IMPLEMENTING NEW ANSI/AAMI ST91:2021 STANDARDS IN UROLOGY

Flexible and Semi-Rigid Endoscope Processing In Healthcare Facilities

Released in March 2022, the new AAMI standard in endoscope reprocessing includes several critical updates from the 2015 version.

The purpose of ST91 is to provide comprehensive guidance to achieve best practices for reprocessing flexible endoscopes.

What is AAMI?

AAMI (Association for the Advancement of Medical Instrumentation) is a nonprofit organization founded in 1967 and includes a diverse community of more than 10,000 healthcare technology professionals supporting the healthcare community in the development, management, and use of safe and effective health technology. AAMI is a primary source of consensus standards, both national and international, for the medical device industry.

Learn more or to order the ST91 Standards: aami.org

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NEW Updates In Reusable Cystoscope and Reprocessing:

Now Classified as "High-Risk Endoscopes"
Identifies complex endoscopes as "high risk" in order to ensure maximum focus on reprocessing elements – cystoscopes and ureteroscopes are included.

Recommendation Against Manual Disinfection
Manual disinfection by soaking the scope in high-level disinfectant solution is NOT RECOMMENDED in ST91. High-level disinfection should occur in an automated endoscope processor, and facilities should consider sterilization options.

Drying Time Verification
Cystoscope channels should be dried after cleaning and disinfection/sterilization. Drying should last a minimum of 10 minutes with pressure-regulated forced instrument air. Extend drying time if moisture is still present.

Cleaning Verification
ST91 recommends that cleaning verification testing take place after each use of a high-risk endoscope. Additionally, the standard now recommends borescopes be incorporated to visually inspect for damage inside channels.

Documentation of Pre-Cleaning at Point-of-Use
Documentation of point-of-care pre-cleaning and proper transport/ handling should include these completed protocol elements: Date and time of completion of use of that device, the time of point-of-use treatment, and the patient identifier.

Testing of AER Rinse Water to Ensure Efficacy
To ensure that the correct water quality is used in each stage of processing, the manufacturers' written instructions for use (IFU) for all equipment and supplies should be used. The healthcare facility should monitor and control the water supply quality to endoscope processing sinks and processing equipment.

Length of Storage Between Reprocessing
Liquid chemically sterilized endoscopes intended for use as critical devices should not be stored with a claim as being patient-ready; instead, they should be used immediately after processing. They may also be used immediately in semi-critical applications. Endoscopes that are processed using a liquid chemically sterilization method but are not meant for immediate use, can be stored in the same way as those under HLD.

A Recommendation to Take Steps Toward Sterilization
The ST91 standard committee recognizes that transitioning from HLD to sterilization as the standard of care will take time as endoscope and sterilizer manufacturers implement necessary technological advances. Healthcare facilities must also provide the budgetary and site accommodations to implement this change.

NEW ST91: Extensive Updates for Endoscope Cleaning and Patient Safety in 2022

The ANSI/AAMI standard provides guidelines for point-of-use treatment, transporting, leak testing, cleaning, packaging, high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible reusable endoscopes. Healthcare facilities also have the option of tip-to-cable sterile, completely single-use flexible video cystoscopes. The comparison below is designed to give facilities insight into implementing either of the two options for inpatient, outpatient, or satellite clinic use.

REUSABLE AND SINGLE-USE COMPARISON

IMPLEMENTING ST91 FOR REUSABLE CYSTOSCOPES AND REPROCESSING OR IMPLEMENTING SINGLE-USE

ST91 Standards and Recommendations	Reusable Cystoscopes	Single-Use Cystoscopes
High-Risk Endoscope Classification	Yes	Not Required
AER or Sterilization Reprocessing Only (No Manual HLD)	Yes	Not Required
Enhanced Drying Time	Yes	Not Required
Cleaning Verification	Yes	Not Required
2-3 Decontamination Sinks	Yes	Not Required
Enhanced Visual Inspections	Yes	Not Required
AER Rinse Water Testing Regimen	Yes	Not Required
Monitor Length of Storage Time	Yes	Not Required
Documentation of Point-of-Care Cleaning and Proper Transportation	Yes	Not Required
Additional Recommendations	**Reusable Cystoscopes**	**Single-Use Cystoscopes**
Training and Competency Testing on Reprocessing Routines	Yes	Not Required
HVAC Compliance for Reprocessing Room	Yes	Not Required
Leak Testing Calibration Schedules	Yes	Not Required
Specified Storage Cabinets	Yes	Not Required

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