Decontamination Standards, Guidelines & Articles in support of using the TOSI 2014

"…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]

Key Elements AAMI ST 79[2]

AAMI realized that the efficacy of any sterilization process, including saturated steam, depends on a consistent system for l*owering and limiting bio-burden before sterilization. AAMI supports the verification of the cleaning process.*

Section 7.5.2.2

"…Many types of soil could be present on reusable medical devices, but **dried blood is especially difficult to remove**. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning. It must be rehydrated and then washed away. Blood adheres to surfaces through mechanical and chemical means. Fibrin filaments in coagulated blood pack themselves into microscopic irregularities in the surface of instruments and have to be mechanically scrubbed away or chemically treated…."

Section 7.5.3.3

"…Mechanical cleaning equipment should be **tested upon installation, weekly (preferably daily) during routine use**, and after major repairs. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software.."

Section 7.5.5

"…Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. ***Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function.*** A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically…."

Section D.1

"..Organic soil such as blood, serum, lipids, tissue fragments, and inorganic salts can impede the disinfection or sterilization process if it is not removed during cleaning…"

Section 10.2 and ANNEX D

"…Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices…"

ANNEX D

"…***Organic soil such as blood***, serum, lipids, tissue fragments, and inorganic salts ***can impede the disinfection or sterilization process*** if it ***is not removed during cleaning***. Most of these soil components are substrates for the sterilants used for disinfection or sterilization; that is, they are competitors for sterilant action. If these soil components are insufficiently removed, they can also protect microorganisms from inactivation by limiting the diffusion of the sterilant to the microorganisms' location on the medical device.…***Coagulated blood test. Metal coupon with strip of coagulated blood soil. After cleaning, visually inspect with comparison to chart to confirm removal of soil. A lumen version is available for testing.*** Blood and protein; detected as visible red (blood) or visible "film" (fibrin,protein) … Valuable as a quality assurance indicator for functionality of washer-disinfector …."

The **TOSI™**, a diagnostic challenge device and the **Winner of the 2010 Excellence in Surgical Products Awards,**[3] 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". [4]

"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**…"[5]

"…any organic matter that remains after cleaning lowers the effectiveness of the disinfectant,…with imperfect cleaning, bacteria could survive the disinfection process and infect the next patient…"[6]

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.**"[7]

"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."[8]

"A commercial monitoring product is available that mimics dried blood, and tests the effectiveness of automated washers. It is designed to parallel worse 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."[9]

"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."[10]

" 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."[11]

"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."[12]

"Getinge™ has developed a performance monitoring program that allows a user to independently verify that key parameters of the cleaning equation under their control (the T.O.S.I. is the product used)."[13]

SurgiSonic® Ultrasonic Cleaner for Tubular Surgical Instruments recommends using the SonoCheck for verification of their equipment.[14]

"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."[15]

"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)."[16]

AORN[17]

The 2011 AORN RP for Cleaning and Care of Surgical Instruments and Powered Equipment Recommendation XXII – Quality section is supporting the testing of mechanical instrument washers before initial use, weekly during service, and after major maintenance.

TJC[18]

In standard E.C.06.2 it states that medical equipment is maintained, tested and inspected

FDA[19]

The FDA, AAMI and other regulatory bodies recommend that **any simulated-use testing be done with a surrogate device that closely approximates the actual types of soils the instrument is to be exposed to in clinical use**. Further, the surrogate device should be made of the same type of material as the instrument it represents.

Healthmark[20]

Healthmark is the only company with comprehensive tests for this purpose - tests to measure water temperature, water quality, cleaning efficiency, and directly test residual soil on instruments- the TOSI: dried blood soil on a stainless coupon is directly analogous to dried blood on a stainless instrument.

This document summarizes AAMI, AORN, JCAHO standards and guidelines. Please note that AAMI, AORN, TJC are copyright material, to read the complete text of these standards go to their web site and purchase the actual standards and guidelines.

---

[1] Journal of Hospital Infection (2010) 74,168-177
[2] AAMI ST 79:2009A;www,aami.org
[3] Surgical Products November / December 2010 ; The CLEAN CHALLENGE
[4] ANSI/AAMI ST79:2006;11.2.2;PAGE 111
[5] Surgical Products; November/December 2010;2010 ESP Winner : A User's Perspective

[6] Spach D, Silverstein F & Stamm W. Transmission of Infection by gastrointestinal endoscopy and bronchoscopy. Annals of Internal Medicine 118,117-128 (1993)
[7] Page 448 ; Zentral Sterilisation; Volume 15-2007
[8] Page 87;The basics of Sterile Processing; Sterile Processing University ,LLC
[9] Page 152; 7th Edition Central Service Technical Manual; IAHCSMM
[10] 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
[11] June 2004-HPN-page 32; Darlene Christiansen; Director of Standards Interpretations and the Office of Quality Monitoring.
[12] Source of information ; www.smith-nephew.com
[13] www.gentinge.com
[14] http://www.surgiclean.com/index.html
[15] www.skytron.com
[16] Alfa M ; Lumen TOSI Report-White paper; 9/23/02
[17] **Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment 2008; www.aorn.org**
[18] www.jcaho.org
[19] http://www.artificialtestsoil.com/FDAreferencePage.htm
[20] http://www.healthmark.info/proformance.html