Example policy for verifying the cleaning process of an Automatic Endoscope Reprocessor (AER) with the FlexiCheck™

NOTE: This document is an example of a policy that may be instituted in a healthcare facility for verifying the cleaning process of an Automatic Endoscope Reprocessor (AER) with the FlexiCheck™. The actual policy in a facility must be based on variables, logistics, and risk-assessments specific to your facility.

Subject: Automatic Endoscope Reprocessor (AER) with FlexiCheck™

Department: Central Service/Endoscope

Approved By: [Name of Dept Supervisor/Manager]

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

Revised: June 2021

Purpose: To verify/monitohe various types of AER that clean scopes and lumen/cannulated instruments to ensure proper cleaning and reduce risk to personnel or patients.

Policy: To verify/monitor daily various AER's and their ability to clean scopes/cannulated or lumen instruments using the FlexiCheck™. The FlexiCheck™ is a blood soil test used, according to the manufacturer's guidelines, to ensure the cleaning process is occurring.

Rationale:

Importance of cleaning:

Due to their complexity, Flexible Endoscopes, in general, cannot be steam sterilized but receive high level disinfection (HLD). We already know, "If it is not clean it cannot be sterilized." Therefore, the cleaning process is also crucial to achieve disinfection. Due to limited cleaning methods, which can be used for reprocessing of Flexible Endoscopes and problematic contamination, this process is essential. Monitoring the cleaning process in regular intervals is important.

Contamination of Flexible Endoscopes: general instruments used for surgical procedures are mainly contaminated with blood. Blood is**,** of course**,** considered infectious**,** but procedures for cleaning with proven efficiency for proteins and monitoring of this are already a state of the art.

Flexible Endoscopes will meet with different types of body soils based on procedure usage. Some examples:

- Biopsies may leave behind blood

- Direct contact with mucus can contaminate the scope with different types of polysaccharides
- Areas with a high microbiological contamination encourages the growths of biofilm inside the Endoscope.

Parameters responsible for cleaning:

The cleaning efficiency of the endoscope washer depends on chemical and mechanical parameters (discussed below). If an endoscope is cleaned by a washer, the level/type of contamination and the state of the instrument is important (i.e.: Certain types of mucus may be harder to clean than others, or proteins might be denatured by chemicals forming a very stable soil). A crack inside the endoscope could permit contamination to penetrate parts of the equipment unable to be reached and cleaned by the washer. *These two scenarios cannot be simulated by the FlexiCheck™ system, which will check the level of cleaning efficiency reached by the washer*.

Chemical cleaning parameters:

The following chemical parameters are responsible but also can limit the cleaning efficiency:

- **Concentration and type of detergent:** a very high chemical cleaning efficiency can be achieved by strong alkaline detergents, which can hydrolyse fat and proteins. Flexible Endoscopes cannot withstand very high pH-levels limiting this part of the process. Mildly alkaline, neutral, or enzymatic detergents can be used. Using the proper type and concentration of cleaning solution, along with contact time, is very important. Consult both the scope manufacture and cleaning solution company to ensure the cleaning solution is compatible to process the scope. Only a hospital approved cleaning solution should be used.
- **Temperature:** high temperatures can strongly increase the efficiency of certain types of detergents but, once again, Flexible Endoscopes cannot withstand a high temperature, which limits this process.
- **Water quality:** Hard water can jeopardise the cleaning efficiency of certain detergents. It is important to monitor the quality of the water on a regular interval.

Mechanical cleaning parameters:

The following mechanical parameters are responsible but also can limit the cleaning efficiency:

- **Water pressure**: a strong mechanical cleaning effect can be achieved by water pressure pumped through a channel. AER control the water pressure delivered to each channel. This is one of the sources of the cleaning efficiency of AER.

- **Water volume**: for proper cleaning, solution should reach contaminated areas in specific amounts. This is especially difficult to achieve in small lumens. Ensuring the correct water volume goes into each channel being cleaned is important. If not, the channel may not be clean. Water volume also plays a role in the rinsing aspect of the cleaning cycle, and the correct volume should be delivered every time. If not, residual cleaning solution might be left in the channel posing a problem for a patient.

Cleaning time:

Time influences both chemical and the mechanical efficiency. It is one of the most important parameters for successful reprocessing and is also an easy way for optimization.

As discussed, both chemical and mechanical parameters are limited for reprocessing of Flexible Endoscopes. *Therefore, the time parameter should be given more consideration.* Consult both the scope & AER manufactures for the proper cycle time for each scope being cleaned.

Standards and Professional Society Recommendations:

In 2006, JCAHO in standard E.C.6.20 it states that medical equipment is maintained, tested, and inspected. This is till the case today.

AORN, SGNA, and IAHCSMM all support having quality improvement programs. Monitoring the cleaning process of an AER using the FlexiCheck™ on at least a weekly time frame helps fulfill these requirements.

1. A 2003 multi-society position paper states: **"Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use."** (Gastrointestinal Endoscopy, Volume 58 No.1; page 5)
2. Highlights of **AAMI ST79**:
    - AAMI realizes that the efficacy of any high-level disinfection/sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bioburden before high-level disinfection/sterilization.
    - Staff qualifications, training, and continuing education are important: "…. Personnel should receive initial orientation, continuing education at regular intervals in-service training on new instrumentation, devices, and equipment. A written standardized program that includes aspects of education and training related to facilities policies and procedures, tools to document education and training were performed and competency was verified…." (Section 4.3.1).
    - Regarding verification of the cleaning process: "…Personnel should visually inspect each item carefully to detect any visible soil. Mechanical cleaning equipment performance should be tested each day it is used and al results

should be recorded. Users should ask device manufacturers to provide test procedures that can be easily replicated and that can assist users in recognizing whether cleaning was effective for all device areas. Steam sterilization cannot be assured unless proper cleaning of the device and reduced bioburden and soil was achieved. Verification and documentation of automated cleaning processes through objective means is an important aspect of quality control…." (Section 7.6.4.5)

3. Excerpts from published articles

- 57% of centers that process scopes were not in compliance with basic national standards[1]
- 53% of biopsy ports valves exhibited some form of debris or potential contamination after cleaning[2]
- "Company blames bronchoscope infections on poor cleaning."[3]
- Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to thoroughly manually clean equipment prior to any manual or automated disinfection or sterilization process[4]
- "It is very clear that every documented case of patient infection linked to a contaminated scope is because of a breach of some of the reprocessing protocol. If you look back on the history, that is what it is – improper disinfection; you do not dry the scope; inadequate cleaning; or somebody forgot to clean the biopsy channel. It has been more human error than anything else… Rules No.1, 2 and 3 are to educate the people who are cleaning the scopes--how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning."[5]
- In one case two colonoscopy patients were infected with hepatitis C (HCV) from an endoscope contaminated by an earlier patient. The investigation concluded that the biopsy channel had not been properly cleaned and the disinfection failed. Only two hours had elapsed between the first patient and the last; so, even if samples had been taken immediately after the first patient, traditional microbiology results would not have been available in time to prevent cross-infection[6]

Procedure:

"The problem risk analysis should identify, define and quantify the risk and identify actions that ca be taken to resolve or prevent the risk. The system should be monitored to ensure that the risk has been corrected or prevented." (AAMI ST79/2017).

The FlexiCheck™ Weekly Test Procedure

1. Testing is done in an empty machine; no scope attached. *(See Figure 1 for steps 2 – 4)*
2. Unscrew FlexiCheck™ device; detach part A (marked with slot) from part B.
3. Open protective pouch of FlexiCheck™ 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 FlexiCheck™ device again.
5. Connect FlexiCheck™ device with one of the channel irrigation system of the washer (luer-lock) and start the cycle according to your manufacture's manual instructions.
6. Open the device after the reprocessing cycle: disconnect part A from part B to remove the FlexiCheck™ without touching the test soil area.
7. For visual evaluation of the result, use the TOSI®-FlexiCheck™ evaluation table.

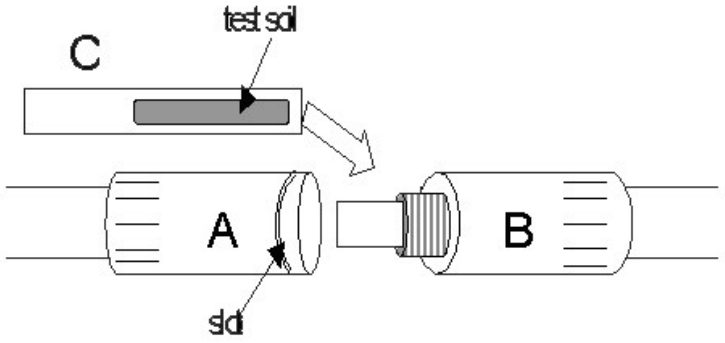

Figure 1

Results:

- This test is done weekly on the equipment.
- Use the test object results to compare with the FlexiCheck™ Chart to determine what adjustments will need to be made.
- Record all results in a logbook (sheet).
- Immediately report any test failure to your department management

Maintenance on Equipment (15,19):

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

Responsibility:

The department personnel (Manager, Supervisor, or Director) should handle:

- proper usage.
- result interpretation.
- and documentation of the FlexiCheck™ indicator when used on an AER.

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

FlexiCheck™ Chart

	**Positive result:** Both test-soils completely removed.
	**Result:** Polysaccharid-test soil completely removed but visible residue of fibrin left. **Indication for:** Protein dissolving parameters not optimal **Optimisation:** Check and/or correct: Cleaning time / temperature / detergent efficiency / dosing
	**Result:** Blood-test soil completely removed but visible residue of Polysaccharide left. **Indication for:** Polysaccharide dissolving parameters not optimal **Optimisation:** Check and/or correct: Water quality / detergent efficiency and dosing / Cleaning time and temperature
	**Result:** Polysaccharide-test soil completely removed but red protein residue left. **Indication for:** Protein denaturating effects (heat or disinfecting agents) **Optimisation:** Check for high temperature or disinfecting agents during the wash cycle. Run cold pre-rinse if possible.
	**Result:** Both spots of test soil completely left. **Indication for:** Missing flow / No cleaning efficiency. **Optimisation:** Check connection of FlexiCheck , machine and cleaning program.

FlexiCheck™ Log Sheet

Equipment name _____ Equipment Serial number #_____

Detergent /Enzyme (Cleaning solution used) type _____

Date Tested	Testers Initials	*Channel/Port Tested #	FlexiCheck™ Result	Program/Cycle Selection Tested	Action Comment
01/01/2011	SMK	1	Pass	Standard	Example
01/01/2011	SMK	2	Fail	Standard	Blood left on test strip

*FlexiCheck™ is scored Pass/Fail. If a failure uses the FlexiCheck™ chart to determine what, if any, adjustments need to be made. 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 (number or letter them if possible so you can trace results back to specific port/channel).

Competency Record for Using the FlexiCheck™

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: _____

AER Equipment/Model Number: _____

Evaluator: _____

Learner: _____

Critical Behaviors	1	2	3
Review the specific information(instructions) from the manufacture on the AER that is being tested (Model/Type/specific)			
Review Hospital Policy on cleaning of Scopes with this specific AER and the FlexiCheck™ policy			
Describes the purpose of cleaning and decontamination of the Scope			
Selects and wears the appropriate personal protective equipment			
Gather appropriate supplies to perform test on the Scope (FlexiCheck™)			
Ensure that no scope is attached to AER during the testing process			
Unscrew FlexiCheck™ – device; detach part A (marked with slot) from part B (see diagram above).			
Open protective pouch of FlexiCheck™ and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil			

Close FlexiCheck™– device again			
Connect FlexiCheck™ device with one of the channel irrigation system of the washer (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 FlexiCheck™ without touching the test soil area.			
For visual evaluation of the result, use the TOSI®-FlexiCheck™ evaluation table			
Record Results			
A positive result is no test soil is left on the test coupon. If a negative result is obtained. Notify the proper person in the department.			

References:

[1] Infection Control and Hospital Epidemiology; Volume 23; 2002
[2] Endonurse 12/6
[3] 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html
[4] http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf, page 1
[5] page 16; New Technologies Require thorough reprocessing; EndoNurse; August/September 2005
[6] *The New England Journal of Medicine* **337**, 237-240 (1997).