Instructions for Use

Lung Assist

XVIVO

Model Numbers:
- 41.01.201, 41.01.203 and 41.01.204

Patented

CE 2797

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

XVIVO B.V.
Bornholmstraat 84
9723 AZ Groningen
THE NETHERLANDS
+3150 3131905
info.xnl@xvivogroup.com
www.xvivogroup.com

24/7 Helpdesk (for urgent calls only)
+31 50 3640116

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

Content

1 Product description

The Lung Assist, from XVIVO B.V., is a pump system providing temperature controlled isolated perfusion of donor lungs to bridge the time span between donor pulmonectomy and lung transplantation in the recipient.

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

- Pump unit
- Thermo unit
- Trolley
- Disposable set

The Lung Assist may only be used with the following disposable set: 41.01.401.

The following reusable accessories are included with the Lung Assist:

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

Figure1: Lung Assist with pump unit, thermo unit,

1.1 Intended use

The Lung Assist is intended to be used for isolated ex-vivo machine perfusion of donor lungs, for a period up to 6 hours.

The Lung Assist is intended for use by trained professionals in a professional healthcare environment. Users are expected to be familiar with standard medical practices as required for organ perfusion. There are two types of users of the device

- sterile surgeon, he/she connects the organ to the subsequent tubing of the disposable set and determines the perfusion conditions. After perfusion the surgeon checks the organ on quality for transplantation and removes the organ from the device.
- non-sterile perfusionist, he/she prepares the device for use, places and primes the disposable system, and operates the device during the perfusion period. After perfusion the perfusionist cleans the device.

1.2 Indications for use

Indications for use of the Lung Assist include in-hospital machine perfusion of donor lungs from all deceased donor types as preservation instead of static cold storage or reconditioning after static cold storage, with the intention to improve transplantation outcome of standard criteria donor lungs, or to assess viability of extended criteria and eligible for discard donor lungs

1.3 Pump unit

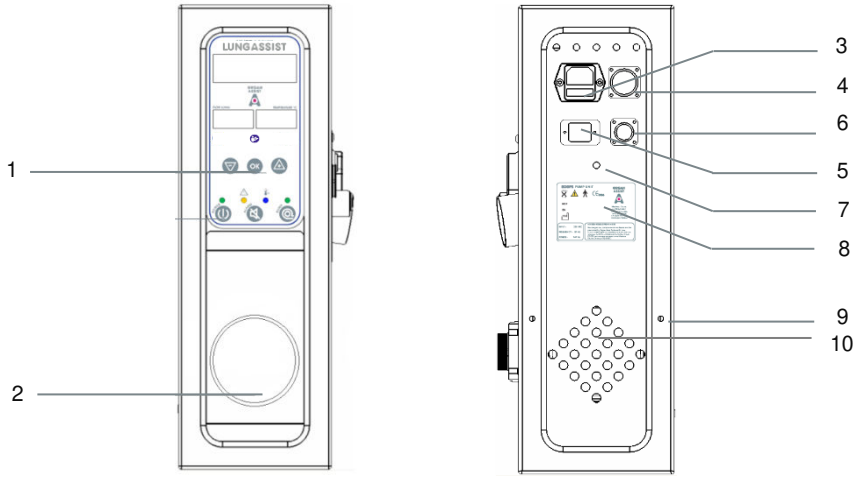


Figure 2: Front and rear view of the pump unit

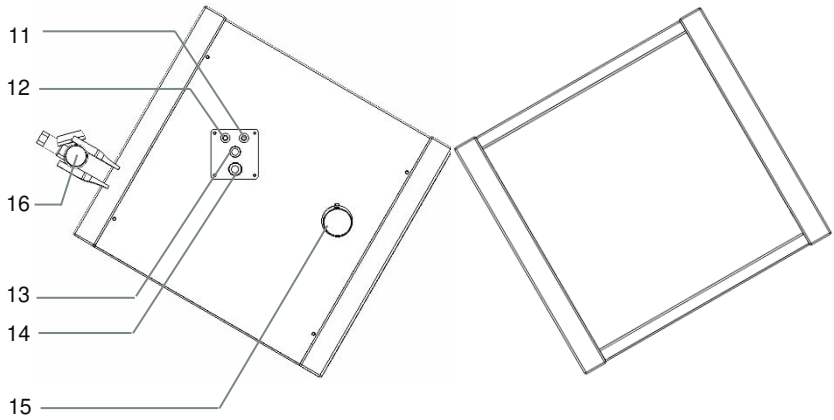


Figure 3: Right and left-hand side view of the pump unit

1. Control panel
2. Oxygen cylinder compartment
3. Electrical power inlet
4. Data cable connection
5. Level sensor connection
6. USB connection
7. Equipotentiality pin
8. Product label
9. Screw hole for connection to trolley
10. Ventilation holes
11. Perfusion temperature connection (venous = blue)(T2)
12. Perfusion temperature connection (arterial = red) (T1)
13. Pressure sensor cable connection
14. Flow sensor connection
15. Magnetic pump coupling
16. Oxygen cylinder (not part of device)

CONTROL PANEL

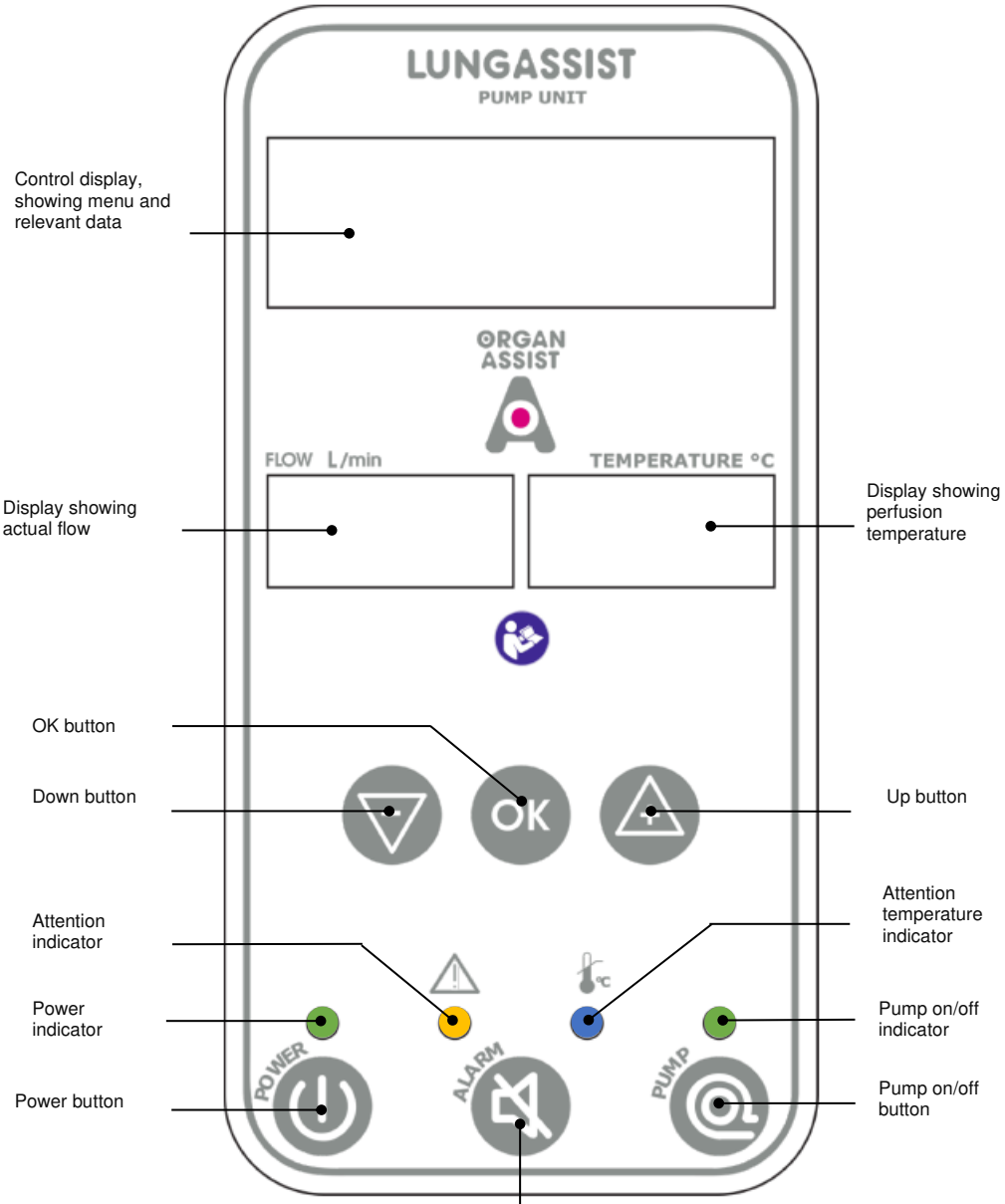


Figure 4: Control

1.4 Thermo unit

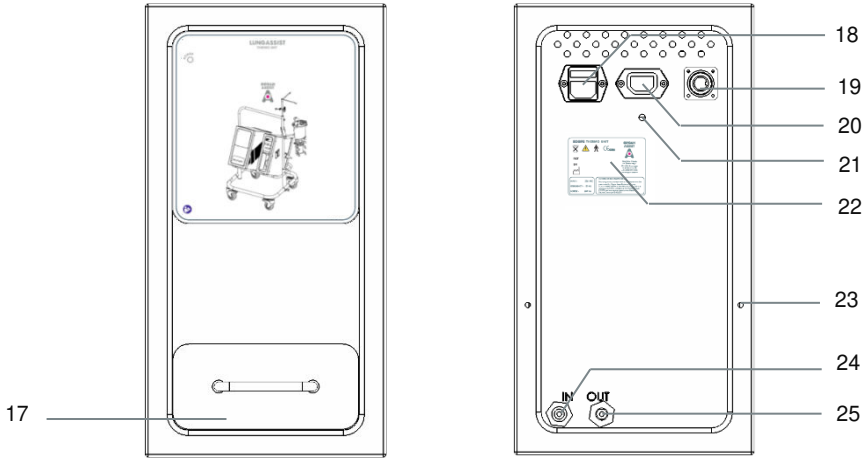


Figure 5: Front and rear view of the thermo unit

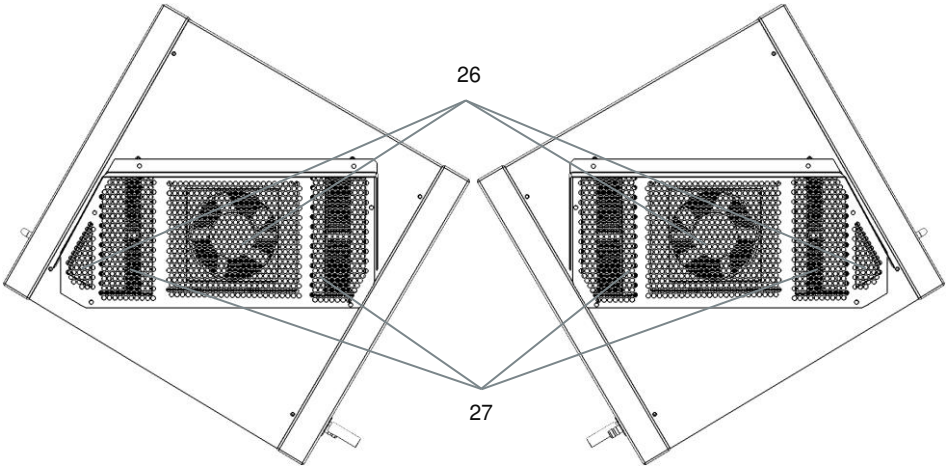


Figure 6: Right and left-hand side view of the thermo unit

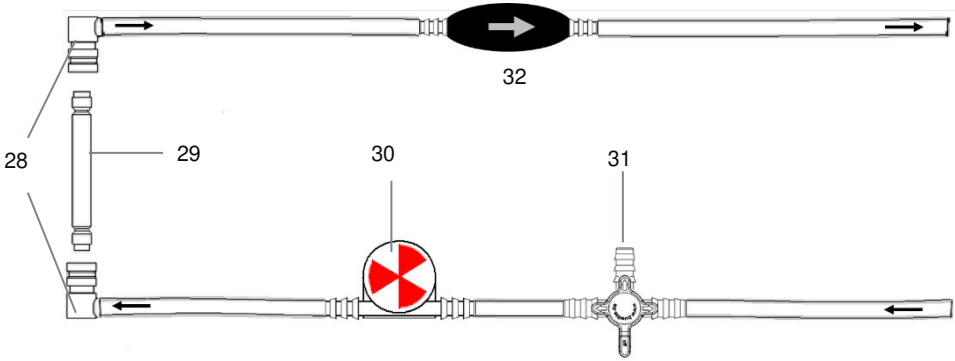


Figure 7: Accessories thermo unit; quick-connect thermo water connectors, flow indicator, thermo water coupling tube and tubing

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

1.5 Trolley

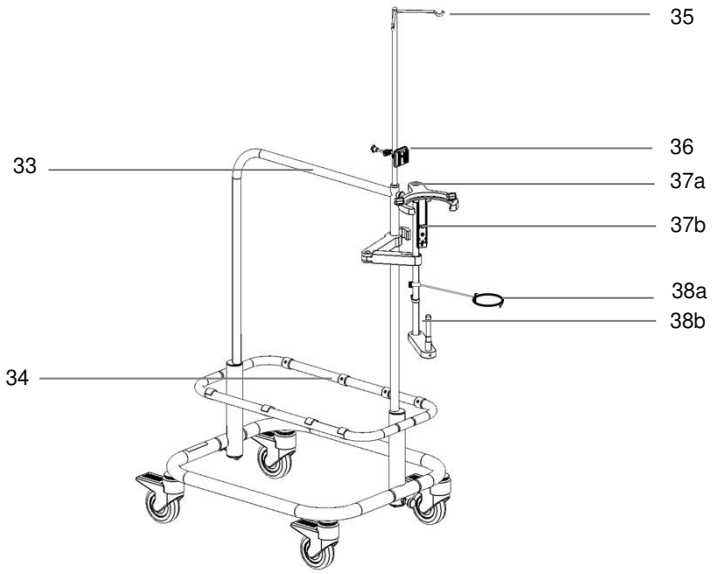


Figure 8: Trolley

33. Push bar
34. Screw holes for connection of pump and thermo unit
35. Infusion pole
36. Pressure sensor holder
37a. Reservoir holder
37b. Level sensor
38a. Oxygenator holder
38b. Leukocyte filter holder

1.6 Disposable set

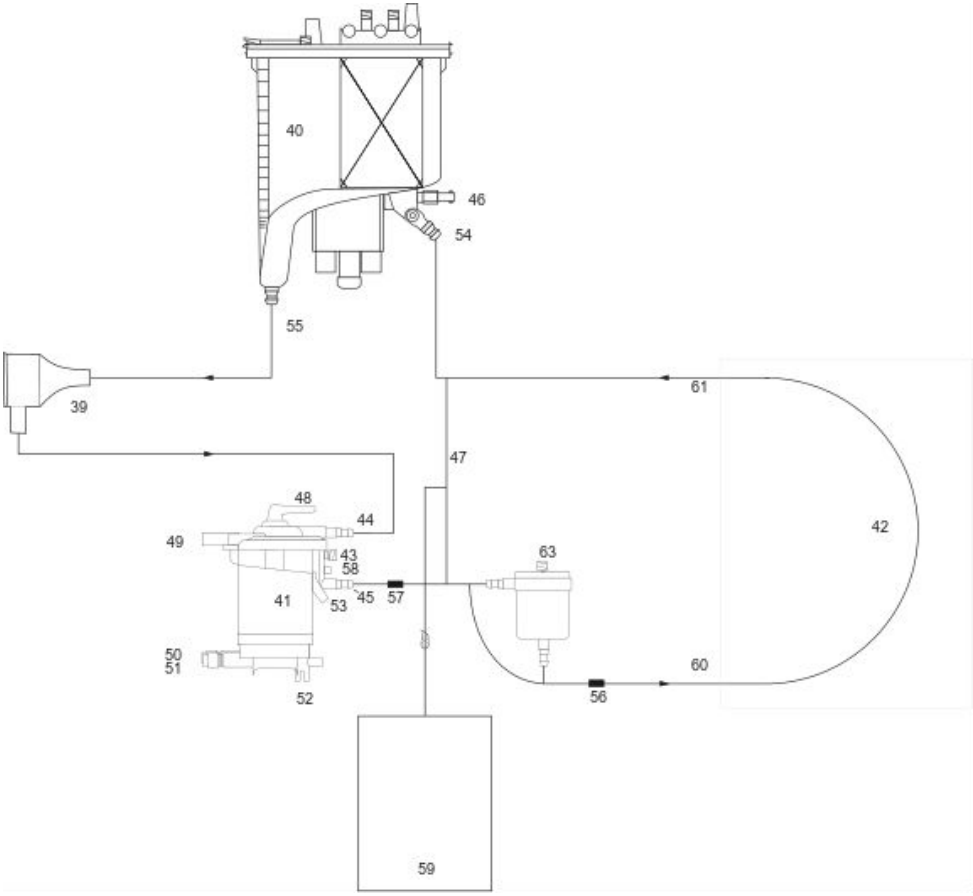


Figure 9: Lung Assist Disposable Set

39. Centrifugal pump
40. Perfusion reservoir
41. Oxygenator
42. Sterile tubing
43. Recirculation port
44. Perfusate inlet
45. Perfusate outlet
46. Temperature sensor (T2, venous)
47. AV-shunt (bypass)
48. De-airing
49. Oxygen inlet
50. Thermo water outlet
51. Thermo water inlet
52. Oxygen outlet
53. Temperature port
54. Venous inlet
55. Outlet perfusion reservoir
56. Pressure sensor (P1)
57. Temperature sensor (T1, arterial)
58. Pressure port
59. Drainage bag
60. Arterial line
61. Venous line
62. Flush line oxygenator
63. Leukocyte filter

1.7 Ordering information

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

Item	Order number
Lung Assist	41.01.101
Pump unit	41.01.201
Thermo unit	41.01.203
Trolley	41.01.204
Disposable	41.01.401
Temperature sensor blue	05.01.301
Temperature sensor red	05.01.302
Flow sensor 3/8”	05.01.304
Training	41.01.801
Regular maintenance	05.01.802

See page 2 for address information or send your request to order@xvivogroup.com

1.8 Product specifications

Perfusion specifications	
Perfusion pump:	Rotary pump, pulsatile 60 BPM
Perfusion flow:	Up to 5,5 L/min
Perfusion pressure:	Up to 20 mmHg
Perfusion temperature:	12 °C - 37 °C
Perfusion oxygenation	Up to 80%
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 880 VA
Fuses pump unit:	Littlefuse: 0215002.txp 2AT 250V HBC
Fuses thermo unit:	Littlefuse: 0215008.txp 8AT 250V HBC
Transport & storage conditions:	5 - 40°C, 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, 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:	800 mm x 625 mm x 1140 mm
Weight:	68 kg
Ingress protection:	IP20

2 Installation

The complete Lung Assist is shipped in separate cardboard packages. The device should be unpacked and inspected by the responsible person.

- Set the trolley in the correct position (figure 1).
- Position the pump and thermo units on the trolley.
- Secure each unit with 2 screws to the trolley (10, 23).
- Attach the holder (36) for the disposable set to the push bar (32) of the trolley.
- Attach the holder (38a) for the Leukocyte filter to the disposable holder (36) on the trolley.
- Connect supplied data cable to both Lung Assist units using the data connector on the back panel of both Lung Assist units (5) (19).
- Connect the level sensor (37) to the port on the back panel of the pump unit (6).
- Connect power cord at the back of the thermo unit (18).
- Connect the small power cord between both Lung Assist units (4) (20).
- Connect the Lung Assist to the hospital potential equalization connector with an equipotential cable to ensure the potential equalization of the Lung Assist with other medical devices (see IEC 60601-1 for ME-systems).
- Connect power cord to a mains electrical outlet with earth 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 LUNG 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.

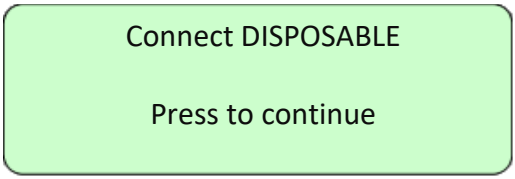
3 Operation

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 Lung Assist by pushing the power button on the control panel.
- Wait until the self-test is completed.
- Press the OK-button to activate the setup procedure.

⚠ 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.
- Attach the separately packed pressure sensor to the pressure line of the perfusion circuit. Take care to connect it tightly and to maintain sterility.
- Place the perfusion reservoir (40) with the oxygenator (41) on the holder of the trolley (figure 10).
- Connect the pump head (39) to the magnetic pump coupling (16) (figure 10).
- Connect the oxygen/gas tubing (49) to the oxygen/gas supply.
- Press the OK-button to proceed to the next step.

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.

NOTE: for de-oxygenation of the perfusate by using the oxygenator (included in the circuit) a cylinder with a special de-oxygenation mixture is needed. Please arrange this mixture with your local gas supplier (6% O2, 8% CO2 and 86% N2).

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

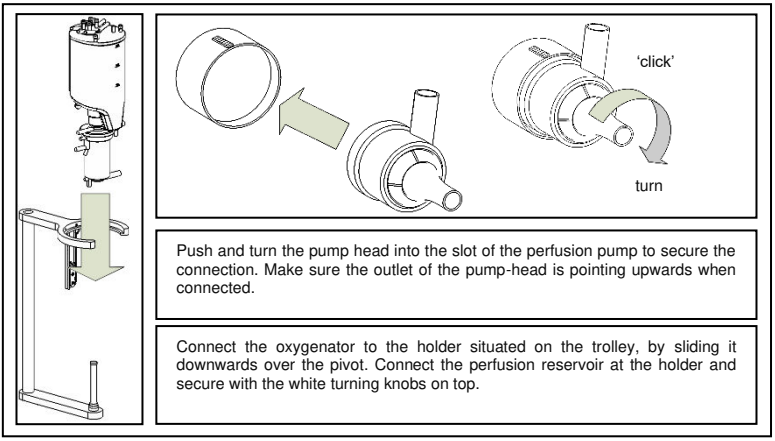


Figure 10: Connection of pump- head and oxygenator to the holder.

- Place the pressure sensor (56) in the holder on the perfusion pole (35).
- Connect temperature sensors according the color coding; (T1 red, 57) to the arterial line of the disposable set (60) (figure 13).
- Connect T2 (blue) to the venous inlet (54) of the perfusion reservoir.
- Connect the flow sensor (figure 14).
- Make sure to connect the sensor connector with the red dot facing upwards (figure 12).

⚠ 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.

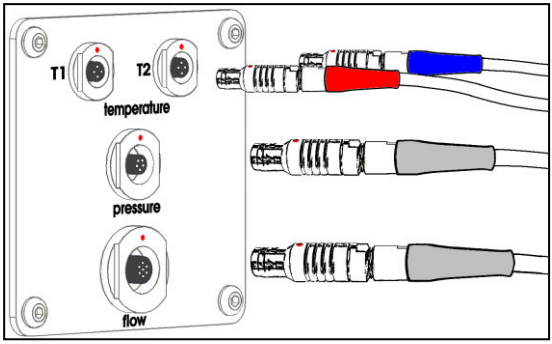


Figure 12: Connecting the sensors

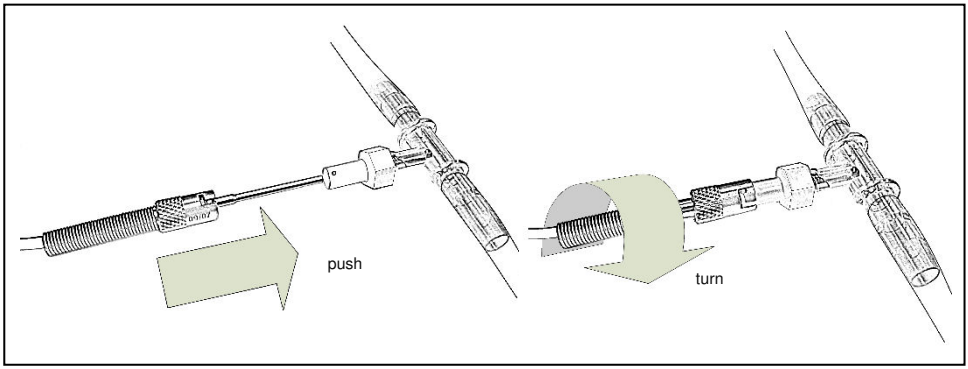


Figure 13: Connecting the temperature sensor

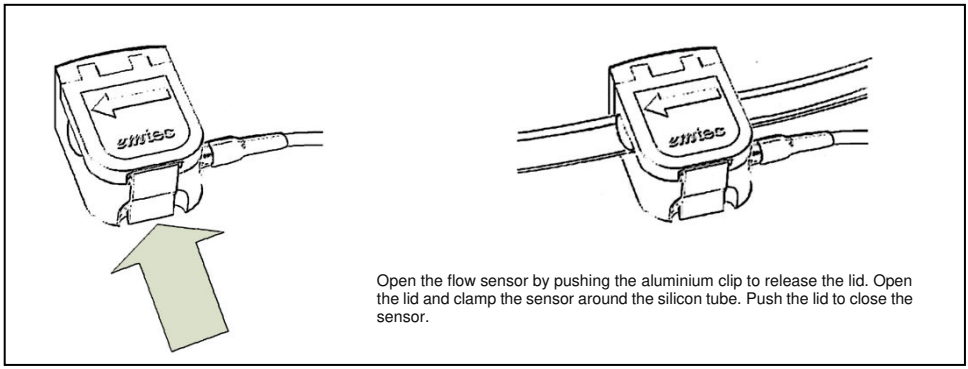


Figure 14: Connecting the flow sensor

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

- Fill the system with the preferred perfusion solution (min. 1,5 L).
- When the system is filled properly, press OK-button to proceed.

In the LUNG 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 LUNG ASSIST.
Using other solutions than machine perfusion solution with the LUNG ASSIST may result in organ damage or the cause of complications.

PRIMING SYSTEM
Turn to adjust
Pump output: ..%
Press to continue

- Press the up- and down-buttons to variate the flow speed. Variation of the pump output will remove air from the tubing of the disposable set.
- Open bypass (47) and clamp the arterial line (60) to prime the bypass (figure 15).
- Clamp bypass and open the arterial line at the same time to prime the arterial line (figure 16).
- Prime the pressure line and remove cap on top of the pressure sensor (transducer) and place a sterile syringe on the opened port (figure 17).
- Pull the blue snap tab while aspirating with the syringe until the pressure line is de-aired and there is enough perfusion solution in the syringe.
- Remove the syringe and close opening by re-placing the cap (figure 17).
- De-air the oxygenator (41) with the use of the flush line on top of the oxygenator.
- De-air the Leukocyte filter (63)
- Press the OK-button to proceed to the next step.

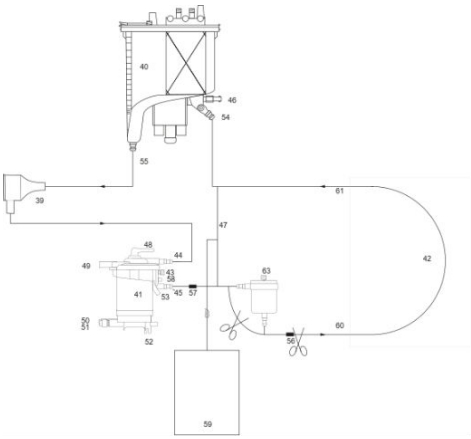


Figure 15: Clamp on arterial line

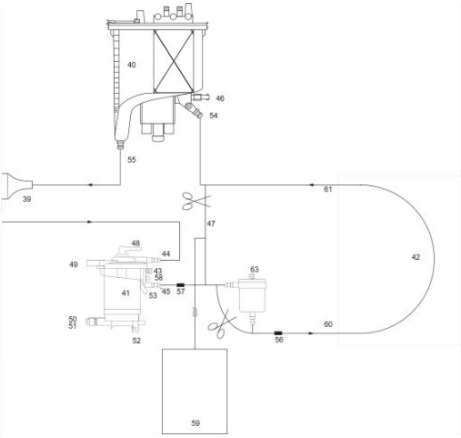


Figure 16: Clamp on bypass

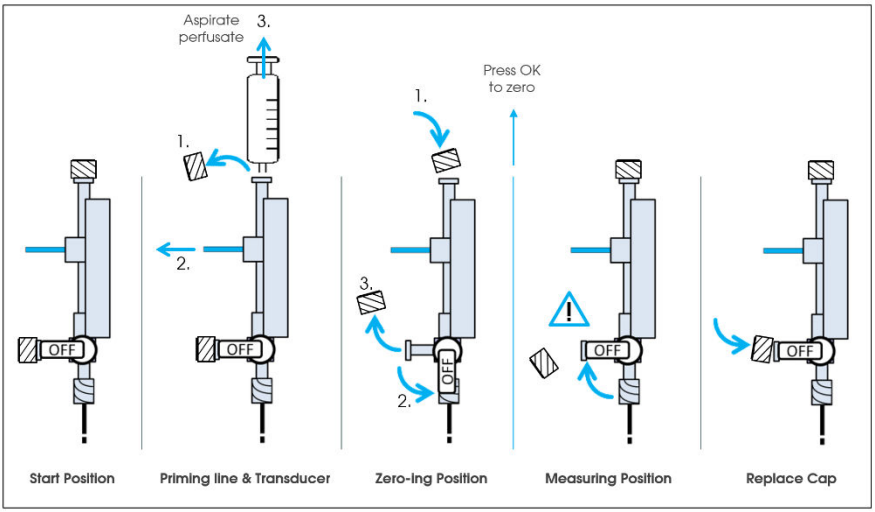


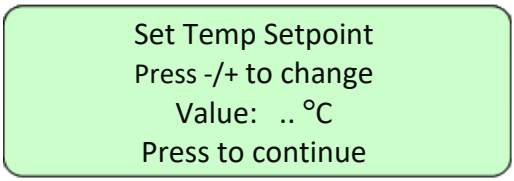
Figure 17: De-airing of the pressure sensor

- Connect the water tubing (28) to the oxygenator (50, 51).
- Fill the water reservoir (17) of the thermo unit (3 L).
- Use the thermo tubing de-airing balloon (31a) to start an initial circulation in the thermo tubing.
- When display shows "Level OK", press OK-button to proceed to the next step.

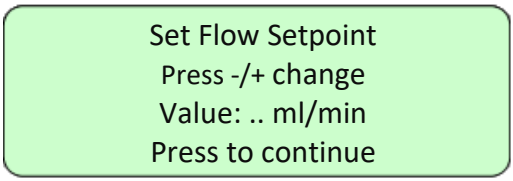
⚠ Make sure that the thermo water pump never runs dry! Only use demineralized water (optional ice) in the thermo reservoir.

Pressure zeroing
Turn transducer valve
Press to continue

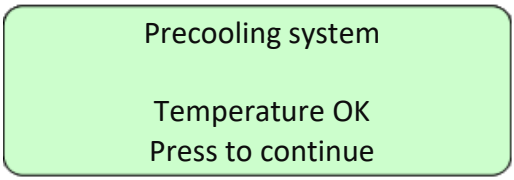
- Set the height of the pressure sensor holder (35) at infusion pole to the same height as the donor body.
- Check if the sensor is placed in the holder.
- Remove cap on top of the pressure sensor (transducer) and place a sterile syringe on the opened port (figure 17).
- Pull the blue snap tab while aspirating with the syringe until the pressure line is de-aired and there is enough perfusion solution in the syringe.
- Remove the syringe and replace the cap. Turn the valve on the pressure sensor (transducer) counter clockwise to open the sensor to measure atmospheric pressure and remove the cap (see figure 17)
- Press the OK-button to zero the sensor to atmospheric pressure. This step will take a few seconds.
- Turn the pressure sensor valve back to measuring (end) position (clockwise, see figure 17).
- Re-place the cap
- Press the OK-button to proceed to the next step.



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



- Set the preferred flow by pressing the up- and down-buttons .
- Press the OK-button to confirm and to proceed to the next step.



- When the temperature has reached the range of the preferred temperature; press the OK-button to proceed.

3.2 Perfusion procedure

- Open the sterile package (42).
- Hand over the sterile tubing to the surgeon.
- Check if bypass line towards is open.
- Clamp the tubes to prevent loss of perfusion fluid.

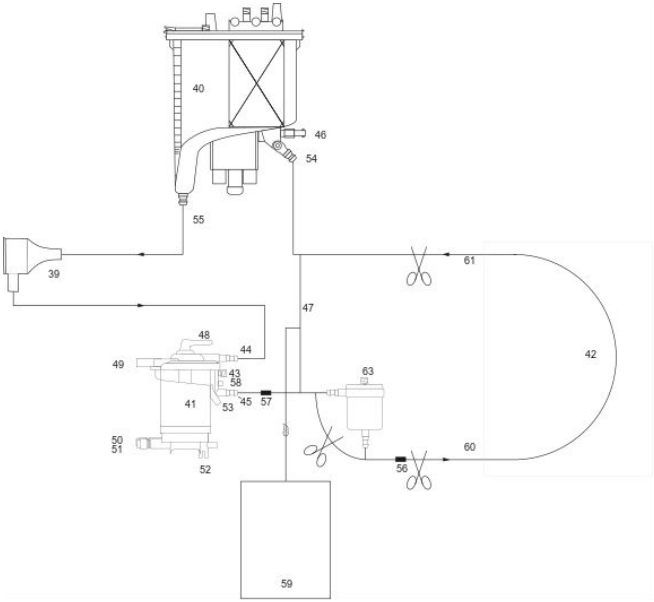
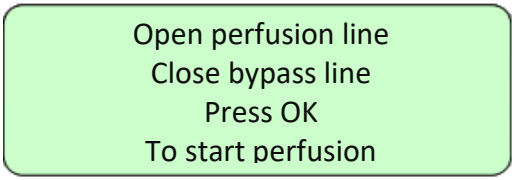


Figure 18: Cannulas connected

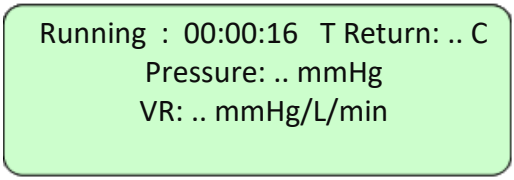
Start Ex Situ perfusion

- While still running over the bypass, press OK-button to start perfusion.
- Turn perfusion flow down to about 80-100 ml/min by entering settings menu (OK-button).
- Connect arterial tubing to pulmonary artery cannula
  (Optional: open clamp on arterial line temporarily to de-air cannula/line connection).
- Connect venous tubing to left atrial cannula.
- Release clamp from arterial line.
- Release clamp from venous line.
- Close bypass line towards reservoir.



Always take care of the perfusion fluid level in the reservoir during the perfusion of lungs. Leakage of anastomoses can cause level drop. Add fluid when needed!

During perfusion the measured values will appear on the display.

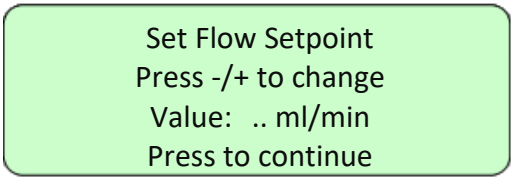


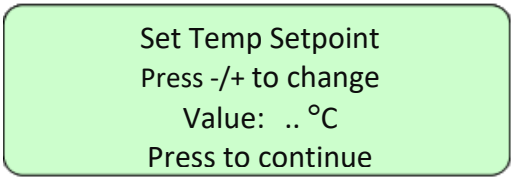
After the perfusion procedure is started, please check all connections and check if the present flow and pressures are as intended. Make sure that the device works as intended and does not resonate, produces extreme noise or shows other shortcomings.

When an error or malfunction appears, please review the trouble shooting section in chapter 6 of this manual. If the troubleshooting section does not solve your problem, please call qualified service personnel or contact XVIVO.

In case of emergency, stop the LUNG ASSIST by pressing the pump button to stop the operation, the device will stop the pump.

During perfusion, the flow and temperature set point can be changed by pressing the OK-button. To change the flow, press the up- and down-buttons until the preferred value appears on the display and confirm by pushing the OK-button.
Now the temperature can be changed as well, turn the button to set the preferred value and confirm by pushing the button, the set flow and temperature will now be used.





Powering off the Lung Assist will reset all values back to the manufacturer's settings.

Note that the preferred flow might not be reached due to the maximum system pressure delimiter, to prevent damage or treatment loss due to high perfusion pressures. This value is a preset safety value and cannot be changed.

3.3 Stopping the operation

- Switch off the pump by pressing the pump button.
- Switch off the whole device by pressing the power button.
- Turn off the oxygen supply.
- Disconnect the sensors from the disposable set. Gently pull the connectors out of their sockets in a straight motion to avoid damage.
- Remove the disposable set.
- Discard the used disposable as medical grade waste, following local regulations
- Connect the water tubing using the supplied water tubing coupler (29) to prevent against unwanted water leakage.

DO NOT REUSE PERFUSION CIRCUITS

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 and flow sensor are re-usable, make sure to separate them from the 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; 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 (31). After drainage close the 3-way tap.
4. Clean the white connectors (28), water tubing coupler (29), 3-way tap and lid of thermo unit reservoir (17) 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 PV 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 PV pump unit.
10. Skip through setup procedure by pushing the OK-button on the PV pump unit. Push until the display shows ”pressure zeroing”.
11. **Circulate disinfection solution** for 30 minutes at room temperature; check if the red flow indicator wheel (30) is spinning to ensure flow.
12. Power off PV 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 PV 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 PV 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 (31). 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 (17).
5. Wait for half an hour.
6. While waiting, connect the sensors:
   - Connect flow sensor, temperature sensors and pressure sensor to the PV 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 PV pump unit.
8. Skip through setup procedure by pushing the OK-button on the PV pump unit. Push until the display shows ”pressure zeroing”.
9. **Circulate decalcifying solution** for 20 minutes at room temperature; check if the red flow indicator wheel (30) 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 PV 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 PV 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 of the LUNG ASSIST or the temperature, pressure or flow sensor connections at the side panel of the LUNG 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 Lung Assist can only be guaranteed when the operator is a skilled and trained professional and has successfully followed a Lung Assist training course.
- Judgement of the measurement results regarding organ quality are of the responsibility of the surgeon.
- Start preparation of the recipient when the machine perfusion procedure is completed.
- The Lung Assist uses externally supplied electricity to operate. Connect the Lung 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 Lung Assist will not completely shut off all power from the device. The power supply of the Lung Assist thermo unit will still produce a low noise when the Lung Assist is switched off.
- The mains plug of the power supply is the separator that connects or disconnects the Lung 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 Lung 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, environment with flammable anesthetics, oxygen rich environment or in locations exposed to direct sunlight or strong artificial light.
- Yearly service by XVIVO is required to assure optimal and safe functioning of the Lung 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 Lung 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 shall not be connected during perfusion, the USB connection should only be used for servicing activities by XVIVO-certified personnel.
- The device does rely on essential performance:
  - Perfusion temperature between 0°C & 43°C
  - Pressure below safety limit

    $$P(T)=0.207 \cdot T+21.381$$

  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 Lung Assist and adjacent systems
  - connect the Lung Assist to an outlet on a separate circuit from that to which adjacent systems are connected
- Use of the 'Lung 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 'Lung 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 'Lung 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 Lung 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.

7 Alarms and troubleshooting

7.1 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.

7.2 **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

7.3 **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 Lung Assist	Follow the instructions in 6.1, Fault Message Explanation.
Pump not working correct	Defect pressure sensor Air in pump head	Replace pressure sensor 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 Data cable not (correctly) connected	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 Bad magnetic connection Pump failure	Reconnect pressure sensor 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.	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

Problem	Probable Cause	Action
Power on, but buttons are unresponsive	Data cable not (properly) connected to both Lung Assist units Lung Assist is internally locked-up	Reconnect the data cable on the back panel of the Lung Assist Power off, wait for 1 minute and power on Disconnect & reconnect mains. 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 tube Use ultrasound gel (or water) between sensor and tubing.

8 Liability and warranty

See the General Terms and Conditions accompanying the sales agreement.

9 Disposal

The Lung 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 Lung 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 Lung Assist.

10 Classifications

10.1 MDD declaration

Classification to 93/42/EEC	Class IIa
Classification to IEC 60601-1	Class I
Classification to IEC 62304	Class A
Protection against electrical shock	Type B

Directive(s): Council Directive 93/42/EEC annex II

Standard(s):

• Safety	International Standard IEC 60601-1
• EMC	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

10.2 EMC declarations

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

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

The Lung 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 Lung 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 Lung 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 Lung 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 Lung Assist requires continued operation during power mains interruptions, it is recommended that the Lung 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.			

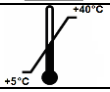
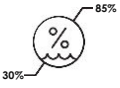
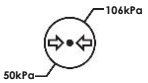
Table 3. Guidance and manufacturer's declaration – RF wireless communication equipment Immunity

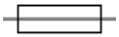
The Lung Assist is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

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.

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

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)
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