TRAFERIX

# X°Port
# Lung Preservation System

Instructions for Use

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Document Number: 909-0011-W-UM-01
Revision: 5

These Instructions for Use and the equipment it describes are for use only by qualified medical professionals trained in the particular technique.

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 these Instructions for Use are only for indicative purposes. Because of continuous product improvements, the illustrations and technical information in the Instructions for Use may differ slightly from the current version of the device.

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# 1 Description of the X°Port Lung Preservation System

The X°Port Lung Preservation System is designed to store, preserve and transport human lungs donated for transplantation at approximately 10°C until the time of implantation.

The X°Port Lung Preservation System (LPS) consists of an insulated chamber, phase-change cooling packs, a cradle to hold the lung bag, and a temperature probe and logger. The X°Port LPS is designed to be mobile, with wheels and a telescopic handle to be used to maneuver the device throughout its travel. The X°Port LPS is designed to protect the lungs during transport and to display and log the internal temperature on an external display.

# 2 Scientific Background

Recent advancements in organ preservation have led to the development of controlled hypothermic preservation as a promising strategy to improve lung viability and enhance transplant outcomes. This approach maintains lungs at a precisely regulated temperature—above freezing but below physiological levels—to slow metabolic activity while minimizing cellular injury. Unlike traditional static ice storage, which exposes lungs to temperatures near or below 4°C, controlled hypothermic preservation provides a more stable thermal environment, mitigating the risk of cold-induced damage, including mitochondrial dysfunction and ischemic injury[1].

Furthermore, controlled hypothermic preservation has been shown to support ongoing reparative metabolism, facilitating the upregulation of anti-oxidative and anti-ferroptotic cellular pathways that protect against oxidative stress and lipid peroxidation[2]. These cellular protective mechanisms contribute to improved post-transplant lung function and may extend the duration of preservation, thereby increasing the availability of viable donor organs.

The importance of temperature regulation in lung preservation has been reinforced by the 2024 American Association for Thoracic Surgery (AATS) expert consensus document on donor lung procurement and preservation, which recommends an optimal preservation temperature range of 4 to 10°C for controlled hypothermic preservation[3]. This temperature range is believed to balance metabolic suppression with the maintenance of essential cellular processes, representing a significant advancement over conventional cold storage techniques.

*The published literature in this document is used for reference only.*
*The studies above were conducted with animal organs, and did not use the X°Port LPS.*

# 3 Indication for Use

The X°Port Lung Preservation System is intended to be used for the static hypothermic preservation of lungs with cold storage solutions indicated for use with lungs during transportation and preservation until transplantation into a recipient.

Preservation times should be evaluated by the transplant surgeon to determine acceptability in accordance with clinical judgement and in the best medical interest of the intended recipient.

# 4 Intended Conditions of Use

The intended users of the X°Port LPS are organ preservationists and nurses. The intended environment of use is a transportation vehicle (car, plane, etc.), a hospital, and an outdoor environment while moving between the hospital facility and the transportation vehicle.

# 5 Contraindications

There are no known contraindications.

# 6 Safety and Regulatory Information

## 6.1 Safety Information

The X°Port LPS conforms to the following standards.

| 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 |

## 6.2 Essential Performance

The X°Port LPS has been designed and validated to ensure the following essential performances, as defined in IEC 60601-1:

- The X°Port shall maintain a safe internal temperature (between 4°C and 12°C) for the lungs for the duration of the use, as per the intended use.
- During use, the temperature value displayed by the temperature logger shall not be incorrect by more than 2.0°C.

## 6.3 Communication Specifications

The X°Port LPS contains a Bluetooth temperature logger. The X°Port LPS is intended to receive and transmit radio frequency (RF) energy via Bluetooth 4.2 low-energy protocol. The temperature logger complies with applicable regulations from FCC (part 15; FCC ID: SRD50130), ISED (IC: 5558A-50130), and other regulatory agencies. No minimum requirement is established for the quality of service (QoS) of the Bluetooth wireless communication. If wireless communication is lost, the temperature must be monitored via the temperature logger display.

- Wireless Data Standard: The X°Port LPS includes a temperature monitor/logger and can transmit temperature data to a mobile device via an optional mobile application using Bluetooth 4.2 Low Energy protocol.
- Radio Power: 2 mW (3 dBm)
- Transmission Range with Line-of-sight: Approximately 50 m (164 ft) with no obstacles
- The temperature logger receives and transmits within the 2.4 GHz ISM band (2.4000 – 2.4835 GHz) and the bandwidth of the receiving section is 2 MHz.

- Modulation scheme: Gaussian frequency-shift keying (GFSK)

## 6.4 Electromagnetic Compatibility

This section describes the electromagnetic environment in which the X°Port LPS 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 home 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. The use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Failure to take these precautions may degrade the electromagnetic compatibility of this equipment. This may lead to incorrect temperature readings. The user should monitor the equipment for signs of improper behavior and discontinue its use of electromagnetic interference is suspected.

**Guidelines and manufacturer's declaration - Electromagnetic emissions**

The X°Port Lung Preservation System 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-Class B | The system uses Bluetooth 4.2 low energy protocol. Consequently, its RF emissions are very low and unlikely to cause interference to nearby electrical equipment. |

**Guidelines and manufacturer's declaration - Electromagnetic immunity**

The X°Port Lung Preservation System 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<br>±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 | 10 V/m<br>80 MHz to 2.7 GHz | Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the X°Port Lung Preservation |
| Proximity fields from RF Wireless communication | IEC 61000-4-3 | 380 – 390 MHz<br>27 V/m; PM 50%;<br>18 Hz | |

| | | | |
|---|---|---|---|
| equipment | | 430 – 470 MHz<br>28 V/m; FM ± 5 kHz;<br>1 kHz sine | System. Otherwise, degradation of the performance of this equipment could result. |
| | | 704 – 787 MHz<br>9 V/m; PM 50%;<br>217 Hz | |
| | | 800 – 960 MHz<br>28 V/m; PM 50%;<br>18 Hz | |
| | | 1700 – 1990 MHz<br>28 V/m; PM 50%;<br>217 Hz | |
| | | 2400 – 2570 MHz<br>28 V/m; PM 50%;<br>217 Hz | |
| | | 5100 – 5800 MHz<br>9 V/m; PM 50%;<br>217 Hz | |
| 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. |
| Immunity to Proximity Magnetic Fields from 134.2kHz RFID Readers | IEC 61000-4-39 | 134.2kHz<br>2.1kHz phase mod.<br>65 A/m | Avoid operating the X°Port Lung Preservation System in close proximity to RFID readers. |
| | | 13.56MHz<br>50kHz phase mod.<br>7.5 A/m | |

# 7 Notices

This document includes notices which call attention to notable information that should be followed during installation, use or maintenance of this equipment. Definitions are given below in the visual style that they will appear in the document.

**NOTICE**

***Maintain the X°Port LPS in an upright position during organ transport as much as possible to prevent movement and injury to the organs.***

**NOTICE**

***Avoid extended exposure of X°Port LPS to direct sunlight and hot environments during transport, as much as possible. Otherwise, the internal temperature may increase quicker than expected.***

**NOTICE**

***Do not leave the X°Port LPS unattended during transport.***

**NOTICE**

***When loading packs into the X°Port LPS, also load a minimum of 8L of cold preservation solution, pre-conditioned at 4°C (or an equivalent volume of pre-conditioned saline or Traferox dunnage) during transport to the donor site, to serve as a thermal mass in the device.***

**NOTICE**

***When handling the lid filled with cooling packs, ensure that the lid is held with the pack tray opening facing upwards (i.e., Traferox logo reads upright), to prevent packs from falling out of the tray.***

# 8 Warnings

This document includes warnings which indicate potentially hazardous situations which, if not avoided, could result in serious injury to one's self, or the organ. Definitions are given below in the visual style that they will appear in the document.

**⚠ WARNING**

***The X°Port LPS shall be disposed according to hospital/institution protocol. Devices that are contaminated and potentially infectious shall be disposed as biohazardous waste.***

**⚠ WARNING**

***Do not modify this equipment without the authorization of the manufacturer.***

**⚠ WARNING**

***Prior to use, inspect all components of the X°Port LPS. Do not use if any components are loose, damaged, or appear to have been tampered with.***

**⚠ WARNING**

***This product is for use in institutions performing lung transplants. Follow all local regulatory, and institutional requirements for performing a clinical lung transplant procedure.***

**⚠ WARNING**

***The system is designed for use with a cold storage solution indicated for use with lungs. The user must follow the instructions for use of the applicable cold storage solution for proper storage and use.***

**⚠ WARNING**

***The X°Port is a single-use product. Do not attempt to reuse. Attempted re-use could result in cross-contamination and infection for lung transplant recipients.***

**⚠ WARNING**

***Cooling packs contain a liquid which is non-toxic but mildly flammable. Consult the Safety Data Sheet provided with these Instructions for Use for information about safe handling and disposal of the cooling packs.***

**⚠ WARNING**

***The X°Port LPS has a lifetime of 18 months from the date of manufacture. Do not use the device beyond the stated expiry date.***

**⚠ WARNING**

***Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the X°Port Lung Preservation System. Otherwise, degradation of the performance of this equipment could result.***

**⚠ WARNING**

***Use of accessories, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.***

**⚠ WARNING**

***Do not expose the X°Port LPS to harsh organic solvents, which may damage the X°Port LPS and impact its performance.***

# 9 Symbols on Labels

| Symbol | Meaning |
|---|---|
| | Follow Instructions for Use |
| | Manufacturer |

| Symbol | Meaning |
|---|---|
| | Catalog number (part number) |
| | Serial number |
| | Weight of device (including lungs) |
| | Do not reuse |
| | Use by date |
| | Indicates a carrier that contains unique device identifier information |
| | Indicates the item is a medical device |
| | Wireless communication |
| | Date of manufacture; manufactured in Canada |
| **Rx only** | Federal law restricts this device to sale by or on the order of a physician. |
| | MR Unsafe: The X°Port device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment. |
| IPX4 | Ingress Protection rating: The device is protected against splashing water. |

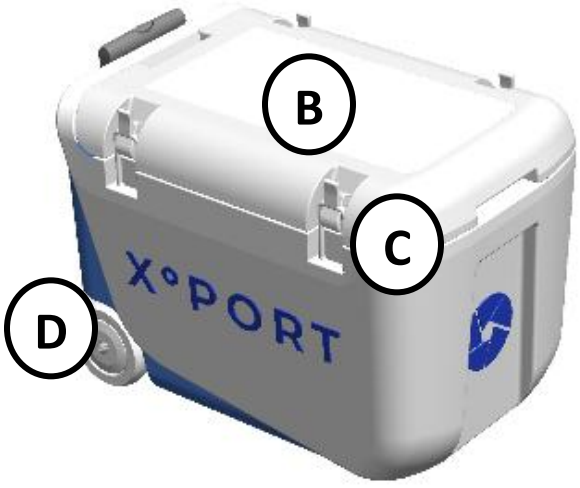
| Symbol | Meaning |
|---|---|
| | X°Port Cooling Packs must be conditioned in a refrigerator at 4°C for 48 hours prior to use. |
| | Date<br>Optional field: which may be used to enter the date when the cooling pack is placed in the refrigerator for conditioning. |
| | Time<br>Optional field: which may be used to enter the time when the cooling pack is placed in the refrigerator for conditioning. |

# 10 List of Required Accessories (Not Supplied with the X°Port LPS)

| Accessory | Recommended Amount | Purpose |
|---|---|---|
| Sterile Organ Bags | 3 bags | To ensure sterility and protection of organ during transport. |
| Lung Preservation Solution | Minimum 8L | Used to flush the organ prior to the cold preservation period. |

# 11 X°Port LPS Device Components

## 11.1 X°Port LPS External Features



A) Retractable handle

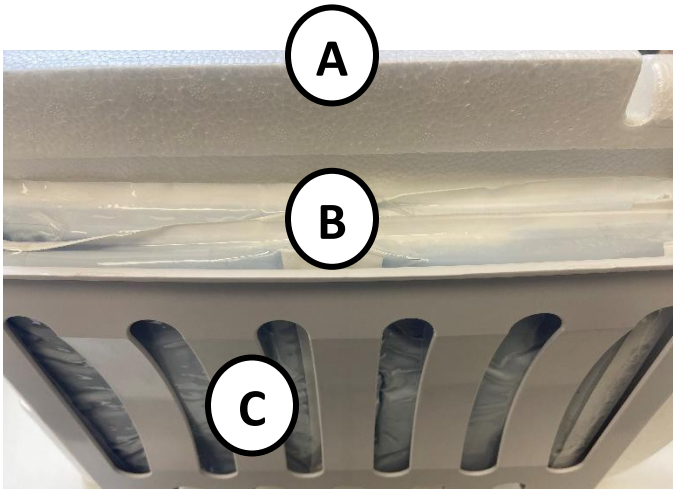
B) Lid

C) Lid latch (×4)

D) Wheels

E) Temperature logger

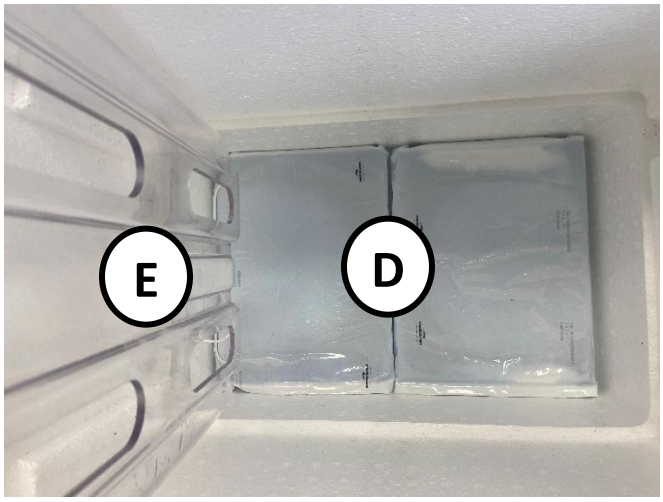
## 11.2 X°Port LPS Internal Features




A) Lid

B) Cooling packs (×4) – *Packaged Externally*

C) Lid tray for cooling packs




D) Cooling packs (×2) - *Packaged Externally*

E) Lung cradle

## 11.3 X°Port Cooling Packs

F) Cooling Packs Packaging

G) Cooling Packs (×6)

## 11.4 X°Port Mobile Application

The 'X°Port' mobile companion application can be downloaded via the Google Play Store (for Android devices), or the Apple App Store (for Apple devices). Using the 'X°Port' mobile application is optional, as the temperature inside the X°Port LPS can be read at any time on the display of the built-in temperature logger. If the companion application is desired, ensure that the application is downloaded on a mobile device prior to using the X°Port LPS for the first time.

**NOTICE**

***If using the mobile application, ensure that automatic application updates are enabled in the Google Play Store or the Apple App Store.***

**NOTICE**

***The X°Port Mobile Application requires Bluetooth, camera and location permissions. Ensure these are enabled prior to operating the application.***

# 12 X°Port LPS Workflow

## 12.1 X°Port LPS Integrity Check

Before using the X°Port LPS, ensure that the product is in good condition, without any external damage. If any damage is noticed, do not use the X°Port LPS and contact Traferox, as per Section 16.

1. Begin by inspecting the cardboard box which the X°Port LPS was shipped in.

☐ There are no obvious signs of damage or tampering.

☐ The cardboard box is sealed with tape.

2. Open the X°Port LPS cardboard box and inspect the unit.

☐ The temperature logger displays a temperature.

☐ The X°Port LPS exterior does not show signs of damage.

☐ The feet of the X°Port LPS under the device are intact .

☐ The wheels of the X°Port LPS are firmly attached.

☐ The latches holding the lid of the X°Port LPS are intact.

☐ The X°Port LPS handle can be extended to its full length (2 levels) and fully retracted.

☐ The X°Port LPS temperature logger does not have a “REC” symbol at the top left corner of the screen.

☐ The X°Port LPS temperature logger does not have a low battery symbol on the screen.

3. Inspect the contents inside the X°Port LPS.

☐ There is a lung cradle at the bottom of the unit.

☐ There is a lid tray secured into the foam lid.

☐ The temperature probe is secured in the lung cradle.

4. Open the carton with the X°Port LPS cooling packs and check that they are in good condition.

☐ There are 6 cooling packs with the X°Port LPS carton.

☐ No blue fluid has leaked out of the cooling packs.

## 12.2 Preconditioning of Cooling Packs

1. Open the X°Port LPS cooling packs carton
2. Remove all 6 cooling packs from the carton and place them into a temperature-regulated refrigerator set at 4°C for a minimum time of 48 hours

**⚠ WARNING**

***The cooling packs are required to be conditioned for the complete duration specified above. Failure to follow this step may result in a higher than intended lung temperature.***

**NOTICE**

***Ensure that there is air flow around the cooling packs inside the refrigerator. Do not stack more than two cooling packs together.***

## 12.3 Setting up the X°Port LPS

1. Retrieve 6 pre-conditioned cooling packs (as per Section 12.2) from the refrigerator.
2. Ensure that the packs are fully frozen. They should feel completely hard to touch (like ice).
3. Open the lid of the X°Port LPS.
4. Lift the lung cradle and place 2 cooling packs into the bottom of the X°Port LPS. Replace the lung cradle.
5. If necessary, reattach the temperature probe into the probe holder.
6. Load the organ cradle with a minimum of 8 liters of cold preservation solution, pre-conditioned to 4°C (or an equivalent volume of pre-conditioned saline or Traferox dunnage).
7. Place 4 cooling packs into the lid tray.

**NOTICE**

***The lid tray is designed to secure four cooling packs during transport. Some force may be required to insert the cooling packs into the tray.***

8. Secure the lid of the X°Port LPS by engaging the four lid latches.
9. (Optional) Using the X°Port application, scan the QR code on the temperature logger of the X°Port LPS, and select 'Start'.

**NOTICE**

***The X°Port application may take several minutes to connect to the temperature logger. Keep the mobile device in close proximity to the X°Port LPS during this time.***

10. (Optional) View and monitor the following information:
    - Recording duration
    - Last temperature

## 12.4 X°Port LPS Transportation

1. Transport the X°Port LPS to the donor hospital. Ensure that the X°Port LPS lid remains closed, unless otherwise required.
2. Maneuver the X°Port LPS using the retractable handle and wheels throughout the transportation.
3. When required, lift the X°Port LPS using the handles on each side of the device.

**⚠ WARNING**

***If the lid is open during transportation of the X°Port LPS to the donor hospital, close and secure the 4 lid latches as soon as possible. Monitor the internal temperature of the X°Port LPS during transport using the temperature logger display and/or mobile application.***

## 12.5 X°Port LPS Organ Loading

1. Open the lid of the X°Port LPS.
2. Place lungs (triple-bagged with single-use sterile organ bags and submerging 2L of fresh preservation solution) into the lung cradle, as shown below.

**NOTICE**

***Use only fresh preconditioned preservation solution when packaging the organ.***
***Do not add ice or saline in the organ bags or directly around the organ. Use appropriately temperature-controlled preservation solution instead.***

3. Secure the lid of the X°Port LPS by engaging the 4 latches.
4. (Optional) Using the mobile application, connect to the X°Port LPS and Select 'Load Organ'.

**NOTICE**

***Selecting 'Load Organ' will identify the time at which the lungs are loaded into the device. Failure to perform this action may result in an inaccurate display of the lung loading time.***

5. If the donor lung is declined for transplantation, using the mobile application, connect to the X°Port and Select ‘Reset X°Port’.

**NOTICE**

***If the 'Reset X°Port' feature is used, the cooling packs must be reconditioned prior to subsequent use, as per Section 12.2.***

**⚠ WARNING**

***Do not open the X°Port LPS during organ transport. If the lid is opened during organ transport, close and secure the 4 lid latches as soon as possible. Monitor the temperature during organ transport using the temperature logger display or mobile application.***

## 12.6 X°Port LPS Mobile Temperature Monitoring

1. During organ transport, monitor the internal temperature of the X°Port LPS using either the display on the temperature logger of the X°Port LPS or the optional X°Port mobile application.
2. If using the mobile application, scan the QR code of the X°Port LPS and connect to the device.
3. The X°Port mobile application displays the following information:
    - Transport start time
    - Recording duration
    - Recording duration (since organ loaded)
    - Last recorded temperature
    - Graphical view of recorded temperature curve

## 12.7 X°Port LPS Organ Unloading

1. Open the lid of the X°Port LPS.
2. If using the mobile application, connect to the X°Port LPS and select 'End Recording'.
3. (Optional) Using the mobile application, retrieve the temperature log of the transportation by selecting the 'Email Data' icon.
4. Remove the lung bag from the X°Port LPS and transfer it to the surgical theater. Take precautions to maintain sterility of the donor lungs.
5. Secure the lid of the X°Port LPS by engaging the 4 latches.

## 12.8 X°Port LPS Disposal

1. Dispose of the X°Port LPS according to hospital/institution procedures. Devices that are contaminated and potentially infectious shall be disposed as biohazardous waste.

# 13 Emergency Procedure

If the temperature inside the X°Port LPS device reaches 12°C (via the integrated screen, or the mobile application), or if the temperature logger is suspected of malfunctioning, the following emergency procedure should be performed to protect the lungs from possible injury.

1. Obtain 2 kg of ice cubes.
2. Open the lid of the X°Port LPS.
3. Pour the ice cubes into the X°Port LPS, surrounding the organ bag.
4. Secure the lid of the X°Port LPS by engaging the 4 lid latches.
5. Continue monitoring the X°Port LPS internal temperature to ensure the temperature drops after addition of ice.

# 14 Cybersecurity

## 14.1 Overview

The X°Port LPS contains a Bluetooth Low Energy sensor and receiver. It communicates with a user's mobile device using the Bluetooth Low Energy protocol. The X°Port LPS will not accept any radio frequency communications using any other protocol, including Bluetooth classic communication protocols.

Connection via Bluetooth is done by scanning the QR code on the X°Port LPS using a mobile device running the X°Port companion application. The X°Port LPS does not have physical ports or other means of electronic data transfer other than the Bluetooth.

## 14.2 Cybersecurity Best Practices

**NOTICE**

***Do not use X°Port Mobile Application on jailbroken Apple devices or rooted Android devices.***

**⚠ WARNING**

***Only install phone apps from the official Google Play Store or the Apple App Store.***

**⚠ WARNING**

***Do not update the X°Port Mobile Application or phone software during a transport.***

**⚠ WARNING**

***Do not use the X°Port Mobile Application when connected to an unsecure WiFi network, such as a public network.***

**NOTICE**

***In the mobile device settings, turn on screen auto-lock and use strong authentication to prevent other users from interfering with the X°Port LPS during transport.***

**NOTICE**

***Signs that the X°Port LPS's cybersecurity is compromised include no display of temperature, unexplained temperature fluctuations, inability to connect to X°Port LPS, and unresponsive X°Port Mobile application. If this device behavior is observed, report to Traferox technical support immediately, and verify the temperature at the end of the transport using an external thermometer.***

**NOTICE**

***If signs of tampering or suspicious activity are noticed, or if there is any doubt of the accuracy of the temperature displayed by the X°Port LPS, verify the temperature of the lung bags at the end of the transport with an external thermometer.***

***Traferox suggests using a calibrated, contact thermometer. The triple-bagged organ should be placed on top of the external thermometer, in the same manner as the X°Port LPS temperature probe.***

**⚠ WARNING**

***Ensure that the organ remains triple-bagged if measuring the temperature using an external thermometer, to maintain sterility. Follow institutional procedures in maintaining sterility of the organ.***

## 14.3 Patient Health Information (PHI)

The X°Port LPS does not process or store any PHI or other confidential information.

## 14.4 Firmware Updates

The X°Port LPS is a single-use device which is manufactured by Traferox and contains a temperature logger also initialized by Traferox.

The device is designed to only be updated by authorized personnel. If a firmware update is necessary, contact Traferox technical support (support@traferox.com).

## 14.5 Software Bill of Materials (SBOM)

The X°Port LPS Software Bill of Material (SBOM) can be provided upon customer request.

## 14.6 Cybersecurity Support

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

# 15 Troubleshooting

The following table describes steps to take in response to common issues encountered with the X°Port LPS.

| Issue | Possible causes | Steps to take |
|---|---|---|
| The mobile application does not connect to the temperature logger in the X°Port LPS. | • The Bluetooth connection could not be established.<br>• A cybersecurity event has occurred<br>• The X°Port mobile application is malfunctioning | • Ensure Bluetooth is enabled on the mobile device and repeat the connection attempt.<br>• Restart the X°Port Mobile Application and repeat the connection attempt.<br>• If the problem persists, contact Traferox's technical support and resolve the issue before initiating transport (Section 16).<br>• If the problem cannot be resolved, monitor the organ temperature using the LCD display. |
| The mobile application does not leave the 'Refreshing data' screen state. | • The Bluetooth connection was lost or is unstable.<br>• The X°Port mobile application is malfunctioning. | • Ensure Bluetooth is enabled on the mobile device and repeat the connection attempt.<br>• Restart the X°Port Mobile Application and repeat the connection attempt.<br>• Move closer to the X°Port LPS.<br>• If the problem cannot be resolved, monitor the organ temperature using the LCD display. |
| The mobile application displays the message 'Bluetooth is not available. Ensure that Bluetooth is enabled and try again.' | • Bluetooth has been disabled in the phone settings | • Enable Bluetooth in the phone's settings, then return to the X°Port Mobile Application.<br>• If the problem cannot be resolved, monitor the organ temperature using the LCD display. |
| The temperature logger was already recording before using the device | • The device was not reset properly after deciding not to proceed with transport | • Using the optional X°Port Mobile Application, scan the QR code.<br>• Once connection is established, press 'Reset X°Port', and confirm.<br>• If it cannot be reset, contact Traferox's technical support, and monitor the organ temperature using the LCD display. |
| During transport, the temperature logger does not display the internal temperature. | • The X°Port LPS is expired, and the temperature logger battery is depleted.<br>• The temperature logger is defective. | • Open the X°Port and verify the organ bag temperature using an external thermometer at the end of the transport.<br>• Contact Traferox's technical support (Section 16). |

| Issue | Possible causes | Steps to take |
|---|---|---|
| During transport, the internal temperature reaches 12°C. | • The X°Port LPS was opened during transport.<br>• The cooling packs were not conditioned at the specified conditions.<br>• The ambient temperature is too high, or the storage duration is longer than specified.<br>• The lung preservation solution was not sufficiently cooled as per its instructions. | • Follow the emergency procedure (Section 13)<br>• Ensure that the X°Port lid remains closed during the transport, and all 4 latches are engaged.<br>• Open the X°Port and verify the organ bag temperature using an external thermometer at the end of the transport and assess transplantability. |

# 16 Technical Support

Any serious incident that has occurred in relation to the device should be reported to the manufacturer. 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

| Item | Specifications |
|---|---|
| External dimensions | Width 40 cm, Length 61 cm, Height 46 cm |
| Internal dimensions | Width 24 cm, Length 31 cm, Height 26 cm |
| Empty weight (including 6 cooling packs) | 11 kg |
| Loaded weight (including lungs and preservation solution) | 16 kg |
| Internal temperature during use | 10°C ± 2°C |
| Ambient temperature | 15 to 25°C |
| Ambient pressure | 70 to 106 kPa |
| Device lifetime | 18 months |
| Temperature probe accuracy | ± 0.5°C |

# 18 References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2. Wang A, Ali A, Baciu C, Bellissimo C, Siebiger G, Yamanashi K, Montagne J, Garza G, Goligher E, Keshavjee S, Liu M, Cypel M. Metabolomic studies reveal an organ-protective hibernation state in donor lungs preserved at 10 °C. J Thorac Cardiovasc Surg. 2024 Aug 22:S0022-5223(24)00699-8. doi: 10.1016/j.jtcvs.2024.08.015. Epub ahead of print. PMID: 39173706.

3. Kukreja J, Van Raemdonck D, Cantu E, Date H, D'Ovidio F, Hartwig M, Klapper JA, Kelly RF, Lindstedt S, Rosso L, Schaheen L. The 2024 American Association for Thoracic Surgery expert consensus document: Current standards in donor lung procurement and preservation. The Journal of Thoracic and Cardiovascular Surgery. 2025 Feb 1;169(2):484-504.