



Frequently Asked Questions



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INTRODUCTION AND GLOSSARY

This document is designed as a quick reference to help answer common questions. This document does not replace the *trophon2 User Manual*. The user should also read the *trophon2 User Manual* before operating the device.

Please refer to the below for a list of common terms related to the trophon[®]2 device that are listed in this FAQ.

trophon2 AcuTrace[®] RFID Technology

trophon2 technology that uses the latest AcuTrace[®] Radio Frequency Identification (RFID) enabled accessories and consumables to simplify the creation of accurate digital records. AcuTrace automatically records the operator, probe and cycle data of completed disinfection cycles and these records can be easily obtained from your trophon2 device to support audit-readiness.

HLD

High Level Disinfection

IFU

Instructions for Use

MEC

Minimum Effective Concentration. The minimum concentration of the disinfectant required for HLD.

Nebuliser

Components that generate and transfer the disinfectant mist into the trophon2 chamber.

Normal machine operation

The trophon2 device is in its normal turned on/operational state (i.e. it is awake, not turned off or in sleep mode).

OEM

Original Equipment Manufacturer e.g. Probe Manufacturer

PPE

Personal Protective Equipment

Purge

Purge is a process that converts any remaining disinfectant in the trophon2 device, into oxygen that is vented into the atmosphere and water that is collected in the waste drawer.

Sleep mode

The trophon2 device is in a power-saving mode.

1 trophon2 DEVICE SPECIFICATIONS

1.1 What are the dimensions of the trophon2 device?

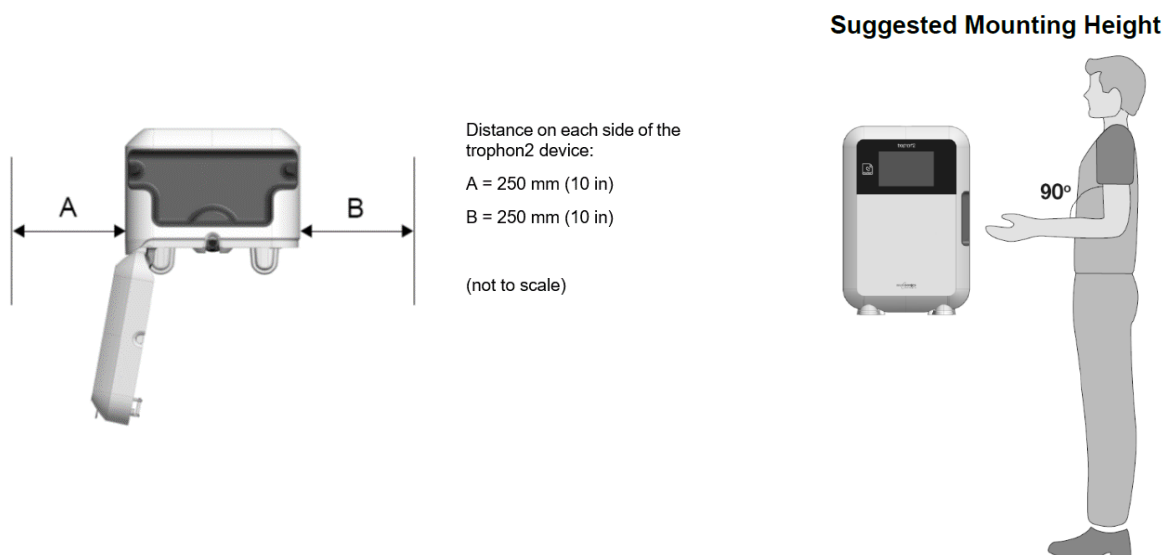
Measurement	Metric Measurement	Imperial Measurement
Height	535 mm	21 in
Width	360 mm	14.2 in
Depth	317 mm	12.5 in

The trophon2 device weighs approximately:

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

NOTE: You should follow your facility's manual handling procedures for guidance on lifting heavy objects.

1.2 How should I position my trophon2 device?



The trophon2 device should be positioned on a level surface that allows for adequate airflow with a clearance of 250 mm (10 in) on either side of the device. It is recommended that the space surrounding the device be kept free of other equipment and clutter. The trophon2 device requires an electrical power source to operate. The trophon2 system does not require special ventilation or plumbing when used according to the *trophon2 User Manual*.

1.3 How much power does my trophon2 device consume?

	During Warm-Up	During Cycle	During Sleep
Power Consumption of Chamber Heating	480 W = 1638 BTU/hr	100 W = 341 BTU/hr	0 W = 0 BTU/hr
Total Power Consumption	580 W	200 W	13 W

2 OPERATING THE trophon2 DEVICE

2.1 Can I use my trophon EPR consumables and accessories with the trophon2 device?

The trophon Printer can be used with both trophon EPR and trophon2 devices. It only requires a new USB cable. Please contact your local Nanosonics representative to place an order.

There is no change to the trophon consumable products, such as trophon Chemical Indicator and trophon Sonex-HL / NanoNebulant, between trophon2 and trophon EPR devices.

The trophon2 device is not backwards compatible with trophon EPR set-up accessories. Instead, the trophon2 device has a new cart and wall mount to continue to allow for ease of use at the patient point of care. Please contact your local Nanosonics representative to place an order.

2.2 What PPE is required when operating the trophon2 device?

As a fully enclosed system, the trophon2 device reduces the need for PPE and mitigates the risk of exposure to hazardous chemicals, fumes and spills that are often associated with wipes and soaks. The only PPE required for the operation of the trophon2 device is disposable gloves.

2.3 Where should I place the trophon2 device?

The trophon2 device is designed to high level disinfect ultrasound probes in healthcare facilities at the control of trained healthcare professionals. Components of the trophon2 system require minimal PPE (gloves only), allowing for its use in a standard workplace or clinical setting.

Nanosonics recommends that the trophon2 device be positioned at the patient point of care such as in the ultrasound examination room, to minimise risks of cross-contamination associated with probe transportation.

The trophon2 device is supported by accessories including the trophon Wall Mount 2 and trophon Cart which promote a point of care workflow with added flexibility and manoeuvrability.

2.4 How quickly does the trophon2 device warm up?

There are a number of critical parameters that need to be met before an HLD cycle can start. For this reason, the trophon2 device needs to warm up and reach a preset temperature. The warm-up time varies according to the length of time that the device is unused.

Scenario	What's going on	Ready in...
Back-to-back	Device stays at operating temperature	Seconds
Probe removed	Device stays at operating temperature	Seconds
Probe left in	Device cools to a lower temperature	Seconds to 4 minutes [^]
From sleep*	Depends on time asleep	Seconds to 10 minutes ^{^^}
From cold	Full heating up & system checks (varies depending on room temperature)	Approximately 9-10 minutes ^{^^^}

^ Protection mechanisms are in place to ensure the probe remains well below the maximum temperature specification provided by the probe manufacturers. To minimise disruption, remove the probe promptly after a cycle has been completed. Refer to *Section 2.10* for further information.

^^Configurable sleep timer function introduced to minimise this disruption. Refer to *Section 2.8* for further information.

^^Daily warm up function introduced so the device can be ready at the start of the day, reducing the wait time and manual process associated with daily setup. Refer to *Section 2.5* for further information.

2.5 Can I set the trophon2 device to warm up at particular times?

Yes, the trophon2 device includes a 'Daily warm up' feature that can be configured to 'wake up' on selected days and times. This feature can assist workflows by ensuring the device is switched on automatically at the time of day specified within the menu options.

To access this setting on your trophon2 device, select **Main Menu** () > **Settings** > **Daily timers**

2.6 How do I configure the clock on the trophon2 interface?

trophon2 Software Version 1.3.10.2 onwards will allow you to set automatic date and time settings.

This will allow trophon2 devices that are networked to synchronise date and time to the local network server (Network Time Protocol or NTP).

Alternatively and with earlier software versions, you can update the time manually by following the on-screen prompts.

To reconfigure the time settings, select **Menu** () > **Settings** > **Time** and follow the on-screen prompts.

2.7 Will the trophon2 device update the time automatically during daylight saving time (DST)?

trophon2 Software Version 1.3.10.2 onwards will automatically update the time during daylight saving time (DST) changes. Ensure you have the correct timezone setting selected for this to function correctly.

For earlier software versions, you will have to update DST changes manually.

To check the timezone and update the time manually, select **Menu** () > **Settings** > **Time** and follow the on-screen prompts.

2.8 Can I turn off or adjust sleep mode?

Yes, the trophon2 sleep timer can be configured in hourly increments up to 24 hours or switched off completely. The trophon2 device will automatically go to sleep if it has not been used for the duration time set on the sleep timer.

2.9 Should I leave the trophon2 device switched on?

It is recommended to leave the trophon2 device powered on at all times. trophon2 has settings such as 'Daily warm up' and 'Sleep Timer' so that your trophon2 device is ready when you are. Leaving the device switched on also allows for self-maintenance functions to occur within the device, improving operational efficiencies.

2.10 What happens if I accidentally leave an ultrasound probe in the trophon2 chamber?

The heaters in trophon2 device will switch off if the probe is not removed within 30 seconds following the completion of the disinfection cycle. This is a protection mechanism that ensures the probe remains well below the maximum temperature specification provided by the probe manufacturers. The chamber will maintain a minimum temperature of 45 °C (113 °F) to enable a short warm up time. Refer to table in *Section 2.4* for further details. If the device goes into sleep mode, the heaters will completely switch off.

To avoid unnecessary warm up time during operation, it is recommended that the probe is removed from the trophon2 chamber immediately after the completion of the disinfection cycle.

NOTE: The trophon2 device should not be used as a probe storage device.

2.11 Is it normal that there is black sediment in the waste drawer?

It is normal for there to be black sediment present in the base of the waste drawer. This sediment is a result of the trophon2 “destructor” process, which converts the hydrogen peroxide into environmentally friendly by-products, oxygen and water. The black dust will reduce after several purge cycles.

2.12 When do I need to purge the trophon2 device?

- Prior to transporting (i.e. lifting or moving) the trophon2 device, if it has previously been in use. (Note if you are simply transporting the device on a trophon2 Cart, you do not need to purge)
- When an on screen message states that your trophon2 device requires purging. This will occur upon disinfectant expiry at 30 days after insertion.

Follow the on-screen instructions to purge. Upon expiry of your trophon Sonex-HL / NanoNebulant disinfectant, purging can be deferred to midnight to avoid disruption to the clinical workflow.

2.13 What wipes can I use to clean and disinfect the trophon2 device?

For cleaning, when cool, wipe the chamber and the outside surfaces of the trophon2 device with a cloth or wipe moistened with a mild, soapy solution, until all surfaces are visibly clean.

For disinfecting, wipe all accessible surfaces of the trophon2 device with an Isopropanol or Quaternary Ammonium (Quat) Wipe.

Refer to *trophon2 Cleaning and Disinfection Guide* for further instructions.

2.14 What operational sounds should I expect to hear from my trophon2 device during a normal cycle?

trophon2 technology has been designed to operate quietly and discreetly during its normal operation.

There are a few normal operating sounds that can be heard at various stages of a trophon2 disinfection cycle.

Fans run intermittently throughout the HLD cycle, constantly during a purge and at certain times during warm-up, producing a whirring sound.

The nebuliser cup fills up at regular intervals, every few cycles and takes only a few seconds. This process produces a mechanical sound, indicating that the pump is engaged as the nebuliser cup fills with trophon Sonex-HL / NanoNebulant disinfectant. This sound will occur when the **Preparing for HLD** message appears on the trophon2 touch screen.

To ensure the chamber cannot be accessed while trophon Sonex-HL / NanoNebulant is present during the HLD cycle, the chamber door will pull closed and lock. You may hear a 'click' at the beginning of the cycle and observe a slight movement of the door. This signifies the door lock has engaged. The same click will be heard at the completion of the cycle. This signifies the door is unlocked.

2.15 What other audio and visual indications will I my trophon2 device produce?

trophon2 devices also produces a combination of audio alarms and visual indications at different stages of the disinfection cycle, notifying the operator that a step has been completed or that the device requires their attention.

Some common examples of when alarms sound and indications appear, include the following:

- After the successful scanning of an AcuTrace Operator Card or AcuTrace Medical Instrument Tag
- At the completion of a successful disinfection cycle
- At the completion of an unsuccessful disinfection cycle
- If the probe is left too long in the device chamber before starting a cycle
- If the trophon2 chamber door is left open for a period of time.

A user can set up repeat alarms that will sound every 30 seconds. Repeat is off by default and must be activated by the user. Alarm volume can also be adjusted to suit the user.

To access this setting go to **Main Menu** () > **Settings** > **Brightness and Alarm**

2.16 What does best storage practice look like?

Regulations and guidelines in most developed countries generally recommend storing reprocessed medical devices in a way that protects them from recontamination.

Nanosonics recommends that following HLD, the ultrasound probe be stored in a trophon Clean Ultrasound Probe Cover to ensure that the probe does not become contaminated. These single-use covers protect the probe by providing a physical barrier to contamination from handling and the environment. These covers give patients and staff confidence that the probe is clean and has been high level disinfected as the Probe Cover is removed in preparation for the procedure. Use of these covers enables probes to be stored in work areas, or at the patient point of care for efficiency of workflows.

2.17 How does the USB export of disinfection records work?

When exporting data from the trophon2 device, all records on the device will be exported to the USB regardless of the data previously exported. Data will NOT be deleted from the device during export.

NOTE: Nanosonics recommends that data should be backed up regularly to ensure complete data records. You should follow data retention procedures as advised by your facility. Contact your IT department for guidance.

2.18 What can I use the USB ports for?

USB ports are not approved for any use except as outlined in the *trophon2 User Manual*.

3 DISINFECTION CYCLE VALIDATION

3.1 How does the trophon2 device confirm an HLD cycle has been successful?

Each HLD cycle is confirmed in two ways:

1. **By a trophon Chemical Indicator.** trophon Chemical Indicators provide an independent verification tool to monitor the minimum effective concentration (MEC) of the disinfectant during the trophon2 disinfection process. The user is prompted to complete a visual assessment of the Chemical Indicator against the Colour Assessment Chart to verify the colour change. The user is then required to log the result of the Colour Assessment on the trophon2 touch screen, selecting **PASS** or **FAIL** according to the criteria of the Colour Assessment Instructions on the Chemical Indicator packaging.
2. **By the trophon2 device.** Multiple independent sensors within the trophon2 device monitor the temperature, mist volume and flow rates, while trophon2 software controls all aspects of the process at all times to deliver effective disinfection. If all parameters meet the required specification, the trophon2 touch screen then displays **Disinfection Pass**.

If the colour of the trophon Chemical Indicator falls within the pass criteria specified on the Colour Assessment Chart on the trophon Chemical Indicator packaging, and trophon2 reads **HLD Cycle Complete**, then the HLD cycle is successful.

3.2 Can I obtain documented validation for evidence that a HLD cycle was successful?

The trophon2 device records and logs the operator and probe data. There is easy access to stored disinfection records on screen, downloaded to a USB in a .csv file or integrated with your network*.

To download logs from your trophon2 device, select **Menu (☰) > Records > Download records to USB**

When coupled with the trophon Printer, the trophon2 device can print adhesive labels for records. The label is generated after each HLD cycle and can be placed alongside the patient information (e.g. accession number, Medical Record Number (MRN), barcode sticker) for complete traceability. Multiple copies of each label may be printed if required. The trophon Printer dispenses two labels by default. This trophon Printer setting can be accessed on the trophon2 touch screen by selecting **Menu (☰) > Settings > Printer label** and selecting the required number of labels. A sample label is illustrated below.

trophon [®] AcuTrace [™]	
8-07-2015	10:54am
SN: 36807-037	Cycle #: 999999
Disinfectant: CGF2356	23-11-2018
Chemical Indicator: 4567MLK	04-12-2019
Clean and Dry:	YES
Operator:	Operator Name
Cycle:	PASS
Chemical Indicator:	PASS
Disinfection:	PASS
Operator:	Operator Name
Probe:	Probe Name
Notes:	

Figure 1 - Sample trophon Printer Label

trophon [®] AcuTrace [™]			
1-01-2021	10:54am		
SN: 36807-037	Cycle: 999999		
Disinfectant: CGF2356	2024-11-23		
Chemical Indicator: 4567MLK	2024-04-12		
Clean and Dry:			
Cycle:	PASS		
Chemical Indicator:	PASS		
Critical Parameters:	PASS		
Stage	Time (m:ss)	Temp. (°C)	Dose (g)
1	1:00	62.8	1.0
2	1:00	62.8	-
3	1:00	62.4	1.0
4	4:00	-	-
Total	7:00	-	-
Limits	=7:00	>=56.0	>=1.0
Disinfection:	PASS		
Operator:	Operator Name		
Probe:	Probe Name		
Notes:			

Figure 2 - Sample trophon2 Printer Label with Parametric Release feature enabled.

When Parametric Release* is enabled, you can also print the devices Critical Parameters table and result, shown in *Figure 2*.

The Parametric Release feature of AcuTrace PLUS® must be enabled for process parameters to be made available to the user on the printer label.

*AcuTrace PLUS is an optional accessory required for this functionality. To integrate with your network, all connectivity, configuration and integration with customer IT systems is the responsibility of the customer. (Refer to *Section 6.2* for more details)

3.3 What do I do if the trophon2 device has indicated a failed disinfection cycle?

Stringent parameters need to be met internally before the **Disinfection Pass** message appears on the screen at the completion of a cycle. If any of these strict parameters are not met during a disinfection cycle, the trophon2 touch screen will display **Disinfection Fail [error code]**. This means the probe has not been successfully high level disinfected and should be removed from trophon2 chamber and the cycle repeated. If a disinfection cycle has failed, the probe is not ready for patient use.

A failed cycle does not mean there is anything wrong with the device; it may simply mean that one of the many specific parameters was not met for that particular cycle.

Follow onscreen instructions to complete the failed cycle and start a new cycle.

If the subsequent HLD cycle is unsuccessful, please record any error codes and the colour of the trophon Chemical Indicator and contact your local service representative.

Error codes are also included on the adhesive label if a trophon Printer is in use.

Please refer to the *Section F1: Incomplete or Failed Cycles* of the *trophon2 User Manual* for instructions relating to a failed cycle.

4 PROBES AND MATERIALS COMPATIBILITY

4.1 Which probes can be used within the trophon2 device?

The trophon2 chamber has been designed to accommodate the head and handle of compatible endocavitary and surface ultrasound probes. Nanosonics has conducted extensive materials compatibility testing together with leading probe manufacturers. trophon has over 1,000 probes approved and endorsed by ultrasound probe manufactures.

For the full compatibility list, please visit our website to check if your probes are compatible with the trophon2 device.

NOTE: trophon2 is unable to accommodate for the HLD of trans-oesophageal echocardiogram (TOE/TEE) transducer reprocessing due to the size of the probe.

4.2 How do I know that the trophon2 device is safe on my probes?

At Nanosonics, we undertake a rigorous probe compatibility program in partnership with OEMs, to confirm ultrasound probes are compatible for use.

Compatible probes listed on the trophon Compatible Ultrasound Probe List, when used in accordance with the *trophon2 User Manual* causes no damage to the functionality of the approved probes. All probes listed on the trophon Compatible Ultrasound Probe List have been approved by OEMs. To find out more about the trophon Probe Compatibility Program, please visit our website. To confirm if your probe is compatible, review the *trophon Compatible Ultrasounds Probe List* at your local Nanosonics website.

4.3 What wipes can I use to clean and dry ultrasound probes before trophon2 HLD?

Cleaning is the removal of visible soil (e.g. organic and inorganic material) from objects and surfaces.¹⁻³ Thorough cleaning is required before HLD and sterilisation because inorganic and organic material that remains on the surface of instruments interfere with the effectiveness of these processes.¹

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.¹

Users should refer to the ultrasound probe manufacturer User Manual. Where available, trophon Companion Cleaning Wipes are a great way to clean ultrasound probes, before trophon high level disinfection.

Similarly, users should refer to the ultrasound probe manufacturer User Manual to select an approved and compatible drying wipe. Where available, trophon Companion Drying Wipes are a great way to dry ultrasound probes until there is no visible moisture or liquid. To dry the probe, Nanosonics recommends a single-use low lint or lint-free wipe.

1. CDC 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities.
2. ANSI, AAMI. ST58:2013 Chemical sterilization and high-level disinfection in health care facilities. 2013.
3. Canadian Standards Association (CSA). CAN/CSA-Z314-18 Canadian medical device reprocessing. 2018.

4.4 Can a trophon2 device disinfect ultrasound probes while they are still connected to the ultrasound machine?

Many probes can be reprocessed while connected to the ultrasound console. Consult with your OEM to confirm if this is permitted.

5 trophon Sonex-HL / NanoNebulant AND trophon CHEMICAL INDICATORS

5.1 What is the shelf-life of the trophon Sonex-HL / NanoNebulant disinfectant cartridge?

trophon Sonex-HL / NanoNebulant cartridges have a 24-month shelf-life from date of manufacture. This date is printed on the cartridge label, indicated by .

Once loaded into the trophon2 device, the contents of the cartridge must be consumed within 30 days. If there is remaining disinfectant in the trophon2 device after this period, the device will prompt users to purge. Refer to *Section E2: Purge Cycle of trophon2 User Manual* for further details.

5.2 What is the shelf-life of the trophon Chemical Indicator?

The trophon Chemical Indicator carton has a 16-month shelf-life from date of manufacture. The expiry date is labelled on every Chemical Indicator carton, indicated by .

5.3 How many disinfection cycles does each cartridge deliver?

If the trophon2 device is left switched on, each cartridge should deliver 35-40 cycles* under normal operating conditions (dependent on use), provided the cartridge does not expire beforehand.

*It is normal for the first cartridge (first installed or first cartridge immediately after a purge cycle) to deliver fewer cycles than stated above.

6 AcuTrace

6.1 How does AcuTrace work when I have multiple trophon devices?

When programming a trophon AcuTrace Operator Card or trophon AcuTrace Medical Instrument Tag, the trophon2 device will write the content onto the Tag or Card itself. Medical Instrument Tags and Operator Cards can be used on any or multiple trophon2 devices without any additional programming.

6.2 How can I integrate the disinfection logs with the Hospital Information System using AcuTrace PLUS?

The disinfection logs can be integrated automatically with the Hospital Information System using AcuTrace PLUS. 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 trophon2 device to the Hospital Information System server.

AcuTrace PLUS provides API gateway access. Upon access, a security certificate is to be obtained from Nanosonics at an additional and ongoing cost.

Alternatively, disinfection records can be downloaded from the trophon2 device onto a USB in a .csv file format. The disinfection data can then be transferred directly to the Hospital Information System server via USB. This feature is available on all trophon2 devices and does not require AcuTrace PLUS. Most users are able to meet relevant traceability requirements for disinfection records when this feature is used in conjunction with the trophon Printer and a manual record-keeping method.

6.3 How do I scan trophon Sonex-HL / NanoNebulant and trophon Chemical Indicator into the trophon2 system?

When AcuTrace is enabled, users are able to log the trophon Sonex-HL / NanoNebulant and trophon Chemical Indicator into the trophon2 system to maintain a comprehensive record of each disinfection cycle.

IMPORTANT: trophon Chemical Indicators must be scanned at the start of every new box. As this is a manual process, it is important for users of trophon2 to complete this step each time a new Chemical Indicator box is opened. Chemical Indicators must be stored in their original packaging and not be shared across trophon devices.

To log a new batch of trophon Chemical Indicators, select **Menu** () > **AcuTrace > Log Chemical Indicators** on your trophon2 touch screen. Scan the AcuTrace symbol located on the rear of the trophon Chemical Indicator box, against the built-in AcuTrace reader on the trophon2 device. A **Scan successful** screen will be displayed once completed, showing the batch number and expiry date of the trophon Chemical Indicators. Scan your AcuTrace Operator Card to confirm that the details have been correctly captured.

If AcuTrace is enabled, the trophon2 device will display a **Cartridge empty** screen and automatically prompt the user to replace the disinfectant cartridge. To insert a new trophon Sonex-HL / NanoNebulant disinfectant cartridge into the trophon2 device, select **OK** on the **Replace cartridge now?** screen. Scan the AcuTrace label on your trophon Sonex-HL / NanoNebulant disinfectant cartridge against the built-in AcuTrace reader on the trophon2 device. A **Scan successful** screen will be displayed once completed, showing the batch number and expiry date of the trophon Sonex-HL / NanoNebulant disinfectant. Scan your Operator Card to confirm that the details have been correctly captured. The cartridge door on the trophon2 device will automatically open, prompting the user to remove the cap from the disinfectant cartridge and load into the device before closing the door. The device will then prepare the disinfectant for first time use.

6.4 Do I need to program every field for the AcuTrace Medical Instrument Tag or AcuTrace Operator Card?

No, however some fields are mandatory and are indicated with an asterisk (*), such as the Probe name for a Medical Instrument Tag and the Operator name for an Operator Card.

When programming the Medical Instrument Tag, it is recommended to enter the Probe Model number into the 'Probe name' field. trophon2 Software Version 1.3.10.2 onwards also requires the Medical Instrument 'Serial number' to be entered as a mandatory field.

When programming the Operator Cards, the 'Operator ID' and 'Other' fields can be updated with relevant information such as internal staff ID number and department, respectively.

6.5 Can I share my AcuTrace Operator Card with another user?

No. The trophon2 device is designed to record the unique operator for each HLD cycle and tracks who puts the probe into trophon as well as who takes it out. It is important that each Operator have their own card to maintain the accuracy and traceability of records according to regional requirements (e.g. national guidelines) AcuTrace RFID technology cannot be integrated with existing facility hardware such as hospital ID cards.

If you require more trophon AcuTrace Operator Cards, please contact your local Nanosonics representative.

6.6 Can I reuse the trophon AcuTrace Medical Instrument Tag or Operator Card?

Nanosonics does not recommend the reuse of trophon AcuTrace Medical Instrument Tags. To ensure the accuracy of disinfection records, Medical Instrument Tags should never be moved between probes. Doing so may compromise the traceability of the Medical Instrument/s being reprocessed using trophon2.

The tags are uniquely identified and are used to link the HLD cycle to the disinfected probe and so the reprogramming or transfer of tags between probes can potentially compromise the consistency of the disinfection traceability system.

NOTE: Damaged tags/cards should be replaced as required. Cutting and removing the end of the Medical Instrument Tag will also inhibit reuse of the tag.

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