Learn How to Improve High-Level Disinfection and Infection Prevention

Hosted by:

Jill Holdsworth

CIC, AL-CIP, FAPIC, CRCST, CHL, NREMT

Medical Affairs Manager

CS Medical

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CSPP.0024.260128

About the Speaker

Jill Holdsworth, CIC, AL-CIP, FAPIC, NREMT, CRCST, CHL

Jill earned her Bachelor of Science in Biology from West Virginia Wesleyan College and her Master of Science in Exercise Physiology from Marshall University, launching her career as a Cardiac Rehabilitation Therapist.

She began her work in Infection Prevention in 2009, achieved Certification in Infection Control (CIC) in 2010, and was named a Fellow of the Association for Professionals in Infection Control and Epidemiology (APIC) in 2016. Jill has held several leadership positions within local APIC chapters, including serving as President of the Washington, DC chapter.

She has also contributed at the national level as a member of the APIC Board of Directors and as Co-Chair of the Association for the Advancement of Medical Instrumentation (AAMI) Protective Barriers Committee.

Currently, Jill serves on the Certification Board of Infection Control and Epidemiology (CBIC) Board of Directors and the Healthcare Sterile Processing Association (HSPA) Certification Council. She is presently the Medical Affairs Manager for CS Medical.

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Objectives

- By the end of this presentation, attendees will be able to:
  - Understand the Joint Commission and Det Norske Veritas (DNV) requirements related to reprocessing and infection prevention.
  - Describe common regulatory citations and barriers to compliance in relation to high-level disinfection & sterilization, transport and storage of ultrasound probes, scopes and surgical instrumentation.
  - Describe solutions to common barriers to patient safety concerns and compliance issues related to high-level disinfection, sterilization, manual cleaning, storage and transport.

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Steps to Successful Ultrasound Probe Reprocessing

1. Point of Use Cleaning
2. Transport Soiled Probe
3. Manually Clean, Scrubbing Crevices with a Brush (not required when reprocessing with Ethos)
4. Rinse and Dry (not required when reprocessing with Ethos)
5. High-Level Disinfect
6. Rinse
7. Dry
8. Store
9. Transport to Next Ultrasound Procedure

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Top 5 AAMI Standards for Medical Device Reprocessing

AAMI Standard	Description	Focus
ANSI/AAMI ST 79	The foundation standard for Sterile Processing: covers facility design workflow, cleaning, inspection, packaging, steam sterilization, storage, monitoring, and quality assurance for reusable medical devices.	Comprehensive steam sterilization & sterility assurance
ANSI/AAMI ST 91	Primary standard for GI, bronch, and other flexible endoscopes: outlines precleaning, leak testing, manual cleaning, HLD/sterilization, drying, storage, transport, and quality control expectations.	Flexible and semi-rigid endoscope processing
ANSI/AAMI ST 108	Establishes water quality requirements (utility vs. critical water), monitoring, corrective actions, system design, and documentation necessary for safe and effective cleaning and sterilization.	Water for the processing of medical devices
ANSI/AAMI ST 58	Provides guidance for the safe and effective use of FDA-cleared liquid chemical sterilants and high-level disinfectants, including MRC testing, IFU adherence, and staff safety considerations.	Chemical sterilization and high-level disinfection
ANSI/AAMI ST 90	Defines QMS requirements tailored to medical device reprocessing including leadership responsibilities, document control, corrective/preventive action, process monitoring, and continuous improvement.	Quality management systems for device processing

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Top 5 AAMI TIRs & Guidance Documents for Medical Device Reprocessing

AAMI TIR / Technical Guidance	Description	Focus
AAMI TIR 99	Provides guidance on the safe handling, cleaning, disinfection/sterilization, inspection, testing, storage, and transport of TEE probes, vaginal/rectal ultrasound probes, and dilators	Processing of dilators, TEE probes, and ultrasound probes
AAMI TIR 109	Outlines requirements for safely transporting processed or contaminated medical devices between facilities, focusing on package integrity, containment, environmental controls, and regulatory considerations	External transport of medical devices
AAMI TIR 12	Guidance for manufacturers on developing validated reprocessing instructions– covering materials, design features, testing, labeling, and end-user safety	Designing, testing, and labeling reusable medical devices for reprocessing
AAMI TIR 30	Manufacturer-focused resource detailing cleaning processes, soil selection, test methods, and acceptance criteria used to validate instructions for cleaning reusable medical devices	Cleaning validation methods & acceptance criteria
AAMI PB 70	Establishes performance levels(1-4) for gowns, drapes, and protective apparel based on liquid barrier resistance– highly relevant for PPE selection and splash protection in decontamination areas	Liquid barrier performance for protective apparel and drapes

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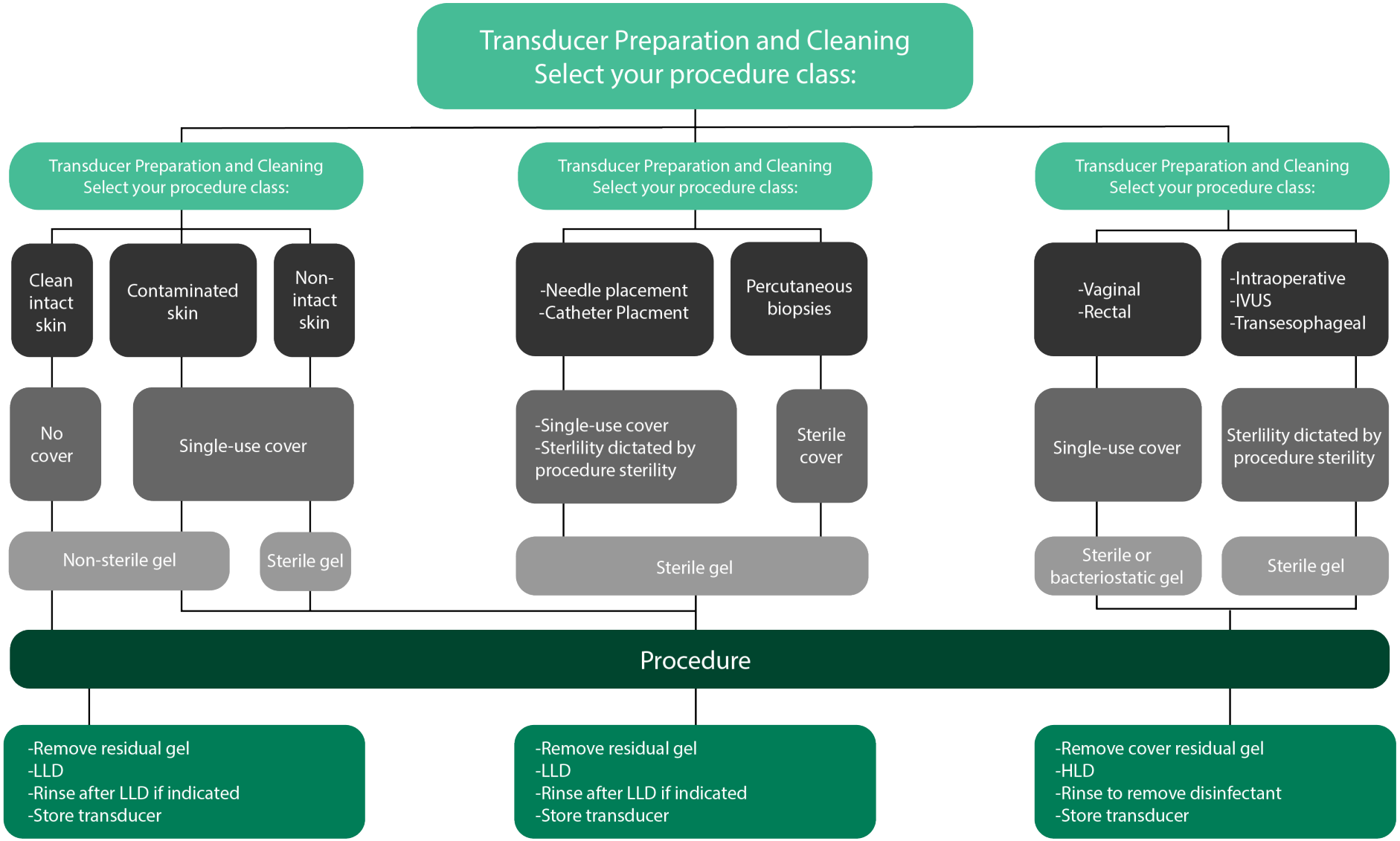
Transducer Preparation and Cleaning
Select your procedure class:
Transducer Preparation and Cleaning
Select your procedure class:
Clean intact skin
Contaminated skin
Non-intact skin
No cover
Single-use cover
Non-sterile gel
Sterile gel
Transducer Preparation and Cleaning
Select your procedure class:
-Needle placement
-Catheter Placment
Percutaneous biopsies
-Single-use cover
-Sterlility dictated by procedure sterility
Sterile cover
Sterile gel
Transducer Preparation and Cleaning
Select your procedure class:
-Vaginal
-Rectal
-Intraoperative
-IVUS
-Transesophageal
Single-use cover
Sterlility dictated by procedure sterility
Sterile or bacteriostatic gel
Sterile gel
Procedure
-Remove residual gel
-LLD
-Rinse after LLD if indicated
-Store transducer
-Remove residual gel
-LLD
-Rinse after LLD if indicated
-Store transducer
-Remove cover residual gel
-HLD
-Rinse to remove disinfectant
-Store transducer

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IC.04.01.01	The Hospital has a hospital-wide infection prevention and control program for surveillance, prevention, and control of health care-associated infections (HAIs) and other infectious diseases.

The policies and procedures are in accordance with the following hierarchy of references:

- Applicable law and regulation.
- Manufacturers' instructions for use (IFUs).
- Nationally recognized evidence-based guidelines and standards of practice, including the Centers for Disease Control and Prevention's (CDC) Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings or, in the absence of such guidelines, expert consensus or best practices. The guidelines are documented within the policies and procedures.

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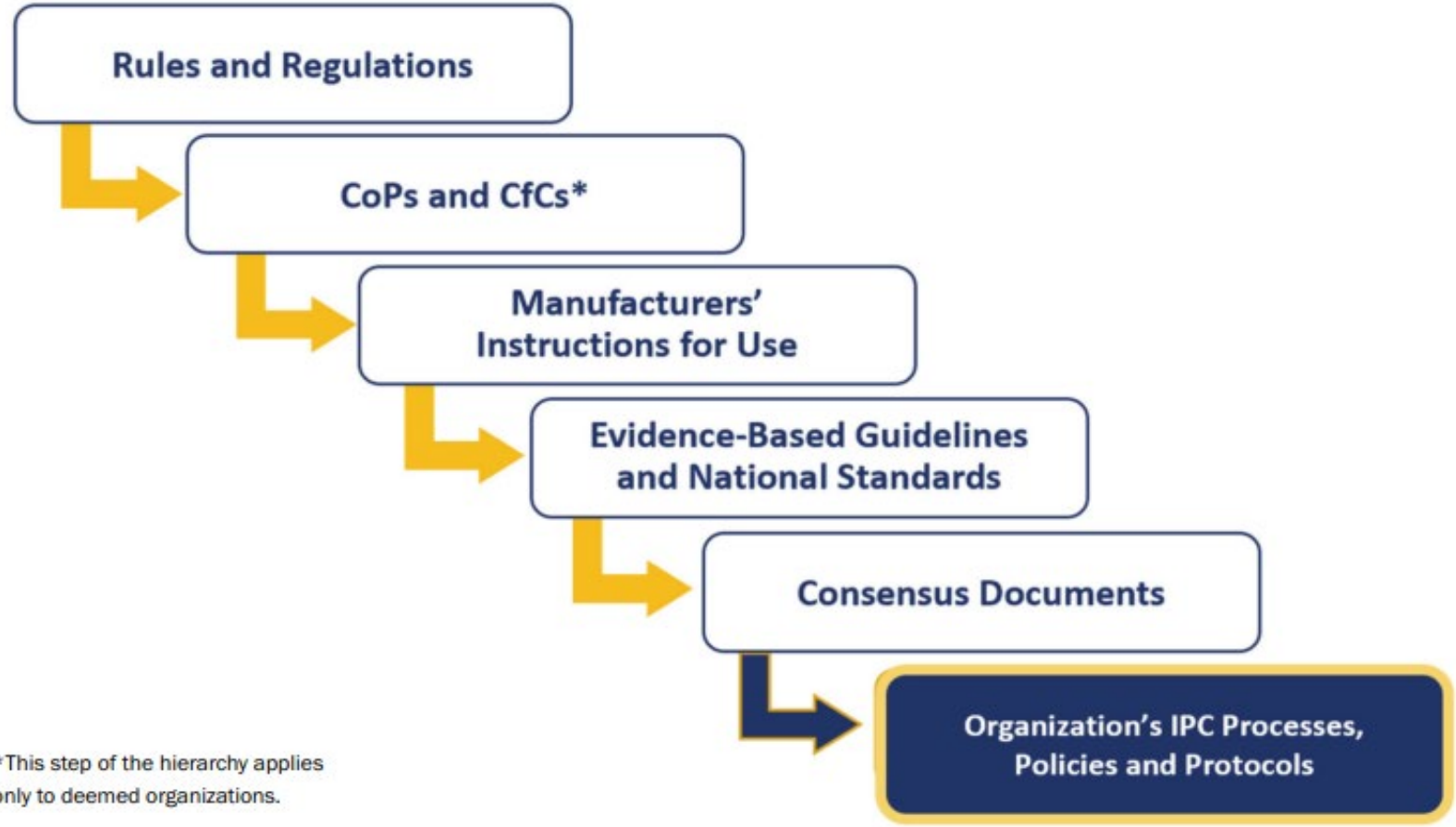
Hierarchical Approach to Cleaning, Disinfection, and Sterilization



*This step of the hierarchy applies only to deemed organizations.

Source: *Joint Commission Perspectives*®, April 2019. *See also* the Hierarchical Guide to Comply with Infection Prevention and Control Requirements on JointCommission.org. This hierarchy does not necessarily apply to JCI because CMS does not have international authority. Accessed May 20, 2023. https://www.jointcommission.org/resources/patient-safety-topics/infection-prevention-and-control/infection-prevention-and-control-hierarchy

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CDC Definitions*

- "**Cleaning** is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using (potable) water with soap or enzymatic products. Thorough cleaning is essential before HLD and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes."
- "**Disinfection** describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores."
- **Low-Level Disinfection (LLD)**—Destruction of most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium tuberculosis or bacterial spores.
- **Intermediate Level Disinfection (ILD)**—Inactivation of M Tuberculosis, bacteria, most viruses, most fungi, and some bacterial spores.
- **High-Level Disinfection (HLD)**—Destruction/removal of all microorganisms, except bacterial spores.

*According to the CDC Guideline for Disinfection in Healthcare Facilities

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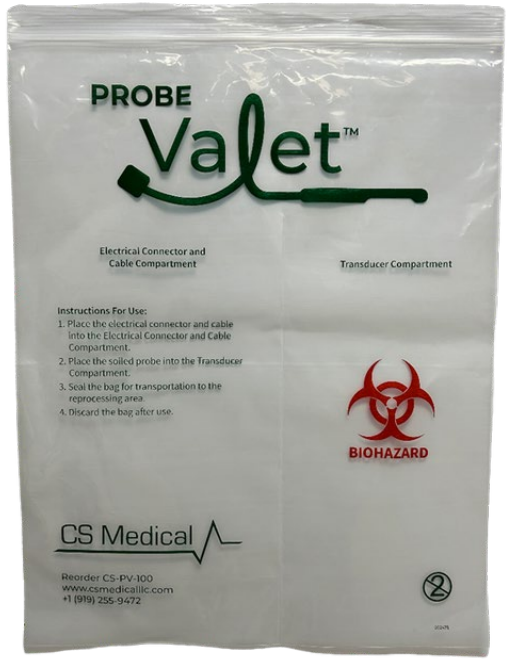
SDMS: Guidelines for Best Practices in Infection Prevention & Control

- Inspection: post procedure, inspect probe for damage immediately
  - Remove transducer cover
  - Immediately clean
    - Remove remaining gel, visible soil, bioburden
  - Disinfect transducer

- Transport via appropriate method
  - Container with lid or impermeable bag
  - Label with biohazard symbol



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Ineffective Probe Transportation Methods

- Examples of ineffective transportation methods – pillow cases, trash bags, and plastic bins
  - Some parts of probe are high-level disinfected, other parts are only surface disinfected
  - Does not protect user from biohazards (no clear biohazard label)
  - Multiple uses could lead to cross-contamination

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Manual Processing Procedures **AAMI ST 91: 8.2.4.1**

- **Manual processing is NOT recommended**
  - If necessary due to a facility's resource limitations, check the manufacturer IFUs for:
    - Device compatibility
    - Temperature and timing
    - PPE recommended by the IFU (also check facility policy)
    - Type of container required (must always be clean and dry)
      - Know how to dispose of chemical waste appropriately (per local/state requirements)
      - Know how to clean properly and safely.
    - THOROUGH cleaning, rinsing and drying must occur prior to HLD
    - Check chemical expiration dates, MRC with test strips & expiration dates of test strips
    - Keep solutions covered to prevent exposure & evaporation
      - Have a plan to monitor exposure per OSHA

- **AAMI TIR 99**: Manual high-level disinfection is not the preferred method due to safety and hazard concerns to the users and inconsistencies in the process from person to person.

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Manual Cleaning—Sink Process **AAMI TIR 99**

- If manual cleaning involving the use of detergent solution and rinsing in a sink is required, this **cannot occur** in the room where the patient procedure was performed nor be performed in the handwashing sink

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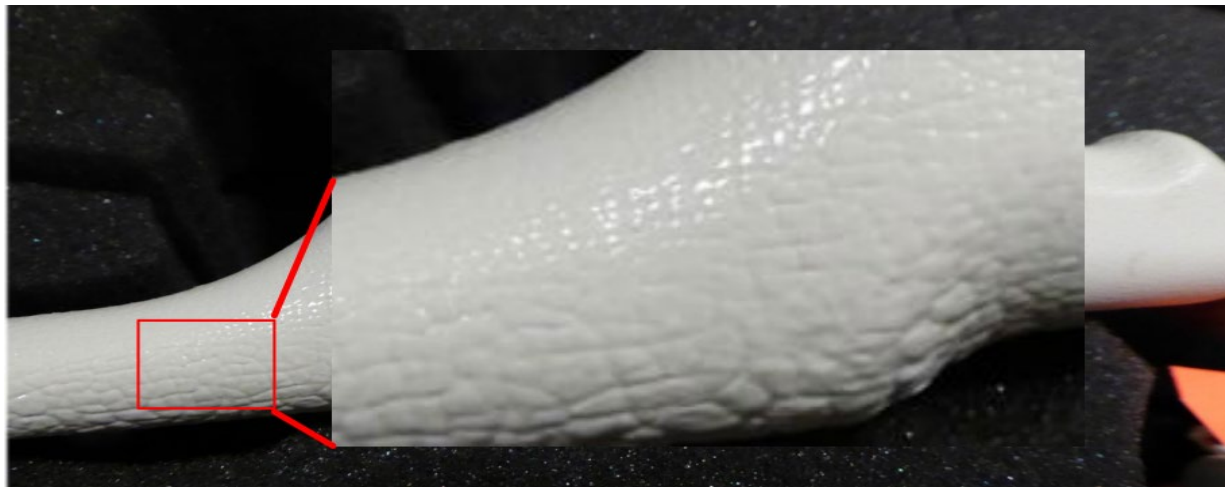
Probe Damage: Wrong Chemical Used



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How costly are damaged probes?

- TEE Probes: **$4,300**
- Transvaginal/Transrectal: **$3,800**

Prices provided by probe repair organization as of 01/26

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MANUAL RINSING **AAMI ST91: 8.4.2.4**

- Remove PPE & don fresh PPE
  - Gloves
  - Skin protection (gown)
  - Fluid resistant mask
  - Fluid resistant shoe covers
- Use **critical water** for final rinse
  - Follow **AAMI ST108**

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Rinsing **AAMI ST 108**

- After cleaning and before high-level disinfection or sterilization, a **Critical Water** rinse is recommended.

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25°C	pH	6.5—9.5	5.0—7.5	5.0—9.2**
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	μS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg $CaCO_3$/L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

*Steam parameters are for monitoring as steam condensate
**See 6.3 a) for specifics. For local steam generation, the condensate pH should be 5.0 to 7.5. For boiler-treated steam, most boilers should be treated to maintain a condensate pH of 7.5 to 9.2
*** When Utility Water is used after chemical high-level disinfection as a final rinse, the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL
**** If hardness is greater than 150 mg/L a water softener is recommended unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness

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Drying After High-Level Disinfection

- Make sure to properly dry probes before moving on to next step to prevent common issues
  - Sterile or gamma irradiated drying cloth
  - Begin at the lens and work toward the handle and cord
- Common Issues
  - Recontamination by microorganisms sticking to damp surface
  - Recontamination by drying with bundled cloths
  - Bacterial growth during storage from damp probes

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Cori L. Ofstead, MSPH
Harry P. Wetzler, MD, MSPH
Alycea K. Snyder, BA
Rebecca A. Horton, DPT

Endoscope Reprocessing Methods

A Prospective Study on the Impact of Human Factors and Automation

1.4% compliance: manual cleaning/automated HLD
75.4% compliance: automated cleaning/HLD

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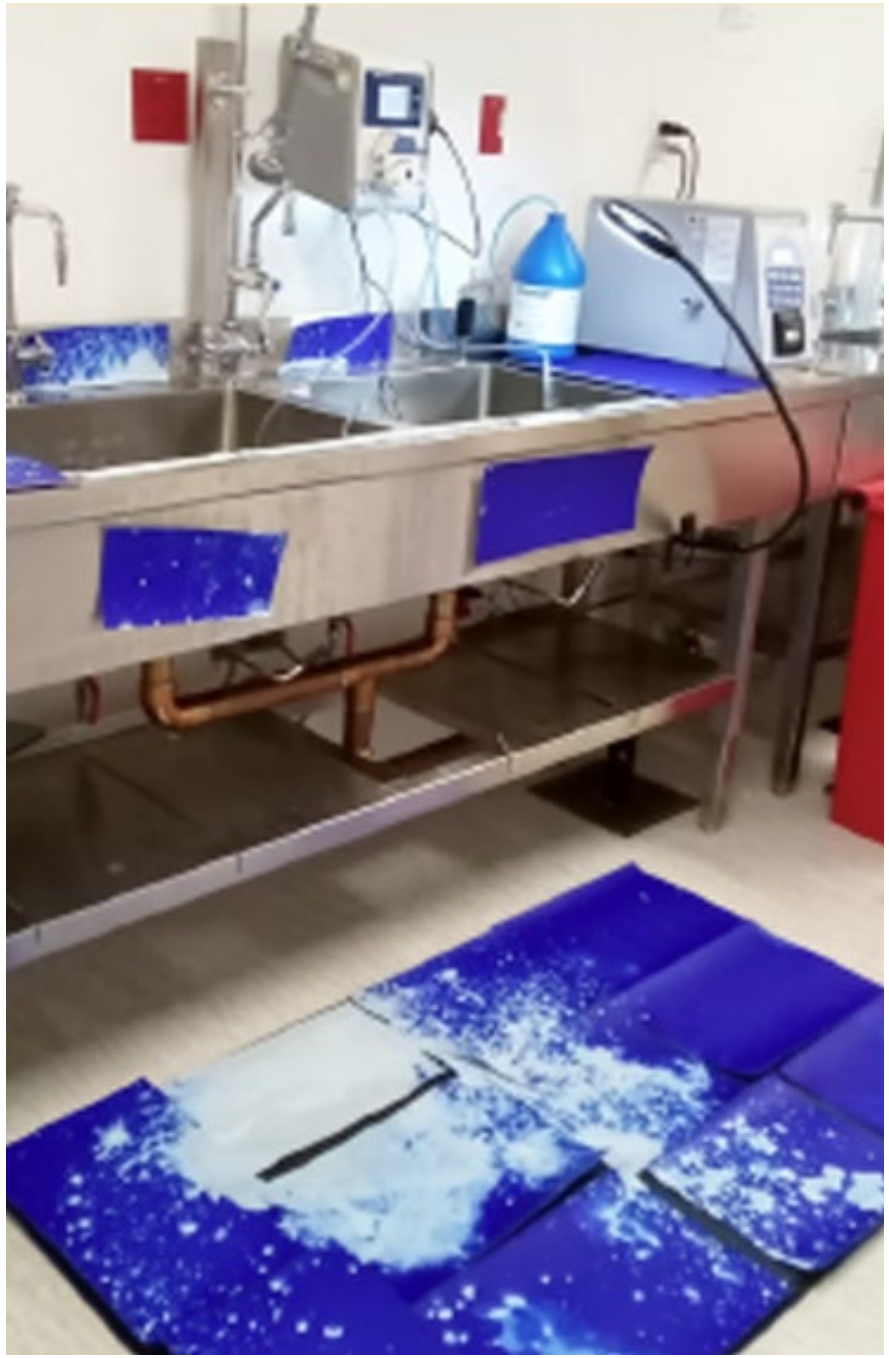

Splash Risk During Manual Cleaning

- Dirty water droplets were detected up to 7.25 feet from the sink where cleaning occurred
- Rinsing the probe per IFU (two minutes under running water) generated more small droplets, large droplets, and confluent puddles of water around the sink than any other activity

Splash generation and droplet dispersal in a well-designed, centralized high-level disinfection unit
Ofstead, Cori L. et al.
American Journal of Infection Control, Volume 50, Issue 11, 1200 - 1207
https://www.ajicjournal.org/article/S0196-6553(22)00629-0/fulltext

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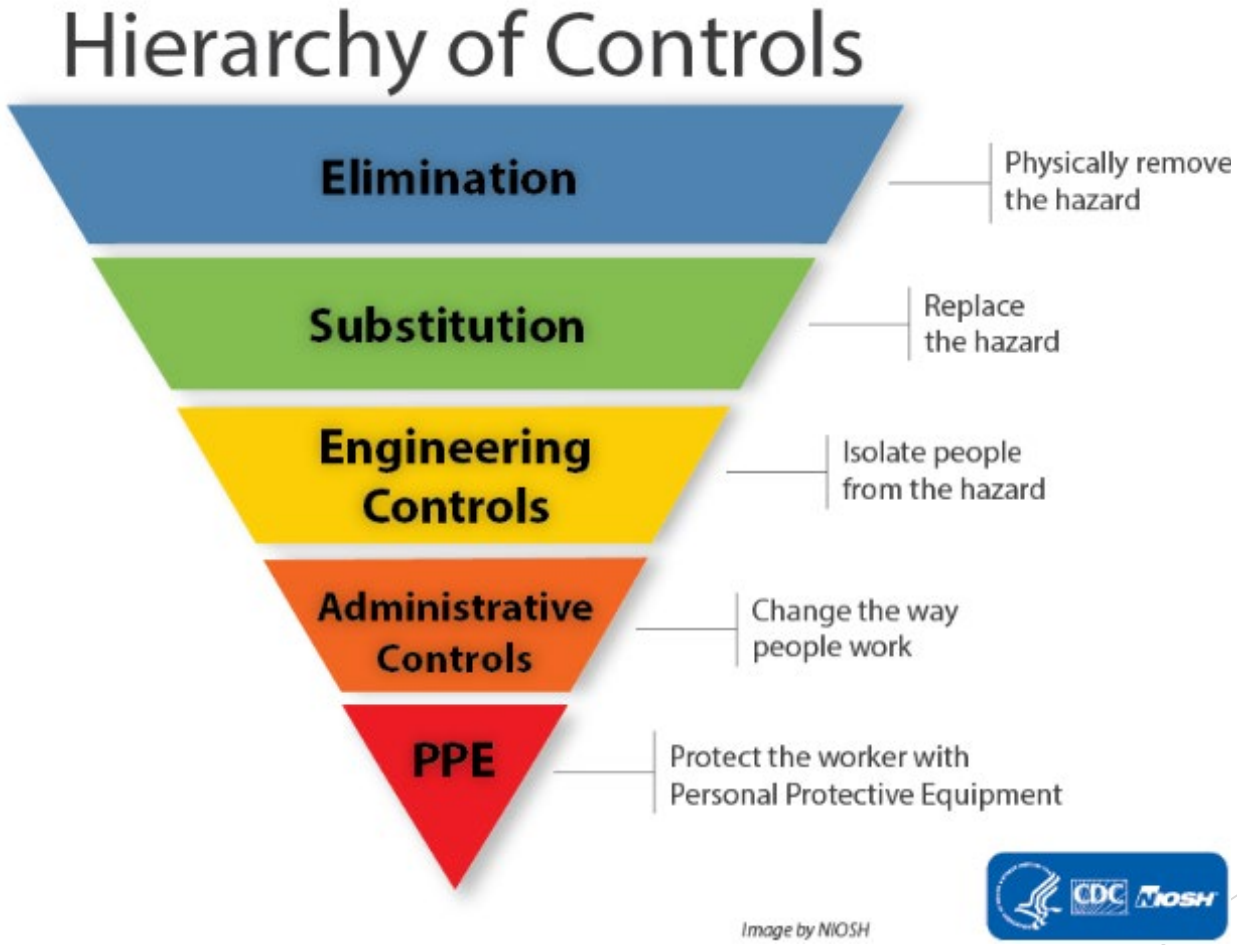
NIOSH Hierarchy of Controls:

Preferred order of actions to best control hazardous workplace exposures



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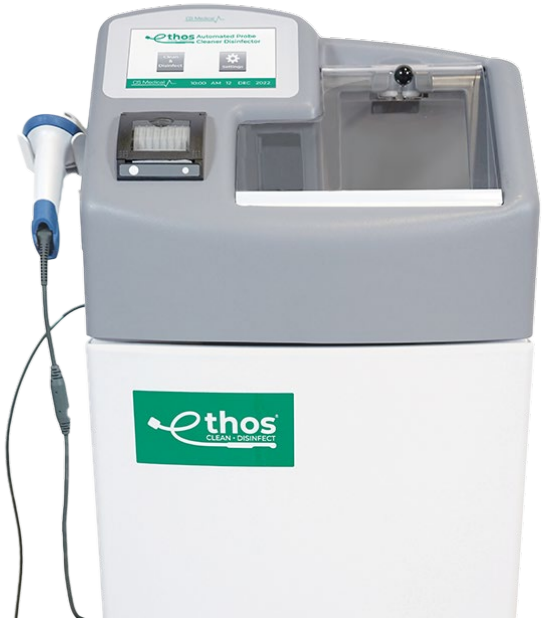
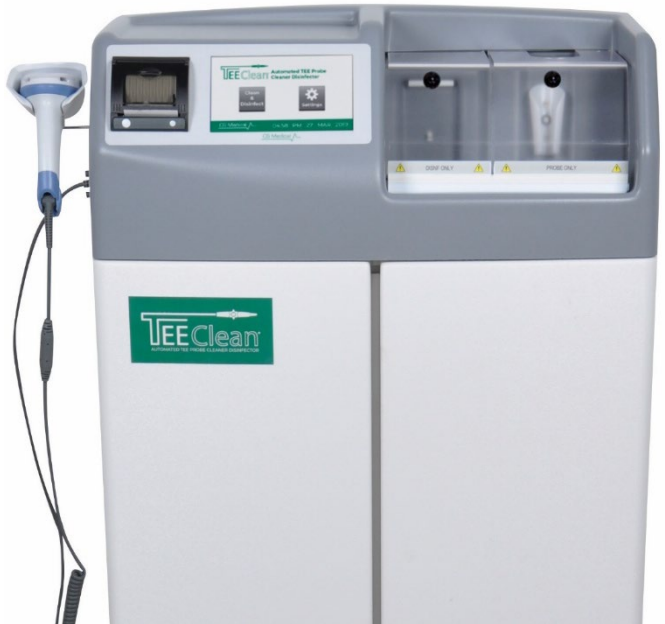
Automating the HLD process **AAMI 8.2.3.1**

An automated process can be more efficient and consistent, resulting in less user exposure and avoidance of prolonged user exposure to chemicals.

Scan for Ethos Info!

Scan for TEEClean Info!





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Workflow

- How you reprocess your ultrasound probes (manual, semi-automated, or automated cleaner disinfector) will affect your workflow

Manual Workflow	Semi-Automated Workflow	Automated Cleaner Disinfector Workflow
Point of Use Processing	Point of Use Processing	Point of Use Processing
Transport	Transport	Transport
Manual Cleaning Process Setup	Manual Cleaning Process Setup	Automated Cleaning, High-Level Disinfection, MRC, and Rinsing
Manual Cleaning	Manual Cleaning	
Manual Rinsing	Manual Rinsing	
Manual Drying	Manual Drying	
Clean-up of Manual Cleaning Process	Clean-up of Manual Cleaning Process	
Transport	Transport	
Manual Disinfection Process Setup	Automated High-level Disinfection and Rinsing	
Vapor Control Set Up		
Manual MRC Test Strips	Manual MRC Test Strips	
High-level Disinfection		
Clean-up of Manual Disinfecting Process		
Manual Rinsing		
Drying	Drying	Drying
Storage	Storage	Storage
Documentation	Documentation semi-Traceability	Documentation Full Traceability

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Workflow

Steps will never be skipped, but will be managed differently depending on method used

- Manual Workflow:
  - Total estimated reprocessing time: 48-88 minutes
  - Total operator hands-on time: 48-88 minutes
- Semi-Automated Workflow:
  - Total estimated reprocessing time: 37-50 minutes
  - Total operator hands-on time: 29-35 minutes
- Automated Cleaner Disinfector Workflow:
  - Total estimated reprocessing time: 27-38 minutes
  - Total operator hands-on time: 9-20 minutes

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The Joint Commission (TJC)
IC Chapter: IC.04.01.01

- EP 2: The infection preventionist is responsible for the following:
  - Competency-based training and education of hospital personnel and staff, including medical staff and, as applicable, personnel providing services in the hospital, on infection prevention and control policies and procedures and their application.
    - Examples of competencies may include donning/doffing of PPE and the ability to correctly perform the processes for high-level disinfection.

CFR Number §482.42(c)(2)(iv)	Medicare Requirements
§482.42(c)(2)(iv)	TAG: A-0775
(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.	

§482.42(c)(2)(v)	TAG: A-0776
(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.	

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Processing of dilators, transesophageal (TEE) and ultrasound probes in health care facilities - **AAMI TIR 99**

- Section 9: Training & Competency
  - Should occur annually
    - **OR** when there is new equipment, devices, supplies, chemicals or per policy

- Personnel should not perform reprocessing duties independently until:
  - Competency is verified and documented for each process step, including:
    - Point of use
    - Transport
    - Cleaning
    - Drying
    - HLD
    - Storage

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IC.04.01.01	The Hospital has a hospital-wide infection prevention and control program for surveillance, prevention, and control of health care-associated infections (HAIs) and other infectious diseases.

EP 4 The hospital's policies and procedures for cleaning, disinfection, and sterilization of reusable medical and surgical devices and equipment address the following:

- Cleaning, disinfection, and sterilization of reusable medical and surgical devices in accordance with the Spaulding classification system and manufacturers' instructions
- Use of disinfectants registered by the Environmental Protection Agency for noncritical devices and equipment according to the directions on the product labeling, including but not limited to indication, specified use dilution, contact time, and method of application
- Use of FDA-approved liquid chemical sterilant for the processing of critical devices and high-level disinfectants for the processing of semi critical devices in accordance with FDA-cleared label and device manufacturers' instructions
- Required documentation for device reprocessing cycles, including but not limited to sterilizer cycle logs, the frequency of chemical and biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection
- Resolution of conflicts or discrepancies between a medical device manufacturer's instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment
- Criteria and process for the use of immediate-use steam sterilization
- Actions to take in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use

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DNV Regulatory Requirements

- **Infection Control Chapter**
  - Validate that all areas of the organization that perform sterilization or high-level disinfection, to include off-site locations as applicable, demonstrate compliance with the organization's policies and procedures and manufacturer's recommendations.

- **Surgical Services Chapter**
  - **SR.1** The organization shall reprocess all surgical instrumentation and medical devices according to the manufacturer's instructions for use (IFU) and ensure access to the IFUs are readily available to all staff reprocessing these items, including all but not limited to:
    - SR 1a. Device manufacturer
    - SR 1b. Chemicals utilized for disinfection, sterilization and high-level disinfection
    - SR 1c Sterilizer manufacturer
    - SR 1d Containment device manufacturer (rigid and soft containment)
  - **SR. 4** The organization shall allow adequate time for reprocessing to ensure adherence to all steps recommended by device manufacturer, including drying and proper storage.

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Storage Best Practices

- Must be stored in a method that protects from contamination per TJC
- TIR99: Maximum storage time is not well-defined
- CS Medical's 7-Day Hang Time Study

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Storage

- AAMI TIR99:2024
  - Cabinets used for storage of probes should be situated in a secure, clean location.
  - A cleaned and disinfected probe should be protected from contact with the cable/plug which has not undergone high-level disinfection.
  - Probes and dilators should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination.
  - A semi-critical probe/dilator that has undergone a high-level disinfection process should be stored with additional protection (e.g., in a clean cabinet).
  - Cabinets should remain closed to protect the integrity of the disinfected probe.
  - Storage cabinets should be cleaned in accordance with the manufacturer's written IFU, or when visibly soiled and according to the facility policy.
  - A multidisciplinary team should perform a risk assessment to determine safe distance from any potential splashes or environmental contamination.

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Ineffective Ultrasound Probe Storage Methods

Common Pitfalls – improperly stored probes tend to experience damage, and cross-contamination, and often lead to HAIs, in addition to being out of compliance with TJC requirements:

- Open-air storage on wall hooks
- Hanging from ultrasound carts
- Inside of shipping cases that held the brand-new ultrasound probe
- Inside of other transportation devices:
  - Tupperware
  - Bags
- Wall Tubes
- Drawers
- Counters

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Storage Example

- Example Storage Cabinet – **CleanShield™** HEPA-Filtered Ultrasound Probe Storage Cabinet
  - Probes hang vertically
  - Individual channels keep probes from touching each other and prevent low-level disinfected parts of the ultrasound probe from touching high-level disinfected parts of the ultrasound probe; thus preventing cross-contamination
  - HEPA filtration also helps to prevent contamination from the environment

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Hand Hygiene

Survey of 100 reprocessing employees

- 47% reported the nearest handwashing sink >6 feet to wear PPE doffing occurs
- 22% answered “NO” when asked if hand sanitizer was conveniently located in the reprocessing space
- 29% report not having hand sanitizer near where they don PPE

Quality Improvement

Table 2—Continuous quality improvement matrix

Equipment to be monitored	What is to be monitored	Frequency
Ultrasound machine	Maintain electrical and annual PM records, model #, and serial number	Upon purchase, repair, and preventive maintenance
Ultrasound transducers	Visual inspections, maintenance records, model # and serial number, imaging quality	Before and after use, repair, and preventive maintenance
Endocavity probe	Visual inspection, maintenance records, model #, serial number, and establish procedures for storage, imaging quality	Before and after use, repair, and preventive maintenance
Transesophageal Echocardiography probe	Visual inspection, maintenance records, model #, serial number, and establish procedures for storage model	After every use, repair, and preventive maintenance

Example: TIR 99 Table 2 excerpt

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kNOw Risk

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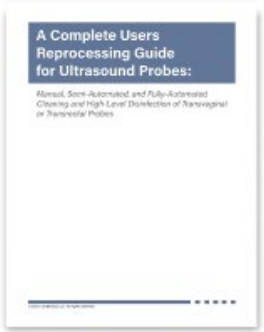

A Complete Users Reprocessing Guide for Ultrasound Probes

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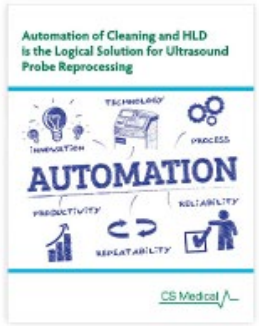

Automation of Cleaning and HLD is the Logical Solution for Ultrasound Probe Reprocessing

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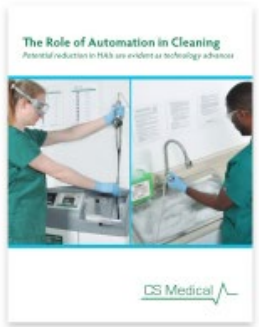

The Role of Automation in Cleaning

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Preventing Damage To Ultrasound Probes

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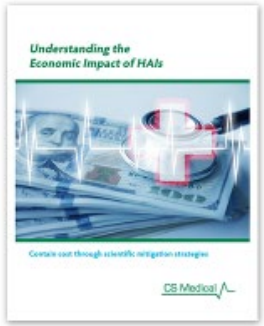

Economic Impact Of HAIs

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Free to Download!

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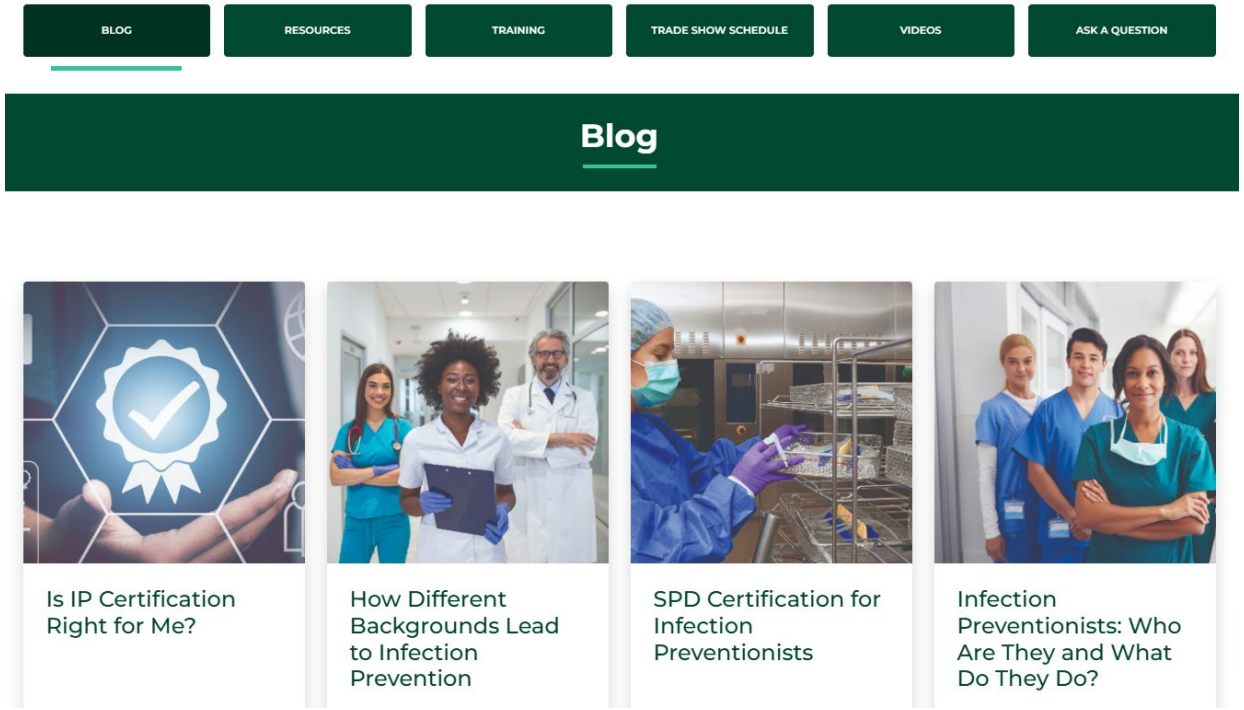
IP Insights

A one-stop shop for all things Infection Prevention.



Check Out Our New Webpage!

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Thank you!

Any Questions?

Jill Holdsworth

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