Example Policy for Daily Monitoring Performance of Ultrasonic Cleaners and/or Automatic Washer 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 healthcare facility for daily cleaning verification monitoring of medical automatic washers using the TOSI® and weekly test kits. The actual policy in a facility must be based on variables, logistics, and risk assessments specific to your facility.

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

Department: Central Service

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter date when this will take effect]

Revised: October 2021

Purpose: This example policy provides 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: Sterile processing staff will be responsible for testing and documenting results of the automated instrument washer on a daily basis to monitor the cleaning function for lumen/cannulated instruments.

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

<u>Standards and Professional Society Recommendations</u>:

1. AAMI ST79; 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. . . .” Ultrasonic 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 employees of the hospital and 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 like 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 easy to wash away, but opaque-cooked egg whites are 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: (7).

Water Quality	Time	Detergent
Enzyme	Temperature	pH Level
Agitation	Speed	Initial Temperature
Drying Time	Obstructions	Insufficient Amount of Chemicals

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 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 Mfr.'s guidelines, helps ensure adherence to both JCAHO and AAMI standards; thus, a properly functioning cleaning process.

PROCEDURE:

"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).

LumCheck™ can be used with an automatic washer having lumen/cannulated items cleaning capability or in an ultrasonic cleaner with the same capability.

Automatic washers have special racks for cleaning lumens/cannulated items. Many ultrasonic cleaners use a pulse/retro-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 ultrasonic cleaning units.

TOSI® LumCheck™ blood soil test is designed to monitor the cannulated or lumen instruments cleaning function of automated instrument washers/ultrasonic cleaners.

LumCheck™ Blood Soil Test

The LumCheck™ 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 (Fig. 1).
3. Open protective pouch of TOSI® – LumCheck™ and insert the test object (part C) into part B as shown in diagram. Do not touch the area covered with test soil.
4. Close LumCheck™ – device again.
5. Connect LumCheck™ –
    a. Ultrasonic Cleaner

i. Connect the LumCheck™ device with a channel irrigation system (e.g., luer-lock).
ii. After connecting, start the cycle according to your Mfr.'s manual instructions (e.g., MIS cycle).

NOTE: If equipment has more than one channel/port, you must check at least one port. If checking more than one port/channel they must all be checked at the same time.

b. Automatic washer
i. Connect the LumCheck™ device with a channel irrigation system found on the special rack for lumen/cannulated items (an MIS type rack) (e.g., luer-lock).
ii. After connection start the cycle according to your Mfr.'s manual instructions (e.g., MIS cycle).

NOTE: If equipment has more than one channel/port, you must check at least one port. If checking more than one port/channel, they must all be checked at the same time.

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 click here:

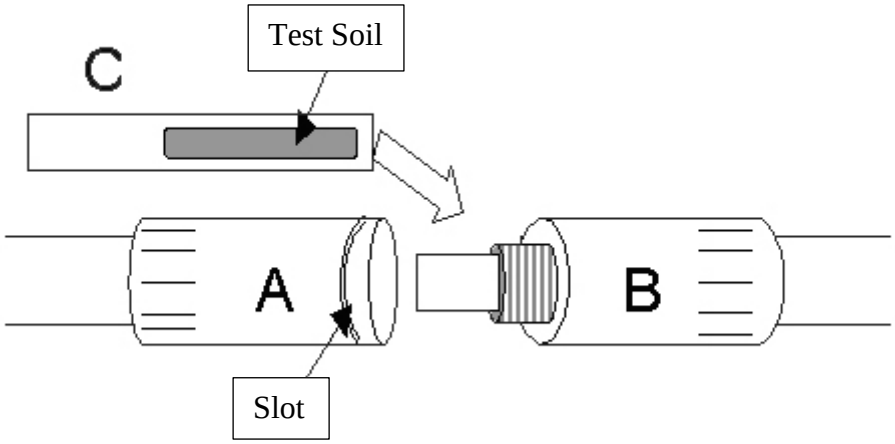

Figure 1

Blood Soil Test – Continued:

- Immediately report any test failure to department management. A test failure may also suggest testing parameters of the cleaning process like temperature, dilution of cleaning solutions, and water quality.
- Use the results found when comparing the test object with the TOSI® chart to determine any necessary adjustments.
- Test at least weekly—*preferably daily*—on the equipment.
- Record all results in a logbook (sheet).

Maintenance on Equipment (6,9).:

- After any maintenance on the equipment, perform a test using the TOSI® LumCheck™ to ensure 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.

LumCheck™ Log Sheet

LumCheck™ Log Sheet

Equipment name_____ Equipment Serial number#_____

Detergent/Enzyme (cleaning solution use) type_____

Date Tested	Testers Initials	*Channel/Port Tested#	LumCheck TOSI Result	Program/Cycle Selection Tested	Action Comment

Sample Competency for Using the LumCheck™:

Name:

Competency Statement: Complies with policy and procedure for the cleaning ability for lumens/cannulated items with the LumCheck™.

Key

1 = Performs independently and consistently. Asks for assistance in new situations.
2 = Performs with minimal guidance and direction. Ask 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 specific information (instructions) from the Mfr. on ultrasonic being tested (Model/Type/specific).			
Review Hospital Policy on cleaning of instruments with this specific ultrasonic 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 (PPE).			
Gather appropriate supplies to perform test (LumCheck™, etc.).			
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 above).			
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 Mfr. 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 remaining 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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