Instructions for Use

XPS™
XVIVO Perfusion System

Software version 5.3.x
Hardware version 1.9

XVIVO

Instructions for Use

This Instructions for Use and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

Refer to accompanied booklet XVIVO Perfusion System (XPS™) with STEEN Solution™ Professional Labeling for summary of post market clinical studies, including contraindications, warnings, precautions, description, operations, patient education and safety and efficacy evaluation.

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XVIVO Perfusion AB, all rights reserved

Subject to technical changes

Because of continuous product improvements, the illustrations and technical information found in the XPS User's Guide may differ (slightly) from the current version of the device.

User Guide References

This document was created using information from:

1) CardioHelp User's Manual/English/0.9.0
2) CardioHelp XVIVO/Technical Data/Maintenance/ English/100813
3) Flow/bubble sensor/ Technical Data/English/100812
4) Hamilton-C3 Operator's Manual 624446/03 Software version 2.0.x (2017-05-12)
5) Hico-Variotherm 550 Instructions for Use/ REF 542801 Rev.2-08/05

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Software version 5.3.x
Hardware version 1.9

CE 2460

Symbols used on device labels and packaging

Symbol	Definition	Symbol	Definition
	Power on/off switch		Recyclable materials
	Manufacturer		Caution
	Date of manufacture		Warning
	Consult operator's manual. Refer to the operator's manual for complete information.		Electrical Shock/ Electrocution
	Indicates the degree of protection against electric shock according to IEC 60601-1. Class II devices have double or reinforced insulation, as they have no provision for protective grounding. (C3 Ventilator only)		Moving parts can crush and cut
	Canadian Standards Association and National Recognized Test Laboratory approval		Alternating current Direct current
	Dispose according to Council Directive 2002/96/EC or WEEE (Waste Electrical and Electronic Equipment)		Equipotential Ground (located at the external ground point next to the input power connector)
	Serial Number		Protective Earth ground (located at every ground stud within the cart frame)
	This way up		Medical device
	Fragile, handle with care		Consult instructions for use
	Keep dry		Do not lift
	Temperature limitations		Importer
	Humidity limitations		Swiss Authorised Representative
	Atmospheric pressure limitations		

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1.1 STEEN Solution™

General overview

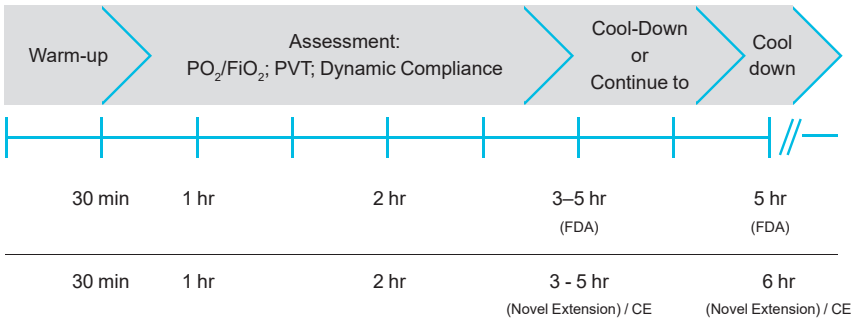
STEEN Solution™ is a physiological salt solution containing (70 g/l) human serum albumin and (5 g/l) Dextran 40. The extracellular electrolyte composition, pH and human serum albumin simulate key properties of human blood plasma. Dextran 40 counteracts tissue oedema and protects the microvasculature against postischaemic reperfusion injury. Human serum albumin provides oncotic pressure preventing oedema.

The solution is sterile (aseptic processing) and intended for single use only. The bottle is made of PETg and equipped with a PE screw cap lined with a silicone septum closure which facilitates aseptic transfer of the solution. The screw cap is sealed by a tamper evident plastic sleeve.

STEEN Solution™ enables safe Ex Vivo Lung Perfusion (EVLP). The intended patient population is adult patients in need of a lung transplantation.

STEEN Solution™ is intended to be used with the XVIVO Perfusion System (XPS™) for flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the function of the lungs can be reassessed for transplantation. The time required by the lungs to reverse the negative effects of neurogenic pulmonary oedema and to achieve a normal fluid balance can vary based on the initial donor environment.

Typically, the duration of normothermic machine perfusion lasts 3-5 hours (per FDA PMA approval) 3-6 hours (per FDA Novel Extension Study) to allow the lungs to slowly warm up, normalize fluid balance and be effectively assessed. In exceptional cases, an additional 1-2 hours may be needed for the lung to be adequately reassessed to allow assessment for transplantation suitability:



1

STEEN Solution™

The XPS™ with STEEN Solution™ Perfusate consists of the XPS Perfusion Cart Hardware, fluid path and non-fluid path disposables, XPS Cart Software, and STEEN Solution™.

1.2 XPS™ Cart Overview

Intended Use

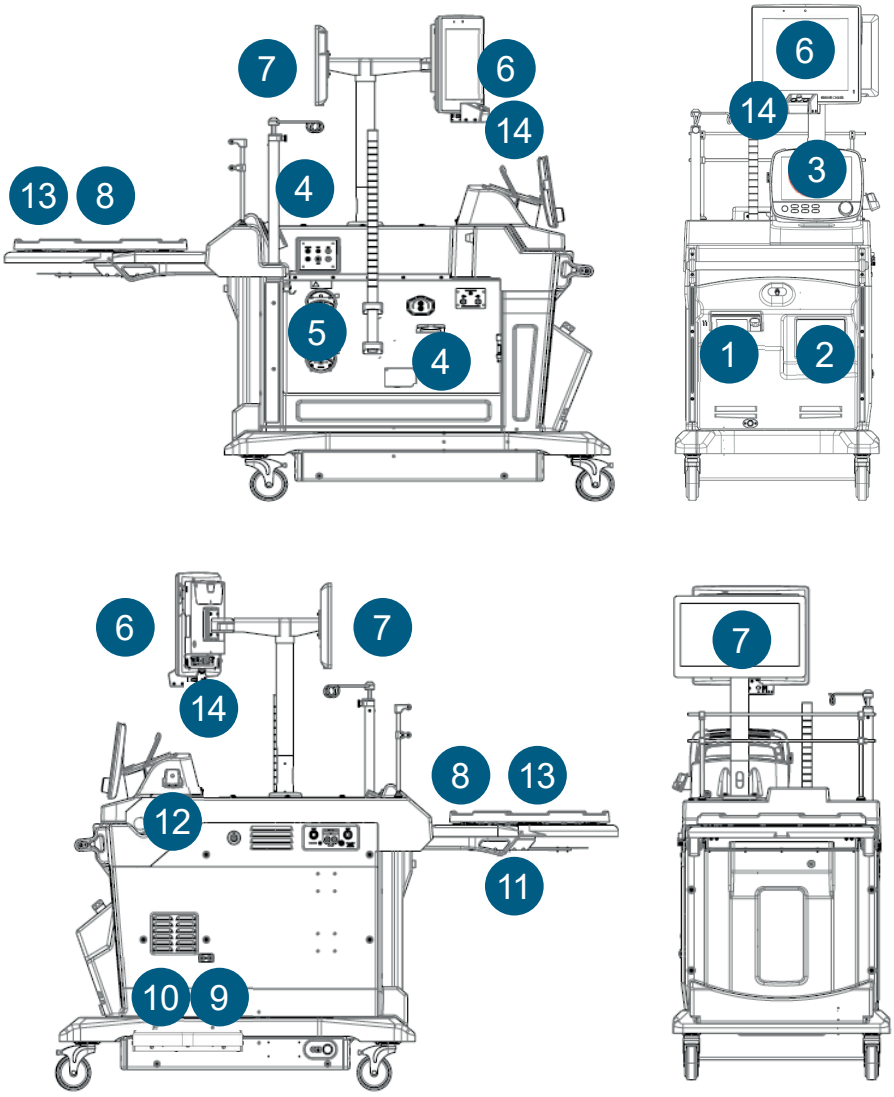
The XVIVO Perfusion System (XPS™) is indicated for use in flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex-vivo function of the lungs can be reassessed for transplantation. (US)

The XVIVO Perfusion System (XPS™) is intended for flushing and temporary continuous normothermic machine perfusion of isolated lungs, during which time the function of the lungs can be assessed for transplantation. (All markets except for US)

Intended use patient population is adults: age ≥ 18 years old

XPS™ Cart Hardware

1. CardioHelp XVIVO pump (includes pressure, temperature, level, bubble and flow sensors)
2. Heater/ cooler
3. C3 Ventilator
4. Perfusate Gas Monitor (PGM)
5. STEEN Solution™ Pumps
6. Touchscreen monitor
7. Display-only monitor
8. XVIVO Organ Chamber™ platform
9. 100% medical O_2 gas cylinder or high pressure wall line for ventilator
10. Gas cylinder containing medical quality O_2 6%, CO_2 8% and Nitrogen 86% for deoxygenation membrane.
11. X-Ray shelf
12. Barcode Scanner
13. Weight Sensor
14. Pump Controllers



Manual Tip

Throughout the XPS IFU, you routinely see three color-coded number circles:

Black represents an instruction only (no associated picture).

Dark blue and/or **blue** indicates an instruction and a representative picture reference.

1.3 XPS™ Operator Warnings and Cautions

Operator warnings

Warning: The volume of STEEN Solution™ perfusate loss in the system may adversely affect ex vivo lung stability. The user's attention to providing adequate, timely replacement is essential for lung safety.

Warning: The XVIVO Perfusion Cart as well as the rest of the XVIVO Perfusion System (XPS™) are intended for use by healthcare professionals only.

Warning: Use of accessories and cables other than those specified as replacement parts may result in increased risk of injury to the XVIVO Perfusion Cart and/or user. Additionally, this may also result in increased RF Emissions and/or decreased immunity to RF energy of the XVIVO Perfusion Cart.

Warning: Do not block or cover the ventilation opening on the XVIVO Perfusion Cart. Overheating could occur, causing decreased functionality of the system.

Warning: Only use the CardioHelp XVIVO with activated flow monitoring which triggers an alarm or intervention as necessary.

Warning: Excessive electromagnetic interference can occur and interfere with the flow measurement of the flow/bubble sensor. This can result in incorrect measurements which cause incorrect value displays, alarms, flow regulation and interventions.

Warning: Peristaltic pump heads can cause injury if touched while in operation with pump hose clamp not engaged.

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

Warning: Position XPS™ close to power outlet to prevent accidental removal of power plug from power socket.

Warning: No modifications to this equipment are allowed.

Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Warning: The UPS in the XPS must be periodically checked for proper operation. The batteries in the UPS must be replaced periodically to maintain proper operation. Batteries in the UPS are to be replaced by qualified service personnel only.

1.3 XPS™ Operator Warnings and Cautions

Operator cautions

Caution: This User's Guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

Caution: The safe and effective use of this medical device depends to a large degree on factors solely under the control of the operator. It is important that all operators of this surgical system read, understand and follow the operating instructions (User's Guide) supplied with this equipment. The responsibility to adhere to the approved labeling and Instructions for Use rests with the user. The Instructions for Use are only provided as suggestions for procedure. The user must, on the basis of his or her medical training and experience, evaluate the suitability of this procedure.

Caution: Federal (USA) law restricts this device to the order of a physician.

Caution: This device complies with the electromagnetic compatibility standard IEC EN60601-1-2. It is possible that this device may interfere with or be disturbed by other electrical devices.

Caution: All disposable components of this device are designed as *single use only* and may not be reused in an ex vivo lung procedure.

NOTE: When administered systemically, human serum albumin and Dextran have been associated with rare allergic reactions. However, no such reactions have been reported with either of these substances when used for ex vivo lung preservation.

NOTE: The XPS™ has been tested and found to comply with the limits for a Class A device, pursuant to CISPR 11 and Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a commercial installation. However, portable and mobile RF communications equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instructions, may cause harmful interference to the XPS™. There is no guarantee that interference will not occur in a particular installation. If this equipment receives harmful interference from RF communications, which can be determined by turning the RF communications equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the XVIVO Perfusion Cart
- Increase the separation between the XVIVO Perfusion Cart and the RF communications equipment
- Connect the XVIVO Perfusion Cart into an outlet on a circuit different from that to which the RF communications equipment is connected
- Deactivate the flow intervention. Incorrect flow values can trigger improper interventions.
- Please note that flow values may be displayed and monitored with reduced accuracy and alarms triggered with reduced accuracy.

2.1 Technical Operation

The XVIVO Perfusion System (XPS™) provides a comprehensive platform for ex vivo lung perfusion and assessment. The XPS™ Perfusion Cart is designed with the following elements:

- CardioHelp XVIVO centrifugal pump drive with integrated temperature (2) and pressure (2) sensors
- Thermoelectric heater/cooler device that uses water to maintain perfusate temperatures at any set point between 15-39°C
- ICU-grade C3 Ventilator with modes designed to provide protective ventilation to the ex vivo lung
- Perfusate management system with integrated pumps to enable the removal or recycling of STEEN Solution™ in the perfusion circuit
- In-line perfusate gas monitor (PGM) to enable real-time trending of pH and PO_2 during the procedure
- Touchscreen computer monitor for the perfusionist and separate display-only monitor for the surgeon that displays data from the hardware components as well as trends important lung function parameters graphically

2.2 XVIVO Disposables

In addition to the hardware cart, the XPS™ includes the following single-use disposable products designed for ex vivo lung perfusion:

- XVIVO Organ Chamber™ to aseptically hold the lungs during the procedure
- XVIVO Disposable Lung Kit
  - Level Sensor Pad
  - Pressure Sensors (Disposable Pressure Transducers)
  - XVIVO Lung Cannula Set™
  - Coaxial Breathing Circuit with Flow Sensor
  - Bacterial/Viral Filter
  - Sterile Drape
  - Arterial Filter
- XVIVO Disposable Lung Circuit™ which includes an integrated centrifugal pump head/ oxygenation and heat exchange membrane, hard-shell reservoir, arterial filter, soft drain reservoir and tubing
- XVIVO PGM Disposable Sensors™ to provide in-line, easily-calibrated trending of the perfusate
- STEEN Solution™ for ex vivo normothermic organ perfusion and assessment

The following chapter details the hardware and disposable set-up and operational procedures for the successful XPS™ operation.

2

XPS™ Power Up

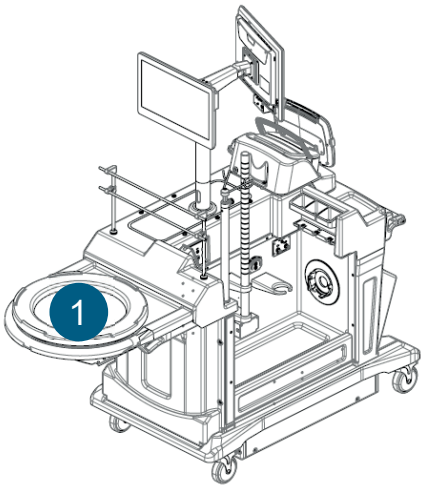
2.2.1 XVIVO Organ Chamber™

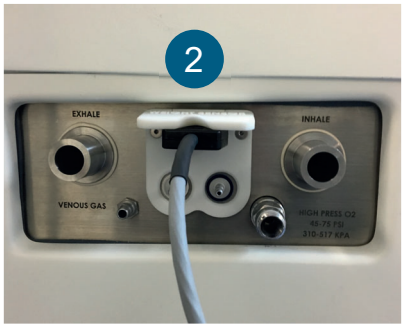
Prime Mode: Disposable Set-up

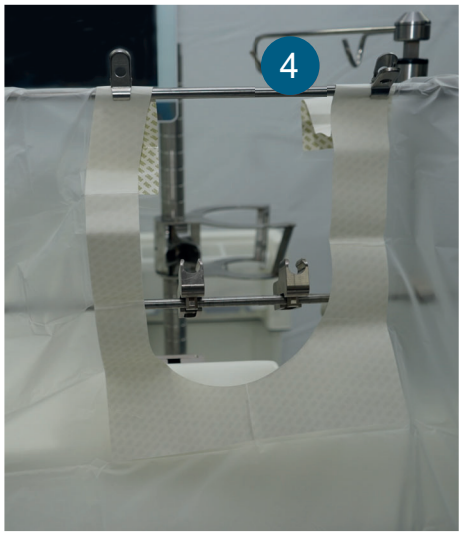
1. Lift the blue chamber table until it clicks into the locked position. Place the weight sensor on the table, within the groves (see section 2.6 for more detail).
2. Connect the weight sensor cable, at the vent panel. To disconnect cable, depress clips (not shown) on each right and left side of connector.
3. Open the separately wrapped sterile clear “U” drape and wrap the non-cut end across the weight sensor and blue chamber table. Wrap the end with the pre-cut slot up and over the top cross bar. Leave a small opening from the pre-cut slot near the area where the perfusion tubing will pass into the sterile area.
4. Secure in place with stainless steel bar clips.

   NOTE:

   Clips can be autoclaved or drape can be clipped by perfusionist from non-sterile side.
5. Open the XVIVO Organ Chamber™ outer box. Remove the Chamber and open the plastic wrap by tearing along the blue dotted line that reads “TEAR TO OPEN” beginning at notch on either end.
6. Remove the Chamber from the poly bag and prepare to pass it off aseptically to the gowned scrub tech/ nurse. Carefully and aseptically, unwrap the first blue drape layer away from the Chamber and pass off to a scrub tech or nurse.
7. Securely place the Chamber on the weight scale to open the second layer, using it to create a sterile field around the Organ Chamber.







2.2.2 XVIVO Disposable Lung Circuit™

Prime Mode: Disposable Set-up

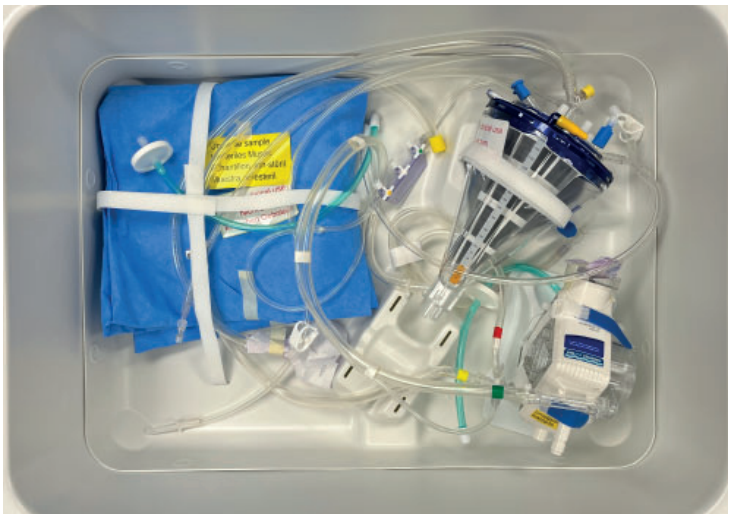
The XVIVO Disposable Lung Circuit™ provides the aseptic interface between the XPS™ cart hardware and the ex vivo lung. The following components are part of the pack:

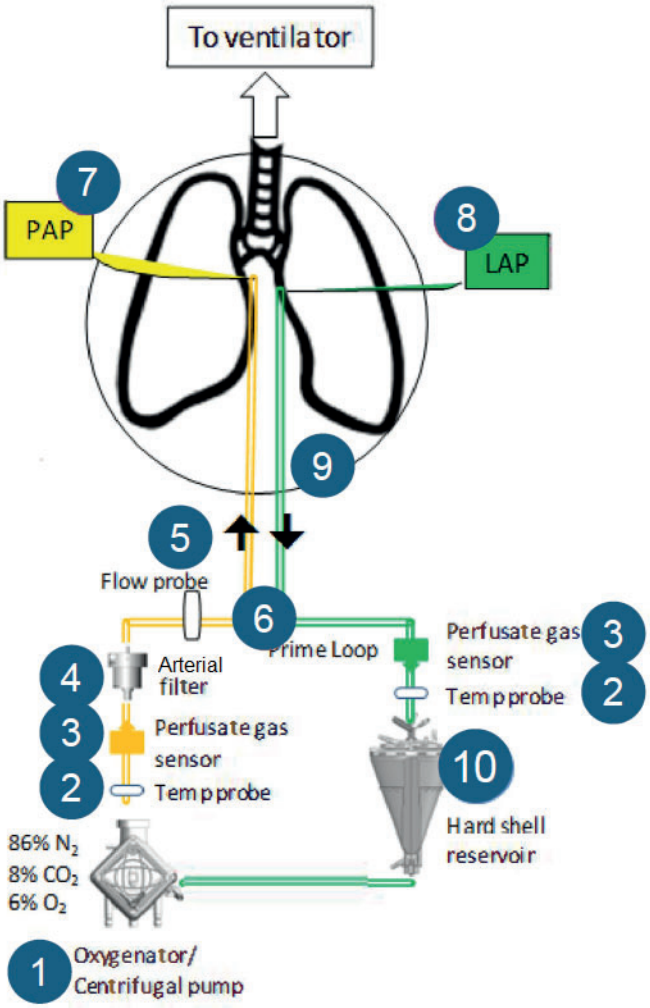
1. Quadrox-iR centrifugal pump head/ oxygenation membrane/ heat exchanger
2. Temperature probe (2)
3. In-line perfusate gas sensor (2)
4. Arterial filter
5. Flow probe
6. Perfusion Loop
7. Pulmonary artery cannula and pressure line
8. Left atrial cannula and pressure line
9. XVIVO Organ Chamber™
10. Hardshell reservoir
11. Level sensor

NOTE:

#s 3, 4, 7, 8, 9 & 11 are packaged separately

Items 2 & 5 are reusable





2.2.3 Connect XVIVO Disposable Lung Circuit™

Prime Mode: Disposable Set-up

Connect the disposables in the order that they come out of the pack:

1. Connect the oxygenator/ pump head to the pump drive. Slightly tilt the device to the right and then click to the left to secure. **Remove yellow cap and (EO) tape.**
2. Place the hardshell reservoir into the reservoir housing with volume marks pointed out (away from mounting pole).
3. Place the arterial filter into its housing: keep top cap for air removal during priming.
4. Aseptically pass off the blue-wrapped perfusion loop section and blue-wrapped drain bag section to the sterile side of the cart.
5. Pass the quick connect end and yellow cap end of the perfusion loop section through the sterile drape opening to the non-sterile wet area.
6. Aseptically, connect the yellow capped end of the perfusion loop to the vertical (bottom) barb of the arterial filter.

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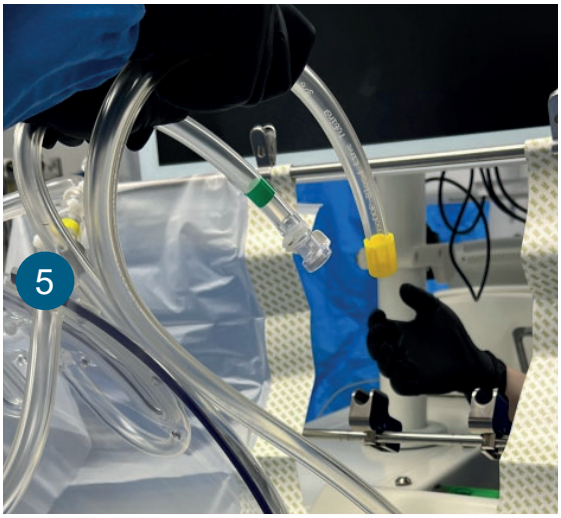


Prime Mode: Disposable Set-up

7 Locate the yellow capped outflow tubing line from the oxygenator for connection to the horizontal (top) barb of the arterial filter. Place filter in housing and keep top cap on for removing air from the filter during circuit priming with STEEN Solution.

8 Sterilely connect the drain bag connector to the XVIVO Organ Chamber's drain port.

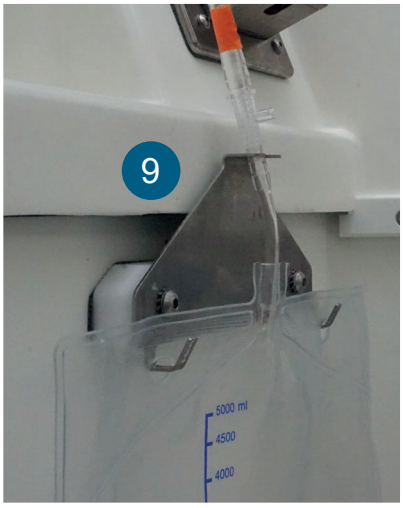
9 Pass drain bag back over to the non-sterile 'wet area' to attach to wall hooks. Remove luer cap from the top of the tubing filter.

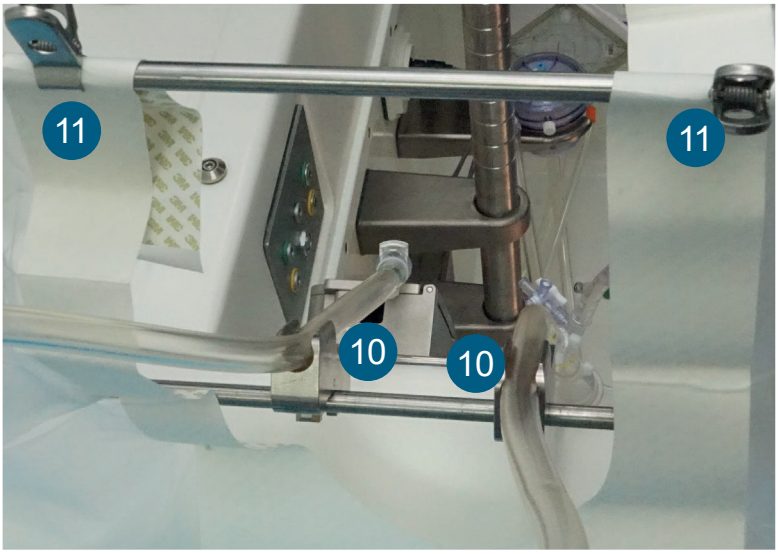
10 Pass the perfusion loop section (from step #4) quick connect ends through the sterile drape opening to the non-sterile wet area. Snap perfusion loop hoses into open tube clamps on bar *through* the cart window (PA/yellow marked tube on right side, LA/green on left) as shown.

11 Surround the tubing with the clear drape cut-out and resecure the drape clips if necessary.

NOTE:

Any kinking in tubing lines may occlude flow rates. Ensure lines are free of kinks or obstructions.





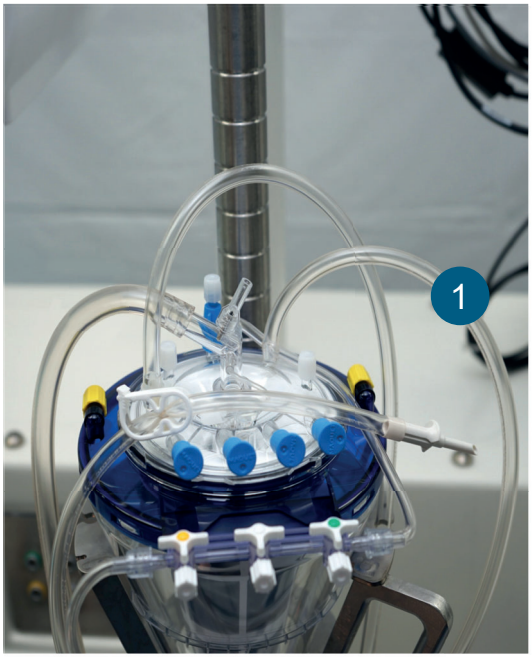
2.2.5 Connect Tubing Lines to the XPS™ Cart

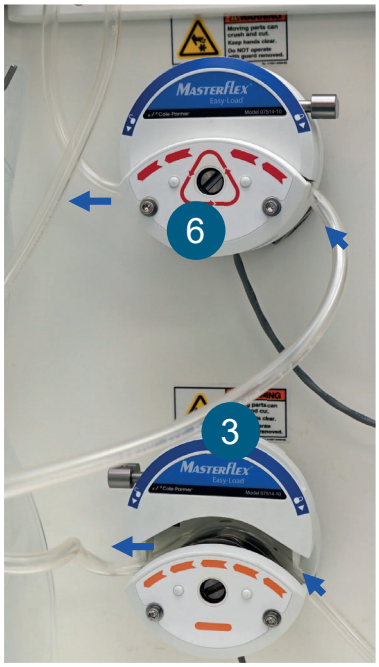
Prime Mode: Disposable Set-up

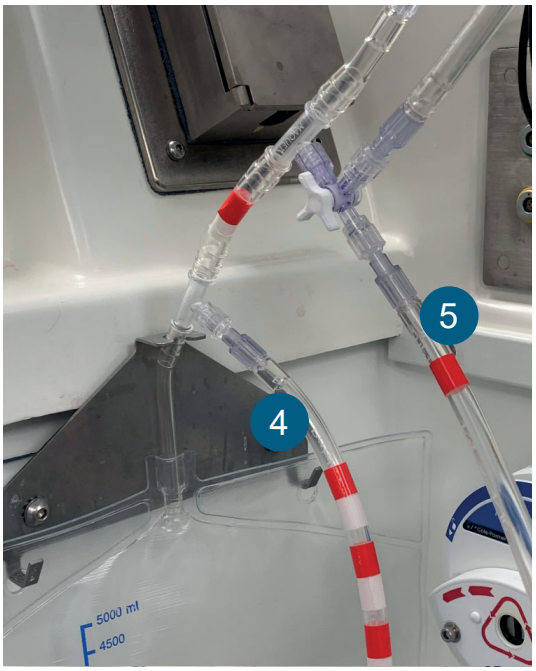
1. Verify STEEN Solution™ single spike tubing to reservoir inlet port.
2. Locate the STEEN Solution™ drain tubing which comes off of the Quadrox-iR oxygenator and is not connected to anything else at its terminal end and has red/white-colored tape.
3. Feed the STEEN Solution™ drain tubing through the Remove pump (lower) head in the flow direction shown by the arrow (Right to Left) and close the pump head onto the tubing.
4. Connect STEEN Solution™ drain tubing to drain bag luer port (near the red/white tape stripe).
5. Locate the STEEN Solution™ recycle tubing which is a 24 inch piece of tubing connected to the drain bag with a red tape stripe.
6. Feed the STEEN Solution™ recycle tubing through the Recycle pump (upper) head in the direction shown. Ensure no kinks in tubing and close the pump head.

NOTE:

Tubing must be inserted from the RIGHT side (entry) to the LEFT side (exit), centered across peristaltic pump heads, carefully fitting between the two tubing channel rails on both the entry and exit ends of the pump head or damage/ kinking to the tubing may occur.







2.2.6 XVIVO PGM Disposable Sensor™

Prime Mode: Disposable Set-up

1 Open sensor package.

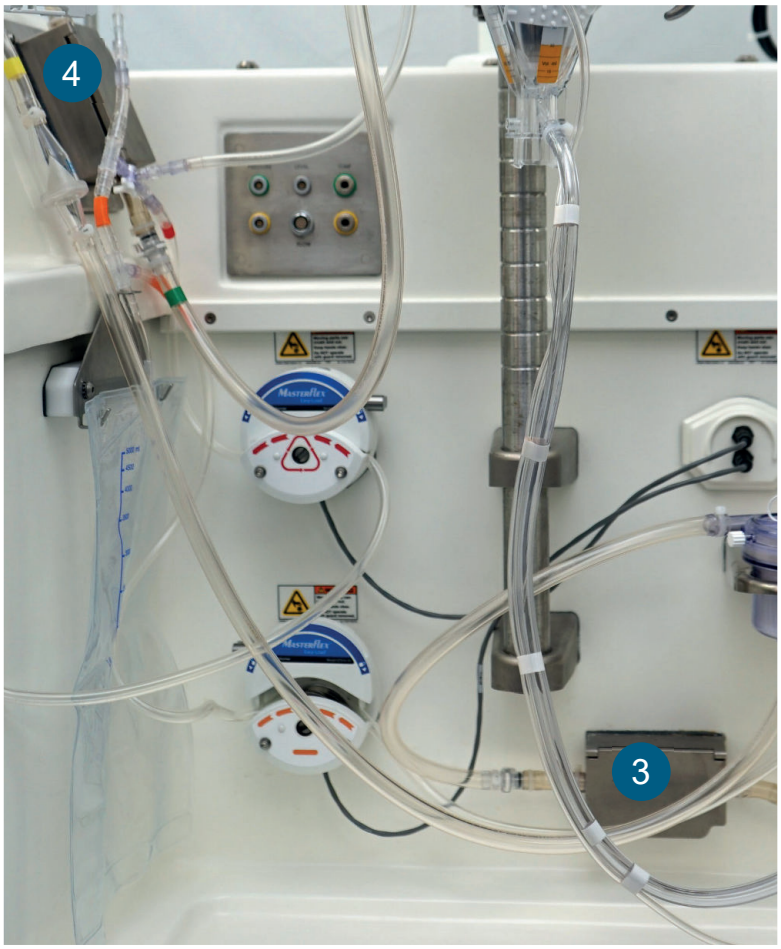
NOTE:

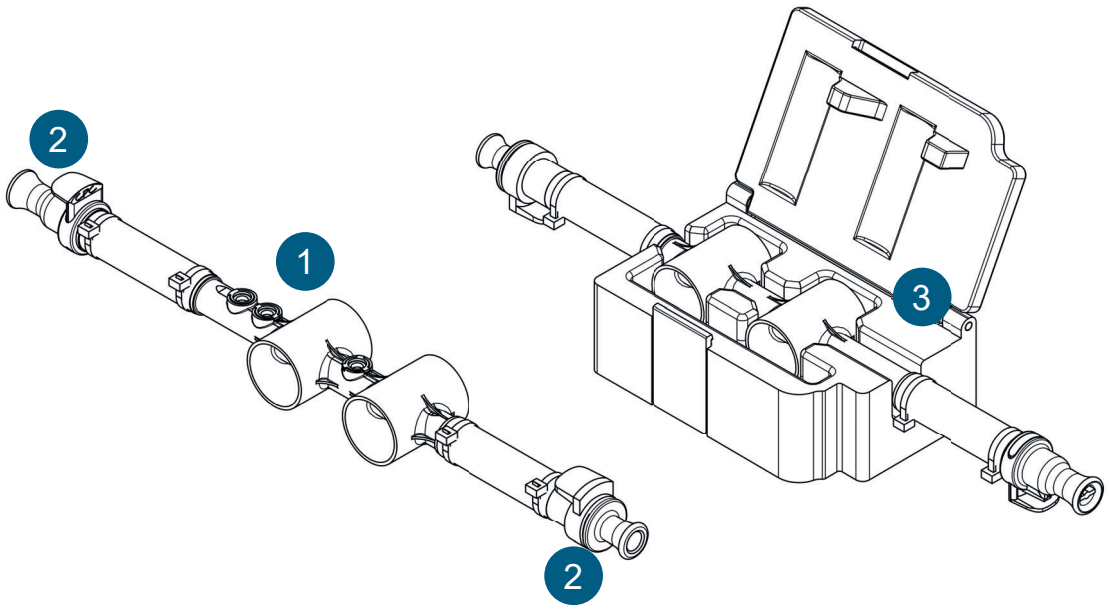
Keep packaging label to enter calibration data into XPS Software in a later step.

2 Aseptically connect sensor to disposable tubing set using quick connects.

3 Insert sensor into housing as shown.

4 Repeat for second sensor.





2.2.7 Set Temperature

Prime Mode: XPS™ Perfusion Cart Hardware

TEMP SENSORS

1. Connect straight LA temperature sensor to reservoir.
2. Connect PA temperature sensor to oxygenator.
3. Ensure temperature sensors are connected to the correct (color-coded) ports on interface panel as shown.

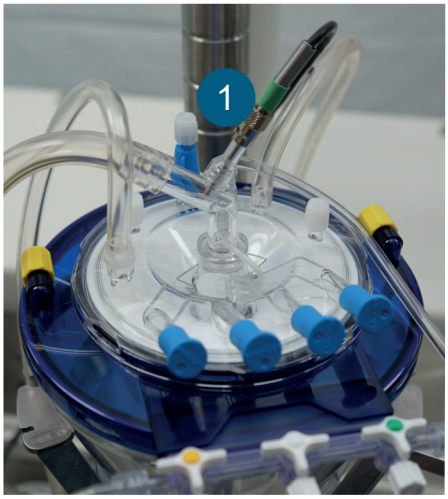
HEATER/COOLER

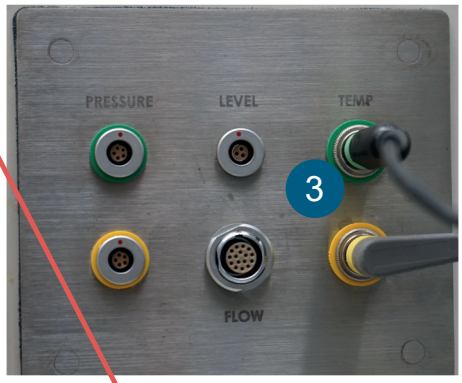
4. Ensure blue hoses are connected to hose panel and Hansen connectors are snapped tightly onto oxygenator (does not matter which blue hose connects to which port on oxygenator).

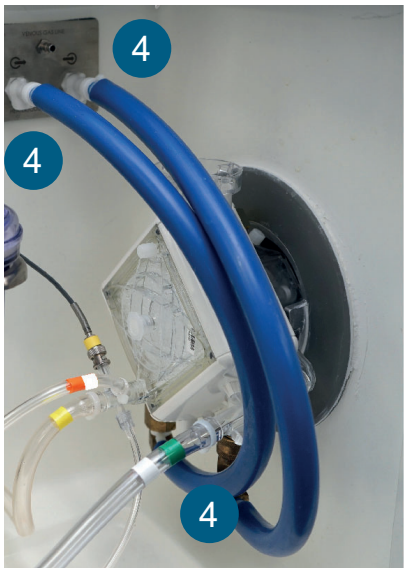
NOTE:

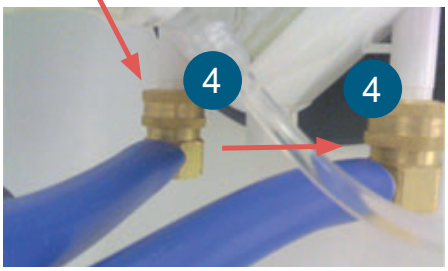
Water will leak out of Hansen connectors if they are not seated correctly. Make sure they snap tightly onto heat exchange ports of oxygenator.

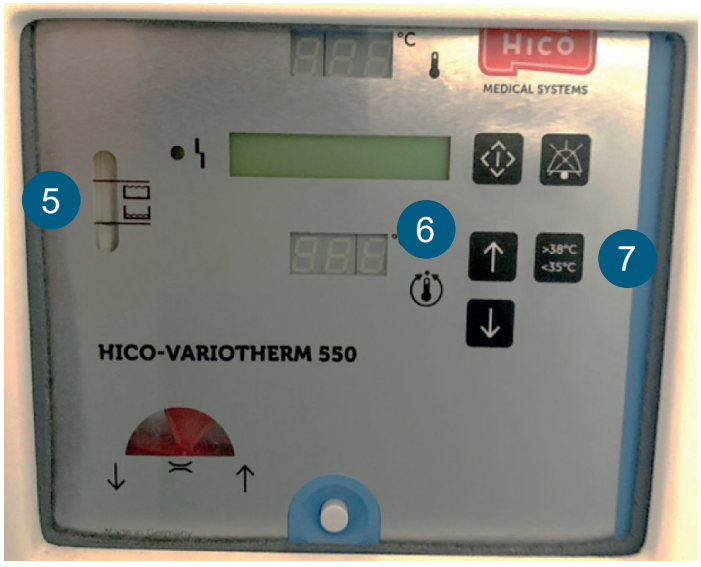
5. Ensure there is enough distilled water in Heater/Cooler reservoir. See Section 9.2 for filling directions.
6. Power-up and set initial temperature of heater/cooler unit to 23°C by using touch keypad.
7. Temperature is >35°C, simultaneously press the temperature release key and the down arrow to achieve desired temperature setting.
8. Circulate water through the oxygenator's heat exchanger membrane to eliminate bubbles and to check for leaks/cracks in the oxygenator housing.











2.3 Power Up

Prime Mode: XPS™ Perfusion Cart Hardware

CAUTION:

Before starting procedure, ensure that all four wheel casters are in locked position by pressing each caster lock to the DOWN position.

1 Remove 6 to 8 bottles of STEEN Solution™ to allow to warm up to room temperature.

NOTE:

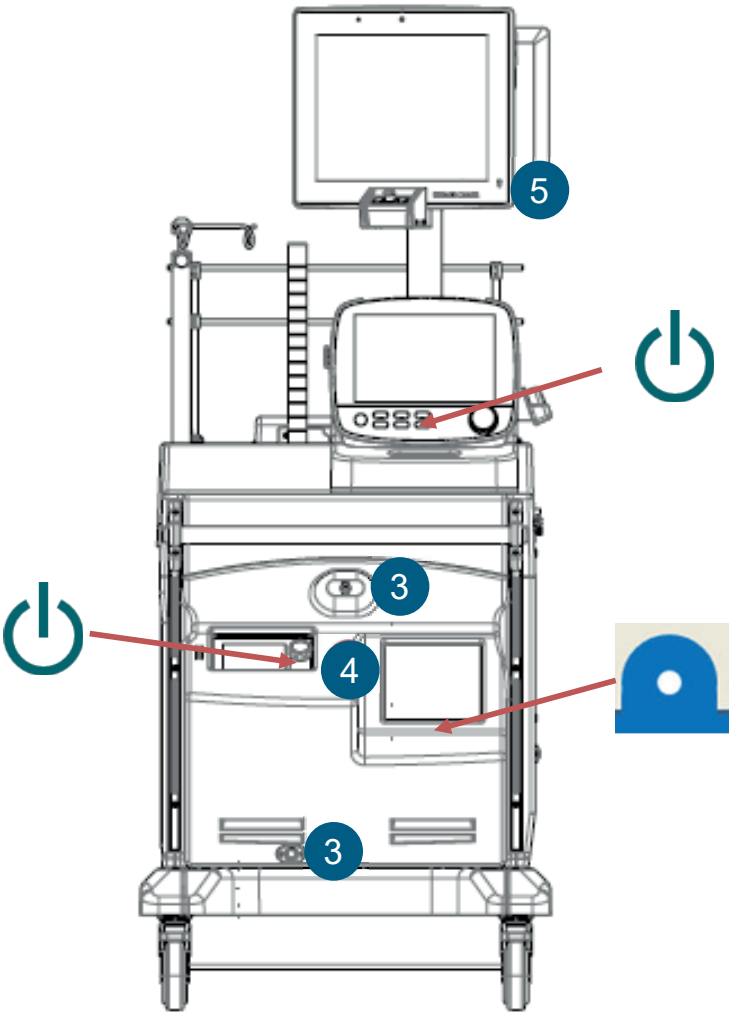
As a precursor to the recommended STEEN Solution™ Exchange step (Section 4.3.7) consider warming half the bottles (3 to 4 bottles) to a normothermic temperature.

2 Ensure XPS™ is plugged into the wall outlet. Note: wall outlet should be equipped with backup power.

3 Turn toggle switch to the up position to initiate XPS™ system battery backup and press the UPS button.

4 Start CardioHelp and HCU by pressing power buttons for each. Set HCU to 23 °C.

5 Start Touchscreen monitor (power button is located on the back of the monitor), and Ventilator by pressing power buttons for each.



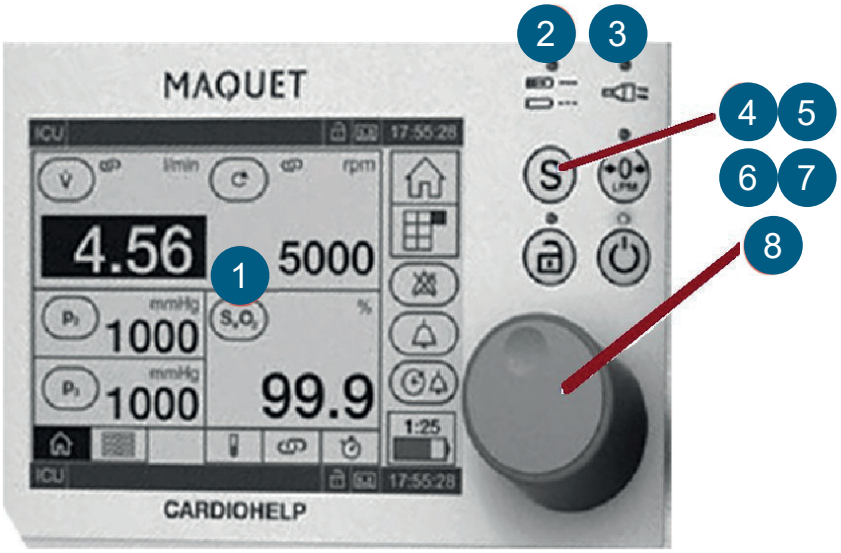
2.4 STEEN Solution™ PRIMING and SETUP

Prime Mode: XPS™ Perfusion Cart Hardware

2.4.1 CardioHelp XVIVO Pump Controls

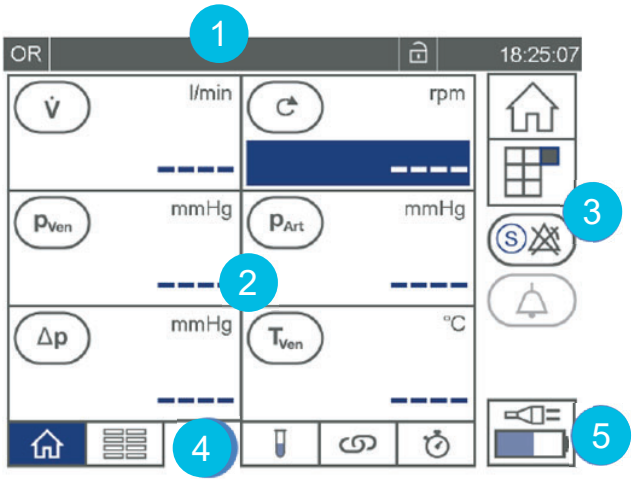
The CardioHelp XVIVO device drives, controls and monitors the STEEN Solution™ perfusate during normothermic ex vivo lung assessment. The control panel includes the following areas:

1 Touch-screen Panel
2 Battery power LED
3 AC/DC power supply LED
4 Safety Button
5 Zero Flow Mode LED/button
6 Unlock LED/button
7 On/Off LED/button
8 Control knob



The main (Home) screen on the Touch display includes the following areas:

1 Status bar
2 Parameter display
3 Toolbar
4 Tab bar
5 Power supply status



2.4.2 Prime Circuit with STEEN Solution™

Prime Mode: XPS™ Perfusion Cart Hardware

1 Place 3 bottles of STEEN Solution™ into the manifold.

2 Locate single spike line and spike one bottle of STEEN Solution™.

3 STEEN Solution™ is gravity fed into the hardshell reservoir using a “Statue of Liberty” method:

Using the single spike line, spike a STEEN Solution™ bottle and hold the inverted bottle above head level.

Holding on to the cap, twist the bottle itself just enough to vent to atmosphere and allow STEEN Solution™ to run through the single spike line and into the reservoir itself.

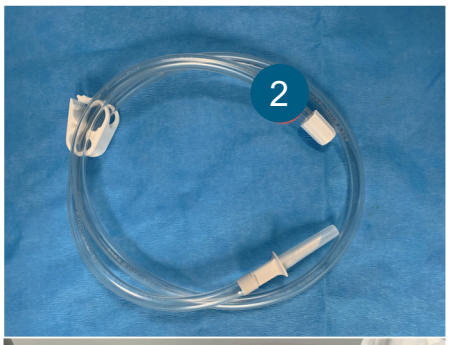
4 Repeat step **3** for a second bottle of STEEN Solution™.

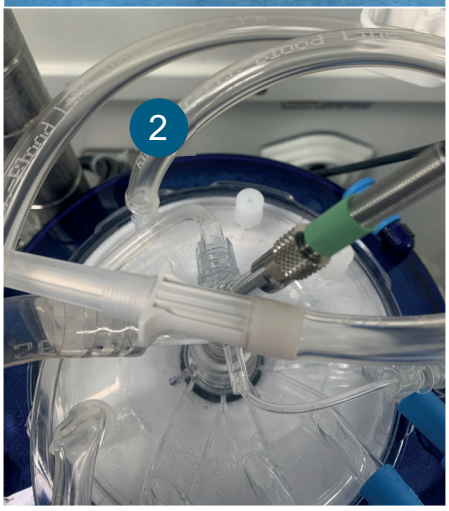
5 To prime the circuit, set the speed of the CardioHelp Pump (turn control knob clockwise) to 3,000 rpm for 2 minutes.

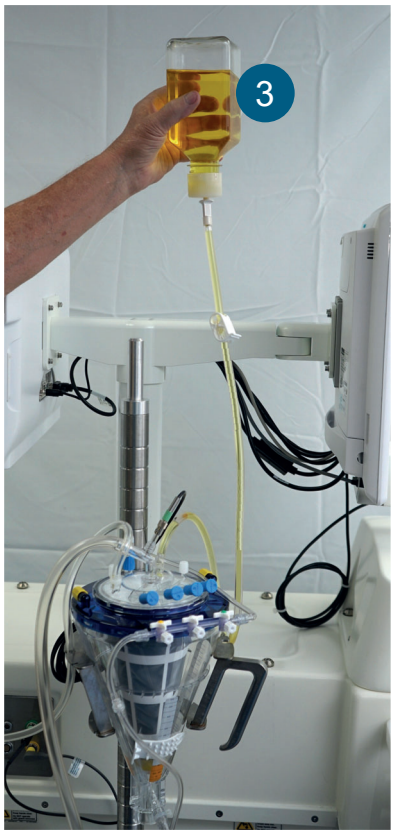
6 Add a third and final bottle of STEEN Solution™ using step **3** during execution of step **5**.

7 Increase the CardioHelp speed to 4,000 rpm for 1 more minute. Inspect the circuit to ensure that there are no visible air bubbles throughout the main tube set.

8 Additives may be added to the reservoir at the determination of the clinician. Those additives can be broad spectrum antibiotics, corticosteroids such as methyl-prednisolone, heparin and when indicated antifungal medication. The dosage depends on the substance(s) used and the decision of the clinician. Be careful to supplement with the additives also in the replacement solution if part of STEEN Solution™ is exchanged during perfusion.







NOTE:
It is recommended to keep the pump control mode set to rpm (instead of lpm) to take advantage of the built-in safety of a centrifugal pump that backs down delivered pressure in response to resistance coming from the lung.

2.4.3 Flow/Bubble and Level Sensors

Prime Mode: XPS™ Perfusion Cart Hardware

FLOW/BUBBLE:

1 Place the flow/bubble sensor around the PA (yellow-banded) circuit tubing at a position close to the duckbill check valve without breaking the sterile barrier as shown.

2 Close the cover with the indicator pointing arrow toward the lung and snap to lock.

LEVEL:

3 Affix disposable level sensor pad to hard shell reservoir with the arrow pointing to the right and bottom edge of sensor lined up near 50ml mark.

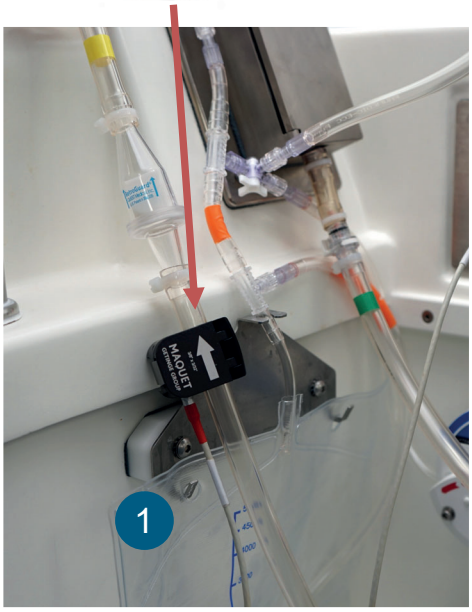
NOTE:

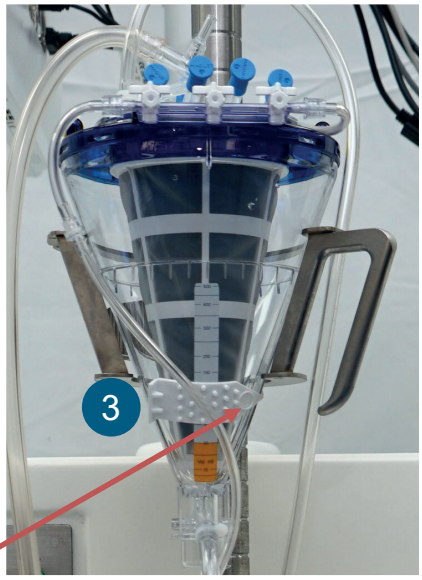
The bottom edge of the sensor indicates the point at which the centrifugal pump will stop should the fluid level drop below the sensor.

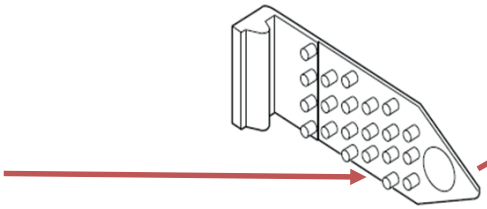
4 Connect the level sensor to the sensor pad.

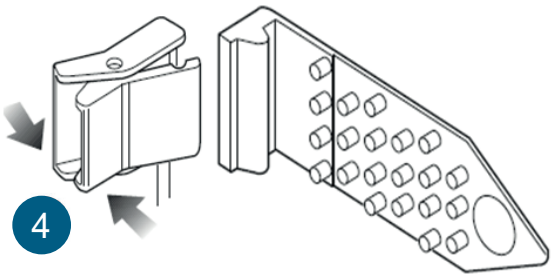
NOTE:

If fluid level should fall below level sensor, pump will stop operation until fluid level is restored. See Section 2.4.2 for reservoir filling instructions.









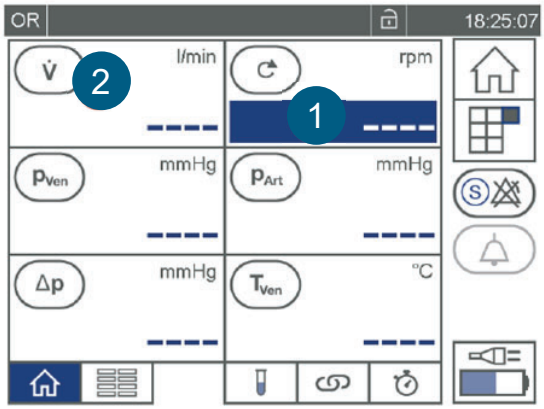
2.4.4 Calibrate Flow Sensor

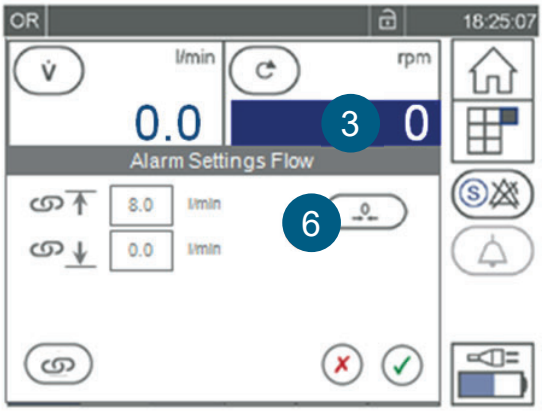
Prime Mode: XPS™ Perfusion Cart Hardware

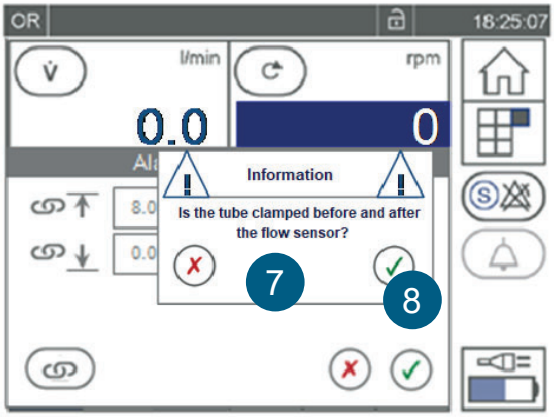
1. Make sure pump is operating in rpm mode (to change mode, see Section 8.3.3).
2. From main touchscreen menu, press the V symbol to open calibration window.
3. Ensure the flow rate is 0 rpm.
4. Clamp the perfusion tubing downstream of flow sensor.
5. Clamp the perfusion tubing upstream of the flow sensor
6. Touch the zero calibration symbol.
7. A message will ask “Is the tube clamped upstream and downstream of the flow sensor?”
8. Confirm that it is by touching the confirm symbol.
9. Release the clamps in the reverse order (**5** upstream and then **4** downstream).

NOTE:

If pump RPM is high (>1000), but the flow rate is displayed as ‘0,’ check for kinks or obstructions in tubing lines and re-zero flow sensor as necessary. If the flow rate still reads ‘0,’ contact XVIVO for service/ support.



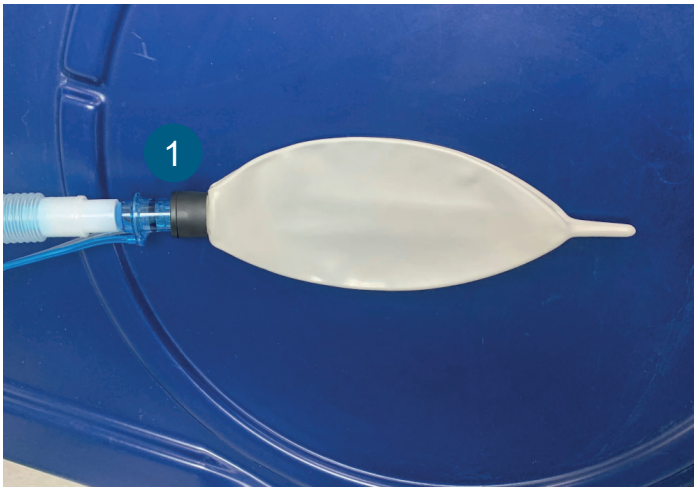




2.4.5 Calibrate C3 Ventilator

Prime Mode: XPS™ Perfusion Cart Hardware

1. Connect breathing bag to ventilator breathing circuit.
2. Connect breathing circuit to XPS side panel :
   - Inhale port
   - Exhale port
3. Connect the flow sensor tubing to the appropriately colored ports.
4. Connect venous mix gas line to XPS vent panel (see section 4.3.2).
5. Connect high pressure oxygen line to port.
6. From the ventilator touch screen, select the Preop check tab.
7. Select each calibration test one at a time by pressing on the buttons to the left in the following order:
   - Tightness
   - Flow Sensor
   - O_2 cell – typically performed during annual service only
8. Follow the on-screen instructions during the calibration procedure.



2.5 Enter Setup Data

Prime Mode: XPS™ Software

1 From the touchscreen monitor, press the “SETUP” tab to open the new screen.

2 Enter data using the on-screen touch keyboard. Up to 512 characters can be added to the Notes field to better describe the procedure, donor information or any other important item to include with the perfusion record.

NOTE:

Height (cm) and Weight (kg) are required entries for calculating perfusion settings.

3 After data is entered, click the “Submit” button to save the data, and to automatically populate the perfusion settings charts.

NOTE:

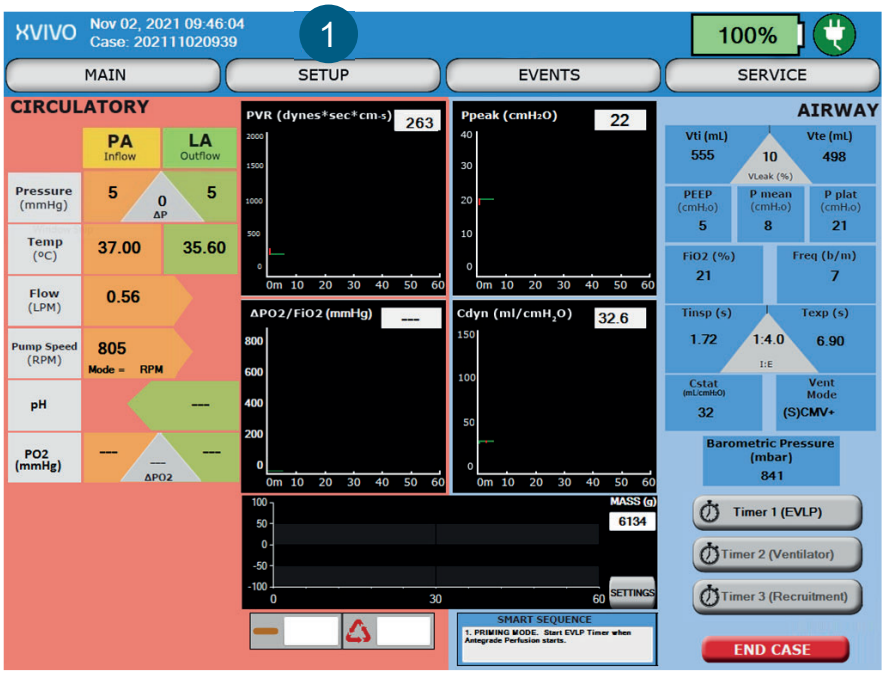
Lung Type setting can be changed (from double to single LT or RT) anytime during the EVLP procedure if needed. Changing the Lung Type and selecting YES (or repressing the blue Submit button) will recalculate the perfusion chart settings.

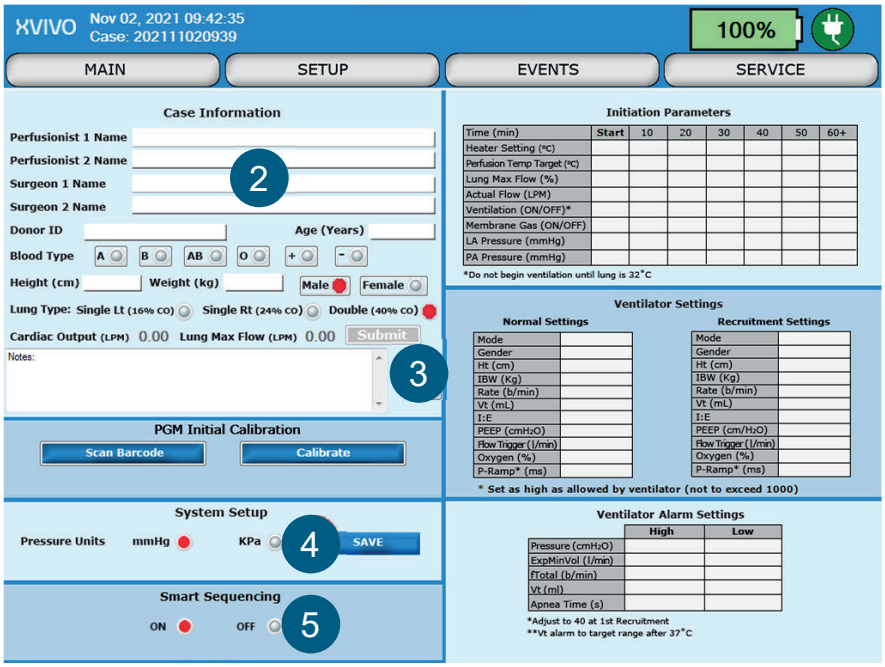
4 Select whether the pressure readings should default in mmHg or KPa values. Once selected, press the “SAVE” button directly to the right.

5 Select/verify Smart Sequencing feature is set to the ON position.

NOTE:

Smart Sequencing is a timer driven procedure for running EVLP. It allows the user to run a seamless EVLP through four recruitments. More user information is provided in Section 4.3.4.





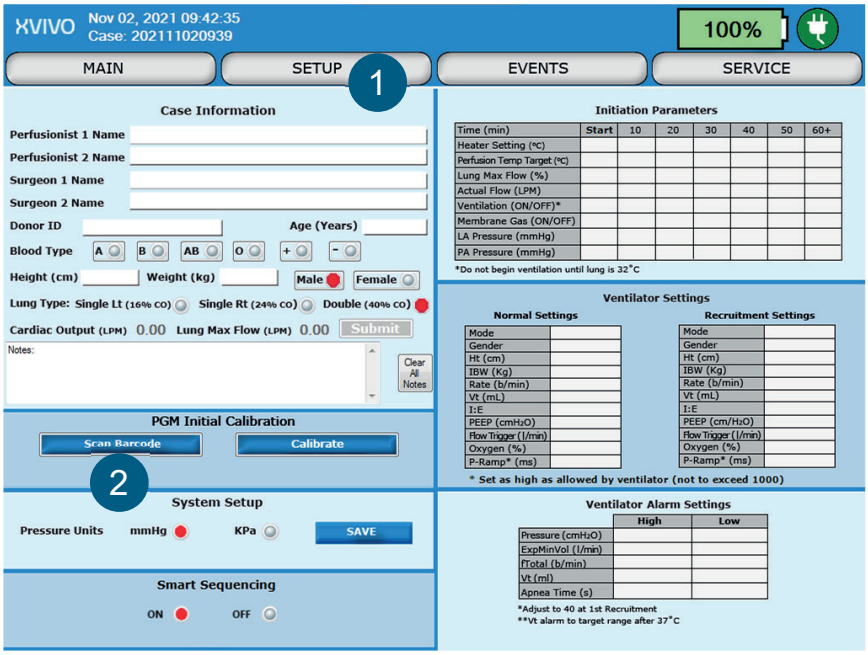
2.5.1 XVIVO PGM Disposable Sensor™ Calibration

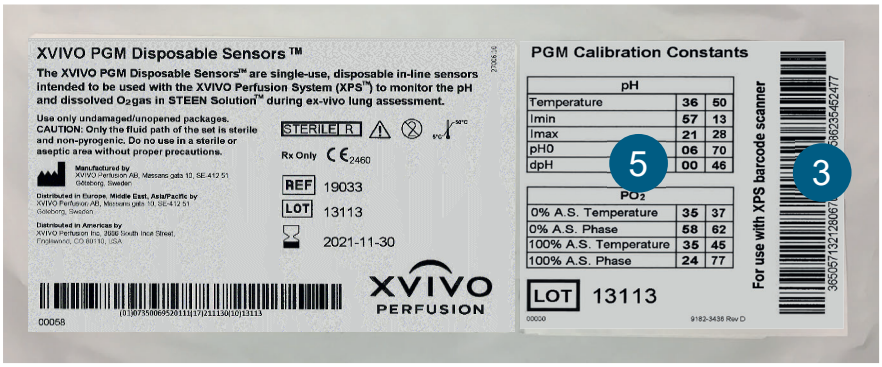
Prime Mode: XPS™ Software

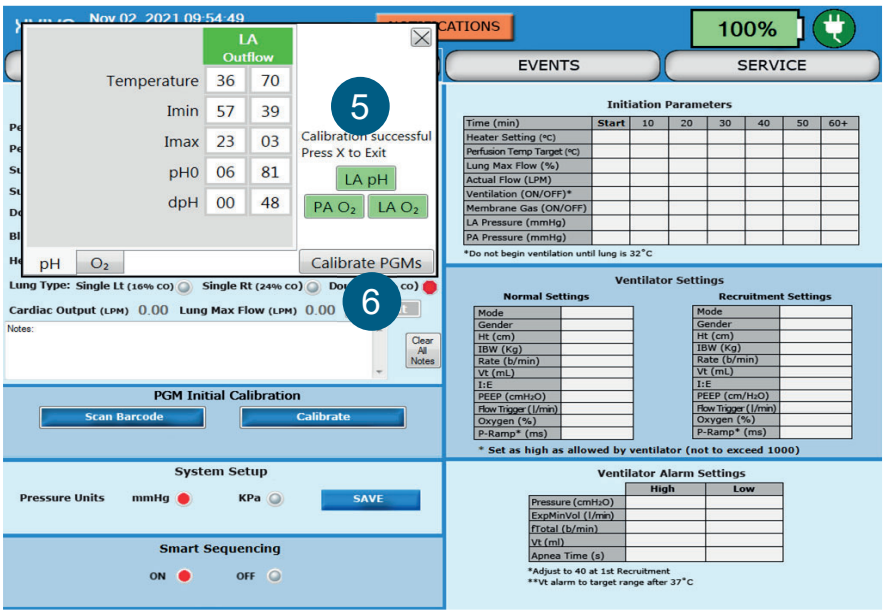
1. From the touchscreen monitor, press the “SETUP” tab to open the setup screen.
2. Select the Scan Barcode button.
3. A text box will appear, and populate when the **vertical** barcode from the PGM Sensor outer wrapping pouch is scanned.
4. Scan the vertical barcode.
5. A PGM calibration box will appear. Ensure that these values match the values on the wrapper. If there is a mismatch, you can adjust the values manually. Select the LA pH button to check or adjust the LA pH data. Select the PA O_2 or LA O_2 button to check or adjust the O_2 data.
6. When values have been verified, click the “Calibrate PGMs” button.

NOTE:

PGM can be calibrated at any time. The PGM data will not be displayed until the perfusate reaches 35°C.



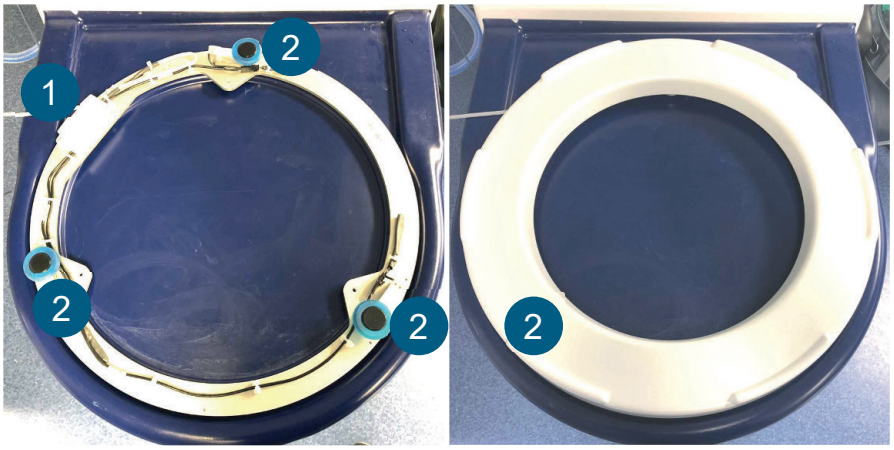


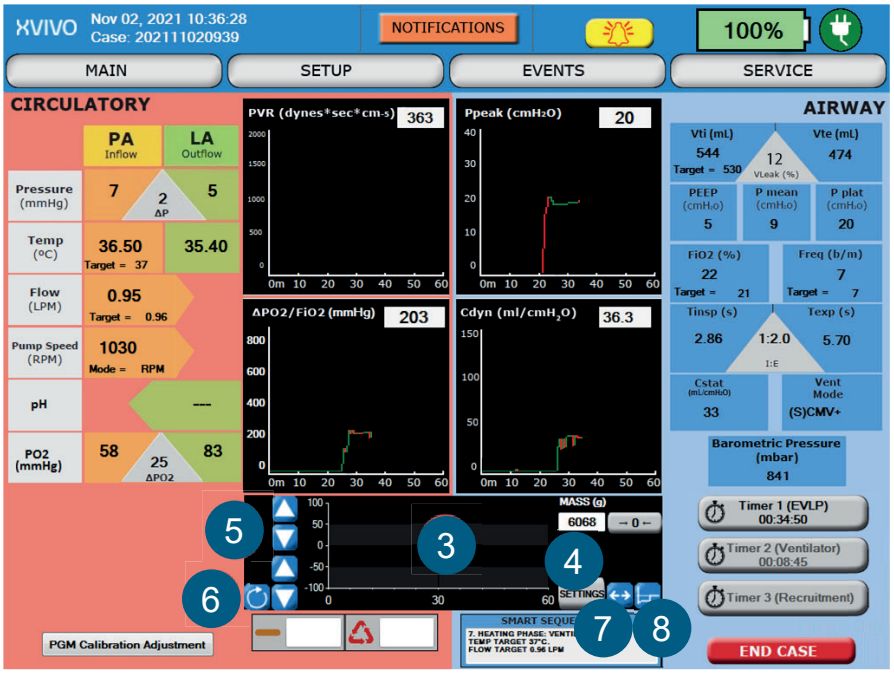


2.6 Weight Sensor

Prime Mode: XPS™ Software

1. The Weight Sensor's foot pads should be within the table's grooves, and the connector port positioned at 10 o'clock.
2. The weight sensor's cover should be placed over the ring and centered on the sensor's rubber pads.
3. When the Weight Sensor's cable is properly connected, the MASS value is non-blank. If blank, see Note below to troubleshoot.
4. In use, the Tare Button zeros the Sensor. Press the Settings button, then the - 0 - button to tare the scale. A blue vertical line appears on the Weight Graph to indicate when a zero function was performed.
5. The 4 arrow buttons to the left of the Weight Graph will modify the range of the Weight Graph's vertical axis: the top two arrow buttons control the graph's maximum, and the bottom two control the graph's minimum.
6. Press the Reset Axis Button to reset the vertical axis to its default range.
7. Press the Last Hour Mode button to enable and disable Last Hour Mode. With Last Hour Mode disabled (default) the Weight Graph's horizontal axis will start at the beginning of the procedure. With Last Hour Mode enabled the Weight Graph's horizontal axis will show only the previous 60 minutes.
8. Press the Tare Past Mode button to enable and disable Tare Past Mode. With Tare Past Mode enabled (default) pressing the Tare Button will affect previous data on the Weight Graph to reflect the new tare value as well as future data. With Tare Past Mode disabled pressing the Tare Button will only affect future data.





NOTE:

If the Weight Value **3** is blank or freezes, follow these steps:

1. Ensure the weight sensor's cable is correctly plugged into the ventilator panel.
2. Unplug the weight sensor's USB cable, wait 5 seconds, and plug it back in.
3. Press the SERVICE button at the top of the screen to go to the Service Page.
4. Press the Weight Sensor Button to reconnect to the weight sensor.

2.7 UPS

Prime Mode: XPS™ Software

1 During normal use, the UPS battery life is shown within the battery icon.

2 The status of the AC/mains power connection (plugged or unplugged into a wall outlet) is shown to the right of the battery icon.

3 When the AC/mains power connection is interrupted and the XPS is on battery power, the AC-disconnected icon is shown to the right of the battery icon. The battery icon displays battery life and AC-disconnected time. The Notifications banner and icon will also appear.

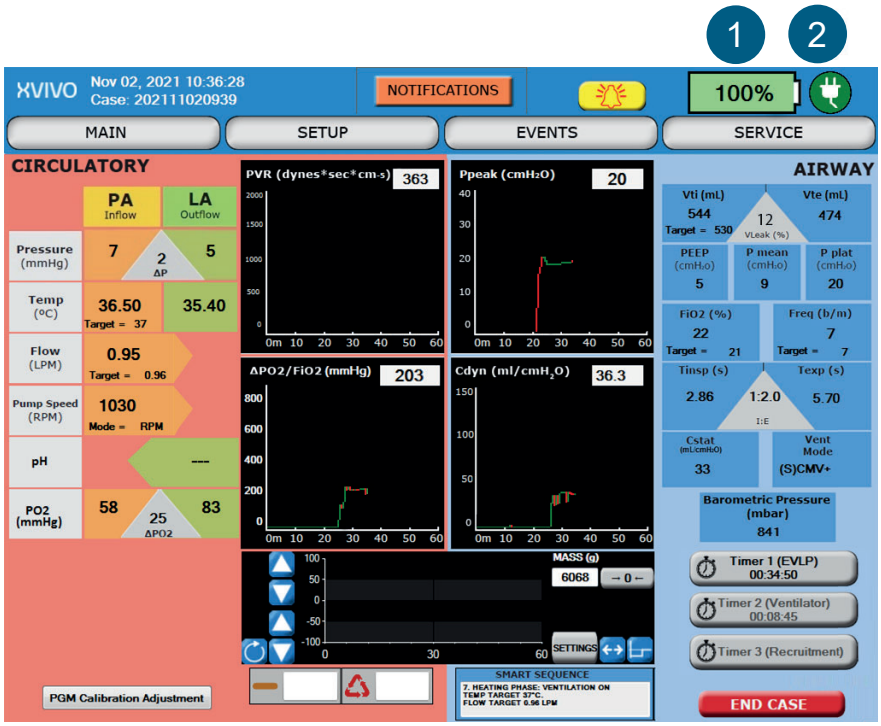
4 The battery icon will display three different colors for levels of battery life:
- green for 68%-100% charge
- orange for 34%-67%
- red for 0%-33%

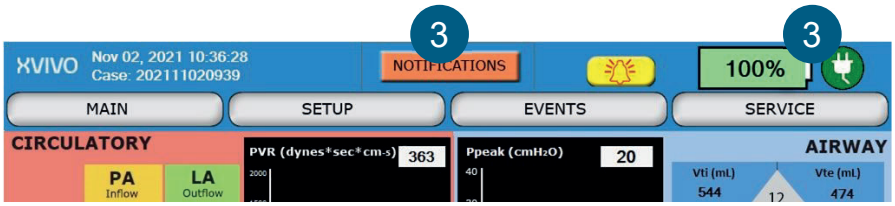
5 **NOTE:**

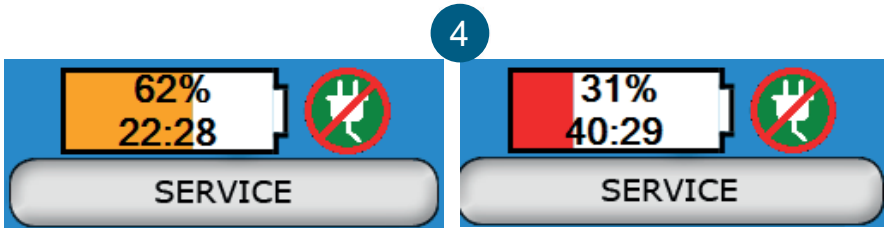
- If the battery falls to 25% state of charge OR it has been 58 minutes since AC was connected then shutdown will be imminent.

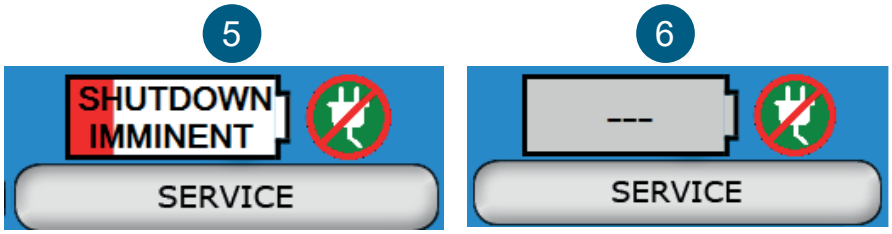
- If the battery falls to 20% state of charge OR it has been 60 minutes since AC was connected then the Shutdown Imminent message will appear within the battery icon.

6 The battery icon color will change to gray and display dashes if the UPS has a hardware or communication problem. In this case, the computer will not automatically shut itself down as described above in point 5.









3.1 Lung Preservation

Donor lungs are procured following the currently accepted method, using cold PERFADEX® Plus as an in-situ flush solution and to store and chill (by ice) the inflated and clamped donor lungs during transportation to the recipient hospital for up to 12 hours. In addition to preservation time restrictions, the main limitation to cold storage of donor lungs is that any injury to the lungs cannot be assessed because at 4°C, cellular metabolism is reduced to <5%.

Therefore, the ability to assess donor lungs at normothermic (37°C) temperatures allows the best method to evaluate lungs at full metabolism. Benefits of Ex Vivo Lung Perfusion (EVLP) include:

Additional time to fully evaluate the donor lung(s) outside of the typically hostile brain death environment

Customized choice of treatment and time to confirm results

Additional time to allows the lung to reestablish itself back to a normal physiologic state

Avoid the typical inflammatory and coagulation responses associated with in-vivo donor assessment and clinical management

3.2 Protective Maintenance

The strategy for EVLP is to prevent any additional stress to the donor lungs through the use of protective ex vivo perfusion strategies as shown in the table below. More specifically, the protective maintenance strategy during EVLP consists of the following overall perfusion parameters:

- STEEN Solution™ is used acellularly (without red blood cells)
- Maximum perfusate flow rate = 40% of calculated cardiac output for double lungs (24% for Rt lung only and 16% for Lt lung only)
- Mechanical ventilation (based on ideal body weight): VT 7ml/kg, rate of 7 BPM, PEEP of 5 cm H_2O, FiO_2: 21%
- Recruitment maneuvers of Vt set to 10ml/kg for the last 10 mins. of every hour
- Keep left atrial pressure at 3-5 mmHg during procedure

Time (min)	0-10	10-20	20-30	30-40	40-50	50-60
Heater Setting	23	32	38	38	38	38
Achieved Temperature	RT	31	32	37	37	37
Percent Calculated Flow	10	20	30	50	80	100
Ventilation	OFF	OFF	ON	ON	ON	ON
Membrane Gas	OFF	OFF	ON	ON	ON	ON
LA Pressure (mm Hg)	3-5	3-5	3-5	3-5	3-5	3-5

3

Lung Preparation

3.3.1 *Ideal* Cannulation

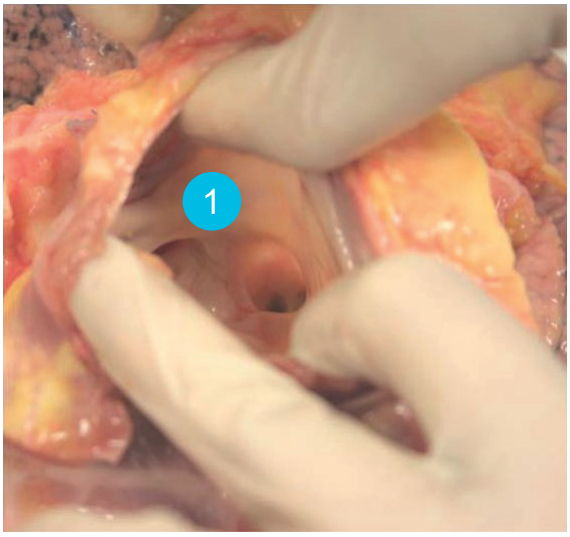
Prime Mode: Lung Preparation

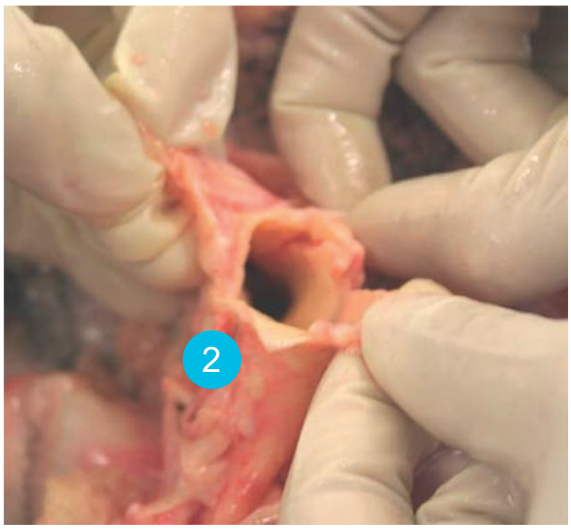
Ideally, the donor lung will have the following characteristics:

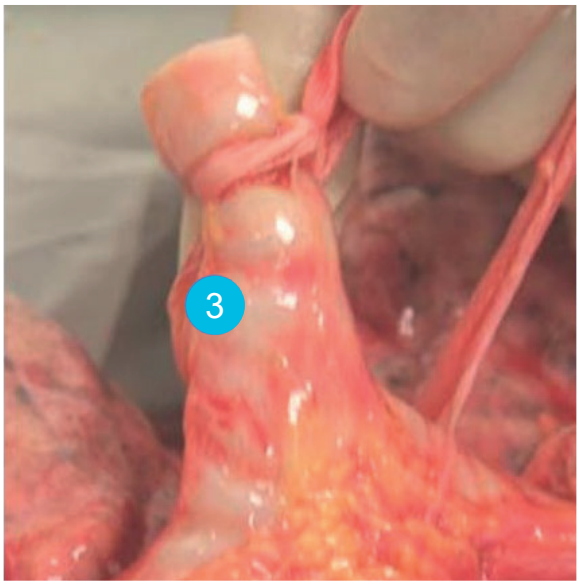
1. Large atrial cuff
2. Long main pulmonary artery
3. Long trachea

Cannulation is typically performed on a sterile draped back table. The following standard surgical instruments should be available:

- 3 Pickups
- 1 Metzenbaum Scissor
- 1 Mayo Scissor
- 1 Needle Driver
- 4 Curved Snaps
- 1 Knife Handle
- 5 Tubing Clamps
- 1 Hammer
- Suction
- K Basins
- Towels
- Sterile Slush
- 15 Blade
- Cannulas
- 2-0 Silks
- 9.0 ET Tube & Syringe
- 4-0 Prolene x 3
- IV Tubing
- Sponges







3.3.2 XVIVO Left Atrial (LA) Cannula

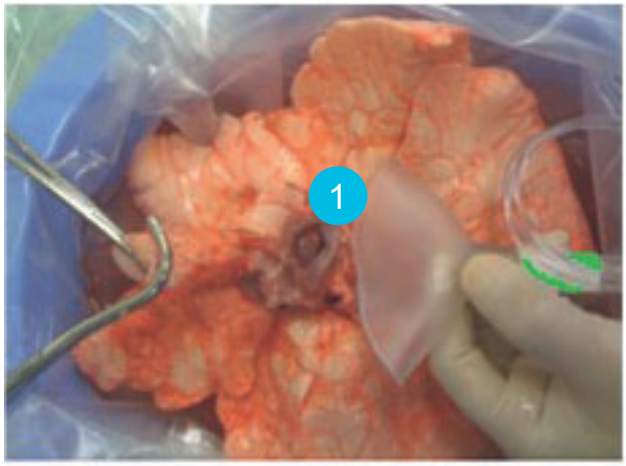
Prime Mode: Lung Preparation

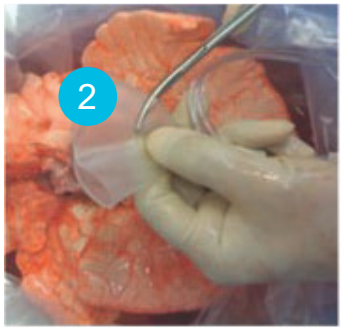
The XVIVO Left Atrial Cannula is the cone-shaped cannula marked with the green taped end.

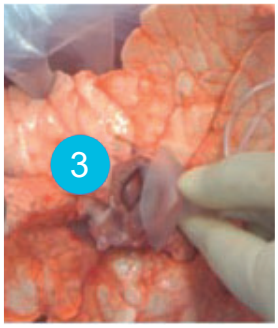
1. Measure the cone end to the donor lung left atrial cuff.
2. Cut the cone to better approximate atrial opening.
3. Re-measure against opening.
4. Connect cone to left atrial cuff with a running 4-0 polypropylene suture.
5. Finished cannula sutured to LA.

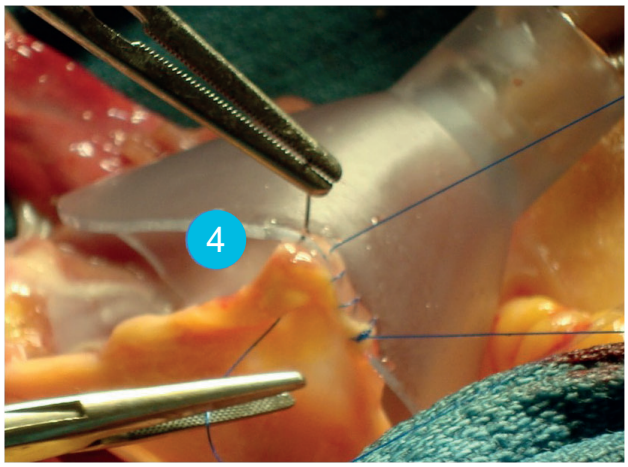
NOTE:

There are two cone cannulas included in the XVIVO Lung Cannula Set™ – the green taped cannula is typically used for the left atrium and is slightly stiffer than the white taped cannula, which is used either as a backup LA cannula or for difficult pulmonary artery (PA) cannulations as shown on the next page (Sec 3.3.3).







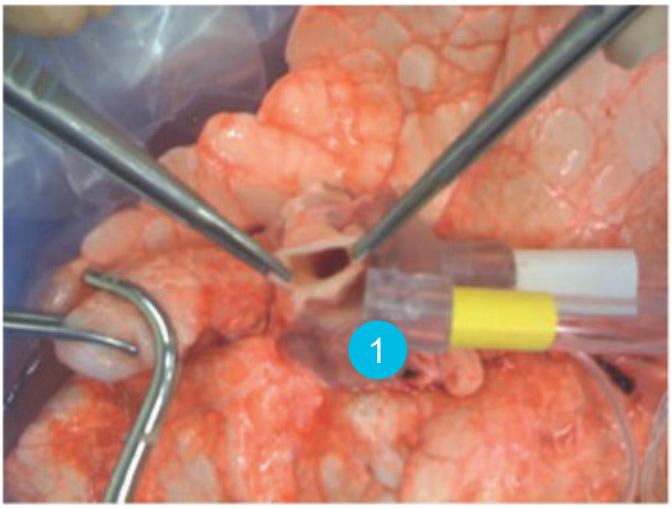


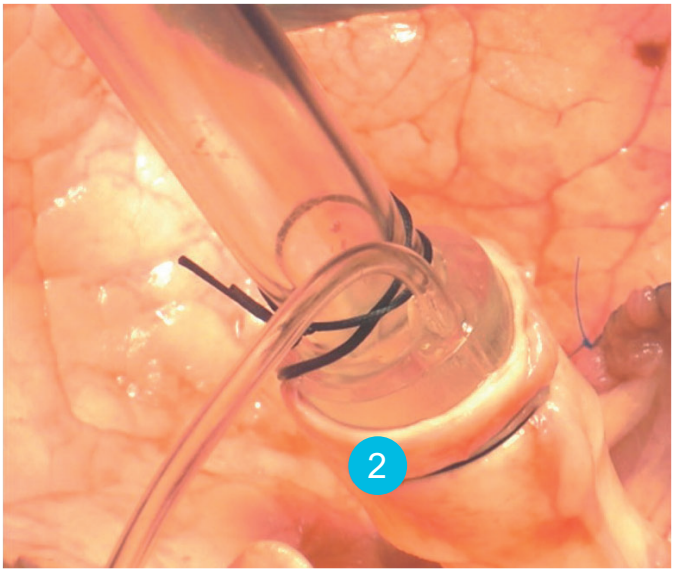
3.3.3 XVIVO Pulmonary Artery (PA) Cannula

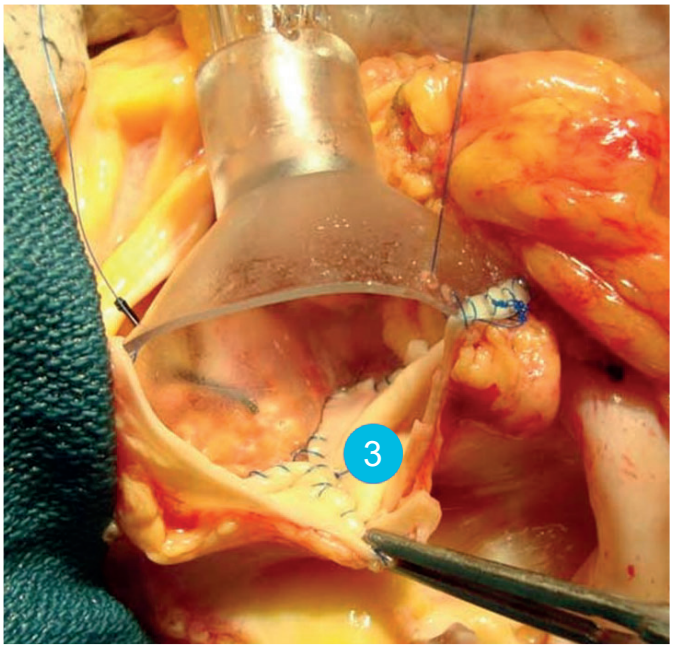
Prime Mode: Lung Preparation

The XVIVO PA Cannula is the straight cannula marked with the yellow-taped end.

1. If the PA is intact, open up the lumen and insert the XVIVO PA Cannula into the opening.
2. Tie around the outside of the PA across the groove at the tip of the cannula with either a silk or umbilical tape to secure in place.
3. If the heart was also recovered for transplant, the main PA will be taken by the cardiac team. In this case, sew together the left and right PAs and use the extra white taped cone cannula to reconstruct the main PA and connect the lung to the circuit.





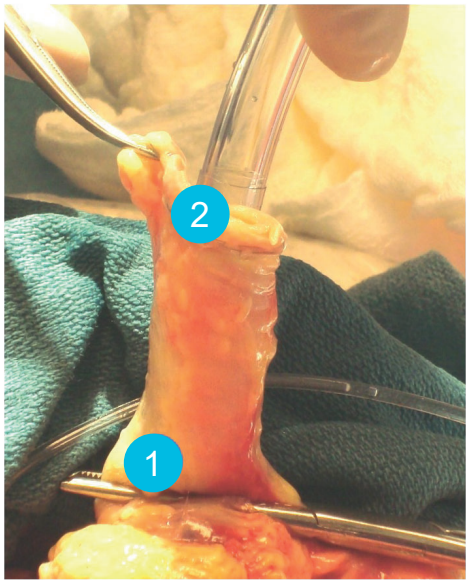


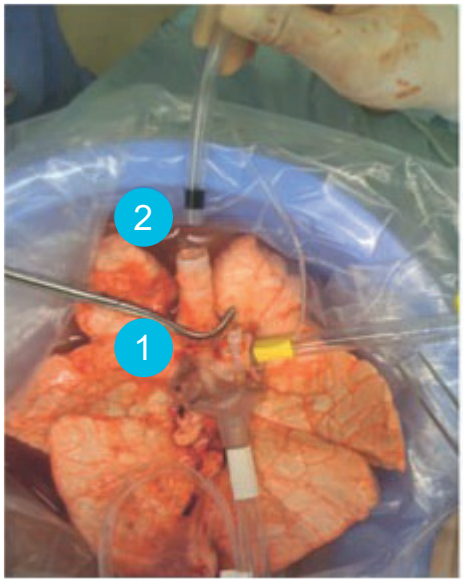
3.3.4 Intubation

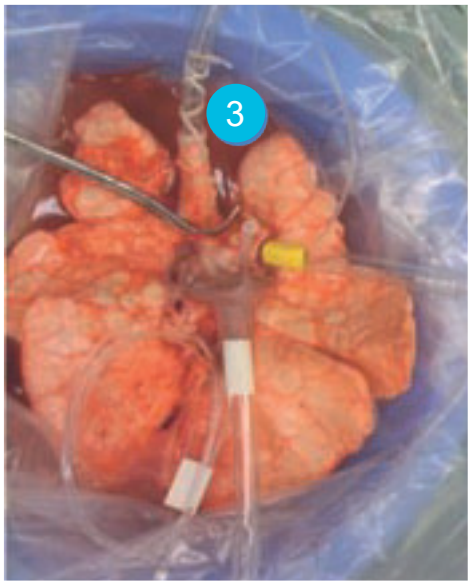
Prime Mode: Lung Preparation

Typically, a standard 9.0 sized endotracheal (ET) tube is used to intubate the ex vivo lung.

1. Clamp the trachea to prevent lung deflation prior to intubation.
2. Insert ET tube into tracheal opening.
3. Tie around the outside of the trachea to secure ET tube in place.





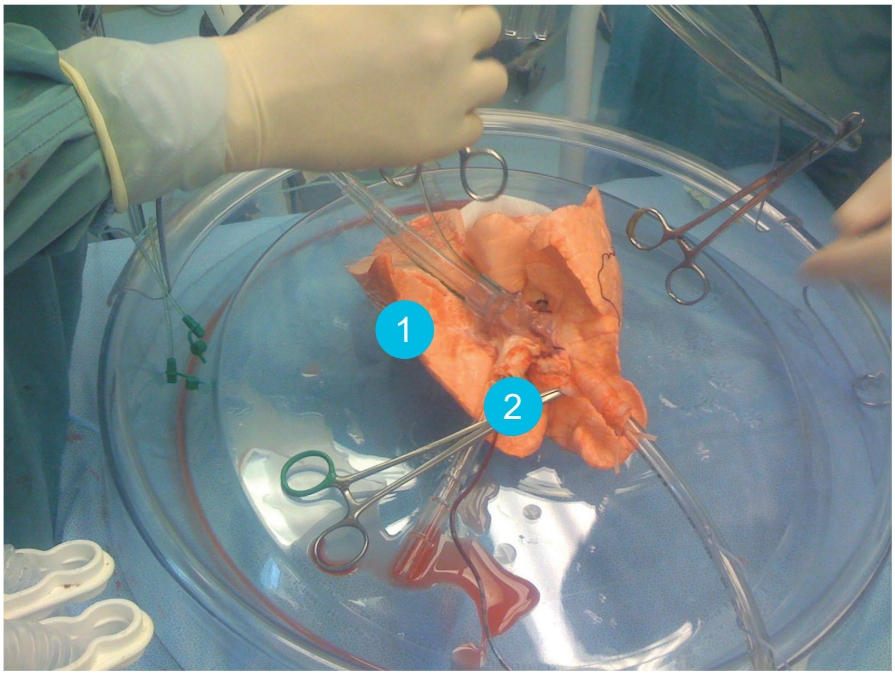


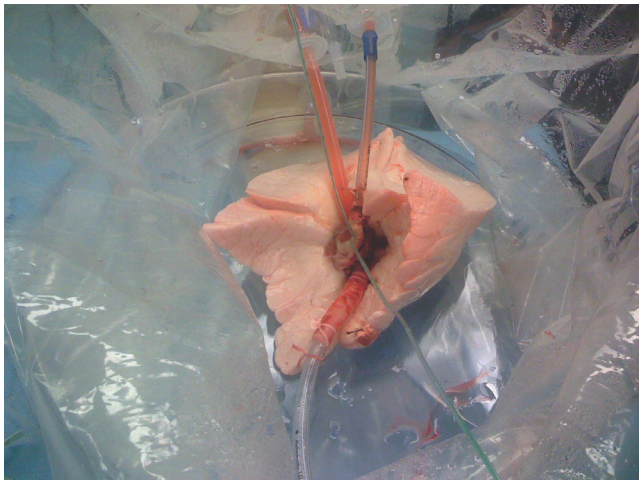
3.3.5 Single Lung Cannulation

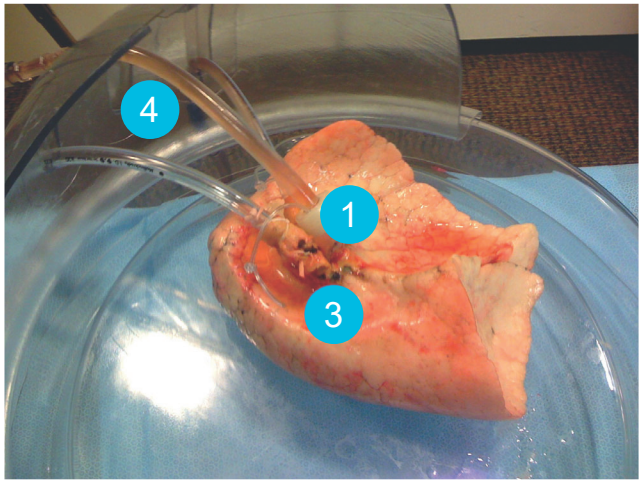
Prime Mode: Lung Preparation

In the case when performing the EVLP technique on a single lung, cannulation of the single right or left lung follows the same procedure as with the double lung with the following differences:

1. LA Cannula (cone) should be shaped according to the diameter of the available atrial cuff and connected with a running 4-0 polypropylene suture as with a double lung.
2. PA Cannula (straight) is introduced into the PA branch and tied in place with a silk suture.
3. ET tube cannulation requires a different approach depending on right or left lung perfusion.
   Right: preserve a portion of the trachea to facilitate ligation of the ET tube with umbilical tape (right bronchus can be short).
   Left: typically, the left bronchus extension is long enough to place and ligate the ET tube in the correct position.
4. For a single lung, all three cannulas (LA, PA and ET) will come out of the top lid portion of the XVIVO Organ Chamber™.



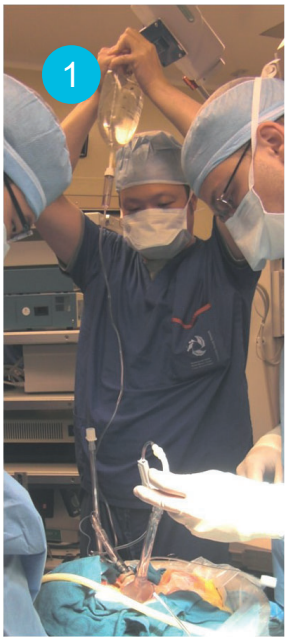


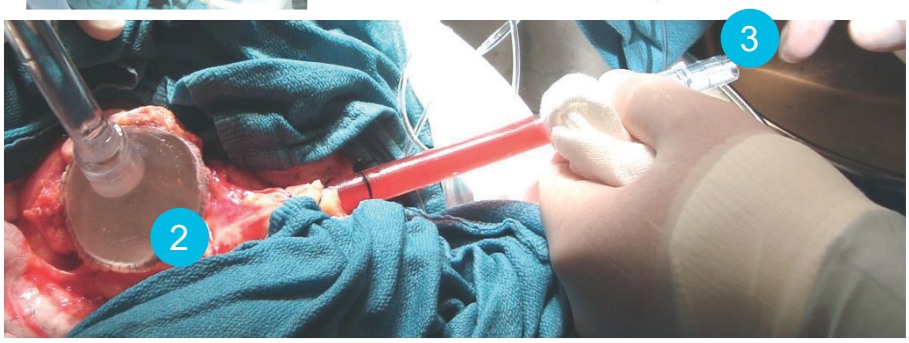


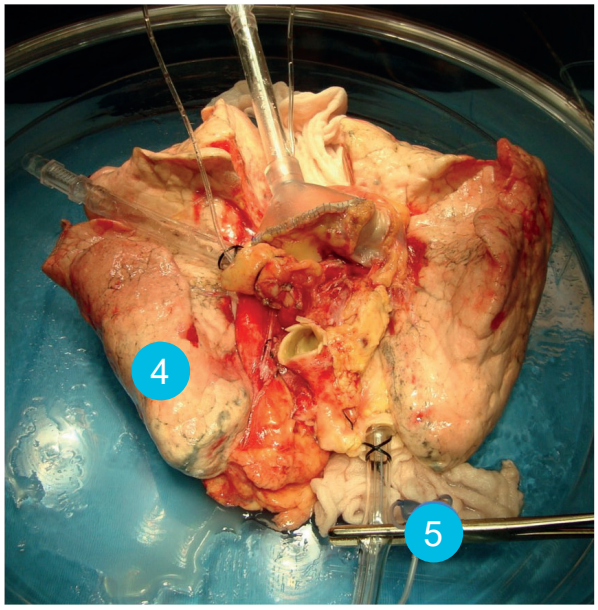
3.3.6 Back Table Flush

Prime Mode: Lung Preparation

1. Perfuse 1L cold buffered PERFADEX® Plus in a retrograde direction (i.e. from LA, to PA).
2. Check for and fix any leaks in the LA and/or PA cannulas.
3. Continue to flush until the effluent comes out clear.
4. Move the lung bloc to the XVIVO Organ Chamber™ on the XPS™ Cart.
5. NOTE the ET tube remains clamped to keep the lungs inflated.



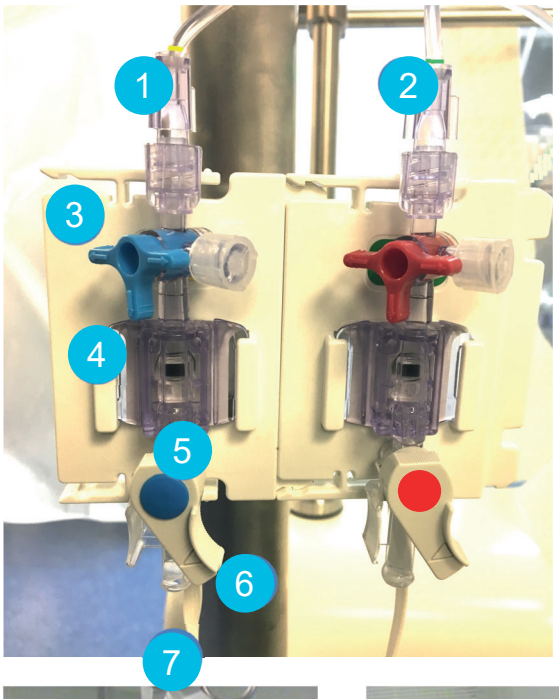




3.3.7 Pressure Sensors

Prime Mode: Lung Preparation

1 Pressure line to PA Cannula
2 Pressure line to LA Cannula
3 Zero Stopcock
4 Pressure Transducer
5 Flush Lever
6 Transducer Connector
7 Line to Saline Flush

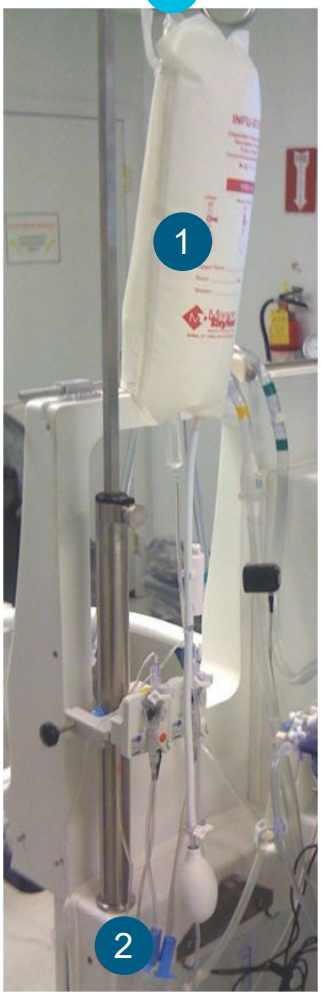


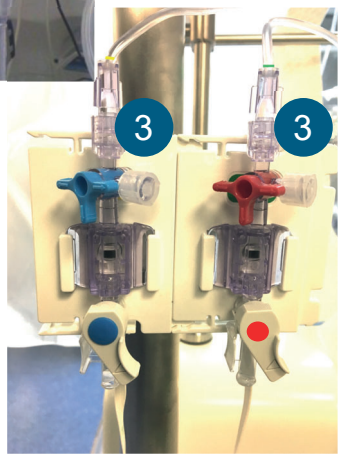
NOTE:

There may be slight differences in the packaging or color of the pressure transducers or stopcocks pictured here.

PRIME WITH GRAVITY - Applying pressure from the pressure cuff during priming may create microbubbles in the lines which are difficult to remove. Therefore, the solution bag needs to be higher than the transducer to prime.

1 Spike a 1L bag of sterile saline to the flush line. Fill part of the drip chamber by squeezing the sides of the chamber first.
2 Open the roller clamp and fill up to the flush device.
3 Prime the side port of the zeroing stopcock and cap with a Luer lock plug.





CAUTION:

Always turn the stopcock off to the transducer or off to the venting lung before attaching the luer lock plug.

4 Check for bubbles and gently tap at areas where bubbles may be hidden from view.
5 Inflate pressure bag to 300mmHg and fast flush the system for 2-3 seconds.

NOTE:

An alternate method using a sterile syringe rather than a 1L bag of saline can be used. Only the transducer connector is added to the transducer pressure dome. A syringe with sterile saline is connected at the bottom of the transducer connector, and flushed. STEEN Solution™ is then drawn back from the lung on the pressure lines, once the lungs have been added to the circuit.

3.3.8 Zero Pressure Sensors

Prime Mode: Lung Preparation

ZEROING

1 Mount the transducers from the disposable lung kit in the appropriate operating position with the stopcock zeroing port at the level of the left atrium of the lung.

NOTE:

At this point, elevation of hard shell reservoir should be adjusted so that fluid level is consistent to level of left atrium and stopcock.

2 Vent the transducer to atmospheric pressure by turning the zeroing stopcock off to the lung.

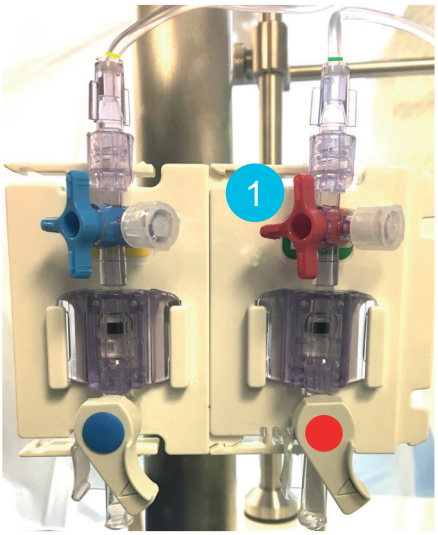
3 Remove the luer caps to vent to atmospheric pressure.

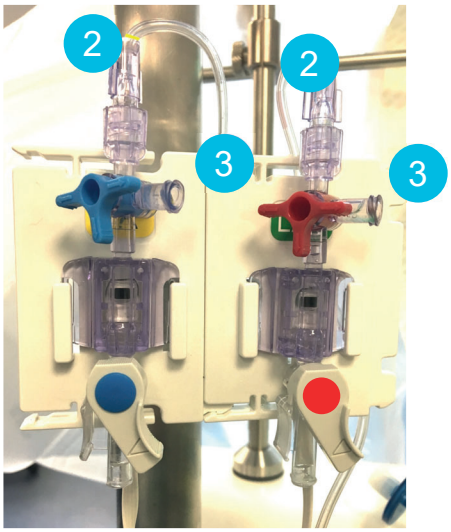
4 At the XVIVO CardioHelp pump main screen, touch a pressure button (PVen) to open the calibration window.

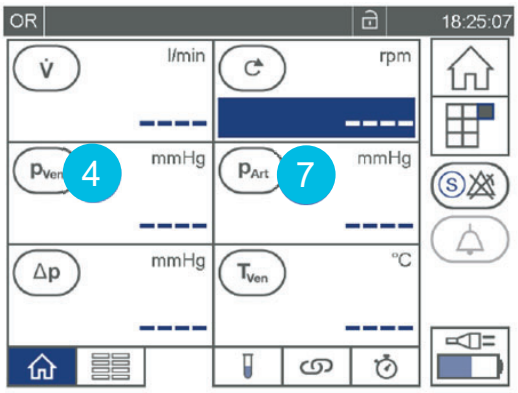
5 Touch the zero calibration symbol.

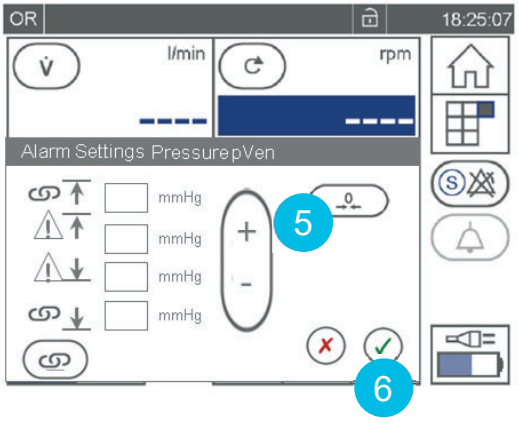
6 Close the pressure settings window by touching the confirm symbol.

7 Repeat steps 4-6 with the other pressure sensor (PArt). Replace the luer caps and move the stopcocks back to the horizontal position (off to atmospheric pressure) as shown in Step 1.









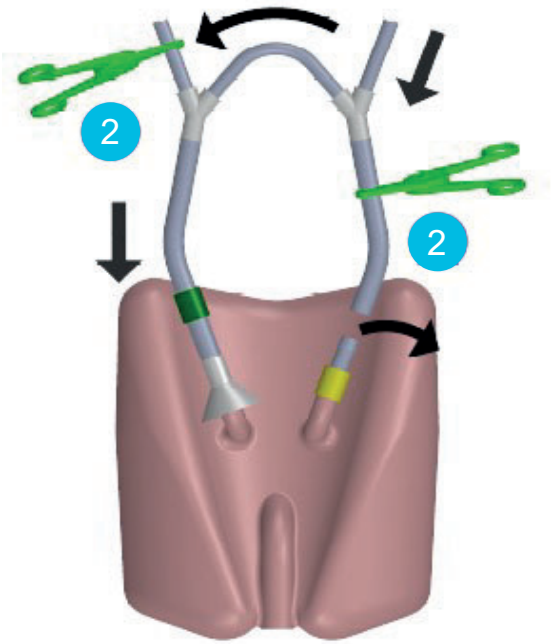
3.3.9 Prime Lung/Retrograde Flow

Retrograde Mode

1 Ensure pump flow <0.15 l/m.

NOTE:

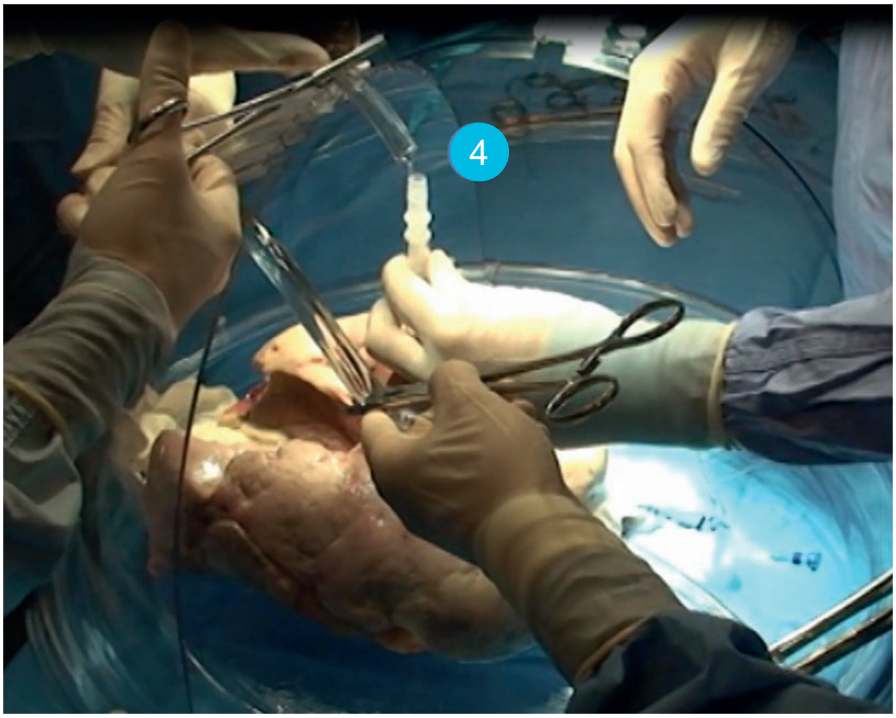
If pump speed exceeds 0.25 l/m when changing perfusion modes, a Notice will sound until the speed is reduced below 0.25 l/m.



2 Clamp the priming loop at the points shown in green to create a retrograde flow.

3 Run the pump slowly at a starting flow rate of 100ml/min and trickle STEEN Solution™ into the left atrium of the lung via the XVIVO Left Atrial (LA) Cannula until it completely fills up with STEEN Solution™

4 Connect the priming loop to the LA Cannula carefully, preventing air from entering the Circuit by slowly filling the LA chamber and tubing with trickling STEEN Solution™



5 Slowly run the centrifugal pump in retrograde flow until STEEN Solution™ fills the XVIVO Pulmonary Artery (PA) Cannula.

6 Continue running in retrograde direction until the STEEN Solution™ perfusate runs clear and free of any clots (approximately 200 ml) out through the PA cannula into waste bag.

NOTE:

It is important to note the fluid level of the hardshell reservoir as additional STEEN Solution™ may be required to avoid triggering the low level alarm.

7 Connect the PA Cannula to the Circuit carefully, preventing air from entering the circuit.

3.3.10 Antegrade Flow

Antegrade Mode: Lung Preparation

1 Ensure pump flow rate <0.15 l/m.

NOTE:

If flow speed exceeds 250 RPMs a message will sound until the flow is reduced below 0.25 l/m.

2 Change the clamps according to the picture to begin antegrade flow

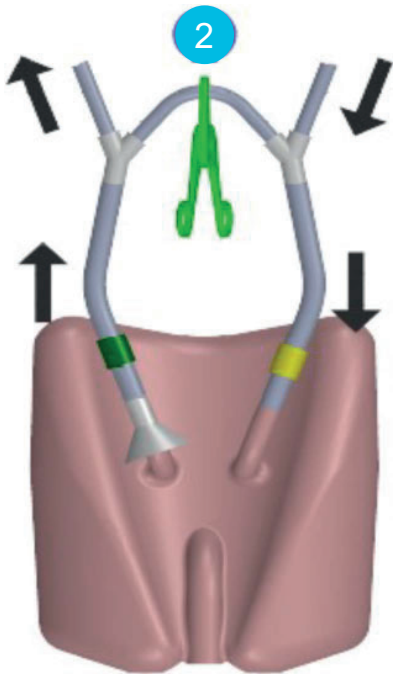
3 Run the pump slowly at a starting flow rate of 150ml/min and check for any bubbles or leaks in the circuit and/or cannulas.

4 Increase temperature of heater cooler to 32°C.

5 As lung begins to warm up, it will tolerate additional flow. Continue to monitor and add more flow according to the warm-up protocol.

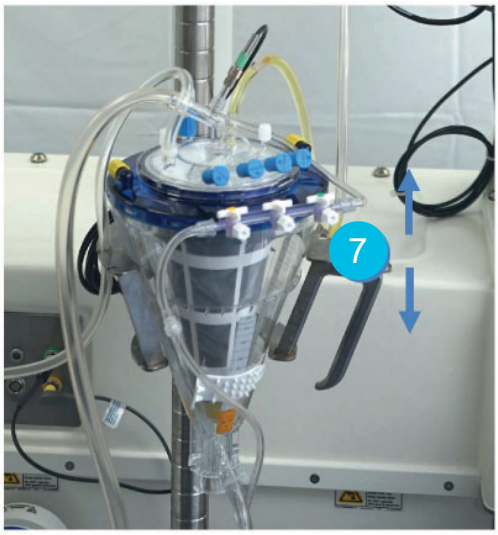
6 Continue increasing temperature to 37°C.

7 NOTE: to safely control the LA pressure, the hardshell reservoir may be raised or lowered to keep the outflow pressure 3-5 mmHg. Every 1 inch of height equals 2 mmHg pressure change.



5

Time (min)	0-10	10-20	20-30	30-40	40-50	50-60
Heater Setting	23	32	38	38	38	38
Achieved Temperature	RT	31	32	37	37	37
Percent Calculated Flow	10	20	30	50	80	100
Ventilation	OFF	OFF	ON	ON	ON	ON
Membrane Gas	OFF	OFF	ON	ON	ON	ON
LA Pressure (mm Hg)	3-5	3-5	3-5	3-5	3-5	3-5



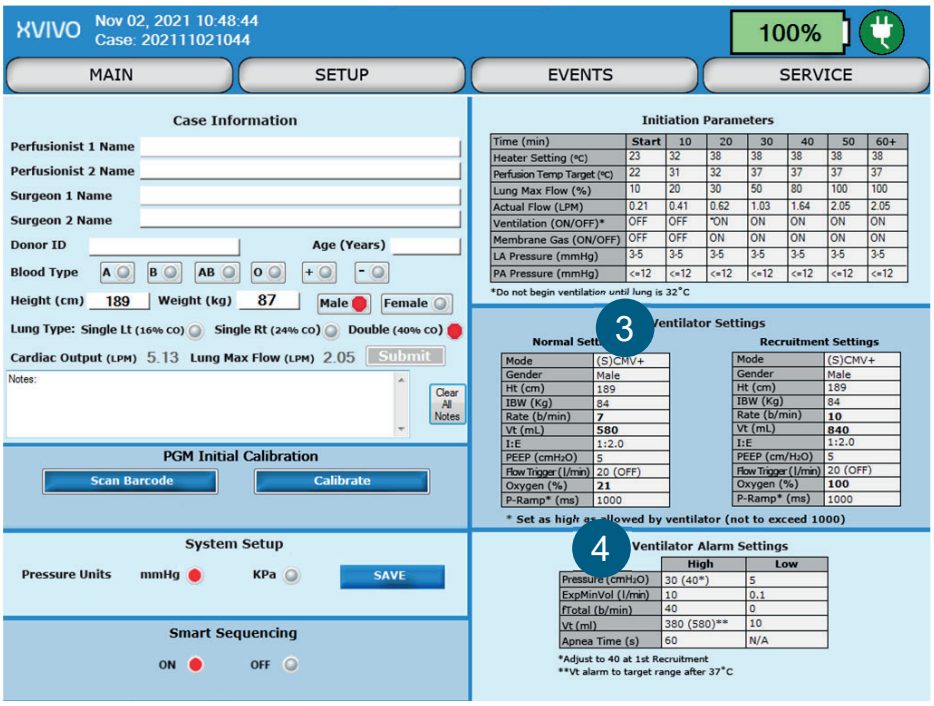
3.3.11 C3 Ventilator Settings

Antegrade Mode: Lung Preparation

1. Select New Patient
2. Enter donor's height and gender to define ideal weight. The C3 uses these parameters to calculate airway dead space of the donor lung(s)
3. Select Controls and set parameters according to the Setup Page Ventilator Settings.
4. Select Confirm on the Ventilator.

NOTE:

Lung Type setting can be changed (from double to single LT or RT) in the SETUP page anytime during the EVLP procedure if needed. Changing the Lung Type and pressing YES (or repressing the Submit button if Smart Sequencing is not active) will recalculate the perfusion chart settings.



3.3.11 C3 Ventilator Settings

Antegrade Mode: Lung Preparation

1 From the Control menu, press the ‘More’ button on left

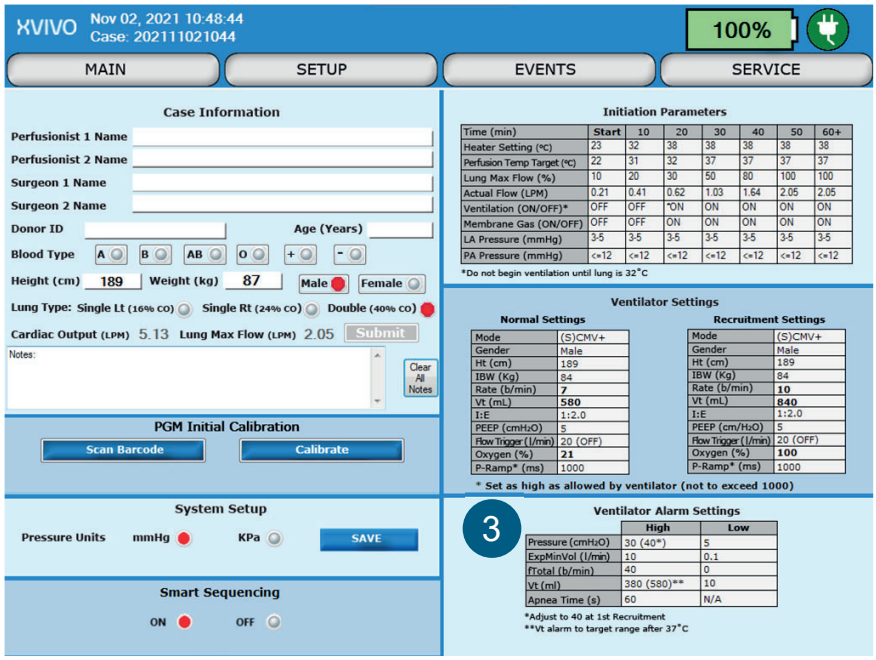
2 Set P-ramp to 1000ms for more physiologic ventilation curves. Depending on lung characteristics, ventilator software may limit P-ramp below 1000 ms. In this case, set P-ramp to as high a setting as available (not to exceed 1000ms).

ALARM SETTINGS

The C3 ventilator features pressure controlled volume ventilation. As such, the Pressure limitation can be set from the alarm settings menu. The upper pressure will not go above the set limit and equals airway pressure plus PEEP to get the total.

3 Select Alarm menu and set: **Pressure, ExpMinVol, Ftotal, Vt,** and **Apnea time** according to the Ventilator alarm settings in the Setup Page.

*To prevent the Tidal Volume from exceeding the recommended 7ml/Kg initial protective setting, the upper limit of the VT alarm may also be set. However, the C3 will *exceed* this limit by a factor of 1.5. Therefore, to prevent the C3 from administering too much volume, divide the calculated upper limit by 1.5 to get the set limit. The C3 will not exceed the calculated volume, *but will alarm continuously* as the delivered volume will still be higher than the alarm set point. Once the lung is around 37°C, this alarm can be changed back to the ideal calculated VT to silence the alarm.



3.3.11 C3 Ventilator Settings

Antegrade Mode: Lung Preparation

1 Once temperature reaches 32°C, bronchoscopy and/or BAL may be performed for STAT Gram stain. When complete, press 'Start Ventilation' after ET clamp is removed.

NOTE:

Ensure ET clamp is removed before start of ventilation.

When ventilation starts, inspiratory resistance will be high and lung compliance will be low.

NOTE:

Lung inflation at retrieval is critical. Collapsed lungs are extremely difficult to re-expand and might demand the use of higher ventilation pressures, which will lead to failure of the evaluation.

The strategy is to limit Peak pressure to 20 cmH_2O, during the period of re-warming, 32 to 37°C.

The pressure limit will not exceed the value set in the Alarms menu before ventilation started.

In a cold lung, calculated VT will not be met, and:

2 Pressure limitation Alarm will activate.

3 Press Alarm silence button

4.1 Ex Vivo Lung Perfusion (EVLP)

Normothermic EVLP permits a more rational utilization of potentially acceptable organs which are currently often discarded despite the relatively reversible nature of their imperfections. The ultimate objective of the EVLP procedure is to expand the donor organ pool and thus reduce or possibly eliminate mortality and morbidity on the transplant waiting list.

EVLP with STEEN Solution™ will help increase the pool of available organs by allowing assessment of marginal lungs in optimized conditions. Several mechanisms contribute to this:

1. The warming and reperfusion period allows time for the lung to reestablish its normal condition in an optimized and safer environment. The *ex vivo* perfusion is carefully controlled using a lung-protective strategy.
2. The physiologic problems caused by neurogenic pulmonary edema in the organ donor with respect to electrolytic balance, colloid-osmotic pressure and temperature are restored during this protective reperfusion period.
3. Any remaining donor blood still in the lungs (containing coagulation factors, complement, activated white cells, inflammatory cytokines and non-physiological substances, including drugs used during donor management) is diluted or filtered away during EVLP. This washing out benefit is not achieved with current hypothermic perfusion as the cold temperature induces vascular constriction within the lung, preventing complete flushing.
4. EVLP facilitates removal of clots in the pulmonary circulation through the use of transient retrograde perfusion at the beginning of the procedure.
5. The ex vivo system provides an excellent environment for recruitment and re-expansion of atelectatic lung areas because it allows for all ventilatory volumes and pressures to be transferred directly to the lungs without interference of the chest wall and diaphragm.
6. EVLP allows time to assess and clean/suction bronchial secretions.
7. The dextran in the perfusate solution facilitates perfusion of the pulmonary micro-vasculature.

4.2 EVLP Strategy

Ideal lung assessment parameters mirror recommendations from the International Heart & Lung Transplant Society. During assessment, trends are more important than actual values and include watching:

- Lung compliance- ΔV/ΔP will vary with lung size
- LA Pressures– should be kept 3-5 mmHg
- Peak Airway Pressures– should be kept around 11-13 cmH_2O
- ΔPO_2:FiO_2 ratios should trend ≥ 350 mmHg

A good lung will be able to maintain good assessment values over time. A failing lung will begin to develop edema, resulting in decreased compliance, increased weight, increased airway pressures, shunting leading to decreased PO_2 values, and increased Pulmonary Vascular Resistance (PVR) leading to increased PA pressures.

The PA pressure should be used in correlation with the LA pressure to maintain a ΔP (PA-LA) value greater than 8mmHg. The LA pressure is a key value to monitor during perfusion with 5mmHg being max.

4

EVLP Procedure

4.3 EVLP Initiation

Antegrade Mode: EVLP Strategy

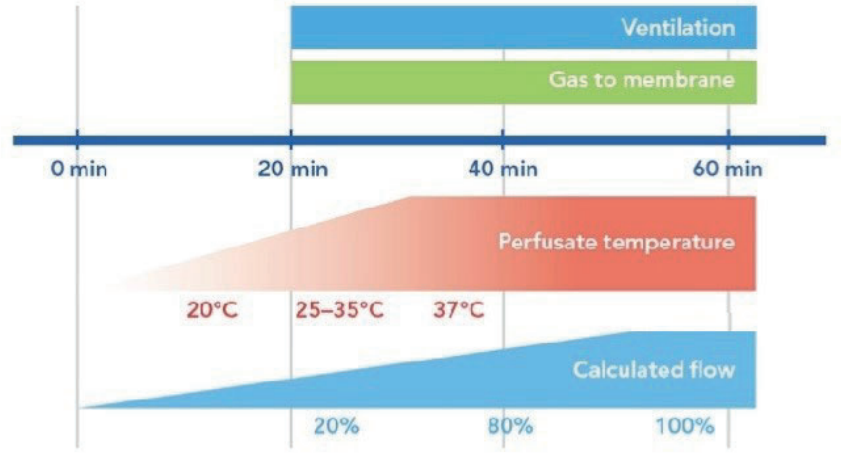
1 Once the lung has reached 30°C , use the percent of calculated flow rate chart to begin adding flow in a stepwise fashion according to the chart.

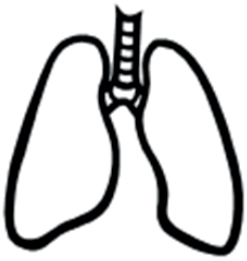
NOTE:

For a double lung, the maximum flow rate is 40% of calculated cardiac output for the donor. The chart indicates which percentage of the maximum (40%) rate should be flowing into the lung. For example, at 10-20 minutes when the lung is 31°C, the Percent Calculated Flow rate indicated in the chart is '20%.' This is actually 20% of the 40% max, or 8% of maximum flow.

For a single right lung, the maximum flow rate is **24%** and for a single left lung, the maximum flow rate is **16%**.

2 According to the chart, at 50-60 minutes, the lung is at maximum flow rate of 100% Calculated Flow, which, for a double lung, is *40% of calculated CO*.





Double Lung Perfusion:

Max Flow Rate= 40% CO

Single (Rt) Lung Perfusion:

Max Flow Rate= 24% CO

Single (Lt) Lung Perfusion:

Max Flow Rate= 16% CO

2

Time (min)	0-10	10-20	20-30	30-40	40-50	50-60
Heater Setting	23	32	38	38	38	38
Achieved Temperature	RT	31	32	37	37	37
Percent Calculated Flow	10	20	30	50	80	100
Ventilation	OFF	OFF	ON	ON	ON	ON
Membrane Gas	OFF	OFF	ON	ON	ON	ON
LA Pressure (mm Hg)	3-5	3-5	3-5	3-5	3-5	3-5

4.3.2 Deoxygenation Gas

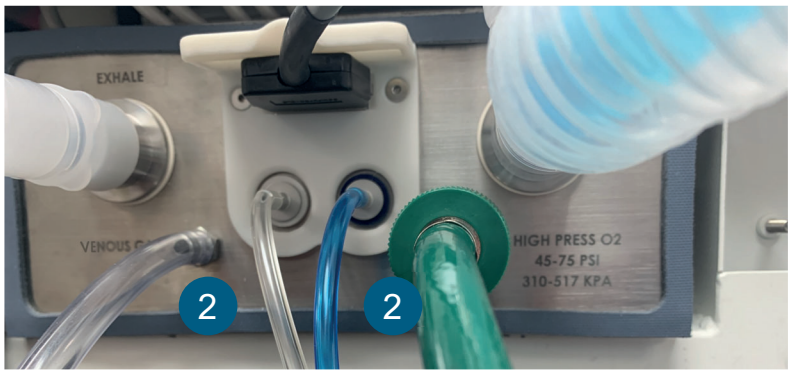
Antegrade Mode: EVLP Strategy

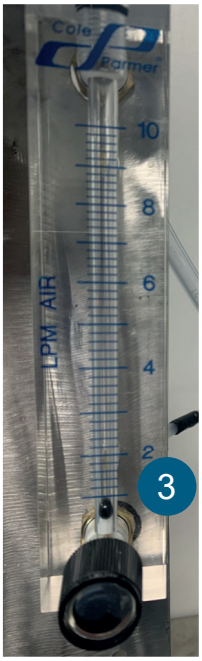
1. Connect the Deoxygenation Gas mix to the oxygenator membrane.
2. Connect both the Oxygen and Deoxygenation Gas supplies to the vent panel.

NOTE:
This Deoxygenation Gas mix is readily available from medical gas providers (often called 'Venous Gas Mix') and is composed of:

8% CO_2
6% O_2
86% N_2

3. Begin flowing Venous Gas mix into oxygenator when lung ventilation starts. Start the flow rate of the Gas mix at 1L/min.
4. Adjust flow rate as necessary to maintain a PCO_2 between 35-45 mmHg (4.7-6 KPa).





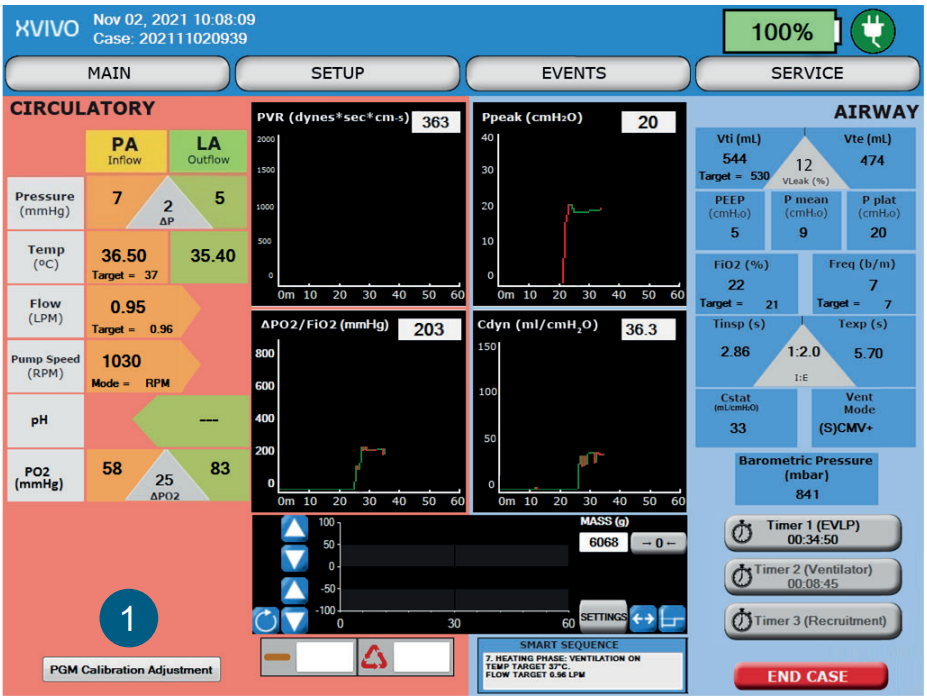
4.3.3 XVIVO PGM Disposable Sensor™ Single Point Calibration

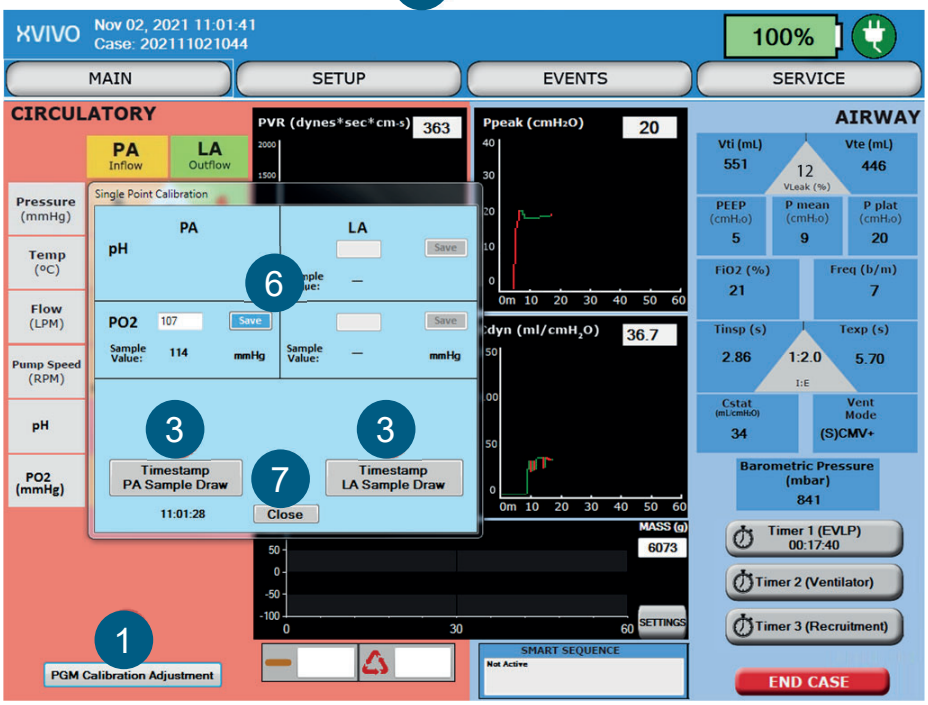
Antegrade Mode: EVLP Strategy

The XVIVO PGM Disposable Sensors™ come pre-calibrated to STEEN Solution™ directly out of the package. However, since this device is a trend-only monitor, clinical decisions should not be based on the PGM sensors alone.

It is required that the user draws a confirmatory sample(s) during the procedure to test with a hospital-calibrated blood gas analyzer to match against the trending numbers provided by the PGM sensors.

Single Point Calibration for pH and PO_2: A Single Point Calibration can be performed at any time during perfusion of the lung, however the **perfusate temperature must be ≥35°C.**





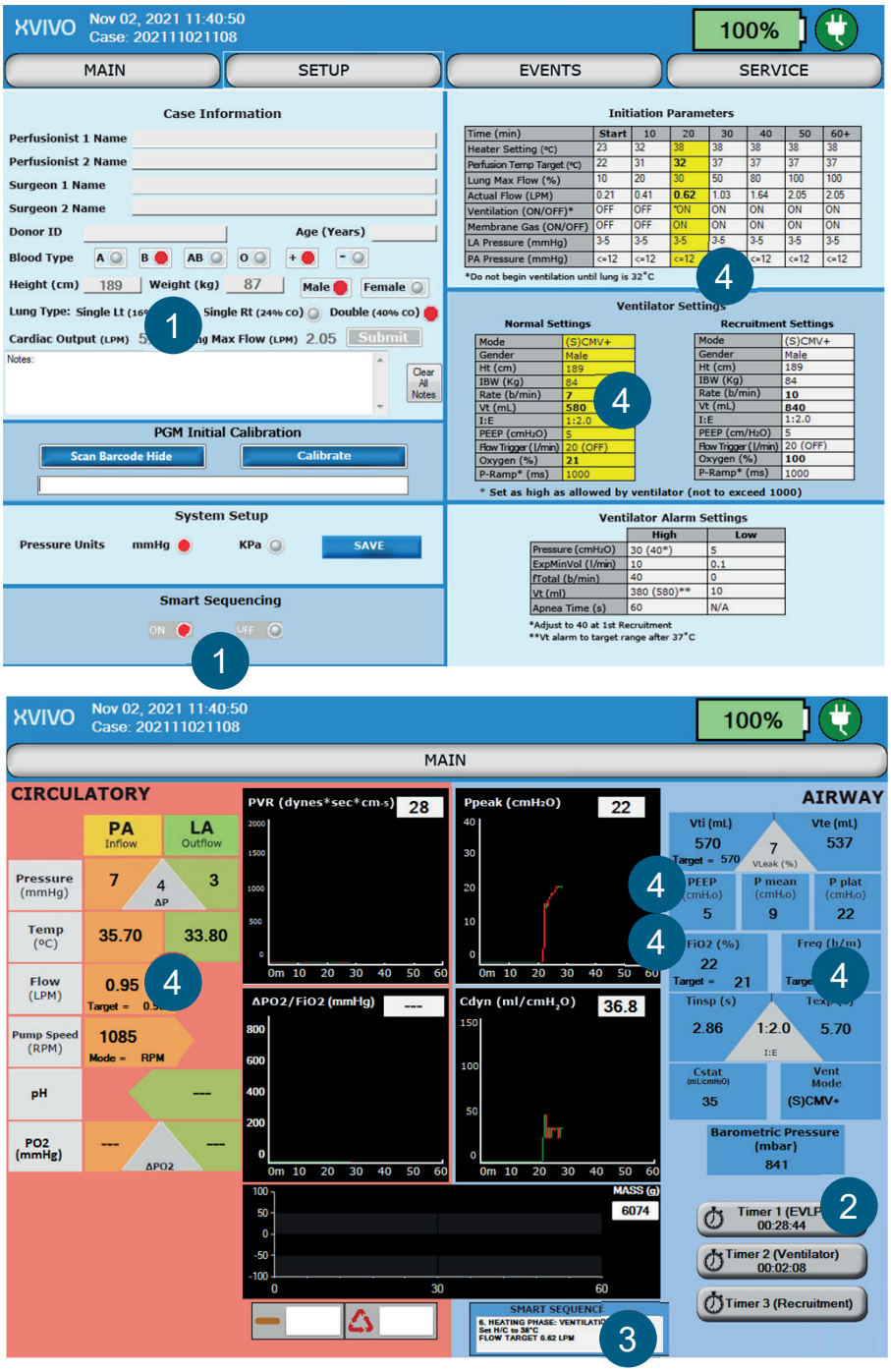
1. Select PGM Calibration Adjustment and a pop-up window will open for calibrating the **PA** (venous) and **LA** (arterial).
2. Two sample draws are required: one from the PA and one from the LA. The samples should be obtained from the respective ports on the pressure sensors, using the stopcock zeroing port.
3. Immediately after the sample draws are taken, select Timestamp PA, then Timestamp LA. This action saves the current PGM reading for calibration against the results of the hospital's blood gas analyzer, once received.
4. While waiting for the blood gas results, the Single Point Calibration window can be closed, and later reopened. An error message will result, but the Timestamp data will be retained when window is reopened.
5. When the data is received from the blood gas analyzer, reopen the PGM Calibration Adjustment window (if closed earlier).
6. Enter in the values of PA PO2, LA pH and PO2. Select the Save button for each entry.
7. Select the Close button when finished.

If a recalibration of the PGM sensor(s) is needed, repeat the steps in Section 2.5.1.

4.3.4 Smart Sequencing

Antegrade Mode: EVLP Strategy

SMART SEQUENCING is an optional feature that guides the user through the EVLP protocol. It utilizes system timers and specific parameters to advance the user through each step of the EVLP. A table of detailed steps is found in the Appendix 1 Additional Features, Section 8.9.



1 To initiate the SMART SEQUENCING feature, donor parameters must be entered, and SMART SEQUENCING must be ON.

2 Following PRIMING and RETROGRADE MODES (sections 2.4 through 3.3.9), SMART SEQUENCING is initiated by starting Timer 1 (EVLP) as ANTEGRADE MODE starts.

3 As sequencing commences, the current step will be indicated in the SMART SEQUENCING window. Between each step a pop-up message box will temporarily appear with a audible sound to notify the user of a change.

4 EVLP parameters to target for each step of the protocol will be highlighted on the setup page and displayed as target values below specific parameters

5 Timer 2 (Ventilator) will automatically start when ventilation is detected at the appropriate step and Timer 3 (Recruitment) will automatically start when recruitments are detected at the appropriate sequence.

NOTE 1:

The XPS software program can be run with SMART SEQUENCING turned off. Parameters, timers and trend graphs operate normally when SMART SEQUENCING is disabled.

NOTE 2:

If SMART SEQUENCING needs to be aborted for any reason, Timer 1 needs to be stopped (**2**), followed by acceptance of an ABORT pop-up message, then the SMART SEQUENCING (**1**) can be turned OFF.

4.3.5 Lung Recruitment 1: Manual Hold

Antegrade Mode: EVLP Strategy

Recruitment maneuvers every hour are important since high airway pressures during the maneuver could lead to alveolar damage and evaluation failure.

CAUTION:

Do not recruit the lung until the LA temperature has reached 37°C.

1 The ventilator has an inspiratory hold key that when pressed and held, will hold for up to 15 seconds. This key should be pressed/held after expiration to hold the inspiration.

NOTE:

If this hold button is pressed before inspiration, it will deliver an extra breath instead.

Since Peak pressure has been limited in the Alarm setup page, the ventilator will control pressure during this maneuver (the ventilator subtracts the PEEP setting, so for a 5 cmH_2O PEEP and Peak Pressure limited to 25 cmH_2O, the peak working pressure will be 25-5= 20 cmH_2O).

4.3.6 Recruitment 2: O_2 Challenge Mode

Antegrade Mode: EVLP Strategy

Each hour, perform an oxygen challenge recruitment procedure:

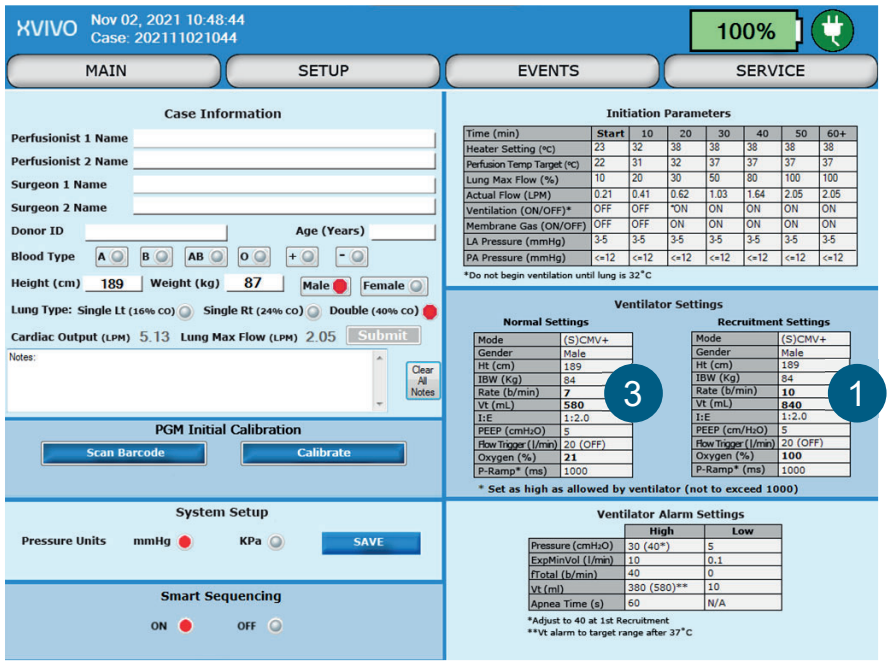
CAUTION:

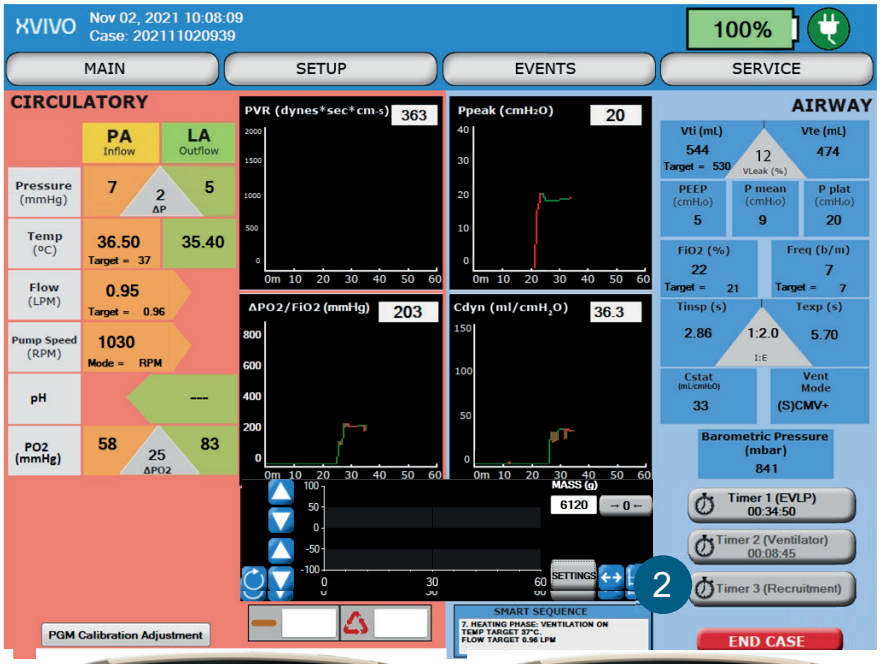
Do not recruit the lung until the LA temperature has reached 37°C.

1. Change **Vt** , **Oxygen** (FiO_2), and **Rate** (frequency) to parameters on the Recruitment Settings table on the Setup Page.
2. Run the Recruitment timer on the main page. Draw arterial and venous perfusate samples for gas analysis using a standard hospital blood gas analyzer.*
   Arterial and venous perfusate samples should be obtained from the respective ports on the pressure transducers.
   All hemodynamic variables should be obtained at the end of the exhalation of the lung.
3. When the recruitment timer expires, change **Rate** (frequency), **Oxygen** (FiO_2) to 21%, and **Vt** to parameters on the Normal Settings table on the setup page.

***NOTE:**

It is recommended that a confirmatory sample be drawn at the beginning and end of the EVLP procedure and/or if there is any doubt that the XPS in-line gas sensors are reading different values than the hospital analyzer.





4.3.7 Chest Radiograph

Antegrade Mode: EVLP Strategy

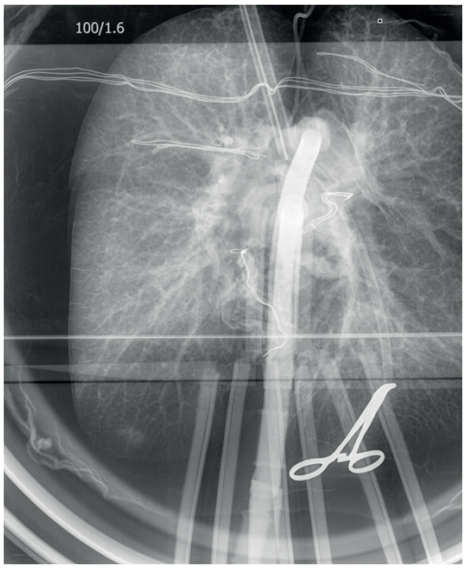
Once the lung has reached 37°C and a recruitment maneuver has been performed, consider taking a chest radiograph.

1 Place X-ray film beneath blue Organ Chamber table.

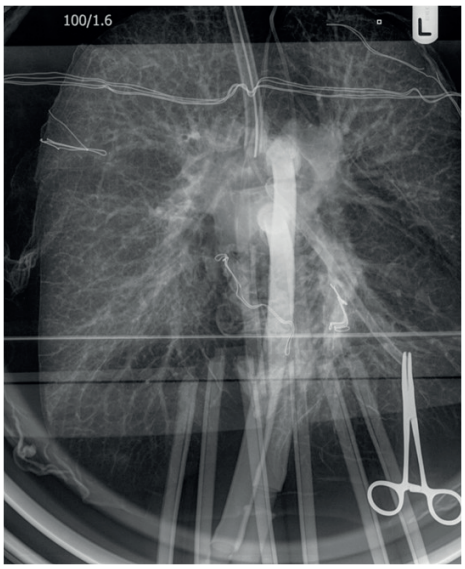
NOTE:

Take care not to disturb the sterile field.

2 Shoot picture onto film.



Begin EVLP (20 minutes)



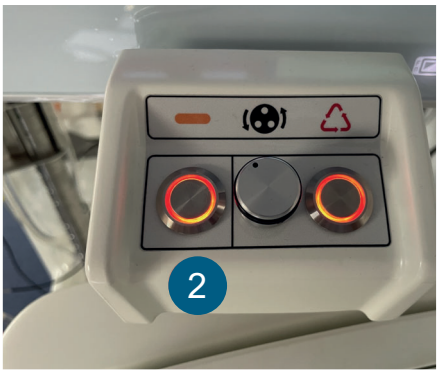
EVLP at 120 minutes

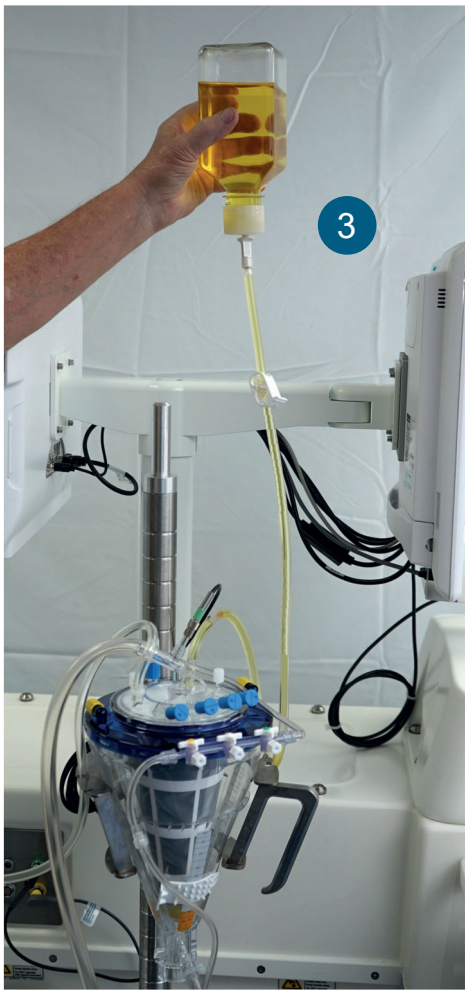
4.3.8 STEEN Solution™ Exchange

Antegrade Mode: EVLP Strategy

It is recommended that the majority of STEEN Solution™ be removed at the end of the first hour of perfusion and replaced with the same volume of normothermic temperature of fresh STEEN Solution™

1. Have ready, 3 fresh bottles of STEEN Solution™ placed in the loading manifold at room or preferably, normothermic temperature.
2. Press and hold the Remove Pump button. The pump button will turn green and perfusate from the circuit will start draining into the drain bag. Release the Remove Pump button when the perfusate fluid level of the hard-shell reservoir reaches the 200mL mark.
3. Using the method described in section 2.4.2, spike a fresh bottle of STEEN Solution™ and add it to the reservoir.
4. Allow a few minutes for the fresh STEEN to circulate within the circuit, then repeat steps **2** and **3** for the remaining two fresh bottles of STEEN Solution™.





NOTE:

After the first hour of perfusion, it is recommended to replace the majority of STEEN Solution™ with fresh solution.

After the exchange of the STEEN Solution™ additional medications may be added to the reservoir at the determination of the clinician. Those additives can be broad spectrum antibiotics, corticosteroids such as methylprednisolone, heparin and when indicated antifungal medication. The dosage depends on the substance(s) used and the decision of the clinician.

4.4 Troubleshooting

Antegrade Mode: Troubleshooting

1. Check position and patency of the cannulas (Sec 4.4.2).
2. Confirm correct calibration of sensors (Sec 3.3.8).
3. Re-check the flow meter whenever a rise in PA Pressure is detected and reduce perfusate flow accordingly via reduction in rpm settings.

NOTE:

High peripheral vascular resistance (PVR) is anticipated in the re-warming period due to vasoconstriction of the pulmonary vasculature secondary to hypothermia of the lung and the perfusate. Strict control of the PAP and a low flow modality (150 mL/min) will warm up the vascular tree without endothelial damage and progressively lower PVR.

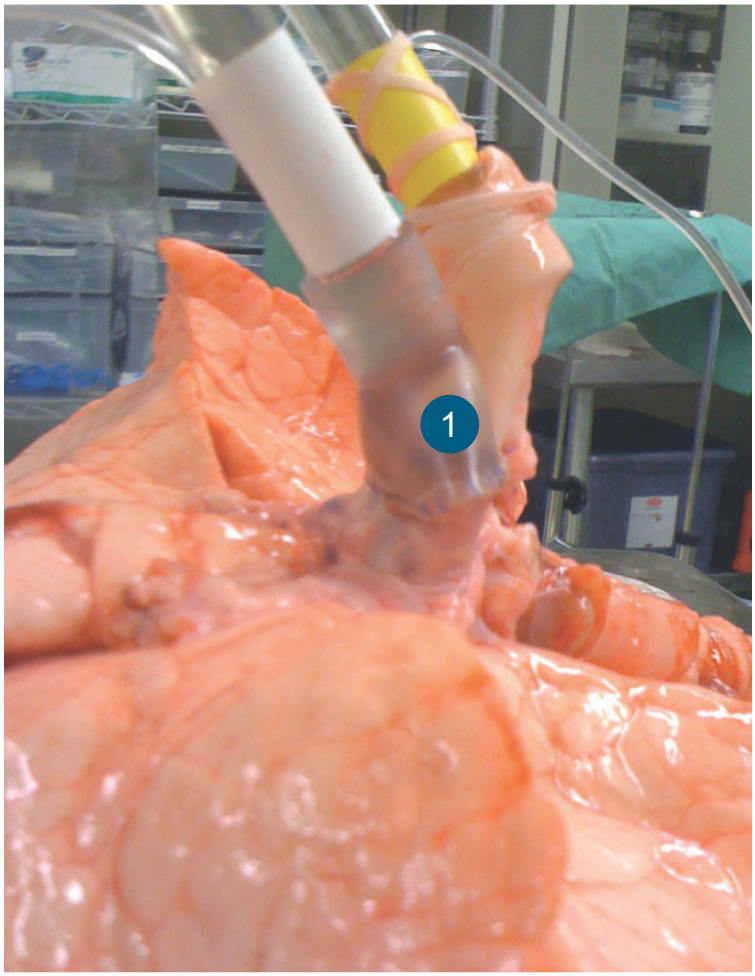
4.4.1 Impaired LA Drainage

Antegrade Mode: Troubleshooting

1 Check position and patency of the cannulas.

2 Confirm correct calibration of pressure sensors (Sec 3.3.8).

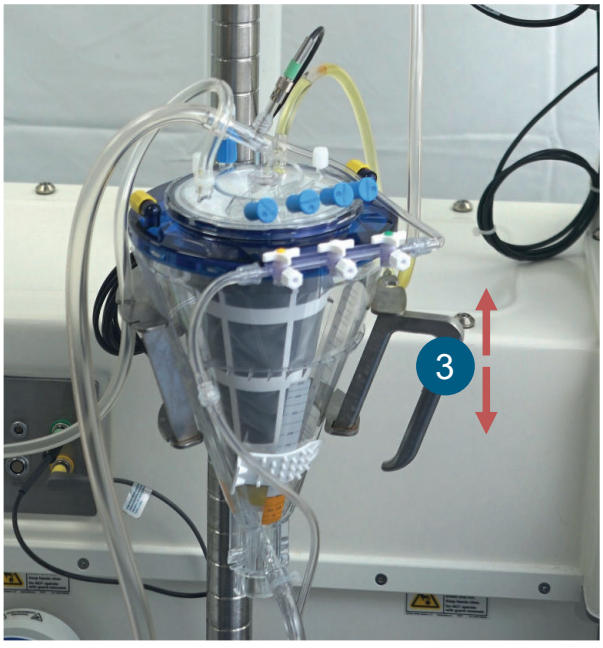
3 Raising or lowering the hard shell reservoir will change LA pressures at approximately 2mmHg/ inch: **The fluid level in the reservoir should be close to the same height of the lung(s).**



NOTE:

Malposition of the LA cannula, kinking of the LA or pulmonary veins, or an airlock in the system will result in outflow blockade increasing PAP. The LAP reading may not change if the obstruction is proximal to the LA pressure monitoring cannula.

A positive LA pressure of 3-5 mmHg is necessary to protect the lung. The absence of venous after-load leads to an unstable geometry of the alveolar-capillary space which alters the pulmonary compliance. LA pressures greater than 5 mmHg may prevent cyclic changes of the lung vasculature during ventilation.



4.4.2 Low pH

Antegrade Mode: Troubleshooting

Low pH is a well-described phenomenon in isolated lung perfusion. Lung tissue carries out an important metabolic activity. Studies with isolated lung perfusion have shown that the majority of the glucose is metabolized through the glycolytic pathway to pyruvate and lactate. The distribution between pyruvate and lactate depends on the redox state of the cells, but in steady state, lactate production is 10 times higher than pyruvate.

Interventions include:

1. Adjust the deoxygenation gas flow rate down to effectively clear CO_2 (Sec 4.3.2).
2. Administer Trometamol (THAM) buffer: 1mL (of 1 Molar concentration) for each negative mmol base excess.
3. Replace complete volume (~1,500cc) of STEEN Solution™ with fresh STEEN Solution™ (sec 2.4.2).

NOTE:

If the gas flow adjustment is not sufficient to normalize pH, careful buffering with a suitable buffer such as sodium bicarbonate or THAM is recommended. It is important to make the adjustment based on the actual pH and to use an iterative process to titrate the pH to the relevant value using pH analysis on a blood gas analyzer between each step of adjustment.

NOTE:

Repeated administration of sodium bicarbonate is not recommended. This tends to increase the perfusate sodium concentration causing capillary constriction and elevation of the PVR.

4.4.3 Low PCO_2

PCO_2 should be maintained between 35 - 45mmHg.

Interventions include:

1. Increase PCO_2 by increasing deoxygen gas. Decrease PCO_2 by decreasing deoxygen gas.
2. Alternatively, expiratory ratio can be adjusted to control PCO_2.

4.4.4 Decreasing STEEN Solution™ Levels in Reservoir

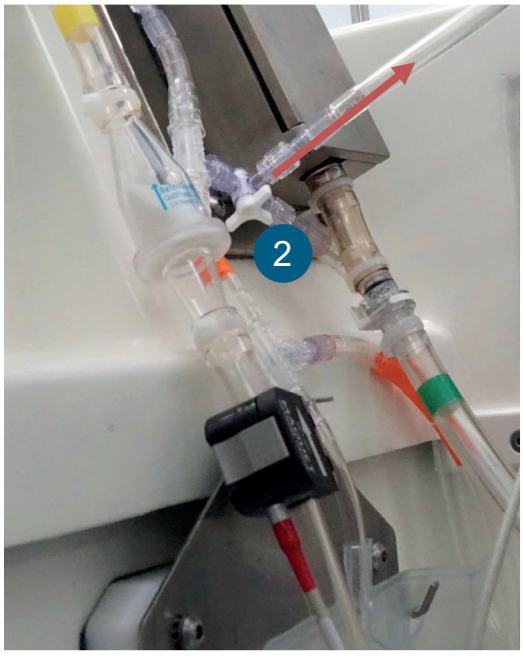
Antegrade Mode: Troubleshooting

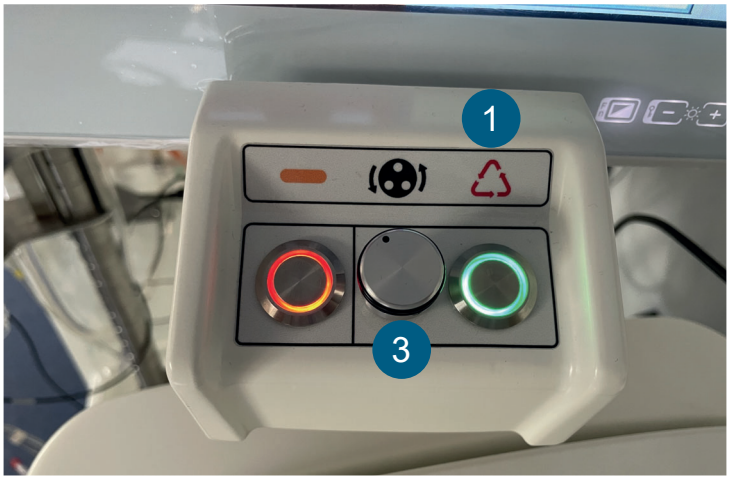
Once stability is achieved, the STEEN Solution™ perfusate level in the reservoir should be noted. Condensation inevitably accumulates from the lungs in a closed chamber and minor changes can be related to this.

Major changes can be related to drainage from the bronchial arteries which can become significant when re-warming is complete and maximal perfusate flow is achieved.

1. The drainage accumulated in the Organ Chamber can be returned to the reservoir using the recycle pump.
2. Ensure the drain stopcock is positioned to **reservoir** path instead of drain.
3. There are 3 speeds on the recycle pump: slow, medium and fast. Speed can be increased by turning the speed control knob clockwise.

Additionally, edema formation as a result of leakage from the capillaries into the interstitial space may occur. This will result initially in a fall in lung compliance, impaired oxygenation and rise in PAP and peak airway pressures.





4.4.5 Restart XPS™ Software

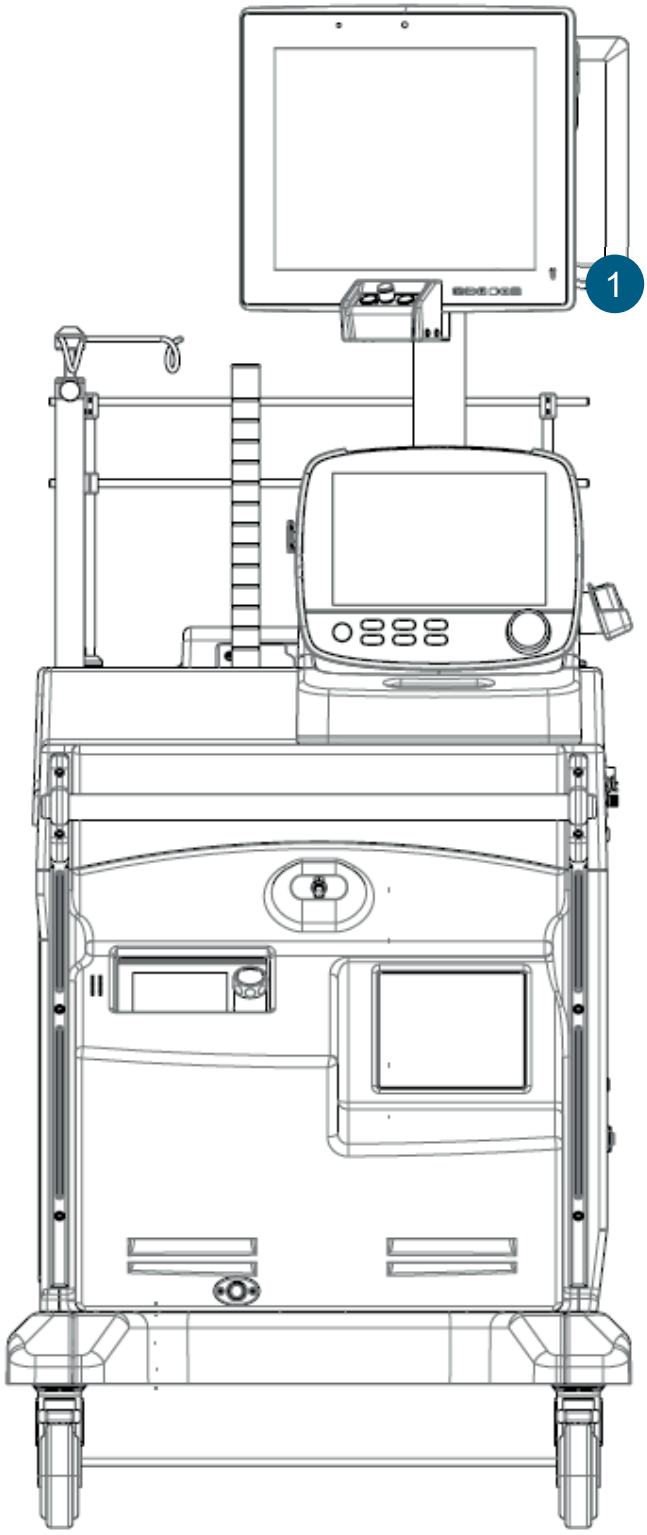
Antegrade Mode: Troubleshooting

If for some reason the XPS™ Software freezes or locks up, the user may have to force a shut down and restart of the system software.

CAUTION:

Restarting the XPS™ Software will reset all data fields including trend graphs, making the user re-enter donor and PGM calibration data again.

1 Turn the main touchscreen monitor power off (press and hold button on back of monitor). Wait 10 seconds then turn it back on.



4.5 Finishing EVLP

Antegrade Mode: Finishing EVLP

4.5.1 Rapid Cool-down

Once evaluation is complete and the lungs have been accepted for transplantation, the cooling process begins:

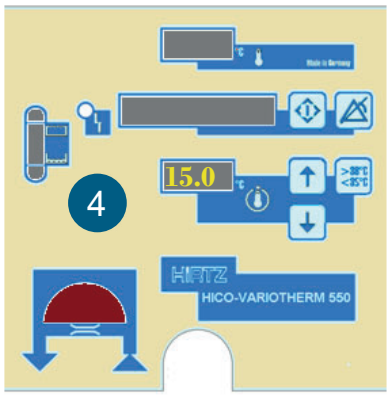
1 Attach funnel tube to cool-down basin at the point shown to the right of the number in picture. Fill with approximately 200ml of distilled water until coil is primed.

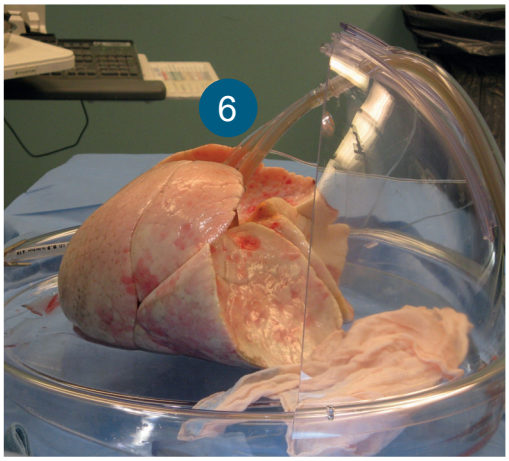
2 Disconnect the heater/cooler blue hose from the right connector on the I/O panel and attach it to the basin connector next to where the funnel was attached.

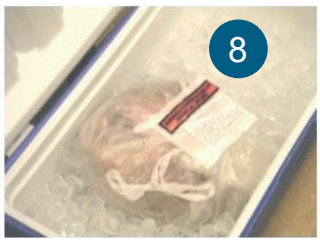
3 Connect the basin hose from the cooling basin (where the funnel was attached) to the right heater/cooler I/O panel.

4 Set temperature of heater/cooler to 15°C.

5 Fill cooling basin with ice and add water until ice is covered. Run until STEEN Solution™ temperature is 15ºC (approx. 7 minutes).







NOTE:

If lung is not cooling fast enough,
1) add more ice.
2) Check HCU set temp (15°C).
3) Make sure HCU pump is running.
4) Consider cold PERFADEX® Plus.

6 The lungs should be clamped moderately inflated with 50% O_2 similar to the standard donor procurement protocol.

7 Disconnect lungs from system and store in sterile bags with PERFADEX® Plus.

8 Place sterile bags in insulated cooler containing ice.

NOTE:

An alternative method for rapid cooling that does not require the cooling basin is as follows:

1) Set the heater/cooler to 15°C.

2) When temperature falls to 32°C, clamp the ET tube when the lungs are 50% inflated.

3) Disconnect lungs from the perfusion circuit and flush with two liters of cold PERFADEX® Plus. Place in sterile bags with PERFADEX® Plus. This method is very similar to a standard donor procurement protocol.

4.5.2 EVLP Failure Assessment

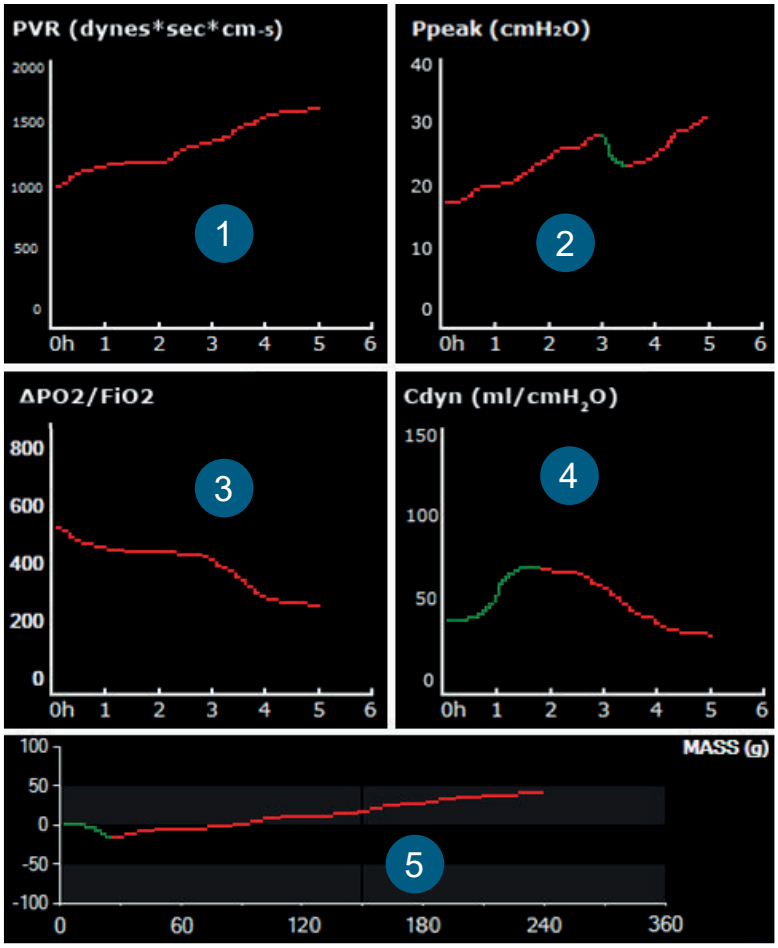
Antegrade Mode: Finishing EVLP

In addition to the failure conditions listed below, the following (exaggerated) trend graphs over time indicate failing lungs:

1. Increase in PVR
2. Prolonged Peak Airway Pressures >20cmH_2O
3. Decrease in ΔPO_2:FiO_2 ratio
4. Decrease in Dynamic lung Compliance
5. Increase in weight

NOTE:

Graphing pixels will record red to indicate declining lung conditions and green to indicate improving conditions during graphing.



Decrease in Lung Compliance with time

Once stability is achieved (usually within one hour), hemodynamic, ventilator and gas exchange parameters should be recorded regularly. Decrease in static lung compliance with time, indicates interstitial edema. Any measurements should be collected after recruitment maneuvers to ensure relevant data collection.

Difference of PO_2 between inflow and outflow lines (Delta PO_2)

This represents failure of gas exchange at the alveolar-capillary membrane. Check the perfusate flow status before making assumptions. Changes in pulmonary perfusate can alter V/Q matching and hence Delta PO_2.

Rising PA and airway pressures

As edema worsens, there is an associated (irreversible) decline in physiological parameters, independent of any control maneuvers described previously.

Presence of fluid in endotracheal tube

This will be the unmistakable sign of irreversible pulmonary edema and inevitable lung failure.

4.5.3 Automated End Case Feature

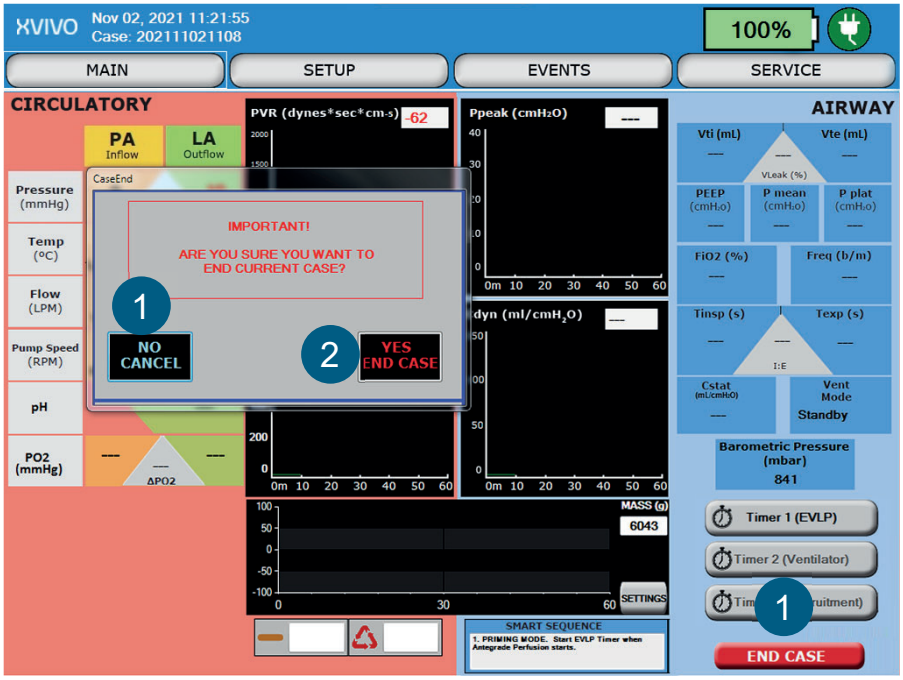
Antegrade Mode: Finishing EVLP

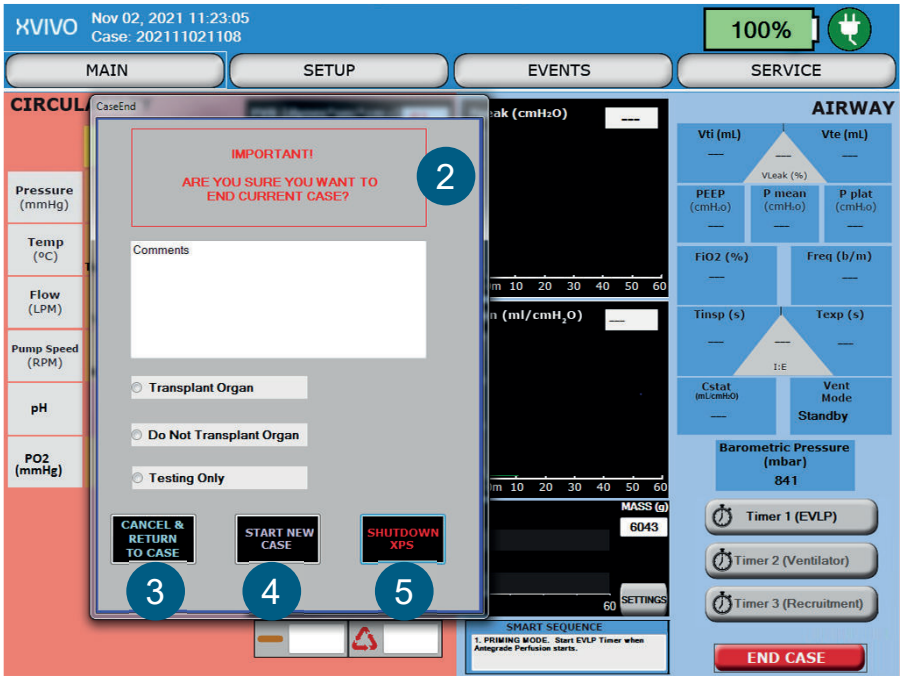
The END CASE button allows the user to exit the XPS software application, enter EVLP case notes, power down the computer or restart the computer. Pressing the END CASE button and letting the software shut down the monitor is the preferred method.

1. Selecting the End Case button will prompt the CaseEnd message box: Selecting “NO CANCEL” will close the pop-up message and resume activity.
2. Selecting YES END CASE will yield a second pop-up message box and allow the user to enter case comments.
3. Selecting the CANCEL AND RETURN TO CASE button will close the pop-up box and resume activity.
4. Selecting the START NEW CASE button will:
   - close the application
   - write the selection to the History Log
   - shutdown the computer
   - re-start the computer
5. Selecting the SHUTDOWN XPS button will:
   - close the application
   - write the selection to the History Log
   - shutdown the computer

Note:

The SHUTDOWN XPS feature will power down only the computer. The XPS will require shutdown per Section 4.5.4.



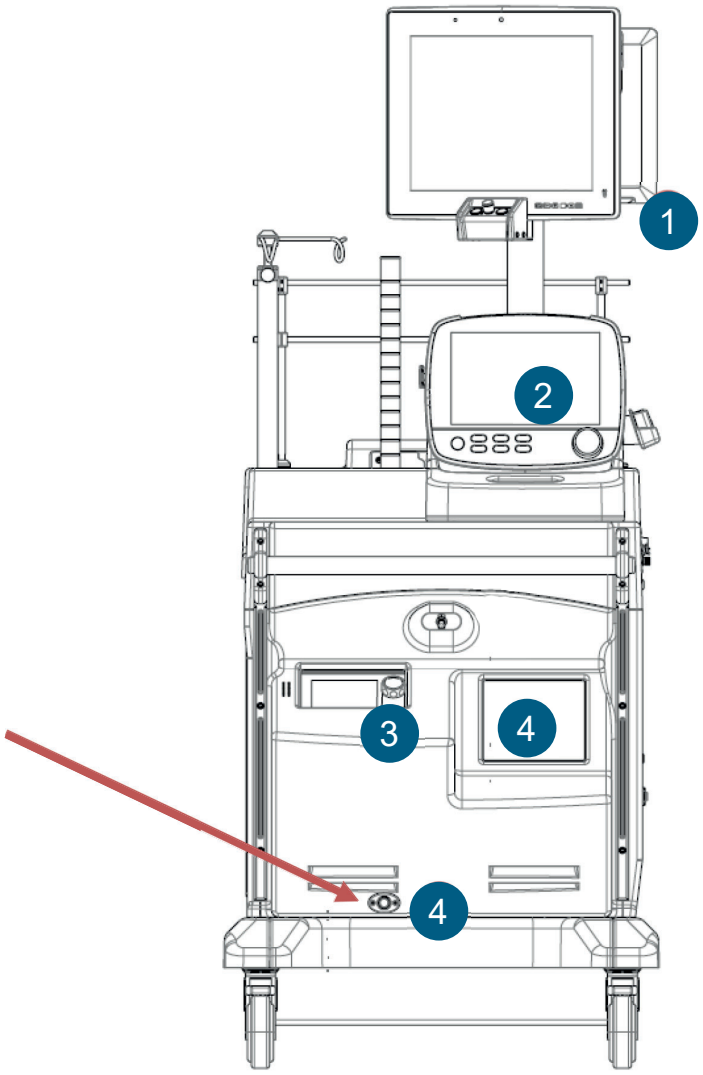


4.5.4 Shutdown and Cleaning

Antegrade Mode: Finishing EVLP

Shutdown

1. The Automated End Case Feature from the previous section will shutdown the touchscreen monitor and display-only monitor.
2. Press the power button on the Ventilator, then select the pop-up menu display “Activate standby”. Then press and hold the power button for > 3 sec. to complete the power shutdown process.
3. Press and hold the Pump’s power button for > 4 sec. Select the “check-mark” on the pop-up menu to complete the shutdown process.
4. Press and release the power button for the Heater/cooler. Verify the touchscreen monitor is off and press and release the UPS power button.



NOTE:

For quickest shutdown (in an emergency situations), press and release the UPS button to force shut-down. Not recommended as a normal standard method.

Cleaning (also see Chapter 9)

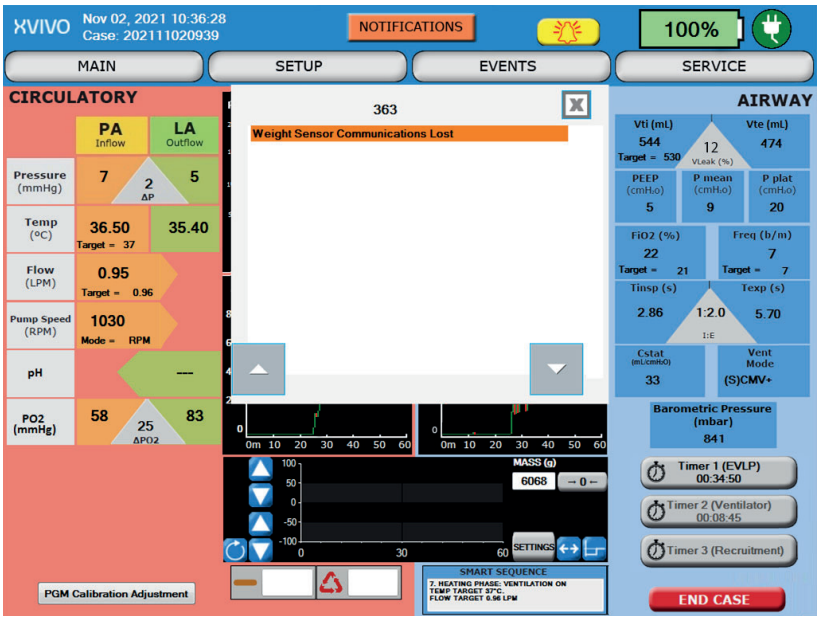
5. Remove circuit from XPS cart and dispose according to hospital biohazard materials policy.
6. Wipe down XPS cart surfaces with a mild disinfectant based on aldehydes, ammonium or alcohol which will not affect plastic materials. If possible, try to avoid using any phenol-based products because they will shorten the life of plastic materials.
7. Dampen a soft cloth with isopropyl alcohol or a nonabrasive glass cleaner to clean touchscreen monitors.
8. Lower the lung table by pulling equally back on the arm rest handles until the table releases and folds down.

Storage

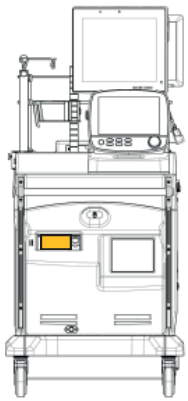
In order to keep system’s backup batteries fully charged (UPS, CardioHelp and ventilator), the system should be stored plugged into an outlet with main power.

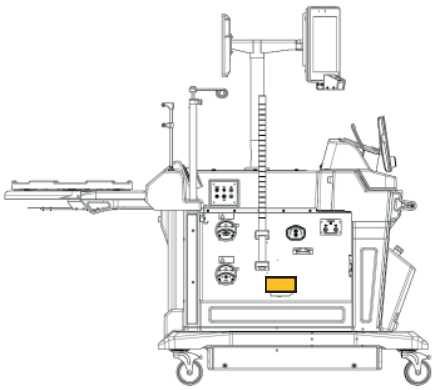
5.0 Notifications

XPS System Notifications are messages to the user instructing them that something has occurred that may require their attention. Notifications are identified when “Notifications” button is displayed at the top header of the XPS software. When the button appears, selecting the button opens the messaging window and describes the occurrence.



In addition to the messaging window, each message, when selected will identify which piece of equipment is causing the notification through a colored graphical view of the XPS system (examples provided below).





5

Notifications

XPS Software

Priming: Notification

1 The XPS Software will generate a Notification if a piece of equipment is not connected to the main touchscreen computer. This can be due to lack of power to the unit, a malfunction of the unit or a physical cable disruption between the unit and the touchscreen computer.

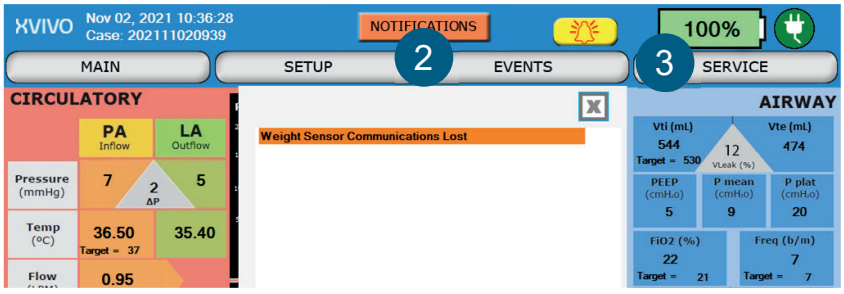
2 Select the NOTIFICATION header to open up the equipment window to see which piece of equipment is causing the XPS Software to generate a notice.

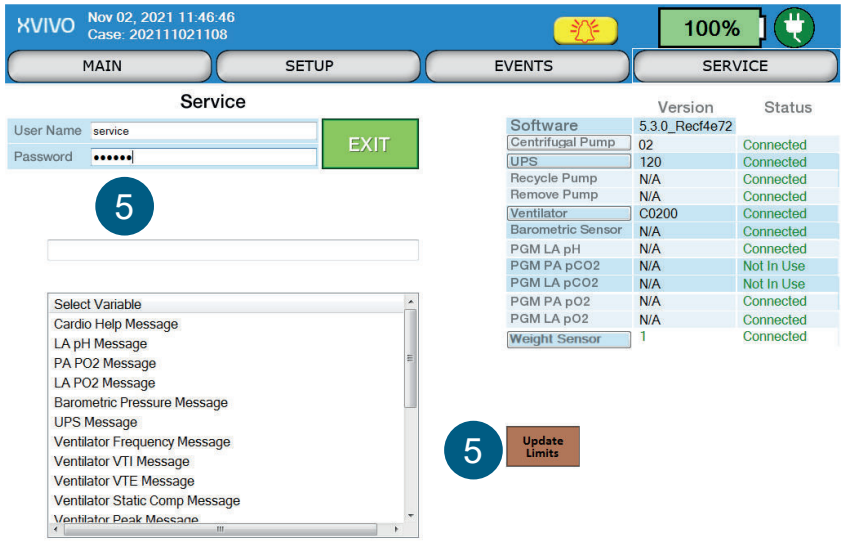
3 Another helpful tool is to press the SERVICE button on the XPS touchscreen. This will open the Service window which shows each piece of equipment and whether or not it is connected to the touchscreen computer.

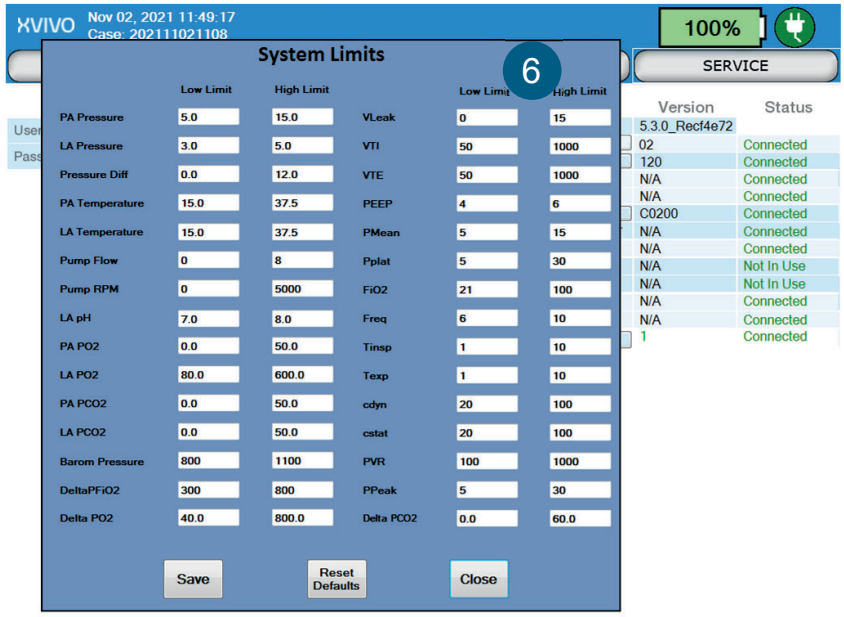
4 A Date/Time Notice will generate if there is a >5 minute difference between the XPS touchscreen computer and any other piece of hardware. Fix this notice by resetting the date and/or time of the offending hardware item.

5 In the SERVICE page, administrators enter their User Name and Password to access and adjust the System Limits (range) of the PGM, Ventilator, Pump and Graphs values by pressing the Update Limits button. The High and Low Limit values will control the color scheme of the data values displayed on the Main page (green = within limits, red = out of range).

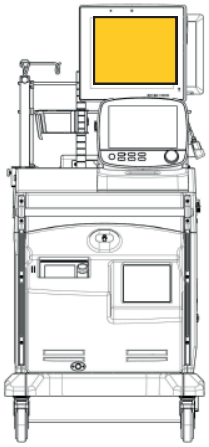
6 System Limits (Low and High) can be configured for each parameter listed. The Save button saves any changes, the Reset Defaults button resets to the default values, and the Close button closes the page without saving changes.







Priming: Notice

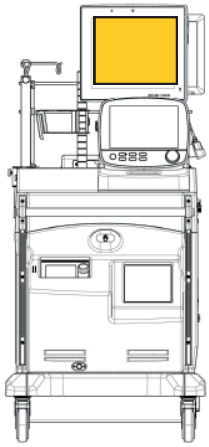


NOTE:

Loss of Mains AC/DC indicates that the main power outlet is no longer working. Switch to another power outlet if the hospital power is still functioning. If the hospital power is also off, consider emergency cooling and cold storage with cold PERFADEX® Plus until power is reestablished.

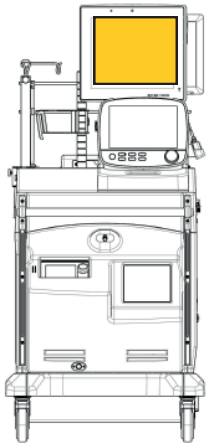
Notice	Definition	Action needed
LA pH PGM Phase Invalid Data	The pH reading does not match calibration curve data	Re-enter PGM calibration data Check disposable to make sure sensor is seated properly in housing. Replace disposable sensor, recalibrate
Loss of Mains AC/DC Switched to Battery Power	The main building power outlet is no longer working, the XPS is unplugged from wall power, or the AC/mains switch has been flipped.	Check that the XPS is plugged into the wall outlet and that the AC/mains switch is in the ON position. If so, then switch to another power outlet if the hospital power is still functioning. If the hospital power is also off, consider emergency cooling and cold storage of lung with cold PERFADEX® Plus until power is re-established.
PA CO_2 Below Limit	The CO_2 reading for the PA is reading below the set notice limit	Increase CO_2 gas sweep from external tank Reset the lower CO_2 notice limit
PA CO_2 PGM Out of Range	The CO_2 reading coming from either the disposable sensor or transmitter housing is out of acceptable range	Check disposable to make sure sensor is seated properly in housing. Replace disposable sensor Re-enter PGM calibration data
PA CO_2 PGM Phase Invalid Data	The CO_2 reading does not match calibration curve data	Re-enter PGM calibration data Check disposable to make sure sensor is seated properly in housing. Replace disposable sensor, recalibrate
PA pH Below Limit	The pH reading for the PA is reading below the set notice limit	Add fresh STEEN Solution™ to system, remove similar volume of old STEEN Solution™ Reset the lower pH notice limit
PA pH PGM Out of Range	The pH reading coming from either the disposable sensor or transmitter housing is out of acceptable range	Check disposable to make sure sensor is seated properly in housing. Replace disposable sensor Re-enter PGM calibration data
PA pH PGM Phase Invalid Data	The pH reading does not match calibration curve data	Re-enter PGM calibration data Check disposable to make sure sensor is seated properly in housing. Replace disposable sensor, recalibrate

Priming: Notice



Notice	Definition	Action needed
Ventilator Cdyn Invalid Data	The dynamic compliance data connection from the ventilator is corrupt	If this value is invalid or out of range use the following calculation Vte/PIP-PEEP. Contact XVIVO to schedule service.
Ventilator Cdyn Out of Range	The dynamic compliance data is outside of normal limits	If this value is invalid or out of range use the following calculation Vte/PIP-PEEP. Contact XVIVO to schedule service
Ventilator Date/ Time Invalid Data	The date/time feature of the ventilator is >5 minutes different from the XPS software date/time.	Adjust date/time of ventilator to match XPS clock
Ventilator FiO2 Invalid Data	The oxygen percentage data connection from the ventilator is corrupt	Use ventilator readings for FiO2 for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator FiO2 Out of Range	The FiO_2 data is outside of normal limits	Use ventilator readings for FiO2 for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator Freq Invalid Data	The frequency of breath data connection from the ventilator is corrupt	Use ventilator readings for Freq for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator Freq Out of Range	The frequency of breath data is outside of normal limits	Use ventilator readings for Freq for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator I:E Ratio Invalid Data	The I:E Ratio data connection from the ventilator is corrupt	Use ventilator readings for I:E ratio for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator InspTime Invalid Data	The inspiration time data connection from the ventilator is corrupt	Use ventilator readings for Inspiration for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator InspTime Out of Range	The inspiration data is outside of normal limits	Use ventilator readings for Inspiration for rest of procedure and ignore XPS software. Contact XVIVO to schedule service

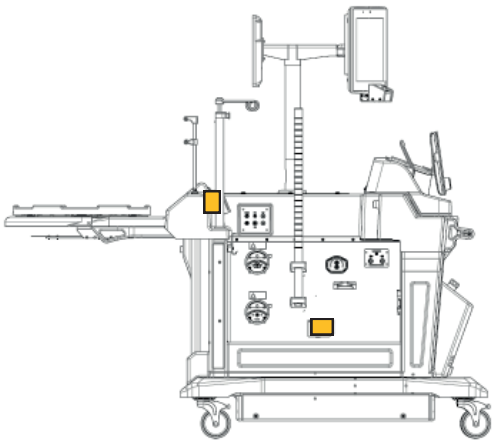
Priming: Notice



Notice	Definition	Action needed
Ventilator Peak Invalid Data	The Peak Pressure data connection from the ventilator is corrupt	Use ventilator readings for Ppeak for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator Peak Out of Range	The Peak Pressure data is outside of normal limits	Use ventilator readings for Ppeak for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator PEEP Invalid Data	The PEEP data connection from the ventilator is corrupt	Use ventilator readings for PEEP for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator PEEP Out of Range	The PEEP data is outside of normal limits	Use ventilator readings for PEEP for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator Static Compliance Invalid Data	The Cstat data connection from the ventilator is corrupt	Use ventilator readings for Cstat for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator Static Compliance Out of Range	The Cstat data is outside of normal limits	Use ventilator readings for Cstat for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator VTE Invalid Data	The Tidal Volume data connection from the ventilator is corrupt	Use ventilator readings for V_T for rest of procedure and ignore XPS software. Contact XVIVO to schedule service
Ventilator VTE Out of Range	The Tidal Volume data is outside of normal limits	Use ventilator readings for V_T for rest of procedure and ignore XPS software. Contact XVIVO to schedule service

5.2 XPS™ Software

Priming: Notice



1 Notifications from the Perfusate Gas Monitor will typically be caused by either a disposable sensor failure or a communication failure between the fiber optic transmitter and the XPS Software monitor.

2 Check to make sure sensors are seated properly in their housings.

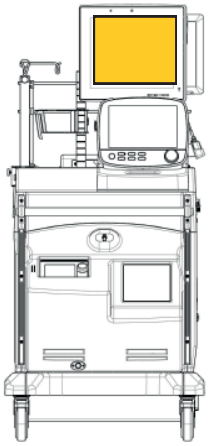
3 PGM readings and PGM Notifications are only displayed after PGM Initial Calibration is performed. So, if no PGM readings are displayed and no PGM Notifications are displayed to describe the failure condition. The likely cause is that the PGM barcode was incorrectly scanned or not applied. (Sec 4.3.3).

4 Replace the disposable sensor with a new one and re-calibrate the sensor as necessary (Sec 4.3.3).

5 Use the hospital's calibrated blood gas analyzer to continue measuring perfusate samples if the PGM system still does not function.

Notice	Definition	Action needed
ADC1 Overflow	Analog to Digital converter data overrun	Wait for data to catch up May need to clear out data files
ADC2 Overflow	Analog to Digital converter data overrun	Wait for data to catch up May need to clear out data files
Amplitude too low	Poor signal from sensor to transmitter	Check position of PGM disposable sensor and re-seat if necessary
FPGA interrupt failure	PGM sensor board failure	Contact XVIVO for service
No sensor calculation	Poor signal from sensor to transmitter	Check position of PGM disposable sensor and re-seat if necessary Check to see if sensor spot is missing from disposable and replace complete sensor housing if necessary
Operating tempera-ture out of range	Temperature is too high for sensor boards to work properly	Move to cooler area Check XPS fan operation
PC register overflow-EEPROM	Configuration/ Calibration embedded software overflow	Contact XVIVO for service
Reference path failure		Contact XVIVO for service
Signal phase shift out of range	Transmission signal is inconsistent between multiple measurements	Contact XVIVO for service
WDT reset occurred	Watch dog timer reinitialized	Contact XVIVO for service

Priming: Notice

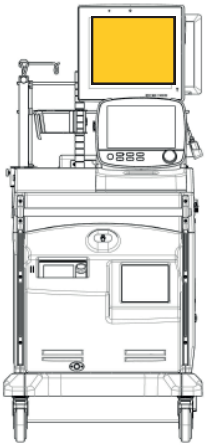


WARNING!

In the event that the 12 volt DC power supply fails, the surgeon monitor will go out and a number of 'PGM' communication errors will appear on the touchscreen monitor. If this occurs, TURN OFF all medical gasses coming into the cart because the internal ventilation fans will also be off and oxygen could potentially build up inside the XPS cart if there are any small leaks in the gas lines.

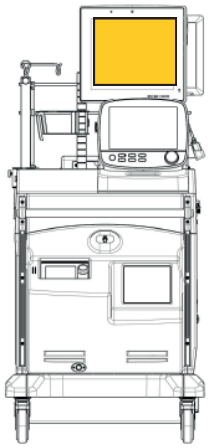
Notice	Definition	Action needed
Barometric sensor corruption	Barometric sensor does not function properly	Use hospital blood gas analyzer Contact XVIVO for service
Centrifugal pump communication lost	Data connection between XPS and centrifugal pump disrupted	Use centrifugal pump readings Reboot software if necessary Contact XVIVO for service
Centrifugal pump flow data corruption	Data connection between XPS and flow sensor disrupted	Check flow sensor readings directly from centrifugal pump control panel Check flow sensor connections Reconnect and re-zero sensor
Centrifugal pump LA pressure data corruption	Data connection between XPS and centrifugal pump disrupted	Use centrifugal pump readings Reboot software if necessary Contact XVIVO for service
Centrifugal pump LA temperature corruption	Data connection between XPS and temperature sensor in centrifugal pump disrupted	Use centrifugal pump readings Check temperature connections Contact XVIVO for service
Centrifugal pump PA pressure data corruption	Data connection between XPS and centrifugal pump disrupted	Use centrifugal pump readings Reboot software if necessary Contact XVIVO for service
Centrifugal pump PA temperature corruption	Data connection between XPS and temperature sensor in centrifugal pump disrupted	Use centrifugal pump readings Check temperature connections Contact XVIVO for service
Centrifugal pump speed data corruption	Data connection between XPS and centrifugal pump disrupted	Use centrifugal pump readings Reboot software if necessary Contact XVIVO for service
Drain STEEN pump communication lost	Connection to peristaltic 'Drain STEEN' pump disrupted	Drain STEEN Solution™ by hand removing from reservoir with large (100cc +) syringe Reboot software if necessary Contact XVIVO for service
LA CO_2 PGM phase data corruption	Data from LA PGM sensors is inconsistent between multiple readings	Check position of PGM disposable sensor and re-seat if necessary
LA pH PGM phase data corruption	Data from LA PGM sensors is inconsistent between multiple readings	Check position of PGM disposable sensor and re-seat if necessary
Left atrium CO_2 monitor communication lost	Data connection between XPS and LA PGM sensor disrupted	Check position of PGM disposable sensor and re-seat if necessary
Left atrium O_2 monitor communication lost	Data connection between XPS and LA PGM sensor disrupted	Check position of PGM disposable sensor and re-seat if necessary
Left atrium pH monitor communication lost	Data connection between XPS and LA PGM sensor disrupted	Check position of PGM disposable sensor and re-seat if necessary

Priming: Notice



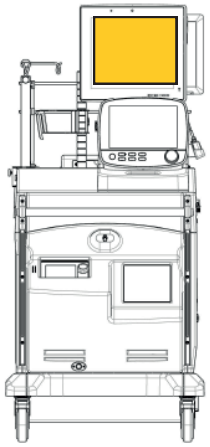
Notice	Definition	Action needed
PA CO_2 PGM phase data corruption	Data from PA CO_2 sensor is Inconsistent (multiple data points)	Check position of PGM disposable sensor and re-seat if necessary
PA pH PGM phase data corruption	Data from PA pH sensor is Inconsistent (multiple data points)	Check position of PGM disposable sensor and re-seat if necessary
Pulmonary artery CO_2 monitor communication lost	Data connection between XPS and PA PGM sensor disrupted	Check position of PGM disposable sensor and re-seat if necessary Check if sensor spot is missing Replace disposable PGM sensor
Pulmonary artery O_2 monitor communication lost	Data connection between XPS and PA PGM sensor disrupted	Check position of PGM disposable sensor and re-seat if necessary Check if sensor spot is missing Replace disposable PGM sensor
Pulmonary artery pH monitor communication lost	Data connection between XPS and PA PGM sensor disrupted	Check position of PGM disposable sensor and re-seat if necessary Check if sensor spot is missing Replace disposable PGM sensor
Recycle STEEN pump communication lost	Connection to peristaltic 'Recycle STEEN' pump disrupted	Drain STEEN Solution™ by hand removing from dome drain port with large (100cc +) syringe connected to luer port Reboot software if necessary Contact XVIVO for service
Ventilator communication lost	Ventilator was communicating with XPS but then communication was lost	Confirm ventilator power is on and standby mode is 'off' Use ventilator controls if working Reboot software if possible Contact XVIVO for service
Ventilator date/ time corruption	The date and/or time is +/- 5 minutes different than the XPS System clock	Reset ventilator date/time
Ventilator freq data corruption	Data between XPS and ventilator disrupted	Confirm ventilator power is on and standby mode is 'off' Use ventilator controls if working Reboot software if possible Contact XVIVO for service
Ventilator I:E ratio data corruption	Data between XPS and ventilator disrupted	Confirm ventilator power is on and standby mode is 'off' Use ventilator controls if working Reboot software if possible Contact XVIVO for service
Ventilator Peak data corruption	Data between XPS and ventilator disrupted	Confirm ventilator power is on and standby mode is 'off' Use ventilator controls if working Reboot software if possible Contact XVIVO for service
Ventilator PEEP data corruption	Data between XPS and ventilator disrupted	Confirm ventilator power is on and standby mode is 'off' Use ventilator controls if working Reboot software if possible Contact XVIVO for service
Ventilator VTE data corruption	Data between XPS and ventilator disrupted	Confirm ventilator power is on and standby mode is 'off' Use ventilator controls if working Reboot software if possible Contact XVIVO for service

Priming: Notice



Notice	Definition	Action needed
Barometric Pressure Sensor Invalid Data	The barometric sensor is not reading or connected properly and will cause the PGM monitor to malfunction	If monitor does not come back online by itself, use hospital blood gas analyzer for pH, pCO_2 and pO_2 readings Have the unit serviced
Centrifugal Pump Date/ Time Invalid Data	The date and/or time does not match up	Reset the date/time of the Centrifugal pump
Centrifugal Pump Date/ Time Mismatch	The date and/or time is > 5 minutes different than the XPS System clock	Reset the date/time of the Centrifugal pump
Centrifugal Pump Flow Invalid Data	The Flow sensor is not properly working or connected	Open the flow sensor and re-seat the perfusate tubing, then close the sensor until it snaps shut and re-zero
Centrifugal Pump Flow Out of Range	The Flow sensor is not properly working or connected	Open the flow sensor and re-seat the perfusate tubing, then close the sensor until it snaps shut and re-zero
Centrifugal Pump LA Pressure Invalid Data	Pressure reading from LA cannula not working properly	Make sure LA pressure cannula is connected correctly to pressure sensor Re-zero pressure sensor
Centrifugal Pump LA Pressure Out of Range	Pressure reading from LA cannula is out of set range	Reset upper and/or lower pressure ranges
Centrifugal Pump LA Temperature Invalid	Temperature reading from LA sensor not connected or working properly	Check temperature sensor connections into wall panel as well as ensure sensor is seated properly into reservoir
Centrifugal Pump LA Temperature Out of Range	Temperature reading from LA sensor is out of set range	Reset upper and/or lower temperature ranges
Centrifugal Pump PA Pressure Invalid Data	Pressure reading from PA cannula not working properly	Make sure PA pressure cannula is connected correctly to pressure sensor Re-zero pressure sensor
Centrifugal Pump PA Pressure Out of Range	Pressure reading from PA cannula is out of set range	Reset upper and/or lower pressure ranges
Centrifugal Pump PA Temperature Invalid	Temperature reading from PA sensor not connected or working properly	Check temperature sensor connections into wall panel as well as ensure sensor is seated properly into oxygenerator

Priming: Notice



Notice	Definition	Action needed
Centrifugal Pump PA Temperature Out of Range	Temperature reading from PA sensor is out of set range	Reset upper and/or lower temperature notice ranges
Centrifugal Pump Speed Invalid Data	Pump RPMs are not reading properly	Make sure pump head/oxygenator is seated correctly in pump housing Replace oxygenator/pump head
Centrifugal Pump Speed Out of Range	Pump RPMs are reading out of set range	Make sure pump head/oxygenator is seated correctly in pump housing Reset upper and/or lower RPM notice ranges
LA CO_2 Below Limit	The CO_2 reading for the LA is reading below the set notice limit	Check ventilator parameters, esp. rate, FiO2 Reset the lower CO_2 notice limit Contact XVIVO to schedule service
LA CO_2 PGM Out of Range	The CO_2 reading coming from either the disposable sensor or transmitter housing is out of acceptable range	Check disposable to make sure sensor is seated properly in housing Replace disposable sensor Re-enter PGM calibration data
LA CO_2 PGM Phase Invalid Data	The CO_2 reading does not match calibration curve data	Re-enter PGM calibration data Check disposable to make sure sensor is seated properly in housing Replace disposable sensor, recalibrate
LA O2 PGM Out of Range	The O_2 reading coming from either the disposable sensor or transmitter housing is out of acceptable range	Check disposable to make sure sensor is seated properly in housing Replace disposable sensor Re-enter PGM calibration data
LA pH Below Limit	The pH reading for the LA is reading below the set notice limit	Add fresh STEEN Solution™ to system, remove similar volume of old STEEN Solution™ Reset the lower CO_2 notice limit
LA pH PGM Out of Range	The pH reading coming from either the disposable sensor or transmitter housing is out of acceptable range	Check disposable to make sure sensor is seated properly in housing Replace disposable sensor Re-enter PGM calibration data
UPS Hardware and/or Communication Problem	There is a hardware or loss of communication problem with the UPS to the XPS software.	Check UPS cable connection to touchscreen monitor Contact XVIVO to schedule service

6.0 Equipment Alerts

Equipment Alerts are considered warnings that equipment may be operating out of normal range and should be checked to confirm optimal function. An equipment alert will emit an audible beep tone, display an alert message at the unit itself (for the heater/cooler, pump and ventilator), and a Notification will appear at the top header of the XPS software (excluding the heater/cooler).

6

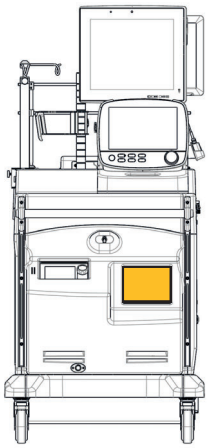
Equipment Alerts

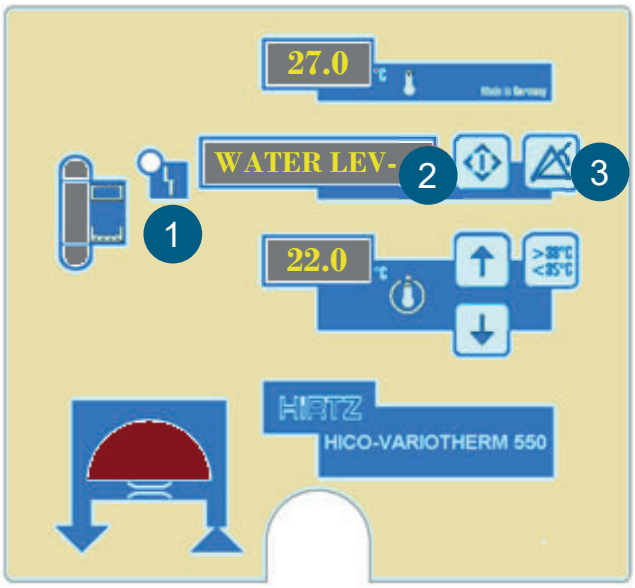
Heater/ Cooler

CardioHelp XVIVO

C3 Ventilator

6.1 Heater/Cooler





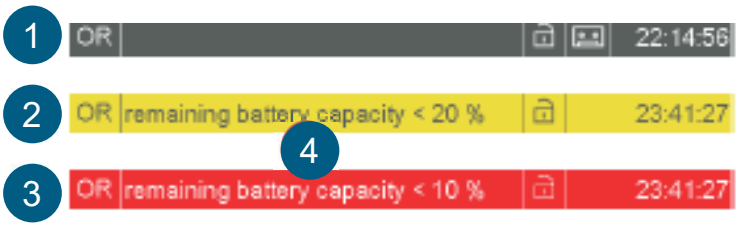
1 Fault lamp (lights during alert or alarm status).

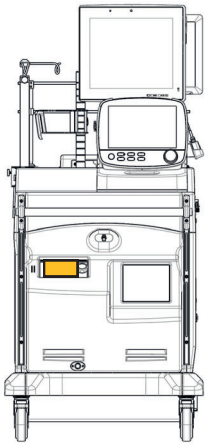
2 Status and error message display.

3 Alert silence button (silence alert beep for 10 minutes).

Alert	Definition	Action needed
Temp.Diff > 1°C	Disconnect and reconnect hose couplings during operation	Press silence button to silence
Water level?	Water level too low Sensor defect	Fill up water to just below MAX-mark on level indicator Contact XVIVO customer service if defect is suspected
Check unit -> customer service	Water tank empty Sensor breakage/short circuit	Fill up water to just below MAX-mark on level indicator Contact XVIVO customer service if defect is suspected
Check unit -> C temperature too low	Unit is too cold (<15°C) Sensor breakage	Warm up unit for some time at room temperature Contact XVIVO customer service if defect is suspected

6.2 CardioHelp XVIVO Alert Panels





Color	Alert Status
Grey	No alert/alarm status- normal operation
Yellow (flashing)	Medium-priority alert (intervention required or imminent pump stop)
Yellow (solid)	Low-priority Alert (no intervention, no pump stop)

1 Normal Status Bar (grey)

2 Alert Status Bar (yellow)

3 Alarm Status Bar (red)

4 Alert/alarm message

5 If the Alert status bar flashes yellow, then an intervention is required by the user or else the pump will eventually stop.

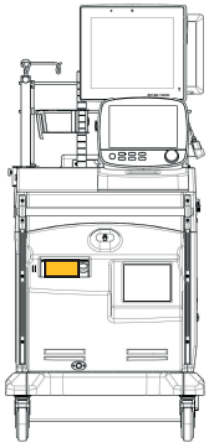
6 A solid yellow bar indicates a non-critical Alert that will not cause the pump to stop.

7 The pump control panel allows the user to pause the alarm as shown in the toolbar menu.

8 **NOTE:** The CardioHelp XVIVO pump software will not allow the user to disable the acoustic alarms.

	Alert	Action needed
	Startup Screen	Go to Home / Main Perfusion Screen
	Menu	Go to Main Menu
	Global override	Global override Mode
	Disable acoustic alarm	NOTE: This mode is not used for the XPS
	Current alarm pause	Pauses current alarm (2min)

6.2.1 CardioHelp XVIVO (Medium-priority)

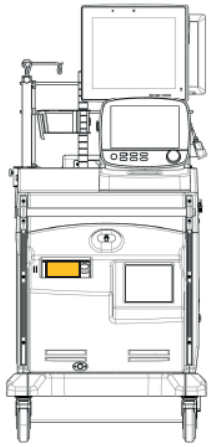


NOTE:

The centrifugal pump alerts listed on this page indicate Medium-priority (*flashing* yellow) alarms which can lead to alarm status and eventual pump stoppage if condition does not improve.

Alert	Definition	Action needed
AC voltage error	There is an error reading from the AC voltage sensor	Check wall power/ try another outlet Contact XVIVO for service
Battery Defect Battery 1 Defect Battery 2 Defect Battery very low	There is a problem with the DC battery source power	Contact XVIVO for service
Bubble sensor defect	The bubble sensor has a problem reading data	Clean bubble sensor Reset bubble detector
Device defect (Ox$)	There is an uncategorized defect with centrifugal pump	Contact XVIVO for service
Device temp. too high	The centrifugal pump internal temperature is >42°C	Check room temperature Check cooling fan operation
Drive temp. not available	Internal temperature sensor is not working appropriately	Contact XVIVO for service
Ext. DC voltage error	The line voltage for the DC power source is out of range (11-28V)	Contact XVIVO for service
Level sensor defect	The level sensor is not reading data	Reset level sensor Replace level sensor
LPM above limit	The liters per minute flow of the pump are greater than the user-defined limit	Should be operating in RPM mode
LPM below limit	The liters per minute flow of the pump are less than the user-defined limit	Should be operating in RPM mode
LPM out of range	Measured data does not match displayed data	Contact XVIVO for service
Mode switched (LPM <-> RMP)	Flow control mode was switched by user from LPM to RPM or vice-versa	Should be operating in RPM mode
Negative LPM detected	The liters per minute flow of the pump are negative (i.e. backflow present)	Should be operating in RPM mode Check clamps to ensure flow direction is antegrade
No disposable detected	Quadrox-iR oxygenator/ pump head is not properly connected	Re-seat oxygenator into housing

6.2.1 CardioHelp XVIVO (Medium-priority)

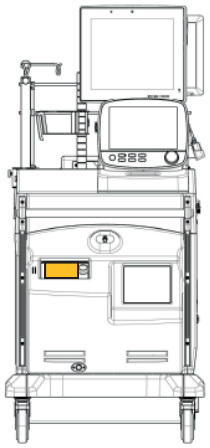


NOTE:

The centrifugal pump alerts listed on this page indicate Medium-priority (flashing yellow) alarms which can lead to alarm status and eventual pump stoppage if condition does not improve.

Alert	Definition	Action needed
pArt above stop limit	The arterial (PA) pressure reading is over the user-defined limit	Check for kinks in pressure lines Re-flush/zero pressure line Change alarm settings
pArt below stop limit	The arterial (PA) pressure reading is under the user-defined limit	Check for kinks in pressure lines Re-flush/zero pressure line Change alarm settings
pVen above stop limit	The venous (LA) pressure reading is over the user-defined limit	Check for kinks in pressure lines Re-flush/zero pressure line Change alarm settings
pVen below stop limit	The venous (LA) pressure reading is under the user-defined limit	Check for kinks in pressure lines Re-flush/zero pressure line Change alarm settings
Remaining battery capacity <20%	Battery needs to be charged or replaced	Check wall power Contact XVIVO for service
RPM above limit	The rotations per minute of the pump are greater than the user-defined limit	Check perfusion lines for kinks Change RPM limit settings Ensure clamps are positioned correctly
RPM below limit	The rotations per minute of the pump are lower than the user-defined limit	Change RPM limit settings
RPM out of range	The RMP measured data is different than the displayed data	Check Quadrox-iR connection to pump housing Contact XVIVO for service
Software error	There is an internal software conflict	Contact XVIVO for service
Wrong target LPM	The target LPM flow rate does not match user-defined level	Should be operating in RPM mode
Wrong target RPM	The target RPM rate does not match user-defined level	Check perfusion lines for kinks Change RPM limit settings Ensure clamps are positioned correctly

6.2.2 CardioHelp XVIVO (Low-priority)

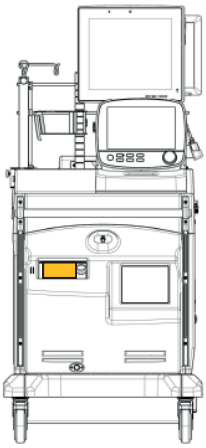


NOTE:

The centrifugal pump alerts listed on this page indicate Low-priority (static yellow) alarms which will not cause pump stop-page, but need to be evaluated/ addressed.

Alert	Definition	Action needed
Battery charger defect	The battery charger is not working correctly	Contact XVIVO for service
Battery 1 not charging Battery 2 not charging	Either battery 1 or 2 is not able to hold a charge	Check wall power connection Contact XVIVO for service
Bubble detected	An air bubble was detected in the PA perfusion line	Check for bubbles Reset bubble detector
Bubble sensor disconnected	Bubble sensor is not sending signal to pump	Reconnect bubble sensor Reset bubble detector
Countdown time elapsed	The countdown timer reached 0	Reset timer
Device defect (Ox$)	There is an internal conflict in the pump system	Contact XVIVO for service
Fan 1 drive defect Fan 2 drive defect	The fan is not operating properly	Contact XVIVO for service
Fan 1 housing defect Fan 2 housing defect	The fan housing is defective causing excessive resistance	Contact XVIVO for service
Fan AC supply defect	AC power to pump fans is not working	Check wall power connection Contact XVIVO for service
Flow sensor defect	The flow sensor is not sending appropriate data to computer	Check flow sensor connection Reconnect flow sensor Re-zero flow sensor
Flow sensor disconnected	The flow sensor is working but is not connected to the perfusion tubing	Reconnect flow sensor Re-zero flow sensor
Flow sensor offset too high	The flow sensor is not positioned properly in the perfusion	Reconnect flow sensor Re-zero flow sensor
Level limit reached	The fluid level in the reservoir is at the low point of the level	Add STEEN Solution™
Level sensor disconnected	The level sensor is working but is not connected to the disposable	Reconnect level sensor

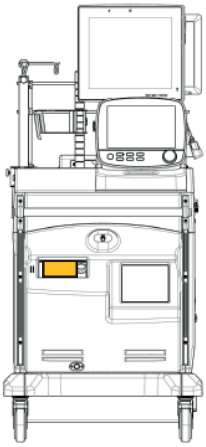
6.2.2 CardioHelp XVIVO (Low-priority)



Alert	Definition	Action needed
LPM above limit	The LPM reading is over the user-defined limit	Should be in RPM mode
LPM below limit	The LPM reading is below the user-defined limit	Should be in RPM mode
No flow signal	The flow sensor is not connected	Reconnect flow sensor
pVen above warn limit	The venous (LA) pressure reading is over the user-defined limit	Check for kinks in lines Reflush/zero pressure lines Change alarm settings
pVen below warn limit	The venous (LA) pressure reading is under the user-defined limit	Check for kinks in lines Reflush/zero pressure lines Change alarm settings
pArt above warn limit	The arterial (PA) pressure reading is over the user-defined limit	Check for kinks in lines Reflush/zero pressure lines Change alarm settings
pArt below warn limit	The arterial (PA) pressure reading is below the user-defined	Check for kinks in lines Reflush/zero pressure lines
RPM above limit	The RPM reading is over the user-defined limit	Check perfusion lines for kinks Ensure clamps are positioned correctly Change RPM limit settings
RPM below limit	The RPM reading is below the user-defined limit	Chang RPM limit settings
Software error	There is a software error with the pump system	Watch for error to reset itself Restart pump if possible
Switched to battery supply	The pump is running off of DC battery power	Check wall power Change wall outlet switch Contact XVIVO for service
TVen above limit	The temperature reading from the LA (reservoir) is over the user-defined limit	Check heater/cooler unit Change alert settings
TVen below limit	The temperature reading from the LA (reservoir) is under the user-defined limit	Check heater/cooler unit Change alert settings

6.2.2 CardioHelp XVIVO (Low-priority)

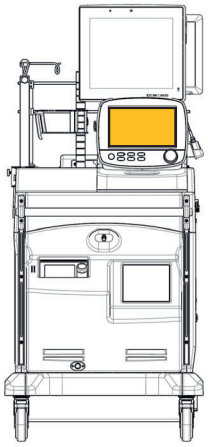
Alert	Definition	Action needed
TArt above limit	The temperature reading from the PA (oxygenator) is over the limit	Check heater/cooler unit Change alert settings
TArt below limit	The temperature reading form the PA (oxygenator) is under the limit	Check heater/cooler unit Change alert settings
Wrong password	Administrator password entered is incorrect	Re-enter password (Admin-level) Contact XVIVO for service



NOTE:

The centrifugal pump alerts listed on this page indicate Low-priority (static yellow) alarms which will not cause pump stop-page, but need to be evaluated/ addressed.

6.3 C3 Ventilator Alert Panels



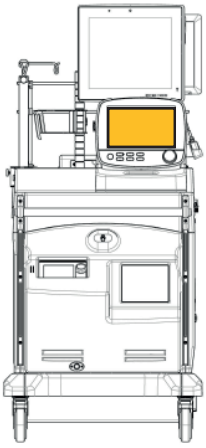
1 Upon active Alert status, the ventilator top LED panel will light yellow.

2 A yellow Alert message will indicate what is causing the Alert.

3 Touching the Alert bar will open up the alarm buffer which shows up to 6 of the most recent alarm conditions.

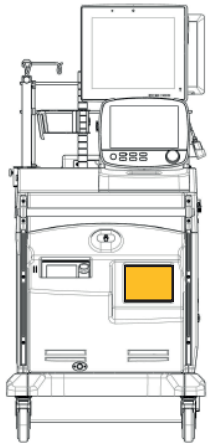
4 Pressing the alarm pause button will stop the audible tone for 2 minutes. A red LED indicator will light

6.3.1 C3 Ventilator



Alert	Definition	Action needed
Battery 1 (or 2) calibration required	Battery 1 (or 2) requires calibration. You may continue to use the battery	Calibrate the battery
High frequency	The measured f_{Total}> the set alarm limit	Check the lung for adequate ventilation Check the alarm limits
High pressure during sigh	A sigh cannot be fully delivered because excessive inspiratory pressure would be required	Check the lung Check the breathing circuit Adjust the Pressure alarm limit and consider disabling the sigh function
IRV	The set I:E ratio is above 1:1, leading to inverse ratio ventilation	Check the timing control settings
Loss of PEEP	PEEP cannot be determined	Check lung Check breathing circuit for leaks Replace circuit if necessary
Low frequency	The measured fTotal< the set alarm limit	Check lung Adjust the low fTotal alarm limit Consider suctioning Check for kinked ET tube Consider possibility of acute asthma
$V_{t\ high}$	The delivered V_t>1.5 the set $V_{t\ high}$ alarm limit. Pressure automatically is reduced by 3 mbar for next breath	Reduce the $P_{support}$ setting Adjust the high $V_{t\ high}$ alarm limit
$V_{t\ low}$	Measured VTE <the set limit for 2 consecutive breaths **NOTE:** when lung is cold, this alert may be active until lung warms up and becomes more compliant	Check the lung Check and adjust the ventilator settings including alarm settings Check for leaks and disconnects Consider suctioning Check for kinked ET tube
O_2 cell cal needed	Oxygen cell calibration data is not within expected range or cell is new and requires calibration	Calibrate the oxygen cell
O_2 cell missing	There is no signal from the oxygen cell	Install an oxygen cell or use an extenal monitor, according to ISO 21647 **NOTE:** to prevent leakage within the ventilator, make sure an oxygen cell is installed at all times, even if an external monitor is used

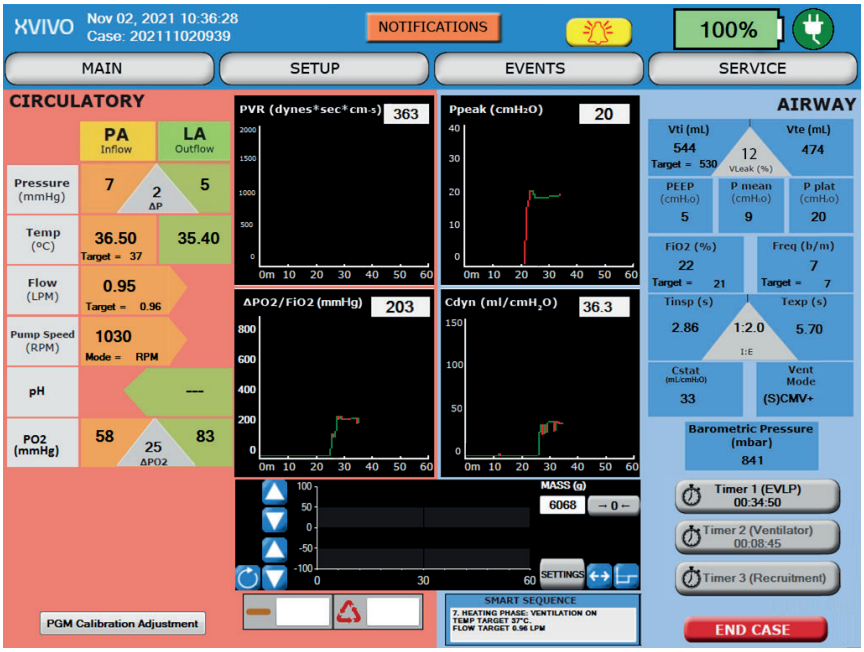
6.3.1 C3 Ventilator



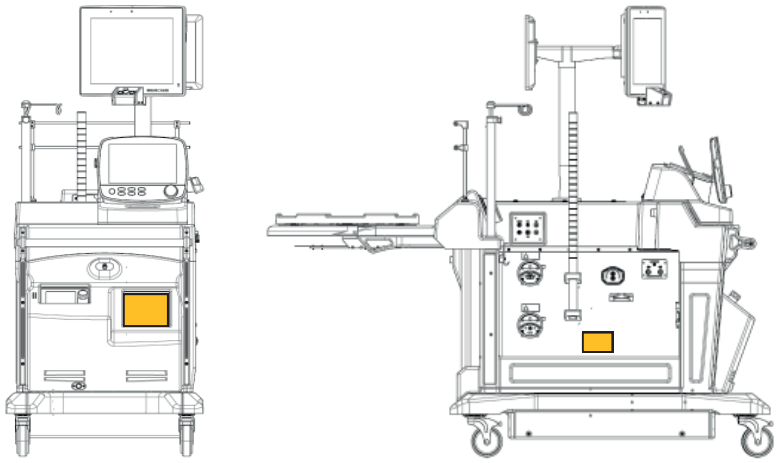
Alert	Definition	Action needed
O_2 cell not system-compatible	The incorrect type of oxygen cell has been installed	Install an oxygen cell intended for the HAMILTON C3 (PN 396200)
Pressure Limitation	Inspiratory pressure, including PEEP/CPAP, is 10 cmH_2O below Pressure. The ventilator limits applied pressure, so the target pressure or volume may not be achieved	Check the lung for adequate ventilation Check ventilator settings and alarm limits **NOTE:** A cold lung will alert for pressure limits until it warms up and becomes more compliant"
Preventative maintenance required	According to its operating hours, the ventilator requires preventative maintenance	Have ventilator serviced Contact XVIVO for service
Replace HEPA filter	The air inlet HEPA filter shows increased resistance	Replace the HEPA filter Contact XVIVO for service
Real time clock failure	Date and time not set	Set date and time
Technical event: XXXXX	A hardware or software malfunction was detected. A technical alarm cannot typically be corrected by the operator. Ventilation will continue	Have the ventilator serviced Contact XVIVO for service
Turn Flow Sensor	The Flow Sensor connections are reversed. Ventilation continues, but the ventilator corrects for the reversed signal	Reverse the ends of the Flow Sensor. The blue sensing line is close to the lung and must be attached to the blue connector. The colorless sensing line is close to the ventilator and must be attached to the white connector.

7.0 Equipment Alarms

Equipment Alarms are urgent warnings that equipment is operating out of normal range and hardware shut down will **imminently follow**. An alarmed equipment will emit a long audible beep tone, display an alert message at the unit itself (for the heater/cooler, pump and ventilator), and will report a Notification (for the pump and ventilator only) at the top header of the XPS software.



Touching the top Notification button will open a list of current Notifications (shown in orange for alarm and yellow for alert). Pressing on any item in the list will open a new window with a graphic depiction of the XPS device with a lit up area to draw the user's attention to the alarming piece of hardware:



7

Equipment Alarms

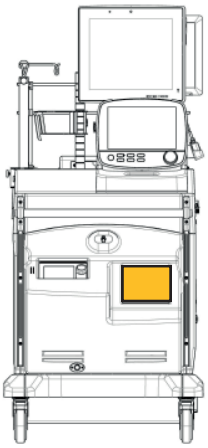
Heater/ Cooler

CardioHelp XVIVO

C3 Ventilator

PGM

7.1 Heater/Cooler

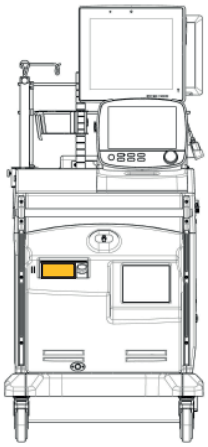


In addition to the displayed alert messages above, the Heater/Cooler may also have these other fault conditions which will not show up as an alert or alarm message. Instead, the conditions are described as are the appropriate action steps to resolve the faults.

Alarm	Description	Action needed
Alarm test defect -> customer service	This alarm is triggered if the unit detects a fault during the automatic or manual function test or has identified that the independent circuit test no longer responds	Press power switch to off position Leave unit switched off for at least 2 hours Contact XVIVO for service if unit remains in alarm state
Check unit -> customer service	This alarm is triggered due to various defects. Check that the tank is full of water first, otherwise it could be a more serious issue.	Check water level and replace if low Press power switch to off position Contact XVIVO for service
Lack of water!?	This alarm triggers if the unit is in danger due to severe lack of water in reservoir. Unit will SHUT OFF.	Press power switch to off position Leave unit switched off for at least 30 minutes Fill up the water tank until the water level indicator is just below the MAX-mark
Power failure	This alarm is triggered if the power supply fails during operation. The Heater/cooler is NOT connected to the UPS system in the cart due to its large power draw re-quirements	Press power switch to off position Plug XPS unit into different wall outlet
Temp.Diff >1°C alert does not resolve after 10 min	The unit isn't cooling sufficiently or the cooling elements and/or pump are defective	Check water level and replace if low Contact XVIVO for service
Water level!? Alert does not resolve after 10 min	Consider sensor defect	Check water level and replace if low Contact XVIVO for service

Other Fault Condition	Possible Causes	Action needed
No or insufficient water circulation	Check for kinked hoses Check Hansen connectors at Oxygenator Check water level	Ensure correct routing of hoses Press couplings together firmly Replace water Contact XVIVO for service
Hansen couplings are stiff	Outer visible seal ring damaged or missing	Apply silicone grease to seals
Hansen coupling leaking	Outer visible ring damaged or missing	Replace the seal ring
Hansen valve of unconnected coupling permanently leaking	Inner seal ring is either damaged or dirty	Plug and release the connector several times, try to clean inner ring Contact XVIVO for service
Set value not reached in cooling	Ambient temperature too high	Try to lower ambient temperature
TEMP.DIFF >1°C Alert does not resolve after 10 min	The unit isn't cooling sufficiently or the cooling elements and/or pump are defective	Check water level and replace if low Contact XVIVO for service

7.2 CardioHelp XVIVO

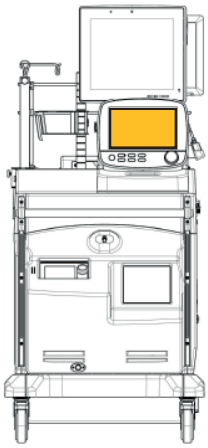


WARNING:

If the pump stops during operation due to an alarm trigger, perfusate supply to the lung will cease. Please ensure that the cause of the interruption to the pump is remedied as quickly as possible and that the pump starts up as soon as possible.

Alarm	Description	Action needed
Backflow Prevention	This alarm is triggered when there is a backflow (negative) pressure reading outside of the limit for > 6 seconds	Pump stops operation Check clamp position Check kinking in tubing
Battery discharged	Backup battery is completely discharged	Move XPS power plug to a different wall power outlet Contact XVIVO for service
Bubble detected	If a bubble is >5mm, this alarm will trigger and shut off pump	Check and clear bubbles in lines Reset bubble detector
Device defect (Ox$) Device defect-Stop (Ox$)	If there is a major defect in pump system hardware or software, system will stop	Contact XVIVO for service
Level limit reached	The level of fluid remaining in the reservoir is below the level indicator, pump will stop	Add STEEN Solution™ as quickly as possible
No batteries detected	Backup batteries are not detected by pump software	Move XPS power plug to a different wall power outlet Contact XVIVO for service
pArt above stop limit	Pressure in the PA (yellow) line to the lung is higher than the user- defined stop limit	Check clamp position Check for kinking in tubing Reset upper pArt limit
pArt below stop limit	Pressure in the PA (yellow) line to the lung is lower than the user-defined stop limit	Check clamp position Check for kinking in tubing Reset lower pArt limit
Pump disposable error	Disposable pump head/ Quadrox-iR oxygenator is not properly seated in pump housing	Check pump head position and re-seat if necessary
pVen above stop limit	Pressure in the LA (green) line from the lung is higher than the user-defined stop limit	Check clamp position Check for kinking in tubing Reset upper pVen limit
pVen below stop limit	Pressure in the LA (green) line from the lung is lower than the user-defined stop limit	Check clamp position Check for kinking in tubing Reset lower pVen limit
RPM control error	The RPM control (hardware or software) is not working appropriately	Contact XVIVO for service
Runaway error	Pump control system has failed	Contact XVIVO for service

7.3 C3 Ventilator



WARNING:

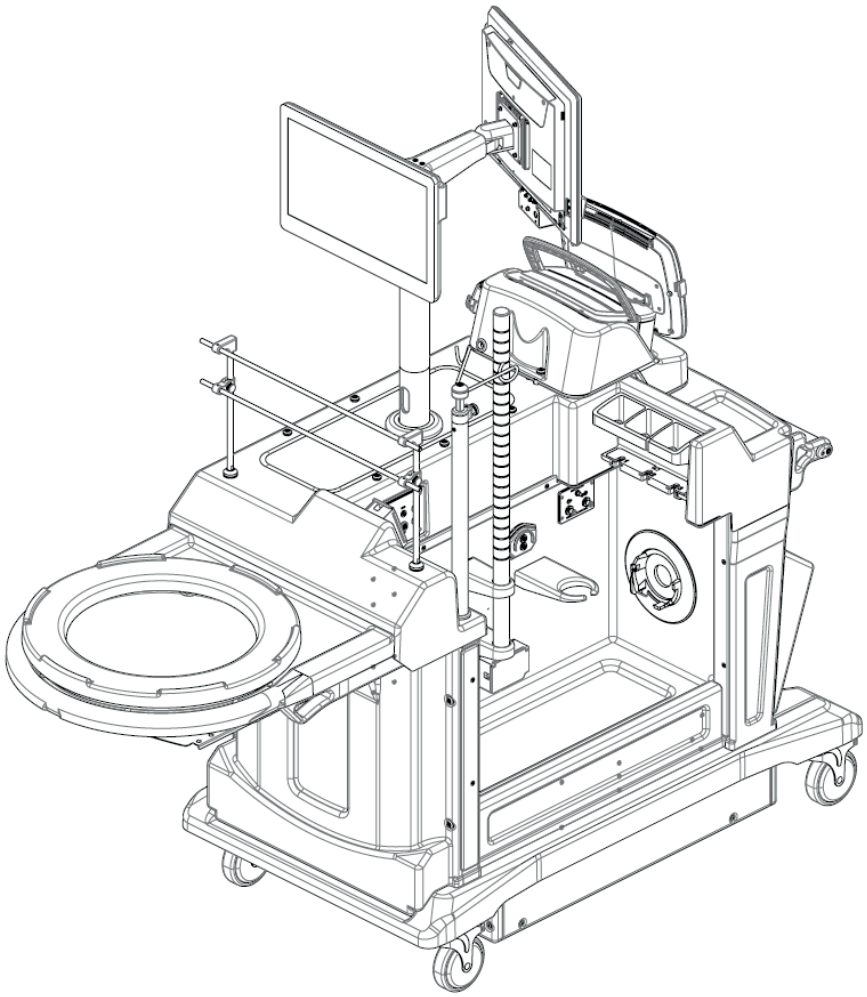
If the ventilator stops during operation due to an alarm trigger, oxygen supply to the lung will cease. Please ensure that the cause of the interruption to the ventilator is remedied as quickly as possible and that it starts up as soon as possible.

Alarm	Description	Action needed
Battery low	The ventilator is running on battery power and the battery can support < 10 minutes of continued operation	Check wall power and move to different outlet if necessary
Battery 1 temperature high	The battery temperature is higher than expected	Move ventilator to a cooler area Contact XVIVO for service
Battery 2 temperature high	The battery temperature is higher than expected	Move ventilator to a cooler area Contact XVIVO for service
Battery power loss	No battery is connected	Contact XVIVO for service
Check flow sensor	Flow sensor measurements are out of expected range. The ventilator switches over to PCV+ mode and displays ventilator pressure (Pvent) instead of Paw	Check flow sensor and sensing lines for connection and kinking Re-calibrate flow sensor Install a new flow sensor
Device temperature high	The internal temperature of the ventilator is higher than expected	Move ventilator to a cooler area Check the cooling fans in the XPS Contact XVIVO for service
Disconnection on patient side	VTE< 1/8 delivered VTI and delivered VTI > 50 ml	Check lung Check breathing circuit for disconnection between the lung and the flow sensor, or for other large leaks (e.g. ET tube, bronchopleural fistula) **WARNING: A fan failure can also cause this alarm, resulting in oxygen enrichment inside the ventilator and a potential fire hazard!
Disconnection on ventilator side	VTI measured at the airway < ½ delivered VTI, and delivered VTI > 50 ml	Check breathing circuit for a disconnection between the ventilator and the flow sensor or for other large leaks (e.g. breathing circuit, humidifier) Reconnect and calibrate the flow Sensor
Exhalation obstructed	End-expiratory pressure ≥ (set PEEP/CPAP + 5 cm H_2O)	Check the lung Check the expiratory limb for obstruction Check the expiratory valve membrane and cover Check the flow sensor tubes for occlusion Adjust breath timing controls to increase the expiratory time Contact XVIVO for service
External flow sensor failed	The flow sensor doesn't work properly	Change flow sensor
High minute volume	The measured ExpMinVol > theset alarm limit	Check the lung Check and adjust the ventilator settings, including alarms
High oxygen	Measured oxygen is > the set alarm limit (low-pressure oxygen) or the user-defined Oxygen + 5% (high pressure oxygen)	Calibrate the oxygen cell Install a new oxygen cell Contact XVIVO for service

Appendix 1: Additional Features

This section outlines additional hardware and software features that may be useful above and beyond the standard features described previously.

These features include General Menu Settings, system software resets (including date/time), additional monitoring alert capabilities, touchscreen calibration controls and graphical data report generation.

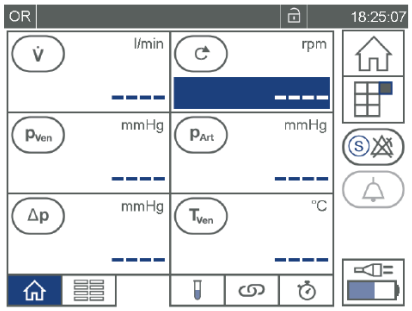


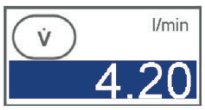
8

Appendix 1: Additional Features

8.1 Display Features

CardioHelp XVIVO

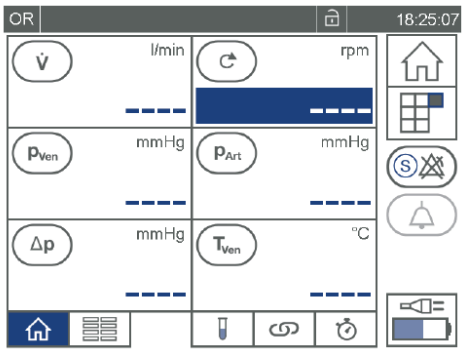


	Measured Value	Meaning
	Blue on white background	Valid measured value
	Bubble monitoring/ level monitoring: Blue check mark	Bubble monitoring/ level monitoring on-line and functional
	Dashes instead of measured values	• Values not available (sensor not connected/working) • Parameter is not supported • Values are outside of valid range
	Measured Rotations per Minute (RPM) value on blue background	In RPM mode. To change speed, touch the 
	Measured Liters per Minute (LPM) value on blue background	In LPM mode

	Symbol	Function
	Startup Screen	Go to Home/ Main Perfusion Screen
	Parameter Screen	Go to Parameter Screen
	Blood parameters	**NOTE:** Not used in this application
	Intervention Screen	Go to the Interventions screen
	Timer Screen	Go to the Timer screen

8.2 Tab Controls

CardioHelp XVIVO

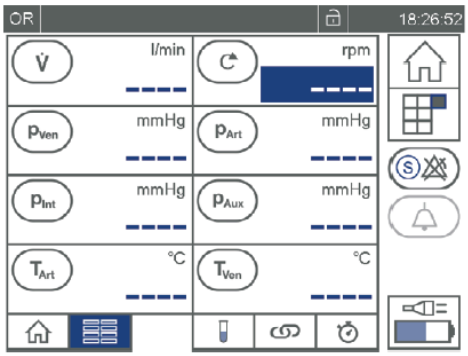


Startup Screen

In this mode, the touchscreen displays the most important parameters. This is also the main screen displayed once the system is turned on.

Displayed parameters:

- Flow Rate (LPM, or 'l/min')
- Pump Speed (RPM or 'rpm')
- Pressures: Arterial, Venous and Delta
- Temperature (Venous)

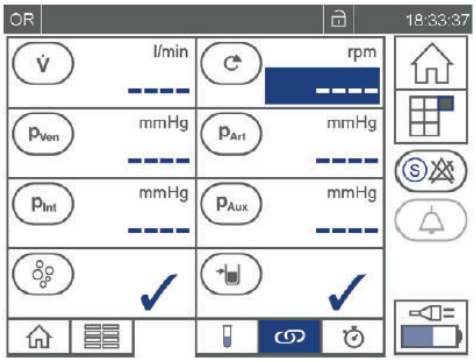


Parameter Screen

In this mode, the touchscreen displays pressure and temperature parameters.

Displayed parameters:

- Flow Rate (l/min)
- Pump Speed (rpm)
- Pressures: Arterial, Venous, Internal & Auxiliary
- Temperatures: Arterial and Venous

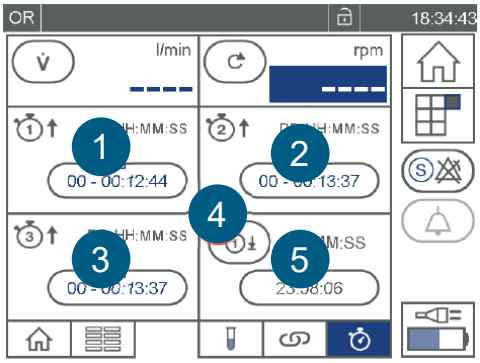


Intervention Screen

In this mode, the touchscreen displays high-priority physiological alarms.

Displayed parameters:

- Flow Rate (LPM)
- Pump Speed (RPM)
- Pressures: Arterial, Venous, Internal & Auxiliary
- Bubble Alarm



Timer Screen

In this mode, the touchscreen displays 4 timers (3 count-up, 1 count-down).

Displayed parameters:

- Flow Rate (LPM)
- Pump Speed (RPM)
- Count-up timers **1**, **2** & **3**
- Count-down timer **4** and set count time **5**

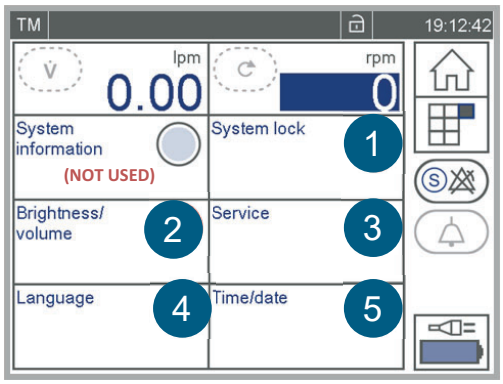
8.3 Menu Features

CardioHelp XVIVO

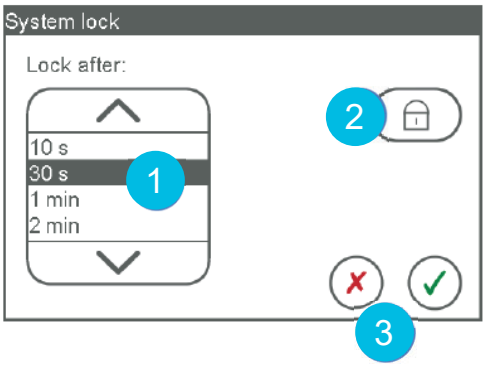
Symbol	Function
Setting	Change the general settings
Pumps	Change the pump mode
Configuration	Configuration Settings – typically not used in this application
Alarm list	Display list of alarms

8.3.1 General Menu Settings:

CardioHelp XVIVO



1. Change the autolock settings
2. Change the brightness/ volume
3. Service **NOTE: Password Protected**
4. Change the display language
5. Change the time & date formats

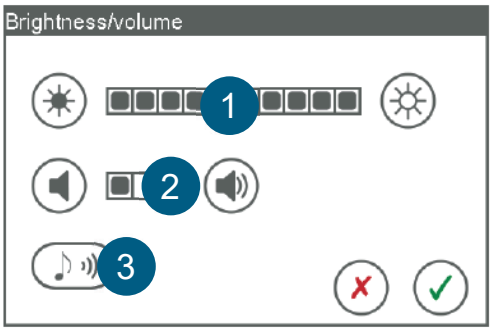


1. Select auto lock-out time
2. By pressing this symbol, the auto-lock feature will be disabled. To enable the feature again, press the following symbol: 
3. To accept changes, press the green checkmark symbol. To reject/cancel, press the red “X”

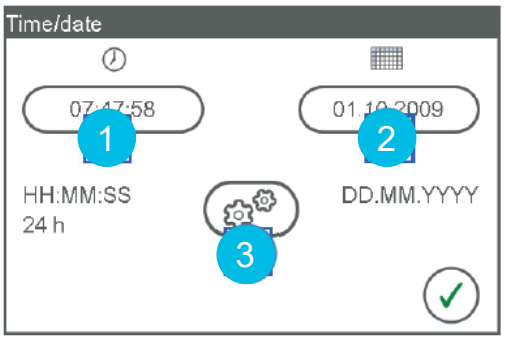
8.3 Menu Features

CardioHelp XVIVO

8.3.1 General Menu Settings:

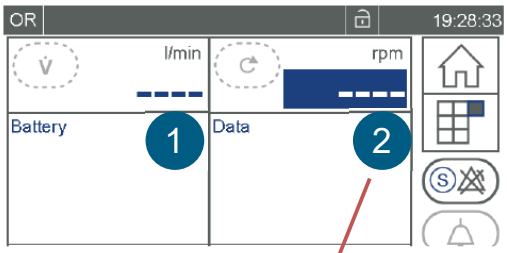


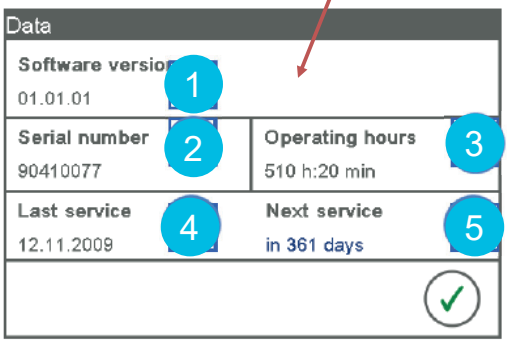
1 Brightness settings
2 Volume settings
3 To test speaker and alarm buzzer, touch this symbol (tests both alarm function and volume)



1 Change time
2 Change date
3 Change time/date format

8.3.2 System Data & Information Settings:





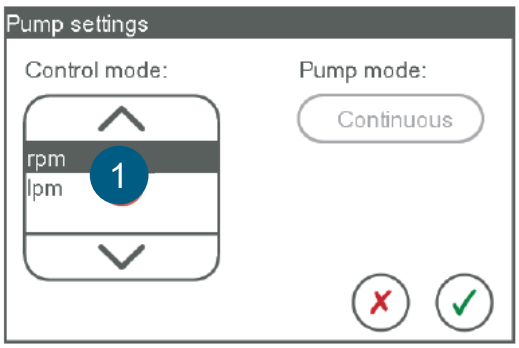
1 Check Battery Status
2 Check System data/information

1 Software version
2 Device serial number
3 Operating time since startup
4 Date of last service
5 Time until next service

8.3 Menu Features

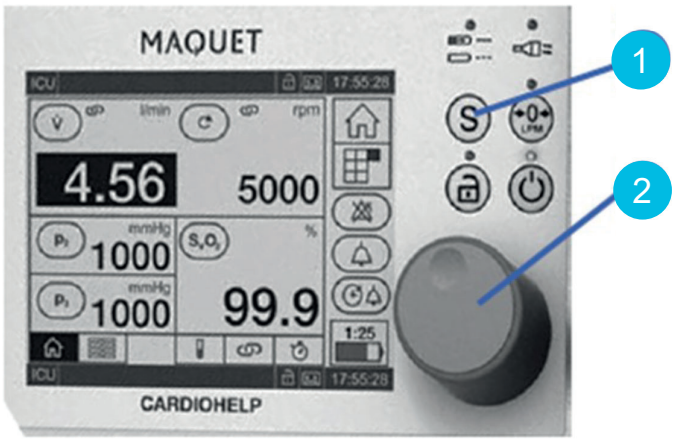
CardioHelp XVIVO

8.3.3 Pump Mode Settings:



1 Select Pump mode button and then select rpm or lpm and confirm.

8.3.4 Calibrate Touchscreen:

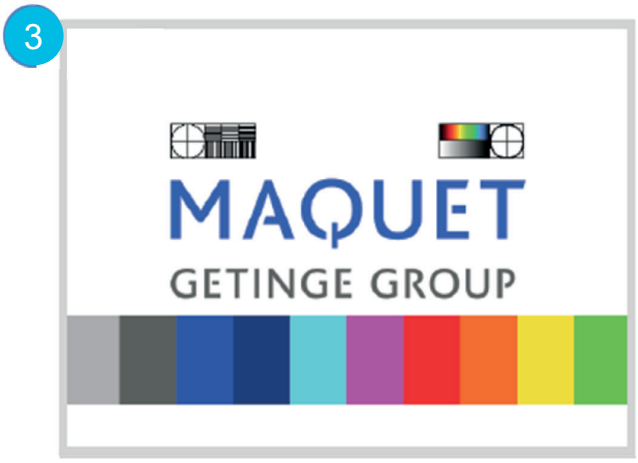


If a problem with the touchscreen calibration develops, press the Safety (1) button and hold while simultaneously pressing the control knob (2) for 10-20 seconds.

NOTE:

Once screen calibration starts, you must finish the procedure before being allowed to do anything else.

3 Press in the center of the “X” as it moves around the screen until the screen calibration is complete.



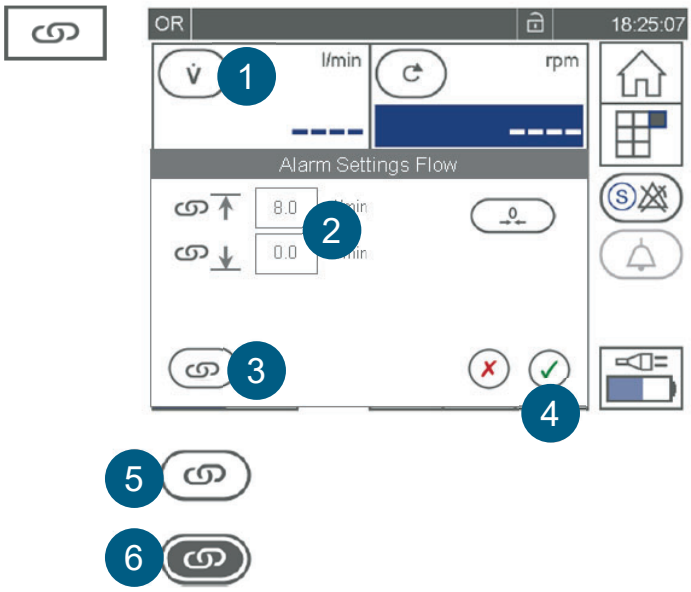
8.4 Intervention Settings

CardioHelp XVIVO

In the CardioHelp XVIVO, the settings for alarms and interventions can be user-defined for the following parameters:

- RPM mode: Flow monitoring
- Temperature monitoring
- Pressure monitoring
- Bubble monitoring

8.4.1 RPM Mode: Flow Monitoring Control



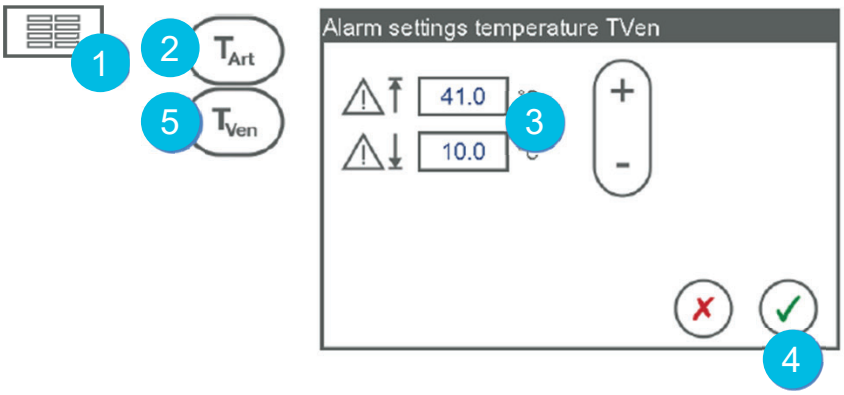
1. In RPM mode, press the flow button.
2. Adjust the low and high intervention limits.
3. Press the intervention button to activate.
4. Select confirm to begin flow control mode.

NOTE:

In flow control mode, when the flow rate is higher or lower than the set limits and the intervention is activated, the pump will adjust its rpms to stay within the set limits.

5. Intervention Deactivated (no flow control)
6. Intervention Activated (pump adjusts speed to keep flow within set limits)

8.4.2 Temperature Monitoring



1. Select Parameter Tab
2. Select Temperature TArt
3. Enter high and low limits
4. Select confirm to set
5. Repeat with TVen

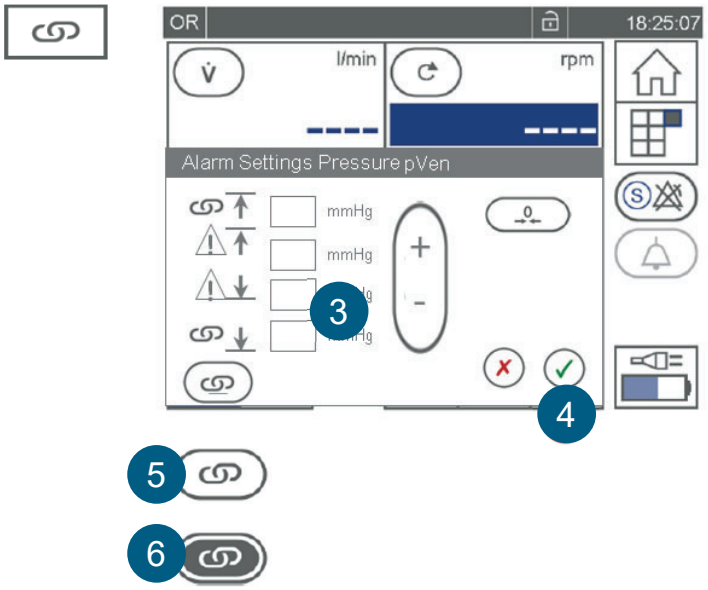
NOTE:

CardioHelp XVIVO will generate an Alert if temperature moves outside of set range, but will not stop pump function

8.4 Intervention Settings

CardioHelp XVIVO

8.4.3 Pressure Monitoring and Control



1 In Pressure Control, P_{Art} can be set to monitor and control high pressures and P_{Ven} can be set to monitor and control low pressures.

2 Press a pressure button to open alarm settings.

3 Enter values for intervention and alarm states.

4 Select confirm to begin pressure control mode.

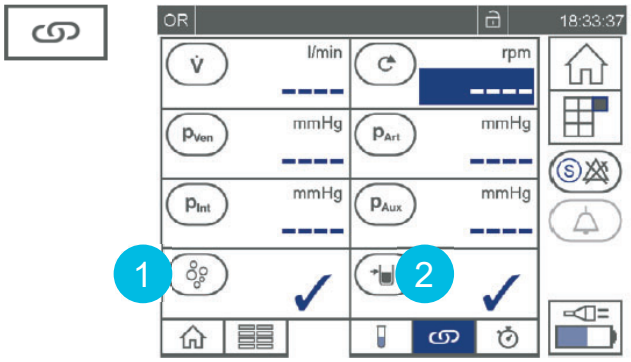
NOTE:

In pressure control mode, when the pressure is at the alarm limit, a low priority alarm will trigger. If the pressure exceeds the intervention (higher) limit, a medium-priority alarm will trigger and the pump will adjust to get the pressure back to set limits. IF PUMP > 10mmHg outside limits, there will be a high priority alarm and the pump will STOP.

5 Intervention Deactivated (no flow control)

6 Intervention Activated (pump adjusts speed to keep flow within set limits)

8.4.4 Bubble & Level Monitoring and Control



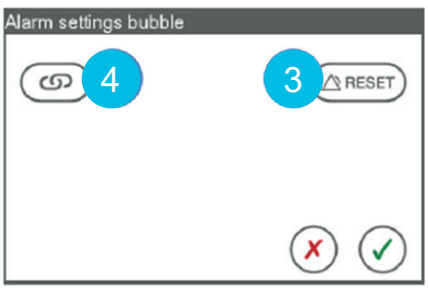
1 Bubble Monitor

2 Level Monitor

3 Reset Bubble Monitor

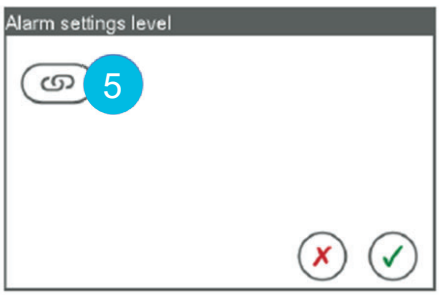
4 Intervention On/Off Bubble Monitor

5 Intervention On/Off Level Sensor



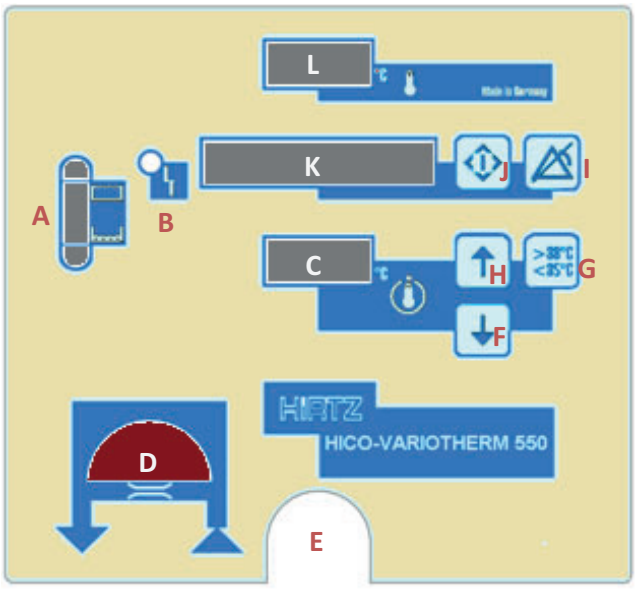
NOTE:

When the interventions are active for the Bubble Monitor (4) and/or the Level Monitor (5), the pump will STOP if the respective intervention is active and there is either a bubble detected in the perfusion line or the level of fluid falls below the level sensor.



8.5 Control Layout

Heater/ Cooler



A) Water level indicator
B) Fault lamp
C) Temperature set value
D) Water flow display
E) Mains power switch
F) Decrease set temperature
G) Temperature release (press to go lower than 35°C or higher than 38°C)
H) Increase set temperature
I) Alert silence
J) Function test
K) Status and error message display
L) Actual temperature value

1 To set temperature above 38°C, simultaneously press these two buttons until set point is reached
2 To set temperature below 35°C, simultaneously press these two buttons until set point is reached
3 During long operations (> 6 hours), perform an equipment function test by pressing the function test key while the unit is operating
4 An alert (low to medium priority) may be silenced for 10 minute intervals by pressing this key.

8.6 Setup Controls

C3 Ventilator

8.6.1 Set Date & Time:

1 Click on System tab
2 Click Date & Time tab
3 Set date &/or time and select Apply to set

8.6.2 Main Screen Orientation:

4 Main monitoring parameters
5 P max
6 Pressure limitation (P max—10 cm H_20)
7 Dynamic lung graphic

8.7 Graphics Monitoring

C3 Ventilator

8.7.1 Graphics Window:

1 Click on Monitoring tab
2 Click Graphics tab
3 Select any of the graphic display options (‘Dynamic Lung’ here)

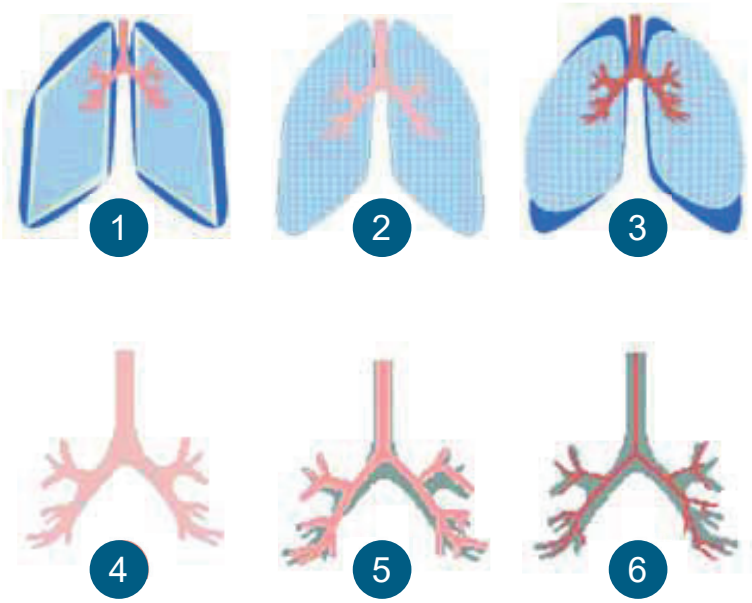
8.7.2 Dynamic Lung:

4 Lung image (this graphic shows a normal lung)
5 Numeric parameters
6 Bronchial tree graphic

8.7 Graphics Monitoring

C3 Ventilator

8.7.3 Dynamic Lung Compliance Graphics



1 Low compliance (dark blue lines around lung depict a normal lung
2 Normal compliance
3 High compliance

4 Normal resistance
5 Moderately high resistance
6 High resistance

8.7.4 Dynamic Loop Display:

7 Dynamic loop waveform

NOTE:

The following dynamic loop waves can be displayed:

- Pressure-Volume
- Pressure-Flow
- Flow-Volume

8.8 Monitored Parameters

C3 Ventilator

Parameter (unit)	Definition
AutoPEEP (cmH_2O)	The difference between the set PEEP and the calculated total PEEP within the lungs. AutoPEEP is the abnormal pressure generated by air trapped in the alveoli due to inadequate lung emptying. Ideally, it should be zero. AutoPEEP is calculated using the LSF method applied to the entire breath. When AutoPEEP is present, volutrauma or barotrauma might develop. In active patients, AutoPEEP may present an extra workload to the patient. AutoPEEP or air trapping may result from an expiratory phase that is too short, which may be observed under these conditions: • Delivered tidal volume too large • Expiratory time too short or respiratory rate too high • Circuit impedance too high or expiratory airway obstruction • Peak expiratory flow too low
Cstat (ml/cmH_20)	Static compliance of the respiratory system, including lung and chest wall compliances. It is calculated using the LSF method, which is a statistical technique called the least squares fitting method. This method is applied on a breath-by-breath basis and is most accurate when the patient is very relaxed. Cstat can help diagnose changes in elastic characteristics of the patient's lungs.
Exp Flow (l/min)	Peak expiratory flow
ExpMinVol (l/min)	Expiratory minute volume. The moving average of the monitored expiratory volume per minute over the last 8 breaths.
fTotal (b/min)	Total breathing frequency. The moving average of the lung's total breathing frequency over the last 8 breaths, including both mandatory and spontaneous breaths.
I:E	Inspiratory:expiratory ratio. Ratio of the patient's inspiratory time to expiratory time for every breath cycle. This includes both mandatory and spontaneous breaths.
Insp Flow (l/min)	Peak inspiratory flow, spontaneous or mandatory
Leak (%)	Leakage percent. The percentage of the delivered inspiratory volume (VTI) that is not returned during exhalation, averaged over the past 8 breaths. Leak can indicate leaks on the patient side of the Flow Sensor (endotracheal tube). It does not include leakage between the ventilator and Flow Sensor.
Oxygen (%)	Oxygen concentration of the delivered gas. It is measured by the oxygen cell in the inspiratory pneumatics. This parameter is not displayed if the oxygen supply is not connected; if the oxygen cell is not installed, is defective, or is not a genuine HAMILTON MEDICAL part; or if oxygen monitoring is disabled.
PEEP/CPAP (cmH_2O)	Monitored PEEP (positive end expiratory pressure)/CPAP (continuous positive airway pressure). The airway pressure at the end of exhalation.
Pmean (cmH_20)	Mean airway pressure. The absolute pressure, averaged over the breath cycle. Pmean is an important indicator of the possible impact of applied positive pressure on hemodynamics.

8.8 Monitored Parameters

C3 Ventilator

Parameter (unit)	Definition
Ppeak (cmH_2O)	Peak airway pressure. The highest pressure during the previous breath cycle. It is influenced by airway resistance and compliance. It may differ noticeably from alveolar pressure if airway flow is high.
RCexp (seconds)	Expiratory time constant. The rate at which the lungs empty, as follows: Actual TE (expiratory time) % emptying: 1 x RCexp 63% 2 x RCexp 86.5% 3 x RCexp 95% 4 x RCexp 98% RCexp is calculated as the ratio between VTE and flow at 75% of the VTE. In adults, an RCexp value above 1.2 s indicates airway obstruction, and a value below 0.5 s indicates a severe restrictive disease. Use RCexp to set optimal TE (Goal: TE x RCexp): In passive patients: Adjust rate and I:E. These actions may reduce the incidence of AutoPEEP.
Rinsp ($cmH_20/(l/s)$)	Resistance to inspiratory flow caused by endotracheal tube and the patient's airways, during inspiration. It is calculated using the LSF method applied to the inspiratory phase.
TE (seconds)	Expiratory time. In mandatory breaths, TE is measured from the start of exhalation until the set time has elapsed for the switchover to inspiration.
TI (seconds)	Inspiratory time. In mandatory breaths, TI is measured from the start of breath delivery until the set time has elapsed for the switchover to exhalation.
VTE (ml)	Expiratory tidal volume. The volume exhaled by the lung. It is determined from the Flow Sensor measurement, so it does not show any volume added due to compression or lost due to leaks in the breathing circuit. If there is a gas leak on the lung side, the displayed VTE may be less than the tidal volume the patient actually receives.
VTI (ml)	Inspiratory tidal volume. The volume delivered to the lung. It is determined from the Flow Sensor measurement. If there is a gas leak on the lung side, the displayed VTI may be larger than the displayed VTE.

8.9 Smart Sequencing Table

Smart Sequencing

Sequence number	Description	Time range	Temp target (C)	Flow target	Ventilation parameters	Actions on automatic timers	Activates next sequence	Pop-up message at start of phase	Smart sequence message
1	PRIMING MODE	0 min	NONE	NONE	OFF	(NONE)	Timer 1 (EVLP) Starts	N/A	1. PRIMING MODE. Start EVLP Timer when Antegrade Perfusion starts.
2	Heating Phase	0-10 min	22	10% of Max	OFF	(NONE)	Timer 1 at 10 minutes	(NONE)	2. HEATING PHASE: Set H/C to 23°C. FLOW TARGET <Target Flow (Start) > LPM
3	Heating Phase	10-20 min	31	20% of Max	OFF	(NONE)	Timer 1 at 20 minutes	10 MINUTE NOTIFI-CATION: Set H/C to 32°C Target Flow of: <ActualFlow_10_Mins>	3. HEATING PHASE: Set H/C to 32°C. FLOW TARGET <Target Flow (10min)> LPM
4	Heating Phase	20-30 min	32	30% of Max	NORMAL SETTINGS	(NONE)	LA Temp at 32	20-MINUTE NOTIFI-CATION: Set H/C to 38°C Target Flow of: <ActualFlow_20_Mins>	4. HEATING PHASE: Set H/C to 38°C. FLOW TARGET <Target Flow (20 mins)> LPM
5	Start Ventilation Notice	20-30 min	32	30% of Max	NORMAL SETTINGS	(NONE)	Ventilation Detected	VENTILATION AND DEOXYGENATION GAS READY TO START Set H/C to 38°C Target Flow of: <ActualFlow_20_Mi ns> Vt = <NORMAL VT> Rate = 7 Oxygen = 21%	5. HEATING PHASE: START VENTILATION AND DEOX GAS Set H/C to 38°C FLOW TARGET <Target Flow (20 Min) > LPM
6	Ventilation Detected	20-30 min	32	30% of Max	NORMAL SETTINGS	Timer 2 (Ventilation) Starts count-up	Timer 1 at 30 minutes	(NONE)	6. HEATING PHASE: VENTILATION ON Set H/C to 38°C FLOW TARGET <Target Flow (20 Min)> LPM
7	Heating Phase	30-40 min	37	50% of Max	NORMAL SETTINGS	(NONE)	Timer 1 at 40 minutes	30-MINUTE NOTIFICATION: Target Temp 37°C Target Flow of: <ActualFlow_30_Mins>	7. HEATING PHASE: VENTILATION ON TEMP TARGET 37°C. FLOW TARGET <Target Flow (30 Min)> LPM
8	Heating Phase	40-50 min	37	80% of Max	NORMAL SETTINGS	(NONE)	Timer 1 at 50 minutes	40-MINUTE NOTIFICATION: Target Flow of: <ActualFlow_40_Mins>	8. HEATING PHASE: VENTILATION ON FLOW TARGET <Flow Target (40 Min)> LPM
9	Full Flow then Breath Hold	50 min	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer 1 at 50.5 minutes	50-MINUTE NOTIFI-CATION: Target Flow of: <ActualFlow_50_Mins> START 15-second BREATH HOLD ON VENTILATOR	9. HEATING PHASE: 15 SECOND BREATH HOLD
10	First Recruitment Notice	50.5 min	37	100% of Max	RECRUITMENT SETTINGS	(NONE)	PO2>80%	START 1st RECRUIT-MENT / O2 CHAL-LENGE Vt = <Recruitment VT> Rate = 10 Oxygen = 100%	10. START 1st RECRUITMENT / O2 CHALLENGE FLOW TARGET <Flow Target Full Flow> LPM
11	First Recruitment Active	~51-61min	37	100% of Max	RECRUITMENT SETTINGS	Timer 3 (Recruitment) starts count-down from 10 min	Recruitment Timer expired	(NONE)	11: 1st RECRUITMENT UNDERWAY
12	First Recruitment Ended Notice	~61 min	37	100% of Max	NORMAL SETTINGS	Timer 3 (Recruitment) at 0 min	PO2 < 40%	END RECRUITMENT Vt = <Normal VT> Rate = 7 Oxygen = 21%	12: END RECRUITMENT
13	2nd Hour Perfusion Mode	62 min	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer at 1 Hour 48 Minutes	(NONE)	13: 2nd-HOUR PERFUSION MODE

8.9 Smart Sequencing Table (cont.)

Smart Sequencing

Sequence number	Description	Time range	Temp target (C)	Flow target	Ventilation parameters	Actions on automatic timers	Activates next sequence	Pop-up message at start of phase	Smart sequence message
14	2nd Breath Hold	108 minutes	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer at 1 Hour 48 Minutes: 30 Seconds	START 15-second BREATH HOLD ON VENTILATOR	14: 15-second BREATH HOLD
15	2nd Recruitment Notice	108.5 minutes	37	100% of Max	RECRUITMENT SETTINGS	(NONE)	PO2>80%	START 2nd RECRUITMENT / O2 CHALLENGE Vt = <Recruitment VT> Rate = 10 Oxygen = 100%	15: START 2nd RECRUITMENT / O2 CHALLENGE
16	2nd Recruitment Active	~109 minutes	37	100% of Max	RECRUITMENT SETTINGS	Timer 3 (Recruitment) starts count-down from 10 min	Timer 3 (Recruitment) expired	(NONE)	16: 2nd RECRUITMENT UNDERWAY
17	2nd Recruitment Ended Notice	~119 minutes	37	100% of Max	NORMAL SETTINGS	Timer 3 (Recruitment) at 0 min	PO2 < 40%	END RECRUITMENT Vt = <Normal VT> Rate = 7 Oxygen = 21%	17: END RECRUITMENT
18	2nd Post Recruitment Perfusion	~120 minutes	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer 1 at 2 Hours 48 Minutes	(NONE)	18: 3rd-HOUR PERFUSION MODE
19	3rd Breath Hold	168 minutes	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer at 2 Hours 48 Minutes: 30 Seconds	START 15-second BREATH HOLD ON VENTILATOR	19: 15-second BREATH HOLD
20	3rd Recruitment Notice	168 minutes; 30 seconds	37	100% of Max	RECRUITMENT SETTINGS	(NONE)	PO2>80%	START 3rd RECRUITMENT / O2 CHALLENGE Vt = <Recruitment VT> Rate = 10 Oxygen = 100%	20: START 3rd RECRUITMENT / O2 CHALLENGE
21	3rd Recruitment Active	~169 minutes	37	100% of Max	RECRUITMENT SETTINGS	Timer 3 (Recruitment) starts count-down from 10 min	Timer 3 (Recruitment) expired	(NONE)	21: 3rd RECRUITMENT UNDERWAY
22	3rd Recruitment Ended Notice	~179 minutes	37	100% of Max	NORMAL SETTINGS	Timer 3 (Recruitment) at 0 min	PO2 < 40%	END RECRUITMENT Vt = <Normal VT> Rate = 7 Oxygen = 21%	22: END RECRUITMENT
23	3rd Post Recruitment Perfusion	~180 minutes	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer 1 at 3 Hours 48 Minutes	(NONE)	23: 4th-hour PERFUSION MODE
24	4th Breath Hold	228 minutes	37	100% of Max	NORMAL SETTINGS	(NONE)	Timer 1 at 3 Hours 48 Minutes: 30 Seconds	START 15-second BREATH HOLD ON VENTILATOR	24: 15-second BREATH HOLD
25	4th Recruitment Notice	228 minutes; 30 seconds	37	100% of Max	RECRUITMENT SETTINGS	(NONE)	PO2>80%	START 4th RECRUITMENT / O2 CHALLENGE Vt = <Recruitment VT> Rate = 10 Oxygen = 100%	25: START 4th RECRUITMENT / O_2 CHALLENGE
26	4th Recruitment Active	~229 minutes	37	100% of Max	RECRUITMENT SETTINGS	Timer 3 (Recruitment) starts count-down from 10 min	Timer 3 (Recruitment) expired	(NONE)	26: 4th RECRUITMENT UNDERWAY
27	4th Recruitment Ended Notice	~239 minutes	37	100% of Max	NORMAL SETTINGS	Timer 3 (Recruitment) at 0 min	PO2 < 40%	END RECRUITMENT Vt = <Normal VT> Rate = 7 Oxygen = 21%	27: END RECRUITMENT
28	4th Post Recruitment Perfusion	~240 minutes	37	100% of Max	NORMAL SETTINGS	(NONE)	N/A	(NONE)	28: EXTENDED EVLP

8.10 History and Trend Logs Viewing and Downloading Files

Events Page

HISTORY LOG

Each case run on the XPS contains a HISTORY log. The log is a list of sequential inputs, events, and notifications that occur throughout the case. A HISTORY log file is created and permanently stored for each case on the XPS's main computer. Copies of this file can be downloaded to an external drive (per instructions) or automatically transferred and displayed by XMAT (if present).

File Details:

File Format: .txt, each event is time stamped

Naming: Year/Month/Day/Hour/Minute at start of case (HistoryYYYYMMDDHHMM.txt)

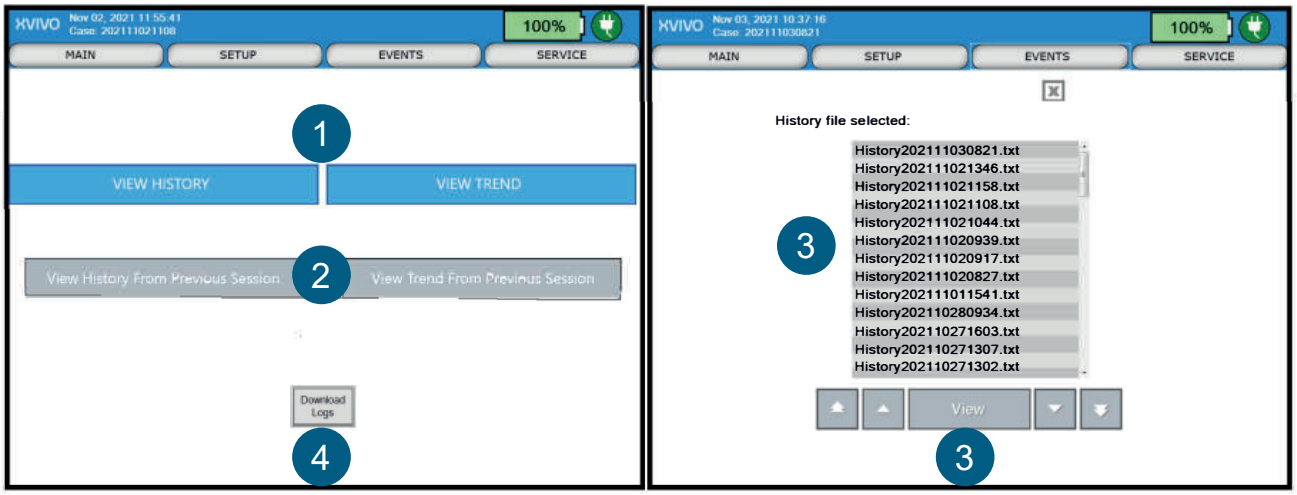
TRENDS LOG

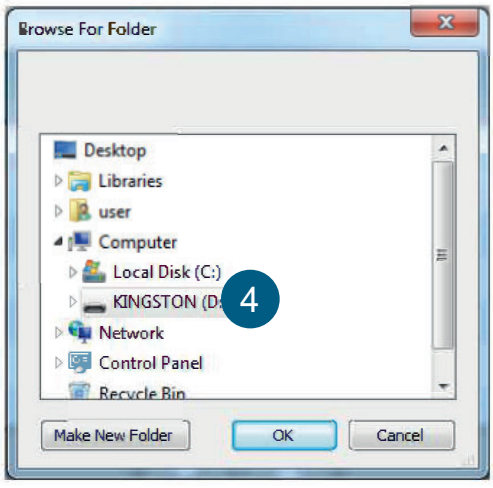
Each case run on the XPS also contains a TREND log. The log is a table of parameters, calculations, and conditions that are collected and stored every 3 seconds during the case (see proceeding table for details). A TREND log file is also created and permanently stored, and can be downloaded for each case on the XPS's main computer. Trend Files can be processed by XMAT (if present).

File Details:

File Format: .txt, rows are sorted by time every 3 seconds, tables are comma delimited

Naming: Year/Month/Day/Hour/Minute at start of case (TrendsYYYYMMDDHHMM.txt)





1. HISTORY and TREND buttons: selecting the blue button will open the current Log file for review. Scroll up/down buttons are provided for real-time viewing along with a button to close the viewing window.
2. The View History (or Trend) From Previous Session (gray) buttons opens the HISTORY or TREND Log to the top or bottom of the Log (file) page.
3. Select the file you would like to review a select the View button.
4. Download Logs: selecting the button will open a 'Browse For Folder" menu to download all History and Trend Log files saved on the XPS computer to a USB Flash Drive. A USB Flash Drive must first be inserted into the XPS computer, as the folders within the D: drive are the only available locations for downloading Log files. A "Make New Folder" option is available if a new destination on the D: drive is desired. After selecting a folder location and clicking the OK button, a "Copy logs to D:" start/cancel pop-up will appear. Selecting "start" completes the downloading process and will automatedly end as indicated by the start download progress bar.

8.11 Trend Log Data

Events Page

The table below details the parameter data of the downloaded TREND Log.

Column Index	Column Header	Sample Data	Name	Units	Notes
0	Elpsd Time	17103	Elapsed Time	sec	
1	lap	3	Left Atrium Pressure	mmHg	
2	laph	6.65	Left Atrium pH	pH	
3	lapco2	0	Left Atrium PCO_2	mmHg	
4	lapo2	119	Left Atrium PO_2	mmHg	
5	pap	10	Pulmonary Artery Pressure	mmHg	
6	paph	6.68	Pulmonary Artery pH	pH	
7	papco2	0	Pulmonary Artery PCO_2	mmHg	
8	papO2	69	Pulmonary Artery PO_2	mmHg	
9	cdyn	100.8	Compliance Dynamic	ml/cmH20	
10	p:f	227	Delta PO2/FiO2	mmHg	
11	Ppeak	9	Peak Pressure	cmH2O	
12	pvr	272	Pulmonary Vascular Resistance	dyn*s*cm-5	
13	lat	36.0	Left Atrium Temperature	Degrees C	
14	pat	37.0	Pulmonary Artery Temperature	Degrees C	
15	vti	403	Tidal Volume Inspiratory	ml	
16	freq	7	Ventilation Rate	b/min	
17	peep	5	Positive End Exp Pressure	cmH2O	
18	i:e	1:02	Inspiratory to Expiratory Ratio	Ratio	
19	fio2	22	Fraction of Inspired Oxygen	%	
20	tinsp	2.9	Inspiratory Time	sec	
21	flow	2.06	Cardio Pump Flow Rate	LPM	
22	rpm	1815	Cardio Pump Speed	rev/min	
23	pwr	0	Time on Backup Power	min:	
24	cst	72	Compliance Static	ml/cmH2O	
25	pbar	980	Barometric Pressure	mmHg	
26	tmr1	1:54:03	Timer1 EVLP	hh:mm:ss	
27	tmr2	1:28:05	Timer2 Ventilator	hh:mm:ss	
28	tmr3	0:04:21	Timer3 Recruitment	hh:mm:ss	
29	pPlat	11	Plateau Pressure	cmH2O	
30	pmean	6	Mean Pressure	cmH2O	
31	ctr pump status	1	Cardio Pump Comm Status	Status Index	0 = Off, 1 = On
32	dgtl I/O status	0	Digital I/O Comm Status	Status Index	0 = Off, 1 = On
33	ups status	1	UPS Comm Status	Status Index	0 = Off, 1 = On
34	recycl status	0	Recycle Pump Comm Status	Status Index	0 = Off, 1 = On
35	add status	0	Add Pump Comm Status	Status Index	0 = Off, 1 = On
36	drain status	0	Remove Pump Comm Status	Status Index	0 = Off, 1 = On
37	vent status	0	Ventilator Comm Status	Status Index	0 = Off, 1 = On
38	barPress status	0	Barometric Pressure Comm Status	Status Index	0 = Off, 1 = On
39	PA pH Status	1	PA pH sensor Comm Status	Status Index	0 = Off, 1 = On

8.11 Trend Log Data (cont.)

Events Page

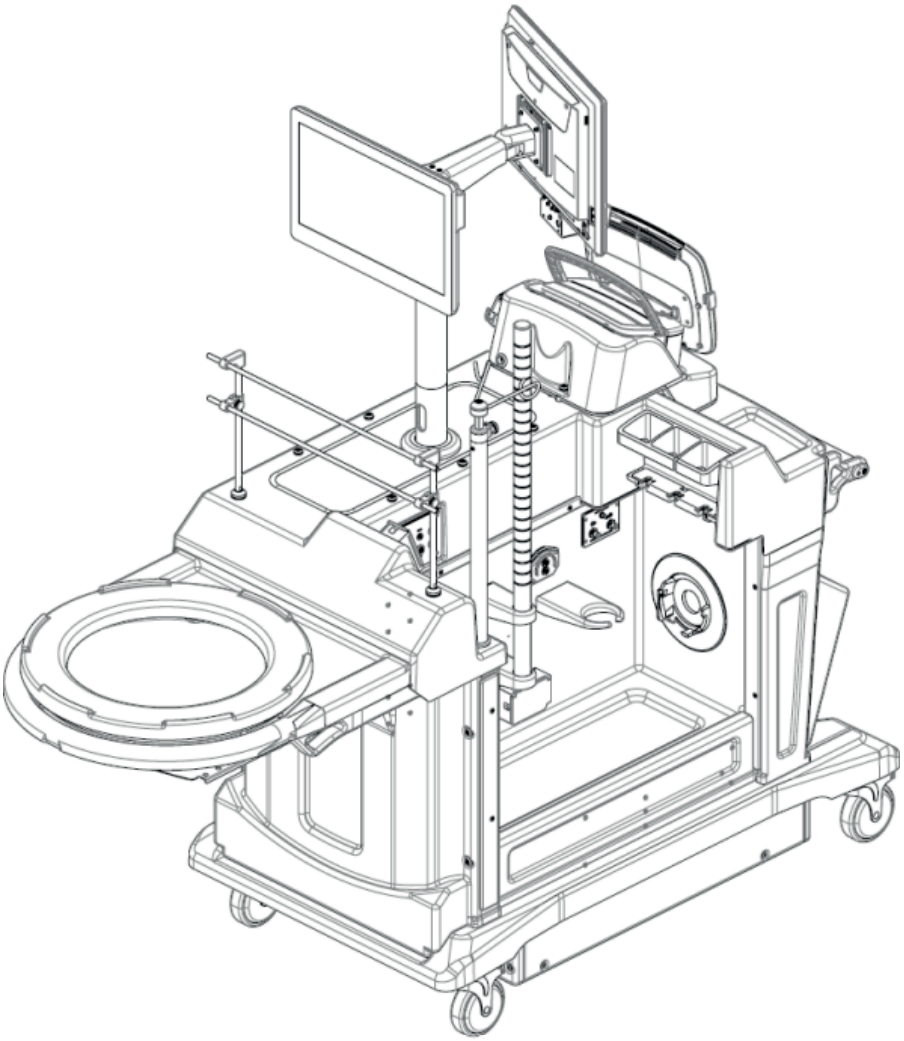
The table below details the parameter data of the TREND Log (cont.).

Column Index	Column Header	Sample Data	Name	Units	Notes
40	LA pH Status	1	LA pH sensor Comm Status	Status Index	0 = Off, 1 = On
41	PA PCO2 Status	0	PA PCO2 sensor Comm Status	Status Index	0 = Off, 1 = On
42	LA PCO2 Status	1	LA PCO2 sensor Comm Status	Status Index	0 = Off, 1 = On
43	PA PO2 Status	0	PA PO2 sensor Comm Status	Status Index	0 = Off, 1 = On
44	LA PO2 Status	0	LA PO2 sensor Comm Status	Status Index	0 = Off, 1 = On
45	weight tared	500	Tared Lung Weight	grams	
46	weight untared	2000	UnTared Lung Weight	grams	
47	weight sensor status	1	Weight Sensor Status	Status Index	0 = Off, 1 = On
48	DeltaP	7	Perfusate Pressure Change	mmHg	PAP-LAP
49	DeltaPO2	74	PO2 Change	mmHg	lapo2 pap2
50	Vte	450	Tidal Volume Expiratory	mmHg	
51	VLeak	10	Leak Calculation	%	Vti-Vte / Vti
52	Texp	5	Expiratory Breath	sec	
53	TempTarg	37	Smart Sequencing Target Temperature	Degrees C	
54	FreqTarg	10	Smart Sequencing Target Frequency	breaths/min	
55	VtiTarg	430	Smart Sequencing Target Vti	ml	
56	FiO2Targ	21	Smart Sequencing Target FiO2	%	
57	AddMod	1	Steen Add Pump Mode	Mode Index	0 = Off, 1 = On
58	RmvMod	1	Steen Remove Pump (Drain) Mode	Mode Index	0 = Off, 1 = On
59	RcyMod	1	Steen Recycle Pump Mode	Mode Index	0 = Off, 1 = Slow, 2 = Medium, 3 = Fast
60	Stage	8	Smart Sequencing Stage	Stage Index	0 = (NOT DEFINED) 1 = PRIMING_MODE 2 = START_ACTIVE 3 = 10_MIN_NOTICE 4 = 20_MIN_NOTICE 5 = START_VENTILATION 6 = VENTILATION_NOTICE 7 = 30_MIN_NOTICE 8 = 40_MIN_NOTICE 9 = 50_MIN_NOTICE 10 = FIRST_REC_NOTICE 11 = FIRST_REC_ACTIVE 12 = FIRST_REC_ENDED_NOTICE 13 = POST_RECRUITMENT_PERFUSION, 14 = MANUAL_HOLD 15 = SECOND_REC_NOTICE 16 = SECOND_REC_ACTIVE 17 = SECOND_REC_ENDED_NOTICE 18 = POST_RECRUITMENT_PERFUSION 19 = MANUAL_HOLD 20 = THIRD_REC_NOTICE 21 = THIRD_REC_ACTIVE 22 = THIRD_REC_ENDED_NOTICE 23 = POST_RECRUITMENT_PERFUSION 24 = MANUAL_HOLD 25 = FOURTH_REC_NOTICE 26 = FOURTH_RECRUITMENT_ACTIVE 27 = FOURTH_REC_ENDED_NOTICE 28 = POST_RECRUITMENT_PERFUSION
61	PumpMod	1	Cardio Pump Mode	Mode Index	0 = Not Communicating, 1 = RPM, 2 = LPM
62	VentMod	2	Ventilator Mode	Mode Index	0 = Standby 6 = ASV 12 = (S)CMV 1 = SPONT 7 = DuoPAP 13 = SIMV 2 = PS1MV+ 8 = APRV 3 = PCV+ 9 = NIV 4 = SIMV+ 10 = NIV-ST 5 = (S)CMV+ 11 = Backup
63	On Battery	1	UPS on Battery	Mode Index	0 = if on wall power OR if the UPS is not communicating 1 = if both disconnected from wall power AND the UPS is communicating
64	Battery SOC	100	UPS Battery State of Charge	%	Integer from 0 to 100 that represents the percentage of the battery's charge
65	FlowTarg	2.00	Smart Sequencing Target Flow	LPM	LPM (liters/min)

Appendix 2: Cleaning & Maintenance

This Appendix 2 provides equipment maintenance on the XPS System as a whole and its individual parts.

This section includes maintenance tasks that are easily performed by the end user. More complex maintenance tasks not included in this section should be referred onto XVIVO to schedule a service call visit.



9

Appendix 2: Cleaning & Maintenance

CardioHelp XVIVO

Heater/Cooler

C3 Ventilator

Perfusate Gas Monitor

XPS Cart

9.1 CardioHelp XVIVO

9.1.1 Cleaning

NOTE:

Do not use chemical solvents (ether or acetone) to clean this device

Only clean using a damp cloth and do not spray device with liquids

In general, wipe down the surfaces with disinfectant after each use. Use a cloth moistened with an aqueous alcohol solution (70% ethanol/ 30% water) or a similar cleaning solution for sensitive medical devices.

9.1.2 Maintenance & Service:

Maintenance and repairs may only be carried out by an authorized XVIVO service technician.

This device as well as the entire XPS Cart should be serviced every 12 months by an authorized XVIVO service technician. The service technician will handle hazardous material disposal (including but not limited to batteries) according to accepted protocol.

Category	Timeline	Service Action
Annual Service	Every 12 months	Contact XVIVO for service
Battery Calibration	Every 3 months	Discharge battery fully per on- screen instructions (can take up to 8 hours to discharge)
Battery swap/ replacement	As required by device	Contact XVIVO for service

9.2 Heater/ Cooler

Category	Timeline	Service Action
Annual Service	Every 12 months	Contact XVIVO for service
Hansen Connector O-rings (blue hose ends)	Every 6 months	Cover with thin layer of silicone grease, replace if leaking
Drain Reservoir	After each use	See below for instructions

DRAIN RESERVOIR:

1 After each use and before storage, the heater/cooler reservoir should be drained.

Connect the HCU Drain Tubing to the left port on the water I/O panel and thread it through the STEEN Recycle pump and close pump head.

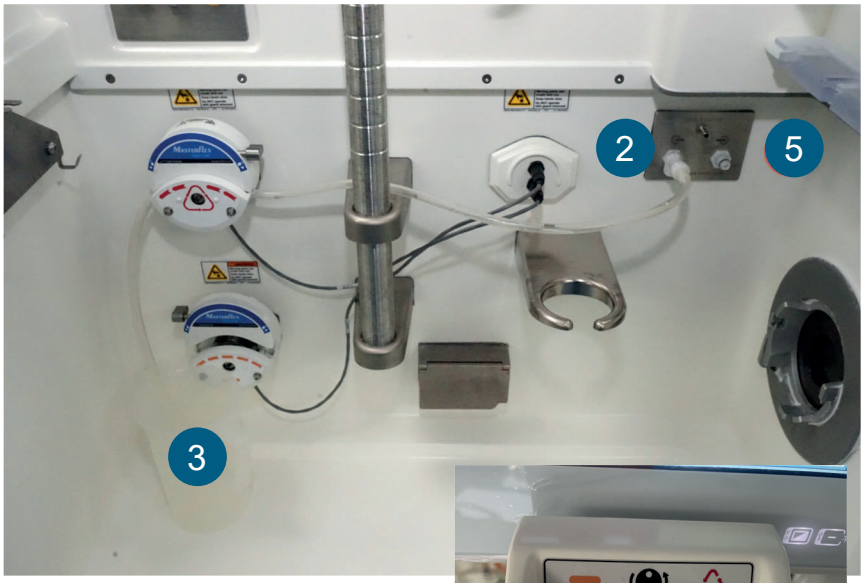
3 Place the tubing into an empty container 2 liters or larger.

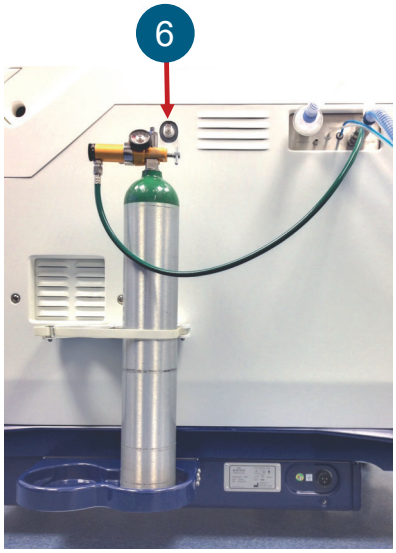
4 Press the Recycle pump controller button to start the Recycle Pump. Stop the Recycle Pump once all water has been removed.

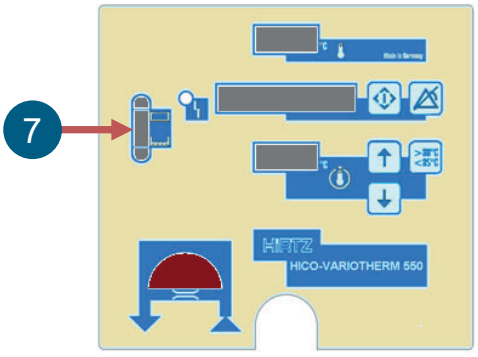
5 Switch the HCU Drain tubing to the right side port and repeat step 4. Remove tubing and container when finished.

6 Prior to use, fill the heater/cooler reservoir back up with distilled water through the fill interface on the side panel.

7 Fill the reservoir until the level indicator reads slightly below the 'MAX' mark.







NOTE:

Distilled water with a 1% solution of surface disinfectant (e.g. Sanosil brand or equivalent with active ingredient of H_2O_2) is recommended for the reservoir to prevent mineral build-up and prolong the life of the unit.

9.3 C3 Ventilator

9.3.1 Cleaning

NOTE:

Do not use chemical solvents (ether or acetone) to clean this device

Only clean using a damp cloth and do not spray device with liquids

In general, wipe down the surfaces with disinfectant after each use. Use a cloth moistened with an aqueous alcohol solution (70% ethanol/ 30% water) or a similar cleaning solution for sensitive medical devices.

9.3.2 Maintenance & Service:

Maintenance and repairs may only be carried out by an authorized XVIVO service technician.

This device as well as the entire XPS Cart should be serviced every 12 months by an authorized XVIVO service technician. The service technician will handle hazardous material disposal (including but not limited to batteries) according to accepted protocol.

Category	Timeline	Service Action
Annual Service	Every 12 months	Contact XVIVO for service
Battery swap/ replacement	As required by device	Contact XVIVO for service
Oxygen Cell replacement	Every 5000h or every 12 months– whichever comes first	Contact XVIVO for service
HEPA filter replacement	Every 5000h or every 12 months– whichever comes first	Contact XVIVO for service
Turbine	Every 20,000 hours	Contact XVIVO for service
Full Service on Ventilator	Every 5 years or 30,000 hours	Contact XVIVO for service

9.4 Perfusate Gas Monitor

9.4.1 Cleaning

NOTE:

Do not use chemical solvents (ether or acetone) to clean this device

Only clean using a damp cloth and do not spray device with liquids

In general, wipe down the surfaces with disinfectant after each use. Use a cloth moistened with an aqueous alcohol solution (70% ethanol/ 30% water) or a similar cleaning solution for sensitive medical devices.

9.4.2 Maintenance & Service:

Maintenance and repairs may only be carried out by an authorized XVIVO service technician.

This device as well as the entire XPS Cart should be serviced every 12 months by an authorized XVIVO service technician.

Category	Timeline	Service Action
Annual Service	Every 12 months	Contact XVIVO for service

9.5 XVIVO Perfusion Cart

9.5.1 Cleaning

NOTE:

Do not use chemical solvents (ether or acetone) to clean this device

Only clean using a damp cloth and do not spray device with liquids

In general, wipe down the surfaces with disinfectant after each use. Use a cloth moistened with an aqueous alcohol solution (70% ethanol/ 30% water) or a similar cleaning solution for sensitive medical devices.

9.5.2 Maintenance & Service:

Maintenance and repairs may only be carried out by an authorized XVIVO service technician.

NOTE:

No User Serviceable Parts Inside

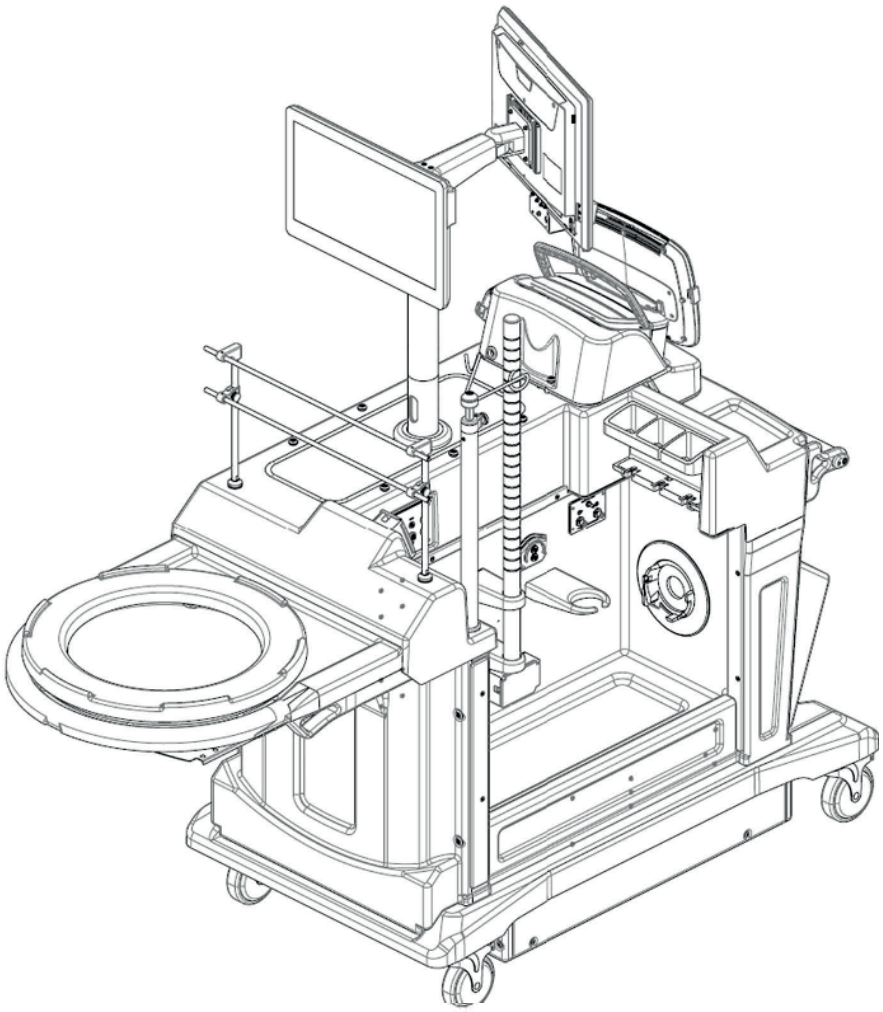
The entire XPS Cart should be serviced every 12 months by an authorized XVIVO service technician. The service technician will handle hazardous material disposal (including but not limited to batteries) according to accepted protocol.

With proper and regular maintenance, the XPS has a product lifetime of about 10 years.

Category	Timeline	Service Action
Annual Service	Every 12 months	Contact XVIVO for service
UPS battery check/replacement	Every 12 months	Contact XVIVO for service
Air intake filters (underside of cart covering intake fans)	Every 12 months	Contact XVIVO for service

Appendix 3: Technical Data

This final Appendix 3 provides technical and safety data on the XPS System as a whole and its individual parts.



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Appendix 3: Technical Data

10.1 Technical Specifications

CardioHelp XVIVO

CARDIOHELP DEVICE	
Protection class in accordance with IEC 60601-1	• Protection class I device (with Protective Ground Connection) • Device with Internal Power Supply
Weight	• Appx 9 kg
Touchscreen	• LCD with background lighting, 5.7, 640 x 480 pixels
Front connections	• Alarm Outlet Connection • Ethernet connection (not used) • USB port type A • USB port type B • AC device plug • Equipotential bonding connection • DC device plug • CAN connection (not used) • Interface for ECG data (not used)
Rear connections	• 4 external pressure sensors • Disposable's sensors • Clamp (not used) • Bubble sensor (not used) • Venous probe • Level sensor • 2 external temperature sensors • Flow/bubble sensor • External CARDIOHELP Drive (not used)
Speaker for acoustic alarms	The volume depends on the priority of the alarm and the defined volume. Minimum ... Maximum volume (approx.): • High priority: 54 ... 69 db(A) • Medium priority: 49 ... 66 db(A) • Low priority: 41 ... 58 db(A)

Power supply	
Power Consumption	140 VA
AC power supply:	
Line Voltage	100 ... 240 V
Frequency	50/60 Hz
Line fuse	2 x T4.0A
DC power supply	
Line voltage	11 ... 28 V

10.1 Technical Specifications

CardioHelp XVIVO

POWER SUPPLY	
Battery	
Type	2 x Lithium-ion, 10.8 V/6450 mAh
Battery life	Min 90 minutes (fully charged batteries)
Charging time	Max. 5 h

AMBIENT CONDITIONS	Operation	Storage	Transport
Temperature	+15 ... +30°C	-20 ... +45°C	-20 ... +55°C
Relative humidity (non-condensing)	30 ... 75%	0 ... 95%	0 ... 95%

a. Applies exclusively to transport without application, i.e., not for patient transport

MEASURED DATA AND DISPLAYED DATA	Measuring accuracies related to the entire system The measuring accuracies named each relate to the entire system, consisting of the CARDIOHELP device		
Parameters	**Measuring range**	**Resolution**	**Measuring accuracy**
Flow	-9.99 ... 9.99 l/min	0.01	-> “Flow”
Speed	0 ... 5000 rpm	1	+/- 20 rpm
Pressures			
Pven, Pint, PArt, PAux	-500 ... 900 mmHg[a]	1	-> “Pressure”
Δp	-500 ... 900 mmHg[a]	1	calculated value[b]
Temperatures:			
T_{Ven} T_{Art}	10.0 ... 45.0 °C[a]	1	+/- 0.5°C

a. when using external sensors: the measuring range depends on the measuring range of the sensor (-> specification of the external sensor)
b. The accuracy is dependant on the accuracy of the measured values Pint and Part (-> “Pressure”)

FLOW	Measuring accuracy
Flow 0 ... 1 l/min	+/-0.1 l/min +/- offset drift
Flow > 1 l/min	+/- 7% of the measured value +/- offset drift
Offset drift	Max. 0.03 l/m in 2 hours

10.1 Technical Specifications

CardioHelp XVIVO

PRESSURE External sensors	Measuring accuracy
Pressure –500 ... –101 mmHg	+/- 3% of the measured value +/- sensor accuracy[a]
Pressure –100 ... +100 mmHg	+/- 3% of the measured value +/- sensor accuracy[a]
Pressure +101 ... 900 mmHg a. -> specification of the external sensor	+/- 3% of the measured value +/- sensor accuracy[a]
Disposable's integrated sensors	**Measuring accuracy**
Pressure –500 ... –151 mmHg	+/- 7% of the measured value
Pressure –150 ... +249 mmHg	**+/- 10 mmHg**
Pressure +250 ... +900	+/- 7% of the measured value
Offset drift	Max. +/- 15mmHg in 30 days

POSSIBLE SETTINGS AND FACTORY SETTINGS	
Speed	0 ... 5000 rpm
Flow	0 ... 7 l/min

Warning limits, alarm limits and interventions

Possible settings

Alarm and warning limits can be set as follows:

- Upper alarm limit ≥ Upper warning limit
- Upper warning limit > Lower warning limit
- Lower warning limit ≥ Lower alarm limit
- Deactivate alarm limit or warning limit

Parameters	Possible settings Limits	Resolution	Factory Setting Lower / Upper limit	Intervention
Flow	-0.00 ... 0.99 l/min	0.01	0.00 / 8.0	deactivated
Speed	0 ... 5000 rpm	1	0/4500	deactivated
Pressures				
P_{int}, P_{Art}, P_{Aux}	-500 ... 900 mmHg[a]	1	Warning: -/400 Alarm: —/500	deactivated
P_{Ven}	-500 ... 900 mmHg[a]	1	Warning: -100/- Alarm: —150/-	deactivated
Δp	-500 ... 900 mmHg[a]	1	Deactivated / 60	–

10.1 Technical Specifications

CardioHelp XVIVO

Parameters	Possible settings Limits	Resolution	Factory Setting Lower / Upper limit	Intervention
Bubbles	–	–	–	activated
Level	–	–	–	activated
T_{Ven} T_{Art}	10 ... 45°C	0.1	10.0 / 41.0	–

a. when using external sensors: Limits depend on the measuring range of the sensor (->Specification of the external sensor)

GENERAL SETTINGS		
Option	**Possible settings**	**Factory Setting**
Pump:		
Controll mode	RPM, LPM	RPM
Data recording		
Interval	3 s, 15 s, 30 s, 45 s, 1 min, 2 min, 5 min, 10 min	5 min
Locking:		
Duration of inactivity	10 s, 30 s, 1 min, 2 min, 5 min	30 s
Automatic lock	activated, deactivated	activated
Brightness/volume:		
Brightness	1 ... 10 (in increments of 1)	10
Volume	1 ... 3 (in increments of 1)	3
Language	German, English, French, Spanish, Italian, Dutch, Swedish, Danish	English
Time/date:		
Date format	DD.MM.YYYY, MM/DD/YYYY	DD.MM.YYYY
Time format	hh:mm:ss, hh:mm	hh:mm:ss
	12 h, 24 h	24 h

AVAILABILITY OF PHYSIOLOGICAL ALARMS FOR EXTERNAL DEVICES

Physiological alarms are made available to external devices without delays.

10.1 Technical Specifications – Oxygenation Membrane (Quadrox-iR)

CardioHelp XVIVO

Specification	Value
Flow rate	0.5– 7 l/min
Maximum recommended gas flow rate	15 l/min
Oxygenation membrane surface area	1.8 m²
Priming volume	273 ml
Heat exchanger surface area	0.4 m²
Speed range of the centrifugal pump	0-5000 rpm
Maximum possible perfusate pressure	750 mmHg
Size of blood inlet and outlet connectors	3/8”
Size of recirculation connector	1/4”
Gas inlet connectors	1/4”
Gas outlet connector	3/8”
Size of water connector	1/2” Hansen coupling
Sampling port at arterial outlet	Luer lock
Quick vent	Luer lock

10.2 Technical Specifications

Heater/ Cooler

Rated Voltage	230 VAC 50/60 Hz
Power Input	320 W
Power Consumption	3.0 A
Temperature Value Range	15-39°C
Safety Shutdown	42.5°C (independent safety shutdown)
Measuring Range	9-50°C
Measuring Deviation	< +0.1°C (display- actual water temp)
Correction Value	0.5°C (water temp- temp display)
Sensor Element	2 x NTC 5K
Pump Capacity	Max: 11 L/min, Max 0.15 bar
Heat Capacity	Approx. 750 W max (at 27°C)
Cooling Capacity	Approx. 500 W max (at 27°C)
Warm-up Time	Approx. 10 min (20-37°C)
Cool-down Time	Approx. 20 min (37-15°C)
Fuse Value	2 x T 3, 15 A
Ambient Temperature	10-30°C
Relative Air Humidity	30-70%
Storage Temperature	10-40°C
Tank Volume	Approx. 0.5-1.0 L (min-max)
Dimensions WxHxD	200 x 290 x 440 mm
Weight	17 Kg (filled)
Noise emission	50 dB(A) (1m)
Alarm level	>65 dB(A) (3m)
Quality Standards	"Medical Product Directive 93/42/EEC, DIN EN 60601-1, DIN EN 60601-1-2, DIN EN 80601-2-35"
Risk Class (93/42/EEC)	II b
UMDNS Code	12-075

10.3 Technical Specifications

C3 Ventilator

10.3.1 Environmental Requirements

Temperature	Operating 5-40°C (41-104F)
Relative Humidity	Operating/storage: 10-95%, noncondensing
Altitude	Up to 4000 m (13,120 ft) above sea level

10.3.2 Pneumatic Specifications

High-pressure oxygen inlet	Pressure: 2.8-6 bar/ 280 to 600 kPa/ 41– 87 psi Flow: Maximum of 200 l/min Connector: DISS (CGA 1240) or NIST
Low-pressure oxygen inlet	Peak pressure: ≤ 6 bar/600 kPa/87 psi Flow: ≤ 15 l/min Connector: Quick-coupling system, compatible with Colder Products Company® (CPC) PMC series
Air supply	Integrated blower
Gas mixing system	Delivered flow: 240 l/min peak flow against ambient pressure (at sea level), 0 to 150 l/min with 100% O_2 Delivered pressure: 0-60 cmH_2O
Inspiratory outlet (to lung port)	Connector: ISO 15 mm female/22 mm male conical
Expiratory outlet (from lung port)	Connector (on expiratory valve): ISO 15 mm female/ 22 mm male conical

10.3.3 Electrical Specifications

Input power	100-240 V AC ± 10%, 50/60 Hz or 12-24 V DC ± 10%
Power consumption	50 W typical, 150 W maximum
Batteries	Electrical specifications for battery 1 or 2: 10.8 V DC, 6.7 Ah, 72Wh, 50W typical, 150W maximum. Type: Lithium-ion, supplied by HAMILTON MEDICAL only. Operating time with one or two fully charged batteries, the blower in use, without option board, and with the following setting: VT = 500 ml, Rate = 15 b/ min, Pcontrol = 30 cmH2O, PEEP = 0 cmH_2O Approx. operating time under these condition are as follows: • One battery, display brightness = 80/20%: 3.5h/3.8 h • Two batteries, display brightness = 80/20%: 7h/8 h

10.3 Technical Specifications

C3 Ventilator

10.3.4 Control Setting Ranges and Resolutions

Setting	Range	Accuracy	Default settings
Apnea backup	On, Off	—	On
ETS (expiratory trigger sensitivity)	5-80%	5%	25%
Flow (l/min)	2 to 80	10% or 1 l/min whichever is greater	15
Flowtrigger (l/min)	APVcmv, (S)CMV, PCV+: 1 to 20, Off	5 l/min	Off
Gender	Male, Female	—	Male
I:E	1:9 to 4:1	—	1:2
Loudness (alarm)	1 to 10	1	5
% MinVol (% minute volume)	25 to 350%	5%	100%
Mode	(S)CMV+, APRV, ASV (Note: these are recom- mended modes for lung ex vivo ventilation)	—	(S)CMV+ (also called APV)
Oxygen	21-100%	"± (volume fraction of 2.5% + 2.5% gas level)"	50%
Pasvlimit	5-60 cmH_20	5% or 1 cmH_20	30 cmH_20
Patient Height	30-250 cm (3-129 kg IBW)	2 cm	174 cm
Pcontrol (control pressure, added to PEEP)	5-60 cmH_20	5% or 1 cmH_20	15 cmH_20
PEEP	0-35 cmH_20	5% or 1 cmH_20	5 cmH_20
P-ramp	0-2000 ms	10 ms	100 ms
P low (APRV)	0-35 cmH_20	5% or 1 cmH_20	5 cmH_20
Rate	4-80 b/min (S)CMV+	1 b/min	7 b/min
Sigh	On, Off	—	Off
T high (APRV)	0.1-40 s	0.01 s	Based on rate (IBW)
TI (inspiratory time)	0.1-12 s	0.01 s	Based on rate (IBW)
Tlow (APRV)	0.2-40 s	0.01 s	Based on IBW
Vt (tidal volume)	20-2000 ml	10% or 10 ml	Based on IBW

10.3 Technical Specifications

C3 Ventilator

10.3.5 Monitored Parameter Ranges, Resolutions & Accuracies

Parameter	Range	Accuracy
Pressure		
Ppeak, Pmean, PEEP	Ppeak, Pmean, PEEP	± 2 cmH_20 + 4% of actual reading
Flow		
Insp Flow	0-260 l/min	± 10% or ± 20 ml/s (whichever is greater)
Exp Flow	0-260 l/min	± 10% or ± 20 ml/s (whichever is greater)
Volume		
VTE, VTI	0-9000 ml	± 10% or ± 10 ml (whichever is greater)
ExpMinVol	0.0-99.9 l/min	± 10% or ± 0.3 l/min (whichever is greater)
Leak	0-100%	± 10% (for leak volumes between 100-2000 ml)
Time		
I:E	9.9 to 1:99	–
fTotal	0-999 b/min	± 1 b/min ± 0.1 s
TI, TE	0-60 s	± 0.1 s
Other calculated and displayed parameters		
Cstat	0-300 ml/ cmH_20	–

10.3 Technical Specifications

C3 Ventilator

10.3.5 Monitored Parameter Ranges, Resolutions & Accuracies

Parameter	Range	Accuracy
Oxygen		
Oxygen	18-105%	± volume fraction of 2.5% + 2.5% of gas level
Vent Status panel		
Oxygen	21-40%	–
PEEP	0-8 cmH_20	–
MinVol	0-350% of normal minute ventilation expressed in l/min	–
Pinsp	0-50 cmH_20	–
RSB	10-400 1/(l*min)	–
% fSpont	100-0%	–
Other calculated and displayed parameters		
IBW	3–139 kg	–

10.3.6 Real-time curves and loops

Parameter	Range
Real time curves	
Volume (V)	0 to 3200 ml
Flow	-300 to 300 l/min
Airway pressure (Paw)	-10 to 80 cmH_20
Time	0 to 15 s
Loops	
Pressure/Volume	X: 0 to 3200 ml; y: -10 to 80 cmH_20
Volume/Flow	X: 0 to 3200 ml; y:-300 to 300 l/min
Pressure/Flow	X: -300 to 300 l/min; y: -10 to 80 cmH_20

10.3 Technical Specifications

C3 Ventilator

10.3.7 Adjustable alarm ranges and resolutions

Parameter	Operating Range	Resolution	Default Settings
ExpMinVol (low)	0.1 to 50 l/min	0.1 l/min for < 1 l/min 0.5 l/min for ≥ 1/l/min and <10 l/min 1 l/min for ≥ 10 l/min	0.6 * Rate * VT
ExpMinVol (high)	0.1 to 50 l/min	0.1 l/min for < 1 l/min 0.5 l/min for ≥ 1/l/min and <10 l/min 1 l/min for ≥ 10 l/min	1.5 * Rate * V_t
fTotal (low)	0 to 99 b/min	1 b/min	0 b/min
fTotal (high)	0 to 99 b/min	1 b/min	40 b/min
Oxygen (low)	18-97%	1%	45%
Oxygen (high)	18-105%	1%	50%
Pressure	15 to 70 cmH20	1 cmH_20	40 cmH_20
V_t (low)	Off, 10 to 3000 ml	5 ml < 100 ml 10 ml ≥ 100 and < 500 ml 50 ml ≥ 500 ml	0.5 * V_t
V_t (high)	Off, 10 to 3000 ml	5 ml < 100 ml 10 ml ≥ 100 and < 500 ml 50 ml ≥ 500 ml	1.5 * V_t

NOTE:

The highlighted default settings are user-configurable.

The items in the boxes represent the manufacturer's recommended default settings for an in-vivo procedure.

10.3 Technical Specifications

C3 Ventilator

10.3.8 Other Technical Data

Parameter	Specification
Patient ideal body weight (determined from Pat. Height setting)	3 to 139 kg (6.6 to 306 lb) *(actual patient weight can be higher (300 kg)
Inspiratory pressure	0 to 60 cmH_20
Maximum limited pressure	60 cmH_20
Maximum working pressure	0 to 60 cmH_20 (a combination of PEEP and Pinsp). Ensured through pressure limiting.
Maximum inspiratory flow	240 l/min (150 l/min with 100% O_2)
Tidal volume/ target tidal volume	20 to 2000 ml
Minute volume capability	Up to 60 l/min
Minimum expiratory time	20% of cycle time; 0.2 s to 0.8 s
Inspiratory valve response time	<13 ms
Automatic expiratory base flow	4 to 20 l/min For Flowtrigger ≤ 2 l/min: 4 l/min For Flowtrigger > 2 l/min: 2 x Flowtrigger
Means of inspiratory triggering	Flow (Flowtrigger control setting)
Oxygen mixer accuracy	± volume fraction of 2.5% + 2.5% of actual reading
Oxygen cell life	1 year or 5000 h nominal. Actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.
Alarm loudness	50 to 65dB (A) at 1 m
Tests and special functions	Tightness test, oxygen cell calibration, Flow Sensor calibration, 100% O_2, manual breath, inspiratory hold maneuver, nebulization (30 min, 8 l/min), communications interface, compensation of breathing circuit resistance and compliance.

10.4 Technical Specifications

PGM Sensors

10.4.1 Technical Data

Supply Voltage	7-18 V (VCC)
Supply Current	140-250 mA (ICC)
Supply current (idle mode at 7V)	80 mA maximum (ICCi)
Detector input stage gain	1-52 (typical 11)
LED current regulation (8 bit)	"0-255 steps (typical 50), max 190 at supply voltage below 9V"
Operating temperature	0-50°C
Storage temperature	-10- 60°C
Dimensions (transmitter)	D x W x H 40 x 100 x 10.7 mm
Dimensions (board)	D x W x H 40 x 100 x 24 mm
Weight	70 g

10.5 Technical Specifications

PGM Sensors

10.5.1 Technical Data pH Sensor

Parameter	Specifikation
Range	pH 6.5-8.5
Accuracy (batch calibration)	± 0.10
Sterilization	Gamma
Calibration	Pre-Calibrated
Response time (t90) at 25°C	< 40 seconds

10.5.2 Technical Data PO_2 Sensor

Parameter	Specifikation
Range	1-100% O2
Drift at 0% O_2 (Stability)	< 0.03% over 39 days (sample interval)
Sterilization	Gamma
Calibration	Pre-Calibrated
Response time (t90)	< 120 seconds

10.6 Technical Specifications

XVIVO Perfusion Cart System

10.6.1 Product Classification

Protection Class Standard	IEC 60601

10.6.2 Physical Characteristics

Dimensions (dome arm down)	W x D x H 29” x 48” x 60”
Dimensions (dome arm up)	W x D x H 29” x 84” x 60”
Weight	Maximum Weight 325 kg

10.6.3 Environmental Requirements

Supply Voltage	
Operating Range	10°C- 30°C
Storage and Transport Range	10°C- 40°C
Relative Humidity	
Operating Range	30– 80% non-condensing
Storage and Transport Range	10– 80% non-condensing
Altitude	
Operating Range	Up to 9,000 feet above sea level
Storage and Transport Range	Up to 11,000 feet above sea level

10.6.4 Pneumatic Specifications

High-pressure oxygen inlet	
Pressure	2.8– 6 bar/ 280– 600 kPa/ 41– 75 psi
Flow	40– 120 l/min STPD
Connector	DISS (CGA 1240) or NIST
Venous gas inlet	
Pressure	Up to 6 bar/ 600kPa/ 87 psi
Flow	Up to 15 l/min STPD
Connector	1/4” hose barb
Inspiratory outlet	
Size	22 mm male conical
Expiratory outlet	
Size	22 mm male conical

10.6 Technical Specifications

XVIVO Perfusion Cart System

10.6.5 Electrical Specifications

Input Power	115 VAC, 60 Hz, 12 Amps (USA) (REF 19030)230VAC, 50Hz, 6 Amps (CE) (REF 19040)
UPS	Minimum 20 minutes operation– UPS only
UPS Battery	Lead-acid, 12 volt, 7.2 amp-hour

10.6.6 Control Settings

STEEN Solution Pumps	
Remove STEEN Pump	One speed only while button pressed
Recycle STEEN Pump	Low, medium & high speed settings

10.6.7 Monitored Parameters

CENTRIFUGAL PUMP	
Pressure	-500 to 900 mmHg
Temperature	10– 45°C
Pump speed	0-- 5000 rpm
Flow rate	0.00- 9.99 l/min
VENTILATOR	
FiO2	0– 100%
VTE	0– 999ml
Ppeak	0-999 cmH_2O
Freq	0-99 b/min
Static Compliance	0-999
PEEP	0-99
I:E ratio	1:9 to 4:1
Dynamic Compliance	0-999
P:F Ratio (calculated trend)	0– 800mmHg
Insp time	0.00– 99.99
PVR	0– 2000
PERFUSATE GAS MONITOR	
pH	4.00– 11.00
PO_2	0– 900mmHg
WEIGHT SENSOR	
Mass	0–9000

10.6 Technical Specifications

XVIVO Perfusion Cart System

10.6.8 Standards and Approvals

IEC EN60601-1-1	Medical electrical equipment- Part 1: General requirements for safety 1: Collateral Standard: Safety requirements for medical electrical systems
IEC EN60601-1-2	Medical electrical equipment– Part 1-2: Electromagnetic compatibility – requirements and tests
IEC EN60601-1-6	Medical electrical equipment– Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN ISO 780	Packaging – Distribution packaging – Graphical symbols for handling and storage of packages
ISO 15223	Medical devices– symbols to be used with medical device labels, labelling and information to be supplied

10.7 Electromagnetic Compatibility (EMC) Declarations (IEC 60601-1-2)

XVIVO Perfusion Cart System

The objective of the EMC declaration is to enable the responsible organization to decide whether the XPS™ is suitable for its electromagnetic environment.

The essential performance characteristic of the XPS™ is to pump STEEN Solution™ in an ex vivo lung circulation model, with the aid of a centrifugal pump.

In foreseeable electrical and mechanical interferences, the XPS™ works as intended within the stated accuracies.

The XPS is intended for operation in the electromagnetic environment detailed below. The customer or the user of the device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment– guidance
RF emissions according to CISPR11	Group 1	The XPS uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electrical equipment.
RF emissions according to CISPR11	Class A	The XPS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions according to IEC 61000-3-3	Not Applicable	

10.8 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

XVIVO Perfusion Cart System

The XPS is intended for operation in the electromagnetic environment detailed below. The customer or the user of the device should ensure 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	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
	±15 kV air	±8 kV air	
Electrical fast transient bursts IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
	±1 kV for input/output lines	±1 kV for input/output lines	
Surges IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment
	±2 kV common mode	±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 1/2 cycle	0% U_T for 1/2 cycle	Mains power quality should be that of a typical commercial or hospital environment. Thanks to its uninterruptible power supply, the XPS will operate during power mains interruptions for at least 20 minutes. It therefore does not need to be powered from an external uninterruptible power supply or external battery.
	0% U_T for 1 cycles	0% U_T for 1 cycles	
	70% U_T for 25/30 cycles (30% dip)	70% U_T for 25/30 cycles (30% dip)	
	0% U_T for 5 s 250/300 cycles	0% U_T for 5 s 250/300 cycles	
	3 A/m	3 A/m	

NOTE: U_T is the AC supply voltage prior to application of the test level

10.8 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

XVIVO Perfusion Cart System

Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
Conducted RF IEC 61000-4-6	3 V_{ms} 150 to 80 MHz outside the ISM bands[a]	3 Vrms	$d=0.35\sqrt{P}$
	3 Vr^{ms} 150 to 80 MHz within the ISM bands[a]	3 Vrms	$d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d=1.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as detemined by an electromagnetic site survey[c] should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.60 MHz

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz and 2.5 GHz are intended to reduce the likelihood of mobile/portable communication systems causing interference, when they are unintentionally brought into the XPS™ area. This is why the additional factor of 10/3 is used in the calculation of the recommended protective distances in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the measured field strength in the location in which the XPS™ is used exceeds the applicable RF compliance level above, the XPS™ must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the XPS™.

d. Over the frequency range 50 KHz-80 MHz, field strengths should be less than 3 V/m.

10.8 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

XVIVO Perfusion Cart System

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power	Distance (m)	Immunity test level (V/m)
385	380 –390	TETRA 400	Pulse modulation[b] 18 Hz	1,8	0,3	27
450	430–470	GMRS 460, FRS 460	5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0,3	28
1 720 1 845 1 970	1 700 — 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0,3	28
2 450	2 400 — 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0,3	28
5 240 5 500 5 785	5 100 — 5 800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0,2	0,3	9

NOTE:
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

10.8 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

XVIVO Perfusion Cart System

Recommended separation distances between portable and mobile RF communications equipment and the XPS

The XPS™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the XPS™ can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the XPS™, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to transmission frequency [m]			
	150 kHz to 80 MHz outside the ISM bands	150 kHz to 80 MHz within the ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d=0.35\sqrt{P}$	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.11	3.8	3.8	7.3
100	3.5	12	12	23

For transmitters rated at an output power not listed above, the distance can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

NOTE 3: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz and 2.5 GHz are intended to reduce the likelihood of mobile/portable communication systems causing interference, when they are unintentionally brought into the patient area. This is why the additional factor of 10/3 is used in the calculation of the recommended protective distances in these frequency ranges.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10.9 XPS Accessories

XVIVO Perfusion Cart System

The following accessories are available for use with the XPS™. Not all products are available in all markets

REF Number	Accessories
19004	STEEN Solution™
19020	XVIVO Organ Chamber™
19022	XVIVO Lung Cannula Set™
19033	XVIVO PGM Disposable Sensors™
19091	XPS™ Disposable Lung Kit
19092	XPS™ Disposable Lung Kit (US only)
19093	XPS™ Disposable Lung Kit (Australia only)
19094	XPS™ Disposable Lung Kit

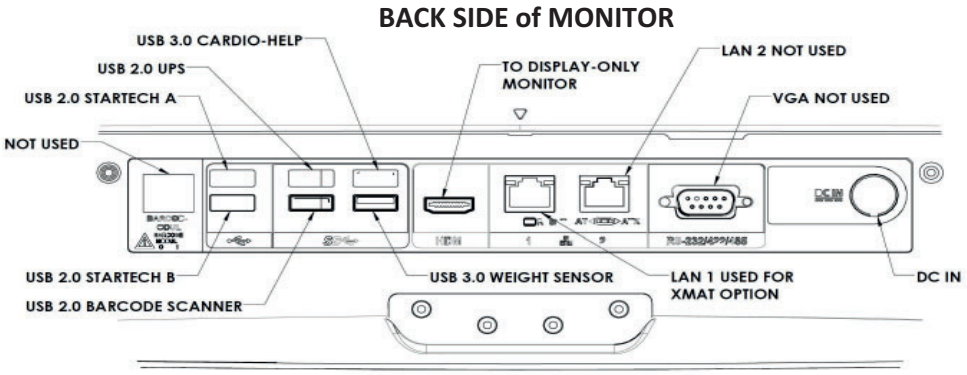
The following cable accessories, including maximum lengths are included with the XPS™

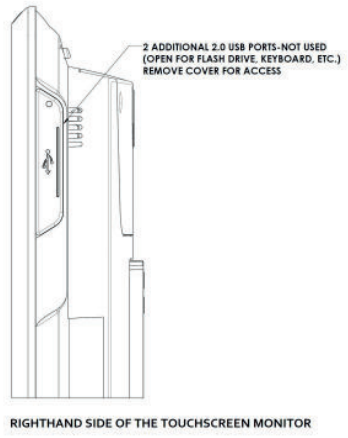
REF Number	Cables/ Accessories	Maximum Cable Lengths
9182-2633	Flow/Bubble Sensor Cable	1 meter
9182-2629	Fluid Level Cable	2 meters
PMF-16826	LA Temperature Probe	3 meters
9182-2631	PA Temperature Probe	3 meters
9182-2632	LA Pressure Probe	0.8 meter
9182-2632	PA Pressure Probe	0.8 meter
9182-1614	Mains Power Cable (US)	3 meters
9182-3314	Mains Power Cable (EU)	3 meters
Contact XVIVO	Mains Power Cable (other)	3 meters

10.10 XPS I/O Connections

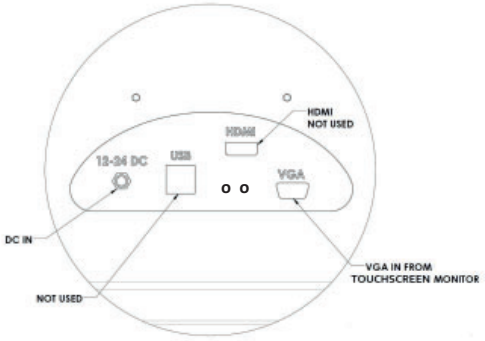
XVIVO Perfusion Cart System

The table below displays the I/O ports name and component connections used with the XPS™. The Touchscreen and Display-only monitors figures display the I/O ports name and component connection used (and not used) with the XPS™.





Equipment	Connection	Notes
Electrical I/O Panel	Temperature sensor ports	LA and PA temperature sensors
	Pressure sensor ports	LA and PA pressure sensors
	Flow/Bubble sensor port	perfusate flow measurement and bubble sensor
	Level sensor port	Perfusate level sensor of hardshell reservoir
Ventilator I/O Panel	Inhale/Exhale ports	Ventilator breathing circuit
	Air Flow	Ventilator flow sensor
	High Pressure O_2	High pressure oxygen connection (41-75 PSI)
	Venous Gas	Venous gas connection from canister
	Weight Sensor	Data communication
Heater/Cooler I/O Panel	Water lines	Connection to heat exchanger connections on oxygenator
	Venous Gas	Venous gas connection to oxygenator



Equipotential Ground Connector:

The Equipotential Ground Connector is used to equalize the potentials between different metal parts of the various Medical Electrical (ME) equipment which make up a ME system, or to reduce the differences of potential which can occur during operation between ME devices and conductive parts of other objects. The Equipotential Ground Connector may be connected directly between ME devices, or to a common ground bus bar of the electrical installation. Reference IEC 60601-1 for ME systems.

10.11 Installation & Environmental Requirements

XVIVO Perfusion Cart System

The XVIVO Perfusion Cart will be shipped in a custom wooden crate container.

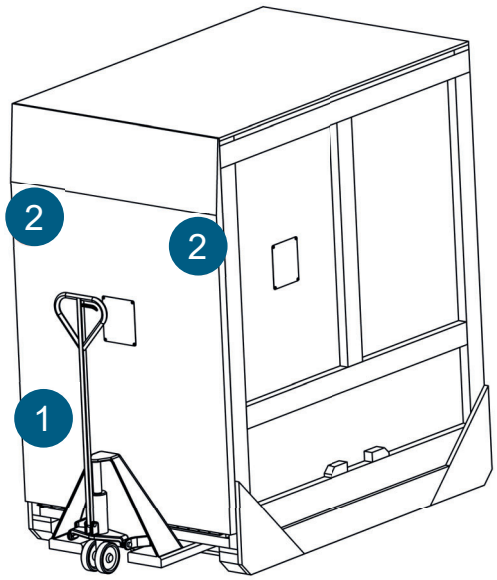
1 The weight of the entire cart and crate approaches 800 pounds (360 kilograms) and should therefore be moved with a mechanical lift device

2 There are two main points of connection on the back door of the crate, each secured with a large screw and wing nut.

The XVIVO Perfusion Cart can be rolled out of the open crate once the crate door is open.

NOTE:

The XVIVO Perfusion Cart will be installed by an authorized XVIVO Representative. This section gives a basic indication of how the cart is unpacked only.



To ensure the system functions properly, the equipment must be installed by an XVIVO Representative and the following conditions must be met:

- The electrical equipment at the installation site must comply with IEC/NEMA requirements and the supply voltage must correspond to equipment specifications
- The unit should NOT be installed close to a heat source
- The unit should NOT be installed in an area subject to water or high humidity
- The unit should NOT be installed in an area subject to violent shocks

The appropriate environmental conditions for correct use of the system are the following: 10-30°C (50-86°F); Room Humidity 30-80% max, non-condensing; up to 11,000 feet above sea level

The appropriate environmental conditions to correctly store the system are the following: 10-40°C (50-104°F); Room Humidity 10-80% max, non-condensing; up to 11,000 feet above sea level

The XPS™ requires special precautions regarding EMC. Install and use the XPS™ according to the guidelines of the EMC declaration tables (section 10.7).

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