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Support for Monitoring the Cleaning Process for Flexible Endoscopes

According to AAMI ST91, healthcare facilities should establish a comprehensive quality assurance and safety program to monitor all aspects of endoscope processing. This program should incorporate both visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes. **Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes.** Therefore**,** the use of methods that are able to measure organic residues that are not readily detectable using visual inspection alone should be considered in facility cleaning policy and procedures.

The following statements from professional societies and governing bodies support the use of a cleaning verification process for flexible endoscopes:

1. **ANSI/AAMI ST91:2015, "Flexible and semi-rigid endoscope processing in health care facilities"**

"Testing cleaning efficacy: **The facility's onsite quality assurance program should include ways to verify that the cleaning equipment used for processing of medical devices is working**. Testing the equipment upon installation, during routine use (daily) and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness... Manufacturer's written IFU should be consulted for recommendations of types and frequency of cleaning efficacy testing. **The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily** (Drosnock 2014, Alfa 2014).

Rationale: Meticulous manual cleaning is essential for the removal of organic contamination that can interfere with high-level disinfection. The manual cleaning step is prone to error… and therefore should be monitored on a basis at least as frequently as is recommended for the cleaning equipment (see ANSI/AAMI ST79). This testing should include at a minimum monitoring of the suction/biopsy channel (ANSI/AAMI ST58).

While currently there is no universal consensus of the value of performing testing on endoscopes that have been through a high-level disinfection process, **numerous studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing**…

AERs are designed to provide flow of solutions to internal channels. Quality testing devices are available for many of the AERs to ensure that the solutions are flowing. To help ensure function of this equipment, testing should be performed at **least weekly**, after major repairs, or whenever there is a concern about equipment function."

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2. AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES 2016:

a. **Manual cleaning of flexible endoscopes should be verified using cleaning verification** tests when new endoscopes are purchased and at established intervals **(eg, after each use, daily).**

i. Cleaning verification tests are used to verify the ability of the cleaning process to remove, or reduce to an acceptable level, the organic soil and microbial contamination that occurs during use of a reusable device. Cleaning verification tests include chemical reagent tests for detecting clinically relevant soils (eg, protein, carbohydrate) and ATP. **Periodic verification of cleaning effectiveness may help reduce errors in manual cleaning and improve effectiveness**

ii. Auditing the manual cleaning of flexible endoscopes provides an objective method for verifying cleanliness and helps ensure that insufficiently cleaned flexible endoscopes are recleaned before HLD or sterilization.

iii. A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, and other involved individuals should establish the type of cleaning verification test to be performed.

iv. There are a number of tests that can be used to assess cleaning efficacy. Chemical tests involve the use of a reagent and observing for a color change that indicates the presence of organic markers such as protein or blood. In a dual phase (ie, simulated-use, inuse) study to validate the use of an audit tool composed of reagent test strips in 43 endoscopy clinics across Canada, Alfa et al collected samples from 30 patient-used endoscopes (ie, 10 colonoscopes, 10 duodenoscopes, 10 gastroscopes) and tested them for residual protein, carbohydrate, and hemoglobin using the audit tool test strips. The test strips had three reagent pads designed to rapidly detect organic residualsof protein, carbohydrate, and hemoglobin after manual cleaning. The researchers confirmed that the audit tool flagged endoscopes with residual protein, hemoglobin, or carbohydrate.

v. There are quantitative tests that can be used for cleaning verification testing of other residual soils, including:

- protein,
- carbohydrate,
- hemoglobin,

vi. The multidisciplinary team should evaluate the need to implement protocols for cleaning verification testing of flexible duodenoscopes with elevator channels.

b. Records related to flexible endoscope processing should include the date and time, identity of the endoscope and endoscope accessories, method and **verification of cleaning** and **results of cleaning verification testing**.

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3. **SGNA Standard of Infection Prevention in the Gastroenterology Setting:**

    a. The use of cleaning monitors for automated washers may help to ensure adequate functioning (Alfa, 2013).
    b. "Visibly clean" is a method routinely used to assess the adequacy of manual cleaning (Alfa et al., 2012; Rutala et al., 2008). This may involve the use of a magnifying glass to inspect for gross soil. Visual inspection is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden (Alfa, 2014). **Rapid cleaning monitors are available. These monitors can provide documentation on cleaning efficacy** but do not reflect microbial activity. **Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD.** Facilities should consider the use of monitors to verify ongoing cleaning adequacy (Alfa, 2013).
    c. Once there is confirmation that an endoscope has been properly reprocessed, it is suggested that a system exist for identifying scopes that are clean and ready to use (Rutala & Weber, 2004; CDC, 2015)

4. **SGNA Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes:**

    a. **Note:** It is impossible to visualize internal channels. Literature suggests that, to confirm the **adequacy of manual cleaning, a rapid cleaning monitor** (or rapid audit tool) for residual organic soil can be used prior to high-level disinfection (Visrodia et al., 2014). If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. The frequency of the testing should be determined by the individual institutions (Alfa et al., 2013, 2014; AAMI, 2015; ASGE, 2014).

5. **ANSI/AAMI ST79 and Quality Monitoring**:

- "Some types of mechanical cleaning equipment are designed to clean and/or disinfect specific kinds of medical devices, such as endoscopes… Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs…(7.5.3.3)"

- **Section 10.2 and ANNEX D states**"…Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices…"

- **"Current data (Alfa, et al., 2002) indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers are as follows: protein, < 6.4 µg/cm2; carbohydrate, < 1.8 µg/cm2; hemoglobin, < 2.2 µg/cm2; sodium ion, < 1 µmole/cm2; and endotoxin, < 2.2 EU/cm2 in the biopsy/suction channel… (Section - D.2 Markers)"**

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- Regarding verification of the cleaning process: "… 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)

- "Furthermore, **visual inspection is not possible for the inner components of medical devices** that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps). **Ideally, cleaning verification by users should include (a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and inner housing and channels of medical devices,** (b) testing the cleaning efficacy of equipment, and (c) monitoring key cleaning parameters (e.g., temperature)…"

6. ASGE: Technologies for monitoring the quality of endoscope reprocessing, 2014:

a. **Bioburden assays:** Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels (e.g. **EndoCheck™** and **ChannelCheck™; HealthMark Industries**, Fraser, Mich.)…EndoCheck™ is able to detect protein and blood residues within the biopsy channel of endoscopes while ChannelCheck™ is able to detect protein, blood and carbohydrate residues within the biopsy channel of endoscopes.

b. **Methodology:** All of the above tests are easily and rapidly performed… The EndoCheck™ test uses a long probe with a swab attached to its tip. The probe is inserted into the endoscope's biopsy channel, and a swab of the channel is obtained. The swab is then cut off the probe and dropped into a test vial containing the test reagent and shaken. The presence of blood or protein residue is displayed by a color change in the reagent. The ChannelCheck™ test offers the advantages of ease of test sample collection, simple test methodology using a test strip similar to a urine dipstick, as well as detection of a wider range of biological soils. The assay uses test strips with 3 pads that allow detection of residual carbohydrate, protein, and hemoglobin. The endoscope's biopsy channel is flushed with 10 mL of sterile deionized water, followed by 10 mL of air to promote expulsion of the water from the distal end of the endoscope. This water is collected into a sample collection container, and the test strip is immersed within it for 10 seconds. The 3 test pads on the test strip indicate the presence of residual carbohydrate, protein, and hemoglobin by a color change within 90 seconds. The colors on the test strip are compared with those on a color indicator chart provided on the test strip bottle.

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c. **Potential Clinical Applications:** Minimizing the potential for transmission of pathogens by using flexible endoscopes is an important issue for facilities at which endoscopies are performed. **These technologies offer endoscopy units the ability to implement surveillance strategies, which may potentially improve the quality of endoscope reprocessing. Emerging technologies for monitoring the quality of endoscope reprocessing offer the ability to perform rapid surveillance, which may potentially help reinforce adherence to the many steps in reprocessing."**

7. CDC HEALTH ADVISORY: Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

This alert supports cleaning verification and auditing in healthcare facilities and states how often cleaning verification should take place.

Audit and Feedback:

a. Healthcare facilities should regularly audit **(monitor** and document) adherence to **cleaning,** disinfection, sterilization, and device storage procedures. Audits should assess all reprocessing steps, including:

- **Monitoring automated endoscope reprocessor performance** (e.g., print out of flow rate, time, and temperature, use of chemical indicators for monitoring high-level disinfectant concentration)

8. FDA Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication

a. Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and **quality monitors** used during the reprocessing procedure.

9. FDA on Reprocessed Flexible Bronchoscopes: FDA Safety Communication - Risk of Infection

a. Implement a **comprehensive reprocessing quality control program**. Your reprocessing program should include written procedures for **monitoring**, training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.

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10. **Ofstead & Associates**, Inc. SGNA Poster presentation 2015. "The effectiveness of reprocessing in accordance with current guidelines: Viable microbes and organic residue found on patient-ready colonoscopes and gastroscopes."
    1. Recommendations: Ensure reprocessing practices meet or exceed standards
    2. **Use rapid indicators to monitor cleaning effectiveness**

11. JCAHO

In standard E.C.6.20 it states that medical equipment is maintained, tested and inspected.

12. **AORN**

- 22.a.2 – page 442 – "…protein indicators are commercially available to assist with evaluation.."
- 22.a.4 – page 442 – "..when investigating surgical infections, documentation of the cleaning process of instruments should be reviewed…"
- RP 19 – page 440- " …competency, education, training…should be documented"
- RP 22.a – page 442 – "..testing washer decontaminators on a regular basis verifies that the equipment is functioning properly.."

13. 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."

14. **FDA, CDC, VA Joint Safety Communication**

- Establish an institutional program for endoscope processing, along with written **procedures for monitoring adherence to the program** and a chain of accountability. Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle.
- Train employees to set-up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and **assess competence.**

15. CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008:

a. Clusters of infections "highlight the importance of training, proper model-specific endoscope connector systems, and **quality-control procedures to ensure compliance** with endoscope manufacturer recommendations and professional organization guidelines.

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b. To achieve and maintain competency, train each member of the staff that reprocesses semicritical and/or critical instruments as follows: 1) provide hands-on training according to the institutional policy for reprocessing critical and semicritical devices; 2) supervise all work until competency is documented for each reprocessing task; **3) conduct competency testing at beginning of employment and regularly thereafter (e.g., annually); and**

c. **Conduct infection control rounds periodically** (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented.

16. CDC, Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing, 2015

a. **Non-culture methods have been used to assess duodenoscope reprocessing by detecting residual organic material after cleaning**. While individual facilities might choose to use such non-culture assays, more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations. They might, however, provide insight regarding the quality of duodenoscope reprocessing if systematically validated.

Non-culture methods are indicators of the presence of residual organic material after cleaning such as protein, carbohydrate and hemoglobin. These include EndoCheck™, ChannelCheck™, ProCheck™, HemoCheck™, and FlexiCheck™. ATP is another marker that can be used to indicate the presence of residual patient material.

17. **Healthmark Industries**

Healthmark is the only company with comprehensive tests for the purpose process monitoring. This includes tests to measure water temperature, water quality, cleaning efficiency, and directly test residual soil on instruments- the TOSI.

Healthmark offers a variety of quality monitoring tools that comply with AAMI ST91 recommendations. Those are ChannelCheck™, EndoCheck™, ProCheck™, HemoCheck™, FlexiCheck™ & the HangTime Kit™. Please visit our website for more information on these products at http://healthmarkgi.com/

Verification tools such as these quality monitors are a method to ensure that endoscopes have met pre-established cleaning criteria and are patient-ready. Quality monitors can be used periodically or on every endoscope being reprocessing. They are also commonly used as competency assessment tools and as audit tools by infection preventionists. Healthmark products help the Endoscopy center manage reprocessing of flexible endoscope through cleaning verification products, tools to improve cleaning outcome and products to organize and track the steps in reprocessing.

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This document summarizes current AAMI, AORN, SGNA, ASGE, CDC, FDA and JCAHO standards and guidelines as well as other published documents. Please note that AAMI, AORN, JCAHO are copyrighted material. To read the complete text of these standards or articles please go to their website and purchase the actual standards and guidelines or articles**.**

Thank you,

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