TRAFERX

X°Port
Heart Preservation System

Instructions for Use

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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.

Contents

1 Description of the X°Port Heart Preservation System 5
2 Scientific Background 5
3 Indication for Use 6
4 Intended Conditions of Use 6
5 Contraindications 6
6 Safety and Regulatory Information 6
6.1 Safety Information 6
6.2 Essential Performance 7
6.3 Communication Specifications 7
6.4 Electromagnetic Compatibility 7
7 Notices 9
8 Warnings 10
9 Symbols on Labels 11
10 List of Required Accessories (Not Supplied with the X°Port HPS) 12
11 X°Port HPS Description 13
11.1 X°Port HPS External Features 13
11.2 X°Port HPS Internal Features 13
11.3 X°Port Cooling Packs 15
11.4 X°Port Mobile Application 16
12 X°Port HPS Workflow 16
12.1 X°Port HPS Integrity Check 16
12.2 Preconditioning of Cooling Packs 17
12.3 Setting up the X°Port HPS 17
12.4 X°Port HPS Transportation 18
12.5 X°Port HPS Organ Loading 18
12.6 X°Port HPS Temperature Monitoring 19
12.7 X°Port HPS Organ Unloading 19
12.8 X°Port HPS Disposal 19
13 Emergency Procedure 20
14 Cybersecurity 20
14.1 Overview 20
14.2 Cybersecurity Best Practices 20
14.3 Patient Health Information (PHI) 21

14.4 Firmware Updates 21
14.5 Software Bill of Materials (SBOM) 21
14.6 Cybersecurity Support 21
15 Troubleshooting 22
16 Technical Support 23
17 Technical Description 23
18 References 24

1 Description of the X°Port Heart Preservation System

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

The X°Port HPS consists of an insulated chamber, phase-change cooling packs, a cradle to hold the organ bag, and a temperature probe and logger. The X°Port HPS is designed to be mobile, with wheels and a telescopic handle, to be used to maneuver the device throughout its travel. The X°Port HPS is designed to protect the heart during transport and to display and log the internal temperature on an external screen. Additionally, the internal temperature, amongst other information, may be monitored via an accessory application running on a mobile device.

2 Scientific Background

Organ transplantation is a life-extending therapy for those with end-stage organ failure. In the transplantation process, the organ is typically excised from the donor, preserved (during an ischemic phase where it does not receive any blood supply) and then transplanted into a recipient patient. The quality of the preservation during the ischemic can influence whether the patient experiences post-transplant graft dysfunction, a concept known as ischemia-reperfusion injury.

Organ preservation was commonly practiced by cold flushing the organ with a specialized solution, followed by placing the organ in a cooler filled with ice. While on ice, the organ experienced uncontrolled temperature environments and injuries associated with cold temperature begin to manifest. Examples of these include mitochondrial dysfunction, cellular free iron release, oxidative damage, and cell death (de Perrot et al., Am J Respir Crit Care Med. 2003).

Any intervention that improves cell health during the preservation process will lead to improvements in short and long-term outcomes in transplant recipients. Controlled hypothermic preservation is a new strategy that has shown superior results compared to preservation of organs on ice. During controlled hypothermic preservation, the organ is preserved in an optimal warmer temperature environment (~10°C) and the organ is preserved without contact with ice. Recent consensus statements from organ transplant societies have described the optimal heart storage temperature to be in the range of 4 to 10°C (Copeland H et al., JHLT. 2020).

Pre-clinical and clinical studies have shown substantial improvements in post-transplant organ quality when using a warmer preservation temperature. In lungs, organ storage at 10°C was shown to lead to improved mitochondrial health and subsequently superior organ preservation quality compared to storage on ice (Ali A et al., Sci Trans Med. 2021). A recent review on kidney transplantation studies has examined hypothermic renal graft preservation at 8–10 °C (Taka M et al., Int. J. Mol. Sci. 2022). The authors state that these hypothermic temperatures are of interest because organ metabolism is reduced to the point where oxygen and nutrient demand is not as great as it is to temperatures closer to normal physiologic conditions. Further, it has been shown that crucial cellular and molecular processes that maintain cellular integrity are still active at 8–10°C, but not at 4 °C, the current gold standard for renal graft preservation. For example, reductive glutamine metabolism is active at ~10 °C, but not at 4 °C, and this process leads to downstream reductive carboxylation. This is essential for maintaining redox homeostasis in hypoxic events or mitochondrial defects, as observed in renal ischemia-reperfusion injury. This concept has also been generalized to other abdominal organs (Martins P et al., Transplantation. 2022).

Studies have also been performed examining the effects of warmer static storage temperatures on hearts. Tyers and colleagues designed a study to investigate the optimal temperature range for myocardial

preservation via intracoronary injection of a preservation solution (Tyers G et al., JTCVS. 1976). After ischemic injury was induced, metabolic function was best preserved in those hearts perfused at 10°C and 15°C, as evidenced by rapid recovery of high-energy phosphates and glycogen to control levels compared to metabolic deterioration in the 4°C group. The authors concluded that temperatures around 10–15°C are optimal for myocardial ischemia. Another study by Keon and colleagues investigated the ideal preservation method and cooling temperature for donor hearts (Keon W et al., Ann Thorac Surg. 1998). The authors found a failure of calcium homeostasis to occur at very low temperatures. The authors concluded that atrial preservation is optimal at about 12°C.

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 HPS.

3 Indication for Use

The X°Port Heart Preservation System is intended to be used for the static hypothermic preservation of hearts with cold storage solutions indicated for use with hearts 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 HPS are organ preservationists and nurses. The intended environment of use is a transportation vehicle (car, plane, etc.), a hospital, and in 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 HPS 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 HPS 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 heart 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 HPS contains a Bluetooth temperature logger. The X°Port HPS 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 HPS 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 HPS 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 Heart 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 Heart 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	The floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
		±15 kV air	
Radiated RF disturbances	IEC 61000-4-3	10 V/m 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 Heart Preservation System. Otherwise, degradation of the performance of this equipment could result.
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	
		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	

Immunity Test	Standard	Test level	Electromagnetic environment – guidelines
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 2.1kHz phase mod. 65 A/m	Avoid operating the X°Port Heart Preservation System in close proximity to RFID readers.
		13.56MHz 50kHz phase mod. 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.

NOTICE

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

NOTICE

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

NOTICE

Do not leave the X°Port HPS unattended during transport.

NOTICE

When loading packs into the X°Port HPS, also load a minimum of 3L 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.

⚠ WARNING

The X°Port ***HPS*** *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 HPS. 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 heart transplants. Follow all local regulatory, and institutional requirements for performing a clinical heart transplant procedure.

⚠ WARNING

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

⚠ WARNING

The X°Port HPS is a single-use product. Do not attempt to reuse. Attempted re-use could result in cross-contamination and infection for heart 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 HPS 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 Heart Preservation System. Otherwise, degradation of the performance of this equipment could result.

⚠ WARNING

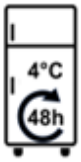
Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

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

9 Symbols on Labels

Symbol	Meaning
	Follow Instructions for Use
	Manufacturer
	Catalog number (part number)
	Serial number
	Weight of device (including heart)
	Do not reuse
	Use by date
	Indicates a carrier that contains unique device identifier information
	Indicates the item is a medical device

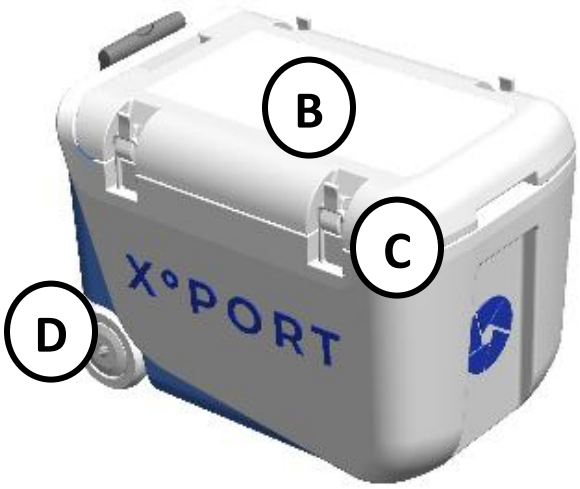
Symbol	Meaning
	Wireless communication
	Date of manufacture; manufactured in Canada
Rx only	Federal law restricts this device to sale by or on the order of a physician.
	MR Unsafe: The X°Port device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
IPX4	Ingress Protection rating: The device is protected against splashing water.
	X°Port Cooling Packs must be conditioned in a refrigerator at 4°C for 48 hours prior to use.
	Date: Optional field, which may be used to enter the date when the Cooling Pack is placed in the refrigerator for conditioning.
	Time: 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 HPS)

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

11 X°Port HPS Description

11.1 X°Port HPS External Features



A) Retractable handle

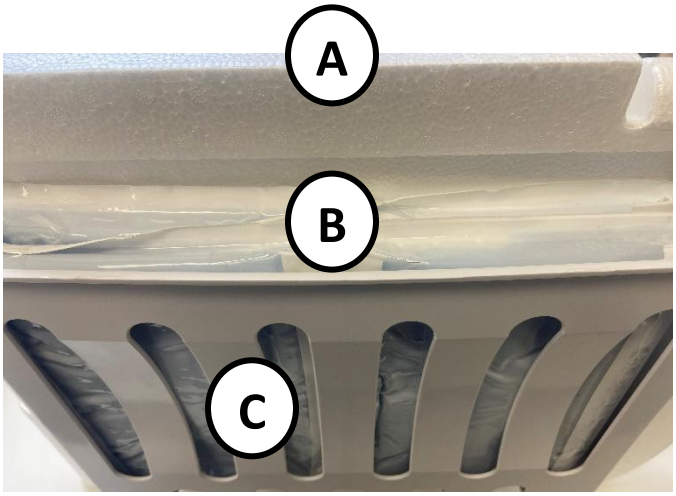
B) Lid

C) Lid latch (×4)

D) Wheels

E) Temperature logger

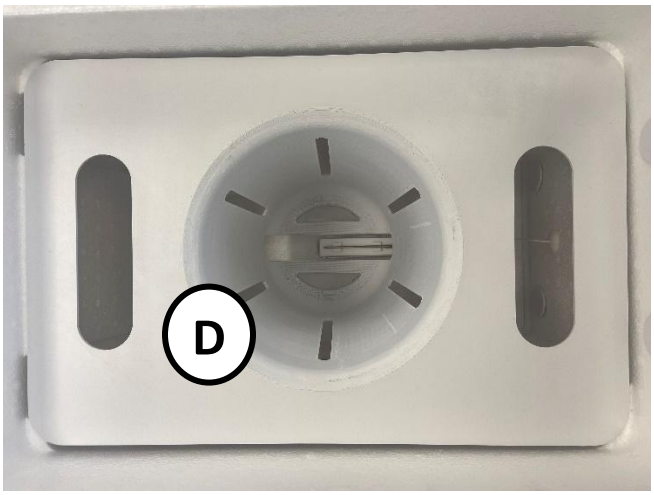
11.2 X°Port HPS Internal Features



A) Lid

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

C) Lid tray for cooling packs



D) Heart cradle

E) Cooling packs (×2) – *Packaged Externally*

F) Organ cradle

11.3 X°Port Cooling Packs

G) Cooling Packs Packaging

H) 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 HPS 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 HPS for the first time.

NOTICE

If the application has been downloaded, ensure that automatic app updates are enabled in the Google Play Store and/or the Apple App Store.

NOTICE

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

12 X°Port HPS Workflow

12.1 X°Port HPS Integrity Check

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

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

☐ There are no obvious signs of damage or tampering.

☐ The cardboard box is sealed with tape.

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

☐ The temperature logger displays a temperature.

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

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

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

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

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

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

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

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

☐ There is a heart cradle in the unit.

☐ There is a second flat organ cradle at the bottom of the unit.

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

☐ The temperature probe is secured in the heart cradle.

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

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

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

12.2 Preconditioning of Cooling Packs

1. Open the X°Port HPS 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 heart 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 HPS

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 and feel like ice.
3. Open the lid of the X°Port HPS.
4. Lift the heart cradles and place 2 cooling packs into the bottom of the X°Port HPS. Replace the heart cradles.
5. If necessary, reattach the temperature probe into the silicone probe holder.
6. Load the organ cradle with a minimum of 3 litres 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 HPS by engaging the 4 lid latches.

9. (Optional) Using the X°Port Mobile Application, scan the QR code on the temperature logger of the X°Port HPS, and select 'Start'.

NOTICE

The X°Port Mobile Application may take several minutes to connect to the temperature logger. Keep the mobile device in close proximity to the X°Port HPS during this time.

10. (Optional) View and monitor the following information:

- Recording duration
- Last temperature

12.4 X°Port HPS Transportation

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

⚠ WARNING

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

12.5 X°Port HPS Organ Loading

1. Open the lid of the X°Port HPS.
2. Place the heart (triple-bagged with single-use sterile organ bags and submerged in 1-2L of fresh preservation solution) into the heart cradle.

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 HPS by engaging the four latches.
4. Using the mobile application, connect to the X°Port HPS and Select 'Load Organ'.

NOTICE

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

5. If the donor organ 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, prior to subsequent use, the cooling packs must be conditioned as per Section 12.2.

⚠ WARNING

Do not open the X°Port HPS 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 and/or mobile application.

12.6 X°Port HPS Temperature Monitoring

1. During organ transport, monitor the internal temperature of the X°Port HPS using either the display on the temperature logger of the X°Port HPS or the optional X°Port mobile application.
2. If using the mobile application, scan the QR code of the X°Port HPS 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 HPS Organ Unloading

1. Open the lid of the X°Port HPS.
2. If using the mobile application, connect to the X°Port HPS 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 organ bag from the X°Port HPS and transfer it to the surgical theater. Take precautions to maintain sterility of the donor heart.
5. Secure the lid of the X°Port HPS by engaging the 4 latches.

12.8 X°Port HPS Disposal

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

13 Emergency Procedure

If the temperature inside the X°Port HPS device reaches 12°C (via the integrated screen, or the mobile application) or if the temperature logger stops working, the following emergency procedure should be performed to protect the heart from possible injury.

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

14 Cybersecurity

14.1 Overview

The X°Port HPS 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 HPS 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 HPS using a mobile device running the X°Port companion application. The X°Port HPS 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 HPS during transport.

NOTICE

Signs that the X°Port HPS's cybersecurity is compromised include no display of temperature, unexplained temperature fluctuations, inability to connect to X°Port HPS, 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 HPS, verify the temperature of the organ bags at the end of the transport with an external thermometer.

NOTICE

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 HPS 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 HPS does not process or store any PHI or other confidential information.

14.4 Firmware Updates

The X°Port HPS 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 HPS 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 or 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 HPS.

Issue	Possible causes	Steps to take
The mobile application does not connect to the temperature logger in the X°Port HPS.	• The Bluetooth connection could not be established. • A cybersecurity event has occurred • The X°Port mobile application is malfunctioning	• Ensure Bluetooth is enabled on the mobile device and repeat the connection attempt. • Restart the X°Port Mobile Application and repeat the connection attempt. • If the problem persists, contact Traferox's technical support and resolve the issue before initiating transport (Section 16). • 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. • The X°Port mobile application is malfunctioning.	• Ensure Bluetooth is enabled on the mobile device and repeat the connection attempt. • Restart the X°Port Mobile Application and repeat the connection attempt. • Move closer to the X°Port HPS. • 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. • 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. • Once connection is established, press 'Reset X°Port', and confirm. • 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 HPS is expired, and the temperature logger battery is depleted. • 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. • Contact Traferox's technical support (Section 16).

During transport, the internal temperature reaches 12°C.	• The X°Port HPS was opened during transport. • The cooling packs were not conditioned at the specified conditions. • The ambient temperature is too high, or the storage duration is longer than specified. • The Heart preservation solution was not sufficiently cooled as per its instructions.	• Follow the emergency procedure (Section 13) • Ensure that the X°Port lid remains closed during the transport, and all 4 latches are engaged. • 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 heart and preservation solution)	14 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

1. Abou Taka, Maria et al. “The Optimization of Renal Graft Preservation Temperature to Mitigate Cold Ischemia-Reperfusion Injury in Kidney Transplantation.” *International journal of molecular sciences* vol. 24,1 567. 29 Dec. 2022, doi:10.3390/ijms24010567
2. Ali A, Wang A, Ribeiro RVP, et al. Static lung storage at 10°C maintains mitochondrial health and preserves donor organ function. Sci Transl Med. 2021;13(611):eabf7601. doi:10.1126/scitranslmed.abf7601
3. Copeland, Hannah et al. “Donor heart and lung procurement: A consensus statement.” *The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation* vol. 39,6 (2020): 501-517. doi:10.1016/j.healun.2020.03.020
4. de Perrot, Marc et al. “Ischemia-reperfusion-induced lung injury.” American journal of respiratory and critical care medicine vol. 167,4 (2003): 490-511. doi:10.1164/rccm.200207-670SO
5. Keon WJ, Hendry PJ, Taichman GC, Mainwood GW. Cardiac Transplantation: The Ideal Myocardial Temperature for Graft Transport. *Ann Thorac Surg*. 1988;46(3):337-341. doi:10.1016/S0003-4975(10)65939-5
6. Martins, Paulo N., Andrea Schlegel, and Davide Ghinolfi. "Cold or Not So Cold?—Static Organ Preservation at 10 C May Prolong Organ Preservation and Facilitate Transplant Logistics." *Transplantation* 106.3 (2022): 427-429.
7. Tyers GFO, Williams EH, Hughes HC, Todd GJ. Effect of perfusate temperature on myocardial protection from ischemia. *J Thorac Cardiovasc Surg*. 1977;73(5):766-771. doi:10.1016/s0022-5223(19)41480-3