North Carolina SPICE
Statewide Program for Infection Control & Epidemiology

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

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Inherent complexity of the equipment

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.

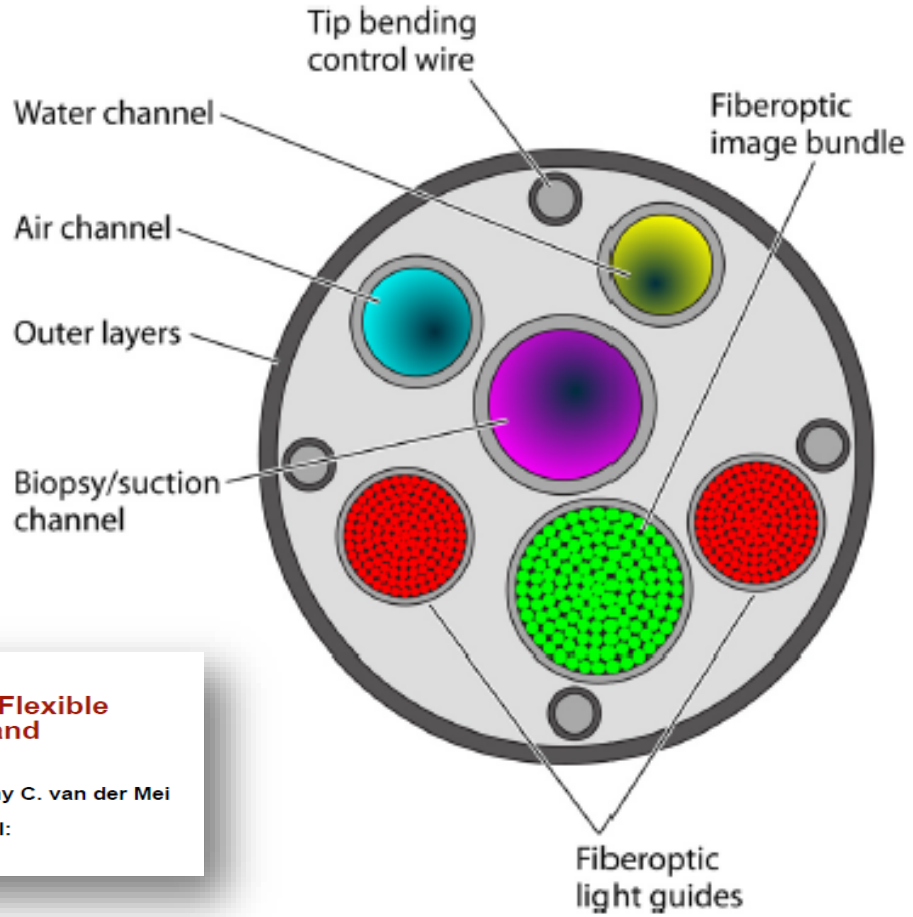

FIG 1 Schematic drawing of a cross section of a flexible endoscope showing the complex design and multiple internal channels (inner diameter, 2.8 to 3.8 mm).

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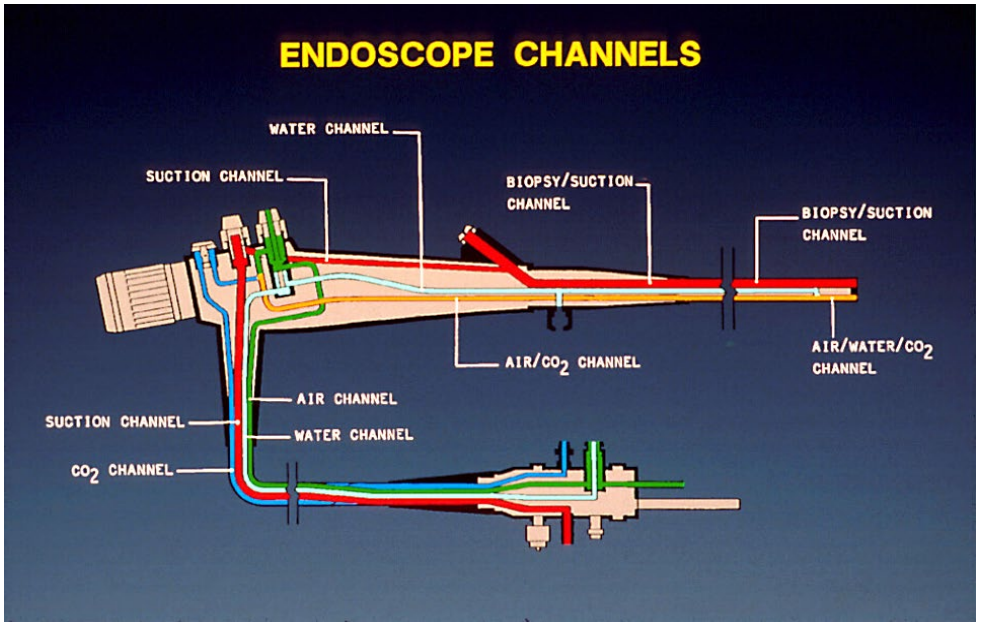
A predisposition for disinfection failures

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, $10^{7\text{-}10}$
- 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)

Table of Contents for Olympus Q180V

Contents

HEALTHCARE EPIDEMIOLOGY INVITED ARTICLE

Robert A. Weinstein, Section Editor

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

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For example…

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

*semi-critical device

Weber and Rutala, ICHE, 33, no 3

Health Care Personnel Accountability

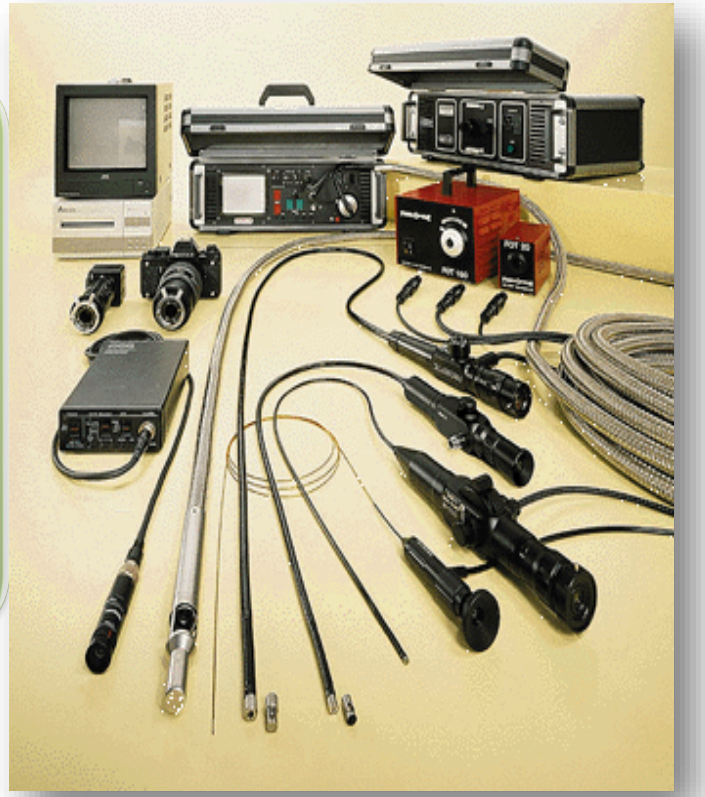
- We are accountable for these processes
  - Be conscientious
- Patients trust us to do this FOR THEM correctly
- Demands for rapid instrument turn-around should be reported to your supervisor.
  - Speak up if you believe there is an issue that could impact patient safety
  - Infection control will lend 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

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GIE®

SPECIAL ARTICLE

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

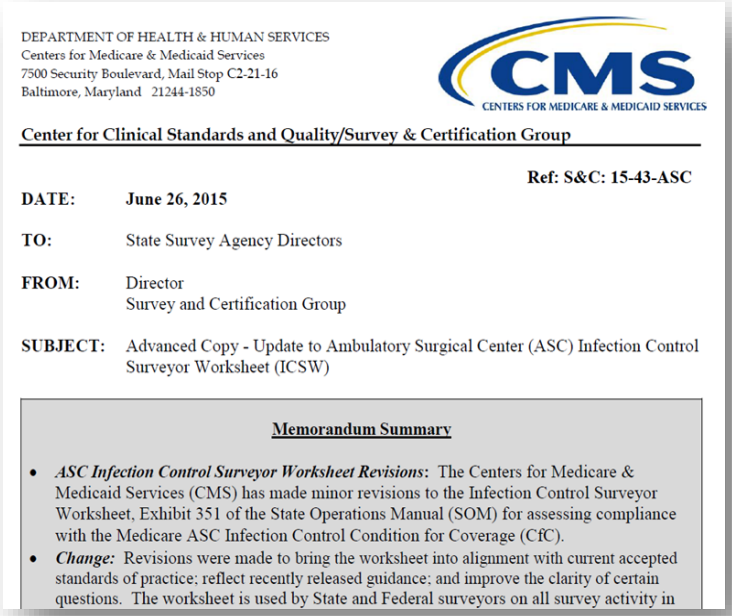
Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

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

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-43-ASC

DATE: **June 26, 2015**

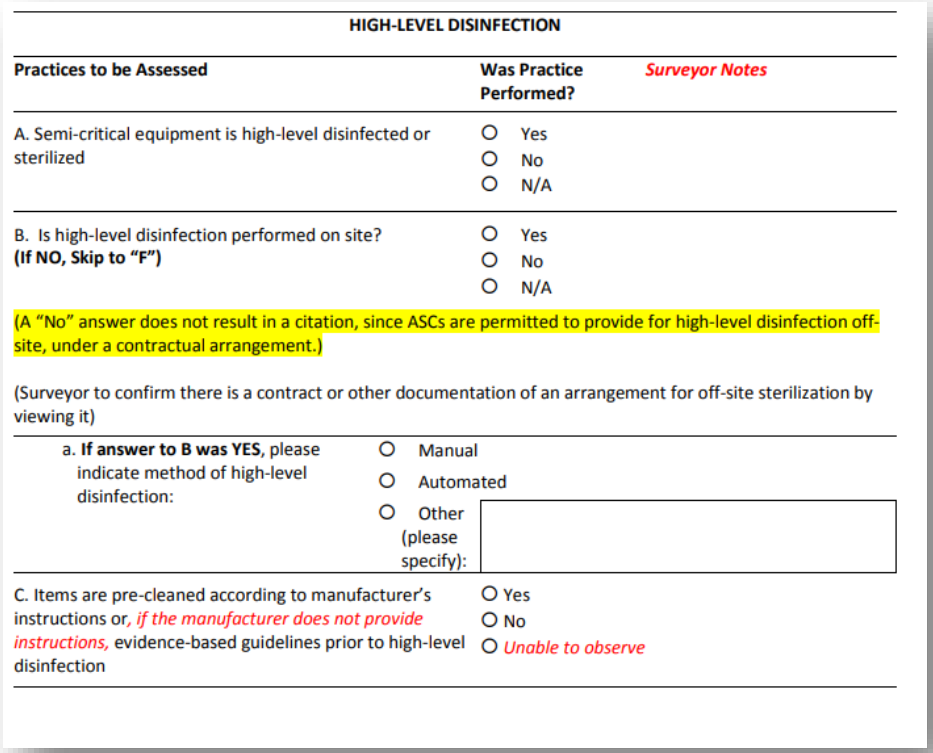
TO: State Survey Agency Directors

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



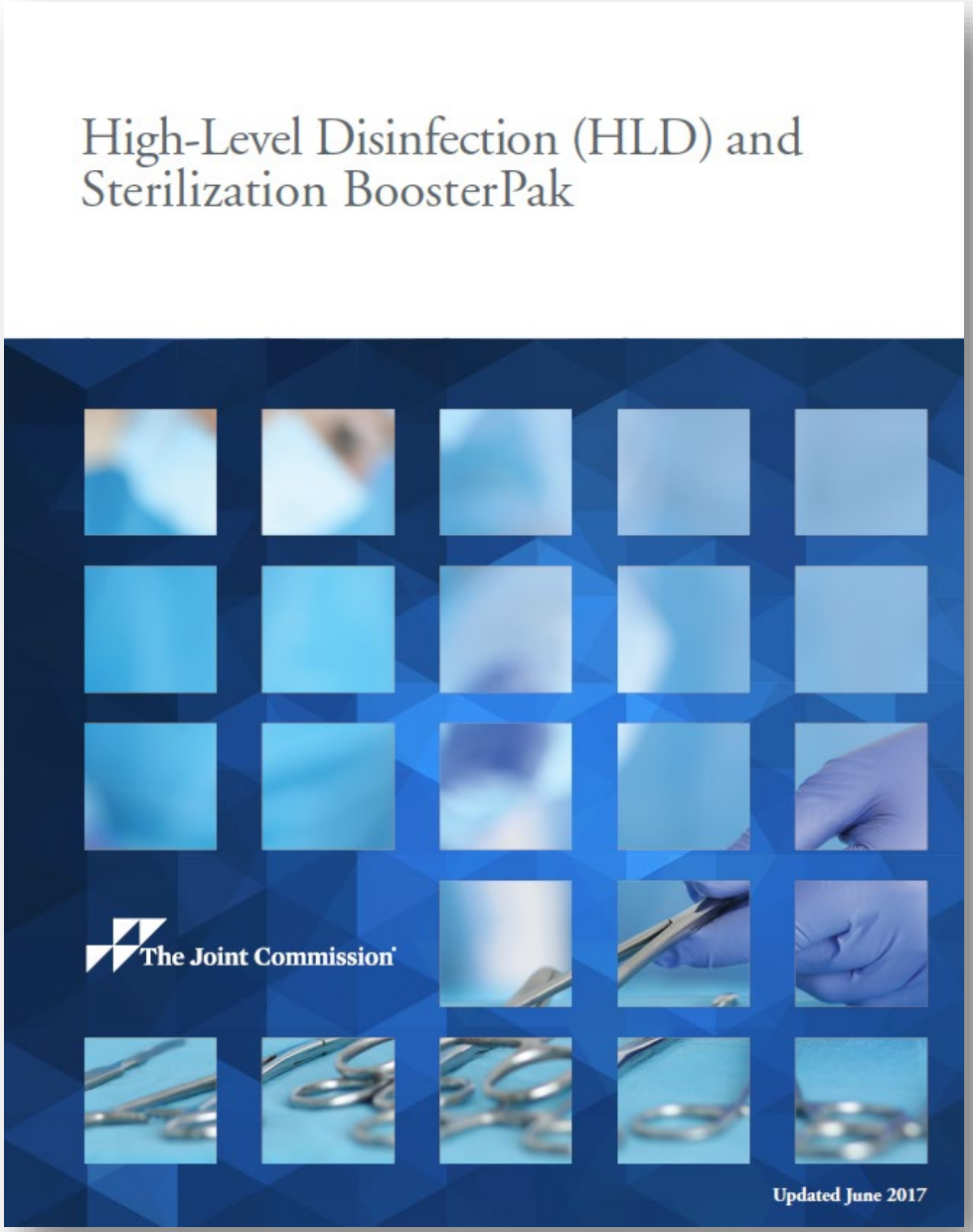
HIGH-LEVEL DISINFECTION

Practices to be Assessed	**Was Practice Performed?**	*Surveyor Notes*
A. Semi-critical equipment is high-level disinfected or sterilized	○ Yes ○ No ○ N/A	
B. Is high-level disinfection performed on site? **(If NO, Skip to "F")**	○ Yes ○ No ○ 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:	○ Manual ○ Automated ○ 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	○ Yes ○ No ○ *Unable to observe*	


High-Level Disinfection (HLD) and Sterilization BoosterPak
The Joint Commission
Updated June 2017

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
Precleaning			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
Transporting			

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."

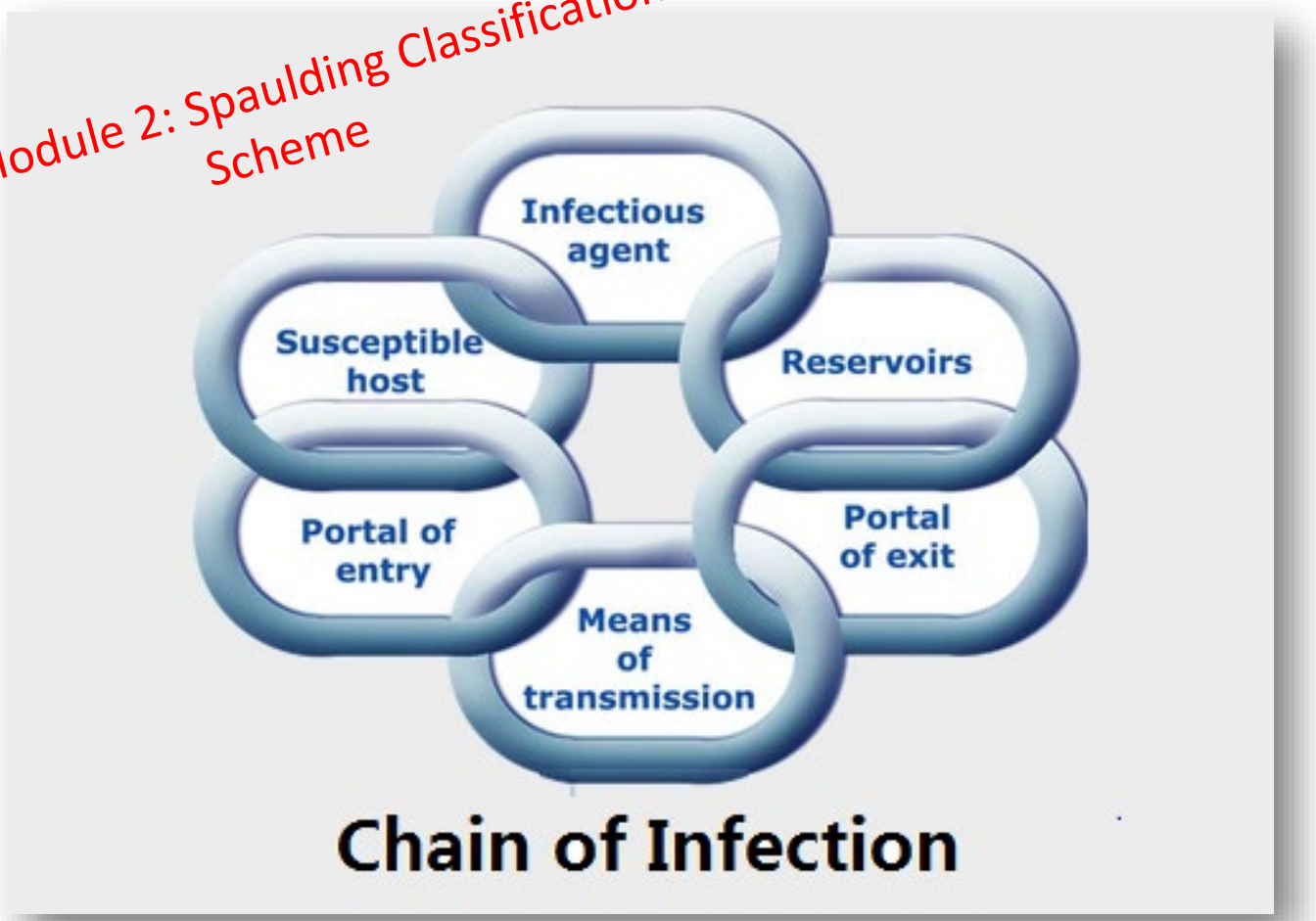
Name: _____ **Date:** _____

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

Competency Statements/Performance Criteria	Verification Method [See legend above]	Not Met [Explain why]
Precleaning 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.	☐DEM ☐S ☐RWM ☐V ☐DO ☐SBT ☐P&P ☐Other ☐DA ☐CS ☐KAT	

Understanding Transmission

See Module 2: Spaulding Classification Scheme



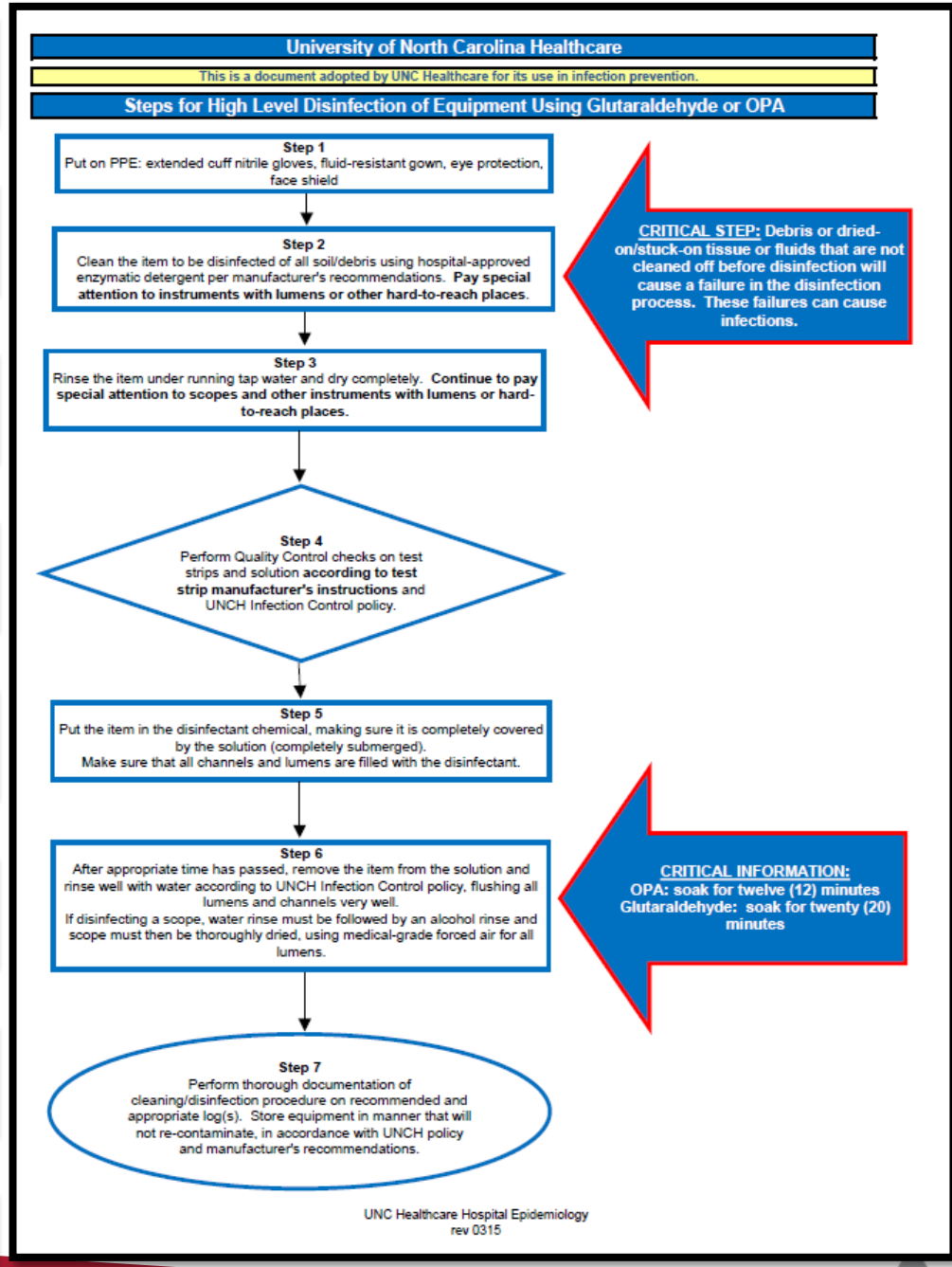
Devices and Validation

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 here 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



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

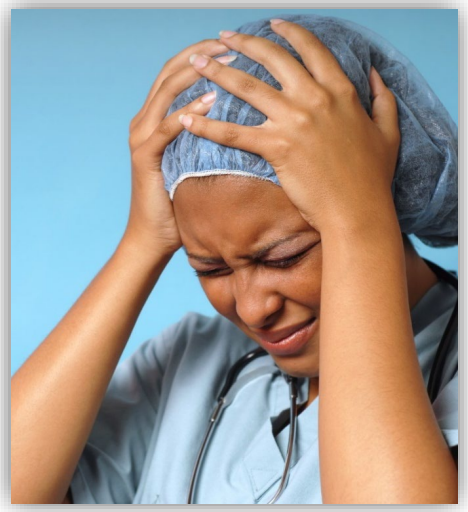
- Perform Quality Control checks on **test strips and solutions** according to manufacturer's instructions for use (IFUs) and institution Infection Control policy.
- **EVERY** test strip in use today requires testing before each HLD cycle.
- **Critical: read and follow IFUs for every test strip and/or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

Lack of Standardization in the Industry

No Standardization in the
Instrument Reprocessing Industry

Enzymatic Detergents - No Standardization

- Different ratios of detergent to H_2O
- Automated dispensing systems
  - Are they REALLY accurate?
  - Are we checking accuracy?
- Some require certain H_2O 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® is an 8 minute soak time
- OPA is a 12 minute soak time
- Rapicide® 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

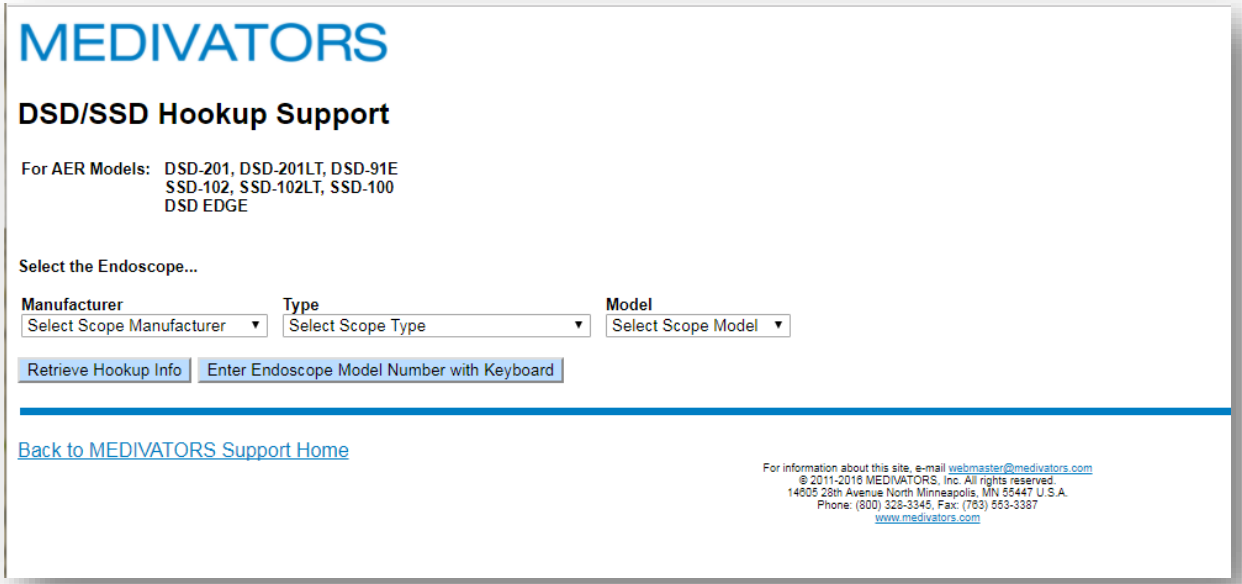
Staff should not leave the instrument processing room during wait times

- 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



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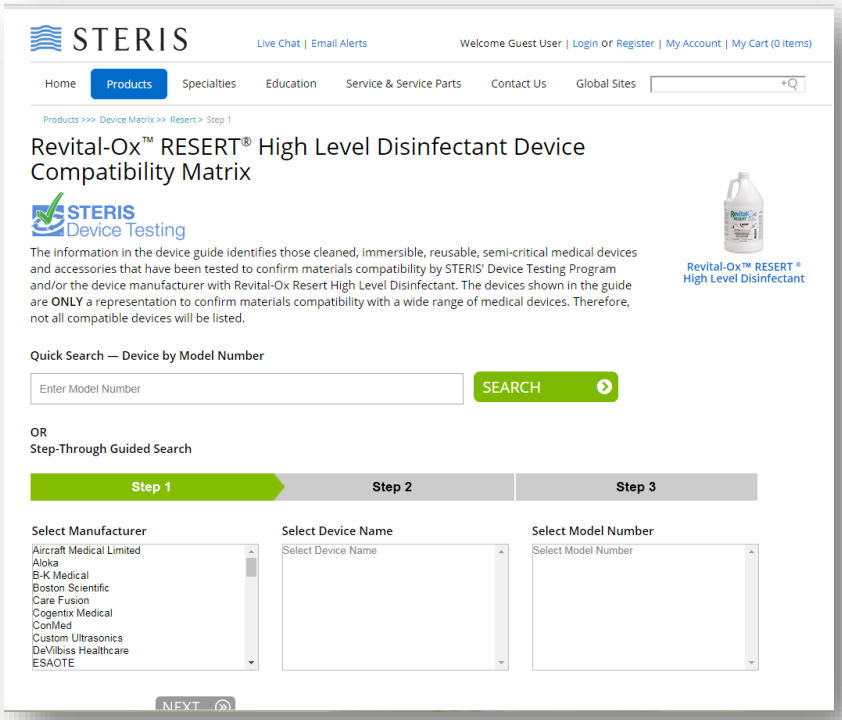
Chemical Validation



- 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 in 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

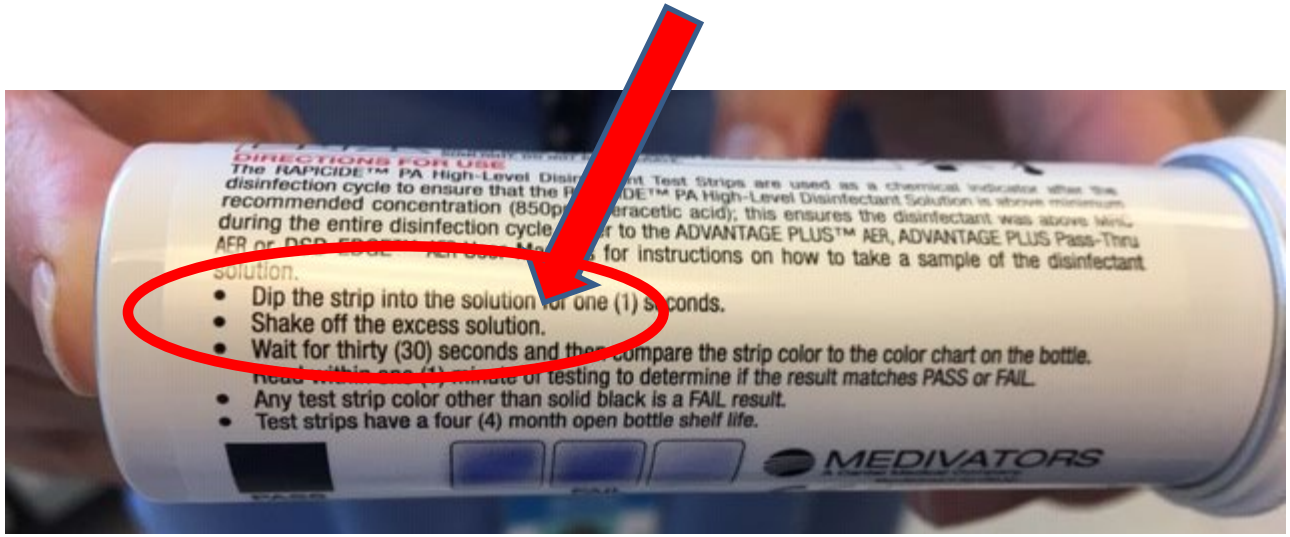
Remember there are 5 portals of entry on the front of the face

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 – **<u>whichever comes first</u>**

- **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
  - ***<u>No shaking or flinging strips to get rid of "excess" chemical</u>***
  - 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.

AAMI ST91 2015

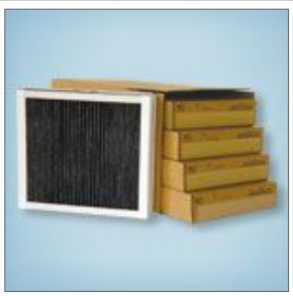
Lumened endoscopes, i.e., nasopharyngeal, cystoscopes, etc., and manual HLD

- 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

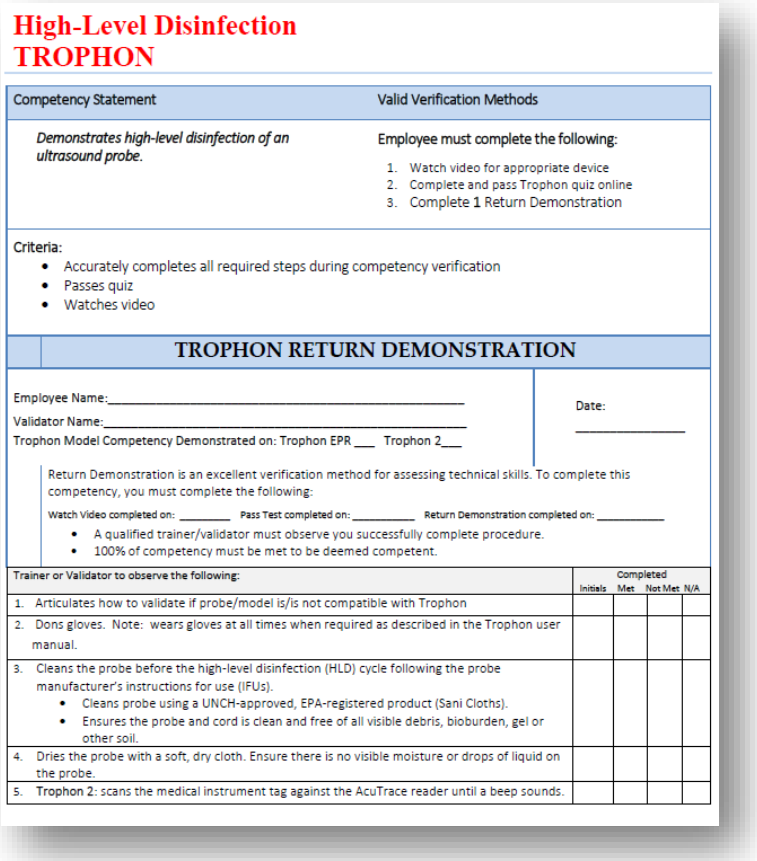
User Stations

Filtration element should be left in the "on" position!



Trophon2 HLD System
Uses a hydrogen peroxide technology

Trophon Competency: 2 pages



High-Level Disinfection
TROPHON

Competency Statement	Valid Verification Methods
Demonstrates high-level disinfection of an ultrasound probe.	Employee must complete the following: 1. Watch video for appropriate device 2. Complete and pass Trophon quiz online 3. Complete 1 Return Demonstration

Criteria:
- Accurately completes all required steps during competency verification
- Passes quiz
- Watches video

TROPHON RETURN DEMONSTRATION

Employee Name:_____

Validator Name:_____

Trophon Model Competency Demonstrated on: Trophon EPR ___ Trophon 2___

Date: _____

Return Demonstration is an excellent verification method for assessing technical skills. To complete this competency, you must complete the following:

Watch Video completed on: _____ Pass Test completed on: _____ Return Demonstration completed on: _____

- A qualified trainer/validator must observe you successfully complete procedure.
- 100% of competency must be met to be deemed competent.

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). • Cleans probe using a UNCH-approved, EPA-registered product (Sani Cloths). • Ensures the probe and cord is clean and free of all visible debris, bioburden, gel or other soil.				
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


PCi
MEDICAL
M
S
MIN
SEC
START/STOP
CLEAR
MEMORY


TAYLOR

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