



Evaluation of an automated high-level disinfection technology for ultrasound transducers

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Summary

Background: Ultrasound transducer reprocessing is required to prevent the transmission of infections between patients. In some regions, reprocessing practices are not sufficient to achieve high-level disinfection (HLD), which can result in contaminated probes. Furthermore, current manual HLD methods use toxic chemicals and are prone to operator error/variability. The development of automated, non-toxic HLD disinfection devices may reduce the risk of transmission and reduce safety risks for operators and patients. This study investigated the disinfection efficacy of a hydrogen peroxide-based, automated HLD device, the Trophon® EPR, against a range of international standards.

Methods: Disinfection efficacy was assessed in carrier and simulated use tests against 21 different species of bacteria, fungi and viruses. Carrier tests were performed by placing carriers throughout the disinfection chamber and measuring the log reduction in viable organisms following disinfection. These tests were performed according to Association of Analytical Communities International Official Methods and European and ASTM International Standards for bactericidal, fungicidal, mycobactericidal, sporicidal and virucidal disinfection. Simulated use tests involving the disinfection of six widely used ultrasound probe models were conducted according to ASTM-E1837-96 using *Mycobacterium terrae* as a test organism.

Results: The device satisfied criteria for HLD and sporicidal disinfection efficacy under all standards tested.

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Conclusions: Automated, hydrogen peroxide-based disinfection devices offer an alternative to manual ultrasound probe disinfection technologies. Such devices reduce the risks of operator error and can improve patient and operator safety by preventing exposure to toxic chemicals. The adoption of next-generation disinfection devices may help to decrease infection risk and improve patient safety.

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Introduction

Ultrasound transducers are reusable medical devices that require appropriate reprocessing between patients to prevent the transmission of infectious disease. Medical devices can be categorized based on the infection risk associated with their intended use according to the Spaulding classification system [1,2]. Under this system, ultrasound transducers that contact broken skin or mucous membranes are classified as semi-critical devices and are required to undergo a minimum of high-level disinfection (HLD) between patients. HLD is generally defined as a complete elimination of all microorganisms although small numbers of bacterial spores may remain. HLD is therefore required for a range of common ultrasound procedures including, among others, intracavity ultrasound, such as transvaginal and transrectal ultrasonography, and surface ultrasound on broken skin (ulcers and wounds).

There are two main approaches to preventing the transmission of infection between patients undergoing such procedures. The first involves covering the ultrasound transducer with a disposable physical barrier (an ultrasound transducer cover or condom). The second method involves manual cleaning of the transducer followed by chemical treatment to disinfect the device. Depending on local regulations, some combination of these two methods is used to reprocess ultrasound transducers. However, recent studies have shown that current approaches are not always adequate. A number of studies have examined transducer cover or condom perforation and have found that perforation is common (0.9–9%), resulting in a significant risk of transmission [3–7]. As a result, it is mandated in the USA, Canada and Australia that intracavity ultrasound transducers be subjected to HLD reprocessing in addition to the use of ultrasound transducer covers. Practices in other regions are much more variable. A recent UK study examined transvaginal ultrasound probe (TVUSP) reprocessing practices in 68 healthcare institutions and found that none met standards for HLD and that reprocessing techniques were inconsistent

across clinics [8]. In addition, studies in Hong Kong and France, among other places, have shown that ultrasound transducers may still be contaminated with infectious agents following reprocessing [9–11]. This carryover is largely attributable to reprocessing techniques that are only capable of low-level disinfection, highlighting the need for clear guidelines for transducer reprocessing. A recent meta-analysis of the infection risk posed by transvaginal and transrectal ultrasonography found that across multiple studies, TVUSPs were contaminated with pathogenic bacteria and viruses with a pooled prevalence of 12.9% and 1%, respectively, following reprocessing. For patients undergoing transrectal ultrasound and guided biopsy, there was a pooled infection rate of 3.1% [10].

The resistance to adopting HLD in those regions where it is not mandated has been attributed to a number of problems, including increased toxicity (residual chemical exposure for patients and workplace risks for reprocessing staff), time-intensive and costly disinfection procedures and the potential to shorten the life of the transducer [11]. These problems arise from the manual nature of reprocessing and the use of toxic chemicals that are required due to the sensitive materials used in ultrasound transducer construction. Common disinfectants include glutaraldehyde, aldehydes, peracetic acid and quaternary ammonium compounds. Typically, such disinfectants require a lengthy reprocessing time involving soaking the transducer for 10–20 min followed by washing to remove the disinfectants before re-use. Due to the toxicity of many chemicals used for HLD, reprocessing is often conducted in a separate room, adding to the time and cost demands of implementing such processes in the clinic.

To address these challenges to adopting routine and effective HLD procedures, new automated reprocessing systems are becoming available. The device evaluated in this paper uses a nebulized mist of 35% hydrogen peroxide to disinfect ultrasound transducers in an automated 7 min cycle (Fig. 1). The disinfection process results in the hydrogen peroxide being broken down into oxygen and water, minimizing toxicity and environmental



Figure 1 The ultrasound transducer disinfection device tested in this study (Trophon® EPR). This device uses hydrogen peroxide to disinfect ultrasound transducers in an automated cycle.

impact with the added benefit that the device can be installed at the point of care. The efficacy of existing manual HLD reprocessing techniques is well documented [12,13]. However, the efficacy of automated devices that use hydrogen peroxide is less well established. We set out to evaluate the bactericidal, mycobactericidal, sporicidal, fungicidal and virucidal efficacy of the device against a range of international standards for HLD.

Materials and methods

To assess the disinfection efficacy of the device, a comprehensive range of microbiological tests was conducted in accordance with international standards for HLD. The range of organisms tested was selected based on their use as previously well-studied indicators for disinfection efficacy and/or on their clinical significance. Appropriate sample numbers were determined depending on the particular standard tested. The standards against which efficacy was tested represent the most widely accepted standards for disinfection efficacy in North America, Europe and internationally.

Automated HLD reprocessing device

The ultrasound transducer reprocessing device evaluated was the Trophon® EPR (Nanosonics Ltd., Australia) (Fig. 1). The device was operated according to the manufacturer's instructions, and testing was carried out using both inoculated carriers and inoculated ultrasound transducers (simulated use tests). Carrier tests were conducted using a customized carrier stand that placed carriers at various

spatially representative points within the chamber. All carrier and simulated use tests were run using a standard processing cycle. Efficacy testing was conducted at four testing centers: AMS Laboratories, Australia (AMS); Nanosonics, Australia (NAN); Biotech Germande, France (BG); and the Institute of Medical Microbiology and Hygiene, Tübingen University, Germany (TU). The device is currently available in the USA, UK, France, Germany, Australia and New Zealand.

Carrier tests – AOAC Official Methods

Bactericidal carrier tests were conducted according to AOAC Official Methods 991.47, 991.48 and 991.49 against *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*, respectively [14–16]. Methicillin-resistant *S. aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE) strains were tested using AOAC Official Method 991.47. Mycobactericidal tests were carried out according to AOAC Official Method 965.12 against *Mycobacterium terrae* [17]. Fungicidal tests were carried out according to AOAC Official Method 955.17 against *Trichophyton mentagrophytes*, and sporicidal tests were carried out according to AOAC Official Method 966.04 against *Clostridium sporogenes* and *Bacillus subtilis* [18,19].

Inocula were prepared according to the aforementioned AOAC Official Methods. The organic challenge was initiated by 5% horse serum. Glass penicylinders, porcelain penicylinders, suture loops or glass slide carriers were inoculated as per the AOAC methods, and test carriers were transferred onto a customized stand (Fig. 2A) for testing within the device. A standard disinfection cycle was

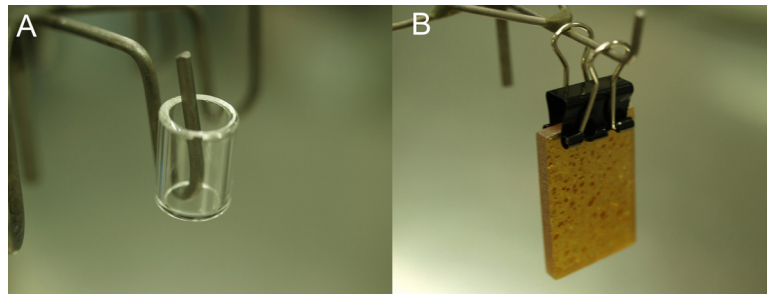


Figure 2 Carrier stage setups used to test the disinfection efficacy of the ultrasound transducer reprocessing device. (A) Carrier stage used for AOAC tests loaded with a glass penicylinder. (B) Carrier stage used for EN tests loaded with a plastic carrier.

run, and the carriers were recovered. Sporicidal tests were subjected to an extended 20 min disinfectant contact time according to AOAC 966.04. Post-processing, carriers were transferred to the appropriate broth supplemented with 125 IU/mL of catalase to neutralize any residual hydrogen peroxide activity. Samples were then cultured as per the AOAC methods, with results reported as growth or no growth. Control samples were also run in accordance with the AOAC Official Methods to establish viable counts for the initial inocula.

Carrier tests – EN and ASTM standards

Bactericidal and sporicidal tests were carried out according to the European standard EN14561 against *S. aureus*, *P. aeruginosa*, *Enterococcus hirae*, MRSA, VRE, *Geobacillus stearothermophilus* and *Clostridium difficile* [20]. Fungicidal tests were carried out in accordance with EN14562 against *Candida albicans* and *Aspergillus niger* [21]. Mycobactericidal tests were carried out according to EN14563 against *Mycobacterium avium* and *M. terrae* [22].

Inocula were prepared according to the aforementioned European standards. The organic challenge substituted 5% horse serum for 5% BSA. Carriers were hard polymer plastic and were 30 mm × 20 mm × 2 mm in dimension. Inocula were spread onto a marked surface of 20 × 20 mm and allowed to dry before being loaded onto the customized carrier stand (Fig. 2B) for transfer to the device. Carriers were subjected to a standard disinfection cycle and were transferred to the appropriate broth supplemented with 125 IU/mL of catalase to neutralize any residual hydrogen peroxide activity. The carriers were cultured as per the relevant standard, and the results are expressed as the mean log reduction in viable organism count versus the control.

Virucidal tests were carried out according to ASTM-E1053 against poliovirus (Type 1), herpes simplex virus (Type 1) and hepatitis A virus [23]. Viral suspensions were prepared as per ASTM-1053 and were used to inoculate 60 mm circular plastic carriers. Carriers were dried and then transferred to the customized carrier stand. The carriers were subjected to a standard disinfection cycle and recovered with fetal bovine serum containing 125 IU/mL catalase solution to neutralize any residual hydrogen peroxide activity before being applied to Vero cells to detect residual infectivity. Test samples were compared with controls to achieve a mean log reduction in infection-competent viral load. Cytotoxicity controls were also run to ensure that any cell death could be attributed to viral infection alone.

Simulated use tests

All simulated use tests were carried out according to ASTM-E1837-96 using *M. terrae* as the test organism [24]. Ultrasound transducers were disinfected before inoculation by soaking in 7.5% hydrogen peroxide solution for 10 min followed by soaking in a sterile solution of catalase (125 IU/mL) for 10 min and finally soaking in sterile deionized water for 10 min. Inocula were prepared according to ASTM-E1837-96 using 5% horse serum as the organic challenge. Four 20 mm × 30 mm regions on the transducer handle, body (one on each side) and window were inoculated with organism and were allowed to dry. Following drying, the inoculated area on the handle was swabbed to establish the control count prior to disinfection. The transducer was then transferred to the disinfection device and was subjected to a standard reprocessing cycle. The transducer was recovered, and the remaining areas were swabbed and transferred to 7H9 broth supplemented with 125 IU/mL catalase to inactivate

Table 1 Carrier tests based on AOAC Official Methods.

	Standard	Testing center ^a	n (carriers)	Growth	Pass/fail ^b
Bactericidal – Glass penicylinders					
<i>S. aureus</i> ATCC 6538	AOAC 991.48	NAN	60	1	Pass
<i>P. aeruginosa</i> ATCC 15442	AOAC 991.49	NAN	60	0	Pass
<i>S. choleraesuis</i> ATCC 10708	AOAC 991.47	NAN	60	1	Pass
MRSA ATCC 43300	AOAC 991.47	NAN	10	0	Pass
MRSA ATCC 29247	AOAC 991.47	NAN	10	0	Pass
MRSA clinical isolate	AOAC 991.47	AMS	10	0	Pass
VRE ATCC 51299	AOAC 991.47	NAN	10	0	Pass
VRE clinical isolate	AOAC 991.47	AMS	10	0	Pass
Mycobactericidal – Porcelain Penicylinders					
<i>M. terrae</i> ATCC 15775	AOAC 965.12	NAN	40	0	Pass
Sporicidal – Porcelain Penicylinders					
<i>C. sporogenes</i> ATCC 3584	AOAC 966.04	AMS	180	0	Pass
<i>C. sporogenes</i> ATCC 3584	AOAC 966.04	NAN	180	0	Pass
<i>B. subtilis</i> ATCC 19659	AOAC 966.04	NAN	180	0	Pass
Sporicidal – Suture Loops					
<i>C. sporogenes</i> ATCC 3584	AOAC 966.04	AMS	180	0	Pass
<i>C. sporogenes</i> ATCC 3584	AOAC 966.04	NAN	180	0	Pass
<i>B. subtilis</i> ATCC 19659	AOAC 966.04	AMS	120	0	Pass
<i>B. subtilis</i> ATCC 19659	AOAC 966.04	NAN	180	0	Pass
Fungicidal – Glass Slide					
<i>T. mentagrophytes</i> ATCC 9533	AOAC 955.17	NAN	10	0	Pass

MRSA = Methicillin resistant *Staphylococcus aureus*; VRE = Vancomycin resistant *Enterococcus*.

^a AMS = ams Laboratories, Australia; NAN = Nanosonics, Australia.

^b Based on AOAC criteria.

any residual hydrogen peroxide. The solutions were then cultured according to ASTM-E1837-96, and the results are reported as the mean log reduction in viable organism count over the control across the three inoculation sites.

Results

Carrier tests – AOAC Official Methods

The carrier test results of the tests performed according to the AOAC Official Methods are presented in Table 1. All controls were within normal ranges, and all samples tested passed the efficacy cut-offs set by the relevant AOAC Official Methods for HLD. Based on these results, the device is capable of HLD under the AOAC Official Methods. Additionally, the device satisfies the criteria for sporicidal claims with an extended 20 min disinfectant contact time.

Carrier tests – EN and ASTM standards

Table 2 shows the results of the carrier tests performed according to the European and ASTM standards. The mean log reduction in viable organism

load after disinfection and the standard error of the mean (SEM) were calculated for each of the carrier test cycles. All controls were within normal ranges, and all samples tested passed the efficacy cut-offs. These data indicate that the device satisfies the criteria for HLD under both EN and ASTM standards.

Simulated use tests

The results of tests simulating worst-case conditions under ASTM-E1837-96 are shown in Table 3. The mean log reduction in viable organism count and the SEM were calculated for each simulated use test. The mycobacterial load was reduced by more than 6 log in all cases. These results indicate that the device is capable of HLD under the simulated use conditions.

Discussion

The efficacy results showed that the device consistently achieved HLD in both carrier and simulated use tests using typical intracavity ultrasound transducers. Aspects of the testing methodologies used were more challenging than would likely be

Table 2 Carrier tests based on EN and ASTM standards.

	Standard	Testing center ^a	<i>n</i> (cycles)	Mean log reduction	SEM	Pass/fail ^b
Bactericidal						
<i>S. aureus</i> ATCC 6538	EN14561	AMS	12	6.92	0.09	Pass
<i>S. aureus</i> ATCC 6538	EN14561	NAN	6	7.40	0.00	Pass
<i>S. aureus</i> ATCC 6538	EN14561	TU	5	6.68	0.12	Pass
<i>S. aureus</i> CIP 4.83	EN14561	BG	3	6.40	0.06	Pass
<i>P. aeruginosa</i> ATCC 15442	EN14561	AMS	6	6.10	0.04	Pass
<i>P. aeruginosa</i> ATCC 15442	EN14561	NAN	6	6.25	0.02	Pass
<i>P. aeruginosa</i> ATCC 15442	EN14561	TU	5	6.79	0.02	Pass
<i>E. hirae</i> ATCC 10541	EN14561	AMS	6	6.67	0.28	Pass
<i>E. hirae</i> ATCC 10541	EN14561	NAN	6	7.00	0.22	Pass
<i>E. hirae</i> ATCC 10541	EN14561	TU	5	6.63	0.10	Pass
MRSA ATCC 43300	EN14561	NAN	3	6.97	0.00	Pass
MRSA ATCC 29247	EN14561	NAN	3	6.80	0.00	Pass
VRE ATCC 51299	EN14561	NAN	3	6.15	0.00	Pass
Mycobactericidal						
<i>M. avium</i> ATCC 15769	EN14563	AMS	6	7.25	0.02	Pass
<i>M. avium</i> ATCC 15769	EN14563	NAN	6	6.85	0.02	Pass
<i>M. avium</i> ATCC 15769	EN14563	TU	5	6.52	0.00	Pass
<i>M. terrae</i> ATCC 15775	EN14563	AMS	12	7.13	0.01	Pass
<i>M. terrae</i> ATCC 15775	EN14563	NAN	6	6.55	0.02	Pass
<i>M. terrae</i> ATCC 15775	EN14563	TU	5	6.02	0.28	Pass
<i>M. terrae</i> CIP 104321	EN14563	BG	3	6.07	0.03	Pass
Sporicidal						
<i>G. stearothermophilus</i> ATCC 7953	EN14561	AMS	6	6.75	0.34	Pass
<i>G. stearothermophilus</i> ATCC 7953	EN14561	NAN	6	6.10	0.04	Pass
<i>G. stearothermophilus</i> ATCC 7953	EN14561	BG	3	6.23	0.07	Pass
<i>C. difficile</i> ATCC 43593	EN14561	NAN	3	6.23	0.05	Pass
Fungicidal						
<i>C. albicans</i> ATCC 10231	EN14562	AMS	6	5.48	0.22	Pass
<i>C. albicans</i> ATCC 10231	EN14562	NAN	6	5.38	0.15	Pass
<i>A. niger</i> ATCC 16404	EN14562	AMS	6	5.47	0.22	Pass
<i>A. niger</i> ATCC 16404	EN14562	NAN	6	6.28	0.24	Pass
<i>A. niger</i> IP 1431.83	EN14562	BG	3	5.93	0.03	Pass
Virucidal						
Polio Virus Type 1 (ATCC VR-192)	ASTM E 1053-11	AMS	7	4.29	0.20	Pass
Polio Virus Type 1 (ATCC VR-192)	ASTM E 1053-11	NAN	10	4.18	0.05	Pass
Polio Virus Type 1 (ATCC VR-192)	ASTM E 1053-11	BG	4	4.28	0.05	Pass
Herpes Simplex Virus Type 1 ATCC VR-733	ASTM E 1053-11	AMS	6	3.85	0.29	Pass ^c
Herpes Simplex Virus Type 1 ATCC VR-733	ASTM E 1053-11	NAN	4	4.00	0.00	Pass
Hepatitis A Virus ATCC CRL-1688	ASTM E 1053-11	AMS	2	4.35	0.15	Pass

MRSA = Methicillin-resistant *Staphylococcus aureus*; VRE = Vancomycin-resistant *Enterococcus*; SEM = Standard error of the mean.

^a AMS = ams Laboratories, Australia; NAN = Nanosonics, Australia; BG = Biotech Germande, France; TU = Tübingen University, Germany.

^b Based on EN or ASTM criteria.

^c Cytotoxicity >2; >3 log reduction required for pass.

encountered in real-world disinfection practices. All penicylinder tests incorporated the presence of mated surfaces where the penicylinders contacted the carrier stand. Such contact points are difficult to disinfect and are the likely cause of the low levels of breakthrough growth of *S. aureus* and *S. choleraesuis* (however, the results still met the

acceptance criteria for HLD) (Table 1). To increase the realism of the tests, appropriate materials were used where possible. All tests performed according to EN standards used plastic carriers (acrylonitrile butadiene styrene) that are typical of those materials used in ultrasound transducer construction. Based on the broad efficacy observed under the

Table 3 Simulated use tests on a range of widely used transvaginal ultrasound transducers.

Manufacturer	Ultrasound transducer model	Testing center ^a	n (transducers)	Mean log reduction	SEM	Pass/fail ^b
ATL	Linear Array L11-5	AMS	4	7.14	0.12	Pass
ATL	Linear Array L11-5	NAN	2	6.99	0.21	Pass
GE	3.5C	NAN	1	7.13	N/A	Pass
Acuson	C3	AMS	2	7.35	0.05	Pass
GE	618E, Model: 2197484	AMS	2	7.20	0.10	Pass
ATL	Curved Array C9-5 ICT	AMS	2	6.80	0.20	Pass
Medison	L3 probe	AMS	2	6.91	0.04	Pass

SEM = Standard error of the mean.

^a AMS = ams Laboratories, Australia; NAN = Nanosonics, Australia.^b Based on ASTM-E1837-96 criteria.

range of tests conducted, the device offers an alternative to users of traditional manual disinfection solutions.

The testing of large numbers of replicate samples across multiple testing centers allowed for the analysis of the consistency of the disinfection efficacy. The SEM for both AOAC Official Methods and simulated use tests was low (less than 0.4 log reductions in viable count across all samples), indicating that the device tested is able to achieve HLD with a low degree of variability. Such consistency may offer advantages over manual HLD reprocessing methods, which may provide more opportunities for operator error or variation. During a study on the human papilloma virus (HPV) contamination of TVUSPs in Hong Kong, researchers noted that the proportion of HPV-positive transducers dropped off over the course of the study [9]. Importantly, the authors attributed this improvement in disinfection efficacy to the staff becoming aware of the study and therefore changing their behavior and being more stringent in performing the disinfection procedure. Such human variation is not unexpected, and some regulatory agencies have set guidelines that give preference to reprocessing techniques that are performed in an automated fashion. The Commission for Hospital Hygiene and Infection Prevention in Germany recommends that automated methods for reprocessing medical devices be used where possible [25]. Similarly, UK guidelines set out by the Department of Health recommend that the manual reprocessing of medical devices should be restricted to those items that cannot be processed in an automated manner [26].

The experiments presented herein all involved lab-based testing with heavy inocula and organic soiling in an effort to represent worst-case scenarios in clinical practice. Although these lab-based tests are widely accepted as evidence of efficacy,

clinical studies that examine performance in a real-world setting would be desirable to fully investigate efficacy. Such clinical investigations will be the subject of future work.

In conclusion, automated devices that utilize hydrogen peroxide-based disinfection technology offer advantages to users and patients. Hydrogen peroxide offers a less toxic alternative to glutaraldehyde-based disinfection technologies, and automation reduces the chance of operator variability in reprocessing. The results from this study show that automated, hydrogen peroxide-based reprocessing devices can achieve HLD of ultrasound probes in both carrier and simulated-use tests. Given the safety benefits to operators and patients, such devices will likely become more widely used in the future.

Disclosure statement

DP is an employee of Nanosonics Ltd. JB is an external consultant to Nanosonics Ltd. The manuscript was written by the authors, and approval of the final manuscript by Nanosonics was not required.

Role of the funding source

Nanosonics Ltd. provided funding for this study and was involved in the study design, data analysis and writing of the manuscript. Some experimental testing was carried out at Nanosonics' facilities as indicated in the data tables.

Ethical approval

Not required.

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