

Taking ultrasound reprocessing to a new level

Nanosonics explains how it works with ultrasound probe manufacturers to ensure that these complex and fragile devices can be effectively disinfected – with minimal risk of damage – via a system that utilises sonically activated hydrogen peroxide.

Ultrasound is an increasingly utilised diagnostic tool across a diversity of healthcare environments. Ultrasound probes themselves are complex medical devices, whose active elements are relatively fragile. Independent studies have demonstrated that between 25 and 30% of probes in clinical use are damaged every year due to routine use.^{1,2,3} Ultrasound probes require gentle handling and proper storage. Use of compatible cleaning and disinfecting methodologies can also minimise potential damage.



Nanosonics is the manufacturer of trophon, which it dubs 'the first major innovation in ultrasound probe high level disinfection for more than 20 years'. In 2009, Nanosonics® launched the trophon EPR, which it said 'set a completely new global standard of care in the disinfection of ultrasound probes'. trophon was, Nanosonics said, 'a faster, simpler, alternative to the existing disinfection processes, mitigating the risk of exposure to toxic chemicals'. It was also 'superior and safer for both patients and healthcare professionals'. The launch of trophon 2 has, Nanosonics says, 'taken ultrasound reprocessing to a new level'.

The trophon family now includes the trophon EPR and trophon 2 devices, which share the same core technology of sonically activated hydrogen peroxide. With over 20,000 units worldwide, approximately 70,000 people each day are protected from the risk of cross-contamination by trophon.

An overview of the technology

trophon is 'a unique and fully automated device for the high-level disinfection of both surface and endocavitary ultrasound probes'. The trophon technology uses a proprietary disinfection solution based on hydrogen peroxide. Each disinfection cycle consumes approximately 2 ml of disinfectant solution. This solution is nebulised in the trophon system, which turns the liquid into

a very fine mist, ensuring total coverage of the probe so that high level disinfection can occur. The probe is exposed to the mist for a predetermined time after which the mist is evacuated from the chamber and broken down into primary by-products of oxygen and water, negating the need for disposal of any chemistry.

Potential causes of probe damage

An understanding of the most common types of probe damage and the contributing factors to such damage can assist in caring



Table 1 - Common probe damage as reported by ultrasound manufacturers and probe repair companies.³

Convex, Linear, Sector, Endocavitary Probes

- Lens damage-wear, holes, swelling, delamination
- Strain relief damage, separation
- Nosepiece and probe separation and cracks
- Cable cuts
- Connector housing electrical damage
- Weak or dead element, dropouts in an image

Speciality 3D / 4D Volume Probes

- Lens cap damage
- Fluid and oil leaks
- Inoperative steering
- Cable cuts
- Connector housing electrical damage
- Weak or dead elements, dropouts in an image

for probes. Probe damage is a common occurrence throughout healthcare facilities. A multi-centre study in the UK found that over 30% of probes in clinics were faulty, 13% of which were completely unfit for use.¹ Another study across 32 hospitals in the European Union found that 26% of probes in clinical use were delaminated, and that 8% had a break in the cable.²

The trophon Probe Compatibility Programme

The trophon Compatibility Programme is conducted collaboratively between ultrasound probe manufacturers and Nanosonics. This collaboration ensures that the technical expertise of the probe manufacturer informs the compatibility protocol development, guaranteeing that required materials compatibility and functional parameters are effectively measured. The ultrasound probe manufacturer provides final probe compatibility approval.

The trophon Probe Compatibility Programme is conducted in partnership with probe manufacturers (OEMs), who make the final determination on compatibility status for each probe model. The testing protocol itself involves several steps. Nanosonics and the probe manufacturer first agree on the probe model to be assessed for compatibility, and relevant technical information about trophon and the probe model is exchanged. After development and mutual agreement on the test protocol, the probe manufacturer delivers probes to the Nanosonics test laboratory. The testing protocol can involve subjecting the probe for up to 18,000 trophon cycles. The Nanosonics test laboratory runs 24 hours a day, seven days a week, and is managed by experts in trophon technology and material science.

Photographic documentation

Prior to the commencement of the testing, baseline photographic documentation of the entire surface of the probe is captured. This documentation is used to determine whether there are any unacceptable physical changes to the probe during the testing. During the testing phase, the probe is inspected daily as it progresses through the testing cycles. At approximately 1,000 cycle intervals, photographic documentation of the entire surface of the probe is taken and compared to the baseline documentation, to ascertain if any visual physical changes, such as discolouration, cracking, or delamination, have occurred.

At the end of the cycle testing, a detailed report, with all the photographic documentation, is returned to the probe manufacturer, along with the probe for technical testing. The probe manufacturer conducts a comprehensive suite of tests to confirm that exposure to trophon has not

caused any functional or unacceptable visual damage (internal/ external) to the probe. This testing typically includes:

- Physical examination.
- Safety testing.
- Probe function and performance.
- Acoustics.
- Image quality/resolution.
- Signal dropout.

Based on the Nanosonics report and the probe manufacturer testing, the probe manufacturer then makes the final determination on compatibility. Only when the probe manufacturer commits to listing trophon as compatible, is the probe listed on the Nanosonics trophon compatible probe list.

Today, more than 1,000 probes across 22 manufacturers have been tested, approved, and endorsed, as compatible for use in trophon.

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References

- 1 Dudley NJ, Woolley DJ. A multicentre survey of the condition of ultrasound probes. *Ultrasound* 2016; 24 (4): 190-7
- 2 Martensson M *et al.* *European Journal of Echocardiography*. 2009; 10 3: 389-94
- 3 UNISYN. A Division of GE Healthcare. Probe care

information. Part Number: JB30898US.

- 4 BMUS, The British Medical Ultrasound Society. Top tips for ultrasound probe care. 2019.



Multi-centre UK study

A multi-centre study in the United Kingdom found that over 30% of probes in clinics were faulty.¹



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