

***Support for Cleaning Verification with the TOSI®**

An article entitled “**Cleaning efficacy of medical devices washers in North America healthcare facilities**”. Makes this statement in the article “...the load check washer monitor uses a colored dye imprinted on a plastic sheet and positioned within a grid-like metal holder, whereas the TOSI® device uses organic materials reflective of blood components that are dried on the surface of a metal coupon...**the load check indicator was not included in this evaluation as it does not contain an organic soil, so it is not relevant to compare the dye it uses as a visual indicator to the levels of organic material from patient-used items..**”¹

The TOSI®, a diagnostic challenge device and the **Winner of the 2010 Excellence in Surgical Products Awards**,² allows surgical facilities to ensure automated instrument cleaning equipment is working effectively, helping to improve efficiency, infection control, and patient staff safety.

"A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected".³

“Quotes from the 2010 ESP Winner: A User’s Perspective.” ...when is used the product for the first time, it did not turn. It wasn’t turning liked the pictures said it would, and I thought the product didn’t work. I called tech support for the product and found that the product did not turn because the washers at the time had no detergent / enzyme coming through the lines, all the spray arms were plugged, the temperature was too high for the detergent / enzyme and the dilution rate was incorrect. **Without this product, we would have continued to think our washer was operating at its full potential...**”⁴

Monitoring the cleaning process with **independent verification products** is now becoming the standard. Nancy Chobin has pointed this out in her article “The Value of Monitoring the Cleaning Process “...the processing area needs a reliable methodology that will monitor the effectiveness of the cleaning process similar to the products in use to monitor the effectiveness of various sterilization process...the TOSI® tools clearly identified sub-optimal cleaning processes/practices. The results correlated well to the artificial controls used and identified the lack of parts of the process (e.g., enzymatic pre-soak, ultrasonic cleaning)...”Please read the complete article at this link.

http://www.iceinstitute.com/shopping/course_material/c_cleaning.html

“Commercially available cleaning indicators (TOSI®) were used to simulate protein adhering to metal. Since the blood components are adhered physiologically to the **TOSI® indicator** without heat or use of organic solvents, **it is considered to be an excellent model for confirming the presence or absence of protein on surgical instruments as an indication of cleaning efficiency.**”⁵

“According to JCAHO, the efficacy of cleaning processes should be verified on a regular basis to demonstrate consistency and efficiency. Commercially available testing devices can be used to verify and demonstrate the consistent efficacy of the cleaning process. For example, the TOSI® line of products from Europe can be used to verify the effectiveness of ultrasonic cleaners, mechanical washers and manual cleaning.”⁶

“A commercial monitoring product is available that mimics dried blood, and tests the effectiveness of automated washers. It is designed to parallel worst case scenarios of instruments processed in mechanical cleaning equipment, and to monitor the machine’s ability to remove bioburden. After the cycle has completed, the monitor is inspected for residual bioburden. If any residue is present, there is a clear indication that some parameters needed for cleaning are not being achieved. Failure of this quality assurance check can alert one about the need to investigate each variable, and it can also assist in identifying and resolving the problem.”⁷

“There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies,

which under normal conditions; achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt.”⁸

“Sterile Processing is an integral part of the care process, so it’s important to assess that equipment is being properly maintained, chemicals are being used properly, infection control and (safety) measures are being applied appropriately and that there is proper ventilation, for example.”⁹

“Ultrasonic Cleaners should be monitored routinely to ensure that they are working properly. Recommended monitoring methods are: 1) Sonocheck monitoring vials (from Healthmark Industries Co. Fraser, MI 48026 USA) which change color when the ultrasonic cleaner is supplying sufficient energy and conditions are correct.”¹⁰

“Getinge™ has developed a performance monitoring program that allows a user to independently verify that key parameters of the cleaning equation under their control.”¹¹

“SKYTRON™ now sending a verifying test with each washer to be used upon installation. User are being informed by the manufacture to do at least weekly verification of their medical automatic process.”¹²

“MEDISAFE™ Sonic Irrigator PCF (Parameter Controlled Flow) has been validated and tested to clean the most complicated, intricate and advanced robotic surgical instruments in the world today, the *da Vinci® EndoWrist instruments*. In keeping with the spirit of our innovative leadership position in the marketplace today, Medisafe America, LLC recommends the **DAILY** monitoring of the cleaning efficacy of our advanced instrument reprocessing equipment, (SI-PCF, SI- Auto, SI – SA, SI- Digital) with an industry accepted PCD or Process Challenge Device. We recommend you use the following to test for: Verification of sufficient cavitation energy with the **Sonocheck™** monitoring vials**. The **Sonocheck™** is an easy to use and interpret, (color changes from blue to yellow) method for monitoring cavitation energy. Verification of the cleaning efficacy for cannulated/lumen items with the **LumCheck™** test kit. Another easy to use check for the cleaning efficiency of lumened instrumentation.”¹³

“Our data demonstrate that the **lumen TOSI®** is a relatively easy challenge and if residual material remains it indicates that the lumen cleaning ability of the washer has been severely impaired (less than ½ usual conditions).”¹⁴

***This document summarizes various articles, and publications. Please note that many of them are copyright material, to read the complete text of these articles and publications go to their web site and purchase the actual articles or publications. Updated 11/2011 SMK**

¹ Alfa, Olsen, Al-Fadhaly; Cleaning efficacy of medical devices washers in North American healthcare facilities; Journal of Hospital Infection (2010) 74,168-177

² Surgical Products November / December 2010 ; The CLEAN CHALLENGE

³ ANSI/AAMI ST79:2006;11.2.2;PAGE 111

⁴ Surgical Products; November/December 2010;2010 ESP Winner : A User’s Perspective

⁵ Page 448 ; Zentral Sterilisation; Volume 15-2007

⁶ Page 87;The basics of Sterile Processing; Sterile Processing University ,LLC

⁷ Page 152; 7th Edition Central Service Technical Manual; IAHCSSM

⁸ Alfa,M.,et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide gas Sterilizer, Infection Control and Hospital epidemiology, 1996; 17:92-100

⁹ June 2004-HPN-page 32; Darlene Christiansen; Director of Standards Interpretations and the Office of Quality Monitoring.

¹⁰ Source of information ; www.smith-nephew.com

¹¹ www.gentinge.com

¹² www.skytron.com

¹³(2009) www.medisafe.com

¹⁴ Alfa M ; Lumen TOSI® Report-White paper; 9/23/02