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

Karen Vickery[a,*], **Vivian Zaiya Gorgis**[b], **Jon Burdach**[c], **Dipika Patel**[d]

[a] *Surgical Infection Research Group, Australian School of Advanced Medicine, Macquarie University, NSW 2109, Australia*
[b] *Sydney Medicine School, Department of Infectious Disease, University of Sydney, Sydney, NSW 2006, Australia*
[c] *Iceclam Pty. Ltd., PO Box 366, French's Forest, NSW 1640, Australia*
[d] *Nanosonics Ltd., Unit 24, 566 Gardeners Road, Alexandria, NSW 2015, Australia*

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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.

* Corresponding author at: Australian School of Advanced Medicine, Macquarie University, 2 Technology Place, North Ryde, NSW 2109, Australia. Tel.: +61 2 9812 3550.
E-mail addresses: karen.vickery@mq.edu.au (K. Vickery), vgorgis@yahoo.com (V.Z. Gorgis), jburdach@gmail.com (J. Burdach), dipika_patel@nanosonics.com.au (D. Patel).

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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.

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