AAMI ST91 is the US national standard for flexible endoscope reprocessing and serves to provide comprehensive guidance for reprocessing of flexible and semi-rigid endoscopes in any healthcare setting. Topics included within this document are precleaning, leak testing, cleaning, cleaning verification testing, storage, high-level disinfection, and sterilization flexible GI endoscopes, bronchoscopes, surgical flexible endoscopes, and semi-rigid endoscopes and accessories. Also included within ST91 are recommendations for healthcare facilities should establish a comprehensive quality assurance and safety program to monitor all aspects of endoscope processing.

Healthmark Industries offers a wide variety of products that allow for compliance with the recommendations laid out in ST91. The AAMI ST91 recommendations and HealthMark products that correlate and comply with that standard are listed below:

1. **Wiping** of endoscopes during precleaning and manual cleaning:
   a. Section 5.5 Manual cleaning c) Wipe the insertion tube with a wet, low-linting or non-linting cloth or sponge soaked in the freshly prepared cleaning solution as soon as possible after the endoscope is removed from the patient or the procedure is completed. Ensure that all endoscope controls are in the free and unlocked position. The cloth or sponge should be single use and disposed of after use.
   b. Section 5.5 Manual cleaning d) Clean the endoscope’s exterior surfaces with a single-use lint-free cloth or sponge.
   c. Section 5.6 Manual rinsing e) Dry the exterior of the endoscope with a lint-free cloth or sponge.
   d. Section 5.7.2 High-level disinfection NOTE—Air bubbles that are on the surface of the scope could interfere with the disinfectant to function properly on that site. Use a lint-free cloth to remove the air bubbles from the surface/exterior of the scope.

**Healthmark Products to comply with wiping recommendations:**

- **Lint Free Wipes** (CC555, CC1212): Use these low linting wipes immediately after use, during cleaning prior to automated or manual disinfection. These wipes will help ensure proper instrument reprocessing.

- **Durasponge** (ESD904101 Round, ESD905201 Flat): The DuraSponge allows for safe precleaning and manual cleaning through wiping of a flexible endoscope and is available in flat or tubular design.

2. **PPE for Endoscopy**:
   a. Section 4.6.2 Personal protective equipment:
      a) In addition to the attire recommended in Section 4.6, personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with sleeves.
      b) Processing personnel should use a style of glove that prevents contact with contaminated water. Gloves that are too short, do not fit tightly at the wrist, or lack cuffs might allow water to enter when the arms move up and down. Exam gloves should not be used for decontamination. General purpose utility gloves fitted at the wrist or above should be used.
c) PPE should also include a fluid-resistant face mask and eye protection. PPE used to protect the eyes from splash could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles.

Healthmark Products to comply with ST91 PPE guidelines:

- **Decontam Gloves**: These gloves are thick and tough enough for use in the decontamination area. This thicker, 15 mil, textured, powder-free latex glove is the decontamination glove of choice by professionals who handle potentially hazardous items.

- **Sleeve Gloves** (various sizes and part numbers): Combination of 11mil nitrile glove and 4 mil protective sleeve. Overall length is 28 inches, providing durable hand and arm protection.

- **Face Shields** wide and with and without drapes: (18000W-100, 18000-100, 16000-100): Ideal for use in areas where maximum protection is required such as endoscopy. Full face shield provides the best splash protection and protection from exposure. A fluid barrier extends below the full face shield and tucks inside the gown providing additional protection.

3. Contaminated Transport

a. Section 5.3 Transporting used endoscopes:

   1. Each endoscope should be isolated and transported with its components in its own closed system to the next stage of processing, as it is considered contaminated. The system should be marked with a biohazard label and must meet OSHA (29 CFR 1910.1030) requirements for transporting hazardous items. The system should be large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.

   2. Transporting steps: a) Isolate and immobilize a single endoscope in a container by naturally coiling it in large loop

Healthmark Products to comply with ST91 PPE guidelines:

- **Round Soaker** and **Transport Trolley** (2220, 2220 Trolley): Round soaker bin has a 20” diameter and is perfectly sized to allow a flexible endoscope to coil naturally and safely for transport or soaking. A lift off lid completely covers the tray. The Trolley can accommodate up to 5 round soaker trays simultaneously.

- **Clean/Dirty Scope Seal Kit** (2220 LOK): Seals have clean/dirty tamper evident seals.

- **2 Part Clean/Dirty Label** (AV-52482): This sticker is used to communicate whether the endoscope contained within a bin is clean or dirty.

- **Biohazard signs**: Meet AAMI and OSHA requirements for labelling of contaminated items for transport.

- **Humipak** (HPSS6577): Instrument manufacturers, AAMI, AORN and others generally recommend that decontamination of instruments begin within 30 minutes of use so that organic soils, particularly blood, do not dry. But often this is not possible. The Humipak consists of a layer of highly absorbent material sandwiched between two layers of water proof film. To use, place individual instruments, or an entire instrument tray inside the
Humipak, add the specified amount of water to the absorbent layer, and seal with the peel away adhesive strip. This creates a water tight, moist atmosphere that will prevent organics from drying over an extended period of time.

4. **Use of Labels to Show Length of Storage and Disinfection Status:**

   a. Section 10.1 General Considerations for Storage of reprocessed endoscopes: Attach a **tag or label** (or other method) to document that the scope has been cleaned or high-level disinfected. The tag or label is affixed to the endoscope after it has been processed and before it is placed in the storage cabinet.

   b. Section 10.1: For quality assurance, the tag should be labeled with the following information:

      a) Date of processing
      b) Name(s) of person(s) who performed the processing
      c) Date of high-level disinfection

   c. Section 10.1: General Considerations The CDC recommends that a policy and procedure be developed to ensure that end-users know whether a particular endoscope has been cleaned and high-level disinfected or sterilized, because when a user leaves an endoscope on a cart or other surface, the status of the scope (used or unused) might not be clear (CDC, 2008).

   d. Section 10.1 Develop protocols to ensure that users can readily identify an endoscope that has been processed and is ready for patient use. Attach a tag or label (or other method) to document that the scope has been cleaned or high-level disinfected. The tag or label is affixed to the endoscope after it has been processed and before it is placed in the storage cabinet.

   e. Section 10.2 Storage of high-level disinfected endoscopes: Each scope should be identified with a tag or other means so that when it is pulled from storage, the user is able to verify that the scope has been processed and is ready for use.

**Healthmark Products to comply with ST91 labelling guidelines:**

- **Self-Looping Labels** (404225-351-GI): These labels offer the solution to managing endoscope reprocessing information in an economical and complete manner. Captures data such as department, scope model, date, time and pass/fail specifications.

- **HLD Label** (DC-100214-71-BL): This label identifies the endoscope as having completed a High-level disinfection cycle including the date and initials or the processor.

- **HangTime Labels** (various models): These labels allow for day and month tracking to determine when an endoscope was last reprocessed. Many colors are available.

5. **ST91 Recommendations for Endoscope Cleaning Brushes:**

   a. Section 5.5 Manual cleaning e) Clean all valve cylinders, openings, and forceps elevator housings with a **cleaning brush of the length, width, and material designated in the endoscope manufacturer’s written IFU**.

   b. NOTE 2—Cleaning brushes should either be single use and disposed of or reusable.
and receive high-level disinfection or sterilization after each use, according to their written IFU.

Healthmark Products that comply with ST91 recommendation for Endoscopy Cleaning Brushes:

- **Endobrushes** (various part numbers and sizes): Healthmark brush offerings include many different sizes and length based on the models of endoscopes. Brushes are color coordinated to match the endoscope manufacturer’s recommendations. These brushes have been designed to maximum cleaning performance while ensuring compatibility. They are single use products and are discarded after a single endoscope cleaning to comply with the ST91 recommendations.

- **Elevator Mechanism Brush** (EMB-001): This single-use brush has been designed for equivalence to Olympus’ MAJ-1888 and is used to clean the elevator mechanism and recess on duodenoscopes and certain other endoscopes.

6. **Use of Thermometers, Timers and Water Level Markers to Comply with ST91:**

   a. Section 5.5 Manual cleaning: b) Prepare fresh cleaning solution for each endoscope according to the solution manufacturer’s written IFU for temperature, if applicable; concentration; and water quality. The temperature of the cleaning solution should be monitored and documented.

   b. Section 5.7.4.1 Disinfection g) Follow the LCS/HLD solution manufacturer’s written IFU for contact time, and temperature. Monitor process with a timer and thermometer and document.

   c. Section 12.4.2 Cleaning verification Cleaning verification of flexible and semi-rigid endoscopes by users should include: c) Monitoring of key cleaning parameters (e.g., temperature).

Healthmark Products:

- **TEMP-Wifi-TH**: This device measures the temperature and humidity of an environment in which it’s situated and transmits data to a PC via Wifi. The data logging sensor helps to configure and send a stream of data at regular intervals to your computer. This gadget makes monitoring data in other locations simple and convenient. The TEMP-Wifi-TH is a durable device that is rechargeable and comes with a USB providing the software needed for installation.

- **TEMP-USB-TP**: This thermometer offers solely temperature readings but has the advantage of dual temperature probes which can gather over 250,000 readings (-40 to 257°F) via two separate probes. This temperature data logger is perfect for a CP department where temperature control is crucial.

- **Watermark**: This watermark is a sticker sized liquid crystal thermometer with a “water fill line” that adheres to the inside of a manual cleaning sink, tub or basin. Following the instructions of your detergent manufacturer, determine the appropriate water level for the bath. In the write in space, note the volume of water. By monitoring the reported temperature on the thermometer, staff can be sure that the solution is in the proper temperature range as dictated by the detergent manufacturer’s IFU.
7. Cleaning Verification Recommendations:

a. According to ST91, 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.

b. 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).

c. 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.”

Healthmark Products to Comply with ST91 Cleaning Verification Recommendations:

- **ChannelCheck** (UCC-101): Cleaning verification test for use on any lumened instrument such as a flexible endoscope. ChannelCheck tests for 3 types of residual soil (protein, carbohydrate and hemoglobin) in one combination test.

- **EndoCheck** (various models and types): Endocheck swabs test for residual contamination in flexible endoscopes. Through use of a swab test, an endoscope can be checked for either residual protein OR residual hemoglobin depending on which type is chosen. Swab diameter sizes are available from 1.0-5.0 mm.

- **FlexiCheck** (Flexchk-101 and 102): This three part kit simulates a flexible endoscope channel and is designed to challenge the cleaning efficiency of endoscope washers (AER’s) with channel irrigation apparatus. Use of FlexiCheck meets the ST91 recommendation to monitor the cleaning efficacy of mechanical cleaning processes such as in the AER.

- **Scope Holder** (SCPH-102): Plexiglass wall-mountable scope holder used to assist in cleaning verification sampling of endoscopes.

8. Visual Inspection and Enhance Optical Inspection Recommendations:

a. According 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.
b. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes. Use of enhanced visualization methods, including inspection with a borescopes, such as the Flexible Inspection Scope (FIS), is being incorporated into current standards and recommendations.

c. Visual inspection of the equipment should include the following:

- Residual organic soil
  - Cracks and other damage to the device
  - Integrity of fiber optic bundles
  - Use of magnification

Healthmark Products to Comply with ST91 Optical Inspection and Enhanced Visual Inspection:

- The **Flexible Inspection Scope (FIS-001)** is a type of video borescope that includes a distal tip composed of a light source and camera lens at the end of a 50cm flexible shaft. Designed for instruments 3.2mm in diameter or larger, the Flexible Inspection Scope allows for visualization of any potentially soiled instrument including the instrument channel of flexible endoscopes.

- Therefore, the **Flexible Inspection Scope (FIS)** is a useful tool for inspection of flexible endoscopes, arthroscopy routers, shavers, reamers, flexible endoscopes and other lumened devices that complies with AAMI ST91 and the AORN guidance. Use of the FIS borescope provides the end-user a simple verification test to inspect the instrument suction channel, channel openings, distal tip, forceps elevator recess on endoscopes and the internal lumens on other medical devices to determine if there are any signs of damage or retained debris.

- **Pocket Magnifier** is a small eye loupe magnifier. The 4x magnification is perfect for up close inspection of devices. Lightweight, but durable, with rubber cushion for additional comfort. The very affordable price makes this a must have tool.

- **MICR007 USB Microscope**: This USB microscope has a 2M pixels LENS and CMOS sensor along with a magnification ratio of 5x-270x. The device comes with an aluminum stand which makes inspection much easier by freeing up both hands.

- **Adjustable Arm Magnifier**: Crystal Clear 5” 3 Diopter (1.75x) lens mounted on a silver-grey metal housing. Fluorescent bulb is protected with a clear plastic diffuser/splash guard. Heavy Duty Adjustable Arm. When fully extended the arm has a reach of 35”.

9. **ST91 Recommendation for Use of Sterilization Trays:**

a. ST91 section. 8.2.4 states that **Rigid containers** should be selected for the sterilization method for which they have been cleared. Endoscope manufacturers may provide recommendations for rigid containers that are compatible with the device and both the container and endoscope manufacturer’s written IFU should be followed. Some sterilization containers are available with prepositioning bracketing or **organizing tray** inserts.
Healthmark Products to Comply with ST91 Recommendations for Sterilization Trays:

- **EO Sterilization Basket:** Built from high-quality stainless steel, and furnished with drop-down handles for convenient transportation and handling. This 18” x 12” sterilization basket was produced for the objective of reprocessing contaminated flexible endoscopes, and comes outfitted with perforated side walls that allow for the desired permeation of ethylene oxide – assuring thorough sterilization of the tainted flexible endoscope.

10. **ST91 Recommendations for Valve Containment:**
   
   a. Section 5.4.2 Manual (dry) leak testing: b) Remove all valves and biopsy port covers, keeping them with the scope throughout the process.
   
   b. Section 5.6 Manual rinsing: f) After cleaning, all detachable valves should be kept together with the same endoscope as a unique set.
   
   c. Section 10.1 General Considerations: To keep the parts together with the scope, a small bag or similar device can be used to attach the parts to the scope.
   
   d. Section 10.2 Storage of high-level disinfected endoscopes: Detachable parts that are to be reused (e.g., air/water and suction valves/pistons) should be processed together and stored with the specific endoscope as a unique set in order to allow traceability. Valves should be dried and lubricated according to the manufacturer’s written IFU.

Healthmark Products to Comply with Valve Containment Recommendations in ST91:

- **Green Mesh Bags (VB604 GN):** Lightweight Plastic coated mesh bag for storage of endoscope valves. Use of this bag complies with the ST91 recommendations to keep the valves and removable parts together with the endoscope for tracking purposes.

11. **ST91 Recommendations for Microbial Surveillance Testing:**
   
   a. Section 12.5.3 Routine testing of stored endoscopes: Numerous incidents of contaminated endoscopes in storage due to a failure in processing are well documented.
   
   b. NOTE—At the time of publication, AAMI was aware that the CDC is considering microbial sampling of endoscopes. No recommendation is made at this time.
   
   c. Section 12.4.3: Several technologies are available that can be used to measure the levels of organic soil and microbial contamination on the cleaned device. The published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes by the user. They include protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP) and an enzyme that detects specific bacteria (Alfa 2012, Alfa 2013, Alfa 2014, Visrodia 2014).

Healthmark Products to Comply with Microbial Surveillance Recommendations in ST91:

- **Flexible Endoscope Sampling Kit (CK-374 or CK-250):** Healthmark Industries and Nelson Laboratories have created an endoscope sampling kit for the purpose of
monitoring and reporting objective results from clinical scopes. Everything necessary to collect and send a sample from a reprocessed endoscope for testing to determine the presence or absence of objectionable microorganisms will be provided in the kit offered by Healthmark. The sample will be sent by the healthcare facility to Nelson Labs for independent testing of the sample for the presence of any microorganisms. If present, the organisms will be identified and quantified. The Endoscope Sampling Kit is intended to be used as a proficiency assessment for healthcare practices and not as a safety assessment for the reprocessed scope (not a “fitness for use” test). This surveillance assessment is important to help the clinical user determine if their scope is safe for use, requires additional reprocessing, requires additional testing or should be quarantined. The kit and related tests are intended as another help to assess the adequacy of healthcare facility scope reprocessing.

- **NOW test (NOW-1000):** This simple and rapid test (<12 hours) checks for Gram negative bacteria, helping to ensure that it is safe to use on the next patient. Utilizing a unique enzyme detection method, the easy to read fluorometer checks for the Gram negative bacterial growth (<10 CFU) by reading telltale fluorescence in the recaptured water. If the fluorometer reading is positive for Gram negative bacteria, reprocess the endoscope following manufacturer guidelines prior to use.

12. Recommendations for Clean Transport:

a. Section 11 Transport of high-level disinfected endoscopes: When transporting an endoscope that has been high-level disinfected, the endoscope should be protected from recontamination. Before removing the endoscope from the storage cabinet, don new exam gloves. Then transport the endoscope using an impervious barrier method that will prevent re-contamination. Examples would be a clean plastic bag, endoscope transfer system (scope in a tote bin with a cover), or similar method. The endoscope should be loosely coiled to prevent damage. The transport system should not be reused for clean transport.

b. Rationale: Disinfected endoscopes can become recontaminated by hands and or communication with surfaces while being handled and transported. Use of a barrier system can prevent recontamination.

c. 5.7.3 Liquid chemical sterilants/liquid chemical sterilization: If the endoscope is to be used immediately, it should be unloaded from any AER, transferred directly into an aseptic transport device and sent to the intended point of use.

Healthmark Products that Comply with Clean Transport Recommendations in ST91:

- **Round Soaker and Transport Trolley** (2220, 2220 Trolley): Round soaker bin has a 20” diameter and is perfectly sized to allow a flexible endoscope to coil naturally and safely for transport or soaking. A lift off lid completely covers the tray. The Trolley can accommodate up to 5 round soaker trays simultaneously.

- **Clean/Dirty Scope Seal Kit** (2220 LOK): Seals have clean/dirty tamper evident seals.

- **2 Part Clean/Dirty Label** (AV-52482): This sticker is used to communicate whether the endoscope contained within a bin is clean or dirty.
For more information on Healthmark Products and compliance with the AAMI ST91 standards as well as any other professional society guidelines, please contact your Healthmark representative or Healthmark Customer Service at 1-586-774-7600

Thank you,

Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM), FAPIC
Manager, Clinical Education - Endoscopy
Healthmark Industries
mdrosnock@hmark.com
www.healthmarkgi.com

References:


2. AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES, Revised February 2016 for publication in Guidelines for Perioperative Practice, 2016 edition.

http://www.cdc.gov/hicpac/Disinfection_Sterilization/toc.html