TransMedics® Organ Care System™
OCS Liver User Guide

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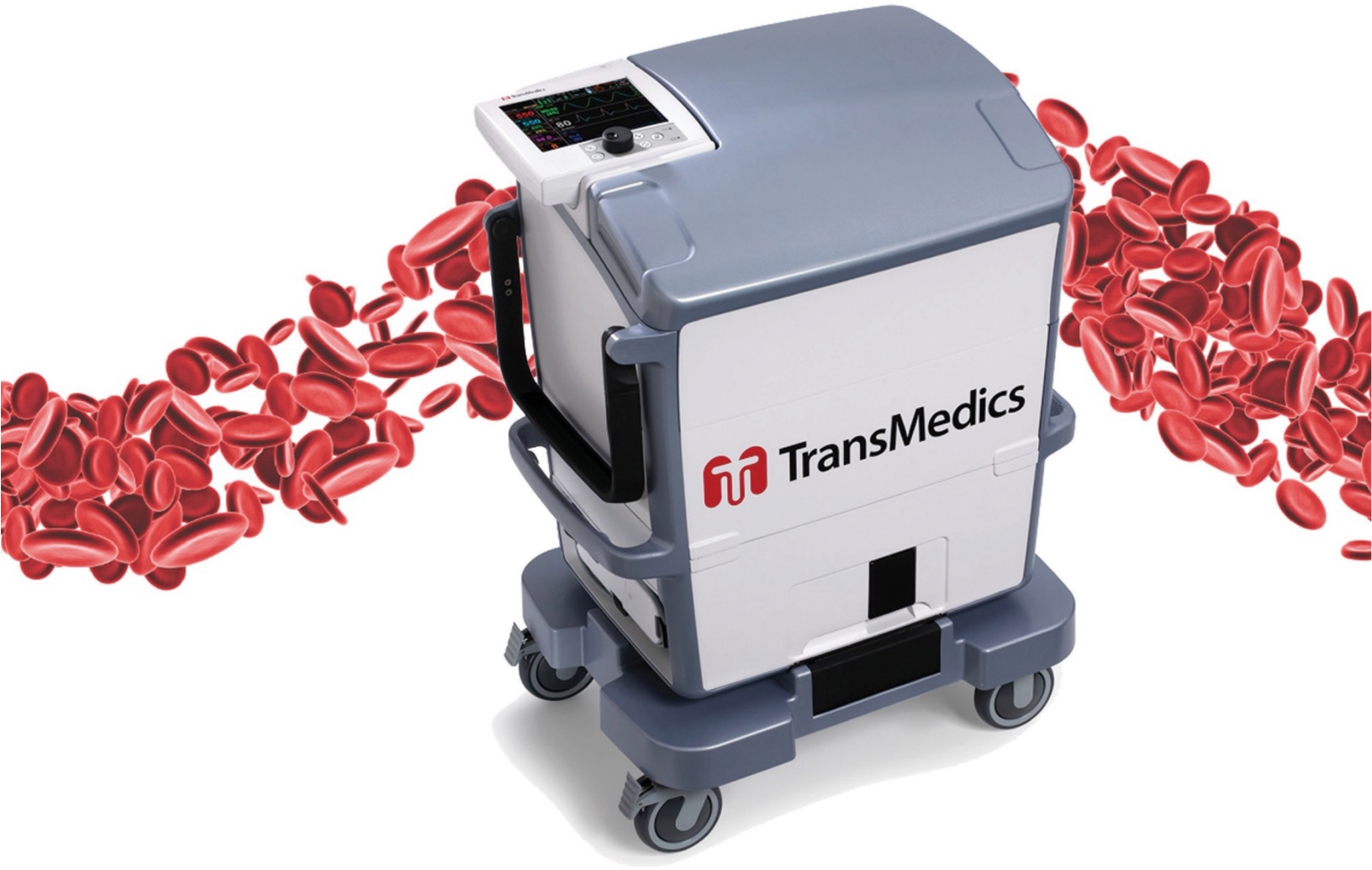

CE 2797

TransMedics®
Bringing new life to organ transplant

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CE 2797

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

Authorized EU Representative:

EC REP

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Patents:

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

Manual PN & Rev
PN 100005719, 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 LVPM AND LIVER CONSOLE

Symbol	Meaning	Symbol	Meaning
	Indicates On (only for a part of the equipment)		Indicates Off (only for a part of the equipment)
	Run/Standby		Non-ionizing, electromagnetic radiation
	Direct current		Alternating current
	Bile cannula connection		Level 1 ingress protection
	Oxygen Saturation/Hematocrit		Blood and Prime Solution Port
PV	Portal Vein cannula connection	PVF	Portal Vein Flow
HA	Hepatic Artery cannula connection	HAF	Hepatic Artery Flow
	Portal Vein flush solution port		Hepatic Artery flush solution port
	Venous sample and injection port		Drainage Bag Connection
	Portal Vein infusion line connection location #1		Portal Vein infusion line connection location #2
	Portal Vein infusion line connection location #3		Hepatic Artery injection port
	Hepatic Artery vent and sample port		Portal Vein vent
	Portal Vein Clamp fine adjustment		Follow Instructions For Use
	SDS Channel location		

NOTE—For detailed information on system status icons that appear on the Wireless Monitor and its display, see Section 3.2.1, "Wireless Monitor."

GLOSSARY OF TERMS

Term	Meaning
ABG	Arterial Blood Gas
Annotations	Notes or comments entered through the Wireless Monitor during the session that are automatically stamped with the time of entry and saved in the session file.
Circuit	Refers to the perfusate loop in the Liver Perfusion Module.
Data Card	A removable SD Data card used to store perfusion, infusion, and monitoring parameters from the current session, which can be downloaded and analyzed on a personal computer.
Erase Bar	A vertical line displayed on the waveform. Newest data is displayed to the immediate left of the erase bar.
Flow Probes	Liver Console probes that you attach to the Liver Perfusion Module. They are used to measure HAP and PVP.
Fr	French size
HA	Hepatic Artery
HAF	Hepatic Artery Flow
HAP	Hepatic Artery Pressure. Displayed on the Wireless Monitor in millimeters of mercury (mmHg).
HCT	Hematocrit
HCT%	Hematocrit, expressed as a percentage by volume.
LvPM	Liver Perfusion Module
L/min	Liters per minute
mL/min	Milliliters per minute
mmHg	Millimeters of mercury
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. During transport, raise the two-position handle to push the system. With the Mobile Base removed, you can set the system flat or carry it with the lift handles.
Organ Care System	The Organ Care System (OCS™) houses the permanent infusion and circulatory pumps, the batteries, a data card, the gas delivery subsystem, the reusable flow probes and SvO_2/HCT probe, and the removable Wireless Monitor. During preservation, it houses the single-use Liver Perfusion Module.
PGI2	Epoprostenol Sodium (Flolan or equivalent)
PV	Portal Vein
PVF	Portal Vein Flow
PVP	Portal Vein Pressure. Displayed on the Wireless Monitor in millimeters of mercury (mmHg).
Power-cycle	To *Power-cycle* the system, use the On/Off switch on the side of the Liver Console to turn the system OFF, wait 10 seconds, and then turn it ON.
pRBC	A unit of packed Red Blood Cells (RBCs).
Priming Solution	The perfusate that is initially circulated through the Liver Perfusion Module circuit prior to organ connection and during organ preservation.

Term	Meaning
Pump Compliance Chamber	Located between the circulatory pump and the perfusate warmer, the red-colored pump flow compliance chamber smooths out the pulsatile flow from the pump.
Run Mode	Power mode where the system is on, the Wireless Monitor is active, and the pump can operate.
SDS	Solution Delivery Subsystem
Session	A session is created in internal system memory when the system is set to Run Mode. Every time Run Mode is entered, you can choose whether to continue using the last session file or create a new one. In ordinary circumstances, data from all procedures associated with an organ should be documented in only one session. The system logs all system error events, all alarm events, trend data for each parameter at 2-minute intervals, and all system operating events that occur in each session.
Standby-cycle	To *Standby-cycle* the system, press the Standby button to switch from Run Mode to Standby Mode and then back to Run Mode. The system will automatically run the Self Test.
Standby Mode	A power mode where the system is on but the Wireless Monitor is off and no perfusion may be performed. Standby Mode is the mode used during OCS™ storage; organs cannot be preserved in this mode. The OCS™ must be plugged in to AC power to avoid battery depletion when storing the OCS™ in this mode.
SvO_2	Mixed venous hemoglobin oxygen saturation percentage.
SvO_2/HCT Probe	A Liver Console probe that you attach to the Liver Perfusion Module. It is used to measure the venous oxygen saturation and hematocrit in the perfusate leaving the liver.
Temp	Temperature, displayed on the Wireless Monitor in degrees Celsius (°C).
TPN	Total Parenteral Nutrition solution
Trend	A trend contains the most recent 24 hours of data, updated every 2 minutes. Each data point represents the average value calculated over the previous two minutes. You can configure trend data to display on the middle and bottom frames on the Wireless Monitor.
Waveform	Real-time waveforms display continuously updated data. The waveforms are drawn from left to right with the most current data. An Erase Bar overwrites the oldest data first. If more than one graphic frame is configured to show real-time waveforms, the Erase Bars are automatically synchronized. Use the Configuration Menu to configure which waveforms are displayed in the middle and bottom frames on the Wireless Monitor.
Wireless Monitor	A small, dockable monitoring system with an LCD screen and controls for configuring system functions and screen displays, and for adjusting system settings during preservation. When removed from its docking station on the Liver Console, the Wireless Monitor operates wirelessly, powered by its own battery.

1. CHAPTER 1: READ THIS FIRST

This chapter contains important information about the documentation for your TransMedics® OCS™ Liver System and about contacting TransMedics.

1.1. Directions to User

This manual provides detailed instructions regarding the clinical use of the OCS™ Liver System, as well as an overview of the system, 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 new system before a qualified health care professional can use it.

1.2. User Training Requirements

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

Completion of the TransMedics training program is required prior to use of the OCS™ Liver System. The training consists of initial hands-on training and periodic refresher training as needed.

1.3. Indications for Use

The indications for use are as follows:

> *The TransMedics® Organ Care System (OCS™) Liver is a portable extracorporeal liver perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of liver allografts from donors after brain death (DBD) or liver allografts from donors after circulatory death (DCD) ≤55 years old in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.*

1.4. Contraindications

The OCS™ Liver System should not be used for:

- Livers with moderate or severe traumatic injury
- Livers with active bleeding (e.g., hematomas)
- Split livers.

1.5. Precautions

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

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

1.6. Patient Counseling

Patients should be provided with the OCS™ Liver Patient Brochure that describes the device, the benefits and risks, and provides an overall summary of the clinical experience with the OCS™ Liver System.

1.7. Conventions

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

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

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

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

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

1.8. Supplies

The components, accessories, and supplies required when using the OCS™ Liver System must be used in accordance with this user manual, associated documents, and accepted medical standards. To order additional parts and supplies, see Chapter 14.

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

1.9. Contacting TransMedics

1—For Customer Clinical Support:

Please contact TransMedics prior to departure to Donor Site on one of the following numbers:

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

2—For Customer Service:

Please contact TransMedics 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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The Netherlands
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2. CHAPTER 2: SAFETY INFORMATION

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

2.1. General Warnings

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 Liver Perfusion Set and the OCS Liver Bile Salts 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 liver transplants. User exposure to donor blood from leakage at connection sites during the blood collection process may occur. Follow Universal Precautions.

2.2. 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 risk of electric shock, this equipment must only be connected to a mains supply 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.

CAUTIONS—

Use the system only at the temperatures, relative humidities, and altitudes specified in Chapter 13, "System Specifications" 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.

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.

2.3. Mechanical and System Safety

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

WARNINGS—

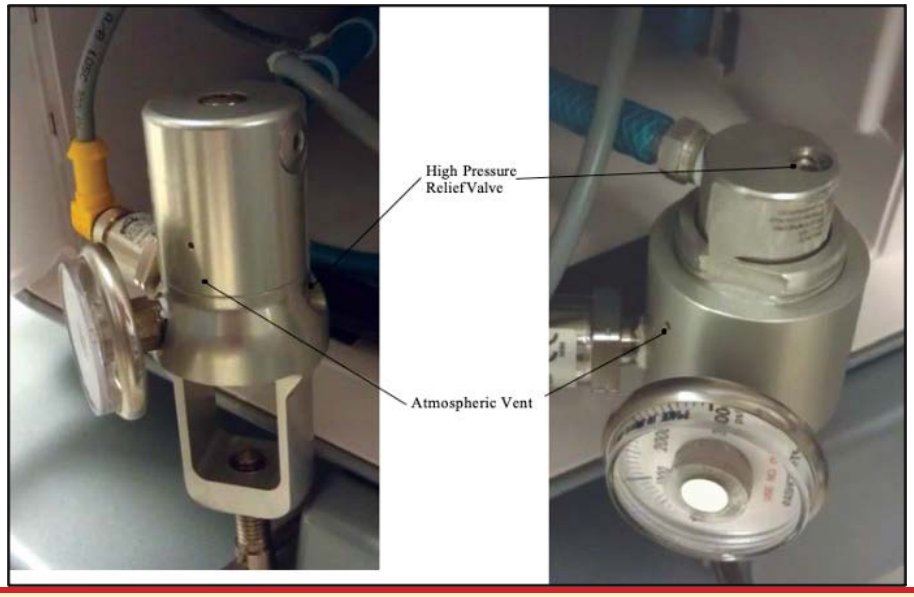
Do not use the system and accessories in the presence of explosive anesthetics.

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. Do not use components that indicate damage.

Keep the Liver Console surfaces and cables clean, cleaning all surfaces and cables before and after each use. Dispose of the LvPM, then clean and disinfect any bodily fluid or blood-contaminated areas of non-sterile parts of the system according to the instructions in Chapter 11. 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 LvPM 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 LvPM 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 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 LvPM 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.)

2.4. Patient and Organ Safety

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

WARNINGS—

The OCS™ Liver Bile Salts Set is intended for use only with the OCS™ Liver System for liver transplantation. It should not be administered in any way directly to a patient.

The OCS™ Liver System is intended for preservation of an explanted liver. It is not intended for direct contact with any patient.

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

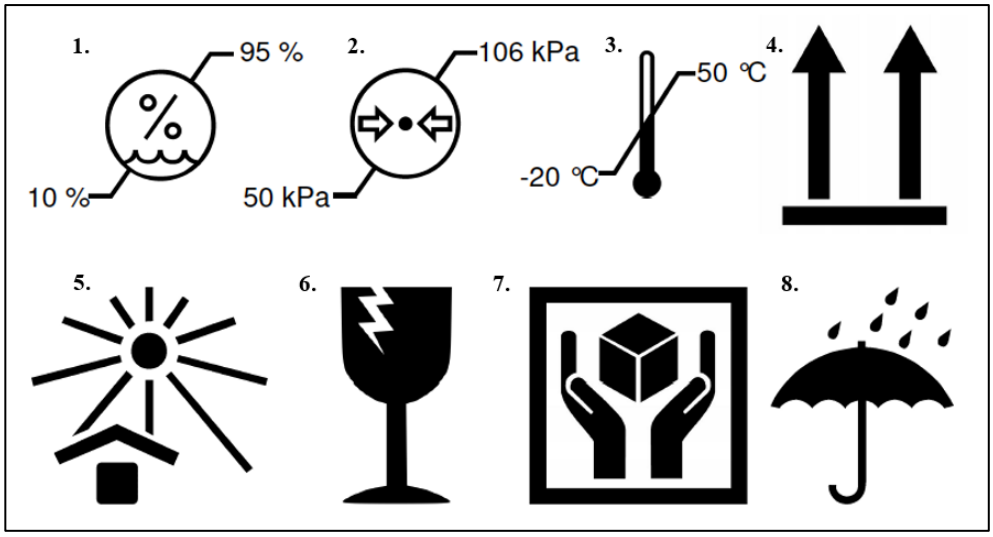
- Touching the organ
- Opening the organ chamber
- Opening the sterile drape
- Accessing the docked Wireless Monitor's controls through the clear film of the TransMedics sterile drape
- Preparing and connecting solutions for use in the circuit
- Adding pRBCs to the reservoir
- Making injections into the circuit
- Sampling fluids from the circuit.

All parts of the LvPM and its sterile accessories are intended for single-use only. Do not attempt to resterilize or reuse the LvPM or any of the sterile accessories. Reuse or resterilization may compromise the structural integrity of the sterile components, thus creating a potential risk to patient safety.

CAUTIONS— TransMedics-approved solutions have been tested on the OCS™ Liver System. Non-TransMedics approved solutions have not been tested, and TransMedics cannot assure their compatibility. If non-TransMedics approved solutions are used with the OCS™ Liver 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.

2.5. 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: SYSTEM OVERVIEW

This chapter provides an overview of the OCS™ Liver System.

3.1. OCS™ Liver System Components

The OCS™ Liver System consists of the following major components:

1. **OCS™ Liver 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™ Liver Perfusion Set:** The Liver Perfusion Set includes the Liver Perfusion Module (LvPM) and LvPS Accessories. The LvPM is a sterile, single use perfusion module that has embedded sensors, perfusion and circuits, and perfusate sampling ports. The LvPS Accessories are sterile, disposable accessories necessary to instrument the liver and manage the perfusate.
3. **OCS™ Liver Bile Salts Set:** The OCS Liver Bile Salts are composed of Sodium Taurocholate, which is infused to the circulating perfusate to replenish bile salt levels during perfusion on the OCS Liver System.

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.

3.1.1. Items Included with the Liver Console

Each Liver Console is shipped with the following components:

- OCS™ Mobile Base
- OCS™ Wireless Monitor
- OCS™ Data Cards
- OCS™ Flow Probes (HA, PV)
- OCS™ SvO_2/HCT Probe
- OCS™ Gas Cylinders
- Rechargeable OCS™ batteries (3)
- Power Cords (country-specific).

3.1.2. Items Included with the Liver Perfusion Set

Each Liver Perfusion Set is shipped with the necessary sterile components required during a liver preservation session. Each Liver Perfusion Set includes the following components:

- OCS™ LvPM
- OCS™ Liver Perfusion Initiation Set

- OCS™ Liver Instrumentation Tool Set
- OCS™ Liver Solution Infusion Set
- OCS™ Liver Perfusion Termination Set.

3.1.3. Additional Items Needed

In addition to the materials supplied by TransMedics, some additional standard hospital equipment may be needed. The following lists items that should be available. However, this list is not all-inclusive; other items may be necessary:

- IV poles for transferring blood and priming solution
- Additional sterile drapes if required
- Specific additives for the perfusate
- Syringes, needles, and other miscellaneous equipment.

3.2. Liver Console Components

Figure 3 below shows the Liver Console and identifies the components with the top cover on and the front panel in the up position. For detailed instructions on setting up and using the Liver Console, see the chapters that follow throughout this manual.

Figure 3: Liver Console (with Covers)

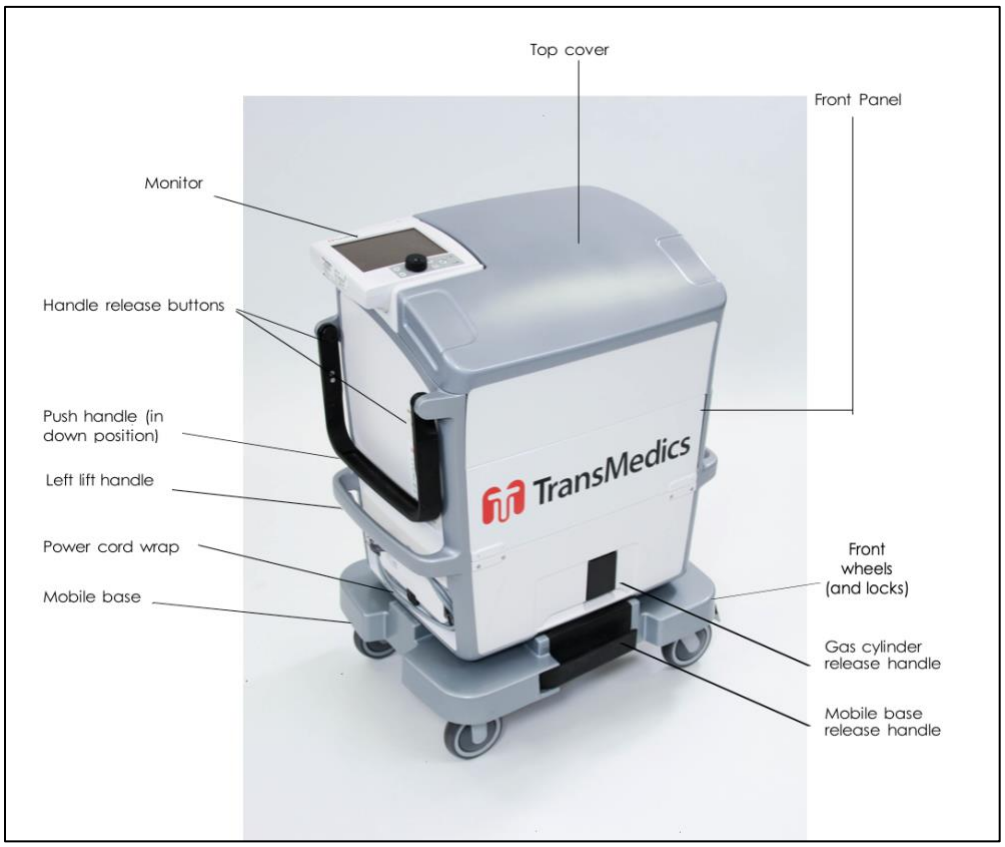
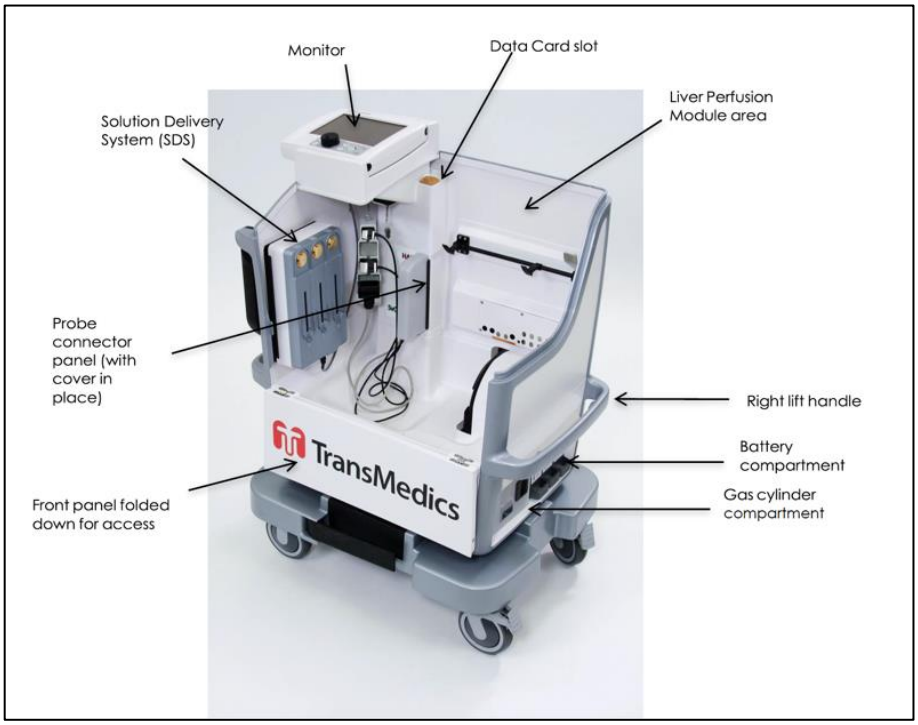


Figure 4 below shows the Liver Console with the covers removed.

Figure 4: Liver Console (with Covers Removed)



3.2.1. Wireless Monitor

The Wireless Monitor tracks the vital functions of an organ perfused with the OCS™ and displays organ- and system-functional parameters. The Wireless Monitor can be used while it is docked on the Liver Console, or it can be removed (undocked) and used remotely, such as when transporting the organ.

The Wireless Monitor's screen displays various system and organ parameters as well as messages to visually and audibly indicate out-of-range alarms and system fault conditions.

NOTE—Only Wireless Monitors for the OCS™ Liver System can be used with the OCS™ Liver System.

3.2.1.1. Wireless Monitor Features

The Wireless Monitor's screen (Figure 5) displays various system and organ parameters as well as messages to visually and audibly indicate out-of-range alarms and system fault conditions.

Figure 5: Wireless Monitor Components

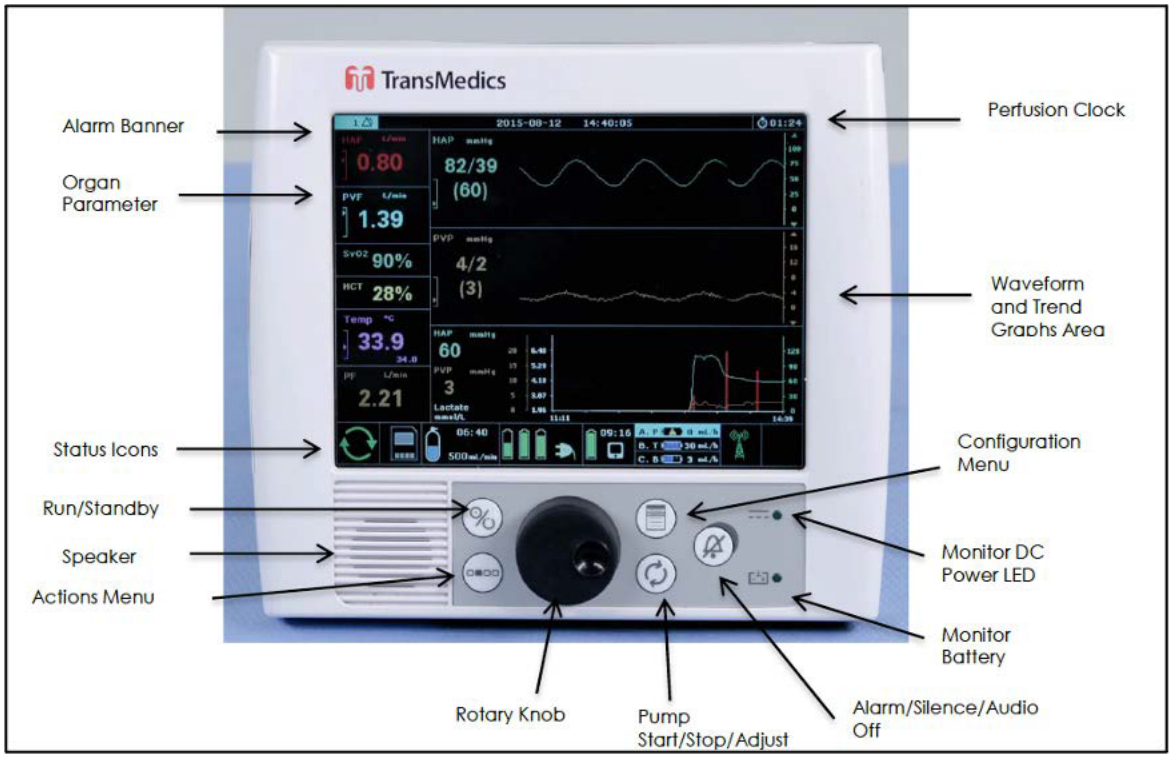


Table 1 below lists and describes the Wireless Monitor components.

Table 1: Wireless Monitor Components

Wireless Monitor Component	Description	For more information, see:
Alarm Banner	The Alarm Banner displays at the top of the Wireless Monitor screen to let you quickly determine when physiological parameters are extended above or below their limits, when gas or battery capacity is running low, and when there is an issue with the system.	Section 3.2.1.3.1, "Alarm Banner"
Organ Parameter Frames	Parameter values are displayed on the left of the screen in real time. Each organ parameter frame includes the name, units of measurement, the value, and whether the alarm is disabled.	Section 3.2.1.3.2, "Organ Parameter Frames"
Status Icons	The status icons that appear along the bottom row of the Wireless Monitor screen help you quickly determine information about the system and preservation session.	Section 3.2.1.3.4, "System Status Icons on the Wireless Monitor"
Speaker	The speaker sounds audible alerts when parameters go out-of-range, when system faults are detected, or when you press a key that is currently unavailable.	
Perfusion Clock	The  icon is displayed in the upper right corner of the Wireless Monitor, along with the elapsed perfusion time.	Section 10.11, "Starting and Resetting the Perfusion Clock"
Graphical Frames (Waveforms and Trends)	The graphical frames area in the center of the screen can be configured to show waveforms and trend data.	Section 10.9, "Managing Real-Time Waveforms"

Wireless Monitor Component	Description	For more information, see:
Wireless Monitor Power and Battery Indicators	At the bottom right of the Wireless Monitor, two LED lights provide information about Wireless Monitor power status.	Section 9.2.1, "Checking Wireless Monitor Power"
Wireless Monitor Controls	Use the rotary knob and push button controls to set the system to Run or Standby Mode, to silence alarms, to display and navigate the Action and Configuration menus, to control the pump and to display menus for configuring the system and performing tasks.	Section 3.2.1.2, "Wireless Monitor Controls"

3.2.1.2. Wireless Monitor Controls

Use the rotary knob and push buttons (Figure 6) on the Wireless Monitor to control the OCS™. Except for the Run/Standby button, these controls are functional when the Wireless Monitor is both docked and undocked. Table 2 below lists and describes the controls.

Figure 6: Wireless Monitor Controls

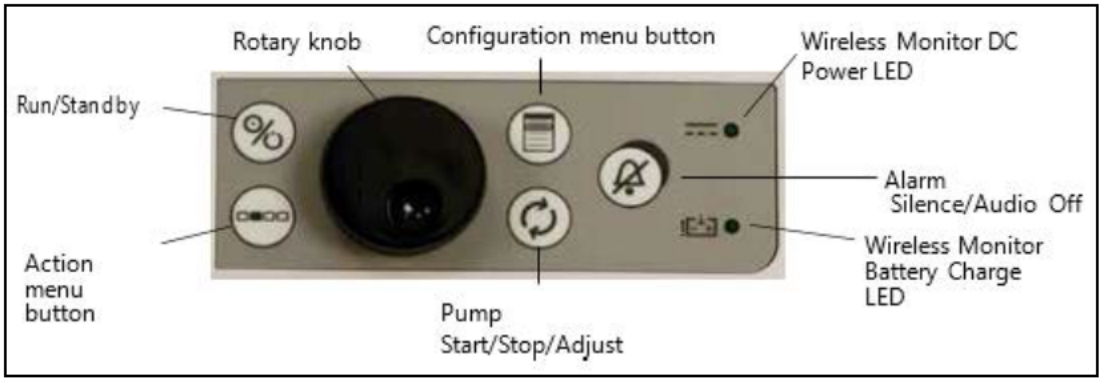


Table 2: Wireless Monitor Controls

Control	Name	Description
	Run/Standby Button	Press this button to transition between Run Mode and Standby Mode. Note: This button can only be used when the Wireless Monitor is docked on the Liver Console. If the Wireless Monitor is not docked, pressing this button has no effect.
	Action	Press this button to display the Action menu in the lower part of the Wireless Monitor to perform tasks such as displaying system status, copying session files, changing waveform scaling, and so on. For a list of Action menu functions, see Table 20, “Action Menu Functions.”
	Configuration	Press this button to display and close the Configuration 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 enable and disable the pump adjust function.
	Rotary knob	Turn this knob to highlight selections and press the knob to select highlighted items. Use this knob to adjust pump flow.

3.2.1.3. Wireless Monitor Display Overview

This section provides general information about the components on the Wireless Monitor display.

CAUTION—The user should remain in close proximity to the OCS™ while in use such that they can read the Wireless Monitor display at all times, or undock the Wireless Monitor such that they can view it at all times.

3.2.1.3.1. Alarm Banner

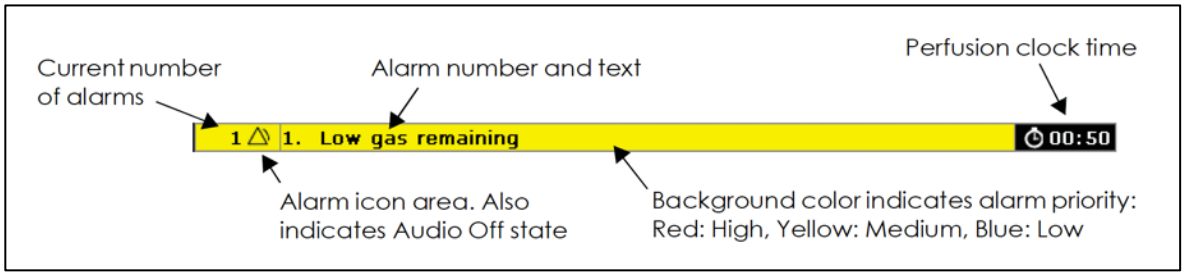
The system produces both visual and audible indicators of various alarm conditions to alert you when there is an important physiological or system condition that requires attention. The Alarm Banner (Figure 7) is displayed at the top of the Wireless Monitor screen. The background color on the left side of the Alarm Banner is that of the highest priority alarm in the banner.

The Alarm Banner displays the following types of alarms:

- Physiological alarm: Indicates that a measured physiological parameter is extended above or below its alarm limits
- Capacity alarm: Indicates a low battery capacity, a low gas cylinder capacity, or a low solution volume
- System Fault alarm: Indicates an equipment failure.

For more information, see Section 10.8, “Managing Alarms.”

Figure 7: Alarm Banner



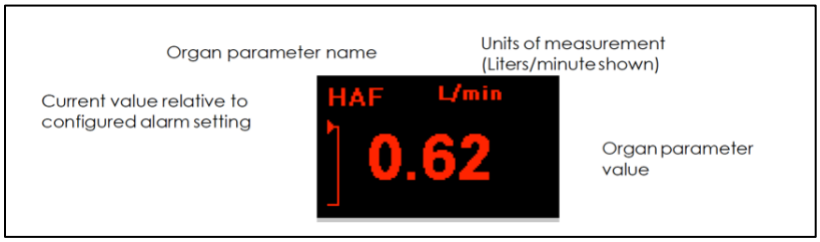
3.2.1.3.2. Organ Parameter Frames

Organ parameter values are displayed in the frames on the Wireless Monitor. Organ parameter values include:

- HAF: Hepatic Artery Flow in liters/minute
- PVF: Portal Vein Flow in liters/minute
- PF: Pump Flow (the sum of HAF and PVF)
- SvO_2: the mixed venous hemoglobin saturation percentage
- HCT: the Hematocrit percentage
- TEMP: Perfusate temperature (°C)
- HAP: Mean Hepatic Artery Pressure, in millimeters of mercury (mmHg)
- PVP: Mean Portal Vein Pressure, in millimeters of mercury (mmHg).

Figure 8 below shows the components that are displayed in the organ parameter frame.

Figure 8: Organ Parameter Frame Components



The value of each organ parameter is also displayed with an arrow (to the left of the value) to indicate its location relative to the upper and lower alarm limits, or relative to the total parameter range if there is no upper or lower limit.

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

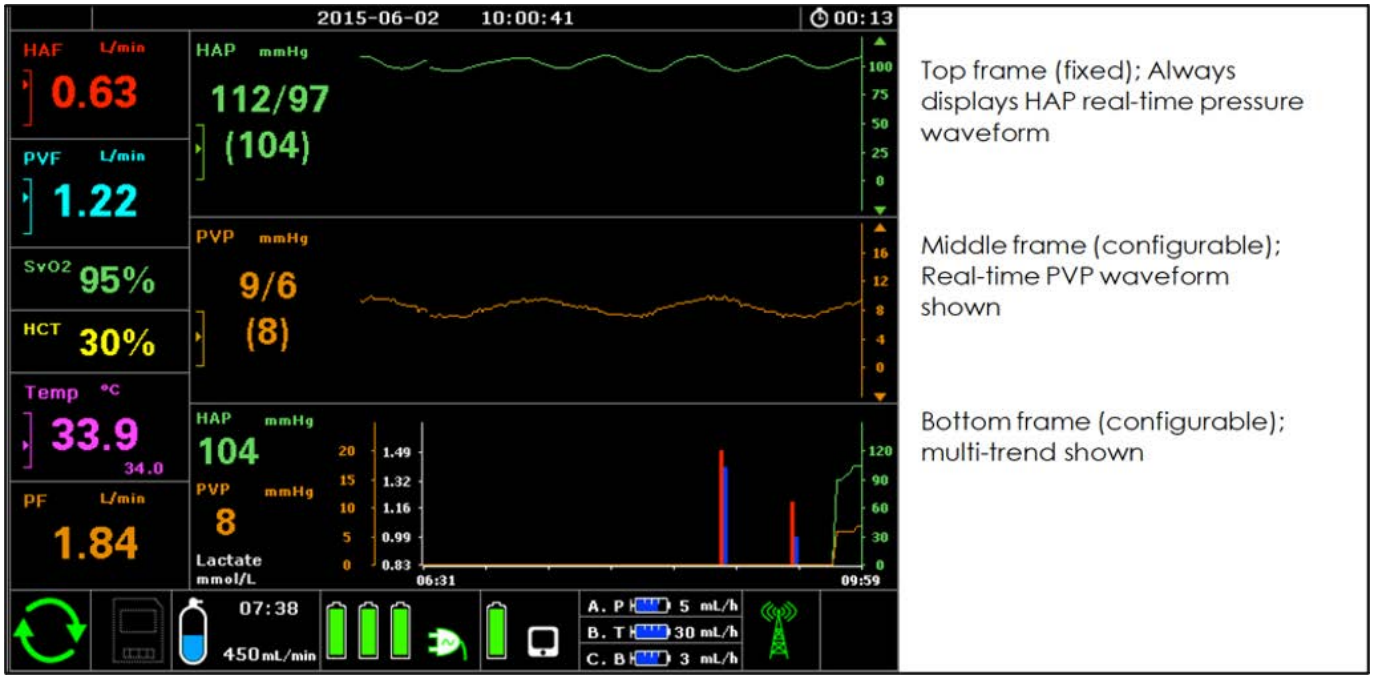
- – – – (three dashes) indicate the current value is below the minimum of the measurable range (under-range)
- + + + (three plus signs) indicate the value is above the maximum value of the measurable range (over-range)
- – ? – (dash-question mark-dash) indicates the data are not available.

For instructions on setting organ parameter values, see Section 10.5, “Configuring Session Settings.”

3.2.1.3.3. Graphical Frames

The main center section of the Wireless Monitor (Figure 9) displays up to three graphical frames to help you quickly determine parameter information and to view trend data.

Figure 9: Graphical Frames

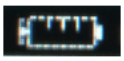


You can configure the middle and bottom graphical frames to display either real-time pressure waveforms or trend data. Each time you change modes during the session, the graphical frames that you configure for that mode are automatically displayed on the Wireless Monitor. For detailed instructions, see Section 10.5, "Configuring Session Settings."

3.2.1.3.4. System Status Icons on the Wireless Monitor

The status icons that appear on the Wireless Monitor help you quickly determine information about the system and preservation session. Table 3 below describes the system status icons that appear on the Wireless Monitor.

Table 3: System Status Icons

Icons	Description
Pump Status	
	Pump On
	Pump Off
	Pump Fault Alarm
Gas Cylinder Status	
	Gas On: Bottle icon shows relative amount of gas remaining in hours and minutes (hh:mm) and the current flow rate in milliliters/minute.
	Gas Off
	Gas Capacity Alarm: Activates with 60 minutes of estimated remaining gas consumption time and displays estimated gas remaining time as gas depletes.
	Gas Fault Alarm
SDS Icons	
	No cassette is inserted.
	Cassette is inserted and that the channel is in Manual Mode.
	Cassette is inserted but the channel is not infusing.
	Channel requires attention. Background color identifies priority.
Battery Status	

Icons	Description
	Battery Active, indicates Wireless Monitor (single battery) or OCS™ (three batteries) and displays the time remaining for each battery.
	Battery Removed
	Battery Capacity Alarm: Activates with 30 minutes of estimated remaining battery life and displays estimated remaining time as the battery depletes.
	Battery Fault Alarm
Data Card Status	
	Data card inserted
	Data card transfer in progress
	No data card inserted
	Data card fault
Wireless Communication	
	Wireless communication between the docked or undocked Wireless Monitor and OCS™ is functioning properly.
	Wireless Fault
Generic System Fault	
	Generic system fault. This icon appears on the lower right corner of the Wireless Monitor display. Refer to the Alarm Banner at the top of the display for further information about the issue and instructions.

3.2.2. Solution Delivery Subsystem (SDS)

The SDS is used to administer solution to the LvPM throughout organ preservation. This subsystem is comprised of the non-disposable SDS Console and one or more disposable line sets (i.e., SDS Line Sets). The SDS Console is incorporated into the Liver Console. The disposable SDS Line Sets are included in the Liver Solution Infusion Set.

WARNING—The SDS is intended only for use with the OCS™ Liver System. Do not remove the SDS from the Liver Console or open the chassis except as required for the cleaning and maintenance functions described in these instructions.

3.2.2.1. SDS Console Components

Figure 10 below shows the SDS Console, and Table 4 below describes the major components defined in that figure.

Figure 10: SDS Console

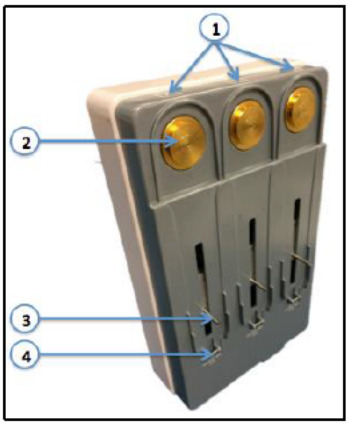


Table 4: SDS Console Component Descriptions

#	Component	Description
1	Solution Delivery Channels (A, B, C)	The SDS is equipped with 3 separate delivery channels. Each channel is labeled (A, B, C) on the top of the SDS Console
2	Pressure Sensor	The pressure sensor detects occlusions and serves as a mounting point for the SDS Cassette.
3	Drive Pin	The drive pin couples the SDS Console to the SDS Cassette. During operation the drive pin moves up and down to inject solution.
4	Mounting Bar	This bar is used to secure the SDS Cassette to the SDS Console.

3.2.2.2. SDS Line Set Components

Figure 11 below shows the SDS Line Set, and Table 5 below describes the major components defined in that figure. The SDS Line Set is a sterilized, single-use disposable for use only with the SDS Console. The SDS Line Set is included in the Liver Solution Infusion Set.

Figure 11: SDS Line Set

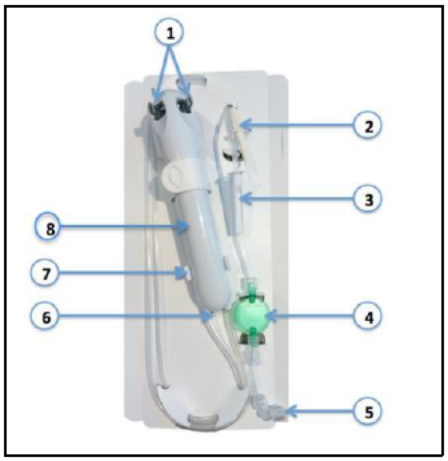


Table 5: SDS Line Set Component Descriptions

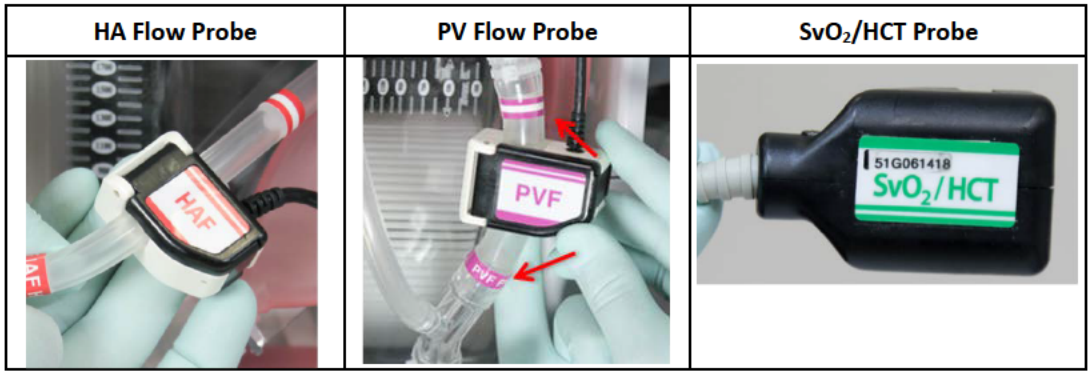
#	Component	Description
1	Attachment Fingers	The attachment fingers are used to insert and remove the SDS Cassette from the SDS console.
2	Bag Spike	Used to spike an IV bag or vial.
3	Roller Clamp	Used to restrict the flow into the LvPM
4	Filter	A combination particulate and air filter.
5	Output Luer Connection	The output connection that interfaces to the LvPM.
6	Mounting Tab	The Mounting Tab is inserted under the Mounting Bar on the SDS Console to securely hold the SDS cassette in place
7	Shipping Lock	Maintains the Cassette in its factory position, ready to interface with the SDS Console drive pin.
8	SDS Cassette	Contains a syringe and valves

3.2.3. Probes

The Liver Console contains 3 probes: Hepatic Artery (HA) Flow Probe, Portal Vein (PV) Flow Probe, and SvO_2/HCT Probe (Figure 12).

The probes are reusable and do not require sterilization since they touch only the exterior of the tubing and never contact the perfusate flowing through the circuit. Each probe is sized and color labeled to match the tubing to which it connects. When not in use on a LvPM, probes are cleaned and stored inside the Liver Console.

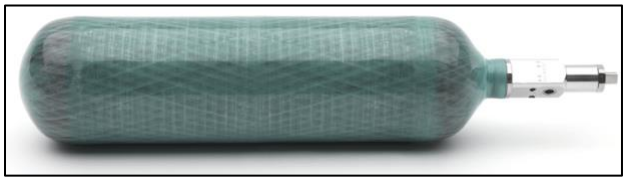
Figure 12: Liver Console Probes



3.2.4. Gas Cylinder

The Liver Gas cylinder (Figure 13) holds approximately 400 L at 3000 psi (21000 kPa), which is enough gas to last approximately 14 hours under ordinary operating conditions. For more details, refer to Section 9.5.1, "Estimating the Remaining Gas Supply." The gas cylinder compartment is located on the right side of the Liver Console behind a clear plastic access door, directly above the Mobile Base's front wheels when the Mobile Base is installed.

Figure 13: Liver Gas Cylinder



For safety information on handling gas cylinders, see Section 1.1, “Handling Pressurized Gas Cylinders.”

For more information on installing and removing gas cylinders, see Section 9.5, “Using the Gas Cylinders.” For details on oxygen monitoring and system response to low gas supply, see Section 3.2.1.3.4, “System Status Icons on the Wireless Monitor.”

3.2.5. System and Wireless Monitor Batteries

One lithium-ion battery is incorporated into the Wireless Monitor and three lithium-ion batteries are installed in the Liver Console. At the end of service life, the battery in the Wireless Monitor is NOT user-replaceable, but you can replace the OCS™ batteries as needed. When transporting the system, be sure to have sufficient quantities of charged batteries to allow for the time you expect the system to be dependent on battery power.

The Wireless Monitor’s lithium-ion battery supplies power to the Wireless Monitor when it is undocked from the Liver 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 Liver Console to restore its operation.

Figure 14: OCS™ Batteries

The OCS™ batteries (Figure 14) are installed in the battery compartment on the right side of the Liver Console, next to the gas cylinder compartment, as shown in Figure 4. When the OCS™ is connected to AC power, the batteries automatically charge.

Under normal operating conditions, each OCS™ battery has sufficient charge to last a little more than one hour, for a minimum of four hours of total power without replacing or recharging the batteries. A fully charged undocked Wireless Monitor battery lasts at least six hours. When the system is connected to AC power and the Wireless Monitor is docked on the system, the Wireless Monitor’s battery and the OCS™ batteries are automatically recharged as needed.

NOTES—

When the OCS™ is in Standby mode and not connected to AC power, the batteries will deplete. TransMedics recommends connecting the OCS™ to AC power whenever possible.

When the OCS™ is connected to AC power and not operational, it can take up to 12 hours to fully recharge all three discharged OCS™ batteries and the Wireless Monitor's battery.

CAUTION—Environmental conditions impact the amount of power actually used by the system. System operation at colder temperatures will cause higher power usage and faster battery depletion. When the system is in operation, you can extend the battery life by placing the OCS™ top cover over the perfusion module whenever practical.

For details on low battery power indicators, see Section 10.8, "Managing Alarms."

3.3. Liver Perfusion Set Components

Each Liver Perfusion Set includes the following components:

- OCS™ LvPM
- OCS™ Liver Perfusion Initiation Set
- OCS™ Liver Instrumentation Tool Set
- OCS™ Liver Solution Infusion Set
- OCS™ Liver Perfusion Termination Set.

3.3.1. Liver Perfusion Module (LvPM)

The LvPM provides the sterile perfusate circuit and a protected environment for the liver within the OCS™. It is designed as a single-use module that mounts into the Liver Console.

The LvPM includes:

- Clamshell-type, liver-specific polycarbonate chamber
- Perfusate sampling ports
- Integrated circulatory (pulsatile) pump head interface
- Integrated perfusate warmer
- Integrated perfusate oxygenator (i.e., gas exchanger)
- Integrated sensors (pressure and temperature) and circuitry to communicate with the Liver Console.

The three figures below show the front and back view of the LvPM and its components, as well as the area where it is mounted onto the Liver Console.

Figure 15: LvPM - Front View

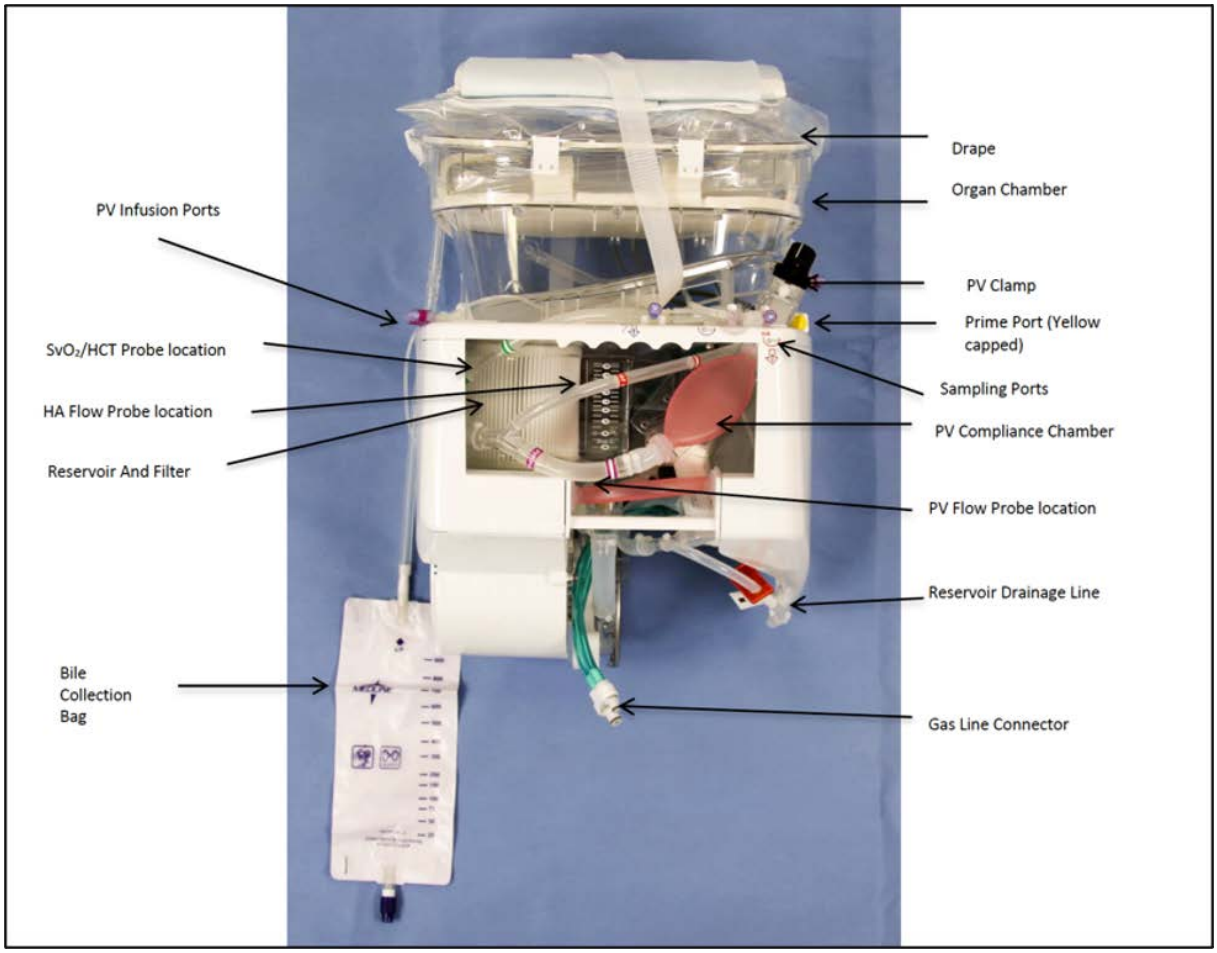


Figure 16: LvPM - Back View

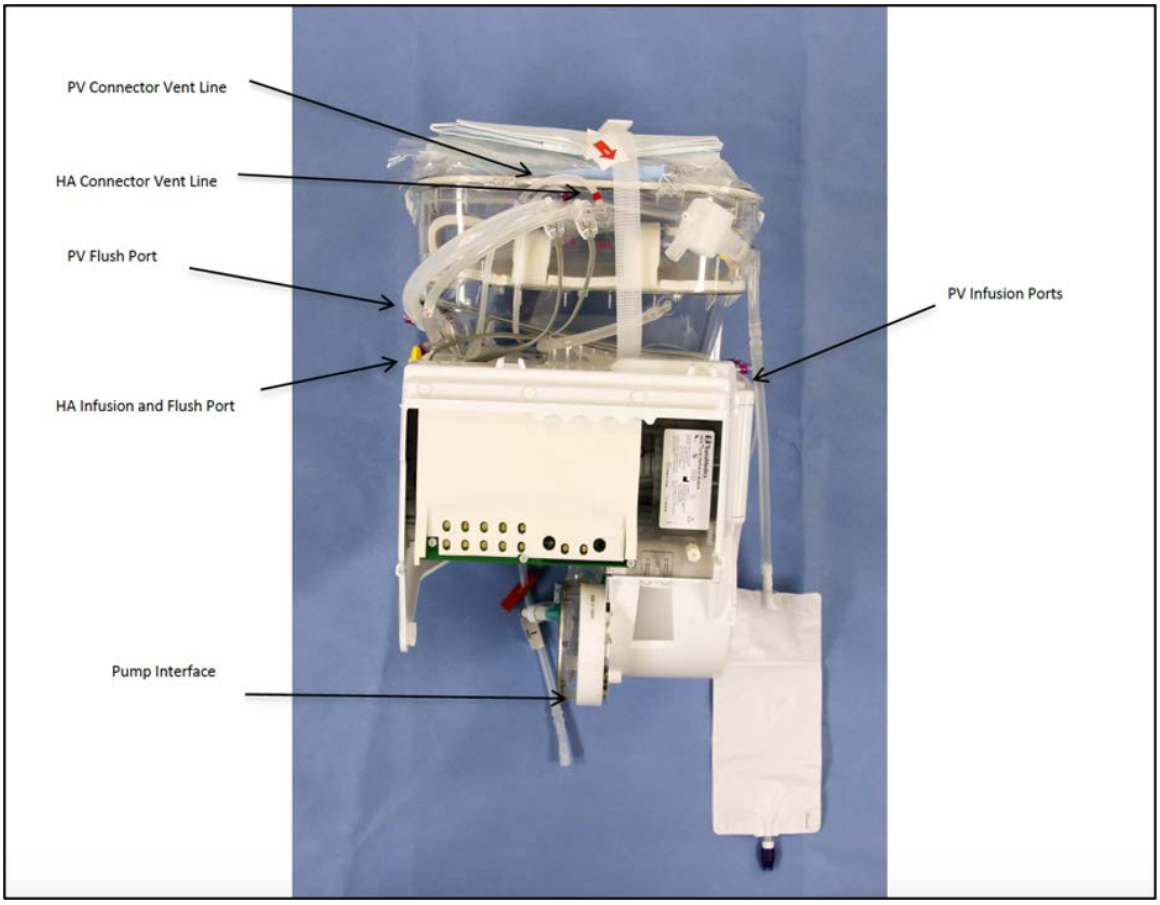
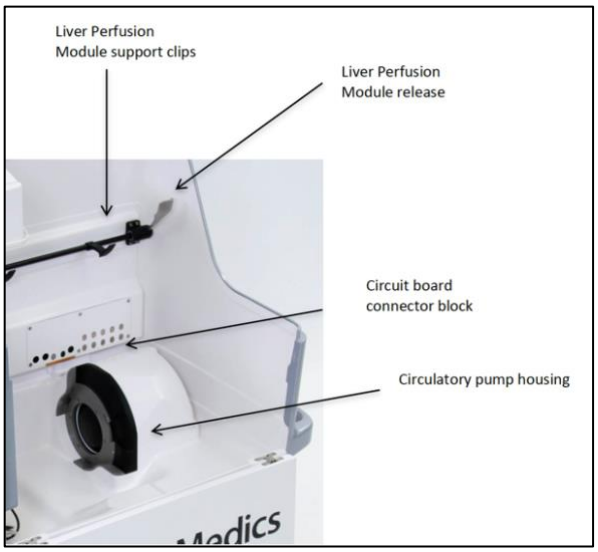


Figure 17: Liver Console with LvPM Area Detail



3.3.2. Liver Perfusion Initiation Set

The Liver Perfusion Initiation Set (Figure 18) is used at the beginning of the perfusion procedure to introduce the user-provided multiple-electrolytes solution (PlasmaLyte® or equivalent), Albumin, and pRBCs to the reservoir and to flush the liver prior to preservation. Table 6 below lists and describes the components shown in this figure.

Figure 18: Liver Perfusion Initiation Set

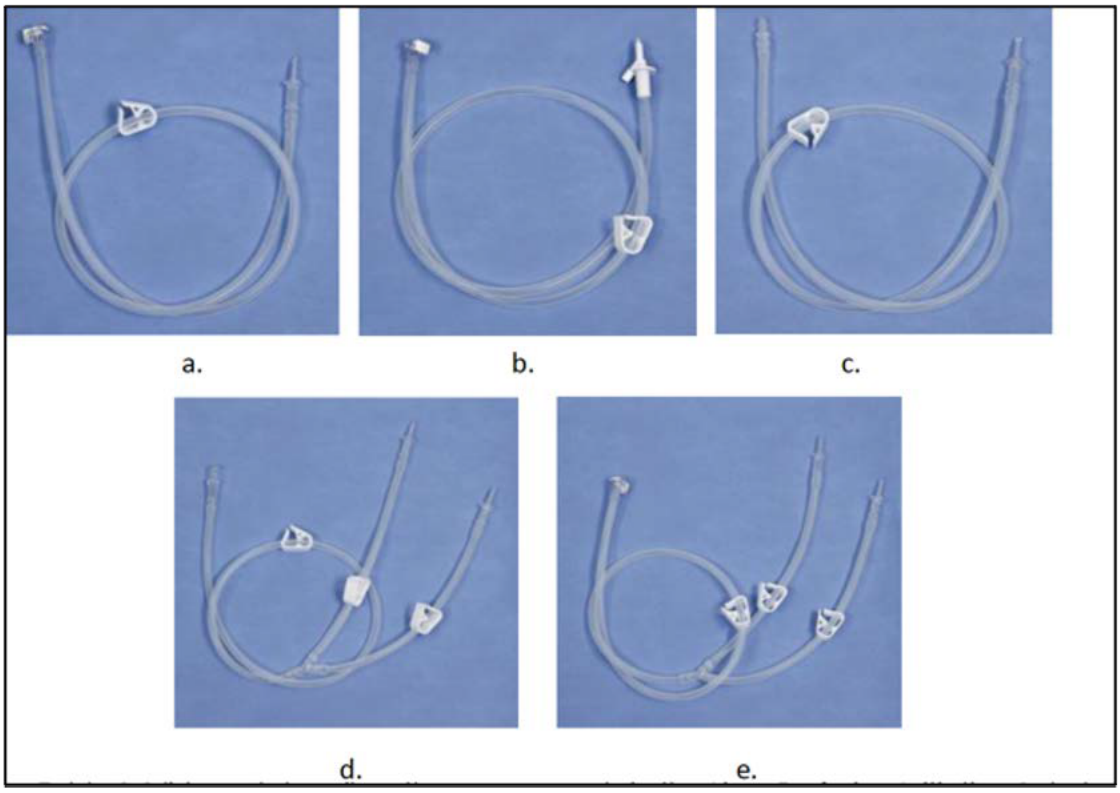


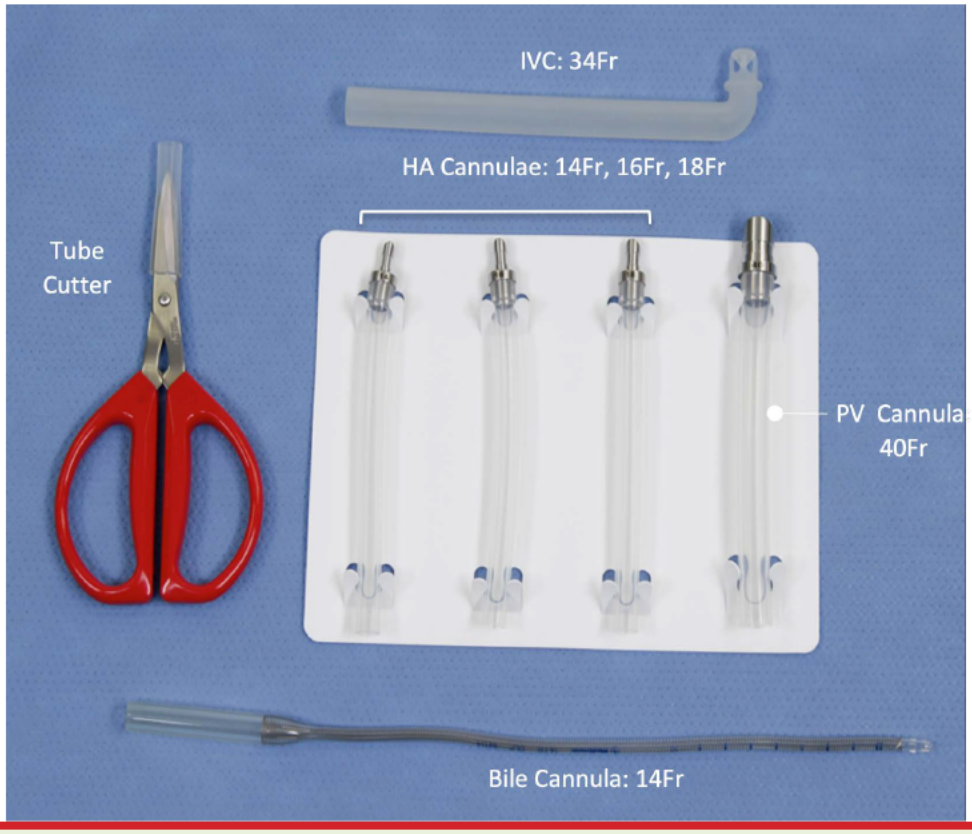
Table 6: Liver Perfusion Initiation Set Components

#	Item	Description
a.	Quick Prime Line	For introducing priming fluid to the reservoir; one end has a quick connect to the Prime line of the LvPM and the other has a spike to connect to a solution bag.
b.	Albumin Prime line	For introducing the Albumin to the reservoir; one end has a quick connect to the Prime line of the LvPM and the other has a vented spike to connect to the Albumin bottle.
c.	HA Initial Flush Line	For introducing flush to the liver through the HA Cannula; one end has a spike, and the other end has a ¼" tube connector.
d.	PV Initial Flush Line	For introducing flush to the liver through the PV Cannula. A Y-shape flush line with two spikes on one end and a 3/8" tube connector on the other.
e.	Dual Blood Prime Line (2)	For introducing packed RBCs to the reservoir; One end has a quick connect to the Prime line of the LvPM and the other end has two arms, each terminated with a spike for connecting to a pRBC unit.

3.3.3. Liver Instrumentation Tool Set

The Liver Instrumentation Tool Set (Figure 19) includes sterilized accessories for instrumenting the liver to the system. Table 7 below lists and describes the components shown in this figure.

Figure 19: Liver Instrumentation Tool Set



NOTE—Although not part of the Liver Instrumentation Tool Set, TransMedics provides a separate 12Fr Bile Cannula for the user that is available upon request.

Table 7: Liver Instrumentation Tool Set Components

Item	Description
HA Cannula	For connecting the hepatic artery to the liver chamber: 14 Fr, 16 Fr, and 18 Fr sizes.
PV Cannula	A 40 Fr cannula to connect the portal vein to the liver chamber.
Bile Cannula	A 14 Fr to connect the bile duct to the liver chamber.
IVC Cannula	A 34 Fr cannula to direct drainage from the liver to the liver chamber
Tube Cutter	For sizing the HA and PV Cannulae to appropriate length

3.3.4. Liver Solution Infusion Set

The Liver Solution Infusion Set is shown in Figure 20 below. Table 8 below lists and describes the components shown in this figure.

Figure 20: Liver Solution Infusion Set

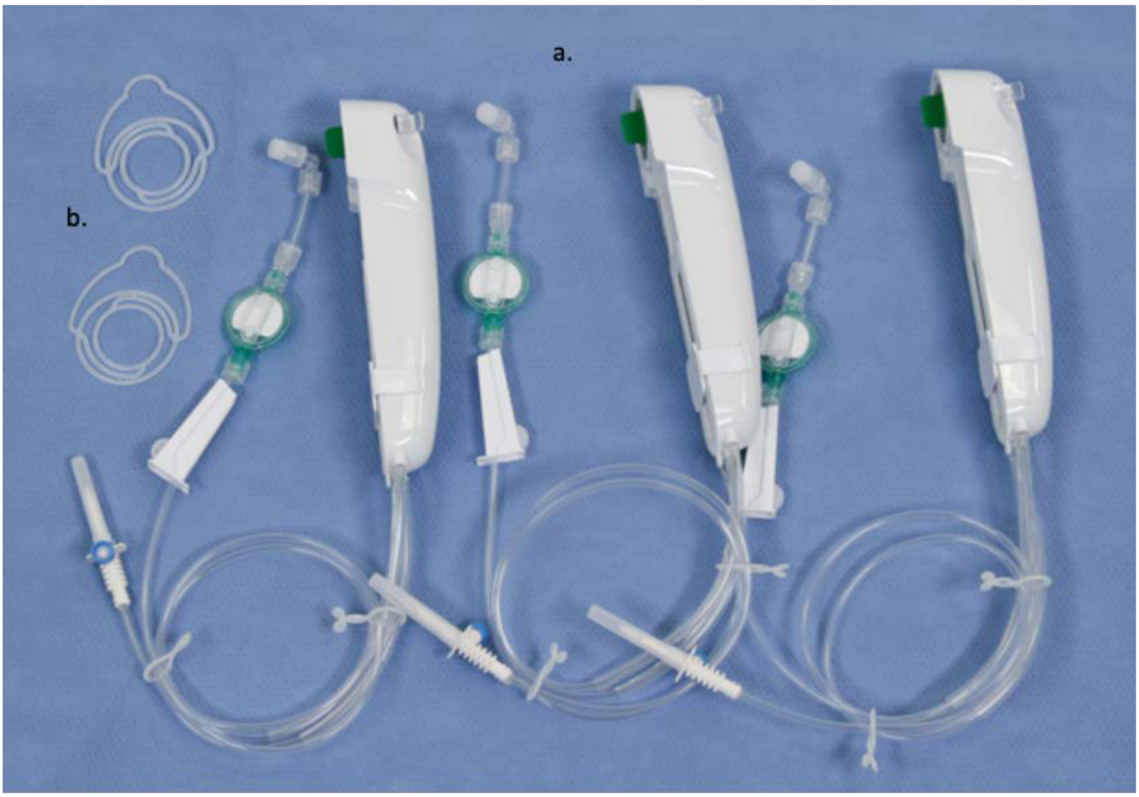


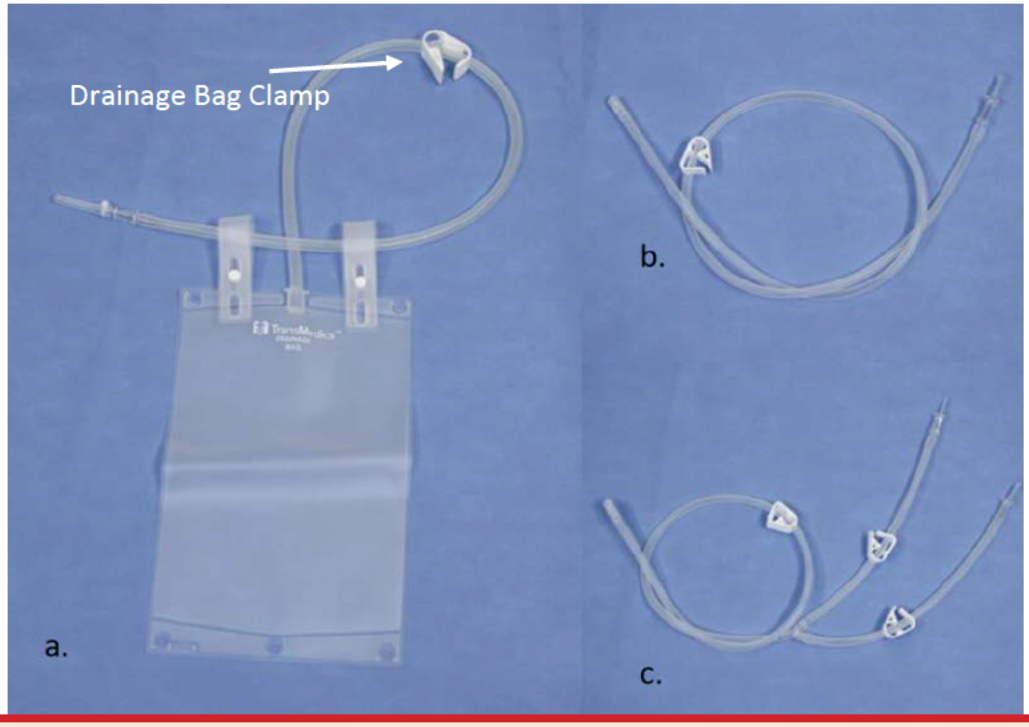
Table 8: Liver Solution Infusion Set Components

#	Item	Description
a.	SDS Line Sets (labeled as Liver Solution Delivery Cassette) (3)	For connecting the solution bags or bottles to be infused to the infusion port in the LvPM, vented spike on one end and a Luer connector on the other.
b.	Bottle Holders (2)	For hanging bottles on OCS™ Liver solution hanger.

3.3.5. Liver Perfusion Termination Set

Figure 21 below shows the Liver Perfusion Termination Set, which is used at the end of the perfusion procedure, and Table 9 below lists and describes the components shown in this figure. The set includes the final flush lines for the HA, the PV, as well as a drainage bag for removing solution from the LvPM. The user must supply a sterile drape for the termination procedure.

Figure 21: Liver Perfusion Termination Set



WARNING—The drainage bag clamp should be released before starting the flow of solution.

Table 9: Liver Perfusion Termination Set Components

#	Item	Description
a.	Liver Drainage Bag	A 4-liter bag to collect the fluids during the final flush
b.	HA Final Flush Line	For introducing flush to the liver through the HA flush port
c.	PV Final Flush Line	For introducing flush to the liver through the PV flush port

3.3.6. LvPM Ports and Stopcocks

3.3.6.1. LvPM Ports

The LvPM includes ports that may be accessed when managing the organ throughout the phases of preservation.

- An HA infusion injection port allows for injection of solutions directly to the liver via the Hepatic Artery.
- The PV infusion port allows for injection of solutions directly to the liver via the Portal Vein.
- A PV flush port allows delivery of flush solution directly to the liver via the Portal Vein.
- A HA flush port allows delivery of flush solution directly to the liver via the Hepatic Artery.
- A Priming Inlet port allows for the addition of priming solution and perfusate to the reservoir.

- Venous sample and injection port permits withdrawal of perfusate from the venous line and injection of medication to the venous line.
- Hepatic Artery vent and sample port permits withdrawal of perfusate from the arterial line.

3.3.6.2. LvPM Stopcocks

The LvPM includes 2 stopcocks:

- The Portal Vein (PV) stopcock is a 2-way stopcock used to close the PV vent line. It allows flow in one direction. It is open when the stopcock is parallel (180°) to the line and is closed when the handle is perpendicular (90°) to the line.
- The Hepatic Artery (HA) sample stopcock is a 2-way stopcock used to control the purging and sample from the HA vent. When open, it allows flow in one direction toward the reservoir. It is open when the stopcock is parallel (180°) to the line and is closed when the handle is perpendicular (90°) to the line.

All stopcocks are provided in the open position in the LvPM package and must be adjusted during use.

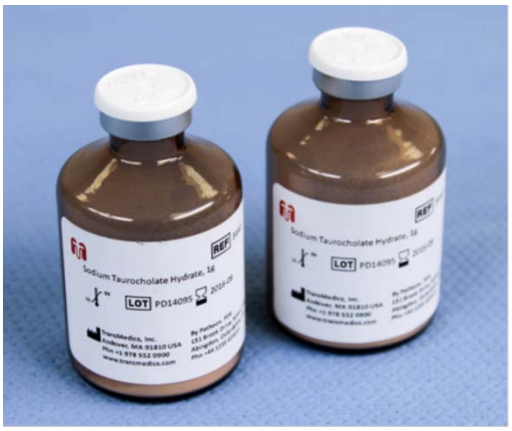
NOTE—While using LvPM ports and valves to adjust and manage the organ perfusion, pay attention to the readings from the user-installed HA and PV Flow Probes and SvO_2/HCT Probe. Adjust or reinstall probes if readings seem inaccurate.

3.4. OCS™ Liver Bile Salts Set

The OCS™ Liver Bile Salts Set (Figure 22) includes two glass vials of gamma-sterilized Sodium Taurocholate. Each vial contains one gram of Sodium Taurocholate.

At the time of use, the OCS™ Liver Bile Salts are reconstituted with Sterile Water for Injection and then delivered to the perfusate in the LvPM circuit through the Liver Solution Infusion Set and controlled by the SDS. The bile salts delivered to the LvPM are intended to replenish the bile salts consumed by the liver during preservation. The OCS™ Liver Bile Salts are not intended to be administered directly to the donor or the recipient. Prior to transplantation into the recipient, the donor liver is flushed on the OCS.

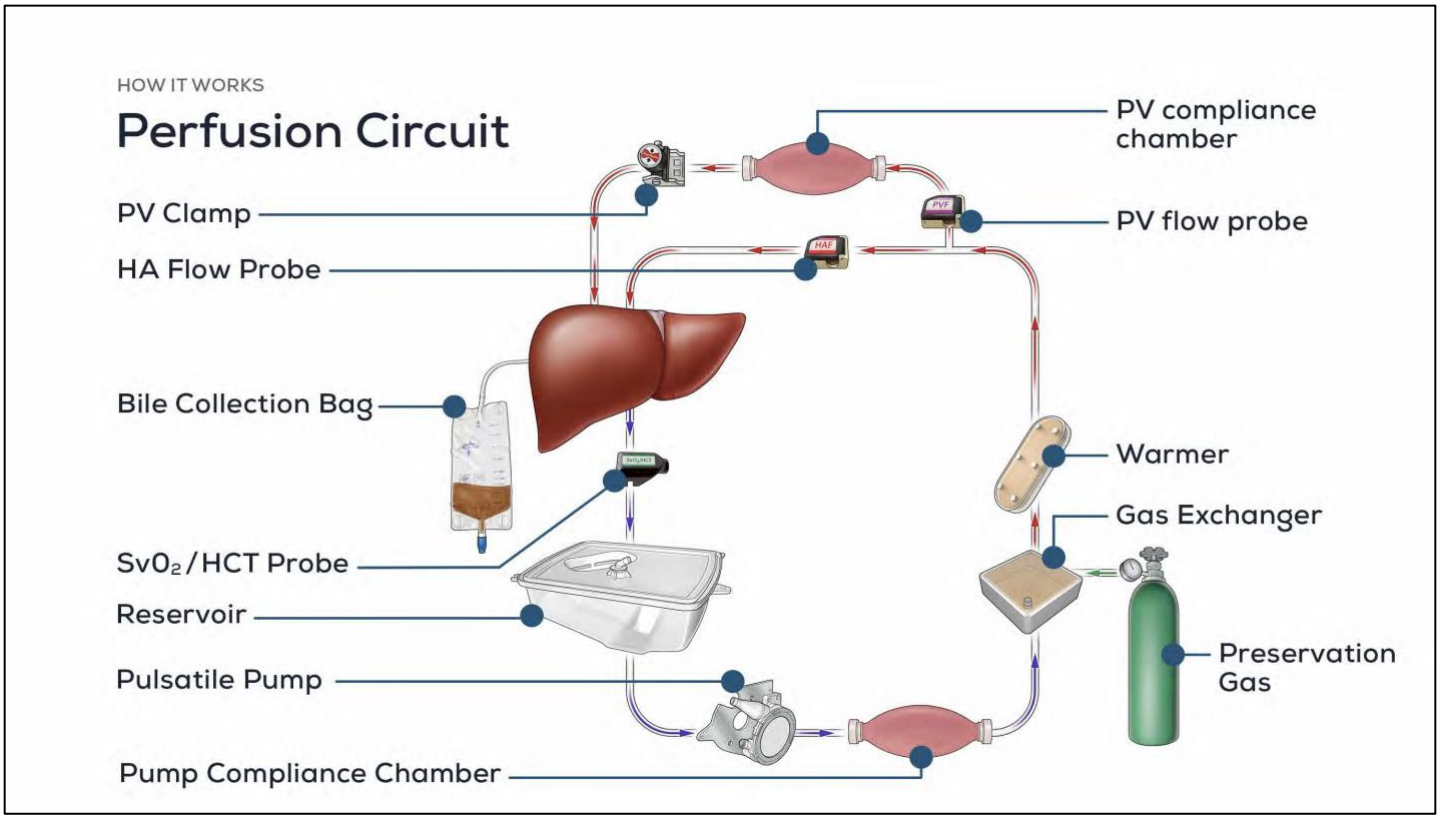
Figure 22: OCS™ Liver Bile Salts Set



3.5. Overview of Use - Perfusate Flow Path

Figure 23 below illustrates the circulation of perfusate through the LvPM circuit. The perfusate is pumped from the reservoir by the Circulatory Pump (pulsatile pump as labeled in figure below) and then directed through the oxygenator. The perfusate then passes through the warmer to reach the desired temperature. The path is then split so that the perfusate is delivered to both the Hepatic Artery (HA) and the Portal Vein (PV). The PV leg of the circuit contains the PV compliance chamber and the PV clamp. The configuration of these two legs of the circuit results in a pulsatile flow of perfusate delivered to the HA and a flow of perfusate to the PV. Deoxygenated perfusate exits the liver from the Inferior Vena Cava (IVC). The perfusate from the IVC is directed to the reservoir through the drain in the liver chamber. Additionally, the liver circuit directs bile produced by the liver through a bile cannula to a collection bag.

Figure 23: Perfusate Flow



3.6. Operational Phases

Table 10 below provide an overview of the main clinical activities associated with the preservation phases.

Table 10: Overview of Main Activities for the Preservation Phases

Preservation Operational Phase	Description of Activities	Section
Phase 1: Pre-retrieval Readiness	Complete OCS™ Liver Console Checklist Complete OCS™ Liver Perfusion Set Accessories Checklist Complete OCS™ Liver Solutions, Medications, Infusions, and pRBCs Checklist Complete OCS™ Liver Bile Salts Checklist Complete Liver Flush Solution Checklist Complete OCS™ Liver Run Bag Content Checklist Preparing the OCS™ Liver System for Transport to the Donor Site	Chapter 4
Phase 2: System Set-up	Setting up the OCS™ Liver System Setting up the Solution Delivery Subsystem (SDS) Preparing the OCS™ Liver System for Liver Instrumentation	Chapter 5
Phase 3: Retrieval and Back Table Preparation	Flushing and Harvesting the Liver Back Table Liver Preparation Instrumenting the Liver on the OCS™ Liver System	Chapter 6
Phase 4: Perfusion Initiation, Transport, and Managing Liver Preservation	Perfusion Initiation on the OCS™ Liver System Transporting the Liver on the OCS™ Liver System Managing Liver Preservation	Chapter 7
Phase 5: Preservation Conclusion and OCS Shut Down	Performing Final OCS™ Liver Sampling Performing the Final Liver Flush Removing the Liver from the OCS™ Liver System Shutting Down the OCS™ Liver System	Chapter 8

Part 1:
CLINICAL GUIDE

4. CHAPTER 4: PRE-RETRIEVAL READINESS

Adequate preparation ensures the smoothest possible organ retrieval run with the OCS™ Liver System. This chapter provides information on the checklists and tasks that are performed during the pre-retrieval readiness phase.

4.1. Liver Console Checklist

1. Confirm that the Wireless Monitor is correctly docked and fully charged. For more details, see Section 9.3 “Docking and Undocking the Wireless Monitor.”
2. Press the OCS™ Liver Run/Standby button  to put the system in Run Mode and to ensure the system passes the Power On Self Test (POST).
3. Ensure Bluetooth is enabled on the Wireless Monitor.
4. Check the date and time, and adjust as needed.
5. Check that the TransMedics supplied data card is installed. For more details, see Section 9.7, “Using the TransMedics Data Cards.”
6. Confirm that there are 3 fully charged OCS™ Batteries. For more details, see Section 9.2, “Checking Battery Power.”
7. Confirm that the OCS™ Liver Gas cylinder is installed properly inside the gas compartment. Then open the cylinder to check the status of the Liver Gas on the Wireless Monitor. Ensure the Liver Gas cylinder is ≥ 50% full (At least 1500 psi) before departure to donor site. Otherwise, replace or take a spare. For more details, including estimating the remaining gas supply, see Section 9.5, “Using the Gas Cylinders.”
8. 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

9. After the Liver Console check, switch back to Standby Mode by pressing  on the Wireless Monitor until the LvPM is installed.

4.2. Liver Perfusion Set Accessories Sets Checklists

Confirm that all Liver Perfusion Set Accessory Sets are available:

- OCS™ Liver Perfusion Initiation Set
- OCS™ Liver Instrumentation Tool Set
- OCS™ Liver Solution Infusion Set
- OCS™ Liver Perfusion Termination Set.

Check for the following:

1. Check the expiration date and look for any obvious shipping damage on the Accessory Sets.
2. If the date has expired or if any damage is found to a packaged Accessory Set, do not use it.
3. Accessory Set packages should not be opened until just before use.

4.3. OCS™ Liver System Medications, Solutions, Infusions, and pRBCs Checklist

Confirm that all medications, solutions, infusions, and pRBCs are available as shown in the checklist below.

- **Medications and Solutions**
  - (b)(4)
- **Infusions**
  - (b)(4)
  - OCS™ Liver Bile Salts (Sodium Taurocholate) - 1g/(b)(4)

- **Packed Red Blood Cells (pRBCs) in a cooler**
  - (b)(4)

4.4. OCS™ Liver Bile Salts Checklist

The OCS™ Liver Bile Salts are provided in sealed vials of 1 g of Sodium Taurocholate to be mixed at the point of use according to the following steps:

- (b)(4)

.

4.5. Liver Flush Solution Checklist

There are two liver flushes that are performed: (1) back table flush (Pre-OCS) – see Section 6.3 and (2) final liver flush – see Section 8.2.

Confirm that you have the following solutions and medications for both flushes:

- (b)(4)

.

4.6. Run Bag Checklist

Confirm that the Run Bag includes the following:

1. Medications, solutions, and infusions (as listed in Section 4.3)
2. The four Liver Perfusion Set Accessory Kits (if not in the Liver Perfusion Set box)
   - It is recommended that you bring a duplicate of the Liver Solution Infusion Set and the Liver Instrumentation Tool Set.
3. 12Fr Bile Cannula
4. Sterile syringes, needles, alcohol wipes, gloves, and petroleum jelly
5. Portable blood analyzer device with unexpired cartridges and extra batteries
6. Fully charged TransMedics-issued training iPad with current OCS™ Liver application
7. Extra OCS™ Liver Gas cylinder, extra gas wrench, extra yoke gasket
8. Recommended items: a flashlight and bungee cords or tie-downs.

4.7. Preparing the OCS™ Liver System for Transport

When selecting a transport vehicle, consider the following:

- Is there a secure, level area large enough to accommodate the system?
- Can you secure the Liver Console to the vehicle to immobilize it during transport, using tie-downs?
- Can you access and open the front panel of the Liver Console?
- Will you have easy access to the OCS™ Battery packs, gas cylinders, and Wireless Monitor?
- Is the temperature of the vehicle adjusted optimally to prevent heat loss? (See the temperature and humidity conditions specified in Section 13.2, “Electrical and Physical Specifications.”)

The steps for preparing the system for transport are as follows:

1. Note: This step is performed only when there is no liver instrumented on the device. Press the button on the Wireless Monitor to set the OCS™ Liver System to Standby Mode.

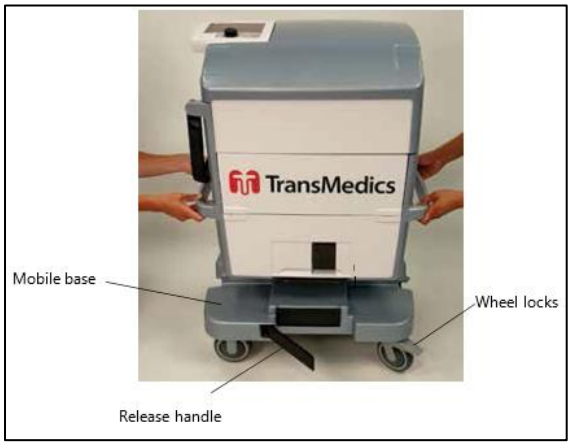
Figure 25: Press Power Button on Wireless Monitor

2. Unplug the system from the AC receptacle and wind the power cord around the power cord wrap.

Figure 26: Cord Placement

3. Press the push handle release buttons, raise the handle and push the system to the loading area. Lock the Mobile Base wheels.
4. Pull the Mobile Base release handle and use 2 people to lift the OCS™ Liver into the transport vehicle.

Figure 27: Lifting the Liver Console off the Mobile Base



5. Position the OCS™ Liver level in vehicle and secure it. Remember to take the Mobile Base with you for use at the Donor Site.

5. CHAPTER 5: SYSTEM SETUP

This chapter provides instructions for the activities that are performed at the Donor Site to set up the OCS and instrument the donor liver.

NOTE—At the Donor Site, allow adequate time for preparation and priming before the liver is instrumented on the OCS™ Liver System.

5.1. Setting Up the OCS™ Liver System

This section provides instructions for unpacking and inspecting the system, installing the LvPM (including connecting the gas lines and probes), and then running the system Self Test.

NOTE—If possible, plug the Liver Console into AC power during setup.

5.1.1. Unpacking and Inspecting the System

Do not remove the LvPM from the sterile bag until just before installation and until the liver has been deemed suitable for transplantation and perfusion on the OCS™ Liver System. Packaged accessories shipped with the Liver Perfusion Set should not be unpacked until just before use.

For descriptions and figures of the components included in the Liver Perfusion Set, see Section 3.3.

To unpack and inspect the sterile Accessory Sets:

- Inspect the packaging of each sterilized component for tears or loss of seal that might compromise sterility. If any tears or damage are found, do not use the damaged item.
- Unpack each sterilized component just prior to use.
- Open the Liver Instrumentation Tool Set components ONLY in a sterile field, using sterile technique.

CAUTION—Check the expiration date on each package. If the date has expired or if any damage is found, do not use the item.

To open the LvPM packaging:

1. Partially lift the bagged LvPM out of the box, supporting the bottom of the Module on the foam insert.
2. Open the bag by locating the notch at the bag's corner and tearing straight across until you reach the other notched corner.
3. Carefully remove the LvPM from the bag and discard the bag.
4. Supporting the bottom of the LvPM on the foam insert, grasp the corner of the foam wrapped around the LvPM and tear off the foam.
5. Remove the foam block from the rear of the LvPM.

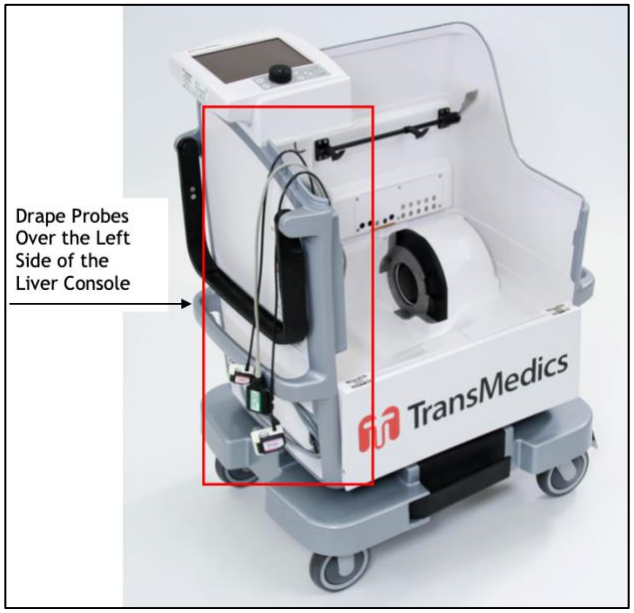
CAUTION—After removing the LvPM from its box (whether or not the Module is in its sterile bag), lay the LvPM on a flat surface on its right side. Laying the LvPM on its back or front may result in damage.

5.1.2. Installing the LvPM

To install the LvPM:

1. With the OCS™ Liver set to Standby Mode, remove the Liver Console top cover, lock the front wheels and open the front panel of the Liver Console.
2. Lift the probes and drape them over the left side of the Liver Console (see Figure 28).

Figure 28: Prepare Liver Console for LvPM Installation



3. Grasp the handgrips on the front and back of the LvPM and tilt it approximately 30° away from the Liver Console to correctly align it for installation (see Figure 29).

Figure 29: Tilt LvPM 30° to Install

4. Lower the bottom of the LvPM so that the circulatory pump on the LvPM aligns with the pump pusher plate on the Liver Console. Figure 30 shows the circulatory pump and the pump pusher plate, and Figure 31 shows the alignment of the components during installation.

Figure 30: Circulatory Pump on LvPM (left) and Pump Pusher Plate (right)

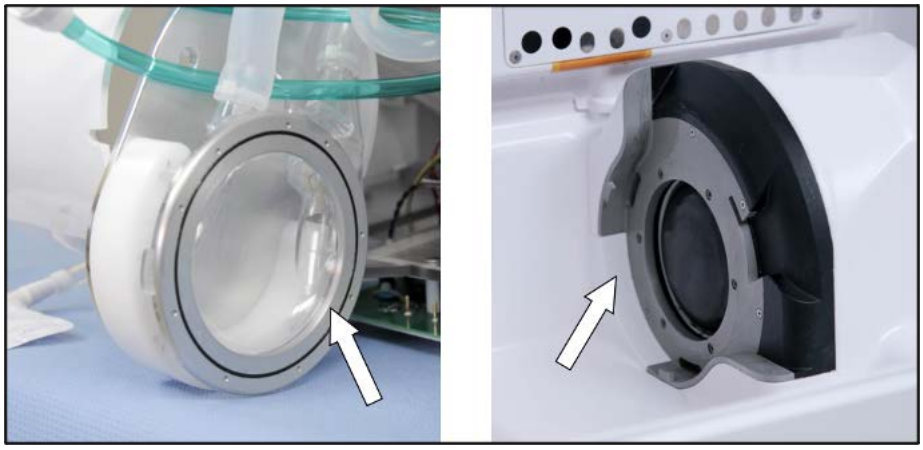
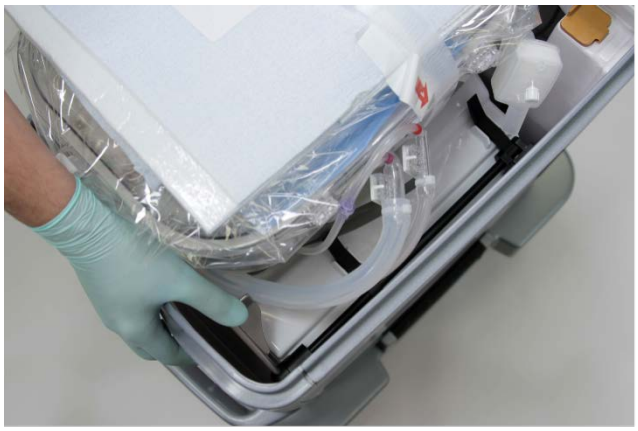


Figure 31: Aligning the LvPM with the Liver Console

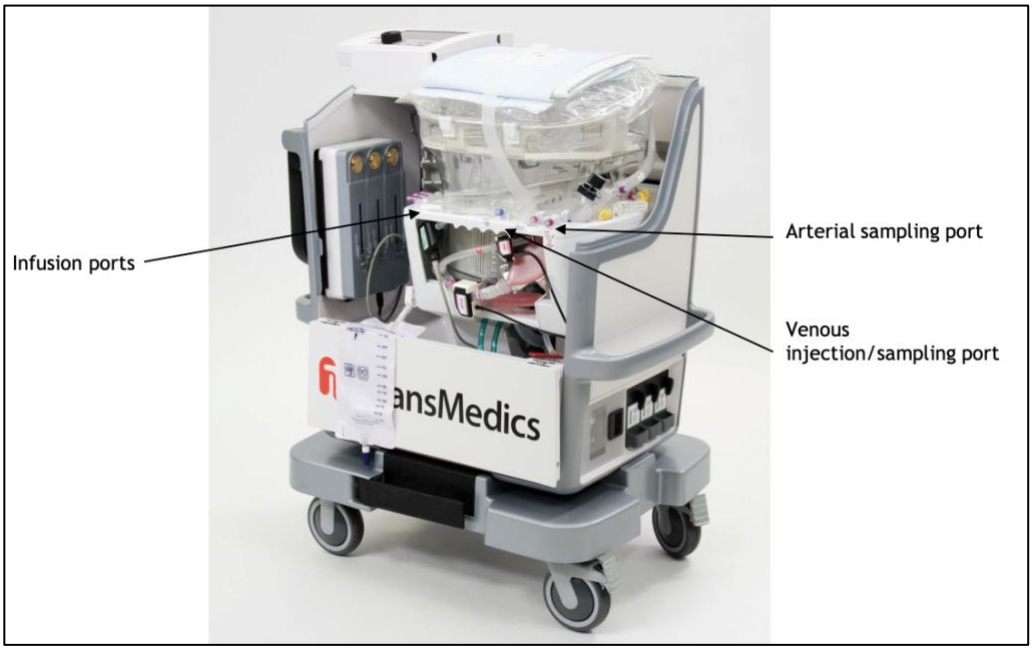
5. Maneuver the LvPM until the pump components slide into the grooves on each side of the locking ring.
6. Gently press the LvPM down and rotate it backward approximately 30° until it engages the Holding Clamps on the back wall of the Liver Console (see Figure 32).
7. Gently pull on the front handgrip of the LvPM to verify that it is locked into place.

Figure 32: Press LvPM Back to Engage the Holding Clamps on Back Wall of the Liver Console



8. Figure 33 below shows the LvPM after it has been installed in the Liver Console.

Figure 33: LvPM Installed in the Liver Console



5.1.3. Connecting the Gas Lines

This section provides detailed instructions on connecting the green gas lines on the LvPM to the Liver Console. The two gas lines (inflow and outflow) are secured together with a bracket.

To connect the gas lines:

1. Locate the bracket with the gas lines on the bottom of the LvPM (Figure 34).
2. Align the connectors on the LvPM with the connectors on the Liver Console.
3. Press the connectors down until they lock into place.

Figure 34: Gas Lines Connected

NOTE—To remove gas lines, pinch the metal tabs on each side of the bracket and lift connectors.

5.1.4. Attaching the Probes

This section provides detailed instructions on attaching the HA Flow Probe, PV Flow Probe, and SvO_2/HCT Probe to the tubing on the LvPM.

Figure 4 shows the probe connector area in the Liver Console. The probe cables are connected to the Liver Console by TransMedics Technical Service during installation of the Liver Console.

Flow probes are attached to the LvPM circuit at the locations where flow rate and direction are to be measured. When connecting the flow probes, match the colors and labels to the similarly marked area of tubing. The probe is placed between the single and double band labels on the tubing of the same color as the flow probe. The probe should be oriented to match the single and double bands on the probe label with the corresponding single and double bands on the tubing.

Flow probes are reusable and do not require sterilization since they touch only the exterior of the tubing and never contact the blood flowing through the circuit. When not in use, the probes are cleaned and left connected to the probe connector panel inside the system and mounted in the probe hanger inside the Liver Console.

5.1.4.1. Attaching the Flow Probes

Both flow probes are attached by following the same procedure. The flow probes and corresponding tubing are color coded as follows:

- HA Flow Probe: Red
- PV Flow Probe: Purple.

<u>To attach each flow probe</u>:

1. Locate the probe to be attached and the associated tubing with matching color coding (see Figure 35). The probe and the tubing each have a solid line of color on one side and a double line of color on the other side.

Figure 35: Probe and Tubing Labeled with Matching Colors (Purple in this Example)

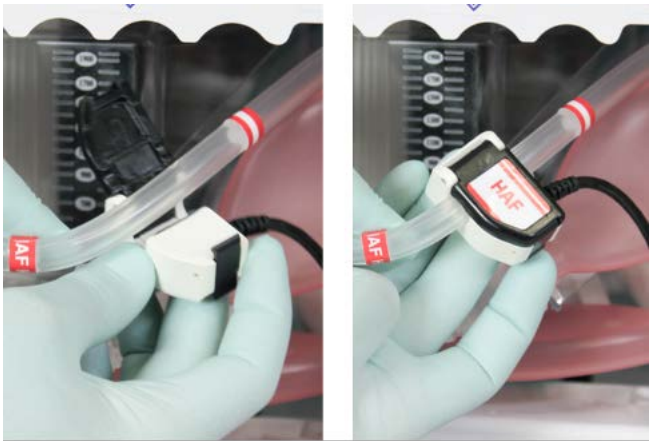
2. Open the probe cover by pressing down on the black latch to release it (Figure 35).
3. Using your finger, apply a small amount of petroleum gel to the inside of the probe.

Figure 36: Open Probe Cover and Apply Petroleum Jelly

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

4. Align the probe between the color bands on the tubing so that the double lines on the probe label align with the double bands on the tubing (double bands mark outflow on the tubing (see Figure 37).
5. Insert the tubing into the sensing cavity of the probe and close the lid (see Figure 37).

Figure 37: Insert Tubing Into Probe and Close Cover

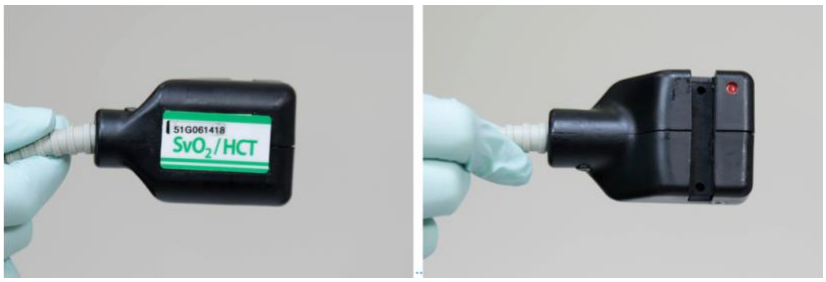


6. Make sure the lid is completely closed and the latch is secure. The fit should be tight, with the full tubing cross-section contacting all inner surfaces of the sensing window. The tubing will be slightly compressed into a rectangular shape.
7. Once fluid is flowing through the tubing during priming, check the Wireless Monitor to verify that the desired flow parameters are being detected.

5.1.4.2. Attaching the SvO_2/HCT Probe

The SvO_2/HCT Probe is designed to be clipped onto a cuvette incorporated into the LvPM's tubing. The probe and the cuvette are color coded in green. A small arrow on the tab of the cuvette indicates flow direction. This directional icon should be aligned with the red dot on the back of the probe. Figure 38 below shows the front and rear view of the SvO_2/HCT probe.

Figure 38: Front and Rear View of the SvO_2/HCT Probe



To attach the SvO_2/HCT Probe:

1. Locate the cuvette on the tubing in the LvPM (see Figure 39). Note the tab on the cuvette showing flow direction.

Figure 39: Cuvette for SvO_2/HCT Probe

2. Align the SvO_2/HCT Probe so that the cuvette is centered in the probe opening (use the single and double green bands on the probe and the tubing to position it properly). Also align the red dot on the probe with the tab on the cuvette.

Figure 40: Align SvO_2/HCT Probe with Cuvette on Tubing

3. Snap the probe into place around the cuvette.

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

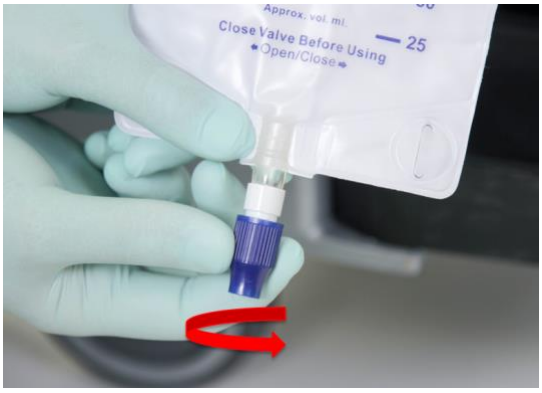
5.1.5. Closing the Bile Drain Valve on the Bile Collection Bag

The bile drain valve on the bile collection bag is packaged and shipped in the open position.

To close the bile drain valve:

1. Locate the valve on the bottom of the bile collection bag.
2. Turn clockwise until hand-tight. This will close the valve.

Figure 41: Close Bile Drain Valve on the Bile Collection Bag



5.1.6. Clamping the Reservoir Drainage Line

The Reservoir Drainage Line is packaged and shipped in the unclamped position.

To close the Reservoir Drainage Line:

1. Locate the Reservoir Drainage Line with the red clamp near gas line.
2. Bring red clamp up the line proximal to reservoir. Engage slide clamp on tubing to close.
3. Tuck Drainage Line back into OCS™ Liver.

Figure 42: Clamp Reservoir Drainage Line

5.1.7. Running the System Self Test

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

To run the system Self Test:

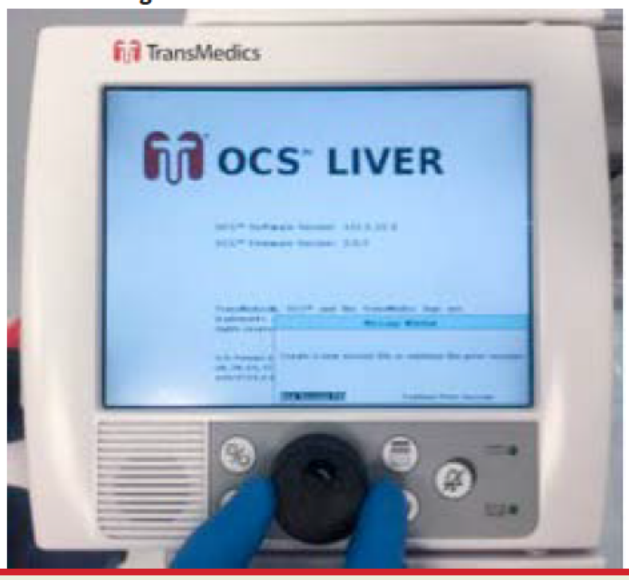
1. Verify that the Liver Console is connected to an AC outlet.
2. Verify that the Wireless Monitor is docked on the Liver Console.
3. Press the Run/Standby button on the Wireless Monitor (Figure 5).

CAUTION—The Run/Standby button on the Wireless Monitor will NOT function unless the Wireless Monitor is docked on the Liver Console.

NOTE—Do not use the Power Switch on the lower left side of Liver Console near AC Power connection to turn OCS™ Liver on and off.

4. The system performs a Self Test and displays the system transitional status messages. If errors occur, error messages are displayed.
   - If errors display indicating problems, refer to Chapter 12: Troubleshooting.
   - If no errors display, click on **New Session File** to proceed.

Figure 43: Select New Session Screen



NOTES—

If the system detects an issue during the Self Test, a message displays with information about the issue until it is resolved. To resolve the issue, follow the steps in Chapter 12: Troubleshooting.

At the beginning of the session, the system may display messages and sound alarms related to sensor probes. These message and alarms can be disregarded until after the system is primed and de-aired. For details of system initialization and messages, see Chapter 10: Managing the System.

5.2. Setting Up the Solution Delivery Subsystem (SDS)

This section provides detailed instructions on how to set up the SDS. Refer to Section 3.2.2, “Solution Delivery Subsystem (SDS)” for an overview of the SDS.

5.2.1. Connecting the Solution to the SDS Line Set

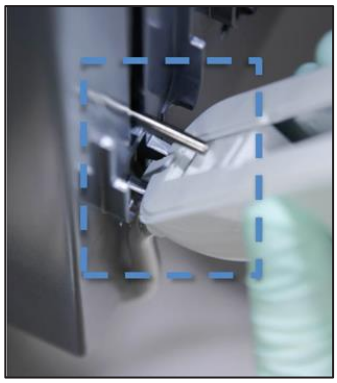
1. Before spiking a vial, place the provided bottle holder over the vial.
2. Insert the piercing spike of the infusion line with a twisting motion into the infusion port of the prepared solution bag or into the vial. Be sure the spike is firmly seated to the port/vial.
3. Hang the infusion bag/vial on the hanger provided in the Liver Console.

5.2.2. Connecting the SDS Cassette to the SDS Console

1. Remove the protective cover from the pressure sensor dome on the SDS Cassette by squeezing the attachment fingers and pulling the protective cover off.
2. Remove the shipping lock from the SDS Cassette.
3. Insert the mounting tab under the mounting bar on the SDS Console.

NOTE—While inserting the SDS Cassette, ensure that the drive pin on the SDS Console is inserted into the receiving socket on the cassette.

Figure 44: SDS Drive Pin Alignment



4. While fully squeezing the SDS Cassette’s attachment fingers, firmly press the SDS Cassette onto the SDS Console’s pressure sensor.
5. Release the attachment fingers.
6. Ensure the attachment of the SDS Cassette to the SDS Console pressure sensor is secure.

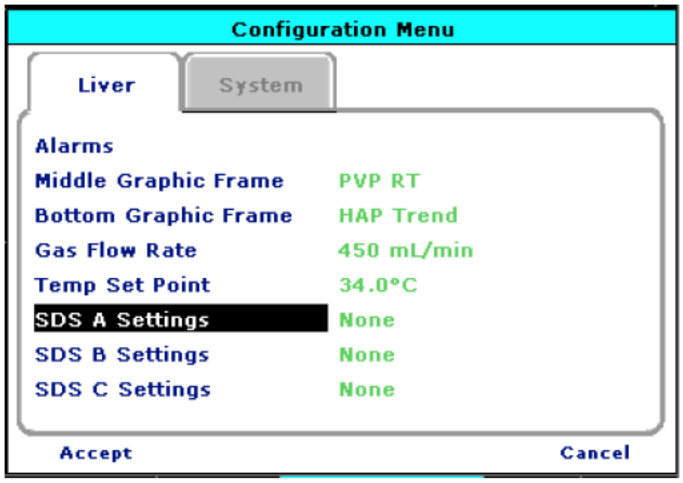
5.2.3. Connecting the Infusion Line to the LvPM

1. Remove the protective cover from the output Luer connection of the SDS Line Set.
2. Connect the line to an infusion port on the LvPM. The TPN and the OCS™ Liver Bile Salts solutions are connected to the Portal Vein infusion ports. The Epoprostenol Sodium (Flolan or equivalent) solution is connected to the Hepatic Artery (HA) infusion/flush line port.

5.2.4. Configuring the SDS Settings

1. Press the Configuration Menu button.
2. Turn the rotary knob to highlight the Liver tab and then press the knob.
3. Turn the knob to scroll through the options until the desired SDS channel is selected.

Figure 45: Configuration Menu



4. Press the rotary knob to select the channel.
5. Each Channel has the following configurable options:

Figure 46: SDS Channel Setting Menu

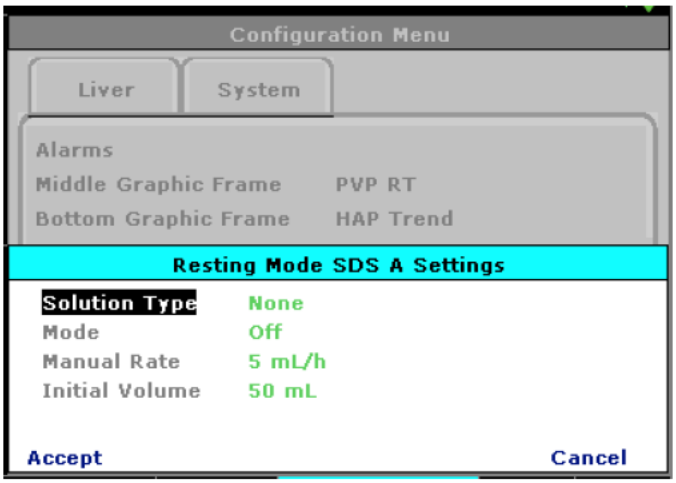


Table 11: SDS Channel Configuration Options

Item	Options	Description
Solution Type	PGI2*, TPN, Bile Salt, or None	Identifies which type of solution is loaded into the SDS channel.
Mode	Off or Manual	Starts and stops the delivery of solution.
Manual Rate	1 mL/hr to 99 mL/hr	Sets the delivery rate when the mode is set to Manual Mode and the pump is on.

Item	Options	Description
Initial Volume	50 mL - 1000 ml in 50 ml increments	Sets the initial volume of solution available. This is used to calculate the time and volume remaining.
*Epoprostenol Sodium (Flolan or equivalent)		

6. Choose a Solution Type by pressing the rotary knob and selecting one from the list.
7. Set the Mode to Manual.
8. Set the infusion rate by selecting Manual Rate and choosing the desired flow rate.
9. Set the Initial Volume in the solution bag.

CAUTION—If the initial volume is not set to match the initial volume in the solution bag, the low solution alert will not be accurate.

10. Select Accept to exit the Liver tab.
11. Select Accept on the Configuration Menu to make the changes take effect.

NOTE—Solution delivery will not begin until the circulatory pump is turned on.

5.2.5. De-Airing an SDS Line Set

NOTE—The SDS Line Sets must be de-aired and primed before OCS™ Liver System priming.

1. Using the Wireless Monitor, open the Actions Menu.
2. Select De-Air SDS.
3. Select the Channel to de-air.
4. Select **De-Air SDS** as many times as needed to purge air from the line set.

NOTE—If the De-Air action is not selectable, read the status indication in the middle of the menu for further direction.

Figure 47: Actions Menu

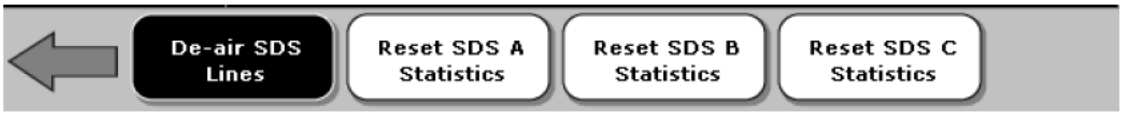


Figure 48: De-air SDS Channel

5.3. Preparing the OCS™ Liver System for Liver Instrumentation

This section provides instructions for priming and preparing the OCS™ Liver System for liver instrumentation.

5.3.1. Priming the OCS™ Liver

This section provides instructions for priming the LvPM. After the LvPM is installed, all setup steps are complete, and the Self Test is complete, the circuit is ready to be primed. Table 12 below provides a summary of the key priming information.

Table 12: Priming Overview

Priming	(b)(4)
Temperature	Set to 34°C
Pump Flow	Gradually increase to 2-3 L/min to de-air the circuit and mix the perfusate, allow temperature to rise to 34°C, then decrease flow to 0.5 L/min until liver is instrumented.
Gas Flow	450 mL/min
Add the Perfusate Additives	See Section 4.3

CAUTIONS—

Ensure that Reservoir Drainage Line Clamp is closed and the bile drain valve is closed prior to priming.

HA and PV vent lines and PV Clamp remain open until organ is instrumented. The vent line should be closed and the PV Clamp engaged after instrumentation.

Use aseptic technique when performing the priming procedure.

To prime the LvPM:

1. Remove the yellow cap from the end of the Quick Prime Line and remove the yellow cap from the Prime Port on the LvPM. Press the two connectors together until they click to lock (Figure 49).

Figure 49: Connect the Prime Line to the LvPM

2. Use the Quick Prime Line to deliver (b)(4) via the Prime Port.
3. Use (b)(4) to the LvPM through the Prime Port.
4. Use (b)(4) via the Prime Port.

Figure 50: Add Albumin to Prime Line

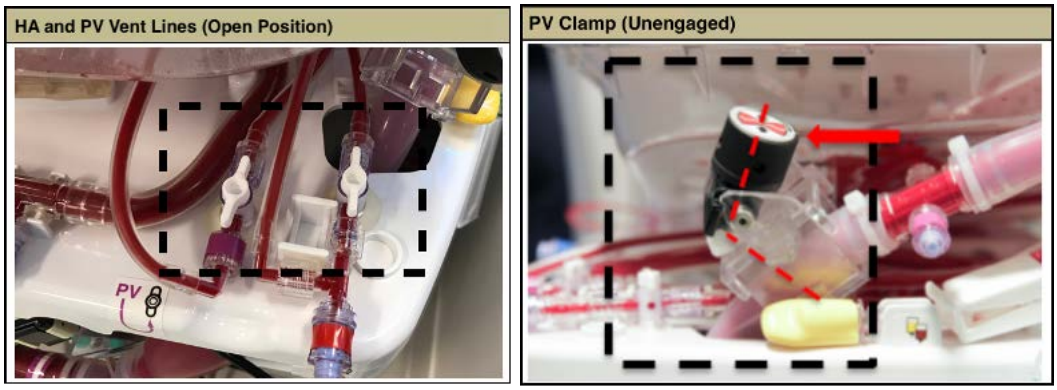
5. When finished, place a sterile yellow cap on Prime Port of the LvPM and close clamp on the line.
6. Once the volume of priming solution reaches at least 1000 mL in the reservoir, begin perfusate circulation. For details, see Section 5.3.2, "Beginning Perfusate Circulation."
7. Use the cylinder wrench to turn on the gas by slowly turning the shut-off valve anti-clockwise.
8. Once pump is turned on, all subsystems (warmer, SDS, gas delivery) will start functioning according to the set points selected/configured.

5.3.2. Beginning Perfusate Circulation

NOTE—Configuration Menu settings can be saved as defaults so that the settings are in place each time a new session is started. For details on using the Configuration Menu and saving system settings, see Section 5.2 "Setting up the Solution Delivery Subsystem (SDS)."

1. Press  to open the Pump Adjust window, and adjust pump flow to 2-3 L/min initially to circulate the perfusate and de-air the module. Make a visual check of all tubing and tap or squeeze as needed to remove any air bubbles.
2. Press  to display the Configuration Menu, select the Liver tab, and do the following:
   - Ensure temperature is set to 34°C.
   - Ensure gas flow rate is set to 450 mL/min.
3. Ensure that the HA and PV vent lines are opened and running and the PV Clamp is not engaged.

Figure 51: HA and PV Vent Lines Open and PV Clamp Unengaged



5.3.3. Injecting Additives into the Perfusate

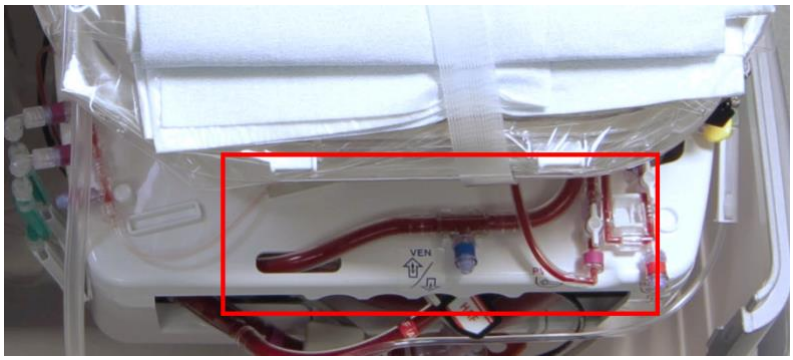
For a complete list of additives to be injected into the perfusate before use, see Section 4.3.

NOTE—Additives, syringes, and medium gauge needles are needed and are not supplied by TransMedics.

5.3.3.1. Additives to be injected into the perfusate:

1. Inject the additives listed in Section 4.3 through the reservoir injection port (Blue Venous Injection Port) (Figure 52).

Figure 52: Infusion and Sampling Ports



2. Let the fluids circulate for approximately 10 minutes or until the system is de-aired. While priming, check the circuit for air bubbles and, if present, tap the lines as vigorously as necessary to dislodge the trapped gas so that it can be removed by the system defoamer.

CAUTIONS—

Check the LvPM's tubing or connections for any leaks or trapped air.

Check the Wireless Monitor to make sure it is registering all system parameters.

Verify that the perfusate temperature begins to increase toward the Temp Set Point.

The minimum safe reservoir volume is 500 mL as indicated on the reservoir (Figure 53). Maintain a volume of at least 500 mL in the reservoir at all times. Lower volumes may result in air being pumped into the organ.

Never allow the perfusate level to exceed the maximum level mark on the reservoir.

Figure 53: Minimum Safe Reservoir Level

5.3.3.2. SDS infusions:

- To be initiated with the pump start:
  - (b)(4)
  - OCS™ Liver Bile Salt prepared solution (b)(4)
- To be initiated as needed:
  - (b)(4)

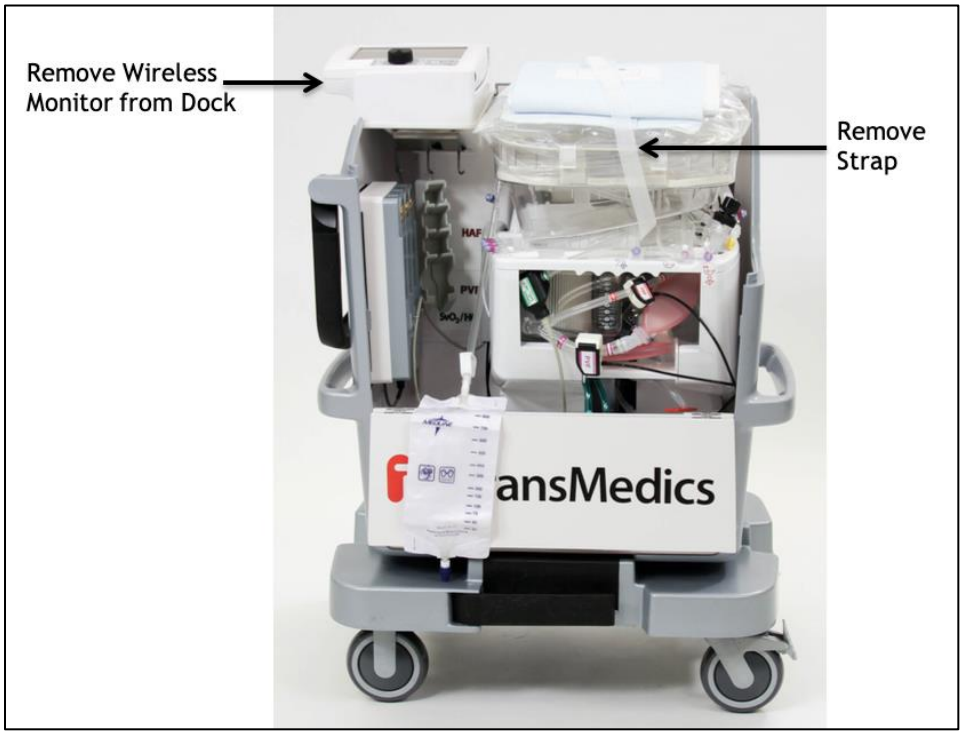
5.3.4. Draping the Work Area

As the liver is being prepared for instrumentation, drape the OCS™ Liver System to avoid contamination when the organ is transferred to the organ chamber. Draping is done aseptically after adding the perfusate components and additives.

To drape the work area:

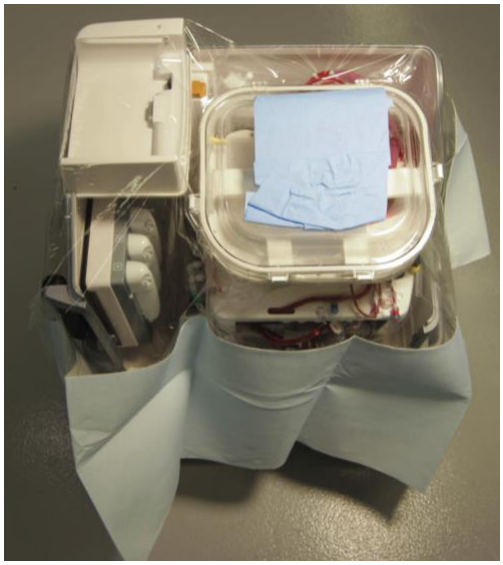
1. A sterile operator can access the Wireless Monitor through the transparent drape. The non-sterile operator should remove the Wireless Monitor from its docking cradle and operate it outside the sterile field (Figure 54).

Figure 54: Remove the Wireless Monitor from the Liver Console



2. Remove the strap on the sterile drape attached to the organ chamber of the LvPM.
3. Grasp the drape at the arrow marking on the top of the drape and pull it backward away from the chamber.
4. Continue unfolding following the arrow markings printed on the drape until the whole drape is extended (see Figure 55).

Figure 55: Sterile Drape Unfolded on OCS™ Liver System



6. CHAPTER 6: RETRIEVAL AND BACK TABLE PREPARATION

6.1. Position the OCS™ Liver System in the Operating Room

1. Position the OCS™ Liver System in the vicinity of the back table and near an AC power outlet. There should also be a gap between the OCS™ Liver System and the wall to allow access to the rear of the unit.
2. Plug the OCS™ Liver System into AC Power.

6.2. Flushing and Harvesting the Liver

The donor liver should be flushed and harvested from the donor according to standard clinical practice.

Once the liver is removed, it must be prepared for instrumentation on the OCS™ Liver System (see Section 6.3 “Back Table Liver Preparation”).

6.3. Back Table Liver Preparation

The section describes how to prepare the liver on the back table to be placed in the OCS™ Liver System. It includes cannulating and flushing the liver on the back table, and then instrumenting the liver in the OCS™ Liver System.

These steps are performed by sterile operators, including the cannulation and back table flush, while the OCS™ Liver System is being primed. These steps require supplies from the Liver Instrumentation Tool Set (see Section 3.3.3). Silk tie and Prolene suture will be needed for securing the cannulae. These are not provided by TransMedics.

6.3.1. Cannulating the Hepatic Artery (HA)

1. Select the appropriately sized HA Cannula.
2. Insert the HA Cannula into the hepatic artery.
3. Secure the HA Cannula using silk tie.

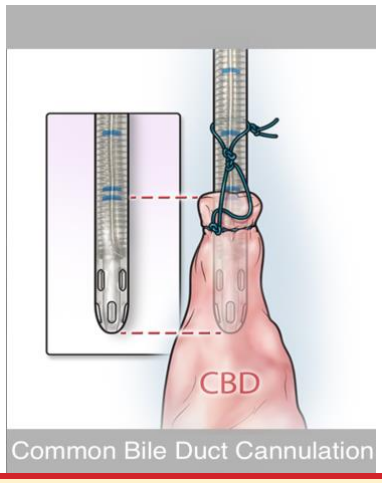
6.3.2. Cannulating the Portal Vein (PV)

1. Insert the PV Cannula into the PV.
2. Secure the PV Cannula using silk tie.

6.3.3. Cannulating the Common Bile Duct

1. Insert Bile Cannula into the Common Bile Duct, up to 1-2 cm.
2. Secure the Bile Cannula using a silk tie and stay stitch, as shown below.

Figure 56: Securing the Bile Cannula



CAUTION—Do not push the cannula deep in the Common Bile Duct. 1-2 cm from the edge should be enough.

6.3.4. Cannulating the Inferior Vena Cava (IVC)

1. Place the IVC Cannula through the supra-hepatic Inferior Vena Cava and secure using purse-string suture and leave the infra-hepatic Inferior Vena Cava open.

6.3.5. Flushing the Liver on the Back Table

1. Flush the liver before placing it into the OCS™ Liver System to cool it homogeneously and flush out any other preservative solution used in the donor.
2. The liver should be flushed on the back table using (b)(4)

6.4. Instrumenting the Liver on the OCS™ Liver System

This section describes how to instrument the liver on the OCS™ Liver System.

To instrument the liver:

1. (b)(4)
2. (b)(4)
3. (b)(4)

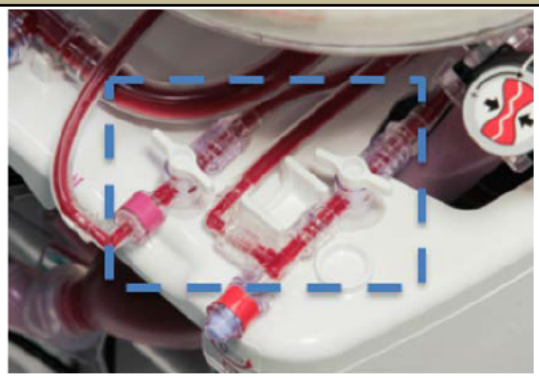
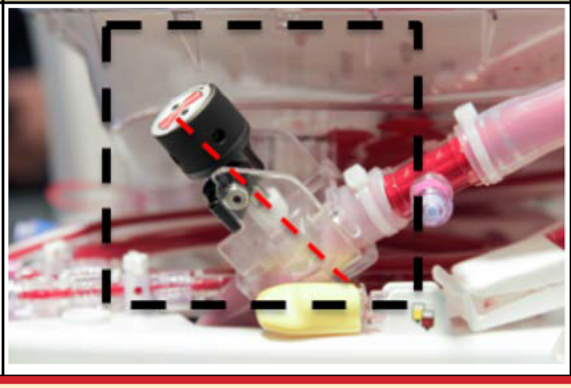
To connect the HA and PV cannulae:

1. (b)(4)
2. (b)(4)
3. (b)(4)
4. (b)(4)
5. (b)(4)
6. (b)(4)

Figure 57: Pump Adjust Knob

7. (b)(4)
8. (b)(4) .
9. (b)(4)

Figure 58: HA and PV Vent Line Positions

HA and PV vent lines (open position)	HA and PV vent lines (closed position)
	
PV Clamp open	**PV Clamp engaged**
	

CAUTIONS—

If leaks or torques are noticed during cannulation:

- Decrease pump flow temporarily as needed.
- Readjust the connection or secure the leak.
- Increase pump flow back to normal target range.

If air bubbles are detected:

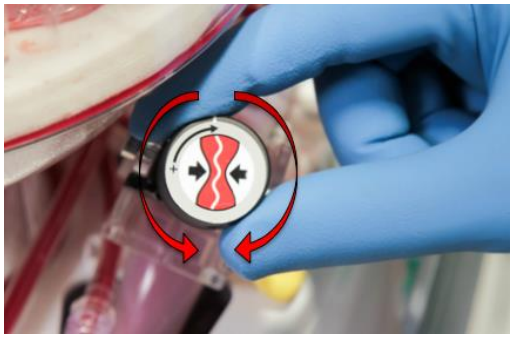
- Open the HA or PV vent line to direct the air bubble to the reservoir.
- Decrease pump flow temporarily as needed to allow air bubble to move to vent line.
- Alternatively, disconnect cannula from the organ chamber connection port and then reconnect again after disposing of air.

7. CHAPTER 7: PERFUSION INITIATION, TRANSPORT, AND MANAGING LIVER PRESERVATION

7.1. Perfusion Initiation on OCS™ Liver System

1. (b)(4)
2. (b)(4)

Figure 59: Adjusting PV Clamp



3. Maintain the following:
   - (b)(4)
4. Ensure that the temperature is rising toward the set point and stable.
5. Check that the liver is uniformly perfused.

NOTE—Use the Epoprostenol infusion (e.g., Flolan or equivalent) **AS NEEDED** to achieve target HAP and maintain it within the recommended range.

CAUTION—Rapid increases in flow rate may injure the liver and should be avoided during initial rewarming on OCS™ Liver System.

6. (b)(4)
7. Perfusate temperature should reach 34°C.
8. Target pressures and flows:
   - (b)(4)

- (b)(4)
- (b)(4)
- (b)(4)

Refer to Section 7.1.1 and Section 7.1.2 below for more information.

9. Run an arterial blood sample within the first 30 minutes, observe Lactate levels, ABG and correct pH as needed.
10. Check if bile can be observed in the cannula. If no bile is observed, check for any kink or twist in the common bile duct.
11. If no further sterile interaction with the liver is needed, apply the organ wrap. Adjust organ stabilizer arms around the Liver to secure its position during transport and close the organ chamber.
12. Remove the sterile drape.
13. Ensure hemodynamics (HAF/PVF and HAP/PVP) are all within ranges.
14. To prepare the OCS™ for transport, see Section 4.7.
15. Confirm that the audio for alarms is on.

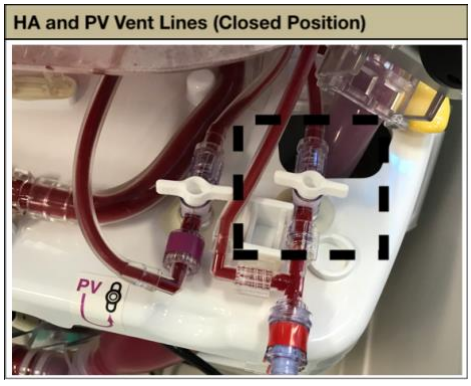
CAUTION—Do not disconnect the OCS™ from AC power or move the OCS™ until the perfusate temperature displayed on the Wireless Monitor reaches 34°C.

7.1.1. Adequate Perfusion through HAP Control

- If the HAP target is achieved with stable lactate, then vasodilator (e.g., Epoprostenol Sodium (Flolan or equivalent)) infusion should be maintained at the lowest flow rate to maintain the HAP.
- If HAP is high, check for kink or torque in HA line. If none is present, start or increase the infusion rate of vasodilator agent (e.g., Epoprostenol Sodium (Flolan or equivalent)), until target HAP is achieved.
- If HAP is low and associated with a too high HAF rate, decrease the infusion rate of the vasodilator agent (e.g., Epoprostenol Sodium (Flolan or equivalent)) until target HAP is achieved.

  Note: If HAP is low, check and tie bleeders, if any, and ensure the HA Vent is closed.

Figure 60: HA and PV Vent Lines Closed



7.1.2. Epoprostenol Sodium (e.g., Flolan or Equivalent) Flow Rate Titration Protocol

- (b)(4)

7.2. Transporting the OCS™ Liver System

1. Close the front panel and reinstall the cover.
2. Unplug the system from AC power and wind the power cord around the power cord wrap.
3. Make sure you have all supplies needed for transport to the Recipient Site.
4. Press the release buttons on the push handle, set the handle, and push the system to the vehicle loading area.
5. At the vehicle, set the wheel locks, and open the Mobile Base release handle. Lift the system off the base using the gray lift handles, keeping the OCS™ Liver System level during the loading process.

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

CAUTION—Tipping the OCS™ Liver System at angles greater than 15 degrees may disrupt fluid paths in the LvPM and lead to system malfunction.

6. Position the system in the vehicle, making sure it is level, and secure it.

NOTE—Remember to take the Mobile Base with you for use at the Recipient Site.

7. For remote monitoring, remove the Wireless Monitor from its docking station and keep it close by.

NOTE—The Wireless Monitor must be kept within approximately 3 meters (9 feet) of the system.

CAUTIONS—

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

If the Wireless Monitor is taken out of range, verify upon its return in range that all parameters are as expected to ensure that a rare instance of a system event did not occur while it was out of range.

7.3. Managing Liver Preservation

During transport and preservation, the liver should be maintained within the ranges shown in Table 13 below.

Table 13: Preservation Ranges

Parameter	Range
Hepatic Artery Pressure (mean HAP):	(b)(4)
Hepatic Artery Flow (HAF):	(b)(4)
Portal Vein Pressure (mean PVP):	(b)(4)
Portal Vein Flow (PVF):	(b)(4)
Perfusate Temperature (Temp):	34°C
Oxygen gas flow:	(b)(4)
Circulating arterial lactate (Lact) trend:	stable or trending down over time

See Table 14 for the OCS™ liver sampling scheme.

7.3.1. OCS™ Liver Perfusate Sampling Scheme

Sampling during liver perfusion: Collect samples from the arterial port of the OCS™ Liver perfusion circuit to measure ABG and lactate level using a standard blood gas analyzer according to Table 14. Liver enzyme profile may be obtained if desired.

1. Donor ABG and lactate should be measured.
2. One arterial sample will be collected within the first 30 minutes of perfusion time.
3. Samples will continue to be collected from the device at approximately hourly intervals until lactate level is trending down. At this time, lactate samples could be done every 2 hours or after any active HAF or HAP adjustments.
4. Immediately before cooling the donor liver on OCS™ Liver prior to transplant, an arterial blood sample should be taken from the HA sampling port to evaluate ABG and lactate levels. Liver enzyme profile may be obtained if desired.

Table 14: OCS™ Liver Sampling

Time	ABG	Lactate
Before harvesting the organ (Donor)	X	X
Within the first 30 minutes of perfusion on Liver Console	X	X
During OCS Preservation - Hourly*	X	X
Immediately before cooling the donor liver on Liver Console for re-implantation	X	X
*If lactate level is trending down, samples could be done every 2 hours or after any active HAF or HAP adjustments.		

8. CHAPTER 8: PRESERVATION CONCLUSION AND SYSTEM SHUT DOWN

8.1. OCS™ Final Liver Sampling

1. Immediately before cooling the donor liver on OCS™ Liver prior to transplant, perform the following steps: Take a blood sample to evaluate ABG and lactate levels. Liver enzyme profile may be obtained if desired.
2. Check stability of the organ perfusion parameters.
3. Check for stable or trending down lactate levels.
4. Check the Bile production rate.
5. When the surgical team is ready to transplant the liver, perform the steps in Section 8.2 (“Performing the Final Liver Flush”) and Section 8.3 (“Removing the Liver from the OCS Liver System”).

NOTE—To maintain warmth and humidity, keep the organ chamber cover closed until the liver is ready to be disconnected from the Liver Console.

8.2. Performing the Final Liver Flush

Prior to removing the liver from the OCS™ Liver System, the liver should be flushed and cooled on the system (b)(4)

The composition of the final liver flush per liter of cold multiple-electrolytes solution (PlasmaLyte® or equivalent) is as follows:

- (b)(4)

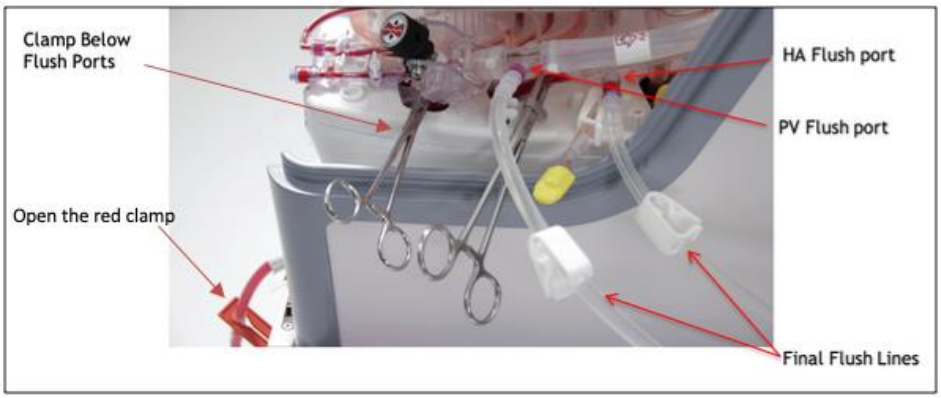
<u>To perform the final liver flush</u>:

1. Using sterile technique, flush and de-air each final flush line included in the Liver Perfusion Termination Set, and connect each line to its corresponding port on the LvPM (PV & HA flush ports).
2. Using pressure bag, pressurize the HA flush solution bag.
3. Connect the OCS™ drainage bag to the clamped drainage line (red clamp) in the LvPM.
4. With two tube clamps ready, start the HA and the PV flush by opening the Final Flush line clamps and clamp each line below the level of the flush port using the tube clamps.
5. Decrease the Pump Flow to 0 L/min and ensure the pump is turned off.

CAUTION—Failure to turn the pump flow to 0 L/min quickly will over pressurize the LvPM and will result in leakage.

6. Open the red clamp to drain the reservoir while flushing the liver.
7. Maintain the HA pressure at 50-70 mmHg as displayed on the Wireless Monitor.

Figure 61: Final Flush Ports and Clamps



8.3. Removing the Liver from the System

1. Drape the system to create a sterile field before opening the organ chamber.
2. Open the organ chamber cover.
3. Unwrap the liver.
4. Clamp the HA and PV Cannulae in the organ chamber.
5. Disconnect the HA and PV Cannulae from the OCS™.
6. Disconnect the bile cannula from the OCS™.
7. Disconnect the IVC cannula from the OCS™.
8. Remove the liver from the OCS™.

CAUTION—When disconnecting the liver from the Liver Console, **a sterile operator performs all actions that are performed inside of the organ chamber**. Other actions may be performed by non-sterile operators.

8.4. Shutting Down the System

8.4.1. Preparing the OCS™ Liver System for Shutdown

To prepare the OCS™ Liver 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.

8.4.2. Removing the Probes from the Tubing

The probes are reusable and do not require sterilization since they do not directly contact perfusate.

To remove the probes:

1. After the liver has been removed, detach the HA Flow Probe, the PV Flow Probe, and the SvO_2/HCT Probe from the tubing as described below:
2. To remove a flow probe from the tubing:
   - Press the latch on the side of the probe until the probe lid opens.
   - Carefully remove the flow probe from the tubing on the LvPM, but leave it connected to the Liver Console.
3. To remove the SvO_2/HCT Probe from the tubing:
   - Firmly grasp the probe with one hand.
   - Use the other hand to gently remove the cuvette from the probe.
4. Clean the probes as described in Section 11.2, "Cleaning and Disinfecting the Probes," and store them on the probe hanger inside the system.

NOTE—Remove the probes from the tubing, but leave them connected to the Liver Console.

8.4.3. 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 LvPM to the Liver Console.

8.4.4. Disposing of the LvPM and Preparing the System for Cleaning

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

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

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

CAUTIONS—

Do not sterilize the Liver 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 LvPM or any of the sterile accessories.

NOTE—The probes require specialized cleaning and disinfection instructions. See Section 11.2, "Cleaning and Disinfecting the Probes" for more details.

Disposal Regulations: The OCS™ Liver 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 Liver Console is expected to be at least five years with a rate of use of 50 preservation sessions per year.

NOTE—See Chapter 11, "Cleaning and Maintaining the OCS™ Liver System" for information on how to clean and disinfect the system after use.

Part 2:
TECHNICAL GUIDE

Chapters 9 - 14 of this user guide provide technical information relating to the set-up, operation, maintenance and troubleshooting of the OCS™ Liver System.

9. CHAPTER 9: SYSTEM SETUP AND CONNECTIONS

This chapter provides information regarding system setup and connections.

9.1. Connecting the System to AC Power

The OCS™ Liver 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.

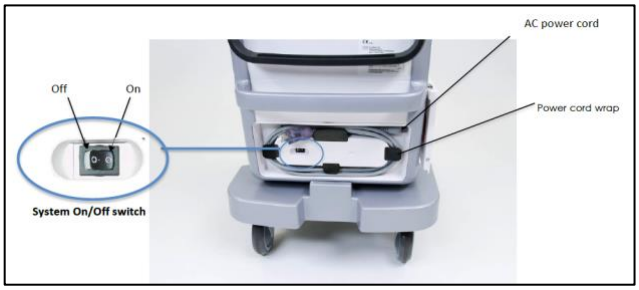
When using and storing the OCS™ where an acceptable AC power receptacle is accessible, TransMedics recommends ALWAYS connecting the system power cord to the AC source, rather than running the system on battery power.

See Section 2.2 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 62).

Figure 62: 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 62).

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.

WARNINGS—

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

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

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

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

Never use a converter adapter to plug the three-pronged AC plug into a two-pronged, ungrounded wall outlet, and do not use additional cables, extension cords, or outlets with the system. Doing so may result in electric shock to the operator and damage to the equipment.

9.2. Checking Battery Power

This section provides instructions for making sure the system and Wireless Monitor have adequate battery power for the preservation session. This section also provides instructions for charging the batteries.

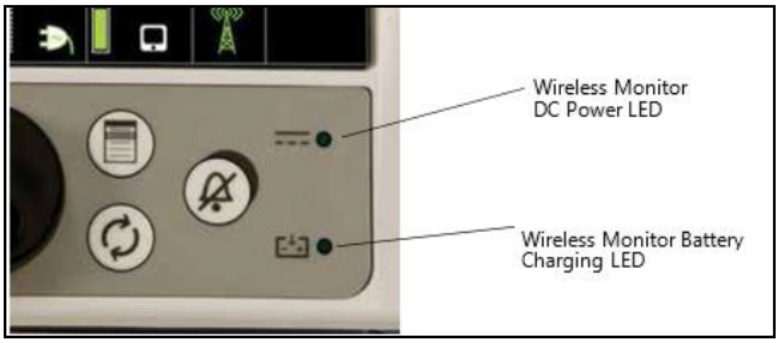
9.2.1. Checking Wireless Monitor Power

When the Wireless Monitor is docked on the OCS™, it automatically uses power from the power source supplying the OCS™, and, if the system is connected to AC power, the Wireless Monitor battery is recharged as needed. When you undock the Wireless Monitor and use it remotely, it uses power from its own battery.

The two LED lights on the Wireless Monitor's control panel provide information about Wireless Monitor power status (Figure 63):

- When the Wireless Monitor is receiving power from the system, the DC Power LED (⎓) is lit.
- When the Wireless Monitor is fully charged, the Battery Charging LED ( ) is solidly lit. When it is charging the light blinks. Otherwise, the LED is off.

Figure 63: Wireless Monitor Power LEDs



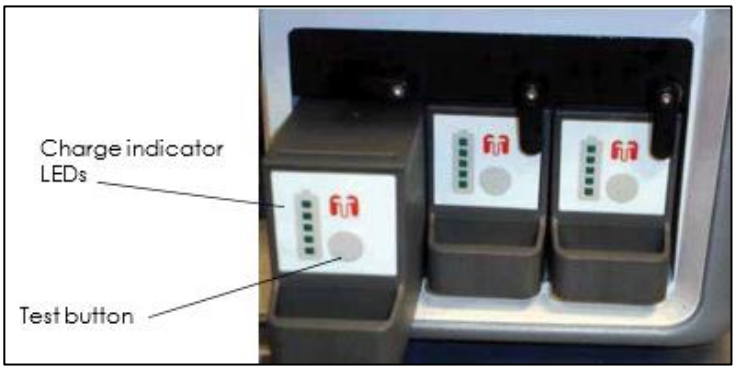
9.2.2. Checking System Battery Power

You can determine the charge status of each battery by viewing the battery status icons on the Wireless Monitor. For more information, see Table 3. If you do not have access to the Wireless Monitor display, perform the following steps to manually check the charge level of each battery.

To check the OCS™ Battery charge LED:

1. Press the test button on the front of each battery (Figure 64). The battery charge LEDs indicate charge level.
2. Determine the charge level and take the appropriate action:
   - If all five indicator LEDs light, the battery is fully charged.
   - If the lower LED flashes and the remaining four LEDs are not illuminated, it indicates that the battery is fully discharged. Replace the battery with a fully charged battery or connect the OCS™ to AC power.
   - If no LEDs light, do not use the battery and contact TransMedics service (+1-978-552-0999).

Figure 64: OCS™ Batteries



9.2.3. Duration of OCS™ Battery Powered Operation

When transporting the OCS™ Liver 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. Under normal operating conditions, the set of three OCS™ Batteries has sufficient charge to last a minimum of four hours of operation. Each additional battery will supply at least 1.3 hours of operation.

WARNING— To avoid loss of battery power during transport, especially due to unanticipated transportation delays, connect the system to AC power whenever available.

The OCS™ batteries are automatically recharged when the system is connected to AC power. Note that the system will charge, in order, the Wireless Monitor, then the OCS™ Batteries, one at a time.

9.2.4. Removing and Installing System Batteries

When one or more OCS™ batteries are discharged, the Wireless Monitor display indicates which batteries are discharged. You can hot swap the batteries one at a time with a fully charged replacement battery while the system continues to operate normally. You cannot remove more than one OCS™ battery at a time.

For details on low battery power indicators, see Table 3, "System Status Icons."

WARNINGS—

If powered by the OCS™ batteries, the system will cease to function when the batteries are fully discharged. To avoid loss of power, regularly monitor the battery status icons and audible alarms on the Wireless Monitor display and replace OCS™ batteries as needed, or connect the system to AC power. (For details on battery capacity alarms that appear on the Wireless Monitor screen, see Table 3.)

Each OCS™ battery includes rechargeable lithium ion battery cells. Lithium is a highly reactive element that can react violently when mixed with water, leading to possible battery leakage, smoke, and fire. Batteries must be handled, stored and disposed of with great care. Failure to adhere to proper lithium handling procedures may cause bodily injury and environmental and equipment damage. Carefully review safety information in Section 1.1, "Handling Batteries."

CAUTION—Before removing an OCS™ battery, make sure you are removing the intended battery. Although the system prevents you from removing more than one battery at a time, it is possible to remove any single battery, potentially leaving the system with NO charged batteries in place and shutting down system operation.

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

1. To test the battery before replacing it, press the battery test button (Figure 64). For instructions on testing battery charge status, see Section 9.2.2, "Checking System Battery Power."
2. Move the battery's retaining lever up and out of the way.

   CAUTION—Once you have removed an OCS™ battery, no other battery can be removed until you install a battery in the open slot and close the retaining lever. Do not try to forcefully remove a battery. Doing so may damage the system and the battery.

3. Firmly grasp the battery handle, pull the discharged battery straight out, and set it aside.
4. Slide the new battery into the open slot and move the retaining lever back in place, making sure the battery is secure.

   CAUTION—Ensure that the battery is oriented correctly (see Figure 64) prior to inserting it in the Liver Console. Push in gently. Excessive force may damage the battery, resulting in bodily injury and environmental and equipment damage.

5. Verify battery function by checking the battery status icon on the Wireless Monitor. For more information on viewing battery status, see Table 3.

NOTES—

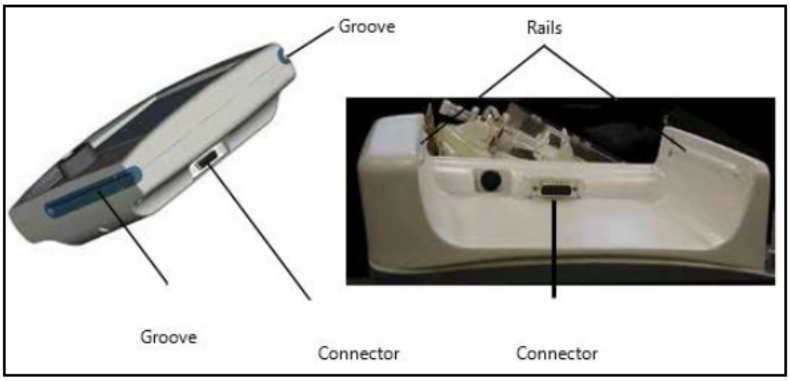
If you will not be immediately recharging the removed battery, return it to the original TransMedics shipping container for storage.

If you need to ship OCS™ batteries, they must be packaged for shipment by qualified personnel and shipped according to applicable transportation laws in the original shipping packages or replacements supplied by TransMedics.

9.3. Docking and Undocking the Wireless Monitor

The Wireless Monitor (Figure 65) has side grooves that slide over matching rails on the top of the Liver Console. A connector on the side of the Wireless Monitor inserts into a connector on the system.

Figure 65: Docking the Wireless Monitor



9.3.1. To Dock the Wireless Monitor

1. Position the Wireless Monitor so that its grooves line up with the rails on the system (Figure 65).
2. Slide the Wireless Monitor all the way into the Wireless Monitor docking 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 Liver Console so that the electrical contacts are fully connected. The DC Power LED (⎓) should be lit indicating the Wireless Monitor is receiving power from the system.

9.3.2. To Undock the Wireless Monitor

1. To undock the Wireless Monitor, use both hands to pull it straight along the rails until the Wireless Monitor clears the Liver Console.

9.3.3. Using the Wireless Monitor Remotely

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

CAUTIONS—

Before undocking the Wireless Monitor, check the Wireless Communication status icon to make sure it is safe to undock the Wireless Monitor (). If the Wireless Fault icon () is displayed, DO NOT undock the Wireless Monitor. Doing so may result in data loss.

Keep the Wireless Monitor within an unobstructed range of approximately 3 meters at all times and as close as possible to the system to facilitate quick response to alarms and other conditions that require intervention. If there is an obstruction between the Wireless Monitor and the system, the effective range may be reduced.

If the Wireless Monitor is out of range of the Liver Console for 10 minutes, it turns itself off. While the Wireless Monitor is off, the rest of the system continues to function. Once the Wireless Monitor is docked on the Liver Console, it turns itself back on and full monitoring functionality is restored.

When the Wireless Monitor is back in range, verify all parameters are as expected in the rare instance that a system event occurred while out of range.

If the Wireless Monitor unexpectedly generates an Out of Range alarm, verify that the OCS™ pump is still functioning and check the status of the organ.

During remote operation, all controls operate normally except the Run/Standby button () which functions only when the Wireless Monitor is docked to the system. The Run/Standby button lets you transition the OCS™ from an inactive state (Standby) to an active state (Run).

If the Wireless Monitor loses the wireless connection to the system, a warning tone emits and continues until the connection is re-established. Refer to the Cautions above for more information. In addition to the warning tone, the Wireless Fault icon blinks and is displayed in red (as shown at right).

If the Wireless Monitor battery fails, the screen goes blank and the Wireless Monitor does not function until it is docked on the system.

NOTE—Even though the Wireless Monitor is out of range, or the screen is blank when no power is available, the OCS™ continues working at the current settings, unless the OCS™ loses power. When the Wireless Monitor returns to normal operation, you can view the messages.

9.4. SDS Status and Monitoring

The OCS™ Liver System provides status pertaining to all 3 of the SDS channels on the main monitoring screen of the Wireless Monitor at all times. Figure 66 below shows the SDS status frame displayed on the lower right side of the Wireless Monitor. Table 15 below defines the values in the figure.

Figure 66: Wireless Monitor Main Screen Status

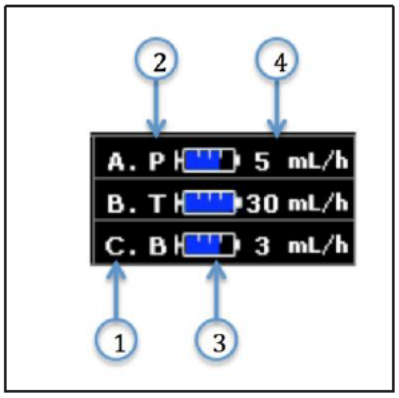


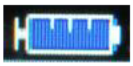
Table 15: Main Screen Status Items

Item	Description
1 - Channel Label	The channel label links the status with the channel as labeled on the SDS Console.
2 - Solution Type	This displays the solution type configured for each channel. PGI2 = Prostacyclin (Epoprostenol Sodium (Flolan or equivalent)) TPN = Total Parenteral Nutrition solution Bile Salt = Bile Salt solution

Item	Description
	N = None
3 - Estimated Volume Remaining	This is a graphical representation of the estimated solution remaining in its container based on the amount that has been delivered and the initial volume.
4- Current Delivery Rate	This displays the rate at which the channel is currently delivering solution.

Table 16 below defines the different icons used to convey status on the main monitoring screen of the Wireless Monitor.

Table 16: Main Screen Icon Descriptions

Icon	Description
	The icon with a dashed outline indicates that no SDS cassette is inserted.
	The icon with a solid outline and blue fill indicates that the SDS cassette is inserted and that the channel is in Manual Mode. The amount of blue fill in the icon is proportional to the estimated percent of solution volume remaining.
	The icon with a solid outline and grey fill indicates that the SDS cassette is inserted but the channel is not infusing. This generally occurs when the circulatory pump is Off. The amount of grey 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.

9.4.1. Solution Delivery Trending

The OCS™ Liver System stores the solution delivery rates over time for all channels. The Wireless Monitor is capable of trending the delivery rate in a trend graph or in conjunction with other trended parameters.

A trend graph can display the most recent 24 hours of session data, updated every two minutes. Each data point represents the average value calculated over the previous two minutes. The user can view 3 1/2 hours of data at once and use the rotary knob to scroll back and forth to review all the saved data.

To display the solution delivery rates trend:

1. Press the Configuration Menu button.
2. Turn the rotary knob to highlight the Liver tab and then press the knob.
3. Select Middle Graphical Frame or Bottom Graphical Frame.
4. Select **Primary**.
5. Choose the solution type to display in a graph: **PGI2**, **TPN**, or **Bile Salt**.
6. If desired select a Secondary parameter to trend.
7. If desired select a blood sample to trend.
8. Select **Accept** to close the Graphical Frame Menu.
9. Select **Accept** to accept changes and close the Configuration Menu.

9.4.2. Monitoring Alarms, Faults, and Advisories

When the SDS detects an operating problem, an audible indication commensurate with the priority of the problem is sounded and an alarm is displayed on the Wireless Monitor. Acknowledgement of alarms for the SDS is the same as all other alarms declared by the Liver Console. Refer to Table 26 for troubleshooting of SDS faults messages.

The SDS alerts shown in Table 17 below are monitored and declared during all modes of solution delivery.

Table 17: SDS Alerts Description

Alert	Description	Potential Actions
Channel Not Infusing	Occurs when a cassette is inserted and the circulatory pump is on but the SDS channel is configured to Off.	If solution delivery is desired, configure the channel to Manual mode.
Low Solution Remaining	Occurs when the SDS calculates that the solution remaining in the container is almost empty.	Replace the solution container with a full container and select Reset Statistics in the action menu for the desired channel.

CAUTIONS—

TransMedics-approved solutions have been tested on the OCS™ Liver System. Non-TransMedics-approved solutions have not been tested, and TransMedics cannot assure their compatibility.

Only the TransMedics-supplied infusion line may be used. Other infusion lines will not work with the OCS™ Liver System.

9.5. Using the Gas Cylinders

To assure that a sufficient supply of oxygen is continuously circulated with the perfusate, carefully monitor the gas status frame and the SvO_2 parameter on the Wireless Monitor display. For details of where gas-related parameters appear on the Wireless Monitor during a preservation session, see Chapter 10: Managing the System. If the system is in Standby Mode or the pump has not been turned on yet, open the gas valve and check the pressure gauge on the gas regulator in the Liver Console.

CAUTIONS—

It is vital to keep careful track of gas status before and during organ preservation. Insufficient gas supply may lead to tissue hypoxia.

Bring a spare gas cylinder if you anticipate that the amount of gas remaining in the gas cylinder will not last for the projected duration of preservation or if you anticipate any possible delays.

9.5.1. Estimating the Remaining Gas Supply

When the system is in Run Mode, the Wireless Monitor provides continuously updated information about remaining gas cylinder capacity. However, when the system is in Standby Mode, you can only estimate the remaining gas supply (without turning on the Wireless Monitor) by viewing the pressure gauge on the gas cylinder. Table 18 below indicates the hours of gas supply left at various pressure readings and flow rates.

Table 18: Hours of Gas Supply Remaining at Various Flow Rates and Cylinder Pressures

Pressure (psi)	Flow Rate (mL/min)										
	300	350	400	450	500	550	600	650	700	750	800
3000	21.5	18.5	16.2	14.4	12.9	11.7	10.8	9.9	9.2	8.6	8.1
2500	17.8	15.2	13.3	11.8	10.7	9.7	8.9	8.2	7.6	7.1	6.7
2000	14.0	12.0	10.5	9.3	8.4	7.6	7.0	6.5	6.5	5.6	5.2
1500	10.2	8.7	7.7	6.8	6.1	5.6	5.1	4.7	4.4	4.1	3.8
1000	6.4	5.5	4.8	4.3	3.9	3.5	3.2	3.2	2.8	2.6	2.4
500	2.6	2.3	2.0	1.8	1.6	1.4	1.3	1.2	1.1	1.1	1.0

9.5.2. Removing and Installing a Gas Cylinder

This section provides instructions for removing an empty gas cylinder and installing a new gas cylinder. It also provides details on how to determine if the regulator's yoke gasket is intact, and if necessary, how to replace it.

CAUTION—To minimize the time without gas supply to the organ, work as quickly as possible when removing and replacing gas cylinders during preservation.

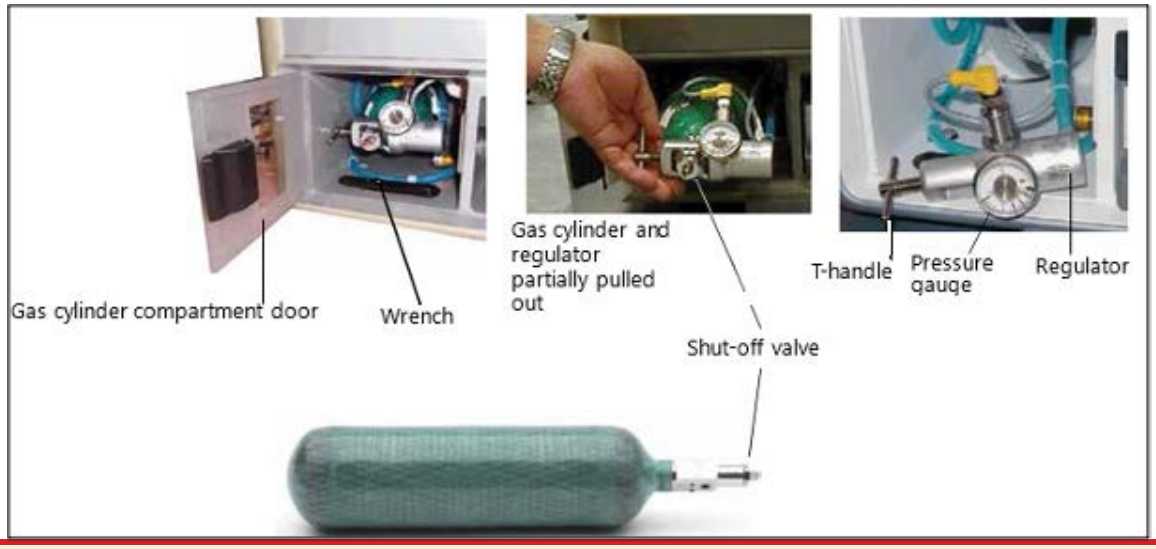
To remove an empty gas cylinder:

1. Lift the cylinder release handle on the front of the Liver Console (Figure 67).

Figure 67: Removing an Empty Gas Cylinder

2. Open the access door to the gas cylinder compartment (Figure 68).
3. Remove the cylinder wrench mounted inside the door at the front of the compartment on a Velcro® mounting strip.
4. Slide the gas cylinder partially out of the compartment so that you can access the regulator fitting.

Figure 68: Gas Cylinder and Regulator

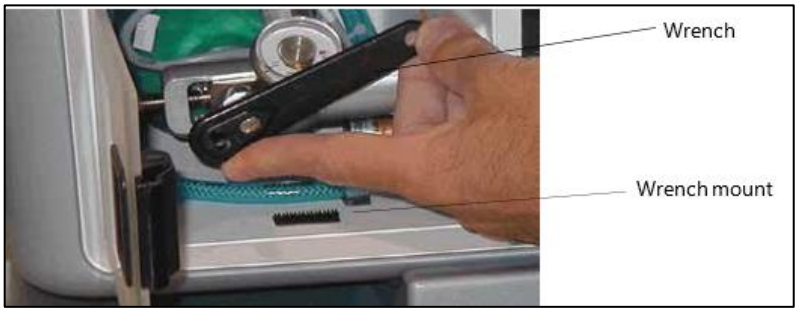


NOTE—You cannot remove the cylinder at this point because the regulator fittings and gauge are attached to the cylinder and are permanently connected inside the compartment.

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

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

Figure 69: Gas Cylinder Compartment Wrench



6. Using your fingers, loosen the T-handle (shown in Figure 68) that holds the cylinder in the regulator by turning the handle counterclockwise. Swing the regulator out of the way.

NOTE—You may hear a hissing sound from some residual gas venting as you disconnect the regulator. If the cylinder continues to vent, then the valve is not completely shut. To correct, immediately close the valve as described in step 5.

7. Gently slide out the empty cylinder. Use caution as the regulator is now hanging by tubing and cabling. Make sure the cylinder is completely detached before pulling it all the way out.

To install a new gas cylinder:

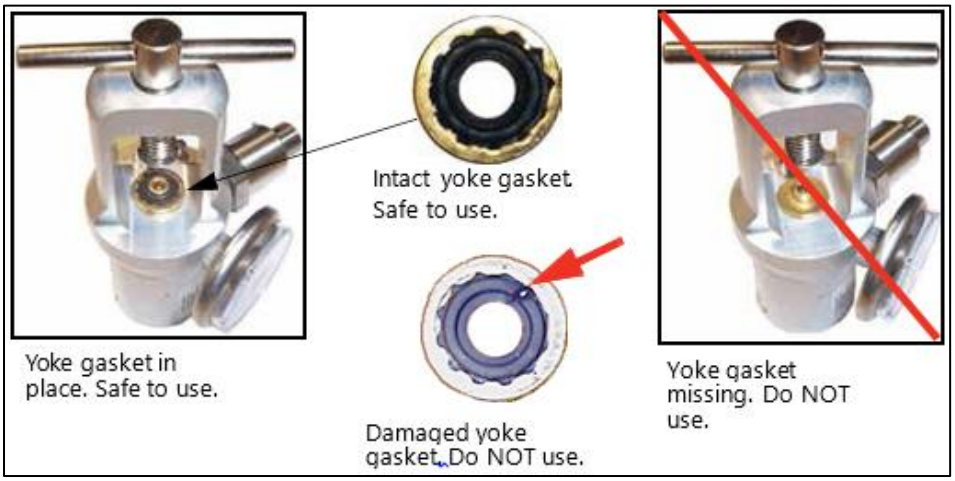
1. Remove the gas cylinder from the packaging, and remove the shrink-wrap packed around the valve, and then remove the white plastic plug.

> **NOTE—**Discard the shrink-wrap and plastic plug, but be sure to KEEP the other packaging to use when returning empty cylinders for refill.

2. Partially insert the new cylinder, with the bottom of the cylinder toward the Liver Console and the cylinder valve toward you.
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 in Section 9.6, "Replacing a Yoke Gasket."

> **WARNING—**Do not look into the high-pressure exhaust sources while connecting the gas cylinder to the regulator. Using a cylinder without a yoke gasket or with a damaged yoke gasket may cause the cylinder to leak high pressure gas, possibly resulting in injury.

Figure 70: Gas Cylinder-Regulator Yoke Gasket



4. Place the regulator on the valve stem and line up the pins on the regulator with the holes on the valve stem.

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

5. Hand-tighten the T-handle by turning the handle clockwise.
6. If you are ready to use the system, to test the gas valve, or to read the pressure level, use the gas cylinder wrench to open the valve slowly, turning it counterclockwise.
7. When the valve is open, ensure that the gauge indicates a high enough reading to meet the projected gas needs (Table 18). 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.
10. Lock the cylinder in place by pressing the cylinder release handle on the front of the system.
11. Close the access door to the gas cylinder compartment.

9.5.3. Returning an EMPTY Gas Cylinder to TransMedics

This section provides instructions for returning a gas cylinder to TransMedics. For safety reasons, a depleted gas cylinder must be fully emptied prior to shipping.

CAUTIONS—

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

Open the valve slowly. Opening it quickly or any further than 1/4 turn may cause the gas cylinder to move rapidly from its current location, which may result in bodily injury and property damage.

Use ONLY packaging or a replacement packaging supplied by TransMedics. Other containers may not sufficiently protect the cylinder from potential damage during shipment, and may not meet regulatory requirements.

To prepare a gas cylinder for shipping:

1. Move the partially empty cylinder to a well ventilated, open area and strap it to a stable cart, or place it on a stable flat surface where it cannot roll or fall.
2. Position the cylinder with the valve outlet face down, away from people and loose objects.
3. Slowly open the valve 1/4 turn.
4. After the cylinder is empty, leave the valve open.
5. Label the cylinder EMPTY, and pack it in the inner packaging in which the cylinder was originally shipped, and return it for replacement.

9.6. Replacing a Yoke Gasket

The yoke gasket is a gasket that seals the regulator to the gas valve. If it is damaged or missing (see example in Figure 70), it must be replaced.

To replace a damaged yoke gasket:

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

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

9.7. Using the TransMedics Data Cards

Transitioning from Standby Mode to Run Mode initiates an active period of OCS™ use known as a session. When the system is in Run Mode, system information is automatically stored internally. The system logs the following data:

- All system error events
- All system operating alarm events
- Trend data for each parameter at 2-minute intervals
- Blood gas sample values as entered by the user.

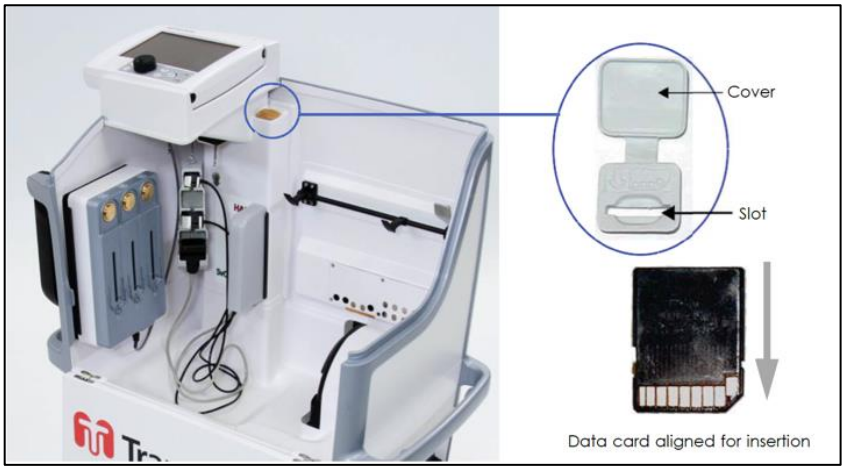
The OCS™ is shipped with data cards. Each card can hold data from multiple preservation sessions. TransMedics recommends installing the card prior to transitioning from Standby Mode to Run Mode, removing the card to retrieve data during the system shutdown protocol after the organ is removed, and then reinstalling it to prepare for the next session.

CAUTION—Use only data cards supplied by TransMedics. Other data cards will not function properly with the OCS™ and may cause a disruption of OCS™ operation.

NOTE— For instructions on transferring data from the OCS™ to the data card, see, Section 10.1.2, "Managing Session Files."

After you install a data card, the system automatically transfers all preservation session data to the data card. The system then updates it at 15-minute intervals. For details on data-related messages and status icons you may see when using a data card, refer to Chapter 10: Managing the System.

Figure 71: Data Card and Installation Slot



<u>To install a data card</u>:

1. With the system top cover removed, locate the data card slot at the back of the system at the top right of the Wireless Monitor docking area (Figure 71).
2. Open the slot cover.

3. Align the card vertically as shown in Figure 71 and gently push it into the slot.
4. Close the slot cover.

To remove a data card:

1. Open the slot cover.
2. Push the edge of the card down until the card releases and partially ejects.
3. Remove the card by pulling it straight up and out of the card slot.
4. Close the slot cover.

9.8. Using the Mobile Base

You 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 installed, the organ chamber is at bedside level. During transport, the push handle can be set to the up position and used to push the system. With the Mobile Base removed, the Liver Console can be set flat or carried by two people with the lift handles. (See

Figure 27.)

CAUTIONS—

Always use two people to lift or carry the OCS™, which may weigh up to 45 kg (100 lb) without organ, fluids, or the Mobile Base.

Always use a hand to open and close the Release Handle. Otherwise the mobile base could be damaged.

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

To remove the Mobile Base:

1. Close the front panel and install the top cover on the Liver Console.
2. Press each wheel lock downward to lock the Mobile Base in place.
3. Pull the Mobile Base release handle outward by hand to release the Mobile Base grips.
4. Using two people, lift the OCS™ with the right and left lift handles.

To mount the Liver Console to the Mobile Base and move the system:

1. Close the front panel and install the top cover on the Liver Console.
2. Orient the Mobile Base so that the rotating wheels face the right of the Liver Console and press each wheel lock downward to lock the Mobile Base into position.
3. Pull the Mobile Base release handle outward by hand to release the Mobile Base grips.
4. Using two people, lift the OCS™ with the right and left lift handles and position it on the Mobile Base.
5. Adjust the Liver Console until the Mobile Base is in place.

6. Push in the Mobile Base release handle by hand to activate the Mobile Base grips.
7. When ready to move the system, lift the wheel locks to unlock the wheels, and set the push handle to the up position.

10. CHAPTER 10: MANAGING THE SYSTEM

This chapter provides information and instructions for managing the OCS™ Liver System.

10.1. Managing Sessions

A session is a period of time during which the system is in active use. During a session, users can perform such tasks as priming the LvPM circuit and preserving and monitoring the liver. This section provides information and instructions for managing each session. It includes how to switch the system from Standby Mode to Run Mode, and how to manage session files.

10.1.1. Using Standby Mode and Run Mode

When the OCS™ power switch is turned ON, you can select one of two power modes: Standby Mode and Run Mode. Standby Mode is intended for when the OCS™ is not in active use. To initiate a session and begin active use of the OCS™, transition to Run Mode. In Run Mode, the OCS™ and Wireless Monitor are fully functional, with monitoring capabilities enabled.

CAUTIONS—

The  button on the Wireless Monitor functions only when the Wireless Monitor is docked on the Liver Console.

To completely turn the system off, press the power switch (located on the lower left side of the system) and unplug the system.

10.1.1.1. Using Standby Mode

Use Standby Mode to conserve power and to recharge the batteries during storage. In Standby Mode:

- The Wireless Monitor display is blank (off)
- The circulatory pump is turned off
- The blood warmer is turned off
- Gas flow is turned off.

Standby Mode is the recommended power mode for storage of the OCS™. While in Standby Mode, the batteries in the Wireless Monitor and OCS™ can be charged if the OCS™ is connected to an appropriate power supply and the On/Off button is set to the On position.

NOTES—

When the OCS™ is in Standby mode and not connected to AC power, the batteries will deplete. TransMedics recommends connecting the OCS™ to AC power whenever possible.

Batteries will not charge if the On/Off button is set to the Off position. TransMedics recommends leaving the On/Off button set to the On position at all times except when the device must be powered down for service or cleaning.

CAUTION—Standby Mode should be used only when an organ is not being preserved.

10.1.1.2. To Enter Standby Mode

Connect the system to AC power if storing the system

With the system in Run Mode, dock the Wireless Monitor and press the  button. The system prompts you to confirm that you want to enter Standby and, if a data card is not installed, to optionally insert a data card.

CAUTION—The  button on the Wireless Monitor functions only when the Wireless Monitor is docked on the Liver Console.

To transfer files and enter Standby mode, insert a data card if necessary and select Enter Standby. If a data card is installed, the system begins transferring session data to the data card.

The Wireless Monitor turns off, and the system transitions to Standby mode.

10.1.1.3. To Enter Run Mode from Standby Mode

1. Press  . The system automatically performs a Self Test and displays system messages. The system prompts you to either create a new session file or to continue the previous session.
2. Do one of the following:
   - To create a new session, select **New Session File**. The system configuration reverts to the saved session defaults.
   - To continue adding data to the previous session, select **Continue Prior Session**. The system configuration retains its latest settings.

NOTE—If the system detects an issue during the Self Test, a message is displayed with information about the issue until it is resolved. For more information about system messages, see Chapter 12: Troubleshooting."

10.1.2. Managing Session Files

This section provides information about the type of data that is collected during each session, and how to copy the session data to a data card.

A session is created in internal system memory when the system is set to Run Mode. Every time Run Mode is entered, you can choose whether to continue using the last session file or create a new one.

When you insert the data card, the latest state of the session files for the current session is copied to the card.

TransMedics recommends that you insert a data card at the beginning of each session.

NOTE—Under ordinary circumstances, data from all procedures associated with an organ should be documented in only one session.

Data are continuously saved in internal memory. The OCS™ will log critical data regardless of the state of the Alarm System and regardless of whether a data card has been inserted by the user. The OCS™ will retain logged data after a total loss of power.

All session data from internal memory is automatically transferred to the user accessible card when the user inserts a data card. If the card is left in this external slot, data from the current session is updated every 15 minutes and upon entering Standby.

The 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 2-minute intervals.

The data saved on the SD data card are in .xls or .txt file format. Table 19 below describes the contents of the session files.

Table 19: Session Data Files

File Name	Data Logged
events.txt	Includes the following text that is associated with the current session: Alarms, annotations, configuration settings, and other changes to system setup and operation, logged by date and time.
trends.xls	Includes trend data associated with the current session for all parameters sampled at two-minute intervals and logged by date and time. The trend data saved on the data card is tab-delimited and the column data format is general.
blood-sample.xls	Includes blood sample data entered by the user associated with the current session for all parameters sampled including the time and type (Arterial or Venous).
system-errors.txt	This text file contains the system's cumulative error history, logged by date and time.

To copy sessions to the data card:

1. Insert the TransMedics data card into the card slot. All available data from the current session are automatically transferred to the card.
2. To obtain data from previous sessions, press  and do one of the following:
   - To copy the last five sessions, select Copy Last Five Sessions.
   - To copy all the sessions that are currently stored in the OCS™'s internal memory, select Copy All Sessions.

CAUTIONS—

To avoid possible operational problems, use only data cards supplied by TransMedics.

While a data transfer is in progress, the data card status icon is displayed with a green arrow. To avoid data loss or corruption, do not remove the card while the transfer is in progress.

NOTE—You can perform other tasks while the session data are being transferred to the card. However, do not remove the card until the data transfer is complete.

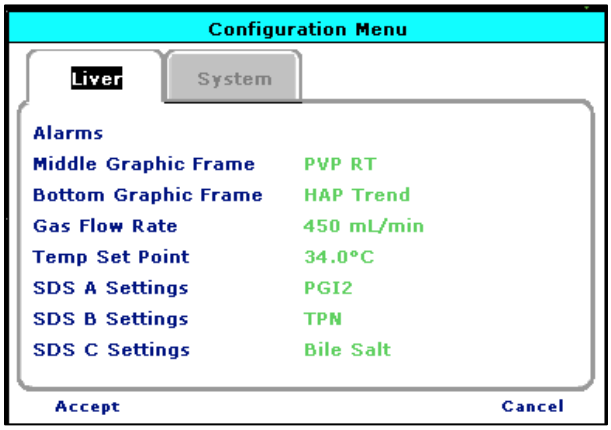
10.2. Using the Configuration Menu

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 Liver tab (Figure 72) to configure parameters such as alarm ranges, gas flow rate or blood temperature.

Menu selections are effected using the rotary knob. As the knob is rotated, menu items are highlighted. When you press 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.

Figure 72: Configuration Menu Tab



To display and use the Configuration Menu:

1. Press the Configuration Menu button to display the **Configuration Menu**.
2. To select a tab, turn the rotary knob to highlight one of the tabs
3. To select the highlighted tab, press the knob. The menu associated with the selected tab is activated. Turn the knob to scroll through the fields on the selected menu.
4. To select an item, highlight it and press the knob. The selected item blinks. Turn knob to the value you want and press the knob again. The knob returns to its item-selection function.
5. To change a parameter, turn the knob to the value you want and press the knob again.
6. To complete configuration changes, do any of the following to exit the **Configuration Menu**:
   - To apply and save the changes, select **Accept**.
   - To cancel the changes, select **Cancel**.
   - To select another tab on the **Configuration Menu**, turn the knob.

10.3. Using the Action Menu

Use the Action menu to perform the tasks in Table 20 below.

Table 20: Action Menu Functions

Action	Description
Display Status	Displays technical information about the Liver Console and the LvPM.
Display Alarm Summary	Displays a summary of the current alarms.
Start/Restart Perfusion Clock	Resets the Perfusion Clock to zero, or if the Perfusion Clock is not currently running, starts the Perfusion Clock.
Add Annotation	Lets user enter text strings that are added to the session event file.
Record Blood Sample Data	Lets user enter blood gas sample data for display as a trend and for inclusion in the session file.
Edit Blood Sample Data	Lets user edit blood gas sample data that has been entered into the session file.
Copy Current Session	Copies the current session folder to the external SD card.
Copy Last Five Sessions	Copies only the most recent five session folders to the external SD card.
Copy All Sessions	Copies all session folders to the external SD card.
Scale HAP	User can switch between fixed real-time waveform scales or use automatic waveform scaling
Scale PVP	User can switch between fixed real-time waveform scales or use automatic waveform scaling
Toggle Trend Scroll	Switches the trend graph scrolling method between scrolling by each sample (with a cursor) and scrolling by 30-minute pages.
De-air SDS Lines	Lets user de-air desired SDS line(s).
Reset SDS A Statistics	If an infusion bottle or bag is depleted and needs to be replaced, this allows user to reset the statistics of the infusion for channel A including the initial volume and calculated remaining time. Total volume infused remains unaffected.
Reset SDS B Statistics	Allows reset of statistics mentioned above for channel B.
Reset SDS C Statistics	Allows reset of statistics mentioned above for channel C.

To display and use the Action Menu:

1. Press  to display the Action Menu shown in Figure 73 below.

Figure 73: Action Menu

2. To scroll through the available menu items, turn the rotary knob to highlight the items.
3. To select the highlighted item, press the knob.
4. If the selected item has a menu associated with it, the menu is activated. Turn the knob to scroll through the fields on the selected menu.

5. To select an item, highlight it and press the knob. The selected item blinks.
6. To change a set-point, turn the knob to the value you want and press the knob again. The knob returns to its item-selection function.

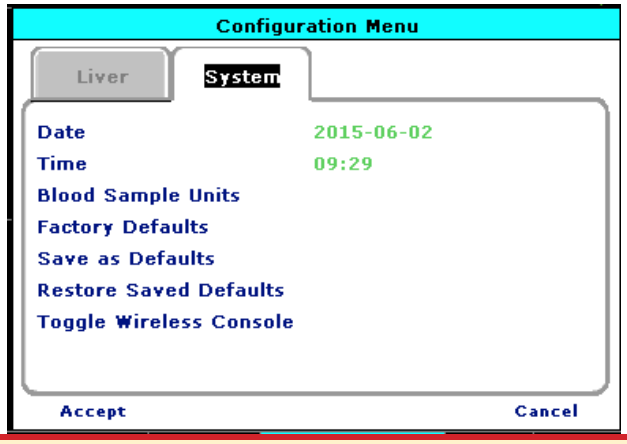
10.4. Configuring System Settings

This section describes how to configure the system settings to include setting the time and the date.

10.4.1. To Configure the System Settings:

1. Set the time and date displayed by the system.
2. Configure the units displayed for the trended blood samples
3. Set the system configuration to factory default settings for alarm limits, graphical frames configurations and blood sample units.
4. Save current system configuration as the Saved Defaults.
5. Set the current system configuration to the Saved Defaults.

Figure 74: Configuration Menu System Tab



CAUTION—The system does not automatically adjust for Daylight Saving Time. If your area uses Daylight Saving Time, you need to manually reset the time to adjust to Daylight Saving Time.

NOTE—Set the system time before starting the perfusion clock. Once the perfusion clock is running, you cannot set the system time until you start a new session.

10.5. Configuring Session Settings

This section describes how to configure the system.

10.5.1. Configuring Alarms

Use the Alarm Setup window (Figure 75) to configure the alarm ranges and settings. You can configure each physiological alarm's enable/disable setting individually.

In the Alarm Setup window, rotate the knob to highlight the value you want to change and press the knob to activate the selection. Rotate the knob 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.

Each time you place the system in Run mode, the alarms that you configure are automatically in effect. The △ icon indicates that an alarm is on and will display on the Wireless Monitor if the value rises above or falls below the settings. The 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.

CAUTIONS—

Do not set alarm limits to extreme values that can render the alarm system useless.

The Liver Console will log critical data regardless of the state of the alarm system.

Alarm system setting are restored automatically after a power loss of any duration.

For more information about alarms, see Section 10.8, "Managing Alarms."

Figure 75: Parameter Alarms

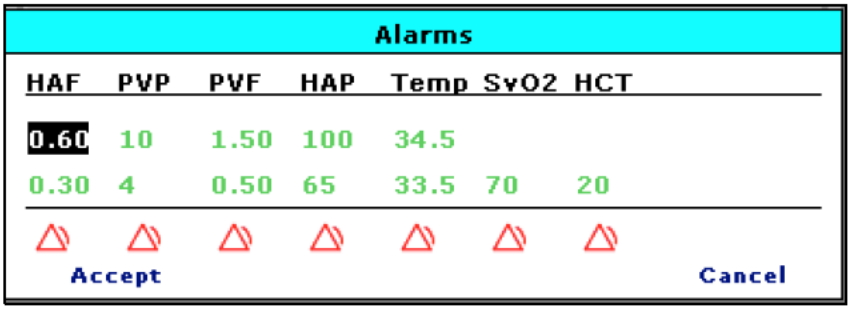


Table 21 below lists the alarm limit ranges and the factory default settings.

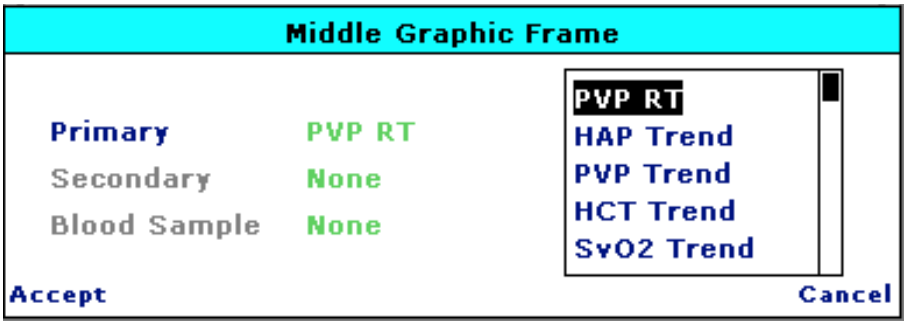
Table 21: Alarm Limits Ranges and Factory Defaults

Parameter	Range	Lower Limit Factory Default	Upper Limit Factory Default
HAF	0.20-1.05 L/min	0.30 L/min	0.6 L/min
PVF	0.45-2.05 L/min	0.50 L/min	1.50 L/min
HAP	40-150 mmHg	65 mmHg	100 mmHg
PVP	0-15 mmHg	4 mmHg	10 mmHg
TEMP	33-38°C	33.5°C	34.5°C
SvO_2	55-95%	70%	n/a
HCT	16-30%	20%	n/a

10.5.2. Configuring Graphic Frames

Use the Middle Graphic Frame (Figure 76) and Bottom Graphic Frame menu options to configure which graphic frames are displayed in the middle and bottom sections of the Wireless Monitor.

Figure 76: Middle Graphic Frame



You can configure the middle and bottom graphical frames to display different combinations of real-time, trend, and blood sample graphs. For each graphical frame, a primary, secondary and blood sample graph may be configured.

10.5.2.1. Setting the Gas Flow Rate

Use **Configuration Menu** to specify the amount of gas flow in mL/min. Each time you enter Run Mode during the session, the gas flow rate that you configure is automatically in effect.

10.5.2.2. Setting the Temperature Set Point

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

CAUTION—When setting temperature, carefully follow the directions for use.

10.5.2.3. Setting the Blood Sample Units

The Liver Console is capable of displaying blood gas samples as entered by the user in a trend graph. Use the System (Figure 72) tab of the Configuration Menu to configure blood sample units for parameters that can have multiple types of units.

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

10.6. Managing Configuration Settings

This section provides information and instructions for saving default settings and restoring system settings. It also lists the system parameters, ranges, and factory-default values.

10.6.1. 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.

10.6.2. Restoring System Settings

Use the **System** tab of the **Configuration Menu** to restore the saved defaults and to restore the factory defaults. Restoring to the saved settings reverts all settings to the last saved session defaults. Restoring to the factory settings reverts all settings to the factory default settings.

CAUTION—Before saving your selections by selecting **Accept** or **Save as Defaults**, be sure to review the displayed settings to make sure you have set these parameters for adequate organ preservation.

Table 22 below lists the system parameters, ranges, and factory-default values. When you restore the system to its factory-default settings, all parameters are changed to the factory-default values shown in this table. For factory-default alarm settings, see Table 21 above.

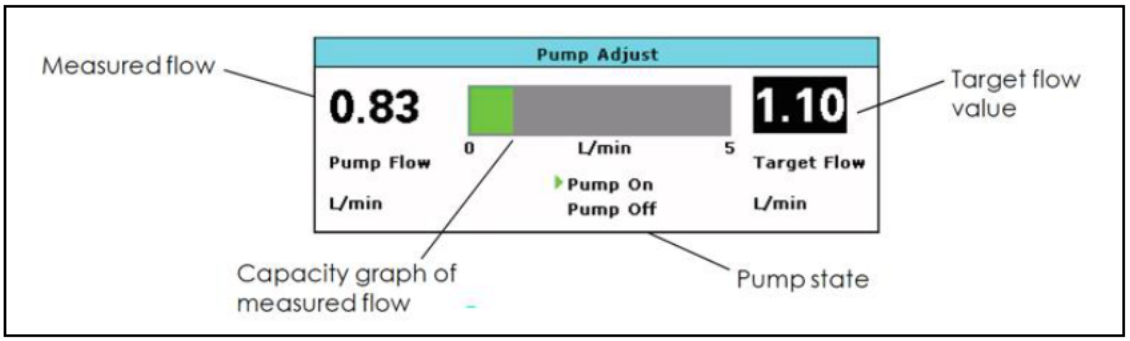
Table 22: System Parameter Ranges and Default Values

Parameter	Range	Factory Default
Gas Flow Rate	0, 300-800 mL/min	450 mL/min
Temp Set Point	Off, 34-37°C	34°C
Time of Day	Hours: 0-23, Minutes: 0-59	current time at factory
Date	Months: 1-12 Days - 1-31 Year - 04-99	current date at factory
Top Graphic Frame	Always HAP real-time waveform	Not configurable
Middle and Bottom Graphic Frames	Real Time Waveform: PVP Trend Display Options: HAP, PVP, HAF, PVF, Temp, SvO_2, HCT, Pump Flow, TPN, PGI2, Bile Salt Blood Sample Display Options: Lactate, pH, pCO_2, pO_2, BEecf, HCO_3, TCO_2, Sodium, Potassium, Calcium, Glucose, Hematocrit, Hb	Middle: PVP real-time Bottom: HAP, PVP, and Lactate
Perfusion Clock	On, Off	Off at system initialization

10.7. Adjusting the Pump

Use the Pump Adjust window (Figure 77) to adjust the flow between 0-5 L/min (liters per minute).

Figure 77: Pump Adjust Window



CAUTION— Perfusate warming, SDS infusion, and gas flow are enabled only when the pump is on (and if the pump becomes faulted). Setting the pump to OFF turns off the circulatory pump, SDS infusion, the gas, and the blood warmer. When the pump flow is off, physiological parameter alarm monitoring is disabled.

To adjust the pump:

1. Press  to open the Pump Adjust window (Figure 77).
2. Do one of the following:
   - To increase pump flow, turn the knob clockwise.
   - To decrease pump flow, turn the knob counterclockwise.
   - To turn the pump off, turn the knob all the way counterclockwise until the green arrow in the status icon indicates that the pump state is off.
   - As you turn the knob, a target flow value displays on the right side of the window, indicating the estimated pump flow that will be produced by your adjustments. The value shown on the left side of the window shows the currently measured pump flow.

   NOTES—

   Invalid adjustments generate an error tone.

   The displayed target flow value is an estimate based on the initial flow and the dialed-in adjustments.
3. To close the Pump Adjust window, press the knob or press  .

NOTE—After 90 seconds of knob inactivity, the Wireless Monitor automatically exits the Pump Adjust window.

10.8. Managing Alarms

The system produces both visual and audible indicators of various alarm conditions to make you aware immediately when there is an important physiological or system condition that requires attention. This section provides information about the visual and audible alarms, and how to manage them.

10.8.1. Overview of Alarms

The Alarm Banner, located at the top of the Wireless Monitor screen, provides summary information about the current alarms. For more information, see Section 3.2.1.3.1, “Alarm Banner.”

Critical alarms that require you to acknowledge them (such as system reset) display with a red background in the Alarm Banner; the text blinks red and gray and the Alarm Banner stays on that alarm message until it is acknowledged. Press  to acknowledge the alarm.

Non-critical alarms rotate through the Alarm Banner and will disappear without user acknowledgement if the condition is resolved. Non-critical alarms can be one of the following three types:

- High priority alarms (red) are system faults (such as a probe fault)
- Medium priority alarms (yellow) are physiologic (such as limit violations), or capacity-related (such as battery/gas low)
- Low priority alarms (blue) are system-related (such as SDS channel not enabled).

The parameter or status icon associated with the alarm flashes on the Wireless Monitor to help you quickly identify the issue and respond accordingly.

The **Low gas remaining** alarm is an example of a medium (yellow) alarm message. It appears on the Alarm Banner and the icon has a corresponding color indication. The alarm indications are dismissed when the condition is resolved. For example, when you turn off the gas, or replace the gas cylinder with a full tank of gas, the low gas alarm condition is resolved.

For more information on configuring alarms, see Section 10.5.1, "Configuring Alarms." When alarm settings for parameters are disabled, or if the parameter has not yet achieved a value within that parameter's configured alarm limit range, or if the pump is off, the icon is displayed with that parameter on the Wireless Monitor.

Table 23 below summarizes the indicators that may occur during system operation. System faults that may require TransMedics service are listed in Chapter 12: Troubleshooting.

Table 23: Types of Alarms

Alarm Type	Example	Visual Indicator	Action Required
Physiological	Parameter value exceeds high or low alarm limit or goes from in-range to out-of-range	Parameter value border blinks and a message is also displayed in the Alarm Banner.	• Investigate the physiological cause of the alarm. • Change the control settings that affect the parameter. • Change the alarm limit. • Press to silence the alarm for one minute. • Press and hold to disable all audible alarm indications.
Capacity	Low system batteries, low Wireless Monitor battery, low gas level	Capacity level alarm is displayed (as shown in Table 3) and a message is displayed in the Alarm Banner	• Replace the battery or gas in response to the capacity alarm. • Connect the system to AC power. • Dock the Wireless Monitor to recharge the battery. • Press to silence the alarm for five minutes. • Press and hold to disable all audible alarm indications.
System Fault	Wireless Monitor wireless link is lost	Associated system icon blinks with a red background and a message is displayed in the Alarm Banner	• Refer to the Alarm Banner message for details in response to the system fault alarm. • Press to silence the alarm until the condition recurs. • Press and hold to disable all audible alarm indications.
Critical System Fault	Reset occurred, Self Test bypassed	Parameter value border blinks and a message is displayed in the Alarm Banner until the fault is acknowledged	• Must be acknowledged. Press to acknowledge and dismiss the alarm. The message continues to display in the Alarm Banner until the alarm is acknowledged.

10.8.2. Audible Alarm Indicators

Audible alarm indicators consist of various alarm sounds associated with the type of fault detected. For example, pressing an incorrect key generates an error tone, sounded at the time of the key press; an out-of-range parameter beeps until the condition is changed or until the alarm is silenced.

The auditory alarm signal sound pressure is approximately 84 dB.

NOTES—

A parameter is expected to fluctuate at the beginning of monitoring, so an alarm will not sound until the value settles into the configured limit range. This alarm state is referred to as "initial suspend." Once a parameter's values are within the limits, alarm processing is enabled, and any time the parameter is out of the preset alarm range, an alarm will sound.

When the condition that caused an alarm is rectified, the associated visual and audible indicators return to normal.

Alarms associated with an out-of-range Wireless Monitor do not affect data collection; all data will continue to be collected, even though the Wireless Monitor is not displaying the data. Once the Wireless Monitor is brought within range, data will display again, and all the data acquired during the out-of-range period will be available for scrolling.

10.8.3. Displaying the Summary of Alarm Messages

The **Display Alarm Summary** item in the **Actions Menu** lets you quickly review the list of current alarm messages.

NOTE—The **Display Alarm Summary** is a snapshot. It does not update in real-time with the changing contents of the Alarm Banner.

10.8.4. Responding to Alarms

The Alarm Silence  button lets you silence (acknowledge) active alarms temporarily, or lets you enable and disable audible alarm alerts indefinitely.

10.8.4.1. To temporarily silence (acknowledge) an alarm

Press  briefly to silence an alarm.

When you silence an alarm:

- The visual flashing of a physiological parameter alarm stops but the border remains highlighted to match the priority as long as the alarm is active.
- There is no icon to represent a silenced alarm in the parameter box.
- Capacity alarms are silenced for five minutes; physiological alarms are only silenced for one minute; system fault alarms are silenced indefinitely.

10.8.4.2. To disable alarm tones

Press and hold  to disable all audible alarm tones indefinitely. Visual alarm indications continue to display. The Wireless Monitor also emits a beep every 2 minutes and a message is displayed in blue on the Alarm Banner to remind you that the audio alarm is off.

The  icon is displayed at the left of the Alarm Banner to indicate audio alarm tones are disabled.

10.8.4.3. To enable alarm tones

Press and hold the  for two seconds. The  icon is displayed in the Alarm Banner to indicate visual and audio alarm tones are enabled.

10.9. Managing Pressure Waveforms

The main center section of the Wireless Monitor displays waveforms or trends, depending on the configuration. The top-most graphic frame on the main monitoring screen always displays the Hepatic Artery pressure (HAP) real-time waveform.

Real-time waveforms are time synchronized and display continuously updated data. The waveforms are drawn from left to right with the most current data. An eraser bar erases the oldest data first.

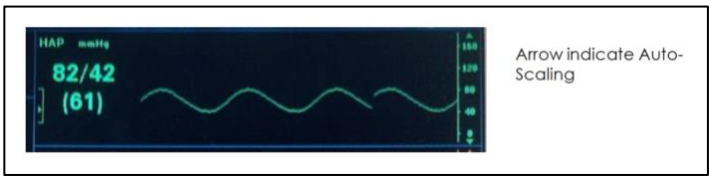
10.9.1. Pressure Waveforms

Real-time pressure waveforms are automatically scaled within a set of fixed ranges that automatically change as the pressure range changes. You can also manually scale the pressure waveforms using the **Actions Menu**. If no pressure data is detected, the parameter value displays as (-?-) and a flat line displays at the bottom of the frame.

10.9.2. Scaling Pressure Waveform Data

In Auto-Scaling mode, the graph is scaled automatically based on the amplitude of the displayed pressure data. Arrow icons are displayed at the top and bottom of the y-axis scale when this mode is active.

Figure 78: Auto-Scaling Waveform



In manual scaling mode, the graph remains at one of the fixed scales that you configure by accessing the Actions Menu. When this mode is active, no arrow icons are displayed at the top and bottom of the y-axis scale.

10.10. Managing Trend Graphs

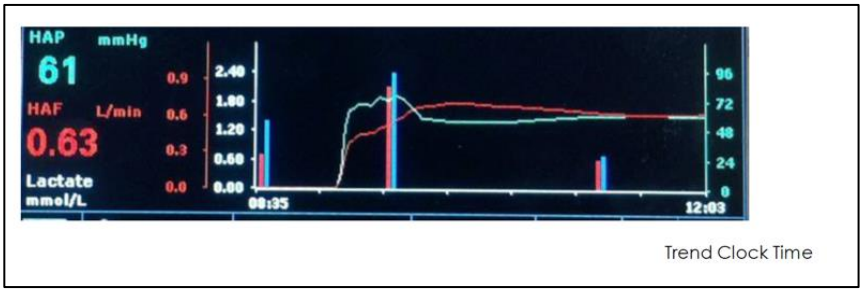
One or both of the bottom two graphical frames can be configured to display a constantly updated trend graph for any physiological parameters and a single blood sample parameter.

A trend graph can display the most recent 24 hours of data, updated every two minutes. Each data point represents the average value calculated over the previous two minutes. You can view 3½ hours of data at once and use the rotary knob to scroll back and forth to review all the saved data.

CAUTION—If the time or date is changed through the **Configuration Menu** before starting the Perfusion Clock, the date and time of the previously saved trend data does not change. The dates and times prior to the change reflect the time and date settings at the time the trend was drawn.

Although each trended parameter has an individual scale display relevant to the parameter, all share the same graph components as those shown in Figure 79. The most recent data is shown to the right in the graph and the oldest data to the left.

Figure 79: Sample Trend



All available trend data is saved with the session file and is transferred to the external data card.

10.10.1. Using Scrolling and Cursor Mode

Use the **Scroll Trends** command in the Action menu to scroll through the current trends displayed in the lower two graphical frames. When scrolling through a trend, each click of the knob represents approximately 30 minutes of data, with the screen showing 3½ hours of data at a time. In **Cursor** mode, you can position a cursor on the trend graph to view the parameter values at that time point. In addition to historical parameter data, results of blood and perfusate samples entered into the system can also be viewed. The values and their associated colors and labels are displayed in the trends window. The color blue and the label **V:** indicates the values of samples taken from the venous site. The color red and the label **A:** indicates the values of samples taken from the arterial site.

NOTE—To quickly determine if you are viewing trended data or live data, the bottom axis (x-axis) blinks when Scroll Trends is active. If the sample time displayed on the right of the x-axis is the current time, the trend data continues to update with the latest data.

To scroll trend data:

1. Press the Action Menu button.
2. Select Toggle Trend Scroll. The x-axis of the trend frame blinks to indicate scroll mode.
3. Turn the knob clockwise to view the most recent time; turn counterclockwise to view the previous data in half-hour increments.
4. Press the knob to switch from scroll mode to cursor mode.
5. A vertical cursor line is displayed in the trend window. Trend values are displayed with labels and colors to indicate the data. Turn the knob clockwise or counterclockwise to move the cursor through the trend window.

6. Press the knob to return to scroll mode.
7. To exit, press and hold the rotary knob for 2 seconds.

10.11. Starting and Resetting the Perfusion Clock

To manually start or restart the perfusion clock, press the **Action Menu** button to display the **Action Menu**. Use the rotary knob to highlight "Reset Perfusion Clock" and press knob to start or reset the clock.

CAUTION—When a new session is started, the perfusion clock is reset to zero and turned off.

NOTES—

Set the system time and date before starting the perfusion clock. Once the perfusion clock is running, you cannot set the system time and date until the next session.

To display trend data on the Wireless Monitor, and to capture it in a session, the perfusion clock must be turned on.

10.12. Managing Blood Sample Data

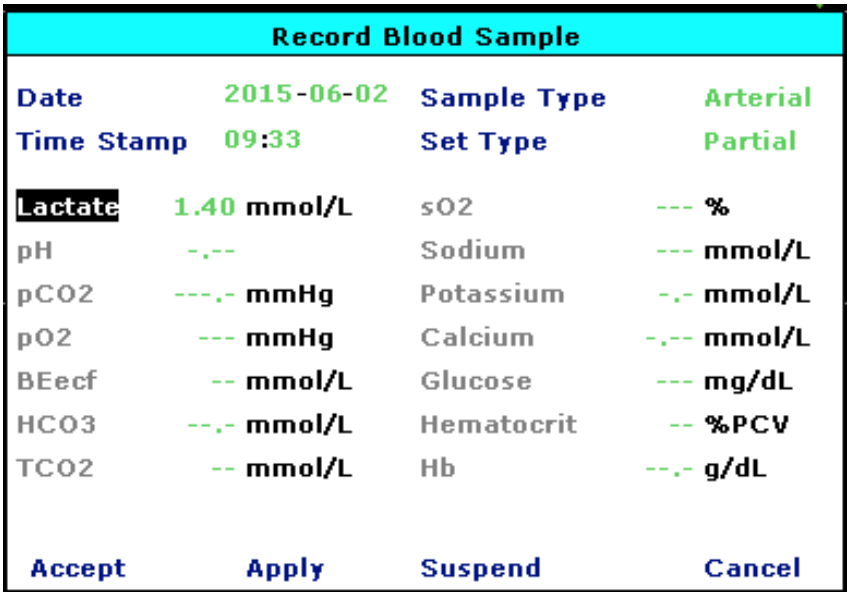
You can enter time-stamped blood sample data into the system from a blood gas analyzer. The data are recorded in the session data set, and can be graphed with other trend graphs of OCS™ parameters.

Use the Action Menu to add, edit, and delete the following types of blood sample data. You can specify the Sample Type (Arterial or Venous), and the Date. You must enter a time in the Time Stamp field.

- Lactate
- pH
- HCO_3
- TCO_2
- SO_2
- Sodium
- Calcium
- Potassium
- Glucose
- pCO_2
- pO_2
- BEecf
- Hematocrit
- Hb

Select **Record Blood Sample** in the Action Menu to add blood sample data during the preservation session. Lactate is the default blood sample. If you need to enter other blood sample types, you can highlight Set Type to select Full Set and turn the knob to highlight other blood sample types.

Figure 80: Blood Sample Input Window



To add blood sample data:

1. Use a blood gas analyzer to analyze the blood sample and output the results.
2. Press **Action Menu** button.
3. Rotate the knob to highlight **Record Blood Sample** and press the knob. The **Blood Sample Input** window is displayed (Figure 80). The last values entered for each blood sample type are listed.
4. Enter the date in the **Date** field.
5. Enter the time of the sample in the Time Stamp field.
6. Select the Sample Type: Arterial or Venous.
7. Do either of the following:
   - Modify the **lactate** value.
   - If you need to enter additional blood sample values, turn the knob to highlight **Full Set**. Press the knob and turn it to highlight the next blood sample type and enter the value.

   To select the value for the lactate blood sample, turn the knob to increase or decrease the value. Press the knob to enter the highlighted value.
8. Do one of the following:
   - To accept the values and close the Blood Sample Input window, select Accept.
   - To apply the values without closing the window, select Apply.
   - To hold the values and close the window, select Suspend. When you reopen the Blood Sample Input window, the last values you entered are displayed.
   - To discard the values and close the window, select Cancel.

9. If you applied or accepted the values, a message is displayed prompting you to confirm that you updated the required fields. Make sure the time, date, and type are entered and select **Accept**, or select **Cancel** and enter the time in the **Time Stamp** field.

To edit and delete blood sample data:

1. Use the Actions Menu to edit and delete blood sample entries taken during the preservation session. You can scroll through the blood sample entries by the time stamp entered for each entry.

NOTE—You can only edit and delete analyte results. You cannot change the data in the **Date**, **Time Stamp**, or **Type** fields.

10.13. Using Annotations

You can add notes and comments during the preservation session as Annotations. You can also use the **Annotation Menu** through the **Action Menu** to enter an organ identifier to the session files. Annotations are automatically stamped with the time of entry and saved in the session file. You can enter up to 60 characters at a time on two lines. Annotations should not contain any information that needs to be protected from unauthorized disclosure.

NOTES—

If you attempt to enter more keywords or characters than permitted, an error tone sounds and the highlight is automatically shifted to the **Accept** button. If you are in the process of adding a keyword when the 60-character limit is reached, the entry is truncated to fit.

The Wireless Monitor will present a reminder if the user has not entered an Organ ID within 35 minutes of the start of a new session.

Select **Add Annotation** in the Actions 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.

10.14. Displaying System Status

The **Display Status** item in the **Action** menu lets you quickly review the current status of system components and settings. This function is also useful when communicating system information to TransMedics.

11. CHAPTER 11: CLEANING AND MAINTAINING THE SYSTEM

This chapter describes how to clean, disinfect, and inspect the OCS™ Liver 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™ Liver 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.

11.1. Cleaning and Disinfecting the System after Use

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

11.1.1. 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.

11.1.2. 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.

11.1.3. 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.

11.1.4. 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.

11.1.5. Cleaning and Disinfection Process

Use Table 24 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 24, 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 11.2, "Cleaning and Disinfecting the Probes."

Table 24: Cleaning and Disinfecting the Liver 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 Liver Console's top cover and open the front panel. 6. Remove and dispose of the LvPM and accessories. 7. Repeat steps 2-4 on the Liver Console's internal surfaces.
Disinfection of Interior of System with Covers Open (LvPM Already Removed)			
Painted surfaces (white) with exception of Circuit Board Connector Block	Bleach wipes Tongue depressors Soft lint-free cloths Lint-free swabs Water	10 minutes	1. Wipe with bleach wipes. Wrap the bleach wipe around a tongue depressor to access smaller areas as needed. 2. Pay particular attention to the floor of the system, where fluids and spills may accumulate, making sure no fluids are left in the unit. 3. Avoid getting any bleach on the gas line connectors when wiping the surrounding painted areas.

Area	Supplies	Exposure Time	Cleaning Procedure
			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 11.2, "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 Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Inside of front panel	Bleach wipes Soft lint-free cloths Water	10 minutes	1. Wipe surfaces with bleach wipes, supporting the panel to avoid breaking it.

Area	Supplies	Exposure Time	Cleaning Procedure
			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. 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	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. Wrap the alcohol wipe around a tongue depressor to access smaller areas as needed.

Area	Supplies	Exposure Time	Cleaning Procedure
	Tongue depressors 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.
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 Soft lint-free cloths Water	5 minutes (twice)	DO NOT ALLOW CONNECTOR PINS TO GET WET. 1. Wipe with alcohol wipes and swabs. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry.
Screen, rotary knob, keypad, black side rails	Alcohol wipes Alcohol swabs Soft lint-free cloths Water	5 minutes (twice)	1. Wipe with alcohol wipes and swabs. 2. Repeat after first 5-minute exposure time has elapsed. 3. After second exposure time, remove the excess of disinfectant with a soft lint-free cloth moistened with water and then dry. 4. Dock Wireless Monitor.
Disinfection of Mobile Base with OCS™ Removed			
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.

Area	Supplies	Exposure Time	Cleaning Procedure
			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 Liver 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.

11.2. 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 HA and PV 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 Liver Console.

To clean and disinfect the SvO_2/HCT Probe:

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

   CAUTION—Do NOT use a brush to clean the SvO_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 Liver Console.

11.3. 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 13.2, “Electrical and Physical Specifications.”
2. Store the probes within the Liver 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 Liver Console and Wireless Monitor batteries.
8. Put the OCS™ in Standby Mode with the Wireless Monitor docked in its cradle.

11.4. Cleaning and Maintenance Task Checklist

Table 25 below provides a checklist for cleaning and maintaining the system and its components.

Table 25: 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
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 Liver 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 Table 3 ("System Status Icons") 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 24.
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

11.5. Routine Inspection Before and After Use

Before and after each use, inspect the Liver 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 LvPM 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 LvPM 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.

12. CHAPTER 12: TROUBLESHOOTING

This chapter describes troubleshooting tips, system messages, and related Technical Service information for the OCS™ Liver System.

12.1. Emergency Support

If a situation arises that threatens the safe perfusion of a donor organ, TransMedics support is available to complement the recommended actions in this section. A TransMedics emergency response representative can be reached at any time by calling the U.S. at +1-978-222-3733 or the EU at +31(0) 20-7084561.

12.2. Technical Service Follow-Up

If an issue is observed during the operation of the OCS™ Liver System, this may indicate the need for follow-up Technical Service to be performed on the equipment after the perfusion run is completed. Technical Service is available via email at service@transmedics.com, or by calling +1-978-552-0999, ext 2.

12.3. Troubleshooting the OCS™ Liver System

Try resolve the issue one step at a time by performing the recommended actions in the order that they appear in Table 26 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  (with the Wireless Monitor docked) once to switch from Run Mode to Standby Mode and a second time to switch back to Run Mode. The system automatically runs the Self Test when entering Run Mode. This sequence shuts off the pump and all subsystems.
- **Power-cycle the system** means to use the On/Off switch on the side of the Liver Console to turn the system OFF, wait 10 seconds, and then turn it ON. This sequence temporarily shuts off the pump and all subsystems. When the OCS™ powers on, it will continue operating at the same settings that were present when it was shut off.
- **Unlatch and latch LvPM** means to unlatch the LvPM, tilt it forward, and wait 30 seconds until the alarm message indicates the LvPM has been removed. Tilt the LvPM back to latch it.

CAUTION—If the blood pump is temporarily shut off as part of the fault recovery process, you must check for air in the Hepatic Artery and Portal Vein lines 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 26: Troubleshooting the OCS™ Liver System

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/LvPM Insertion	During Run Mode - Priming	During Run Mode - Preservation
Pumping			
Pump Failure	1. Remove and reinsert LvPM. 2. Power-cycle the system.		1. Cool liver with cold flush and preserve it cold.
Heating			
Blood temperature sensor failure	1. Unlatch and latch the LvPM. 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 LvPM. 2. Standby-cycle the system.		1. Cool liver with cold flush and preserve it cold.
Blood warmer too hot; Blood too hot	1. Wait one minute for the message to clear with the pump running and fluid in the LvPM. 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 LvPM. 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. Cool the liver with cold flush and preserve it cold.
Blood warmer failure	1. Turn off the pump, remove the LvPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 24 or vigorously scrub them with alcohol wipes, then reinstall the LvPM. 2. Standby-cycle the system.		1. Cool liver with cold flush and preserve it cold.
Single blood warmer element failure	1. Turn off the pump, remove the LvPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 24 or vigorously scrub them with alcohol wipes, then reinstall the LvPM. 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 and accept the change. Then set the gas flow rate to the desired value.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/LvPM Insertion	During Run Mode - Priming	During Run Mode - Preservation
			2. If restarting the gas does not correct the problem, monitor the blood gases. 3. Cool the liver with cold flush and switch to cold preservation if the blood gas levels fall outside of the optimal ranges.
Pressure Probes			
Pressure probe failure: Dual HAP Pressure probe failure: Dual PVP	1. Unlatch and latch the LvPM. 2. Standby-cycle the system. 3. Replace the LvPM. 4.	1. Unlatch and latch the LvPM. 2. Standby-cycle the system.	1. Proceed with perfusion and monitor PVF, HAF, and lactate. If unstable and cannot be maintained, cool the liver with cold flush and preserve it cold.
PM			
Perfusion Module failure	1. Turn off the pump, remove the LvPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 24 or vigorously scrub them with alcohol wipes, and then reinstall the LvPM. 2. Standby-cycle the system. 3. Replace the LvPM.	1. Turn off the pump, remove the LvPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 24 or vigorously scrub them with alcohol wipes, and then reinstall the LvPM. 2. Standby-cycle the system.	1. Unlatch and re-latch the LvPM after vigorously scrubbing the silver contact buttons with alcohol wipes. 2. Cool the liver with cold flush and preserve it cold.
Perfusion Module not present	N/A	1. Remove the LvPM, clean the silver contact buttons on the circuit board connector block with metal cleaner per Table 24 or vigorously scrub them with alcohol wipes, and then reinstall the LvPM. 2. Standby-cycle the system. 3. Follow-up with OCS™ Service.	1. Unlatch and re-latch the LvPM after vigorously scrubbing the silver contact buttons with alcohol wipes. 2. Cool the liver with cold flush and preserve it cold.
Flow Probes			
Check flow probe: HAF	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 the Console.		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 liver perfusion. Monitor HAP, PVF, and lactate trend. If unstable and cannot be maintained, cool the liver with cold flush and preserve it cold.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/LvPM Insertion	**During Run Mode - Priming**	**During Run Mode - Preservation**
Check flow Probe: PVF	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 liver perfusion. Monitor HAP, HAF, and lactate trend: if unstable and cannot be maintained, cool the liver with cold flush and preserve it cold.
Missing probe: HAF Missing probe: PVF	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 LvPM. 3. Ensure the probe is properly connected to Console. 4. Standby-cycle the system.	1. Ensure the probe is properly seated to cuvette on LvPM. 2. Ensure the probe is properly connected to the Console. 3. Proceed without the functioning probe by monitoring blood gases and HCT using the portable blood gas analyzer.
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. Cool the liver with cold flush and preserve it cold.
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.
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.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/LvPM Insertion	**During Run Mode - Priming**	**During Run Mode - Preservation**
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 a 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.	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 a battery 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 charging failure. Battery may be used. [or battery 2 or battery 3]	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 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.		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 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.
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, access trend graphs on the Wireless Monitor.		
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, view trend data on the Wireless Monitor as needed.	
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.		

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/LvPM Insertion	During Run Mode - Priming	During Run Mode - Preservation
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. 2. Check and correct for kinks in the tubing between the cassette and solution container. Restart solution delivery by setting channel to Manual 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 LvPM. Restart solution delivery by setting channel to Manual 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. 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. 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.	
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 (PGI2 3 mL/hr; TPN 30 mL/hr; Bile Salt 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		1. This message will be displayed if the system power switch was turned on or in the case of a system/software reset.

Message	Recommended Action(s) Depending on When Detected		
	During Self Test/LvPM Insertion	During Run Mode - Priming	During Run Mode - Preservation
	software error and the system will return to full operation within 60 seconds. 3. Press the Alarm Silence button to acknowledge/dismiss the message. If desired, Standby-cycle to perform the Self Test.		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.
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. 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. Dock the Wireless Monitor.

12.4. 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.

12.5. 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 1.9, "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.

13. CHAPTER 13: SYSTEM SPECIFICATIONS

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

13.1. Safety and Regulatory Specifications

Table 27 below lists the safety and regulatory specifications for the OCS™ Liver System.

Table 27: Safety & Regulatory Specifications

Category	Specifications
Regulatory specifications	European Communities Council Directive 93/42/EEC, as amended, concerning medical devices
Safety standards system meets	IEC 60601-1:2005 CORR. 1 (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 29 and Table 30
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

13.2. Electrical and Physical Specifications

Table 28 below lists the electrical and physical specifications for the OCS™ Liver System.

Table 28: 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 (Liver Console and Sterile Components)	
Ambient Temperature:	-20°C to +50°C (-4°F to +122°F)
Relative Humidity (non-condensing, steady state):	10% to 95%

Parameter	Specifications
Weight	
System (without organ or fluids or base):	< 45.4 kg (< 100 lbs)
Mobile Base:	< 13.6 kg (< 30 lbs)
Gas Blend	80% O_2, 0.1% CO_2, balance N_2

13.3. Electromagnetic Emissions and Immunity

The OCS™ Liver System is intended for use in the electromagnetic environment specified in Table 29 and Table 30 below. The customer or user of the OCS™ should ensure that they are used in such an environment.

Table 29: 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 needs 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 30 below lists the guidance and manufacturer's declaration of electromagnetic immunity for the OCS™ Liver System.

Table 30: Guidance and Manufacturer's Declaration: Electromagnetic Immunity

Immunity Test	IEC 60601 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%.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0 0% UT 1 cycle 70% UT 25 cycles, 50 Hz single phase at 0^0 0% UT 250 cycles, 50 Hz single phase at 0^0	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 Liver Console and its Wireless Monitor is a minimum of 3 meters.

13.4. Essential Performance

- Pump warmed, oxygenated perfusate to the liver
- Deliver infusions at desired rate to the liver on the OCS™
- Monitor and display pressure, flow, and temperature
- Allow the user to control the functions of the OCS™ and collect perfusate samples.

13.5. Accuracy of Displayed Values

Table 31 below provides the accuracy of the values displayed by the OCS™ Liver System.

Table 31: Accuracy of Displayed Values

Value	Range	Accuracy
Hematocrit (HCT)	15 to 50%	± 5%
Saturation (SvO2)	50 to 99%	± 5%
Flow (HAF)	0 to 2.0 L/Min	± 12% ± 0.14 L/min
Flow (PVF, Pump)	0 to 6.5 L/min	± 12% ± 0.28 L/min
Temperature (Temp)	0 to 45°C	± 1°C
Pressure (HAP, PVP)	0 to 225 mmHg	Greater of ± 7% or ± 10 mmHg

14. CHAPTER 14: PARTS AND SUPPLIES

Table 32 below lists the parts and supplies that you 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 Section 1.9, "Contacting TransMedics."

Table 32: Parts and Supplies

Part Number	Name	Description
3000	OCS Liver Console	As described in Section 3.
3200	OCS Liver Perfusion Set	As described in Section 3.
3440	OCS Liver Bile Salts Set	Set of bile salts, two vials.
OCS Liver Console subcomponents that can be ordered separately		
1404	OCS Data Card	A removable SD data card used to store perfusion parameters from the preservation session, which can be downloaded and analyzed on a personal computer.
1408	OCS Battery	As described in Section 3.
1411	OCS Mobile Base	As described throughout this document.
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 the U.S.
3406	OCS Liver Gas Cylinder	As described in Section 3.
OCS Liver Perfusion Set subcomponents that can be ordered separately		
3400	OCS Liver Perfusion Initiation Set	As described in Section 3.
3401	OCS Liver Instrumentation Tool Set	As described in Section 3.
3421	OCS Liver Perfusion Termination Set	As described in Section 3.
3457	OCS Liver Solution Infusion Set	As described in Section 3.
1467	Solution Delivery Cassettes, 3-pack	One component from OCS Liver Solution Infusion Set, as described in Section 3. Serves as spare parts.
3450	OCS Bile Cannula, 12Fr	Sterile packaging includes: 12Fr Bile Cannula.
Other		
3501	OCS Liver Documentation Set	The labeling documentation set (English).
1460	OCS Console Contact Button Cleaner	For maintenance of the silver buttons on the Circuit Board Connector Block.

15. APPENDIX A: OCS LIVER PROTECT TRIAL

15.1. Summary Overview of OCS Liver PROTECT Trial Design & Objectives

The OCS Liver PROTECT trial was a prospective, multi-center, randomized trial of 300 patients randomized 1:1 to the OCS Liver or Control (cold storage). The trial enrolled 300 patients at 18 U.S. liver transplant sites between January 2016 and October 2019. The clinical objective of the trial was to compare the safety and the effectiveness of the OCS Liver System versus cold storage (Control) to preserve and assess donor livers intended for transplantation that may benefit from warm oxygenated perfusion compared to cold static storage from one or more of the following donor characteristics:

- Donor age ≥ 40 years old; or
- Expected total cross clamp/cold ischemic time ≥ 6 hours; or
- Donor after Cardiac Death (DCD donor) with age ≤ 55 years old; or
- Steatotic liver > 0% and ≤ 40% macrosteatosis at time of retrieval (based on retrieval biopsy readout (only if the donor liver was clinically suspected to be fatty by the retrieval surgeon at time of liver retrieval)).

15.1.1. Primary Effectiveness Endpoint

The Primary Effectiveness Endpoint is the incidence of Early liver Allograft Dysfunction (EAD), defined as the presence of one or more of the following criteria: 1) AST level > 2000 IU/L within the first 7 postoperative days; 2) bilirubin ≥ 10 mg/dL on postoperative day 7; 3) INR ≥ 1.6 on postoperative day 7; or 4) primary non-functioning graft within the first 7 days (defined as irreversible graft dysfunction requiring emergency liver re-transplantation or death, in the absence of immuniologic or surgical causes).

15.1.2. Secondary Effectiveness and OCS Donor Liver Assessment Endpoints

- OCS donor liver assessment during perfusion
- Patient survival at day 30 post-transplantation
- Patient survival at initial hospital discharge post liver transplantation.

15.1.3. Safety Endpoint

The safety endpoint is the incidence of liver graft-related serious adverse events (LGSAEs) in the first 30 days post liver transplantation, which are defined as: 1) primary non-function (defined as irreversible graft dysfunction, requiring emergency liver re-transplantation or death within the first 10 days, in the absence of immunologic or surgical causes); 2) ischemic biliary complications (ischemic biliary strictures, and non-anastomotic bile duct leaks); 3) vascular complications (liver graft-related coagulopathy, hepatic artery stenosis, hepatic artery thrombosis, and portal vein thrombosis); or 4) liver allograft infections (such as liver abscess, cholangitis, etc.).

15.1.4. Other Clinical Endpoints

- Length of initial post-transplant ICU stay
- Length of initial post-transplant hospital stay

- Evidence of ischemic biliary complications diagnosed at 6 and at 12 months
- Extent of reperfusion syndrome as assessed based on the rate of decrease of lactate
- Pathology sample score for liver tissue samples.

15.1.5. Analyses Populations

The primary analysis population was pre-specified as the Per Protocol (PP) population which consists of all randomized patients who were transplanted and had no major protocol violations and for whom the donor liver received the complete preservation procedure as per the randomization assignment. In the PP analyses, patients were analyzed in the groups to which they were randomized. 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. In the mITT population, patients were analyzed as randomized. The mITT analyses are the secondary analyses of effectiveness.

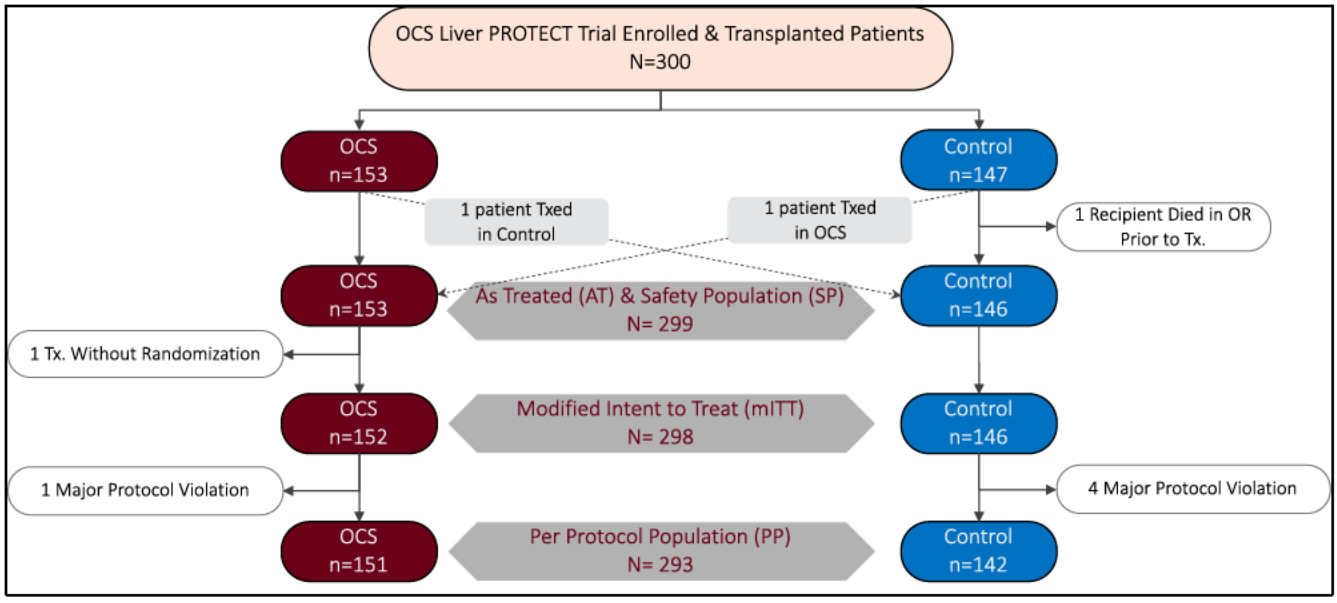
The As Treated (AT) population consists of all treated patients, i.e., all patients who were transplanted in the trial with a donor liver preserved with either OCS or Control. In analyses based on this population, patients were analyzed as treated. Analyses of safety endpoints are performed based on the AT population.

15.2. Clinical Results

15.2.1. Trial Enrollment

Three hundred (300) patients were randomized 1:1 to the OCS Liver or Control (cold storage) at twenty (20) U.S. sites between January 24, 2016 and October 15, 2019. The enrollment consort diagram is presented in Figure 81 below.

Figure 81: Enrollment Consort Diagram



15.2.2. Donor Demographic and Baseline Characteristics

The donor demographics and baseline characteristics are shown in Table 33. The donor organs used in this trial were associated with some clinical risk factors that may make them less likely to be used for transplantation due to the limitation of cold ischemic storage, e.g., donors with advanced age, multiple co-morbidities like steatosis, long cross-clamp time, or donation after circulatory death (DCD). In fact, ~60% of the donor livers in the study met more than one of these donor characteristics. Both donor groups were similar in risk factors of age ≥ 40 years, cross clamp time > 6 hours and macrosteatosis; however, the OCS arm included substantially more DCD donors. DCD liver transplantation is considered to be associated with higher clinical risks due to the impact of warm ischemic injury of the agonal phase on the incidence of EAD and ischemic biliary complications post-transplant (Mateo, et al., 2006; Mathur, et al., 2010, Lee et al., 2014).

Table 33: Donor Demographic and Baseline Characteristics (AT Population)

Parameter	OCS (N=152 [2])	Control (N=146)
Donor Age (years): mean ± SD	45.84 ± 14.90	46.96 ± 15.22
Cause of death		
• Cerebrovascular Hemorrhage	44 (28.9%)	50 (34.2%)
• Head trauma	35 (23.0%)	29 (19.9%)
• Cardiac	13 (8.6%)	10 (6.8%)
• Other (Anoxia, CSF infection, Suicide, Stroke)	60 (39.5%)	57 (39.0%)
Donor Characteristics [1]		
• ≥ 40 years old	102 (67.1%)	93 (63.7%)
• Total cross clamp ≥ 6 hours	48 (31.6%)	56 (38.4%)
• DCD ≤ 55 years old	28 (18.4%)	13 (8.9%)
• Steatotic liver > 0% and ≤ 40% macrosteatosis at time of retrieval	95 (62.5%)	86 (58.9%)
• Multiple Donor Characteristics	95 (62.5%)	85 (58.2%)

(1) Multiple donor characteristics (inclusion criteria) could be met (total 60.4% of all donors).

(2) Does not include donor organ for Patient (b) (6) as this patient was not randomized.

15.2.3. Recipient Demographic and Baseline Characteristics

The recipient demographics and baseline characteristics are shown in Table 34. The majority of the recipients were males (66-69%), with a mean age of 57-58 years and a mean MELD score of 28. Almost a third of the recipients had a history of diabetes and the most prevalent primary diagnosis was alcoholic cirrhosis. The two treatment groups were similar in all demographic and baseline characteristics with no significant differences noted.

Table 34: Recipient Demographic and Baseline Characteristics (AT Population)

Parameter	OCS (N=153)	Control (N=146)
Recipient Age (yrs): mean ± SD	57.07 ± 10.33	58.59 ± 10.04
Gender		
• Male	102 (66.7%)	100 (68.5%)
• Female	51 (33.3%)	46 (31.5%)
BMI (kg/m^2): mean ± SD	29.67 ± 5.38	29.51 ± 5.51
MELD Score: mean ± SD Median	28.4 ± 6.90 29.0	28.0 ± 5.71 29.0
History of diabetes	44 (28.8%)	44 (30.1%)
History of liver cancer	60 (39.2%)	63 (43.2%)
Primary diagnosis		
• Cholestatic Diseases	9 (5.9%)	8 (5.5%)
• Chronic Hepatitis	27 (17.6%)	36 (24.7%)
• Alcoholic Cirrhosis	54 (35.3%)	48 (32.9%)
• Metabolic Diseases	6 (3.9%)	6 (4.1%)
• Primary Hepatic Tumors	14 (9.2%)	15 (10.3%)
• NASH	24 (15.7%)	20 (13.7%)
• Other	19 (12.4%)	13 (8.9%)

15.2.4. OCS Donor Liver Preservation and Assessment

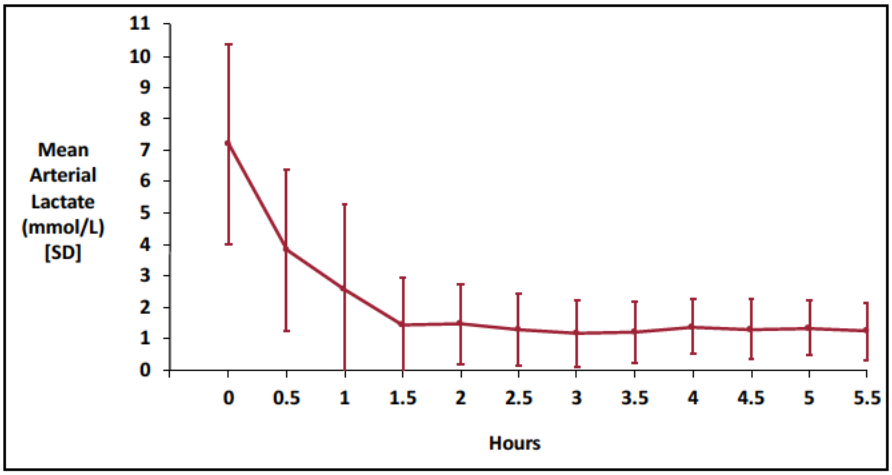
Donor livers were perfused on OCS and were maintained in a near physiologic condition based on OCS perfusion parameters, bile production and blood gas results of the perfusate (Table 35 below). Importantly, the OCS Liver lactate trend showed steady declining and stable trend throughout perfusion indicating that the donor liver has been resuscitated from the non-physiologic insult of organ donation and procurement to a metabolically active normal liver function. (Figure 82)

Table 35: OCS Liver Perfusion Parameters and Perfusate Chemistry Levels

OCS Perfusion Parameters and Perfusate Chemistry	OCS (N=152)
OCS Liver Perfusion Time (mins) mean ± SD	276.6 ± 117.4
Hepatic Artery Pressure (mmHg) - mean ± SD	70.6 ± 16.2
Hepatic Artery Flow (L/min) - mean ± SD	0.7 ± 0.2
Portal Vein Pressure (mmHg) - mean ± SD	5.4 ± 2.3

OCS Perfusion Parameters and Perfusate Chemistry	OCS (N=152)
Portal Vein Flow (L/min) - mean ± SD	1.3 ± 0.1
Total Bile Production (ml) - mean ± SD	28.3 ± 15.9
pH- mean ± SD	7.43 ± 0.1
PaO_2 (mmHg) mean ± SD	420.2 ± 80.7
PCO_2 (mmHg) mean ± SD	41.5 ± 14.6
HCO_3 (mmHg) mean ± SD	28.6 ± 10.3

Figure 82: OCS Liver Perfusion Lactate Trend for Transplanted Livers in PROTECT Trial



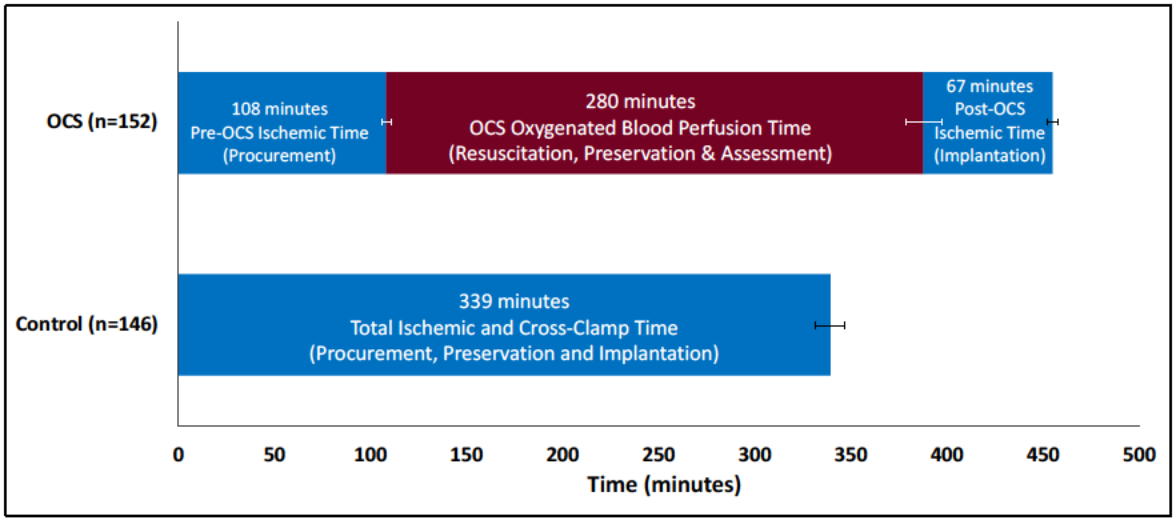
The use of OCS Liver System altered the nature of the critical time from removal from the donor body to reimplantation into the recipient (i.e., total out of body or cross-clamp time). The use of the OCS Liver System significantly reduced the total cold ischemic time on the liver allografts by limiting the ischemic times to 2 obligatory time periods:

- Pre-OCS Ischemic Time: This is the time needed to surgically remove the donor liver from the body of the donor, perform the back table surgical preparation and instrument it on the OCS Liver System. The OCS instrumentation takes ~10-15 mins;
- Post-OCS Ischemic Time: this is the time needed to surgically reimplant the liver allograft into the recipient.

Otherwise, throughout the OCS perfusion, the conditions for the donor liver allograft were not ischemic given that it was perfused on OCS with warm, oxygenated blood perfusate until it was ready to be transplanted.

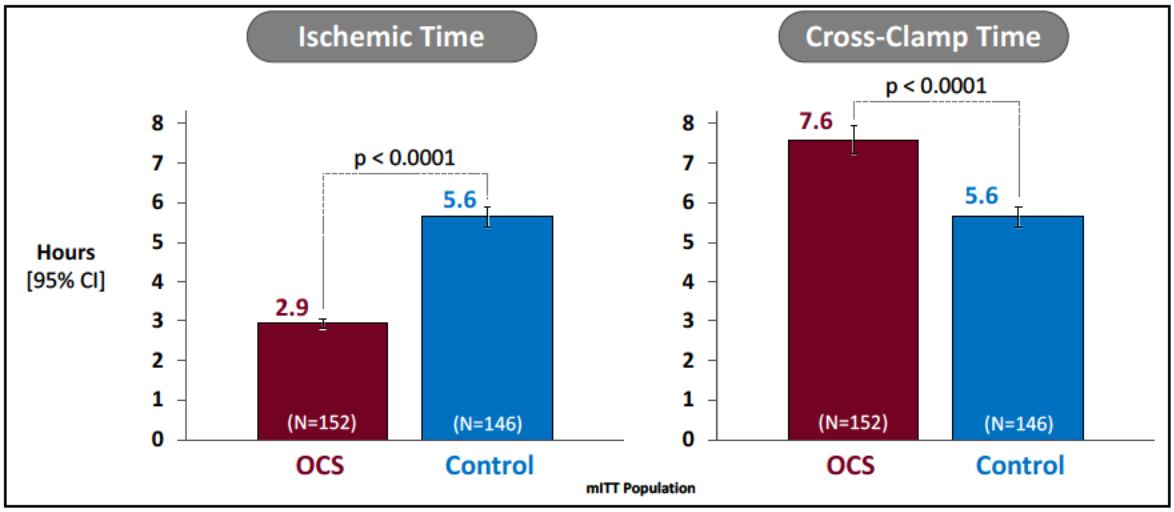
On the other hand, Control liver allografts were ischemic from the time they were procured from the donor body until they were implanted into the recipient. Figure 83 below demonstrate these critical time windows.

Figure 83: Overall Out of Body Times in PROTECT Trial



Based on the above unique characteristics of the OCS, the injurious total ischemic time was significantly reduced on the OCS Liver System compared to Control, despite the OCS having significantly longer total cross-clamp (out of body) time (Figure 84 below).

Figure 84: Total Ischemic and Cross-Clamp (Out of Body) Times in PROTECT Trial



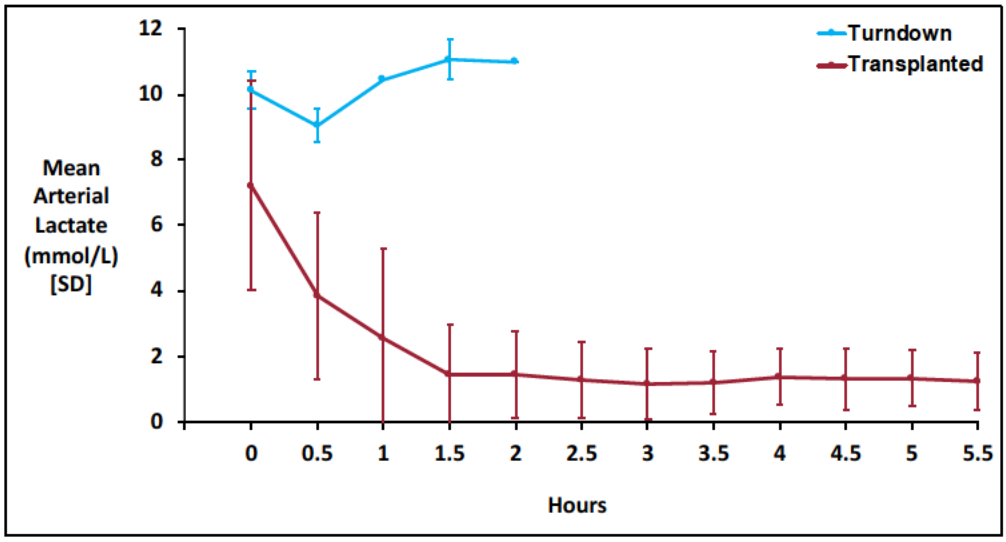
15.2.5. Donor Liver Clinical Turndown After Assessment on OCS Liver System

Given that the OCS Liver System enabled assessment of the donor livers ex-vivo, there were 3 DCD donor livers that were preserved and assessed on the OCS Liver System and were clinically turned down for transplantation due to rising lactate while being perfused on OCS Liver System in 2 cases and due to pre-retrieval pathology results in the third case. (See Figure 85).

The unique OCS Liver assessment capability provided a critical opportunity to the transplanting surgeon for additional clinical assessment, which resulted in a clearer understanding of the quality of the donor liver and led to an elimination of donor livers with significant pathology to maximize safety for the transplanted recipients. These results represent a clinical benefit of the OCS Liver System compared to ischemic cold

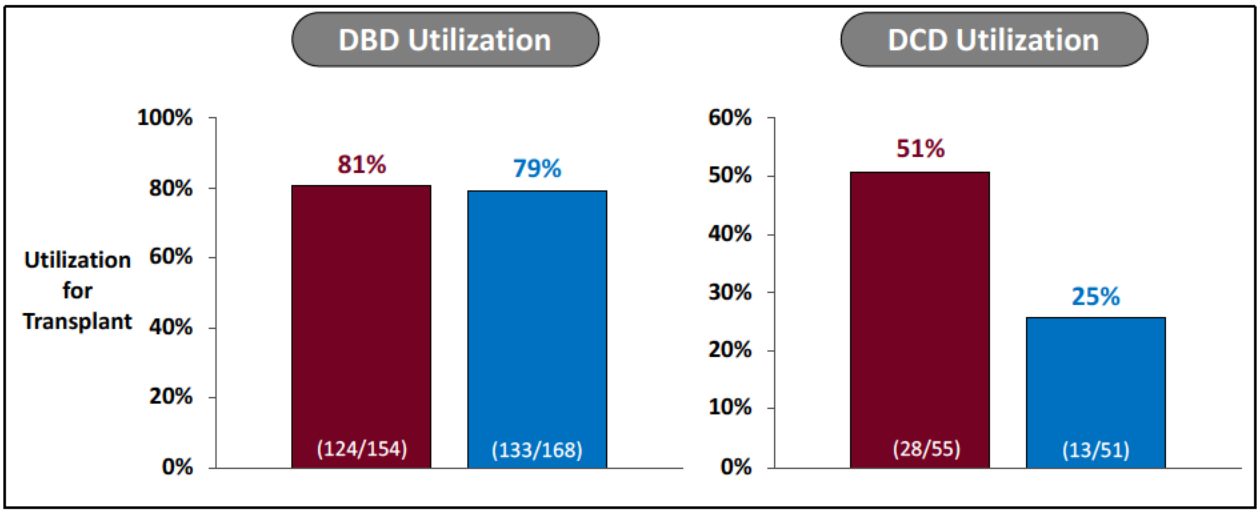
storage which does not enable any assessment of a donor liver allograft once it is removed from the donor body.

Figure 85: Mean OCS Liver Arterial Lactate Trend for Turned Down Donor Livers Compared to OCS Transplanted Donor Livers in PROTECT Trial



The impact of the preservation modality on donor liver utilization for transplantation from DBD and DCD donors in PROTECT trial was analyzed Figure 86 below shows that the use of OCS resulted in significantly higher rate of utilizing DCD donor livers for transplantation compared to ischemic cold storage (Control). There was no difference in DBD donor liver utilization between the OCS and Control arms.

Figure 86: DBD and DCD Donor Liver Utilization Rates in PROTECT Trial



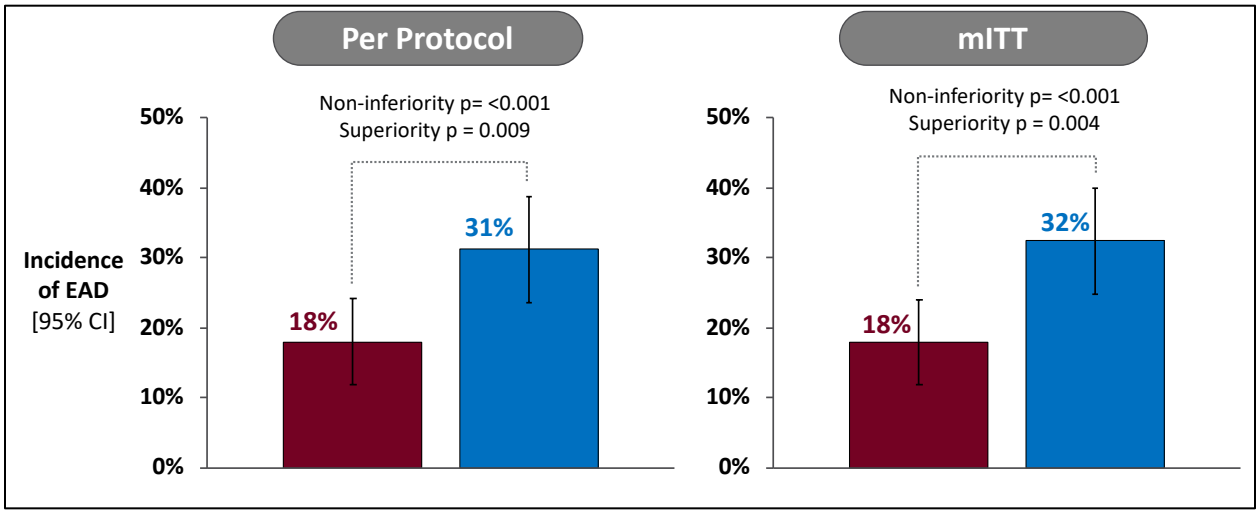
These data suggest that OCS Liver System provided additional opportunity for ex-vivo clinical optimization and assessment of the DCD liver grafts resulting in doubling the yield of DCD livers transplanted (50.9% vs. 25.5%) compared to the Control arm. These results confirm the potential clinical benefits of machine perfusion to

provide additional clinical assessments of the liver allografts. The ability to assess the donor livers allows transplant surgeons to gain more clinical confidence with the liver allograft and should increase the utilization of donor livers for transplantation and increase access for patients in need in the U.S. DCD livers are seldom transplanted in the U.S. today due to concerns about ischemic/reperfusion injury of the graft and the potential for severe post-transplant ischemic biliary complications (Kwong, et al., 2020, Mateo, et al., 2006; Mathur, et al., 2010, Lee, et al., 2014).

15.2.6. Primary Effectiveness Endpoint

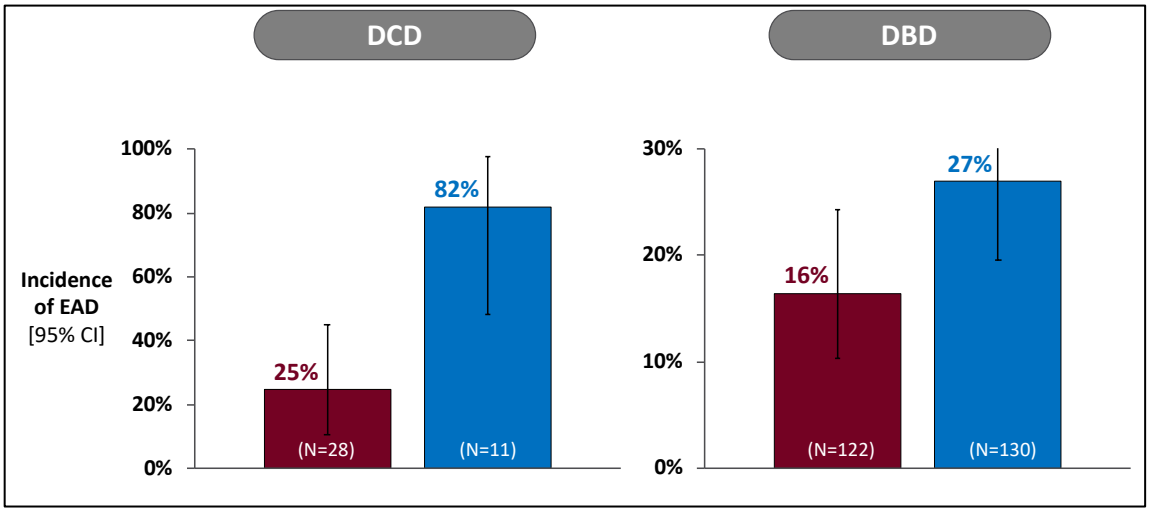
The OCS Liver PROTECT trial met its primary effectiveness endpoint by demonstrating statistical non-inferiority and superiority of outcomes of the OCS arm compared to Control in both the PP and mITT populations. Specifically, the results demonstrated that use of OCS Liver System was associated with a significant reduction of Early Allograft Dysfunction (EAD) compared to the Control in the primary analysis PP Population (OCS 18% vs. Control 31% p=0.009). The same results were experienced in the mITT population (OCS 18% vs. 32% p=0.004). See Figure 87 below.

Figure 87: OCS Liver PROTECT Trial Primary Effectiveness Endpoint - Incidence of Post-Transplant Early Allograft Dysfunction (PP and mITT Populations)



The same positive impact on EAD was experienced in both DBD and DCD donor cohort in the PROTECT trial. This finding further supports the robustness of the positive clinical impact of the OCS Liver System across both DBD and DCD donor livers (Figure 88).

Figure 88: Incidence of Post-Transplant EAD in DBD and DCD Donor Cohorts in PROTECT Trial (PP Population)



15.2.7. Pathology Assessment

The PROTECT trial included an independent core pathology assessment of liver biopsies obtained pre- and post-transplant in 3 distinct sample time points:

Sample 1: was taken to assess the condition of the donor liver prior to initiation of any preservation method. This is to provide a baseline picture of the donor livers studied in PROTECT.

Sample 2: was taken after the preservation period was completed and prior to transplantation into the recipient. This sample was taken only for hypothesis generation on the mechanism of potential pathological changes in the donor liver allograft.

Sample 3: was taken after transplantation and reperfusion of the donor liver allograft in the recipient's body. This sample represent the most clinically relevant histological assessment point on the overall preservation and reperfusion injury histological markers on liver allografts. This is particularly true in the PROTECT trial because the preservation methods for OCS and control differed substantially in that the control liver was ischemic and not metabolically active while the OCS liver was perfused, oxygenated and metabolically active.

Histopathological evaluation of sample 3 (post-transplant) demonstrated that the significant reduction of EAD associated with the use of OCS Liver System was validated mechanistically by the histopathological assessment. Independent and blinded histological assessment revealed substantially less moderate-severe lobular inflammation post-transplant for OCS livers. Lobular inflammation is a marker of ischemia and reperfusion injury (Ali, et al., 2015; Kakizoe, et al., 1990; Sosa, et al., 2016) (Figure 89 and Figure 90 below).

Figure 89: Post-Transplant Pathology Assessment – Incidence of Liver Lobular Inflammation (mITT Population)

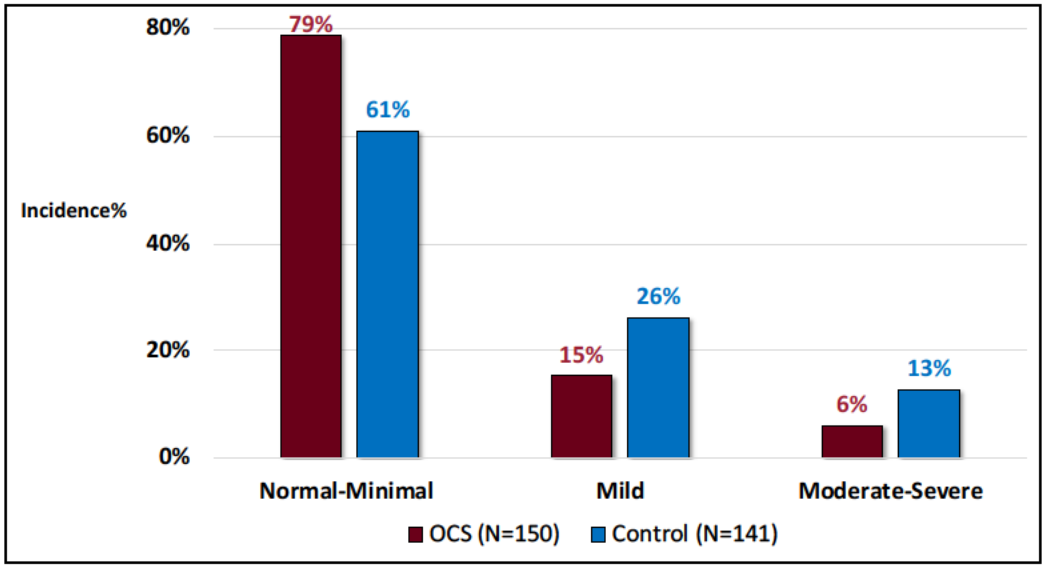
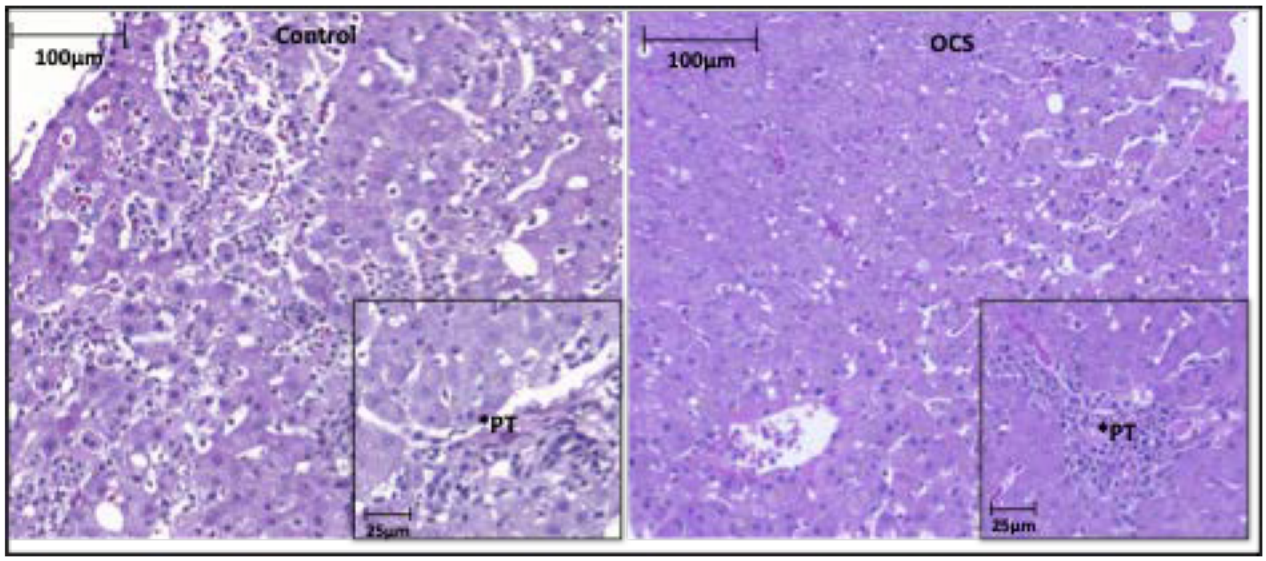


Figure 90: Post-Transplant Histology Representative Sample for Severe Lobular Inflammation



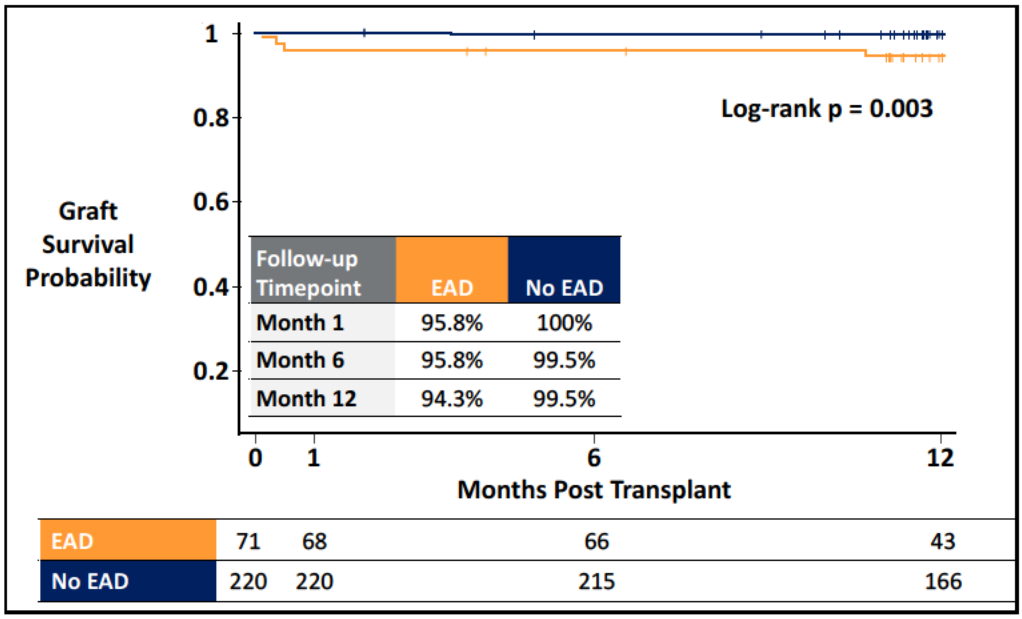
Representative histology to show an example of severe lobular inflammation in a Control (Left) liver post reperfusion with insert showing minimal portal inflammation, and OCS-treated liver (Right) showing absence of lobular inflammation and minimal portal inflammation, insert.

15.2.8. Major Liver Transplant Clinical Benefits of Reducing EAD Post-Liver Transplantation

To elucidate the major clinical benefits of reducing EAD post-liver transplantation, we performed post-hoc analyses stratifying key clinical outcomes of the PROTECT trial based on the presence or absence of EAD in the overall PROTECT trial population, similar to the approach taken by Olthoff, et al.(2010). The results showed that EAD was associated with:

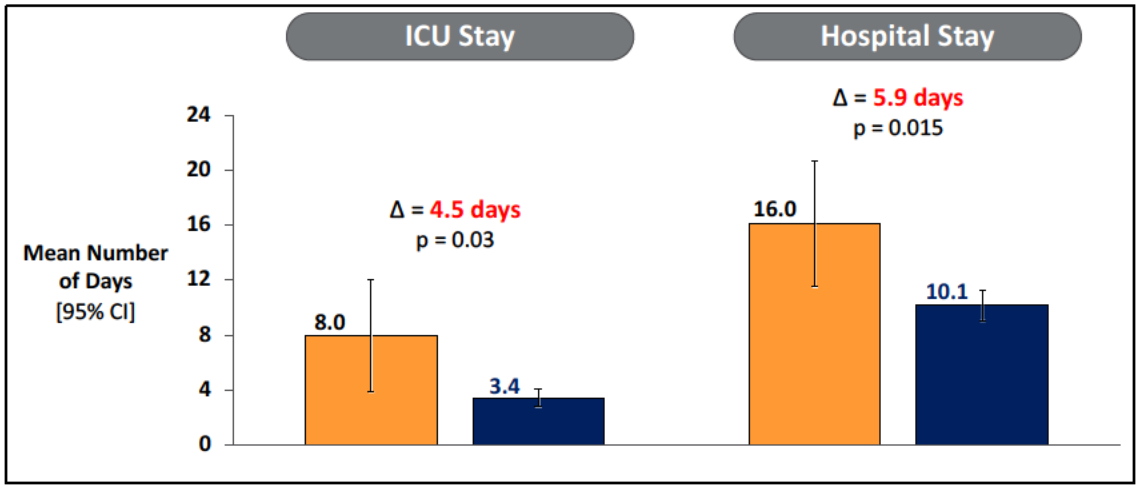
- Significantly increased risk for post-transplant graft failure. Graft failure is a serious and devastating clinical outcome for liver transplant recipients. Graft failure would require a re-transplantation or the patient would die (see Figure 91 below).

Figure 91: Kaplan-Meier Liver Graft Survival for PROTECT Subjects (EAD vs. No EAD) (PP Population)



- Significant increase in Initial ICU and hospital length of stay post-transplantation. These findings show that the presence of EAD significantly increased hospital resource utilization and ultimately would increase the overall cost for the liver transplant procedure (see **Figure 92** below).

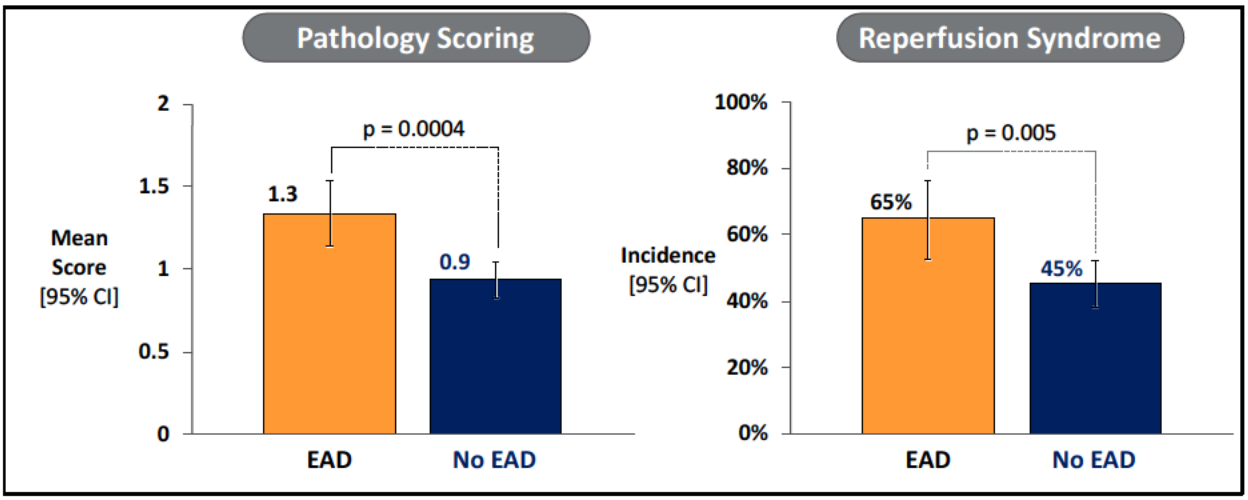
Figure 92: Length of ICU and Hospital Stay Post-Liver Transplantation (EAD vs. No EAD) (PP Population)



- Significant increase in the overall pathology score (which includes specific IR injury pathological markers) for liver biopsies taken 90-120 minutes post-reperfusion in the recipient as assessed by independent blinded scoring by the core pathology lab (see Figure 93 below).
- Significant increase in post-transplant reperfusion syndrome where reperfusion syndrome is defined by an increase in lactate level over time from anhepatic phase through ~120 minutes after reperfusion in

the recipient abdomen. This result indicates that recipients with EAD may be associated with a significantly higher risk of post-transplant hemodynamic instability, which could lead recipients to have a more complicated post-transplant clinical course (see Figure 93 below).

Figure 93 Post-Transplant Overall Pathology Scoring for Biopsies taken 90-120 Minutes Post-reperfusion (left) and incidence of reperfusion syndrome (right) based on increase in lactate level from anhepatic phase through reperfusion in recipient abdomen (EAD vs. No EAD) (PP Population)



These results demonstrate that the ability of the OCS Liver System's to reduce EAD would add significant clinical benefits for liver transplant recipients in the U.S. by potentially reducing the risk of graft failure, reducing time spent in the ICU and time spent in the hospital as well decreasing the risk of hemodynamic instability post-transplant.

15.2.9. Secondary Effectiveness and OCS Donor Liver Assessment Endpoints

The OCS Liver PROTECT trial met all secondary effectiveness endpoints.

OCS Liver System Assessment: The advantage of the OCS system is that it allows for continuous monitoring of the donor liver during preservation. The measurement of lactate levels, bile production, hepatic artery pressure, and portal vein pressure were all were successfully obtained and measured during preservation.

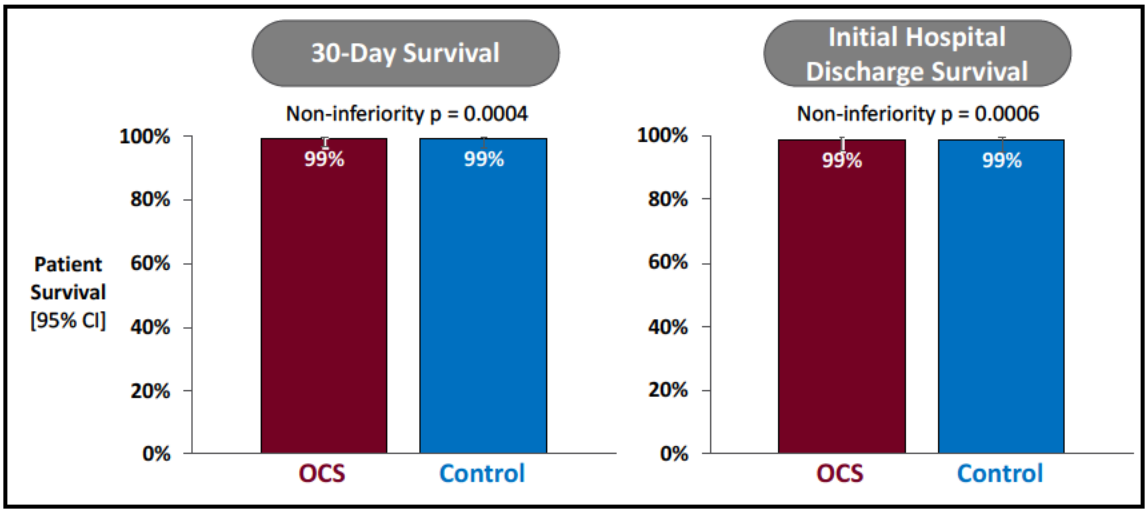
Table 36: First Secondary Endpoint – OCS Liver Assessment Parameters During Perfusion

OCS Liver System Assessments During Perfusion	93% (144/155)	p-value 0.002*
Lactate Level	94% (145/155)	
Hepatic Artery Pressure	100% (155/155)	
Portal Vein Pressure	100% (155/155)	
Average Bile Production Rate	99% (154/155)	
* p-value from a one-sided exact binomial test, testing the null hypothesis that the true proportion is less than or equal to 0.85 versus the alternative hypothesis that it is greater than 0.85.		

Recipient Survival at Day 30 and at initial hospital discharge: The OCS arm 30-day recipient survival and recipient survival to initial hospital discharge was high and statistically non-inferior to the Control arm in both

the PP and mITT analysis. In the PP population, the 30-day survival for both the OCS and Control was 99.3% and the initial hospital discharge survival was 98.7% OCS vs. 98.6% Control (see Figure 94).

Figure 94: Secondary Effectiveness Endpoint - Recipients' Survival at Day 30 and at Initial Hospital Discharge (PP Population)

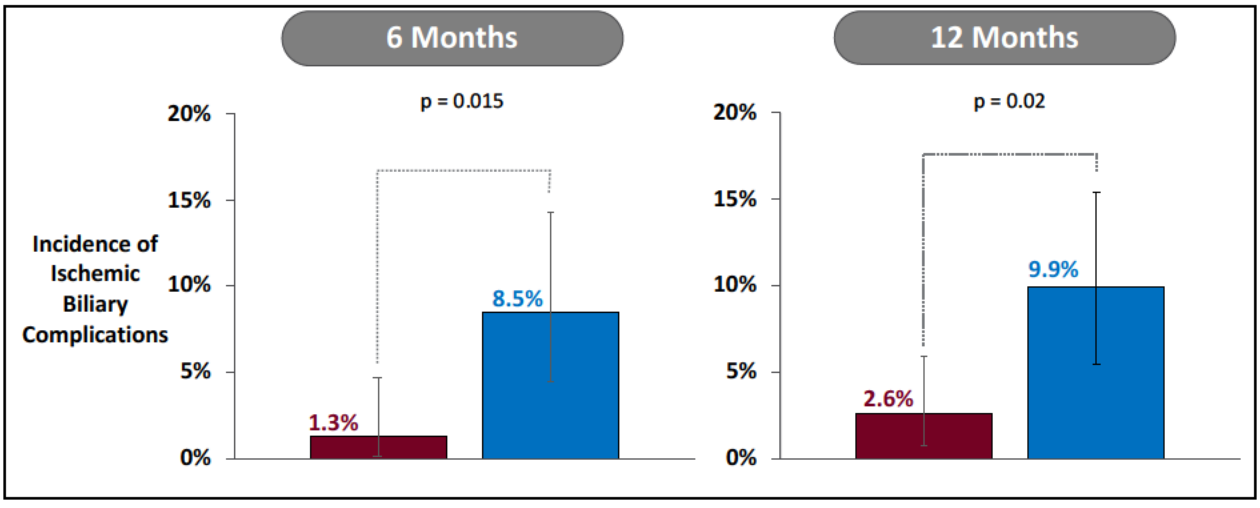


15.2.1. Other Clinical Endpoints

15.2.1.1. Incidence of Ischemic Biliary Complications at 6 and 12 Months

Ischemic biliary complications are one of the most serious complications that negatively impact long-term viability of the liver allograft and the patient. The OCS arm demonstrated a statistically significantly lower incidence of ischemic biliary complications compared to the Control arm at 6 and 12 months follow-up in both the PP population (see Figure 95 below).

Figure 95: Incidence of Ischemic Biliary Complications Through 6 and 12 Months Post-Liver Transplant (PP Population)



15.2.1.2. Extent of Reperfusion Syndrome as Assessed by Recipient Lactate Levels Post-transplant

Reperfusion syndrome was more severe in the Control group compared to OCS based on an ad hoc analysis showing higher recipient mean lactate levels post-reperfusion in the Control group (see Table 37).

Table 37: Assessment of Reperfusion Syndrome – Recipients' Mean Lactate Levels Post-reperfusion in Recipient PP Population)

Timepoint	OCS Recipient Arterial Lactate (mmol/L) ± SD) N=152	Control Recipient Arterial Lactate (mmol/L) ± SD) N=146
Anhepatic	3.47 ± 1.706	3.55 ± 1.621
0-40 min after reperfusion	4.05 ± 2.092	4.57 ± 2.532
90-120/150 min after reperfusion	3.64 ± 2.220	4.33 ± 2.987

15.2.2. Post-transplant ICU Stay and Initial Hospital Stay

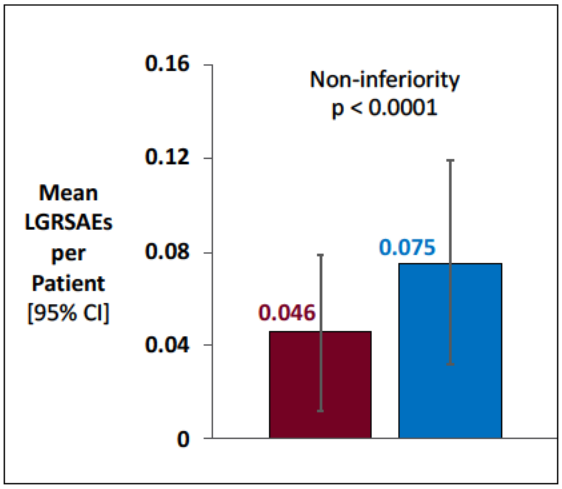
There was no difference in the length of initial post-transplant ICU and hospital stay for the OCS arm compared to the Control arm. The mean ICU stay was 107 hours for OCS compared to 111 hours for Control. The mean hospital stay was 12 days for OCS compared to 11 days for Control).

However, as described above, there was a significant increase in initial ICU and hospital length of stay post-transplantation for subjects with EAD, and there was a higher incidence of EAD in the Control group compared to the OCS group.

15.2.3. Safety Endpoint

The OCS Liver PROTECT Trial met its primary safety endpoint by demonstrating that the average number of liver graft-related serious adverse events (LGRSAEs) per patient within the first 30 days post-transplantation in the OCS arm was non-inferior to the Control arm (see Figure 96).

Figure 96: Safety Endpoint – Average number of LGRSAEs Per Transplanted Patient Within the First 30 Days Post-Transplant



When analyzing the specific LGRSAEs as shown in Table 38, it is important to note that the OCS arm did not experience any ischemic biliary complications in the first 30 days post-transplant and was associated with a lower incidence of vascular complications compared to Control arm.

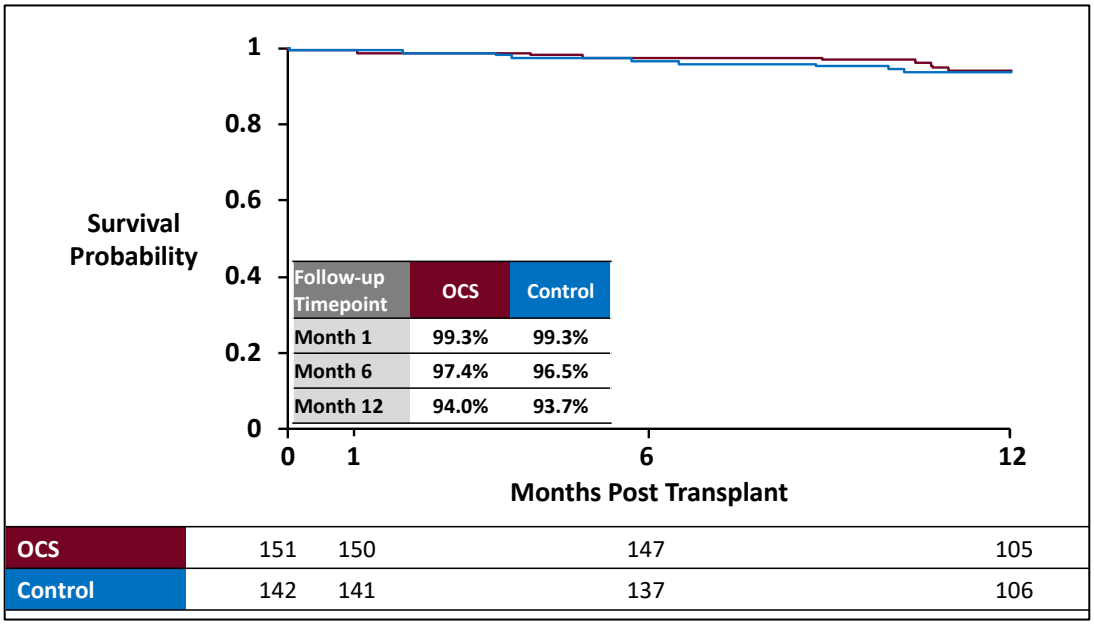
Table 38: LGRSAEs within 30 Days (AT Population)

LGRSAE within 30 Days Post Transplant	OCS (N=153)		Control (N=146)	
	Patients	Events	Patients	Events
Any LGRSAE	7 (5%)	8	11 (8%)	13
Non-functioning graft	0	0	0	0
Ischemic biliary complication	0	0	2 (1%)	2
Vascular complication	7 (5%)	8	9 (6%)	11
Liver allograft infection	0	0	0	0

15.2.4. Overall Patient Survival

Overall patient survival was high and comparable between the OCS and Control arms. The 30-day patient survival for both arms is 99.3%. The patient survival is 97.4% and 96.5% at 6 months and 94.0% and 93.7% at 12 months for OCS and Control, respectively. See Figure 97 below.

Figure 97: Kaplan-Meier Overall Patient Survival at Day 30 and through 6 and 12-Month Follow-up Visit (PP Population)



15.2.5. Serious Adverse Events

Serious Adverse Events were collected through 30 days post-transplant or initial hospital discharge. LGRSAEs were collected through 6 months post-transplant, and ischemic biliary complications were collected through

12 months post-transplant. A comprehensive summary of all of these events is shown in Table 39 below. As previously discussed, ischemic biliary complications were lower in OCS compared to the control group. The remaining SAEs were typical of those experienced by liver transplant patients, and there were no differences between the two groups in the overall number of adverse events.

Table 39: CEC-adjudicated Treatment-Emergent SAEs by Preferred Term (As Treated Population) – Comprehensive Listing Includes all SAEs through 30 days/hospital discharge post-transplant and LGRSAEs through 6 months and ischemic biliary complications through 12 months post-transplant (SAEs that occurred in ≥2% of patients are shown)

Preferred Term	OCS (N=153)		Control (N=146)	
	Subjects n (%)	Events n	Subjects n (%)	Events n
Any serious adverse event	82 (53.6)	150	72 (49.3)	148
Anaemia	3 (2.0)	3 (2.0)	1 (0.7)	1 (0.7)
Atrial fibrillation	3 (2.0)	3 (2.0)	4 (2.7)	4 (2.7)
Intracardiac thrombus	2 (1.3)	2 (1.3)	2 (1.4)	3 (2.0)
Ascites	1 (0.7)	1 (0.7)	3 (2.1)	3 (2.0)
Pyrexia	2 (1.3)	2 (1.3)	4 (2.7)	4 (2.7)
Biliary ischaemia	4 (2.6)	4 (2.7)	14 (9.6)	14 (9.5)
Hepatic artery stenosis	2 (1.3)	2 (1.3)	4 (2.7)	4 (2.7)
Transplant rejection	5 (3.3)	5 (3.3)	7 (4.8)	8 (5.4)
Wound infection	3 (2.0)	3 (2.0)	0	0
Biliary anastomosis complication	13 (8.5)	13 (8.7)	6 (4.1)	6 (4.1)
Drug toxicity	5 (3.3)	5 (3.3)	2 (1.4)	2 (1.4)
Post procedural bile leak	4 (2.6)	4 (2.7)	11 (7.5)	11 (7.4)
Post procedural haemorrhage	5 (3.3)	5 (3.3)	7 (4.8)	7 (4.7)
Convulsion	2 (1.3)	2 (1.3)	5 (3.4)	5 (3.4)
Delirium	1 (0.7)	1 (0.7)	4 (2.7)	4 (2.7)
Renal failure acute	11 (7.2)	11 (7.3)	7 (4.8)	7 (4.7)
Pleural effusion	1 (0.7)	1 (0.7)	4 (2.7)	4 (2.7)
Respiratory failure	3 (2.0)	3 (2.0)	3 (2.1)	3 (2.0)

15.3. Summary of the Clinical Results of the OCS Liver PROTECT CAP

The OCS Liver PROTECT Continued Access Protocol (CAP) was approved by FDA for 74 subjects. The PROTECT CAP is a single-arm study but otherwise the study design was the same as the OCS Liver PROTECT trial.

A total of 74 subjects have been enrolled in OCS Liver PROTECT CAP. As of the database closure date all 74 subjects have reached 30 days post-transplant, only 50 subjects have reached 6 months, and 19 subjects have reached 12 months. The study is on-going, and data are still being collected, monitored, verified, and adjudicated for all transplanted patients. A summary of the available data for these 74 subjects is provided in the sections that follow.

15.3.1. Donor Characteristics and Demographics

Donor demographics and characteristics are shown in Table 40 below. There have been no donor liver turndowns after OCS perfusion in the PROTECT CAP. The donor characteristics are similar, except that PROTECT CAP has a higher percentage of DCD donors (23% in CAP) compared to PROTECT (18%). DCD livers are generally considered as higher risk and are associated with higher rates of EAD and graft failure (Lee et al., 2014).

Table 40: Donor Demographic and Baseline Characteristics, OCS Liver PROTECT CAP

Parameter	OCS Patients (N=74)
Donor Age Mean ± SD	47.12 ± 13.804
Cause of Death	
• Anoxia (n (%))	37/74 (50.00%)
• Cerebrovascular/Stroke (n (%))	24/74 (32.43%)
• Head Trauma (n (%))	12/74 (16.22%)
• CNS Tumor (n (%))	0/74 (0.00%)
• Other [1] (n (%))	1/74 (1.35%)
Donor Inclusion Criteria [2]	
• Donor age ≥ 40 years old (n (%))	50/74 (67.57%)
• Expected total cross clamp/cold ischemic time ≥ 6 hours (n (%))	33/74 (44.59%)
• Donor after circulatory death (DCD) with age ≤ 55 years old (n (%))	17/74 (22.97%)
• Steatotic liver greater than 0% macrosteatosis and less than or equal to 40% macrosteatosis at time of retrieval (n (%))	37/74 (50.00%)
• Multiple Donor Characteristics	43/74 (58.11%)

(1) Bacterial meningitis
(2) Multiple donor characteristics (inclusion criteria) could be met.

15.3.2. Recipient Demographic and Baseline Characteristics

Recipient demographic and baseline characteristics are shown in Table 41 below and are similar to the OCS Liver PROTECT trial, except that PROTECT CAP has a higher percentage of primary hepatic tumor (17.6% in CAP) compared to PROTECT (9.2%).

Table 41: Recipient Demographic and Baseline Characteristics, OCS Liver PROTECT CAP

Parameter	OCS Patients (N=74)
Age (years): Mean ± SD	57.01 ± 11.572
Gender:	
• Male	56/74 (75.68%)
• Female	18/74 (24.32%)
BMI (kg/m^2): Mean ± SD	29.18 ± 6.258
MELD Score: Mean ± SD	27.69 ± 6.034
Medical history	
• History of diabetes	22/74 (29.73%)
• History of liver cancer	30/74 (40.54%)
Primary Diagnosis	
• Alcoholic Cirrhosis	30/74 (40.54%)
• Cholestatic Diseases	5/74 (6.76%)
• Chronic Hepatitis	12/74 (16.22%)
• Metabolic Diseases	1/74 (1.35%)
• NAFLD/NASH	10/74 (13.51%)
• Primary Hepatic Tumor	13/74 (17.57%)
• Other	3/74 (4.05%)
○ Cholangiocarcinoma	2/74 (2.70%)
○ Primary Biliary Cholangitis	1/74 (1.35%)

15.3.3. Early Allograft Dysfunction (EAD)

EAD for all patients was adjudicated by the CEC and is shown in Table 42 below. The rate of EAD is slightly higher than that observed in the PROTECT trial. The difference in EAD between PROTECT and CAP is not statistically significant (p=0.2178, Fisher's Exact test).

Table 42: EAD Results, OCS Liver PROTECT CAP

	OCS Subjects (N=74)
EAD	19/74 (25.68%)
• AST level > 2000 IU/L within the first 7 postoperative days	15/74 (20.27%)

	OCS Subjects (N=74)
• Bilirubin ≥ 10 mg/dl on postoperative day 7	4/74 (5.41%)
• INR ≥ 1.6 on postoperative day 7	5/74 (6.76%)
• Primary non-functioning graft within the first 7 days	0/74 (0.00%)

15.3.4. Patient Survival/Graft Survival

By the date of database closure, all 74 patients met the 30-day post-transplant follow-up. The 30-day patient and graft survival were 98.7%. Long-term follow-up of the CAP patients is ongoing. To-date, a total of 5 deaths have occurred among the 74 patients. Summary of the causes of deaths reported were as follows:

- **Patient 1** (b)(6) **:** 73 y.o. recipient with MELD score of 28, BMI of 40 and severely compromised cardiac function. Arrested several times intra-operatively and experienced DIC and pulmonary embolism requiring TPA administration during the transplant procedure. Liver function was negatively impacted due to severe hemodynamic compromise and DIC due to cardiac arrest. Patient expired on day 111 from generalized sepsis.
- **Patient 2** (b)(6) **:** 47 y.o. recipient with MELD score of 40 and diagnosis with alcoholic liver cirrhosis. The patient expired on day 30 due to sepsis secondary to perforated duodenal ulcer.
- **Patient 3** (b)(6) 73 y.o. recipient with MELD score of 28. Patient expired on day 59 due to sepsis of respiratory origin.
- **Patient 4** (b)(6) **):** 57 y.o. recipient with MELD score of 15. Patient expired on day 75 due to respiratory failure secondary to pre-existing hepatopulmonary syndrome.
- **Patient 5** (b)(6) **:** 61 y.o. recipient with MELD score of 32. Patient expired on day 108 from respiratory sepsis secondary to mycobacterium lung abscess.

All of the causes of death and liver graft relatedness have been CEC reviewed and adjudicated.

15.3.5. Summary of PROTECT CAP Results

There has been a total of 74 subjects transplanted in the OCS Liver PROTECT CAP. The results for the OCS Liver PROTECT CAP to date are similar to those observed in the OCS arm of the OCS Liver PROTECT trial. Long-term follow-up is ongoing on all CAP patients.

15.4. Summary of Clinical Evidence Supporting the Approval of the OCS Liver System

The OCS Liver PROTECT trial is a large, multi-center, randomized, controlled trial in the U.S. that was conducted to evaluate the clinical impact of OCS Liver perfusion and assessment on post-transplant clinical outcomes in liver transplantation from DBD and DCD donors.

The results of the OCS Liver PROTECT trial provide ample evidence of effectiveness, safety, and favorable benefit/risk profile to support the OCS Liver System approval for the proposed clinical indication:

OCS Liver System Demonstrated Effectiveness:

- The OCS Liver PROTECT trial met the primary endpoint and demonstrated statistical superiority in reduction of EAD in both PP and mITT populations compared to the Control arm. EAD is the most common severe complication after liver transplantation. EAD is associated with significant risk of graft failure requiring re-transplantation and prolonged ICU and hospital stay, which negatively impact patients' clinical quality of life and healthcare resource utilization post-transplant.
- The OCS Liver PROTECT trial met all secondary effectiveness endpoints demonstrating that liver grafts can be assessed and monitored extracorporeally using the OCS Liver System.
- The use of the OCS Liver System demonstrated a clinically significant reduction of the most serious long-term post-transplant complication of ischemic biliary complications compared to Control at the 6 and 12-month follow-up timepoints in both the PP and mITT populations. Ischemic biliary complications negatively impact long-term viability of the liver allograft and patient survival.
- The use of OCS Liver System resulted in significant reduction of ischemic time on the donor liver which resulted in less ischemia/reperfusion (IR) injury in the OCS arm compared to Control based on blinded pathological assessment.
- The OCS livers were associated with high and comparable patient survival at 30 days, at initial hospital discharge, and at 6 and 12 months compared to the Control arm.
- The results of the OCS Liver PROTECT CAP provide additional supporting evidence of the effectiveness of the OCS Liver System to preserve livers (including DCD livers) with a lower rate of EAD compared to Control arm of PROTECT.

OCS Liver System Demonstrated Safety:

- The OCS Liver PROTECT trial met its safety endpoint by demonstrating that the average rate of LGRSAEs in the OCS arm was statistically non-inferior to the Control arm.
- When analyzing the specific LGRSAEs, the OCS arm did not experience any ischemic biliary complications in the first 30 days post-transplant and was associated with lower incidence of vascular complications compared to Control arm.
- Rate of reported device malfunctions was low. Importantly, all 3 donor livers in these reported cases of device malfunction were transplanted and analyzed successfully in the results of the OCS Liver PROTECT trial. There was no increased risks or additional risks observed to donor organs or recipients as a result of these reported incidents.
- There were no safety signals seen in patient mortality, graft survival, or LGRSAEs. Serious Adverse Events (SAEs) were those typically experienced post-liver transplant and were similar for the OCS and Control groups.

The OCS Liver System Demonstrated Favorable Public Health Benefit/Risk Profile by :

- Positively impacting DBD and DCD donor liver utilization for transplantation
- Significantly improving post-transplant clinical outcomes

Clinical benefits associated with OCS Liver positive impact on DBD and DCD donor organ utilization for transplantation:

- The OCS Liver System significantly reduced ischemic injury/time on donor livers despite long out of body time. This capability may potentially enable safe distant liver procurement to maximize utilization of the donor liver allografts from both DBD and DCD donors
- OCS Liver System's assessment capabilities resulted in two distinct potential clinical benefits in liver transplantation:
  - Substantial increase in DCD donor liver utilization for transplantation (i.e., OCS 28/55 (51%) vs. Control 13/51 (26%)).
  - It enabled more clinical datapoints to be evaluated *ex-vivo* that may have assisted in the identification of hidden pathologically damaged DCD liver allografts, protecting the intended recipients from potentially poor outcomes.

Broader utilization of DBD and DCD livers for transplantation in the U.S. would be a substantial clinical public health benefit to meet the growing demand for liver transplant therapy and could potentially reduce the waiting list mortality for patient waiting for a liver transplantation.

Clinical benefits associated with OCS Liver improved post-transplant clinical outcomes:

- The use of the OCS Liver System was associated with significant reduction in incidence of EAD post-liver transplantation. The data in the PROTECT trial as well as studies in the literature demonstrate that the reduction of EAD is associated with:
  - Significant reduction in risks for post-transplant graft failure;
  - Significant reduction of post-transplant ICU and hospital length of stay of transplant recipients;
  - Significant reduction of liver allograft ischemia/reperfusion injury based on histological assessment; and
  - Significant reduction in post-transplant reperfusion syndrome for transplant recipients as assessed by recipients' lactate levels post-transplantation.
- The use of the OCS Liver System was also associated with clinically significant reduction of ischemic biliary complications at 6 and 12 months post-transplant.
- There were no safety signals with a low number of LGRSAEs

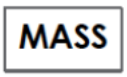
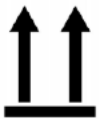
Improved clinical outcomes after liver transplantation would be a significant public health benefit as it would make liver transplant outcomes more successful while potentially reducing post-transplant healthcare resource utilization.

In conclusion, the OCS Liver PROTECT trial was the first of its kind trial to target a specific group of DBD and DCD liver donors that may be challenging to utilize with cold storage. Achieving the above superior clinical effectiveness and safety outcomes should enable expansion of donor liver utilization from DBD liver allografts and expansion of the donor pool by using DCD liver allografts to help end-stage liver failure patients access this curative transplant therapy.

16. APPENDIX B: SYMBOLS GLOSSARY

This glossary describes the symbols used on the packaging for the OCS™ Liver 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 7000-2502	Graphical symbols for use on equipment.	Sterilized using irradiation
	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 OCS™ and perfusion module
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	WEEE—Subject to waste electrical and electronic equipment regulations, i.e. not for general waste
	IEC 60529	Degrees of Protection provided by enclosures (IP Code).	Level 1 ingress protection
	ISO 7000-0632	Graphical symbols for use on equipment.	Temperature limit
	ISO 7000-0626	Graphical symbols for use on equipment.	Keep dry
	ISO 7000-0624	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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