906-0004-PRB-02

TRAFERX

TorEx Lung Perfusion System

Physician Labeling

English

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Contents

Device Description 4

The TorEx Lung Perfusion Cart 4

The TorEx Lung Perfusion Organ Chamber 8

The TorEx Lung Perfusion Cannulae 11

Perfusion Console 12

The BELLAVISTA® 1000 Ventilator 13

The TorEx Cart Control Screen 17

TorEx Lung Perfusion Drain Kit 18

TorEx Lung Perfusion Accessories Kit 18

TorEx Lung Perfusate 19

Indications for Use 20

Contraindications 20

Warnings 20

Operating Instructions 23

TorEx Cart Preparation 23

Organ Chamber Setup 24

Ventilation Circuit Setup 26

System Priming and De-Airing 29

Cannulation (on surgical back table) 30

Connection of lung to the TorEx Lung Perfusion circuit 32

Endotracheal Tube Connection 37

System Ramp-Up 39

Steady State EVLP 42

Recruitment 42

Assessment 43

Perfusate Exchange 43

Mobility 44

X-Ray and Bronchoscopy 45

Ending Perfusion 46

Emergency Procedure 48

Cart Shutdown 48

Performance Characteristics 50
Maintenance and Cleaning 52
Maintenance 52
TorEx Lung Perfusion Cart 52
Perfusion Console 52
BELLAVISTA® 1000 Ventilator 53
TorEx Lung Perfusion Cart heater/cooler circuit maintenance and disinfection 53
Cart Cleaning and Disinfection 53
Troubleshooting 54
Residual risks 55
Clinical Performance 56
Manufacturer Information 57

Device Description

The TorEx Lung Perfusion System is an integrated system designed for clinical use that simplifies the Toronto Technique for ex vivo lung perfusion (EVLP) by combining all the necessary equipment required to perform the procedure and placing its controls within a central location.

The TorEx Lung Perfusion System houses the lungs in a sterile environment, while ventilating and perfusing them under normothermic conditions. The TorEx Lung Perfusion System consists of a mobile cart (hardware and software), a single use disposable perfusion kit containing organ chamber, and lung perfusion cannulae.

The TorEx Lung Perfusion Cart

The front view of the TorEx Lung Perfusion Cart, without a TorEx Lung Perfusion Organ Chamber engaged, is shown in Figure 1.

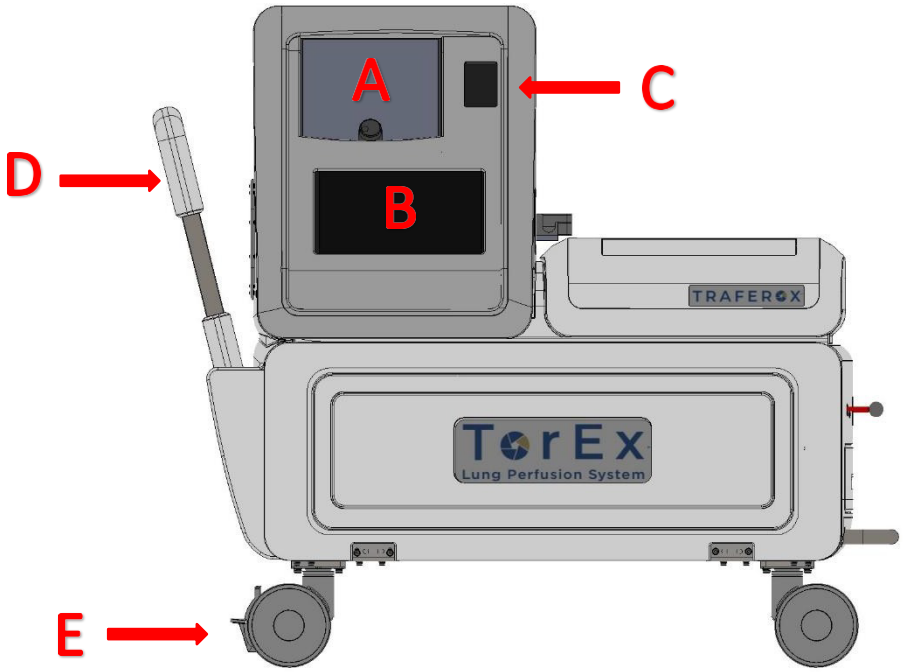


Figure 1: Front view of the TorEx Lung Perfusion Cart without a TorEx Lung Perfusion Organ Chamber attached

The TorEx Lung Perfusion Cart has three touchscreens:

- **A)** Perfusion console
- **B)** BELLAVISTA® 1000 ventilator
- **C)** Cart control screen

Mobility features include:

D) Handlebar

E) Castors with locking mechanism

Figure 2 displays the back view of the TorEx Lung Perfusion Cart without a TorEx Lung Perfusion Organ Chamber attached.

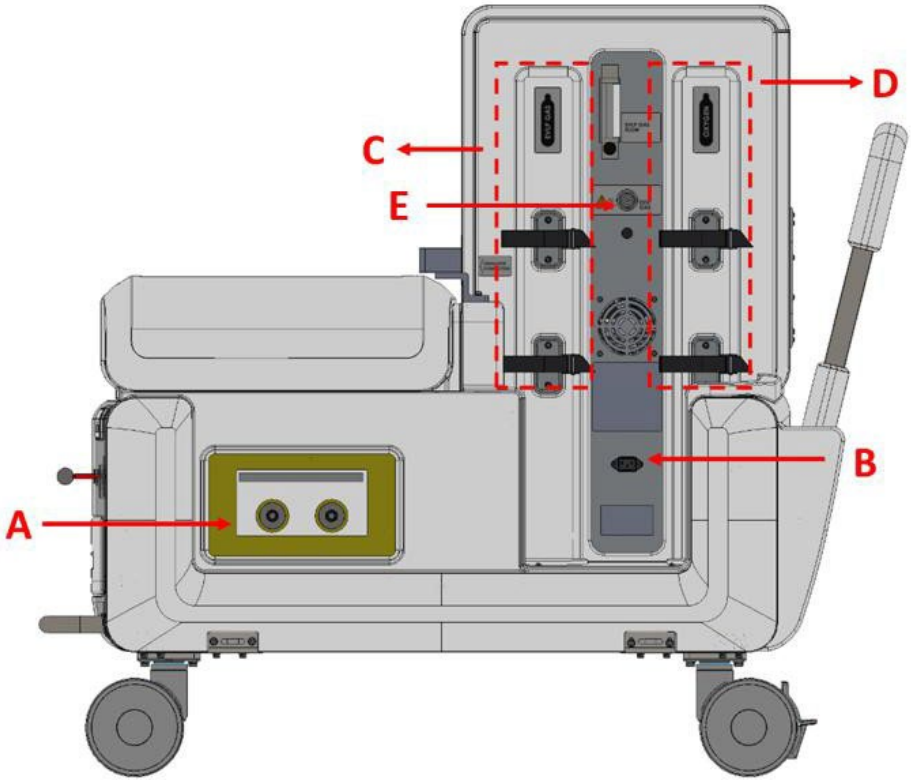


Figure 2: Back view of the TorEx Lung Perfusion Cart without a TorEx Lung Perfusion Organ Chamber attached

A) External heater connection ports

B) Power cord inlet

C) EVLP gas cylinder holder

D) Oxygen gas cylinder holder

E) EVLP gas inlet (DISS 2220 male connection)

Note: DISS 2220 female to ¼" barb connector (540-0007) is not shown, but is supplied with the Cart.

Figure 3: Angled views of the TorEx Lung Perfusion Cart without a TorEx Lung Perfusion Organ Chamber attached

A) Oxygen inlet connection (DISS 1240 male)

B) Document holder

C) Ventilation outlet

D) TorEx Lung Perfusion Organ Chamber holder

E) Organ Chamber locking rods

F) Drip tray holder access

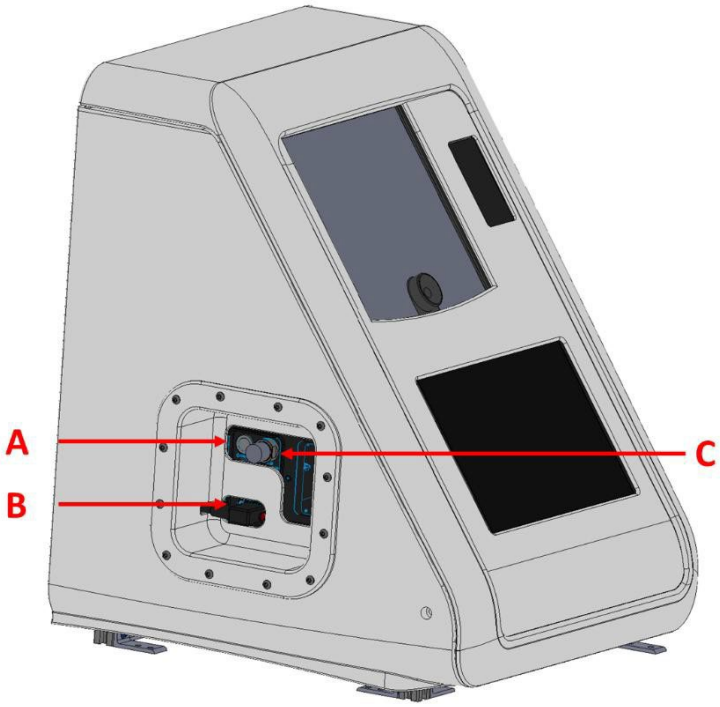


Figure 4: Ventilator

A) Ventilator/Perfusion Console power button

B) Ventilator power cable connection

C) Oxygen Inlet connection

The TorEx Lung Perfusion Organ Chamber

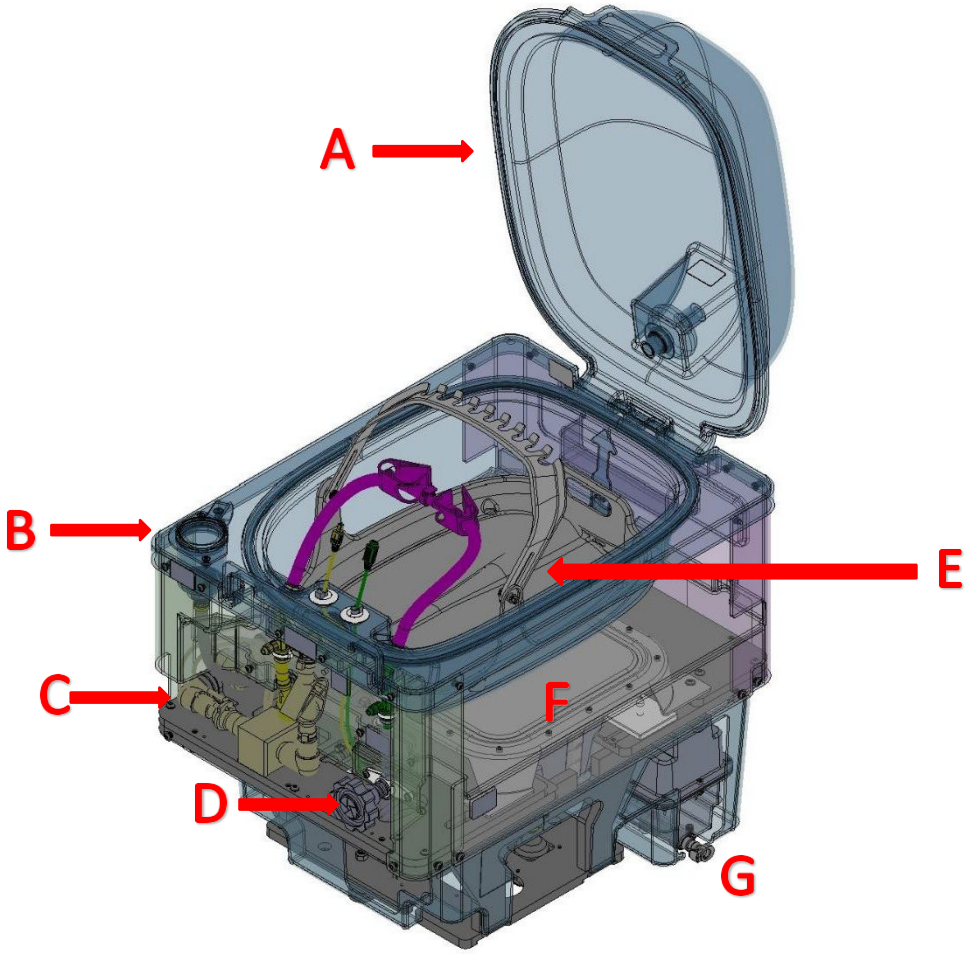


Figure 5: Front view of the TorEx Lung Perfusion Organ Chamber

A) Organ Chamber lid

B) Perfusion solution fill port

C) Ventilator flow sensor

D) LA Pressure control knob

E) Lung tray

F) X-ray cassette slot

G) Waste reservoir drainage port

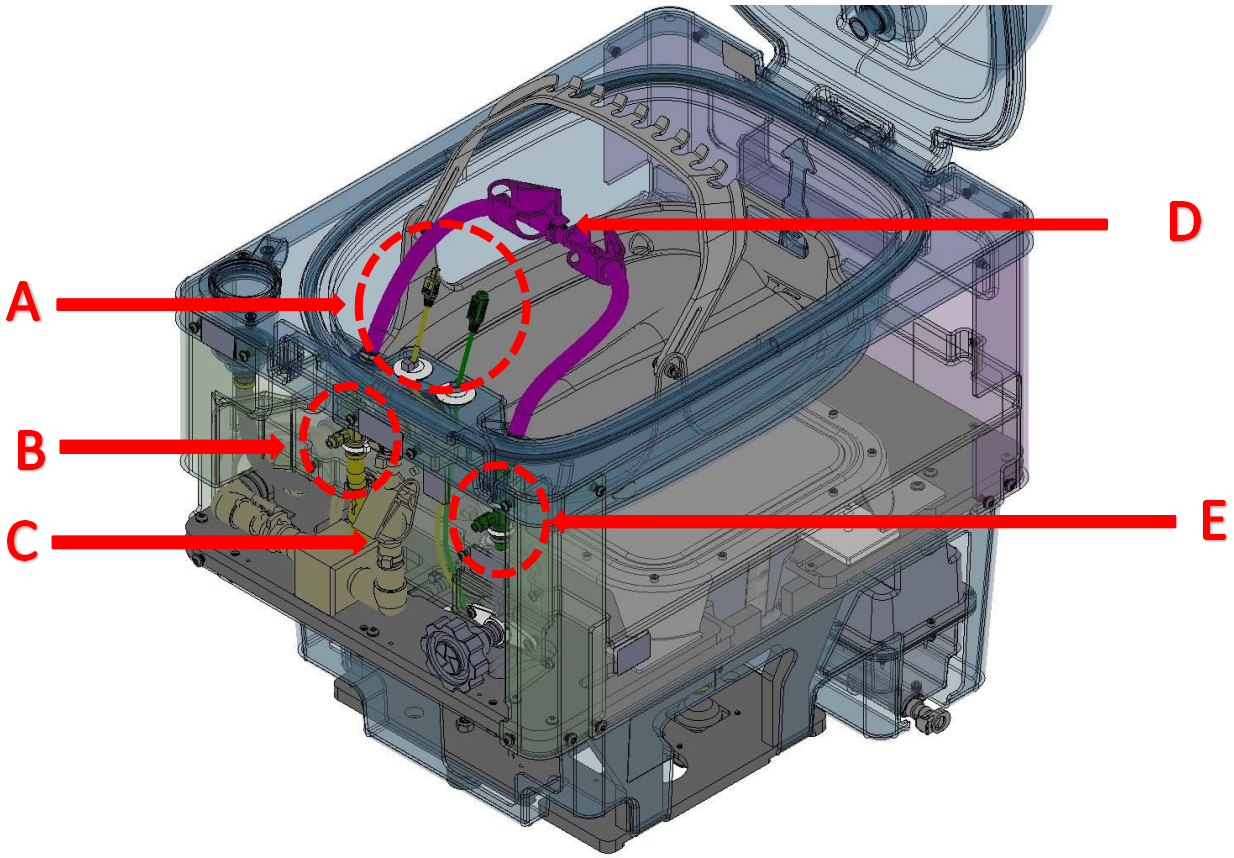


Figure 6: Front view of the TorEx Lung Perfusion Organ Chamber (zoomed in)

A) Pressure line connectors

B) Perfusate sample ports

C) Airway clamp

D) LA and PA connection tubes

E) Bronchoscopy port

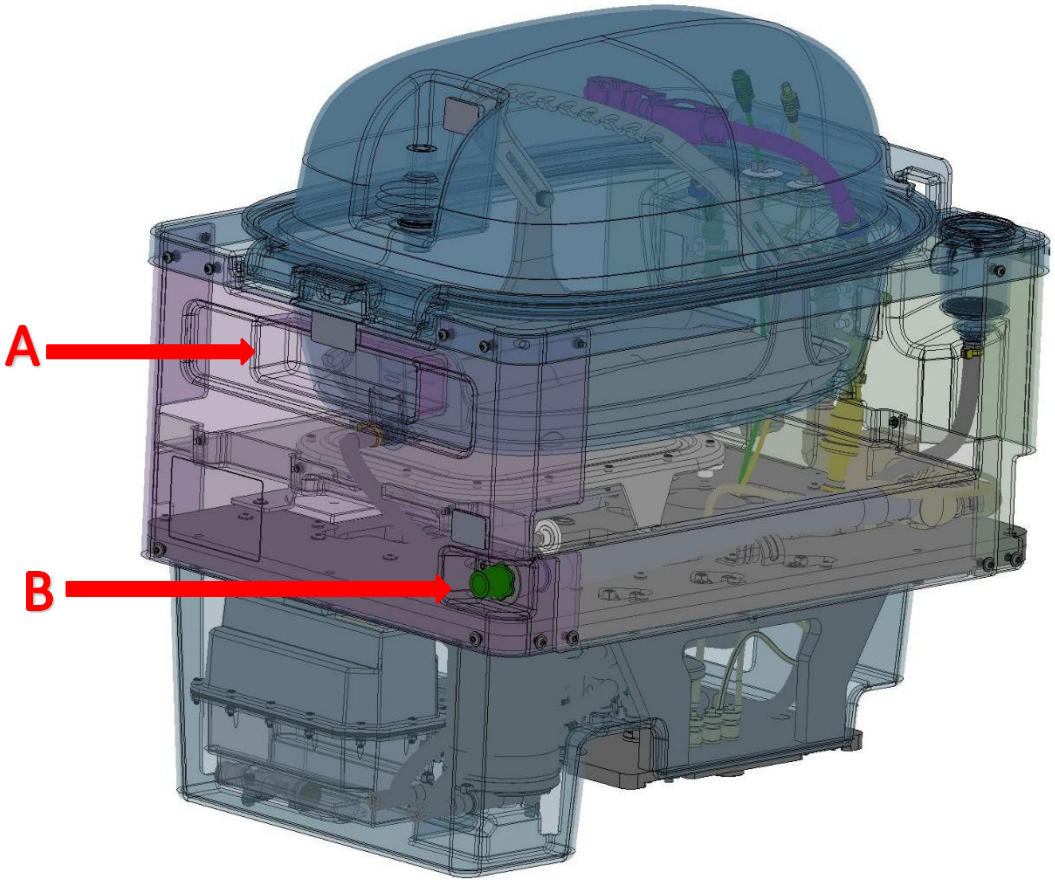


Figure 7: Back view of the TorEx Lung Perfusion Organ Chamber (lid on)

A) Organ Chamber handle

B) Ventilation tubing connection

The TorEx Lung Perfusion Cannulae

Figure 8: TorEx Lung Perfusion Left atrium Cannulae. Options shown from left: 3cm, 4cm, 5cm and Rescue Cannula. The LA Rescue Cannula is provided standard in the TorEx Lung Perfusion Kit. Other sizes are available to order separately.

A) Quick connection
B) Suction port connector
C) Hydrostatic pressure line connection
D) Suction ring
E) Rescue cannula skirt

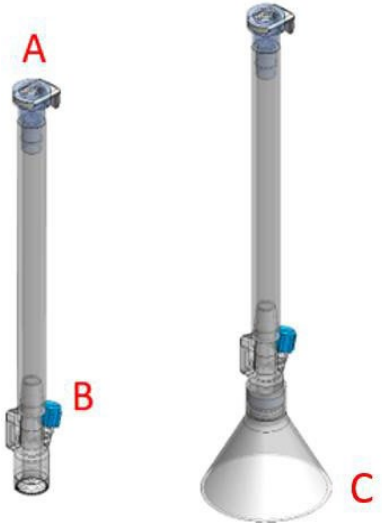


Figure 9: TorEx Lung Perfusion Pulmonary Artery Cannulae (2cm and Rescue Cannula). Both are provided standard in the TorEx Lung Perfusion Kit.

A) Quick connection
B) Hydrostatic pressure line connection
C) Rescue cannula skirt

Perfusion Console

The perfusion flow rate and pressure are controlled and monitored with the Perfusion Console (Figure 10).

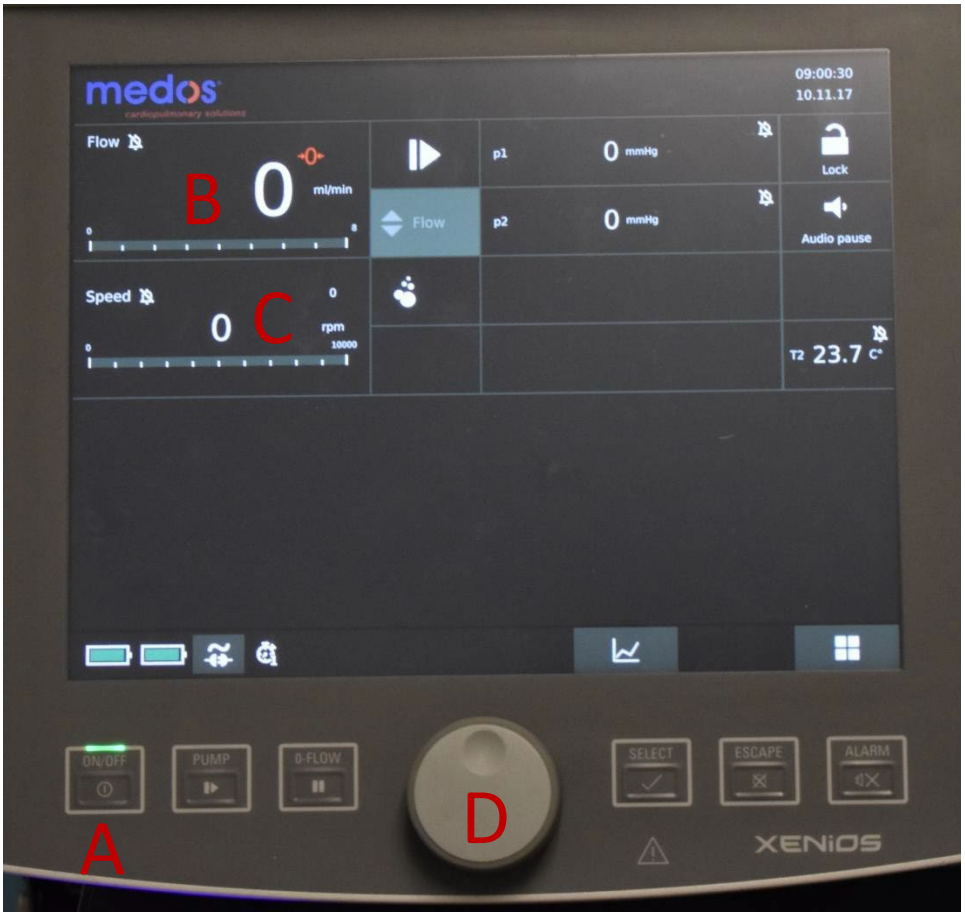


Figure 10: Perfusion Console with home screen displayed

A) Perfusion Console is powered with an on/off push button

B) Flow of perfusate

C) The speed of the pump.

D) Control knob to adjust pump speed

The BELLAVISTA® 1000 Ventilator

The ventilation in the TorEx Lung Perfusion System is controlled through the BELLAVISTA® 1000 ventilator. When powered up, the BELLAVISTA® 1000 ventilator will display a startup screen (Figure 11). Calibration of the ventilator is recommended before use.

Figure 11: The start-up screen of the BELLAVISTA® 1000 ventilator

- **A)** Ventilation circuit calibration
- **B)** Ventilation settings
- **C)** The ability to start ventilation can all be controlled from this screen.

While in operation during an EVLP, the 'Cockpit' screen (Figure 12), 'Expert Monitoring' (Figure 13) screen, and 'Maneuvers' screen (Figure 14) are used.

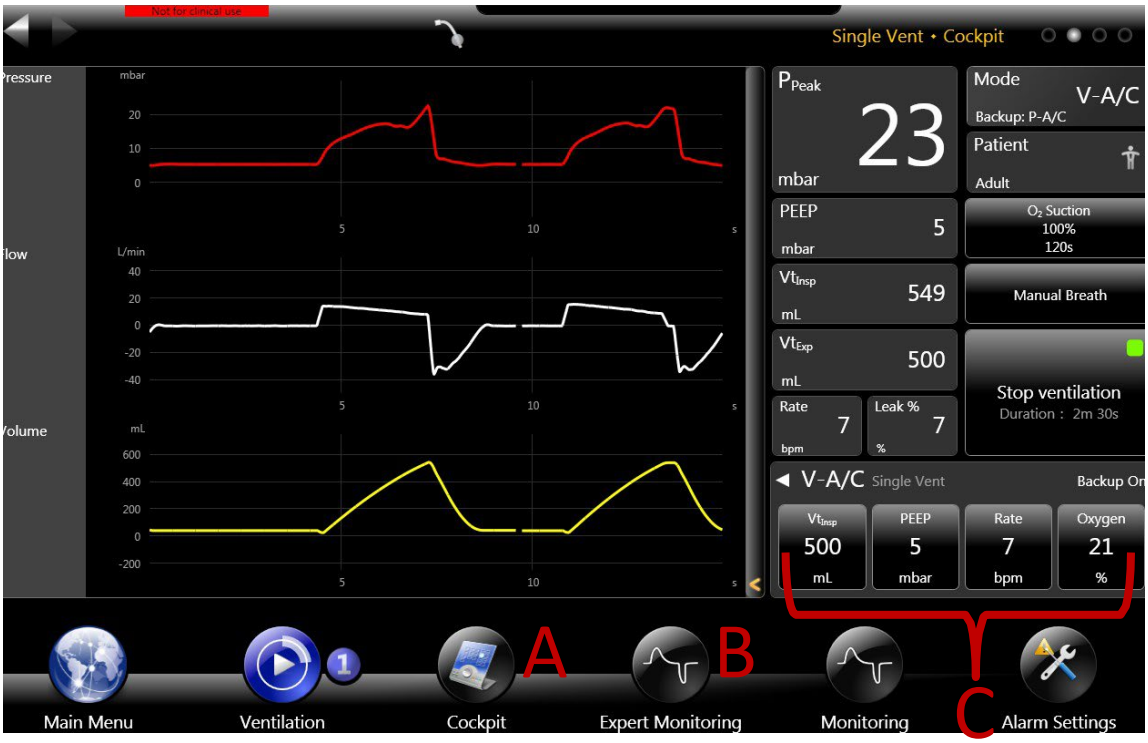


Figure 12: The 'Cockpit' screen of the BELLAVISTA® 1000 ventilator

A) 'Cockpit' access screen

B) Access to 'Expert Monitoring' screen

C) Ventilation parameters that can be adjusted in the 'Cockpit' screen

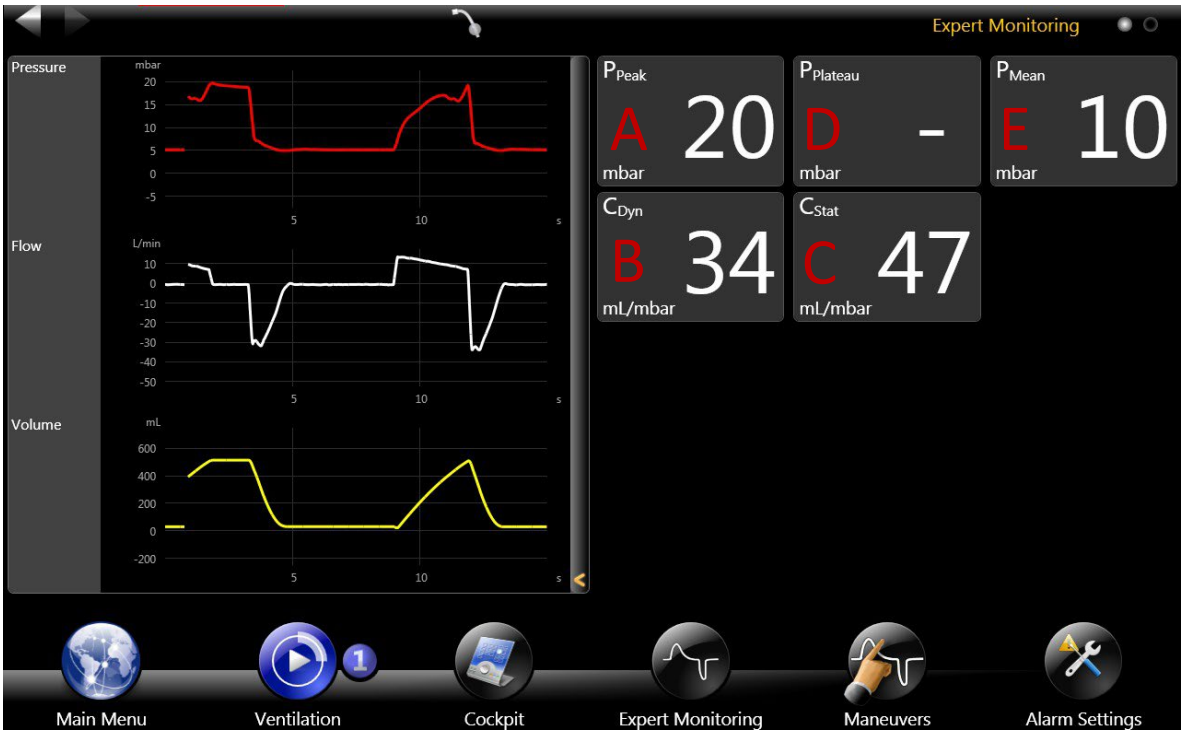


Figure 13: The 'Expert Monitoring' screen of the BELLAVISTA® 1000 ventilator

In the 'Expert Monitoring' screen, the following variables are displayed.

A) P_{Peak}: Peak Airway Pressure

B) C_{Dyn}: Dynamic Lung Compliance

C) C_{Stat}: Static Lung Compliance

D) P_{plat}: Plateau Airway Pressure

E) P_{mean}: Mean Airway Pressure

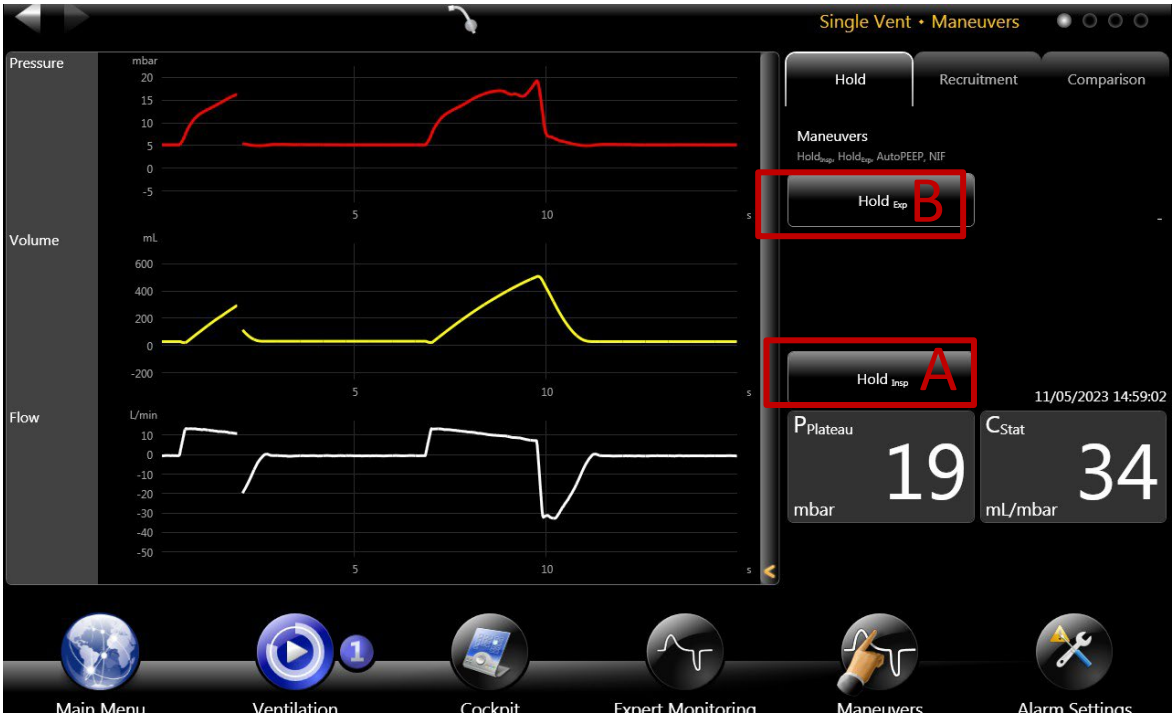


Figure 14: 'Maneuvers' screen of the BELLAVISTA® 1000 ventilator

In the ‘Maneuvers’ screen, an inspiratory hold can be performed using the A) ‘Hold $_{Insp}$’ button.

In the ‘Maneuvers’ screen, an expiratory hold can be performed using the B) ‘Hold $_{Exp}$’ button.

The TorEx Cart Control Screen

The Cart Control screen, which runs the TorEx Lung Perfusion Software, can be found on the top right of the TorEx Lung Perfusion Cart (Figure 15).

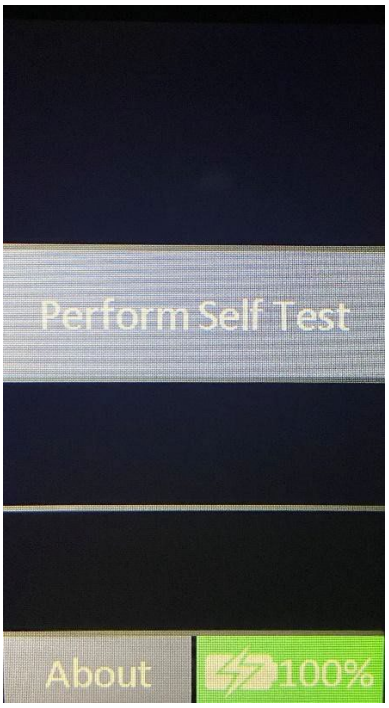


Figure 15: The Cart Control screen

The Cart Control screen displays:

- the current stage of the perfusion
- the percentage of remaining battery charge and an indication of whether the TorEx Lung perfusion Cart is running on battery power or on mains power
- alarms for hazardous conditions in the system.

TorEx Lung Perfusion Drain Kit

The TorEx Perfusion Drain Kit can be used as required to drain excess waste perfusate from the TorEx Organ Chamber waste reservoir. The Drain Kit is assembled of PVC tubing and has a QuickConnect fitting (Figure 16).

Figure 16: TorEx Lung Perfusion Drain Kit

To use the TorEx drain kit, it is connected to the waste reservoir via Quick-Connect fitting and the waste perfusate is directed to flow through PVC tubing. The TorEx Drain Kit is supplied inside of the TorEx Lung Perfusion Kit PVC tray.

TorEx Lung Perfusion Accessories Kit

The TorEx Lung Perfusion Accessories Kit contains non-sterile single-use disposable accessories used during EVLP. It consists of the following items.

- Ventilation Hose (part 201-0003) – non-sterile
- Ventilator Calibration Adapter (part 402-0056) – non-sterile
- Drip Tray (part 500-0001) – non-sterile
- Biohazard trash liner (part 805-0034) – non-sterile
- Hydrostatic pressure sensing lines (part 301-0065) – sterile
- Cutter (part 703-0029) – non-sterile
- Cleaning Brush (part 703-0054) – non-sterile
- Zip ties (700-0010) – non-sterile
- TorEx Lung Perfusion Kit – Instructions for Use (part 908-0001-UM-01)

The cutter is used to open the Tyvek lid of the TorEx Lung Perfusion Kit in order to access the Organ chamber. The ventilation hose is used to connect the ventilator outlet to the ventilation circuit of the organ chamber. The ventilation hose is connected to the ventilator when starting an EVLP procedure.

The ventilator calibration adapter is supplied for use during mandatory calibration of the ventilation circuit, prior to an EVLP procedure. The drip tray is a plastic tray that is inserted into the cart drip pan to collect any accidental fluid spillage onto the cart. The drip tray is to be discarded as biohazardous waste after each EVLP procedure.

The hydrostatic pressure sensing lines are used with hydrostatic pressure sensors and an external pressure monitor. They are connected to the hydrostatic pressure ports on the PA and LA Cannulae and to pressure transducers located near an external pressure monitor. The hydrostatic pressure sensing lines can be used with the Organ Chamber lid closed. The cleaning brush is used to perform the cleaning procedure (Cart Cleaning and Disinfection) on the TorEx Cart after each case. Zip ties are also included which are meant to be placed on tubing joints if required during the procedure (i.e., a small leak is detected).

The biohazard trash liner is to be used to collect all biohazardous waste produced during the EVLP procedure.

TorEx Lung Perfusate

The TorEx Lung Perfusate (low potassium dextran with albumin) is a clear, sterile, non-pyrogenic, non-toxic physiological salt solution containing human serum albumin and dextran 40. Human serum albumin serves to provide normal oncotic pressure, preventing the formation of lung edema during the perfusion period. Dextran 40 coats the lung endothelium, serving as a mild scavenger and protecting from excessive leukocyte interaction. This solution is an extracellular (low potassium) electrolyte solution with physiological colloid osmotic pressure designed for use as a temporary continuous normothermic machine perfusion solution for ex vivo assessment of isolated lungs after removal from the donor. The extracellular composition avoids vascular spasm under normothermic conditions.

Table 1 below shows the ingredient list for TorEx Lung Perfusate.

Table 1: TorEx Lung Perfusate Composition

Ingredient	Amount
Dextran 40	5 g/L
Sodium chloride	98 mmol/L
Glucose/dextran monohydrate	11 mmol/L
Potassium chloride	4.6 mmol/L
Calcium chloride	1.5 mmol/L
Sodium dihydrogen phosphate monohydrate	1.2 mmol/L
Sodium bicarbonate	15 mmol/L
Magnesium chloride	1.2 mmol/L
Albumin	70 g/L

Indications for Use

The TorEx Lung Perfusion System is indicated for use in continuous normothermic machine perfusion of donor lungs, initially deemed unsuitable for transplantation, during which time the ex vivo function of the lungs can be reassessed for transplantation in adults. The TorEx Lung Perfusion System includes a mobile cart with embedded software, single-use sterile Organ Chamber and Cannulae set and is used with TorEx Lung Perfusate solution to perform ex vivo lung perfusion for up to 6 hours.

Note: The TorEx System is used to evaluate the quality of donated lungs, but the final determination of the suitability of the lungs for transplant remains with the transplanting surgeon.

Contraindications

There are no known contraindications.

Warnings

⚠ WARNING

Do not perform maintenance on the ventilator, perfusion system, or battery while EVLP is in progress.

⚠ WARNING

Equipment must be connected to a supply mains with protective earth in order to avoid risk of electric shock.

⚠ WARNING

Unpacking of the TorEx Lung Perfusion Cart should be performed only by qualified Traferox personnel.

⚠ WARNING

All equipment associated with the TorEx Lung Perfusion System should be placed in a manner so that the power cable connection always remains accessible.

⚠ WARNING

The TorEx Lung Perfusion Cart should be disposed of as electronic waste.

⚠ WARNING

The TorEx Lung Perfusion Organ Chamber and the TorEx Lung Perfusion Cannulae should be disposed of as biohazardous waste.

⚠ WARNING

The TorEx Lung Perfusion Cart remains energized even without a connection to mains power.

⚠ WARNING

Do not modify this equipment without authorization of the manufacturer.

⚠ WARNING

Only trained Traferox personnel can perform service on the TorEx Lung Perfusion System.

⚠ WARNING

This product is for use in institutions performing ex vivo lung perfusion. Follow all local regulatory and institutional requirements for performing a clinical ex vivo lung perfusion procedure.

⚠ WARNING

The system is designed for use with TorEx Lung Perfusate. Do not use any other lung perfusion solution.

⚠ WARNING

TorEx Lung Perfusate is not intended for infusion in human patients.

⚠ WARNING

When engaging and removing the Organ Chamber, ensure that precautions are taken to avoid injury due to heavy lifting. Employ additional personnel to lift the TorEx Lung Perfusion Organ Chamber if needed.

⚠ WARNING

The procedure is provided as a recommended workflow for the use of this product. Any alteration to the workflow provided is at the discretion of the user. Read this document before attempting to use the product.

⚠ WARNING

Do not use if the packaging of the TorEx Lung Perfusion Kit is damaged, unintentionally opened before use, or if the packaging is exposed to environmental conditions outside of those specified.

⚠ WARNING

Components of the TorEx Lung Perfusion Kit should be used as soon as the package is open. *Attempted re-sterilization of the organ chamber may result in degradation of device safety and/or efficacy as the device has not been tested for exposure to more than one sterilization cycle.*

⚠ WARNING

The components of the TorEx Lung Perfusion Kit are single-use products. Do not attempt to reuse. *Attempted re-use of the Organ Chamber could result in cross-contamination and infection for lung transplant recipients.*

⚠ WARNING

The components of the TorEx Lung Perfusion Kit cannot be re-sterilized after they have been removed from their sterile package.

⚠ WARNING

Do not re-use perfusate from the waste reservoir.

⚠ WARNING

The TorEx Lung Perfusion Cart contains a LiFePO4 rechargeable battery. This battery should not be replaced or serviced by anyone other than Traferox's trained service personnel. Improper replacement of the battery or the use of an incompatible battery may cause equipment malfunction, fire, or leakage of corrosive substances and may harm the operator.

⚠ WARNING

Use the power cable provided along with the TorEx Lung Perfusion System to power the system. Do not use a power cable longer than 3 m or an extension cord to power the TorEx Lung Perfusion System.

⚠ WARNING

Using other cables or accessories than those listed in these instructions may negatively affect electromagnetic compatibility (EMC) performance.

⚠ WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ WARNING

Do not place devices employing near-field communication in close proximity to

the TorEx Lung Perfusion System.

⚠ WARNING

The TorEx Lung Perfusion System should not be used in an aircraft or in any transport vehicle.

Operating Instructions

TorEx Cart Preparation

1. Bring the TorEx Lung Perfusion Cart into the operating/organ perfusion room. Ensure the TorEx Lung Perfusion Cart is near an electrical outlet, bronchoscopy tower, heater/cooler as well as the room's oxygen and vacuum supply (if available).
2. Remove 2L of TorEx Lung Perfusate from storage (at 2°C to 8°C) approximately 20 minutes before priming of the circuit. Note: This is to allow for the perfusate to come to room temperature.
3. If mobility is required, ensure the TorEx Lung Perfusion Cart is connected to onboard EVLP and O_2 gas tanks. Check the gas levels of the onboard EVLP and O_2 gas tanks prior to engaging in mobility. A minimum pressure of 50 bar is recommended.
4. Position the external heater/cooler unit beside the TorEx Lung Perfusion Cart to allow the heater/cooler system tubing enough length to reach the back of the TorEx Lung Perfusion Cart. Ensure that the external heater/cooler unit has access to power and is primed and ready for operation as per the manufacturer's instructions. Connect the external heater/cooler to the ports on the back of the TorEx Lung Perfusion Cart.

   ⚠ WARNING

   The maximum allowed pressure for the heater/cooler lines is 1 bar.

5. Open the drip tray holder on the TorEx Lung Perfusion Cart and place the drip tray in the holder.
6. Plug the TorEx Lung Perfusion Cart into mains power using the power cord found on the back of the unit.
7. Power on the ventilator by pushing the power on button on the side of the ventilator (near the oxygen inlet).
8. Power on the perfusion console by pushing on the power-on button near the screen of the console.
9. Select "Advanced Mode", and then press "exit" to return to main display.
10. If not already activated, touch the Cart Control screen to activate the display.
11. On the Cart Control screen, confirm the TorEx Lung Perfusion Cart battery is sufficiently charged.
12. Run the self-test of the TorEx Lung Perfusion Cart by pressing the 'Perform Self Test' button on the Cart Control Screen. The Cart Control Screen will ask for confirmation and then assess the functionality of its components. See the 'Troubleshooting'' section if an error occurs during the self-test. If the self-test is successful, the screen will indicate that the system is in Idle mode.

NOTICE

Ensure that the self-test on the Cart Control Screen has passed before opening the packaging on a TorEx Lung Perfusion Organ Chamber.

13. Connect an oxygen line to the ventilator's oxygen inlet. If Cart mobility is desired, place a size-E oxygen cylinder on the Cart and connect the oxygen line to the regulator. If Cart mobility is not needed, the oxygen line can be connected to the oxygen supply of the operating room.
14. Connect an EVLP gas line to the EVLP gas port on the back of the TorEx Lung Perfusion Cart. If cart mobility is required, place a size-E EVLP gas cylinder on the Cart and connect the EVLP gas line to it. Otherwise, any EVLP gas cylinder can be used.

⚠ WARNING

The maximum allowed pressure for the Oxygen and EVLP gas inputs is 7 bar.

15. Open the Oxygen gas line. The BELLAVISTA® 1000 will regulate the oxygen flow once ventilation has begun.

Organ Chamber Setup

After the Cart is set up, the TorEx Lung Perfusion Organ Chamber can be attached to the TorEx Lung Perfusion Cart. Only when the self-test has passed should a packaged TorEx Lung Perfusion Organ Chamber be opened.

⚠ WARNING

Use only Traferox original TorEx Lung Perfusion Organ Chambers and TorEx Lung Perfusion Cannulae with the TorEx Lung Perfusion Cart.

1. Remove the TorEx Lung Perfusion Organ Chamber tray from its box and inspect it, including the sealing membrane, for any damage. If damage is visible or suspected, do not use the Organ Chamber. Contact Traferox Technologies' support (Manufacturer Information) to obtain a replacement.

⚠ WARNING

Using an Organ Chamber from a damaged package may introduce contaminants in the lungs. Do not use the Organ Chamber if the sterile package is damaged, unintentionally opened before use, or if the packaging is exposed to environmental conditions outside of those specified.

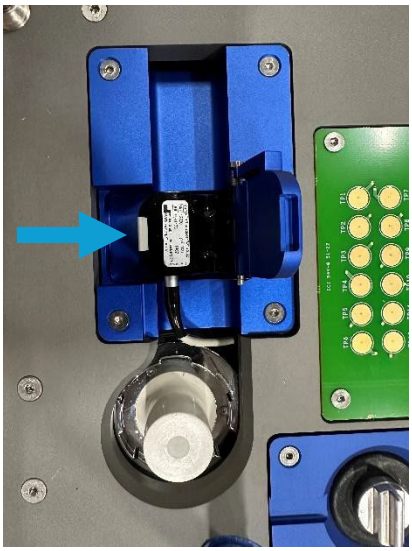
⚠ WARNING

Attempted re-sterilization of the organ chamber may result in device malfunction as the device has not been tested for exposure to more than one sterilization cycle.

2. Open the TorEx Lung Perfusion Kit package and remove the TorEx Lung Perfusion Organ

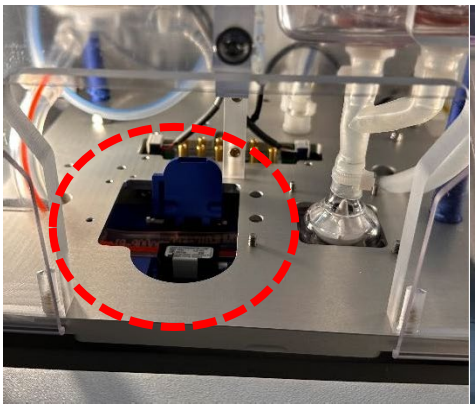
Chamber.

3. Inspect the TorEx Lung Perfusion Organ Chamber for any damage. If damage is suspected, do not use the Organ Chamber and contact Traferox Technologies (Manufacturer Information) for a replacement.
4. Open the blue flow sensor lid by pressing against the front of the latch, shown below.

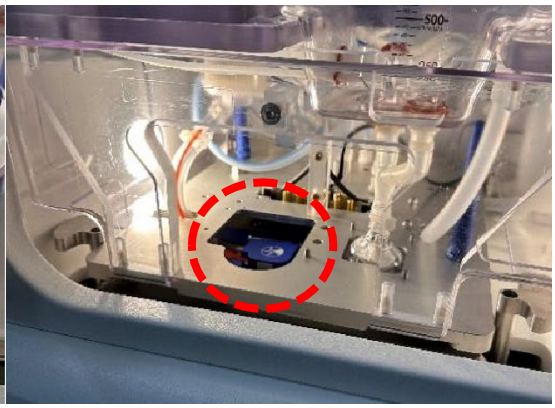


TorEx Lung Perfusion Cart flow sensor

5. Locate the locking rods on the side of the cart and pull them fully outward.
6. Using the guide pins on the cart, fully insert the TorEx Lung Perfusion Organ Chamber into the TorEx Lung Perfusion Cart.
7. Push the locking rods on the side of the Cart to lock the Organ Chamber in place. It may be necessary to apply downward force on the Organ Chamber to allow the locking clamps to slide into place. Locking rods should be fully inserted into the side of the cart.
8. From the side of the cart, press the fluid circuit tubing into the flow sensor and close the flow sensor lid. Ensure lid remains closed.



Flow Sensor Cover Open



Flow Sensor Cover Closed

NOTICE

Ensure that the temperature probe and flow sensor display show a reading on the Perfusion Control Console after the TorEx Lung Perfusion Organ Chamber is inserted into the TorEx Lung Perfusion Cart. Note that the flow reading of "---" is acceptable until perfusate is introduced to the circuit.

9. Extend the ventilation tube out of the back of the TorEx Lung Perfusion Organ Chamber (Location B, Figure 7) and attach to the ventilation port on the Cart.

NOTICE

Ensure the ventilation tube is tightly connected to the ventilation port to minimize air leakage in the ventilation circuit.

Ventilation Circuit Setup

The ventilation circuit will be prepared for use; locate the ventilator (BELLAVISTA® 1000) screen on the front of the TorEx Lung Perfusion Cart.

1. Press the Circuit Test button and follow the prompts on the BELLAVISTA® 1000 console. The ventilator calibration adapter (part of the TorEx Lung Perfusion Accessory Kit) is required for this step.
2. Once complete, the Circuit Test icon will display the date and time of completion. If the ventilation circuit test is not successful, see the Troubleshooting section. A successful calibration should be performed before progressing through the procedure.
3. Reconnect ventilation circuit components

Note that the oxygen sensor inside the ventilator should be calibrated before each use:

1. On the main menu screen, go to "Settings" and then "Calibration Assist"
2. Press "O2 Sensor Calibration". The ventilator can be used while calibration is in progress.

The 'Human EVLP' profile is pre-loaded onto the BELLAVISTA® 1000 ventilator and is recommended for use for human lung EVLP.

NOTICE

If a high leak rate is detected during ventilation, check that ventilation tubing connections are secure by applying force at the connection points. A warning will appear on the ventilator screen when a 'high leak' is detected.

The BELLAVISTA® 1000 ventilator will require the input of multiple ventilation parameters. These parameters are related to the ideal body weight of the donor, as per the requirements set forth by the Toronto EVLP protocol. Table 2 describes the ventilation parameters that should be calculated prior to EVLP.

SUPPLEMENTARY INFO

Protective ventilation (6-8 mL/kg) is recommended to prevent acute lung injury to protect alveolar barrier integrity (Lee WL et al. Intensive Care Med, 2000)

Table 2. EVLP Parameters to be calculated

	Double Lung	Left Single Lung	Right Single Lung
Cardiac Output (L/min)	$= \sqrt{\frac{Height\ (cm) \times IBW\ (kg)}{3600}} \times 2.4 \frac{L}{min}$	$= \sqrt{\frac{Height\ (cm) \times IBW\ (kg)}{3600}} \times 2.4 \frac{L}{min}$	$= \sqrt{\frac{Height\ (cm) \times IBW\ (kg)}{3600}} \times 2.4 \frac{L}{min}$
Maximum Flow Rate	= 40% of the donor's cardiac output (Cardiac Output × 0.4)	= 16% of the donor's cardiac output (Cardiac Output × 0.16)	= 24% of the donor's cardiac output (Cardiac Output × 0.24)
10% of the Flow Rate	= Maximum Flow Rate × 0.1	= Maximum Flow Rate × 0.1	= Maximum Flow Rate × 0.1
20% of the Flow Rate	= Maximum Flow Rate × 0.2	= Maximum Flow Rate × 0.2	= Maximum Flow Rate × 0.2
30% of the Flow Rate	= Maximum Flow Rate × 0.3	= Maximum Flow Rate × 0.3	= Maximum Flow Rate × 0.3
50% of the Flow Rate	= Maximum Flow Rate × 0.5	= Maximum Flow Rate × 0.5	= Maximum Flow Rate × 0.5
80% of the Flow Rate	= Maximum Flow Rate × 0.8	= Maximum Flow Rate × 0.8	= Maximum Flow Rate × 0.8
Normal Tidal Volume	= donor's ideal body weight (kg), multiplied by 7 ml/kg	= donor's ideal body weight (kg), multiplied by 7 ml/kg × 0.4	= donor's ideal body weight (kg), multiplied by 7 ml/kg × 0.6
Assessment Tidal Volume	= donor's ideal body weight (kg), multiplied by 10 ml/kg	= donor's ideal body weight (kg), multiplied by 10 ml/kg × 0.4	= donor's ideal body weight (kg), multiplied by 10 ml/kg × 0.6
Recruitment Tidal Volume	= donor's ideal body weight (kg), multiplied by 15 ml/kg	= donor's ideal body weight (kg), multiplied by 15 ml/kg × 0.4	= donor's ideal body weight (kg), multiplied by 15 ml/kg × 0.6

Note: IBW = Ideal Body Weight

SUPPLEMENTARY INFO

The low-flow strategy permits extended lung perfusion (6 h) without compromising lung histology based on regional flow (Cypel et al. JHLT, 2008).

SUPPLEMENTARY INFO

During lung rewarming, high vascular resistance is expected. Gradual rewarming of the lung (through periodic flow increments) helps to mitigate the amount of shear stress on the lung endothelium during this period (Cypel et al. JHLT, 2008).

SUPPLEMENTARY INFO

Switching from double lung to single lung perfusion can be performed during EVLP by clamping the main pulmonary arteries, veins, bronchus of the lung to be excluded. Before exclusion, the EVLP settings should be changed to single left/right lung parameters.

NOTICE

It is strongly recommended that the values for the above calculations be displayed in the EVLP room during EVLP to provide a quick reference. An EVLP form is also provided for this purpose (see supplementary document).

At various stages of the protocol, one of three ventilation parameter sets will be entered onto the BELLAVISTA® 1000 ventilator. These parameter settings are called

'Normal' - for use during steady-state EVLP

'Assessment' - for use when performing an assessment at each XX:55 mark during the EVLP

'Recruitment' - for use when performing a recruitment at each XX:30 mark (beyond the first hour) during EVLP.

Table 3 describes the Normal, Assessment and Recruitment parameters that will be entered during human lung EVLP.

Table 3: Ventilation parameters to be used during human lung EVLP

Ventilation Parameter	***Normal***	***Assessment***	***Recruitment***
Tidal Volume (Vt_{insp})	***Normal Tidal Volume (7mL/kg)***	***Assessment Tidal Volume (10 mL/kg)***	***Recruitment Tidal Volume (15mL/kg)***
Fraction inspired O2 (%FiO_2)	***21%***	***100%***	***21%***
Respiratory Rate (Rate)	***7***	***10***	***7***
Positive end-expiratory pressure (PEEP)	***5***	***5***	***5***

NOTICE

It is strongly recommended that the above tables with values specific to the donor's lungs be displayed in the operating room during a given EVLP to provide a quick reference. The Human EVLP Form can be used for this purpose.

System Priming and De-Airing

1. Select 'Prime System' on the Cart Control screen and Confirm the action.
2. Open the fill port on the TorEx Lung Perfusion Organ Chamber.
3. Slowly introduce the perfusate into the fill port funnel.

> **⚠ WARNING**
>
> ***Do not spill perfusate outside of the fill port. Spilled perfusate can cause electrical short circuits of the TorEx Lung Perfusion Cart.***

4. Continue until 2L of perfusate has been introduced into the system.
5. Close the cap on the fill port.

> **NOTICE**
>
> ***If flow reading is not presented as a numeric value, remove the organ chamber, apply alcohol or gel onto the flow sensor and re-install organ chamber as per 'Organ Chamber Setup' above.***

6. On the perfusion console, select 'Flow', then select the arrow on the bottom right of the screen to go to the next page, and select 'Zero calibration' to zero the flow sensor reading.

> **NOTICE**
>
> ***Do not use the physical '0-Flow' button on perfusion console.***

7. On the perfusion console, press the 'Pump' button and turn the control knob on the Perfusion Console clockwise to increase the speed to 1000 RPM.
8. After approximately 20 seconds, turn the knob clockwise to increase the pump speed to 2000 RPM
9. After approximately 20 seconds, turn the knob clockwise to increase the pump speed to 4000 RPM.
10. After approximately 20 seconds, turn the knob clockwise to increase the pump speed to 6000 RPM.
11. Allow the system to run at 6000 RPM for at least 30 seconds and ensure the perfusion circuit is free of air bubbles. If air bubbles are present, see the Troubleshooting section

> **NOTICE**
>
> ***It is important to ensure that the perfusion circuit is completely de-aired. Air bubbles may interfere with the flow sensor's readings and may obstruct flow within the lung.***

12. On the Perfusion console, turn the knob counter-clockwise to decrease the pump speed to 2000 RPM.
13. If required, introduce applicable medications as per approved medical practices and/or procedures:
    a. Utilizing a needled syringe, withdraw the medication.

b. Dispose of the syringe's needle as per institutional procedure.
c. Twist the syringe onto the LA sampling port.

⚠ WARNING

Do not perforate the LA or PA sampling ports with a needle as it will cause leakage. Utilize the luer-lock system of the LA and PA sampling ports.

d. Depress the plunger to add the medication, then disconnect and dispose of the syringe.

Cannulation (on surgical back table)

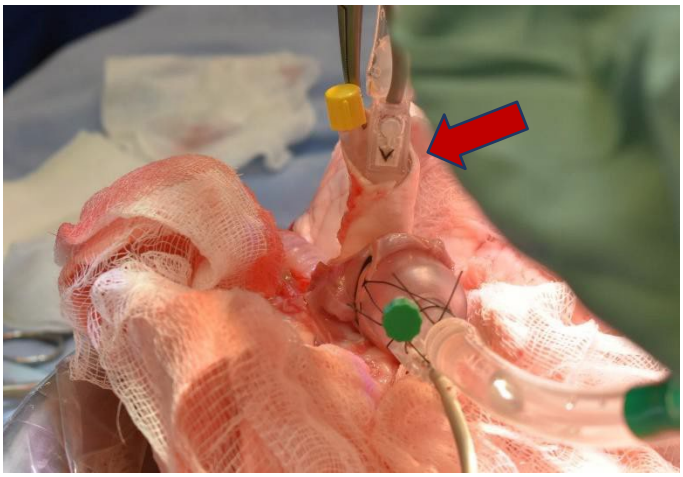
⚠ WARNING

All interaction with the lung must be performed by a sterile user (as per institutional procedure)

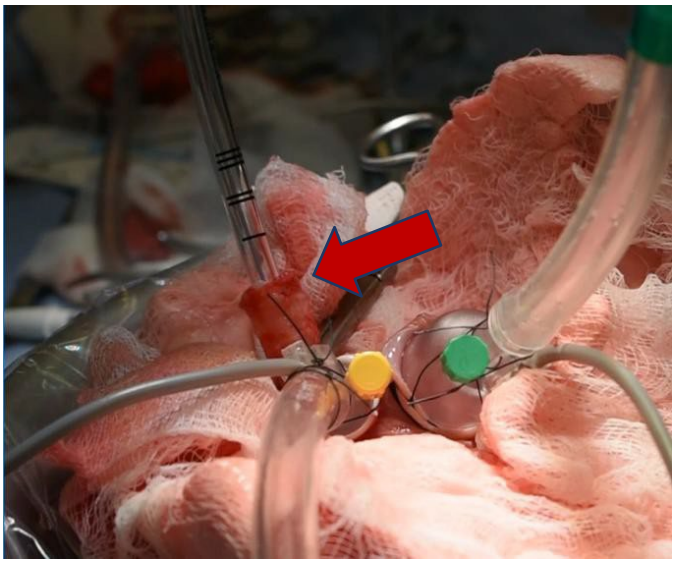
1. Remove the TorEx Lung Perfusion Cannulae from the TorEx Lung Perfusion Kit. Bring the Cannulae to the surgical backtable and remove the TorEx Lung Perfusion PA and LA Cannulae from their packaging.
2. Verify that luer caps are secured to both of the TorEx Lung Perfusion Cannulae.
3. Insert TorEx Lung Perfusion LA Cannula into the Left atrial cuff. Size cannula by trimming the cannula skirt to fit that of the atrium. Once sized, the cannula can be sown onto the atrium using 4-0 prolene.

4. If using optional LA suction cannula (2cm, 3cm or 4cm), attach a ¼" vacuum hose to the vacuum port on the TorEx Lung Perfusion LA Cannula and apply no more than 200 mm Hg of negative pressure. This will aid in keeping the left atrium secured to the TorEx Lung Perfusion LA Cannula.

5. Insert the TorEx Lung Perfusion PA Cannula into the main pulmonary artery. Two snaps holding adjacent ends of the artery can be used to guide the cannula into the artery.



6. Tie the pulmonary artery to the TorEx Lung Perfusion PA Cannula using silk ties.
7. Place a kocher proximal to the main bifurcation to maintain lung inflation, prior to removal of surgical staple line (placed during organ retrieval). This is to prevent lung deflation during ex vivo intubation.
8. Remove cuff from endotracheal tube (if present). This will allow better placement of the endotracheal tube. Insert the endotracheal tube into the trachea.



9. Tie the endotracheal tube to the trachea using silk ties.
10. Place a tubing clamp on the endotracheal tube and remove kocher.
11. Once complete, perform a 1L retrograde flush by flushing cold lung preservation solution through an IV infusion line into the LA cannula. This step is required to clear residual debris in the lung and check for leaking from the cannulation points. Table 4 shows the volumes to be used for single/double lungs before/after perfusion.
12. Remove the luer caps on the hydrostatic ports of the LA and PA cannulae.

13. Attach a hydrostatic extension line (supplied within the TorEx Lung Perfusion Accessories Kit) to both of the LA and PA hydrostatic ports.

Table 4: Pre-EVLP and Post-EVLP Cold Flush Volumes

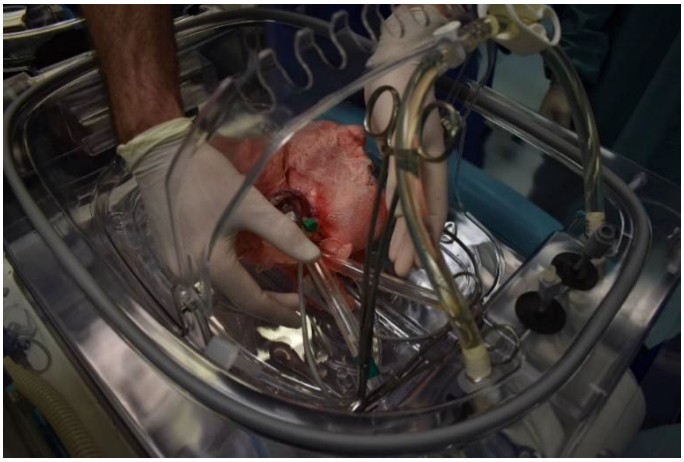
	Pre-EVLP Retrograde	Post-EVLP Anterograde
Double Lung	1	2
Single Lung	0.5	1

Connection of lung to the TorEx Lung Perfusion circuit

⚠ WARNING

All interaction with the lung or any components within the organ chamber must be performed by a sterile user

1. Open the cover of the organ chamber on the TorEx Lung Perfusion Organ Chamber by pulling the latch at the front of the organ chamber upwards and outwards and lifting the lid.
2. Adjust the tube holder on the lung tray so that it is pointing roughly straight up. Lock it in position using the thumbs nuts on the tube holder.
3. Carefully place the lung(s) on the lung tray within the organ chamber.



⚠ WARNING

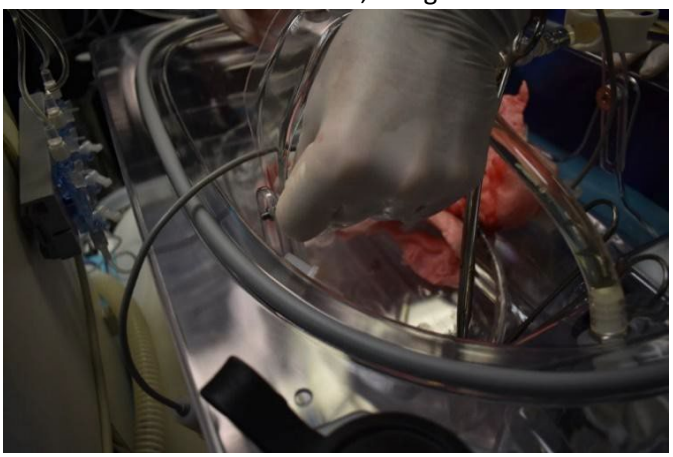
Ensure that the trachea is not twisted or kinked and that the endotracheal tube is pointing towards the ET tube connection in the Organ Chamber.

4. Tilt the TorEx Lung Perfusion LA and PA Cannulae downwards and drain any liquid from the TorEx Lung Perfusion LA and PA cannulae, then position the TorEx Lung Perfusion LA and PA Cannulae upright.

⚠ WARNING

Any liquid in the TorEx Lung Perfusion Cannulae may cause inaccurate zeroing of the pressure sensors. If any liquid is noted in the TorEx Lung Perfusion Cannulae, then redo this step.

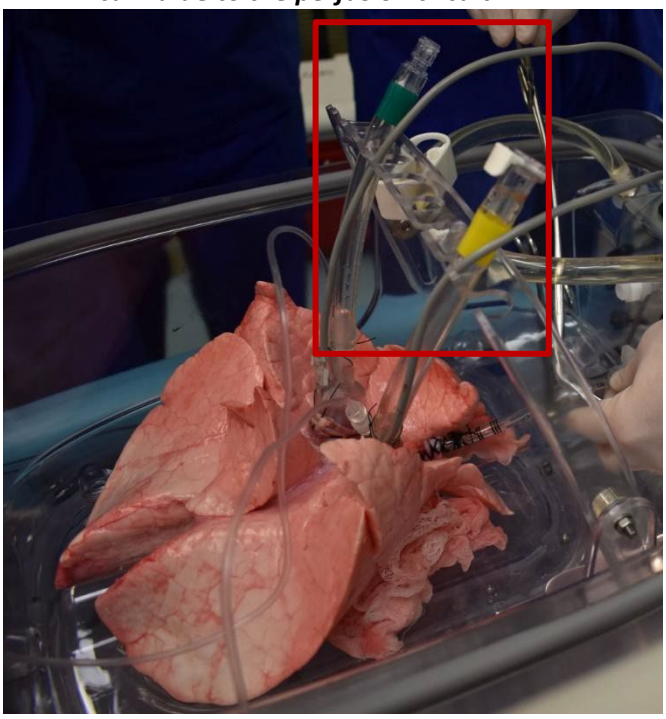
5. If necessary, adjust the tube holder on the lung tray such that it can hold the TorEx Lung Perfusion LA and PA Cannulae, using the thumb screws on the tube holder.



6. Slide the TorEx Lung Perfusion Cannulae tubing into the tube holder, ensuring that that they hold the TorEx Lung Perfusion Cannula with a slight tension at an angle of approximately 70 degrees.

⚠ WARNING

Do not apply excessive force to the cannulae or to the lung tissue when connecting the cannulae to the perfusion circuit.



NOTICE

Ensure there is a slight tension on the TorEx Lung Perfusion Cannulae, causing a 'tenting' of the lung tissue attached to the TorEx Lung Perfusion Cannulae. This will promote proper perfusate flow in and out of the lung.

7. Connect the LA and PA hydrostatic extension lines to the LA and PA hydrostatic sensors, respectively. Set up the hydrostatic sensors to an applicable patient monitoring system according to the manufacturer's instructions.
8. Flush the hydrostatic extension lines and pressure sensors with sterile saline and ensure no air bubbles are present in the lines.

⚠ WARNING

Ensure there is no air in the lines and ensure that the hydrostatic pressure sensors are zeroed.

9. On the TorEx Lung Perfusion Software, press the 'Run Perfusion' button and confirm.
10. On the Patient monitoring system, verify that the LA and PA pressure sensors show a pressure reading. Align the height of the hydrostatic pressure sensors with the mid-point of the lung.
11. Zero the hydrostatic pressure sensors according to the manufacturer's instructions. If a pressure reading is not present, disconnect and reconnect the pressure sensor cable.

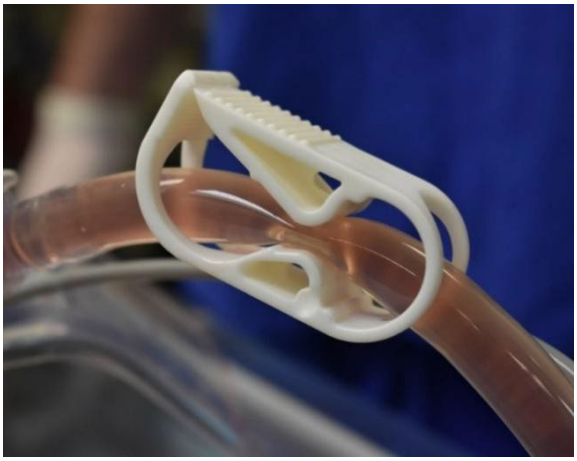
NOTICE

Ensure the PA hydrostatic sensor is connected to the PA cannula, and the LA hydrostatic sensor is connected to the LA cannula.

NOTICE

The next steps require 2 people. The first to control the Perfusion Console and the variable valve and the second to manage the lung and the connections.

12. Slowly turn the LA pressure control knob clockwise, until a flowrate of 500 mL/min is achieved.
13. Occlude the LA branch in the Organ Chamber using LA clamp.



14. Disconnect the PA branch from the LA branch and verify that the fluid column in the LA branch does not drain.
15. Hold the PA branch above the PA Cannula quick connect and allow the perfusate to flow from the PA branch into the TorEx Lung Perfusion PA Cannula.

NOTICE

DO NOT connect the TorEx Lung Perfusion PA Cannula until the line is completely de-aired.

16. Position the quick connects to minimize fluid leakage to the organ chamber.
17. Using the perfusion control knob, maintain the flowrate at 200 mL/min. Adjust pump speed as necessary to completely de-air the TorEx Lung Perfusion Cannulae.
18. The TorEx Lung Perfusion PA Cannula tubing will slowly fill with perfusate. Perfusate will also begin to fill the TorEx Lung Perfusion LA Cannula tubing.

19. When the TorEx Lung Perfusion PA Cannula tubing is full of perfusate, connect the PA branch tubing to the TorEx Lung Perfusion PA Cannula tubing. Verify that the quick connect clicks into position.

NOTICE

Minimize the amount of air in the TorEx Lung Perfusion Cannulae tubing. If air remains within the PA cannula, disconnect the quick connect and attempt to de-air again.

20. Direct perfusate flow from the LA cannula into the LA branch until the LA branch is fully de-aired.

21. Connect the LA cannula to the LA branch. Verify that the quick connect clicks into position.

NOTICE

Minimize the amount of air in the TorEx Lung Perfusion Cannulae tubing.

22. Release the LA clamp on the LA branch and return pump speed to 2000 RPM.
23. Adjust the flowrate on the Perfusion console to the 10% of the max flow-rate value, as calculated in 'Table B. EVLP Parameters to be calculated'.
24. Adjust the variable valve to obtain an LA Pressure of 3-5 mm Hg (read from patient monitor)

NOTICE

Avoid excessive LA pressures when increasing the flow during the ramp-up phase. When increasing the flow, first open the LA variable valve slightly, increase the pump speed in small increments of 100 rpm, and re-adjust the LA variable valve.

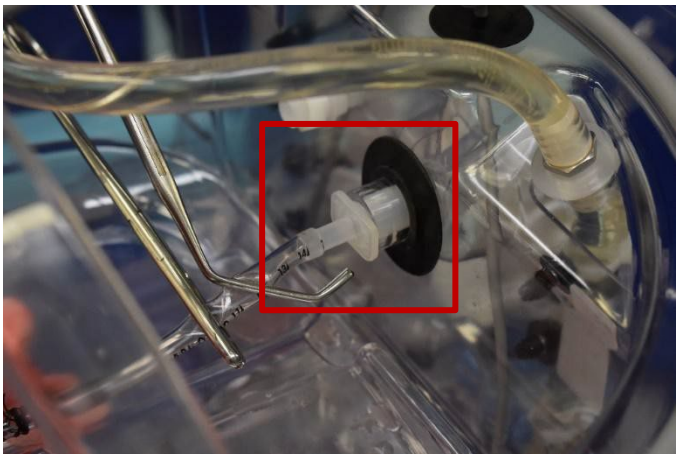
25. Press Timer 1 on the Perfusion Console to start the elapsed perfusion timer. All instructions will now be based on the timing from this timer.

SUPPLEMENTARY INFO

A positive atrial pressure during EVLP leads to better vascular perfusion, reducing lung edema formation when using an acellular perfusate (Linacre V et al. JHLT, 2016).

Endotracheal Tube Connection

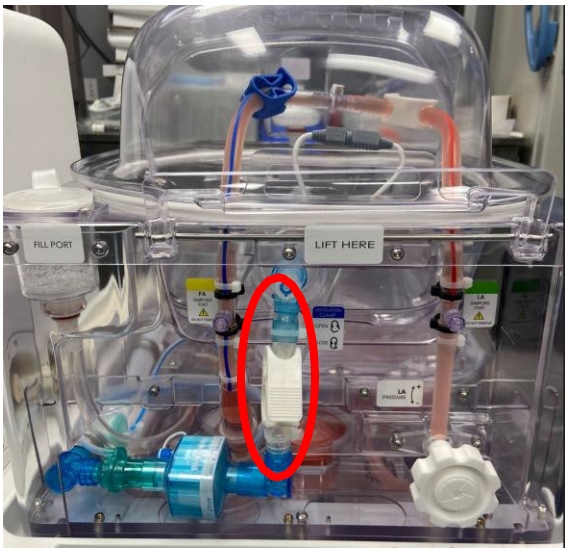
1. If needed, trim the endotracheal tube connected to the lung to ensure that it can connect to the TorEx Lung Perfusion Organ Chamber ventilation tube without causing tension on the lung. Ensure to cut distal from the tubing clamp to prevent deflation of the lung.
    a. Remove mouthpiece of endotracheal tube
    b. Cut the tubing to an appropriate length to ensure the lungs are not too proximal (to avoid squishing the upper lobe) or distal (to allow the lungs to fit within the lung tray) to the ventilator connection
    c. After cutting to size, replace the mouthpiece onto the endotracheal tube.
2. Connect the endotracheal tube to the TorEx Lung Perfusion Organ Chamber



3. Engage the ventilation clamp on the ventilation tube.

NOTICE

Ensure that the ventilation clamp is fully engaged before proceeding.



4. Once the endotracheal tube and ventilation tube are connected, and the ventilation clamp is in place, remove any surgical clamps on the endotracheal tube.

System Ramp-Up

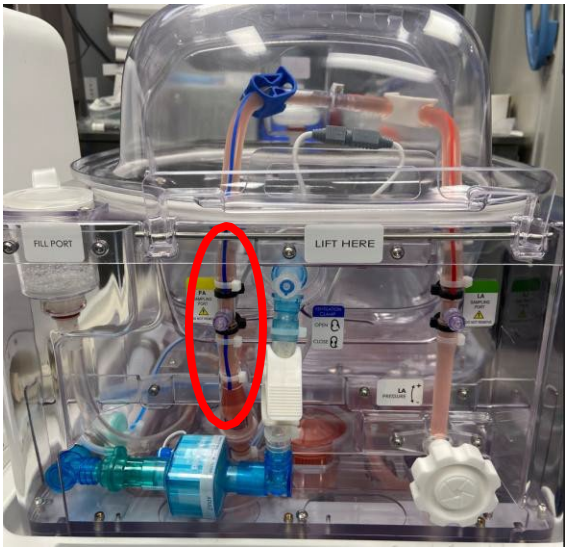
Table 5: Summary of Strategy for Initiation of Ex vivo Lung Perfusion

	Perfusion time						
	0	10	20	30	40	50	55
Perfusion temperature (°C)	21	30	32	37	37	37	37
Flow (% calculated of total)	10	20	30	50	80	100	100
Ventilation			Start				
Gas exchanger			Start				
Left atrium pressure (mm Hg)	3-5	3-5	3-5	3-5	3-5	3-5	3-5
Assessment							Start

1. Check for any leaks in the fluid circuit, and in the TorEx Lung Perfusion Cannulae to perfusion circuit connection. See the 'Troubleshooting'' section If any leaks are observed.
2. At the 00:10 mark on the perfusion clock:
    a. On the Perfusion console, set the flow-rate to 20% of the Maximum Flow-Rate value, as calculated in 'Table 2. EVLP Parameters to be calculated'.
    b. Re-adjust the variable valve to obtain a reading of 3-5 mm Hg on the LA sensor.
    c. Set the temperature to 30 °C on the external heater/cooler as per the manufacturer's instructions.
3. At the 00:20 mark on the perfusion clock:
    a. On the Perfusion console, set the flow-rate to 30% of the Maximum Flow-Rate value, as calculated in 'Table 2. EVLP Parameters to be calculated'.
    b. Re-adjust variable valve to achieve 3-5 mm Hg on the LA sensor.
    c. Set the temperature to 32 °C on the external heater/cooler as per the manufacturer's instructions.
4. On the BELLAVISTA® 1000 ventilator, input the ***Normal*** Ventilation Parameters, as calculated in 'Table 2. EVLP Parameters to be calculated'.
    a. Select the human lung profile.
    b. Press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO_2) to 21% on ventilator by moving the sliding bar until it reads 21%, then press 'Apply'.
    c. Press the 'Vt_{insp}' button. Adjust the tidal volume to the value calculated by moving the sliding bar until it reads the desired value, then press 'Apply'.
    d. Press the 'PEEP' button. Adjust the ***positive end-expiratory pressure*** to the value calculated by moving the sliding bar until it reads the desired value, then press 'Apply'.
    e. Press the 'Rate' button. Adjust the respiratory rate to '7' by moving the sliding bar until it reads '7', then press 'Apply'.
5. Once perfusate temperature reaches 32°C, press the 'Start Ventilation' button on the BELLAVISTA® 1000 ventilator.
6. Start the flow of EVLP gas from the gas tank. Set the EVLP gas pressure to 3 bar, and flow-rate to 0.8 L/min using the EVLP gas flow meter on the back of the TorEx Lung Perfusion Cart. If using

an external supply of EVLP gas with a flow regulator, open the external flowmeter fully and use the onboard flowmeter to set the flow-rate.

7. Release the ventilation clamp on the ventilation tube. After at least one minute, examine the donor lung for any leaks and tears. See the 'Troubleshooting' section if leaks or tears are observed.
8. Close the Organ Chamber lid and secure the latch.
9. At the 00:30 mark on the perfusion clock:
    a. On the Perfusion Console, set the flow-rate to 50% of the Maximum Flow-Rate value, as calculated in 'Table 2. EVLP Parameters to be calculated'.
    b. Re-adjust the variable valve to achieve 3-5 mm Hg on the LA sensor
    c. Set the temperature to 37 °C on the heater/cooler as per the manufacturer's instructions.
10. Label one sample collection syringe with the sampling port and time of sampling.
11. Remove the cap from one sample collection syringe and withdraw a perfusate sample from the PA sample port by inserting the syringe. Pull back the plunger, ensuring that an amount of perfusate compatible with the Blood/Gas Analyzer is withdrawn (typically 2 mL).



12. Cap the syringe once the sample is drawn.
13. Perform blood gas analysis using an external (not supplied) blood gas analyzer. Refer to the blood gas analyzer's Instructions for Use if needed.

NOTICE

The target PA pCO2 level is between 35 and 45 mm Hg. Depending upon the pCO2 level, adjust EVLP gas flow-rate by no more than 1 L/min. The pCO2 level can be evaluated and further adjusted at the 1-hour mark on the perfusion clock.

14. At the 00:40 mark on the perfusion clock:
    a. On the Perfusion console, set the flow-rate to 80% of the Maximum Flow-Rate value, as calculated in 'Table 2. EVLP Parameters to be calculated'.
    b. Re-adjust the variable valve to achieve 3-5 mm Hg on the LA sensor.
15. At the 00:50 mark on the perfusion clock:

a. On the Perfusion console, set the flow-rate to 100% of the Maximum Flow-Rate value, as calculated in the 'Table 2. EVLP Parameters to be calculated' section.
b. Re-adjust variable valve to achieve 3-5 mm Hg on the LA sensor.

16. At the 00:55 mark, note the LA pressure, PA pressure, perfusion circuit flow, and perfusate volume loss according to the graduated marks on the perfusate reservoir.
17. At the 00:55 mark on the perfusion clock, set the ***Assessment*** Ventilation Parameters, as calculated in the 'Table 2. EVLP Parameters to be calculated' section;
    a. On the BELLAVISTA® 1000 ventilator, press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO_2) to 100% on ventilator by moving the sliding bar until it reads 100%, then press 'Apply'. Similarly, adjust VT_{insp} and Respiratory rate to the settings shown in Table 3.
18. At the 0:57 mark on the perfusion clock perform an airway assessment. Record peak airway pressure, mean airway pressure, plateau airway pressure, dynamic lung compliance, and static lung compliance.
19. At the 1:00 mark on the perfusion clock, take perfusate samples for blood gas analysis.
    a. Label two sample collection syringes with the sampling port and time of sampling.
    b. Remove the cap from two sample collection syringes and withdraw perfusate samples from both the PA and LA sample ports by inserting the syringe into the luer ports.
    c. Pull back the plunger, ensuring that an amount of perfusate compatible with the Blood/Gas Analyzer is withdrawn (typically 2 mL).
    d. Cap the syringes once the samples are drawn.
20. Perform Blood Gas Analysis using an offline blood gas analyzer. See the manufacturer's instructions for use regarding performing blood gas analysis.
21. On the BELLAVISTA® 1000 ventilator, return to the ***Normal*** ventilation parameters, as calculated in the 'Table 2. EVLP Parameters to be calculated' section;
    a. press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO_2) to 21% on the ventilator by moving the sliding bar until it reads 21%, then press 'Apply'.

SUPPLEMENTARY INFO

Explanatory Table of Lung Assessment Parameters

Peak Airway Pressure	a measure of airway resistance during normal ventilation
Dynamic Lung Compliance	a measure of the lung's elasticity during periods of gas flow (breathing)
Static Lung Compliance	a measure of the lung's elasticity during periods of inspiratory pause
Plateau Airway Pressure	a measure of airway resistance during periods of inspiratory pause
Mean Airway Pressure	the mean pressure applied during ventilation
Delta PaO_2/FiO_2	A measure of the lungs' oxygenation capacity (LA pO_2 – PA pO_2) / Fraction inspired O2
Pulmonary Vascular Resistance	A measure of the lungs' resistance to flow
Perfusate Loss	A measure of lung edema formation

Steady State EVLP

The system is now entering into a steady-state EVLP phase. During steady-state EVLP, the lungs will be assessed and recruited at regular intervals. X-Ray and bronchoscopy will also be performed to provide added assessment data.

The ventilation and perfusion parameters during steady-state EVLP are summarized in the table below.

Steady-State EVLP Settings

Measure	Settings
Tidal volume	7 ml/kg
PEEP	5 cm H_2O
Respiratory rate	7 breaths/min
FiO_2	21%
Flow rate	40% of estimated cardiac output
Left atrial pressure	3–5 mm Hg

During steady-state EVLP, perfusate will be removed periodically from the system, and replaced with fresh perfusate.

NOTICE

The TorEx Lung Perfusion System is indicated for intra-institutional travel only.

Recruitment

At every XX:30 mark on the perfusion clock (after the first hour assessment), perform a recruitment. Refer to the ***Recruitment*** ventilation parameters, as calculated in the 'Table 2. EVLP Parameters to be calculated' section.

1. On the BELLAVISTA® 1000 ventilator, press the 'Cockpit' button, and then press the 'Vt_{Insp}' button.
2. Increase ventilator tidal volume to the ***Recruitment*** value as calculated in the 'Table 2. EVLP Parameters to be calculated' section in 3 to 4 equal, sequential steps. This is accomplished by increasing the tidal volume on the ventilator while the lung is exhaling.

   ⚠ WARNING

   DO NOT increase to the full tidal volume in a single step as it may damage the lung. Do this in 3 to 4 steps.

3. Once you reach the recruitment tidal volume or a P_{Peak} of 25 cm H_2O, whichever comes first, press the 'Main Menu' button on the BELLAVISTA® 1000 ventilator, and then the 'Maneuvers' button.
4. Press the 'Hold $_{Insp}$' button for 10 seconds to perform an inspiratory hold.
5. Wait 3 seconds and repeat. Perform 3 inspiratory hold maneuvers total.

6. Gradually reduce the tidal volume back down to normal tidal volume, as calculated in the 'Table 2. EVLP Parameters to be calculated' section in 3 or 4 steps.

Assessment

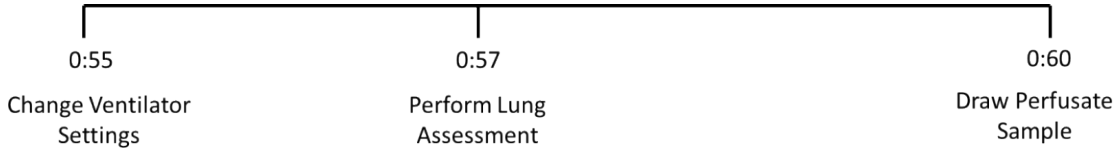


Figure 17: Schema of performing standardized EVLP lung Assessment

1. At the XX:55 mark on the perfusion clock, on the BELLAVISTA® 1000 ventilator, press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO_2) to 100% on ventilator by moving the sliding bar until it reads 100%, adjust the respiratory rate to 10 breaths/min, and increase tidal volume based as calculated in the 'Table 2. EVLP Parameters to be calculated' section in 3 or 4 steps, then press 'Apply'.
2. At every XX:57, perform an assessment:
    a. Record Peak airway pressure, mean airway pressure, dynamic lung compliance, perfusion flow rate, LA and PA pressures.
    b. Perform inspiratory hold for 3 seconds and note plateau airway pressure
    c. Perform an expiratory hold immediately thereafter and note static lung compliance
3. At every XX:60, perform a perfusate analysis:
    a. Label two sample collection syringes with the sampling port (LA or PA) and the time of sampling.
    b. Remove the cap from the two sample collection syringes and withdraw perfusate samples from both the PA and LA sample ports by inserting the syringe.
    c. Pull back the plunger, ensuring that an amount of perfusate compatible with the Blood/Gas Analyzer is withdrawn (typically 2 mL).
    d. Perform blood gas analysis using a blood gas analyzer. See the blood gas analyzer manufacturer's instructions for use regarding performing blood gas analysis.
4. On the BELLAVISTA® 1000 ventilator, return to the ***Normal*** ventilation parameters, as calculated in the 'Table 2. EVLP Parameters to be calculated' section.
5. Press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO_2) to 21% on the ventilator by moving the sliding bar until it reads 21%, adjust respiratory rate to 7 breaths/min and reduce tidal volume to steady-state volume increase tidal volume based as calculated in the 'Table 2. EVLP Parameters to be calculated' section in 3 or 4 steps, then press 'Apply'.

Perfusate Exchange

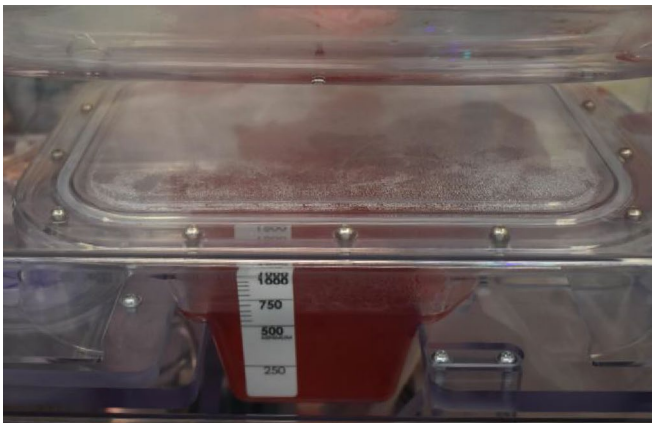
Immediately following an assessment (XX:60), a perfusate exchange should be performed.

Table 6: Standard clinical perfusate exchange protocol

	Perfusate exchange volumes (mL)			
	1st hour	2nd hour	3rd hour	4th hour
Double Lung	500	250	250	250
Single Lung	250	125	125	125

To perform a perfusate exchange:

1. Perform the perfusate drain:
    a. Select the 'DRAIN' button on the Cart Control System screen.
    b. Watch the reservoir.
    c. If unable to drain desired volume, drain only until 500 mL of perfusate remains in the reservoir.



    d. Drain volume as specified.
    e. Once the perfusate has been removed, end the draining by pressing the 'Stop Drain' button on the Cart Control screen.
2. Perform the perfusate top-up;
    a. Add perfusate as specified. Close the lid on the port when done.

NOTICE

Ensure that there is over 500 mL of perfusate in the reservoir at all times. If the level drops below 500 mL, add perfusate by performing the top-up described above. See the 'Troubleshooting' section if perfusate levels are continuously dropping.

Mobility

The TorEx Lung Perfusion System may be moved within the institution during steady-state EVLP.

1. Before moving the system:
    a. Ensure that the TorEx Lung Perfusion Cart is connected to onboard EVLP and O_2 gas tanks.
    b. Ensure the Organ Chamber lid is closed and the lid latch is secure.

⚠ WARNING

Do not open the Organ Chamber lid in a non-sterile environment.

c. Unplug the TorEx Lung Perfusion Cart from the wall and store the power cord on the TorEx Lung Perfusion Cart.
d. Verify on the Cart Control screen that the battery charge is sufficient to allow transporting the Cart.
e. Check the status of the Perfusion Console and the BELLAVISTA® 1000 ventilator and ensure they are operating as expected.
f. Ensure that all the wheel locks are in the unlocked position.

2. Move the TorEx Lung Perfusion System by pushing the TorEx Lung Perfusion Cart, using the handle. A second individual, to guide TorEx Lung Perfusion Cart along the path, may be useful to ensure a smooth movement.

⚠ WARNING

Ensure that the TorEx Lung Perfusion Cart is slowly pushed to prevent the lung from moving.

NOTICE

Monitor the temperature of perfusate during transportation.

NOTICE

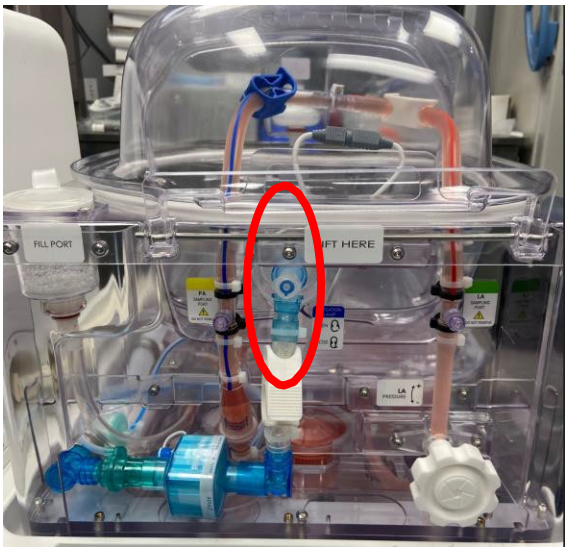
When fully charged, the battery charge will sustain operation for at least 30 minutes.

3. Once the TorEx Lung Perfusion System has arrived at its destination, lock the cart wheels.
4. Plug the TorEx Lung Perfusion System's power cord into the wall. Confirm on the Cart Control screen that the TorEx Lung Perfusion Cart is now operating using mains power.
5. Plug the external heater/cooler into a nearby outlet.
6. If desired, hookup the TorEx Lung Perfusion System to O_2 gas lines within the new area.

X-Ray and Bronchoscopy

At the 1:00 and 3:00 mark on the perfusion clock (or as needed), an X-Ray may be performed. At the 1:30 and 2:30 mark on the perfusion clock (or as needed), a bronchoscopy may be performed. Perform bronchoscopy and X-Ray as per the institution's internal procedures, and the X-Ray and bronchoscope's instructions for use.

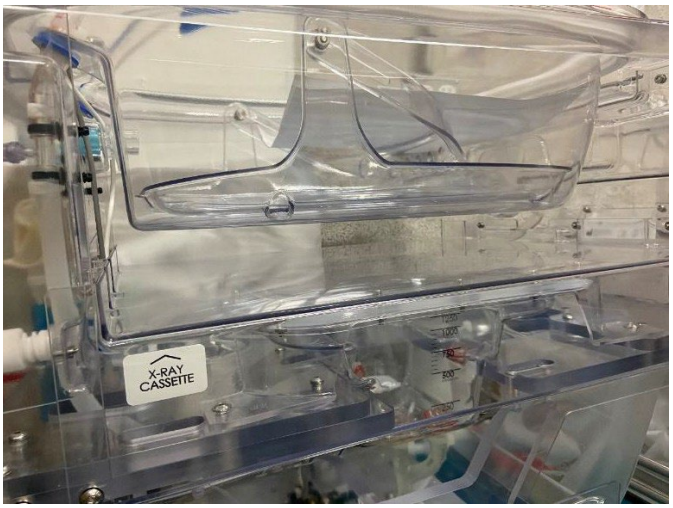
The TorEx Lung Perfusion Organ Chamber is equipped with a bronchoscope port which can be opened to insert a bronchoscope into the lungs via the trachea.



NOTICE

Ensure the bronchoscope port is closed upon completion of the bronchoscopy procedure.

To aid in performing X-Ray photography, the TorEx Lung Perfusion Organ Chamber is equipped with an X-Ray tray slot.

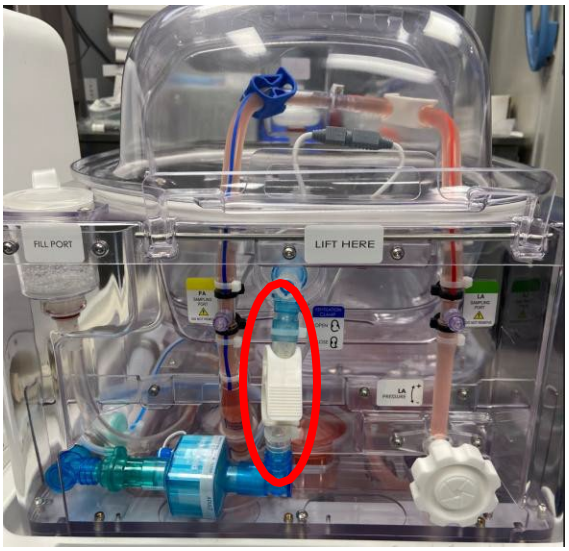


Ending Perfusion

When ready to end the EVLP procedure, perform the following ramp-down steps.

1. On the BELLAVISTA® 1000 ventilator, press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO2) to 50% by moving the sliding bar until it reads 50%.
2. Set the temperature to 10°C as per the heater/cooler's Instructions for Use.
3. Once the perfusate temperature reaches 10°C, stop the perfusate pump. Press the 'Pump' button on the Perfusion console and confirm.
4. On the TorEx Lung Perfusion Organ Chamber, open the variable valve completely.

5. Engage the ventilation clamp on the endotracheal tube while performing an inspiratory hold to close the airway.



6. Ensure the lung is inflated. If the lung is not inflated, disengage the clamp and reattempt.

NOTICE

If the lung is not fully inflated, reattempt to ensure that the clamped lung is fully inflated.

7. Apply an additional external tubing clamp to the lung's trachea to ensure the lung remains inflated after removal from the system.
8. On the BELLAVISTA® 1000 ventilator, press the 'Ventilation' button, and then press the 'Stop Ventilation' button. Slide the arrow as instructed to stop ventilation.
9. Open the TorEx Lung Perfusion Organ Chamber and disconnect the electrical connections.
10. Fully occlude the LA and PA branches using the clamps.

⚠ WARNING

The perfusion pump must be stopped before clamping the LA and PA branches, to avoid harmful pressure inside the perfusion circuit.

11. Disconnect the TorEx Lung Perfusion LA and PA Cannulae from the Organ Chamber perfusate circuit connections. Disconnect the hydrostatic pressure lines.
12. Remove the lung from the TorEx Lung Perfusion Organ Chamber, and place on a surgical backtable.
13. Obtain lung preservation solution stored at 2-8°C.
14. Perform post-EVLP anterograde flush (Table 4) by connecting a bulb syringe directly to the TorEx Lung Perfusion PA Cannula and introduce the preservation solution by pouring it slowly through a pour spout.
15. Disconnect the TorEx Lung Perfusion Cannulae from the lung by cutting the silk ties.
16. Using a surgical stapler, staple the trachea closed to keep the lungs inflated.
17. Prepare the lungs for transport/storage as per hospital procedure.

Emergency Procedure

In case of an equipment failure, or if a perfusion needs to be ended prematurely, an emergency stop procedure may be executed as follows.

1. Clamp the endotracheal tube:
    a. If the cause of the emergency procedure is failure of the ventilator, then immediately engage the ventilation clamp on the endotracheal tube. If the ventilator is still functioning, press the 'Cockpit' button, and then press the 'Oxygen %' button. Adjust the Oxygen (FiO_2) to 50% by moving the sliding bar until it reads 50%.
    b. Ensure that the lung is inflated. Press the 'Main Menu' button on the BELLAVISTA® 1000 ventilator, and then the 'Maneuvers' button. Press the 'Hold $_{Insp}$' button and immediately engage the airway clamp. If the lung is not inflated, disengage the clamp and reattempt.
2. Apply an additional external tubing clamp to the lung's endotracheal tube to maintain inflation of the lung.
3. Turn off the ventilator, if still functioning.
    a. On the BELLAVISTA® 1000 ventilator, press the 'Ventilation' button, and then press the 'Stop Ventilation' button.
    b. Slide the arrow as instructed to stop ventilation.
4. Turn off the heater/cooler unit if it is still functioning.
5. If the Perfusion console is still functioning, turn off the pump by pressing the 'Pump' button on the Perfusion console, and then press the green check on the screen when the 'Stop the Pump' indicator appears.
6. On the TorEx Lung Perfusion Organ Chamber, open the variable valve completely.
7. Open the Organ Chamber and disconnect the LA and PA Cannulae electrical cables.
8. Disconnect the LA and PA Cannulae from the perfusate circuit.
9. Place lung onto a surgical backtable/sterile field.
10. Attach a bag of cold lung preservation solution directly to a pour spout and slowly pour the preservation solution into the lung via a bulb syringe through the TorEx Lung Perfusion PA Cannula. Recommended volumes are found in Table 4.
11. Remove TorEx Lung Perfusion Cannulae from the lung by cutting the silk ties.
12. Using the surgical stapler, staple the trachea closed to keep the lungs inflated.
13. Prepare the lungs for transport as per hospital procedure.

Cart Shutdown

Once the perfused lung has been removed from the TorEx Lung Perfusion System, the used TorEx Lung Perfusion Organ Chamber and TorEx Lung Perfusion Cannulae can be disposed of, and preparation of the TorEx Lung Perfusion Cart for next use can begin.

⚠ WARNING

Used TorEx Lung Perfusion Organ Chamber, TorEx Lung Perfusion LA and PA Cannulae, and perfusate are considered biohazardous waste. Handle all biohazardous waste in accordance with the institution's policies and procedures.

1. Press the ‘End perfusion’ button on the TorEx Lung Perfusion Software to drain the perfusate into the waste reservoir.
2. Turn off the flow of EVLP and Oxygen gas and unhook any external EVLP and O_2 gas lines from the back of the TorEx Lung Perfusion Cart.
3. Disconnect the ventilation tube from the Organ Chamber.
4. Obtain a biohazardous container for fluid and the TorEx Lung Perfusion Drain Kit.
5. Remove the drain port cover, shown below, and connect the drain kit to the waste reservoir quick connect.

6. Direct the waste perfusate flow into the biohazardous container. To stop the flow, engage the clamp on the drain kit tubing.
7. Once draining is complete, remove the drain hose and dispose in the biohazardous waste as per the institution’s procedures.
8. Once all the perfusate has been drained, press ‘Idle Cart’ on the Cart Control screen to reset all valves to their idle state.
9. Drain the water out of the external heater/cooler as per the manufacturer’s instructions to ensure that water is not in the TorEx Lung Perfusion Cart’s heater/cooler tubing.
10. Disconnect the ventilation hose from the back of the Organ Chamber.
11. Unlock the organ chamber by pulling the two locking rods.
12. Press the flow sensor release latch and ensure the sensor lid remains open
13. Carefully lift the organ chamber off the cart’s interface; observe the flow sensor interface to ensure that the tubing is not caught by the flow sensor lid.
14. Remove the TorEx Lung Perfusion Organ Chamber from the TorEx Lung Perfusion Cart and dispose in the biohazardous waste as per the institution’s procedures.

> **⚠ WARNING**
>
> ***The weight of the TorEx Lung Perfusion Organ Chamber will have increased due to liquid inclusion during the EVLP procedure. Utilize two able-bodied personnel to lift and remove the TorEx Lung perfusion Organ Chamber.***

15. Dispose of the used TorEx Lung Perfusion Cannulae as biohazardous waste as per the institution’s procedures.
16. Open the drip tray holder and discard the drip tray liner as biohazardous waste

17. On the Cart Control screen, check the status of the battery. If the battery is not at 100%, it is recommended that the TorEx Lung Perfusion Cart be connected to mains power. Once the battery is fully charged, the power cable can be disconnected.

NOTICE

Disconnect the power cable to ensure that the TorEx Lung Perfusion Cart is isolated from mains power.

Performance Characteristics

1. Physical characteristics – Cart (Uncrated)
    - Dimensions: Length 132 cm (52 in); Width 80 cm (32 in); Height 119 cm (47 in)
    - Weight: 199 kg (439 lb) unloaded
      220 kg (485 lb) with Organ Chamber, lungs and perfusate
    - Lifetime: 10 years
2. Physical characteristics – Organ Chamber (unpackaged)
    - Dimensions: Length 60 cm (24 in); Width 44 cm (18 in); Height 63 cm (25 in)
    - Weight: 17 kg (37 lb)
    - Sterility: Provided sterile (sterilized with Ethylene Oxide)
3. Power and gas supply requirements
    - Voltage: 115 Vac
    - Frequency: 60 Hz
    - Power: 450 VA
    - Fuses: T6.30A-H(L)
      (located inside isolation transformer, not accessible by user)
    - Gas supply
        - O2 connection: DISS 1240 male
        - O2 (onboard): Size E cylinder
        - O2 (external): Max. pressure 7 bar (101 psi)
          Flow 2.2 l/min
        - EVLP gas composition: 86% N2, 8% CO2, 6% O2
        - EVLP gas connection DISS 2220 male

      Note: DISS 2220 female to ¼" barb connector is supplied with the cart.

        - EVLP gas (onboard): Size E cylinder
        - EVLP gas (external): Max. pressure 7 bar (101 psi)
          Flow 2.2 l/min

4. Water supply for heating and cooling the lungs
    - Heating/cooling liquid: Water
    - Temperature: 10 to 40°C (50 to 104°F)
    - Maximum pressure: 1 bar (14 psi)
    - Minimum flow: 2 l/min (0.5 gal/min)
5. Patient monitor (including hydrostatic sensors)
    - Sensor type: Hydrostatic
    - Pressure range: -20 to 100 mm Hg
    - Resolution: 1 mm Hg or better
6. Environment
    - Operating ambient temperature: 17 to 24°C (63 to 75°F)
    - Operating ambient humidity: 20 to 80%
    - Storage temperature (Cart, Organ Chamber): 5 to 40°C (41 to 104°F)
    - Storage humidity (Cart): 20 to 90%
    - Storage humidity (Organ Chamber): 0 to 80%
    - Operating and storage pressure: 70 to 106 kPa (20.7 to 31.3 in Hg)
    - Operating altitude 0 to 2000 m (6560 ft)
7. Measurements
    - PA flow: Range 0 to 3500 mL/min
      Resolution 100 mL/min
    - Perfusate Temperature: Range 5 to 42°C
      Resolution 1°C
      Accuracy better than 1°C
    - EVLP gas flow: Range 0 to 2.2 L/min
      Resolution 0.2 L/min
      Accuracy 0.2 L/min
    - Tidal volume: Range 0 to 1200 mL
      Resolution 1 mL
      Accuracy 10%
    - Peak airway pressure, plateau airway pressure and mean airway pressure:
      Range 0 to 70 cm H2O
      Resolution 1 cm H2O
      Accuracy 6 cm H2O
    - Static lung compliance
      Range 0 to 1000 mL/mbar
      Resolution 1 mL/mbar
8. Control ranges
    - Perfusion flow 0 to 3500 mL/min
    - LA pressure 0 to 10 mm Hg
    - Breath rate 7 to 10 bpm
    - Tidal volume 0 to 1200 mL

- Positive End-Expiration Pressure (PEEP) 0 to 10 cm H2O

9. Electrical safety

   - Protection Class I
   - Applied Parts Type BF

10. Battery

    - TorEx Lung Perfusion Cart battery
      Model K2B12V19EB, 12 V, 19 Ah, LiFePO4.
      Provides at least 30 min of operation while Cart is disconnected from mains. Battery is charged automatically by the TorEx Lung Perfusion Cart when it is connected to mains power.

11. Miscellaneous

    - Protection against liquid ingress (Cart)
      IPX0
    - No part of the system contains latex

Maintenance and Cleaning

Maintenance

To ensure that the TorEx Lung Perfusion Cart is ready for operation, the following maintenance activities should be performed.

TorEx Lung Perfusion Cart

Action	Interval	Procedure
General Inspection	Before each use	Inspect the outer panels, the casters, and the gas regulators for any damage. Check the Cart-Organ Chamber interface for any damage, dirt, debris or liquid spills. If any damage is found, do not use the System and contract Traferox's customer support.
Cleaning	After each use	See Cart Cleaning and Disinfection.
Full maintenance and inspection of the unit	Every 6 months	This must be performed by Traferox's trained service personnel.

The following components of the TorEx Lung Perfusion Cart require specific maintenance.

Perfusion Console

Action	Interval	Procedure
Control panel inspection	Before each use	Check touchscreen for damage (scratches or cracks). Contact Traferox's customer support if the control panel is defective.
Air filter cleaning	Every 6 months	This must be performed by Traferox's trained service personnel. The air filter is located on the bottom of the lung

		perfusion power supply unit and cannot be accessed by the user.
Full maintenance and inspection of the perfusion console	Every 6 months	This must be performed by Traferox's trained service personnel.

BELLAVISTA® 1000 Ventilator

Action	Interval	Procedure
Replacing filters	Every 6 months	This must be performed by Traferox's trained service personnel. The blower inlet filter and the cooling fan inlet filter must be replaced. It is necessary to open the TorEx Lung Perfusion Cart to access the filters.
Full maintenance and inspection of the ventilator	Every 6 months	This must be performed by Traferox's trained service personnel. The brass filter must be replaced at that time also.

TorEx Lung Perfusion Cart heater/cooler circuit maintenance and disinfection

Refer to manufacturer's instructions on how to maintain the external heater/cooler system.

Action	Interval	Procedure
Disinfection of connections and fittings	Before connection and after disconnection	Clean and disinfect external surfaces, connectors, and fittings
Disinfection of internal connections and tubing	Every week	Place the Heater/Cooler cleaning jig (402-0081) onto the interface area and lock in place. With Heater/Cooler connected to the Cart, follow the Heater/Cooler system disinfection protocol.
Emptying the Heater/Cooler circuit tubing	Before storage	Place the Heater/Cooler cleaning jig (402-0081) onto the interface area and lock in place. With the Heater/Cooler disconnected from the Cart, connect a pressurized air source to the Heater/Cooler inlet connector to blow out residual liquid
Full maintenance and inspection of the Heater/Cooler Circuit	Every 6 months	This must be performed by Traferox's trained service personnel. The Heater/Cooler tubing lines will be replaced.

Cart Cleaning and Disinfection

Preparation before cleaning	1. Cleaning procedures should begin as soon as possible following Cart Shutdown. 2. Prevent soil from drying. 3. Remove any excess soil by wiping with a non-linting wipe on accessible areas of the Cart.
Cleaning Instructions	1. Prepare an enzymatic detergent solution (e.g., Dr. Weigert MultiZym, Steris Prolystica) according to the manufacturer's instructions. 2. Use a clean lint-free cloth moistened with the enzymatic detergent solution to clean the Cart exterior surfaces and organ chamber interface. Wipe down all surfaces of the TorEx Lung Perfusion Cart. Ensure that all surfaces that have

	come in contact with potentially biohazardous material are thoroughly wiped. Use the larger end of the double-ended brush provided to loosen hard-to-remove soil. 3. Use lint-free cloth moistened with RO water to rinse the Cart surfaces. Wipe down all surfaces. Use another RO water moistened lint-free cloth to wipe down all surfaces and ensure removal of residual detergent. 4. Use a dry clean lint-free cloth to wipe and dry all surfaces. The smaller end of the double-ended brush can be covered with a lint-free cloth and used to dry crevices and other small features. Allow all surfaces to dry completely for at least 5 minutes before moving onto the disinfection step.
Visual Inspection	Inspect surfaces for cleanliness. If visible soil remains, re-clean device following the cleaning instructions above.
Disinfection	1. Spray CaviCide 1 (Metrex) on Cart surfaces. 2. Allow disinfectant contact time of minimum 3 minutes. 3. Wipe all surfaces with disinfectant CaviWipes.
Drying	1. Allow Cart to air dry under ambient conditions. 2. Place the manifold dust shield (520-0048) on top of the TorEx Lung Perfusion Cart

Troubleshooting

Cart Set-up	
Perfusion console fails self-test	1. Repeat the self-test procedure 2. Consult the manufacturer manual to troubleshoot.
Cart fails self-test	1. Ensure a TorEx Lung Perfusion Organ Chamber is not attached to the TorEx Lung Perfusion Cart 2. Inspect the valves to ensure nothing is blocking their operation 3. Reboot the Cart Control screen and redo the self-test. 4. Contact Traferox technical support if the issue persists.
BELLAVISTA® 1000 ventilator fails self-test	1. Repeat the self-test procedure. 2. Consult the manufacturer manual to troubleshoot.
Organ Chamber Engagement	
Tubing not bubble-free during the ramp-up procedure	1. Turn the speed of the Perfusion console pump back to zero. 2. Repeat instructions 8 to 12 of the System Priming and De-Airing section.
During the Perfusion console start-up, the 'T1', 'Flow', and 'Motor' boxes are not green.	1. Ensure the TorEx Lung Perfusion Organ Chamber is fully engaged. 2. Contact Traferox technical support if the issue persists.
Flow sensor not detecting perfusion flow	1. Remove Organ chamber 2. Add lubricant or alcohol to flow sensor 3. Re-attempt to engage Organ Chamber until a flow reading is displayed
Leak is observed at a connection in the perfusion circuit.	1. If possible, apply one of the provided zip ties to the leaking connection. The zip tie should be placed on the tubing over the connector. Apply as much force as required to stop the leak.
Cannulation	

Electrical connections on the TorEx Lung Perfusion LA and PA Cannulae are exposed to liquid.	1. Since liquid ingress may damage the electrical connections, retrieve a new Cannula, and ensure that the caps on the electrical connections are tight. 2. If additional Cannula are not available, use hydrostatic pressure readings for monitoring LA and PA pressure.
Steady-state EVLP	
Leaks or tears in the lungs are observed during the start of perfusion and ventilation	1. If small leaks are observed, monitor the volume of perfusate in the reservoir and ensure that the volume in the reservoir stays above 500 mL. Increase the frequency of perfusate solution addition. 2. If a large leak is observed, consult with the surgical team to determine if re-attachment of the cannulae or surgical repair of the lung are required.
Perfusate level in reservoir drops below 500 mL	1. Ensure the Cart Control system is in the proper mode ('Run perfusion' if in steady-state EVLP), and that the system is not in the 'Drain' sub-mode. 2. Look for leaks in tears in the lung-to-Cannulae connections. 3. Monitor the volume of perfusate in the reservoir and ensure that the volume in the reservoir stays above 500 mL. 4. If necessary, add more perfusate.
Excess air bubbles observed in perfusion circuit	1. Clamp PA branch, the clamp LA branch 2. Disconnect lung from circuit using quick connects. 3. Connect PA branch to LA branch 4. Repeat de-airing process as per System Priming and De-Airing.

Residual risks

The TorEx Lung Perfusion System has been designed to reduce all risks to the user and patients as far as possible. The following risks remain when using the system. The user should be mindful of these risks when using the system in clinical practice.

Hazard	Harm	Potential cause
Pathogens on Cart or outside of Organ Chamber.	Infection, lungs exposed to pathogens, recipient at risk.	Pathogens picked up during intra-hospital transport.
Incorrect perfusate flow rates.	Damage to lung tissue or vasculature.	The user calculates the wrong target flow, or the user does not set the pump speed correctly to achieve the intended flow.
High perfusate pressure applied to lungs.	Damage to lung vasculature.	User does not adjust the valve to achieve proper LA pressure.
Inadequate ventilation parameters.	Damage to lung alveoli.	User miscalculates ventilation parameters and sets too high tidal volume.
Inadequate ventilation or perfusion parameters	Injury to lung, or improper assessment of lungs.	User forgets to start ventilation or to ramp up perfusion flow and temperature as specified in the EVLP protocol.

Hazard	Harm	Potential cause
EVLP gas not delivered to oxygenator.	Injury to lung, or improper assessment of lungs.	EVLP gas source not connected; EVLP cylinder valve is not opened; EVLP gas cylinder is empty; EVLP gas flow controller is set to no flow.
High Tidal Volume	Injury to lung, or improper assessment of lungs.	User forgets to change default tidal volume

Clinical Performance

A. Expanded Retrospective Real-World Evidence Using the TorEx Lung Perfusion System

A large-scale retrospective real-world evidence analysis was conducted to characterize the observed outcomes, safety and performance of the TorEx Lung Perfusion System in routine clinical practice. The analysis included 221 patients who received lungs assessed with the TorEx system and 379 patients who underwent transplantation without EVLP. The TorEx Study was conducted using either STEEN Solution or TorEx Lung Perfusate (TLP). Specifically, 203 patients (91.9%) were perfused using STEEN Solution and 18 patients (8.1%) were perfused using TLP. The study was conducted at a high-volume transplant center to provide information regarding post-transplant outcomes observed in real-world clinical data.

The occurrence of PGD3 at 72 hours was evaluated across both groups. PGD3 occurred in 16/204 (7.8%) of patients in the TorEx group compared to 38/349 (10.9%) in the non-EVLP control group. Overall survival was comparable between groups, with a 1-year survival rate of 132/161 (82.0%) in the TorEx group and 231/283 (81.6%) in the non-EVLP control group. Secondary clinical outcomes, including duration of mechanical ventilation, ICU length of stay, and hospital length of stay, were also comparable between groups.

The racial distribution in the TorEx group was 68.7% White, 1.8% Black, 4.1% Asian, and 25.3% other races. Ethnicity was reported with 0.9% of TorEx group participants who identified as Hispanic/Latino and 21.7% categorized as Unknown/Not Reported. The device is intended for use across diverse patient populations, and the demographic reporting is provided to support transparency and assessment of applicability.

Manufacturer Information

Company Name	Traferox Technologies Inc.
Address	3505 Laird Road, Unit 16, Mississauga, Ontario, L5L 5Y7, Canada
Email	info@traferox.com
Customer Support	support@traferox.com
Website	www.traferox.com

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