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trophon®3
User Manual

L03279 2.0 05/2025

trophon® NanoNebulant® - SAFETY DATA SHEET

Scan QR code to access electronic Safety Data Sheet (eSDS) for trophon NanoNebulant

ENGLISH

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trophon®3
User Manual

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Read this User Manual before operating the trophon®3 device to determine the correct procedures.

For further information, contact your customer service representative or visit the Nanosonics website.

All technical specifications and system approvals are listed in Appendix 1: trophon®3 Device Technical Specifications N05035-2.

The content of this User Manual is correct at the time of product purchase.

trophon® NanoNebulant® is the product name of the trophon®3 disinfectant used in all regions where the trophon®3 device is available for sale, with the exception of US, Mexico and Canada.

trophon® Sonex-HL® is the product name of the trophon®3 disinfectant in the US, Mexico and Canada.

Nanosonics' technologies are protected by a combination of patents, trademarks, and exclusive proprietary rights: http://www.nanosonics.com/nanosonics-patent

Your trophon®3 device representative is:

Attach Business Card or information sticker/stamp here.

CE 0197 RoHS

Conforming to WEEE Directive 2012/19/EU under Article 7 Recovery

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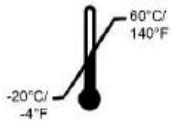
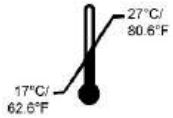
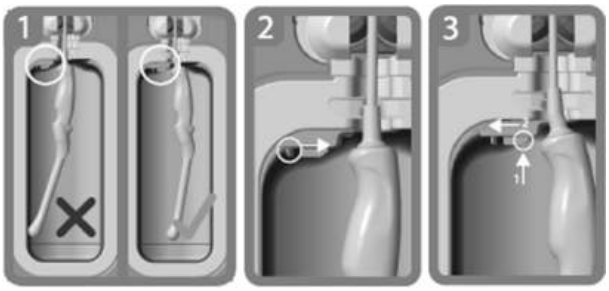
Part A – WARNINGS, INTRODUCTION AND INSTRUCTIONS

SECTION A1: Important Labels, Symbols and Warnings

A1.1 Labels and Symbols

	Caution		Warning
	Consult Instructions For Use		Corrosive
	Environmental Conditions: trophon Storage and Transport Conditions: Temperature range: -20 °C to +60 °C / -4 °F to +140 °F		Single Use Only
	Fragile / Handle With Care		UN 2014 – Hydrogen Peroxide
	Do not disassemble		Dangerous Voltage
	Separate collection for electrical and electronic equipment.		Keep Dry
	Keep Out of Direct Sunlight		This Way Up
	Batch Number		Product Number
	Serial Number		Expires (year and month)
	Legal Manufacturer		Date of Manufacture
	Oxidizer – 5.1		Corrosive – 8
	Warning: Hot Surface		Warning: Moving parts, do not touch mechanism
	Cannot be transported by air freight		Wear Gloves

	Environmental Conditions: Operating temperature range for the trophon device: 17 °C to 27 °C / 62.6 °F to 80.6 °F		AcuTrace® RFID Zone
	EU Importer	EC REP	European Authorised Representative
CE 0197	Conforming to Medical Devices Regulation (EU)2017/745 (MDR)		Conforming to RoHS 3 (EU 2015/863)
MD	Medical Device		
Touch Screen Symbols			
	Start up from sleep		Cycle Start
	Connected to network		Disconnected from network
	trophon software download		Menu
PACS	No Data Transmission to PACS Server		



Integrated Probe Positioning Guide

A1.2: Warnings

Hot Temperatures

- Do NOT touch surfaces in the internal chamber. They can be hot and cause burns.
- Ensure the probe is correctly positioned in the chamber. See C3.3 Positioning the Probe for correct positioning of probe.

Malfunctions

- Do NOT attempt to open the chamber door during a cycle, power failure or system malfunction.
- All repairs must be carried out by authorised service providers.

Transporting the trophon3 device

Follow your facility's manual handling procedures for guidance on lifting heavy objects.

- The trophon3 device weighs approximately:

  Unpackaged 22 kg (48.5 lb).
  Packaged 25 kg (55 lb).

- If your trophon3 device has been used, purge the trophon3 device before transportation to remove the trophon NanoNebulant. (SECTION E2: Remote Software Updates).

Electrical Device

- Use the power cable supplied with the trophon3 device, connect to an earthed power outlet with the correct voltage and frequency as specified on the product and in Appendix 1: trophon3 Device Technical Specifications N05035-2. Incorrect voltage can damage the product.
- The trophon3 device must not be connected to the same circuit as critical patient or life support equipment.
- Spilled fluid can result in electrical shock. Avoid spilling fluids on or around the trophon3 device. Do not immerse any parts of the trophon3 device in liquid.
- Do not attempt to access the internal mechanics. This may result in electric shock.

Protective Wear and Spills

- Wear clean disposable gloves throughout the complete high level disinfection (HLD) process including but not limited to operating the trophon3 device and handling:
  - trophon NanoNebulant. Temporary bleaching and/or irritation of the skin may occur if gloves are not worn.
  - Probes before and after a HLD cycle.
  - trophon Chemical Indicators before and after a HLD cycle.
  - Waste drawer when emptying or obtaining the Manual Door Lock key.
- Wear appropriate personal protective equipment (PPE) when managing spills.
- Never return spills to original cartridges for re-use.

Any serious incidents in relation to the trophon3 device or trophon NanoNebulant should be reported to Nanosonics and / or the authority of your member state.

SECTION A2: Introduction to the trophon3 device

A2.1 Indications for Use

The trophon3 device is intended for the high-level disinfection (HLD) of non-lumened, reusable, transiently invasive and non-invasive medical instruments/devices* e.g. devices that are intended for use for imaging, diagnostic, ablation, coagulation and their accessories.

The trophon3 system consists of a multiple-use device, combined with a single-use disinfectant “trophon NanoNebulant”, delivered from a multi-dose cartridge.

The trophon3 device is suitable for use in general hospital and health care facilities by trained personnel.

The trophon NanoNebulant should be used with the following contact conditions:

Minimum Operational Cycle Time: 4 minutes

Minimum Concentration: 31.5%

Minimum Disinfectant Dose: 1.0 g

Minimum Chamber Temperature: 56 °C

The trophon3 device is NOT intended to reprocess single-use probes or instruments, or to pre-clean medical instruments.

Chemical indicator use is required with every HLD cycle. Only the trophon Chemical Indicator product is the approved chemical indicator for use with trophon3 device.

* The terms “ultrasound probe” and “probe” in the User Manual refer to approved medical instruments.

A2.2 Disinfection Process

At the start of the HLD cycle, the trophon3 device creates an aerosol of concentrated hydrogen peroxide. This is distributed over the exposed surface of the probe providing thorough HLD of the probe’s shaft and handle. Once used, the hydrogen peroxide is converted into its constituents; oxygen and water. During a purge cycle, the converted oxygen is vented into the atmosphere and the water is collected inside the waste drawer located at the side of the trophon3 device for emptying.

The contact conditions are fixed cycle parameters that the end user cannot modify.

A2.3 Microbiocidal Activity Claims

The high-level disinfection performance of trophon3 has been demonstrated for the EU by testing in accordance with relevant harmonised standards (EN standards) for medical instrument disinfection. trophon3 is demonstrated to be an instrument disinfectant in the medical area according to EN 14885 and the following:

- Bactericidal in accordance with EN 13727 and EN 14561
- Mycobactericidal in accordance with EN 14348 and EN 14563
- Fungicidal in accordance with EN 13624 and EN 14562
- Virucidal in accordance with EN 14476, ASTM E1053 and EN 17111.
- Sporicidal in accordance with EN 14347, modified EN 14561 and modified EN 17126.

A2.4 Compatible Probes, Disinfectants and Chemical Indicators.

For details of probes that can be used in the trophon device, refer to the trophon Compatible Ultrasound Probes List on the Nanosonics website.

Use only trophon NanoNebulant and trophon Chemical Indicators when high level disinfecting with the trophon devices. No other disinfectant or chemical indicator has been approved for use with the trophon3 device.

A2.5 Training

Before setting up or using your trophon3 device, ensure that all users are trained in safety procedures and potential hazards, as outlined in this User Manual.

All users must complete the online training module at **www.nanosonicsacademy.com** and hold current certification. It is recommended all staff use their employer-issued email address where available when registering and completing training.

A2.6 Environment and User Profile

The trophon3 device is designed for use in healthcare facilities to high level disinfect ultrasound probes under the control of trained healthcare professionals.

The trophon NanoNebulant, trophon Chemical Indicator, and trophon3 system are designed to be used with minimal PPE (gloves only) and in a standard workplace or clinical setting, such as at the patient point-of-care (for example, patient examination rooms). Special ventilation and other safety precautions are not required when used as per these instructions.

SECTION A3: Instructions

Read these instructions before using the trophon3 device:

- trophon NanoNebulant Safety Data Sheet (SDS) see page 3 for access or contact customer service representative to request a copy.
- Occupational or Workplace Health and Safety Guidelines (OH&SG, OSHA, WHS) for your institution for lifting, spills etc.
- trophon Chemical Indicator Instructions for Use (IFU).
- trophon NanoNebulant IFU.
- trophon accessory IFUs for any additional accessories purchased with the trophon3 device (see Appendix 4: trophon3 Device Accessories).
- Probe manufacturer’s instructions.

Failure to follow instructions may result in:

- Burns, bleaching, electric shock or other injury.
- High level disinfection not achieved.
- Residual disinfectant remaining on the probe, which may cause injury when removing.
- Equipment damage.

Part B – SETUP

SECTION B1: Overview of the trophon3 device

B1.1 Features of the trophon3 Device

Following is a list of the parts of the trophon3 device, with numbers relating to the illustrations in Figures 1, 3, 4, and 5.

1. AcuTrace reader.
2. User Interface (UI).
3. Chamber door handle.
4. Manual door lock opening mechanism cover.
5. Cartridge door. **Warning: Do NOT force open** (cartridge door will automatically open when required).
6. Waste drawer.
7. Power switch.
8. Power socket.
9. Ethernet port.
10. 3 × USB Ports.*
11. Chamber door (opened).
12. Chemical Indicator holder.
13. Probe in correct position.
14. Door lock mechanism. **Warning: Do NOT put fingers into the mechanism**.
15. Cable clamp.
16. Cable seal.
17. Integrated Probe Positioner (IPP).

* The 3 USB ports may be used in any order.

Figure 1 Front

Figure 2 Back

Figure 3 Right Side

Figure 4 Left Side

Figure 5 Chamber

B1.2 Cable Tray

The cable tray holds the probe cable away from the chamber door and stores the cable during HLD. Remove the tray for cleaning, as shown in Figure 6 and wipe with a cloth moistened with a soapy solution.

Figure 6 Cable Tray

SECTION B2: Installation Guide

B2.1 Positioning your trophon3 Device

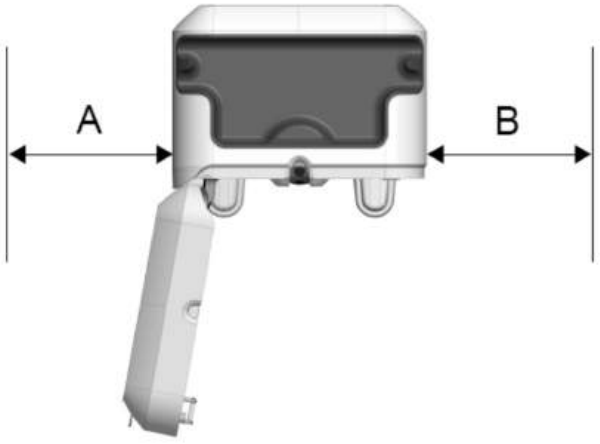
The trophon3 device weighs approximately 22 kg (48.5 lbs). Follow your facility's manual handling procedures for guidance on lifting heavy objects.

The trophon3 device can be mounted on a bench, wall or cart.

1. Ensure the surface is level, can support the weight and allows adequate airflow (see Appendix 1: trophon3 Device Technical Specifications N05035-2).
2. There are no specific illumination requirements for using the trophon3 device. Follow your facility's standard for work environment illumination guidance.
3. Ensure the area around your trophon3 device is free from other equipment and clutter. Position as shown in Figure 7 to ensure access to all features.

The trophon3 device can also be mounted to the wall using the trophon Wall Mount 2 or for a mobile solution, use the trophon Cart. Please refer to the product IFUs for details.

The trophon3 device should be placed at a height from the floor level to accommodate a range of user heights. Refer to Figure 8 for a guide to an ergonomically safe work zone.



Distance on each side of the trophon3 device:

A = 250 mm (10 in)

B = 250 mm (10 in)

(not to scale)

Figure 7

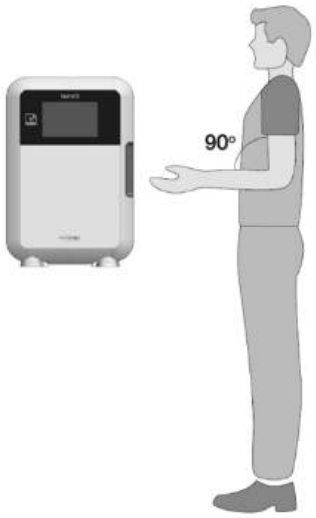


Figure 8. Suggested Mounting Height

B2.2 Powering On

The trophon3 device must not be connected to the same circuit as critical patient or life support equipment.

1. Attach the power cable supplied to the power socket of the trophon3 device.
2. Connect to mains power.
3. Turn on the power switch, located on the left side of the trophon3 device.

NOTE: Keeping the trophon device connected to power allows it to go to sleep automatically. While the trophon device is in sleep mode, it will perform self-maintenance functions.

B2.3 Initial Setup

The Initial Setup launches automatically, prompting you to configure the optional settings when turning on the trophon3 device for the first time. Follow the onscreen instructions.

B2.4 Warm-up Cycle

1. The warm-up cycle prepares the trophon3 device for operation and will begin automatically when the device is powered on.

2. The screen message will indicate when the trophon3 device is ready for use. Follow the onscreen instructions.

B2.5 Touch Screen

The trophon3 device is operated using the touch screen User Interface (UI).

NOTE: The UI can be operated with gloves.

Cleaning the Touch Screen of the trophon3 Device

The screen can be wiped clean using a soft, non-abrasive, low-lint or lint-free cloth or wipe.

B2.6 Basic Settings

In general, to access settings on the trophon3 device:

1. Select ***Menu → Settings***.

2. Select the required setting and follow the onscreen prompts.

The available settings are:

Sleep timer:

The default sleep timer is OFF. This, can be adjusted in this setting. For details, see C3.8 Sleep Mode.

Language

Choose appropriate language for your region.

Date and Time

You can set the time and date manually.

To set the date and time, select ***Menu → Settings → Date and Time***.

Within these menus, the following settings require inputs: Region, Timezone, Date, Date Format, Time, Time Format. It is important to set these settings accurately to ensure the accuracy of the disinfection traceability records.

The trophon3 device will ask you to set the timezone, and then the time. The device will update the time when daylight saving time (DST) starts and ends according to the timezone set.

NOTE: It is important to ensure the correct timezone is set in order for the DST to update correctly.

Printer label

Select the number of printer labels; up to 4 records can be printed.

Daily timers

Configure a preset daily wake and sleep time.

Brightness and Alarm

Configure the brightness of the trophon3 touch screen and the volume of the trophon3 device alarm.

Network

Network access is required to allow for automatic time setting and the remote update of trophon3 software.

Consult your facility's IT administrator or network parameters expert to complete this setting.

The trophon3 device can be connected to a network via the Ethernet port or to a wireless network by a USB Wi-Fi Adapter or USB Cellular Adapter .

- **Ethernet**

The device supports the Transmission Control Protocol (TCP)/ Internet Protocol (IP). You can set a static IP address, or you can use the Dynamic Host Configuration Protocol (DHCP), which directs the router to assign a valid IP address. Select:

Menu → Settings → Network → Ethernet

Then select ***Static IP*** or ***DHCP***. If you use a static IP address, the screen will request network parameters. Your network administrator can provide an IP address that is not in use and will advise appropriate values for the subnet mask and the default gateway.

- **USB Wi-Fi Adapter**

The trophon3 device can be connected to a Wi-Fi network using a USB Wi-Fi adapter. Only connect one USB Wi-Fi Adapter to trophon3.

Nanosonics recommends the use of the **Edimax EW-7811Un V2** (WPA3), **TP-Link TL-WN725N** (WPA2) or **TP-Link TL-WN72N** (WPA2) USB Wi-Fi adapters.

Alternative USB Wi-Fi adapters may be used however, they must meet the following specifications to be compatible with the trophon3 device:

- Wireless Standard: 802.11N (up to 2.4Ghz)
- USB Type: USB 2.0
- Linux Compatibility: Kernal 2.6 or later
- Certifications: RoHS & WEEE
- Network security: WPA2-Personal and WPA2-Enterprise
- Chipset: Realtek RTL8188EUS

To activate the USB Wi-Fi adapter, select:

Menu → Settings → Network → Wi-Fi

Connect a compatible USB Wi-Fi adapter to one of the 3 x trophon3 USB ports (see section B1.1 Features of the trophon3 Device). Turn **ON** the Wi-Fi status and select the desired Wi-Fi network. The trophon3 device will prompt operators to input login credentials for first time connection to a network.

The trophon3 device automatically connects to the Wi-Fi network if a compatible USB adapter is connected and the Wi-Fi network has been previously selected.

Note: The list of available Wi-Fi networks on the trophon3 device will not include unsecured networks.

To disconnect from the Wi-Fi network, toggle the Wi-Fi status to **OFF**.

To display the network properties, select the connected network, then select ***Properties***. On this page, select 'forget' to forget the network credentials. This will also disconnect from the network and username password will be forgotten.

- **USB Cellular Adapter**

The trophon3 device can be connected to a cellular network using a USB cellular adapter. Only connect one USB cellular adapter to trophon3.

Only USB cellular adaptors with the following specifications are compatible with the trophon3 device:

- Wireless Standard: LTE (up to 4g)
- USB Type: USB 2.0
- Linux Compatible
- Certifications: RoHS & WEEE
- Security Authentication: SIM or eSIM

To activate the USB cellular adapter:

Connect a compatible USB Cellular adapter to one of the 3 x trophon3 USB ports (see section B1.1 Features of the trophon3 Device).

The trophon3 device will automatically detect if a compatible USB adapter is connected, indicated by a screen detailing the cellular specifications. A warning screen will show if the USB cellular adapter is no detected or compatible.

To view the cellular network settings, select:

Menu → Settings → Network → Cellular

It is the user's responsibility to ensure the cellular or Wi-Fi USB adapter is compatible and meets your local radio compliance requirements.

Nanosonics recommends the use of Wi-Fi and cellular only when ethernet is unavailable and a network connection is required. It is recommended to prioritise the use of the ethernet, followed by Wi-Fi and then cellular. It is not recommended to simultaneously connect to a combination of ethernet, Wi-Fi or cellular networks.

When a trophon3 device is connected to a network (ethernet, Wi-Fi or cellular) is indicted at the top right of the idle screens, by the following globe symbol:

When a trophon3 device is not connected to a network (ethernet, Wi-Fi or cellular) is indicted at the top right of the idle screens, by the following globe symbol:

- **DICOM**

For users that have activated the functionality of traceability on device via DICOM.

To view DICOM network settings, select:

Menu → Settings -> Network -> DICOM

When a trophon3 device is not connected to a DICOM PACS server, it is indicated at the top right of the idle screens, by the following symbol:

To configure DICOM server list, select:

Menu → Settings -> Network -> DICOM -> Servers

To configure DICOM server settings, select:

Menu → Settings -> Network -> DICOM -> Services

To check subscription and other DICOM settings, select:

Menu → Settings -> Network -> DICOM -> Setting

Software Update

To check for trophon3 software updates, see SECTION E2: Remote Software Updates.

B2.7 AcuTrace

AcuTrace is an automated HLD traceability system that uses Radio Frequency Identification (RFID). AcuTrace-enabled consumables and accessories contain RFID chips that store information and can be read by the built-in AcuTrace reader on the trophon3 device.

Each medical instrument (ultrasound probe) is allocated a trophon AcuTrace Medical Instrument Tag and individual trophon3 operators are assigned a trophon AcuTrace Operator Card. This is important to meet compliance documentation requirements in many regions.

The reprogramming of Medical Instrument Tags and Operator Cards is not recommended, as this may impact the historical disinfection traceability system.

The trophon3 AcuTrace reader is located on the device as shown:

Figure 9. The AcuTrace Reader

AcuTrace-compatible products that have an embedded RFID chip can be identified by this symbol:

Scan the symbol on the AcuTrace reader when prompted.

Products that are AcuTrace-compatible have this symbol on the outer packaging:

This symbol cannot be read by the AcuTrace reader.

The following products are compatible with AcuTrace:

trophon AcuTrace Operator Card

The trophon AcuTrace Operator Card links the HLD cycle to the operator responsible for the workflow. For example, the screen of the trophon3 device prompts the operator to scan their Operator Card against the AcuTrace reader when preparing a probe for disinfection and at the completion of disinfection cycle.

⚠ **When scanning the Operator Card, ensure it is kept still against the AcuTrace reader, until he trophon3 device acknowledges that the card has been read.**

Refer to the trophon3 Installation Guide for further information on how to program a trophon AcuTrace Operator Card.

Following is a summary of the information fields stored for each operator in their Operator Card.

Field name	Size	Recommended or example use
Operator	25 characters	Operator name, operator initials, operator unique ID
Operator ID	20 characters	For example, internal staff ID number
Other	10 characters	For example, department

When programming trophon AcuTrace Operator Cards, the operator can choose to use their personal information or any other coded identifier (e.g. employee number). If personal information is used, please see Appendix 4: trophon3 Device Accessories for privacy policy details.

trophon AcuTrace Medical Instrument Tag

The trophon AcuTrace Medical Instrument Tag stores probe identification information. While programming the Medical Instrument Tag, the operator must input a 'Probe name'. The operator is also required to input the medical instrument 'Serial number'. Attach the trophon AcuTrace Medical Instrument Tag at a distance from the probe that will not interfere with patient examinations or closing of the door of the trophon3 device. Operators scan the Medical Instrument Tag on the AcuTrace reader when prompted by an onscreen message, prior to HLD, to link the HLD cycle to the probe.

⚠ **When scanning the Medical Instrument Tag, ensure it is kept still against the AcuTrace reader, until the trophon3 device acknowledges that the tag has been read.**

Refer to the trophon3 Installation Guide for further information on how to program a trophon AcuTrace Medical Instrument Tag.

Following is a summary of the information fields stored for medical instruments.

Field name	Size	Recommended or example use
Probe name	25 characters	Probe model description
Serial number	20 characters	Probe serial number (Required for trophon3 Software)
Other	10 characters	Department, manufacturer or both

trophon Chemical Indicator and trophon NanoNebulant

The trophon Chemical Indicator carton and trophon NanoNebulant cartridge can be scanned by the AcuTrace reader to track batch and expiry dates of these products.

Refer to each product IFU for more information on its AcuTrace capability and how to program.

B2.8 AcuTrace Settings

AcuTrace features can be enabled or disabled (ON / OFF) via the menu of the trophon3 device.

The option to log Operator Cards and / or Chemical Indicator batch information can also be disabled in this setting.

Disabling removes the scanning of Operator Cards from all instances where scanning the operator card is needed, including the disinfection workflow. This is reflected in the cycle records stored on the trophon3 device and the trophon Printer labels.

Disabling logging of chemical indicators removes the need to scan the Chemical Indicator.

1. Select ***Menu → AcuTrace → AcuTrace Settings***.
2. Select the preferred status **ON** / **OFF** for each setting (AcuTrace Status, Log Operator Cards and Log Chemical Indicators) and follow the onscreen prompts.

Nanosonics recommend enabling ALL options in this setting menu for full traceability. Clinical guidlelines endorse tracing the operators of disinfection procedures.

If 'Log Chemical Indicator' is disabled, it is the operator's responsibility to ensure Chemical Indicators are within their expiry date when used.

SECTION B3: trophon AcuTrace PLUS

trophon AcuTrace PLUS allows the trophon3 device to open an API to share data contained within the device internal storage to other system, such as a Hospital Information Systems or centralised storage of disinfection data. Upon access, a security certificate is to be obtained from Nanosonics at an additional and ongoing cost.

To connect to the Hospital Information system, users are required to develop, configure and integrate an API, a middleware software, which will allow the automatic retrieval of disinfection data from the trophon3 device to the Hospital Information System server.

All connectivity, configuration and integration with the customer IT system is the responsibility of the customer, including the development and cost associated with the API middleware.

This package also enables the Parametric Release functionality of the trophon3 device.

For detailed information on trophon AcuTrace PLUS, consult the trophon AcuTrace PLUS Activation Card IFU.

B3.1 Activation

To activate trophon AcuTrace PLUS, select ***Menu → AcuTrace → AcuTrace PLUS*** and follow the onscreen instructions.

Users will be requested to scan the trophon AcuTrace PLUS Activation Card, if purchased from Nanosonics. Follow the onscreen instructions during the initial setup.

B3.2 Network Parameters Setup

For trophon AcuTrace PLUS API integration, the trophon3 device requires network access.

Note, all of the AcuTrace settings need to be set to ON to allow Parametric Release.

Information on how to configure your network settings is available in B2.6 Basic Settings.

PART C – OPERATION

SECTION C1: Loading the trophon NanoNebulant Disinfectant Cartridge

The cartridge door opens automatically, DO NOT force it open.

Check expiry date of the trophon Nanonebulant. If expired, it cannot be used to run disinfection cycles.

A trophon NanoNebulant disinfectant cartridge needs to be inserted into the trophon3 device before a HLD cycle can commence.

Refer to the trophon NanoNebulant IFU for detailed instructions on how to scan and log, insert, or remove disinfectant cartridges.

Inserting a Disinfectant Cartridge

The screen on the trophon3 device will automatically prompt users to scan (if AcuTrace is enabled) and insert a new disinfectant cartridge, when required. Follow the onscreen instructions and refer to the trophon NanoNebulant IFU.

Note: The trophon3 device will notify the user upon scanning, if the trophon NanoNebulant cartridge is 30 days or less from expiration. Users will be reminded again on the first cycle, 1 day before expiry.

The trophon NanoNebulant will also expire 30 days after insertion into the trophon3 device, regardless of the expiry date shown on the disinfectant label.

Once trophon NanoNebulant is expired a purge will be required. Refer to SECTION E2: Remote Software Updates.

SECTION C2: Logging the trophon Chemical Indicators

No other chemical indicators are approved for use in the trophon3 device.

Check expiry date of the trophon Chemical Indicators. Expired Chemical Indicators cannot be used to run disinfection cycles.

If the Log Chemical Indicators option is enabled, log the new batch of trophon Chemical Indicators:

1. Select ***Menu → AcuTrace → Log Chemical Indicators***.
2. Follow the onscreen instructions.

Note: When Log Chemical Indicators option is enabled, Chemical Indicators must be scanned at the start of every new carton. As this is a manual process, it is important for users of the trophon3 device to complete this step each time a new Chemical Indicator carton is opened. trophon Chemical Indicators must be stored in their original packaging and not be shared across trophon devices outside of its original packaging.

Note: The trophon3 device will notify the user during the first cycle of the day if the trophon Chemical Indicators logged in the system are 30 days from expiry. Users will be reminded again 5 days before expiry and everyday thereafter.

Do not use Chemical Indicators past their expiration date. Confirm Chemical Indicators are within expiry before use.

Disinfection cycles will not run after the Chemical Indicators have expired. Log trophon Chemical Indicators with valid expiry date to continue use of the trophon3 device.

SECTION C3: Routine HLD Cycle

C3.1 Preparing the Probe

Wear gloves throughout the complete HLD process.

Clean and dry the probe and check carefully for probe defects prior to commencing the HLD process, as per the probe manufacturer's instructions. Ensure that the probe has been thoroughly dried after cleaning, with a low-lint or lint-free wipe and that no visible debris is present.

C3.2 Inserting the trophon Chemical Indicator

A whole trophon Chemical Indicator must be used for each disinfection cycle and may only be used once. Refer to the trophon Chemical Indicator IFU.

C3.3 Positioning the Probe

1. If AcuTrace is enabled, when prompted, scan the trophon AcuTrace Medical Instrument Tag against the AcuTrace reader.
2. Open the chamber door and load the probe and a Chemical Indicator.
3. Two clamps (see Figure 10) hold the probe cable securely in the chamber.
4. Wearing gloves, insert the probe into the trophon3 device by gently pulling the probe cable against the cable clamp (see Figure 10a). Then carefully pull the cable upwards until the probe is suspended in the correct location and the probe cable is held by the cable seal (see Figure 10b). Refer to Figures 11–12 and note a correctly positioned probe in the trophon3 device.

⚠ **Do not pull the probe down when loaded in the cable clamp.**

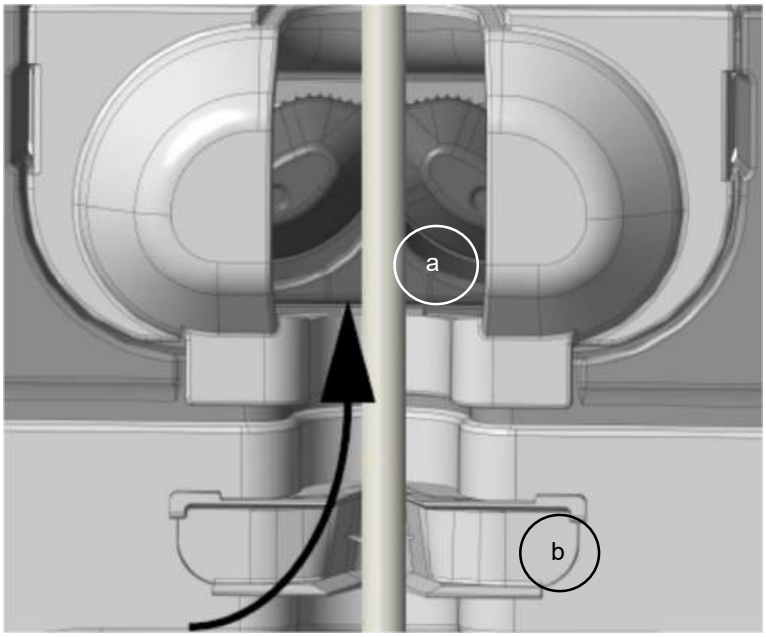


Figure 10

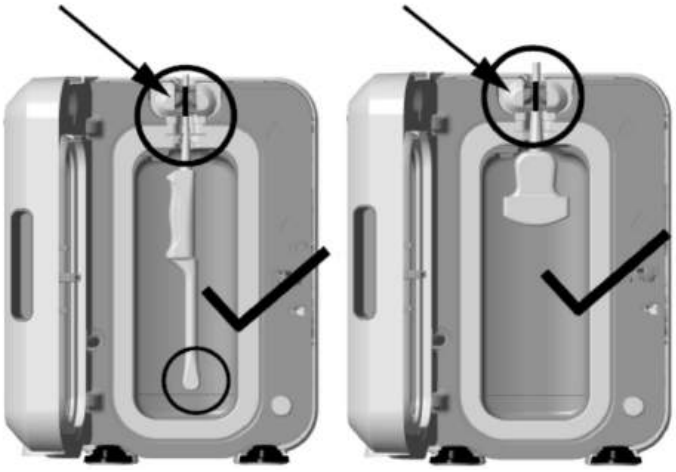


Figure 11

Figure 12

5. Ensure that the probe is correctly positioned in the chamber. The probe must not make contact with the chamber wall and must be positioned at or above the embossed line at the bottom of the chamber. See Figure 11.

6. If the probe is disconnected from its connector end, the external portion of the cable and connector can be secured by placing the connector carefully inside the cable tray.

NOTE: Incorrect positioning of the probe may result in:

- Unsuccessful HLD cycles.
- Residual disinfectant remaining on the probe's surface. This may lead to temporary bleaching or irritation of the skin, or both, if gloves are not worn.
- Uncertain probe compatibility as stated in the trophon Compatible Ultrasound Probes List.

It is customer's responsibility to ensure the probe is correctly positioned in the chamber. Probe compatibility with the trophon3 device and successful HLD cannot be guaranteed if the probe is incorrectly positioned in the chamber.

NOTE: Curved probes must be correctly inserted in the trophon3 device. See Figure 13.

Figure 13

Curved Probes

The Integrated Probe Positioner (IPP) improves the positioning of approved curved probes in the chamber of the trophon3 device. Refer to the trophon Compatible Ultrasound Probes List for further details of probes that can be used in the trophon3 device. Position the probe curve towards the **left** of the trophon3 device's chamber. To engage the IPP, once the probe is inserted into the probe clamp, push the left side of the IPP and slide to the right (see Figure 14). This should displace the probe cable until the probe is no longer in contact with the chamber wall (Figure 13).

To release the IPP, depress the trigger (see Figure 15) and slide to the left.

NOTE: If the IPP is not required for the probe (as per the trophon Compatible Ultrasound Probes List), ensure that it has been completely released and fitted to the left.

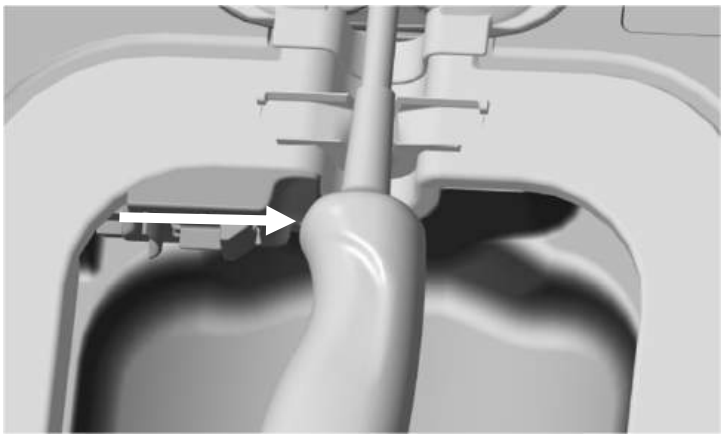


Figure 14

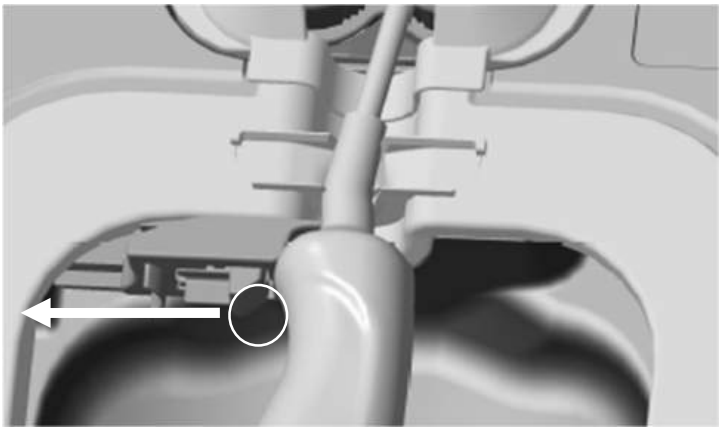


Figure 15

C3.4 Closing the Chamber Door

- The chamber door utilises a two-stage closure mechanism. Carefully close the chamber door to the first click and do not force it shut. The door will automatically close further to seal and lock at the start of the HLD cycle.
- If the door is not properly closed, a screen message will prompt you to close the chamber door.

DO NOT force open or manually unlock the chamber door during a HLD cycle.

C3.5 Disinfecting the Probe

Ensure the probe is clean and dry. Start the cycle by either step 1 or 2 below:

1. Scanning the operator card on the AcuTrace reader (if AcuTrace and Log Operator Card is enabled).

2. Pressing the start button on the screen (if AcuTrace and Log Operator Card is disabled).

The HLD cycle will take 4 minutes to complete, the cycle progress is indicated on the screen.

In the unlikely event that mist is escaping from the chamber, avoid direct contact with the mist and remain at distance from the trophon3 device until completion of the operating cycle and the mist is no longer visible. Contact your customer service representative. Refer to Part D – Troubleshooting for further information.

C3.6 Removing the Probe

After completion of a successful HLD cycle, the ultrasound probe and chamber may have surface temperatures up to 45 °C and 60 °C / 113 °F and 140 °F respectively. Take care not to touch the chamber. The probe will feel warm to touch but is safe for handling and use with gloves on.

1. Wear gloves and follow the onscreen instructions.

2. Using two hands, gently remove and wipe the probe with a dry, clean, single-use, low-lint or lint-free cloth. Visually inspect the probe and remove any present disinfectant residue.

NOTE: Take care when removing the probe to ensure minimal contact and avoid contact with the chamber. Remove the used trophon Chemical Indicator and verify the color change against the Color Assessment Chart on the Chemical Indicator packaging. Discard the used Chemical Indicator.

C3.7 Confirming the HLD Cycle

1. Close the trophon3 chamber door and follow the onscreen instructions to record the Chemical Indicator result.

2. The trophon3 device will indicate a passed or failed cycle. If the trophon Chemical Indicator and/or trophon3 device indicate a failed cycle, repeat steps from Section C3.1 Preparing the Probe

A disinfection cycle will only be completed and logged once the operator has confirmed the Chemical Indicator result, and scanned their Operator Card to confirm (if AcuTrace AND Log Operator Card is enabled). Any errors or power-related issues should be considered a fail. Refer to SECTION F1: Incomplete or Failed Cycles.

3. If the trophon3 device indicates a passed cycle, the probe is now ready for use or storage in a clean, single-use, approved probe storage solution such as the Clean Ultrasound Probe Cover. Once stored, discard the gloves.

The medical instrument (probe) is ready for patient use **only** after the disinfection cycle is completed as described above.

C3.8 Sleep Mode

trophon3 has a power-saving mode to reduce power when inactive. Sleep mode will be entered either:

- By inactivity for an extended period of time (can be set and adjusted by user). This can be adjusted or turned off through selecting ***Menu → Settings → Sleep timer***.
- At a particular time of day using a daily timer. This can be adjusted by selecting ***Menu → Settings → Daily timer***.

Sleep mode will be indicated by the onscreen symbol:

Touch the symbol to wake up the trophon3 device to prepare it for use.

PART D – RECORDS

SECTION D1: Record Options

The trophon3 device logs all complete disinfection cycles. A complete disinfection cycle is as defined in Section C3.7 Confirming the HLD Cycle.

The most recent records can be viewed on the trophon3 touch screen. A complete set of records can be downloaded to external storage via USB.

If a trophon Printer is connected to a trophon3 disinfection device, a cycle record will be automatically printed when each HLD cycle is completed. Up to 4 records can be printed, however, 2 records are printed by default.

Refer to the trophon Printer User Manual for more information.

The trophon3 device has been designed and validated for use with its own accessories. This includes the trophon Printer. Use of unapproved accessories may result in incompatibility and reduced product performance such as compromised accuracy and lifespan of printed records.

To access the records, select:

Menu → Records

Then choose to view one of the record list options detailed below and follow the onscreen instructions.

Last Cycles

View most recent HLD cycles on the touch screen and option to print the details of a selected cycle.

Download records to USB

Disinfection cycle records can be downloaded via USB. Insert a USB drive into any of the three ports on the left hand side of the trophon3 device, select ***Download records to USB*** and follow the onscreen instructions.

*AcuTrace must be enabled to view this record

Reprint Cycles

Reprint labels of any historical cycle. Search by cycle number or date.

Disinfectant*

Disinfectant cartridges scanned and used by the trophon3 device.

Chemical Indicator*

Chemical Indicator batches logged and used by the trophon3 device.

Medical Instrument*

Probes scanned for disinfection in the trophon3 device.

Operator*

An operator of the trophon3 device. Operators log their use by scanning their trophon AcuTrace Operator Card.

NOTE: The Operator listed (if AcuTrace is enabled) is the user responsible for logging the pass or fail Chemical Indicator result via the Operator Card at the end of HLD cycle.

SECTION D2: Record Backups

It is recommended that you regularly back up device logs and store them accordingly. Device logs can be exported as described in SECTION D1: Record Options.

It is also strongly recommended that you complete a backup immediately before a scheduled service, repair or software update of the trophon3 device, in the unlikely event that records are lost. The user is responsible for backing up all data prior to any service activity including a software update. Nanosonics is not responsible for any loss of data under any circumstances.

PART E – MAINTENANCE AND ROUTINE CARE

SECTION E1: Preventative Maintenance & Service

Your trophon3 device requires annual preventative maintenance and a major service at every 5,000 cycles.

Once the ***Service Due*** reminder screen message is displayed, please contact your customer service representative to arrange a service. Contact details, if not provided by your distributor can be found on the Nanosonics website.

The service options found: ***Menu→ Maintenance*** are used to troubleshoot device malfunctioning and should only be used when advised by service personnel.

For more details, see SECTION G1: Service Schedule.

SECTION E2: Remote Software Updates

Remote software updates require a network connection

Nanosonics occasionally release new software updates, which can take up to 20 minutes to install. You may continue to use trophon3 whilst the updates are being downloaded however, when installation is in progress, the trophon3 cannot be used.

When a software update is available, the below icon will be displayed:

Click this icon and follow the onscreen instructions to download, if automatic download is **OFF**.

To check the software version or for information about software releases, go to:

Menu →Settings→Software Updates

E2.1 Automatic Downloads

To set up automatic downloads of new software, go to:

Menu →Settings→Software Updates and select ***ON.***

E2.2 Scheduled Installation

Installation can be selected to initiated immediately or scheduled to run overnight, go to:

Menu →Settings→Software Updates and select the preferred option***.***

SECTION E3: Purge Cycle

The purge cycle removes and converts any remaining disinfectant from the trophon3 device into oxygen and water.

E3.1 When to Run a Purge Cycle

- Prior to transporting the trophon3 device, if it has previously been in use.
- When an onscreen message states that your trophon3 device requires purging. This will occur upon disinfectant expiry at 30 days after insertion. Follow the onscreen instructions to purge.

NOTE: Purging can be deferred until convenient on the day of expiry.

Initiate a purge cycle:

- When the trophon3 device detects an error that requires a service call.
- Before lifting or moving the trophon3 device.
- For troubleshooting purposes when directed by service support only.

E3.2 How to Initiate a Purge Cycle

NOTE: Once the purge cycle has started it may be paused but it cannot be cancelled. Do not switch the trophon3 device off during purging as this will restart the purge cycle. Do NOT attempt to open the chamber or cartridge door during the purge cycle.

To initiate a purge cycle:

1. Wear gloves and ensure that the waste drawer is empty and fully inserted into the trophon3 device Refer to Figure 3 for location of the waste drawer.
2. Select: ***Menu → Maintenance → Purge***. Follow the onscreen instructions.

The purge cycle will typically take less than 30 minutes.

3. When purging is complete, put on gloves, empty the waste drawer and follow the onscreen instructions.
4. Load a new trophon NanoNebulant cartridge (unless transporting), follow the onscreen instructions and refer to the trophon NanoNebulant IFU.

SECTION E4: Cleaning and Disinfecting

- Do NOT submerge the trophon3 device, or pour liquids over it.
- Keep the trophon3 device level and upright at all times.
- Keep the power socket completely dry (see Figure 4).

For cleaning, Nanosonics recommends that the surfaces of the trophon3 device be cleaned in accordance with organisational policies and following the detection of visible contamination. When cool, wipe the chamber and outside surfaces of the trophon3 device with a cloth or wipe moistened with a mild general purpose detergent, or soap and water solution, such as dish soap or general cleaners, until all surfaces are visibly clean.

For disinfecting, Nanosonics recommends that the surfaces of the trophon3 device be disinfected in accordance with organisational policies. Wipe all accessible surfaces of the trophon3 device with an Isopropanol or Quaternary Ammonium (Quat) wipe.

SECTION E5: Transporting the trophon3 Device

NOTE: The procedure below is not necessary for transportation of the device, within a facility, using the trophon Cart.

To transport the trophon3 device:

- Purge the disinfectant. Do not insert a new disinfectant cartridge until the trophon3 device is relocated.
- Switch off the trophon3 device power switch and unplug from the mains.
- Keep the trophon3 device upright at ALL times.
- Pack using only Nanosonics-approved packaging.

SECTION E6: Disposal of the trophon3 Device

The trophon3 device is not biohazardous waste and shall be disposed in accordance with applicable local Regulations. Dispose of trophon3 devices responsibly by contacting your Nanosonics representative to advise the appropriate collection point for the recycling of electrical and electronic equipment.

PART F –TROUBLESHOOTING

SECTION F1: Incomplete or Failed Cycles

This section describes the most common causes for a cycle malfunction and the advised steps to action.

F1.1 Mains Power Failure

If the mains power supply to the trophon3 device is lost before the trophon Chemical Indicator step is confirmed, the current cycle will not complete and the cycle may not be recorded.

- Once the power is restored, follow the onscreen instructions to remove the probe safely from the trophon3 device.
- Discard the used Chemical Indicator and replace with a new one.
- Repeat the HLD cycle.
- If power cannot be restored and the probe is urgently required, follow SECTION F2: Manual Door Lock Override.

F1.2 Cycle Fault

If an error occurs during or at the end of a cycle, a cycle fault will be detected. A cycle that produces **any** error message is a failed cycle and you should follow the onscreen instructions to fix and repeat the HLD cycle. Refer to C3.7 Confirming the HLD Cycle, for the outline of a complete cycle.

In case of a repeated fault or serious malfunction, note the screen error message and contact your customer service representative. Do NOT attempt to use the trophon3 device or the probe.

SECTION F2: Manual Door Lock Override

Use ONLY when the probe is locked in the chamber and must be **urgently** retrieved.

Chamber surfaces may be hot and disinfectant present.

Gloves must be worn to avoid contact with disinfectant.

Do NOT manually open the door during a HLD cycle. Disinfectant mist will be present and contact must be avoided.

1. Ensure the trophon3 device is powered off.
2. Open the waste drawer, remove any liquid and obtain the key (Figure 16).
3. Locate the Manual Door Lock Opening Mechanism Cover on the right side of the trophon3 device (Figure 17). Align the 4 key notches with the indents on the cover and turn the key **ANTI CLOCKWISE** to unscrew.
4. Once the Manual Door Lock Opening Mechanism Cover is removed, align the 4 notches with the grooves of the Manual Door Lock Opening Mechanism inside. Push and turn **CLOCKWISE** to 90 degrees to unlock the chamber door (Figure 18).

The probe is NOT DISINFECTED and CANNOT be used until it has completed a successful HLD cycle or high level disinfected by an alternative method.

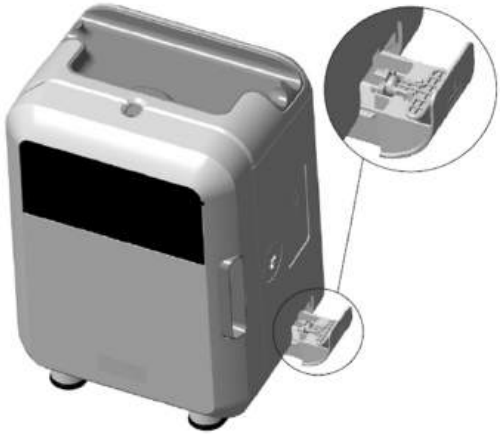


Figure 16

Figure 17

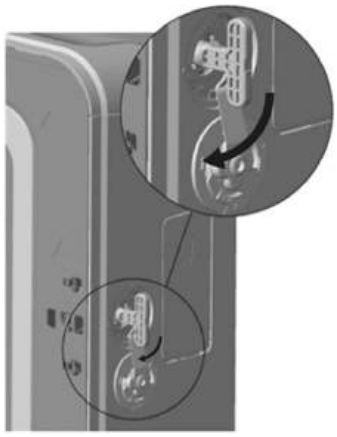


Figure 18

SECTION F3: Diagnostics

Use this table to diagnose and resolve basic problems. If a probe requires urgent retrieval from the trophon3 device, follow SECTION F2: Manual Door Lock Override.

If the problem persists, contact your trophon3 representative.

Symptom	Check / action the following:
There is no power to the trophon3 device. The screen is blank.	• The trophon3 device is completely plugged in and switched ON at both the trophon3 device's power switch and at the wall outlet. • The correct power cable for your region is used.
The chamber door will not open.	• There is power to the trophon3 device. • There is no HLD, warm up or purge cycle running.
The chamber door will not close or lock.	• The probe is loaded correctly. • There is nothing obstructing the chamber door or locking mechanism.

The chamber door is open and locked.	• Power the trophon3 device OFF and back ON using the power switch. Refer to Figure 4. The trophon3 device should then automatically unlock the chamber door. • If the above are not successful, power OFF the trophon3 device and follow SECTION F2: Manual Door Lock Override.
The cartridge door does not open.	• There is power to the trophon3 device. • A HLD cycle is not in progress. • The waste drawer is empty and fully inserted. • There is nothing obstructing the cartridge door. **Note:** The cartridge door is automatic, and should not be forced open.
The cartridge door will not close.	• Correct cartridge type has been inserted. • Cartridge is correctly positioned. • Cartridge lid has been removed.
The probe will not sit correctly in the chamber.	• The probe is compatible for use in the trophon3 device – see Section • A1.2: Warnings. The probe is loaded correctly. • The IPP is correctly engaged or released – see C3.3 Positioning the Probe
The cycle will not start.	• The probe is loaded correctly. • The chamber door is closed. • Confirm probe is clean & dry before pressing start. • All onscreen instructions have been followed correctly.
Liquid is leaking from the Trophon3 device.	**WARNING: Any fluid leaking from the trophon3 device may contain hydrogen peroxide.** If liquid or mist is seen coming from the trophon3 device at any time: • Do not come into contact with the mist or liquid. • Wear appropriate PPE. • Ensure area is well ventilated. • Allow the trophon3 device to complete the cycle. • Turn off the trophon3 device and remove the power cord. • Contact your customer service representative. • Consult the trophon NanoNebulant SDS.
The trophon3 device is failing multiple cycles.	• Record any error codes and color of the trophon Chemical Indicator and contact your customer service representative.
The trophon3 device takes too long to warm up between cycles	• Ensure that the probe is removed promptly at the end of each cycle.

PART G – SERVICE REQUIREMENT AND WARRANTY PROVISION

Contact your trophon3 device representative if you have any questions about:

- The trophon3 device, consumables or accessories
- The warranty

Each trophon3 device has a comprehensive warranty against defects in material and workmanship for 12 months from the date of purchase. The specific warranty terms and conditions are defined in Appendix 2: Product Warranty Terms and Conditions of this manual. Please be aware of the exclusions.

To ensure the safety and efficacy of your HLD operations, the trophon3 device requires servicing as described below.

Modifying the trophon3 device without authorisation will void your warranty.

SECTION G1: Service Schedule

When the trophon3 device is due for service, a ***Service Due*** message will be displayed on the screen to prompt service arrangements. The message will be indicated prior to commencing a HLD cycle at weekly intervals until a service is performed.

Service due information can also be accessed by selecting:

Menu → Maintenance → Service data

The service options found: ***Menu → Maintenance*** are used to troubleshoot device malfunctioning and should only be used when advised by service personnel.

Nanosonics has made the service provision available to customers through either our direct service or our service partners including local distributors who have been trained and authorised to service the trophon3 device. Only authorised customer service or suitably trained personnel should service the trophon3 device with genuine parts supplied from Nanosonics.

For trophons that had been connected to the network, if the trophon has returned from service, a reconnection to the network may be required.

Part H– CYBERSECURITY

Protect your hospital network and restrict unauthorized access to both the network and any connected medical devices. Monitor network activity and keep antivirus and firewalls updated.

Consult Nanosonics Service if you notice any inconsistencies or strange behaviour from the trophon3 device.

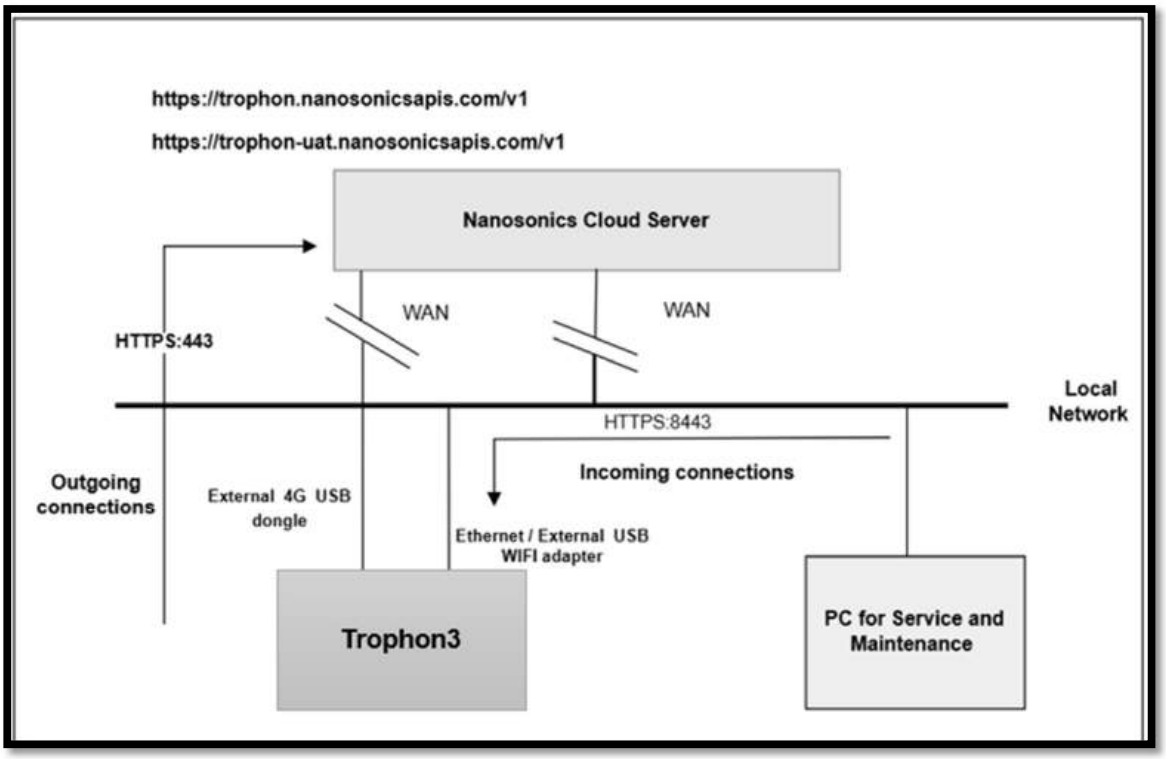
It is recommended to connect the trophon3 device to the hospital network via the ethernet, to ensure software updates can be made. Software updates are critical to ensure the trophon3 device has the latest features and best protection available.

Consult your IT department to set up the network at time of installation. If required, contact your customer service representative to request a copy of the Manufacture Disclosure Statement for Medical device Security (MDS2).

trophon3 Cybersecurity Architecture

The trophon3 Cyber Architecture (Figure 19) gives a pictorial view of the connections made by and to the trophon3 device in a network environment.

Figure 19: Cybersecurity Architecture



trophon3 SBOM

If required, contact your customer service representative to request SBOM information.

trophon3 Software Updates

trophon3 Device Software Update Methods:

1. **Authorized Service Technician Update**:
   - A certified technician performs the software update on-site.
2. **Remote Software Update**:
   - When connected to the Nanosonics cloud service, the trophon3 device can receive updates remotely.
   - Users are notified via the device GUI when a new update is available.
   - Users can choose to proceed with or disregard the update.

Events and logging

- **Key Device Behaviors**: Logs include setting changes, operations running an HLD, and etc.
- **Abnormal Events**: Recorded in device logs, accessible only by a Nanosonics representative using specialized software on an external device.
- **Cloud Connection Activity**: Logged in the device internal logs, available via authenticated connection.

trophon3 device protective features

The trophon3 device implements strong cryptographic protection on the network communications. Network communications are limited to only the essential web services for the Service and Maintenance (S&M) software. Those S&M services require approved security certificates to allow access. All other network communications are ignored.

Backup and Restore features / restoring authenticated user

Your trophon3 device configuration is verified along with the device software to create an intrinsic set of parameters used to operate the device. Since the device configuration is part of the software, there is no need to backup, restore or change this configuration.

Log Files

Any abnormal events will be recorded in the device logs. These are not user accessible but may be accessed by a Nanosonics representative using appropriate software on an external device.

trophon3 device end of life

The trophon3 device software is prepared by Nanosonics and does not depend upon external components for operation. As such, Nanosonics can ensure continued support for upgrades of the device software into the future.

Secure decommission of the trophon3 device

There is no patient information stored on the trophon3 device. Decommissioning of the device is acceptable without erasure of data.

trophon3 device Software Licenses

The trophon3 device software uses statically linked components that are under MIT, GPL-2.0, LGPL 2.1, BSD 3-clause, EPL 1.0, GPL-3.0 Apache-2.0 licenses.

- MIT license [1]: Yocto Project-Dunfell, libudev

- GPL 2.0 license [2]: Linux Kernel, U-Boot

- Apache-2.0 license [3]: Libraries used in Java and Qt backend, eg; spring, grpc, netty, httpclient, dbus, quartz, log4j, derby etc

- BSD 3-clause [4]: protobuf-java, libupb

- LGPL 2.1 [5]: hibernate, libz

- EPL1.0 [6]: junit

- GPL 3.0 [7]: libgpr

Please see below for links to the referenced license notes:

[1] https://opensource.org/license/mit

[2] https://www.gnu.org/licenses/old-licenses/gpl-2.0.txt

[3] https://www.apache.org/licenses/LICENSE-2.0.txt

[4] https://opensource.org/license/bsd-3-clause

[5] https://www.gnu.org/licenses/old-licenses/lgpl-2.1.en.html

[6] https://www.eclipse.org/legal/epl/epl-v10.html

[7] https://www.gnu.org/licenses/gpl-3.0.en.html

APPENDIX 1: trophon3 device Technical Specifications N05035-2

N05035-2 Electrical Specification	Rated mains input voltage: 230 V AC Rated mains input current: 6 A, 50/60 Hz Mains Inlet: IEC type C13 Equipment must be connected to an earthed outlet using the power cable supplied with the trophon3 device.
Data port	Ethernet connector RJ45 USB Port: Type A
Environmental Specification	Operating temperature range: 17 °C to 27 °C / 62.6 °F to 80.6 °F
Storage and Transport Conditions	Temperature range: -20 °C to +60 °C / -4 °F to +140 °F
Physical Characteristics	**Weight of trophon3 device:** Unpacked: 22 kg (48.5 lbs) Packed: 25 kg (55 lbs) **Dimensions of trophon3 device:** 535 mm high × 360 mm wide × 317 mm depth (21 in high × 14.2 in wide × 12.5 in depth)
Electromagnetic Compliance	The trophon3 device has been tested and found to comply with the limits for emission (electromagnetic Interference) pursuant to EN61326-1:2013 (CISPR 11 Group 1 Class B limits)

APPENDIX 2: Product Warranty Terms and Conditions

Terms

This warranty is given by Nanosonics Limited ABN 11 095 076 896 of

7-11 Talavera Road, Macquarie Park NSW 2113, Australia (**Nanosonics**).

Nanosonics warrants to the customer that the trophon3 device is free from defects in material and workmanship that materially affect its function under normal use and service for a period of 12 months commencing upon the date of purchase (**warranty period**).

Exclusions

This warranty does not apply in the following circumstances (regardless of how those circumstances arise):

a. where the trophon3 device has not been used, handled, installed, stored, cleaned and serviced in accordance with the relevant user manual or other written instructions issued by Nanosonics (including where used in temperature or other external conditions exceeding those set out in the product specification, or serviced by persons other than Nanosonics' approved service personnel);

b. where modifications have been made to the trophon3 device, other than by Nanosonics or its authorised service providers;

c. where unauthorised consumables, accessories or other chemicals or items have been used with the trophon3 device;

d. where authorised consumables, accessories or other chemicals or items have been used inappropriately or incorrectly with the trophon3 device;

e. where the trophon3 device is used in conjunction with other equipment or products (other than multiple use ultrasound probes as described in the user manual), without Nanosonics' prior written consent;

f. where the trophon3 device has been damaged due to external or environmental causes of any kind (including factors such as voltage fluctuations, excess voltage or power failure);

g. where the trophon3 device has been damaged as a direct or indirect result of any malicious or negligent act or omission by any person (other than Nanosonics or its authorised service providers);

h. where the defect does not materially affect the function of the trophon3 device (for example scratches or marks on the external surface of the trophon3 device); or

i. where the serial number or product label has been removed, changed, deleted or made unrecognisable, or if the number or label is no longer clearly distinguishable for other reasons beyond Nanosonics‘ control and therefore it is not possible to conclusively identify the product; or

j. where you have not followed a reasonable instruction of Nanosonics however communicated to you.

This warranty applies to the trophon3 device only; the warranty does not cover accessories or consumables used with the device, nor the replacement of used disinfectant cartridges or of parts which need periodic replacement during the life of the product as a result of the ordinary use made of them.

How to make a claim

Please contact your trophon3 customer service representative with any queries regarding this warranty or post warranty repairs. If you wish to make a warranty claim, please contact your trophon3 customer service representative.

Nanosonics will make arrangements for the collection of your trophon3 device. You will be responsible for uninstalling, reinstalling and recommissioning the trophon3 device, regardless of whether or not it is found to be defective. If Nanosonics finds on examination that the trophon3 device is defective in materials and workmanship and is within the warranty period, then we will repair or replace the defective trophon3 device at our discretion. In this case, Nanosonics will bear the reasonable cost of collection and return delivery of the repaired trophon3 device, or replacement trophon3 device, to you at a time stipulated by Nanosonics. If we are unable to repair or replace the trophon3 device for any reason, we will discuss with you an appropriate solution including upgrading you to a newer model or refunding the purchase price.

If Nanosonics finds on examination that the trophon3 device is **not** defective in materials and workmanship in Nanosonics' sole opinion, or if you are not entitled to the benefit of this warranty (for example, if any of the above exclusions apply, or the claim was not made within the warranty period), then Nanosonics may require you to bear the cost of collection and return delivery of the trophon3 device to you, and the costs of any repairs to the trophon3 device, or replacement trophon3 device, requested by you.

You acknowledge that the servicing, repair or software update may result in the loss of user-generated data stored on the trophon3 device. You are responsible for backing up all data prior to any service activity or repair, including a software update. You accept that Nanosonics is not responsible for any loss of data under any circumstances.

Goods presented for repair may be replaced by refurbished goods of the same type rather than being repaired. Refurbished parts may be used to repair the goods.

Australia*: The following statement only applies if you are a 'consumer' for the purpose of the Australian Consumer Law at Schedule 2 of the Competition and Consumer Act 2010.*

Our goods come with guarantees that cannot be excluded under the *Australian Consumer Law*. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. The benefits under this product warranty are in addition to other rights and remedies you may have under law in relation to our goods.

New Zealand*: The following statement only applies if you are a 'consumer' for the purpose of New Zealand's Consumer Guarantees Act 1993.*

Our goods come with guarantees that cannot be excluded under the Consumer Guarantees Act 1993. This guarantee applies in addition to the conditions and guarantees implied by that legislation.

United States*: The following statement only applies to purchasers of the trophon3 device in the United States.*

This warranty is a limited warranty and is the sole and exclusive warranty applicable to the product(s) described herein and is made in lieu of all other warranties, express or implied, including without limitation warranties of merchantability or fitness for a particular purpose.

Other Countries*:* You may have statutory rights in relation to the trophon3 device and these are not affected by this warranty.

APPENDIX 3: MicroDoc Licence Agreement

By purchasing and/or installing and/or using the trophon3 device, you accept and agree to be bound by the terms of the below End User License Agreement (**EULA**) relating to the use of MicroDoc Oracle Java SE Embedded 8 software (the **Software**) utilised in the trophon3 device. If you do not agree to all of the terms of the EULA, you must not install and/or use the trophon3 device.

The capitalised terms below have the same meaning as appear in the EULA entered into between Nanosonics and MicroDoc GmbH for the Software (a copy of which is available on request).

- The user is permitted to the use of the MicroDoc Deliverables only according to the *Product Registration Form* (which may be provided on request);
- The user is prohibited from redistributing the *MicroDoc Deliverable;*
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- The *LICENSEE* hereby notifies the *End User* that the Programs may contain source code that, unless expressly licensed for other purposes, is provided solely for reference purposes pursuant to the terms of the *End User* license agreement;
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- The *LICENSEE* hereby notifies the *End User* that use of the Commercial Features for any commercial or production purpose requires a separate license from Oracle. "Commercial Features" means those features identified in Table 1-1 (Commercial Features In Java SE Product Editions) of the Program Documentation accessible at **http://www.oracle.com/technetwork/indexes/documentation/index.html**

- The *END USER may only* distribute the *MicroDoc Deliverables* only as incorporated in and as an integral part of their product according to the *Product Registration Form*.

APPENDIX 4: trophon3 Accessories*

The additional accessories below are designed for use with the trophon3 device and available for purchase:

trophon AcuTrace Operator Card

The trophon AcuTrace Operator Card can be scanned on the trophon3 device to link the HLD cycle to the operator responsible for various aspects of the workflow.

The trophon3 device collects and stores operator information that has been programmed into the Operator Card and such information is accessible and collected by Nanosonics during servicing (when cycle logs are downloaded). Nanosonics collects the information for the purposes of conducting performance analysis and reporting as part of providing technical and customer support services for trophon3 devices. To the extent operator information comprises of personally identifiable information of an operator, such information will be handled, used and disclosed in accordance with our Privacy Policy, available on our website, as updated from time to time. Our Privacy Policy details how an individual can exercise their various rights in respect of their personal information. If there are any questions about our handling of personal information, please do not hesitate to contact us by emailing: privacy@nanosonics.com.

trophon AcuTrace Medical Instrument Tag

The trophon AcuTrace Medical Instrument Tag is attached to the probes and scanned at the start of a HLD cycle to link HLD to the disinfected probe.

trophon AcuTrace PLUS Activation Card

An add-on package that allows the trophon3 device to connect to Hospital Information Systems for automated sharing and centralised storage and processing of disinfection data. This package also enables the Parametric Release functionality of the trophon3 device. Refer to Section B3 for further details.

trophon Wall Mount 2

The wall mount allows appropriate wall attachment of trophon3 device.

trophon Cart

The cart permits mobility of the trophon3 device.

Clean Ultrasound Probe Cover

Specialised probe covers that provide effective storage between HLD cycles.

trophon Printer & Label Roll

The trophon3-compatible printer uses the label roll to print disinfection records.

trophon Printer Wall Mount

Suitably attaches the trophon Printer to the wall.

trophon Printer Cart Mount

Allows attachment of the trophon Printer to the trophon Cart.

trophon Companion Drying Wipes

Multi-purpose drying wipe.

Only use approved accessories or the trophon3 device may be ineffective.

trophon Wireless Ultrasound Probe Holder

trophon Wireless Ultrasound Probe Holder, when used in accordance with its labelling, is a non-sterile wireless ultrasound probe holder. It is intended to hold a wireless ultrasound probe in the trophon chamber.

GLOSSARY

AcuTrace

The RFID technology used by the trophon3 device and associated products as part of the disinfection traceability system.

Cable clamp

Mechanism at the top of the trophon chamber to grip and hold the probe cable during HLD.

Cartridge

The disinfectant product container that is inserted into the trophon3 device.

Chemical Indicator

A consumable that indicates the delivery of the correct concentration and dosage of disinfectant during a cycle to ensure HLD.

Disinfectant

The consumable liquid in cartridge used by the trophon3 device responsible for HLD.

Cable Seal

A sealing mechanism at the top of the trophon3 chamber (below the cable clamp) to prevent disinfectant leaking from the chamber.

High Level Disinfection (HLD)

A process that inactivates all microbial pathogens, except large numbers of bacterial endospores.

Instruction for Use (IFU)

Instruction guide for recommended use of the product.

Integrated Probe Positioner (IPP)

Mechanism inside the trophon3 chamber to assist with the correct positioning of probes during HLD.

Minimum Effective Concentration (MEC)

The minimum concentration of the disinfectant required for HLD.

Purge Cycle

The process of removing all disinfectant from the trophon3 system.

RFID

Radio Frequency Identification

Safety Data Sheet (SDS)

An outline of the potential health risks posed by a hazardous chemical and the safe working procedures required to mitigate those risks.

User Interface (UI)

The human controlled interaction with software or machine.

Compatible Ultrasound Probes List

A list of probes that have been tested and approved for use in the trophon3 device by Nanosonics, in conjunction with the probe Original Equipment Manufacturers (OEMs).

PACS

Picture Archiving and Communication System

DICOM

Digital Imaging and Communications in Medicine

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