Instructions for Use

Kidney Assist

XVIVO

Figure 1 Kidney Assist system

Content

The instructions in this document describes the intended use. 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 Perfusion Set thoroughly before use.

1. Product description

1.1 Intended use

1.1.1 Intended purpose

The Kidney Assist is intended to be used for ex-vivo hypothermic and normothermic oxygenated machine perfusion to preserve and evaluate donor kidneys prior to transplantation.

1.1.2 Application period

The Kidney Assist is intended for hypothermic perfusion up to 24 hours and normothermic perfusion up to 6 hours.

1.1.3 Intended medical indication

The Kidney Assist is indicated for use with deceased donor kidneys.

1.1.4 Patient population

The Kidney Assist is (indirectly) intended for patients in need of a kidney transplant.

1.1.5 Contra-indications

There are no known contra-indications.

1.1.6 Warnings

Not applicable.

1.1.7 Intended Clinical Benefit

The Kidney Assist enables successful transplantation of deceased donor kidneys.

1.1.8 Intended user profile

The Kidney Assist is intended to be used in a clinical environment and operated by trained and licensed healthcare professionals familiar with medical practices required for organ perfusion.

Safe use of the Kidney Assist can only be guaranteed when the user has read and understood the instructions for use and successfully completed a training course provided by XVIVO. During the training the user will learn how to install and operate the Kidney Assist and what to do if errors occur by a specialist of XVIVO. During the training, the user will learn how to install and operate the Kidney Assist and what to do if errors occur.

1.2 Principles of operation, mode of action

1.2.1 Principles of Operation

Prior to each procedure a new single-use Kidney Assist Perfusion Set is connected to the Kidney Assist and primed with 2 to 4 liters of perfusion solution. After de-airing of the system, the kidney is placed in the perfusate-filled reservoir and the cannulated renal artery is connected to the perfusion circuit.

During operation, the perfusion solution in the reservoir flows via the pump head of the perfusion circuit to the oxygenator, where it is cooled or heated (depending on perfusion protocol), filtered and oxygenated. From there, it flows through the cannulated renal artery into the kidney. After passing the kidney, the perfusate flows freely back in the reservoir.

1.2.2 Mode of action

Following cold storage of the donor kidney and before transplant, the kidney is connected to the Kidney Assist via a single-use perfusion set and continuously perfused with a cold or warm oxygenated perfusion solution, (depending on protocol) allowing for a continuous supply of oxygen and nutrients, and removal of waste products.

During Hypothermic Oxygenated Machine Perfusion with the Kidney Assist, the donor kidney is perfused with a suitable cold solution to slow down cellular deterioration and support residual metabolic function, thereby reducing the detrimental effect of ischemia-reperfusion injury.

During Normothermic Oxygenated Machine Perfusion with the Kidney Assist, the donor kidney is perfused with a suitable warm solution to maintain the kidney in a near-physiological state enabling viability assessment prior to transplantation into a recipient.

1.3 Kidney Assist

XVIVO's Kidney Assist is an in-hospital system for ex-vivo hypothermic and normothermic oxygenated machine perfusion of donor kidneys prior to transplantation into recipients. The system consists of two primary components: the reusable Kidney Assist and a single use perfusion set.

To facilitate in-hospital transport, the pump and Thermo unit are affixed to a dedicated tabletop trolley. This trolley ensures portability and a work surface, including an organ reservoir holder for placing the kidney reservoir of the perfusion set.

The perfusion data is accessible through XVIVO Insights which is a web application that continuously mirrors the perfusion characteristics and potential device generated notification messages, see section 4.

The Kidney Assist is used together with a sterile, preassembled, single-use perfusion set, the Kidney Assist Perfusion Set [REF 21.401].

Each perfusion set includes a dual-lid reservoir and cannula(s) for the kidney, and one perfusion circuit. The perfusion circuit contains an oxygenator with heat exchanger and arterial filter, pump head with magnetic coupling, pressure sensor and compatible tubing.

For the Kidney Assist to achieve its intended purpose, the system needs to be used in combination with other components not manufactured by XVIVO, such as:

- Certified machine perfusion solution suitable for hypothermic conditions
- Blood based derivative or machine perfusion solution suitable for normothermic conditions
- Gas supply

For a complete list of components and accessories included in the Kidney Assist system, see Table 1 below.

Table 1. Components included in the Kidney Assist system

Reusable devices/components
Kidney Assist (art.nr 21.101)
- Pump Unit
- Thermo Unit
- Trolley
- Reusable Accessories:
· Power cord thermo unit
· Power cord between pump unit and thermo unit
· Data cable between pump unit and thermo unit
· Pressure sensor cable (1x)
· Temperature sensors (2x)
· Flow sensor
· Instructions for Use
· Thermo water tubing
· Water tubing couplers (2x)
Single-use devices
Kidney Assist Perfusion Set (art.nr 21.401)
- Kidney Reservoir
- Centrifugal pump head (1x)
- Oxygenator/heat exchanger (1x)
- Pressure sensor (1x)
- Reservoir lid (2x)
- Cannulas

1.3.1 Pump unit

The Kidney Assist contains one pump unit for perfusion of the renal artery. The pump unit operates in a pulsatile mode of 60 BPM to mimic physiological blood flow with a pressure that can vary from 0 to 90 mmHg according to the chosen settings.

The pump is pressure-controlled at a user-set perfusion pressure. Adjustments of pressure setting and interaction with the menu and messages are performed through the touch buttons incorporated in the control panel. Dedicated software is installed in the pump unit. The pump unit also controls the Thermo unit.

The control panel on the front of the pump unit continuously 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, see section 8, will be displayed on the main display, combined with colored LEDs on the front of the unit.

The maximum allowable pressure, flow and temperature are limited by the software, and these are set by the manufacturer in a pre-configured setting that cannot be altered by the user. The maximum allowable perfusion pressure is temperature dependent, see section 2.12.

Perfusion temperature is user adjustable, see section 1.3.2 for details.

Figure 2: Front and rear view of the pump unit.

1. Control panel
2. Electrical power inlet
3. Data cable connection
4. USB connection
5. Equipotentiality pin
6. Product label
7. Screw joint
8. Antenna

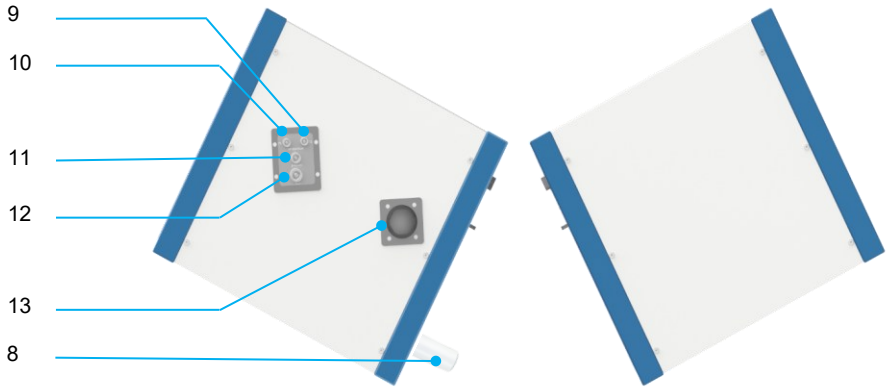


Figure 3: Right and left-hand side view of the pump unit

9. Reservoir temperature connection (T2)
10. Perfusion temperature connection (T1)
11. Pressure sensor cable connection
12. Flow sensor connection
13. Magnetic pump coupling

1.3.1.1 Control panel

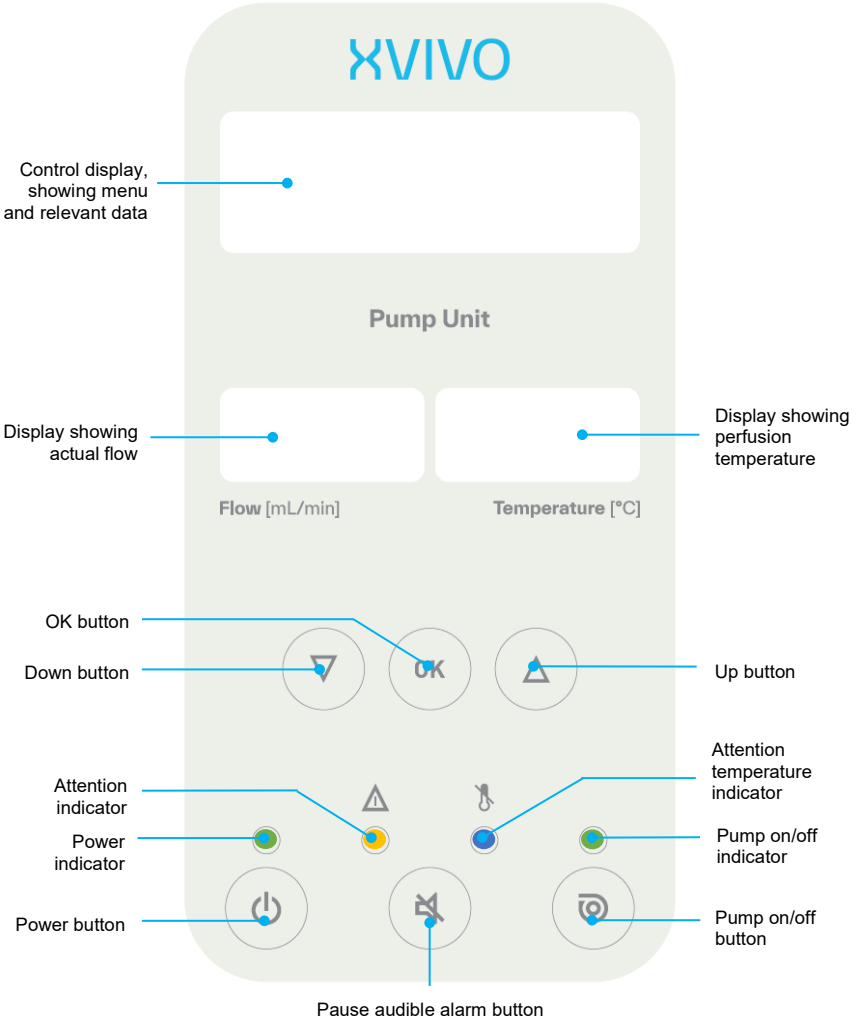


Figure 4 Control panel pump unit

1.3.2 Thermo unit

The Thermo unit controls the temperature of the perfusion solution. The perfusion temperature is user-adjustable from 12 °C to 37 °C. When set below 12°C the system enters full cooling mode, targeting a temperature between 1 °C to 12 °C. During the full cooling mode, adding ice to the Thermo unit may be necessary to reach the desired temperature.

The Thermo unit maintains the temperature of the circulated perfusion solution using Peltier elements. Depending on the set temperature, these elements cool or heat the internal water-circuit using thermoelectric effect. To transfer the temperature of the internal water circuit to the perfusion solution, the Thermo unit is connected via silicone tubing to the heat exchanger ports of both oxygenators, see Figure 5 and Figure 7. The outlet port of the Thermo unit is connected to the “water in” port of the heat exchanger and the inlet port of the Thermo unit is connected to the “water out” port of the heat exchanger.

To ensure an adequate waterflow, a flow indicator (spinning wheel) is positioned in the water tubing on both sides. A de-airing balloon allows for de-airing of the internal water circuit. The Thermo unit is connected to the pump unit by the data cable and communicates with the Pump unit to achieve the desired temperature.

Figure 5 Front and rear view of the Thermo unit

⚠	Do not block inlet and outlet vents on either side of the Kidney Assist Thermo unit, this could affect the performance of the device.
☞	Only use demineralized water in the Thermo unit reservoir.
☞	Ice can be added to accelerate the cooling process.

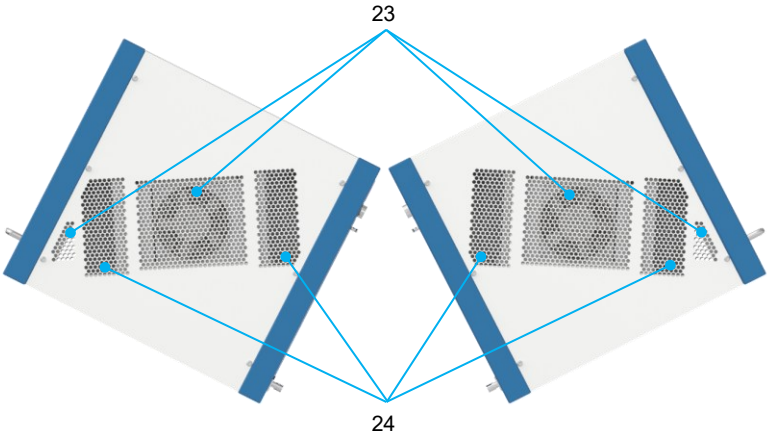


Figure 6 Right and left-hand side view of the Thermo unit

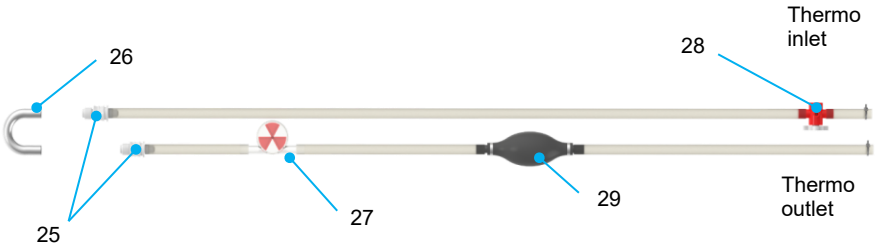


Figure 7 Thermo tubing

14. Thermo reservoir
15. Electrical power inlet
16. Data cable connection
17. Electrical power outlet
18. Equipotentiality pin
19. Product label
20. Screw connection for trolley
21. Thermo water inlet connector
22. Thermo water outlet connector
23. Air inlet vents
24. Air outlet vents
25. Water connector
26. Water tubing coupler
27. Flow indicator
28. Water drainage valve
29. Thermo tubing de-airing balloon

1.3.3 Trolley

The Thermo unit and the pump unit are mounted on a trolley (see Figure 8). The trolley is equipped with caster wheels with brakes and a push bar to allow for in-hospital transport.

At the top of the trolley a tabletop is mounted to create a work surface. On the tabletop, the kidney reservoir holder is located; a cavity wherein the kidney reservoir of the disposable perfusion set (see Figure 9, item 3) is placed. The thermal insulating properties of the tabletop maintain the perfusion temperature in the kidney reservoir. Under the tabletop, a thermo cover is located to shield the perfusion lines from the hot air generated by the Thermo Unit and thereby improving the thermal performance of the system. On the right side of the table, a pressure sensor holder is mounted wherein the disposable pressure sensor is placed at the same height of the kidney, the pressure sensor holder is fitted with a bracket to avoid unintentionally repositioning of the pressure sensor valve. At the right side of the trolley, an oxygenator holder is located for placement of the oxygenator of the perfusion set. Additionally, the holder is equipped with a clamp to accommodate the sample manifold.

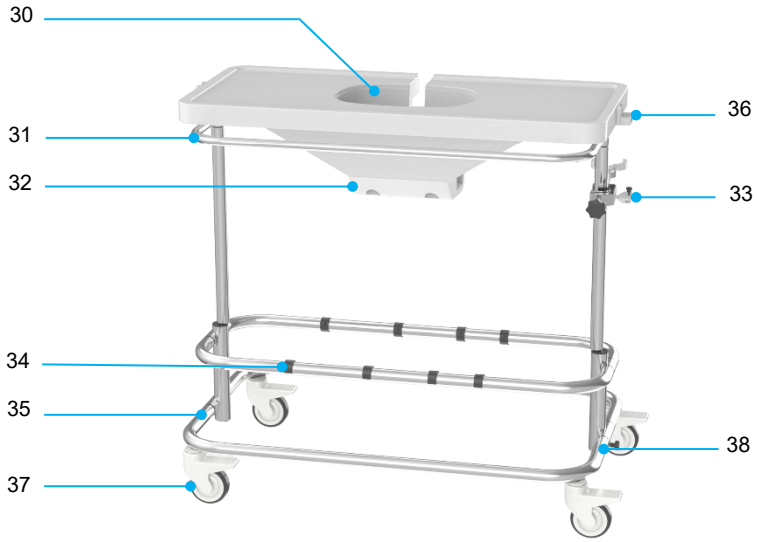


Figure 8 Trolley

30. Tabletop with kidney reservoir holder
31. Push bar
32. Thermal cover
33. Screw holes for pump and Thermo unit
34. Product label
35. Brakes on caster wheels
36. Pressure sensor holder
37. Oxygenator holder
38. Sample manifold holder

Do not load more than 15 kg on the tabletop, including organ and liquids.

1.4 Perfusion set

The Kidney Assist Perfusion Set is a single use disposable, accommodating both the Kidney and the perfusion solution during each perfusion, figure 9. All components are sterile and packaged in a polyethylene tray sealed by a Tyvek sheet

Perfusion solution inside the perfusion circuit flows from the Kidney reservoir to the pump head. From the centrifugal pump the flow is towards the venous inlet port of the oxygenator. Small air bubbles in the fluid will be trapped in the venous bubble trap of the oxygenator. Inside the oxygenator, perfusion solution flows through the integrated heat exchanger to reach the pre-set temperature and gas exchange will take place.

To oxygenate the perfusion solution, the “gas in” port of the oxygenator is connected to an external gas supply. The perfusion solution then leaves the oxygenator, through the built-in arterial filter where small particles (e.g. micro-aggregates or micro-emboli) during perfusion will be removed from the perfusion solution - via the arterial outlet port. From there the fluid flows to the cannulas and into the Kidney. After passing the Kidney, the fluid flows freely back in the Kidney reservoir.

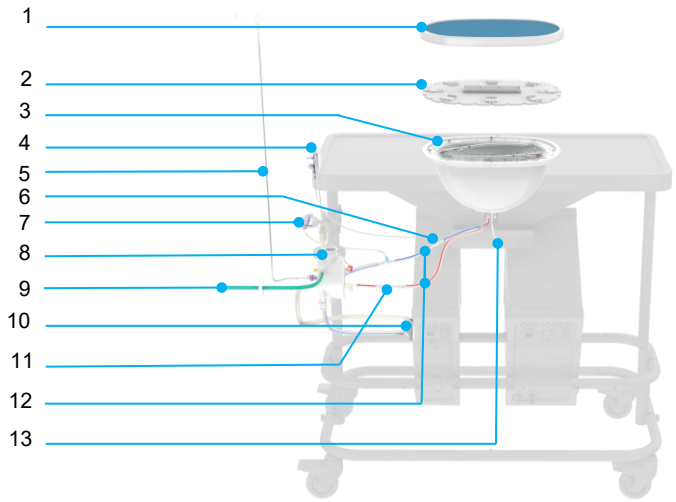


Figure 9: Disposable set.

1. Sterile lid with drape
2. Inner lid
3. Sterile reservoir
4. Pressure sensor
5. Filling line
6. Temperature sensor T2 connection
7. Sample manifold
8. Oxygenator
9. Oxygen line
10. Pump head
11. Flow sensor tube
12. Perfusion lines
13. Residue line

Additional components not shown in Figure 9:

1x Inner lid	1x Straight-connector
1x Second lid	1x Residue line
1x Y-connector	1x Stepped male Luer Lock connector

2. Operating instructions

2.1 Installation

The complete Kidney Assist is shipped on a pallet. The device has to be unpacked, checked and installed by an XVIVO authorized person.

2.2 Preparation

- Set the trolley in the correct position and apply the brakes on the caster wheels (Figure 8, item 35).
- Connect power cord to the mains power with earth connection. When the mains power is connected, the orange indicator at the front of the Thermo unit will light up.
- Connect the Kidney Assist to the hospital potential equalization connector with an equipotential cable to ensure the potential equalization of the Kidney Assist with medical electrical devices and conductive parts of other objects.
- To power on the Kidney Assist, press and hold the power button on the pump unit until the device powers on. Wait until the display show “Connect Perfusion Set”.

Connect the Kidney Assist to a grounded electrical outlet rated for voltage and amperage according to the labelled ratings on the product back panel, otherwise electrical safety cannot be guaranteed.

2.3 Fill and de-air thermo unit

- Place the thermo tubing (Figure 7) with the water tubing coupler (item 26) as low as possible. Ensure that during filling and de-airing (section 2.3.1), the thermo unit inlet and outlet (Figure 7, items 21 and 22) are at the highest point, so air bubbles move toward the thermo unit.
- Fill the water reservoir of the Thermo unit (Figure 5, item 14) with approximately 3 liters of demineralized water.
- Note that there shall be no oxygenator attached to the thermo unit tubing at this point.

2.3.1 De-air thermo tubing

- Repeatedly squeeze the de-airing balloon (Figure 7, item 29) to push out as much air as possible from the thermo tubing.
- Note that after connecting the oxygenator the de-airing step shall be repeated to remove any air introduced during the connection (see section 2.8.7).

2.4 Placement of perfusion set

The sections below describe the instructions of the Kidney Assist device in combination with the Kidney Assist Perfusion Set.

- Carefully open the 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.
- Remove the Tyvek cover from the tray and take the perfusion set out including its accessories. After opening, the sterility of the product depends on the techniques of the user.
- Check if the product is intact and whether the connections are secure; retighten where necessary. Make sure the tubing of the perfusion set is not kinked.

⚠ Before starting the procedure, check the pump, sensors, cables and connections for damage. Do not use a damaged device as it may impact user or organ safety

⚠ Use dedicated perfusion set (REF 21.401) only, as otherwise the device may be damaged, or organ could be seriously damaged.

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

⚠ Carefully check the product and packaging. Do not use if the packaging or Kidney Assist Perfusion Set is significantly damaged or even if there is the slightest doubt regarding the sterility of the product.

- Place the kidney reservoir in the cavity of the Kidney Assist table (Figure 8, item 30).
- Orientate the tubing towards the pump unit
- Place the pressure sensor in the holders at the side of the tabletop (Figure 8, item 36).
- Place the oxygenator in the holder of the trolley (Figure 8, item 37) by pressing them into the clamp, see (Figure 10).

Figure 10 Connection of oxygenator to the holder

- Before connecting the pump head to the magnetic pump coupling; remove the metal clip, marked with an orange ‘remove before use’ label.
- Connect the pump head to the magnetic pump coupling located on the outer side of the Kidney Assist pump unit (Figure 3, item 13).
- To connect it, push the pump head into the coupling and turn the pump head to lock it. Ensure it is placed correctly, see Figure 11. The outlet of the pump heads shall be orientated horizontally to easily de-air the pump heads.

Figure 11 Connection of pump head

- If intending to sample the perfusion fluid during the process, attach the separately packaged sample line to the circuit:
  - Place the sample manifold in the dedicated clamps on the side of the trolley for proper positioning, see Figure 12 (green arrow).
  - The orientation of the sample line in the perfusion circuit is color coded by the red and blue caps. Connect the red marked end of the sample line to the port on the oxygenator with the red cap. Connect the blue marked end of the sample line to the port of the kidney reservoir outlet with the blue cap, see Figure 12.
  - Ensure a secure and sterile connection by tightly fastening the components.

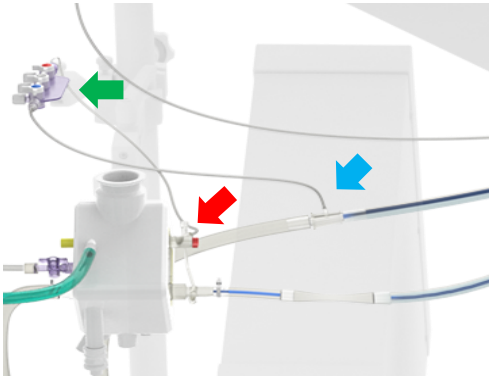


Figure 12 Connection of the sample lines. Employ the red arrow to link the red marked sample line to the oxygenator port and use the blue arrow to connect the blue marked end of the sample line to the kidney reservoir outlet port. The sample manifold is indicated with the green arrow.

- Connect the oxygenator to the oxygen/gas supply using the green tubing with the incorporated gas filter.

2.5 Gas supply

It is preferable to use the gas supply of the operating theatre.

When no gas supply is available a cylinder can be used. When a cylinder is used always check if there is enough gas available in the cylinder. XVIVO is not responsible for incorrect use of the gas supply. The gas flow/perfusion fluid flow ratio is limited to 0.5 - 2 :1 by the specifications of the oxygenator. In addition, the maximum gas flow rate is 5.6 L/min.

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

2.6 Connect oxygenator to the thermo tubing

- Ensure that the thermo unit is filled with water and de-aired, see section 2.3.
- Connect the thermo tubing to the oxygenator (Figure 13) using the water connectors (Figure 7, item 25). The oxygenator has two thermo tubing connectors, and either connector can be used for the inlet or outlet. Ensure one tube is connected to the thermo inlet and one to the thermo outlet (see Figure 7).

Check for leakage as oxygenator internal leaks and damage can lead to contamination. Do not use the oxygenator if there are any leaks.

Figure 13 Connect the thermo tubing to the oxygenator

2.7 Connect sensors

2.7.1 Temperature sensor

- Connect the red T1 sensor to the oxygenator outlet (Figure 14).

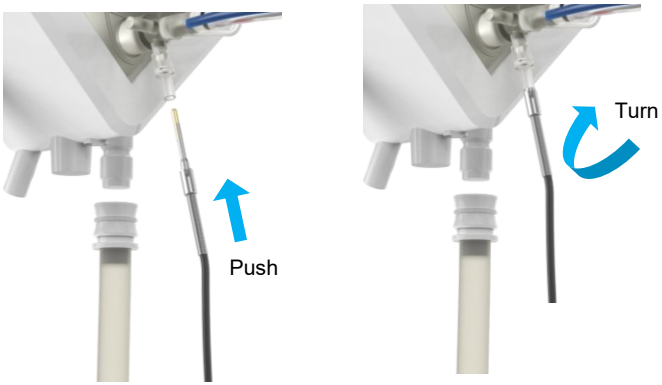


Figure 14 Connection of the temperature sensor to the oxygenator

- Connect the T2 sensor to the perfusion line, Figure 15; it is located at the outlet of the kidney reservoir.

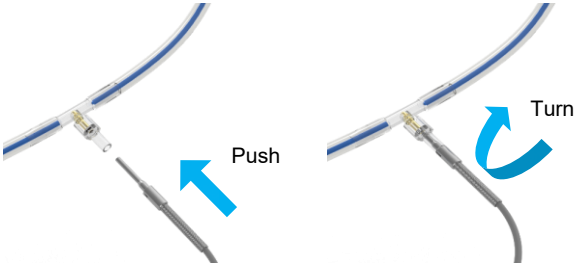


Figure 15 Connection of the temperature sensor to the perfusion set

2.7.2 Flow sensor

- Connect the flow sensor to the pump unit.
- Connect the flow sensor (Figure 16) to the silicone tubing (Figure 16, item 11), located near the arterial side of the oxygenator. Open the flow sensor by pushing the aluminum clip to release the lid. Open the lid and clamp the sensor around the silicon tubing. Push the lid to close the sensor.

Figure 16 Connecting flow sensor to perfusion set

Make sure that the arrow on the flow sensor is pointing towards the reservoir. Wrong connection of this sensor will give an incorrect flow measurement.

2.7.3 Pressure sensor

- Connect the pressure extension cable to the pressure sensors, which is placed in the holder at the side of the tabletop (Figure 8, item 36).

2.7.4 Connection of sensors to pump unit

- Connect the temperature sensors, flow sensor and pressure sensor (Figure 17) to the pump unit (Figure 3, item 9, 10, 11 & 12. Make sure to match the color coding of the temperature sensors. Make sure to connect the sensor connection with the red dot facing upwards.

Connect the sensors to the right receptacles, else it could cause damage the connectors and receptacles.

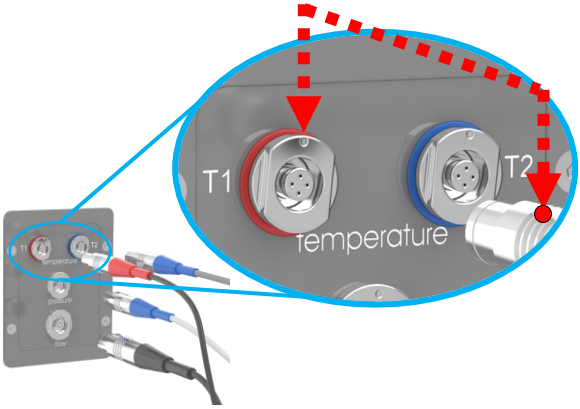


Figure 17 Connecting the sensors to the pump unit. Ensure proper alignment for each sensor, by orienting the sensor connection with the red dot facing upwards.

The system is now ready for priming, and setup as depicted in Figure 18.

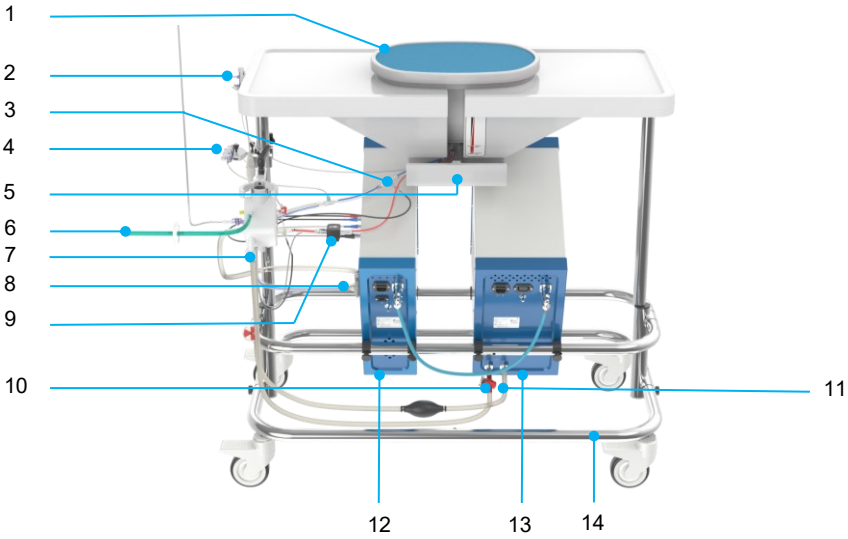


Figure 18 Complete system setup

1. Reservoir with sterile lid and drape
2. Pressure sensor
3. Temperature sensor T2
4. Sample line
5. Residue line
6. Oxygen line
7. Oxygenator
8. Pump head
9. Flow sensor Thermo tubing inlet
10. Thermo tubing outlet
11. Thermo tubing inlet
12. Pump Unit
13. Thermo Unit
14. Trolley with tabletop

2.8 Priming and de-airing

2.8.1 Filling the circuit

- To fill the circuit; connect the filling line to the oxygenator. Make sure to connect it tightly and maintain sterility.
- Remove the yellow de-airing cap on the oxygenator, Figure 19. Do not discard the yellow cap.
- Fill the system with the preferred perfusion solution via the filling line (minimum of 2 liters in total). After filling, close the line using the clamp and turn the swivel valve to a closed position to avoid leakages.
- When the system is filled, press OK button to proceed.

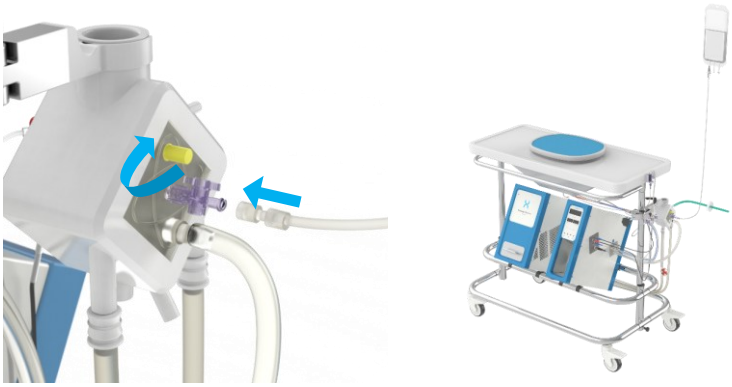


Figure 19 Removal of the yellow cap and connection of filling line

⚠ Use only certified machine perfusion solution. Use of other solutions may result in organ damage.

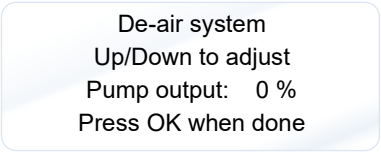
⚠ Do not spill fluid on the thermo unit (vents), pump unit, sensors or other electronic components as this may damage the device or cause inaccurate measurements.

2.8.2 Initiate de-airing

To fully de-air the perfusion set, air is removed by adjusting the pump flow using the up- and down- buttons on the pump, manipulating the tubing, and aspirating a syringe at selected ports. De-air in the direction of the flow from the reservoir and back into the reservoir in the following order:

- Tubing from the reservoir to the pump head
- Pump head
- Oxygenator (via sample line or directly via oxygenator)
- Tubing from oxygenator to reservoir
- Pressure sensor

Start the de-airing of the circuit by following the detailed steps below.



- Press the up- and down-buttons of the pump unit to vary the flow when needed during the process. Variation of the flow will help to remove air from the perfusion circuit.
- Start by de-airing the tubing leading from reservoir towards the pump head. Increase pump output to evacuate air towards the pump head. Manipulate the tubing to remove air manually.
- Continue to 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. If needed, disconnect the pump head to remove air manually. Do not tap on the pump head with clamps or other hard tools.
- If a sample line is connected, de-airing of the oxygenator is done via the sample line, see section 2.8.2.1. Otherwise, de-airing is done directly via the red valve on the oxygenator, see section 2.8.2.2.

2.8.2.1 Option 1: De-air oxygenator via the sample line

- Place the syringe on the blue port of the sample valve to de-air the venous sample line. The venous sample line is connected to the return tubing going out from the reservoir.
- Open the blue valve on the sample port, see Figure 20.

Figure 20 De-air the oxygenator via the sample line by aspirating with a syringe. Ensure that the blue valve is in the orientation indicated.

- Aspirate the syringe to remove air.
- Close the blue port of the sample line and remove the syringe.
- Place the syringe on the red port of the sample valve to de-air the oxygenator. Open the red valve on the sample port, see Figure 21.

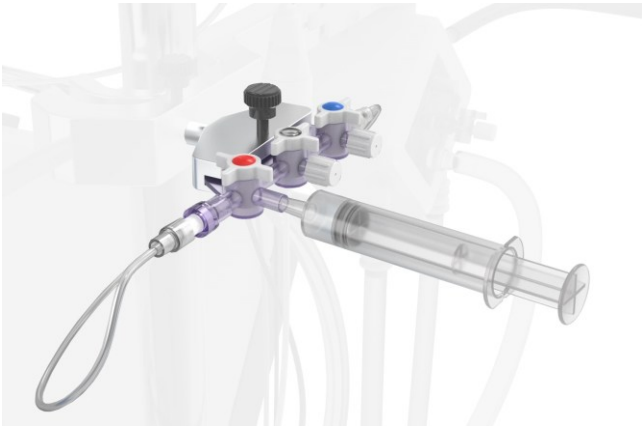


Figure 21 De-air the oxygenator via the sample line by aspirating with a syringe. Ensure that the red valve is in the orientation indicated.

- Turn the red valve on the oxygenator down to the pre-filter position, (Figure 22, Position 1; pre-arterial filter).
- Aspirate the syringe to remove air.

- Turn the red valve on the oxygenator up to the post-filter position, (Figure 22, Position 2; post-arterial filter).
- Aspirate the syringe to remove air.
- Turn the red valve on the oxygenator to the horizontal (closed) position.
- Close the red port of the sample line and remove the syringe.

2.8.2.2 Option 2: De-air oxygenator directly

- Place the syringe directly on the red port of the oxygenator.
- Turn the red valve on the oxygenator to the pre-filter position, (Figure 22, Position 1; pre-arterial filter).
- Aspirate the syringe to remove air.
- Turn the red valve on the oxygenator to the post-filter position, (Figure 22, Position 2; post-arterial filter).
- Aspirate the syringe to remove air.
- Turn the red valve on the oxygenator to the horizontal (closed) position.
- Remove the syringe.

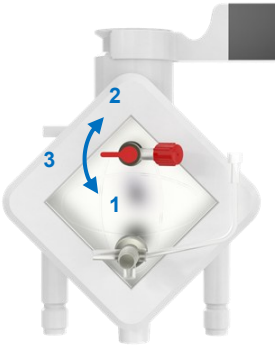


Figure 22 De-airing valve of the oxygenator

Position 1 (Pre-filter):	De-airing upstream of arterial filter
Position 2 (Post-filter):	De-airing downstream of arterial filter
Position 3 (Closed):	De-airing port closed

2.8.3 Finalize de-airing

- Place the yellow cap back on the oxygenator.
- De-air the tubing that runs from the oxygenator to the reservoir. Manipulate the tubing to remove air manually.
- Remove the cap on top of the pressure sensor and place a sterile syringe on the port (Figure 23; step 1).
- To fill the pressure line and remove any air, pull the blue snap tab (Figure 23; step 2) while aspirating with the syringe (step 3). Stop once the air has been removed.
- Place the cap back on the pressure sensor (Figure 23; step 4)

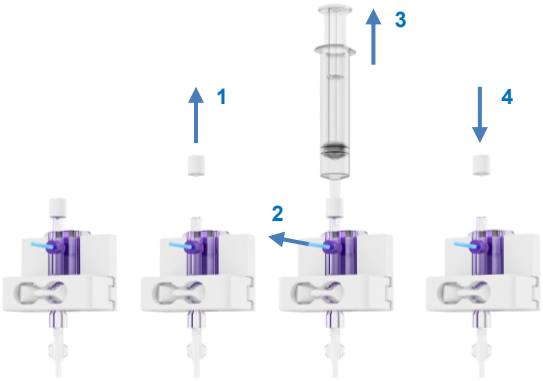


Figure 23 De-airing the pressure sensor

- Press OK on the pump unit to continue.
- Make sure to check that no air bubbles accumulated at the flow sensor. Open the aluminum clip to release the lid (see Figure 16). Open the lid and check for air bubbles. Remove any air bubbles by manipulating the tubing. Push the lid to close the sensor.

2.8.4 Zeroing the pressure sensor

To zero the pressure sensor, follow the steps below.

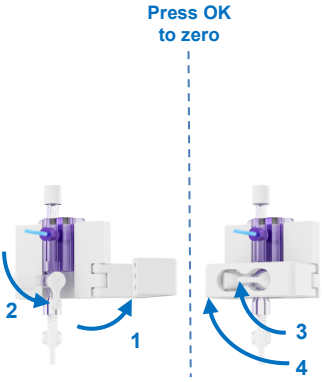


Figure 24 Zeroing of the pressure sensor

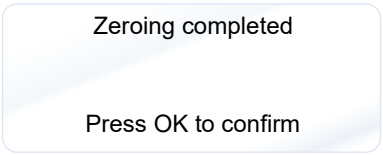
- Open the bracket of the pressure sensor holder to access the valve on the pressure sensor (Figure 24; step 1). As instructed on the display, turn the valve on the pressure sensor downwards to open the sensor to measure atmospheric pressure (step 2).

Pressure zeroing
Turn transducer
valve down
Press OK when done

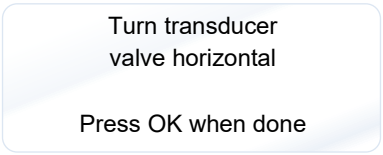
- In the pump unit menu, press the OK button to zero the sensor to atmospheric pressure. The pressure zeroing step will take 8 seconds.
- Do not touch the device and perfusions set during this step, as any user interference may impact the accuracy of pressure readings.

Pressure zeroing in
process
Wait ..
Pres: 0 mmHg

- The display will indicate that the pressure sensor has been zeroed successfully, Press OK confirm.



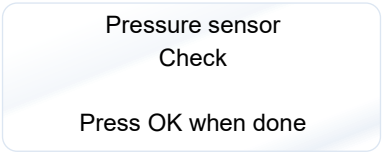
- Turn the pressure sensor valve back to horizontal position (see Figure 24; step 3) and close the bracket of the pressure sensor holder to protect the valve from unintentional opening (step 4). Press OK on the pump unit to continue.



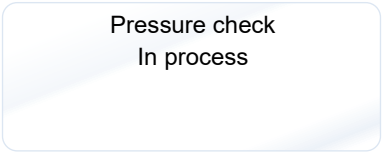
2.8.5 Pressure check

The device will verify whether the steps outlined in previous sections are performed correctly and if the pressure sensor is appropriately connected to the perfusion circuit.

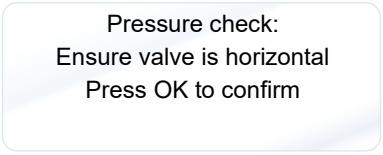
- Press OK to start the pressure check.



- In this step the Kidney Assist will check if the pressure sensor is appropriately connected to the perfusion circuit. This step will take a few seconds.



- In case the Kidney Assist is not able to determine if the pressure sensor is appropriately connected to the perfusion circuit, check if the position of the valve of the pressure sensor is in the horizontal position, see Figure 24, step 3). Press OK if the valve of the pressure sensor is in the horizontal position.



2.8.6 Set perfusion parameters

- Select the desired perfusion temperature, by utilizing the up and down buttons on the pump unit.

Set Temperature
Up/Down to adjust
Value: 20 C
Press OK when done

- Press OK to confirm the selected temperature and to proceed to the next step.
- Set the preferred perfusion pressure on the pump unit.

Set Pressure
Up/Down to adjust
Value: ... mmHg
Press OK when done

- Press OK to confirm and to proceed to the next step.

2.8.7 De-air the oxygenators

- Pinch or clamp both thermo tubing.
- Remove the oxygenator from the holder (Figure 8, item 37) and tilt it so the water outlet connector, identified by the air bubbles moving away from the oxygenator, is positioned above the water inlet connector (see Figure 25). This allows any trapped air to rise into the thermo tubing. Avoid kinking the thermo tubing, as this will restrict flow. Avoid straining the temperature sensor cable. If needed, temporarily remove the temperature sensor from the oxygenator to make tilting easier.
- Reconnect the oxygenator to holder (Figure 8, item 37).
- Unpinch or unclamp the thermo tubing
- Ensure that the flow indicator (red wheel) on the thermo tubing (Figure 7, item 27) is spinning fast enough. The three individual propeller blades should no longer be distinguishable by eye; only a continuous motion should be visible.
- If the flow indicators are spinning slowly (individual propeller blades are visible) or not turning, repeat the steps described above, and/or the steps in section 2.3.1, as an air lock is likely preventing water flow and proper temperature exchange.
- Do not proceed with the perfusion if the thermo tubing flow is low, as it will prevent adequate temperature exchange with the perfusate.

⚠ Check for leakage as oxygenator internal leaks and damage can lead to contamination. Do not use the oxygenator if there are any leaks.

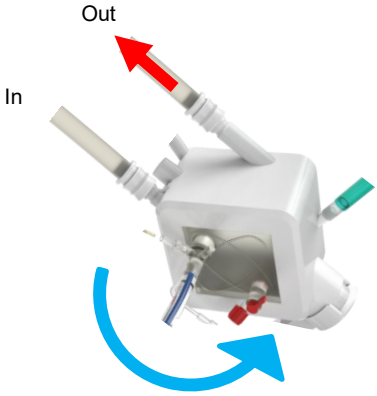


Figure 25:Tilt the oxygenator (blue arrow) so that the outlet connector (red arrow) is at the highest point, allowing water to move out from the oxygenator.

2.9 Cannulation

To connect the donor kidney to the Kidney Assist, cannulation of the renal artery is needed, see Figure 26. Different approaches can be used depending on the vascular state of the Kidney, the most common approach is by utilizing an aortic patch and a 'kidney adapter'. When no aortic patch is present, different cannulas can be used. The ureter can be cannulated (when necessary) and connected to the residue line via an extension tube. The 'kidney adapter' and different cannulas are not manufactured by XVIVO and are not part of the perfusion set, however, they can be ordered at XVIVO, see section 10.

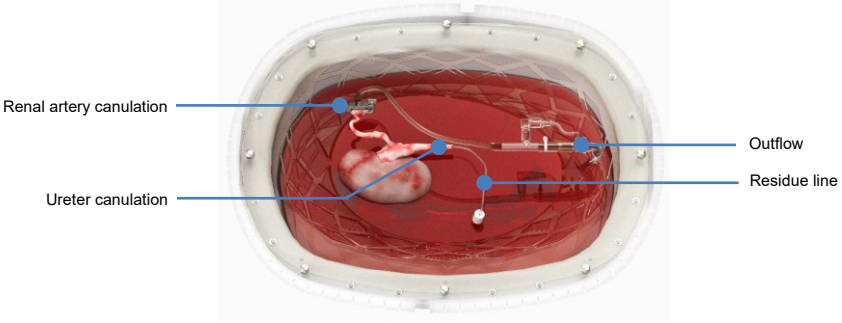


Figure 26: Cannulation of kidney

2.9.1 Kidney adapter

When an aortic patch is still connected to the renal artery, the connection can be made by using a kidney adapter (Figure 27). This connection results in protection of the endothelial layer of the renal artery. The aorta patch can be placed in the clamp of the adapter, which is available in different sizes (small, medium and large). Subsequently, the tubing connector of the adapter can be connected to the outlet of the perfusion circuit. The adapter can be connected directly to the outlet of the perfusion circuit inside the perfusion reservoir.

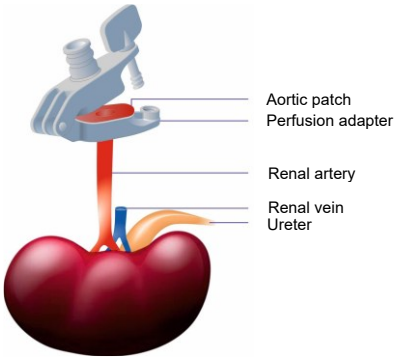


Figure 27: Kidney Adapter canulation

2.9.2 Cannulas

When there is no piece of aorta attached to the renal artery, the artery can be cannulated directly as shown in Figure 28. The cannulas for direct cannulation are available in different sizes (e.g. 8, 10 or 12 French) and can be ordered at XVIVO. The connector of the cannulas can be connected directly to the outlet inside the perfusion reservoir as well.

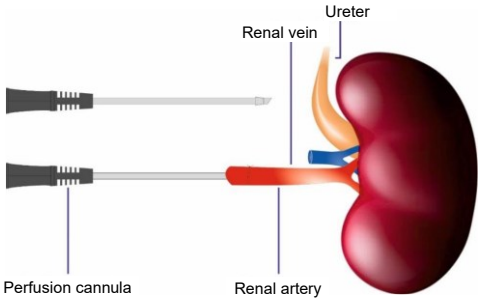


Figure 28: Direct canulation

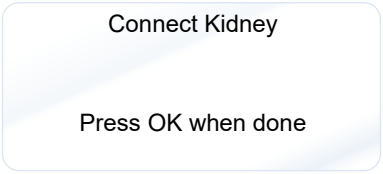
2.9.3 Ureter cannulation

The ureter can also be cannulated and connected to the residue line using an 8 French cannula, to allow for collection of urine.

2.10 Perfusion procedure

2.10.1 Starting the perfusion procedure

- Ensure that the display is in the connect kidney step.



- Turn on the gas supply and adjust the flow rate to the desired value, max. 5.6 L/min
- Aseptically open the sterile drape of the kidney reservoir to create a sterile field.
- Place the kidney in the kidney reservoir.
- Note that the kidney is supported by the net and the fluid in the reservoir. To ensure an accurate pressure measurement, it is essential to align the height of the kidney to the pressure sensor as shown in Figure 29. The tip of the cannula should be on the same height as the center of the pressure sensor.
- The height of the organ can be adjusted by changing the perfusate volume in the reservoir.
- If needed, the pressure setting value can be adjusted to compensate for height differences. The degree of correction depends on the height difference. The pressure value should be adjusted by 1 mmHg for every 1.3 cm of height difference.
    - If the kidney is located below the pressure sensor the pressure setting shall be decreased.
    - If the kidney is located above the pressure sensor the pressure shall be increased.

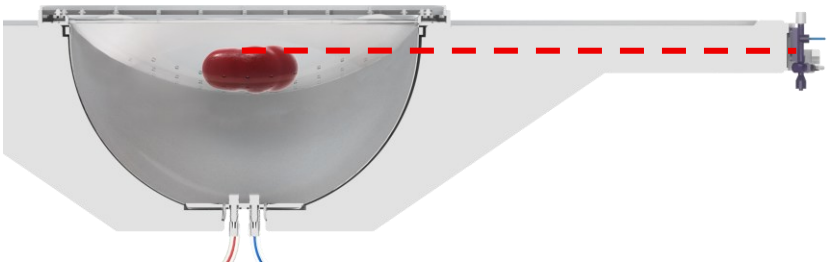


Figure 29: Height of the kidney relative to the pressure sensor

- De-air by filling up the cannula with the solution from the outlet. Connect the cannula with the outlet connector.
- A suture can be attached to the rim of the reservoir and the cannula, to ensure correct positioning of the cannula and to achieve optimal perfusion.

⚠ Ensure that the renal artery is not twisted as this may compromise the perfusion.

- Press OK to confirm that the kidney is cannulated.
- The display will prompt for confirmation that the oxygen is flowing. If uncertain, refer to section 2.5.

Confirm flow
of oxygen

Press OK to confirm

- The display will ask for confirmation to start the perfusion.

Ready to start
Perfusion?

Press OK to start

- When the perfusion is stable, close the kidney reservoir using the inner lid.
- During perfusion, the perfusion parameters will appear on each display.

Running: hh:mm:ss
T Return: .. C
Pressure: .. mmHg
VR: .. mmHg/L/min

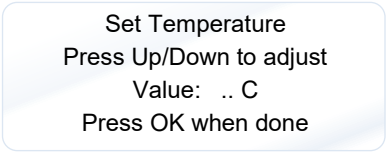
2.10.2 During the perfusion procedure

- Throughout the procedure, monitor the perfusion parameters. If needed the pressure and temperature set point can be changed.

Set Pressure
Up/Down to adjust
Value: .. mmHg
Press OK when done

- To change the pressure, press the up and down buttons on either the pump unit until the preferred value appears on the display and confirm by pushing the OK button.

- The temperature can be changed on the pump unit, by first selecting a pressure and then selecting the preferred temperature using the up- and down buttons and confirm by pushing the OK-button. The user set pressure and temperature will now be used.
- To achieve a temperature below 12 °C, set the temperature to 'Full Cooling.' The system will actively cool, aiming to attain the coolest temperature achievable by the device.




In case of an emergency, stop the Kidney Assist by pressing the pump buttons to stop the pump.


In case of emergency, and failing power button, disconnect pump head to stop perfusion.


Do not leave the device unattended, check regularly.


If device fails and perfusion cannot be restarted, continue preservation using static cold storage.

- If an error or malfunction occurs, consult section 8 for troubleshooting. If the alarms and troubleshooting section does not solve the problem, please call qualified service personnel, or contact XVIVO Global Helpdesk.

2.11 Additional drape

The Kidney Assist Perfusion Set is provided with a second lid with an additional sterile drape to maintain sterility during perfusion and/or in-hospital transport.

- Ensure the outer rim of the reservoir is dry.
- Unpack the second lid additional sterile drape.
- Remove the foil from the double-sided tape at the bottom of the second lid.
- Place the second lid over the reservoir and ensure the orientation is correct, the red arrow on the bottom of the label should point in the direction of the pump unit, see Figure 30.
- If desired, the original drape can be cut off around the additional drape, make sure the additional drape is not damaged.

Figure 30: Placement of second lid.

2.12 Alarm limits

The Kidney Assist is equipped with temperature dependent limits for flow and pressure to prevent damage or organ loss. These values are preset and cannot be changed. In case a limit is reached, the device will reduce pump speed to maintain safe perfusion. Permittable pressures at varying temperatures are shown in Figure 31. Permittable flows at varying temperatures are shown in the Figure 32.

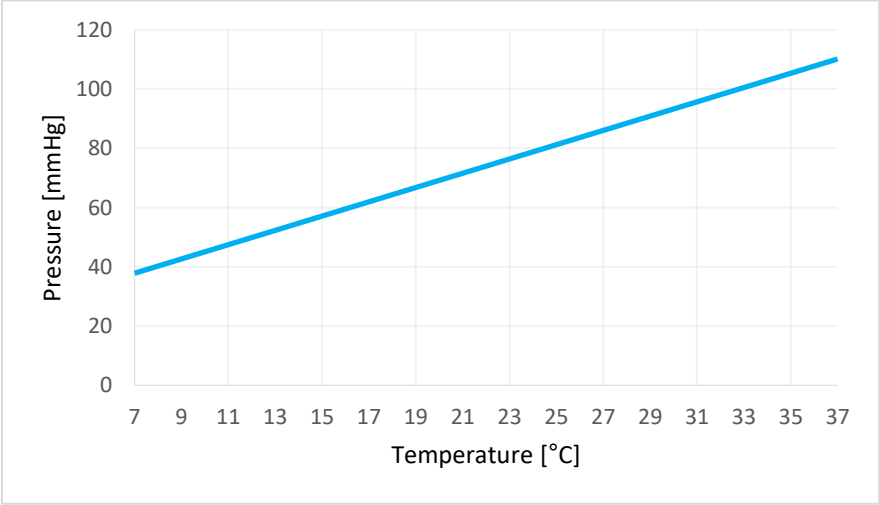


Figure 31 Pressure limits at varying temperatures

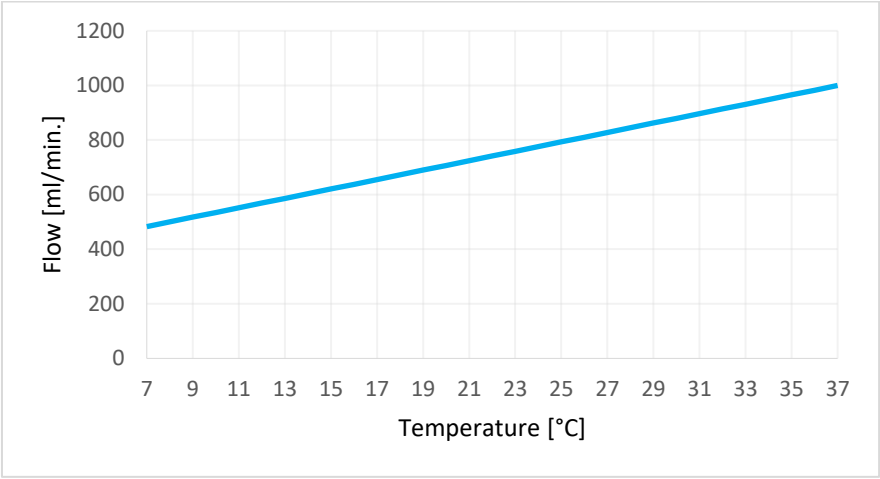


Figure 32 Flow limits at varying temperatures

In cases where a supratruncal aorta is not present, smaller cannulas (e.g., 8, 10, or 12Fr) can be used.

Each cannula has a specific pressure drop that is related to the inner lumen and length of the cannula. Pressure drop signifies the difference of the pressure inside the cannula compared to the pressure at the outlet. When opting for smaller cannulas (<24 French), be aware of the pressure drop and the need to compensate the user set pressure to maintain consistent perfusion pressure. See Figure 33 for the flow versus pressure dependency curves.

As an example, using a 10Fr arterial cannula at a volume of 300mL warrants an addition of 50 mmHg (see Figure 33) to the set pressure (see section 2.8.6). If the desired set pressure is 40 mmHg, the set pressure should be adjusted to 90 mmHg to compensate for the pressure drop.

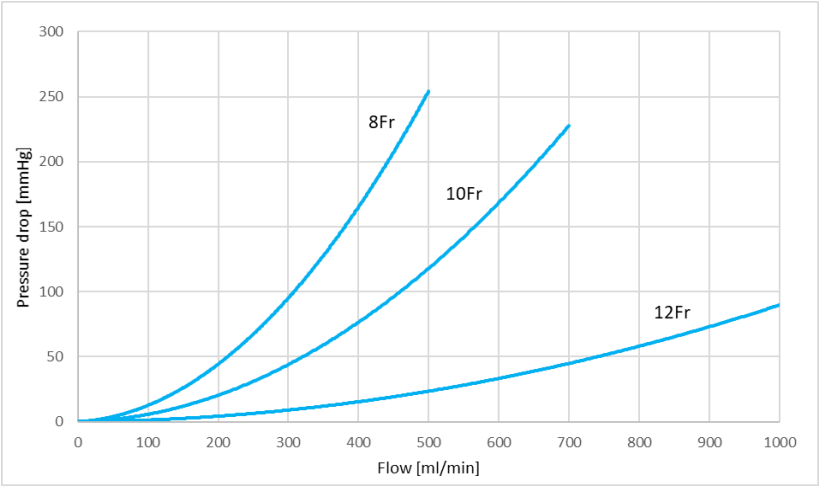


Figure 33 Pressure drop at varying flows

2.13 Sampling and adding supplements

Sampling of the perfusion fluid is performed from the oxygenator via the sample ports on the sample manifold (see Figure 12) by using a syringe. The same port can also accommodate the addition of supplements to the circuit. Follow the detailed steps below, and ensure maintaining sterility:

- Remove the cap of the sample port.
- Connect a sterile (Luer) syringe to the sample port.
- Open the valve.
- Extract a sample by aspirating the perfusion solution (considering the dead volume) or, if applicable, insert the supplements in the circuit.
- Close the valve.
- Disconnect the syringe.
- Reconnect the cap on the sample port.
- After sampling, check if the valve is in the closed position.

2.14 In-hospital transport

The Kidney Assist can use its internal battery supply to allow for transportation within the hospital during the perfusion procedure for a maximum of 20 minutes. When the mains power is disconnected for transport, the display will show a warning and the current battery charge. An alarm will warn the user every minute as a reminder that the device is running on batteries.

During this time the perfusion will continue but the Thermo unit is disabled to conserve battery power. Within 20 minutes, reconnect the mains power or switch to cold storage to

ensure safe use of the device. In case the transportation takes too long, an alarm will notify when the battery is low, see section 8.2.

To transport the Kidney Assist:

- Make sure the kidney reservoir is covered to ensure sterility e.g. by using the second lid with an additional sterile drape, see section 2.11.
- Disconnect the oxygen line from the oxygen supply.
- Disconnect the mains power (an alarm will notify that the mains power is disconnected).
- Disconnect the equipotential cable.
- Release the brakes on the wheels of the trolley.
- Carefully move the device using the push bar to the new location.
- Re-activate the brakes on the wheels of the trolley.
- Re-Connect the equipotential cable to the potential equalization connector.
- Re-Connect the mains power and keep connected to charge the internal battery.
- Re-Connect the oxygen line to the oxygen supply.

2.15 Stopping the operation

- Stop the perfusion flow by pressing the pump button on the pump unit.
- When the second lid with an additional sterile drape is applied, open the drape by carefully tearing the gas tape and unfold the drape.
- Disconnect and remove the kidney from the kidney reservoir.
- Switch off the system by pressing the power button on the pump unit for 3 seconds. Powering off the Kidney Assist will reset the set parameters back to the manufacturer's pre-set settings.
- Turn off the external gas supply.
- Disconnect the sensors from the perfusion circuit. Gently pull the connectors out of their sockets in a straight motion to avoid damage.
- The sensors, pressure extension cable and connectors of the device need to be kept clean and dry.
- Disconnect the thermo tubing from the oxygenator. Connect the thermo tubing to each other using the supplied water tubing coupler.
- Remove the complete perfusion set.
- Discard the used perfusion set as medical grade waste, following local regulations. Accessories from the perfusion set that are not used during the procedure should be discarded.
- Directly after use, clean the Kidney Assist according to the instructions in section 3.

Discard the used perfusion set as medical grade waste, following local regulations.

DO NOT RE-USE Kidney Assist Perfusion Set.

The Kidney Assist Perfusion Set is intended for single use only.

The power cord should remain connected to mains power to charge internal battery to ensure sufficient battery charge for in-hospital transport or power failure. Minimal charging time is 8 hours. The power cord shall be connected to mains power at regular intervals (every 2 months) when left unused for a long period of time.

The temperature sensors, flow sensors, pressure sensor cables and thermo tubing are reusable, make sure to separate them from medical waste disposal after use.

3. Cleaning and disinfection

Use only the prescribed cleaning and disinfection products.

3.1 After every procedure

The Kidney Assist can be subject to contamination by accidental spillage of the perfusion solution and from contact with soiled hands of the operator. The contamination may not be visible. Thorough cleaning with the prescribed cleaning and disinfection product, before and after every use, is required. Local regulations or guidelines should be followed for infection control.

3.1.1 Required materials

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

3.1.2 Cleaning instructions

1. Place the Kidney Assist in a clean environment complying with the operating conditions.
2. Wear gloves during the cleaning and disinfection procedure. First clean the accessible surfaces of the Kidney Assist with the prescribed cleaning product. Remove the contamination from the surfaces, corners and crevices. Do not use any abrasives as this will damage the surface of the device.

3. Disinfect the surfaces with an unused lint free cloth with the prescribed disinfection product making sure the surfaces are moistened.
4. Allow the surface to remain undisturbed until visibly dry or refer to the instructions of the disinfectant product.
5. Visually inspect for damage or deterioration of the surfaces. In case of doubt about functionality or cleanability consult XVIVO.
6. Drain, disinfect and decalcify the water reservoir on a regular basis, see section 3.2 and 3.3, to guarantee optimal performance of the device.
7. When the device is not in use, keep it connected to mains power to recharge the internal batteries.
8. After cleaning, the device may be stored with the device cover.

⚠ Do not allow cleaning and disinfection products to enter electrical connectors or ventilation areas of the Kidney Assist as this may cause damage or risk on electrical shock.

3.2 Weekly disinfection of the Thermo unit

1. Wear protective gloves and goggles during the disinfection process.
2. Prepare 2 liters of 0.5% Chloramine-T solution following the manufacturer's instructions. Examples of suitable disinfection agents for the Thermo unit include Disifin® (www.disifin.co.uk)) and Halamid® (www.halamid.com).
3. Drain the water from the Thermo unit and water tubing using the water drainage valve (see Figure 7, item 28). After drainage close the valve.
4. Clean the water connectors (see Figure 7, item 25), water tubing coupler (Figure 7, item 26), water drainage valve and lid of Thermo unit reservoir (Figure 5, item 14) using a surface disinfectant.
5. Close the water circuit.
6. Add 2 liters 0.5% Chloramine-T solution to the Thermo unit reservoir.
7. Connect the flow sensor, temperature sensors and pressure sensor cable to the pump unit.
8. Submerge the flow sensor in a cup with tap water.
9. Connect a separate pressure sensor to the pressure sensor cable.
10. Note: No need to connect a perfusion set.
11. Connect the power cable of the device to mains power.
12. Power on the pump unit.
13. Skip through the setup procedure by pushing the OK button on the pump unit. Push until the display shows “pressure zeroing”.
14. Circulate disinfection solution for 30 minutes at room temperature; check if the red flow indicator wheel (Figure 7, item 27) is spinning to ensure flow.
15. Power off the pump unit and drain Thermo unit and water tubing (see step 3).

16. First Rinse: Add 2 liters of demineralized water to the Thermo unit, circulate the water for 5 minutes at room temperature; check if the red flow indicator wheel is spinning to ensure flow. (follow steps 12 and 13 to start the circulation)
17. Power off the pump unit and drain the Thermo unit and water tubing (see step 3).
18. Second Rinse: Add 2 liters of demineralized water to the Thermo unit, circulate the water for 5 minutes at room temperature; check if the red flow indicator wheel is spinning to ensure flow. (follow steps 12 and 13 to start the circulation)
19. Power off the pump unit and drain the Thermo unit and water tubing (see step 2).
20. Fill the Thermo unit with 2 liters of demineralized water to prepare the unit for next use.

3.3 Yearly decalcifying of the Thermo unit

1. Connect the water tubing coupler (Figure 7, item 26) to the water connectors (Figure 7, item 25)) .
2. Drain the Thermo unit and water tubing using the water drainage valve (Figure 7, item 28). After drainage close the water drainage valve.
3. Prepare 2 liters of a decalcifying solution using citric acid as the primary and only active ingredient. Dilute the citric acid as prescribed in demineralized water.
4. Add 2 liters of decalcifying solution to the Thermo unit reservoir (Figure 5, item 14).
5. Wait for half an hour.
6. While waiting, connect the sensors:
7. Connect the flow sensor, temperature sensors and pressure sensor cable to the pump unit.
8. Submerge the flow sensor in a cup with water.
9. Connect a separate pressure sensor to the pressure sensor cable. .
10. Note: No need to connect a perfusion set!
11. After the waiting time, power on the pump unit.
12. Skip through setup procedure by pushing the OK button on the pump unit. Push until the display shows ”pressure zeroing”.
13. Circulate decalcifying solution for 20 minutes at room temperature; check if the red flow indicator wheel is spinning to ensure flow.
14. Power off the pump unit and drain the Thermo unit and water tubing (see step 2).
15. First Rinse: Add 2 liters of demineralized water to the Thermo unit, circulate the water for 5 minutes at room temperature; check if the red flow indicator wheel is spinning to ensure flow (follow steps 11 and 12 to start the circulation).
16. Power off the pump unit and drain the Thermo unit and water tubing (see step 2).
17. Second Rinse: Add 2 liters of demineralized water to the Thermo unit, circulate the water for 5 minutes at room temperature; check if the red flow indicator wheel is spinning to ensure flow. (follow steps 11 and 12 to start the circulation)
18. Power off the pump unit and drain the Thermo unit and water tubing (see step 2).

19. Fill the Thermo unit with 2 liters of demineralized water to prepare the unit for next use.

4. XVIVO Insights

XVIVO Insights (www.xvivoinsights.com), is an App and web application that continuously mirrors the perfusion characteristics, and potential device generated notification messages. The perfusion run data is accessible through a dedicated website requiring a username and password for login. Kidney Assist [21.101] is compatible with Insights, however availability may be limited to certain regions. Contact your sales representative to activate XVIVO Insight and create an account for your device.

The perfusion characteristics are sent to a secure cloud database that can be accessed through the XVIVO Insights web application. The data for a specific run can be temporarily shared with XVIVO personnel to allow for remote troubleshooting.

Note that a stable 2G, 3G, or 4G mobile wireless network is required to establish a connection between the device and XVIVO Insights, as detailed in section 4.1. Depending on network coverage, signal boosters might be needed to ensure a stable connection. Explore possibilities by consulting with the local hospital infrastructure department.

4.1 Communication module specifications

The Kidney Assist is equipped with a GSM communication module that transfers the perfusion parameters of the device in use to be accessed in real time. 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:

- Radio Access Technology (RAT): LTE Cat M1, LTE Cat NB1,= 2G GPRS / EGPRS
- 4G (LTE FDD) bands: 2, 3, 4, 5, 8, 12, 13, 20 and 28
- 2G bands: 850, 900, 1800 and 1900

Modulation RAT:

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

Frequencies used:

- 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) and Band 28 (700 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

Users are not allowed to make changes to the Kidney Assist.

This system does not contain parts that can be serviced by the user, servicing can only be performed by XVIVO authorized personnel.

Replacement parts are available, to order a replacement part, see section 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.
- Safe use of the Kidney Assist can only be guaranteed when the operator is a skilled and trained professional and has successfully followed a Kidney Assist training course.
- Judgement regarding organ quality is the responsibility of the surgeon.
- Start preparation of the recipient when the machine perfusion procedure is completed.
- Any serious incident that has occurred in relation to the Kidney Assist 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
- Do not use outside prescribed operation environment, higher temperatures may lead to less efficient cooling.
- Use only manufacturer supplied sensors.
- 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.
- Maintenance and servicing of the device, including replacement of the batteries, may only be performed by XVIVO-certified personnel. This modification will void the warranty and violates the conformity assessment of the Kidney Assist.
- Do not replace the IEC power cord or fuses. This modification will void the warranty and violates the conformity assessment of the Kidney Assist.
- Discard the used device following local regulations.
- The USB cable is not allowed to be connected during perfusion.
- The device does rely on essential performance:
  - Perfusion temperature between 0°C & 43°C
  - Pressure below safety limit:
    $P(T) = 2.41 \cdot T + 40.76$
- In the unlikely event that, electromagnetic interference does occur, and degradation of the essential performance above is observed, please try one or more of the following measures:

- Increase the distance between the Kidney Assist and adjacent systems.
- Connect the Kidney Assist to an outlet on a separate circuit from that to which adjacent systems are connected.

- The POWER button on the Kidney Assist will not completely shut off the power from the device. The internal power supply of the Kidney Assist Thermo unit will still produce a low noise when the Kidney Assist is switched off.
- The mains power plug of the power supply is the separator that connects or disconnects the Kidney Assist from the mains power. Avoid positioning the equipment such that access to the mains power plug, etc. is limited (so that disconnection becomes difficult).
- Use of the Kidney Assist adjacent to or stacked with other equipment should be avoided because 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, sensors and cables other than those specified, except for replacement parts sold by XVIVO, could result in increased electromagnetic emissions or decreased electromagnetic immunity of the 'Kidney Assist' 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', including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- In the unlikely event that interruption caused by ESD discharge occurs, restart the device and confirm correct functioning. In case of malfunction, e.g. flow measurement, continue preservation using static cold storage.
- The Kidney Assist is not intended to be in contact with the patient and therefore falls outside the definition of applied part. The perfusion set is in contact with the subsequent isolated organ. However, the following parts are treated as type B applied parts since they are in direct contact with the perfusion solution:
  - Pressure sensor cables
  - Temperature sensors
  - Flow sensors
  - Magnetic pump coupling

7. Liability 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).

8.1 Alarm signals

Message	Priority	Audible Signal	Visible Signal (LED)	
Warning	**Low priority** (LP) User awareness is required, optimal perfusion compromised.	E C — — Sound pressure level: > 65 dBA @ 1m		Yellow for general, Cyan for temperature.
Error	**Medium priority** (MP) Prompt user response is required, else fallback to cold storage.	C C C — — — Sound pressure level: > 65 dBA @ 1m		Yellow for general, Cyan for temperature

The above manufacturer-configured alarms are pre-set and automatically restored after power interruption. The delay for the system to identify an alarm state is about 3 seconds.

The generation of the alarm cannot be inactivated. The audible signal can be temporarily paused by pressing the ‘pause audible alarm 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 will not automatically cease when the triggering event no longer exists; to reset the alarm, press the OK button.

On startup of the Kidney Assist, all visible alarm signals and the auditory alarm are activated shortly to verify the functionality of the alarm system.

8.2 Alarm message explanation

Table 2: Error messages

Alarm messages	Problem	Probable Cause	Solution
ERROR Check sensor FLOW:OK THERMO:OK P1:OK T1:XX T2:OK	T1 sensor disconnected, loose, or fluid ingress in connector	Connector is loose, unplugged, or affected by fluid	Reconnect the sensor and clean the connector with contact spray if fluid ingress is present.
ERROR Check sensor FLOW:OK THERMO:OK P1:XX T1:OK T2:OK	Pressure sensor disconnected, loose, or fluid ingress in connector	Connector is loose, unplugged, or affected by fluid	Reconnect the sensor and clean the connector with contact spray if fluid ingress is present.
ERROR Self-test FAILED Flowboard Rx/Tx Service required	Internal hardware problem	Failure of device	Device repair is required, contact XVIVO Service
Alarm activates directly after startup, with no warning on the display.	Watchdog failure	Non-responding software	Shutdown the device for 10 seconds and restart. If the issue persists, device repair is required, contact XVIVO Service
ERROR Pressure too high Check System	Pressure spikes	Pressure sensors not working properly. Movement of cannulas	Check pressure sensor Don't lift up the cannulas
ERROR Temperature too low Perfusion stopped	Temperature below 1 ºC	Bad temperature control	Check temperature sensors Device may require service
ERROR Temperature too high Perfusion stopped	Temperature above 42 ºC	Bad temperature control	Check temperature sensors. Device may require service
WARNING No Flow data recorded	Flow sensor measurement error	Wrong reading	Reconnect flow sensor

Table 3: Warning messages

Alarm messages	Problem	Probable Cause	Solution
WARNING Check sensor FLOW:OK THERMO:OK P1:OK T1:XX T2:OK	T1 sensor disconnected, loose, or fluid ingress in connector	Connector is loose, unplugged, or affected by fluid	Reconnect the sensor and clean the connector with contact spray if fluid ingress is present.
WARNING Check sensor FLOW:OK THERMO:OK P1:OK T1:OK T2:XX	T2 sensor disconnected, loose, or fluid ingress in connector	Connector is loose, unplugged, or affected by fluid	Reconnect the sensor and clean the connector with contact spray if fluid ingress is present.
WARNING Check sensor FLOW:XX THERMO:OK P1:OK T1:OK T2:OK	Flow sensor disconnected, loose, or fluid ingress in connector	Connector is loose, unplugged, or affected by fluid	Reconnect the sensor and clean the connector with contact spray if fluid ingress is present.
WARNING Check sensor FLOW:OK THERMO:XX P1:OK T1:OK T2:OK	Data cable disconnected, loose, or fluid ingress in connectors.	Connectors are loose, unplugged, or affected by fluid	Reconnect the data cable and clean the connectors with contact spray if fluid ingress is present.

Alarm messages	Problem	Probable Cause	Solution
WARNING Pressure not reached Set pressure revised	No pressure build-up, rpm too high, no pressure in pressure line	Perfusion level too low, pump head incorrectly placed, kink in tubing, or valve of pressure line in incorrect position	Inspect the perfusion set and cannulas for leaks. Ensure that the pressure sensor is zeroed correctly, and the valve is in the correct position (see section 0). Check for kinks in the tubing, reconnect pump head, and ensure there is perfusate in the tubing.
WARNING Pressure limit Set pressure revised	Pressure too high	High resistance	Pressing the button will result in 75% of set pump output
WARNING Flow limit reached	Flow too high	Low resistance	Inspect the perfusion set and cannulas for leaks. Ensure that the pressure sensor is zeroed correctly, and the valve is in the correct position (see section 0). Check for kinks in the tubing, reconnect pump head, and ensure there is perfusate in the tubing.
WARNING Temperature limit Check System	Temperature range is outside 3 ºC of set temperature	Obstructed thermo tubing or (low) perfusion flow	Ensure the thermo unit, thermo tubing, and oxygenators are de-aired properly (see section 2.3 and 2.8.7), and flow indicators are spinning fast enough (see 2.8.7). Add ice to the Thermo unit to cool down.
WARNING In/out temp gap >XºC Check perfusion flow	T2 sensor disconnected from perfusion set. Flow too low	Temperature T2 sensor not connected to perfusion set. Obstructed thermo tubing or (low) perfusion flow	Ensure the thermo unit, thermo tubing, and oxygenators are de-aired properly (see section 2.3 and 2.8.7), and flow indicators are spinning fast enough (see 2.8.7). Check connection temperature T2 sensor in perfusion set. Check for sufficient perfusate flow
WARNING Water level low Fill THERMO UNIT	Level too low in Thermo unit	Loose or open connection	Inspect the thermo tubing for leaks. Ensure the data cable is connected properly. Fill Thermo unit with water
WARNING Perfusion level low. Add perfusate	Level too low or bad connection flow sensor	No or not enough fluid. Loose, open or bad connection	Ensure there is perfusion solution in the perfusion set. Moisten the flow sensor on the tubing interface
WARNING Mains disconnected Battery X% Connect power cable	Power plug not connected. Broken cable	Disconnected cable. Wear and tear	Plug the power cord to the wall outlet and device Replace cable. Try a different mains outlet
WARNING Battery power low Battery X% Connect power cable	Battery nearly empty while running on battery	Device disconnected from mains power. Wear and tear	Plug the power cord to the wall outlet and device. Replace power cable.

Alarm messages	Problem	Probable Cause	Solution
WARNING Battery power low Battery X%	Power plug connected but battery power low, compromised backup.	Battery not charged after running on battery. Device not connected to mains for a long time	Keep the device connected to the wall outlet and let the battery continue to charge.
WARNING Flow Board Service advised	Internal hardware problem	Failure of device	Perfusion may continue, as there is no safety risk. However, device repair is required, contact XVIVO Service
WARNING No Flow data recorded	Internal hardware problem	Failure of device	Perfusion may continue, as there is no safety risk. However, device repair is required, contact XVIVO Service
WARNING Backup battery Damaged	Battery cannot hold charge	Damaged battery	Perfusion may continue, as there is no safety risk. However, device repair is required, contact XVIVO Service

8.3 Probable causes

Problem	Probable Cause	Action
Unrecoverable perfusion	Failure of device	Continue preservation using static cold storage
No power	No Power at outlet Fuse blown	Make sure outlet has power Call XVIVO service
Beeping or flashing LEDs	Errors detected by the Kidney Assist	Follow the instructions in section 8.2, Fault Message Explanation.
Pump not working correct	Defect pressure sensor	Replace pressure sensor
	Air in pump head	Prime the pump head/perfusion set
	Pump head not correctly coupled to pump motor	Reconnect pump head
	Pump defect	Call XVIVO service Continue preservation using static cold storage
Pump is unable to reach pressure set point	Pump is running on battery power	Make sure outlet is connected with AC power (the power LED on the Thermo unit will be unlit if no AC power is available)
Thermo unit non-functioning	No power at outlet Data cable not (correctly) connected	Ensure the thermo unit, thermo tubing, and oxygenators are de-aired properly (see section 2.3 and 2.8.7), and flow indicators are spinning fast enough (see 2.8.7). Make sure outlet is connected with AC power (the power LED on the Thermo unit will be unlit if no AC power is available) Fasten the data cable connector until it holds firmly
Pump Error	Pressure sensor incorrect connected Fluid ingress in pressure sensor/ pressure sensor extension cable Bad magnetic connection Pump failure	Reconnect pressure sensor Clean pressure sensor extension cable connectors Reconnect pump-head Call XVIVO service Continue preservation using static cold storage
Temperature does not change	No water, too much air in water tubing and Thermo unit.	Ensure the thermo unit, thermo tubing, and oxygenators are de-aired properly (see section 2.3 and 2.8.7), and flow indicators are spinning fast enough (see 2.8.7).

Missing or incorrect display elements at power-on	Display or internal computer failure	Power off, wait for 1 minute and power on Disconnect & reconnect mains power, Power “On” If problem not solved, call XVIVO service
Leaking perfusate	Loose fitting or defective perfusion set.	Retighten the fittings
Leaking Thermo unit water	Bad connection of tubing to Thermo unit	Retighten connection
Power on, but buttons are unresponsive	Data cable not (properly) connected to both Kidney Assist units. Kidney Assist is internally locked-up	Reconnect the data cable on the back panel of the Kidney Assist Power off, wait for 1 minute and power on Disconnect & reconnect mains power. Power “On”
No flow reading	Flow sensor wrong connected. Bad connection with tubing	Connect flow-sensor with the arrow facing the same direction as the flow through the tubing Use ultrasound gel (or water) between sensor and tubing.

9. Product specifications

Device specifications	
Perfusion pump:	Rotary pump, pulsatile 60 BPM
Perfusion flow:	up to 569 ml/min @ 12 °C / up to 1 L/min @ 37 °C
Perfusion pressure:	Up to 50 mmHg @12°C / up to 90 mmHg @ 37 °C
Perfusion temperature:	12 °C - 37 °C or full cooling mode
Accuracy:	Pressure: ± 12% or 1 mmHg Temperature: ± 2°C Flow: of ±20% or ±0,07 L/min
Perfusion solution:	Any certified machine perfusion preservation solution (2-4 L)
Displayed:	Perfusion time, flow, pressure, temperature, reservoir temperature, vascular resistance, menu, messages
Alarm:	Alarm sound level pressure: 65 dB(A)
Battery capacity:	20 minutes (Lithium-ion Battery, 10.8V / 9220mAh / 99.6Wh)
Battery charging:	Self-charging if connected to Mains (min. 8 h)
Power:	AC 110V/60 Hz or 230V/50 Hz 740 VA
Fuse pump unit:	Littlefuse: 0215002.txp 2AT 250V HBC
Fuse thermo unit:	Littlefuse: 0215008.txp 8AT 250V HBC
Maximum load on table top:	15 kg, including organ and perfusion solution
Transport conditions:	Temperature: -20 - 60°C (Kidney Assist) Temperature: -20 - 50°C (Kidney Assist Perfusion Set) Humidity: 5 - 95 %RH non-condensing Atmospheric pressure: 50 kPa to 106 kPa
Storage conditions:	Temperature: 10 - 30°C Humidity: 5 - 85 %RH non-condensing Atmospheric pressure: 50 kPa to 106 kPa
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:	1120 mm x 925 mm x 625 mm
Weight:	68 Kg
Ingress protection:	IP20
Alarms:	Perfusion temperature between 0°C & 43°C Pressure below safety limit: P(T)=2.41·T+40.76

10. Ordering information

The following Kidney Assist parts, accessories and perfusion sets can be (re)ordered:

Item	Order number
Kidney Assist	21.101
Pump unit	21.201
Thermo unit	21.203
Trolley	21.204
Kidney Assist Perfusion Set	21.401
Device cover	05.212
Temperature sensor blue	05.301
Temperature sensor red	05.302
Flow sensor ¼”	05.303
Pressure extension cable	05.01.317
Perfusion adapter – small	05.508
Perfusion adapter – medium	05.509
Perfusion adapter – large	05.510
Cannula for organ perfusion - 8 Fr	05.507
Cannula for organ perfusion - 10 Fr	05.503
Cannula for organ perfusion - 12 Fr	05.504
Thermo water tubing set	05.325
Thermal cover	05.331
Training	21.801
Regular maintenance	05.802
Sample holder (for front Thermo unit)	05.01.330
Sample manifold holder	05.217
Oxygenator holder	11.328

See last page for address information or send your request to: order.xnl@xvivogroup.com

11. Disposal

The Kidney Assist is subject to the European directive 2012/19/EU on waste electrical and electronic equipment (WEEE). Do not dispose of the device yourself. If users in the European Union wish to discard the device at the end of its useful life, contact XVIVO to arrange a retrieval of your Kidney Assist. 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.

Local regulations must be followed for the disposal of the Kidney Assist 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

12.1 MDR declaration

Classification to EU- 2017-745 (MDR)	Class IIb
Classification to IEC 60601-1	Class I
Protection against electrical shock	Type B
Software Classification IEC 62304	Class B
Regulations:	Medical Device Regulation (MDR), EU 2017/745 EU Directive 2011/64 & 2015/863 (RoHS) EU Regulation 1907/2006 (REACH) EU Directive 2014/53 (RED)
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

GPS module, Ublox SARA-R412M:

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

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.

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

12.2 EMC declarations

- Declaration on electromagnetic emissions (Table 1),
- Declaration on electromagnetic immunity (Table 2),
- Declaration on RF wireless communication equipment immunity (Table 3),
- Declaration on proximity magnetic fields immunity (Table 4).

Table 1. Guidance and manufacturer's declaration – electromagnetic emissions		
The Kidney Assist is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions test–guidance	**Compliance**	**Electromagnetic environment**
RF emissions CISPR11 (EN 55011)	Group 1	The Kidney Assist uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11 (EN 55011)	Class A	The emissions characteristics of the Kidney Assist make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2. Guidance and manufacturer's declaration – electromagnetic immunity			
The Kidney Assist is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100KHz for power supply lines ±1 kV for input/ output lines	±2 kV 100KHz for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 & ±1 kV line(s) to line(s) ±0,5, ±1 & ±2 kV line(s) to earth	± 0,5 & ±1 kV line(s) to line(s) ±0,5, ±1 & ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25/30 cycles 0% U 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 70% UT for 25/30 cycles 0% U for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Kidney Assist requires continued operation during power mains interruptions, it is recommended that the Kidney Assist be powered from an uninterruptible power supply or a battery. * Temporary, self-recoverable loss of function is allowed.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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	3V 0,15 to 80 MHz 6 V in ISM bands between 0,15 & 80 MHz 80 % AM at 1 kHz	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	3 V/m see table 4	3 V/m 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

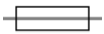
The Kidney Assist is intended for use in the electromagnetic environment specified below.
The customer or the user of this device should assure that it is used in such an environment.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Compliance level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band	Pulse modulation 217 Hz	28

1845		1, 3, 4, 25; UMTS		
1970				
2450	2450 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	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 – proximity magnetic fields		
The Kidney Assist is intended for use in the magnetic field environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Test frequency	**Modulation**	**Immunity test level (A/m)**
30 KHz	CW	8
134,2 KHz	Pulse modulation 2,1 KHz	65
13,56 MHz	Pulse modulation 50 KHz	7,5

13. 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 2797	CE mark and Notified Body number (Medical Devices Regulation 2017/745/EU)
	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)
	Stand-by button (IEC 60601-1, symbol D.1 - 29)
$IP_{N_1N_2}$	Ingress protection (IEC 60601-1, symbol D.3 - 2)
	Identification of USB-port (ISO 7000-3650)
	To ensure grounding reliability, use hospital or commercially grounded electrical connections only (IEC 60601-1, symbol D.1 - 6 / IEC 60417-5019)
	Equipotentiality connection. (IEC 60601-1, symbol D.1 - 8 / IEC 60417-5021)
	Replaceable fuse, specific type, current and voltage ratings noted above this symbol. (IEC 60417, symbol 5016)
	Keep dry (ISO 15223-1, symbol: 5.3.4)

	Fragile, handle with care (ISO 15223-1, symbol: 5.3.1)
	This side up (ISO 7000 – 0623)
	Storage condition, temperature limit (ISO 15223-1, symbol: 5.3.5)
	Storage condition, humidity limitation (ISO 15223-1, symbol: 5.3.8)
	Storage condition, atmospheric pressure limitation (ISO 15223-1, symbol: 5.3.9)
	Importeur / importateur / importatore (ISO 15223-1, symbol: 5.1.8)
	Important information
	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)

14. Appendix B: Abbreviations

A	Amperes
AC	Alternating current
BPM	Beats per minute
°C	Degrees Centigrade
CE	Conformité Européenne
cm	Centimeter (1 cm = .01 m)
DC	Direct current
EMC	Electromagnetic compatibility
EU	European Union
h	hour
Hz	Hertz
IEC	International Electrotechnical Commission
kg	Kilogram (1 kg= 1000 g = 2.2 lbs)
KPa	Kilopascal (1 Pa = 0,01 millibar)
L	Liter (1L =0.001 m^3)
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MDD	Medical Device Directive
min	minute
mL/min	Milliliters per minute (1 mL/min = 0.00006 m^3/sec)
mmHg	Millimeters of mercury (1 mmHg = 1 torr = 133.3 Pa)
P	Pressure
Q	Flow
RH	Relative humidity
T	Temperature
V	Volts
VR	Vascular Resistance

Notes:

Notes:

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