Example Policy for Daily Cleaning Verification monitoring of a medical automatic washer using the TOSI• and Weekly Test Kits

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NOTE: This document is an example of a policy that may be instituted in a health-care facility for daily cleaning verification monitoring of medical automatic washer using the TOSI® and weekly test kits. The actual policy in a facility must be based on variables, logistics and risk-assessments that are specific to your facility.

Subject: Daily Verification of Medical Automated Instrument Washer/Disinfector Cleaning Performance

Department: CSSD, CPD, SPD, MDRD, SPA, any department using a medical automatic washer

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter the date when this will take effect]

Revised: June 2021

Purpose: To challenge the cleaning efficacy of mechanical cleaning equipment and proteolytic detergent.[1]

Policy: This policy is for inspection and testing daily of any medical automatic instrument washer with the TOSI® surrogate test and its supporting test product kits. The TOSI® is to be used according to the manufacturer's guidelines to ensure that the cleaning process is occurring, and the medical automated instrument washer is functioning properly.[2]

RATIONALE and SUPPORT for VERIFICTION TESTING with the TOSI®:

- According to ANSI/AAMI ST79 every medical facility (as defined in ST79) that has a medical automatic instrument washer should put in place a cleaning verification process that consists of "defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and providing process controls along with verification methodologies that ensure adequate, consistent cleaning levels.

- Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on device manufacturers' written IFUs and published recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after applying the established cleaning process. For verification of routine cleaning processes, users should incorporate test methods

that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific items after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks once these benchmarks have been defined.[3]

- ***ST79 goes on to state that "Mechanical cleaning equipment performance should be tested each day (daily) it is used, and all results should be recorded."[4]***

- The Joint Commission standard E.C.6.20 states that all medical equipment is maintained, tested, and inspected.

- The medical automatic washer is considered a piece of medical equipment.[5] Medical washers need to be properly functioning to provide the best patient care possible and to help reduce the incidence of hospital-acquired infections.

- "Cleaning, not sterilization (or disinfection), is the first and most important step in any instrument processing protocol. Without first subjecting the instrument to a thorough, validated, and standardized (and ideally automated) cleaning process, the likelihood that any disinfection or sterilization process will be effective is significantly reduced." [6] , [7]

- Any medical automated washer/disinfector cleans and decontaminates dirty surgical instruments, so they can be handled safely, repackaged, and sterilized for a future surgery. The danger of handling instruments contaminated with blood is obvious in this age of hepatitis, CJD and HIV. The procedures for sterilizing instruments are based on years of scientific testing of cleaning instruments. If surgical instruments are not clean, the procedures are ineffective. Dried blood on instruments is hazardous to the employees of the hospital and to the next surgical patient upon which the instruments are used. [8] , [9] , [10], [11]

- Cleaning dried blood represents a significant challenge to effective cleaning. Blood coagulates, which means it goes from a free-flowing liquid to a solid that contains tough, microscopic fibers called fibrin. These fibers form as the blood coagulates and jam themselves into microscopic irregularities in the surface of the stainless-steel instrument. This is a physical attachment to the surface through mechanical means, not chemical means as with traditional adhesives. The action is like the roots of plants growing into cracks in rocks, anchoring themselves to the surface.

- Another factor that makes blood difficult to clean is its ability to become insoluble when heated. Heating causes blood to "denature." Denaturing is like what happens to eggs cooked in a frying pan. Transparent uncooked egg whites are easy to wash away, but opaque, cooked egg whites are much more difficult to remove. Dried, uncooked egg is even more difficult to wash away, as is dried blood. The proteins in blood are like albumin proteins in eggs.

- Washers fail to clean for many reasons. Suitable surrogate tests should provide a means of monitoring the variables that influence the effectiveness of a washer. Some of these variables are water quality, time, detergent, enzyme, temperature, pH level, agitation, speed, initial temperature, drying time, obstructions, and insufficient amount of chemicals. [12]

- Proper cleaning is critical. The TOSI® provides an independent objective test of clean and allows the healthcare professional to monitor and ensure proper cleaning in the medical automated instrument washer/disinfector process.

- JC, AAMI, AORN, IAHCSMM, CMS and other groups, recommend that Sterile Processing Areas have quality management programs in place.

- ANSI/AAMI ST90, called "Processing of health care products—Quality management systems for reprocessing" is a new standard that specifies the minimum requirements for a quality management system that can be used by healthcare organizations that process medical devices. It was developed to help healthcare professionals more effectively, efficiently, and consistently reprocess (clean, decontaminate, disinfect, and sterilize) reusable medical devices to prevent infections, pyrogenic reactions, or other adverse events. This document supports putting place quality monitoring for all mechanical cleaning equipment.

- The 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 and should have validation studies behind their claims as a verification tool for cleaning. The TOSI® is the standard for cleaning verification for automatic washers. It follows the ASTM D7225 guidelines (the only cleaning verification test on the market, that meets this standard).

- The word TOSI® stand for *Test Object Surgical Instrument* and has the most literature supporting its use and ability to help ensure a medical automatic instrument washer is performing properly.[13]

- The design of the TOSI® reflects one of the most difficult areas of a surgical instrument to get clean, the box lock area. It also has a slanted narrowing gap design. The TOSI® is comprised of hemoglobin, fibrin and albumin on a stainless-steel plate that represents a surgical instrument. Hemoglobin is the protein released from red blood cells. It is water soluble. Thus, no chemistry is needed to wash away this component of the test. Water alone should remove it. Albumin is also water soluble, and the same rules apply to albumin as hemoglobin.

- Fibrin is the coagulating agent in blood. When we get cut, it is fibrin protein that binds together to clot and block bleeding. Fibrin is highly water insoluble. On the TOSI® test, it is the translucent layer. It is below the hemoglobin/albumin layer.

Being water insoluble, chemical agents, enzymes, or high alkaline detergents, are needed to break it down and render it water soluble. This occurs in a process called hydrolysis. Literally, this means the chemical agent alters the fibrin protein, rendering it water soluble.[14]

- The TOSI® test truly represents what every sterile processing department is trying to accomplish: clean blood off stainless steel instruments, including in the hard-to-reach areas of a medical devices. Thus, the TOSI® is a true surrogate testing devise.

- Using the TOSI® and its various supporting tests according to the manufacturer's IFU helps to ensure adherence to guidelines and standards and thus a properly functioning cleaning process.[15]

Procedure:

Verification and documentation of automated cleaning processes through objective means is an important aspect of quality control. Cleaning encompasses the removal of organic residues (e.g., blood, tissues, bone fragments, secretions and excretions) and microorganisms from the patient, from handling, or from water exposure during reprocessing. There are many outputs that should be measured to help ensure a medical automatic washer is working properly. Some outputs are done daily, weekly, monthly, quarterly and even yearly as per the OEM's IFU and a quality system approach for monitoring the medical automatic washer outputs to help ensure it is properly functioning.

Healthmark provides a work (log) sheet with many of the key outputs that should be monitored. Begin with performing an equipment inspection as specified on the log sheet. Start with the spray nozzles/arms and proceed with all items listed on the work sheet. After observations and equipment check are completed, proceed with testing the medical automatic washer with the TOSI® in each machine and record all results.[16]

Daily Inspection & Testing:

- Follow manufacturer guidelines concerning the daily inspection of equipment (spray arms, screens, etc.), use the Healthmark log sheet to record results of inspection.
- Inspect the level of the detergent daily. (Mark the container of the solution daily with the date at the level of the solution in the container.) This will allow visual verification that the solution is being used.
- At the beginning of each day all washers will be tested with TOSI®
- Depending on the rack used each level of the rack must be tested at the same time. If the rack has two levels, then two tests are used; if the rack has three levels, three tests are used. One test per level on each rack is the standard.
- Secure one TOSI® in the center of an empty tray in each washer/disinfector. Do this as many times as you have shelves.

- If multiple shelves are present, place a tray with a TOSI® on each shelf.
- Load a rack with its TOSI® in each washer/disinfector to be tested. The TOSI® should be placed in an empty tray in an empty chamber (bottom of the tray).
- Process using the normal procedure/cycle (usually the instrument cycle).
- After completion of the wash cycle. Examine the TOSI® for visual cleanliness. Compare the test to the TOSI® Troubleshooting Wall Chart. [17]
- Record results.
- Immediately report any test failure to department management.
- Use the results found when comparing the test object and to the TOSI® chart to determine what, if any, adjustments need to be made. Make necessary adjustments.
- Retest once adjustments have been to ensure adjustments have corrected the concern.
- Record all results.
- Repeat testing each day the washer is used.

Daily Inspection and Testing:

In addition to the *Daily Inspection and Testing* described above, once a week a complete test of all the inputs of the automatic washer (temperature, pH, hardness, etc.) should be performed along with testing with the TOSI®. Healthmark provides a weekly test (log) sheet to record results.

Water Quality:
Follow these steps first for cold water, then hot water:

- Use an Aqua Test (WTS-101) test strip.
- Dip entire strip into water for 5 seconds, then remove.
- Shake once briskly to remove excess water from the test strip.
- Wait 20 seconds.
- Compare color within 10 seconds to pH, Total Alkalinity, Total hardness on the interpretation chart.
- Report any deviations from expected values.
- Note that water conditions do change seasonally. It is important to establish a base line (target values) for your water and to compare your results to that base line/value.

Pre-Rinse– Water Temperature:

- Use a TempaChek™-90 for this test.
- Use one (1) TempaChek™-90 per washer.
- Peel thermometer from release paper.
- Apply to any clean, dry surface, ensuring that the indicator has adhered to the surface (i.e., apply to the smooth surface on the TOSI® rack)
- TempaChek™-90 should be removed and read immediately after the **Cold-Water Rinse** stage. If the machine has a window, the result can be read through the window; if not, the cycle must be stopped. Certain models of STERIS, Belimed, Getinge, & Hamo machines cannot be stopped; results must be read through the window.

- Record results on log sheet.
- Temperature should not exceed 110 ˚F. Immediately report any result that exceeds this temperature.

Thermal Disinfection Stage:

- Use one TempaChek™-170 on each level of the instrument rack.
- Peel thermometer from release paper.
- Apply to any clean, dry surface, ensuring that the indicator has adhered to the surface (i.e., apply to the smooth surface on the TOSI® rack).
- TempaChek™-170 should be removed and read after the **Thermal Disinfection Stage** and before the drying stage, if possible; again, some washers cannot be stopped or aborted, thus results are read through the window.
- Record results on log sheet.
- Report any deviation from targeted temperature.
- TESTING IS COMPLETED AFTER THIS CYCLE COMPLETES.

Testing to Challenge Staff Practice:

- Follow this protocol to challenge the loading practices of Sterile Processing Personnel.
- The frequency of testing is set by the department (daily, weekly…) number of washers and staff to be tested. In each washer/disinfector that is to be tested, secure one TOSI® in the center of a tray of dirty instruments.
- The larger the set, the greater the cleaning challenge for the washer. Place the tray (with the TOSI®) on any one of the shelves if multiple shelves are present. If possible, mark the tray with a tag to be easily identified once the cycle is complete.
- Load the rest of medial automatic washer/disinfector with dirty instruments / tray as per your facility policy.
- Process using your normal procedure / cycle.
- Upon completion of the cycle examine the tray of instruments that the TOSI® Test was placed in for visual cleanliness. Compare the test to the TOSI® Troubleshooting Wall Chart.
- Record results.
- Make any adjustments to the medical automatic washer/disinfector, staff loading practices, etc., as needed according to the results found from the test object and comparing them to the TOSI® Troubleshooting Wall Chart.

Over time, continue to vary the shelf and position of the tray, type of trays and instruments tested to test all possible configurations and staff loading technique. This process can help better understand the impact of loading instruments in trays, keeping hinged instruments in the open position and spreading them out to reduce the shadowing (spray pattern) on instruments.

Maintenance on Equipment:

- After any maintenance on the equipment, perform a test using the TOSI® Washer Test to ensure that the equipment is cleaning properly.
- Follow the weekly test process to ensure all parameter are within your facilities values.
- Have the maintenance person wait until the test results are complete before leaving.

Possible False Positive Results with the TOSI®:

- Tiny Red Spot-on TOSI® Plate: Very rarely, but nonetheless possible, is a slight imperfection in the stainless-steel plate which leads to oxidation of the metal. The result is a little red spec which could be confused with the hemoglobin soil on the TOSI®. The easiest way to double check is to directly employ mechanical action (with a gloved hand, preferably with the aid of an instrument cleaning brush) under water. If the spec remains, then it is not the TOSI® soil that remains.

- Ghosting on the TOSI® Plate: A whitish staining is observed on the TOSI® plate, which can be confused with fibrin protein remaining on the TOSI®. This usually happens at a facility that has hard water. If allowed to dry and the TOSI® is read at that point, hard water staining may be observed on the TOSI® plate. The simplest method is to submerge gently the TOSI® plate in a bath of water. If the ghosting "disappears" when wetted, this indicates a non-test soil residue (likely hard water minerals or detergent) and not the TOSI® test soil.

Disposal:

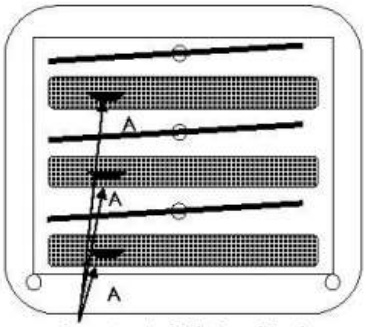
Since the TOSI® is run in the mechanical cleaning equipment; there is a chance for contamination. Therefore, it is recommended to dispose of the used TOSI® in a biohazard container in compliance with facility protocols.

Responsibility:

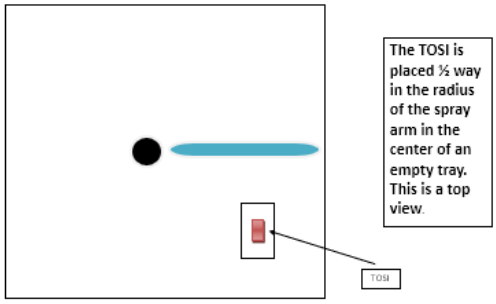
Central Service personnel are responsible for the proper use, result interpretation, and documentation of the TOSI® indicator when used on an automated instrument washer (1,5,12,13).

Staff in-service and training on the equipment and proper TOSI® use should be done at least once each year.

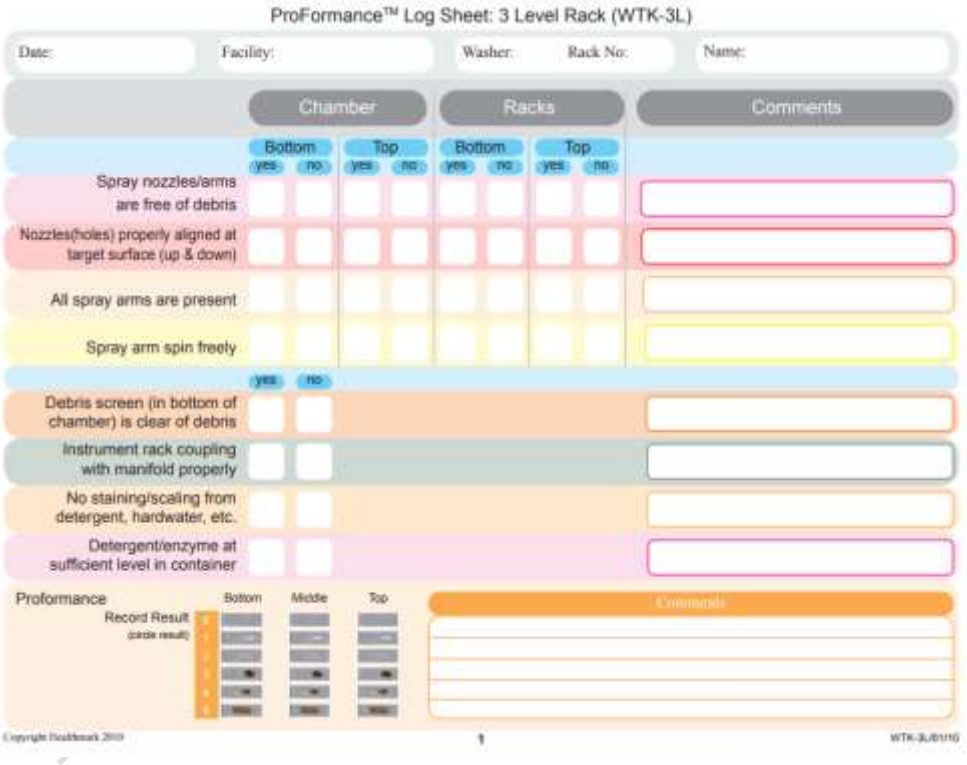
TOSI® PLACEMENT



Location A - Multi-Level Rack
Place one (1) TOSI® on each level. Arrange so that TOSI® is in the center of the radius of the spinner arm.



DAILY INSPECTION LOG SHEET EXAMPLE



ProFormance™ Log Sheet: 3 Level Rack (WTK-3L)

Date:	Facility:	Washer:	Rack No:	Name:

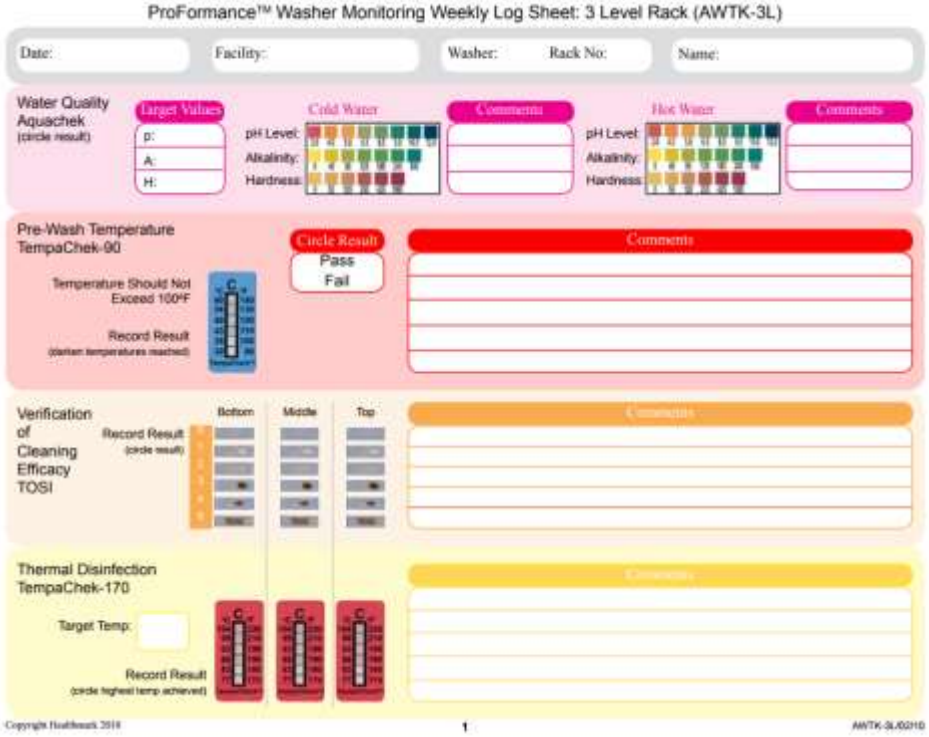
	Chamber				Racks				Comments
	Bottom		Top		Bottom		Top		
	yes	no	yes	no	yes	no	yes	no	
Spray nozzles/arms are free of debris									
Nozzles(holes) properly aligned at target surface (up & down)									
All spray arms are present									
Spray arm spin freely									

	yes	no	
Debris screen (in bottom of chamber) is clear of debris			
Instrument rack coupling with manifold properly			
No staining/scaling from detergent, hardwater, etc.			
Detergent/enzyme at sufficient level in container			

Proformance	Bottom	Middle	Top	Comments
Record Result (circle result)				

1
WTK-3L(01/19)

WEEKLY INSPECTION LOG SHEET



References:

[1] http://www.healthmark.info/CleaningVerification/TOSI/TechnicalBulletinWasher.pdf

[2] http://www.healthmark.info/CleaningVerification/TOSI/TOSI-IFU_2017-08-07.pdf

[3] 2017 Association for the Advancement of Medical Instrumentation; ANSI/AAMI ST79:2017. Section D.3 Cleaning verification tests for users
[4] 2017 Association for the Advancement of Medical Instrumentation; ANSI/AAMI ST79:2017. Section 7.6.4.5 Verification of the cleaning process
[5] 7.6.4.3.3
[6] 510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations,. The System 83 plus Washer -Disinfector; Custom Ultrasonics, Inc,1998, page 7

[7]http://www.healthmark.info/MktingPieces/ProductBrochures/2006/ProformanceJournal.pdf

[8] Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385

[9] Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310

[10] OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000

[11] http://www.proformance-test.com/SupportMaterial/BloodAsASoilonSurgicalInstruments.htm

[12] http://www.proformance-test.com/SupportMaterial/TechnicalBulletin1.html

[13] https://www.hmark.com/tosi.php

[14]http://www.healthmark.info/CleaningVerification/TOSI/BloodCoagulation.pdf

[15] http://www.healthmark.info/CleaningVerification/TOSI/ValidationofTOSI.pdf

[16] http://www.healthmark.info/CleaningVerification/TestKits/TOSIonlyLog-3Level2010-10.pdf

[17] http://www.healthmark.info/CleaningVerification/TestKits/ProformanceInterpGuide2010-04.pdf