TRAFERX

TorEx Lung Perfusion System

Instructions for Use

English

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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.

Before attempting to operate the equipment, read this manual thoroughly, paying particular attention to all WARNINGS and NOTICES incorporated in it.

These Instructions for Use may describe some products, features, or configurations that are not available in all countries. Please contact your local representative for the availability of products and features in your region.

The images present in "Instructions for Use" are only for indicative purposes.

Because of continuous product improvements, the illustrations and technical information found in the instructions for use may differ (slightly) from the current version of the device.

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1 Description of the TorEx Lung Perfusion System

The **TorEx Lung Perfusion System** is a novel system, designed for clinical use, that simplifies the Toronto ex vivo lung perfusion (EVLP) technique by integrating all the necessary equipment required to perform the procedure, while placing their 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. As per the Toronto EVLP protocol, the system is designed to operate using an albumin-buffered acellular solution as the perfusate.

The **TorEx Lung Perfusion System** (part 906-0004) consists of:

- TorEx Lung Perfusion Cart (part 901-0003)
- TorEx Lung Perfusion Kit (part 908-0001)

The **TorEx Lung Perfusion Cart** is re-usable and houses the components used to perform perfusion and ventilation of the lungs; notably a ventilator, perfusion pump, gas cylinders (O_2 and EVLP), power supplies, etc. The **TorEx Lung Perfusion Cart** is mobile and includes an onboard battery for continued operation while disconnected from mains power. The **TorEx Lung Perfusion Cart** has connection ports for an external heater/cooler to be attached to control the perfusate temperature. It also includes graphical user interfaces with controls and touchscreens, including the Cart Control Computer equipped with the **TorEx Lung Perfusion Software.** The **TorEx Lung Perfusion Software** controls the status of a pinch valve, monitors the status of the Cart battery, and implements alarms, error messages and information messages.

The **TorEx Lung Perfusion Kit** contains single-use components required during EVLP. The kit includes:

- TorEx Lung Perfusion Organ Chamber (part 902-0003) – sterile, single use
- TorEx Lung Perfusion PA Cannula (part 903-0009) – sterile, single use
- TorEx Lung Perfusion LA Rescue Cannula (part 903-0011) – sterile, single use
- TorEx Lung Perfusion PA Rescue Cannula (part 903-0012) – sterile, single use
- TorEx Lung Perfusion Drain Kit (part 907-0001) – sterile, single use
- 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
- 72” Hydrostatic pressure sensing lines (part 301-0065) – sterile
- Uline Economy Cutter with Safety Sticker (part 703-0029) – non-sterile
- Cleaning Brush (part 703-0054) – non-sterile
- Zip ties (part 700-0010) – sterile
- Male Luer Lock to Male Luer Lock w/Spin Lock in Tyvek Qty 4 (part 703-0109) - sterile
- 24” Hydrostatic pressure sensing lines (part 301-0193) – sterile
- TorEx Lung Perfusion Kit – IFU (part 908-0001-UM-01)

The **TorEx Lung Perfusion Organ Chamber** holds the donor's lungs in a sterile chamber. It also houses the entire perfusion fluid circuit, including the pump head and the gas exchanger, as well as ports to add, drain and sample the perfusate fluid. It also includes ventilation tubes, filters and sensors.

The **TorEx Lung Perfusion Cannulae** are used to connect the perfusion fluid circuit to the pulmonary artery and to the left atrium cuff of the lungs. The standard TorEx Lung Perfusion Kit contains a straight PA cannula (for the pulmonary artery) and a skirted LA cannula (left atrium). A rescue PA cannula is also provided as part of the kit, to be used when there is insufficient tissue within the artery to tie in the straight cannula. The LA Cannulae are also available in multiple sizes of 3cm, 4cm and 5cm, which are not provided as part of the kit and may be ordered separately. These cannulae are designed to be used based on anatomical considerations and can be tied into the left atrium when sufficient tissue is available. Each cannula includes a connection for hydrostatic pressure sensors.

The **TorEx Lung Perfusion Drain Kit** is used to drain used perfusate from the waste reservoir of the TorEx Lung Perfusion Organ Chamber to a biohazardous waste container for disposal.

2 Clinical Background

For those with end-stage lung disease, lung transplantation is both a life-saving and life-prolonging therapy. One of the issues faced in lung transplantation today is the limited number of donor lungs available to meet the growing list of recipients who require a transplant – resulting in recipient waitlist mortality. One of the factors contributing to this ongoing issue are low donor lung utilization rates. Often, donor lungs are declined for transplantation based on questionable viability, with up to 80% of lungs discarded in some regions.

As a solution, *ex vivo* lung perfusion (EVLP) was developed as a technique to allow for the assessment and recovery of donor lungs under normothermic conditions prior to the time of implantation. During EVLP, important functional parameters of lung health are monitored, helping the transplant surgeon make an informed decision on the suitability of lungs for transplantation, while active reparative processes are ensued. Using this technique, centers have reported the recovery of ~70% of donor lungs that would have otherwise been discarded and deemed unusable.

Recommended Indications for placing lungs on EVLP (Watanabe et al. *JTD*, 2021)
Best donor PaO_2/FiO_2 lower than 300 mm Hg
Presence of pulmonary edema on chest X-ray or in the clinical assessment
Poor lung/lobe compliance
High risk history
Lung from marginal donation after cardiac death donation (DCD) donor

The most cited and established EVLP protocol is the Toronto EVLP protocol. First reported in 2008 (Cypel et al. *JHLT*, 2008), the Toronto EVLP protocol uses lung protective strategies to allow for functional maintenance over an extended period (~12h). These include lung protective ventilation, protective flows, an acellular perfusate, and a closed left atrium. Clinical studies have demonstrated the utility of the Toronto technique for using extended criteria donor lungs (Cypel et al. *NEJM*, 2012), with comparable short and long-term recipient outcomes to that of standard criteria healthy lungs.

With broadening indications and interventional therapy investigations, EVLP continues to serve as the basis for future developments within the field of lung transplantation.

SUPPLEMENTARY INFO

Selected Publications demonstrating the success of the Toronto EVLP protocol in clinical lung transplantation

Study Authors	Year Published	Journal	Group	Key Findings
Cypel M et al.	2011	*NEJM*	Toronto	Transplantation of high-risk donor lungs using EVLP (n=20) led to results similar to those obtained with conventionally selected lungs
Cypel M et al.	2012	*JTCVS*	Toronto	Transplantation of high-risk donor lungs using EVLP (n=50) led to results similar to those obtained with conventionally selected lungs.
Aigner C et al.	2012	*AJT*	Vienna	Transplantation of high-risk donor lungs using EVLP (n=9) led to results similar to those obtained with conventionally selected lungs.
Zych B et al.	2012	*JHLT*	Harefield	Transplantation of high-risk donor lungs using EVLP (n=6) led to good early outcomes (100% survival at 3 months)
Boffino et al.	2014	*Eur J CTS*	Torino	Transplantation of high-risk donor lungs using EVLP (n=8) led to results similar to those obtained with conventionally selected lungs.
Sage et al.	2014	*Eur J CTS*	France	Transplantation of high-risk donor lungs (n=31) led to results similar to those obtained with conventionally selected lungs.
Tikkanen et al.	2015	*JHLT*	Toronto	Transplantation of high-risk donor lungs using EVLP (n=63) led to acceptable long-term survival, graft function, and improvements of quality of life that were comparable with conventionally selected lungs.
Machuca et al.	2015	*AJT*	Toronto	Lungs from Donation after Cardiac Death donors that underwent EVLP (n=32) led to shorter hospital lengths of stay and tendency towards shorter length of mechanical ventilation than those without EVLP (n=30)
Yeung et al.	2016	*Lancet Respr Med*	Toronto	Outcomes of lungs preserved for more than 12 hours using EVLP (n=97) were similar to lungs preserved for less than 12 hours using conventional methods
Divithotawela et al.	2019	*JAMA Surg.*	Toronto	Use of EVLP-treated lungs led to an increase in the number of patients undergoing transplantation (n=230), with comparable long-term outcomes with data up to 9 years.

Study Authors	Year Published	Journal	Group	Key Findings
Cypel M et al.	2020	*Lancet Respr Med*	Toronto	Donor organ treatment with UVC perfusate irradiation during EVLP (n=11) significantly decreased HCV viral loads within the first 7 days after transplantation and demonstrate the proof-of-concept for minimizing viral load ex vivo before transplantation.
Undurraga et al.	2021	*Rev Med Chil*	Chile/Latin America	Use of EVLP successfully reconditioned 5 donor lungs for transplantation

3 Indication for Use

The TorEx Lung Perfusion System is indicated for use in continuous normothermic machine perfusion of donor lungs, with questionable function, during which time the ex vivo function of the lungs can be reassessed for transplantation. The TorEx Lung Perfusion System includes a mobile cart with embedded software, single-use sterile Organ Chamber and Cannulae set and is used with approved perfusate solution to perform ex vivo lung perfusion for up to 12 hours.

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

4 Intended Users and Intended Use Environment

The TorEx Lung Perfusion System is intended for use by qualified organ perfusion specialists and lung transplant surgeons that perform EVLP. The system is intended to be used in the operating room of a hospital or similar environment.

5 Contraindications

There are no known contraindications.

6 Warnings

6.1 Warning and Notes

This document will utilize three text styles to draw attention to specific information, referred to as warnings and notes. Definitions are given below in the visual style that they will appear in the document.

⚠ WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury to one's self, or the organ.

NOTICE

Calls attention to notable information that should be followed during installation, use or maintenance of this equipment.

ⓘ SUPPLEMENTARY INFO

Calls attention to additional information referenced from the literature about performing the EVLP technique

6.2 General 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 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 an approved ex vivo lung perfusion and lung preservation solution. The user must follow the instructions for use of the perfusion solution and lung preservation solution for proper storage and use of the products for lung perfusion. It is strongly recommended to read the instructions for use for the perfusion solution and lung preservation solution before use.

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.

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.*

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

Do not re-use perfusate from the waste reservoir.

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.

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.

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

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.

Do not place devices employing near-field communication in close proximity to the TorEx Lung Perfusion System.

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

6.3 General Notes

NOTICE

The TorEx Lung Perfusion System should be stored in a secure area, preventing unauthorized access and tampering with the system.

7 Safety and Regulatory Information

7.1 Safety Information

The TorEx Lung Perfusion System conforms to the following safety standards.

Safety Standard	Title
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-8	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical system

7.2 Essential performance

The TorEx Lung Perfusion System has been designed and validated to ensure the following essential performances, as defined in IEC 60601-1.

- The system shall maintain ventilation of the lungs in physiologically safe parameters for the planned duration of the ex vivo lung perfusion.
- The system shall maintain perfusion of the lungs in physiologically safe parameters for the planned duration of the ex vivo lung perfusion.

7.3 Electromagnetic compatibility (EMC)

This section describes the electromagnetic environment in which the TorEx Lung Perfusion System should be used.

This device is classified as medical electrical equipment and is therefore subject to special precautionary EMC requirements. It may only be installed and operated in a professional healthcare facility environment in accordance with these Instructions for Use. Do not use the device in the vicinity of strong magnetic fields (e.g., magnetic resonance equipment). The equipment could be

affected by portable or mobile wireless communication devices and it should not be operated in close proximity to such devices. These precautions are necessary to prevent adverse events to patients or loss of organs, and to reduce risks to operators.

Failure to take these precautions may degrade the electromagnetic compatibility of this equipment. This may lead to incorrect sensor readings (flow, pressure, etc.) or to incorrect perfusion or ventilation parameters and may cause injury to the lungs. The user should monitor the equipment for signs of improper behavior and discontinue its use of electromagnetic interference is suspected.

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidelines and manufacturer's declaration - Electromagnetic emissions

The TorEx Lung Perfusion System console is intended for operation in an environment as described below. The user of the System should ensure that it is operated in such an environment.

RF Emissions Test	Standard	Conformity	Electromagnetic environment – guidelines
RF emissions	CISPR 11	Group 1	The system uses RF energy solely for its internal functioning. Consequently, its RF emissions are very low and unlikely to cause interference to nearby electrical equipment.
RF emissions	CISPR 11	Class A	The console is suitable for use in all establishments other than domestic buildings and buildings directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Emission of harmonics	IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flicker	IEC 61000-3-3	---	

Guidelines and manufacturer's declaration - Electromagnetic immunity

The TorEx Lung Perfusion System console is intended for operation in an environment as described below. The user of the System should ensure that it is operated in such an environment.

Immunity Test	Standard	Test level	Electromagnetic environment – guidelines
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	The floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF disturbances	IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM @ 1 kHz	Portable and mobile radio equipment should not be operated closer to the TorEx Lung Perfusion System (including cables) than the recommended separation distance, which is calculated as follows: d = 0.35 $\sqrt{P}$ 0.15 – 80 MHz outside of ISM bands
Proximity fields from RF Wireless communication equipment	IEC 61000-4-3	380 – 390 MHz 27 V/m; PM 50%; 18 Hz 430 – 470 MHz 28 V/m; FM ± 5 kHz; 1 kHz sine	

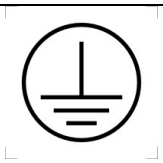
		704 – 787 MHz 9 V/m; PM 50%; 217 Hz	d = 1.2 $\sqrt{P}$ 0.15 – 80 MHz within ISM bands d = 1.2 $\sqrt{P}$ 80 – 800 MHz d = 1.2 $\sqrt{P}$ 0.8 – 2.5 GHz Where d is the recommended distance in meters and P is the transmitter power rating in watts. Interference is possible in the vicinity of devices that bear the following label:
		800 – 960 MHz 28 V/m; PM 50%; 18 Hz	
		1700 – 1990 MHz 28 V/m; PM 50%; 217 Hz	
		2400 – 2570 MHz 28 V/m; PM 50%; 217 Hz	
		5100 – 5800 MHz 9 V/m; PM 50%; 217 Hz	
Conductance disturbances induced by RF fields	IEC 61000-4-6	3 Vrms outside of ISM bands from 0.15 MHz to 80 MHz	
		6 Vrms inside ISM bands from 0.15 to 80 MHz 80% AM @ 1 kHz	
Fast transient electrical disturbance	IEC 61000-4-4	±2 kV 100 kHz repetition frequency for mains power lines	The quality of the mains power supply should be that of a typical commercial or hospital environment.
Impulse voltages / surges	IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line	The quality of the mains power supply should be that of a typical commercial or hospital environment.
		±0.5 kV, ±1 kV, ±2 kV Line-to-ground	
Magnetic field at power frequency (50/60 Hz)	IEC 61000-4-8	30 A/m	The strength of power-frequency magnetic fields (50/60 Hz) should be that found in a typical commercial or hospital environment.
Voltage dips, short interruptions and variations on power supply lines	IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The quality of the mains power supply should be that of a typical hospital environment. Note: The System has internal battery backup power and does not need to be powered by an external uninterruptible power supply.
		0% U_T; 1 cycle 70 % U_T; 25/30 cycles Single phase: at 0°	
		0% U_T; 250/300 cycles	
Immunity to Proximity Magnetic Fields from 134.2kHz RFID Readers	IEC 61000-4-39	134.2kHz 2.1kHz phase mod. 65 A/m	Avoid operating the TorEx Lung Perfusion System in close proximity to RFID readers.
		13.56MHz 50kHz phase mod.	

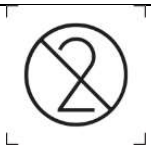
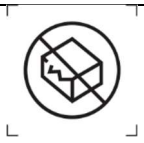
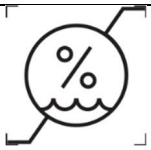
		7.5 A/m	

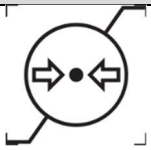
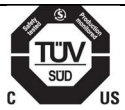
U_T is the AC supply voltage prior to application of the test level.

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

8 Symbols on Labels

Symbol	Meaning
	Follow Instructions for Use
	Protective earth (ground)
	Type BF applied part
	Caution / Warning
	Refer to Instructions for Use
	Manufacturer
	Date and country of manufacture

Symbol	Meaning
	Catalog number (part number)
	Lot number
	Serial number
	Use by date
	Do not reuse
	Indicates a single sterile barrier system, sterilized using ethylene oxide
	Do not use if package is damaged
	No stepping on surface
	Temperature limits for storage
	Humidity limits for storage

Symbol	Meaning
	Atmospheric pressure limits for storage
	Weight of Cart (including Organ Chamber)
	Indicates the item is a medical device
	Indicates a carrier that contains unique device identifier information
Rx only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	TUV Certification mark
	Do not resterilize
	MR Unsafe: The TorEx device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	Indicates a single sterile barrier system with protective packaging inside, sterilized using ethylene oxide

9 List of Components

Single-Use Components included in the TorEx Lung Perfusion Kit (908-0001)

Item	Part Number
TorEx Lung Perfusion Organ Chamber	902-0003
TorEx Lung Perfusion PA Cannula	903-0009
TorEx Lung Perfusion LA Rescue Cannula	903-0011
TorEx Lung Perfusion PA Rescue Cannula	903-0012
TorEx Lung Perfusion Drain Kit	907-0001
Ventilation Hose	201-0003
Ventilator Calibration Adapter	402-0056
Drip Tray	500-0001
Biohazard Trash Liner	805-0034
Hydrostatic pressure sensing lines 72”	301-0065
Uline Economy Cutter with Safety Sticker	703-0029
Cleaning Brush	703-0054
Zip Ties	700-0010
Hydrostatic pressure sensing lines 24”	301-0193
Male Luer Lock to Male Luer Lock w/Spin Lock	703-0109
TorEx Lung Perfusion Kit - IFU	908-0001-UM-01

Components included with the TorEx Lung Perfusion Cart (901-0003)

Item	Part Number
Heater/Cooler Cleaning Jig	402-0081
EVLP Gas Connector (DISS 2220 female to ¼” barb connector)	540-0007
Manifold Dust Shield	520-0048

Additional Consumables (not supplied or sold by Traferox)

The following items should be available for the EVLP procedure.

Item	Quantity	Purpose
3 mL luer-lock sampling syringes	9-23 units *(bulk recommended)*	To sample perfusate for blood gas analyses
20 mL luer-lock sampling syringes	4-6 units *(bulk recommended)*	To clear venous line/collect perfusate samples for research
Endotracheal tube (7.5mm)	1 unit	To intubate ex vivo lung for ventilation
Suction tubing	2 unit	To allow for insertion of vacuum cannula/suction
0-silk Ties	2 units	To secure cannulae and endotracheal tube
4-0 prolene suture	2 units	To suture rescue cannula to left atrium (when sizable cuff not available)
5-0 prolene suture	2 units	To suture rescue cannula to pulmonary artery (when sizable cuff not available)
Heparin	3000 IU (3ml)	Recommended EVLP perfusate medication (see note below)
Methylprednisolone	500 mcg	Recommended EVLP perfusate medication (see note below)
Imipenem/Cilasatin	500 mg	Recommended EVLP perfusate medication (see note below)
Organ Isolation Bag	3 units	To store lungs after EVLP
Surgical Stapler	1 unit	To perform lung biopsies/closing trachea
Surgical Stapler Reloads	3 units	For surgical stapler
Peroxide based disinfectant wipes	1 box	To clean device after use
Surgical gowns	2-5 units *(bulk recommended)*	To manipulate lung during EVLP procedure
Sterile gloves	2-5 units *(bulk recommended)*	To manipulate lung during EVLP procedure
Perfusate Solution	3 L (dependent on perfusion length)	Acellular Colloid plasma-like solution to perfuse lungs
Lung preservation solution	3L	Low-potassium dextran solution for cold storage before/after EVLP
Oxygen (100%) Gas Tank	1 tank	Control FiO_2 during ventilation
EVLP (8% CO_2, 6% O_2, balance with N_2) Gas Tank	1 tank	De-oxygenate perfusate
Sterile Saline	1 L	To flush hydrostatic sensor lines

Note: Recommended EVLP perfusate medications are part of the Toronto EVLP technique described in the scientific literature (Cypel et al. JHLT, 2008).

SUPPLEMENTARY INFO

Due to the presence of oxygen supply to lung cells derived from the ventilator, aerobic metabolism can ensue without the need of an oxygen carrier (i.e., red blood cells) in the perfusate. Do not add red blood cells to the perfusate. Hemolysis secondary to mechanical damage may occur if red blood cells are added.

10 Required External Equipment

Equipment	Requirement	Compatible models*
Standard Blood/Gas Analyzer	Ability to measure/report pO_2, pCO_2, pH, glucose, and lactate levels	Not specified
Heater/Cooler System	3/8" Hanson-type connectors (see note below)	Heater/Cooler System 3T (LivaNova) Heater/cooler unit 40 (Maquet)
EVLP gas tank	diameter less than 111mm	N/A
O_2 gas tank (if no hospital hookup available)	diameter less than 111mm	N/A
Bronchoscope + Bronchoscope Tower	Suction available, 8.5 Bronchoscope Recommended	Not specified
X-ray	Trained X-ray technician and approval to perform radiographical procedures at location. Maximum X-ray cassette size is 45 cm (18 in) x 40 cm (16 in)	Not specified
Patient Monitor	Ability to measure and display at least 2 hydrostatic pressure channels	Phillips IntelliVue MX450
Hydrostatic Pressure Sensors	Sterile, single-use pressure transducers	Edwards TruWave disposable pressure transducers

* The TorEx Lung Perfusion System is compatible and has been validated with the equipment specified. Compatibility with other equipment has not been established by Traferox. Please contact Traferox's technical support (section 16) to inquire about compatibility of other equipment.

11 TorEx Lung Perfusion System Components

11.1 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.

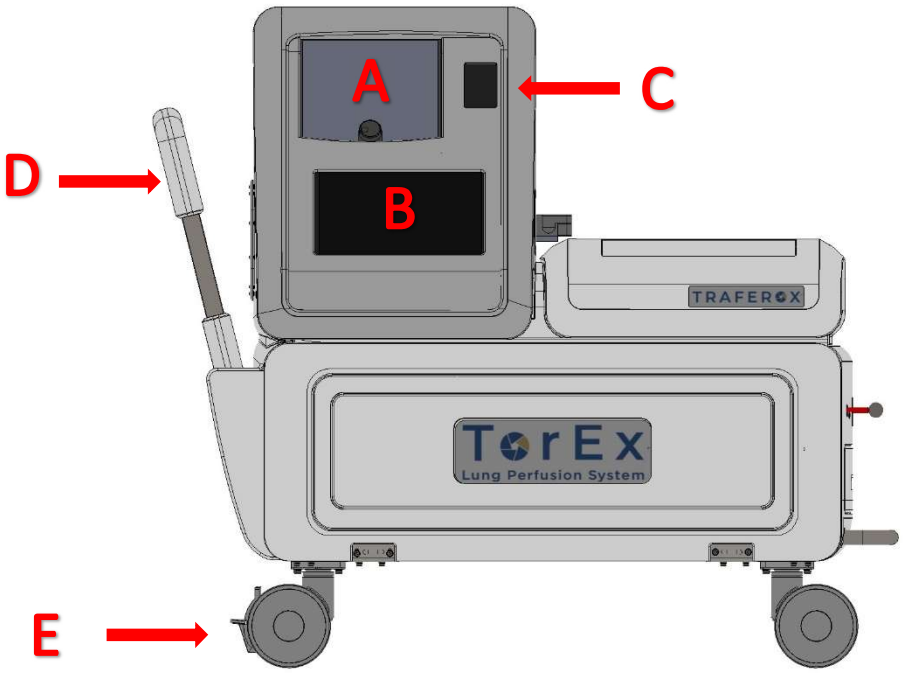


Figure 1: Front view of the TorEx Lung Perfusion Cart without a TorEx Lung Perfusion Organ Chamber attached

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.

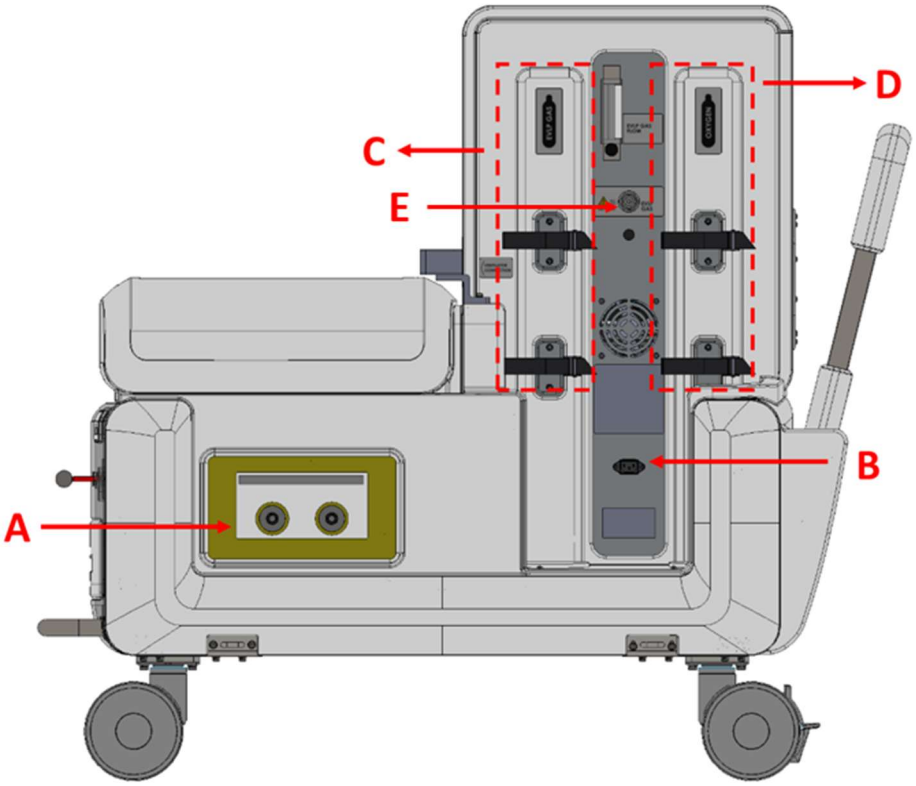


Figure 2: Back view of the TorEx Lung Perfusion Cart without a TorEx Lung Perfusion Organ Chamber attached

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

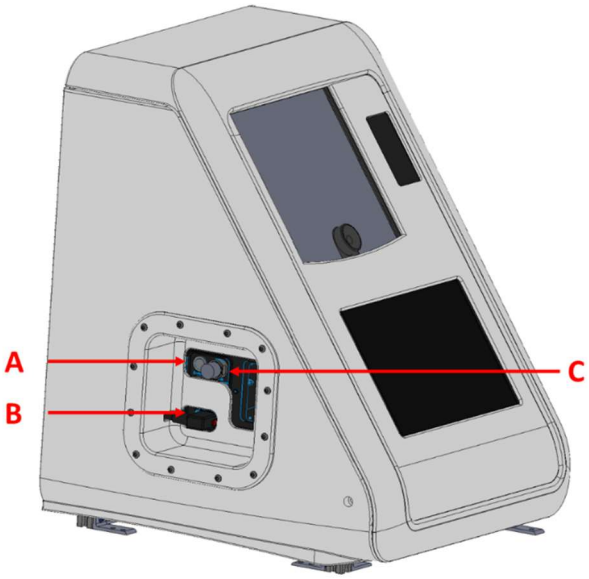


Figure 4: Ventilator

- **A)** Ventilator/Perfusion Console power button
- **B)** Ventilator power cable connection
- **C)** Oxygen Inlet connection

11.2 The TorEx Lung Perfusion Organ Chamber, 902-0003

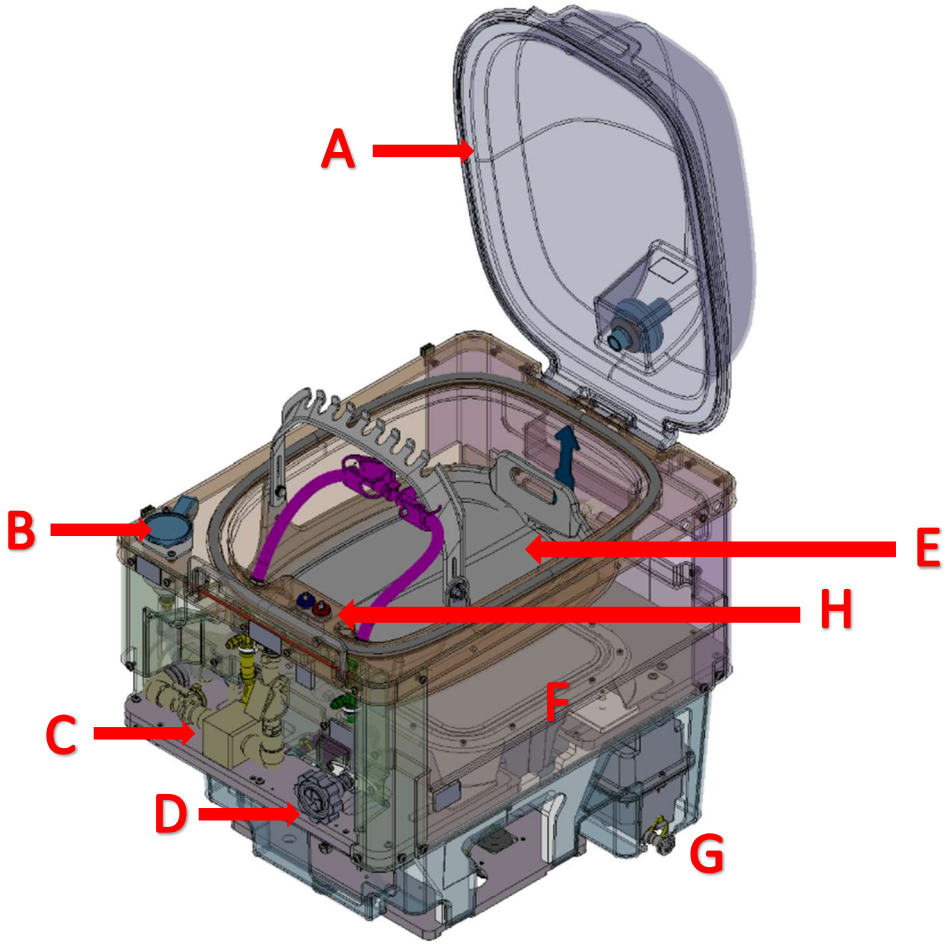


Figure 5: Front view of the TorEx Lung Perfusion Organ Chamber

- **A)** Organ Chamber Lid
- **B)** Perfusion Solution Fill Port
- **C)** Ventilator Connection Point
- **D)** LA Pressure Control Knob
- **E)** Lung Tray
- **F)** X-Ray Cassette Slot
- **G)** Waste Reservoir Drainage Port
- **H)** LA/PA Hydrostatic Ports

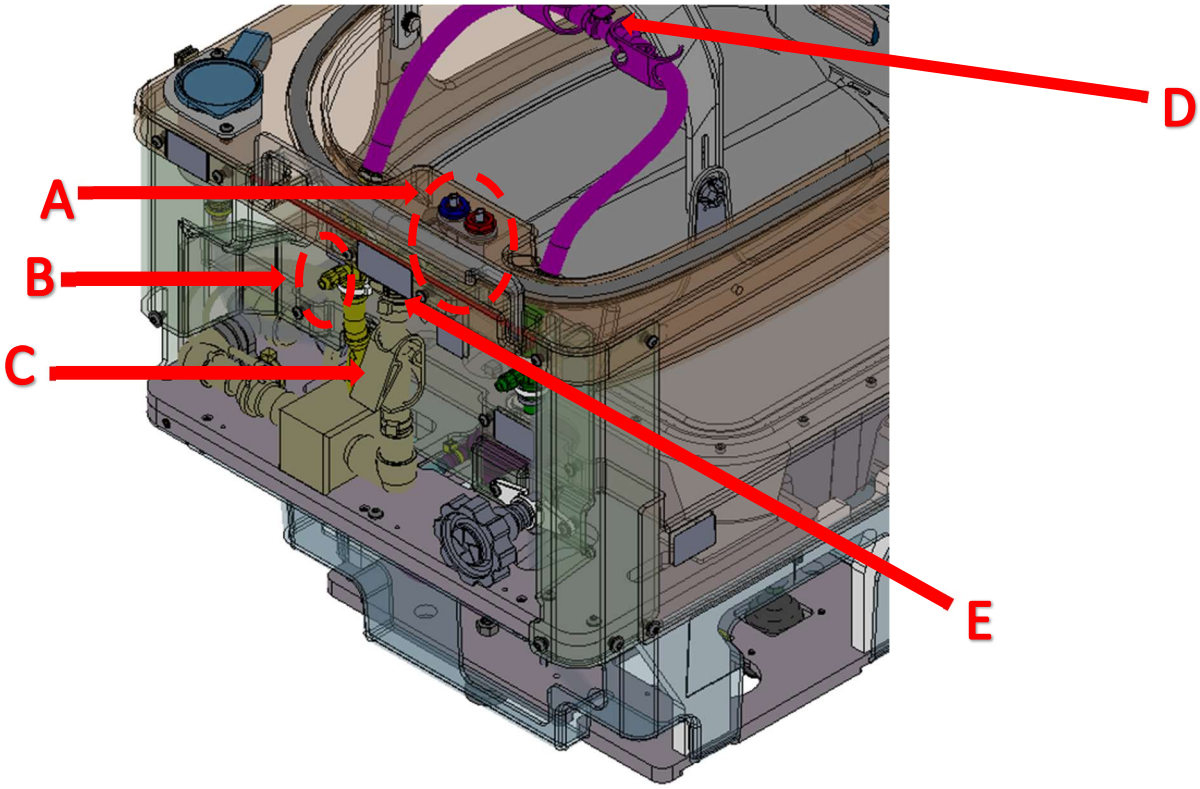


Figure 6:Front view of the TorEx Lung Perfusion Organ Chamber (zoomed in)

A) LA/PA Hydrostatic Ports
B) Perfusate sample ports
C) Airway clamp
D) LA and PA connection tubes
E) Bronchoscopy port

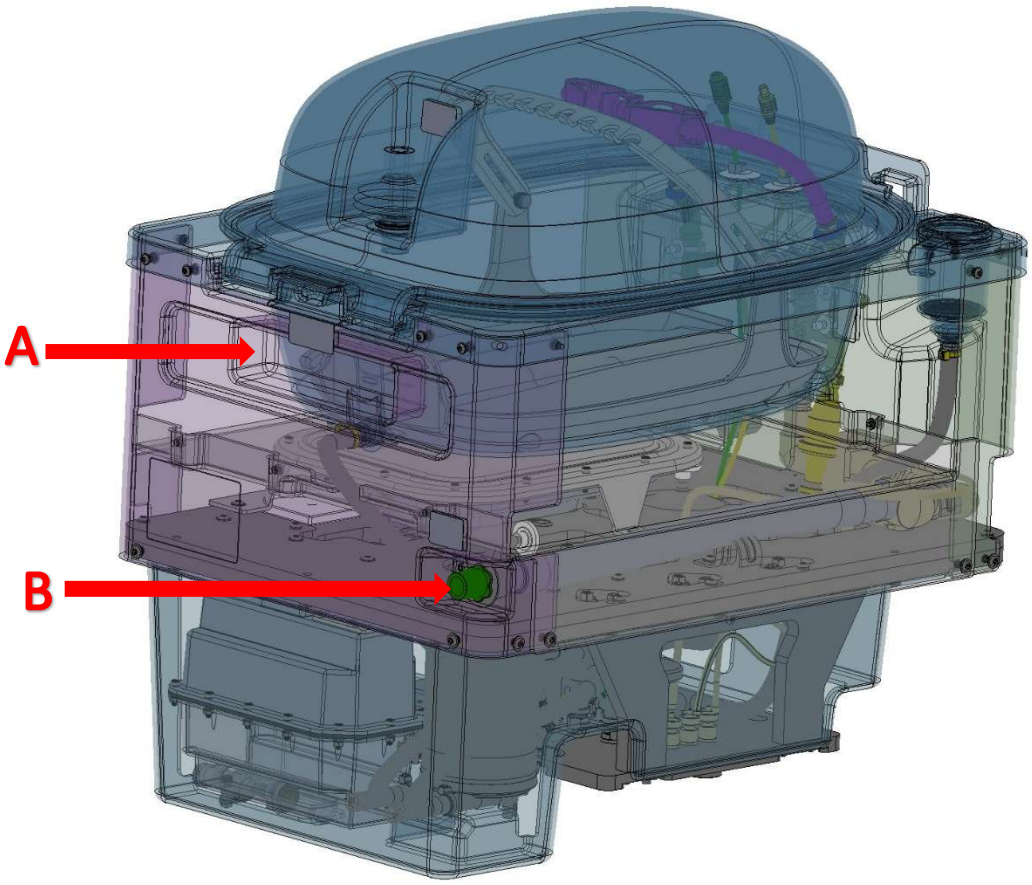


Figure 7:Back view of the TorEx Lung Perfusion Organ Chamber (lid on)

A) Organ Chamber handle
B) Ventilation tubing connection

11.3 The TorEx Lung Perfusion Cannulae

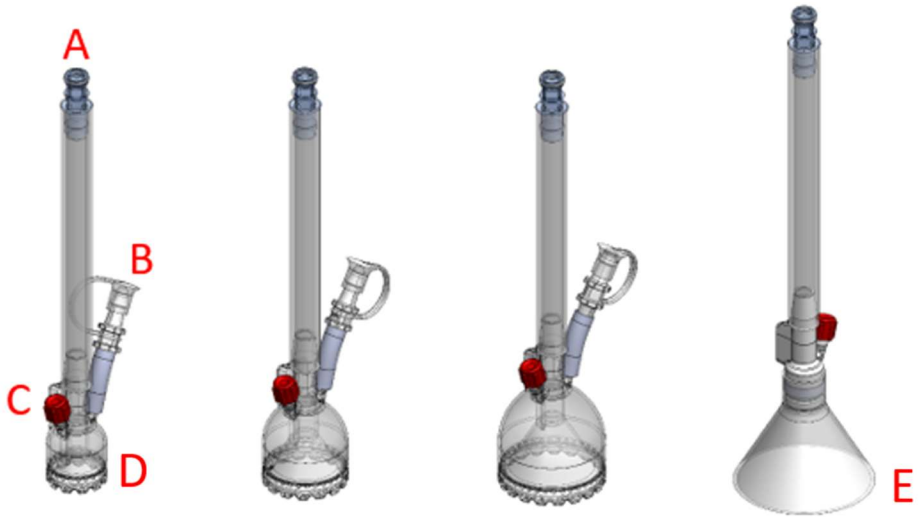


Figure 8:TorEx Lung Perfusion Left Atrium (LA) Cannulae. Options shown from left: 3cm, 4cm, 5cm and Rescue Cannula. The LA Rescue Cannula is provided standard in the TorEx Lung Perfusion Kit. Other sizes are available to order separately

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

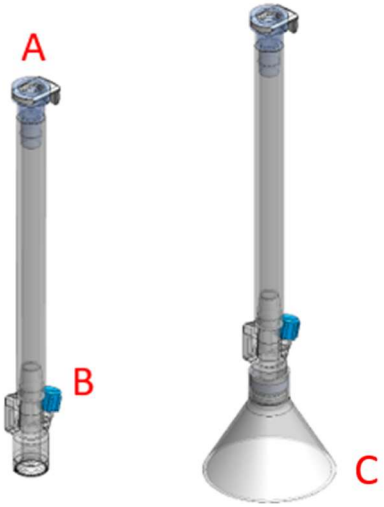


Figure 9:TorEx Lung Perfusion Pulmonary Artery (PA) Cannulae (2cm and Rescue Cannula). Both are provided standard in the TorEx Lung Perfusion Kit.

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

11.4 Perfusion Console

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

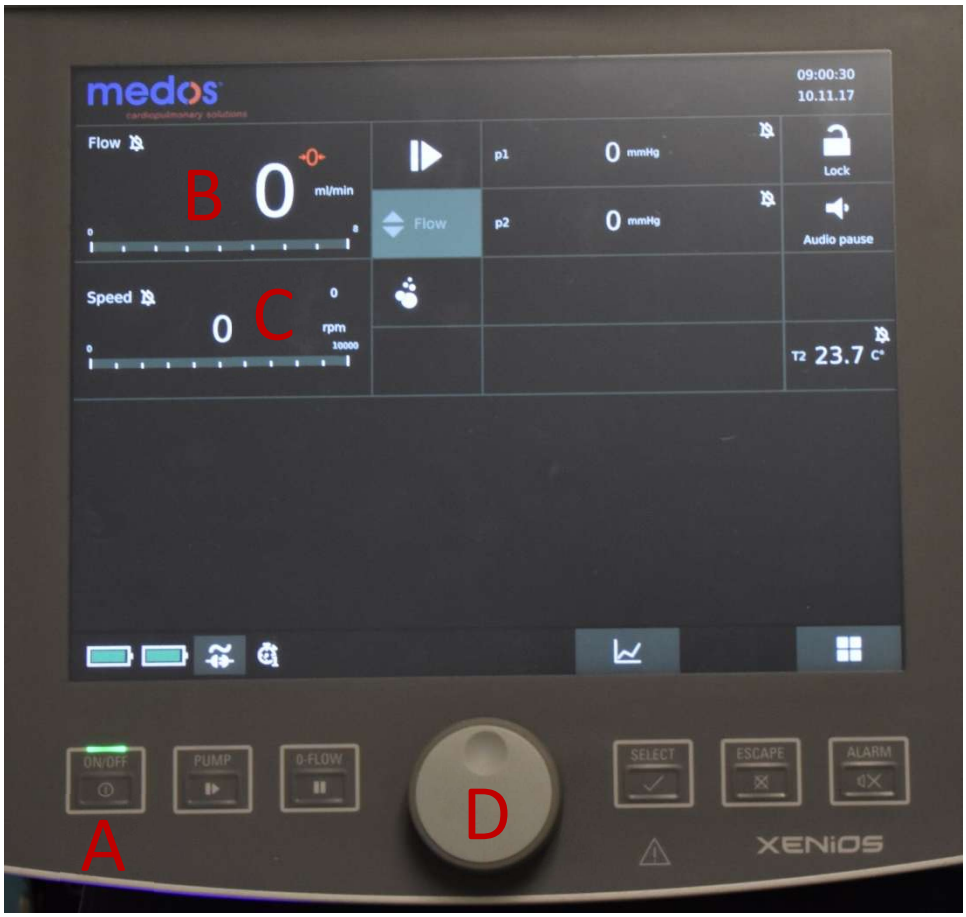


Figure 10: Perfusion Console with home screen displayed

- **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

11.5 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.

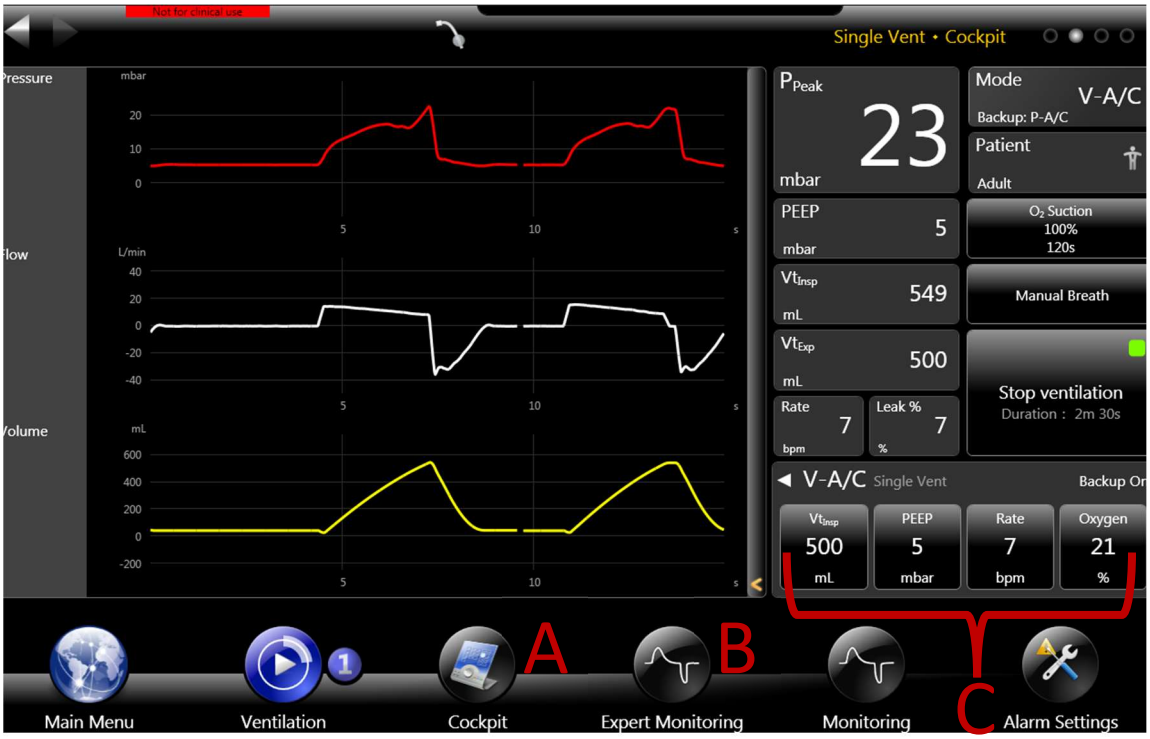


Figure 12:The 'Cockpit' screen of the BELLAVISTA® 1000 ventilator

- **A)** 'Cockpit' access screen
- **B)** Access to 'Expert Monitoring' screen
- **C)** Ventilation parameters that can be adjusted in the 'Cockpit' screen

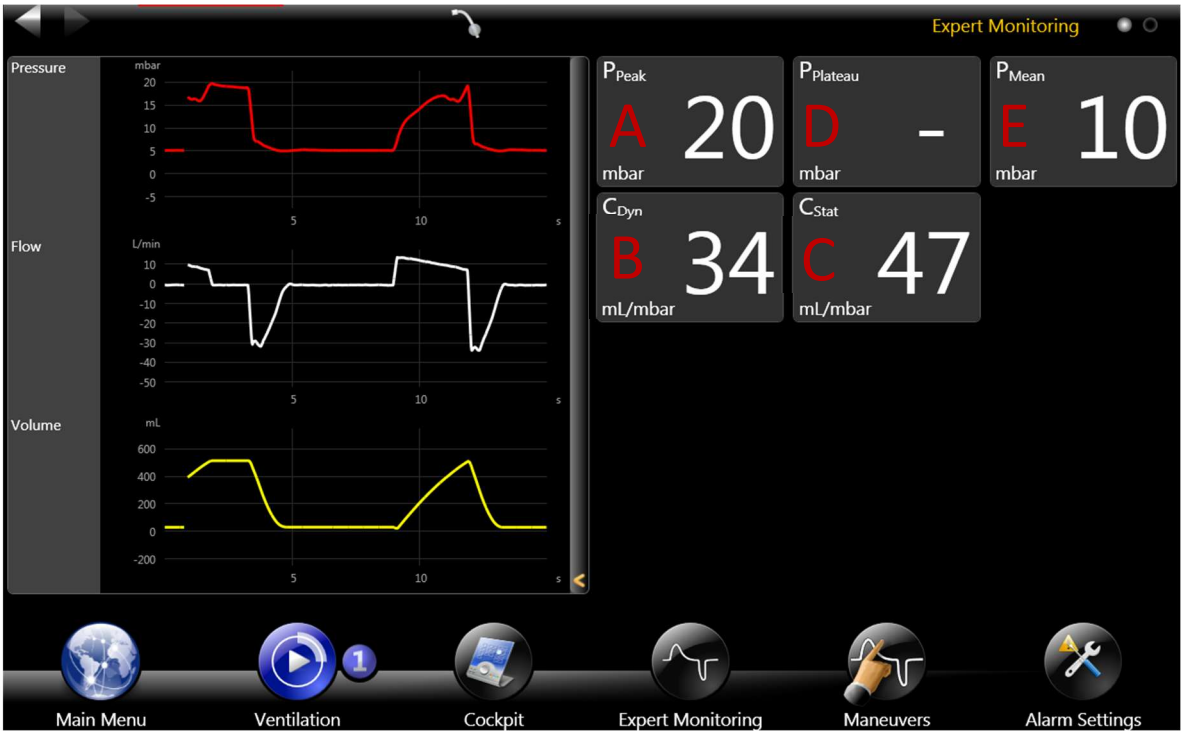


Figure 13:The 'Expert Monitoring' screen of the BELLAVISTA® 1000 ventilator

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

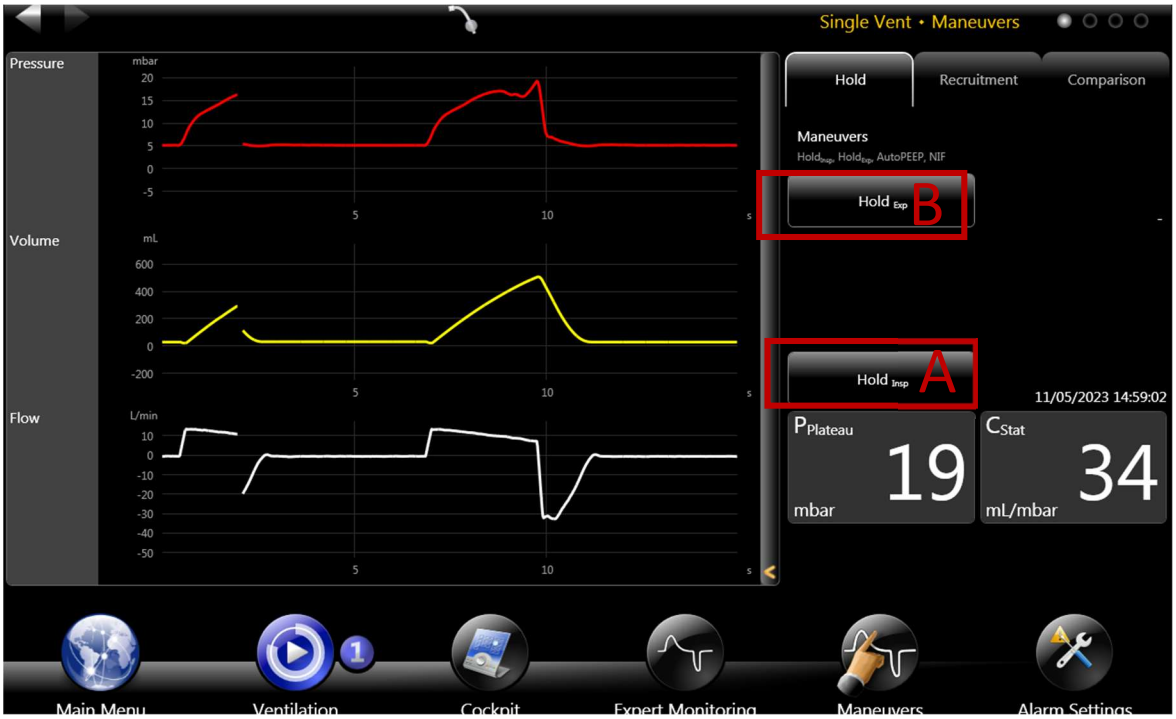


Figure 14:'Maneuvers' screen of the BELLAVISTA® 1000 ventilator

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.

11.6 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).

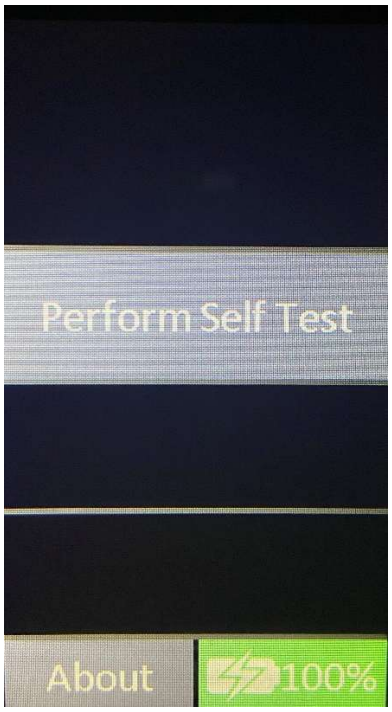


Figure 15:The Cart Control screen

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.

12 EVLP procedure

12.1 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 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 a 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.

12.2 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 (section 16) to obtain a replacement.

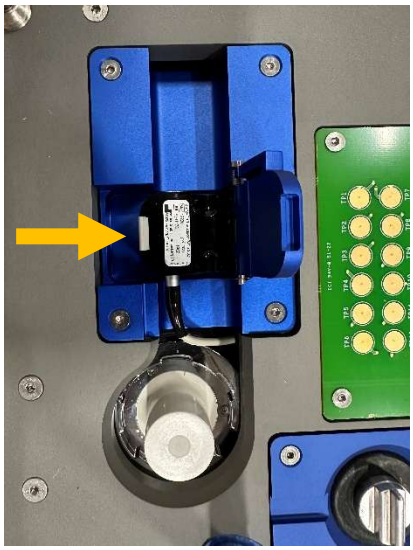
   ⚠ WARNING

   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

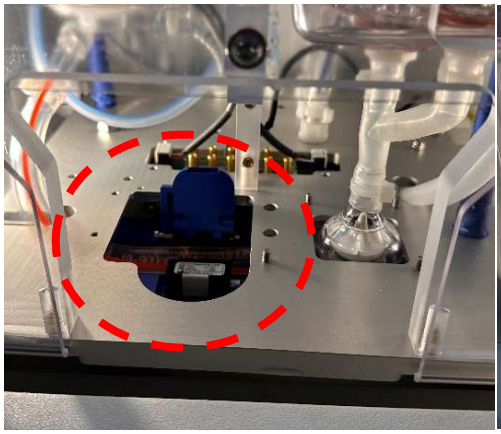
   Attempted re-sterilization of the organ chamber may result in device malfunction as the device has not been tested for exposure to more than one sterilization cycle.

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 (section 16) for a replacement.
4. Open the blue flow sensor lid by pressing against the front of the latch, shown below.

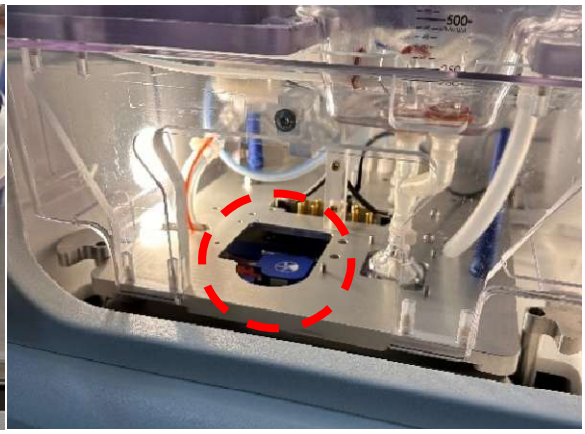


TorEx Lung Perfusion Cart flow sensor

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.

12.3 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 1 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 1: 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 x 0.4)	= 16% of the donor's cardiac output (Cardiac Output x 0.16)	= 24% of the donor's cardiac output (Cardiac Output x 0.24)
10% of the Flow Rate	= Maximum Flow Rate x 0.1	= Maximum Flow Rate x 0.1	= Maximum Flow Rate x 0.1
20% of the Flow Rate	= Maximum Flow Rate x 0.2	= Maximum Flow Rate x 0.2	= Maximum Flow Rate x 0.2
30% of the Flow Rate	= Maximum Flow Rate x 0.3	= Maximum Flow Rate x 0.3	= Maximum Flow Rate x 0.3
50% of the Flow Rate	= Maximum Flow Rate x 0.5	= Maximum Flow Rate x 0.5	= Maximum Flow Rate x 0.5
80% of the Flow Rate	= Maximum Flow Rate x 0.8	= Maximum Flow Rate x 0.8	= Maximum Flow Rate x 0.8
Normal Tidal Volume	= donor's ideal body weight, multiplied by 7 ml/kg	= donor's ideal body weight, multiplied by 7 ml/kg x 0.4	= donor's ideal body weight, multiplied by 7 ml/kg x 0.6
Assessment Tidal Volume	= donor's ideal body weight, multiplied by 10 ml/kg	= donor's ideal body weight, multiplied by 10 ml/kg x 0.4	= donor's ideal body weight, multiplied by 10 ml/kg x 0.6
Recruitment Tidal Volume	= donor's ideal body weight, multiplied by 15 ml/kg	= donor's ideal body weight, multiplied by 15 ml/kg x 0.4	= donor's ideal body weight, multiplied by 15 ml/kg x 0.6

Note: IBW = Ideal Body Weight

SUPPLEMENTARY INFO

The low-flow strategy permits extended lung perfusion (6h) 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) help 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 2 describes the ***Normal, Assessment*** and ***Recruitment*** parameters that will be entered during human lung EVLP.

Table 2. 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.

12.4 System Priming and De-Airing

1. Connect the Heater Cooler to the System:
    a. Connect the heater cooler to the back of the TorEx Lung Perfusion Cart, attachment point A in Figure 2.
2. Select 'Prime System' on the Cart Control screen and Confirm the action.
3. Open the fill port on the TorEx Lung Perfusion Organ Chamber.
4. 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.

5. Continue until 2L of perfusate has been introduced into the system.
6. 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.

7. 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 to use the physical '0-Flow' button on perfusion console.

8. 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.
9. After approximately 20 seconds, turn the knob clockwise to increase the pump speed to 2000 RPM
10. After approximately 20 seconds, turn the knob clockwise to increase the pump speed to 4000 RPM.
11. After approximately 20 seconds, turn the knob clockwise to increase the pump speed to 6000 RPM.
12. 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.

13. On the Perfusion console, turn the knob counter-clockwise to decrease the pump speed to 2000 RPM.
14. 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.

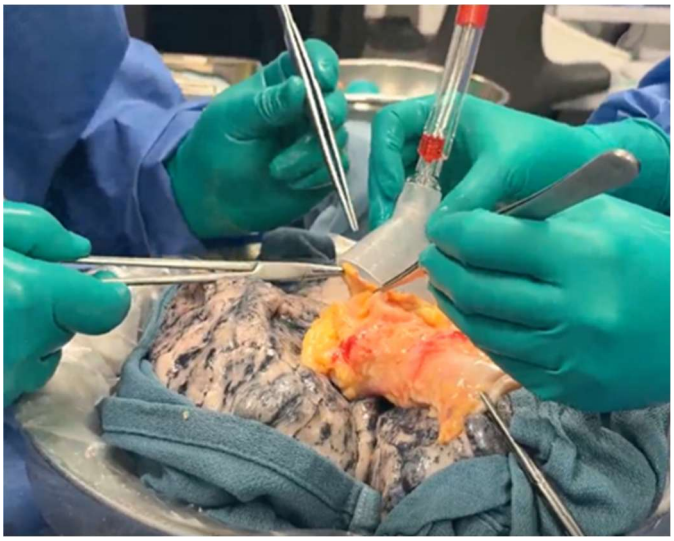
    d. Depress the plunger to add the medication, then disconnect and dispose of the syringe.

12.5 Cannulation (on surgical back table)

⚠ WARNING

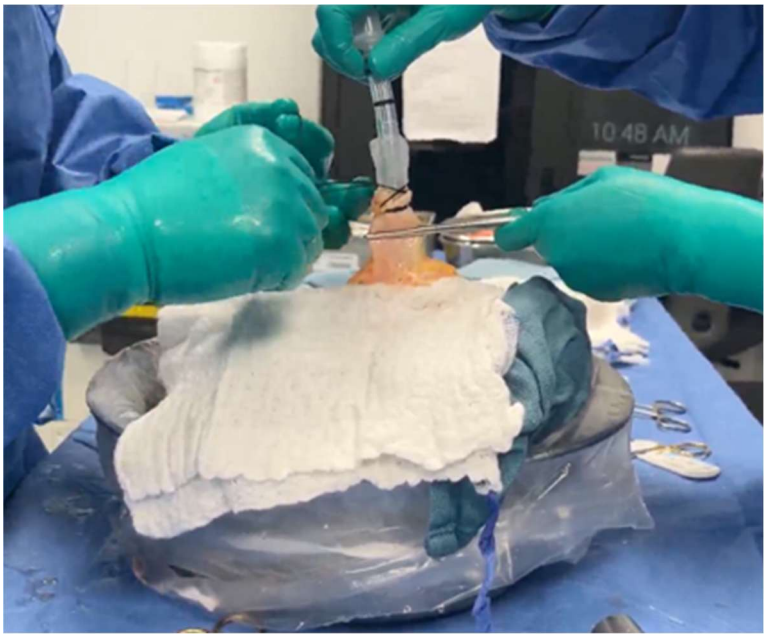
All interaction with the lung must be performed by a sterile user (as per institutional procedure)

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 (identified by a blue band) and LA Cannulae (identified by a red band) from their packaging.
2. Verify that luer caps are secured to both of the TorEx Lung Perfusion Cannulae.
3. Size the TorEx Lung Perfusion LA Rescue Cannula (identified by a red band) against the left atrial cuff. Trim the skirted region of the cannula to an appropriate diameter and suture the cannula to the left atrial cuff using 4-0 prolene.



4. Optional: If using the 3cm, 4cm, or 5cm LA Cannula (which must be ordered separately), select the LA cannula that matches the size of the atrial cuff. Insert the cannula into the left atrial cuff. 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. Tie the left atrial cuff to the TorEx Lung Perfusion LA Cannula using silk ties.
5. Insert the TorEx Lung Perfusion PA Cannula (identified by a blue band) 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. Cut the endotracheal tube to be about 10 cm long. 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 3 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 24" hydrostatic extension line (supplied within the TorEx Lung Perfusion Accessories Kit) to both of the LA and PA hydrostatic ports on the cannulas.

Table 3. Pre-EVLP and Post-EVLP Cold Flush Volumes

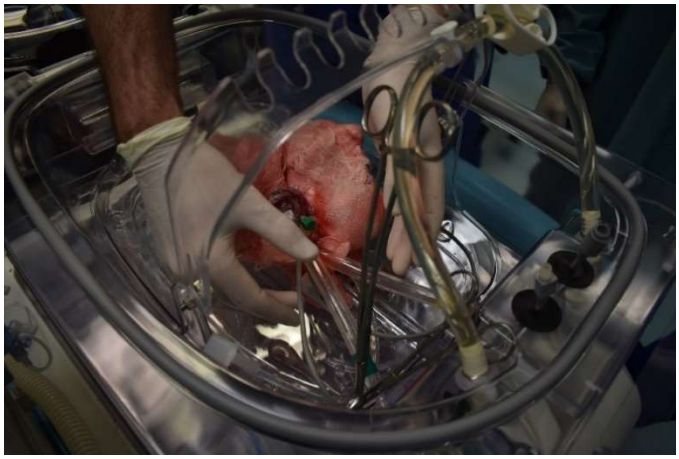
	Pre-EVLP	**Post-EVLP**
	Retrograde	**Anterograde**
Double Lung	1	2
Single Lung	0.5	1

12.6 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

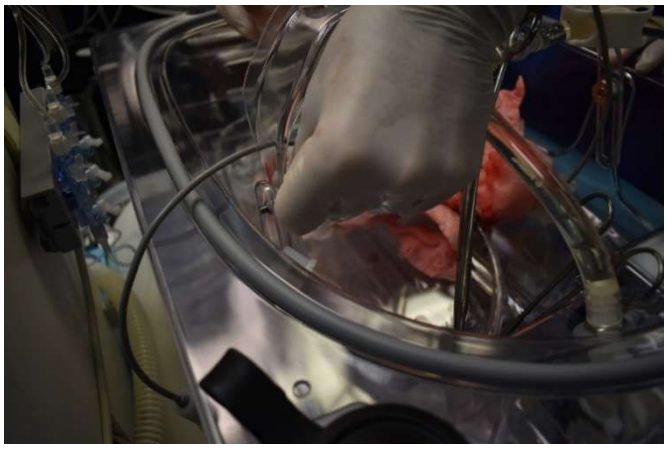
Ensure that the trachea is not twisted or kinked and that the endotracheal tube is pointing towards the ET tube connection in the Organ Chamber.

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.

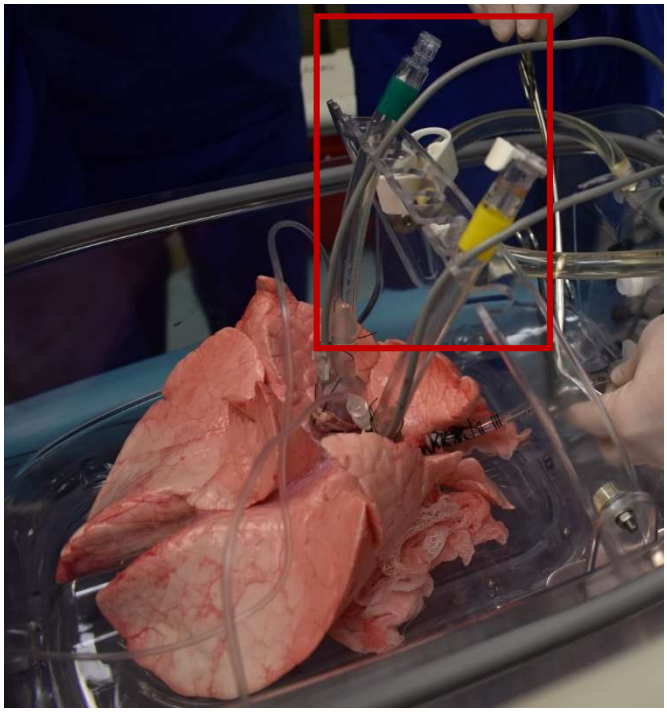
5. If necessary, adjust the tube holder on the lung tray such that it can hold the TorEx Lung Perfusion LA and PA Cannulae, using the thumb screws on the tube holder



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.
    a. If Organ Chamber contains the Hydrostatic Pressure line connectors, depicted in Figure 5 item H or Figure 6 item A, do the following:
        i. Attach a Male Luer Lock to Male Luer Lock w/Spin Lock to the TorEx Lung Perfusate Organ Chamber LA and PA hydrostatic ports at the front interior of the Organ Chamber to each.
        ii. Attach the 24" extension hydrostatic lines (supplied by Traferox) from the LA and PA Cannulae to the TorEx Lung Perfusate Organ Chamber hydrostatic ports at the front interior of the Organ Chamber.

        Note: Ensure that the LA and PA pressure line are connected to the correct hydrostatic ports on the TorEx Lung Perfusate Organ Chamber. LA pressure line attaches to the luer connection that is RED, PA pressure line attaches to the luer connection that is BLUE.

        iii. Attach the longer (72") extension hydrostatic lines (supplied by Traferox) from the hydrostatic ports on the exterior of the TorEx Lung Perfusate Organ Chamber to the Hydrostatic Sensor (not supplied by Traferox).
        iv. Attach the hydrostatic sensors to an external patient monitoring system according to the manufacturer's instructions.

    b. If Organ Chamber does not contain the Hydrostatic Pressure line connectors, depicted in Figure 5 item H or Figure 6 item A, do the following:
        i. Attach the 72" extension hydrostatic lines (supplied by Traferox) from the LA and PA Cannulae to an external 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.

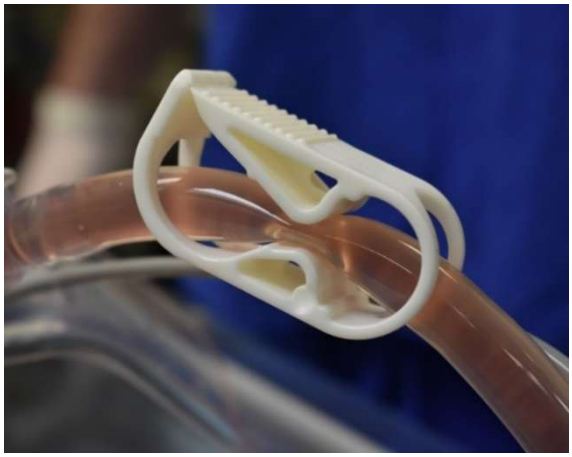
NOTICE

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 the 'Ex Vivo Lung Perfusion Calculations' section.
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.

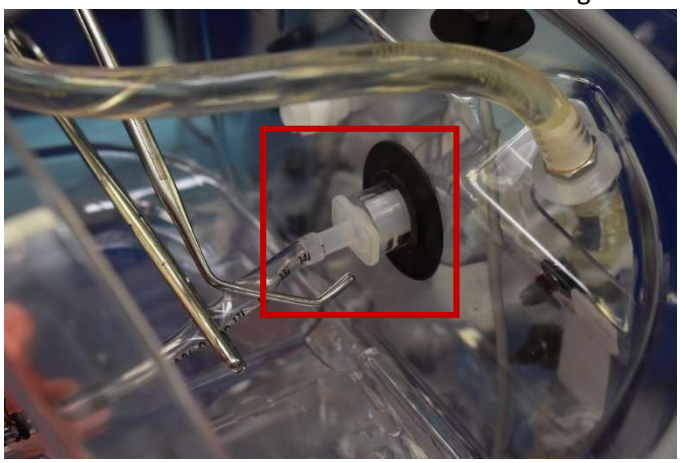
SUPPLEMENTARY INFO

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).

12.7 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.

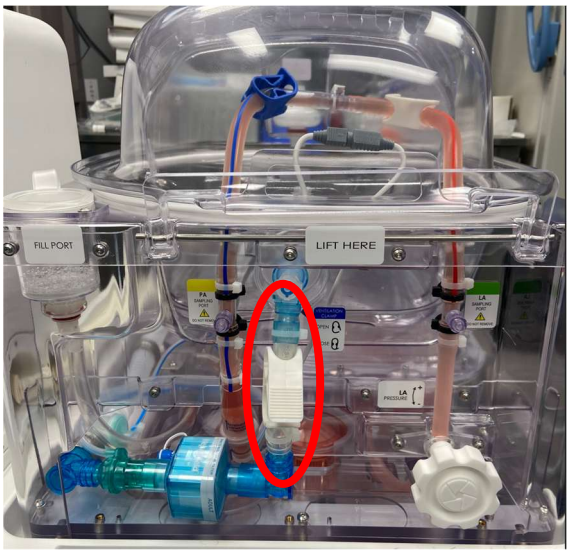
2. Connect the endotracheal tube to the TorEx Lung Perfusion Organ Chamber.



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.

12.8 System Ramp-Up

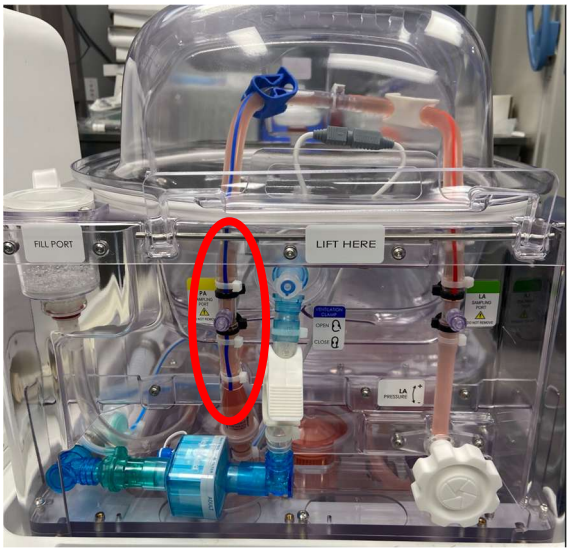
Table 4. Summary of Strategy for Initiation of Ex vivo Lung Perfusion

	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 the 'Ex Vivo Lung Perfusion Calculations' section.
    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 the 'Ex Vivo Lung Perfusion Calculations' section.
    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 the 'Ex Vivo Lung Perfusion Calculations' section.
    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 the 'Ex Vivo Lung Perfusion Calculations' section.
    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 the 'Ex Vivo Lung Perfusion Calculations' section.
    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 'Ex Vivo Lung Perfusion Calculations' 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 'Ex Vivo Lung Perfusion Calculations' 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 2.
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 'Ex Vivo Lung Perfusion Calculations' 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

12.9 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.

Finally, if mobility is required, the TorEx Lung Perfusion System should be moved only during steady-state EVLP. See the 'Mobility' section for details.

NOTICE

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

12.10 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 'Ex Vivo Lung Perfusion Calculations' 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 'Ex Vivo Lung Perfusion Calculations' 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 'Ex Vivo Lung Perfusion Calculations' section in 3 or 4 steps.

Assessment

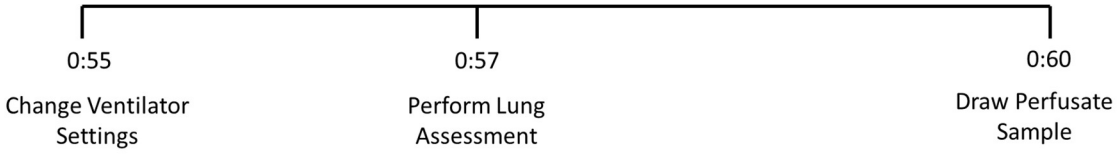


Figure 16: Schema of performing standardized EVLP lung Assessment

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 'Ex Vivo Lung Perfusion Calculations' 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 'Ex Vivo Lung Perfusion Calculations' 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 'Ex Vivo Lung Perfusion Calculations' section in 3 or 4 steps, then press 'Apply'.

12.11 Perfusate Exchange

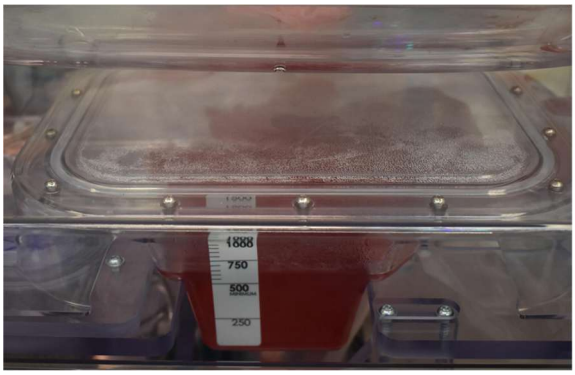
Immediately following an assessment (XX:60), a perfusate exchange should be performed.

Table 5. 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.

12.12 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

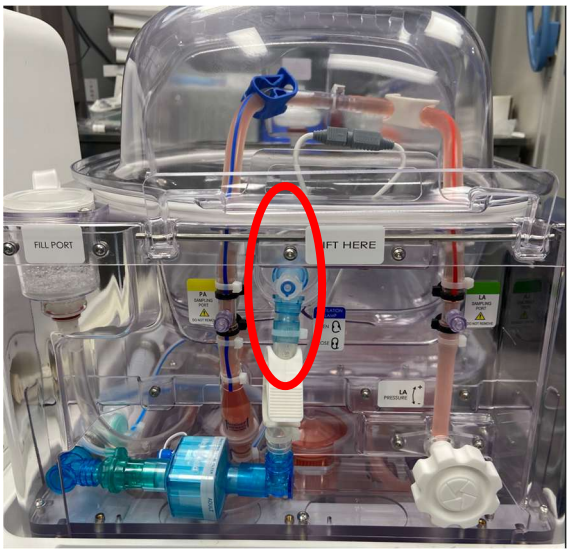
When fully charged, the battery charge will sustain operation for at least 30 minutes.

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.

12.13 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.

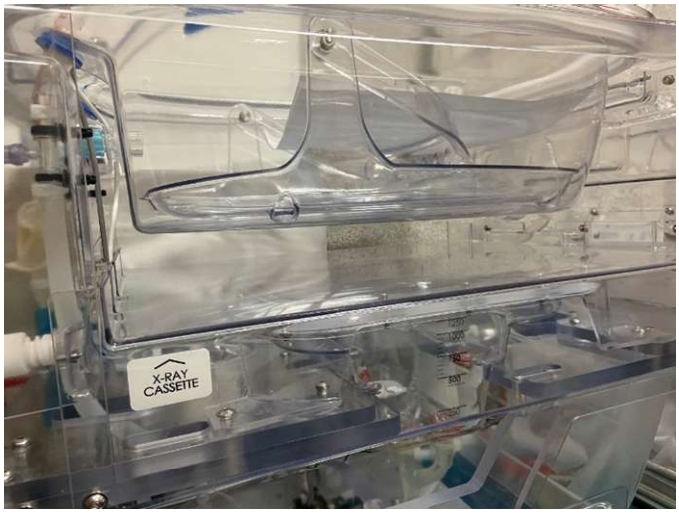
The TorEx Lung Perfusion Organ Chamber is equipped with a bronchoscope port which can be opened to insert a bronchoscope into the lungs via the trachea.



NOTICE

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

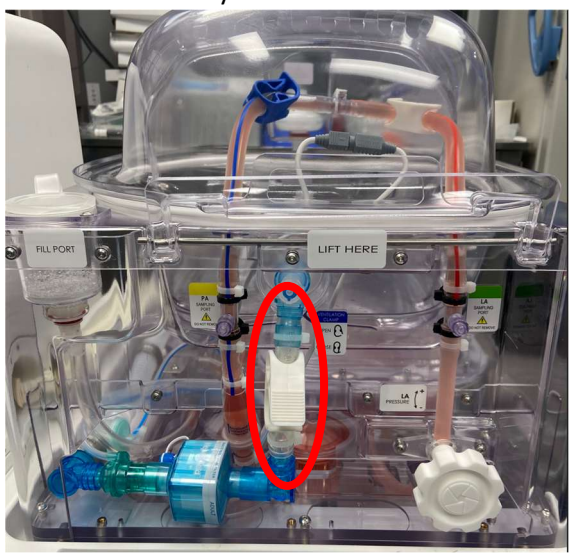
To aid in performing X-Ray photography, the TorEx Lung Perfusion Organ Chamber is equipped with an X-Ray tray slot.



12.14 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.
12. Disconnect the hydrostatic pressure lines.
13. Remove the lung from the TorEx Lung Perfusion Organ Chamber, and place on a surgical backtable.
14. Obtain lung preservation solution stored at 2-8°C.
15. Perform post-EVLP anterograde flush (Table 3) 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.
16. Disconnect the TorEx Lung Perfusion Cannulae from the lung by cutting the silk ties.
17. Using a surgical stapler, staple the trachea closed to keep the lungs inflated.
18. Prepare the lungs for transport/storage as per hospital procedure.

12.15 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 3.
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.

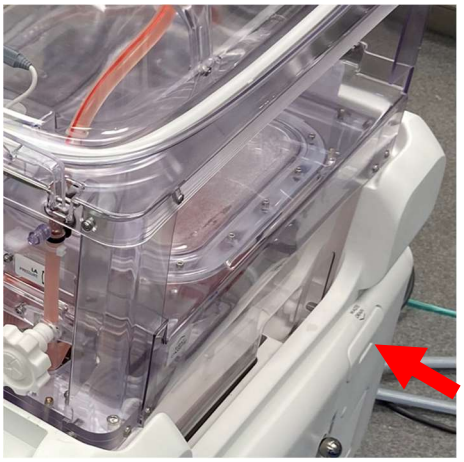
12.16 Cart Shutdown

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.

12.17 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

13 Alarms and Information Messages

The TorEx Lung Perfusion System features an alarm system that alerts the user of hazardous conditions during the EVLP procedure. Alarms are shown on the Cart Control screen and include both a visual signal and an auditory signal. The same system is used to inform the user of errors and other conditions that may affect the operation of the system. The alarm system complies with IEC 60601-1-8. The table below lists all alarm conditions, error messages and information messages, along with the cause and the actions to take to resolve the situation.

Alarms are shown in prominent black text over a yellow background and are accompanied by an auditory signal consisting of three beeps, repeating every 30 seconds. Information messages are shown in prominent black text over cyan background and are accompanied by a single non-repeating beep. Error messages are shown in black text over yellow background and are accompanied by a single beep.

Alarms and information messages are shown and sounded within 5 seconds of the onset of the hazardous situation. Alarm messages will be seen by the user in front of the TorEx Lung Perfusion Cart from any distance up to 4 meters.

The alarm system has no configurable setting and is always active while perfusion is going on. There is no need for the user to verify the alarm functionality.

REF	Message	Type	Cause	Actions to take
E1	Organ Chamber not detected	Alarm (medium severity)	The presence of the Organ Chamber is no longer detected inside the Cart while perfusion is underway.	• Make sure that the Organ Chamber is correctly seated inside the Cart. • If the issue persists, contact Traferox technical support.
E2	Valve malfunction	Alarm (medium severity)	A valve is not in the correct state to implement the perfusion.	• Ensure the valve is not obstructed. • If the issue persists, contact Traferox technical support.
E3	Battery status cannot be read	Information message	The communication with the power system that manages the battery is failing.	• Ensure the cart is plugged in. • Contact Traferox technical support.
E4	Low battery	Information message	The charge status of the Cart battery is below 10% of its full charge.	• Plug in the cart
E5	Critical battery	Alarm (medium severity)	The charge status of the Cart battery is below 5% of its full	• Plug in the cart • If the issue persists, contact Traferox technical support.

			charge, allowing for less than 15 min of operation under battery power.	
E6	Organ Chamber not detected	Error message	The user attempts to start perfusion when no Organ Chamber is present in the Cart.	• Make sure that the Organ Chamber is correctly seated inside the Cart. • If the issue persists, contact Traferox technical support.
E7	*Not used*	---	---	---
E8	Drain the cannulae and zero the pressure sensors	Information message	This is a reminder to zero the cannulae before starting perfusion.	• Zero the hydrostatic pressure sensors according to the manufacturer's instructions
EV1	Excessive Leak *Implemented by Bellavista ventilator*	Medium priority alarm	There is a leak in the ventilation circuit. Lungs may not be properly ventilated.	• Check that the ventilation hose is tightly connected to the ventilator outlet and to the Organ Chamber. • Check the connections in the ventilation circuit at the front of the Organ Chamber. • Check that the clamp on the ventilation circuit is open.

14 Training

Training is provided by Traferox employees to the users of the system for the safe and effective use of the system. Please see our technical support (section 16) if you have any questions or concerns.

15 Installation, Service and Maintenance

Installation and Service

The unpacking and installation of the TorEx Lung Perfusion System must be performed by Traferox's trained service personnel.

Any repair or service other than the regular maintenance described below must also be performed by Traferox's trained service personnel. Only replacement parts approved by Traferox may be used for repair and service. Email Traferox at support@traferox.com if repair or service is required.

Routine maintenance

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

- Perform cart cleaning and disinfection procedure defined in section 12.17
- Ensure that the TorEx Lung Perfusion Cart's battery has a full charge.

15.1 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 section 12.17
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.

15.2 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.

15.3 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.

15.4 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.

16 Technical Support

Additional paper copies of this document can be provided upon request.

Any cybersecurity vulnerability that has occurred in relation to the device should be reported to the manufacturer. In order to report a cybersecurity vulnerability to the manufacturer, or any questions/concerns regarding cybersecurity of the device, please email support@traferox.com.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authority having jurisdiction. In order to report such incident to the manufacturer, or for any questions/concerns regarding the use of the device or the contents of this manual, please email support@traferox.com.

17 Technical Description

1. Physical characteristics – Cart (Uncrated)

    - Dimensions: Length 132 cm; Width 80 cm; Height 119 cm
    - Weight: 199 kg unloaded, 220 kg with Organ Chamber, lungs and perfusate
    - Lifetime: 10 years

2. Physical characteristics – Organ Chamber (unpackaged)

    - Dimensions: Length 60 cm; Width 44 cm; Height 63 cm
    - Weight: 17 kg
    - 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 (in 115 V configuration)
        - O2 (onboard): Size E cylinder
        - O2 (external): Max. pressure 7 bar
          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
          Flow 2.2 l/min

4. Water supply for heating and cooling the lungs

    - Heating/cooling liquid: Water
    - Temperature: 10 to 40°C
    - Maximum pressure: 1 bar
    - Minimum flow: 2 l/min

5. Patient monitor (including hydrostatic sensors)

    - Sensor type: Hydrostatic
    - Pressure range: -20 to 100 mm Hg
    - Resolution: 1 mm Hg

6. Environment

    - Operating ambient temperature: 17 to 24°C
    - Operating ambient humidity: 20 to 80%
    - Storage temperature (Cart, Organ Chamber): 5 to 40°C
    - Storage humidity (Cart): 20 to 90%
    - Storage humidity (Organ Chamber): 0 to 80%
    - Operating and storage pressure: 70 to 106 kPa
    - Operating altitude 0 to 2000 m

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

18 Troubleshooting

Cart Set-up	
Perfusion console fails self-test	1. Repeat the self-test procedure 2. Contact Traferox technical support if the issue persists.
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. If the self-test fails again, reboot the ventilator and attempt the self-test procedure 3. Contact Traferox technical support if the issue persists.

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.

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.
Tidal volume below 250 mL	1. If tidal volume below 250 mL is required, select 'Human EVLP Low Volume' profile.
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 section 12.6

19 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.
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

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21 Appendix

When performing porcine ex vivo lung perfusion (for training or research purposes), the EVLP protocol should be modified as follows. This includes changes to the lung assessment and to the lung recruitment maneuver. In the following figure and tables describe these changes.

Table A1. Ex vivo lung perfusion calculations for porcine lung donor

	Double Lung
Cardiac Output	$= (Donor\ animal\ weight\ in\ kg) \times 0.10$
Maximum Flow Rate	= 40% of the donor's cardiac output (Cardiac Output × 0.4)
10% of the Flow Rate	= Maximum Flow Rate × 0.1
20% of the Flow Rate	= Maximum Flow Rate × 0.2
30% of the Flow Rate	= Maximum Flow Rate × 0.3
50% of the Flow Rate	= Maximum Flow Rate × 0.5
80% of the Flow Rate	= Maximum Flow Rate × 0.8
Normal Tidal Volume	= donor's body weight, multiplied by 7 ml/kg
Assessment Tidal Volume	= donor's body weight, multiplied by 7 ml/kg
Recruitment Tidal Volume	Increase tidal volume to peak airway pressure of 25 cm H_2O

Recruitment Maneuver: 3 inspiratory holds x 3 secs (each)

Table A2. Assessment and Normal tidal ventilatory settings for Porcine lungs

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

Table A3. Perfusate replenishment strategy

Time	**Volume**
First hour	250 mL
Every other hour	100 mL