

Suggested weekly policy for monitoring the automatic cleaning process of various equipment that cleans scopes and lumen/cannulated instruments using the FlexiCheck cleaning verification method

SUBJECT: DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 12/07

PURPOSE:

To *monitor* the automatic cleaning process of various equipments that clean scopes and lumen/cannulated instruments to ensure proper cleaning *and reduce risk to personnel or patients.*

POLICY:

FlexiCheck test is designed to monitor the cleaning function of an automated scope/instrument washer ability to clean scopes/cannulated or lumen instruments. To ensure that the automated scope/instrument washer *process* is cleaning properly scopes/lumen/ cannulated instruments, a T.O.S.I. FlexiCheck blood soil test should be used to monitor the occurrence of cleaning scopes / lumen / cannulated instruments. The T.O.S.I. FlexiCheck blood soil test is to be used according to the manufacturer's guidelines to ensure that the cleaning process is occurring and the automated scope/instrument washer is functioning properly.

RATIONALE:

Importance of cleaning

Due to the complexity Flexible Endoscopes cannot be steam sterilised but disinfected only. We already know: If it's not clean it can't be sterilised, therefore the cleaning process is also crucial to achieve disinfectioning. Due to limited cleaning methods, which can be used, for reprocessing of Flexible Endoscopes and problematic contamination this process is especially critical.

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 efficiency are already a stand of the art. Since Flexible Endoscopes are used in many ways they will come into contact with different types of soil. The direct contact to mucus skin will

contaminate the scope with different types of Polysaccharides, very different to the blood proteins. When a biopsy is performed, blood is still an important soil to test for. In addition to this problem of multiple soil, Flexible Endoscopes are often used in areas with a high microbiological contamination, which 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 also depends on the level and type of contamination and the state of the instrument. Certain type of mucus might be harder to clean than others or proteins might be denaturated by chemicals forming a very stable soil. A crack inside the Endoscope could also allow a contamination to penetrate parts of the equipment which cannot be reached by the washer, making it harder to clean than normal. 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 which limitates this part of the process. Mildly alkaline, neutral or enzymatic detergents can be used. Publications regarding the efficiency of different detergents are available on request.

Temperature

High temperatures can strongly increase the efficiency of certain types of detergents but once again Flexible Endoscopes cannot withstand high temperatures which limits this process also.

Water quality

Like for all cleaning processes hard water can jeopardise the cleaning efficiency of certain detergents.

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 a high water pressure pumped through a channel. Again this is ruled out because Flexible Endoscopes are too delicate.

Water volume

For a good cleaning effect a large amount of detergent solution should get in contact with the contaminated area. This is especially very difficult to achieve in small lumens.

Cleaning time

Since time influences both the chemical and the mechanical efficiency, it is one of the most important parameters for successful reprocessing and is also an easy way for optimisation.

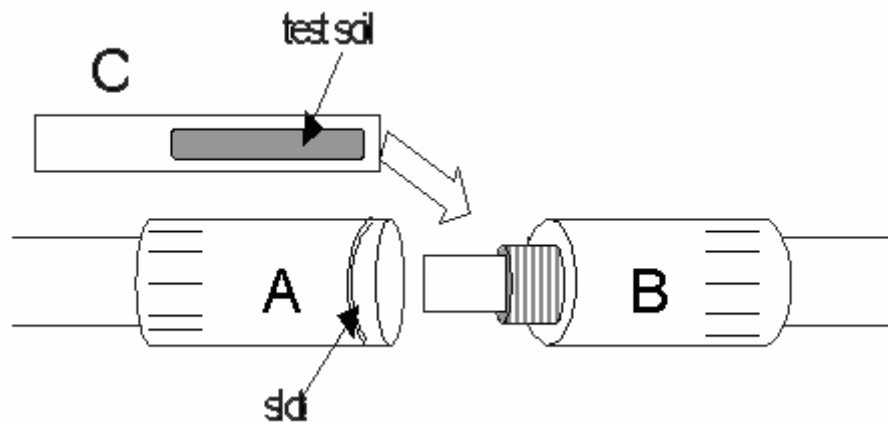
As discussed, both chemical and mechanical parameters are limited for reprocessing of Flexible Endoscopes therefore, the time parameter should be given more consideration!

PROCEDURE:

“A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected. (AAMI ST 79/2006)”

The FlexiCheck is a weekly test.

1. Unscrew FlexiCheck – device; detach part A (marked with slot) from part B (see diagram below).
2. Open protective pouch of TOSI – FlexiCheck and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil.
3. Close LumCheck – device again.
4. Connect FlexiCheck device with one of the channel irrigation system of the washer (luer-lock) and start the cycle according to your manufacture manual instructions
5. Open the device after the reprocessing cycle: disconnect part A from part B to remove the TOSI – FlexiCheck without touching the test soil area.
6. For visual evaluation of the result, use the TOSI-FlexiCheck evaluation table.



Results

- Immediately report any test failure to department management.
- Use the results found when comparing the test object and to the T.O.S.I. FlexiCheck chart to determine what, if any, adjustments need to be made. Make necessary adjustments.

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

Maintenance on Equipment (15,19):

- After any maintenance on the equipment, perform a test using the T.O.S.I. FlexiCheck 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:

The department personnel(Manager,Supervisor,Director) are responsible for the proper use, result interpretation, and documentation of the T.O.S.I.FlexiCheck indicator when used on an automated scope washer.

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

REFERENCES:

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 ST 79:**

- AAMI realizes that the efficacy of any high-level disinfection/sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bio-burden before high-level disinfection/sterilization.
- Staff qualifications, training, and continuing education are important: “... Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented....” (Section 4.3.1)
- Regarding verification of the cleaning process: “...Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. ***Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function.*** A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically....” (Section 7.7.5)

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 don’t 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

4. Technical sources

FlexiCheck information

<http://www.healthmark.info/proformance.html>

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).