Behind the Mask:

Fundamentals of Semi-Critical Device Reprocessing

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UNMC Nebraska Medicine

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Meet our Subject Matter Experts

UNMC Nebraska Medicine

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Lauren is an Infection Preventionist with a background as Registered Nurse. She has a wide variety of healthcare experience having worked in neurology, neurosurgery, ambulatory surgery, home health and with the Nebraska Biocontainment unit. As an IP, her primary focus has been in critical care, oncology, VAE prevention and as the IP to the Nebraska Biocontainment Unit. Her recent work has been spent in a grant funded role to develop innovative tools to aid IPs in rural and remote settings.

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Alisha is an Infection Preventionist and Registered Nurse with 21 years of experience in a variety of healthcare settings including ambulatory, acute care, and surgical areas. Over the past 13 years, she has worked as an Infection Preventionist in outpatient surgery as well as at a large academic medical center. Her recent work has focused on utilizing her IPC expertise to develop infection control tools and resources to assist Infection Preventionists in under-resourced settings.

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- The views and opinions expressed during this webinar are those of the presenters and do not necessarily reflect those of the University of Nebraska Medical Center or The Nebraska Medical Center.

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IPC Program Objectives

- Identify the critical components of effective high-level disinfection and semi-critical device reprocessing practices in healthcare settings.
- Interpret evidence-base guidelines, regulatory requirements, and industry standards to ensure compliance and best practices.
- Implement practical strategies to monitor, audit, and enhance semi-critical device reprocessing within healthcare facilities.
- Evaluate semi-critical reprocessing processes through performance monitoring to identify gaps and drive continuous improvement.
- Synthesize knowledge of semi-critical device reprocessing to develop collaborative approaches, foster accountability, and promote quality infection prevention practices across interdisciplinary teams.

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Spaulding Classification			
Patient Contact	**Device classification**	**Minimum Inactivation Level**	**Examples**
Intact Skin	Non-Critical	Low/Intermediate level disinfectant	Glucometers Wheelchairs Blood Pressure Cuffs Environmental Surfaces ~Bedrails, Call light, door handles
Non-intact skin or mucous membranes	Semi-critical	High-level disinfection	Endoscopes, speculums, laryngoscopes, respiratory therapy equipment, anesthesia equipment, etc.
Sterile areas of the body, including bloodstream	Critical	Sterilization	Surgical instruments, IV cannula

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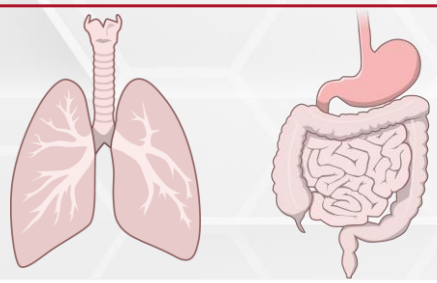
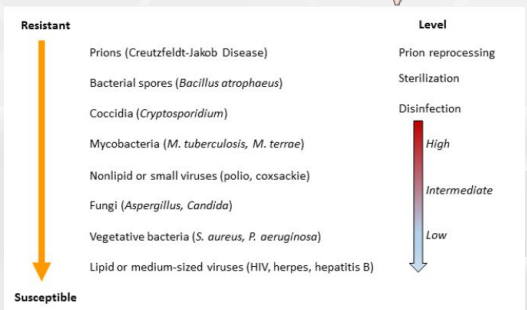
Semi-Critical Devices & HLD

- Semi-Critical Devices:
  - Objects that touch mucous membranes or non-intact skin
  - e.g., lungs, gastrointestinal tract, urinary tract
- Transmission occurs via contact
- Requires High-Level Disinfection at a minimum
  - Kills ALL microorganisms BUT allows for small numbers of bacterial spores





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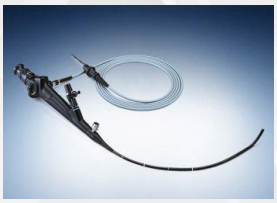
Semi-Critical Devices & HLD

Common Semi-Critical Devices:

- Endoscopes
- Laryngoscopes
- Bronchoscopes
- Specula
- Esophageal manometry probes
- Some ultrasound Probes
- Endocavitary Probes (rectal/ vaginal)
- Cystoscopes
- Anorectal manometry catheters
- Diaphragm fitting rings
- Tonometer
- Cryosurgical Instruments
- Some Respiratory Therapy Equipment
- Anesthesia machine circuits
- Dermatology Instruments



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Challenges with Spaulding

- Per Spaulding, objects should be disinfected depending on the intended use
- Not all devices fit perfectly into Spaulding Classification *(e.g., oral thermometers with probe cover)*
- Concern for high-risk devices *(e.g., closed-channel duodenoscopes)*
  - Complex design/ Design flaws
  - Inadequate safety margins
  - Conversations to shift from disinfection to sterilization *(Rutula, Weber. Gastrointestinal Endoscopes: A Need to Shift from Disinfection to Sterilization)*
- Emerging Pathogens/ increased chemical resistance

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Why We Care

- High-Risk
  - Complex Devices & Processes
- Numerous cases of transmission & outbreaks associated with semi-critical devices
- Regulation & Accreditation
  - U.S. Food and Drug Administration (FDA)
  - Centers for Medicare and Medicaid (CMS)
  - Centers for Disease Control and Prevention
  - The Joint Commission
    - Top cited clinic standard *Previously IC 02.01.01 EP2 → Now IC 04.01.01 EP4*


'Superbug' linked to 2 deaths at UCLA hospital

Doug Stanglin, USA TODAY 11:09 a.m. EST February 19, 2015

CBS NEWS / January 22, 2015, 12:29 PM

Deadly superbug infected patients at Seattle hospital

Scope disinfection failure suspected in superbug cluster, leads UPMC to alter methods

Superbug outbreak extends to Cedars-Sinai hospital, linked to scope

281 Hartford Hospital Patients Exposed to Drug-Resistant E. Coli

Medical scope now tied to Wisconsin outbreak

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FDA/CDC Health Alert- Sept. 2015

IMMEDIATE Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Equipment

- Due to Infection control lapses with non-compliance with reprocessing procedures
  - Failures to follow Manufacturer Instructions for Use (MIFU)
- Recommendations for Healthcare Facilities:
  - Review Procedures for cleaning, disinfection & sterilization
  - Review training
  - Audit and feedback
  - Infection Control Policies & Procedures

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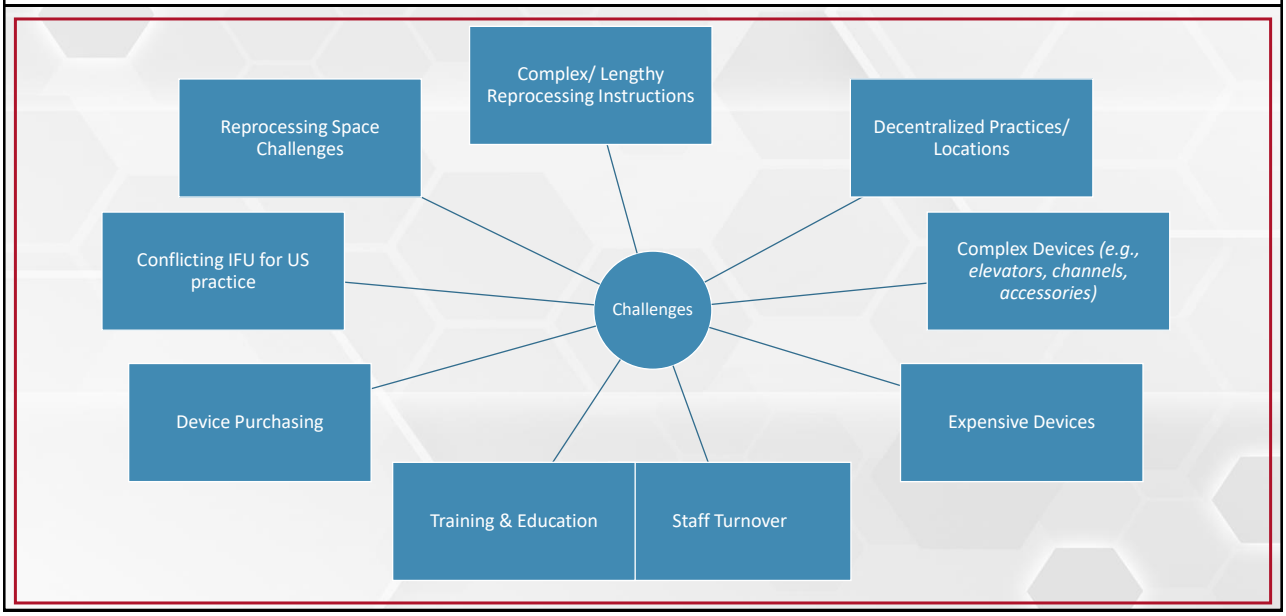
Common Challenges



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IPC Preparation & Process

Prepare
- Policies & Procedures
- Guidelines/ Standards
- Devices/ Products in Use
- Manufacturer Instructions for Use

Monitor
- HLD
- PPE
- Environment of Care

Evaluate
- Data
- Trends/ Gaps
- Education

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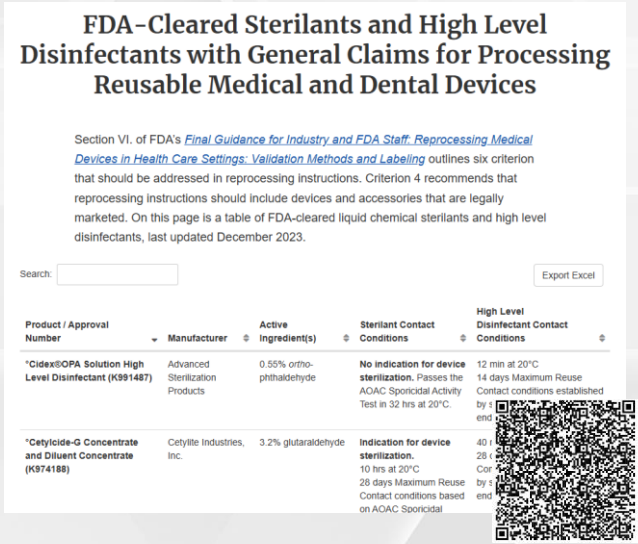
Common HLD Disinfectants

- Glutaraldehyde
- Glutaraldehyde with phenol-phenate
- Hydrogen peroxide
- Sodium hypochlorite- hypochlorous acid
- Ortho-phthalaldehyde (opa)
- Combinations of peracetic acid

Emerging Products
- ULT Wipes (Chlorine dioxide)

Key Points:
- Access to IFUs & SDS
- Dilution
- Concentration
- Duration
- Temperature
- Handling requirements (e.g., PPE)



FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices

Section VI. of FDA's *Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* outlines six criterion that should be addressed in reprocessing instructions. Criterion 4 recommends that reprocessing instructions should include devices and accessories that are legally marketed. On this page is a table of FDA-cleared liquid chemical sterilants and high level disinfectants, last updated December 2023.

Search:

Export Excel

Product / Approval Number	Manufacturer	Active Ingredient(s)	Sterilant Contact Conditions	High Level Disinfectant Contact Conditions
*Cidex®OPA Solution High Level Disinfectant (K991487)	Advanced Sterilization Products	0.55% *ortho*-phthaldehyde	**No indication for device sterilization.** Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C.	12 min at 20°C 14 days Maximum Reuse Contact conditions established by
*Cetylcide-G Concentrate and Diluent Concentrate (K974188)	Cetylite Industries, Inc.	3.2% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal	40 28 Cor by

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Environment of Care

- Space Configuration
- Space Function
- Workflow
- Ventilation
- Engineering Controls
- Environmental Surfaces
- Reprocessing Equipment
- Waste Management
- Clean Storage

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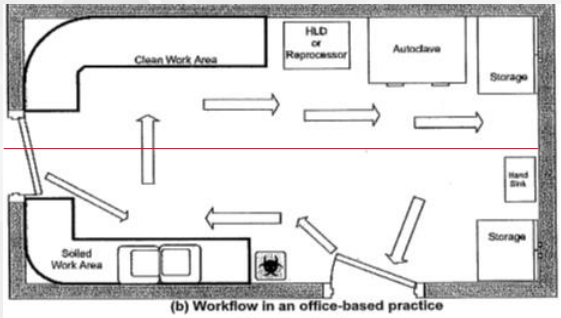
Workstation Design

Ideal Room Set Up

- Dirty to clean workflow *(unidirectional)*
- Clear separation of clean and dirty *(Ideally 2 rooms)*
- 2 Sinks (or 1 sink with divider)
  - *Plus sink dedicated for hand hygiene alone*
- Readily available PPE

Partner with Safety Department:

- Ventilation supportive of chemicals used *(e.g., glutaraldehyde, OPA)*
- Eyewash station within 10 second travel from chemicals
- Spill kits readily available
- SDS & IFUs readily available to staff



(b) Workflow in an office-based practice

Figure 2—Workflow

Common Challenges

- Small spaces
- Workflow
- Cross-contamination during reprocessing
- Complex reprocessing requirements

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Personal Protective Equipment

Minimum PPE required to safely perform HLD includes:

- ✓ Fluid-resistant face mask
- ✓ Eye protection *(full-length face shields or goggles)*
- ✓ Disposable procedure gloves
- ✓ Fluid-resistant gowns
- ✓ Shoe covers

*Additional PPE may be recommended on the Chemical Safety Data Sheet provided by the manufacturer *(e.g., aprons, gowns with thumb loops, etc.)*

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Performance Monitoring

Process Monitoring:
- Environment of Care
- PPE Use
- Sharps Safety
- HLD Device & Chemical Processes in accordance with IFUs
- Device Storage
- Device Transport *(to and from point of use)*
- Documentation

CDC ICAR Tool

CDC QUOTs

HICPAC Flexible Endoscope Rounding Tool

Education & Training
- Evaluate competency training and education, frequency, who provides education, etc.

Quality Monitoring
- ATP, cultures, etc.

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HLD Overview

Procedure room	**Pre-Clean**	Remove visible soil (at point of use) Reduce bioburden
Reprocessing room	**Transport**	From point of care to reprocessing area OSHA approved and labeled container
	Leak Test	Wet or dry Before cleaning
	Clean	2 sinks Enzymatic solution
	Inspection	Lighted magnification Soil marker tests (optional)
	Disinfection	Manual, automated
	Rinse	Remove debris and chemicals
Drying and storage area	**Drying & Storage**	Thoroughly dry Protect from contamination
	Validation Monitoring	Culturing protocols Audit and feedback
	Transport & Patient Use	Aseptic Transport

MIFU

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Pre-Cleaning

Purpose
- Removes bioburden and gross debris
- Prevents biofilm formation
- Keep device moist

What the IP needs to remember
- Completed at the **point of use**
  - ➢ BEFORE manual cleaning

What is your facility's process for making sure pre-cleaning occurs?

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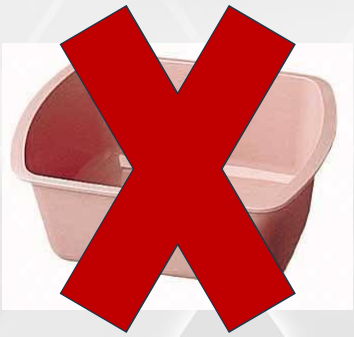
Transport

Transport from point of use directly to the decontamination room OSHA compliant:
- Closeable
- Constructed to contain/protect all contents and prevent leakage of fluids
- Labeled as biohazard
- Transported promptly



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Leak Testing

Purpose:

- Detect damage to internal and external components
- Prevent fluids from exacerbating the damage

What the IP needs to remember:

- As soon as possible after arrival to decontamination area
- Dry leak test: before immersion
- Wet leak test: water only
- Minimally coiled scope

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Leak Testing

Typical leak testing procedure

1. **Test leak tester**
2. **Dry leak test**
   - *Pressurize leak tester to prescribed amount*
   - *Monitor for fall in pressure*
   - *Deflate leak tester*
3. **Wet leak test**
   1. *Pressurize leak tester to prescribed amount*
   2. *Immerse endoscope into clean water*
   3. *Articulate the endoscope*
   4. *Flush channels if applicable*
   5. *Observe for continuous bubbles*
   6. *Remove from water*
   7. *Depressurize*

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Cleaning

Pre-Clean → Transport → Leak test → **Clean** → High Level disinfect

Purpose:
Removes all foreign matter- so disinfectant can touch the surface
- Internal and external components

Things for the IP to remember
- Within prescribed timeframe
- Enzymatic Cleaner/ Solution
  - Dilution
  - Temperature
- Correct size of brushes- *single use is preferred*
- Immerse while cleaning
- Each step is important

MIFU

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Manual Cleaning

- ✓ Not a disinfectant!
- ✓ Temperature
- ✓ Soak time
- ✓ Dilution
- ✓ Measurement

MIFU

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Cleaning Verification and Inspection

Required:

Visual inspection

- Optimal lighting
- Magnification
  - Damage- cracks or tears
  - Debris

Borescopes- still controversial

Recommended if feasible:

- Cleaning Verification Testing
  - ATP testing
  - Protein, carbohydrate, hemoglobin

- Identify what you will test
- Identify where you will test
- Define a “pass” or “fail”
- Define process for a fail
- Document the pass or fail

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Manual Cleaning

Prepare solution

- Correct dilution
- Correct temperature
- Correct contact time

Completely submerge

- Prevent aerosolization and splashing

Remove debris by Wipe and brush the scope per IFU

- Wipe exterior with a clean compatible sponge or lint-free cloth,
- Brush the distal end of the endoscope using a brush of an appropriate length, width, and/or material;
- Flush, brush, and aspirate any ports, valves, and channels
- Remove debris from the brush with each passage through the channels and continue to brush until clean
- Articulate all the endoscope features
- Clean reusable accessories

Discard the detergent and other disposable items

Rinse with utility or tap water based on the IFU

- interior channels, exterior surface, and endoscope accessories;

Purge the channels with air to remove water

Dry the exterior with a new lint-free cloth

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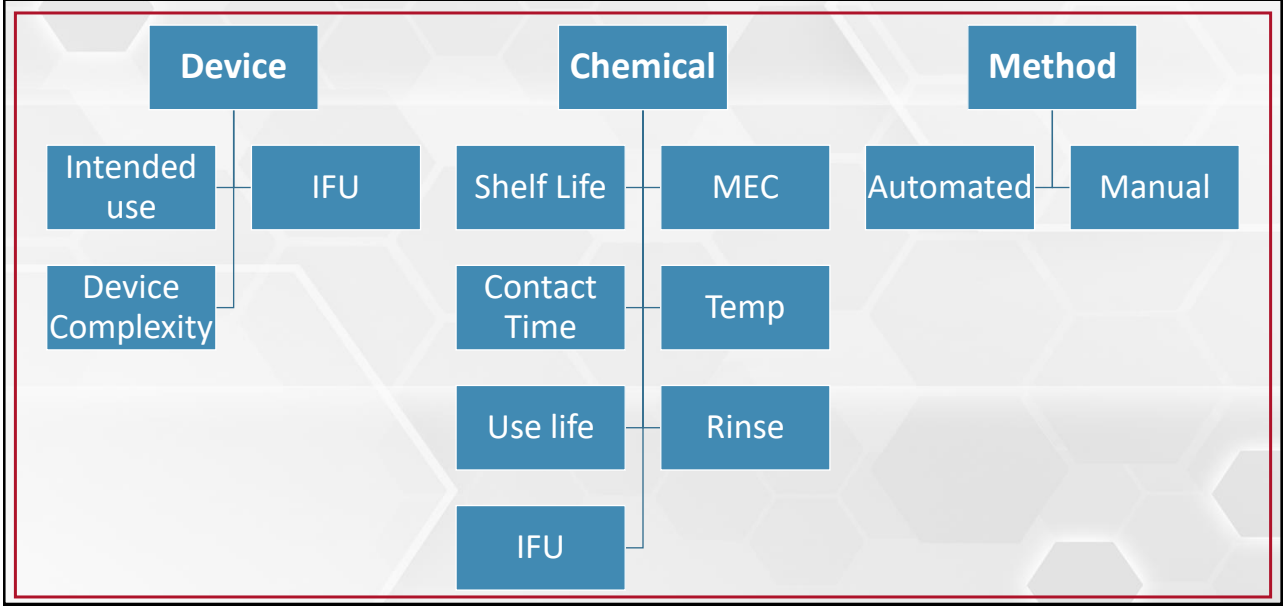
High Level Disinfection



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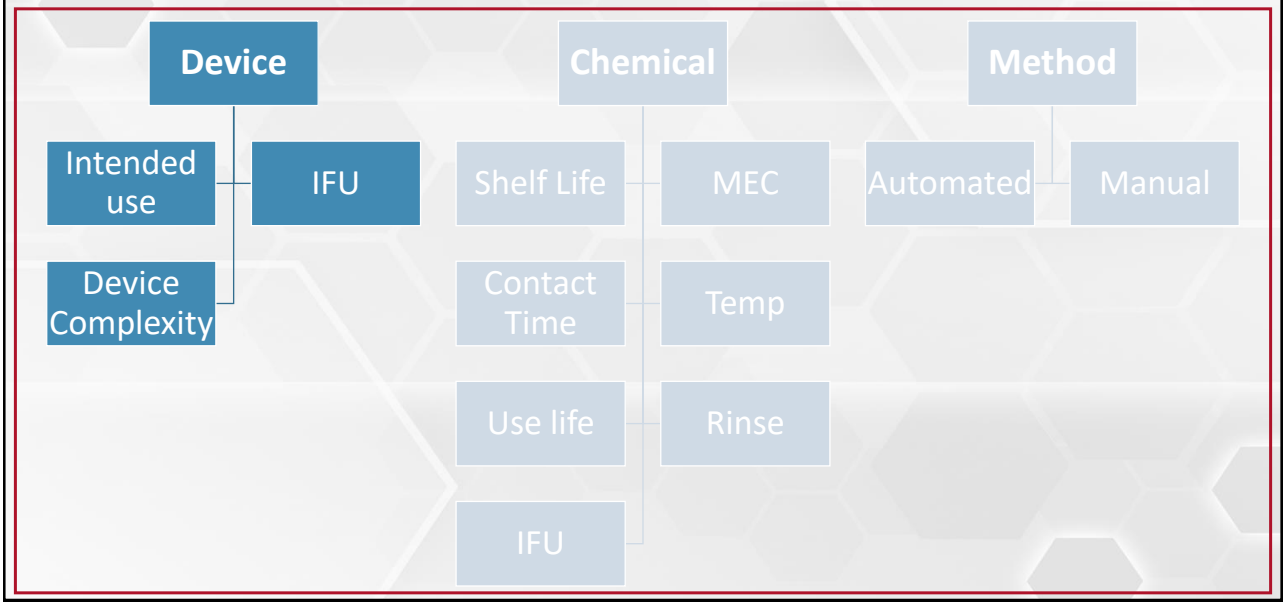
High Level Disinfection



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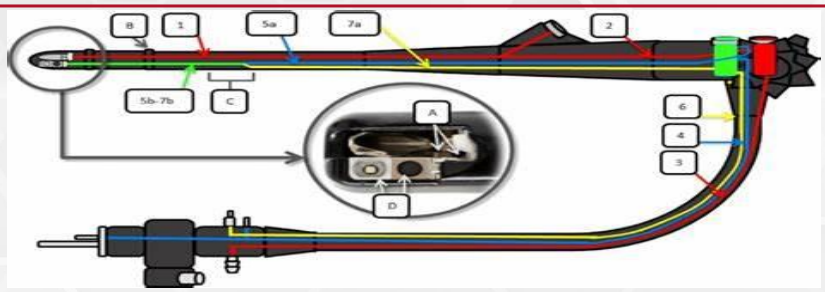
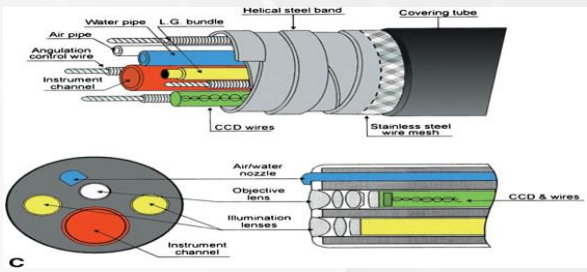
Device Complexity





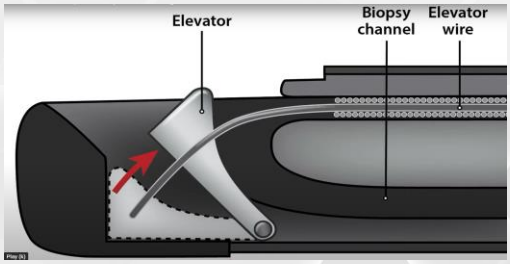


Image from researchgate.net Schematic duodenoscope channel segments (numbers): (1) Instrument... | Download Scientific Diagram

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High Level Disinfection

- **Device**
  - Intended use
  - IFU
  - Device Complexity
- **Chemical**
  - Shelf Life
  - MEC
  - Contact Time
  - Temp
  - Use life
  - Rinse
  - IFU
- **Method**
  - Automated
  - Manual

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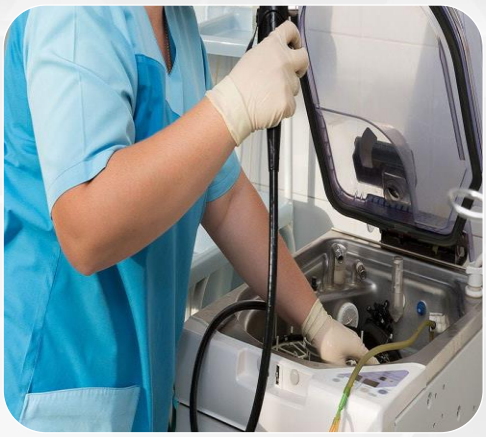
Methods- Automated



Benefits

- Validated settings and process
- Reduce chance of human error
- Many choices available

Drawbacks

- Not compatible with all devices
- $$$
- Require proper hook ups
- Ongoing maintenance
- Still need back up processes incase of

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Methods- Manual

Common Errors

- Improper container labeling
- Inadequate contact time
- Improper temperature control
- Incorrect device tracking
- Missing chemical lot number
- Failure to maintain MEC
- Inadequate rinsing
- Poor drying practices
- Failure to follow IFU
- Lack of training and competency

Benefits

- Repeatable
- Staff understand process

Drawbacks

- Risk for failure
- Steep learning curve
- Increased contact with chemicals and BBP

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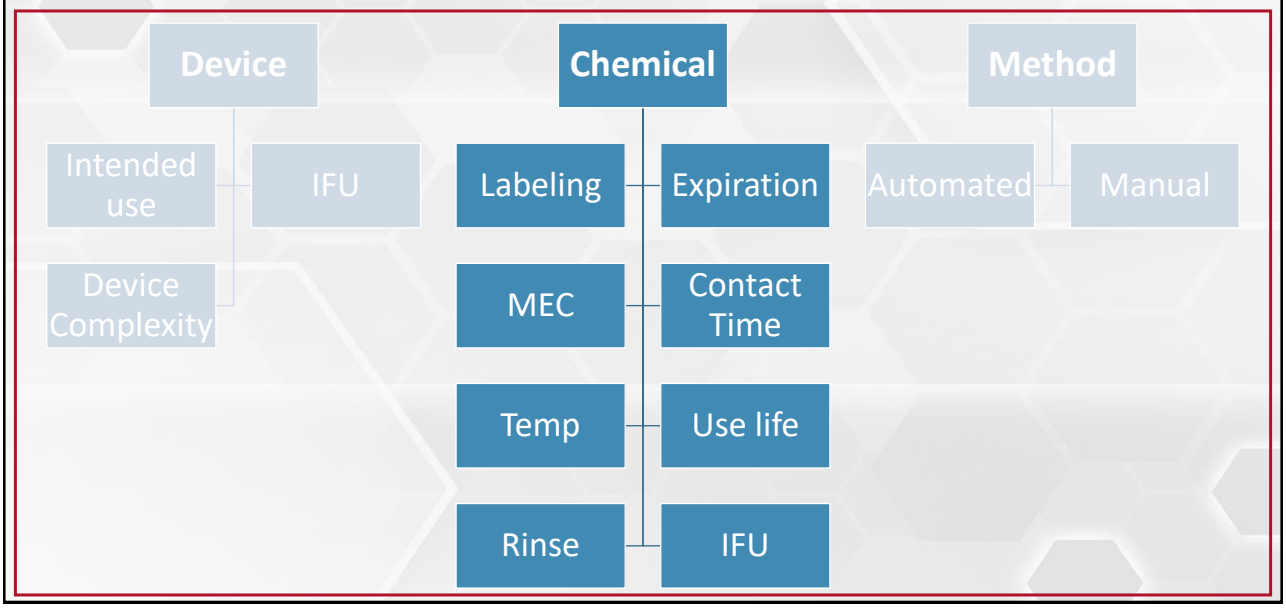
High Level Disinfection



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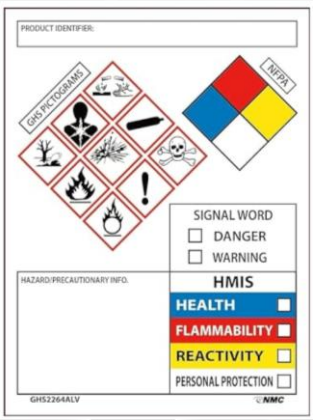
High Level Disinfection

****OSHA requirements: Hazard warnings, chemical identity****



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Expiration Dates

Know your expiration dates!

Opened Chemical	Unopened bottles and chemicals	Test Strips
• Label container with pour/ activation date and discard date • Test before each use • Discard earlier if needed	• Ensure expiration date is not beyond use date	• Label bottle with open date and expiration date • Store away from moisture, heat, light • Close cap • Discard earlier if needed

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Chemical

Disinfectant	Use life
Ortho-phthalaldehyde (OPA)	14 days
Hydrogen peroxide	21 days
Glutaraldehyde	Up to 28 days
Peracetic acid	Single-use only
Chlorine	Variable`

May

Date Opened	Cidex Discard Date +13 days	Test Strip discard date +89 days
5/1/2024	5/14/2024	7/29/2024
5/2/2024	5/15/2024	7/30/2024
5/3/2024	5/16/2024	7/31/2024
5/4/2024	5/17/2024	8/1/2024
5/5/2024	5/18/2024	8/2/2024
5/6/2024	5/19/2024	8/3/2024
5/7/2024	5/20/2024	8/4/2024
5/8/2024	5/21/2024	8/5/2024
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5/29/2024	6/11/2024	8/26/2024
5/30/2024	6/12/2024	8/27/2024
5/31/2024	6/13/2024	8/28/2024

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Chemical

Disinfectant	Contact time	Temperature	Use life
Ortho-phthalaldehyde (OPA)	12 minutes	20–25°C	14 days
Hydrogen peroxide	8-30 minutes (varies)	20–25°C	
Glutaraldehyde	20-90 minutes	20–25°C	Up to 28 days
Peracetic acid	~12 minutes	50–56°C (in AERs)	Single-use only
Chlorine	10-30 minutes (varies)	20–25°C	

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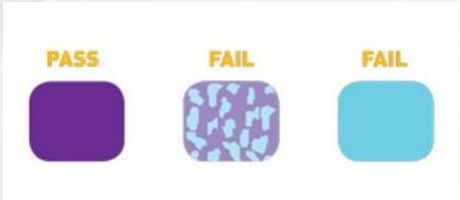
Quality Control Testing

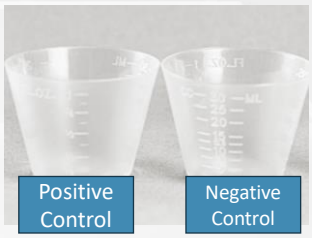
Quality control (QC) testing strips

- Verify the minimum effective concentration (MEC)

Test the test strips
- ✓ When opened
- ✓ Periodically

Test the chemical
- ✓ With each use





Test strips opened: 1/1/2025
90-day shelf life: 3/31/2025
Bottle expiration date: 3/8/2025

MIFU

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High Level Disinfection

1. Ensure the device is clean
2. Ensure device is dry
3. Check solution temperature
4. Test the MEC
5. Validate expiration dates
6. Submerge the device
7. Fill all channels, lumens
8. Close lid
9. Set timer

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Final Rinse

Purpose:
Removes chemical residual

Aseptic technique

- Fresh PPE

Verify

- Type of water needed for each rinse
  - Often critical
- Time for each rinse
- Amount of water required for each rinse (2 gallons)
- Number of required rinses
- Channels or lumens

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Drying

Purpose

Avoid moisture in scope channels to prevent microbial growth and biofilm formation.

Interior	• Instrument air or HEPA-filtered air-filtered air that is free of contaminants
Exterior	• Dry with clean, lint-free cloth.
Accessories	• Dry with clean, lint-free cloth.
Recommendations may include	• Alcohol rinse • Forced air through lumens and channels

MIFU

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Storage

Purpose

Protect from damage

Protects from contamination

Requirements

- Store in a manner that protects from damage or contamination
- Hang straight
- No kinks or coiling
- No contact with other devices
- No contact with cabinet walls/floor
- Distal tip hanging freely
- Cabinet clean
- Follow policy on length of time
- Restricted, clean area that promotes unidirectional flow
- Closed cabinet
- Labeled with reprocessing date and initials

Considerations

- Vertical or horizontal
- Bronchoscopes stored with GI scopes
- HEPA filtration
- Forced air through channels
- Hang time

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Documentation

Test Strip	Solution	Device	HLD Details	Storage	Maintenance
• Test strip lot number • Expiration date • Result of test strip QC	• Date opened • Expiration • Lot number • Date tested • Test pass/fail	• Device identifier	• Date and time • Person performing • Chemical used • MEC pass/fail • Solution temp • Exposure time	• Scope tagging	• Daily/routine maintenance • Calibration records • Temperature logs

WARNING: IFUs FOR DEVICE, DISINFECTANT, AND TEST STRIPS MUST BE FOLLOWED

Test strip bottle first opend:		Do not use test strips after this date:		
Test strip QC date:		QC test performed by:		
QC test results: Negative ____ ____ ____ Positive: ____ ____ ____			Test strip bottle lot #:	
Solution opened Date	Solution test Date: Time:	Device identificaiton	Date of HLD	Patient identifier
Solution expires Date	Pass / Fail	Temp / Exposure time	Time of HLD	
Solution lot number:			Initials of Reprocesor:	

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IP Role in Device Reprocessing

Policy & Procedure	• Partner with reprocessing personnel and other relevant departments to develop and update device reprocessing policies and procedures for device reprocessing • Ensure policies and procedures address semi-critical devices
Education & Training	• Ensure staff training is sufficient for healthcare workers on HLD procedures and protocols • Ensure teams provide staff education with updated IFUs and as new products come into the facility
Surveillance & Reporting	• Collect and analyze HLD data • Monitor for lab and process trends that may indicate lapses in practice • Provide data to relevant committees
Performance Monitoring & Evaluation	• Audit HLD practices and provide feedback to staff • Monitor processes *(e.g., adherence to standards and manufacturer IFUs)* for semi-critical device reprocessing

Communication & Collaboration	• Collaborate with reprocessing personnel and teams
	• Collaborate with device and product vendors
	• Utilize bi-directional communication to ensure:
	  • The IPC program is updated when new products are being introduced to the facility
	  • The IPC program shares important and relevant infection prevention information back with the reprocessing teams

Product Selection & Evaluation	• Partner with the value analysis team and relevant stakeholders to review products, devices, and their reprocessing instructions for implementation at the facility • Attempt product standardization throughout the facility

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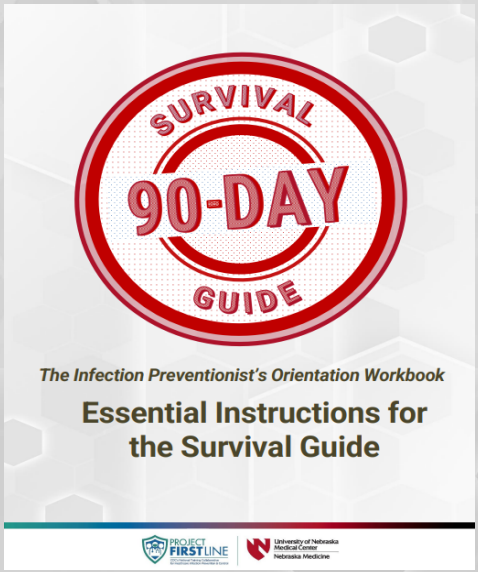
NEW RESOURCE ALERT!



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Join Us Next Time:

Office Hours

June 19th, 2025
12-1pm CST

Next Webinar: Critical Device Reprocessing

July 17th, 2025

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Questions

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References

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Resources

SGNA HLD Guidelines	https://www.sgna.org/portals/0/hld__final.pdf
The Science Behind Endoscope Reprocessing (APIC)	The Science Behind Endoscope Reprocessing
Centers for Disease Control and Prevention. Summary of Recommendations: Disinfection and Sterilization in Healthcare Facilities	https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html
Multisociety guidance for sterilization and high-level disinfection.	Multisociety guidance for sterilization and high-level disinfection | Infection Control & Hospital Epidemiology | Cambridge Core
Multisociety guidance for sterilization and high-level disinfection supplementary material	S0899823X25000418sup001.pdf
HICPAC HLD Sample Audit Tool	FlexEndoReprocessing-AuditTool.pdf

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Office Hours

- If you have a questions
  - Raise hand and our admin will take you off mute

    OR
  - Enter your question into the chat

- If you have additional questions that are not answered, you can email us at ***infoforipslice@nebraskamed.com***

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