

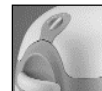
LifePort™

Kidney Transporter



Operator's Manual





This Operator's Manual references
LifePort™ Kidney Transporter
Model Numbers:LKT-100 & LKT-100-P

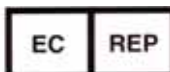


For technical assistance and to reorder supplies
and single use disposables, please contact:



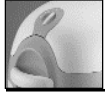
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www.organ-recovery.com



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LifePort™ Kidney Transporter manufactured in the USA for Organ Recovery Systems



Ownership Information

Retain the following in your records:

Institution _____

Contact _____

Model Number _____

Serial Number _____

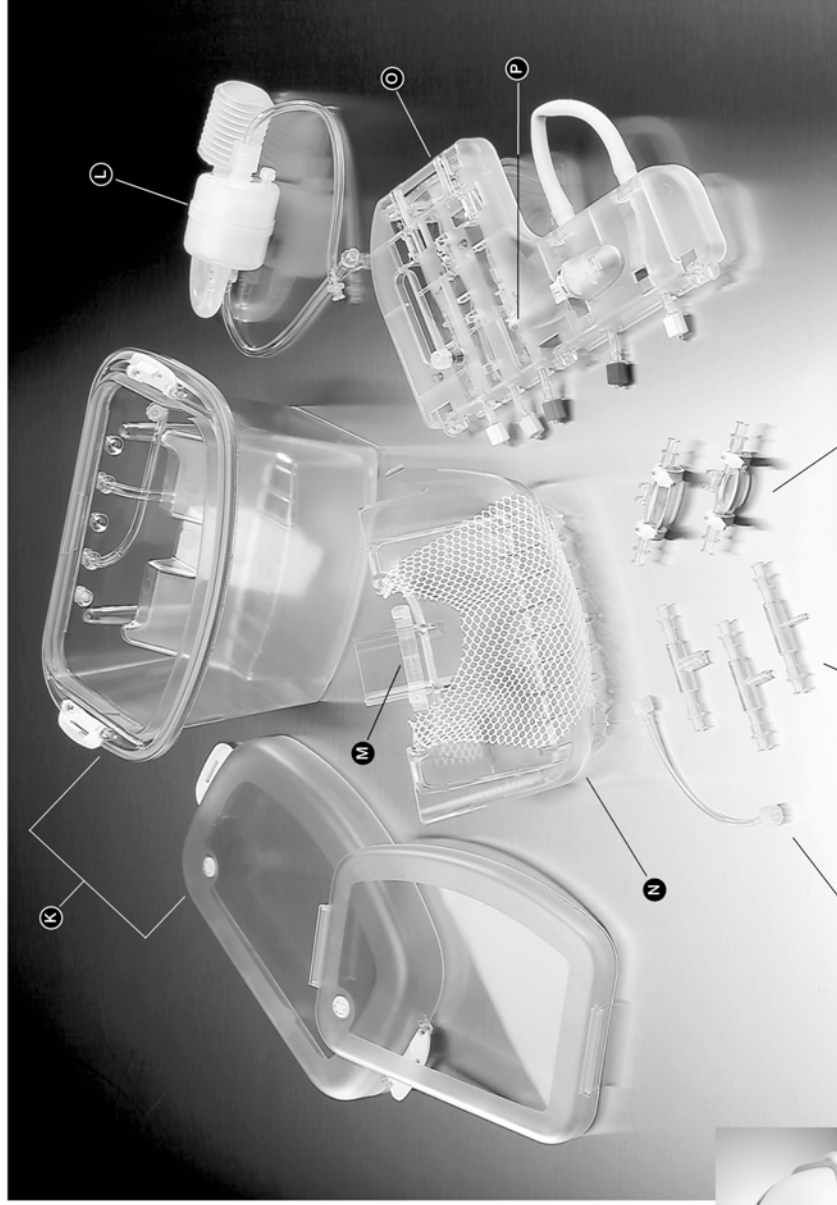
Date of Purchase _____

LifePort™ Kidney Transporter

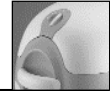
- A ICE CONTAINER**
accepts replenishment
without interrupting
perfusion
- B PUMP DECK**
effortlessly receives
the Perfusion Circuit
- C BUBBLE DETECTORS**
ultrasonically protect
the organ from air
embolisms
- D CASSETTE WELL**
maintains a
consistent hypothermic
environment
- E CONTROL PANEL**
sets perfusion
in motion
- F INFUSION PUMP**
delivers reliable
performance with
instrument-quality
precision
- G OUTER DISPLAY**
provides real-time
data
- H ERGONOMIC HANDLES**
comfortably fit grips
of all sizes
- I INSULATING COVER**
protects during
transport
- J SAFETY LATCH**
locks down the
cover securely



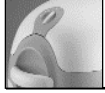
- K ORGAN CASSETTE** features vented dual lids
- L FILTER** removes harmful particles
- M CANNULA MOUNT** allows proper arterial positioning
- N ORGAN CRADLE** easy to remove, supports and secures the kidney
- O TUBEFRAME** neatly manages setup and connection
- P PRESSURE SENSOR** built in to every Perfusion Circuit
- Q COUPLER** pairs cannulas to manage additional renal arteries
- R STRAIGHT CANNULA** inserts directly into the renal artery
- S SEALING™ CANNULA** connects securely to calcified aortic patches and accommodates multiple renal arteries
- T AC PLUG** powers up LifePort™ on any voltage
- U DATA PORT** guides the flow of critical perfusion information
- V BATTERIES** drop in, hot swap, and charge when plugged in



- T**
- U**
- V**



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Chapter 1: SAFETY REQUIREMENTS

1.1 IMPORTANT INFORMATION

It is important that all personnel who will operate the LifePort™ Kidney Transporter read and understand this manual before operating the device. All personnel should follow all warnings and precautions outlined below, for their safety and the safety of those around them.

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

WARNING. Any operation, procedure, practice, etc., which if not strictly observed, might result in injury or long-term health hazards to personnel or patients.

CAUTION. Any operation, procedure, practice, etc., which if not strictly observed, might result in damage or destruction of equipment or loss of treatment effectiveness.

1.2 WARNINGS

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.

USE ASEPTIC PROCEDURES WITH THE LIFEPORT™ PERFUSION CIRCUIT

The Perfusion Circuit is provided pre-sterilized from the manufacturer. To minimize the potential for infection of the kidney (and its eventual recipient), aseptic procedures must be used whenever handling the kidney and perfusate, or whenever opening the Cassette or Tubeset. Aseptic procedures include the use of sterile field, gown, gloves, and instruments and aseptic management of IV tubing, as would be typical in surgical and nursing practice.

USE UNIVERSAL PRECAUTIONS WITH THE KIDNEY AND PERFUSATE

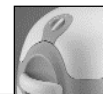
The kidney and perfusate may carry undetected pathogens from the donor. Use proper precautions (e.g. gloves, masks, gowns, goggles or equivalent eye protection, biohazard bags) in handling the kidney, and in handling and disposing of the Perfusion Circuit and perfusate to prevent the possible transmission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

CHECK THE TRANSPORTER AND PERFUSION CIRCUIT BEFORE EACH USE

Visually check the Transporter and Circuit for overall integrity and transport-worthiness before each use. Do not use if parts are loose, cracked, or broken, or liquid is leaking. Turn the Transporter on, check ice and battery levels, and check its operation using the startup methods outlined below.

DO NOT REUSE PERFUSION CIRCUITS OR CANNULAS

The cassettes, tube-sets, and cannula are sterile as supplied, method of sterilization is ethylene oxide gas, and are intended for single-use. After use, they should be disposed of in accordance with local guidelines for biomedical waste.



DO NOT OPEN THE DEVICE TO SERVICE IT

SHOCK HAZARD IF PUMP DECK IS REMOVED

All aspects of the Transporter that are meant to be attended by the operator are accessible without opening the device. If there is a service problem, please call qualified service personnel.

USE ONLY GROUNDED ELECTRICAL CONNECTIONS

Connect the 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 the Transporter from internal power.

USE ONLY MANUFACTURER-APPROVED ACCESSORIES

Only manufacturer-approved accessories (e.g., batteries, perfusion circuits, power cable, data cable) are designed to work properly with the Transporter. Do not substitute other batteries, perfusion circuits, cables, or accessories.

USE ONLY IN SAFE ENVIRONMENTS

DANGER: Possible Explosion Hazard. Do not use the device in the presence of flammable anesthetics. The Transporter is not designed for use in the presence of explosive mixtures of anesthetic gases with air, oxygen, or nitrous oxide.

1.3 PRECAUTIONS



READ INSTRUCTIONS CAREFULLY

USE GOOD CLINICAL JUDGMENT

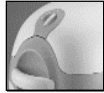
Use standard precautions and good clinical judgment when performing any medical procedures.

BECOME FAMILIAR WITH THE TRANSPORTER AND ITS CONTROLS

Spend sufficient time learning to use the device. People who are new to kidney perfusion should learn from practitioners experienced in organ perfusion, and by experimenting with the device on animal and human kidneys not intended for transplant. Various settings should be tried and a sense obtained as to the effects on the kidney.

USE ONLY ICE AND WATER IN THE TRANSPORTER 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 the Transporter. To avoid inadvertently freezing the kidney, **ONLY USE ICE AND WATER** in the Transporter Ice Container.



Chapter 1: SAFETY REQUIREMENTS

SECURE THE KIDNEY, PERFUSION CIRCUIT, COVERS, AND LIDS BEFORE TRANSPORTING THE TRANSPORTER

To best protect the Transporter and the kidney, all parts of the device, including the kidney, must be in place during transportation. Check Kidney Net, latches, lids, fittings, panels, and doors to make sure that they are securely positioned at the beginning and throughout every case.



All LifePort™ Disposable Accessories are for single use only.



All LifePort™ Disposable Accessories are sterile as supplied. Do not sterilize any LifePort™ Disposable Accessory.

KEEP THE TRANSPORTER UPRIGHT DURING TRANSPORTATION. AVOID DIRECT SUNLIGHT AND HOT OR COLD TEMPERATURE EXTREMES.

The Transporter is designed to be transported under the same environmental conditions as would be appropriate for people. Avoid extended exposure to outdoor conditions (sunlight, heat or cold), which can shorten the time that the Transporter can maintain proper cold temperatures. If the Transporter has to be operated under these conditions, the user should frequently monitor the Transporter temperature and maintain proper ice levels to keep the kidney sufficiently cold.

MAKE SURE THAT ICE AND BATTERY LEVELS ARE SUFFICIENT FOR THE ANTICIPATED TRANSIT DURATION.

The Transporter will work best when the batteries are fully charged and the ice container completely filled before each use.

USE PROPER PERFUSION PRESSURES

Use the lowest perfusion pressure needed to perform the intended procedure. This reduces the risk of damage to the organ.

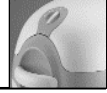
USE ONLY MACHINE PERFUSION SOLUTION

The Transporter is designed to work with machine perfusion solutions only. Check the labeling of the perfusion solution and make sure that it is intended for machine perfusion. If you are uncertain about which solutions are appropriate, contact Organ Recovery Systems for information on recommended perfusates that work best in the Transporter.

MAKE SURE THAT THE RENAL ARTERY IS ADEQUATELY CANNULATED

For proper kidney perfusion, all renal arteries must be cannulated and leak tight. Use a cannula and cannulation technique that minimizes the trauma to the arteries. Try to attach the cannula to those areas of the artery that would be discarded by the transplant surgeon, to minimize the impact on the transplanted graft.

Check and resolve incomplete perfusion or cannulation leaks when perfusion is started, and regularly during perfusion. Also, check to make sure that there are no twists or kinks in the renal artery that would occlude flow.



MAKE SURE THAT THE PERFUSION CIRCUIT IS PROPERLY CONNECTED AND SEALED

During every installation and initial operation of a new Perfusion Circuit in the Transporter, check all seals, connections, and fittings to make sure that they are properly installed and leak tight. To prevent contamination or loss of perfusate, resolve or replace any leaking part before transporting an organ in the Transporter.

CONNECT THE SYSTEM TO ELECTRIC SUPPLIES ACCORDING TO LABELING

The Transporter uses externally supplied electricity to operate. Check the voltage and amperage ratings of the external supplies and make sure they match the labeled ratings for electricity inputs shown on the rear of the Transporter.

ASSURE ADEQUATE VENTILATION

Do not block the ventilation areas on the side and bottom of the Transporter, especially when external power is connected.

BEWARE OF ROTATING PARTS

Keep hands, clothing, jewelry, ID lanyards, etc. away from the vicinity of the Infusion Pump when the Transporter is turned on.

USE PRECAUTIONS WHEN LIFTING

A fully loaded Transporter weighs 20.4 kg (45 lbs). Use proper lifting practices to avoid injury. Do not attempt to lift the Transporter by the lid. Use the handles.

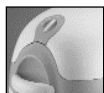
ELECTROMAGNETIC COMPLIANCE

The 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.

The 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 Appendix B on Page 42 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 the Transporter to an external electrical power source on a commercial aircraft. Do not connect the Data Cable to the Transporter during flight on a commercial aircraft.



Chapter 2: INTRODUCTION & GENERAL INFORMATION

2.1 INTRODUCTION

Please read this manual carefully before using the system. If more information is needed about installation, organ perfusion, or if you have any questions, please contact Organ Recovery Systems.

The LifePort™ Kidney Transporter is a compact and reliable medical instrument that is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, transportation, and eventual transplantation into a recipient.

2.2 PURPOSE OF MANUAL

The instructions within this manual should be carefully followed for safe, trouble-free, and effective equipment use.

This manual provides the essential information necessary for installation, operation, and routine servicing of the Transporter. It contains important operation and maintenance information for personnel who have been trained in organ perfusion.

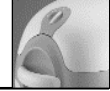
This manual is NOT to be used as a replacement for training in the art or science of organ perfusion. This manual does NOT contain information for servicing internal components of the system.

2.3 ABBREVIATIONS

The abbreviations used in this manual are listed in Table 2.1 with their definitions.

TABLE 2.1 ABBREVIATIONS

A	Amperes
AC	Alternating current
A-hr	Ampere-hours
°C	Degrees Celsius
cm	Centimeter (1 cm = .01 m)
L	Liter (1L =0.001 m ³)
lb(s)	Pound (1 lb = 0.45 kg)
LCD	Liquid Crystal Display
LED	Light emitting diode
kg	Kilogram (1 kg = 2.2 lbs)
mL/min	Milliliters per minute (1 mL/min = 0.00006 m ³ /sec)
mm Hg	Millimeters of mercury (1 mm Hg = 1 torr = 133.3 Pa)
V	Volts



2.4 SAFETY

The responsibility for safety when using this device resides with the healthcare professionals who use it. The 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 and the International Electro-technical Commission.

Electrical and mechanical safety features have been designed into the Transporter to ensure safe operation. These features are as follows:

- a. The electrical and electronic components are contained within a secure enclosure.
- b. Perfusate temperature, flow rates and pressure levels are only adjustable within a set range, which cannot be changed by the operator. Through the control panel, the operator can set the desired perfusate pressure within the set range.
- c. Perfusate pressure, flow rate, and temperature are continuously monitored.
- d. A power indicator light is provided to indicate when the unit is ON. STOP, WASH, PRIME, and INFUSE lights are provided to indicate whether the Transporter is stopped, washing, priming, or infusing.
- e. Acceptable operating ranges are established within the Transporter for pressure, temperature, flow rate, battery charge state, bubbles in the perfusate, and configuration integrity. Hardwired and software interlocks are built in to bring the Transporter to a failsafe condition if an unacceptable operating state is detected.
- f. An error indicator light, audible alarm, and descriptive message are given by the Transporter if an unacceptable operating state is detected.

2.5 PHYSICAL DESCRIPTION

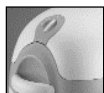
The Transporter is a portable instrument that is designed to contain and perfuse a transplantable kidney under cold and aseptic conditions. An insulated, plastic housing encloses the kidney and perfusate within a disposable Perfusion Circuit, along with the rest of the Transporter components, which include a Control Panel, Outer Display, Ice Container, Pump Deck, sensors, and electronics.

The Transporter is designed to integrate with the clinical environment by using readily available supplies, requiring minimal user intervention, and by being portable and easy to use.

The LifePort™ Kidney Transporter comprises the following major systems:

MAIN ENCLOSURE

The Transporter is enclosed in a rugged, insulated plastic housing which is designed to be portable. The lower housing contains the Control Panel, Outer Display, Ice Container, Pump Deck, electronics module, and disposables. It provides two carrying handles, which enable lifting the Transporter onto a cart or into a car. An insulated, removable, latched lid covers the lower housing during perfusion to keep the kidney secure and at the proper temperature.



CONTROL PANEL

The Control Panel allows the user to select the operating mode and infusion pressure setpoint. It is a horizontal panel located next to the pump deck, and can be accessed only when the insulating cover is removed. By closing the cover over the deck Control Panel, the Transporter operator can prevent inadvertent and unauthorized access to the controls.

UPPER CONTROL PANEL GRAPHIC



POWER BUTTON AND LED INDICATOR

The POWER Button is a touch pad used to turn the user controls of the Transporter on and off. The POWER Button does not disconnect power from the Transporter. When the power is ON, the POWER LED indicator glows green, the displays are turned on, and the user controls are operational. When the power is OFF, all displays are turned off; however, the Transporter will still charge the batteries and the cooling fan will continue to operate.

MODE BUTTONS AND LED INDICATORS

Four buttons allow the user to select the desired mode for the Transporter. Next to each button is an LED, which when illuminated indicates the selected mode.

STOP

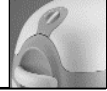
The STOP Button is used to stop the Infusion Pump and close the Infuse Valve. When the STOP Button is pressed, perfusion of the kidney ceases.

WASH

When the user presses the WASH Button, the pump operates with the Wash Valve open and the Infuse Valve closed. By pressing WASH, the Transporter user can circulate perfusate through the Circuit without perfusing the kidney. The Wash mode is employed at the beginning of each use to fill the Circuit with perfusate and to equilibrate the Transporter temperature.

PRIME

The PRIME Button is pressed to enable the tubing downstream of the Infuse Valve to be cleared of air. The user will press PRIME while connecting the cannulated kidney to the Transporter to enable remaining air to be vented from the Infuse Line before the final connection is secured.



During Prime, the Infusion Pump will operate and the Infuse Valve will be open. Once the kidney is connected, the Transporter will sense the increased pressure and will automatically stop the pump, close the valve and exit from prime mode. An audible alarm alerts the user that Prime has ceased.

INFUSE

The INFUSE Button initiates the kidney perfusion mode. When the user presses INFUSE, the Infusion Pump begins to turn and increases in speed until pressure setpoint is reached. Then the pump speed stabilizes to maintain the perfusate pressure into the kidney at that setpoint.

+ AND – BUTTONS FOR CHANGING PRESSURE

These buttons are used to increase or decrease the perfusate pressure going into the kidney. When the user presses the + Button, the pressure setpoint increases by 1 mm Hg. When the user presses the – Button, the pressure setpoint decreases by 1 mm Hg. Hold the + or – Button down to change the setting rapidly. The pressure can only be changed when the Transporter is stopped or in Wash mode.

PRESSURE SETPOINT DISPLAY

The pressure setpoint is indicated on a 2-digit LCD display. The system is capable of pressures in the range of 10 to 65 mm Hg, adjustable in 1 mm Hg increments.

OUTER DISPLAY

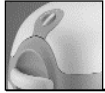
The Outer Display allows the user to observe the status of the Transporter whether the cover is in place or removed. It has four numeric displays, which provide information about the pressure, flow rate, vascular resistance, and temperature. It also has a 2-line alphanumeric display that can be scrolled to provide more information about the perfusion history. A backlight button, scrolling arrows, and power and error LEDs complete the Outer Display.

OUTER DISPLAY GRAPHIC



PRESSURE SETPOINT DISPLAY

The pressure setpoint is indicated on a 2-digit LCD display. It shows the same information as the Control Panel pressure setpoint display.



Chapter 2: INTRODUCTION & GENERAL INFORMATION

FLOW RATE DISPLAY

Flow rate is indicated to the user on a 2¹/₂-digit LCD display. This display shows the actual volumetric rate of perfusate entering the renal artery. Flow rates higher than 199 mL/min are stored in the data file.

RESISTANCE DISPLAY

The resistance display indicates the quotient of pressure divided by flow, given in units of mm Hg/(mL/min). It is a 2¹/₂-digit LCD representing vascular resistance, which is one indicator of kidney viability. Resistances ranging from 0.00 to 1.99 can be displayed. Resistances higher than 1.99 are displayed as 1.99 flashing. Resistances higher than 1.99 are stored in the data file.

TEMPERATURE DISPLAY

The temperature display is a 3-digit LCD, which provides the user with an indication of the temperature within the insulated cold section of the Transporter. It can display temperatures ranging between 0.0 and 30.0°C. Temperatures below zero degrees are displayed as 0.0 flashing.

The Transporter preserves kidneys hypothermically, so the temperature display provides important information to the user about the kidney's preservation conditions.

MESSAGE DISPLAY

The message display is a 2-line, 24-character alphanumeric LCD. Normally it gives the user indications on mode of operation, power status, and time of perfusion. Errors and other status indications are shown on the message display upon occurrence.

By scrolling the message display using the Scroll Buttons, the user can review information about the ongoing perfusion including maximum and minimum temperature.

POWER LED INDICATOR

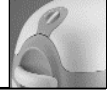
The Power LED indicator glows a steady green whenever the Transporter's power is ON. The Power LED indicator flashes green whenever the external power is present and the power is OFF.

ERROR LED INDICATOR

The Error LED indicator flashes red whenever an error is encountered by the Transporter. When the Error LED is illuminated, the user should check the message display to read the error description, and then take appropriate action as described in this manual. If more than one error is identified, use the scroll keys to read all the reported error descriptions.

BACKLIGHT BUTTON

The Backlight Button enables the user to toggle the display backlight on and off, to improve the display legibility in darkness or low light. The backlight will automatically turn off 30 seconds after the last user input.



SCROLL BUTTONS

The Scroll Buttons provide a way for the user to scroll through the message display, one line at a time, to review information about the current perfusion session.

ICE CONTAINER

The Ice Container is a sealed enclosure with a removable lid, which the user can fill with a mixture of ice and water to provide a stable cold temperature environment for the kidney.

PUMP DECK

The Pump Deck is the fluid management area of the Transporter. On the Pump Deck, the Perfusion Circuit goes through a pump, valves, and sensors, which control the perfusates pressure, speed, and routing.

INFUSION PUMP

This peristaltic pump provides the energy to flow perfusate through the kidney. By moving rollers against the pump tubing, the pump is able to push the perfusate through the kidney, while keeping it sealed within the Perfusion Circuit. The Transporter electronics regulate the pump speed to control perfusion pressure into the kidney.

BUBBLE DETECTORS

Two non-contact bubble detectors on the Pump Deck check the perfusate to prevent bubbles from entering the kidney.

The first bubble detector is upstream of the Bubble Trap and Wash Line. A bubble detected by the first bubble detector will be diverted away from the kidney and into the Wash Line, after which the Transporter will resume perfusing.

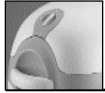
The second bubble detector is immediately before the kidney, and will prevent air bubbles from entering the kidney by causing perfusion to stop altogether.

PRESSURE SENSOR CABLE

A Pressure Sensor Cable is located at the rear of the Pump Deck. This connection provides the Transporter computer with information about the perfusion pressure felt by the kidney. If at any time the connection with the Pressure Sensor is broken, the Transporter will stop and alert the user.

INFUSE AND WASH VALVES

Two electrically activated valves, working together, determine whether the perfusate goes into the kidney or bypasses the kidney. The INFUSE valve controls perfusate going into the kidney and the WASH valve controls the bypass. When the Transporter is in INFUSE mode, the INFUSE valve is open and the WASH valve is closed, allowing perfusate to flow into the kidney. In WASH mode and during bubble purge, the WASH valve is open and the INFUSE



Chapter 2: INTRODUCTION & GENERAL INFORMATION

valve is closed, directing the perfusate through the bypass line, avoiding the kidney and flowing directly back into the perfusate reservoir.

TUBE FRAME LOCKING ARM

An aluminum locking arm is used to secure the Tube frame to the Pump Deck.

ELECTRONICS

The Transporter electronic circuits control functions and user interaction, manage power, and enable communications over standard interfaces. All the circuits are contained within the Transporter electronics module.

INTERNAL CIRCUITS

The following circuits reside within the Transporter electronics module:

- ▶ Computer
- ▶ Batteries and battery charger
- ▶ Communications interface
- ▶ Power supply
- ▶ Sensor interface
- ▶ Pump and valve driver circuits
- ▶ Fan

EXTERNAL CONNECTIONS

The Transporter connects with external supplies and devices through its back panel. The back panel has a standard AC power cord connector and Data Port, a serial interface connector.

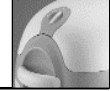
CIRCUIT BREAKER

Two circuit breakers, located on the Transporter back panel, will trip if a short circuit occurs. Depressing the button resets the breaker.

LIFEPORT™ DISPOSABLE ACCESSORIES

Single-use disposables are an integral part of the Transporter. Disposables are used to contain the kidney and perfusate under aseptic conditions during transport, to connect the kidney to the Perfusion Circuit, and to help maintain aseptic conditions while working inside the cassette. The disposables integrate with the reusable part of the Transporter to provide the proper conditions for preserving, perfusing, and transporting the kidney. Each disposable is factory pre-sterilized and delivered to the point of use in an easy-to-open sterile pack. To reorder disposables please contact Organ Recovery Systems at (847)824-2600.

The following disposable components are available:



LIFEPORT™ PERFUSION CIRCUIT

The Perfusion Circuit contains the fluid management components necessary for perfusing a kidney. The two main components of the circuit, the Organ Cassette and the Tubeset, are described in detail below:

ORGAN CASSETTE

The kidney is held within the Organ Cassette while aboard the Transporter. It is supported in a housing by a Kidney Cradle, and is held in place with a Kidney Net. The watertight Organ Cassette acts as the perfusate reservoir, where the kidney is maintained partially submerged in the perfusate bath. Two transparent lids, a sterile inner lid and a non-sterile outer lid, provide a redundant watertight Cassette seal. Each lid has independent closures to hold it in place.

The Organ Cassette has Infuse, Wash, and Return ports that mate with the Tubeset with standard Luer connections. Inside the cassette, the Infuse Line continues and terminates with a male Luer fitting used to connect to a cannula.

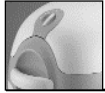
TUBESET

The Tubeset is the sealed fluid path that draws from the perfusate bath and delivers perfusate into the kidney. It consists of the following main components:

- ▶ Tube frame—This component positions the tubing with respect to the pump, valves, and sensors of the Pump Deck. It guides the user in attaching the Tubeset to the Pump Deck.
- ▶ Bubble Trap—Located on the Tube frame, this part helps keep air from entering the Infuse Line.
- ▶ Infuse, Wash, and Return Lines—Located on the Tube frame, these tubes are used to manage perfusate flow and are connected by Luer fittings with the Organ Cassette.
- ▶ Pump Tubing—Extending from the Tube frame, this loop of tubing gets stretched around the Infusion Pump.
- ▶ Sample Port—Protruding from the top of the Tube frame, this port allows the user to sample perfusate or inject fluids without opening the Circuit.
- ▶ Pressure Sensor and Connector—Within the Infuse line is a flow-through pressure sensor which measures the perfusate pressure within the Perfusion Circuit. It sends pressure information to the Transporter computer. The connector, atop the Tube frame, must mate with the Pump Deck Pressure Sensor Cable.
- ▶ Filter—Located under the Cassette, this filter collects material that could block kidney vasculature from achieving proper flows.
- ▶ Compliance Chamber—Located under the Organ Cassette, this chamber helps maintain steady perfusion pressures.

LIFEPORT™ DISPOSABLE CANNULAS

A cannula attaches the Perfusion Circuit to the kidney's renal artery. The user may choose a particular cannula depending on the anatomy of the kidney: large artery, multiple arteries, or plaque on artery. A range of cannula adjustability and sizes are available.



Chapter 2: INTRODUCTION & GENERAL INFORMATION

STERILE DRAPE FOR LIFEPORT™ KIDNEY TRANSPORTER

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

ACCESSORIES

The following accessories are included with the Transporter:

- ▶ Power cord
- ▶ Data cable
- ▶ Flow Constrictor
- ▶ Batteries
- ▶ Operator's Manual

2.6 PERFUSION MODE

The Transporter can be optionally configured at the factory to operate in either Pulsatile or Continuous mode. The user may choose either perfusion mode at the time they order the Transporter. The perfusion mode is indicated in the Transporter Model # found on the label on the back of the device:

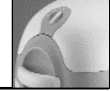
LKT-100Continuous
 LKT-100-P.....Pulsatile

A Transporter set to run in Continuous mode will maintain steady infusion at the pressure set by the user on the Control Panel.

A Transporter set to run in Pulsatile mode will pulse the pressure at a fixed pulse repetition rate to a systolic pressure set by the user on the Control Panel. The diastolic pressure is determined in response to the kidney vascular resistance. The diastolic pressure can be found on the alphanumeric belt display.

2.7 LIFEPORT™ KIDNEY TRANSPORTER 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, transportation, and eventual transplantation into a recipient.
Capacity	Single kidney
Power	AC or battery
Coolant source	Ice/water bath, 5 ¹ / ₂ liters
Perfusate pump	Peristaltic pump



Pressure control	Closed loop pressure regulation, 10 to 65 mm Hg
Perfusion mode (factory set)	Continuous or Pulsatile
Flow Rates	Continuous Mode, 0 to 240 mL/min Pulsatile Mode, 0 to 120 mL/min (maximum rates decrease by 25% when powered by batteries)
Dimensions	24" x 14.5" x 14.25" (61.0cm x 36.8cm x 36.2cm)
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 (fully charged)	24 hours
Perfusate used	Hypothermic machine perfusate
Data download (optional)	Serial interface (RS 232) data download of all perfusion and status data collected since INFUSE state was entered after Power ON.
Operating and Storage Conditions	Temperature: -15°C to 50°C Humidity: 0 to 90% Pressure: 700 to 1060 hPa (equivalent to an elevation of -380m to 3,000m or -1250ft to 10,000ft)

DEVICE CLASSIFICATIONS

FDA	Class II Medical Device
IPX1	The Transporter is protected from vertical water droplets.
Class I	The Transporter employs Class I protection from electric shock.

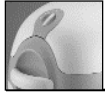
LifePort™, Single Kidney Transporter. This device is Class IIa per Annex 9, Rule 2 of Council Directive 93/42 EEC of 14 June 1993

2.8 DEVICE DISPOSAL

Local regulations must be followed for the disposal of the Transporter and Lithium Batteries. If in doubt, consult Organ Recovery Systems at (847)824-2600.

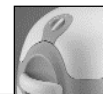
2.9 MAINTENANCE AND REPAIR

CAUTION: The Transporter has no user serviceable parts.



Chapter 2: INTRODUCTION & GENERAL INFORMATION

Maintain, clean, and keep the Transporter ready to use according to directions in this manual. If the Transporter is not functioning properly refer to Chapter 7: Troubleshooting or contact Organ Recovery Systems at (847)824-2600.



3.1 INTRODUCTION

The Transporter system is shipped in a special container that is marked for appropriate handling. It should be opened and checked by a responsible person trained and qualified in working with electronic medical equipment.

3.2 INSPECTION

Please inspect the Transporter on arrival for any signs of damage that may have occurred in transit. After carefully removing the Transporter and its accessories from the shipping container, please save the packing materials for future shipping and storage.

After unpacking, thoroughly inspect the system and all accessories for damage. During this inspection, ensure that:

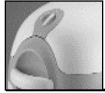
1. The Transporter housing is not bent or distorted
2. There are no dents, chips, or cracks in the housing surface
3. Manual controls and movable parts, such as connectors, operate properly
4. Control panels are properly aligned
5. All items on the shipping documents are accounted for

Report any damage found from this inspection to the carrier immediately. If you have any concerns about the condition of the Transporter or Accessories, contact Organ Recovery Systems.

3.3 SITE SELECTION

A home station should be designated for each Transporter where it can be set up and recharged between cases. The home station should be a secure area and provide a clean bench top or tabletop space where the Transporter can be stored, operated, and maintained. The following facilities and utilities are required:

- ▶ Climate controlled 24 hours a day to standard office or laboratory conditions (approximately 21°C, 50% humidity)
- ▶ No direct sunlight
- ▶ AC electrical outlets (2 to 4 plugs: 120V/15A in the USA)
- ▶ Storage for Transporter disposables, batteries, tools, and spares
- ▶ Space nearby to place the Transporter Cover when it is removed
- ▶ Easy access to crushed or cubed ice
- ▶ Easy access to a sink for clean-up and to provide water for the ice bath
- ▶ Easy access to medical waste disposal
- ▶ Easy access to refrigerated storage for perfusate and other medicines
- ▶ Tabletop space for battery charger and computer (recommended)
- ▶ Serial (RS232) connection for computer (recommended)
- ▶ Storage for transplant coordinator gear: cart, bags, procedure kits, coolers
- ▶ Proximity to operating rooms and ready access to car, ambulance, or helicopter loading areas



Chapter 3: INITIAL INSTALLATION

3.4 EQUIPMENT SETUP AND CHECKOUT

Perform the following trial run with the Transporter to make sure that it is ready to work properly. After each step, observe the system to make sure that the Transporter works as described and that there are no malfunctions, leaks, or irresolvable errors. Check Chapter 7—Troubleshooting, if difficulties arise during setup and checkout.

SET UP THE TRANSPORTER

The Transporter weighs 20.9 kg (45 lbs) fully loaded. Use proper lifting procedures to avoid injury. Do not attempt to lift the Transporter by the cover.

Holding the handles, lift the Transporter and place on its home station table or countertop so that the Outer Display is easily accessible and facing you. Unlatch and remove the Transporter cover, and store it nearby. Before starting these tests, look at the Transporter carefully to make sure that it is complete, secure and intact, and that nothing appears broken.

FILL THE ICE CONTAINER

Open the lid to the Ice Container and fill it with crushed or cubed ice, making sure to push the ice as far as possible into the ice bath. Pour about 0.5 liter of cold water (less than 10°C) into the Ice Container, which will gradually loosen the ice. Add more ice and water until the Ice Container is filled with an ice and water mixture, maximizing the amount of ice added. Close the Ice Container lid once it is filled.

LOAD THE PERFUSION CIRCUIT

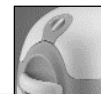
(For detailed instructions, refer to the Lifeport Kidney Perfusion Circuit (LKT—201) Instructions For Use.)

Unpack a sterile Perfusion Circuit and assemble the Circuit into the Transporter, positioning and securing the Tube frame on the Pump Deck so that the tubing mates properly with the pump, valves, and sensors. Page 25 describes proper Circuit loading. Open the Cassette lids and pour 1 liter of cold (less than 10°C) saline into the Cassette housing. Close the Cassette lids.

ENERGIZE THE TRANSPORTER

Connect the power cable to the Transporter back panel, and then plug it into the mains power. Press the POWER Button on the Upper Control Panel and observe that the POWER LED illuminates, and that the LCDs flash full on and then show normal values. The PRESSURE LCD will show a default value (in the range of 20 to 40 mm Hg depending on the factory preset), the FLOW and RESISTANCE LCDs will display “- -”, the TEMPERATURE LCD will display the ice bath temperature (less than 10°C) and the top line of the message display will say “READY.”

If the Transporter detects any errors during its power on self test, the top line of the alphanumeric display will say “Power up test FAILED!!!!” and the second line of the alphanumeric display will provide the name of the error. It is common that the temperature of the Transporter will be high when first energized. When the ice bath temperature is above 8°C, the Transporter will beep, the red ERROR LED will illuminate, and the second line of the message display will read, “Check ice.” If this happens, push STOP to temporarily silence the audible alarm, make sure that the Ice Container is properly filled and in position. It is possible to run the Transporter in WASH mode in spite of the “Check ice” error; however, PRIME and INFUSE modes will not be accessible until you get the temperature below 8°C.



Other errors may also occur at power on. Review the troubleshooting section for specific information on how to deal with other possible errors.

TEST OPERATING MODES

Press the pressure + and – buttons and verify that the pressure setpoint changes up or down by 1 mm Hg with each press. Then, using the buttons, set the pressure to 40 mm Hg.

Press the WASH button and observe the pump rotation. Check to see that the perfusate is drawn from the cassette, into the pump, and then down into the filter. Within a couple of minutes, perfusate should flow out of the filter, into the bubble trap, then into the wash port of the cassette. Check to make sure that the perfusate is contained within the tubing, not leaking, and not flowing through the infuse line into the cassette.

Press the PRIME button and observe the flow divert into the infuse line of the cassette. Check to make sure that the perfusate is contained within the tubing, not leaking, and flowing only into the infuse line of the cassette, and not flowing into the wash port. Open the Cassette lids and squeeze or clamp the infuse tubing. The Transporter should beep, the pump should stop, and the alphanumeric display should read, “Stopped – Check tubing.” Release the tubing and press the STOP button, which should clear the error.

Open the Organ Cassette and place the flow restrictor on the infuse line inside the cassette. Press the INFUSE button. The pump should start up and then begin regulating pressure at the setpoint level. Check to see that a flow rate and vascular resistance are displayed on the front panel. Press the STOP button to end the infuse test. Turn the Transporter off by pressing the POWER key. Verify that the power indicator is flashing.

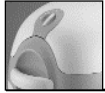
TEST THE BATTERIES

Open the Transporter battery door by sliding it in a direction away from the product label. Insert the batteries. Replace the battery door. The battery door should be in place whenever the Transporter is operated or transported. Allow the batteries to charge for at least five hours. The batteries will charge automatically whenever they are in the Transporter and it is plugged into mains power. After five hours' charging the batteries should be ready to run the Transporter for 24 hours. Run the ENERGIZE and TEST OPERATING MODES tests as described above, except use battery instead of mains power. The power indicator will not flash when only batteries are present and the Transporter is off.

CHECK THE TRANSPORT DURATION (optional)

Scroll down to observe battery data on the alphanumeric display. The batteries should display a range between 95% to 100% capacity.

With the batteries fully charged and a full Ice Container, operate the Transporter in INFUSE mode with the flow restrictor on the infuse line and keeping the lid closed for 24 hours. Verify that the ice and batteries last for the entire 24-hour duration of the test.



Chapter 3: INITIAL INSTALLATION

TEST EXTERNAL COMMUNICATIONS AND SET USER SPECIFIC INFORMATION

Retrieve the Data Cable from the Power Box. The round connector of the Data Cable plugs into the Data Port located on the external connections panel of the Transporter, located on the back of the unit. The opposite end plugs into a 9-pin serial connector of a personal computer. The Transporter is configured to communicate with a terminal or a personal computer running a terminal emulation program, such as Windows HyperTerminal. The instructions below are written for a personal computer running HyperTerminal on Windows 95/98/2K/XP.

Connect the Data Cable to the Transporter and the PC. Press the Power Button to turn on the Transporter. The Power On Self Test will stop at “Connect Sensor, Push STOP” if no Perfusion Circuit is present. A loaded circuit is not necessary for downloading data. Launch HyperTerminal, which can often be found in the Start Menu under Accessories/Communications/HyperTerminal.

Set the terminal or emulator to communicate over com1 (or whichever communication port is registered to the 9-pin serial connector) at 57,600 baud, no parity, 8 data bits, 1 stop bit. Set the terminal emulation mode to vt100. This is found in the Properties window under the File menu.

Type “LS↵.” (↵ represents enter or the carriage return key.) The Transporter will return a list of the stored files. The Transporter is capable of storing 5 files and lists each file with the time and date the Transporter began to infuse.

Type “get 1↵” to download File 1. The data should begin to load into the HyperTerminal window.

Once the data has finished loading. Set the current date for the Transporter by typing “date ###/###/###↵” The date format is Month/Day/Year. For example, to set March 5th, 2003, enter “date 03/05/03↵”

Set the current time for the Transporter by typing “time ##:##:##↵” The format is 24-hour military time. For example, to set 10:45PM, enter “time 2245↵”

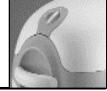
There is an opportunity for one of the start up screens to be personalized. After completing Power On Self Test, the Transporter can show a screen that contains the text “Property of xxxxxxxxxx.” To set ownership information, type “id xxxxxxxxxx↵”. Up to 24 characters will be displayed.

For a complete description of the Transporter’s external communication capabilities, see section 5.6.

CLEAN-UP AND REVIEW

Press STOP then POWER and empty the Ice Container at the end of the test. Remove the Organ Cassette and properly dispose of it.

Problems uncovered during any of these tests should be investigated and resolved. Be aware to look for leaks, misrouted flow, and extra or missing error messages. The system should always stay dry and error-free. If you need assistance, contact Organ Recovery Systems.



4.1 PROFESSIONAL INFORMATION

Before using the Transporter in a clinical setting, practitioners must understand the device and kidney perfusion thoroughly. Practice on discarded or animal kidneys to become familiar with all aspects of portable kidney perfusion in the Transporter. Be aware of the following important factors:

1. Infusion pressure should be selected according to good clinical practice to assure sufficient flow, while preventing vascular damage.
2. Cannulation should be secure enough to avoid perfusate leaks, while preventing damage to the transplanted artery.
3. The cannulated artery must be inspected and positioned to avoid any twists or kinks that would occlude the flow of perfusate.
4. Aseptic conditions must be maintained for the kidney and perfusate at all times. Sealing the Organ Cassette while following sterile procedures will be required.
5. Cold conditions for the kidney must be maintained by keeping the Ice Container filled. Use only ice and water to prevent freezing.

INDICATIONS FOR USE

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

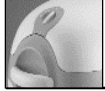
4.2 OVERVIEW

Using the Transporter involves performing the following procedures:

1. Preparing the Transporter and supplies at home station
2. Cooling the Transporter and traveling to the recovery site
3. Kidney recovery, cannulation, and perfusion in the Transporter
4. Traveling with the Transporter to the transplant site
5. Removing the kidney from the Transporter for transplant
6. Returning to home station and cleaning up

4.3 USING THE TRANSPORTER

The instructions below are designed for preparing the Transporter at its Home Base, traveling to the recovery site, and then to the transplant site. These instructions should be modified based on actual use. The instructions are also designed for two operators, one being gowned and gloved. These instructions should also be modified, in the case of the single operator, paying special attention to the procedures performed inside a sterile field.



Chapter 4: OPERATING INSTRUCTIONS

PREPARING THE TRANSPORTER AND SUPPLIES AT HOME BASE

The Transporter must be maintained in a ready-to-use condition, so that it can be available to the kidney recovery team at short notice. Typically, the kidney recovery team will have their pack of supplies complete and ready, so that they can go to the donor operation quickly and with a minimum of errors. The Transporter and its supplies and accessories are designed to be an integral part of the recovery team's supply pack, which can be seamlessly included in the recovery and transplant process. The following preparations should be performed to maintain the Transporter in a ready-to-use state:

1. Cubed or crushed ice, 10 lbs or more, readily available in a freezer or icemaker
2. Batteries in the Transporter and fully charged. Maintain the batteries' charge by keeping the Transporter plugged into mains power.
3. Perfusion Circuit, sterile drapes, and cannula packed and ready
4. Portable wheeled cart available and ready
5. Surgical instruments, suture, solution decanter, and supplies packed and ready
6. Chilled distilled, sterile or regular tap water (about 5 liters) in the refrigerator
7. Machine perfusion solution and organ flush solution in the refrigerator and chilled
8. Spare parts such as additional charged batteries, power cord, spare cannula, etc.

COOLING THE TRANSPORTER AND TRAVELING TO THE RECOVERY SITE

As the transplant team prepares to go to donor site to recover a kidney, they should prepare and transport the Transporter in the following way:

COOL THE TRANSPORTER

Open the lid and fill the Ice Container with crushed or cubed ice, making sure to push the ice as far as possible into the ice bath container. Pour about 0.5 liter of cold water (less than 10°C) into the Ice Container, which will gradually loosen the ice. Add more ice and water until the Ice Container is filled with an ice and water mixture, maximizing the amount of ice added. Close the Ice Container lid once it is filled. Make sure that the lid is secure, sealed, and leak tight.

RECHECK THE BATTERIES

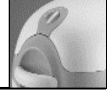
Check the batteries to make sure that all are fully charged. Press the POWER button and verify that the Transporter powers up. Press the POWER button again to turn it off.

SECURE THE TRANSPORTER AND SUPPLIES FOR TRAVEL

Close and latch the Transporter Cover and place it on a wheeled cart. Place the other supply packs containing the disposables, instruments, and supplies on the cart as well. Put the perfusate and flush into a cooler with ice, and place the cooler on the cart.

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.



TRANSPORT THE LIFEPORT™ AND SUPPLIES

If you are taking a vehicle, push the cart with Transporter and supplies to the vehicle, and place the Transporter on the seat or in the trunk. Secure the Transporter from sliding or rolling. The cart and supply packs can also be loaded onto the seats or into the trunk.

The 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. If the Transporter is transported in a car seat, the normal seatbelt can be used to restrain the Transporter while driving.

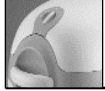
At the recovery site, the Transporter and supply packs can be reloaded onto the cart, which can be pushed to the donor operating room.

KIDNEY RECOVERY, CANNULATION, AND PERFUSION IN THE TRANSPORTER

INITIAL PREPARATION IN THE OPERATING ROOM (OR)

The transplant coordinator should work with the OR nursing staff to make sure that the Transporter setup will be properly integrated with the rest of the equipment and workflow used during the donor surgery. The resources and space required to use a Transporter in a donor surgery are mostly similar to the standard requirements for any kidney recovery. However, the following specific preparations should be made:

1. Find a non-sterile table in the OR for the Transporter: Or, the wheeled cart may be parked in the OR, where the cart can act as a table. The table or parking place should be near the sterile back table to ease the process of transferring the kidney from the sterile back table into the Transporter. If a power plug is nearby, then it can be used to power the Transporter and charge and preserve the batteries. Follow hospital procedures for moving equipment into the OR.
2. Introduce the Perfusion Circuit, cannula, Sterile Drape, and instruments into their proper positions on a sterile back table, using aseptic techniques: Each LifePort™ disposable device is sterile packed in a peel-back pouch or central supply wrap, enabling them to be either dropped onto the table or handed off to a scrubbed-in assistant. Visually inspect all material for damage, discard and replace if necessary. It is not necessary to disconnect the tube frame from the cassette. Leave the Tube frame attached suspended from the side of the Organ Cassette. **Check the tightness of all fittings.**
3. Remove the Organ Cradle and fill the Organ Cassette with perfusate: A person who is gowned and gloved should set aside both of the cassette lids and position the cassette so that a person outside the sterile field can decant 1-liter **cold** perfusate into the cassette housing, while maintaining the cassette and lids within the sterile field. Use only perfusates that are approved for machine perfusion of kidneys.
4. Seal the Perfusion Circuit before transferring to the Transporter: After the liter of perfusate has been decanted into the cassette, the cassette lids can be replaced and secured by the person who is gowned and gloved, who can then hand the filled and sealed Circuit, to a person outside the sterile field. This procedure can be modified to accommodate a single practitioner working alone.



Chapter 4: OPERATING INSTRUCTIONS

5. Load the Perfusion Circuit into the Transporter: Lower the filled and sealed cassette into its mating cavity in the Ice Container. Carefully assemble the tube frame onto the Pump Deck and pump. The Tube frame is assembled with the Tube frame UPRIGHT perpendicular to the Pump Deck. Only with the Tube frame perpendicular will the hinges slide into the receivers on the Pump Deck. The Tube frame cannot be assembled properly if it is loaded horizontally.

After the hinges are located, the Tube frame is rotated down over the Pump Deck. The pump tubing must be stretched around the head of the Infusion Pump. The Infusion Pump raceway should be closed and latched. The Pump Deck Locking Arm should be rotated 90 degrees and snapped into place. With the locking arm in place the user should connect the Pressure Sensor Cable from the Pump Deck to the Pressure Sensor Connector on the Tube frame.

6. Energize the Transporter: Press the POWER Button on the Control Panel and observe that the POWER LED illuminates, and that the LCD's flash full on and then show normal values. The PRESSURE LCD will show a default value (in the range of 20 to 40 mm Hg depending on the factory preset), the FLOW and RESISTANCE LCDs will display "- -", the TEMPERATURE LCD will display the ice bath temperature (less than 10°C) and the top line of the alphanumeric display will say "READY."

If the Transporter detects any errors during its power on self test, the top line of the alphanumeric display will say "Power up test FAILED!!!" and the second line of the alphanumeric display will provide the name of the error. Review the troubleshooting section for specific information on how to deal with errors.

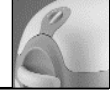
7. Prime the Perfusion Circuit: Start the pump by pressing the WASH button, and continue in WASH mode until perfusate is flowing through the Perfusion Circuit and the air has been flushed from the tubing and bubble trap. If leaking perfusate is observed, stop the pump and resolve and clean up the leak before proceeding.

Once the air has been flushed from the wash line, press STOP, then press the PRIME button and continue in PRIME mode to remove air from the infuse line. Allow the Transporter to run in PRIME while waiting for the kidney to be introduced to the circuit. **Running in PRIME will equalize the temperature of the pressure sensor and perfusate in order to allow for more accurate readings.**

The Transporter is ready to receive the kidney. Replace the Transporter Cover to save ice if the procedure is delayed.

CANNULATION

Typically right after cross-clamp, the donor aorta is dissected and the abdominal organs are flushed with an appropriate cold solution in situ. Afterwards, the kidneys are removed en bloc and taken to the back table for preparation and cannulation. At this stage the recovery surgeon separates the left and right kidneys from each other, and applies a cannula to each kidney in the proximity of its renal artery. This procedure is performed within the sterile field.



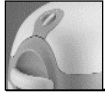
Cannulation is the key step in using the Transporter. Various types and sizes of cannulas are available. The following steps need to be considered and performed in choosing proper cannula and to achieve successful cannulation:

1. Minimize trauma to the part of the renal artery that will remain on the transplanted kidney: Cannulas are available that contact only the areas on the aorta that will be discarded before transplant. Select a cannula that matches the size and anatomy of the aorta and that encompasses all of the renal arteries. Other cannulas are available to be placed inside a renal artery.
2. Perfuse all of the renal arteries: It is not uncommon for a kidney to be supplied by multiple renal arteries. Identify and cannulate all of the renal arteries to assure sufficient perfusion and adequate preservation. Multiple cannulas may need to be used to conduct perfusate into multiple arteries.
3. Seal all leaks: Leaks can arise through holes in the arteries that occurred in the surgical process, and can arise in the sealing surface between the cannula and the artery. Gravity flow small amounts of flush solution into the cannula, and then check and repair all leaks. Have a surgeon or designated surgical technician help if needed to repair leaks in the artery.
4. Secure the cannula: Place the cannulated kidney into the Organ Cradle. Snap the cannula into the Cannula Mount. Adjust the height of the mount by squeezing the sides and sliding to a height where the artery will not kink. Do not overtension the artery. Make sure that the cannula is securely closed and attached to the artery, so that it will remain in place during transportation and perfusion.
5. Visually inspect the renal artery, ensuring there are no twists or occlusions: Correct any twists or occlusions before starting the perfusion procedure.

PLACEMENT OF THE KIDNEY IN THE PERFUSION CIRCUIT

Once the kidney is cannulated, it can be moved from the back table into the Perfusion Circuit. Take the following steps to introduce the kidney into the Perfusion Circuit, maintaining aseptic and secure conditions:

1. Remove the Transporter Cover and the outer Organ Cassette lid: A person outside the sterile field should remove the Transporter Cover. If the Transporter is in Wash mode, press the STOP button to stop the Infusion Pump. Remove the outer cassette lid. Be careful not to touch the inner cassette lid or underside of the outer cassette lid. Place the outer cassette lid upside-down onto a clean table where it will not be disturbed.
2. Drape the Transporter and remove the inner Organ Cassette lid under aseptic conditions: A gowned and gloved practitioner should drape the Transporter. The Sterile Drape gasket should be secured and the drape unfolded, covering the Transporter and exposing the inner lid. Refer to the “Sterile Drape Instructions For Use (LKT-300)” for additional detail. Remove the inner lid of the Organ Cassette and place it on a table in the sterile field.



Chapter 4: OPERATING INSTRUCTIONS

3. Place the kidney in the Organ Cassette under aseptic conditions: Scrubbed-in, carefully transfer the kidney in the Organ Cradle from the back table to the Transporter. Once at the Transporter, lower the Organ Cradle into the cassette. Be careful to avoid capturing the Infuse Line between the cradle and cassette.

PRIMING

Before perfusion can start, the air bubbles have to be removed from the Infuse Line and renal artery. Bubble removal can be accomplished by the following procedure:

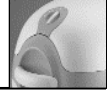
1. Remove the cannula end cap: Keeping scrubbed-in and with the Transporter draped, unscrew the Luer fitting on the top of the cannula to provide a path for bubbles to escape.
2. Connect the Infuse Line: In the cassette, the Infuse Line connects to the cannula by tightening the Luer fitting.
3. Remove the air from the Infuse Line and kidney: Press the PRIME button through the Sterile Drape. The pump will start and perfusate will start to flow into the cannula. As the cannula fills with perfusate, the bubbles will float out the vent. Looking through the cannula clear material, you can see the bubbles being vented. Tapping the cannula with a clamp, or aspirating using a needle-tipped syringe may help remove all the bubbles.
4. Cap the cannula vent: Once the bubbles have been cleared, replace the cannula end cap. The increasing pressure should cause the Transporter to beep and the pump to stop automatically. If the pump does not stop automatically, press the STOP button and inspect the tubeset to make sure it is properly assembled, then re-run the priming steps.

INITIAL PERFUSION

Perform the following steps to initiate kidney perfusion:

1. Set the perfusion pressure: Still scrubbed-in, set the perfusion pressure in mmHg by pressing the + and – arrow keys on the touch pad through the sterile drape, watching the pressure setpoint numbers displayed on the LCD.

Double check the perfusion pressure to make sure the setpoint is as you intend.
2. Begin perfusion: Press the INFUSE button through the Sterile Drape. The pump should slowly start speeding up and then level off once the set pressure is reached.
3. Check kidney and circuit for proper flow: Check the cannula, tubing, flow rate, renal artery, and renal vein to reassure yourself that the perfusate flow is correct and unimpeded. Visually check for leaks. Leaks at the cannula may be sealed by repositioning the tissue or adjusting the tension on the seal. Re-run the priming steps if bubbles are introduced during these maneuvers.
4. Secure the kidney: The kidney can be secured into position on the Organ Cradle by draping the Kidney Net across the kidney and securing it to the top of the cradle. Two fixing posts along the top of the Organ Cradle lock onto the mesh of the Kidney Net.



5. Check Transporter parameters: Check the Pressure, Flow, Vascular Resistance, and Temperature on the Outer Display to make sure that these are within proper clinical ranges. Check the alphanumeric display to verify that the Transporter is in INFUSE mode and that the infusion timer has started.
6. Replace the inner cassette lid and remove the Sterile Drape.
7. Replace the outer cassette lid and close and latch the Transporter Cover. This maneuver can be performed by someone outside the sterile field, if the gowned and gloved practitioner needs to return to the sterile field.

The Transporter is now ready for transport.

TRAVELING WITH THE TRANSPORTER TO THE TRANSPLANT SITE

TRANSPORT FROM THE RECOVERY SITE

After the recovery, secure the Transporter and supplies for travel. Recheck the Transporter cover to make sure it is closed and latched. Place the other supply packs containing the disposables, instruments, and supplies on the cart as well.

MAKE SURE YOU TAKE EVERYTHING YOU BROUGHT

Reviewing your checklist, double check all your equipment and supplies to make sure that nothing is being left behind.

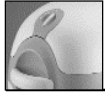
TRANSPORT THE TRANSPORTER AND SUPPLIES

If you are taking a vehicle, push the cart with Transporter and supplies to the vehicle, and place the Transporter on the seat or in the trunk. Secure the Transporter from sliding or rolling. The cart and supply packs can also be loaded onto the seats or into the trunk. If transported in a car seat, the normal seatbelt can be used to restrain the Transporter while driving.

PERFUSION IN THE PERFUSION LAB

Before going to the transplant site, the Transporter may spend some time in a perfusion lab. Here the kidney is perfused and monitored inside the Transporter, to maintain its transplantable condition until the recipient surgery is ready. In the perfusion lab, the following activities may take place:

1. Sterility and hypothermia maintenance: the kidney is maintained under cold and aseptic conditions, while it is sealed in the cassette and surrounded by ice in the Transporter ice bath.
2. Monitoring the kidney: pressure, flow, vascular resistance, and temperature can be regularly recorded to observe the vascular trends in the kidney during perfusion.
3. Monitoring the perfusate: perfusate samples may be taken aseptically, via the needleless port, to watch the levels of perfusate gases, electrolytes, and substrates.



Chapter 4: OPERATING INSTRUCTIONS

4. **Recharging the supplies:** The Transporter may be plugged into mains power to enable continued operation while recharging the batteries. The Ice Container should be checked occasionally and replenished when the ice is running low and temperature is beginning to rise.

TRAVELING TO THE TRANSPLANT SITE

When the transplant team is ready, the Transporter and supplies can be transported to the transplant team via a combination of the wheeled cart and vehicles, as required.

Make sure the ice and batteries are charged before traveling. The Transporter is designed so the batteries and ice will last for 24 hours of operation with the cover in place and latched. Keep a close eye on the battery and ice levels during kidney preservation on the Transporter. The Transporter will alarm when the ice and batteries have less than 2 hours remaining; however, make a habit of checking temperature and battery level.

Check the temperature on the Outer Display to make sure that it is steady and below 8°C. If the temperature is climbing towards 7° or 8°C, then open the Transporter Cover and visually check the ice level. If the ice is mostly melted, then remove some water from the Ice Container (using a cup, scoop, hand pump, or electrical pump) and refill with ice.

Check the battery level on the message display. (Whenever the Transporter is not in transit, the user should plug the Transporter in to mains power, so that the batteries can be maintained in a charged condition.) If the batteries are running low, the user should plug the Transporter into mains power if possible. If mains power is not available, then the depleted Transporter batteries may be replaced with extra charged Transporter batteries. Batteries may be replaced without disrupting device function. Be sure to replace the batteries only one at a time, to ensure that the Transporter will continue to operate during battery replacement.

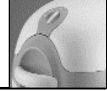
At the transplant hospital, the Transporter can be carried or pushed on the wheeled cart into the transplant OR. Follow hospital procedures for moving equipment into the OR. Find a non-sterile table in the OR for the Transporter. Or park the wheeled cart in the OR, where the cart can act as a table. The table or parking place should be near the sterile back table to ease the process of transferring the kidney from the Transporter to the back table. If a power plug is nearby, then it can be used to power the Transporter and charge and preserve the batteries.

Perfusion parameters should be monitored to make sure that the Transporter is working properly at all times.

REMOVING THE KIDNEY FROM THE TRANSPORTER FOR TRANSPLANT

When the transplant surgeon is ready for the kidney, unlatch and remove the Transporter cover. Then remove the outer cassette lid and place it upside-down on a table where it will be undisturbed. Press the STOP button to stop the infusion pump.

A scrubbed-in member of the transplant team should cover the Transporter with the Sterile Drape and remove the inner cassette lid. Perform the following procedure to remove the kidney from the Organ Cassette:



1. Put the empty stainless steel bowl for the kidney on to the draped Transporter near the cassette.
2. Remove the Kidney Net from the kidney.
3. Disconnect the cannula from the infusion tubing.
4. Direct the Infuse Line into the stainless steel bowl and press the PRIME button to flow cold perfusate into the bowl. When enough perfusate has been transferred, press the STOP button to stop the flow.
5. Carefully detach the cannula from the Cannula Mount, lift the kidney from the Organ Cassette, and place it in the bowl.
6. Carry the bowl to the back table or to the recipient table to do pre-transplant preparation on the kidney.

Once the kidney has been removed from the Transporter it can be powered off, and prepared to return to home station.

RETURNING TO HOME STATION AND CLEANING UP

The perfusate, Perfusion Circuit, and Cannula are single use devices and should go into medical waste disposal. The Transporter and power cord should return to home station where the Transporter can be cleaned with a 70% Isopropanol solution to remove perfusate residue. See Chapter 6 for cleaning instructions.

Use universal precautions when performing perfusate cleanup, to prevent possible contact with blood borne pathogens. Once home, the batteries should be recharged and the supply kits should be repacked in preparation for the next transplant.



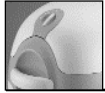
CAUTION: DO NOT CLEAN THE TRANSPORTER WITH THE MAINS POWER CONNECTED



CAUTION: DO NOT IMMERSE THE LIFEPORT™ KIDNEY TRANSPORTER



CAUTION: DO NOT ALLOW CLEANING SOLUTIONS TO ENTER THE REAR PANEL ELECTRICAL CONNECTORS, THE VENTILATION HOLES, OR THE BATTERY AREA



5.1 INTRODUCTION

In operation, the Transporter uses special accessories and supplies. To work properly, it is important to use only accessories and supplies that Organ Recovery Systems has provided or has identified as compatible with the Transporter. For best results, become familiar with the accessories and supplies, and how they interact with the Transporter, the kidney, and the clinical process. The main Transporter accessories and supplies are described in the following paragraphs.

5.2 BATTERIES

The Transporter uses four specially designed lithium ion rechargeable batteries as its portable source of power. **DO NOT SUBSTITUTE BATTERIES: USE ONLY ORGAN RECOVERY SYSTEMS LIFEPORT™ BATTERIES.** It is possible to operate with any number from one to four batteries, since each delivers the 11 to 12 volts that the Transporter requires; however, it is always best to use all four batteries, which you should keep as fully charged as use permits. You can check the state of each battery's charge by pressing the battery's ON button and observing the display located on each battery.

The status of the batteries in the Transporter can also be checked by scrolling the message display.

Access the batteries through the battery door on the Transporter rear panel. Each battery can be slid in and out of a slot. When inserted in the proper orientation, the battery should be flush with the slot panel, with the fabric pull available to the user. If the battery does not push flush, it may be in the wrong orientation. Turn the battery 180 degrees and try again. Always replace the battery door. The Transporter should not be operated or shipped without the battery door in place.

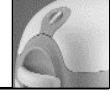
The Transporter's built-in charger will replenish the batteries whenever the Transporter is plugged into an electrical outlet. It's a good habit to plug into an electrical outlet whenever the Transporter is not in transit so that the batteries can stay at the highest possible charge. Normally, it will take five hours to completely recharge all four batteries. Spare charged batteries should be kept handy to accommodate long transportations or successive Transporter uses.

During storage of the Transporter without a mains power connection, the batteries will slowly drain. After 30 days the batteries will have no charge and will need a full 5 hour recharge. For periods of storage for longer than 30 days, remove the batteries from the device. Long periods of storage may damage the batteries.

Lithium Batteries must be disposed of according to local regulations. If in doubt, consult Organ Recovery Systems at (847)824-2600.

5.3 BATTERY CHARGER (optional)

An optional battery charger, which can be used to maintain a supply of spare charged batteries, is available from Organ Recovery Systems. Plug the battery charger into a mains outlet to energize it, and insert the batteries into their respective slots to initiate charging. A charge state indicator will display when the batteries are fully charged.



5.4 POWER CORD

The Transporter comes equipped with a power cord (hospital grade-US), which can be connected to the Transporter back panel and to a standard grounded power outlet of commercial or hospital quality.

5.5 EXTERNAL COMMUNICATIONS (optional)

The Data Cable provided can be used with a personal computer or printer to capture data being generated by the Transporter. Data from previous procedures can also be downloaded from stored files. The Transporter is designed to transmit but no perfusion commands can be received. The Data Cable plugs into the Data Port, a serial interface connector on the external connections panel found in the back of the unit. Whenever the Transporter is in Infuse mode, its internal computer is capturing perfusion and status data once every 10 seconds.

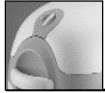
Data recording begins when the Transporter enters the Infuse Mode for the first time once powered up. Data recording continues until the Transporter is powered down. To start a new data file, cycle the power (power off then power on). The Transporter stores data from five perfusion cases. Be sure to download the data after each case. The data files will need to be erased prior to beginning a new case if all five files are full.

Each of the Transporter's five data files can hold up to 48 hours of perfusion data. If a single perfusion case runs longer than 48 hours, a new file can be created only by turning the Transporter off, then on and resuming the perfusion. The stored data includes:

1. sequential record number
2. infuse time
3. pressure set point
4. measured pressure (continuous mode only)
5. measured systolic pressure (pulsatile mode only)
6. average pressure (pulsatile mode only)
7. measured diastolic pressure (pulsatile mode only)
8. flow rate
9. organ resistance
10. Ice Container temperature
11. bubble trap temperature
12. error condition status (presence or absence of each error condition)
13. perfusion system state and sub state
14. Transporter Cover status (open/closed)

Data communication can operate in two modes, PC Query and Download. PC Query mode is configured to work with a smart terminal or a personal computer running a terminal emulation program, such as Windows HyperTerminal. The data is output as a tab-delimited file and can be read into many types of database programs. The examples below are written for a personal computer running HyperTerminal on Windows 95/98/2K/XP.

CAUTION: Accessory equipment connected to the Data Port must be certified IEC950 for data processing equipment. Furthermore all configurations shall comply with the systems standard IEC60601-1-1. 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 IEC60601-1-1. If in doubt, consult Organ Recovery Systems at (847)824-2600.



Chapter 5: SUPPORT ACCESSORIES AND SUPPLIES

Connect the Data Cable to the Transporter and the PC. Press the Power Button to turn on the Transporter. The Power On Self Test will stop at “Connect Sensor, Push STOP” if no Perfusion Circuit is present. A loaded Perfusion Circuit is not necessary for downloading data. Launch HyperTerminal. Often HyperTerminal can be found in the Start Menu under Accessories/Communications/HyperTerminal.

Set the terminal or emulator to communicate over com1 (or whichever communication port registered to the 9-pin serial connector) at 57,600 baud, no parity, 8 data bits, 1 stop bit. Set the terminal emulation mode to vt100. This is found in the Properties window under the File menu.

To capture the data to a file, select “Capture Text...” under the Transfer menu. Enter the file name and location where the data should be saved. Press “Start.”

PC Query MODE COMMANDS

Listing file records: “LS↵.” (↵ represents enter or the carriage return key.)

By typing “LS↵” the Transporter will return a list of the stored files. This list shows the file number along with the time and day the file was created. The creation information is based on the first time the Transporter enters Infuse mode since power up. An example of the data returned from “LS↵” is:

File	Date	Time
1	02/23/03	11:23:49
2	02/25/03	16:45:23
3	Empty	
4	02/14/03	22:34:39
5	02/17/03	20:12:48

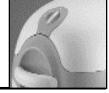
Note that the files might not be listed in chronological order. Be sure to double check the infusion time when determining which file belongs to a particular case. In the example above, there is no data stored in File 3.

Downloading Files: “get #↵”

Type “get 1↵” to download file 1, “get 2↵” for file 2, etc. The data should load onto the screen. Files should be downloaded after each perfusion case. When using HyperTerminal on a PC to save a data file, the capture text command must be used prior to the get command. In HyperTerminal go to the Transfer menu and select “Capture Text...”. Select the file location and name where the data should be stored on the PC and then click “Start.” Now type “get X↵” to download the data stored in File X.

Erasing Files: “del #↵”

Type “del 1↵”, hyperterminal will respond with “delete.....Y for Yes, type “Y↵” to erase file 1, “del 2↵” for file 2, etc. It is best practice to download data to a PC following each case, verify the PC data file, and then erase the Transporter data. This will ensure that no critical data get erased inadvertently. Remember that the data files will need to be erased prior to beginning a new case if all 5 files are full.



Stream real-time data: "stream↵"

The Transporter can download real-time data to the terminal by entering "stream↵". This data stream will continue until the "↵", or enter, is pressed. HyperTerminal on a PC can continuously save this streaming data to a file stored on the PC. The Transporter will continue to save the data in its own file.

Setting the Date: "date xx/xx/xx↵"

Set the current date for the Transporter by typing "date xx/xx/xx↵". The date format is Month/Day/Year. For example, to set March 5th, 2003, enter "date 03/05/03↵".

Setting the time: "time ####↵"

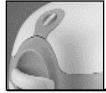
Set the current time for the Transporter by typing "time ####↵". The format is 24-hour military time. For example, to set 10:45PM, enter "time 2245↵".

Setting Property-of information: "id xxxxxxxx↵"

One of the start-up screens may be personalized to reflect user/owner name. After completing Power On Self Test, the Transporter can show a screen that contains the text "Property of xxxxxxxx." To set ownership information, type "id xxxxxxxx↵". Up to 24 characters will be displayed.

DOWNLOAD MODE

The Transporter can also begin to stream data to a terminal without receiving commands. To download the current information, press and hold the Backlight Button on the Front Display for 5 seconds. After a few seconds, the Transporter will begin to stream data to the terminal. New lines of data will appear every 10 seconds. Data continues to be stored in the Transporter's internal files.



Chapter 5: SUPPORT ACCESSORIES AND SUPPLIES

STERILE | **EO**

The LifePort™ Disposable Accessories are supplied pre-sterilized from the factory. Further sterilization should not be attempted.



The LifePort™ Disposable Accessories are disposable and single-use.
Do not re-sterilize. Do not reuse.

Aseptic practice should be followed when opening and using the Organ Cassette and Tubeset, particularly to maintain the cleanliness of the inner surfaces that will contact the kidney and perfusate. Refer to Section 4.3.

The Transporter surfaces should be kept clean. Wipe with a 70% Isopropanol solution to clean. Wipe down all exposed surfaces for a minimum of 15 seconds. Inspect for damage or deterioration of the surfaces. Allow to air dry. Drain, clean, and air-dry the Ice Container between each use.



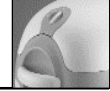
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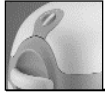


7.1 TROUBLESHOOTING PROCEDURES

Most problems that you encounter in operating the LifePort™ Kidney Transporter will be easily solved. The first thing to check when troubleshooting the system 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 the Transporter still does not work, check the following troubles, probable causes, and actions.

7.2 TROUBLESHOOTING

Trouble	Probable Cause	Action
No power	Dead batteries, batteries not charged, and disconnected from mains power	Replace with fresh batteries or plug into mains. Make sure batteries are fully charged before using.
	No Power at outlet	Make sure outlet has power.
	Tripped circuit breaker	Reset breaker by pressing in the button on the external connections panel located on the back of the unit.. Call service.
Beeping or flashing LEDs	Errors detected internally by the Transporter	Follow the instructions in 7.3, Fault Message Explanation.
Missing or incorrect display elements at power-on	Failure of displays or internal computer	Call service.
Leaking perfusate	Loose fitting or defective Tubeset.	Retighten all fittings. Replace tubeset if defective.
Leaking coolant	Broken container or seal. Lid not tightened	Tighten lid and look for leaks. Call service if leaks cannot be resolved.
Power on, but buttons are unresponsive	Transporter is internally locked-up	Power off then on. Disconnect mains, then remove all batteries and replace them. Power "On". If problem does not resolve, call service.
Message Display is blank. (Unit functioning properly)	Electrical shock reset display.	Power off then on. If display does not return, call service.

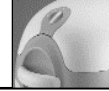


7.3. FAULT MESSAGE EXPLANATION

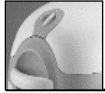
The Transporter has alarms that are sounded when out of range conditions are encountered for bubbles, pressure, flow, and temperature. The Transporter can recover from many of these errors and perfusion will automatically resume. The Transporter should enter a failsafe mode if any unrecoverable fault condition is encountered. Scroll the message display to view all of the fault conditions. The error indicators will remain to alert the user. To clear the indicators for errors which are no longer valid, press the mode button with the blinking LED.

Check the following list of fault messages, possible causes, and recommended actions to determine how to respond if the Transporter alarm sounds. In most cases the audible alarm can be cancelled or temporarily muted by pressing the STOP touch pad.

Fault Message	Probable Cause	Actions
Power up test FAILED	An error occurred during the Power Up Self Test	1. Power Off then On. If problem persists, note the message on the second line and call for service. One exception is the 'Connect Sensor Push STOP' message, see below.
Load Perfusion Circuit	The Tube frame is not properly installed	1. Make sure that the Tube frame is properly installed and the Tube frame Locking Arm is in the correct position. 2. A sensor failure may exist; call service.
Check Ice	The Ice Container Temperature Sensor is reading above 8°C.	1. Replenish ice. 2. Allow up to 15 minutes for the sensor to drop to the proper temperature if the system was warm prior to installing a filled Ice Container. 3. Possible Sensor failure; call service.
Too Cold or Near Freezing	The Ice Container Temperature Sensor is reading below 0.5°C.	1. Incorrect coolant; use ice slush made from regular water. 2. Environmental conditions too cold; move Transporter into a warmer environment. 3. A sensor failure may exist; call service.
Too Much Pressure	Pressure Sensor is seeing higher than expected values.	1. High G forces are being created during transit; cushion or reduce impact. 2. A Pump, Valve or Sensor failure may exist; call service.



Fault Message	Probable Cause	Actions
Can't Reach Pressure	Pump cannot achieve the set arterial pressure.	<ol style="list-style-type: none"> 1. Leaking cannula or artery; visually inspect and correct all leaks under aseptic conditions. 2. Leak in Perfusion Circuit; tighten loose fittings, replace circuit if leaking. 3. Low resistance kidney; no action for maximum flow or reduce the set pressure. 4. Clogged filter; replace circuit or, if available, replace filter.
Check Tubing	System is sensing unexpected conditions in the Perfusion Circuit.	<ol style="list-style-type: none"> 1. Tube frame not positioned properly; check frame and locking arm position. 2. Kidney not connected; visually inspect kidney and cannula, correct all leaks under aseptic conditions. 3. A pressure greater than 120% of the set pressure is persisting; inspect pressure sensor and call service. 4. Fluid pressure is not equalizing during non-infuse modes; check for arterial and venous occlusions, check valves and call service.
High Resistance	System is measuring resistances above 3.00	<ol style="list-style-type: none"> 1. Consult supervising physician.
Occlusion	System is sensing unexpected pressures during Infuse.	<ol style="list-style-type: none"> 1. Blocked Infuse Line tubing or twisted or occluded artery; find and remove blockage or untwist.
Bubbles	System becomes unable to remove air without user intervention.	<ol style="list-style-type: none"> 1. Air is persisting in the upstream bubble detector; check Perfusion Circuit for leaks and loose fittings. 2. Air bubble in the Infuse Line; re-prime the circuit and kidney, under aseptic conditions.
Setpoint Error	Device unable to set pressure alarm levels.	<ol style="list-style-type: none"> 1. Press 'Stop' to clear alarm and enter 'Stop' mode. Re-enter Infuse. If alarm persists, call service.
Check Filter	Filter may be clogged.	<ol style="list-style-type: none"> 1. Filter is restricting flow; replace Circuit or, if available, replace Filter. 2. Pump error; call service.



Chapter 7: TROUBLESHOOTING

Fault Message	Probable Cause	Actions
Low Battery	Only 4 hours of battery life remaining: 2 hours of infusion plus 2 hours of temperature monitoring.	1. Low battery power remaining; plug into mains power or exchange for replenished batteries.
Sensor Error Connect Sensor Push STOP	System becomes unable to interact with pressure sensor properly.	1. The pressure sensor has become disconnected; reconnect pressure sensor. 2. The Transporter is unable to set the overpressure alarm setpoint; call service.
Pump Error	Pump is not responding normally.	1. Pump failure; call service.
???? in battery status	Computer has lost communication with batteries.	1. Operate Transporter with Mains power; call service.

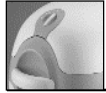
Chapter 8: STORAGE & SHIPMENT

STORAGE

Clean the Transporter according to Chapter 6 before storing. The Transporter should be stored indoors in a dry location out of direct sunlight. For periods of storage for longer than 30 days, remove the batteries from the device. Long periods of storage could damage the batteries. The Transporter should be stored in a temperature controlled space. The device will operate normally after storage between -15°C to 50°C, 0 to 90% humidity, and at a pressure of 700 to 1060 hecto-Pascal (hPa) (equivalent to an elevation of -380m to 3,000m or -1,250ft to 10,000ft).

SHIPMENT

The Transporter is designed to withstand shipment by common carrier. To ship the Transporter, be sure to use the corrugated carton, with foam inserts, provided by Organ Recovery Systems. With an empty Ice Container, the lid should be removed for shipment.



Appendix A: LABEL GRAPHIC EXPLANATION



Reference Model Number



Serial Number



Lot Number



Sterile, method is ethylene oxide



Single Use Only



Attention! Consult Accompanying Documents.



Manufacture Date, Year/Month



To assure grounding reliability, equipment should be connected to a power system of commercial or hospital quality.



Caution: Electric shock hazard if pump deck is removed.
Refer servicing to qualified service personnel.



Data Port, RS232 Serial Data



Circuit breaker, Push to reset.



Battery Slot Graphic showing slot numbering and insertion orientation.
Replace batteries only with manufacturer's battery model L-BAT.



Storage Condition: Humidity



Storage Condition: Temperature



Storage Condition: Pressure

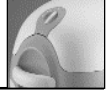


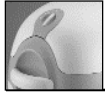
European Conformity Mark (CE Mark)



EU Authorized Representative

Appendix A: LABEL GRAPHIC EXPLANATION





Appendix B: EMC INFORMATION AND TABLES

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

This device 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. If the Transporter does cause interference, which can be determined by turning the 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 the Transporter and the receiver
- ▶ Connect the Transporter to an outlet on a separate circuit from that to which the receiver is connected

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

WARNING: To assure compliance with EMC requirements, use only manufacturer supplied cables:

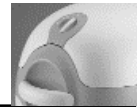
Data Cable Part # 20680
 Power Cable Part # 17664
 (US only, contact manufacturer for international power cable part numbers)

WARNING: Use of power cords or communications cables, other than those specified, may result in increased emissions or decreased immunity of the LifePort™ Kidney Transporter.

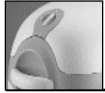
WARNING: The LifePort™ Kidney Transporter should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Transporter should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emissions		
The LifePort™ Kidney Transporter is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePort™ Kidney Transporter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The 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. The LifePort™ Kidney Transporter 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.
RF emissions CISPR11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	


Appendix B: EMC INFORMATION AND TABLES



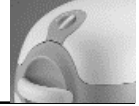
Guidance and manufacturer's declaration - electromagnetic immunity			
The LifePort™ Kidney Transporter is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePort™ Kidney Transporter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LifePort™ Kidney Transporter requires continued operation during power mains interruptions, the LifePort™ Kidney Transporter can be powered from the internal battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the ac. mains voltage prior to application of the test level.			



Appendix B: EMC INFORMATION AND TABLES

Guidance and manufacturer's declaration - electromagnetic immunity			
The LifePort™ Kidney Transporter is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the LifePort™ Kidney Transporter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{3} \right] \sqrt{P}$ $d = \left[\frac{3,5}{10} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{10} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
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. ⁰			
<p>^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 the LifePort™ Kidney Transporter is used exceeds the applicable RF compliance level above, the 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 the LifePort™ Kidney Transporter.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Appendix B: EMC INFORMATION AND TABLES



Recommended separation distances between portable and mobile RF communications equipment and the LifePort™ Kidney Transporter			
<p>The LifePort™ Kidney Transporter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifePort™ Kidney Transporter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifePort™ Kidney Transporter as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power or transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	808 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{3} \right] \sqrt{P}$	$d = \left[\frac{3,5}{10} \right] \sqrt{P}$	$d = \left[\frac{7}{10} \right] \sqrt{P}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,17	0,35	0,70
10	3,69	1,11	2,21
100	11,67	3,50	7,00
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			