Decontamination Standards, Guidelines & Articles in support of using the TOSI® 2018

"…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 6.3.1

"…Biofilm consists of an accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily. Biofilm has the effect of protecting microorganisms from attempts to remove them by ordinary cleaning methods used in the sterile processing area. Biofilm can form on many surfaces but is particularly problematic in devices with lumens. Once biofilm forms, direct friction and/or oxidizing chemical are needed to remove it. Prompt cleaning reduces the population of microorganisms and thus helps to prevent the formation of biofilm…"

Section 13

"…Mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs. When evaluating or changing to a new type of cleaning solution and after all major repairs, all cycles used should be tested to ensure that the cleaning solution and cleaning action are effective. A major repair is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment..."

Section 7.1

"…Medical devices, instruments, and equipment used in patient care become contaminated with microorganisms and should be decontaminated. Infection prevention and control is enhanced when soiled supplies and equipment are correctly and safely handled, and when reusable medical items are thoroughly cleaned. Adherence to the principles of infection prevention and control will help prevent the spread of potentially infectious or disease-producing microorganisms from one person to another and will help ensure that all items are safe for handling during inspection, assembly, preparation, and packaging..."

Section 7.2

"…Policies and procedures provide facility instruction for maintaining consistency and effectiveness of the cleaning and decontamination processes consistent with applicable standards and recommended practices. Audits of the process can help to identify gaps, so methods can be identified to improve the process…"

Annex D.1

"…Cleaning verification by users should include (a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and the inner housing and channels of medical devices, (b) testing the cleaning efficacy of equipment, and (c) monitoring key cleaning parameters…"

ANNEX D

"…Facility's on-site quality assurance program should include ways to verify that the cleaning equipment used for reprocessing of medical devices is working properly. The variability of results for lumens cleaned by automated washers (Zuhlsdorf et al., 2002) underscore the importance of in-use verification of manual cleaning, which is generally less efficient than automated cleaning. Two basic components of user verification of cleaning efficacy are 1. Establishing reasonable benchmarks for the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients, 2. Using rapid, easy to perform, test that reliably demonstrate that the cleaning benchmarks have been achieved…"

ANNEX D.3

"…**Verification tests for ultrasonic cleaners**-***Test for cavitation in ultrasonic bath*****:** Indication can be physical measurement or visual assessment. ***Test for Soil removal (external) in ultrasonic bath:*** Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath. ***Test of removal (internal within lumens) in ultrasonic bath*****:** Indication is visual assessment of absence of marker on a coupon placed in the ultrasonic bath. **Verification test for mechanical washers:** ***Test for soil removal***: Indication is visual assessment or absence of marker on a coupon placed in the washer.

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 sterile processing CQI program could also include review of aspects of design, decontamination processes, personnel, handling of contaminated items, packaging, sterilizer loading and unloading, IUSS, sterility maintenance, and problem investigation". [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]

"Commercially available testing devices can be used to verify and demonstrate the consistent efficacy of the cleaning process. One example is the TOSI® line of products, which can be used to verify (a) the effectiveness of ultrasonic cleaners, mechanical washer, regular cart washers, cart washers validated and used for processing surgical instruments, and AERs and (b) the cleanliness of lumened instruments."[8]

Under the section Equipment Testing, it states "ANSI/AAMI ST79, 10.2, recommends a quality assurance program to ensure that the mechanical equipment is working properly. Commercially prepared products can be obtained to verify the cleaning effectiveness of the equipment."[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]

SurgiSonic® Ultrasonic Cleaner for Tubular Surgical Instruments recommends using the SonoCheck™ for verification of their equipment.[12]

"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)."[13]

AORN
The 2017 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.[14]

TJC
In standard E.C.06.2 it states that medical equipment is maintained, tested and inspected.[15]

Infection Control (IC) standard IC.02.02.01-which requires hospitals to reduce the risk of infections associated with medical equipment, devices and supplies-continues to be one of the most commonly cited standards listed as noncompliant. In 2017, 72 percent of surveyed hospitals and critical access hospitals were found to be noncompliant with this standard.

After a careful evaluation of high-level disinfection (HDL) and sterilization process steps, The Joint Commission has refined its scoring to focus on the process steps that pose the highest risk to patients if they fail and Infection Control scoring is intended to help hone in on the highest-risk process steps to become more compliant with IC.02.02.01, and they went into effect on Sept. 1, 2018.

FDA
The FDA recommends that any simulated-use testing be done with a device that closely approximates the actual types of soils the device is to be exposed to in clinical use.[16]

Healthmark
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.[17]

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.

References:

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[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 177-178; The Basics of Sterile Processing; Sterile Processing University, LLC
[9] Page 145; 8th 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] http://www.surgiclean.com/index.html
[13] Alfa M; YJHIN 1720—1/6/2004—09:05—DMESSENGER—106432— MODEL 6 — pp. 1–9
[14] Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment 2017; www.aorn.org
[15] www.jcaho.org
[16] https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf
[17] http://www.healthmark.info/proformance.html