The importance of disinfectant coverage

evaluating trophon® HLD efficacy on complex surface features of ultrasound probes

The importance of disinfectant coverage

Ultrasound probes are a diverse group of medical devices, varying in shape, size and surface features. The ultrasound probe body is at risk of contamination during use, and contact can then occur with the patient directly or indirectly. This means that an appropriate level of reprocessing must be applied to the entire surface of the probe body, not just select areas. For ultrasound probes used in semi-critical or critical procedures (i.e. those that contact mucous membranes, non-intact skin or sterile tissue), a minimum of high-level disinfection (HLD) must be achieved across the entirety of the body. A high-level disinfectant can only be effective when it comes into direct contact with the surfaces of the contaminated device for the stated contact time.[1]

Ensuring complete coverage of the device surface can be challenging. Any HLD process for ultrasound probes must be able to reliably achieve surface coverage on probes of dozens of different shapes and sizes. Many probes also have indentations or other surface features that create concealed or shadowed areas (Figure 1), which may be less accessible to some disinfection modalities and potentially affect HLD efficacy.[2-6]

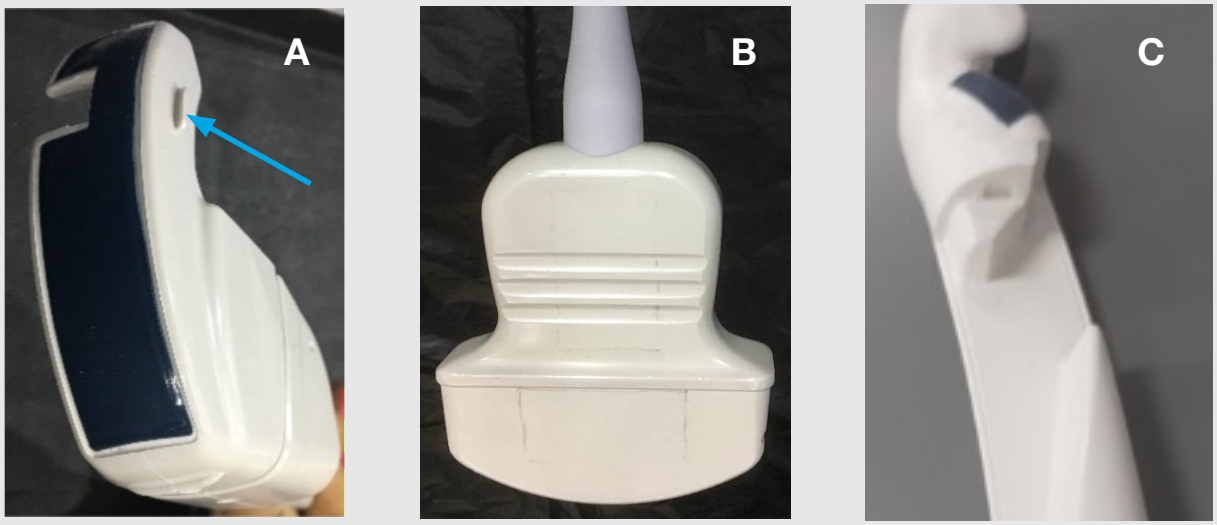


Figure 1. Examples of surface features of ultrasound probes: an orientation marker located on the side of the probe body (A); grooves to assist with grip (B); notch for attachment of needle guide (C).

Coverage capabilities of different HLD methods

HLD wipes

For manual HLD wipes, the ability to achieve complete wetting of the probe surface is of critical importance. Coloured dye wipe kits can be used to visualise problem areas for a wipe-based cleaning process.

A study of manual HLD wipes showed that complete surface wetting was not achieved for both endocavitary and surface probes (Figure 2). Participants in the study had 2-5 years experience using HLD wipes prior to the study, and performed HLD following the IFU.[2]

While complete coverage was observed on larger and smooth surfaces, wetting was difficult to achieve around the attachment points for biopsy guides, and around the seam where the two halves of the probe housing meet.[2] This incomplete coverage observed in the study suggests that HLD may not have been reliably achieved in these areas.

Figure 2. Probes shown after using blue-coloured cleaning wipes to identify wetting gaps. Adapted from Kühnel & Gühne 2024.[2]

UV-C

In a study based on a particular UV-C device involving simulated irradiance over the surface of 3D scans of ultrasound probes, a large difference between the minimum and maximum irradiance values was seen.[3] The distribution of UV-C radiation on both surface probes and endocavitary probes was uneven, and showed the presence of shadowing effects adjacent to notches and grooves (Figure 3).

Concerns have also been raised around the ability of UV-based devices to overcome the effect of shadowing, where indentations or microscopic surface textures may shield microorganisms from disinfection to various degrees.[4-6] There is a lack of data showing that UV-C can be uniformly applied to complex surfaces to achieve adequate disinfection.[3] Given the variations in surface topology of different medical devices, as well as surface imperfections that develop during use, this is likely to create challenges for meeting the requirement of HLD for every device, every time.

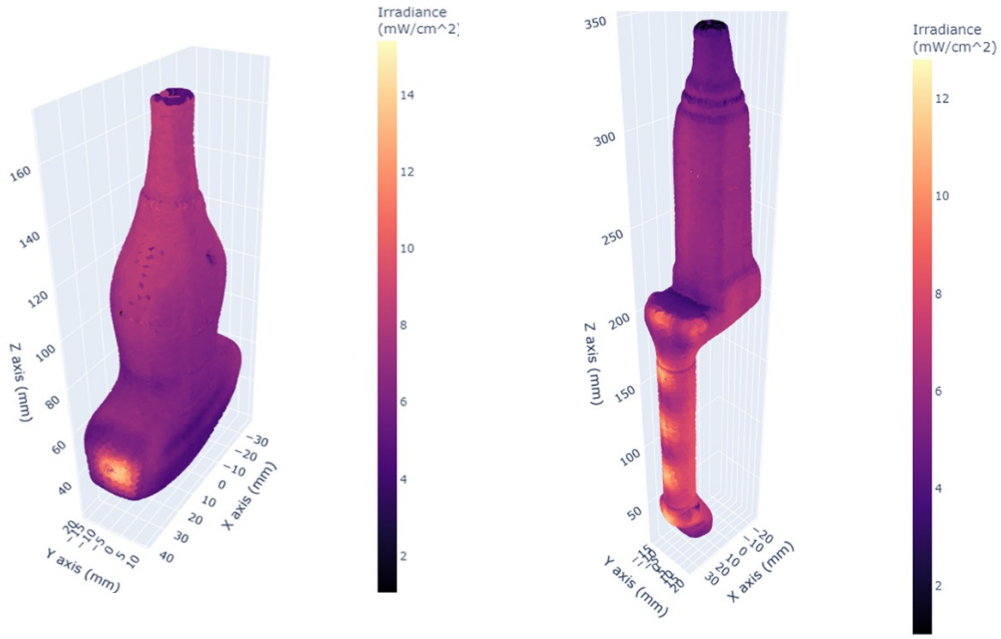


Figure 3. 3D scatter plots of simulated irradiance distribution over the surface of ultrasound probes. Adapted from Yeoh et al. 2024.[3]

Hydrogen peroxide mist

The trophon device is an automated system for the high-level disinfection of ultrasound probes. The device uses ultrasonic vibrations to convert hydrogen peroxide into mist particles. HLD is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered into the disinfection chamber containing the ultrasound probe. The droplets of mist produced are small and can access difficult to reach surfaces of the probe including grooves, crevices and imperfections.

Clinical assessment of ultrasound probes

Nanosonics conducts an in-depth probe compatibility program in collaboration with ultrasound probe manufacturers. Part of this program is a clinical assessment, which evaluates aspects of an ultrasound probe that are relevant to clinical safety and performance within the trophon device. This includes assessment of:

- Clinical type of probe (e.g. convex, linear array, endocavitary)
- Intended use of the probe
- Materials used in the construction of the probe
- Design and size of the probe, compared with the geometry of similar probes previously evaluated in the trophon device
- Surface features that may present a challenge for HLD, including indentations, grooves, rough surfaces, detachable components and connector ports

The outcome of the assessment determines whether any of these aspects warrant further testing of the ultrasound probe.

It is critical to perform testing for difficult to disinfect areas of the probe, such as surface indentations, as these regions can interfere with the ability to achieve full disinfectant coverage. Nanosonics aims to ensure that the trophon device can reliably achieve coverage in these areas by performing microefficacy testing whenever a probe contains features that have not been validated previously, including unique surface features.

Microefficacy testing methodology

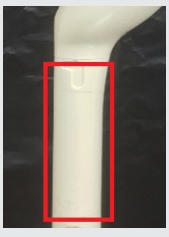
Through the probe compatibility process, Nanosonics has performed microefficacy testing on a large range of probe types and models (Table 1). This includes probes with indentations or surface features including grooves, seams, orientation markers, buttons, and attachment points for accessories.

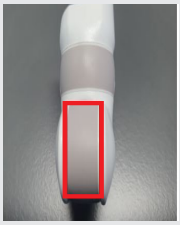
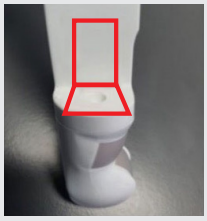
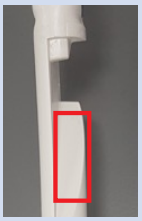
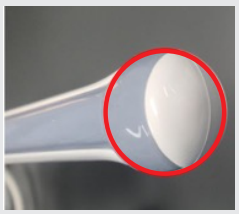
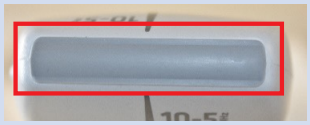
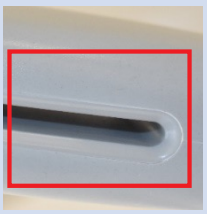
This testing is performed according to recognised standards for simulated-use testing. Multiple inoculation sites are chosen on each probe to ensure that areas which could create issues with compatibility, including surface features identified during the clinical assessment, are sampled and assessed. For high-level disinfection, regulators define a 6-log reduction in a *Mycobacterium* species as acceptance criteria.[1,7]

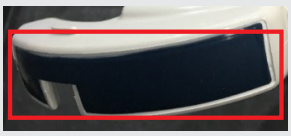
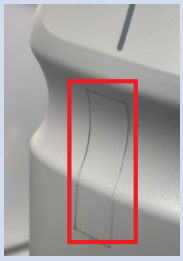
This testing data is representative of the vast majority of ultrasound probes in clinical use. It shows that the efficacy of the trophon device in areas of unique surface features is equivalent to that seen in comparatively smooth or easy to disinfect regions of the probe, indicating that even complex indentations and geometries receive a minimum effective dose for HLD.

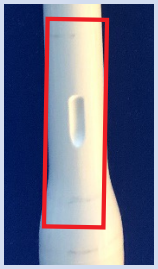
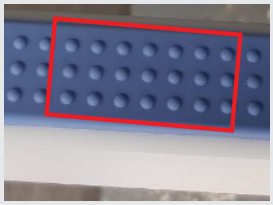
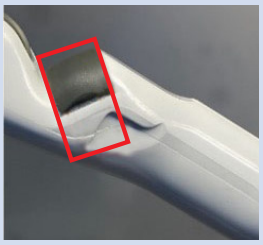
Microefficacy Results

Table 1. Examples of microefficacy testing results performed during clinical assessments.

Probe	Inoculation site	*M. terrae* log reduction	Pass/Fail
1	A 	6.29	PASS
	B 	6.29	PASS
2	A 	6.43	PASS
	B 	6.43	PASS
3	A 	6.95	PASS
	B 	6.95	PASS

Probe	Inoculation site	*M. terrae* log reduction	Pass/Fail
4	A 	>7.24	PASS
	B 	>7.24	PASS
5	A 	>6.15	PASS
	B 	>6.15	PASS
6	A 	>7.09	PASS
	B 	>7.09	PASS
7	A 	>6.56	PASS
	B 	>6.56	PASS

Probe	Inoculation site	*M. terrae* log reduction	Pass/Fail
8	A 	6.92	PASS
	B 	6.92	PASS
	C 	6.92	PASS
9		>8.33	PASS
10		>6.97	PASS
11		>7.02	PASS
12		>7.20	PASS

Probe	Inoculation site	*M. terrae* log reduction	Pass/Fail
13		6.50	PASS
14		6.54	PASS
15		7.10	PASS
16		6.76	PASS
17		7.26	PASS
18		6.83	PASS

Conclusion

Given the diverse shapes, sizes and features of ultrasound probes, ensuring high-level disinfection coverage across a range of devices can be difficult. Certain features, like indentations or notches, can create concealed or shadowed areas that present a challenge for some disinfection modalities. Nanosonics seeks to ensure trophon device compatibility with a large range of probes through clinical ultrasound probe assessments. As part of these assessments, microefficacy testing is performed for probes with unique features not previously tested, including features on the probe surface. The results of testing conducted to date show that the trophon device delivers equivalent microefficacy in regions with complex surface features as it does in regions that are comparatively easy to access.

The trophon® family includes trophon® EPR and trophon®2 devices which share the same core technology of 'sonically activated' hydrogen peroxide.

References: 1. FDA 2000. Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. **2.** Kühnel C, Gühne F. Visualization of effectiveness: the use of a colored cleaning wipe set for visible disinfection of ultrasound probes. Hygiene 2024; 4(2):189-196. **3.** Yeoh L et al. UV-C disinfection of ultrasound probes: Challenges of uneven irradiance on complex surfaces. PLoS ONE 2024; 19(10):e0312931. **4.** Kowalski W et al. Ultraviolet disinfection efficacy test method using bacteria monolayers. J Microbiol Methods 2022;200:106541 **5.** Ratliff K et al. Evaluating the impact of ultraviolet C exposure conditions on coliphage MS2 inactivation on surfaces. Letters in Applied Microbiology 2022; 75:933-41. **6.** Demeersseman N et al. Shedding a light on ultraviolet-C technologies in the hospital environment. J Hosp Infect 2023; 132:85-92. **7.** International Organization for Standardization. ISO 15883-4:2018 - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

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