# Frequently Asked Questions about trophon3 and trophon2 Plus

Here you'll find answers to the most common questions we receive. Whether you're just getting started or looking for specific details, this resource is designed to help you quickly find the information you need.

We have broken down the information into three (3) sections

- 1. The 4 minute HLD Cycle
- 2. trophon3 device
- **3.** trophon2 device and trophon2 Plus software upgrade

## The 4 minute HLD Cycle

### How does the 4 minutes cycle compare to the 7 minutes cycle?

 Devices with the 4 minute cycle use the same trophon Sonex/NanoNebulant disinfectant cartridges, deliver equivalent disinfectant contact time and amount on probe surfaces and use the same trophon Chemical Indicator for validation of the cycle.

#### What are the critical parameters of the 4 minute HLD cycle?

Both the 7 minute and 4 minute cycles leverage the same trophon technology of which the critical parameters are temperature, dosage, concentration and time. Temperature and concentration remain the same between the two cycles. Dosage and disinfectant contact time remain equivalent, whereas the total cycle time has been reduced.

### • Does the 4 minutes cycle use higher chamber temperatures?

 No. The chamber temperature is equivalent between the two cycles. The 4 minute cycle reaches a lower maximum temperature..

## • Does the 4 minute cycle use a higher volume of disinfectant?

 No. The dose of trophon NanoNebulant/Sonex delivered in each cycle is equivalent to the 7 minute cycle. The disinfectant contact time is also equivalent.

## Are there any changes to the trophon Chemical Indicators or Sonex/NanoNebulant?

 No. trophon3 device and trophon2 Plus software upgrade will continue to use the same trophon Chemical Indicators and Sonex/NanoNebulant.

## Does the 4 minute cycle leave a higher level of disinfectant residual on ultrasound probes?

 No. The residual disinfectant level has been validated to be under the required safety level limits and it is equivalent to the 7 minute cycle.

### • What has changed in the 4 minute compared to the 7 minute cycle?

 The cycle algorithm has been optimised to provide greater efficiency while maintaining critical parameters. In particular, mist generation and supply to the chamber has been improved and the rate of mist removal from the chamber has been significantly enhanced. These improvements have lead to a significant reduction in overall cycle time.

### What ultrasound probes are compatible with devices that have the 4 minute cycle?

 All ultrasound probes currently approved for use with the trophon2 device remain compatible with the trophon2 Plus software upgrade and trophon3 device.

#### Have ultrasound probe manufacturers approved the use of the 4 minute cycle?

 Ultrasound compatibility of the trophon2 Plus software upgrade remains equivalent to the trophon2 device. Nanosonics is working with all OEMs to ensure compatibility will be reflected in their compatibility guides.
 Refer to Nanosonics compatibility page for confirmation of probe compatibility.

### Does the 4 minute cycle have the same microbial efficacy of the 7 minute cycle?

- Microbiological disinfection efficacy has been validated to demonstrate high-level disinfection according to relevant guidelines and regulatory standards. The trophon2 Plus software upgrade and trophon3 device share the same core technology as other trophon family devices of sonically activated hydrogen peroxide. All trophon family devices share equivalent critical parameters and therefore provide equivalent microefficacy.
- Customer Information Notices (CIN177 for trophon2 Plus and CIN181 for trophon3) have been developed to support customer engagements.

## Can all trophon2 devices with the 7 minute cycle be upgraded to the 4 minute cycle?

 The 4 minute cycle is delivered via software upgrade without the need of hardware changes. The trophon2 Plus software upgrade is available to certain trophon2 devices. Contact your Nanosonics representative to enquire about the eligibility. (Internal only: all trophon2 devices are upgradable, commercial teams to define the criteria for eligibility)

#### Do devices using the 4 minute cycle meet local regulatory requirements?

 Yes. In markets where devices with the 4 minute cycle have been made available, all relevant requirements from regulatory standards and guidelines have been met.

### trophon3 device

- What is the software version of trophon3 out of the box?
  - o The first software version of trophon3 is v1.8.

#### • What are the new features of trophon3 and trophon2 Plus compared to trophon2?

 4 minute HLD cycle and traceability via DICOM (assuming the trophon2 is running the latest software version available).

#### Does the trophon3 device have the same microbial efficacy of trophon2?

- Microbiological disinfection efficacy has been validated to demonstrate highlevel disinfection according to relevant guidelines and regulatory standards. The trophon3 device shares the same core technology as other trophon family devices of sonically activated hydrogen peroxide. All trophon family devices share equivalent critical parameters and therefore provide equivalent microefficacy.
- A Customer Information Notice (CIN181) has been developed to support customer engagements.

#### Does Nanosonics have data supporting the equivalent efficacy?

Yes. This is part of internal documentation and regulatory requirements.

#### What ultrasound probes are compatible with trophon3 devices?

 All ultrasound probes currently approved for use with the trophon2 device remain compatible with the trophon3 device.

## Have ultrasound probe manufacturers approved the use of trophon3 with their probes?

- Ultrasound compatibility of trophon3 device remains equivalent to trophon2 device. Nanosonics is working with all OEMs to ensure trophon3 device compatibility will be reflected in their compatibility guides.
- Refer to Nanosonics compatibility page for confirmation of trophon3 compatibility

### • Can existing trophon2 devices be upgraded to trophon3 devices?

o No. trophon3 is a brand-new device released in manufacturing.

### • Are existing trophon2 accessories and consumables compatible with trophon3?

 Yes. A Customer Information Notice (CIN179) has been developed to support customer engagements.

### What are the differences between a trophon3 and a trophon EPR device?

o Refer to Customer information CIN180 for a direct comparison table.

### trophon2 device and trophon2 Plus software upgrade

### What is trophon2 Plus?

o trophon2 Plus is a software upgrade available to trophon2 devices and offers a 4 minute HLD cycle and traceability via DICOM as the key different features compared to a trophon2 device. The software version that has the two features available for activation is v1.8.

#### • Can all trophon2 devices receive software v1.8?

- Yes. Software v1.8 and later will be released to production and for service upgrades. A customer upgrading to v1.8 does not automatically activate the 4 minute cycle and traceability via DICOM.
- A Customer Information Notice (CIN178) has been developed to support customer engagements.

## Can customers access the traceability via DICOM without upgrading to 4 minute HLD cycle?

 No. A prerequisite for traceability via DICOM is to upgrade a trophon2 to trophon2 Plus which comes with a 4 minute HLD cycle.

## How are trophon2, trophon2 Plus and trophon3 devices visually different?

- Cosmetically, they are similar since all three device types share the same external enclosures and general look and feel. Attributes that distinguish the devices:
  - trophon3 logo on the touchscreen lens at the of the device.
  - trophon2 Plus adhesive applied to the front cover of the device (not a regulatory requirement).
  - the device information screen in the menu lists the device type:
     trophon2, trophon2 Plus and trophon3 using the respective logos.

### Are trophon2 Plus devices available from production?

- No. Nanosonics will manufacture trophon2 and trophon3 devices. The trophon2
   Plus software upgrade is only available as a field upgrade to existing trophon2 devices.
- o In circumstances where trophon3 is not available for sale in a particular country or not approved by the customers (e.g. requiring SKU registrations, existing healthcare contracts, etc) and the trophon2 Plus software upgrade is available, and a customer is purchasing a brand-new device, then the trophon2 device can be upgraded to trophon2 Plus before it reaches the customer. This scenario will be addressed ad-hoc within the region.