Instructions for Use

Kidney Assist Transport

XVIVO

Figure 1: Kidney Assist Transport

XVIVO

Content

The instructions in this document describes the intended use for users in the United States of America. XVIVO is not responsible for any damage caused by not operating the device according to these instructions or outside of the described environment. Read these instructions and the instructions of the disposable Kidney Assist Transport Perfusion Set thoroughly before use.

1 Product description

The Kidney Assist Transport from XVIVO B.V. (referred as "XVIVO") enables isolated and oxygenated donor kidney perfusion during transport from donor to recipient in transplantation procedures.

The system consists of the reusable device Kidney Assist Transport and a disposable Kidney Assist Transport Perfusion Set.

The Kidney Assist Transport is only to be used in combination with the Kidney Assist Transport Perfusion Set, article number 23.401.

The following accessories are included with the Kidney Assist Transport:

- Ice reservoirs (2x)
- Batteries (4x)
- Battery charger
- Power supply
- Sample bottles (2x)
- Oxygen drain insert
- Oxygen flow regulator

Additional items required, but not included by XVIVO are:

- Perfusion solution
- Oxygen cylinder (ML6 or M4 types are supported) **

** *XVIVO advices to use a medical oxygen cylinder that contains sufficient capacity of; at least 144L or 5.1ft³ at atmospheric pressure, e.g. the ML6 cylinder type, to sustain the application period of 24 hours without replacing the cylinder. In case a smaller capacity cylinder is used, like the M4 cylinder type, ensure to timely replace the oxygen cylinder. The Kidney Assist Transport utilizes standard and globally available medical oxygen cylinders with PIN-index to connect the oxygen flow regulator. Dimensions of the cylinder shall not exceed 110mm or 4,3" in diameter and a length of 282mm or 11" including valve*

Intended use

Indications for use

The Kidney Assist Transport is intended to be used for the pulsatile hypothermic oxygenated machine perfusion of kidneys for the preservation, transport and eventual transplantation into a recipient.

1.1 **Application period**

The Kidney Assist Transport is a portable pump system that continuously allows hypothermic pulsatile perfusion of donor kidneys with oxygenated preservation solution during transport from donor to recipient in transplantation procedures for a period up to 24 hours.

Intended user profile

The Kidney Assist Transport is intended to be used in a clinical or non-clinical environment and operated by trained and licensed personnel who are expected to be up to date with state-of-the-art knowledge on machine perfusion and solutions and are familiar with handling of medical/surgical equipment and a-septic procedures. Safe use of the Kidney Assist Transport can only be guaranteed when the user has read the instructions for use and successfully followed a training course provided by XVIVO. The Kidney Assist Transport training will be provided by a product specialist of XVIVO. During the training, the user will learn how to install and operate the Kidney Assist Transport and what to do if errors occur.

Contra-indications

Not known

Clinical benefits

The Kidney Assist Transport enables successful transplantation of deceased donor kidneys

Principles of operation, mode of action

Mechanical perfusion can remove the fluid from the organs and make them suitable for transplantation. In some donors, who have died after cardiac arrest, damage may also occur due to absence of blood circulation during a certain period. In the case of kidneys, this could lead to the recipient being put back on dialysis for a while after the transplant. According to Moers 2009, Machine-perfused kidneys had a lower risk of graft failure in the first year after transplantation. In summary, some studies suggest [1] that mechanical perfusion enhances the preservation and quality of deceased donor organs. However other randomized studies have observed no significant difference between machine perfusion and cold storage [2].

After procurement of the donor kidney, the renal artery is connected to a cannula and a cold preservation solution (perfusate) is pumped through the kidney while adding oxygen to the perfusate. The Kidney Assist Transport uses a small oxygen cylinder whereby the oxygen flow is set at 0.1 L/min. The Kidney Assist Transport pumps the perfusate through the kidney vasculature in a pulsatile way (60 bpm). The Kidney Assist Transport pump speed is pressure controlled. The mean pressure can be set by the user, in the range of 0 to 50 mmHg.. Perfusate and kidney are cooled to hypothermic conditions using crushed ice outside the sterile reservoir in the dedicated ice reservoirs. The Kidney Assist Transport continuously registers renal resistance and flow and temperature measurements. All kidneys must be perfused with a certified machine perfusion solution, for example: Belzer UW Machine Perfusion Solution.

1.2

Kidney Assist Transport

The Kidney Assist Transport is a thermo isolated enclosure wherein the kidney is cooled passively by ice. A separate compartment holds the electronics, batteries and a dedicated medical oxygen cylinder. The device has sufficient battery power, holds enough oxygen and ice for an application period of 24 hours of hypothermic oxygenated perfusion. When used stationary, an external power supply can be connected for continuous power. Pressure controlled pulsatile perfusion is generated by a rotary pump driven by an electromotor.

User-friendly firmware allows the user to change perfusion parameters by the touch buttons incorporated in the control panel. Settings and parameters of the perfusion are numerically displayed on the control panel on the top of the enclosure.

1) *Moers., et. al. Machine Perfusion or Cold Storage in Deceased-Donor Kidney Transplantation. New Engl. J. of Med, 2009*
2) *Watson CJ, Wells AC, Roberts RJ, et al. Cold machine perfusion versus static cold storage of kidneys donated after cardiac death: a UK multicenter randomized controlled trial. Am J Transplant. 2010;10:1991–1999*

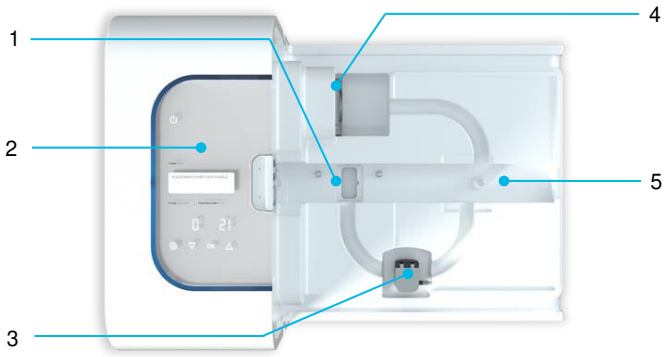


Figure 2: Top view of the Kidney Assist Transport Device without perfusion set, oxygenator drain insert, and ice reservoirs

1. Oxygenator drain insert location
2. Control panel
3. Flow sensor
4. Magnetic pump coupling
5. Temperature sensor

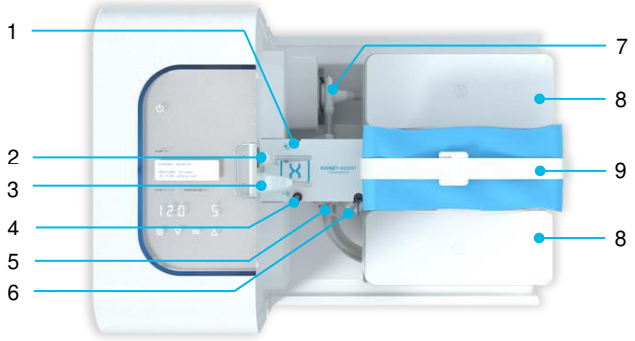


Figure 3: Top view of the Kidney Assist Transport Device, showing perfusion set and ice reservoirs

1. Filling line
2. Oxygen connector
3. Pressure sensor connector
4. Sampling port
5. De-airing valve
6. Pressure sensor with vented cap
7. Pump head
8. Ice reservoir with lid
9. Sterile drape

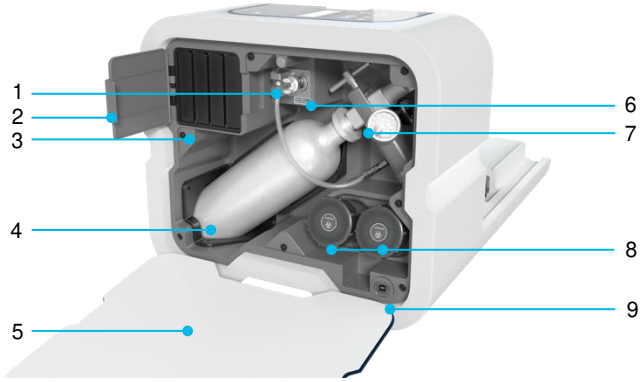


Figure 4: Inside view of the Kidney Assist Transport compartment

1. Oxygen flow indicator
2. Battery compartment door
3. Batteries (4x)
4. Oxygen cylinder
5. Compartment door
6. Oxygen connection with safety valve
7. Oxygen regulator
8. Sample storage
9. USB port

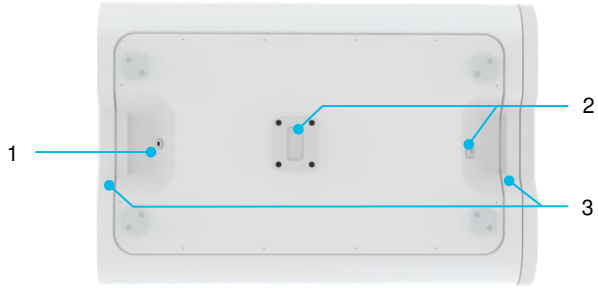


Figure 5: Bottom view of the Kidney Assist Transport Device

1. Connector external power supply
2. Oxygen vents
3. Carrying handles

1.2.1 Control panel

The control panel on the top of the Kidney Assist Transport displays the perfusion parameters (flow, temperature and vascular resistance) as well as messages and warnings. The parameter vascular resistance (VR) is continuously calculated by dividing the mean pressure in mmHg by the flow in ml/min. Alarms will be displayed on the main display, combined with colored LED's on the front of the unit.

Adjustments of pressure setting and interaction with the menu and messages are performed through the touch buttons incorporated in the control panel. The control panel is protected against accidental activation, the controls will be locked when the panel is not used for 3 minutes. To unlock; press and hold the OK button for 3 seconds.

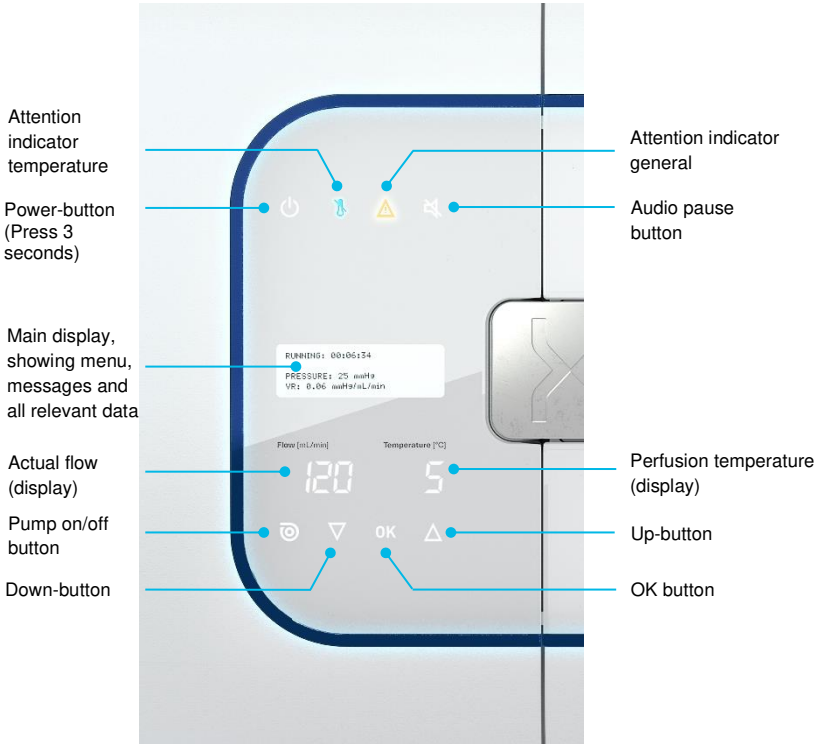


Figure 6: Control panel, displays and buttons

Kidney Assist Transport Perfusion Set

1.3

The disposable Kidney Assist Transport Perfusion Set is for single use and for use in combination with the Kidney Assist Transport only. Read the instructions of the disposable set thoroughly before use. The purpose of the Kidney Assist Transport Perfusion Set is to perfuse human organs to be transplanted with an approved pump perfusion solution. Pulsatile perfusion is maintained by the centrifugal pump head, pulsating the perfusion solution from the reservoir through the oxygenator to the kidney in the kidney holder in the reservoir. Oxygenation is performed by the hollow fiber membrane oxygenator which facilitates the gas exchange with the perfusion solution.

The Kidney Assist Transport Perfusion Set contains a perfusion circuit, consisting of a: reservoir, oxygenator, pump head, pressure sensor, filling line, oxygen line, sample port, sterile drape and compatible tubing preassembled in a cartridge for ease of use. Kidney holder, lids, cannulas and syringes are included separately in the tray.

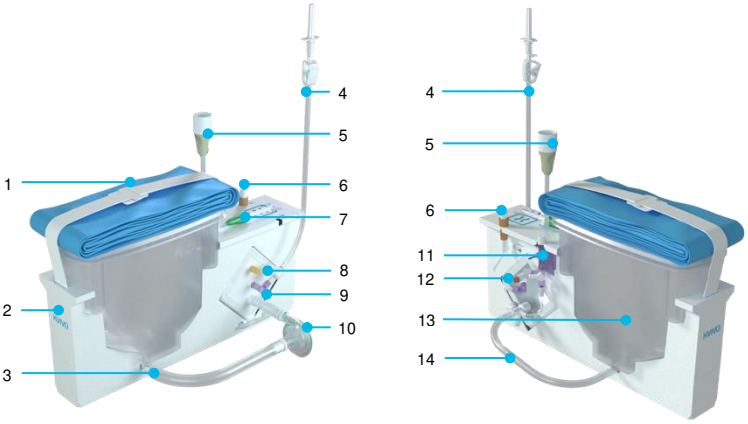


Figure 7: Kidney Assist Transport Perfusion Set cartridge

1. Sterile drape
2. Perfusion circuit cartridge
3. Reservoir outflow
4. Filling line
5. Pressure sensor connector
6. Sampling port
7. Oxygen line
8. Yellow cap de-airing filter
9. Oxygenator
10. Pump head
11. Pressure sensor with vented cap
12. De-airing/sample valve
13. Reservoir
14. Reservoir inflow

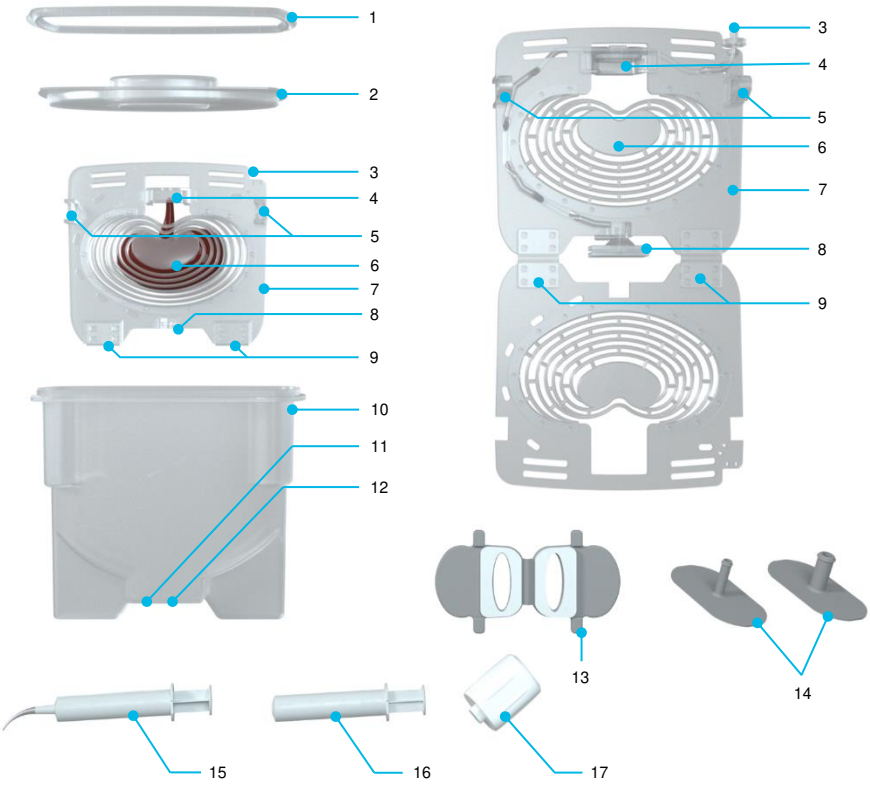


Figure 8: Kidney holder and separate components

1. Outer lid
2. Inner lid
3. De-airing valve
4. Adjustable cassette with patch holder
5. Locking clamps
6. Flexible kidney net
7. Kidney holder
8. Perfusion cup
9. Hinge
10. Reservoir
11. Perfusate outlet
12. Perfusate inlet
13. Patch holder (small and large size available)
14. Straight canula with artificial patch small (3mm) and large (5mm)
15. Monoject 412 Syringe
16. 10 mL Luer Lock syringe (2 pieces)
17. Non-vented cap for the pressure sensor

2 Operating instructions

Installation

The Kidney Assist Transport is shipped in protective packaging. The device must be unpacked, checked and commissioned by XVIVO authorized personnel.

2.1 Preparation

- Place the device on a hard, horizontal and stable surface.
- 2.2 Prior to use, clean and disinfect the Kidney Assist Transport according to the instructions in section 3.
- Open the compartment door (figure 4, item 5), by gently pressing on the top, to gain access to the oxygen and battery compartment.
- Ensure that the oxygenator drain insert, which is removed during cleaning, is placed back in the device before use (figure 2, item 1).

Figure 9: Oxygenator drain insert, which can be manually removed (left) and placed back (right) into the device

- Open the door of the battery compartment (figure 4, item 2). Place four fully charged batteries (figure 4, item 3). Only use compatible batteries supplied by XVIVO. Check the charge of each battery by pushing the “push” symbol on the battery. Every LED represents 25% capacity.
- Connect the oxygen regulator (figure 4, item 7) to a fully filled oxygen cylinder (figure 4, item 4) by tightening the thread of the regulator by hand. Make sure that the seal of the cylinder has been removed. In addition, check that the valve is clean and has no sign of oil or lubricant. If needed wipe the cylinder clean.

- On the oxygen regulator set the flow to 0.1 L/min.
- The oxygen valve on top of the cylinder can now be opened slowly. Ensure that the pressure increases progressively in the pressure gauge until the valve is fully opened and the pressure has stabilized. In case oxygen escapes immediately close the valve and check the joint in the connection of the cylinder. The safety valve in the connector prohibits oxygen flow until the perfusion set is connected.
- Securely strap the oxygen cylinder in its holder inside the compartment and close the compartment door.
- In case of stationary use;
  - Connect the external power cord to the device by slightly lifting the device and plugging in the power plug into the connector at the bottom of the device (figure 5, item 1). NOTE: The device shall not charge the batteries when connected to the mains, batteries must be charged in the separate charger.
  - Medical oxygen can be delivered from the hospital supply, connect an oxygen line to the oxygen connection (figure 4, item 1). Ensure the oxygen flow is set at 0.1 L/min and does not exceed the ratings on the label next to the connector, see figure 11.

2.3 Placement of perfusion set and priming

- Carefully open the Kidney Assist Transport Perfusion Set box and remove the tray out of the packaging.
- Visually inspect the tray and Tyvek cover (sterile barrier) for damage and check the expiry date on the label. If the packaging or product seems damaged, do not use it. After opening, the sterility of the product depends on the techniques of the user.

Before starting the procedure, check the pump, sensors, cables and connections. Do not use a damaged device.

Check the expiry date on the packaging of the perfusion set, do not use after the expiry date.

The Kidney Assist Transport Perfusion Set is sterile in an unopened and undamaged packaging.
Carefully check the product and packaging. Do not use if the packaging or Kidney Assist Transport Perfusion Set is significantly damaged, or even if there is the slightest doubt regarding the sterility of the product.

- Remove the Tyvek cover from the tray and take the cartridge (figure 7) out of the tray. Check if the product is intact and whether all connections are secure; retighten where necessary.

- Remove the metal clip, marked with a red 'remove before use' label, from the pump head. Place the cartridge in its position in the Kidney Assist Transport. Pay attention to the position of the pump head, oxygenator and reservoir. Push down on the reservoir to make sure it is resting on the temperature sensor (figure 2, item 5)

- Connect the pump head (figure 7, item 10) to the magnetic pump coupling (figure 2, item 4), press it down firmly to ensure it is placed correctly.

- Connect the pressure sensor (figure 7, item 5) to the connector panel (figure 10).

- Connect the green oxygen tubing (figure 7, item 7) to the oxygen connector (figure 10). When the oxygen connection is established, the safety valve in the connector is open and oxygen can flow. Presence of oxygen flow can be checked on the flow indicator in the oxygen cylinder compartment (figure 11). A floating ball is visible when there is oxygen flow present.

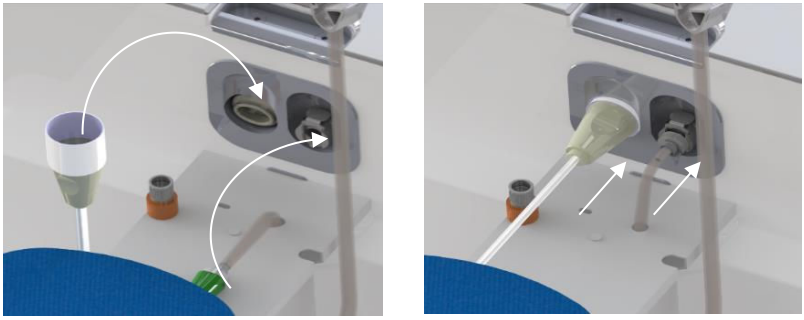


Figure 10: Connection of pressure and oxygen connectors

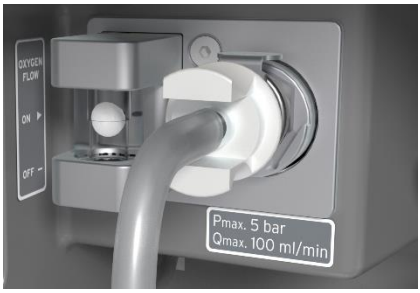


Figure 11: Flow indicator (left) and oxygen connection with safety valve (right)

- Open the flow sensor by pushing the aluminum clip to release the lid. Insert the Reservoir inflow tubing (figure 7, item 14) and push the lid to close the sensor (figure 12).

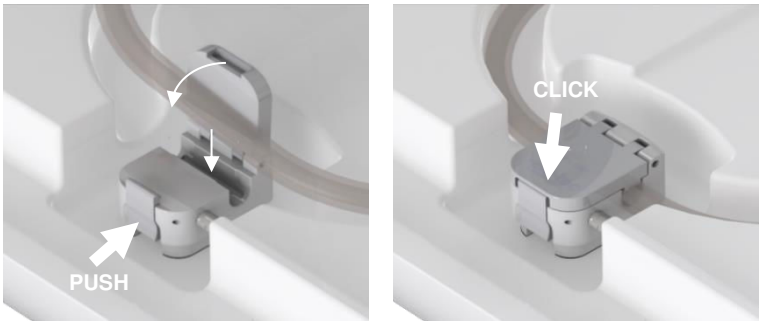


Figure 12: Connection of flow sensor

The Kidney Assist Transport should not be used in contact with flammable agents, gases or liquids and not to be used in an oxygen rich environment.

- Unroll the filling line (figure 7, item 4) and open the tubing clamp on the filling line. Attach the spike to a bag/bottle with certified machine perfusion solution.
- Fill the system with 1 liter cold (below 10°C) machine perfusion solution using the filling line.
- Close the tubing clamp and place the filling line back into the intended holder.

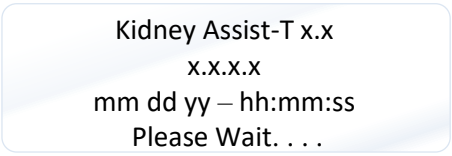
Only use certified machine perfusion solution for the Kidney Assist Transport. Check the labelling of the perfusion solution and make sure that it is intended for machine perfusion. If you are uncertain about which solutions are appropriate, contact XVIVO for information on recommended perfusates that work best with the Kidney Assist Transport. Using other solutions than machine perfusion solution with the Kidney Assist Transport may result in organ damage or the cause of complications.

The control panel is protected against accidental activation. Controls will be locked when the panel is not used for 3 minutes. To unlock; press and hold the OK button for 3 seconds.
In case of alarms and errors, the controls automatically unlocked.

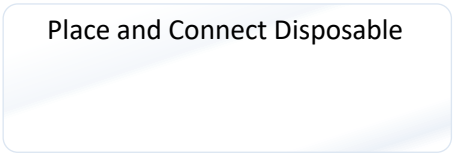
The power button is protected against accidental activation. To switch the Kidney Assist Transport ON or OFF, press and hold the POWER button for 3 seconds.

- Power on the Kidney Assist Transport by pressing the power button on the control panel continuously for 3 seconds. A sequence of instructions on the display will guide you through set-up. Additional messages will pop-up when actions are required, see chapter 8 Alarms and troubleshooting.
  NOTE: When advancing to far in the set-up menu, for example by pressing the OK button to many times, restart the device and return to the appropiate set-up step.

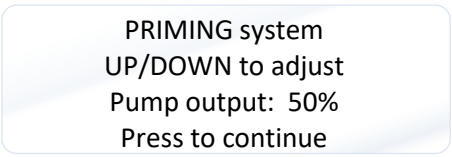
- To display the software configuration, press the OK button during the self-test. This will show the following info display:



- Check if the disposable is placed correctly and press the OK button to activate the priming procedure.



- In priming mode, de-air all tubing, pump head, oxygenator and pressure sensor. Press the up- and down buttons to variate flow. Variation of pump speed will help to remove air.



- After de-airing, the vented cap of the pressure sensor can be replaced by a non-vented cap (figure 8, item 17).

- Remove the yellow cap of the de-airing membrane of the oxygenator (figure 7, item 8). Please keep the yellow cap, it needs to be placed back after de-airing.

- De-air the pump head. In case there is air in the pump head, stop the pump manually by pushing the pump on/off button. Allow the air to move to the upper side of the pump head. Then restart the pump and increase pump output to evacuate air towards the oxygenator.

- De-air the oxygenator via the sample port by using a syringe. First remove the cap on the sample port. Turn the red de-air valve, see figure 13, on the oxygenator down (pre arterial filter) and aspirate until air is removed. Switch the red valve up (post arterial filter) and aspirate again until all air is removed. Switch valve to closed position (middle position) and place the cap on the sample valve.

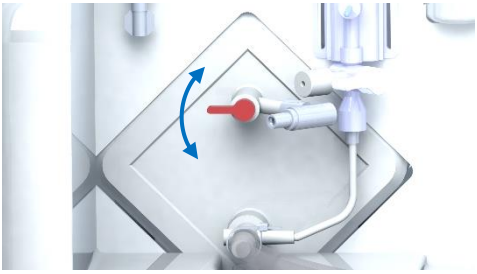


Figure 13: Air valve on oxygenator

- Prime the pressure sensor by pulling the blue snap tab until a few drops of perfusate drip out. (figure 14).

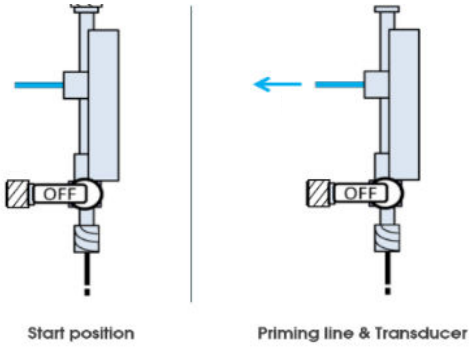


Figure 14: Priming pressure sensor.

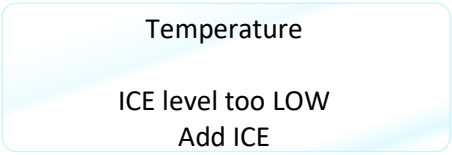
- Open the flow sensor to check the tubing underneath for air bubbles. If necessary, squeeze the tube to remove the air bubbles.

- Place the yellow cap on the de-airing membrane on the oxygenator (figure 7, item 8).

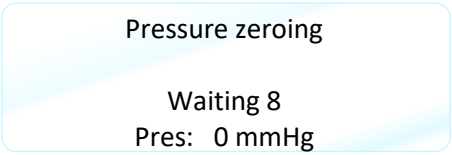
- When the perfusion circuit is completely free of air press the OK button to proceed to the next step.

- Fill the ice reservoirs (figure 3, item 8) completely with crushed ice. Close the lids of both ice reservoirs and place them against the perfusion reservoir. Place the Kidney Assist Transport cover over the perfusion compartment to keep the interior cool, see section 2.5.

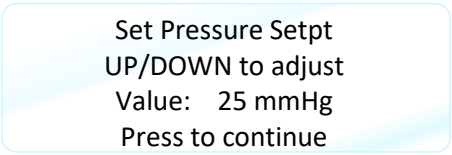
- When the system is sufficiently cooled (10°C), the system will automatically proceed to the next step. Typically, it takes about 30 minutes before the complete device is cooled down enough. This time varies, for example depending on the temperature of the perfusion solution applied.



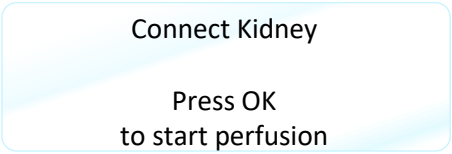
- The system will automatically calibrate the pressure measurement. The pump stops while pressure is being zeroed. After zeroing the system will automatically proceed to the next step.



- Set the preferred perfusion pressure. The recommended pressure setting of 25 mmHg is default. Press the OK button to confirm and to proceed to the final step.



- Wait with pressing the OK button until the kidney is connected to prevent the device from starting the perfusion.



Connecting kidney

The following steps need to be performed a-septically. The kidney and Kidney Assist Transport materials in these steps need to remain sterile.

2.4 The kidney holder is designed to fit all sizes of kidneys, see section 9 for the maximum organ capacity. Care should be taken to make sure the kidney fits properly on the flexible net in the holder without constrictions that could lead to perfusion problems or tissue damage.

- Place the donor kidney on a flat and sterile surface.
- Remove the sterile packaging of the separately delivered kidney holder (figure 8, item 7). The kidney holder is already in the opened position.
- Push the aortic patch of the renal artery gently through the opening of the patch holder as shown in the illustration below. Make sure not to force the patch! Position the aortic or artificial patch correctly in between the soft materials of the patch holder. Make sure the renal artery is not twisted or collapsed, then fold the patch holder to close it (figure 15).
- In case no aortic patch is present, use the straight cannula with artificial patch (figure 16), available in 3 or 5 mm diameter. Secure the cannula in the renal artery with a firm ligature. Guide the artificial patch through the opening of the patch holder and close the holder by bringing both sides towards each other as in figure 15.

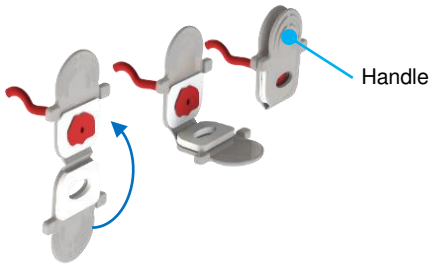


Figure 15: Connecting the aortic patch to the patch holder.

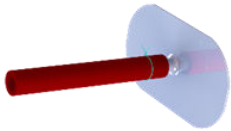


Figure 16: Straight canula with artificial patch.

- Hold the patch holder by the ribbed handle (figure 15) and pinch lightly when handling the canulated kidney.
- Place the kidney on the flexible net of the kidney holder (figure 8, item 6).
- Push the patch holder with renal artery in the cassette of the kidney holder (figure 8, item 4). Move the cassette to set the correct length for the renal artery,

see figure 17. Make sure the artery is not kinked or twisted which would result into a bad perfusion.

- Guide the ureter around the kidney within the kidney holder (figure 17) and make sure it is not kinked or twisted.

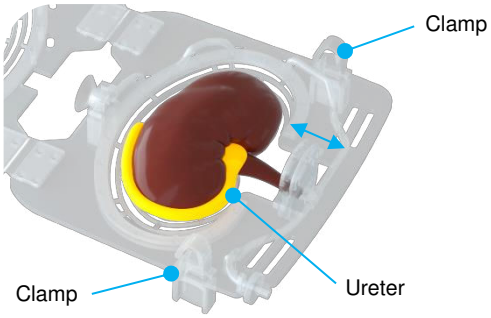


Figure 17: Placing ureter and adjust patch holder position.

- Close the kidney holder by moving both sides towards each other. Make sure the ureter is not wedged in between and the holder is locked by the clamps (figure 17).
- Prime the kidney by injecting some preservation solution with a sterile syringe through the perfusion cup. Always take care of gently injection of fluid. A too high pressure can damage the internal tissue of the artery. Potential leakage of the kidney connection can be discovered by priming also.

Make sure the renal artery is not twisted during manipulation. Twisting of the artery could result in bad or no perfusion of the kidney.

2.5 Perfusion procedure

The kidney is now ready for perfusion and can be connected to the Kidney Assist Transport.

- Create a sterile field by a-septically unfolding the drape (figure 7, item 1) located at the top of the reservoir.
- A-septically open the kidney reservoir and place the kidney holder with primed kidney into the reservoir (figure 8). Push the kidney holder in the reservoir until the perfusion solution reaches the de-airing valve (figure 8, item 3).

- Close the reservoir with the two separately packed sterile lids. First place the inner lid and then the outer lid (figure 8, items 2 and 1). Fold the lock around the edge of the reservoir to lock the outer lid at the reservoir (figure 18).

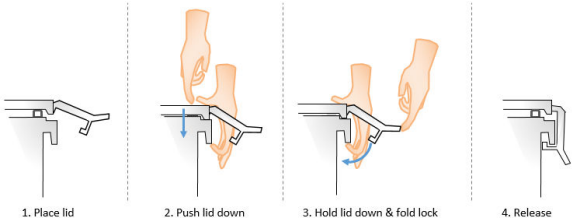
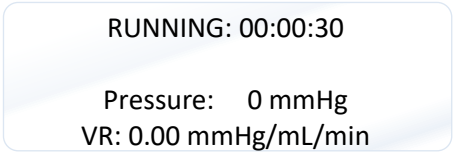


Figure 18: Closing the outer lid.

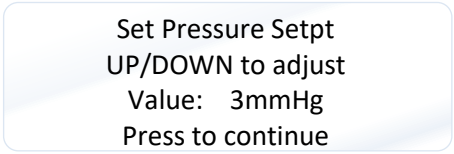
- Press the OK button on the device to start perfusion.
- Remove the sterile drape around the reservoir.
- Slide the cover on the pump unit, press both parts firmly together and make sure the lock of the cover is closed completely (until the click), it should be flush with the housing (figure 19).

Figure 19: Closing the cover

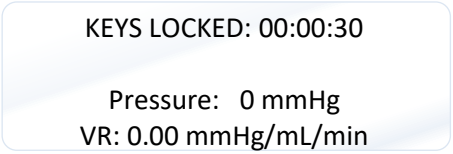
- During perfusion, the measured values of flow, temperature and pressure will appear on the display. The vascular resistance (VR) is displayed as well, as calculated by mean pressure (mmHg)/ flow (ml/min).



- During perfusion, the pressure set point can be changed by pressing the OK button. Use the UP and DOWN buttons until the preferred value appears on the display and confirm by pushing the OK button.



- When the controls are locked to avoid accidental change of parameters, press the OK button continuously for 3 seconds to unlock.



- Regularly check whether perfusion is being performed as expected and the Kidney Assist Transport has not generated alarms.

In case of emergency, stop the pump by pressing the pump on/off button (in case control panel is locked, keep pressing for 3 seconds). For safety purposes, also close the oxygen supply by reconnecting the oxygen safety valve to the oxygen connector and /or closing the oxygen regulator.

The Kidney Assist Transport has software protection that prohibits too high pressures for the organ. If the pressure runs up to 70 mmHg, the software safety measures shall turn off the pump.

Sampling

Sampling of the perfusion fluid is performed from the oxygenator via the sample port (figure 7, item 6) by using a syringe. Turn the sample valve (figure 7, item 12, and figure 13) on the oxygenator down to take a sample from the pre arterial filter. Turn the valve up to take a sample from the post arterial filter. Switch the valve to the closed position (middle position) after sampling. To avoid accidental leakage, the perfusion set is equipped with an automatic closing sample port.

2.6 To take a sample of the perfusion solution, follow the steps below, be aware to maintain the sterility!

- Remove the cap of the sample port
- Connect a sterile (Luer) syringe to the sample port
- Open the 3-way valve on the oxygenator
- Take a sample by aspirating the perfusion solution
- Close the 3-way valve of the oxygenator
- Disconnect the syringe
- Reconnect the cap on the sample port
- After sampling, check if the valve is in the closed position

2.7 Transport

Before transporting the Kidney Assist Transport, make sure the lock of the cover is closed completely, see figure 19. The device can be carried by two persons, dedicated carrying handles are incorporated in the bottom for ease of carrying (figure 5, item 3). When carried by two persons, make sure one person stabilizes the device in a horizontal position to avoid spillage.

- Insert organ identification information/documents in the compartment door, see figure 4, item 16, which has a transparent document holder that is visible from the outside and always remains with the kidney.

- Place the device on a hard, horizontal and stable surface during transport, for example the trunk of a car. Avoid blocking of the oxygen vents (figure 5, item 2) at the bottom of the Kidney Assist Transport.

- During transport, the control buttons are locked to prevent unwanted access to settings. To activate the settings menu and allow for adjustments, the OK button needs to be pushed consecutively for 3 seconds.

Make sure to transport the Kidney Assist Transport in a ventilated environment. Transport of oxygen increases the risk of fire and/or explosions.

Stopping the operation

2.8

- Switch off the pump unit by pressing the pump on/off button.
- Switch off the Kidney Assist Transport by pressing the power button.
- Remove the ice reservoirs.
- Open the reservoir, with due consideration of the sterile contents, by removing both lids.
- Take the kidney holder out of the reservoir.
- Open the kidney holder and remove the kidney.
- Stop the oxygen supply by closing the valve on the flow regulator
- Remove the used Kidney Assist Transport Perfusion Set.
- Discard the used Kidney Assist Transport Perfusion Set as medical grade waste, following local regulations.
- Place the batteries on the supplied charger to recharge for next use. Connecting to the mains by the external power supply shall not charge the batteries.
- Remove the oxygen cylinder from the machine and disconnect the flow regulator. The flow regulator should be cleaned and reused. Contact your oxygen supplier to refill the cylinder.
- Directly after use, clean the Kidney Assist Transport according to the instructions in section 3.

DO NOT RE-USE Kidney Assist Transport Perfusion Set.

The Kidney Assist Transport Perfusion Set is intended for single-use only. After use, it should be disposed of in accordance with local guidelines for biomedical waste material. Accessories from the Kidney Assist Transport Perfusion Set that are not used during the procedure should be discarded also, do not store them separately.

Powering off the Kidney Assist Transport will reset all configuration parameters back to the manufacturer's pre-set settings.

3 Cleaning and disinfection

The Kidney Assist Transport can be subject to contamination by accidental spillage of the perfusion fluid and from contact with soiled hands of the operator, the contamination may not be visible. Thorough cleaning, then low-level disinfection with the prescribed cleaning and disinfection product, after every use and prior its first and subsequent uses, is required.
Local regulations or guidelines shall be followed for infection control.

Required materials:

- Cleaning product: mild, non-aggressive cleaning detergent.
- Disinfection product: standard 70% alcohol solution or low-level disinfectant product (utilizing quaternary ammonium compounds as the active ingredient).
- Lint free cloth.

Cleaning instructions:

1. Place the Kidney Assist Transport on a hard, horizontal and stable surface in a clean environment complying to the operation conditions.
2. Open the compartment door (figure 4, item 15) to the oxygen and battery compartment by gently pressing on the top of the compartment door. Remove power supply, batteries, oxygen cylinder and sample holders and close the compartment.
3. Remove the cover, the ice reservoirs and the oxygen drain insert from the Kidney Assist Transport.
4. Remove ice and water from the ice reservoirs and dry with a lint free cloth.
5. Wear gloves during cleaning and disinfection process. First clean the surfaces of the Kidney Assist Transport including the cover, ice reservoirs and oxygen drain with the prescribed cleaning product, make sure all surfaces are moistened with the prescribed cleaning product. Remove all contamination from all surfaces, corners and crevices. Do not use any abrasives as this will damage the surface of the device
6. Disinfect all surfaces with an unused lint free cloth with the prescribed disinfection product making sure all surfaces are moistened.
7. Allow the surface to remain undisturbed until visibly dry or refer to the instructions of the disinfectant product.
8. Visually inspect for damage or deterioration of the surfaces. In case of doubt about functionality or cleanability consult XVIVO.

Do not allow the cleaning fluid to enter connectors!

Use only the prescribed cleaning and disinfection product: standard 70% alcohol solution or low-level disinfectant product (utilizing quaternary ammonium compounds as the active ingredient).

4 GPS-tracking ready

The Kidney Assist Transport is GPS-tracking ready through a built-in tracker in the pump-unit. The tracker allows the location of the device in use to be monitored in real time. The GPS tracker communicates over existing 2G, 3G and 4G wireless networks, the required SIM-card is already in place. The GPS-tracker communicates its location to an external server that can be accessed by the user by a secured connection. Back-end is not available yet at the time of release of this document, please contact XVIVO for more information.

The GPS tracker is compliant to United States Federal Communications Commission (FCC) and registered as FCC ID: XPYUBX18ZO01.

The GPS module communicates with following wireless technology:

- 3G & 4G Bands: LTE Cat M1, NB1 Band: 3,8,20 (EU) & 2,4,5,12,13 (US)
- 2G Band: 900,1800 (EU) & 850,1900 (US)

Modulation RAT:
LTE Cat M1 Half-Duplex, LTE Cat NB1 Half-Duplex, 2G GPRS / EGPRS

Frequencies used:

- 3G & 4G Bands: LTE FDD bands: Band 2 (1900 MHz), Band 3 (1800 MHz), Band 4 (1700 MHz), Band 5 (850 MHz), Band 8 (900 MHz), Band 12 (700 MHz), Band 13 (750 MHz), Band 20 (800 MHz)
- 2G bands: GSM 850 MHz, E-GSM 900 MHz, DCS 1800 MHz, PCS 1900 MHz

Effective radiated power:

- LTE category M1 / NB1: Class 3 (23 dBm)
- 2G GMSK: Class 4 (33 dBm) for GSM/E-GSM bands, Class 1 (30 dBm) for DCS/PCS bands
- 2G 8-PSK: Class E2 (27 dBm) for GSM/E-GSM bands, Class E2 (26 dBm) for DCS/PCS bands

5 Maintenance

No changes should be made to the Kidney Assist Transport by the user.
This system does not contain parts that can be serviced by the user, servicing can only be performed by trained XVIVO personnel.
Replacement parts are available, to order a replacement part, refer to chapter 10.
It is required that your device is serviced by XVIVO every 12 months.

6 Warnings and precautions

- Use of the device in procedures other than those described in this manual may result in injury.
- Caution: Federal US law restricts this device to sale by or on the order of a physician.
- Safe use of the Kidney Assist Transport can only be guaranteed when the user is a skilled and trained professional and has successfully followed a Kidney Assist Transport training course.
- Any serious incident that has occurred in relation to the Kidney Assist Transport should be reported to XVIVO and the competent authority of the Member State in which the user and/or patient is established.
- Please contact XVIVO directly with any complaint at: qa.xnl@xvivogroup.com
- The accompanying power supply is part of the device. Only use the included 'Power Supply, Protek PMP30M-12-A' external power supply (Article no. 05.360).
- The mains plug of the power supply is the separator that connects or disconnects the Kidney Assist Transport and its power supply from the mains. Avoid positioning the equipment such that access to the mains plug, etc. is limited (so that disconnection becomes difficult).
- Use only the accompanying battery charger (Article no.: 05.634).
- Judgment of the measurement results regarding organ quality is the responsibility of the surgeon.
- Start preparation of the recipient when machine perfusion procedure is completed.
- In case of emergency and failing power button: disconnect pump head to stop perfusion.
- In the unlikely event that perfusion is unrecoverable, continue preservation using static cold storage.
- Do not install, use and/or store this unit in a poorly ventilated room or in locations exposed to direct sunlight or strong artificial light.
- Do not use outside prescribed operation environment, higher temperatures may lead to less efficient cooling.
- Yearly service is required to assure optimal and safe functioning.
- Servicing to any component of this device is to be performed by XVIVO certified personnel only. Unauthorized repair or modifications will void the warranty and may violate the conformity of the Kidney Assist Transport with the requirements of the applicable safety standards and regulations. Maintenance and servicing are not permitted while the device is functioning.

- The USB connection is for servicing activities only and may not be connected during perfusion.
- The Kidney Assist Transport does rely on essential performance:
  Pressure below safety limit: P < 70 mmHg
- In the unlikely event that, electromagnetic interference does occur and degradation of the essential performance is observed, please try to increase the distance between the Kidney Assist Transport and adjacent systems.
- Use of the Kidney Assist Transport adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The use of accessories, transducers and cables other than those specified, with the exception of replacement parts sold by XVIVO, could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Kidney Assist Transport and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Kidney Assist Transport, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Avoid use of the device near the following strong sources of EM emissions that may be present in the device use environment (e.g., hospital, transport): high frequency (HF) surgical equipment, RFID readers, and electronic article surveillance (i.e., theft detection) systems. Otherwise, degradation of the performance of this equipment could result.

7 Liabillity and warranty

See the General Terms and Conditions accompanying the sales agreement.

8 Alarms and troubleshooting

If a problem cannot be resolved during a clinical perfusion, call the 24/7 Helpdesk at: +31 50 3640116 (for urgent calls only).

Alarm signals

8.1

Message	Priority	Audible Signal	Visible Signal (LED)	
Warning	**Low priority** User awareness is required, optimal perfusion compromised.	E C — __	———	Yellow for general, Cyan for temperature.
Error	**Medium priority** Prompt user response is required, else fall back to cold storage.	C C C — — —	- - -	Yellow for general, Cyan for temperature

Audible alarm is the main alarm, visible alarms are supportive to the audible alarms and are an indication of the source of initiation. Users are required to stay in the vicinity of the device, never leave the device unattended.

Only one manufacturer-configured alarm pre-set is available which is automatically restored after power interruption. The delay for the system to positively identify an alarm state is about 3 seconds.

The generation of the alarm cannot be inactivated. The audible signal can be temporarily suppressed by pressing the mute button, this will disable the audible signal for 3 minutes meanwhile the visible alarm signal will remain. After 3 minutes, the audible alarm will continue.

The alarm signal shall automatically cease when its triggering event no longer exists, however its messages are shown on the display during the complete procedure to ensure the receiving party is aware of the problem and to evaluate the condition of the organ.

Alarm messages

8.2

Alarm messages	Problem	Probable Cause	Solution
Self-test FAILED	Internal hardware problem	Failure of device	Service
Continues buzzer alarm directly after start-up, no display warning	No pressure sensor	Pressure sensor not connected to pump unit	Connect pressure sensor
Pressure Sensor Disconnected Check Sensor	Sensor loose or disconnected	Sensor incorrect connected or disconnected	Reconnect sensor
WARNING Perfusion level low	Perfusion level too low or bad connection flow sensor	Loose, open or bad connection, leakage	Check connections, Wet flow sensor, Refill perfusion solution
WARNING ICE level too low	Perfusion temperature is higher than 10°C	Ice is melted, perfusion time longer than 24 hours Cover not fully closed	Add ice Close cover
WARNING Temp limit exceeded	Perfusion temperature is higher than 10°C	Ice is melted Cover not fully closed	Add ice Close cover
ERROR Flow limit	Flow too high	Low resistance	Inspect all connections
WARNING Battery power low	Battery nearly empty	Perfusion time longer than 24 hours Batteries not fully charged	Replace batteries or connect to external power source
WARNING No Flow data	Flow sensor measurement error	Wrong reading	Reconnect sensor
WARNING Pressure limit Set point adjusted	Pressure too high	High resistance	Pressing the button will result in 75% of set pump output
ERROR Pressure not reached	No pressure build-up, rpm too high, no pressure in pressure line	Perfusion level too low, pump head incorrectly placed or valve of pressure line in incorrect position	Refill circuit, reconnect pump head or turn valve of pressure line in correct position
ERROR Pressure too high Check System	Pressure too high	Pressure sensor error or internal problem	Check and reconnect pressure sensor Restart device

Probable causes

8.3

Problem	Probable Cause	Action
Unrecoverable perfusion	Failure of device	Continue preservation using static cold storage
No power	Battery empty	Replace batteries
Beeping or flashing LEDs	Errors detected by the KA-T	Follow the instructions in 5.1, Fault Message Explanation.
Pump not working correct	Pressure sensor defect	Replace pressure sensor
	Air in pump head	Prime pump head/disposable set
	Pump head not correctly coupled to pump motor	Reconnect pump head
	Pump defect	Call service Continue preservation using static cold storage
Temperature too high	Perfusion time longer than 24 hours, melted ice, cover not fully closed	Add ice Close cover
Missing or incorrect display elements at power-on	Display or internal computer failure	Power off, wait for 1 minute and power on. If this does not solve the problem, call service
Leaking perfusate	Loose fitting or defective Tube set.	Retighten all fittings.
Power on, but buttons are unresponsive	internal computer failure	Power off, wait for 1 minute and power on. If this does not solve the problem, call service
No flow reading	Flow sensor incorrectly connected	Connect Flow-sensor with the arrow facing the same direction as the flow through the tube
	Bad connection with tubing	Use ultrasound gel between sensor and tubing.

9 Product specifications

Product specifications	
Organ capacity:	≤ 88mm x 157mm x 71mm ≤ 3.5” x 6.2” x 2.8”
Perfusion pump:	Rotary pump, pulsatile 60 BPM
Perfusion flow:	up to 250 ml/min
Perfusion pressure:	up to 50 mmHg (limited by software at 70mmHg)
Perfusion temperature:	2°C -10°C, cooling by ice
Perfusate oxygenation:	up to 85 %
Oxygen supply:	100% medical grade oxygen Minimum cylinder volume to support application period of 24H is 144L 5.1ft3 at atmospheric pressure, e.g. ML6 cylinder type. Maximum dimensions of the cylinder: 110mm (4,3”) in diameter and 282mm (11”) in length including.
Oxygenator performance:	pO2max @ 250 ml/min perfusion flow= 90kPa, time to reach pO2max @ 250 ml/min perfusion flow= < 4min
Accuracy:	Pressure: ± 12% or 1 mmHg Flow: ± 0.07 L/min Temperature: ± 1.5°C
Perfusion solution:	Any certified machine perfusion solution (1 L)
Display:	Perfusion time, flow, pressure, temperature, vascular resistance, menu, messages
Alarm:	Alarm sound level pressure range: 60 – 70dB(A) (at 1 meter distance)
Battery capacity:	24 hours
Battery charger:	2-bay charger
Power:	• 12 VDC 1,2A from external power supply Input: 100 - 240 VAC, 1 - 0.6A, 47 - 63 Hz Output: 12VDC, 2.5A • 12V by 4 rechargeable Li-Ion Batteries, 11.25V / 8850mAh / 99.6Wh
Transport conditions: (short term ≤ 7 days)	Temperature: 2 - 50°C Humidity: 5 - 95 %RH non-condensing Atmospheric pressure: 50 kPa to 106 kPa Do not expose the device to direct sunlight or strong artificial light
Storage conditions: (long term ≥ 7 days)	Temperature: 10 - 30°C Humidity: 5 - 85 %RH non-condensing Atmospheric pressure: 50 kPa to 106 kPa Do not expose the device to direct sunlight or strong artificial light
Operating conditions:	Temperature 18 - 24°C, Humidity: 30 - 75%RH non-condensing Atmospheric pressure: 70.0 kPa to 106.0 kPa Background noise level: < 50dBA Do not use the device in a poorly ventilated area
Product lifetime	7 years
Dimensions:	615mm x 395mm x 340mm
Weight:	27,2 kg (including oxygen cylinder, ice and perfusion solution)
Ingress protection:	IP33

10 Ordering information

The following list contains orderable items for Kidney Assist Transport:

Item	Order number
Kidney Assist Transport	23 101
Kidney Assist Transport Perfusion Set	23 401
Kidney Assist Transport battery (1 pcs.)	05.363
Kidney Assist Transport battery charger 2 bay	05.364
Oxygen flow regulator	05.375
Sample bottles	05.376
Ice reservoir	23.301
Ice reservoir lid	23.302
Oxygen drain insert	23.303
Documents guide	23.304

To order any of the above items or country specific power cords and adaptor plugs send your request by email to order.xnl@xvivogroup.com

11 Disposal

The Kidney Assist Transport is subject to the European directive 2012/19/EU on waste electrical and electronic equipment (WEEE) and European directive 2006/66/EC on waste batteries and accumulators. Do not dispose the device or batteries yourself. If users in the European Union wish to discard the device and/or batteries at the end of its useful life, contact XVIVO to arrange a retrieval of your Kidney Assist Transport and/or batteries. XVIVO shall ensure that your discarded product undergoes the necessary treatment, recovery and recycling procedures free of charge.

For disposal in countries outside of the European Union, local regulations must be followed for the disposal of the Kidney Assist Transport.

Local regulations must be followed for the disposal of the Kidney Assist Transport parts. By doing so you will ensure that your disposed product undergoes the necessary treatment, recovery and recycling and thus prevent potential negative effects on the environment and human health.

12 Classifications

Classification to EU- 2017-745 (MDR)	Class IIb
Classification to FDA	Class II
Classification to IEC 60601-1	Class II
Protection against electrical shock	Type B
Software Classification IEC 62304	Class B
Regulations:	EU Regulation 2017-745 (MDR) FDA Title 21, chapter I, subchapter H
Applied standard(s):	
Safety:	IEC 60601-1
EMC:	IEC 60601-1-2
Software:	IEC 62304
Usability	IEC 62366
Risk analysis:	ISO 14971
Quality:	ISO 13485

Power Supply, Protek PMP30M-12-A:

- Classification to IEC 60601-1 : Class II
- UL ES 60601-1, CSA C22.2 No. 60601; Report E178020

Batteries, RRC2020:

- UL 2054; Certificate 20120423-MH49040B
- UN 38.3; report STL Technologies CO. LTD 1709006
- IEC 62133; Report BA-12CA13477-A-1

GPS module, Ublox SARA-R412M:

- FCC, CFR47 Part 15 (FCC ID: XPYUBX18ZO01)

Notified body: BSI (NL)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

12.1

EMC declarations

- Declaration on electromagnetic emissions (Table 1),
- Declaration on electromagnetic immunity (Table 2),
- Declaration on RF wireless communication equipment Immunity (Table 3).

Table 1. Guidance and manufacturer's declaration – electromagnetic emissions

The Kidney Assist Transport is intended for use in the electromagnetic environment specified below. The customer or the user of the Kidney Assist Transport should assure that it is used in such an environment.

Emissions test–guidance	Compliance	Electromagnetic environment
RF emissions CISPR11 (EN 55011)	Group 1 Class B	The Kidney Assist Transport 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.
Harmonic emissions IEC 61000-3-2	Class A	The Kidney Assist Transport is suitable for use in for usage in domestic establishments that are directly connected to a low voltage power supply network, which supplies domestic environment.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2. Guidance and manufacturer's declaration – electromagnetic immunity

The Kidney Assist Transport is intended for use in the electromagnetic environment specified below. The customer or the user of the Kidney Assist Transport assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100KHz for power supply lines ±1 kV for input/ output lines	0 - ± 2kV at 100KHz 0 - ± 1kV at 100KHz	Mains power quality should be that of a typical commercial or domestic environment.
Surge IEC 61000-4-5	± 0.5 & ±1 kV for power supply line to line ± 0.5 & ±1 kV for power supply line to Earth ±0.5, ±1 & ±2 kV for input / output lines line(s) to earth	0 - ± 1kV 0 - ± 2kV 0 - ± 2kV	Mains power quality should be that of a typical commercial or domestic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25/30 cycles 0% UT for 250/300 cycles	0% UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle at 0º 70% UT for 25/30 cycles (50/60 Hz) at 0º 0% UT for 250/300 cycles (50/60 Hz)	Mains power quality should be that of a typical commercial or domestic environment. To ensure continued operation during mains power interruptions, it is recommended that the device is powered from an uninterruptible power supply or a battery. UT is the AC. mains voltage prior to application of the test level.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m at 50Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3V 0.15 to 80 MHz 6 V in ISM bands between 0.15 & 80 MHz 80 % AM at 1 kHz	3 Vrms outside ISM bands, 0.15 to 80 MHz 6 Vrms inside ISM bands, 0.15 to 80 MHz	Portable and mobile RF communications equipment should be used no closer than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter to any part of the device including cables.
Proximity RF fields IEC6100-4-3	see table 4	see table 4	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by XVIVO.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3. Guidance and manufacturer's declaration – RF wireless communication equipment Immunity

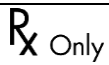
The Kidney Assist Transport is intended for use in the electromagnetic environment specified below. The customer or the user of the Kidney Assist Transport should assure that it is used in such an environment.

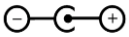
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2450 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

5500						
5785						
NOTE : The frequencies and services listed are representative examples that are based on RF wireless communications equipment in use at the time of publication of IEC 61000-4-3. The test specification does not attempt to cover every frequency and service used in every country.						

Table 4. Guidance and manufacturer's declaration – immunity to proximity magnetic fields (RFID)			
The Kidney Assist Transport is intended for use in the proximity magnetic fields environment specified below. The customer or the user of the Kidney Assist Transport should assure that it is used in such an environment.			
Test frequency	**Modulation**	**Distance (m)**	**Immunity test level (W)**
134.2 kHz	Pulse modulation 2.1 kHz [a)]	0.1	13
13.56 MHz	Pulse modulation 50 kHz [a)]	0.1	1.3
a) The carrier shall be modulated using a 50 % duty cycle square wave signal.			

Appendix A: Description of symbols

	Caution (ISO 15223-1, symbol: 5.4.4)
	Serial number (ISO 15223-1, symbol: 5.1.7)
	Catalogue number (model number) (ISO 15223-1, symbol: 5.1.6)
	Medical Device (Medical Devices Regulation 2017/745/EU)
	Manufacturer (ISO 15223-1, symbol: 5.1.1)
	Date of manufacture (ISO 15223-1, symbol: 5.1.3
	CE mark and Notified Body number (Medical Devices Regulation 2017/745/EU)
	Labelling-Prescription devices. (21 CFR 801.109 / 21 CFR 801.15(c)(1)(i)F)
	FCC mark
	WEEE symbol, indicating separate collection for waste of electrical and electronic equipment in Europe

	Follow instructions for use (mandatory) (IEC 60601-1, symbol D.2 – 10)
12VDC/1A	Electrical power input, direct current (IEC 60601-1, symbol D.1 - 4 / IEC 60417-5031)
	Electrical polarity AC adapter
	Replaceable fuse, specific type, current and voltage ratings noted above this symbol (IEC 60417, symbol 5016)
IPN_1N_2	Ingress protection (IEC 60601-1, symbol D.3 - 2)
	Identification of USB-port (ISO 7000-3650)
	Biological risks (ISO 15223-1, symbol: 5.4.1)
	Storage condition, temperature
	Indicates the range of humidity to which the medical device can be safely exposed
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	Stand-by button (IEC 60601-1, symbol D.1 - 29)
	Navigation / setting button ‘DOWN’
	Navigation / setting button ‘UP’
	Select / accept button
	Pause audible alarm button (mute)
	Stop / start pump button
	Temperature alarm (visual indicator)
	General alarm (visual indicator) IEC 60601-1, symbol D.2 / ISO 15223-1, symbol: 5.4.4

Appendix B: Abbreviations

A	Amperes
BPM	Beats per minute
°C	Degrees Celsius
CE	Conformité Européenne
cm	Centimeters (1 cm = .01 m)
DBD	Donation after Brain Death
DCD	Donation after Circulatory Death
DC	Direct current
ECD	Expanded Criteria Donors
EMC	Electro Magnetic Compatibility
EU	European Union
Hz	Hertz
IEC	International Electrotechnical Commission
KAT	Kidney Assist Transport
kg	Kilograms (1 kg= 1000 g = 2.2 lbs)
L	Liters (1L =0.001 m3)
LCD	Liquid Crystal Display
LED	Light Emitting Diode
mAh	milli-Ampere-hour
ml/min	Milliliters per minute (1 ml/min = 0.00006 m3/sec)
mmHg	Millimeters mercury (1 mm Hg = 1 torr = 133.3 Pa)
PLED	Polymeric Light Emitting Diode
P	Pressure
Q	Flow
T	Temperature
V	Volts
VR	Vascular resistance

Footnote
Device contains approved Radio: C030-R412M, FCC ID: XPYUBX18ZO01
This device complies with Part 15 of the FCC Rules and Industry Canada license-exempt RSS standards. Operation is subject to the following two conditions:

1) This device may not cause harmful interferences, and
2) This device must accept any interference received, including interference that may cause undesired operation.

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