Instructions for Use

Kidney Assist

XVIVO

Figure 1 Kidney Assist, with pump unit, thermo unit, and disposable holder connected to the trolley

Content

1. Product description

The Kidney Assist, from XVIVO B.V. (referred as “XVIVO”), is a pump system providing temperature controlled oxygenated isolated perfusion of donor kidneys to bridge the time span between donor nephrectomy and kidney transplantation in the recipient.

The Kidney Assist is a modular system consisting of four main modules:

- Pump unit
- Thermo unit
- Trolley including table top
- Disposable set

The Kidney Assist may only be used with the following disposable set: 21.401.

The following reusable accessories are included with the Kidney Assist:

- Power cord thermo unit
- Power cord between the pump unit and thermo unit
- Data cable between pump unit and thermo unit
- Pressure sensor cable
- Temperature sensors (2x)
- Flow sensor
- Instructions for Use
- Thermo water tubing
- Water tubing couplers (2x)

1.1 Intended use

The Kidney Assist is intended to be used for isolated temperature-controlled ex-vivo pulsatile oxygenated machine perfusion of donor kidneys, for a period up to 6 hours.

1.2 Kidney Assist

1.2.1 Pump unit

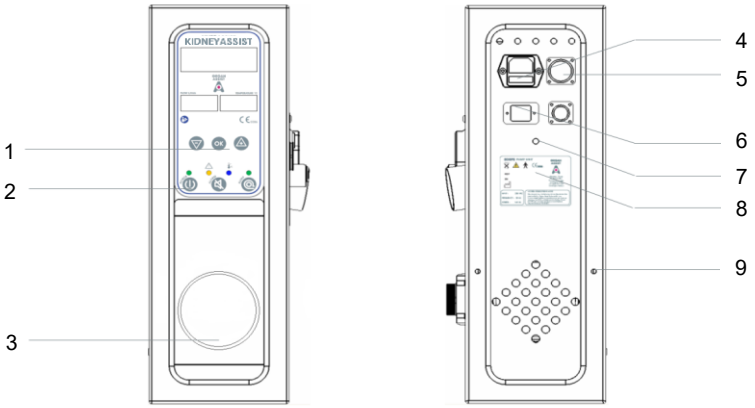


Figure 2 Front and rear view of the pump unit.

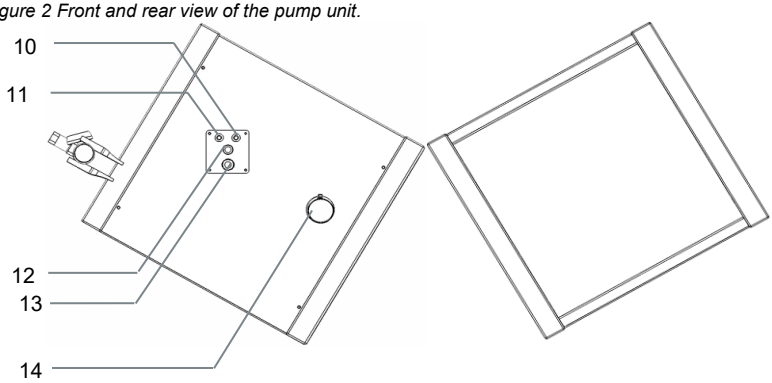


Figure 3 Right and left-hand side view of the pump unit

1. Control panel
2. Oxygen cylinder
3. Oxygen cylinder compartment
4. Electrical power inlet
5. Data cable connection
6. USB connection
7. Equipotentiality pin
8. Product label
9. Screw joint
10. Reservoir temperature connection (T_2)
11. Perfusion temperature connection (T_1)
12. Pressure sensor cable connection
13. Flow sensor connection
14. Magnetic pump coupling

1.2.1.1 Control Panel

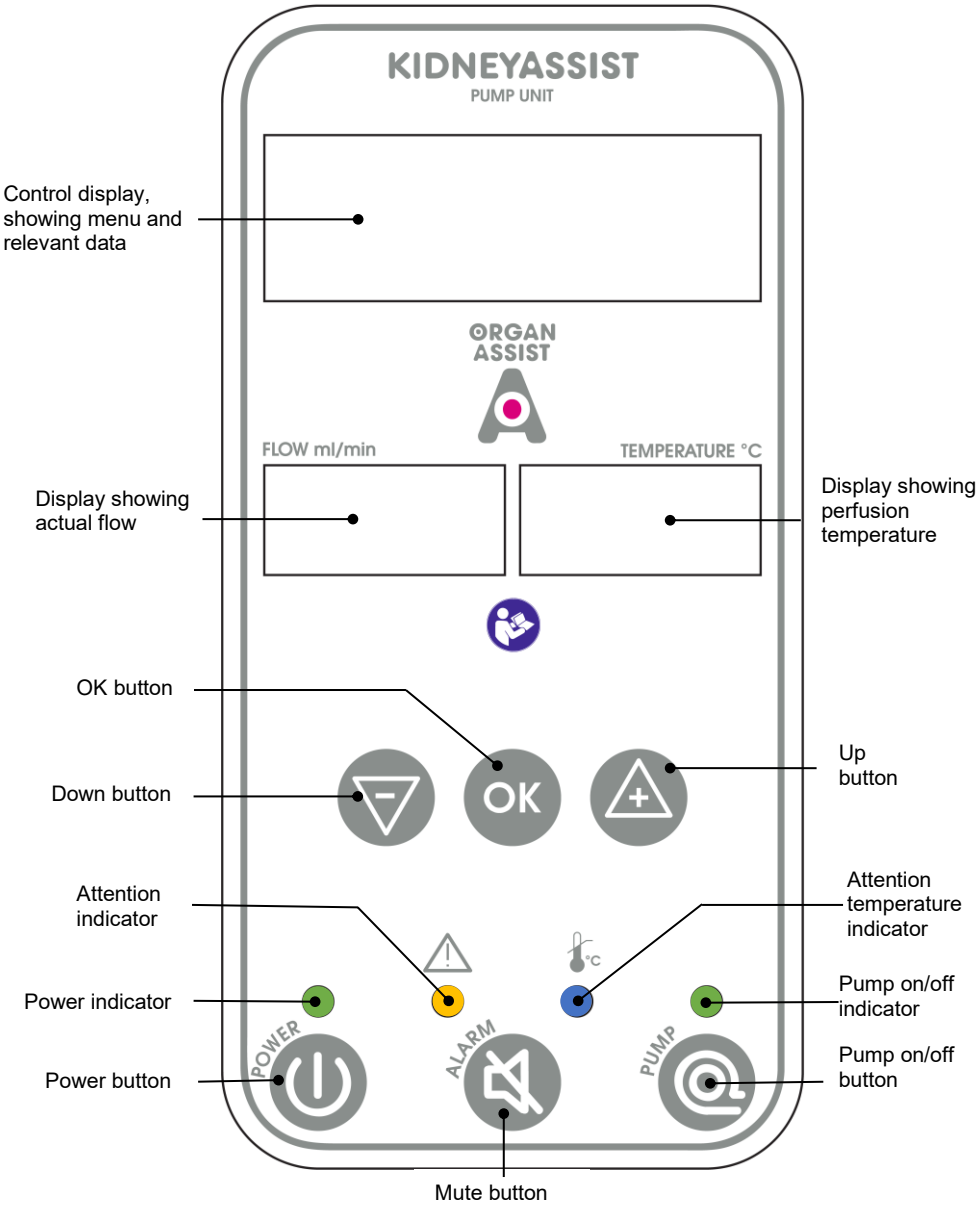


Figure 4 Control panel pump unit

1.2.2 Thermo unit

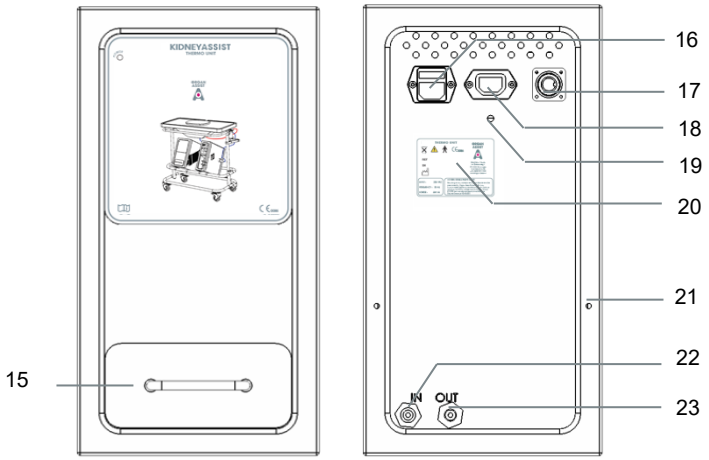


Figure 5 Front and rear view of the thermo unit

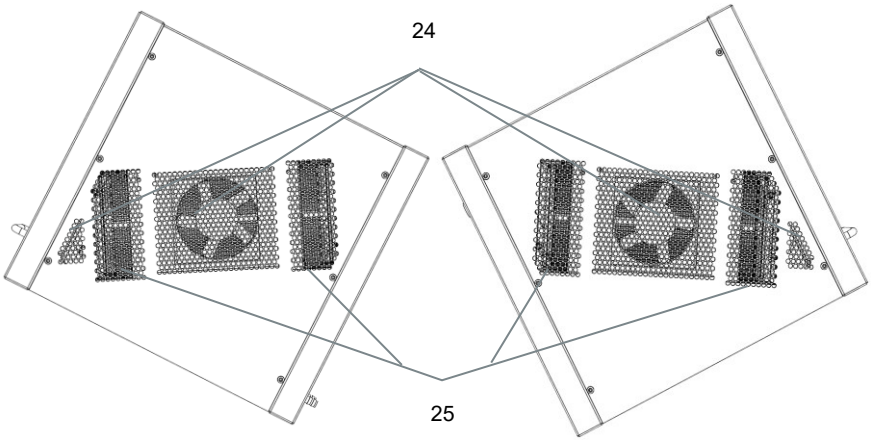


Figure 6 Right and left-hand side view of the thermo unit

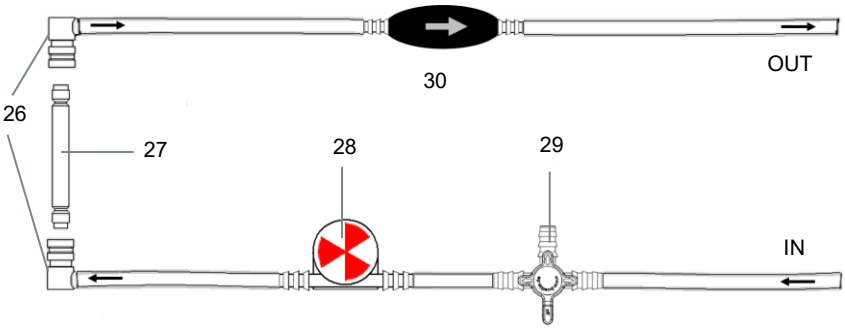


Figure 7 Accessories thermo unit; quick-connect thermo water connectors, flow indicator, thermo water coupling tube and tubing

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

1.2.3 Trolley

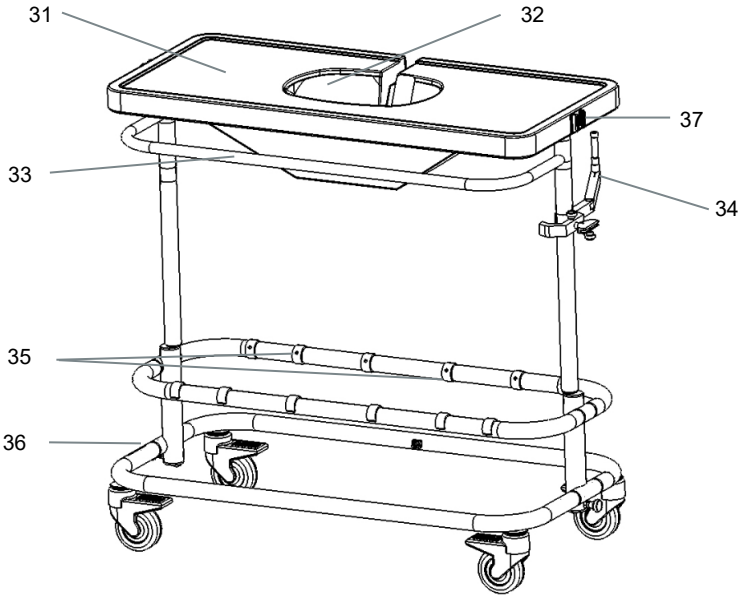


Figure 8 Trolley

31. Table
32. Organ reservoir holder
33. Push Bar
34. Oxygenator holder
35. Screw holes for connection of pump and thermo unit
36. Product label
37. Pressure sensor holder

1.2.4 Disposable set

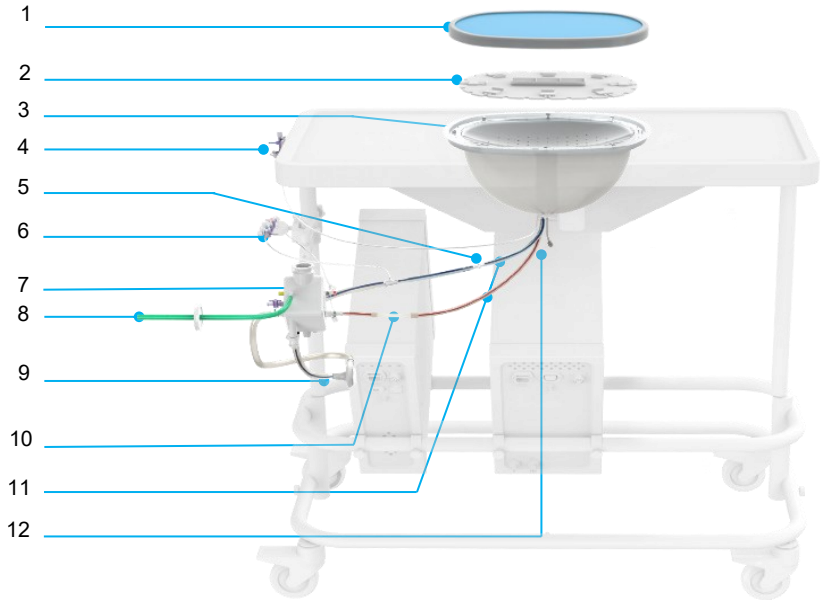


Figure 9 Disposable set

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

Additional components not shown in Figure 9

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

1.3 Ordering information

The following Kidney Assist parts, accessories and single use disposables can be (re)ordered:

Item	Order number
Kidney Assist	21.01.101
Pump unit	21.01.201
Thermo unit	21.01.203
Trolley	21.01.204
Kidney Assist Perfusion Set	21.401
Device cover	05.212
Temperature sensor blue	05.01.301
Temperature sensor red	05.01.302
Flow sensor ¼"	05.01.303
Perfusion adapter – small	05.01.508
Perfusion adapter – medium	05.01.509
Perfusion adapter – large	05.01.510
Cannula for organ perfusion - 8 Fr	05.01.507
Cannula for organ perfusion - 10 Fr	05.01.503
Cannula for organ perfusion - 12 Fr	05.01.504
Thermo water tubing extern	05.01.325
Training	21.01.801
Basic maintenance	05.01.802

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

1.4 Product specifications

Perfusion specifications	
Perfusion pump:	Rotary pump, pulsatile 60 BPM
Perfusion flow:	Up to 1000 ml/min
Perfusion pressure:	Up to 50 mmHg @12°C Up to 90 mmHg @37 °C
Perfusion temperature:	User set temperature: 12 °C - 37 °C Full cooling mode target range: 1 °C - 12 °C
Accuracy:	Pressure: ± 1.5% or 1 mmHg Flow: ± 0.07 L/min Temperature: ± 1°C
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: 65dB(A)
Battery capacity:	20 minutes (Lithium-ion Battery, 11.25V / 8850mAh / 99.6Wh)
Battery charging:	Self-charging if connected to Mains (min. 8 h)
Power:	AC 110V/60 Hz or 230V/50 Hz 740 VA
Fuses (HA/PV):	Littlefuse: 0215002.txp 2AT 250V HBC
Fuses thermo unit:	Littlefuse: 0215008.txp 8AT 250V HBC
Maximum load on table top:	15 kg, including organ and perfusion solution
Transport & storage conditions:	5 - 40°C (41°F to 104°F), 30 - 85 %RH Atmospheric pressure: 50,0 kPa to 106,0 kPa Do not expose the device to direct sunlight or strong artificial light
Operating conditions:	Room temperature 18-24°C C (64°F to 75°F); 30 - 85 %RH Atmospheric pressure: 70,0 kPa to 106,0 kPa Background noise level: < 50dBA Do not use the device in a poorly ventilated area
Product life time	7 years
Dimensions:	1120 mm x 925 mm x 625 mm
Weight:	68 kg
Ingress protection:	IP20

2. Installation

The complete Kidney Assist is shipped in separate cardboard packages. The device has to be unpacked and checked by the authorized person responsible.

- Set the trolley in the correct position (Figure 1).
- Position the pump and thermo unit on the trolley.
- Secure each unit with 2 bolts to the trolley (35).
- Attach the aluminum holder (34) for the disposable system to right hand side of the trolley and secure the holder using the screw clamp.
- Connect supplied data cable to the Kidney Assist unit using the data connector on the back panel of the Kidney Assist (5 and 17).
- Connect power cord to the IEC inlet located on the back panel of the thermo unit (18).
- Connect power cord to pump unit and thermo unit (4 and 16).
- Connect power cord to the mains connection.
- Disinfect the thermo unit as described in section 4.2.

The mains should be easily accessible to disconnect the device from mains.

Do not replace the IEC power cord by using another cord directly connected to the mains supply. This modification will void the warranty and violates the conformity of the Kidney Assist with the requirements of the Medical Device Directive 93/42/EEC.

Do not block the air intake vents and air outlet vents of the thermo unit.

3. Operation

3.1 Preparing the perfusion procedure

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

- Power on the Kidney Assist by pushing the power button on the control panel.
- Press the OK-button to activate the setup procedure.

Connect DISPOSABLE

Press to continue

⚠ A sequence of message screens will guide you through set-up and running. Extra messages will pop-up when actions are required, see section 6.1

- Unpack a sterile perfusion circuit.
- Place the organ reservoir into the holder of the table.
- Place the oxygenator on the holder (Figure 10).

Figure 10: Connection of oxygenator to the holder

- Before placing 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 sides of the Kidney Assist pump units (Figure 3, item 14). Push the pump head in the coupling and turn the pump head to lock it, see Figure 11, ensure it is placed correctly. The outlet of the pump heads shall be orientated horizontal to easily de-air the pump heads.

Figure 11 Connection of pump-head

- Connect the oxygenator to the oxygen supply using the green tube with the incorporated gas filter. If planning to take samples of the perfusion fluid during the perfusion, connect the separately packed sample lines to the circuit. The orientation of the sample line in the perfusion circuit is colored 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 liver reservoir outlet tubing with the blue cap. Make sure to connect it tightly and to maintain sterility.
- Connect the thermo water tubing to the oxygenators using the water connectors (26).

3.2 Gas supply:

It is preferable to make use of the gas supply of the operating theatre. Consult the instructions of the oxygenator for requirements of the oxygen supply.

When there is no oxygen/gas supply 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. Set a recommended gas flow/perfusion fluid flow ratio of 0.5:1 - 2:1, with maximum gas flow rate of 5.6L/min.

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

- Place the pressure sensor into the pressure sensor holder at the side of the table (37).
- Connect the pressure sensor cable to the pump unit (12) and to the pressure sensor.
- Connect temperature sensors (10 and 11) according to the color coding (Figure 12).
- Connect the T1 sensor to the oxygenator outlet (Figure 9).
- Connect the T2 sensor (blue) to the perfusion line (Figure 14).
- Connect the flow sensor (13), Figure 13.
- Make sure to connect the sensor connection with the red dot facing upwards.

Every sensor is different and is not interchangeable. Connect the sensors to the right sub connectors, else it could cause damage.

Do not spill any fluid on the electronic connectors; this may cause a deviation of the measured values or to an alarm.

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

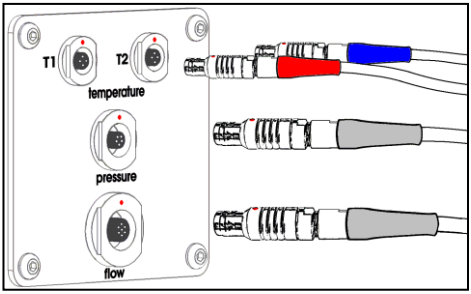


Figure 12 Connecting the sensors

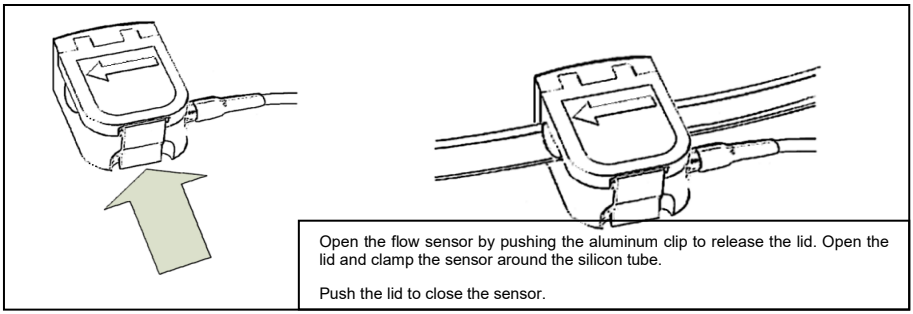


Figure 13 Connection of flow sensor to disposable system

Make sure that the arrow on the flow sensor is facing the same direction of the flow through the tube (towards the reservoir). Wrong connection of this sensor will not give a correct flow measurement.

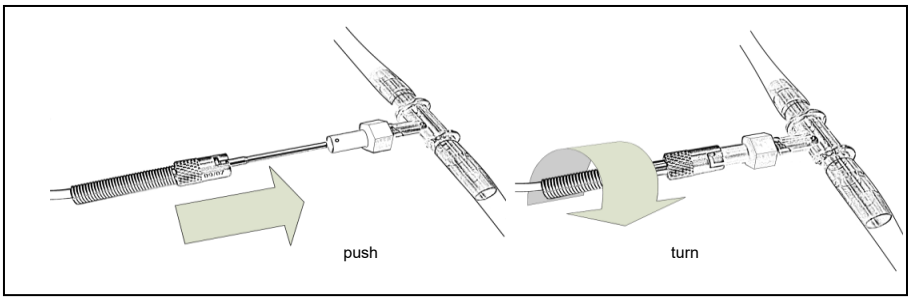


Figure 14 Connection of the temperature sensor to the disposable system

- To fill the circuit; connect the separately packed filling line to the oxygenator, see figure 15. Take care to connect it tightly and maintain sterility.
- Remove the yellow de-airing cap on the oxygenator, see Figure 15. Do not discard the yellow cap, store carefully.
- Fill the system with the preferred perfusion solution (min. 2 L) via the filling line. After filling, close the filling line by the clamp and the swivel valve to avoid unintended leakages.

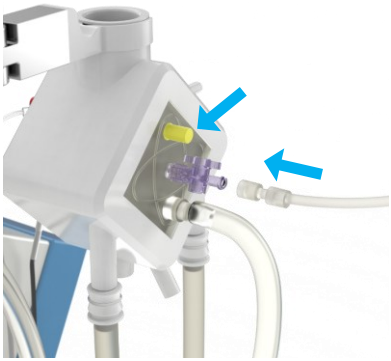


Figure 15 Connection of filling line

- When the system is filled properly, press OK-button to proceed.

In the Kidney Assist use certified machine perfusion solution only.

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.

Using other solutions than machine perfusion solution with the Kidney Assist may result in organ damage or the cause of complications.

PRIMING SYSTEM
Press -/+ to adjust
Pump output: .. %
Press to continue

- Press the up- and down-buttons of the pump unit to variate the flow speed. Variation of the pump output will remove air from the tubing of the disposable circuit.
- De-air the oxygenator via the de-airing valve if no sample line is connected to the oxygenator. If a sample line is connected to the oxygenator de-air the oxygenator via the sample line.
- First remove the cap on the de-airing valve or sample line. Turn the red de-air valve 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 de-airing valve or the sample line.
- If applicable, de-air both sides of the sample line.
- Replace the yellow cap on the oxygenator.
- Press OK button to proceed to the next step.

Please note that the pump unit is able to read the status of the thermo unit.

- Connect the water tubing (26) to the oxygenator.
- Fill the water reservoir (15) of the thermo unit (2-3 L).
- Use the thermo tubing de-airing balloon (30) to start an initial circulation in the thermo tubing.

⚠ Make sure that the thermo water pump never runs dry! Only use demineralized water (optional ice) in the thermo reservoir.

Pressure zeroing
Turn transducer
Valve
Press to continue

- Remove the cap on top of the pressure sensor and place a sterile syringe on the port (Figure 16).
- To remove all air from the pressure line, pull the blue snap tab while aspirating with a syringe. Stop when all air has been removed.
- Place the cap back on the pressure sensor.
- Turn the valve on the pressure sensor downwards to open the sensor to measure atmospheric pressure (Figure 16).
- In the pump unit menu, press the OK button to zero the sensor to atmospheric pressure. This step will take a few seconds.

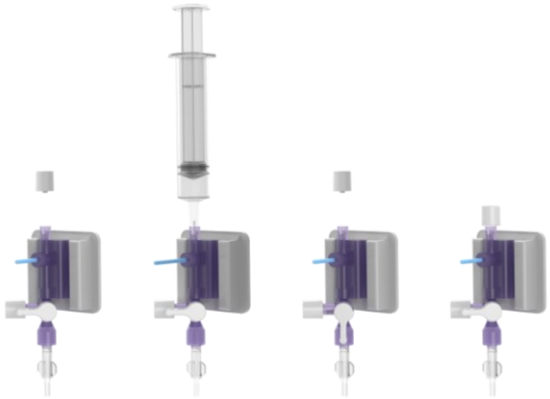


Figure 16 Priming and zeroing of the pressure sensor

⚠ Before continuing to the next step, please ensure that the pressure sensor valve is in the correct position (Figure 16).

Set Temp Setpoint
Press +/- to adjust
Value: .. °C
Press to continue

- Set the preferred temperature of the perfusion solution by using the up- and down button.
- Press OK-button to confirm and to proceed to the next step.

Set Pressure Setpt
Press -/+ to adjust
Value: .. mmHg
Press to continue

- Set the preferred perfusion pressure of the pump unit.
- Press the OK-button to confirm and to proceed to the next step.

⚠ Before continuing to perfusion, please ensure that all connections of the perfusion circuit are free of leakages.

3.3 Perfusion procedure

- Turn on the oxygen supply and adjust oxygen flow such that required saturation is reached (please check the user manual of the oxygenator for maximal flow).
- Cannulate the renal artery by connection of a perfusion adapter with the aorta patch or renal artery cannulation.
- The urether can be cannulated and connected to the urine collecting tube via an extension tube.
- Open the sterile drape to create a sterile area.
- Place the kidney into the reservoir.
- De-air and connect the adapter of cannula to the inlet tubing.
- Start perfusion by pressing the OK-button.
- Close reservoir with the lid.

3.3.1 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 17. Permittable flows at varying temperatures are shown in Figure 18.

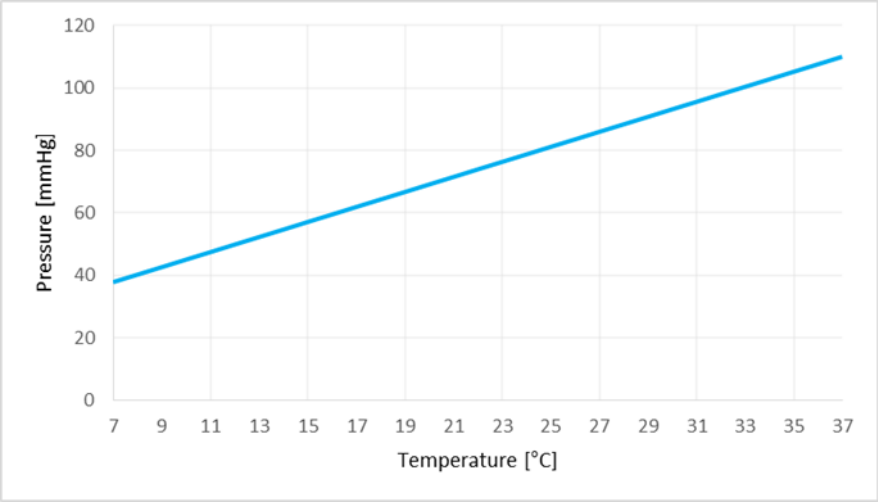


Figure 17Pressure limits at varying temperatures

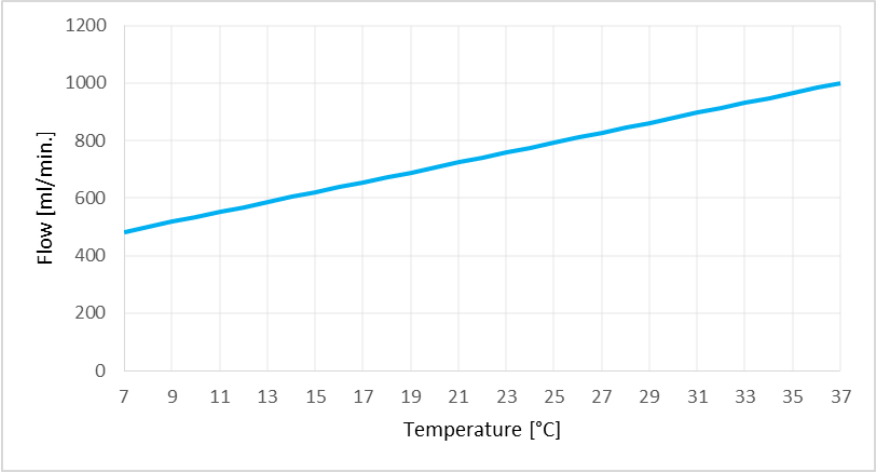


Figure 18 Flow limits at varying temperatures

When using small cannulas (<24Fr), be aware of the pressure drop. See Figure 19 for corrections.

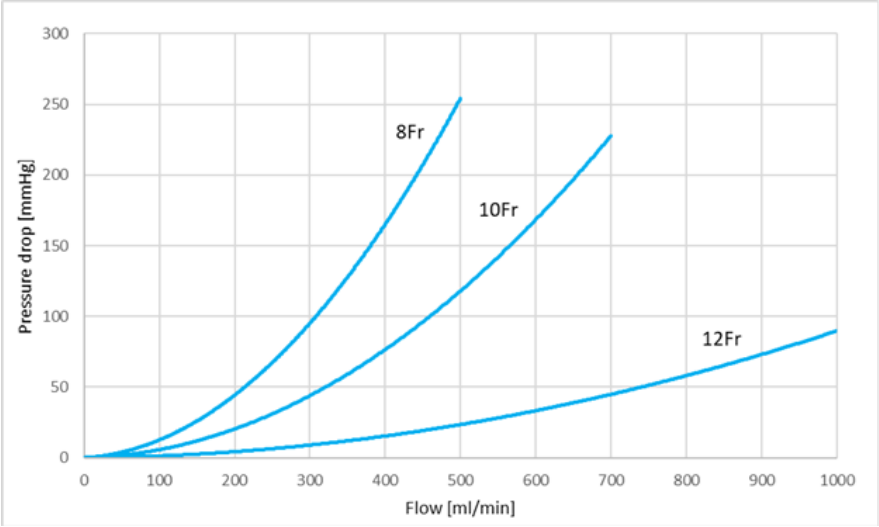


Figure 19 Pressure loss corrections

- During perfusion the measured values will appear on the display.

Running: 00:15:27
T Return: .. °C
Pressure: .. mmHg
VR: .. mmHg/mL/min

After the perfusion procedure is started, please check all connections and check if the present flow and pressures are as intended. Make sure that the device works as intended and does not resonate, produces extreme noise or shows other shortcomings.

When an error or malfunction appears, please review the troubleshooting section (section 6). If the troubleshooting section does not solve your problem, please call qualified service personnel or contact XVIVO.

If perfusion is unrecoverable, continue preservation using static cold storage

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

Set Pressure Setpt
Press +/- to change
Value: .. mmHg
Press to continue

- During perfusion, the pressure and temperature set point can be changed by pressing the OK-button.
- To change the pressure, press the OK- button and use the up and down button until the preferred value appears on the display and confirm by pushing the OK-button.
- Subsequently the temperature can be changed, use the up and down button to set the preferred value and confirm by pushing the OK-button.

Set Temp Setpoint
Press +/- to change
Value: .. °C
Press to continue

- Powering off the Kidney Assist will reset all values back to the manufacturer's settings.
- Note that the preferred pressure might not be reached due to the maximum system flow delimiter, to prevent damage or treatment loss due to high perfusion flows. This value is a preset safety value and cannot be changed.

3.4 Stopping the operation

- Switch off the pump unit by pressing the pump button.
- Switch off the whole system by pressing the power button.
- Turn off the oxygen supply.
- Remove the kidney from the reservoir.
- Disconnect the sensors from the disposable set. Gently pull the connectors out of their sockets in a straight motion to avoid damage.
- Remove the used disposable set.
- Discard the used disposable as medical grade waste, following local regulations.
- Connect the water tubing using the supplied water tubing coupler (27) to prevent against unwanted water leakage.

DO NOT REUSE Kidney Assist Perfusion Sets

The tubing, tubing-sets, pump head, oxygenator and reservoir are intended for single-use only. After use, they should be disposed of in accordance with local guidelines for biomedical waste material.

The temperature sensors, flow sensor and pressure sensor cable are reusable, make sure to separate them from medical waste disposal after use!

4. Cleaning

4.1 After every procedure

- Clean the exterior of the device with a non-aggressive cleaning fluid or detergent to remove all inequities.
- Allow to air dry and inspect for damage or deterioration of the surfaces.
- Do not use any abrasives as this will damage the surface of the device.
- When the device is used on a regular basis, please keep it connected to mains to reload the batteries
- Drain, disinfect and decalcify the water reservoir on a regular basis, see sections 4.2 and 4.3, to guarantee optimal performance of the device.

4.2 Weekly: disinfection thermo unit

1. Wear protective gloves and goggles during the disinfection process.
2. Create 2 liters of 0.5% Chloramine-T solution(DISIFIN, Halamid or Chlorina),; follow instructions of the disinfectant manufacturer (for example: 4 DISIFIN tablets in 2 liters of demineralized water (www.disifin.co.uk)).
3. Drain the water from the thermo unit and water tubing using the 3-way tap (29). After drainage close the 3-way tap.
4. Clean the white connectors (26), water tubing coupler (27), 3-way tap and lid of thermo unit reservoir (15) 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 sensors:
   - Connect the flow sensor, temperature sensors and pressure sensor cable to the pump unit.
   - Submerge the flow sensor in a cup with tap water.
   - Connect separate pressure sensor e.g. from a used disposable set or new standard pressure sensor (e.g. Edwards TruWave).

   Note: No need to connect a complete disposable system!
8. Connect power cable of the device to mains.
9. Power on the pump unit.
10. Skip through setup procedure by pushing the OK-button on the pump unit. Push until the display shows ”pressure zeroing”. (During this step the thermo unit is switched on automatically)
11. **Circulate disinfection solution** for 30 minutes at room temperature; check if the red flow indicator wheel (28) is spinning to ensure flow.
12. Power off the pump unit and drain thermo unit and water tubing (*see step 3*).
13. **First Rinse**: Add 2 liter 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 9 and 10 to start the circulation)*

14. Power off the pump unit and drain the thermo unit and water tubing (*see step 3*).
15. **Second Rinse**: Add 2 liter 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 9 and 10 to start the circulation)*
16. Power off the pump unit and drain the thermo unit and water tubing (*see step 2*).
17. Fill the thermo unit with 2 liters of demineralized water to prepare the unit for next use.

4.3 Yearly: decalcifying thermo unit

1. Connect water tubing coupler in thermo water circuit.
2. Drain the thermo unit and water tubing using the 3-way tap (29). After drainage close the 3-way tap.
3. Prepare 2 liter of decalcifying solution specific for apparatus or (coffee) machines (for example diluted citric acid), use prescribed dilution in demineralized water.
4. Add 2 liter of decalcifying solution to the thermo unit reservoir (15).
5. Wait for half an hour.
6. While waiting, connect the sensors:
   - Connect flow sensor, temperature sensors and pressure sensor to the pump unit.
   - Submerge the flow sensor in a cup with water.
   - Connect separate pressure sensor e.g. from a used disposable set or new standard pressure sensor (Edwards Truwave).

   Note: No need to connect a complete disposable system!
   After the waiting time,
7. Power on the pump unit.
8. Skip through setup procedure by pushing the OK-button on the pump unit. Push until the display shows ”pressure zeroing”. (During this step the thermo unit is switched on automatically)
9. **Circulate decalcifying solution** for 20 minutes at room temperature; check if the red flow indicator wheel (28) is spinning to ensure flow.
10. Power off pump unit and drain thermo unit and water tubing (*see step 2*).
11. **First Rinse**: Add 2 liter 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 7 and 8 to start the circulation)*
12. Power off the pump unit and drain the thermo unit and water tubing (*see step 2*).
13. **Second Rinse**: Add 2 liter 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 7 and 8 to start the circulation)*
14. Power off the pump unit and drain the thermo unit and water tubing (*see step 2*).
15. Fill the thermo unit with 2 liters of demineralized water to prepare the unit for next use.

Do not allow cleaning solutions to enter the air vents, back panel electrical connectors, ventilation holes or the temperature, pressure or flow-sensor connection at the side panel of the Kidney Assist.

5. General safety instructions

- Federal law restricts the sale of this device to physicians and medical professionals only.
- Read these instructions and the instructions of the disposable set thoroughly before use.
- 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 of the measurement results regarding organ quality are of the responsibility of the user.
- Start preparation of the recipient when the machine perfusion procedure is completed.
- The Kidney Assist uses externally supplied electricity to operate. Connect the Kidney Assist to a grounded electrical outlet rated for voltage and amperage according to the labeled ratings on the product back panel.
- The POWER button on the Kidney Assist will not completely shut off all power from the device. The power supply of the Kidney Assist thermo unit will still produce a low noise when the Kidney Assist is switched off.
- The mains plug of the power supply is the separator that connects or disconnects the Kidney Assist from the mains. Avoid positioning the equipment such that access to the mains plug, etc. is limited (so that disconnection becomes difficult).
- Disconnecting mains in running mode will switch the device to back up battery power operation.
- 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.
- The power cord should remain connected to Mains to charge back-up battery. Minimal charging time is 8 hours. The power cord should be unplugged from the AC outlet when left unused for a long period of time.
- Do not block the ventilation areas on both sides of the Kidney Assist thermo unit, this will affect the performance of the device.
- Do not use outside prescribed operation environment, higher temperatures may lead to less efficient cooling.
- 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.
- Yearly service is required to assure optimal and safe functioning of the Kidney Assist.
- Maintenance and servicing of the device may only be performed by XVIVO-certified personnel. Unauthorized repair or modifications, including replacement of batteries, will void the warranty and may violate the conformity of the Kidney Assist with the

requirements of the Medical Device Directive 93/42/EEC. Maintenance and servicing are not permitted while the device is functioning.

- The USB connection may not be connected during perfusion, as this violates the conformity of the Kidney Assist with the requirements of the Medical Device Directive 93/42/EEC.
    - 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

- 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, 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’ 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 disposable set is in contact with the subsequent isolated organ. However, the following part are treated as type B applied parts since they are in direct contact with the perfusion fluid:
    - Pressure sensor cables
    - Temperature sensors
    - Flow sensors
    - Magnetic pump coupling

6. 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).

6.1 Alarm signals

Message	Priority	Audible Signal	Visible Signal (LED)
Warning	**Low priority** (LP) User awareness is required, optimal perfusion compromised.	E C — —	Yellow: general alarms Blue: temperature related alarms
Error	**Medium priority** (MP) Prompt user response is required, else fallback to cold storage.	C C C — — —	Yellow: general alarms Blue: temperature related alarms

Only one manufacturer-configured alarm preset is available which is automatically restored after power interruption.

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 not automatically cease when its triggering event no longer exists; to reset the alarm, press the OK-button.

The delay for the system to positively identify an alarm state is about 3 seconds.

6.2 Alarm message explanation

Prio	Alarm	Problem	Probable Cause	Solution
	Self-test FAILED message on display during startup	Internal hardware problem	Failure of device	Service
(MP)	Medium priority alarm with no display message during startup	No pressure sensor	Pressure sensor not connected to pump unit	Connect pressure sensor
(LP) or (MP)	Sensor disconnected !! CHECK SENSORS !!	Sensor loose	Sensor incorrect connected	Reconnect sensor
(LP)	WARNING Perfusion level low. !! Add perfusion fluid !!	Level too low or bad connection flow sensor	Loose, open or bad connection	Check connections, wet flow sensor. Refill perfusion solution
(LP)	WARNING Pressure limit Set point adjusted	Pressure too high.	High resistance	Pressing the button will result in 75% of set pump output
(LP)	WARNING Flow limit Set point adjusted	Flow too high	Low resistance	Inspect all connections
(LP)	WARNING Temp limit Check System	Temperature range is outside 3 ºC of set temperature	Obstructed thermo water or perfusion flow	Add ice to the thermo unit to cool down or warm water to warm up Check tubing
(LP)	WARNING Water level low Fill THERMO UNIT	Level too low in thermo unit	Loose or open connection	Check connections (thermo tubing, data cable) Fill thermo unit with water
(LP)	WARNING Battery power low Connect Mains	Battery nearly empty	Device disconnected from mains	Connect the device to AC Power
(LP)	WARNING No Flow data	Flow sensor measurement error	Wrong reading	Reconnect flow sensor
(LP)	WARNING Mains disconnected Connect Mains	Plug not connected Broken cable	disconnected wear and tear	Check all power cords Replace cable
(MP)	ERROR Hardware Alarm Check System	Pressure spikes	Sensors not working properly	Check pressure and temperature T1 sensor
(LP)	WARNING T Return Out Range Check perfusion flow	T2 sensor disconnected from disposable set Flow too low	Temperature T2 sensor not connected Obstruction of flow	Check connection temperature T2 sensor. Check for sufficient flow
(MP)	ERROR Temp high limit Perfusion stopped	Temperature above 42 ºC	Bad temperature control	Check temperature sensors and system Service
(MP)	ERROR Temp low limit Perfusion stopped	Temperature below 1 ºC	Bad temperature control	Check temperature sensors and system Service
(LP)	WARNING Pressure not reached Set Point adjusted	No pressure build-up, rpm too high, no pressure in pressure line.	Perfusion level too low, blockage in perfusion line, pump head incorrectly placed or valve of pressure line in incorrect position	Refill circuit, check for blockage or kinks in perfusion lines, reconnect pump head or turn valve of pressure line in correct position

6.3 Probable causes

Problem	Probable Cause	Action
Unrecoverable perfusion	Failure of device	Continue preservation using static cold storage
No power	No Power at outlet	Make sure outlet has power
	Fuse blown	Call XVIVO service
Beeping or flashing LEDs	Errors detected by the KIDNEYASSIST	Follow the instructions in 6.1, Fault Message Explanation.
Pump not working correct	Defect pressure sensor	Replace pressure sensor
	Air in pump head	Prime the pump head/disposable system
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	Make sure outlet is connected with AC power (the power LED on the thermo unit will be unlit if no AC power is available)
	Data cable not (correctly) connected	Fasten the data cable connector until it holds firmly
Pump Error	Pressure sensor incorrect connected	Reconnect pressure sensor
	Bad magnetic connection	Reconnect pump-head
	Pump failure	Call XVIVO service
		Continue preservation using static cold storage
Temperature does not change	No water, too much air in water tubing and thermo unit.	De-air water tubing and/or add water to thermo unit.
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 “On”
		If this does not solve the problem, call service
Leaking perfusate	Loose fitting or defective Tube set.	Retighten all fittings
Leaking thermo water	Bad connection of tubing to thermo unit	Retighten connection
Power on, but buttons are unresponsive	Data cable not (properly) connected to Kidney Assist unit	Reconnect the data cable on the back panel of the Kidney Assist
	Kidney Assist is internally locked-up	Power off, wait for 1 minute and power on. Disconnect & reconnect mains. Power “On”
No flow reading	Flow sensor wrong connected	Connect Flow-sensor with the arrow facing the same direction as the flow through the tube
	Bad connection with tubing	Use ultrasound gel (or water) between sensor and tubing

7. Liability and warranty

See the General Terms and Conditions accompanying the sales agreement.

8. Disposal

The Kidney Assist is subject to the European directive 2012/19/EU on waste electrical and electronic equipment (WEEE). Do not dispose 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.

9. Classifications

9.1 MDD declaration

Classification to 93/42/EEC:	Class IIa
Classification to IEC 60601-1:	Class I
Classification to EN 62304:	Class A
Protection against electrical shock:	Type B
Directive(s):	Council Directive 93/42/EEC annex II
Standard(s):	
Safety: EMC:	International Standard IEC 60601-1 International Standard IEC 60601-1-2
Software:	International Standard IEC 62304
Usability:	International Standard IEC 62366
Risk Analysis:	International Standard ISO 14971
Quality:	International Standard ISO 13485
Notified body:	BSI (NL) Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands

9.2 EMC declaration

- 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 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

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.

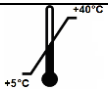
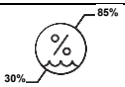
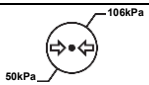
Table 3 Guidance and manufacturer's declaration – RF wireless communication equipment Immunity

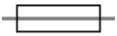
The Kidney Assist is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	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	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	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	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	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.

10. Appendix A: Graphic symbols

	LOT number
	SERIAL number
	Sterile, method using Ethylene Oxide
	Reference model number
	Do not reuse or resterilize, single use only
	Do not use if package is damaged
	Date of manufacture
	Manufacturer
	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
	To ensure grounding reliability, use hospital or commercially grounded electrical connections only
	Do not open the device! Risk of an electrical shock
	Read the instructions for use before operating the device
CE 2797	CE mark and Notified Body number

	WEEE symbol, indicating separate collection for waste of electrical and electronic equipment in Europe
	Equipotentiality terminal for the connection of a Potential Equalization Conductor
	Replaceable fuse, specific type, current and voltage ratings noted above this symbol
	USB-port, should only be used for servicing activities by XVIVO-certified personnel
	Importeur / importateur / importatore

11. 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
EU	European Union
h	hour
Hz	Hertz
IEC	International Electrotechnical Commission
kg	Kilogram (1 kg= 1000 g = 2.2 lbs)
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)
mm Hg	Millimeters of mercury (1 mm Hg = 1 torr = 133.3 Pa)
P	Pressure
Q	Flow
RH	Relative humidity
T	Temperature
V	Volts
VR	Vascular Resistance

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