

# trophon®2 User Manual



# trophon<sup>®</sup>2 User Manual

#### Read this manual before operating the trophon®2 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.

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

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NanoNebulant is the product name of the trophon2 disinfectant used in all regions where trophon2 is available for sale, with the exception of US and Canada.

Sonex-HL is the product name of the trophon2 disinfectant in the US and Canada.

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#### Your trophon2 representative is:

Attach Business Card or information sticker/stamp here.		

#### **FCC Compliance Statement**

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning: Any changes or modifications not expressively approved by Nanosonics could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules and Innovation, Science and Economic Development (ISED) Canada's licence-exempt RSS standards. Operation is subject to the following two conditions:

- (1) This device may not cause interference; and
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme avec Partie 15 des règlements de la FCC et Innovation, Sciences et Developpement economic Canada RSS standard exempts de licence

- (s). Son utilisation est soumise à Les deux conditions suivantes:
- 1. cet appareil ne peut pas provoquer d'interférences et
- 2. cet appareil doit accepter Toute interférence, y compris les interférences qui peuvent causer un mauvais fonctionnement du dispositif

# C€0197 Conforming to MDD 93/42/EEC; certified by Notified Body TUV Rheinland



ROHS
2011/65/EU
Conforming to RoHS Directive 2011/65/EC



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



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# PART A – INTRODUCTION, INSTRUCTIONS AND WARNINGS

#### **SECTION A1: INTRODUCTION TO THE TROPHON2**

#### **A1.1 Accessories**

**Accessories\*** designed for use with the trophon2 include:

- trophon AcuTrace Operator Card
- trophon AcuTrace Medical Instrument Tag
- trophon Wall Mount
- trophon Cart
- trophon Logbook
- trophon Clean Ultrasound Probe Cover
- trophon Printer & Label Roll
- trophon Printer Wall Mount
- trophon Printer Cart Mount

Only use trophon approved accessories or the trophon2 may be ineffective.

\*Some accessories are available for certain trophon2 variants only. Contact your trophon representative for more information.

#### A1.2 Intended Use

Australia, New Zealand & Europe:

The trophon2 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.

#### Rest of World:

The trophon2 is designed to provide High-Level Disinfection (HLD) of validated ultrasound probes\*. HLD is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber containing the ultrasound probe.

This trophon2 system consists of a multiple use device, combined with a single use disinfectant, delivered from a multi-dose cartridge. The system uses proprietary cartridges of hydrogen peroxide disinfectant which are intended to be used exclusively with the trophon2 device only. The use of a trophon2 Chemical Indicator is required with every trophon2 HLD cycle which performs an independent confirmation for customers in identifying whether a HLD cycle has been successful.

The trophon2 is NOT intended to reprocess single-use devices or pre-clean medical instruments.

Chemical Indicator use is required with every (HLD) cycle.

#### **A1.3 Disinfection Process**

At the start of the HLD cycle, the trophon2 creates an aerosol of concentrated hydrogen peroxide. This is distributed over the exposed surface of the probe providing thorough, HLD of the shaft and the handle of the probe. The trophon2 then breaks down the hydrogen peroxide into small amounts of oxygen and water which is evaporated into the atmosphere. During a purge, oxygen is vented into the atmosphere and water is collected in the waste drawer at the side of the trophon2.

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

#### **A1.4 Disinfection Records**

Disinfection records up to 5 years can be accessed on the trophon2 screen, printed via the trophon Printer or downloaded to USB. Refer to home, select *Disinfection Records* and follow the onscreen instructions.

<sup>\*</sup> The terms "ultrasound probe" and/or "probe" in the User Manual refer to approved medical instruments.

#### A1.5 AcuTrace™ Technology

The AcuTrace Technology provides a traceability system that allows operator and instrument identification and recording through the trophon2 Acutrace Operator Card and trophon2 AcuTrace Medical Instrument Tag products.

Disinfectant and Chemical Indicator batch information can also be traced and recorded through AcuTrace.

Refer to each product Instructions For Use (IFU) for details.

#### A1.6 Validated Probes and Disinfectants

For details of probes that can be used in the trophon2 refer to:

trophon2 Validated Probes List at the Nanosonics website.

Use only trophon2 disinfectant cartridges when high level disinfecting with the trophon2

#### A1.7 Training

Before setting up or using your trophon2, ensure that all users:

- Are trained in safety procedures and potential hazards, as outlined in this manual.
- Visit Trophon2/Login on the Nanosonics website to complete the online training module and receive trophon2 certification.

#### A1.8 Environment and User Profile

The trophon2 is designed for use in healthcare facilities to high level disinfect ultrasound probes under the control of trained healthcare professionals.

The disinfection cartridge, Chemical Indicator, and trophon2 system are designed to be used with minimal personal protective equipment (gloves only), and in a standard workplace or clinical settings, including at the patient point-of-care. Special ventilation and other safety precautions are not required when used as per the manufacturer's instructions.

#### A1.9 Instructions

#### Read these instructions before using the trophon2:

- Safety Data Sheet (SDS) enclosed with the trophon2.
- Occupational or Workplace Health and Safety Guidelines (OH&SG, OSHA, WHS) for your institution for lifting, spills etc.
- · Chemical Indicator (IFU)
- trophon2 disinfectant cartridge IFU
- Instructions for trophon2 accessories.
- Probe manufacturer's instructions.

If you do not follow instructions:

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

#### A1.10 Warnings

#### **Hot Temperatures**

- Do NOT touch surfaces in the internal chamber. These are hot and can cause burns.
- To avoid probe damage, ensure the probe is correctly positioned in the chamber. (See section C2.3 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 trained personnel.

#### **Transporting the trophon2**

- The trophon2 weighs approximately 22kg (46lb).
- The packaged trophon2 weighs approximately 25kg (55lb).
- If your trophon2 has been used, purge the trophon2 before moving, to remove hydrogen peroxide. (See section C3).

#### **Electrical Device**

- Use the power cable supplied with the trophon2, connect to an earthed power outlet with the correct voltage and frequency as specified on the product and in Appendix 1. Incorrect voltage can cause damage to product.
- The trophon2 must not be connected to the same circuit as a patient critical or life support device.
- Spilled fluid can result in electrical shock. Avoid spilling fluids onto or around the trophon2. Do not immerse any parts 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 HLD process including but not limited to running the trophon2 and handling:
  - o disinfectant cartridges, as temporary bleaching and/or irritation of the skin may occur if gloves are not worn
  - o probes before and after a HLD cycle
  - o chemical indicators before and after a HLD cycle
  - o emptying the waste drawer
- Wear appropriate personal protective equipment (PPE) when managing spills.
- Never return spills to original cartridges for re-use.

#### SECTION A2: IMPORTANT WARNINGS, LABELS and SYMBOLS

#### A2.1 Labels and Symbols

<u> </u>	Caution		Corrosive
Ţį	Consult instructions for use	<b>(!</b> )	Warning
$\Diamond$	Start (of action)	8	Single Use Only
1	Fragile / Handle With Care		Warning: Hot Surface
	Do not disassemble	<b>F</b>	Dangerous Voltage

X	Separate collection for electrical and electronic equipment	宁	Keep Dry
紫	Keep Out of Direct Sunlight	$\square$	Expires (year and month)
LOT	Batch Number	REF	Product Number
	Cannot be transported by air freight	<u>††</u>	This Way Up
	UN 2014		Wear Gloves
OXIDIZER 5.1	Oxidizer – 5.1	CORROSIVE	Corrosive – 8
***	Legal Manufacturer	<u>~</u>	Date of Manufacture
-20°C/ 4°F	Environmental Conditions: trophon2 Storage and Transport Conditions: Temperature range: -20°C to +60°C / -4°F to +140°F	27°C/ 80.6°F	Environmental Conditions: trophon2 Operating temperature range: 17°C to 27°C / 62.6°F to 80.6°F
=	Menu		Home
AcuTrace <sup>™</sup>	AcuTrace	?	Help
Probe Positioning Guide			

# PART B – OVERVIEW OF TROPHON2 FEATURES AND INSTALLATION GUIDE

# **SECTION B1: TROPHON2 FEATURES**

# **Front**



Back



Figure 1

Figure 2



Figure 3

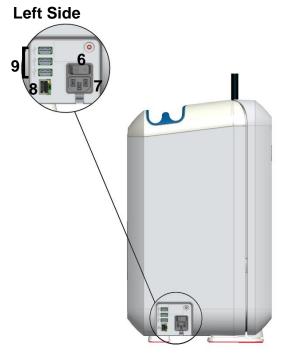
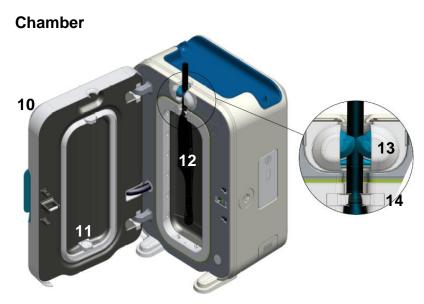


Figure 4



- 1. User display/ touch screen
- 2. Chamber door handle
- Cartridge door. Do NOT force open. (Cartridge door will automatically open when required).
- 4. Manual Door Lock Opening Mechanism
- 5. Waste drawer
- 6. Power switch
- 7. Power socket
- Ethernet port
- 9. USB Ports
- 10. Chamber door (opened)
- 11. Chemical Indicator holder
- 12. Probe in correct position
- 13. Cable clamp
- 14. Gland seal

Figure 5

procedures for guidance on lifting heavy objects

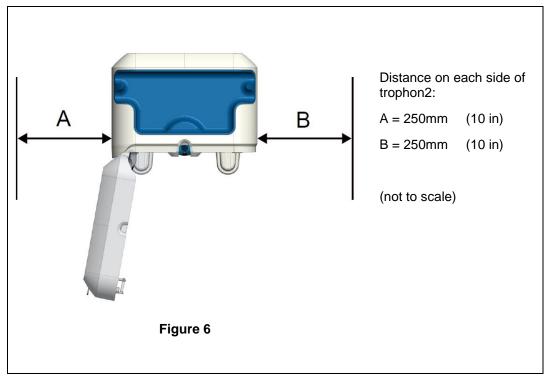
### **SECTION B2: INSTALLATION GUIDE**

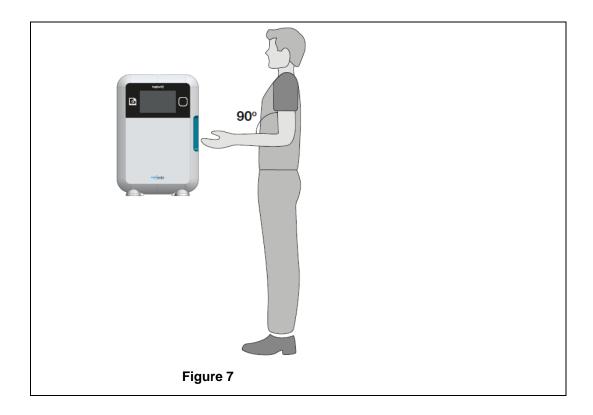
### **B2.1 Positioning your trophon2**



- 1. Ensure the surface is level, can support the weight and allows adequate airflow (see Appendix 1). There are no specific illumination requirements to use the trophon2. Follow your facilities standard for work environment illumination guidance.
- 2. Ensure the area around your trophon2 is free from other equipment and clutter. Position as shown in Figure 6 to ensure access to all features.

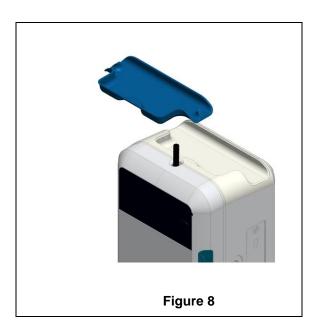
The trophon2 should be placed at a height from the floor level to accommodate a range of user heights. Refer to Figure 7 for a guide to an ergonomically safe work zone.





#### **B2.2 Cable Management System Installation**

The Cable Management System (CMS) holds the ultrasound cable away from the chamber door and stores the cable during HLD. Remove the intray for cleaning (figure 8) and wipe with a cloth moistened with a soapy solution.



#### **B2.3 Powering On**

- The trophon2 must not be connected to the same circuit as a patient critical or life support device.
- 1. Attach the power cable supplied to the trophon2 power socket.
- 2. Connect to mains power and switch on.
- 3. Turn on the power switch, located on the left side of the trophon2.

NOTE: To maximise the life of the disinfectant cartridge, keep your trophon2 switched on at all times, except when the machine needs to be moved.

#### **B2.4 Basic Settings**

#### For all settings:

1. Press the menu button at the top left of the touch screen

#### **Date and Time**

Select Set Date and Time and follow the onscreen messages.

#### Language

Select Language and follow the onscreen messages.

#### **Alarm Settings**

- Select Alarm Settings and press OK.
- Change the alarm repeat or volume settings by following the onscreen messages.
- If alarm repeat is enabled, the alarm will repeat every 30 seconds for the following situations:
  - a. The probe is left in the trophon2 after a HLD cycle.
  - b. An error message is displayed and requires a response.

#### Contrast

Select Contrast and follow the onscreen messages.

#### **B2.5 Warm-up Cycle**

- 1. The warm up cycle prepares the trophon2 for operation and will begin automatically when the machine is powered on.
- 2. Warm up time will count down on the screen
- 3. The screen message will indicate when the warm up is complete and the trophon2 is ready for use. Follow the onscreen instructions.

# PART C - ROUTINE USE, MAINTENANCE AND CARE

#### SECTION C1: LOADING THE DISINFECTANT CARTRIDGE



The cartridge door opens automatically, DO NOT force open.

A trophon2 disinfectant cartridge needs to be inserted into the trophon2 before a HLD cycle can commence.

#### **Inserting a Disinfection Cartridge**

- 1. Cartridge door will automatically open when the cartridge needs replacing. Do NOT force the cartridge door open as this may damage and render the device non functional.
- 2. To insert cartridge, wear gloves and follow the onscreen instructions.
- Remove cap from the cartridge and place cartridge NECK FIRST into the holder until the bottom of the cartridge is in line with the top of the holder. Do NOT force the cartridge into the holder.
- 4. Gently close the cartridge door.

#### Removing a Disinfectant Cartridge

Cartridge removal is required when the cartridge has expired or is empty and will be indicated by a screen message. If the cartridge has expired, purge the trophon2. Refer to Section C3 for purging instructions.

- 1. Wear gloves and follow the inscreen instructions.
- 2. Grip the exposed base of the cartridge and lift out of the holder. Avoid touching the neck and lid. Do not shake the used cartridge.

#### **Disposal of Disinfectant Cartridge**

Follow the procedures of your institution and / or local environmental and government regulatory requirements for disposal of CORROSIVE or OXIDIZING materials,

Refer to the trophon2 disinfectant IFU for detailed instructions on how to scan, insert, replace or remove trophon2 disinfectant cartridges.

#### SECTION C2: ROUTINE HIGH LEVEL DISINFECTION CYCLE

#### **C2.1 Preparing the Probe**

Wear gloves throughout the complete HLD process.

Clean and dry the probe and check clearly for probe defects BEFORE commencing the high level disinfection process, as per the probe manufacturer's instructions. Ensure the probe is completely dry and no visible debris is present.

#### C2.2 Inserting the Chemical Indicator

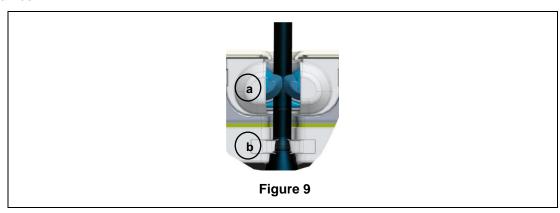
A trophon2 Chemical Indicator must be used for each disinfection cycle. No other chemical indicators are approved for use in the trophon2. Each Chemical Indicator may only be used once. Place the trophon2 Chemical Indicator into the holder when the screen instruction indicates to. Refer to the trophon2 Chemical Indicator IFU. You may then position the probe in the chamber.

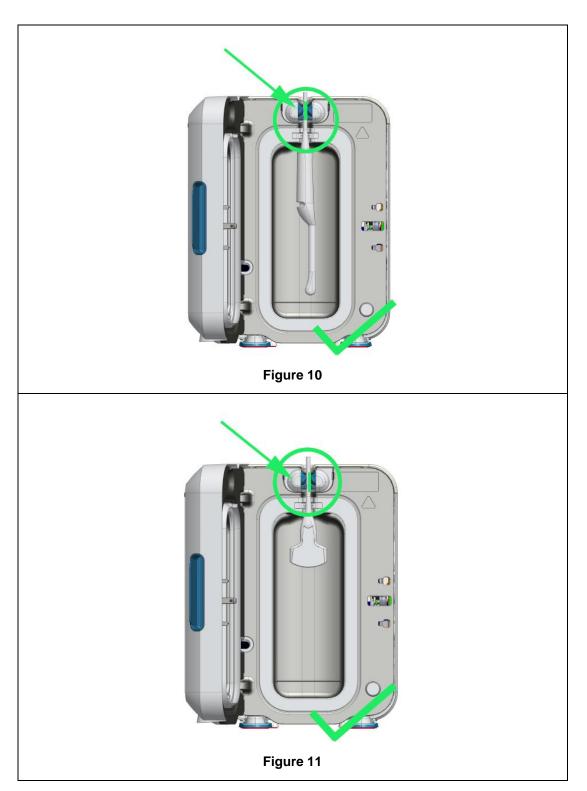
#### **C2.3 Positioning the Probe**

- 1. When ready, the trophon2 will advise to scan a Medical Instrument Tag. Scan the trophon Medical Instrument Tag or select skip to continue without scanning.
- 2. Open the chamber door and load probe and chemical indicator as per the on screen instructions.
- 3. Two clamps hold the probe securely in the chamber. See Figure 9.

The probe has a short sleeve at the back of the handle, covering the electrical cable. This is the Probe Gland

- 4. Wearing gloves, insert the probe into the trophon2 by gently pulling the probe cable against the cable clamp (Figure 9a). Then carefully pull the cable upwards until the probe is suspended in the correct location and the probe gland is held by the gland seal (Figure 9b). Refer to figures 10-12 for a correctly positioned probe in the trophon2.
- 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 above the embossed line at the bottom of the chamber.



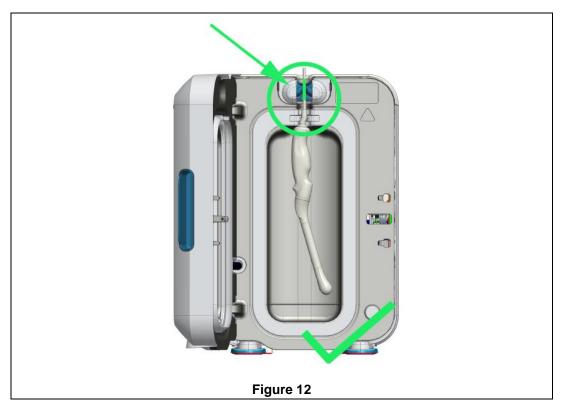


- 6. Secure the external portion of the cable and connector by:
  - Placing the connector carefully inside the tray.
  - Coiling the cable neatly and safely around the cable holder on the side of the tray assembly.

**NOTE:** Incorrect positioning of the probe may result in:

- Failed HLD cycles.
- Residual disinfectant remaining on the probe surface. This may lead to temporary bleaching and / or irritation of the skin if gloves are not worn.
- Damage to the probe may occur if in contact with the chamber wall.

**NOTE:** Curved probes must be correctly inserted in the trophon2. See Figure 12.



#### **C2.4 Closing the Chamber Door**

- Carefully close the chamber door to the first click and do not force shut. The door will automatically close further to seal and lock at the start of a HLD cycle.
- If the door is not properly closed, the trophon2 will display a screen message outlining to close the chamber door.
- **!** DO NOT open the chamber door during a HLD cycle.

## **C2.5 Disinfecting the Probe**

Once the door is closed, the trophon2 will request confirmation that the probe is clean and dry prior to HLD. Door will lock upon confirmation.

- 1. Scan the trophon2 Operator Card to confirm or select *Skip* to continue and follow the onscreen instructions.
- 2. If the probe has NOT been cleaned and dried, press *No.* Remove the probe, clean and dry the probe and repeat above steps from C2.3.
- 3. Once the probe is cleaned and dried and the probe has been correctly inserted into the trophon2, press Start to lock the chamber and initiate the cycle or *Cancel* to unlock the machine, remove the probe and follow the onscreen instructions.
- 4. The progress of the disinfection cycle is indicated on the screen.
- 5. The HLD cycle will take 7 minutes to complete.
- <u>WARNING</u>: In the unlikely event mist is visibly escaping from the chamber, remain at a distance from the trophon2 until completion of the operating cycle and the mist is no longer visible. Do not come into direct contact with the mist. Contact your customer service representative (see Part D Troubleshooting).

#### **C2.6 Removing the Probe**

**NOTE:** After completion of a successful HLD cycle, the ultrasound probe and chamber may have surface temperatures up to 45°C/ 113°F and 60°C/ 140°F respectively. Care should be taken 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 on screen instructions.

- Immediately remove the used Chemical Indicator from the trophon2 and verify the colour change against the chart on the Chemical Indicator carton. Record the result using the printer or logbook accessories if required.
- 3. Discard the used Chemical Indicator and follow the onscreen instructions
- 4. Remove the probe carefully using minimal contact after the cycle is complete. Avoid touching the probe against the chamber's hot surface. Avoid compromising the probe's high level disinfected surface before use.
- 5. Wipe the probe with a clean, low lint, single-use, dry cloth. Visually inspect the probe and remove any present disinfectant residue.
- 6. If a pass was verified by the Chemical Indicator colour and trophon2, the HLD cycle was successful proceed to step 7 below. If a fail was verified against the Chemical Indicator, repeat steps from section C2.1.
- 7. Discard gloves.
- 8. Close the chamber door. The probe is now ready for use or storage.

#### **C2.7 Sleep Mode and Shutdown Procedures**

#### **SECTION C3: PURGE CYCLE**

The purge cycle removes any remaining disinfectant from the cartridge as well as inside the trophon2 and converts the disinfectant into oxygen and water.

#### C3.1 When to Run a Purge Cycle

- When an onscreen message states that your trophon2 requires purging. This will occur upon disinfectant expiry at 30 days after insertion. Follow the onscreen instructions to purge.
- Prior to transporting the trophon2, if it has previously been in use.

#### Manually initiate a purge cycle:

- When the trophon2 detects an error that requires a service call.
- Before lifting or moving the trophon2.
- For troubleshooting purposes when directed by service support only

#### C3.2 How to Manually Run a Purge Cycle

**NOTE:** Once the purge cycle has started it may be paused but it cannot be cancelled. Do not switch the trophon2 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 manually initiate a purge cycle:

- 1. Wearing gloves, ensure the empty waste drawer is fully inserted into the trophon2.
- 2. Select *Menu*, then select *Disinfectant Management and Shipping* and then select *Purge*. Follow the on screen instructions.

The purge cycle will typically take 20 minutes (maximum of 100 minutes).

- 3. When purging is complete, put on gloves and follow the screen messages.
- A new cartridge will need to be added, follow on screen instructions and refer to the disinfectant IFU.

#### C3.3 Transporting the trophon2

- Before transporting the trophon2, you must purge the disinfectant, switch off the trophon2 at the power switch and unplug the trophon2 from the mains.
- Keep the trophon2 upright at ALL times.
- Only use Nanosonics approved packaging when transporting the trophon2.

#### **SECTION C4: INCOMPLETE OR FAILED CYCLES**

This section describes the most common situations in which a cycle has not been completed satisfactorily and the required actions to take (see also Part D – Troubleshooting).

#### **C4.1 Mains Power Failure**

If the mains power supply to the trophon2 is lost while in operation, the current cycle will not complete.

- Once power is restored follow the onscreen messages to remove the probe safely from the trophon2.
- 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 C4.3.

#### C4.2 Cycle Fault

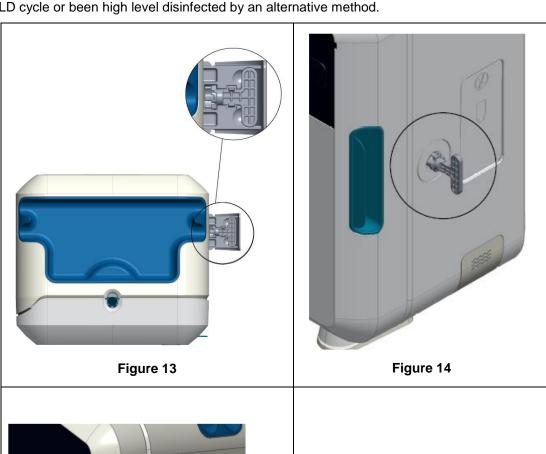
If a problem occurs during or at the end of the cycle, a cycle fault will be detected. Follow the onscreen messages to fix the fault and repeat the HLD cycle.

In case of a repeated fault or serious malfunction, contact your customer service representative citing the error message shown on the screen. Do NOT attempt to use the trophon2 or the probe.

#### C4.3 Manual Door Lock Override

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

- **(!)**
- There may still be disinfectant in the chamber and chamber surfaces may be hot. 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 must not be made contact with.
- 2. Ensuring the trophon2 device is powered off, obtain the door lock key located in the waste drawer (Figure 13).
- 3. Align the 4 notches on the key with the indents on the Manual Door Lock Opening Mechanism Cover on the right side of the trophon2 (Figure 14) and turn the key **ANTI CLOCKWISE** to unscrew the cover.
- 4. Once the Manual Door Lock Opening Mechanism Cover is removed, align the 4 notches with the groves of the Manual Door Lock Opening Mechanism inside, push and turn **CLOCKWISE** to 90 degrees and unlock the chamber door (Figure 15).
  - The probe is **NOT DISINFECTED** and **CANNOT** be used until it has completed a successful HLD cycle or been high level disinfected by an alternative method.





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#### **SECTION C5: ROUTINE CARE AND MAINTENANCE**

#### **C5.1 Regular Cleaning**

- 1. Do NOT submerge the trophon2, or pour liquids over it.
- 2. Keep the trophon2 level and upright at all times.
- 3. Keep the power socket completely dry (see Figure 4).
- 4. For cleaning, when cool, wipe inside the chamber and the outside of the trophon2 with a cloth moistened with a mild, soapy solution, until all surfaces are visibly clean.
- 5. For disinfecting, wipe all accessible surfaces of the trophon2 with an Isopropanol or Quat Wipe.

# **C5.2 Preventative Maintenance Service**

Your trophon2 requires annual preventative maintenance and a major service at 5,000 cycles.

Once the service due reminder message is displayed on the screen, please contact your customer service representative to arrange a service.

#### **SECTION C6: DISPOSAL OF TROPHON2**

Contact your trophon2 representative to advise the appropriate collection point for the recycling of electrical and electronic equipment.

# **PART D - TROUBLESHOOTING**

Use this table to diagnose and resolve basic problems. If a probe is present and you need to retrieve it urgently, follow section C4.3.

# If the problem persists, contact your trophon2 representative.

Symptom	Check for the following:
There is no power to the	The trophon2 is completely plugged in and switched ON at both
trophon2.	the trophon2 power switch and at the wall outlet.
2. The screen is blank.	The correct power cable for your region is used.
3. The chamber door will not	There is power to the trophon2.
open.	There is no HLD, warm up or purge cycle running.
4. The chamber door will not	The probe is validated for use in the trophon2 – see section A1.2.
close or lock.	The probe is loaded correctly.
	There is nothing obstructing the chamber door or locking
	mechanism
5. The chamber door is open	Power the trophon2 OFF and back ON using the power switch
and locked.	(see Figure 4). The trophon2 should then automatically unlock the
	chamber door.
	If the above are not successful, power OFF the trophon2 and
C. The contrides door door not	follow section C4.3.  There is power to the trophon2.
6. The cartridge door does not open.	All cycles are complete.
ореп.	The waste container is empty and fully inserted.
	There is nothing obstructing the cartridge door from opening.
	Note: the cartridge door is automatic, and should not be forced
	open.
7. The cartridge door will not	Correct cartridge type has been inserted.
close.	Cartridge is correctly positioned.
	Cartridge lid has been removed.
8. The probe will not sit	The probe is validated for use in the trophon2 – see section A1.2.
correctly in the chamber.	The probe is loaded correctly.
9. The cycle will not start.	The probe is loaded correctly.
	The chamber door is closed.
40.1: :1: 1	Confirm probe is clean & dry before pressing start
10. Liquid is leaking from the	WARNING: Any fluid leaking from the trophon2 may
trophon2.	contain hydrogen peroxide.  If liquid or mist is seen coming from the trophon2 at any time:
	Do not come into contact with the mist or liquid.
	Wear appropriate PPE.
	Ensure area is well ventilated.
	Allow the trophon2 to complete the cycle.
	Turn off the trophon2 and remove the power cord.
	Contact your customer service representative.
	Consult the Safety Data Sheet.
11. The trophon2 is failing	Record any error codes and colour of the chemical indicator and
numerous cycles.	contact your customer service representative.
12. The trophon2 takes too long	Ensure that the probe is removed immediately at the end of each
to warm up between cycles	cycle.
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#### PART E – SERVICE REQUIREMENT AND WARRANTY PROVISION

Contact your trophon2 representative if you have any questions about:

- The trophon2, consumables and accessories
- The warranty

Each trophon2 has a comprehensive warranty against defects in material and workmanship for 12 months from the date of installation. The specific warranty terms and conditions are defined in appendix 2 of this manual. Please be aware of the exclusions.

To ensure the safety and efficacy of your HLD operations, trophon2 needs to be serviced every 12 months or every 5000 disinfection cycle, whichever comes first.

**Service Schedule:** When the device is due for service, a service due message will be displayed on the screen to remind the user to arrange the service. The reminder 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 via the *System Information* tab, located in the trophon2 menu.

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 trophon2. Only authorised customer service personnel should service the trophon2 with genune parts supplied from Nanosonics.

Modifying the trophon2 without authorisation will void your warranty.

#### APPENDIX 1: TROPHON2 TECHNICAL SPECIFICATIONS N05000-1, N05000-2

N05000-1 Electrical Specification	Rated mains input voltage: 100V, 120V AC Rated mains input current: 6Amp, 50/60Hz Mains Inlet: IEC type C13 Equipment must be connected to an earthed outlet using the power cable supplied with the trophon2.
N05000-2 Electrical Specification (part numbers for different variants to be confirmed)	Rated mains input voltage: 230V AC Rated mains input current: 6Amp, 50/60Hz Mains Inlet: IEC type C13 Equipment must be connected to an earthed outlet using the power cable supplied with the trophon2.
Data port	Ethernet connector RJ45 USB Port: Type A
Environmental Specification	Operating temperature range: 17 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 unpacked trophon2: 22kg Dimensions of trophon2: 533mm high x 360mm wide x 317mm depth
Electromagnetic Compliance	The trophon2 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 14 Mars Road, Lane Cove, NSW 2066 Australia (**Nanosonics**).

Nanosonics warrants to the customer that the trophon2 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).

You may have statutory rights in relation to the trophon2 and these are not affected by this warranty.

#### **Exclusions**

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

- a. where the trophon2 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 trophon2, other than by Nanosonics or its authorised service providers;
- c. where unauthorised consumables, accessories or other chemicals or items have been used with the trophon2;
- d. where the trophon2 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;
- e. where the trophon2 has been damaged due to external or environmental causes of any kind (including factors such as voltage fluctuations, excess voltage or power failure);
- f. where the trophon2 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):
- g. where the defect does not materially affect the function of the trophon2 (for example scratches or marks on the external surface of the trophon2); or
- h. where the serial number or product label has been removed, changed, deleted or made unrecognizable, 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.

This warranty applies to the trophon2 and defective parts only; the warranty does not cover 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 trophon2 customer service representative with any queries regarding this warranty or post warranty repairs. If you wish to make a warranty claim, please contact your trophon2 customer service representative.

Nanosonics will make arrangements for and bear the cost of the collection of your trophon2. You will be responsible for uninstalling, reinstalling and recommissioning the trophon2, regardless of whether or not it is found to be defective. If Nanosonics finds on examination that the trophon2 is defective in materials and workmanship and is within the warranty period, then we will repair or replace the defective trophon2 at our discretion. Nanosonics will bear the cost of return delivery of the repaired trophon2, or replacement trophon2, to you. If we are unable to repair or replace the trophon2 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 trophon2 is **not** defective in materials and workmanship, 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 returning the trophon2 to you, and the costs of any repairs to the trophon2, or replacement trophon2, requested by you.

You are responsible for backing up all data on the trophon2 if it is being repaired, and acknowledge that repair of the trophon2 may result in the loss of user-generated data stored on the trophon2.

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 trophon2 in the United States.

This warranty is a limited warranty, 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.





# Manufactured by: **Nanosonics Limited**

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