Example for daily monitoring the performance of sonic cleaners and/or automatic washers cleaning ability for lumens/cannulated items with the LumCheck™ Cleaning verification test

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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: Monitoring the performance of a sonic cleaners and/or automatic washers cleaning ability for lumens/cannulated items daily.

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: Sept 2018

PURPOSE: The purpose of this example policy it to provide the means to monitor the automatic cleaning process of lumen/cannulated instruments to ensure proper cleaning and reduce risk to personnel or patients. (1,9,10,11,12*)*

POLICY: The sterile processing staff will be responsible for testing and documenting the results of the automated instrument washer on a daily basis to monitor the cleaning function for lumen/cannulated instruments.

RATIONALE: TOSI® LumCheck™ blood soil test is designed to monitor the cleaning function of an automated instrument washer ability to clean cannulated or lumen instruments. To ensure that the automated instrument washer process is cleaning properly lumen/cannulated instruments, a TOSI® LumCheck™ blood soil test should be used to monitor the occurrence of cleaning lumen/cannulated instruments. The TOSI® LumCheck™ blood soil test is to be used according to the manufacturer's guidelines to ensure that the cleaning process is occurring and the automated instrument washer is functioning properly. (1,6,7,8,9,10,11,12,13)

STANDARDS AND PROFESSIONAL SOCIETY RECOMMENDATIONS

1. ST 79; 2017 section 7.6.4.5 & 13.2 states this on daily testing
*"…*Mechanical cleaning equipment should be tested each day it is used and all results should be recorded and upon installation, 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 a software upgrade or the replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, ultrasonic generators, or computer controls…" Sonic cleaners are considered mechanical cleaning equipment by AAMI.

2. "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." (11)

3. Mechanical cleaning methods minimize personnel risk of cross-contamination, improve cleaning effectiveness, increase productivity, and are more easily monitored for quality performance. 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. (1,2,3,4,8)

4. Cleaning dried blood is much more difficult than cleaning dirt. 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 similar to the roots of plants growing into cracks in rocks, anchoring themselves to the surface.

5. The blood cells colored with hemoglobin are fairly easy to wash off instruments, but the clear fibrin material is much more difficult to remove.

Thick droplets of dried blood have so much fibrin; even the colored hemoglobin can be trapped and held in place. (5,6)

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

7. Washers fail to clean for many reasons. *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. (7)

8. Proper cleaning is critical. The variability of results for lumens cleaned by automated washers (Zuhlsdorf et al., 2002) underscores the importance of in-use verification of manual cleaning, which is less efficient than automated cleaning. Two components of cleaning efficacy are a.) establishing reasonable benchmarks for the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients and b.) using rapid, easy-to-perform tests that reliably demonstrate that the cleaning benchmarks have been achieved. (1)

9. JCAHO and AAMI both recommend that Sterile Processing departments have process performance in place (1,5,8,12). Using the TOSI® LumCheck™ blood soil test according to the manufacturer's guidelines helps ensure adherence to both JCAHO and AAMI standards and thus a properly functioning cleaning process.

PROCEDURE FOR INSPECTION:

"The problem risk analysis should identify, define and quantify the risk and identify actions that can be taken to resolve or prevent the risk. The system should be monitored to ensure that the risk has been corrected or prevented." (1)

The LumCheck™ can be used in either an automatic washer that has the capability to do lumens/cannulated items or a sonic cleaner that also has that capilibility.

Automatic washers have special racks for cleaning lumens/cannulated items. It is these types of racks that should be used. Many sonic cleaners use a flow system to flush (or pull / suction) lumens/cannulated items (with approved cleaning solution), the LumCheck™ should be used to check the performance of these types of sonic cleaning units.

TOSI®LumCheck™ blood soil test is designed to monitor the cleaning function of an automated instrument washer (or sonic cleaner) ability to clean cannulated or lumen instruments.

LumCheck™ Blood Soil Test

The LumCheck™ is a daily test:

1. Testing is done in an empty load (no instruments).
2. Unscrew LumCheck™ – device; detach part A (marked with slot) from part B (see diagram below).
3. Open protective pouch of TOSI® – LumCheck™ and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil.
4. Close LumCheck™ – device again.
5. Connect LumCheck™ –
    a. Sonic Cleaner
        i. Connect the LumCheck™ device with one of the channel irrigation system of the sonic (for example luer-lock). If equipment has more than one channels (ports) you must check at least one port. If checking

more than one port (channel) they must all be checked at the same time.

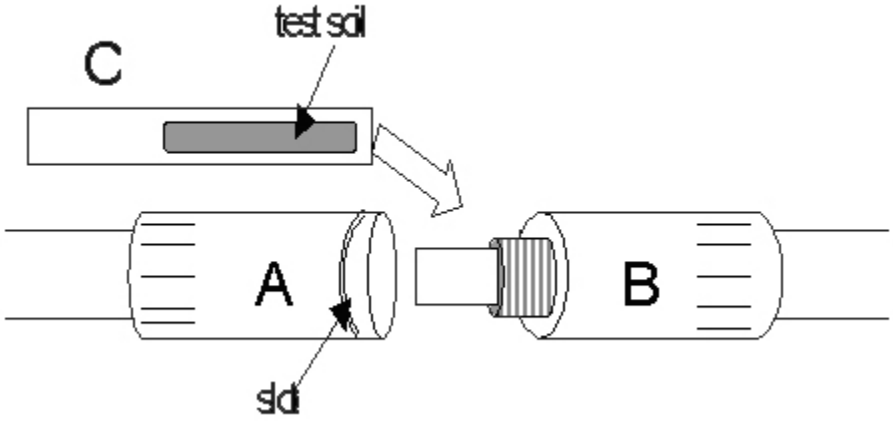
ii. After connection start the cycle according to your manufacturer's manual instructions (example MIS cycle).

b. Automatic washer

i. Connect the LumCheck™ device with one of the channel irrigation system found on the special rack for lumen / cannulated items (a MIS type rack) (for example luer-lock). If equipment has more than one channels (ports) you must check at least one port. If checking more than one port (channel) they must all be checked at the same time.

ii. After connection start the cycle according to your manufacturer's manual instructions (example MIS cycle).

6. Open the device after the reprocessing cycle: disconnect part A from part B to remove the TOSI® – LumCheck™ without touching the test soil area.
7. For visual evaluation of the result, use the TOSI® evaluation table.



Blood Soil Test – Continued:

- Immediately report any test failure to department management.
  - A failure may suggest testing of other parameters of the cleaning process like temperature, dilution of cleaning solutions and water quality.

- 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.
- This test is done at least weekly preferably daily on the equipment.
- Record all results in a log book (sheet).

Maintenance on Equipment (6,9):

- After any maintenance on the equipment, perform a test using the TOSI® LumCheck™ to ensure that the equipment is cleaning properly.
- Follow the weekly test process.
- Have the maintenance person wait until the test results are complete before leaving.

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)

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

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Competency Record for Using the LumCheck™

Name: _____

Competency Statement: Complies with policy and procedure for …

Key

1 = Performs independently and consistently. Ask for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.
Comments:

_____
_____
_____

Competency Achieved: _____(Date)

Equipment/Model Number: _____

Evaluator: _____

Learner: _____

Critical Behaviors	**1**	**2**	**3**
Review the specific information(instructions) from the manufacture on the sonic that is being tested (Model/Type/specific)			
Review Hospital Policy on cleaning of instruments with this specific sonic and the LumCheck™ policy			
Describes the purpose of cleaning and decontamination of surgical instruments especially those with lumens			
Selects and wears the appropriate personal protective equipment			
Gather appropriate supplies to perform test (LumCheck™…)			
Ensure that no instruments are attached to equipment during the testing process (test empty).Must test at least one channel.			
Unscrew LumCheck™ – device; detach part A (marked with slot) from part B (see diagram			

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below).			
Open protective pouch of LumCheck™ and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil			
Close Lumcheck™– device again			
Connect LumCheck™ device with one of the channel irrigation system of the equipment to be tested (luer-lock) and start the cycle according to your manufacture instructions			
Open the device after the reprocessing cycle: disconnect part A from part B to remove the LumCheck™ without touching the test soil area.			
For visual evaluation of the result, use the TOSI® / LumCheck™ evaluation table			
Record Results			
A negative result is no test soil is left on the test coupon. If a positive result (test soil left behind) is obtained. Notify the proper person in the department.			

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References:

1. ANSI/AAMI-ST79; 2017
2. Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385
3. Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310
4. OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000
5. www.jcaho.org
6. http://www.proformance-test.com/WallChart/WallChart.html
7. http://www.proformance-test.com/SupportMaterial/TechnicalBulletin1.html
8. http://www.proformance-test.com/SupportMaterial/BloodAsASoilonSurgicalInstruments.htm
9. http://www.proformance-test.com/SupportMaterial/StandardisedTestSoilBlood1.htm
10. http://www.proformance-test.com/index.html
11. 510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations,. The System 83 plus Washer -Disinfector; Custom Ultrasonics, Inc,1998, page 7.
12. www.aorn.org
13. http://www.healthmark.info/MktingPieces/ProductBrochures/2006/ProformanceJournal.pdf