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Major Article

A new sampling algorithm demonstrates that ultrasound equipment cleanliness can be improved

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Background: Australia has established guidelines on cleaning for reusable ultrasound probes and accompanying equipment. This is a preliminary study investigating cleanliness standards of patient-ready ultrasound equipment in 5 separate health care facilities within a major city.
Methods: The cleanliness was assessed using rapid adenosine triphosphate (ATP) testing used with a sampling algorithm which mitigates variability normally associated with ATP testing. Each surface was initially sampled in duplicate for relative light units (RLUs) and checked for compliance with literature recommended levels of cleanliness (<100 RLUs). Triplicate sampling was undertaken where necessary. A cleaning intervention step (CIS) followed using a disposable detergent wipe, and the surface was retested for ATP.
Results: There were 253 surfaces tested from the 5 health care facilities with 26% (66/253) demonstrating either equivocal or apparent lack of cleanliness. The CIS was conducted on 148 surfaces and demonstrated that for >91% (135/148) of surfaces, the cleaning standards could be improved significantly ($P > .001$). For 6% (9/148) of devices and surfaces, the CIS needed to be repeated at least once to achieve the intended level of cleanliness (<25 RLUs).
Conclusions: This study indicates that ATP testing is an effective, real-time, quality assurance tool for cleanliness monitoring of ultrasound probes and associated equipment.

In February 2017, the Australian College for Infection Prevention and Control and the Australasian Society for Ultrasound in Medicine (ASUM) released joint guidelines for the reprocessing of ultrasound transducers.[1] The document was developed in response to the results of an Australasian ultrasound-specific survey to determine current understanding of infection prevention and control in ultrasound practice.[2,3] The additional goal was to increase awareness, via multiple published studies, for the potential of cross-contamination and infection transmission in ultrasound practice.

The ultrasound unit as a whole may be a vector for the transmission of potential pathogens to patients and staff.[4] High-level disinfection for the reprocessing of intracavity transducers is accepted by most practitioners as a necessary adjunct to all invasive ultrasound examinations; however, the Australasian survey results indicate a lack of understanding for the need for correct low-level disinfection (LLD) of all scanning-related equipment after every use.[2]

Bacterial contamination can be present on not only the transducer but also the keyboard, transducer connectors, gel bottles, and machine handles.[5] Contamination cannot be excluded by visual inspection alone, with one study showing that only 51% of blood-contaminated samples were visibly stained and a second study showing that 23% of external transducers had bacterial contamination postscan.[6,7] If gross contaminants, including ultrasound gel, are not removed prior to LLD, the effectiveness of subsequent LLD disinfection could be reduced, leading to the possibility of persistence of active virus or bacteria.

The literature reveals multiple studies reporting contamination within the ultrasound unit involving external transducers. Early

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reports were generally written around the risks of nosocomial infection arising from poorly or uncleaned ultrasound devices.[4,8-10] More recent articles have investigated incidents of bacterial contamination, evidence of cross infection, methods for cleaning and decontamination, and even device degradation through inappropriate cleaning and decontamination.[11-16] Each of these factors concomitantly lifts the risks associated with iatrogenic infection where the ultrasound probe could act as the critical fomite. A variety of bacterial pathogens and even environmental spore formers have been identified and associated with human infection, including unusual opportunistic pathogens such as *Acinetobacter lwoffii* and *Pseudomonas stutzeri*.[5] If the ultrasound unit keyboard, handle, transducer, electrical cord, and connector are not regularly cleaned between patients, they may pose as a vector for transmission of potential pathogens between the operator and the patient. The entire ultrasound unit should be considered as a potential source of infection. The pooled risk of cross infection via ultrasound probes has been estimated at 3.1% of patients.[17]

What is needed is a rapid method of assessment for cleanliness of ultrasound probes and associated equipment. Cleanliness testing using rapid adenosine triphosphate (ATP) equipment has been suggested as superior to both visual inspection and microbial sampling because it provides a real-time and quantitative measure of cleanliness.[18] Although the use of ATP testing is becoming more common for assessing instrument cleanliness,[19] there remains concerns over applicability, imprecision, and variability.[20-22] Unfortunately, many articles written around ATP testing do not account for inherent variability, and propose evidence that is consequently unsustainable.[23,24]

To overcome the difficulties with variability, a new algorithm-based sampling method has been proposed to mitigate the problems encountered in field use with ATP testing.[25] This method requires multiple samples and also includes a cleaning step to internally validate the cleanliness and cleanability of the surface or device being assessed. This limited scope study sought to classify the devices and surfaces tested into 3 broad groups: clean, equivocal (probably unclean), and dirty (definitely unclean).

Participants in the study were contacted through the ASUM with the clearly stated outcome of anonymity and peer review publication of the results. This article outlines this research project in anticipation of further and more detailed follow-up studies into this important area of infection prevention and iatrogenic risk.

METHODS

ATP testing was conducted at 5 hospital ultrasound clinics within Sydney, Australia. Within each clinic, individual ultrasound suites were selected on the basis of availability after cleaning and high-level disinfection where appropriate. At some locations, the ultrasound instruments and probes were stored in an adjacent room. In each situation, the equipment tested was confirmed by staff as patient ready for use.

Measurement method

ATP testing was conducted on 3 separate days using ATP bioluminometer and associated swabs (Hygiena; Key Diagnostics, Sylvania, Australia). ATP testing devices express results in a relative light unit (RLU) scale. The Hygiena device was selected after validation experiments confirmed that the point of a zero reading for ATP (0 RLU) equates to a repeatable outcome in terms of quantitated ATP measurements.[21] The reproducible precision at the lower level of the dynamic range was important when distinguishing clean surfaces from less clean surfaces at the lower limit of quantitation for the ATP testing device.

An initial cleanliness threshold, which is specific to the Hygiena ATP testing device, was set at 100 RLUs. The level of 100 RLUs has been recommended by others, despite differences in sampling areas used of 100[26] and 10 cm^2.[27,28]

The dimensions of the swabbing areas recommended for ATP testing have varied from a 100 cm^2 area (10 × 10 cm) in both food[29] and health care,[18] whereas other authors have chosen a smaller area of 16 cm^2 (4 × 4 cm).[30] Using a swab area of 2 × 5 cm (10 cm^2) has also been recommended for both food and health care surfaces.[27,28]

The 10 cm^2 rationale is practical for health care surfaces and reusable medical devices such as ultrasound probes and allied equipment.

Swabbing method

Using an aseptic technique, a fresh swab was uncapped and the distal tip was applied in a rolling action across a 10-cm^2 sampling area. The swab was then recapped, the reagent was released and mixed for 5-10 seconds, the swab was placed into the bioluminometer, and the detection system was activated. The readings were available after 15 seconds and recorded both manually and stored within the Hygiena ATP device memory.

Stage 1: ATP testing

Our previous research has concluded that repeated testing as outlined in a sampling algorithm is required to mitigate sampling and inherent error.[25]

In this study, each of the selected surfaces was sampled in duplicate on adjacent segments of the surface with each sample matched for sampling area (in most instances an area of 2 × 5 cm = 10 cm^2). The second ATP sample was taken on all surfaces on an adjacent area. Equivocal results arose where duplicate results indicated that one reading was above the 100-RLU threshold and one was below the 100-RLU threshold. Where results were equivocal or there was visible soiling present, a third ATP swab was taken.

Stage 2: Cleaning intervention step

Our hypothesis was that surfaces classified as dirty, or equivocal, could be shown to have a residual presence of ATP soil that was readily removable. This can be demonstrated through a validated cleaning intervention step (CIS), examined using ATP on a before and after basis.

This step provides evidence on the potential for achieving a cleaner surface if the cleaning is conducted with a controlled aseptic technique. After the initial sampling (duplicate or triplicate), a CIS was conducted. The CIS was not conducted on clean surfaces where the duplicate samples were both <50 RLUs.

This step used disposable detergent wipes (neutral pH) which had been validated as suitable for use with the ATP testing swabs (Speedy Clean wipes, or Matrix Wipes; Whiteley Corporation, Sydney, Australia). Disposable detergent wipes have a validated role in surface cleaning.[31,32] This wiping process is not intended to replace sanitization of the surface, but rather is used only to clean away any ATP-rich residue that might be present on the surface in the area of sampling.

The principle used when cleaning with the disposable wipe was to use only 1 wipe, on 1 surface, wiped in 1 direction.[31-33] The wipe was used by first removing the wipe using aseptic technique (including hand hygiene with an alcohol-based handrub), and then one side of the wipe was rubbed broadly across the sampling area of the implement or across an area of >10 cm^2 for a surface to fully wet the sampling area. The wipe was then folded in half with the unused side on the outer aspect. The disposable wipe was then wiped