiratory distress	2 (3.2%)	0 (0.0%)
	Respiratory failure	4 (6.5%)	1 (1.5%)
Vascular disorders		3 (4.8%)	1 (1.5%)
	Hemorrhage	1 (1.6%)	1 (1.5%)
	Hypotension	1 (1.6%)	0 (0.0%)
	Peripheral artery aneurysm	1 (1.6%)	0 (0.0%)

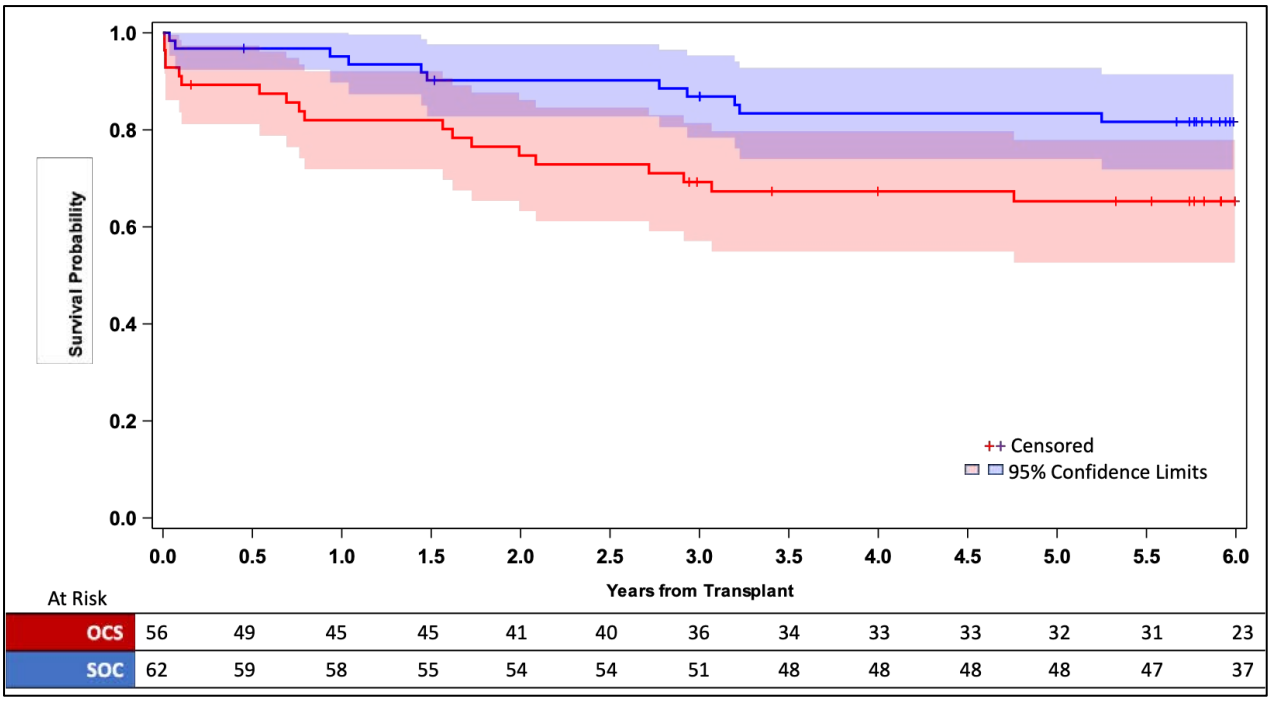
*No. (%) - Number of recipients with at least one SAE of the indicated type (percentages calculated based on the total number of recipients). Recipients experiencing multiple events under the same system organ class/preferred term are counted only once for that system organ class/preferred term.

13.7. Other Study Observations

13.7.1. Longer term survival

A *post hoc* Kaplan-Meier analysis of long-term survival based on data from the UNOS heart transplant registry is shown in Figure 72 for recipients treated in the U.S. only, which demonstrated a lower overall survival trend in the OCS arm (82.0% at 1 year and 74.7% at 2 years) compared to the SOC arm (95.1% at 1 year and 90.2% at 2 years). However, cardiac graft related deaths in both arms were similar (3 for OCS and 4 for control). The majority of the deaths in both arms were due to other causes and are typical for heart transplant patients (e.g., late infection, malignancy).

Figure 72: Kaplan-Meier Analysis of Overall Survival – PROCEED II (AT Population; U.S. Subgroup)



13.7.2. Clinicopathologic Analysis of Turned-Down Donor Hearts

In the three clinical studies of the OCS Heart System, a total of 27 donor hearts were turned down after being preserved using the OCS Heart System, including 18 in the EXPAND Heart study, 4 in the EXPAND Heart CAP study, and 5 in the PROCEED II study. The pathology core laboratory reports were available for 26 of these turned-down hearts, which indicated findings of acute diffuse or multifocal myocardial damage in 23 hearts despite that these hearts had stable antemortem hemodynamics, normal (or essentially normal) cardiac anatomy, and normal ventricular function by echocardiography. It is unknown whether the injury was due to use of the OCS Heart System.

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14. APPENDIX D: CLINICAL REFERENCES

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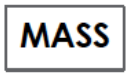
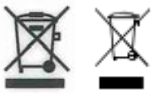
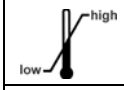
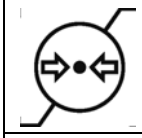
15. APPENDIX E: SYMBOL GLOSSARY

This glossary describes the symbols used on the packaging for the OCS™ Heart 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
	ISO 7000-2608	Graphical symbols for use on equipment.	Do not resterilize

Symbol	Standard and Symbol Reference	Standard Title	Symbol Definition
			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 Heart Console and HPM
	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
	ISO 7000-0621	Graphical symbols for use on equipment.	Fragile, handle with care
	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

Symbol	Standard and Symbol Reference	Standard Title	Symbol Definition
	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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