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New Clinical Evidence for Endoscope processing is in. Implement ANSI/AAMI ST91 Today!

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- **Successful completion:** Participants must complete the entire program and submit required documentation. No partial credit will be given.
- **Conflict of interest:** Employee of STERIS.
- **Commercial company support:** Fees are underwritten by education funding provided by STERIS.
- **Non-commercial company support:** None.
- **Alternative/Complementary therapy:** None.

Continuing Education

- STERIS Corporation is an approved provider of continuing education by California Board of Nursing (provider # CEP 11681) and the Board of Ambulatory Surgery Certification (provider # 1417).
- This program is approved for:
  - 1 hour(s) of GI specific content credit by American Board of Certification for Gastroenterology Nurses (ABCGN)
  - 1 AEU(s) & 1 IPCH(s) by BASC
  - 1 contact hour(s) of continuing education credit
    - HSPA
    - CBSPD
    - CBRN

Continuing Education

CCI® The Leader in Perioperative Certification

Through a partnership with CCI®, it also meets CNOR® and CSSM® recertification requirements for perioperative nurses.

Learning Objectives

- Identify key clinical evidence driving the changes in ANSI/AAMI ST91
- Implement ANSI/AAMI ST91 guidelines to develop a comprehensive department for GI, bronchoscopy and other flexible endoscope processing
- Prioritize critical processes and applications for patient safety

FDA Post Market Surveillance

- 4.1- 6.6% contamination rate of duodenoscopes with “high concern microorganisms” (FDA 522 Post Market Surveillance Studies August 2019)
  - Gram-negative rods
  - Staphylococcus aureus
  - Beta-hemolytic Streptococcus species
  - Enterococcus species
  - Yeasts

49% of Endoscopes Retained Water


American Journal of Infection Control

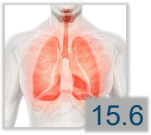
Major Article

Residual moisture and waterborne pathogens inside flexible endoscopes: Evidence from a multisite study of endoscope drying effectiveness

Cori L. Ofstead MSPH *, Otis L. Heymann BA, Mariah R. Quick MPH, John E. Eiland RN, MS, Harry P. Wetzler MD, MSPH

Fig. 1: Retained fluid droplets found inside endoscope channels

Infection Rates per 1,000 Endoscopic Procedures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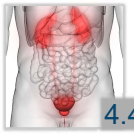
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Endoscopy

ORIGINAL ARTICLE

Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA

3.0

1.1

American National Standard

ANSI/AAMI ST91:2021

Flexible and semi-rigid endoscope processing in health care facilities

AAMI

WHY

- Adjunct to CDC and SGNA recommendations
- Required by state law
- Based on the most recent clinical evidence

Definitions

American National Standard

ANSI/AAMI ST91:2021

Flexible and semi-rigid endoscope processing in health care facilities

AAMI

Should: statement is a recommendation

Shall: statement is a requirement

May: a statement that expresses permission

Must: a requirement driven by external constraints or obligations

Might: a statement of possibility

ANSI/AAMI ST91:2021 pg. xi

Comprehensive processing Guide

American National Standard

ANSI/AAMI ST91:2021

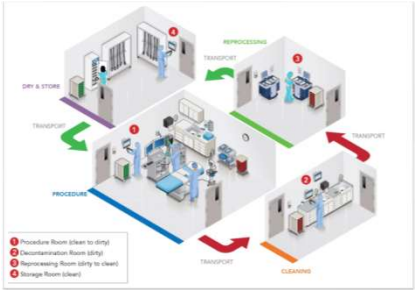
Flexible and semi-rigid endoscope processing in health care facilities

AAMI

"These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use."

- Area design and environment
- Personnel
- Process
- Quality control

Processing Area Design



Processing Area Design

"Until such time (major renovations or new construction) that two separate processing rooms can be provided, strict unidirectional processing procedures should be in place to reduce risks of cross-contamination."

ANSI/AAMI ST91 Section 4.2.2 pg. 13

"Dirty" Side Design Considerations

Room

- Traffic Control / Doors
- Space
- ANSI/ASHRAE/ASHE 170
- Negative Room Pressure
- Pass thru windows
- Cleanable

Work Area

- Utility water
- Instrument air
- Lighting
- Inspection/Leak test areas
- Hand Washing
- Emergency Eye Wash / Showers

"Clean" Side Design Considerations

Room

- Traffic Control / Doors
- Space
- ANSI/ASHRAE/ASHE 170
- Positive Room Pressure
- Pass thru windows
- Cleanable

Work Area

- Dedicated rinse sink
- Instrument air/HEPA filtered
- Lighting
- Inspection
- Utilities
- Drying
- Hand Washing/ Emergency Eye Wash / Showers

Personnel

- Policies & Procedures
- Shall complete competency verification
- Should be certified within 2 years
- Annual training and when changes occur

The Exposure Control Plan

Standard Precautions	Hand Hygiene	Attire	Personal Protective Equipment (PPE)
• Centers for Disease Control and Prevention (CDC) • OSHA Blood-borne pathogen regulation	• Short fingernails • No artificial nails • CDC and WHO guidelines	• Uniforms provided by the facility • Head and facial hair covered • Non-skid shoes • No jewelry or wristwatches	• Attire • General-purpose utility or chemical resistant gloves • Liquid-resistant coverings, shoe covers and face mask • Eye protection

Point Of Use Treatment

Don PPE
↓
Prepare Cleaning Solution
↓
Wipe Insertion Tube
↓
Flush channels
↓
Inspect

Point Of Use Treatment

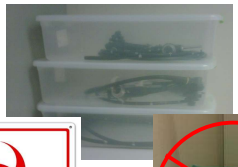
- Don PPE
- Prepare Cleaning Solution
- Wipe Insertion Tube
- Flush Channels
- Inspect

Point Of Use Treatment

- Don PPE
- Prepare Cleaning Solution
- Wipe Insertion Tube
- Flush channels
- Inspect

Transport

- Endoscope and its components
- Closed container or cart
- Labeled Biohazard
- Kept Moist



Handoff Communication

Patient Identifier

Date of Procedure

Completion Time of Point-of-Use

How Much Time Is Allowed?

"If no timeframe is given, manual cleaning should be initiated within **one hour** or as determined by the facility based on their own documented risk assessment."

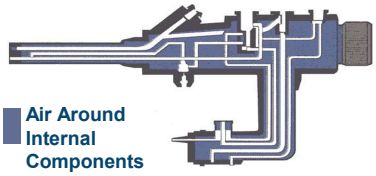
ANSI/AAMI ST91, 7.5.1 pg. 36

Delayed Processing

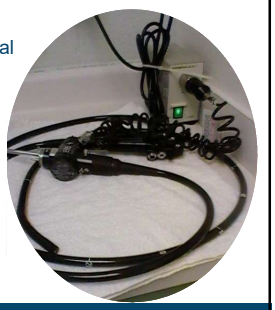
- Cleaning starts with submersion in cleaning solution
- Document time period
- Follow Manufacturer IFU for delayed processing
- Documented procedures

Leak Test

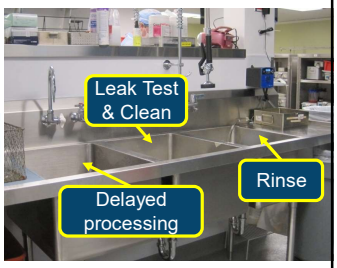
- Detects damage that could expose internal components



Air Around Internal Components



Sinks



Manual Cleaning – Prepare

- Fresh compatible cleaning solution
- Video cap attached
- Fresh non-linting cloth or appropriate sponge
- Brushes as defined by endoscope and accessories IFU
- Compatible suction and flushing mechanisms

Manual Cleaning – Clean

- Beneath the cleaning solution surface
- Soft lint-free cloth or appropriate sponge
- Use appropriate brush for ports, openings and elevator housing
- Brush accessible channels
- Aspirate and flush channels per IFU
- Soak as directed

Elevator Guide

Manual Cleaning - Rinse

- Volume of water
- Number of rinses
- Water pressure
- Utility Water per ANSI/AAMI ST108

Common Water Conditions	Standard Specification
Hardness	< 150 Mg/L
Conductivity (mg/L = ppm)	< 500 µS/cm
pH	6.5-9.5
Total Alkalinity	<400 mg CaCO3/L
Bacteria	<500 CFU/ml
Endotoxin	n/a

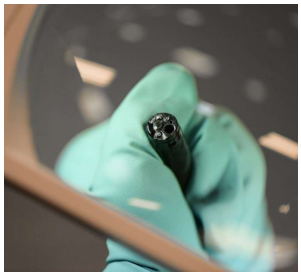
*Refer to ST108 for the complete specification

Drying After Cleaning

- Residual could dilute in HLD or LCS process
- Residual could interfere with terminal sterilization
- Designated drying area
- Clean non-linting cloth
- Forced instrument or HEPA filtered air

Lighted Magnification Inspection

- Lighted magnification 5x-10x
- Inspect for:
  - Cleanliness
  - Integrity
  - Moisture
  - Damage



Borescope Inspection

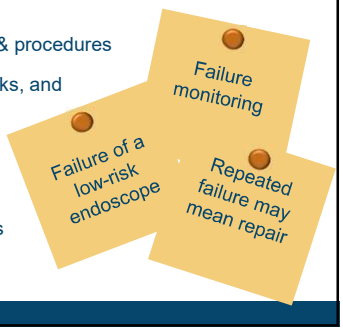
- Inspect accessible channels and openings
- Inspect for:
  - Residual Soils
  - Surface Damage
  - Residual Moisture
  - Manufacturer's inspection criteria
- Competency Program

Cleaning Verification Testing

- Residual Soils - Organic or inorganic
- Not visible
- After cleaning prior to disinfection/sterilization
- Every high-risk endoscope
- Periodically for low-risk endoscopes

Cleaning Verification Program

1. Create standard work, policies & procedures
2. Identify soil markers, benchmarks, and endoscopes
3. Training and competency
4. Perform user verification
5. Implement and report on results



High-Risk Endoscope

"Endoscopes that have been associated with infectious outbreaks including those that are difficult to process and increase the risk of incomplete clearance of contaminating infectious organisms, including bronchoscopes, cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes, ureteroscopes, and others as determined by the facility."

ANSI/AAMI ST91 3.31 pg. 6

Microbiocidal Process

Biocidal Process Definitions

Disinfection

Liquid Chemical Sterilization

Terminal Sterilization

Choosing The Right Biocidal Process

Critical Device

- Introduced into the blood
- Contact sterile tissue or body space
- Sterilization

Semi-Critical Device

- Contact intact mucous membranes or non-intact skin
- Disinfection, preferably sterilization

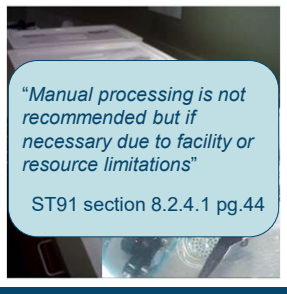
"It is advised that flexible and semi-rigid endoscopes to be used in semi-critical applications be sterilized prior to use."
ANSI/AAMI ST91 pg. xiii

Semi-Critical Endoscope Sterilization

- Based on Risk Assessment
  - High-risk endoscope
  - Patient population
  - Infection rates
  - Outbreak organisms

Manual High-Level Disinfection / Liquid Chemical Sterilization

Don PPE
↓
Prepare HLD/LCS Solution
↓
Submerge and flush lumens
↓
Remove and purge
↓
Utility/Critical Water Rinse



"Manual processing is not recommended but if necessary due to facility or resource limitations"

ST91 section 8.2.4.1 pg.44

Automated High-Level Disinfection And Liquid Chemical Sterilization

Don PPE
↓
Load and attach connectors
↓
Run Cycle
↓
Purging

"If an endoscope is left in the basin of an AER or LCS for an extended period of time (i.e., more than one hour), the endoscopes should be put back through the HLD/LCS process before it is stored or used"

ST91 section 8.2.3.2 pg.43

Important Considerations For Manual OR Automated HLD And LCS

Follow IFU
- Safety
- Preparation, contact time and rinsing
- Disposal

Single vs. Multi Use
- Maximum reuse
- No topping-off
- Test strips for concentration

Important Considerations For Manual OR Automated HLD And LCS

Chemistry Contact
- Remove trapped air
- Appropriate connectors
- Validated for processor

Rinse Water Quality
- Correct number of rinses
- Manual: Critical (ST108) or Sterile Water
- Processor: Follow IFU
- Fresh water for every rinse (by immersion)

When To Dry HLD/LCS Endoscopes

- Prevents microbial growth and biofilm formation during storage
- Semi-critical endoscopes
  - Prior to patient use
- Critical Endoscopes Processed in LCS
  - Use immediately with no drying or dry prior to storage
  - If HLD AER Dry before storage and use

Important Drying Considerations

- AER purge but do not dry
- Use of 70 – 90% alcohol

If the use of alcohol is a consideration, a multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should conduct a risk assessment to determine whether endoscope lumens should be flushed with 70 % to 90 % ethyl or isopropyl alcohol.

ANSI/AAMI ST91 section 8.2.5.1 pg. 46

Endoscope Drying Channels After Cleaning

Extend Drying Time if Still Wet

Minimum
- 10 Minutes
- Drying verification – Annex K

Check with OEM for Max PSI

Pressure-Regulated
- Forced Instrument or HEPA Filtered Air
- Regulated to protect endoscope

Dedicated / Sectioned Drying Cabinet
- HEPA-filtered air

Storage

- Closed Cabinet
  - HEPA Filtered Air
  - Directed HEPA filter air (preferred)
- Storage Time / “hang time”

Terminal Sterilization

Prepare endoscope

↓

Package in sterile barrier

↓

Run Cycle

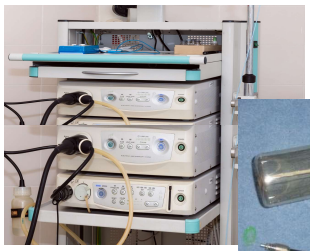
↓

Release the load

Terminal Sterilization Options

Ethylene Oxide Sterilization	Hydrogen Peroxide and Hydrogen Peroxide - Ozone
• Validated	• Validated
• Venting cap and/or removal of cleaning cap	• Venting cap and/or removal of cleaning cap
• ANSI/AAMI ST41	• ANSI/AAMI ST58

Don't Forget The Accessories!



Quality Control

- Policies and Procedures
- Endoscope and accessories identification and traceability
- Process monitoring and testing
- Preventative maintenance and repairs
- Documentation
- Quality process improvement

Prioritize And Plan Implementation

1. Obtain ANSI/AAMI ST91
2. Audit your process
3. Perform a risk assessment
4. Prioritize - Pareto analysis
5. Make a plan

Action Items

- Obtain copies of the applicable standards and guidelines for flexible endoscope processing for your department
- Create an assessment tool based on ANSI/AAMI ST91
- Audit, prioritize and plan your compliance path to ANSI/AAMI ST91

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