LifePort®
Kidney Transporter

LifePort Kidney Transporter 1.1
Operator's Manual

This Operator's Manual references
LifePort Kidney Transporter
Model Numbers:
LKT101P
LKT101PNG

CE
2460

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LifePort Kidney Transporter manufactured in the USA for Organ Recovery Systems, Inc.

Updated 01/19/2024

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Introduction

Purpose of Manual

This manual provides the essential information necessary for installation, operation, and routine care of LifePort Kidney Transporter. The instructions within this manual should be carefully followed for safe and effective equipment use. It contains important operation and maintenance information for personnel trained to use this device.

It is important that all personnel who will operate LifePort Kidney Transporter:

- Read and understand this manual before device operation.
- Follow all warnings and precautions outlined in the sections ***Operational Precautions and Limitations*** and ***Hazards*** for their own safety and the safety of those around them.

This manual is **NOT** to be used as a replacement for training in the practice or science of organ perfusion. Specific practice regarding machine perfusion of kidneys recovered from pediatric donors, or donor kidneys intended for pediatric recipients, must be conducted according to the protocols specified by the transplant physician and institution policies. This manual does **NOT** contain information for servicing internal components of LifePort Kidney Transporter. If more information is needed about installation, organ perfusion, or if you have any questions, please contact the Organ Recovery Systems 24/7 Perfusion Helpline.

In this manual, the following definitions apply for all **WARNING** and **CAUTION** statements.

WARNING: A warning statement covers any operation, procedure, practice, etc., which if not strictly observed, might result in serious injury or long-term health hazards to personnel or patients.

CAUTION: A caution statement covers any operation, procedure, practice, etc., which if not strictly observed, might result in mild or moderate injury or damage or destruction of equipment or loss of performance.

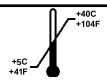
Abbreviations

The abbreviations used in this manual are listed and defined in the following table.

A	Ampere
AC	Alternating Current
°C	Degrees Celsius
cm	Centimeter (1 cm = .01 m)
EMC	Electromagnetic compatibility
EU MDD	European Union Medical Device Directive
FCC	Federal Communications Commission
FDA	Food and Drug Administration
Hz	Hertz
ID	Identification or Identification Number
IEC	International Electrotechnical Commission
IR	Infrared
lb(s)	Pound (1 lb = 0.45 kg)
kg	Kilogram (1 kg = 2.2 lbs)
LKT	LifePort Kidney Transporter
mL/min	Milliliters per minute
mmHg	Millimeters of mercury (1 mmHg = 1 Torr = 133.3 Pa)
RF	Radio Frequency
V	Volts

Label Graphics Explanations

The following table provides an explanation of the label graphics for LifePort Kidney Transporter system.

	Warning/Caution		Do Not Reuse
	Lot Number		Do Not Resterilize
	Serial Number		Temperature limits
	Reference Number		Sterilized Using Aseptic Fill
	Sterilized Using Ethylene Oxide		Consult Instructions for Use
	Manufacturer		Use By, YYYY-MM-DD
	Date of Manufacture, YYYY-MM-DD		Keep Dry
	Keep Away From Sunlight		Electric Shock Hazard
	Prescription Medical Device	IPX1	Protected against falling water.
	Power button/standby power		Circuit breaker. Push to reset.
	Data Port (USB)		Interference may occur in the vicinity of equipment.
	Battery slot graphic showing slot numbering and insertion orientation.		Medical – General medical equipment as to electrical shock, fire and mechanical hazards in accordance with ANSI/AAMI ES60601-1.
	Medical Device		Country of Origin
	Importer		Single Sterile Barrier System
	Single Sterile Barrier with protective packaging inside for aseptic field		Audible Alerts - ON/OFF

System Description

Intended Use

LifePort Kidney Transporter (LKT) is intended for use in continuous hypothermic machine perfusion of kidneys.

Indications for Use

LifePort Kidney Transporter is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, optional transportation and eventual transplantation into a recipient.

Target Population

The targeted populations are both adults and pediatrics.

The intended patient population for machine preserved kidneys are kidney transplant-eligible patients under the care of a licensed kidney transplant surgeon. The patient, however, does not come in contact with LifePort Kidney Transporter system.

Intended User

Primary users of LifePort Kidney Transporter system will be medical professionals who have been trained to operate LifePort Kidney Transporter system. It is expected that users of LifePort Kidney Transporter system will also have a substantive working knowledge and clinical experience with donor organ recovery and transplantation.

Clinical Benefit

Hypothermic machine perfusion of kidneys using LifePort Kidney Transporter system with KPS-1 Kidney Perfusion Solution has been demonstrated through clinical evidence to improve kidney function post transplantation by reducing delayed graft function.

Device Performance/Performance Characteristics

LifePort Kidney Transporter system is intended to be used with KPS-1 Kidney Perfusion Solution to provide continuous hypothermic machine perfusion of kidneys for the preservation, transportation, and eventual transplantation into a recipient. The device maintains the organ in a cool, aseptic container during perfusion and transport to achieve this function.

Device Lifetime

LifePort Kidney Transporter has an estimated device service lifetime of 5 years.

Residual Risk

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended users, there are no known side effects that can occur during or after use and thus no residual risk is associated with use of LifePort Kidney Transporter.

Serious Incident Reporting

User should report the occurrence of any serious incident to Organ Recovery Systems and to the competent authority of the Member state in which the user and/or patient is established.

Safety

LifePort Kidney Transporter is safe when used as described in this manual. It is designed to meet recognized U.S. and international standards for medical equipment and systems, as stated by the Underwriters Laboratories (UL) and the International Electrotechnical Commission (IEC).

Electrical and mechanical safety features have been designed into LifePort Kidney Transporter to ensure safe operation.

These features are as follows:

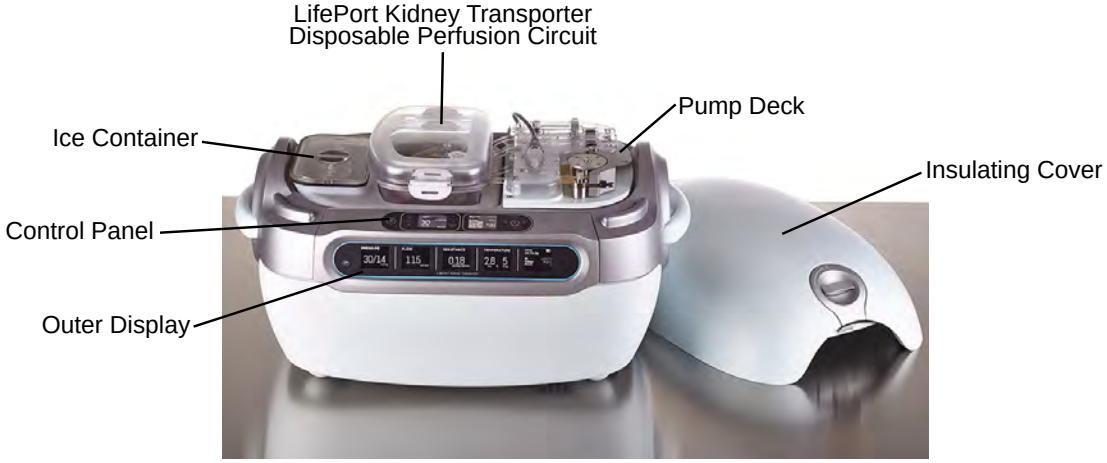
- The electrical and electronic components are contained within a secure enclosure.
- Pressure levels are only adjustable within a set range. Temperature and flow rates cannot be adjusted by the operator. If any of these values fluctuate outside of normal ranges, alerts may be triggered.
- Perfusate pressure, flow rate, and temperature are continuously monitored.
- Display screens illuminate when the power is on. Stop, Wash, Prime, and Infuse controls are provided and identified, depending on the mode of operation and options available.
- Acceptable operating ranges are established within LifePort Kidney Transporter for pressure, temperature, flow rate, battery charge state, bubbles in the perfusate, and configuration integrity. Hardware and software interlocks are built-in to bring LifePort Kidney Transporter to a fail-safe condition if an unacceptable operating state is detected.
- LifePort Kidney Transporter gives an audible alert and a descriptive message if an unacceptable operating state is detected.

Contraindications

There are no known contraindications when used as directed.

Physical Description

LifePort Kidney Transporter is designed to integrate with the clinical environment by using readily available supplies, requiring minimal user intervention, and by being easy to use. LifePort Kidney Transporter is a portable, isolated kidney perfusion and transport system, designed to support a donated kidney and to maintain the organ in a near-normal physiologic state under hypothermic aseptic conditions. An insulated plastic housing encloses the kidney and perfusate within a LifePort Kidney Transporter Disposable Perfusion Circuit. LifePort Kidney Transporter components include an Ice Container, Pump Deck, Control Panel, Outer Display, Bubble Detectors, External Connections Panel, sensors, and four lithium-ion batteries. Two handles make the unit easy to lift and carry.



Cover

An insulated, removable, latched Cover securely closes over the housing to protect the kidney and maintain the proper temperature during perfusion.

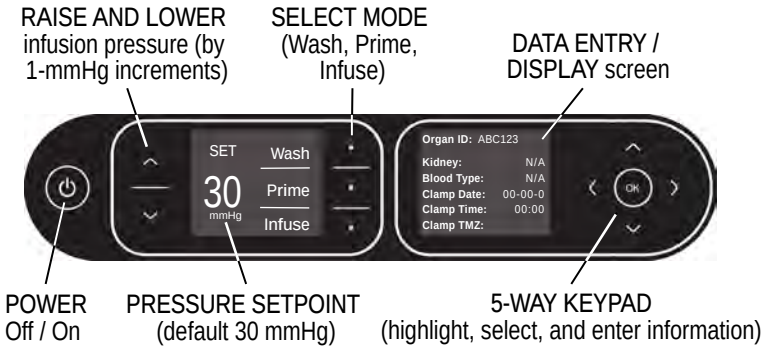
Ice Container

A molded thermoplastic Ice Container with a removable lid is designed to be filled with a recommended mixture of ice and water to provide a hypothermic temperature environment for the donor kidney.

With the Ice Container properly loaded, LifePort Kidney Transporter preserves kidneys hypothermically to the same degree as conventional static storage methods, even when powered off.

Control Panel

The Control Panel is located next to the Pump Deck. The panel can be accessed only when the Cover is removed, which prevents inadvertent and unauthorized access to the controls. The left screen displays the current pressure setpoint and the operational mode. The right screen displays user-entered information.

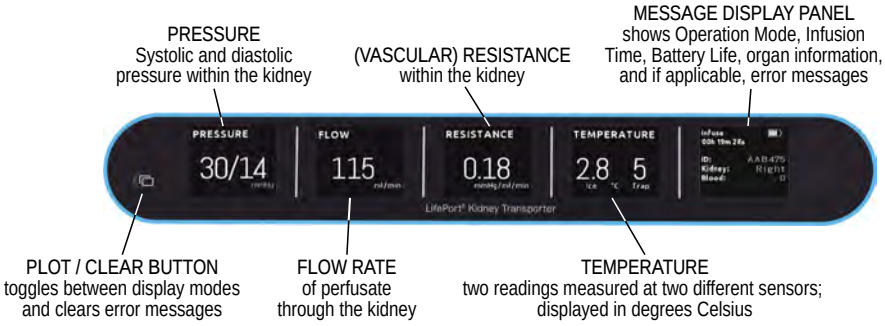


Outer Display

The Outer Display is a horizontal panel visible whether the Cover is in place or removed. It provides information on operational parameters as well as additional information about the perfusion history.

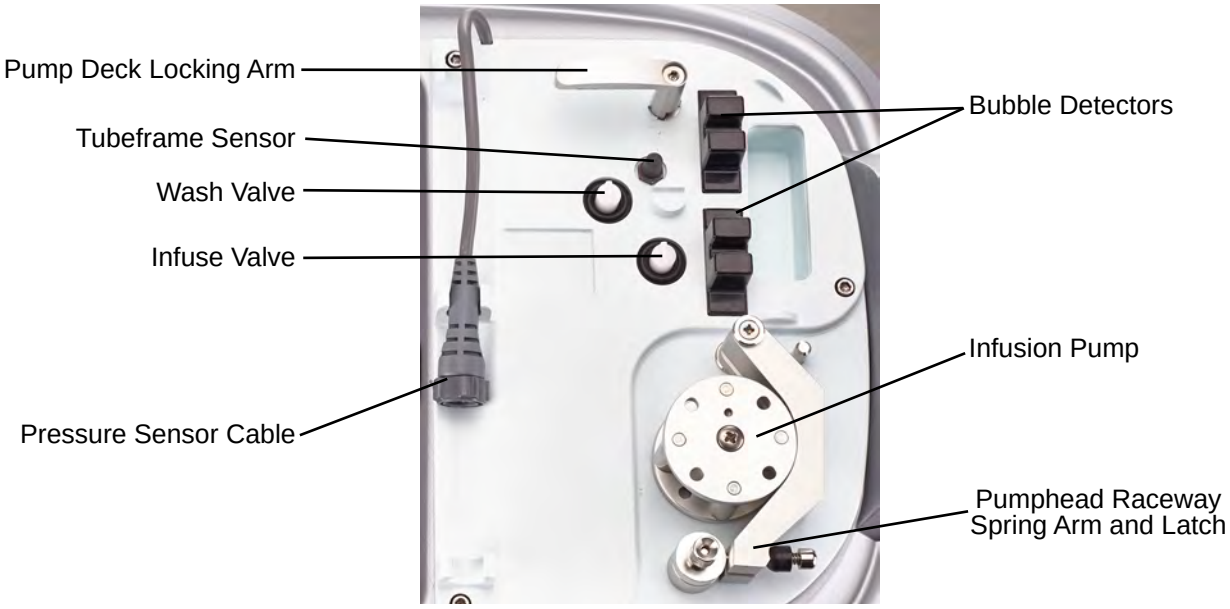
The display can be toggled between numerical values and trend lines of values for flow and resistance.

The temperature display shows the temperatures of the Ice Container as read at a sensor located near the Ice Container and the temperature of the perfusate within the Bubble Trap as read by a sensor.



Pump Deck

On the Pump Deck, LifePort Kidney Transporter Disposable Perfusion Circuit tubing traverses a peristaltic pump, valves and sensors, which control the pressure, speed, and fluid pathway of the perfusate.



- **Pump Deck Locking Arm**—secures the Perfusion Circuit Tubeframe in place on LifePort Kidney Transporter.
- **Tubeframe Sensor**—detects when the LifePort Kidney Transporter Disposable Perfusion Circuit Tubeframe is properly placed.
- **Infuse and Wash Valves**—determine whether the perfusate enters or bypasses the kidney. In Infuse and Prime Modes, the Infuse Valve is open and the Wash Valve is closed, allowing perfusate to flow into the kidney. In Wash Mode and while purging bubbles, the Wash Valve is open and the Infuse Valve is closed, directing the perfusate through the Wash Line, directly back into the perfusate reservoir.
- **Pressure Sensor Cable**—provides LifePort Kidney Transporter with information about the perfusion pressure felt by the kidney. If the Pressure Sensor connection is broken, LifePort Kidney Transporter stops and displays an error message.
- **Bubble Detectors**—check the perfusate to prevent bubbles from entering the kidney. One is located upstream of the Perfusion Circuit Bubble Trap to divert detected bubbles away from the kidney and into the Wash Line, after which LifePort Kidney Transporter will resume perfusing. The other is located immediately before the Infuse Valve and prevents detected bubbles from entering the kidney by stopping perfusion altogether.
- **Infusion Pump**—a peristaltic pump that propels perfusate through the kidney. It circulates perfusate through the kidney by moving rollers against the Perfusion Circuit Pump Tubing Loop. LifePort Kidney Transporter regulates pump speed to control perfusion pressure.

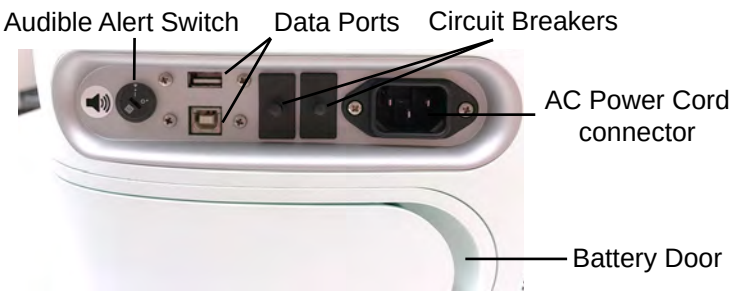
  WARNING: Beware of rotating parts. Keep hands, clothing, jewelry, ID lanyards, etc. away from the vicinity of the Infusion Pump when LifePort Kidney Transporter is powered on.

- **Pumphead Raceway**—consists of a spring arm and latch which hold the Perfusion Circuit Pump Tubing Loop in place around the Infusion Pump.

External Connections Panel

LifePort Kidney Transporter connects with an external power source and other devices through the External Connections Panel, which provides a standard AC Power Cord connector and USB-A and USB-B Data Ports.

Two Circuit Breakers trip if a short circuit occurs. Pressing the button resets the breaker.



CAUTION: Use only grounded electrical connections. Connect LifePort Kidney Transporter to a grounded electrical outlet rated for voltage and amperage according to the labeled ratings on the product back panel. If there is any question about the ground integrity, operate LifePort Kidney Transporter from internal power.

CAUTION: You may remove AC mains power by unplugging the Power Cord from the back of the unit. Exercise care when choosing the location of your LifePort Kidney Transporter so that removal of Power Cord is not difficult.

Audible Alert Switch

The Audible Alert Switch is standard on all new units. If you would like this installed on an existing device, contact Organ Recovery Systems.

The switch is used to turn audible alerts on and off. The switch is located either on the External Connections Panel (pictured above) or within the Battery Compartment (pictured below), depending on the device date of manufacture.

To turn audible alerts on, use a flathead screwdriver and turn the switch position to “I”. To turn audible alerts off, turn the switch position to “O”.

CAUTION: Audible alerts should only be turned off when temporary silencing of such alerts is required. It is the user’s responsibility to turn audible alerts on/off, utilizing the Audible Alert Switch as directed.

Operational Accessories

It is important to use only the accessories supplied by Organ Recovery Systems, as listed below.

Power Cord

LifePort Kidney Transporter comes equipped with a hospital grade Power Cord that connects to the LifePort Kidney Transporter External Connections Panel and to a standard grounded power outlet of commercial or hospital quality. Do not substitute an alternate Power Cord.

CAUTION: Do not substitute the Power Cord. Use only the Power Cord supplied from Organ Recovery Systems. For information, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

Data Cable

The 6-ft (2m) Data Cable connects LifePort Kidney Transporter to an external computer. The USB-B end connects to the Data Port on the LifePort and the USB-A end connects to the USB port of a personal computer.

Batteries

LifePort Kidney Transporter uses four specially designed lithium-ion rechargeable batteries as its portable source of power.

CAUTION: Do not substitute batteries. Use only LifePort Kidney Transporter batteries from Organ Recovery Systems. For information, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

When powered on, LifePort Kidney Transporter draws power from one battery at a time, using the batteries in sequence. It is possible to operate LifePort Kidney Transporter with one to four batteries, as each battery delivers the 11 to 12 volts required. However, it is recommended to use all four batteries, keeping the batteries as fully charged as possible.

NOTE: Total battery life can be found under Device Information on the Message Display Panel.

Access the batteries through the Battery Door on the LifePort Kidney Transporter External Connections Panel. Each battery is designed to slide in and out of the slots provided. When inserted properly, the battery should be flush with the slot panel, with the pull-tab visible and available for removing the battery. If the battery does not push flush, it may be in the wrong orientation. Turn the battery 180 degrees and try again.

The following tips will help you obtain maximum life and serviceability from the batteries.

- Always replace the Battery Door. LifePort Kidney Transporter must not be operated or shipped without the Battery Door in place.
- LifePort Kidney Transporter will recharge the batteries whenever it is plugged in. Plug in LifePort Kidney Transporter whenever not in transit to keep the batteries at the highest possible charge. It takes approximately five hours to completely recharge all four batteries.

  NOTE: Keep extra charged batteries on hand when long transport times are anticipated or when successive uses of LifePort Kidney Transporter with short turnaround times are expected.

- During storage of LifePort Kidney Transporter without connection to AC mains, the batteries will slowly drain. After 30 days without charging, the batteries could have little or no charge and will need a full five-hour recharge.
- For periods of storage for longer than 30 days, remove the batteries from LifePort Kidney Transporter.

  CAUTION: Extended storage may damage the batteries.

Safe Disposal of LifePort Kidney Transporter and LifePort Batteries

Lithium-ion batteries must be disposed of according to local regulations. For safe disposal of LifePort Kidney Transporter or LifePort Kidney Transporter batteries, call the Organ Recovery Systems 24/7 Perfusion Helpline to arrange for pickup from your facility.

LifePort Kidney Transporter Disposable Products

Single-use Disposables, an integral part of the LifePort Kidney Transporter system, are used to maintain the kidney and perfusate under aseptic conditions, to connect the kidney to the Perfusion Circuit, and to help maintain aseptic conditions while working inside the Perfusion Circuit. Each LifePort Kidney Transporter Disposable is factory sterilized and delivered in a sterile pack.

WARNING: For single use only. Do not reuse, reprocess, or resterilize. Reusing, reprocessing, or resterilization of single-use devices creates a potential risk of patient or user infections due to contamination. This contamination may lead to injury, illness, or other serious patient complications. Discard any unused portion of the product.

NOTE: To reorder LifePort Kidney Transporter Disposables, please contact Organ Recovery Systems.

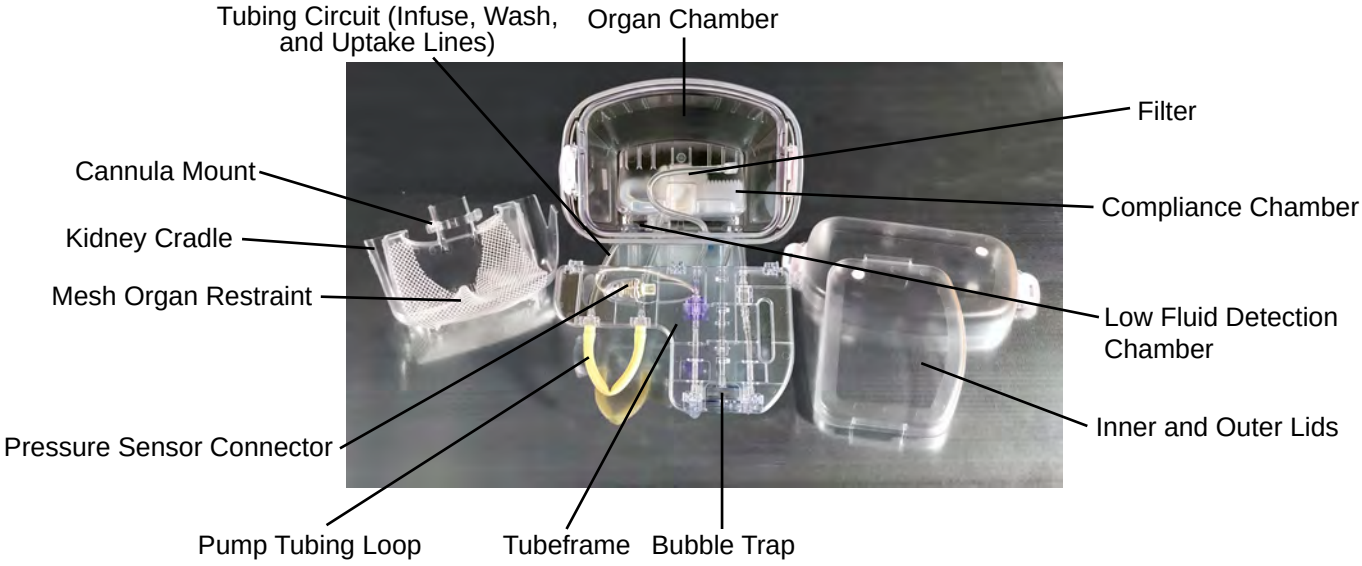
LifePort Kidney Transporter Disposable Cannulas

LifePort Kidney Transporter Disposable cannulas attach LifePort Kidney Transporter Disposable Perfusion Circuit to the kidney's renal artery. A large range of cannula types and sizes are available, making it possible to choose the cannula most compatible to the anatomy of the kidney.

LifePort Kidney Transporter Disposable Sterile Drape

The LifePort Kidney Transporter Disposable Sterile Drape is used to aid in maintaining aseptic conditions while working within the LifePort Kidney Transporter Disposable Perfusion Circuit.

LifePort Kidney Transporter Disposable Perfusion Circuit



LifePort Kidney Transporter Disposable Perfusion Circuit contains the fluid management components necessary for perfusing a single kidney and is comprised of following:

- **Organ Chamber**—the housing that contains the kidney and acts as the perfusate reservoir, where the kidney is maintained partially submerged.
  - **Low Fluid Detection Chamber**—provides real-time recognition of low fluid levels and an automatic stop of active perfusion if perfusate volume drops below a certain level.
  - **Inner and Outer Lids**—a transparent, sterile Inner Lid and transparent Outer Lid provide a redundant watertight seal.
  - **Kidney Cradle**—supports the kidney.
    - **Mesh Organ Restraint**—holds the kidney in place in the Kidney Cradle.

        - **Cannula Mount**—adjustable mount on the Kidney Cradle that holds the cannula in place.
- **Tubeframe**—plastic frame that positions the tubing around the Infusion Pump, valves, and sensors of the Pump Deck.
    - **Tubing Circuit**—the sealed fluid pathway that draws perfusate from the Organ Chamber for circulation into the kidney, is comprised of the following:
        - **Bubble Trap**—helps prevent air from entering the Infuse Line.
        - **Infuse, Wash, and Uptake Lines**—manage perfusate flow.
        - **Pump Tubing Loop**—extends from the Tubeframe and stretches around the Infusion Pump.
        - **Compliance Chamber**—helps maintain steady perfusion pressures.
        - **Filter**—collects material that could block kidney vasculature from achieving proper flows.
    - **Pressure Sensor Connector**—a flow-through Pressure Sensor within the Infuse Line that measures perfusate pressure within the Perfusion Circuit. Connects to the Pump Deck Pressure Sensor Cable and sends pressure data to LifePort Kidney Transporter.

Unpack, Setup, and Run Preliminary Tests

Overview

This section provides information for receiving, unpacking, setup and preliminary testing of LifePort Kidney Transporter. Refer to ***LifePort Kidney Transporter Use*** for routine operating instructions.

Introduction

LifePort Kidney Transporter is shipped in a special container that is marked for appropriate handling. It should be opened and checked only by a person trained and qualified to work with electronic medical equipment.

Select a Home Base Station

Designate a home base station for each LifePort Kidney Transporter where it can be set up and recharged between cases. The home base station should be a secure area, provide a clean benchtop or tabletop space, and meet the following requirements:

- Climate-controlled area of approximately 21°C, 50% humidity.
- No direct sunlight.
- AC mains electrical outlets (2 to 4 plugs: grounded, 120V/15A in the USA).
- Storage for LifePort Kidney Transporter Disposables, batteries, tools, and spares.
- Access to crushed or pelletized ice (hollow cubes not recommended).
- Access to a utility sink for cleanup and to provide water for the ice bath.
- Access to medical waste disposal.
- Access to refrigerated storage for perfusate and other medications.
- Tabletop space for a computer with USB port (recommended).
- Storage space for transplant coordinator gear: cart, bags, procedure kits, and coolers.
- Proximity to operating rooms and ready access to car, ambulance, or helicopter loading areas.

Unpack and Inspect

Carefully remove LifePort Kidney Transporter and its accessories from the shipping container. Save the packing materials for shipping and storage.

After unpacking, thoroughly inspect the system and all accessories for damage to ensure that:

- LifePort Kidney Transporter housing is not bent or distorted.
- There are no dents, chips, or cracks in the housing surface.
- Manual controls and movable parts, such as connectors, operate properly.
- Control Panel and Outer Display are properly aligned.
- All items listed on the shipping documents are present.

Report any damage found from this inspection to the carrier immediately. If you have any concerns about the condition of LifePort Kidney Transporter or its accessories, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

Run Preliminary Tests

Upon receipt of a new LifePort Kidney Transporter and prior to clinical use, it is recommended that the user complete the following tests. After each step, ensure LifePort Kidney Transporter functions as described and that there are no malfunctions, leaks, or irresolvable errors. If difficulties arise during setup and testing, refer to ***Troubleshooting and Diagnostics.***

Set Up LifePort Kidney Transporter

WARNING: LifePort Kidney Transporter weighs 45 lbs (20.4 kg) fully loaded. Use proper lifting procedures to avoid injury.

1. Place LifePort Kidney Transporter so that the Outer Display is easily accessible.
2. Unlatch and remove LifePort Kidney Transporter Cover and store it nearby.
3. Complete your review of LifePort Kidney Transporter, ensuring it is secure, intact, and that nothing appears damaged, before starting the preliminary tests.

Fill the Ice Container

NOTE: USE ONLY ICE AND COLD WATER in LifePort Kidney Transporter Ice Container. A mixture of ice and cold water in the Ice Container will ensure that temperatures remain within the appropriate range for clinical kidney preservation.

1. Open the Ice Container and fill with crushed or pelletized ice, pushing the ice as far in as possible.
2. Pour approximately 1 Liter of cold water (less than 10°C) into the Ice Container, which will gradually loosen the ice.
3. Add more ice and another 0.5–1.0 Liter of cold water until the Ice Container is full, maximizing the amount of ice added.
4. Replace and lock the Ice Container Lid.

Load LifePort Kidney Transporter Disposable Perfusion Circuit

NOTE: As this is a preliminary test, aseptic technique does not have to be followed. For detailed, sterile instructions, refer to LifePort Kidney Transporter Disposable Perfusion Circuit Instructions For Use.

1. Ensure Locking Arm and Pumphead Raceway are open on LifePort Kidney Transporter.
2. Unpack LifePort Kidney Transporter Disposable Perfusion Circuit and place into the Ice Container.
3. Position the Tubeframe upright, perpendicular to the Pump Deck. Insert the hinges into the receivers before rotating the Tubeframe flat onto the Pump Deck.
4. Stretch the Pump Tubing Loop around the Infusion Pump. Close and latch the Pumphead Raceway.
5. Rotate the Pump Deck Locking Arm 90 degrees until it clicks into place.
6. Connect the Pressure Sensor Cable from the Pump Deck to the Pressure Sensor Connector on the Tubeframe.
7. Remove the Inner and Outer Perfusion Circuit Lids and pour 1 Liter of cold (less than 10°C) water into the LifePort Kidney Transporter Disposable Perfusion Circuit.
8. Replace and secure the Inner and Outer Perfusion Circuit Lids.

Energize the LifePort Kidney Transporter

1. Connect the Power Cord to LifePort Kidney Transporter External Connections Panel and plug it into an AC mains electrical outlet.
2. Verify the Audible Alert Switch is turned to “I”.
3. Press and hold the **POWER** button until you hear an audible beep, then release.
4. On the Control Panel, you should observe the following:
    - The screens illuminate.
    - The pressure setpoint shows default value of 30 mmHg.
    - Mode control displays show **WASH**, **PRIME**, and **INFUSE**.

4. On the Outer Display, you should observe the following:
    - The screens illuminate.
    - Pressure, Flow, and Resistance all read zero.
    - Temperature shows the temperature of the Ice Container.

NOTE: The temperature reading may be high when first energized. When the Ice Container temperature is above 8°C, LifePort Kidney Transporter will not function and indicate an error message. It may take several minutes before the display reads below 8°C and the device is operational.

If errors occur during setup or while energizing, refer to ***Troubleshooting and Diagnostics*** for information on how to proceed.

Test Operating Modes

Set Pressure

1. Press the pressure **UP/DOWN** arrow buttons and verify that the pressure can be adjusted by 1 mmHg with each press.
2. Using the **UP/DOWN** arrow buttons, set the pressure to 40 mmHg.

Wash

1. Press the **WASH** button and verify Infusion Pump rotation.
2. Verify that water is drawn through the Tubing Circuit, down into the filter, into the Bubble Trap, and through the Wash Line. Verify that the water is contained in the tubing, without leaking, and is not flowing through the Infuse Line.
3. Press the **STOP** button to exit Wash Mode.

Prime

1. Press the **PRIME** button and observe that the flow diverts into the Infuse Line.
2. Verify water is contained within the tubing, without leaking, and is not flowing through the Wash Line.
3. Remove the Outer and Inner Perfusion Circuit Lids.
4. Squeeze or clamp the Infuse Line. LifePort Kidney Transporter will cease function, provide an audible alert, and the Message Display Panel should read: **High Pressure**.
5. Release the Infuse Line and press the **STOP** button to clear the error message.

Infuse

NOTE: We recommend users make an entry under **ORGAN ID** before running an Infuse test. If an entry is not made, the device will record the file using a default timestamp.

1. On the 5-way keypad, press **OK**, use the arrow buttons to select **ORGAN INFORMATION**, and press **OK** again.
2. Select **ORGAN ID**, then press **OK**.
3. Select the alphanumerics for the Organ ID you wish to assign, pressing **OK** with each selection.
4. Scroll to **DONE**, press **OK**, and select **SAVE** to confirm.
5. Select **KIDNEY**, then press **OK**.
6. Select **NA**, press **OK**, and select **SAVE** to confirm.
7. Select **BLOOD TYPE**, then press **OK**.
8. Select **NA**, press **OK**, and select **SAVE** to confirm.

NOTE: Attach an 18-gauge flow restrictor or an 18-gauge needle onto the Luer fitting on the Infuse Line.

9. Press the **INFUSE** button.

10. Verify that pressure, flow, resistance, and temperature readings are displayed on the Outer Display.

NOTE: TRAP temperature represents the temperature measured at the Bubble Trap, which is only displayed during active infusion.

11. Verify that the **ORGAN INFORMATION** you entered is displayed.
12. Press the **STOP** button to exit Infuse Mode.
13. Press and hold the **POWER** button to turn off LifePort Kidney Transporter.

Test Batteries

Upon receipt of a new LifePort Kidney Transporter and prior to clinical use, it is recommended that the user complete the Preliminary Tests with and without the batteries. Allow the batteries to charge in LifePort Kidney Transporter for at least five hours prior to clinical use.

1. Open LifePort Kidney Transporter Battery Door by sliding it away from the product label.
2. Insert the batteries.
3. Replace the LifePort Kidney Transporter Battery Door.
4. Verify the Outer Display shows that LifePort Kidney Transporter is plugged in and charging. Allow the batteries to charge in LifePort Kidney Transporter for at least five hours before unplugging the Power Cord.
5. Repeat the ***ENERGIZE*** and ***TEST OPERATING MODES*** tests as described above, using battery power.

NOTE: Ensure that the Power Cord is unplugged before repeating the tests to accurately assess battery power.

Check Duration of Operation (Optional)

1. Press **OK**.
2. Select **DEVICE INFORMATION**, then press **OK**.
3. View percentage of battery charge. The screen returns to the main screen in 10 seconds.
4. With the batteries fully charged, Power Cord unplugged, and the Ice Container full, operate LifePort Kidney Transporter in Infuse Mode for 24 hours. During this test:
   - Keep the flow restrictor positioned on the Infuse Line.
   - Keep the Cover closed for the entire 24 hours.
5. Verify that the ice and batteries last throughout the entire duration of the test.

Enter Device Information

1. Press **OK**, use the arrow buttons to select **DEVICE INFORMATION**.
2. Select **DEVICE ID**, then press **OK**.
3. Select the alphanumerics for the name you wish to assign LifePort Kidney Transporter, pressing **OK** with each selection.
4. Scroll to **DONE**, press **OK**, and select **SAVE**.
5. Select **DATE** to enter the current month, day, and year and press **OK**. Select **SAVE** to confirm.
6. Select **TIME** to enter the current time and press **OK**. Select **SAVE** to confirm.
7. Select **TIME ZONE (TMZ)** to enter the alphanumerics of the time zone you wish to assign, pressing **OK** with each selection.

   NOTE: The time zone must be in 3 characters, e.g., “CST” for “Central Standard Time”.

8. Scroll to **DONE**, press **OK**, and select **SAVE**.
9. Select **LANGUAGE** and scroll to the desired language you want LifePort Kidney Transporter to display.
10. Scroll to **DONE**, press **OK**, and select **SAVE**.

External Communications using Data Station

Data Station is an optional software application that can be installed on a computer. Data Station software allows communication between LifePort Kidney Transporter and a computer, making it possible to monitor LifePort Kidney Transporter operations.

Consult the Data Station Operator’s Manual to install the application on the computer(s) you plan to use to monitor LifePort Kidney Transporter.

Clean Up and Review After Use

LifePort Kidney Transporter must be thoroughly cleaned and disinfected prior to its first and subsequent uses. For complete cleaning and disinfecting instructions, see ***Clean and Disinfect After Use***.

LifePort Kidney Transporter should always stay dry and error-free. Anomalies uncovered during any of these preliminary tests such as leaks, misrouted flow, and extra or missing error messages should be investigated and resolved.

If you need assistance, contact Organ Recovery Systems 24/7 Perfusion Helpline.

LifePort Kidney Transporter Use

Introduction

This section provides information on routine use of LifePort Kidney Transporter from setup through cleanup during a clinical case.

NOTE: Be sure to keep the batteries plugged in and charging when LifePort Kidney Transporter is not in use.

Professional Overview

Before using LifePort Kidney Transporter in a clinical setting, thoroughly familiarize yourself with the device and kidney perfusion. Consider practicing on discarded or animal kidneys. Various settings should be tried and a sense obtained as to the effects on the kidney.

Be aware of the following important factors:

- Select an infusion pressure for use according to good clinical practice to assure sufficient flow while preventing vascular damage.
- Secure cannulas to avoid perfusate leaks while preventing damage to the transplanted artery.
- Inspect and position the cannulated artery to avoid any twists or kinks that would occlude the flow of perfusate.
- Maintain aseptic conditions for the kidney and perfusate at all times. Sealing the Organ Chamber while using standard aseptic technique is required.
- Maintain hypothermic conditions for the kidney by keeping LifePort Kidney Transporter Ice Container filled. Use only ice and water to prevent freezing.

Maintain LifePort Kidney Transporter for Quick Response Use

Before you receive the call that LifePort Kidney Transporter is needed, keep it ready to go at a moment's notice by performing the following procedures.

Prepare the Home Base Station

LifePort Kidney Transporter and its supplies and accessories are designed to be an integral part of the recovery team's supply pack, to be seamlessly included in the recovery and transplant process.

Have the following prepared to keep LifePort Kidney Transporter in a ready-to-use state:

- Crushed or pelletized ice—10 lbs (5–6 kg) or more—readily available in a freezer or ice maker.
- Batteries loaded in LifePort Kidney Transporter and kept fully charged. Maintain the batteries' charge by keeping LifePort Kidney Transporter plugged in.
- Perfusion Circuit, Sterile Drapes, and cannulas packed and ready.
- Portable, wheeled cart available and ready.
- Surgical instruments, suture, solution decanter, and supplies packed and ready.
- Spare accessories on hand, such as additional charged batteries, Power Cord, etc.
- Distilled, sterile, or regular tap water (about 5 Liters)—chilled in the refrigerator.
- Perfusion solution and organ flush solution—chilled in the refrigerator.

WARNING: Use only machine perfusion solution in LifePort Kidney Transporter. Check the labeling of the perfusion solution and make sure that it is intended for machine perfusion.

NOTE: If you are uncertain about which solutions are appropriate, contact the Organ Recovery Systems 24/7 Perfusion Helpline for information on recommended perfusates that work best in LifePort Kidney Transporter.

Prepare LifePort Kidney Transporter for Recovery

These instructions can be modified according to your institution's procedures. When you receive the call that LifePort Kidney Transporter is needed, perform the following procedures to prepare the device before taking it to recover a kidney:

- Make sure you have everything you need—using a checklist, double check all your equipment and supplies to make sure it is all packed and on the cart.
- Recheck the batteries—check that the batteries are fully charged. Press the **POWER** button and verify that the LifePort Kidney Transporter powers up. Press the **POWER** button again to turn it off.
- Visually check LifePort Kidney Transporter and Disposable Perfusion Circuit—check for overall integrity and transport-worthiness before each use. Do not use if parts are loose, cracked, or broken, or liquid is leaking.

Travel with LifePort Kidney Transporter and Supplies

If you're traveling with LifePort Kidney Transporter, take the following precautions:

- Secure LifePort Kidney Transporter from sliding or rolling. If the device is placed on a vehicle seat, the normal seat belt can be used to restrain it while driving.
- If necessary, turn off audible alerts by turning the Audible Alert Switch to the "O" position.

CAUTION: Audible alerts should only be turned off when temporary silencing of such alerts is required. It is the user's responsibility to turn audible alerts on/off, utilizing the Audible Alert Switch as directed.

- Check LifePort Kidney Transporter Cover to make sure it is closed and latched.

Fill LifePort Kidney Transporter Ice Container

WARNING: To avoid inadvertently freezing the kidney, **USE ONLY ICE AND WATER** in LifePort Kidney Transporter Ice Container. A mixture of ice and water in the Ice Container will ensure that temperatures remain within the appropriate range for kidney preservation.

NOTE: As a safeguard to the kidney, LifePort Kidney Transporter will not operate unless the Ice Container temperature is chilled between 1–8°C. After installation of the Ice Container, it may take several minutes before the display reads a temperature below 8°C.

1. Remove the Cover from LifePort Kidney Transporter and remove the Ice Container.
2. Open the Ice Container and fill it with crushed or pelletized ice, pushing the ice as far in as possible.
3. Pour approximately 1 Liter of cold water (less than 10°C) into the Ice Container, which will gradually loosen the ice.
4. Add more ice and another 0.5–1.0 Liter of water until the Ice Container is full, maximizing the amount of ice added.
5. Replace and lock the Ice Container Lid.
6. Place locked Ice Container in LifePort Kidney Transporter.

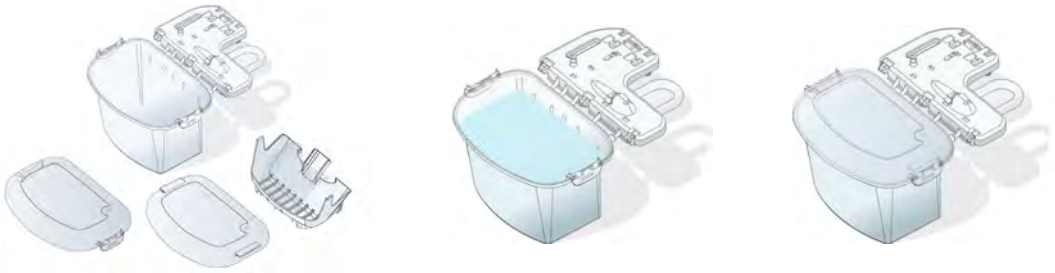
Load LifePort Kidney Transporter Disposable Perfusion Circuit

Once you have verified the kidney and checked for any contraindications against proceeding, use these instructions to load the LifePort Kidney Transporter Disposable Perfusion Circuit into LifePort Kidney Transporter.

CONSULT INSTRUCTIONS FOR USE: This procedure can also be found in the LifePort Kidney Transporter Disposable Perfusion Circuit Instructions for Use.

WARNING: Where noted, perform the following procedure on an aseptic field using standard aseptic technique.

1. *Using standard aseptic technique*, prepare a sterile field and introduce all necessary materials.
2. *Using standard aseptic technique*, remove Outer Perfusion Circuit Lid and Inner Perfusion Circuit Lid and place onto the sterile field.
3. *Using standard aseptic technique*, remove the Kidney Cradle and set aside within the sterile field.
4. *Using standard aseptic technique*, fill LifePort Kidney Transporter Disposable Perfusion Circuit with 1 Liter chilled (1–8°C) perfusate.
5. *Using standard aseptic technique*, replace and secure Inner Perfusion Circuit Lid followed by the Outer Perfusion Circuit Lid.



WARNING: LifePort Kidney Transporter Disposable Perfusion Circuit inner surfaces are considered sterile, while outer surfaces are not considered sterile.

6. Place Perfusion Circuit into LifePort Kidney Transporter.
7. Position the Tubeframe upright, perpendicular to the Pump Deck. Insert the hinges into the receivers before rotating flat onto the Pump Deck.

8. Open the Pumphead Raceway and stretch the Pump Tubing Loop around the Infusion Pump. Close and latch the Pumphead Raceway.

CAUTION: Do not use any tools or implements to stretch the Pump Tubing Loop onto the Infusion Pump.

9. Rotate the Pump Deck Locking Arm 90 degrees until it clicks into place.
10. Connect the Pressure Sensor Cable from the Pump Deck to the Pressure Sensor Connector on the Tubeframe.
11. Press and hold the **POWER** button until you hear an audible beep, then release.
12. Press the **WASH** button to enter Wash Mode.

Enter ORGAN ID Information

The ability to enter the **ORGAN ID**, **BLOOD TYPE**, **KIDNEY TYPE**, and **CROSS CLAMP TIME** are optional and for your convenience. The information is locked once perfusion begins and can only be edited within Data Station upon completion of the perfusion case. Each perfusion file will be identified by **ORGAN ID**.

NOTE: Do not enter Protected Health Information (PHI) or Personally Identifiable Information (PII) into LifePort Kidney Transporter.

If kidney information is not entered:

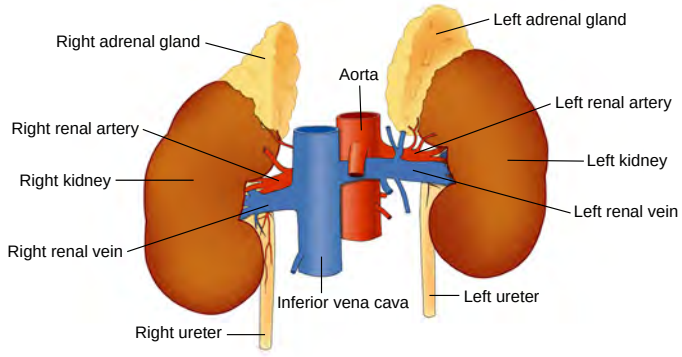
- **ORGAN ID** will default to the time stamp when Infuse Mode begins. The timestamp format is **MMDDYYHHMMSS**.
- **KIDNEY TYPE** will default to **NA**.
- **BLOOD TYPE** will default to **NA**.

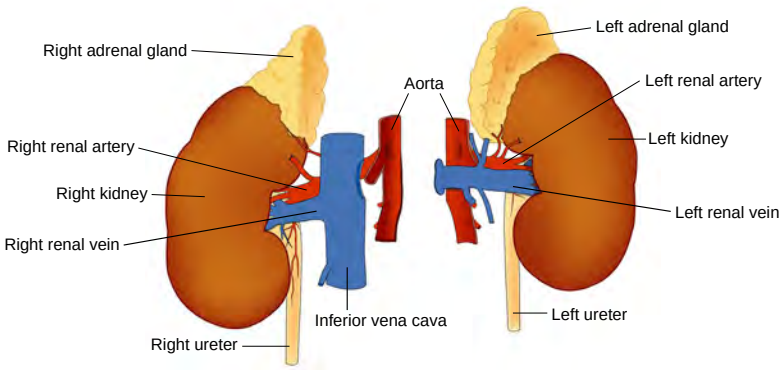
To enter kidney values, perform the following steps:

1. Press **OK**, use the arrow buttons to select **ORGAN INFORMATION**, and press **OK** again.
2. Select **ORGAN ID** and press **OK**.
3. Select the alphanumerics for the **ORGAN ID** you wish to assign, pressing **OK** with each selection.
4. Scroll to **DONE**, press **OK**, and select **SAVE** to confirm.
5. Select **KIDNEY** and press **OK**.
6. Select **LEFT** or **RIGHT,** as appropriate, press **OK**, and select **SAVE** to confirm.
7. Select **BLOOD TYPE** and press **OK**.
8. Select the **A**, **B**, **AB**, or **O**, as appropriate, press **OK**, and select **SAVE** to confirm.
9. Select **CLAMP** for cross clamp time and press **OK**.
10. Enter the correct cross clamp time, press **OK**, and select **SAVE** to confirm.

Isolate the Kidney Vascular Structure

Use the procedures specified by your institution for isolating the kidney vascular structure. The following diagrams depict typical kidney anatomy. Kidneys with atypical anatomy can also be cannulated using LifePort Kidney Transporter Disposable Cannulas.





Cannulate the Kidney

CONSULT INSTRUCTIONS FOR USE: When using LifePort Kidney Transporter Disposable Cannula, refer to its Instructions for Use.

WARNING: Perform the following procedure using standard aseptic technique.

1. Select the appropriately sized vascular cannulas for cannulating the renal artery.

   NOTE: Choose the appropriate cannula based on kidney vasculature:

   - Universal SealRing—used when the vessel to be perfused ends with or without an aortic patch or similar condition.
   - SealRing—used when the vessel to be perfused ends with an aortic patch or similar condition.
   - Straight—used when the vessel to be perfused ends without a patch or when intimal damage to the lining is not a concern.
   - Coupler—used to connect two or more cannula when multiple vessels are to be perfused.

2. Cannulate the kidney according to clinical standard of care.

Place the Kidney

After cannulation, the kidney must be secured in the Kidney Cradle and placed in LifePort Kidney Transporter Disposable Perfusion Circuit in LifePort Kidney Transporter.

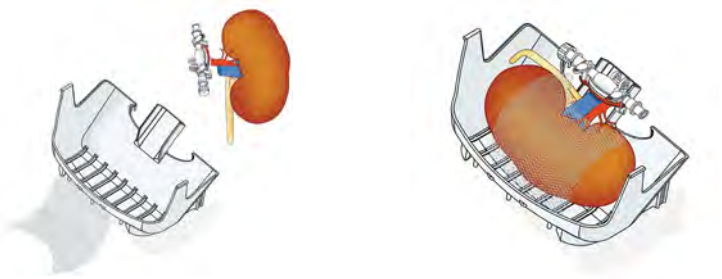
Place the Kidney in Kidney Cradle

WARNING: The following procedure is performed on an aseptic field using standard aseptic technique.

1. Place the cannulated kidney in the Kidney Cradle with the renal vein facing out and snap the cannula into the Cannula Mount.

   NOTE: If perfusing multiple vessels, connect only the main vessel cannula to the Cannula Mount.

2. Adjust the height of the Cannula Mount and rotation of the cannula to position the vessel to allow for the unimpeded flow of perfusate.
3. Visually inspect the vessel, ensuring there are no twists or occlusions.
4. Secure the Mesh Organ Restraint over the kidney in the Kidney Cradle, allowing for slight swelling while being perfused.



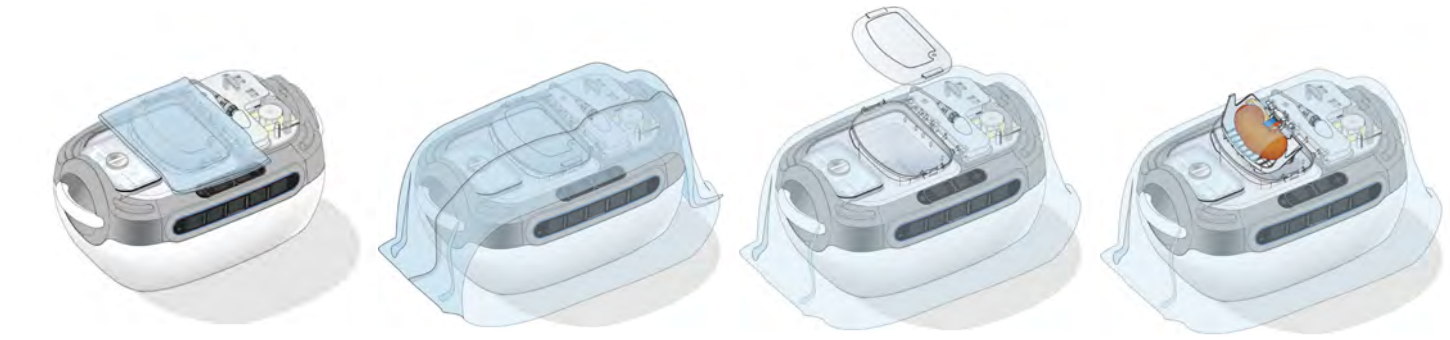
Place the Kidney Cradle in LifePort Kidney Transporter

A person outside the sterile field should perform the following:

- Remove the LifePort Kidney Transporter Cover, if necessary.
- Press the **STOP** button to exit Wash Mode, if necessary.
- Remove the Outer Perfusion Circuit Lid.

WARNING: Perform the following procedure on an aseptic field using standard aseptic technique.

1. Carefully place LifePort Kidney Transporter Disposable Sterile Drape onto LifePort Kidney Transporter, lining up the drape gasket with the Organ Chamber.
2. Ensure the arrow on the orientation guide is pointing toward the Pump Deck.
3. Unfold Sterile Drape in the following order: **right**, **left**, **front**, and **back**. The drape gasket should fit securely around the Organ Chamber with the tabs snapping into place under the lid latches.
4. Unlatch and remove the Inner Perfusion Circuit Lid and place it facedown onto the sterile field.
5. Transfer the cannulated kidney in the Kidney Cradle to LifePort Kidney Transporter, being careful to avoid catching the Infuse Line.



Prime and Initiate Perfusion

Once the Kidney Cradle containing the cannulated kidney has been placed into the LifePort Kidney Transporter Disposable Perfusion Circuit Organ Chamber in LifePort Kidney Transporter, it's time to prime the Infuse Line to remove any bubbles from the line and renal artery. Once LifePort Kidney Transporter has finished priming, you can perfuse the kidney.

WARNING: The following procedure is performed on an aseptic field using standard aseptic technique.

1. Connect the Infuse Line to the cannula on the Cannula Mount and tighten the Luer lock fitting.
2. Remove the End Cap from the cannula to provide a path for bubbles to escape.
3. Through the Sterile Drape, press the **PRIME** button.

4. Check for bubbles in the perfusate, flowing from the disconnected end of the cannula.
5. Replace the End Cap on the cannula. LifePort Kidney Transporter should automatically stop priming, display a visual "High Pressure" error message, and give an audible alert. If LifePort Kidney Transporter does NOT stop and there is no audible alert, there may be a leak.

NOTE: Leaks may originate from the cannulation site or arteries, or from the Perfusion Circuit. There are two types of leaks to look for:

A. Leaks from the cannulation site or artery. Identify and address any leaks.
B. Leaks from the Perfusion Circuit. Press the **STOP** button and check the Perfusion Circuit. If perfusate is leaking out of the Perfusion Circuit, call the Organ Recovery Systems 24/7 Perfusion Helpline. Replace Perfusion Circuit and repeat the priming procedure above. Retain the leaking Perfusion Circuit for possible return.

6. Through the Sterile Drape, use the **UP/DOWN** arrows to choose the pumping pressure.

NOTE: The default pressure setting is 30 mmHg.

7. Through the Sterile Drape, press the **INFUSE** button to start perfusion. This will also begin the recording of perfusion data and other parameters.
8. Replace and secure the Inner Perfusion Circuit Lid.
9. Remove the Sterile Drape by either lifting up and away from the sterile field or by cutting it away.
10. A person outside the aseptic field should replace and secure the Outer Perfusion Circuit Lid.

Check Kidney Parameters

LifePort Kidney Transporter Outer Display provides the following comprehensive information on the status of perfusion:

- **Pressure**—these are the measured systolic and diastolic pressures of the perfusion process, as LifePort Kidney Transporter attempts to achieve the systolic pressure you have set. The systolic value is often lower, but should never be higher, than the set pressure.
- **Flow**—the volume of perfusate moving through the kidney over time. Flow changes, depending on how the kidney is responding to the pumping. This value is expected to increase over time, as the kidney vasodilates, thus allowing the set pressure to deliver a growing flow rate.
- **Resistance**—the force required to pump perfusate through the kidney. This value is expected to decrease, as kidney "loosening" provides less and less resistance to pumping over time. Resistance and Flow are inversely proportional.
- **Temperature**—the temperature of the ice bath ("Ice") and the perfusate ("Trap"). Perfusate temperature is measured in the Bubble Trap prior to entering the kidney. The ice bath value will increase as the ice melts, prompting the user to add more ice. An audible alert and error message warning to "Check Ice" begins at 5°C. If temperature reaches 8°C, perfusion will stop and the error message, requiring user intervention, "Too Warm, Add Ice" will display. The Trap value displays the perfusate temperature only during infusion, not while LifePort Kidney Transporter is stopped.

NOTE: Press the **PLOT/CLEAR** button on the far-left side of the Outer Display to temporarily display trending data for flow and resistance.

The far-right side of the Outer Display is the Message Display which provides a range of ID, error, and functional information.

- **Current Mode of Operation**—the upper left corner tells LifePort Kidney Transporter's current mode of operation, corresponding to the controls on the top of the unit: **INFUSE**, **STOPPED**, **PRIME**, or **WASH**.
- **Battery vs. AC Power**—the icon in the upper right corner shows whether LifePort Kidney Transporter is operating on AC or battery power.

NOTE: If LifePort Kidney Transporter is connected to a power source but is not operating, an "electric plug" icon on the Outer Display will be visible, indicating that it is charging.

- **Organ and Device ID Information**—is displayed when no errors are present.
- **Errors**—are displayed accompanied by an audible alert. In addition, the field affected by the error flashes its information in yellow or red. For complete information on resolving errors, see ***Error Message Explanations***.

The number to the left of the battery icon provides infuse time, telling how long LifePort Kidney Transporter has been perfusing. The timer begins when LifePort Kidney Transporter enters Infuse Mode for the first time after powering on and continues until LifePort Kidney Transporter is turned off.

Data Station Monitoring

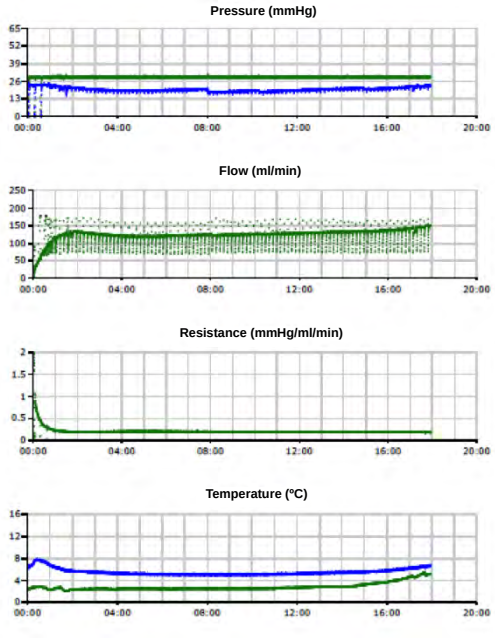
Data Station is an optional software application that can be installed on a computer. By connecting LifePort Kidney Transporter to the Data Station computer, you can monitor all LifePort functions, in real time, on the Data Station dashboard. The Data Station is capable of monitoring multiple devices.

NOTE: If the Data Station computer is networked or accessible via the Internet, you can access LifePort Kidney Transporter data from any computer able to connect to it.

Kidney Behavior on LifePort Kidney Transporter

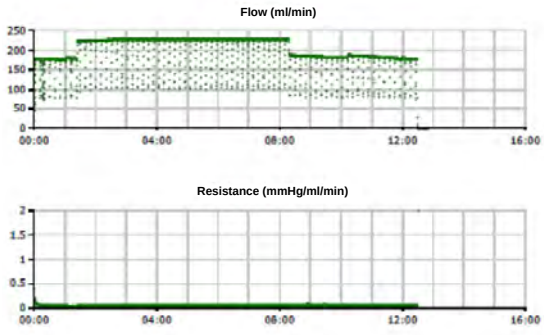
The graphs below—excerpted from page 2 of a Data Station case report—show four parameters of the typical behavior of a kidney on LifePort Kidney Transporter: Pressure, Flow, Resistance, and Temperature.

It is normal to see flow increase while resistance decreases. This indicates that the kidney is vasodilating. LifePort Kidney Transporter automatically adjusts the flow rate to achieve the indicated pressure.



Leaks at the Cannula or Open Side Branch

This graph shows immediate flow but no build-up of resistance. This can indicate a leak at the cannula site or an open lateral branch of the renal artery.



Nonresponsive Kidney

A nonresponsive kidney—not responding to machine perfusion—typically shows some degree of flow but no concurrent decrease in resistance. In this case, it may be appropriate to review available donor, kidney, procurement, and recipient data before making any decision.

Remote Monitoring

LifePort Kidney Transporter is capable of detecting certain situations during perfusion and providing a visual and audible alert on such events.

When LifePort Kidney Transporter is connected to a network computer, the Data Station software can be setup to send these alerts via email or text message to any smartphone.

Travel with LifePort Kidney Transporter and Supplies

If you're traveling with LifePort Kidney Transporter, take the following precautions:

- Secure LifePort Kidney Transporter from sliding or rolling. If the device is placed on a vehicle seat, the normal seat belt can be used to restrain it while driving.
- If necessary, turn off audible alerts by turning the Audible Alert Switch to the "O" position.

CAUTION: Audible alerts should only be turned off when temporary silencing of such alerts is required. It is the user's responsibility to turn audible alerts on/off, utilizing the Audible Alert Switch as directed.

- Check LifePort Kidney Transporter Cover to make sure it is closed and latched.

After the recovery, secure LifePort Kidney Transporter and supplies for travel. LifePort Kidney Transporter can withstand the normal handling involved in traveling between hospitals; however, it should be kept in an upright orientation to minimize the potential for leaks, spills, or air bubbles.

Refill Ice / Swap Batteries

LifePort Kidney Transporter is designed so the fully charged batteries and ice will last for 24 hours of operation with the Cover in place and latched. Monitor battery and ice levels during kidney preservation on LifePort Kidney Transporter.

NOTE: LifePort Kidney Transporter will alert when the batteries have two hours remaining or when the temperature in the Ice Container reaches 5°C.

Add More Ice

Check that the temperature on the Outer Display is steady and below 8°C.

If the temperature reaches 5°C, LifePort Kidney Transporter displays a visual alert and an audible beep. Open LifePort Kidney Transporter Cover and visually check the ice level.

If the ice is mostly melted, remove and retain some water from the Ice Container (using a cup, scoop, hand pump, or electrical pump) and refill with ice and retained water.

NOTE: This is part of the non-sterile section of LifePort Kidney Transporter and can be performed without interrupting perfusion.

Replace Batteries

Check the battery level on the Message Display Panel. Whenever LifePort Kidney Transporter is not in transit, plug in LifePort Kidney Transporter so that the batteries are maintained in a charged condition.

If the batteries are running low, plug LifePort Kidney Transporter into an AC mains electrical outlet, if possible.

If an outlet is not available, the depleted LifePort Kidney Transporter batteries may be replaced with fully charged LifePort Kidney Transporter batteries. Batteries may be replaced one at a time without disrupting LifePort Kidney Transporter function.

CAUTION: Replace the batteries only one at a time to ensure that LifePort Kidney Transporter will continue to operate.

Remove Kidney From LifePort Kidney Transporter

The procedure for removing the kidney from LifePort Kidney Transporter is detailed below. This procedure may be modified as necessary.

WARNING: Where noted, perform the following procedure on an aseptic field using standard aseptic technique.

1. Unlatch and remove LifePort Kidney Transporter Cover.
2. Remove the Outer Perfusion Circuit Lid and place upside-down on a table where it will be undisturbed.
3. *Using standard aseptic technique,* carefully place LifePort Kidney Transporter Disposable Sterile Drape onto LifePort Kidney Transporter, lining up the drape gasket with the Organ Chamber. Ensure the arrow on the orientation guide is pointing toward the Pump Deck.
4. *Using standard aseptic technique,* unfold Sterile Drape in the following order: **right**, **left**, **front**, and **back**. The drape gasket should fit securely around the Organ Chamber with the tabs snapping into place under the lid latches.
5. *Using standard aseptic technique,* unlatch and remove the Inner Perfusion Circuit Lid and place it facedown onto the sterile field.
6. Press the **STOP** button.
7. *Using standard aseptic technique,* unscrew or cut the Infuse Line.
8. *Using standard aseptic technique,* carry the Kidney Cradle, with the cannulated kidney, to the sterile field.
9. *Using standard aseptic technique,* unhook the Mesh Organ Restraint.
10. *Using standard aseptic technique,* unstrap, open, and remove the cannula.
11. Once the kidney has been removed from LifePort Kidney Transporter and accepted by the transplant surgeon, proceed to ***Clean and Disinfect After Use***.

Clean and Disinfect After Use

Once the kidney has been removed from LifePort Kidney Transporter Disposable Perfusion Circuit, replace both Perfusion Circuit Lids and power off LifePort Kidney Transporter.

All LifePort Kidney Transporter Disposables and perfusate are single-use devices and should go into medical waste disposal.

WARNING: Use Universal Precautions when performing perfusate and equipment cleanup to prevent possible contact with bloodborne pathogens.

LifePort Kidney Transporter does not come in contact with the donor organ. The donor organ should always be within the sterile field provided by LifePort Kidney Transporter Disposable Perfusion Circuit and Sterile Drape.

LifePort Kidney Transporter must be thoroughly cleaned and disinfected after each use. Prior to cleaning and disinfecting, assemble the following agents and supplies:

- 70% isopropanol (solution, wipes, or swabs)
- Hospital grade pre-moistened germicidal wipes (Super Sani-Cloth®, CaviWipes™)
- Soft, lint-free cloths
- Water

WARNING: Do not clean LifePort Kidney Transporter while plugged into AC mains.

WARNING: Do not use cleaning solutions containing acetone, ammonia, benzene, xylene, or similar solvents. Do not use abrasive cleaning tools or pressurized spraying devices. Do not clean or disinfect by autoclave or sterilize with EO gas. Doing so will void the warranty.

Perform the following steps to thoroughly clean and disinfect LifePort Kidney Transporter after each use:

1. If applicable, wipe up any visible contaminants from LifePort Kidney Transporter with a soft, lint-free cloth.
2. Remove and empty Ice Container. Dry with a soft, lint-free cloth. Clean and disinfect all Ice Container surfaces with 70% isopropanol. Allow to air dry.
3. In circumstances where LifePort Kidney Transporter appears to have more residue or debris than usual, clean with hospital grade pre-moistened germicidal wipes. Wipe with a dampened soft, lint-free cloth. If excess residue is not visible, this step is not required.
4. In all cases, clean and disinfect all surfaces of LifePort Kidney Transporter, including but not limited to the Cover, Bubble Detectors, Power Cord, and Control Panel, with 70% isopropanol. Allow to air dry.

WARNING: To assure proper disinfection, you must allow adequate exposure time for each agent used.

CAUTION: Do not immerse LifePort Kidney Transporter.

CAUTION: Do not allow cleaning solutions to enter the electrical connectors, ventilation holes, or battery area.

CAUTION: Ice Container and Ice Container Lid are reusable parts of the LifePort Kidney Transporter. Do not dispose of them.

Return LifePort Kidney Transporter and Power Cord to Home Base Station. Additionally, the batteries should be recharged and the supply kits should be repacked in preparation for the next transplant.

Data Capture and Download (Optional)

Optionally, data being generated and stored on LifePort Kidney Transporter can be downloaded and stored on a computer.

NOTE: LifePort Kidney Transporter is designed to transfer historical data, excluding perfusion commands. The Data Cable plugs into the Data Port, a USB connector on the External Connections Panel. Whenever LifePort Kidney Transporter is in Infuse Mode, it captures perfusion and status data every 10 seconds.

Using A Computer

Data recording begins when LifePort Kidney Transporter enters Infuse Mode for the first time after powering on. Data recording continues until LifePort Kidney Transporter is turned off.

To start a new data file, cycle the power (power off, then power on). LifePort Kidney Transporter can store a maximum of five perfusion cases at a time. Files should be downloaded to a computer after each case is finished. After downloading, the cases can be deleted from LifePort Kidney Transporter.

Each LifePort Kidney Transporter data file can hold up to 48 hours of perfusion data. If a single perfusion case runs longer then 48 hours, a new file can be created only by cycling the power and resuming the perfusion. The stored data includes:

- Sequential record number
- Infuse time
- Pressure setpoint
- Average pressure
- Measured systolic and diastolic pressures
- Flow rate
- Organ resistance
- Ice Container and Bubble Trap temperatures
- Error condition status (presence or absence of each error condition)
- Perfusion system state and sub state
- LifePort Kidney Transporter Cover status (open/closed)

CAUTION: Accessory equipment connected to the Data Port must be certified IEC 62368 for data processing equipment. Furthermore, all configurations shall comply with the systems standard in cl. 16 of IEC60601-1. Any person who connects additional equipment to the Data Port configures a medical system and is therefore responsible for ensuring that the system complies with the system standard in cl. 16 of IEC60601-1. If in doubt, consult the Organ Recovery Systems 24/7 Perfusion Helpline.

Using A Flash Drive

If a computer is not readily available for evaluating the data file, you can download the file onto a flash drive and evaluate the data on a computer when one is available.

1. Power on LifePort Kidney Transporter.

NOTE: If LifePort Kidney Transporter does not have a Perfusion Circuit installed, press **STOP** to clear the “Sensor Not Connected” error and press **OK**.

2. Insert USB flash drive into USB-A port on LifePort Kidney Transporter.
3. Use the arrow buttons to select **DOWNLOAD FILE**.
4. Use arrow buttons to select file to download.
5. Press **OK** and **SAVE**. Top display will flash **SAVING FILE** until complete. When download is complete, display will return to download file screen.
6. You can download additional files, if desired, or use the arrow buttons to select **DONE** and press **OK**.
7. Remove the USB flash drive.

Troubleshooting and Diagnostics

Most problems that you encounter in operating LifePort Kidney Transporter will be easily solved. The first thing to check when troubleshooting is to make sure that power is available from either the batteries or through the Power Cord plugged into a standard electrical outlet. If the power light comes on but LifePort Kidney Transporter still does not work, check the following guide.

Troubleshooting Procedures

Trouble	Probable Cause	Action
No Power	Dead Batteries Outlet Tripped Circuit Breaker	1. Replace with fresh batteries or plug into an external power supply. 2. Make sure the outlet has power. 3. Reset breaker by pressing the button on the External Connections Panel located on the back of LifePort Kidney Transporter. If problem is not resolved, please call Organ Recovery Systems 24/7 Perfusion Helpline.
No Audible Alerts	Audible Alert Switch is Off	With a flathead screwdriver, turn switch to the “I” position. If problem is not resolved, please call Organ Recovery Systems 24/7 Perfusion Helpline.
Beeping or Flashing Display	Beeping or Flashing Display, Accompanied by an Error Message	Follow the instructions in ***Error Message Explanations***. If problem is not resolved, please call Organ Recovery Systems 24/7 Perfusion Helpline.
Missing/Incorrect Display	Display or Internal Computer Error	1. Power **OFF**. 2. Power **ON**. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Leaking Perfusate	Perfusion Circuit Lids Not Tightened Defective Perfusion Circuit	1. Relatch the Perfusion Circuit Lids and look for any leaks near the gaskets. 2. Replace the Perfusion Circuit. Call Organ Recovery Systems 24/7 Perfusion Helpline to return Perfusion Circuit for investigation. If problem is not resolved, call Organ Recovery Systems 24/7 Helpline.
Leaking Coolant	Broken Ice Container or Seal	Observe the Ice Container for any damage. If damaged or if problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Unresponsive Buttons	Internal Lock-up	1. Power **OFF**. 2. Disconnect Power Cord and remove all batteries. 3. Wait 30 seconds and then replace batteries. 4. Power **ON**. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Blank Display	Display or Internal Computer Error	1. Power **OFF**. 2. Power **ON**. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.

Error Message Explanations

LifePort Kidney Transporter sounds audible alerts when it encounters out-of-range conditions for bubbles, pressure, flow, and temperature. Many of these errors are self-correcting and perfusion will automatically resume.

LifePort Kidney Transporter enters a fail-safe mode of static cold storage if any unrecoverable fault condition is encountered.

Scroll through the Message Display Panel to view all of the fault conditions. The error indicators will remain viewable until cleared.

To clear the indicators for errors, which are no longer valid, press either the **STOP** or **PLOT/CLEAR** button, as advised on the screen.

Check the following list of abbreviations, observed problems, probable causes, and recommended actions. In most cases the audible alert can be cancelled or temporarily muted by pressing either the **STOP** or **PLOT/CLEAR** button, depending on the type of alert.

Error Message	Probable Cause	Action
Bubbles in Infuse Line	Air bubble in the Infuse Line	1. Check Perfusion Circuit for leaks and the connection to the cannulated kidney, using standard aseptic technique when necessary. Correct any leaks, under aseptic conditions, if necessary. 2. Re-prime the Perfusion Circuit. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Can't Reach Pressure	Leaking Cannula or Artery Leak in Perfusion Circuit Low Resistance Kidney	1. Under aseptic conditions, visually inspect the connection to the cannulated kidney and correct any leaks, if necessary. 2. Check Perfusion Circuit for leaks. Replace Perfusion Circuit if leaks cannot be corrected. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Check Ice	The Ice Container Temperature is 5°C or higher but still below 8°C	Replenish ice before temperature reaches 8°C, otherwise LifePort Kidney Transporter will cease perfusion and revert to static cold storage. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Check Filter	Filter May Be Clogged	1. Do not attempt to dislodge obstruction from filter. 2. Replace Perfusion Circuit. 3. Contact Organ Recovery Systems 24/7 Perfusion Helpline to return Perfusion Circuit for investigation.
Equalizing	Temporary fluid path disruption	Clear message and monitor. Pump should resume normal operation without intervention. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
High Pressure	System Experiencing Unexpected Pressure Conditions	1. Inspect Pressure Sensor and Pressure Sensor Connector. 2. Under aseptic conditions, check for arterial and venous obstructions. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.

Error Message	Probable Cause	Actions
Kidney High Resistance	System Measuring Excessively High Resistance	1. Under aseptic conditions, loosen Mesh Organ Restraint, adjust position of renal artery, and/or check for occlusions within the Perfusion Circuit. 2. Consult supervising physician. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Kidney Not Connected	Tubeframe Not Positioned Properly Leaking Cannula or Artery Kidney Not Connected	1. Check Tubeframe and Locking Arm position. 2. Under aseptic conditions, visually inspect kidney and cannula and correct all leaks under aseptic conditions. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Load Perfusion Circuit	The Tubeframe Not Properly Installed or Latched	1. Check Tubeframe and Locking Arm position. 2. Check Pressure Sensor Cable connection. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Low Battery	Less Than 4 Hours Battery Life Remaining: 2 Hours Perfusion Plus Additional 2 Hours Monitoring	1. Plug into AC Mains. 2. Hot swap batteries for charged batteries. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Motor Current Failure	LifePort Not Responding Normally	Call the Organ Recovery Systems 24/7 Perfusion Helpline.
Near Freezing	Incorrect Coolant Environmental Conditions Too Cold (Ice Container temperature has dropped below 0.1°C)	1. Check that ice and water only are used to fill Ice Container. 2. Move LifePort into a warmer environment. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Occlusion	Unexpected Pressures During Infuse Mode	1. Under aseptic conditions, check that Infuse Line is unobstructed. 2. Under aseptic conditions, ensure there are no blockages or twists in the artery. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
POST Failure	Internal Error	1. Remove all power to LifePort Kidney Transporter: remove all four LifePort batteries and unplug from AC Mains. 2. Restore power to LifePort and press Power button. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Pressure Sensor Failure	Pressure Sensor Disconnected	Reconnect the Pressure Sensor. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Pressure Sensor Setpoint Error	LifePort Kidney Transporter Unable to Set Pressure Alert Levels	1. Press **STOP** to clear alert. 2. Press **INFUSE** to re-enter Infuse Mode. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.

Error Message	Probable Cause	Actions
Purge Bubbles	Automatic Wash Cycle during Infuse Mode Possible Air Leak	1. Run LifePort Kidney Transporter in Wash Mode. 2. If this is a persistent error, check Perfusion Circuit for cracks, leaks, and/or loose fittings. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Too Cold	Incorrect Coolant Environment Conditions Too Cold (Ice Container temperature has dropped below 0.5°C)	1. Check that ice and water only are used to fill Ice Container. 2. Move LifePort into a warmer environment. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Too Warm Add Ice	Ice Container Temperature Above 8°C	1. Replenish ice as soon as possible. 2. Allow time for the temperature to read below 8°C and press **INFUSE** to restart perfusion. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Upstream Bubbles	Air Persisting in Upstream Bubble Detector	Check Perfusion Circuit for leaks. If problem is not resolved, call Organ Recovery Systems 24/7 Perfusion Helpline.
Watchdog	Internal Error	Call the Organ Recovery Systems 24/7 Perfusion Helpline.

Power On Self Test (POST)

On each power up, LifePort Kidney Transporter performs a Power On Self Test or “POST”. The CPU within LifePort Kidney Transporter checks its memory functions, temperature sensors, Bubble Detectors, and its internal failure routines. In the unlikely event that one of these tests fail, LifePort Kidney Transporter will display “POST failure” and it will list the POST error message. Should one of these errors occur, remove all power to LifePort Kidney Transporter by reinstalling the batteries and Power Cord. If the POST message continues to display, call the Organ Recovery Systems 24/7 Perfusion Helpline.

Maintenance

Overview

LifePort Kidney Transporter has no user serviceable parts.

WARNING: Do not open LifePort Kidney Transporter to service it. Shock hazard exists if Pump Deck is removed. All aspects of LifePort Kidney Transporter that are meant to be attended by the Operator are accessible without opening the Device. If there is a service problem, please call the Organ Recovery Systems 24/7 Perfusion Helpline.

Maintain, clean, and keep LifePort Kidney Transporter ready to use according to the directions in this manual. If LifePort Kidney Transporter is not functioning properly, refer to ***Troubleshooting and Diagnostics*** or contact Organ Recovery Systems 24/7 Perfusion Helpline.

Storage

If LifePort Kidney Transporter will not be used for several days or weeks, thoroughly clean the device according to ***Clean and Disinfect After Use*** before storing. LifePort Kidney Transporter should be stored indoors in a dry location out of direct sunlight. The Ice Container Lid should be ajar.

For periods of storage for longer than 30 days, remove the batteries from LifePort Kidney Transporter.

CAUTION: Extended storage may damage the batteries.

Store LifePort Kidney Transporter in a temperature-controlled space. LifePort Kidney Transporter will operate normally after storage in conditions ranging from 5°C to 40°C.

Repairs

If LifePort Kidney Transporter requires repairs it will need to be shipped by common carrier. Be sure to use the corrugated carton, with foam inserts—either the original carton or the carton containing the loaner—as provided by Organ Recovery Systems.

WARNING: Unauthorized modifications to LifePort Kidney Transporter will void the warranty and may damage the device and/or organ. This may also result in user being harmed.

Specifications, Precautions, Limitations

Product Specifications

Description	Portable, self-contained renal preservation system, which utilizes hypothermic perfusion.
Indications for Use	LifePort Kidney Transporter is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, optional transportation and eventual transplantation into a recipient.
Capacity	Single kidney
Power Source	AC or battery Voltage – 100 to 240 VAC, Frequency – 50 to 60 Hz, Current – 1 Amp
Coolant Source	Ice/water bath, 5-1/2 Liters
Perfusate Pump	Peristaltic pump
Pressure Control	Closed loop pressure regulation, 10 to 65 mmHg
Perfusion Modes	Pulsatile
Flow Rates Measurement	Between 20 mL/min to 150 mL/min, accuracy is ±15%
Dimensions	24” x 14.5” x 14.25” (61.96cm x 36.83cm x 36.195cm)
Approximate Weight	45 lbs (20.4 kg) fully loaded
Transport Duration	Up to 24 hours between ice replenishment and battery replacement (or recharge)
Batteries	Four x 11.1 V lithium-ion batteries
Battery Life	24 hours (fully charged)
Perfusate Used	Hypothermic machine perfusate
Data Download	USB data download of all perfusion and status data collected since the point when the INFUSE state was begun following Power ON.
Storage Conditions	Temperature: 5°C to 40°C
Operating Conditions	Not to exceed 35°C on AC mains Not to exceed 40°C on battery

Device Classifications

Medical Device	Class II	FDA listed device
	Class IIa	EU MDD 93/42/EEC
Type of protection from electric shock	Class I / Internally Powered	
Protection from water ingress	IPX1	LifePort Kidney Transporter is protected from vertical water droplets.
Cleaning recommendations	LifePort Kidney Transporter can be cleaned with a 70% isopropanol solution to remove perfusate residue and other detritus.	

Equipment is suitable for Continuous Operation.

WARNING: Equipment is **NOT** suitable for use in the presence of a **FLAMMABLE ANESTHETICS** or **NITROUS OXIDE**, without proper safety precautions per hospital or organization guidelines or procedures.

Electromagnetic Compatibility

LifePort Kidney Transporter needs special precautions regarding electromagnetic compatibility (EMC) and should be used in accordance with the EMC information provided in this manual.

LifePort Kidney Transporter can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio or television reception. However, there is no guarantee that the interference will not occur in a particular installation. LifePort Kidney Transporter does cause interference, which can be determined by turning LifePort Kidney Transporter on and off. Try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna.
- Increase the distance between LifePort Kidney Transporter and receiver.
- Connect LifePort Kidney Transporter to an outlet on a separate circuit from that to which the receiver is connected.

Portable and mobile RF communications equipment can affect LifePort Kidney Transporter.

CAUTION: To assure compliance with EMC requirements, use only manufacturer-supplied cables. If you have questions or would like to order new cables, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

CAUTION: Use of Power Cords or communications cables, other than those specified, may result in increased emissions or decreased immunity of LifePort Kidney Transporter.

CAUTION: LifePort Kidney Transporter should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, LifePort Kidney Transporter should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC EMISSIONS		
LifePort Kidney Transporter is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePort should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment: Guidance**
RF emissions CISPR11	Group 1	LifePort Kidney Transporter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The LifePort is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC IMMUNITY			
LifePort Kidney Transporter is intended for use in the electromagnetic environment specified below. The customer or the user of LifePort Kidney Transporter should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment: Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT FOR 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % UT for 1 cycle and 70% UT for 25 cycles at 0° 0% UT for 250 cycles at 0°	0 % UT FOR 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % UT for 1 cycle and 70% UT for 25 cycles at 0° 0% UT for 250 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of LifePort Kidney Transporter requires continued operation during mains power interruptions, LifePort Kidney Transporter can be powered from the internal battery.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
UT is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC IMMUNITY			
LifePort Kidney Transporter is intended for use in the electromagnetic environment specified below. The customer or the user of LifePort Kidney Transporter should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment: Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and Amateur Radio Bands	3 V 6 V	Portable and mobile RF communications equipment should be used no closer to any part of LifePort Kidney Transporter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $D=\left[\frac{3.5}{3}\right]\sqrt{P}$ 150 kHz to 80 MHz $D=\left[\frac{3.5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz $D=\left[\frac{7}{3}\right]\sqrt{P}$ 800 MHz to 2.5 GHz …where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which LifePort Kidney Transporter is used, exceeds the applicable RF compliance level above, LifePort Kidney Transporter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating LifePort Kidney Transporter.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Operational Precautions and Limitations

The following information will affect the success in using LifePort Kidney Transporter.

Should Be Used Only By Trained Professionals—Federal law restricts the sale of this device to physicians and medical professionals only. Use of the device in procedures other than those described in this manual may result in injury.

Do Not Reuse Perfusion Circuits or Cannulas—The Perfusion Circuits, Sterile Drapes, and cannulas are sterile as supplied and are intended for single-use. The method of sterilization is ethylene oxide gas. After use, they should be disposed of in accordance with local guidelines for biomedical waste.

Use Only Manufacturer-approved Accessories—Only manufacturer-approved accessories are designed to work properly with LifePort Kidney Transporter. Do not substitute other batteries, cables, or accessories.

Use Only Ice and Water in the LifePort Ice Container—A mixture of ice and water in the Ice Container will assure that temperatures remain within the appropriate range for kidney preservation in LifePort Kidney Transporter. To avoid inadvertently freezing the kidney, **ONLY USE ICE AND WATER** in LifePort Kidney Transporter Ice Container.

Single Use Only Disposables—LifePort Kidney Transporter Disposables are intended for single use only.

Disposables Already Sterile—LifePort Kidney Transporter Disposables are sterile as supplied. Do not resterilize.

Connect the System to AC Mains According to Labeling—LifePort Kidney Transporter uses externally supplied electricity to operate. Check the voltage and amperage ratings of the AC mains electrical outlets and make sure they match the labeled ratings for electricity inputs shown on the rear of LifePort Kidney Transporter.

Assure Adequate Ventilation—Do not block the ventilation areas on the side and bottom of LifePort Kidney Transporter, especially when external power is connected.

Electromagnetic Compliance—LifePort Kidney Transporter has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 18 of the FCC rules and to the Medical Device Directive 93/42/EEC and to the Electromagnetic Compliance (EMC) Directive 89/336/EEC. These limits are designed to provide a reasonable protection against normal interference in a commercial or hospital setting.

LifePort Kidney Transporter needs special precautions regarding EMC and should be used in accordance with the EMC information provided in this manual. Please refer to ***Electromagnetic Compatibility*** for details.

Air Transport—Prior to beginning air transport, make sure that ice and battery levels are sufficient for entire transport duration. Do not connect LifePort Kidney Transporter to an external electrical power source on a commercial aircraft. Do not connect the Data Cable to LifePort Kidney Transporter during flight on a commercial aircraft.

CAUTION: All LifePort Kidney Transporter users should be familiar with Organ Recovery Systems Kidney Perfusion Solution (KPS-1®) Instructions for Use (IFU).

Hazards

Overview

This section contains information on hazards involved in using LifePort Kidney Transporter system that can pose risk to the operator as well as to the environment—information that will affect clinician and staff safety when using LifePort Kidney Transporter.

WARNING: Possible Explosion Hazard. Do not use LifePort Kidney Transporter in the presence of flammable anesthetics. LifePort Kidney Transporter is not designed for use in the presence of explosive mixtures of anesthetic gases with air, oxygen or nitrous oxide. **USE ONLY IN SAFE ENVIRONMENTS**.

WARNING: Do not open LifePort Kidney Transporter to service it. Shock hazard exists if Pump Deck is removed. All aspects of LifePort Kidney Transporter that are meant to be attended by the Operator are accessible without opening the Device. If there is a service problem, please call the Organ Recovery Systems 24/7 Perfusion Helpline.

WARNING: Beware of rotating parts. Keep hands, clothing, jewelry, ID lanyards, etc. away from the vicinity of the Infusion Pump when LifePort Kidney Transporter is powered on.

WARNING: Unauthorized modifications to LifePort Kidney Transporter will void the warranty and may damage the device and/or organ. This may also result in user being harmed.

WARNING: Use Universal Precautions with the kidney and perfusate. The kidney and perfusate may carry undetected pathogens from the donor. Use proper precautions (e.g. gloves, masks, gowns, goggles, or equivalent eye protection, biohazard bags) in handling the kidney and in handling and disposing of the Perfusion Circuit and perfusate to prevent the possible transmission of pathogens to medical personnel.

WARNING: Where noted, perform procedures on an aseptic field using standard aseptic technique.

WARNING: LifePort Kidney Transporter Disposable Perfusion Circuit inner surfaces are considered sterile, while outer surfaces are not considered sterile.

WARNING: Use only machine perfusion solution in LifePort Kidney Transporter. Check the labeling of the perfusion solution and make sure that it is intended for machine perfusion.

WARNING: To avoid inadvertently freezing the kidney, **USE ONLY ICE AND WATER** in LifePort Kidney Transporter Ice Container. A mixture of ice and water in the Ice Container will ensure that temperatures remain within the appropriate range for kidney preservation.

WARNING: For single use only. Do not reuse, reprocess, or resterilize. Reusing, reprocessing, or resterilization of single-use devices creates a potential risk of patient or user infections due to contamination. This contamination may lead to injury, illness, or other serious patient complications. Discard any unused portion of the product.

WARNING: Do not use cleaning solutions containing acetone, ammonia, benzene, xylene, or similar solvents. Do not use abrasive cleaning tools or pressurized spraying devices. Do not clean or disinfect by autoclave or sterilize with EtO gas. Doing so will void the warranty.

WARNING: Do not clean LifePort Kidney Transporter while plugged into AC mains.

WARNING: Use precautions when lifting. A fully loaded LifePort Kidney Transporter weighs 45 lbs (20.4 kg). Use proper lifting practices to avoid injury.

CAUTION: Use only grounded electrical connections. Connect LifePort Kidney Transporter to a grounded electrical outlet rated for voltage and amperage according to the labeled ratings on the product back panel. If there is any question about the ground integrity, operate LifePort Kidney Transporter from internal power.

CAUTION: You may remove AC mains power by unplugging the Power Cord from the back of the unit. Exercise care when choosing the location of your LifePort Kidney Transporter so that removal of Power Cord is not difficult.

CAUTION: Do not allow cleaning solutions to enter the rear panel electrical connectors, the ventilation holes, or the battery area.

CAUTION: Audible alerts should only be turned off when temporary silencing of such alerts is required. It is the user's responsibility to turn audible alerts on/off, utilizing the Audible Alert Switch as directed.

CAUTION: Use only cables and accessories approved by Organ Recovery Systems. Non-approved cables and accessories may damage the system or interfere with accuracy. For information, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

CAUTION: Do not substitute the Power Cord. Use only the Power Cord supplied from Organ Recovery Systems. For information, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

CAUTION: Do not substitute batteries. Use only LifePort Kidney Transporter batteries from Organ Recovery Systems. For information, contact the Organ Recovery Systems 24/7 Perfusion Helpline.

CAUTION: Extended storage may damage the batteries.

CAUTION: Replace the batteries only one at a time to ensure that LifePort Kidney Transporter will continue to operate.

CAUTION: Do not immerse LifePort Kidney Transporter.

CAUTION: Ice Container and Ice Container Lid are reusable parts of the LifePort Kidney Transporter. Do not dispose of them.

CAUTION: Audible alerts should only be turned off when temporary silencing of such alerts is required. It is the user's responsibility to turn audible alerts on/off, utilizing the Audible Alert Switch as directed.

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