

# Instrument Reprocessing: High-level Disinfection and Sterilization in Outpatient Settings

## Module 4 High-level Disinfection

Judie Bringhurst MSN RN CIC

# Objectives

- Learn the rationale for High Level Disinfection (HLD).
  - Why can't we just wipe these devices off with a SaniCloth®?
- Learn technique for checking minimum effective concentrations.
  - For before each use testing of the chemical and test strip QC.
- Understand the importance of and your responsibility for performing HLD correctly.
  - Our liability as a healthcare system and as healthcare personnel.

# Caveats: Today's training is NOT

- *Everything* you need to know about HLD.
  - Special equipment, machines, and environments require specialized training onsite.
- All you'll EVER need to know...
  - New research is revealing new information about certain pathogens and certain endoscopes.

# Competency

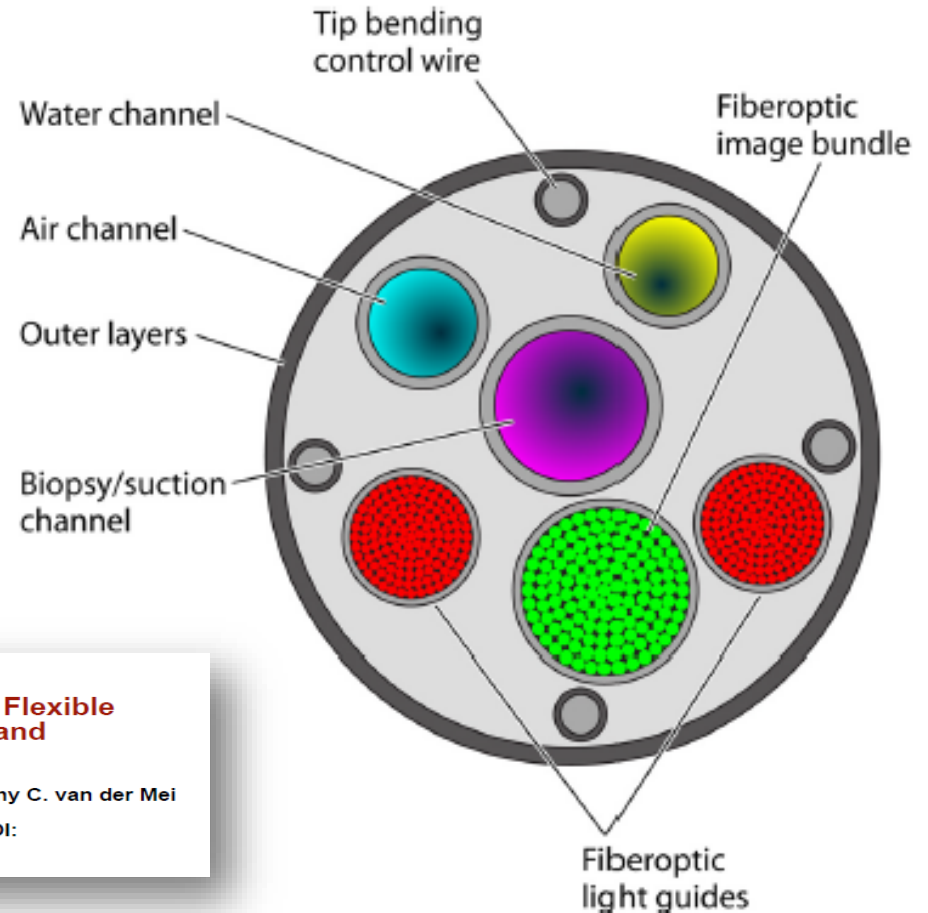
- Four elements to competency:
  1. Training
    - HLD workshop, practice at your site with a competent person
  2. Demonstration
    - You can perform HLD with no assistance
  3. Observation
    - Competent person observes your entire process
  4. Documentation
    - Competent person completes your competency form

# Competency

- HLD Competency frequency:
  - Staff should perform three elements of competency at least every 365 days:
    1. Demonstration
      - You can perform HLD with no assistance
    2. Observation
      - Competent person observes your entire process
    3. Documentation
      - Competent person completes your competency form

# Inherent complexity of the equipment

Kovaleva et al.



Clinical Microbiology  
Reviews

## Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy

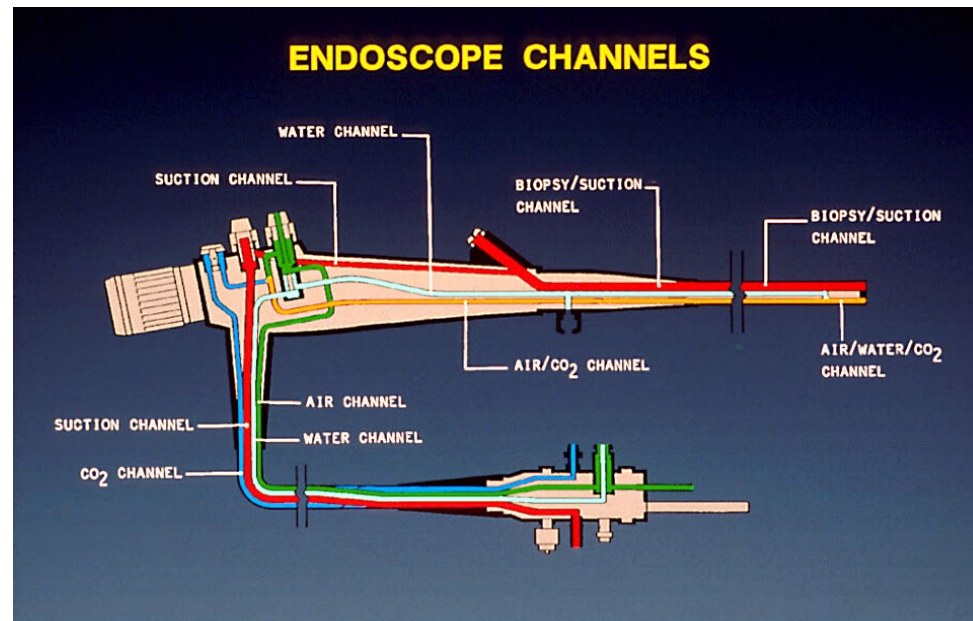
Julia Kovaleva, Frans T. M. Peters, Henny C. van der Mei  
and John E. Degener  
*Clin. Microbiol. Rev.* 2013, 26(2):231. DOI:  
10.1128/CMR.00085-12.

FIG 1 Schematic drawing of a cross section of a flexible endoscope showing the complex design and multiple internal channels (inner diameter, 2.8 to 3.8 mm).

# A predisposition for disinfection failures

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Heat labile
- Long, narrow lumens
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens,  $10^{7-10}$
- Cleaning (4-6  $\log_{10}$  reduction) and HLD (4-6  $\log_{10}$  reduction) essential for patient safe instrument



# Instructions for use (IFU) complexity (human factors)

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# Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know

**William A. Rutala and David J. Weber**

Hospital Epidemiology, University of North Carolina Health Care System, and Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill

702 • CID 2004:39 (1 September) • HEALTHCARE EPIDEMIOLOGY

High level disinfection and sterilization processes that fail to comply with scientifically-based guidelines lead to outbreaks of infection.

Rutala & Weber

# For example...

- 2000 – 2012: Bronchoscopes\* only:
  - 25 Outbreaks and pseudo-outbreaks in the lit
  - 82 infections
  - 4 deaths

\*semi-critical device

# Health Care Personnel Accountability

- We are accountable for these processes
  - Be conscientious
- Patients trust us to do this FOR THEM correctly
- Demands for rapid instrument turn-around should be reported to your supervisor.
  - Speak up if you believe there is an issue that could impact patient safety
  - Infection control will lend support
- Anything less can lead to an infection
- Medico-legal ramifications
  - Publicity
  - Legal: beyond civil suits
    - Some terminating in murder charges
      - New England Compounding Company

# Resources

20 million GI endoscopic procedures annually

In a large review, 281 instances of pathogen transmission were attributed to GI endoscopy

*In each instance, transmission was associated with breaches in accepted cleaning and disinfection guidelines*



*Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2016*



AGA INSTITUTE



## Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update



Prepared by: REPROCESSING GUIDELINE TASK FORCE

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This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

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0016-5107/\$36.00  
<http://dx.doi.org/10.1016/j.gie.2016.10.002>

# CMS: Infection Control Worksheet

Two multi-page documents specifically for inspecting infection prevention practices in acute care and ambulatory surgical facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-43-ASC

DATE: June 26, 2015

TO: State Survey Agency Directors

FROM: Director  
Survey and Certification Group

SUBJECT: Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)

### Memorandum Summary

- **ASC Infection Control Surveyor Worksheet Revisions:** The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CfC).
- **Change:** Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in

HIGH-LEVEL DISINFECTION		
Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Semi-critical equipment is high-level disinfected or sterilized	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
B. Is high-level disinfection performed on site? (If NO, Skip to "F")	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)		
(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)		
a. If answer to B was YES, please indicate method of high-level disinfection:	<input type="radio"/> Manual <input type="radio"/> Automated <input type="radio"/> Other (please specify):	
C. Items are pre-cleaned according to manufacturer's instructions or, if the manufacturer does not provide instructions, evidence-based guidelines prior to high-level disinfection	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	

# High-Level Disinfection (HLD) and Sterilization BoosterPak



June, 2017

Updated June 2017



## HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

**Purpose:** Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.”

**Auditor:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Audit Item	Yes	No	Comments/Action
<b>Precleaning</b>			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
<b>Transporting</b>			

## HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes

**Purpose:** Facilities can use this sample Competency Verification Tool as a template to develop their own tool to assess the competency of personnel tasked with processing all types of reusable flexible endoscopes and accessories. This sample tool is designed to be used in conjunction with the Audit Tool. Facilities are encouraged to use the tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.”

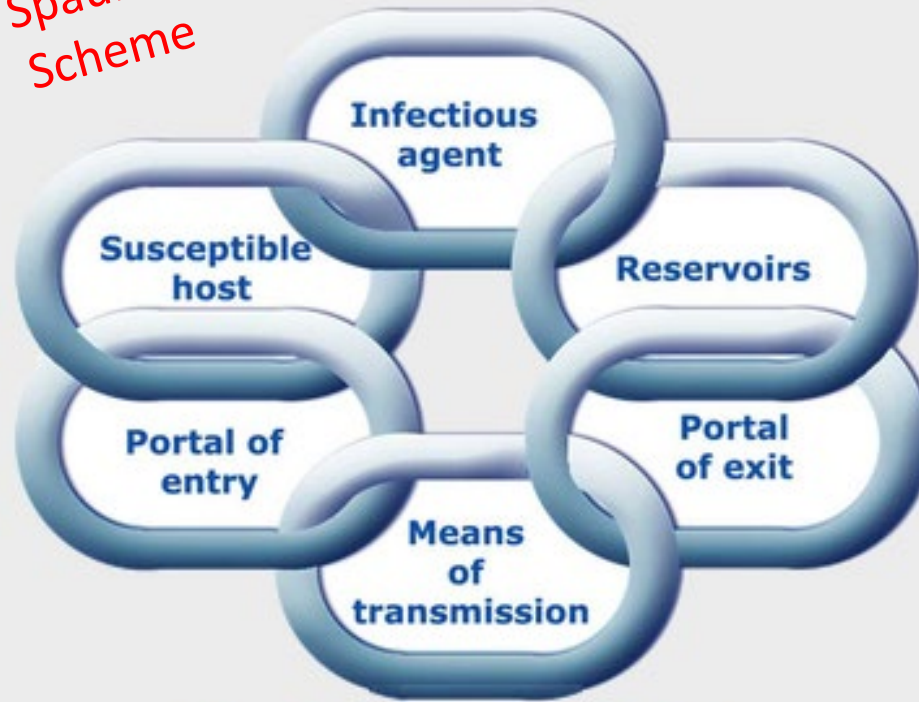
**Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

DEM = Demonstration      S = Skills Laboratory      RWM = Review of Written or Visual Materials/Policy      V = Verbalization  
 DO = Direct Observation      SBT = Scenario-based Training      P&P = Procedure Review (Specify P&P #s \_\_\_\_\_)      O = Other: \_\_\_\_\_  
 DA = Documentation Audit      CS = Controlled Simulation      KAT = Knowledge Assessment Test

Competency Statements/Performance Criteria	Verification Method [See legend above]	Not Met [Explain why]
<p><b>Precleaning</b></p> <p>1. Precleans flexible endoscopes and accessories at the point of use as soon as possible after the endoscope has been removed from the patient (or the procedure is completed) and before organic material has dried on the surface or in the channels of the endoscope.</p>	<input type="checkbox"/> DEM <input type="checkbox"/> S <input type="checkbox"/> RWM <input type="checkbox"/> V <input type="checkbox"/> DO <input type="checkbox"/> SBT <input type="checkbox"/> P&P <input type="checkbox"/> Other <input type="checkbox"/> DA <input type="checkbox"/> CS <input type="checkbox"/> KAT	

# Understanding Transmission

See Module 2: Spaulding Classification Scheme



**Chain of Infection**

# Devices and Validation

All devices that are reprocessed must be:

- Validated by device manufacturer
- Validated by the manufacturer of the AER
- Is the sterilizer or AER validated to be efficacious with those lumens?
  - Length, diameter play a role
  - Are there hookups or adapters that must be used to perfuse lumens?
  - Are the correct hookups in use?

# The Seven Steps of High-Level Disinfection

1. Don PPE

2. Decontaminate

3. Rinse and Dry

4. Quality control checks

5. High Level Disinfect

6. Timing soak and rinse

7. Documentation and storage

## Steps for High Level Disinfection of Equipment Using Glutaraldehyde or OPA

### Step 1

Put on PPE: extended cuff nitrile gloves, fluid-resistant gown, eye protection, face shield

### Step 2

Clean the item to be disinfected of all soil/debris using hospital-approved enzymatic detergent per manufacturer's recommendations. Pay special attention to instruments with lumens or other hard-to-reach places.

### Step 3

Rinse the item under running tap water and dry completely. Continue to pay special attention to scopes and other instruments with lumens or hard-to-reach places.

### Step 4

Perform Quality Control checks on test strips and solution according to test strip manufacturer's instructions and UNCH Infection Control policy.

### Step 5

Put the item in the disinfectant chemical, making sure it is completely covered by the solution (completely submerged). Make sure that all channels and lumens are filled with the disinfectant.

### Step 6

After appropriate time has passed, remove the item from the solution and rinse well with water according to UNCH Infection Control policy, flushing all lumens and channels very well. If disinfecting a scope, water rinse must be followed by an alcohol rinse and scope must then be thoroughly dried, using medical-grade forced air for all lumens.

### Step 7

Perform thorough documentation of cleaning/disinfection procedure on recommended and appropriate log(s). Store equipment in manner that will not re-contaminate, in accordance with UNCH policy and manufacturer's recommendations.

**CRITICAL STEP:** Debris or dried-on/stuck-on tissue or fluids that are not cleaned off before disinfection will cause a failure in the disinfection process. These failures can cause infections.

**CRITICAL INFORMATION:**  
OPA: soak for twelve (12) minutes  
Glutaraldehyde: soak for twenty (20) minutes

# The Role of PPE - Personal Protective Equipment

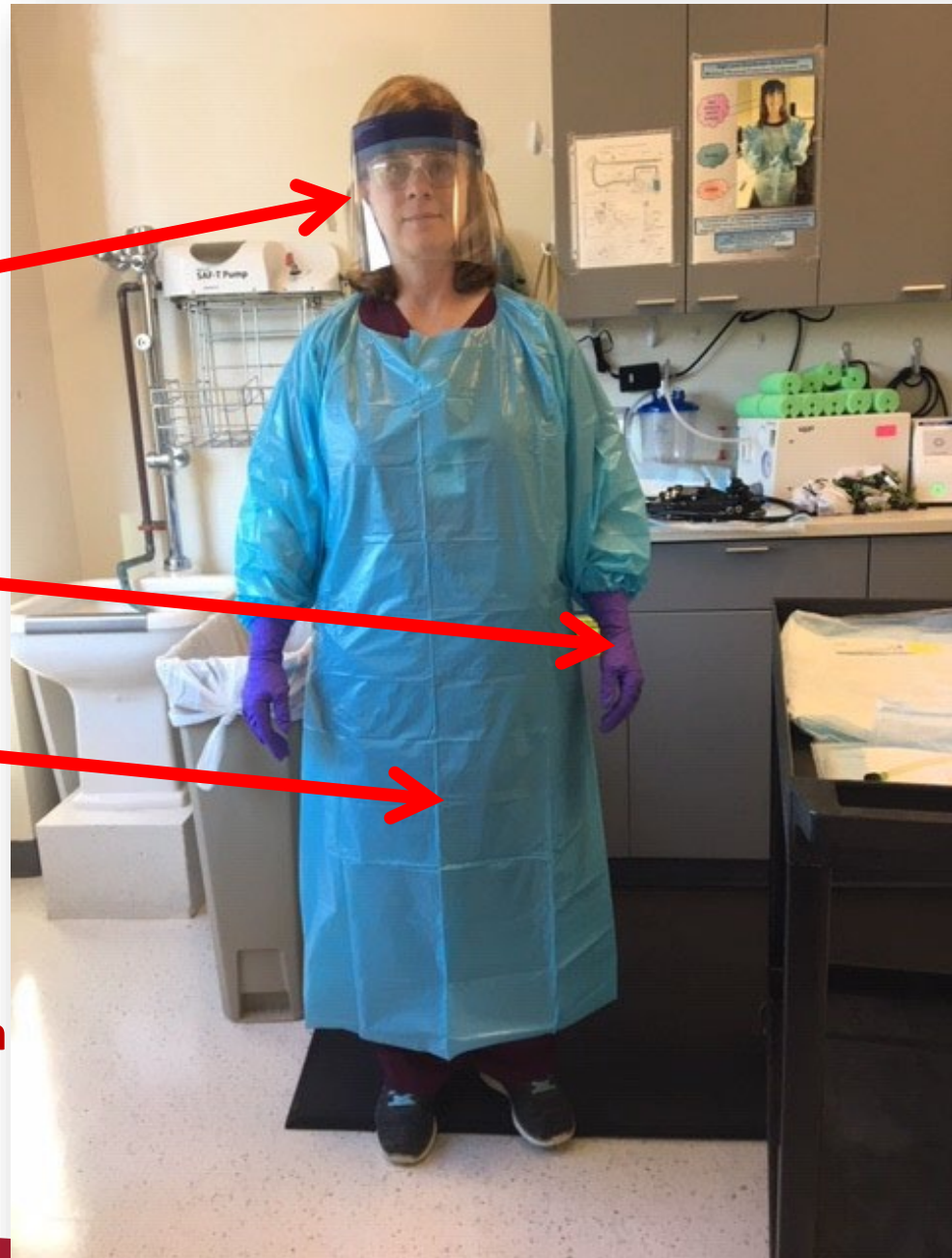
Face shield  
AND safety  
glasses

Extended cuff  
(12") gloves

Impervious  
gown

**PPE provides protection  
TO YOU**

**from serious injuries or illnesses which  
result from contact with blood, body  
fluids, & chemicals.**



See Module 3: Decontamination,  
Precleaning, and Transport for critical  
Personal Protective Equipment (PPE)  
information

**\*\*Module 3 also includes information  
regarding the reprocessing  
environment\*\***

# High-level disinfection quality control checks

- Perform Quality Control checks on **test strips and solutions** according to manufacturer's instructions for use (IFUs) and institution Infection Control policy.
- **EVERY** test strip in use today requires testing before each HLD cycle.
- **Critical: read and follow IFUs for every test strip and/or solution**

# Lack of Standardization in the Industry

No Standardization in the  
Instrument Reprocessing Industry





# Enzymatic Detergents - No Standardization

- Different ratios of detergent to H<sub>2</sub>O
- Automated dispensing systems
  - Are they REALLY accurate?
  - Are we checking accuracy?
- Some require certain H<sub>2</sub>O temperatures for efficacy
- All must be precisely measured
- All require specific and different soak times
- None are disinfectants – a risk to staff!!



## HLD Soak Times and Usage: No Standardization

- Most glutaraldehyde is a 20 minute soak time (unheated) (per CDC guideline)
- Revital-ox Resert<sup>®</sup> is an 8 minute soak time
- OPA is a 12 minute soak time
- Rapicide<sup>®</sup> HLD glutaraldehyde is only FDA approved to be used heated in an automated endoscope reprocessor (AER)
- Peracetic acid can only be used as parts A and B in an AER



## Test Strips: No Standardization

Staff should not leave the instrument processing room during wait times

- Cidex® glutaraldehyde strips
  - 75 seconds – pass = purple, fail = orange
- Cidex® OPA strips
  - 90 seconds – pass = purple, fail = teal
- Revital-Ox® strips
  - 60 seconds – pass = dark blue, fail = mottled
- Rapicide® PA strips
  - 30 seconds – pass = black, fail = shade of gray/black



## Device Validation



- Are HLD chemicals validated by device manufacturer?
- Is the device validated by the manufacturer of the HLD chemical?
- Does the device have lumens?
- Is the sterilizer or AER validated to be efficacious with those lumens?
  - Length, diameter play a role
  - Are here hookups or adapters that must be used to perfuse lumens?
  - Are the correct hookups in use?
- Your device manufacturer must supply you with validation documents

# Device/Hook-up Validation

**MEDIVATORS**

**DSD/SSD Hookup Support**

For AER Models: DSD-201, DSD-201LT, DSD-91E  
SSD-102, SSD-102LT, SSD-100  
DSD EDGE

Select the Endoscope...

<b>Manufacturer</b>	<b>Type</b>	<b>Model</b>
Select Scope Manufacturer ▼	Select Scope Type ▼	Select Scope Model ▼

[Retrieve Hookup Info](#) [Enter Endoscope Model Number with Keyboard](#)

---

[Back to MEDIVATORS Support Home](#)

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14605 28th Avenue North Minneapolis, MN 55447 U.S.A.  
Phone: (800) 329-3345, Fax: (763) 553-3387  
[www.medivators.com](http://www.medivators.com)

# Chemical Validation

The screenshot displays the STERIS website interface for the Revital-Ox RESERT High Level Disinfectant Device Compatibility Matrix. The page includes a navigation bar with links for Home, Products, Specialties, Education, Service & Service Parts, Contact Us, and Global Sites. A search bar is located on the right side of the navigation bar. The main content area features the product title, a sub-header for STERIS Device Testing, and a paragraph explaining the purpose of the compatibility matrix. A 'Quick Search' section allows users to search by device model number, and a 'Step-Through Guided Search' section is currently on Step 1, 'Select Manufacturer', with dropdown menus for manufacturer, device name, and model number. A 'NEXT' button is visible at the bottom of the guided search section. An image of the Revital-Ox RESERT High Level Disinfectant bottle is shown on the right side of the page.

**STERIS** Live Chat | Email Alerts Welcome Guest User | Login or Register | My Account | My Cart (0 Items)

Home Products Specialties Education Service & Service Parts Contact Us Global Sites +Q

Products >>> Device Matrix >> Resert > Step 1

## Revital-Ox™ RESERT® High Level Disinfectant Device Compatibility Matrix

**STERIS** Device Testing

The information in the device guide identifies those cleaned, immersible, reusable, semi-critical medical devices and accessories that have been tested to confirm materials compatibility by STERIS' Device Testing Program and/or the device manufacturer with Revital-Ox Resert High Level Disinfectant. The devices shown in the guide are **ONLY** a representation to confirm materials compatibility with a wide range of medical devices. Therefore, not all compatible devices will be listed.

**Revital-Ox™ RESERT® High Level Disinfectant**

Quick Search — Device by Model Number

Enter Model Number

OR

Step-Through Guided Search

**Step 1** Step 2 Step 3

Select Manufacturer

- Aircraft Medical Limited
- Aloka
- B-K Medical
- Boston Scientific
- Care Fusion
- Cogentix Medical
- ConMed
- Custom Ultrasonics
- Devibiss Healthcare
- ESAOTE

Select Device Name

Select Model Number



- Rigid bronchoscopes HLD'd via Steris System 1e by *NON-central sterile* staff with *no training* in HLD
- Bronchoscope manufacturer had not validated these scopes to be safely reprocessed in the Steris System 1e (SS1e) – an automated endoscope reprocessor (AER)
- SS1e manufacturer had not validated these scopes to be safely reprocessed in their AER
- Staff believed their practice was safe...
- “...it’s not a sterile site anyway...”

## Portals of entry



- Routes through which pathogens enter their new host(s)
- Can be sterile tissue
- Can be non-sterile tissue
- To cause an infection, microbes must enter our bodies via a portal
- We have four:
  1. Respiratory tract
  2. GI tract
  3. Urogenital tract
  4. Breaks in the skin or mucous membrane

Remember there are 5 portals of entry on the front of the face



# Techniques

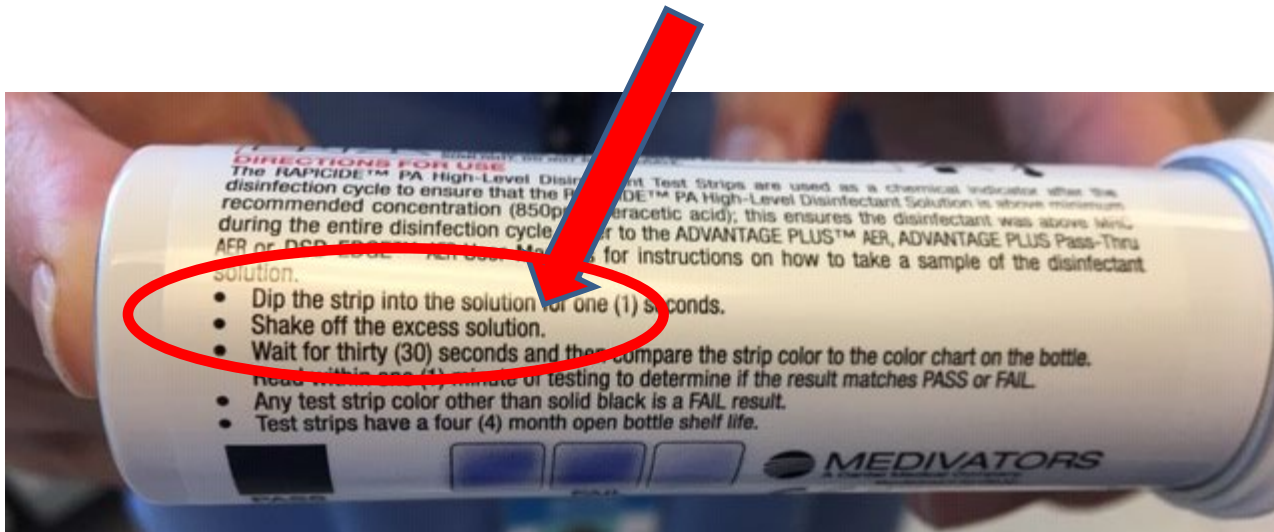
- **Managing test strips**

- Caps completely closed
- Expiration dates clearly marked with felt-tipped pen, NOT ball point
  - Cover writing with clear tape if necessary to conserve the date
- Expiration dates are per and stamped expiration date – **whichever comes first**

- **Dipping your strips**

- Hold straight up and down
- Leave submerged for exactly the length of time indicated in IFUs
- Touch end of strip to prepared paper towel and lay down gently
- **No shaking or flinging strips to get rid of “excess” chemical**
- Set timer and wait, in room, for time indicated by IFUs

**No shaking or flinging strips to get rid of “excess” chemical**



# High-Level Disinfect

## High Level Disinfect

- Follow manufacturer's IFUs for all HLD equipment, accessories, and devices
  - Expiration dates
  - Validation
  - Documentation



## Leak Testing is required for all rubber-coated endoscopes



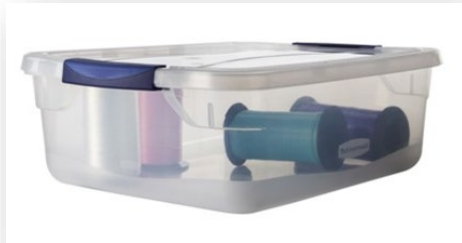
1. The rubber coating can develop cracks, chips, and other leaks.
2. Leak testing must be performed after every use.
3. Leak testing must be done as soon as possible after the endoscope arrives in the processing area and before immersion of the endoscope into processing solutions.
4. Follow the endoscope manufacturer's written IFU for the leak testing protocol.
5. Multiple types of leak testing processes are available and the one selected for use should be followed completely, addressing all steps in the required sequence.
6. Endoscopes that fail their leak test must be removed from use and returned to the manufacturer for repair.

Lumened endoscopes, i.e., nasopharyngeal, cystoscopes, etc., and manual HLD



- Must be completely covered by the disinfectant -- *completely* submerged under the surface of the disinfectant
- All channels and lumens must be filled with the disinfectant
  - Use a syringe and leave syringe attached during soak times

# Containers for Manual HLD



13"x 7"x 5"



20"x 7"x 5"



29"x 8.5"x 5"



8.5"



23"x 15"x 5.5"



# User Stations







# Trophon Competency: 2 pages

## High-Level Disinfection TROPHON

Competency Statement	Valid Verification Methods
<i>Demonstrates high-level disinfection of an ultrasound probe.</i>	<p>Employee must complete the following:</p> <ol style="list-style-type: none"> <li>1. Watch video for appropriate device</li> <li>2. Complete and pass Trophon quiz online</li> <li>3. Complete 1 Return Demonstration</li> </ol>
<p>Criteria:</p> <ul style="list-style-type: none"> <li>• Accurately completes all required steps during competency verification</li> <li>• Passes quiz</li> <li>• Watches video</li> </ul>	
TROPHON RETURN DEMONSTRATION	
Employee Name: _____	Date: _____
Validator Name: _____	
Trophon Model Competency Demonstrated on: Trophon EPR ___ Trophon 2 ___	
<p>Return Demonstration is an excellent verification method for assessing technical skills. To complete this competency, you must complete the following:</p> <p>Watch Video completed on: _____ Pass Test completed on: _____ Return Demonstration completed on: _____</p> <ul style="list-style-type: none"> <li>• A qualified trainer/validator must observe you successfully complete procedure.</li> <li>• 100% of competency must be met to be deemed competent.</li> </ul>	
Trainer or Validator to observe the following:	Completed Initials Met Not Met N/A
1. Articulates how to validate if probe/model is/is not compatible with Trophon	
2. Dons gloves. Note: wears gloves at all times when required as described in the Trophon user manual.	
3. Cleans the probe before the high-level disinfection (HLD) cycle following the probe manufacturer's instructions for use (IFUs). <ul style="list-style-type: none"> <li>• Cleans probe using a UNCH-approved, EPA-registered product (Sani Cloths).</li> <li>• Ensures the probe and cord is clean and free of all visible debris, bioburden, gel or other soil.</li> </ul>	
4. Dries the probe with a soft, dry cloth. Ensure there is no visible moisture or drops of liquid on the probe.	
5. Trophon 2: scans the medical instrument tag against the AcuTrace reader until a beep sounds.	

Automated Endoscope Reprocessors – they all have their own, specific competency



## Timing, Temperatures, and Final Rinsing



# Soak Times

- Glutaraldehyde
  - 20 minutes at 25 degrees C
    - 77 degrees F
- OPA
  - 12 minutes at 20 degrees C
    - 68 degrees F
- Resert XL
  - 8 minutes at 20 degrees C
- Temperatures must be logged once a day for manual HLD processes (automated processes log temperature each cycle)
- But if you forget where all this information is, it's all in the manufacturer's IFUs

## Final Rinses

- After appropriate soak time:
  - remove item from disinfectant solution
  - rinse well with water according to manufacturer's IFUs and national guidelines
    - including lumens and channels, with copious amounts of filtered, sterile or tap water.
- Discard rinse water after each use or cycle
- Additionally, channels and lumens are flushed with alcohol and dried with forced air

# Documentation and Storage



## Documentation

- Document on the Infection Prevention approved log:
  - Test date
  - Chemical temperature
  - Test strip lot #
  - Date test strips expire
  - Test strip quality control pass or fail if manufacturer's IFUs direct
  - Date disinfectant expires
  - Disinfection minimum effective concentration (MEC) pass or fail **EVERY SINGLE TIME** YOU PLACE A DEVICE INTO THE HLD CHEMICAL!

# Flexible scope tracking

1. Pt's MRN and scope unique ID must be documented in that patient's medical record for that encounter/procedure
2. Pt's MRN must be entered into the high-level disinfection logs

# Summary Module 4

- Rationale for High Level Disinfection (HLD)
- Spaulding classification scheme (module 2) should be followed
- Importance of and our responsibility for performing HLD correctly
- Liability as a system, private practice, and/or healthcare personnel
- Techniques for checking minimum effective concentrations
- Variability in chemicals, minimum effective concentration validation processes
- Variability in methods, i.e., manual vs. automated, for HLD

Amy – end of module 4