The New AAMI ST91: An Updated Standard for Flexible Endoscope Processing

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Healthmark Industries
Clinical Education Specialist
Member, AAMI WG84 (ST91)
o Healthcare career - More than 40 years.
  • 20 years in Endoscopy.
  • 4 years system role – overseeing HLD and endoscope processing for health system. Included launch of the Centralized Endoscope Reprocessing Department on the main medical campus.

o Memberships: SGNA, ASGE, APIC, AAMI, AORN

o Contribute endoscope processing and HLD content for several professional society and trade publications.
Disclosures

• I am an employee of Healthmark Industries - Fraser, Michigan USA – a manufacturer and distributor of medical products to healthcare facilities and healthcare professionals.

• No compensation has been received for this presentation.

• All opinions are those of the presenter.

• This presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).
Healthmark Policy

- Healthmark’s Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

- This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.
Objectives

• Discuss the updated national standard, ANSI/AAMI ST91, highlighting key differences between the 2015 version and latest update.

• Identify current best practices in the processing of flexible endoscopes as outlined in ST91 and other guidelines.

• Outline how engineering quality assurance parameters into endoscope processing can help to reduce Hospital Acquired Infections (HAI) and Surgical Site Infections (SSI) and help to determine if an endoscope is patient ready.
What are expected cleaning and disinfection/sterilization practices based on?

1. Manufacturers’ Instructions For Use (IFU)
2. National guidelines and standards
3. Institutional policies
Regulations/Standards/Guidelines

**Regulations**
- A rule or directive made and maintained by an authority
- Mandatory

**Standards**
- Requirements and specifications to ensure consistency and fit for purpose
- Voluntary, but can become mandatory

**Guidelines, Recommended Practices, Technical Information Reports**
- Technical guidance, information or preferred procedures regarding a given topic
- Voluntary but with interpretation

*Logos of organizations like OSHA, FDA, CDC, ASGE, SGNA, AAMI, AORN, and The Joint Commission are shown.*
Performance-based documents - to assist the health care industry with performance, use, acceptance, and advancement of health technology – outline performance and safety requirements for a device.

Standards may also be user-oriented – to promote safe use, application, and maintenance in a health care setting.

The use of standards is voluntary.

However, if you reference the standards in your policies, accrediting surveyors will audit you to those standards.
For **ENDOSCOPE REPROCESSING**, what are standards & guidelines based on?

- All the major groups support in principal
  - Quality improvement
  - Quality assurance
  - Monitoring of processes
- Clinically relevant & evidence-based practices
- Peer reviewed literature
- Other articles and research.
- Manufacturer’s IFUs
- This is, and has been, a dynamic process
ANSI/AAMI ST 91 (2015)

- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for endoscope reprocessing in ANY setting
- Excludes TEE/ultrasound probes
AAMI WG84

ANSI/AAMI ST 91 (next edition)
- FINAL REVIEW DRAFT –
  - Circulating for approvals.
  - Hopefully published end of 2021.

TIR 99
- Continued work on developing TIR99 – processing of US probes & dilators.
What’s around the corner?
Focused changes to ST91

| “Point of use treatment” (vs. “ precleaning”) |
| “High-risk endoscopes” |
| Cleaning verification |
| Borescopic Inspection |
| Drying |
| Storage |
| Handling |
Focused changes to ST91

- Recommendations against manual disinfection
- Addition of references as support
- Adding FDA MAUDE database citations
- Appendices for inspection, Simethicone, cleaning verification
- Much attention to detail in wording – e.g., “should” and “shall”
References

- Focused effort to include references from RESEARCH

- MAUDE database citations

- Informative ANNEXES
  - Repairs
  - IFU conflict management
  - Visual inspection
  - Cleaning verification
  - Simethicone
  - Surveillance testing
  - Storage risk assessment
  - Drying

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
MAUDE database

- “…reports of adverse events involving medical devices”.
- “…voluntary reports since June 1993…”
- “user facility reports since 1991…”
- “distributor reports since 1993…”
- “manufacturer reports since August 1996…”
- “…searchable database data contains the last 10 year’s data”.

“Mandatory reporters: manufacturers, importers and device user facilities.

Voluntary reporters: health care professionals, patients and consumers.”
What do the words mean within an AAMI Document?

**Must** = only describes an “unavoidable” situations, including those mandated by government regulation.

**Shall** = requirements strictly to be followed to conform to the recommended practice.

**Should** = indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required.

**May** = indicates that a course of action is permissible within the limits of the recommended practice.

**Can** = a statement of possibility and capability.
High-risk endoscopes

- Associated with infectious outbreaks.
- Difficult to process.

- Elevator channel endoscopes, bronchoscopes, ureteroscopes, cystoscopes.
- Others as determined by facility.
Endoscope Processing Workflow – HLD / Sterilization

Sterilization

- Reuse

Storage

- Sterilization

Drying

HLD

- PRE-CLEANING (POINT OF USE)
- STORAGE
- DRYING
- HIGH LEVEL DISINFECTION
- INSPECTION
- CLEANING VERIFICATION

- LEAK TESTING
- MANUAL CLEANING
- RINSING AFTER MANUAL CLEANING
“Point of use treatment” (vs. “precleaning”)

To reflect everything done at point of use – including precleaning -

• Disconnecting accessories.
• Preparing handoff communication.
• Preparation for transport.
Soiled transport

• Delayed processing protocol reinforced.

• Scopes kept moist for transport.

• Transport container or cart:
  • Nonporous
  • Leak-proof on sides and bottom
  • Puncture-resistant
  • Labeled as biohazard
Leak Testing

• Daily pressure output validation for automated and manual leak testers.
• Follow manufacturer IFU.
• Documentation of testing.

• When a leak is discovered –
  • Follow endoscope manufacturer IFUs for processing.
  • Tag the scope.
  • Remove from use.
Cleaning

Manual
Again, delayed processing protocol reinforced.
Utility water rinse.
Drying – exterior and channels.

Automated
Reinforces FDA direction re: duodenoscopes – AER cleaning as a supplement only (to thorough manual cleaning).

Enhanced visual inspection and cleaning verification

- Enhanced visual inspection -
  - Endoscope dried first.
  - Lighted magnification.

- Cleaning verification -
  - “High-risk endoscopes” after each use.
  - Repeated failures – send scope for evaluation/repair.

- Borescopic inspection -
  - Channels, distal tip, valve openings.
  - Follow endoscope mfr. IFUs for what to inspect.
High-level disinfection (HLD)

• Recommendations against manual disinfection.
  • Manual guidance given; but automated processing (AER) promoted.

• AER flow QC testing – as per mfr. IFU.

• Scope left in AER more than one hour – repeat HLD cycle.

• PPE used for decontam. should not be worn when handling post-AER.
Drying, Storage and Handling

• Need to dry scopes prior to storage or reuse.

• Minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air.

• Cabinets:
  o PREFERRED - internal channel drying cabinets.
  o AT A MINIMUM - conventional cabinets with HEPA-filtered air circulating.

• Monitor with drying verification tests.
• No endoscope storage in procedure room or processing room.
• Hand hygiene and clean gloves when handling.
• Post-HLD/patient ready tag ON THE SCOPE.
• Multidisciplinary risk assessment re: “hang time”.

[Links to Medivators.com products related to endoscope reprocessing, transport and storage, and drying systems]
Additional highlights

• Gives recommendations for:
  • Certifications for technicians performing reprocessing
  • Monitoring the manual cleaning process
  • Monitoring automated cleaning processes
  • Monitor water quality and temperature of chemicals
  • Keeping valves together with the endoscope as a unique set
Additional highlights

• Gives recommendations for:
  • Multidisciplinary QA and safety program.
  • Risk Assessments.
  • Documentation and record keeping.
  • Device repair and loaned scopes.

• Informative annexes:
  • Alternatives for keeping cool in the processing environment
  • Purchase considerations in selecting AERs and LCSPSSs
  • Reference material for repairs
  • Manufacturer’s written instructions for use (IFU) conflict management
  • Endoscope visual inspection
  • User verification of cleaning processes
  • Effects of simethicone on flexible endoscopes
  • Safety considerations for high-level disinfectants and liquid chemical sterilants
  • Endoscope microbiocidal methods
  • Endoscope storage risk assessment
  • Endoscope drying
Endoscope Processing Workflow – HLD / Sterilization

Sterilization
- Reuse
- Storage
- Sterilization

Drying

HLD
- Pre-Cleaning (Point of Use)
- Leak Testing
- Manual Cleaning
- Rinsing After Manual Cleaning
- Inspection
- Cleaning Verification

- Storage
- Drying
- High Level Disinfection
Endoscope Processing Workflow – HLD / Sterilization

Sterilization:
- Reuse
- Storage
- Sterilization

Common weak points/lapses

HLD:
- PRE-CLEANING (POINT OF USE)
- LEAK TESTING
- MANUAL CLEANING
- RINSING AFTER MANUAL CLEANING
- INSPECTION
- CLEANING VERIFICATION

Drying
Two deaths reported

5/6/16

• Olympus was informed that following ERCP procedures, six patients were infected with E. coli, and two of the six patients expired.
  • A borescope was used to inspect the biopsy and suction channels.
  • Brown stains and scrape marks were found on the biopsy channel interior at 5 cm from the distal end.
  • The suction channel had similar brown stains at various locations.

Endoscope Processing Workflow – HLD / Sterilization

**Sterilization**
- Reuse
- Storage
- Sterilization

**Quality control needed**
- Surveillance testing
- Drying monitors

**HLD**
- Pre-cleaning (point of use)
  - Storage
  - Drying
  - High level disinfection
  - Rinsing after manual cleaning
  - Inspection
  - Cleaning verification
  - Leak testing
  - Manual cleaning
The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication – August 29, 2019

- Recommending transition to newer designs that aid in or eliminate reprocessing (e.g., disposable scopes, disposable tips).

- Ensure staff are meticulously following reprocessing instructions.

- Post market safety surveillance studies: ~5% culture positive including high concern organisms after proper reprocessing.

- Human factors studies: user materials (IFUs) are not sufficient to consistently ensure user adherence; and users are not following the IFU properly.
Other important FDA recommendations

• Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.

• Consider supplemental measures (sterilization or liquid chemical sterilant processing system) compatible and consistent with the scope’s labeling.

• Monitor your reprocessing procedures.
  • Examples of monitoring are sampling and culturing using the FDA/CDC/ ASM Duodenoscope Surveillance Sampling & Culturing Protocols – https://www.fda.gov/media/111081/download

• Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.
ATP Testing – what it is and what it isn’t

The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety:
FDA Safety Communication – August 29, 2019

“One potential method to monitor the effectiveness of duodenoscope reprocessing is the use of test strips that detect adenosine triphosphate (ATP), an indicator of the presence of live microbes.”

• ATP testing is not done with test strips.

• Some companies were promoting use of ATP at end of processing (e.g. after HLD); and/or as a test for microbial surveillance (which it's not).

• FDA to date does not regulate cleaning verification.
Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication – August 4, 2015

Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.

• Microbiological Culturing

• Ethylene Oxide Sterilization

• Use of a Liquid Chemical Sterilant Processing System

• **Repeat High-Level Disinfection**  No longer referenced.
FDA/CDC/ASM Duodenoscope Culture Method

• First published March 2015 and updated February 2018

• Validated method

• Supersedes the CDC Interim Method

• Flush – brush – flush method (sterile water)

• Recommends a neutralizer broth and longer incubation time

https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf
Microbial Surveillance

Options include:

• Traditional culturing
• Gram negative test kits
• Not ATP or cleaning verification tests

• AAMI (2015):
  • No recommendation is made in the current version because of the timing of release.

• AAMI (draft)
  • Voluntary; but can be used as part of an overall quality control program.
  • Health care facilities consider own needs and available resources to implement.

• AORN:
  • Base decision on a risk assessment.

• SGNA:
  • Surveillance cultures can be used as a method for assessing reprocessing quality and aid in identifying particular endoscope defects that hamper effective reprocessing.
Spaulding Classification

- **Critical devices**
  - High risk of infection (sterile tissue)
  - Sterilization recommended
- **Semi-critical devices**
  - Intermediate risk of infection (non-intact skin or mucous membranes)
  - STERILIZATION, if not possible then High-level disinfection
- **Non-critical devices**
  - Low risk of infection (intact skin)
  - Intermediate or low-level disinfection
Sterilization of endoscopes

• Spaulding:
  • Standard of care for critical and semi-critical devices
  • Semi-critical: If sterilization is not possible, then HLD

• More modalities compatible with surgical flexible endoscopes

• Sterilization is dependent on adequate cleaning, drying and device preparation
Sterilization

- Surgical scopes - many compatible with vaporized hydrogen peroxide systems
- **STERRAD** in Olympus IFU
- **V-Pro** not in IFU - found in customer letters
- **ETO** compatible with all Olympus scopes
- Sterilization is **dependent on adequate cleaning, drying and device preparation**
- Store sterilized scopes flat in wrap according to hospital policy
Revised labelling for Olympus URF-P6, URF-P6R, V, V2, V2R

- Ureteroscope recall

- Olympus new manuals and letter dated 1/17/18
  - Scope tips can break off in patient
  - Also changed reprocessing instructions
    - Requires sterilization!
    - Removed HLD info
    - Inspection required prior to use
Develop an action plan for sterilization

• Inventory scopes – what models do you have

• Look at compatibility with sterilization methods

• Move all scopes that can be easily sterilized to sterilization!
  • Surgical flexible scopes: bronchoscopes, ureteroscopes, cysto, hystero, ENT, etc.

• Look at remaining scope inventory (GI scopes)
  • Prioritize by risk (e.g., duodenoscopes)
  • Based on FDA recommendations, do something: sterilize, culture, liquid chemical sterilization, disposable scopes.

• May need to adjust inventory levels of scopes
Trends and technology

• Semi- and fully-disposable endoscopes.

• Increasing number of endoscope drying modalities.

• R&D: low temperature sterilization and automated cleaning.

• Increased emphasis on bronchoscopes and other “high-risk endoscopes” - cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes, ureteroscopes.

• Aerosol and splash risks in endoscopic procedures and endoscope processing.
Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers

April 1, 2021

The U.S. Food and Drug Administration (FDA) wants to raise awareness among health care providers, including those working in reprocessing units in health care facilities, about the risk of infections associated with reprocessed urological endoscopes, including cystoscopes, ureteroscopes, and cystourethoscopes, used for viewing and accessing the urinary tract. The FDA has received numerous Medical Device Reports (MDRs) which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices.

The FDA is currently investigating the potential causes and contributing factors associated with the reported infections and contamination issues. While some reports indicate
Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication

Date Issued: June 25, 2021

The U.S. Food and Drug Administration (FDA) is providing updated information about medical device adverse event reports and recommendations for health care providers on bronchoscopes.

This is a supplement to the [2015 safety communication](#) on reprocessed flexible bronchoscopes.

**Recommendations for Patients and Caregivers**

The recommendations have not changed from the September 2015 safety communication.
This is, and has been, a dynamic process – stay connected and up-to-date

The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

https://www.fda.gov/medical-devices/medical-device-safety/safety-communications

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

https://emergency.cdc.gov/HAN/
Conducting visual examinations of flexible endoscopes: A focus on channels and ports
Conducting visual inspections of flexible endoscopes using lighted magnification
Performing biochemical tests to verify cleaning effectiveness for flexible endoscopes
The endoscope drying imperative: what, why, when, where, and how?
Minimizing the risk of exposure, injury, and infection during bronchoscopy
What’s inside your scopes? Simethicone and other insoluble products used during endoscopy.
Proper use of personal protective equipment (PPE) during endoscopy and reprocessing.
Hand hygiene in healthcare settings.
Respiratory protection: Unmasked
Uncovering device adverse events to improve safety for patients and personnel.
Making a splash: contaminated droplet dispersal in decontamination areas
Ultrasound probes: Challenges, risks, and strategies for improving patient safety.
Biofilm: A slimy microbial community that lives on medical devices
Summary recap
Focused changes to ST91

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Additional highlights

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• Informative annexes:
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- PRE-CLEANING (POINT OF USE)
- STORAGE
- DRYING
- HIGH LEVEL DISINFECTION
- CLEANING VERIFICATION
- INSPECTION
- RINSING AFTER MANUAL CLEANING
- MANUAL CLEANING
- LEAK TESTING
What’s around the corner?
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What is a Consultative Practice Review?

The Clinical Affairs Team at Healthmark Industries is pleased to introduce the Consultative Practice Review (CPR) Program. This program, also known as an informal audit, allows a Healthmark Clinical Educator to visit your healthcare facility to review sterile processing, endoscopy processing, or high-level disinfection practices against current national standards, such as AAMI ST79, ST91, and ST90 and other professional society guidelines, such as AORN, SGNA, and AORN. The Joint Commission standards and OSHA regulations will also be referenced where applicable.

What to Expect

Upon request from a facility, a pre-check form will be distributed to the facility to gather information about the department and current equipment to make the process more efficient and customer-focused.

For Sterile Processing, a checklist is used as a guide to verify best practices from the point of use to decontamination to sterilization to sterile storage, including transport pre- and post-patient use. Guidance is primarily referenced from AAMI ST79. The entire process can be reviewed, or it can be split into specific segments, such as decontamination or sterile storage.

For Endoscopy Processing, a checklist is used as a guide to verify best practices from the point of pre-treatment through cleaning of the scope. Typically, the entire process is observed, but specific segments could also be reviewed individually. Guidance references the endoscopy standards or organizations referenced in institutional policy - AAMI, SGNA, AORN.

After completing the CPR, a detailed report is generated for the facility to review.

There is no charge for this service as it is considered a value-added benefit for Healthmark customers and facilities needing assistance on processing issues. CPRs are scheduled based on demand and the availability of a Healthmark educator and the local Healthmark Sales Representative who will be on-site to assist in the process.

Contact Us or Submit a Request

For more information, please contact the Healthmark Clinical Education Team at jwhelan@hmark.com
To request a CPR, please complete the form at https://www.surveymonkey.com/r/EducationRequestForm

DISCLAIMER: The free consultation provided by Healthmark does not cover a complete audit and does not include all facility processes. The consultant may also make suggestions and recommendations of the consultant's experience, background, and education process and may not be held to recommendations and standards that facilities comply with. Results of the CPR are non-binding and implementation of recommendations are at the discretion of the healthcare facility.
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Southern California
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949-228-3789
Healthmark Solutions –

• For each step of endoscope processing.

• That address areas of increased emphasis with ST91.
QC for leak testing

**LEAK TESTER TESTER**

- Measures actual PSI delivered from manual and automated leak testing equipment.
Enhanced visual inspection

- Multiple lighted magnifiers.
- **FLEXIBLE INSPECTION SCOPE** – borescopic inspection.
<table>
<thead>
<tr>
<th>Product name</th>
<th>Residual test for</th>
<th>Weblink to IFU</th>
<th>Sampling method</th>
<th>Measurement</th>
<th>Measurement range</th>
<th>Interpretation time</th>
<th>Applicability to flexible endoscopes</th>
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<td><strong>ChannelCheck</strong></td>
<td>Protein Carbohydrate Hemoglobin</td>
<td><a href="http://www.healthmark.info/CleaningVerification/ChannelCheck/ChannelCheck-IFU.pdf">http://www.healthmark.info/CleaningVerification/ChannelCheck/ChannelCheck-IFU.pdf</a></td>
<td>Lumen FLUSH</td>
<td>visual comparison to Color Control Chart</td>
<td>Protein 30 μg/ml Carbohydrate 25 μg/ml Hemoglobin 0.25 μg/ml</td>
<td>90 seconds</td>
<td>Accessible lumens - esp. working channel.</td>
</tr>
<tr>
<td><strong>HemoCheck</strong></td>
<td>Hemoglobin</td>
<td><a href="http://www.healthmark.info/CleaningVerification/HemoCheck/HemoCheck-IFU.pdf">http://www.healthmark.info/CleaningVerification/HemoCheck/HemoCheck-IFU.pdf</a></td>
<td>Surface or lumen SWAB</td>
<td>visible color change down to 0.1µg</td>
<td>30 seconds</td>
<td>(1) Any accessible surface - incl. ports, distal tip, and elevator mechanisms; (2) With the proper swab from Healthmark, can be used to sample internal channels as well.</td>
<td></td>
</tr>
<tr>
<td><strong>ProChek-II</strong></td>
<td>Protein</td>
<td><a href="http://www.healthmark.info/CleaningVerification/ProCheck/ProChek-II-IFU.pdf">http://www.healthmark.info/CleaningVerification/ProCheck/ProChek-II-IFU.pdf</a></td>
<td>Surface or lumen SWAB</td>
<td>visible color change down to 1µg</td>
<td>5 minutes</td>
<td>(1) Any accessible surface - incl. ports, distal tip, and elevator mechanisms; (2) With the proper swab from Healthmark, can be used to sample internal channels as well.</td>
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<tr>
<td><strong>ProChek-W</strong></td>
<td>Protein</td>
<td><a href="https://www.hmark.com/PT-SQ-001.pdf">https://www.hmark.com/PT-SQ-001.pdf</a></td>
<td>Lumen FLUSH</td>
<td>semiquantitative visual comparison to color interpretation chart</td>
<td>0 µg/ml - 30 µg/ml</td>
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Non Linting Wipes

Scope Dry Check

Hydrocheck
Moisture Detection
Microbial surveillance

• **NOW! Test**: 12-hour surveillance test for Gram-negative organisms.

• **Flexible Endoscopy Sampling kit (FESK)** – Send out culturing program – all supplies included.
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