Core Concepts of Cleaning, High-Level Disinfection and Sterilization

DukeHealth

dicon DUKE INFECTION CONTROL OUTREACH NETWORK

Duke Program for Infection Prevention and Healthcare Epidemiology

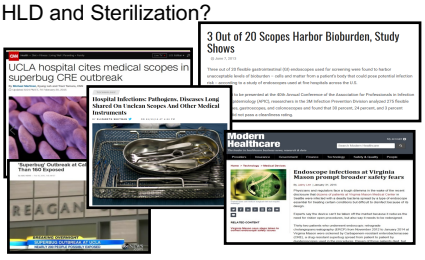
Objectives

- Understand our role in performing high-level disinfection (HLD) and sterilization.
- Define key terms related to HLD and sterilization.
- Verbalize key steps in HLD and Sterilization
- Discuss the differences between HLD and sterilization and the rationale for each.
- Verbalize the steps in quality control (QC) testing and minimum effective concentration (MEC) testing for HLD and sterilization processes.
- Understand our liability as a health care system and as health care personnel.

Overview

Why do we need HLD and Sterilization?

Breaches in high-level disinfection and sterilization processes can result in outbreaks of Hepatitis B/C, as well as the transmission of other infectious viral or bacterial organisms.



> 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

Challenges

- Reprocessing with HLD has a *narrow margin of safety*
  - Any deviation from steps can lead to the survival of microorganisms leading to increased risk of infection
- Cognitively demanding process
  - Because of the number of tasks and detail involved, steps can easily be omitted
  - Most items have specific instruction-for-use leading to the inability to standardize
- Endoscope designs may create challenges in our ability to achieve HLD
  - Elevator, multi-lumens, buttons
- Guidelines and instructions for use can change or be updated
- Drift in practice
- Despite meticulous efforts to reprocess thoroughly, endoscopes may remain contaminated with pathogens that may result in exposures

Good News!

- Sterilization has an enormous safety margin
  - Outbreaks are rare
  - Industry is making progress in the development of both single-use items and devices that can be sterilized as well as better designs

Potential Future Methods to Prevent Endoscope-Related Outbreaks

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

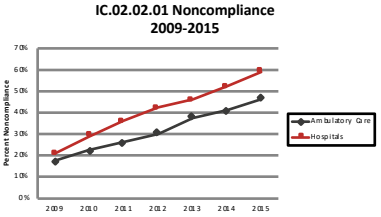
- Optimize current low temperature sterilization methods or new LTST proving SAL 10^{-6} achieved (2 LTS technologies, FDA-cleared)
- Disposable sterile GI endoscopes/bronchoscopes (2 manufacturer's)
- Steam sterilization for GI endoscopes (1 bronchoscope manufacturer)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, stool or blood tests to detect GI cancer, stool DNA test)
- Improved GI endoscope design (to reduce or eliminate reprocessing challenges-based on 50y of experience unlikely to resolve problem; closed channel duodenoscopes increased risk)

Mechanisms of Scope-related Outbreaks

- Patient-to-Self
  - Pathogens may spread from the GI tract through the bloodstream to susceptible organs or may spread to adjacent tissues that are breached
- Patient-to-Patient
  - Via improperly processed scopes or malfunctioning equipment
- Patient-to-Heath Care Personnel (HCP) or HCP-to-Patient
  - Related to improperly used personal protective equipment (PPE)
- Toxic reactions caused by chemical substances that remain on devices after processing
- Endemic transmission of infections associated with GI endoscopes may go unrecognized
  - Inadequate surveillance of outpatient procedures
  - Long lag time between colonization and infection
  - Low frequency of infections

The Joint Commission

- One of the top five noncompliant issues in recent years
- Out of 13 "immediate threats to life" (ITLs) discovered during surveys in 2016, 74% of them were directly related to improperly sterilized or high-level disinfected equipment



Joint Commission (continued)

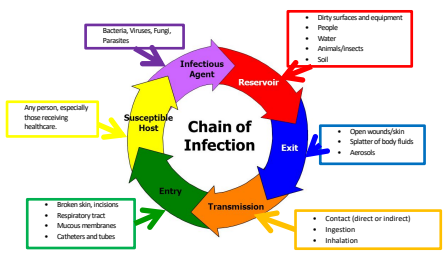
Findings of ITL Root Cause Analyses r/t HLD or Sterilization

- Misguided belief that there is low risk of transmission of organisms to patients
- Lack of knowledge or training
- Lack of evidence-based guidelines in use
- Lack of leadership support and oversight
- Lack of dedicated staff member to perform HLD (shared responsibility)
- Physical design or space act as a barrier to proper HLD or sterilization
- Lack of monitoring or documentation of HLD or sterilization
- No centralized equipment processing and storage to facilitate tracking of equipment in the event of an outbreak

What's Our Role?

- Patients trust us to perform these activities with due diligence
  - Consistently perform all steps thoroughly and accurately in accordance with
    - Manufacturer's instructions for use
    - Evidence-based guidelines
    - Duke policy/procedure
  - Maintain up-to-date manufacturer's instructions for use for all devices and equipment associated with HLD and sterilization
  - Maintain current knowledge of national guidelines
  - Mentor and support each other to prevent drift in practices
  - Report concerns about patient safety issues related to reprocessing using the safety reporting system

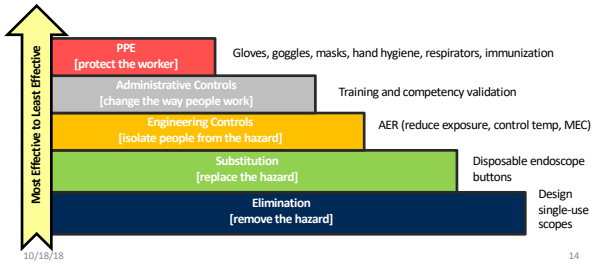
Break the Chain of Infection



Break the Chain of Infection

- Our job is to break one or more of the links in the chain
  - ✓ HAND HYGIENE
  - ✓ STANDARD PRECAUTIONS
  - ✓ STERILIZE OR DISINFECT EQUIPMENT, DEVICES AND INSTRUMENTS
  - ✓ CLEAN AND DISINFECT THE ENVIRONMENT

Hierarchy of Controls



Key Terms

Source: CDC "Guideline for disinfection and sterilization in healthcare facilities" 2008 http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

- Decontamination: The removal of pathogenic microorganisms from objects so they are safe to handle, use, or discard.
  - The term "decontamination" is a general term and may include cleaning, disinfection, and/or sterilization as appropriate.
- Pre-Cleaning: The physical removal of visible material from an instrument or device immediately after use at the bedside before transporting the item for additional processing in a designated reprocessing area.
- Cleaning: The physical removal of soil and organic material from objects, usually done with water and detergents.
  - The first and most important step in both high-level disinfection and sterilization.
    - Manual
    - Ultrasonic
    - Washer-disinfectors
    - Washer-sterilizers

Key Terms

- Disinfection: The elimination of many or all pathogenic microorganisms (except bacterial spores) achieved by chemicals or pasteurization on inanimate objects or surfaces.
  - Low-Level: destruction of most bacteria, some viruses & some fungi.
  - High Level: destruction/removal of all organisms except for bacterial spores.

Key Terms

- Sterilization: The complete elimination or destruction of all forms of microbial life and is accomplished in the hospital by steam under pressure, dry heat, ethylene oxide gas, low temperature sterilization technologies (e.g., hydrogen peroxide gas plasma, Sterrad) or liquid chemicals.
- Chemical Indicator (CI)
  - Color change indicates exposure to the sterilization process
  - Every sterilized item gets one
  - Bowie-Dick test (dynamic air-removal test) performed daily to ensure air removal from chamber of a pre-vacuum steam sterilizer (not gravity)
- Biological Indicator (BI)
  - Highly resistant spores are used to test the effectiveness of the sterilization process
  - Proves that the conditions necessary to achieve sterilization were met during the cycle being monitored
    - At least one BI from the same lot should be incubated (and not sterilized) as a control to verify pre-sterilization viability of the test spores
  - Steam sterilizers should be checked at least once a week (or more often based on the volume reprocessed) at the direction of Infection Prevention

Key Terms

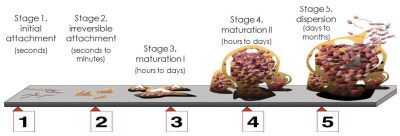
- Instructions for use (IFU): A document prepared by a manufacturer mandated by the FDA that provides information about a product's intended use. It contains information about how to safely use, maintain, decontaminate and store any device, piece of equipment, or product.
  - Make sure you have the most recent version (check annually)
  - www.onesourcedocs.com or contact the manufacturer directly
- Pre-soaking: items are completely submerged (with hinges, screws, etc. open) to prevent blood and organic material from drying on the instruments and in crevices.

Key Terms

- Enzymatic detergent: A solution containing biological catalysts that remove and break down proteins from the surfaces of items. Enzymatic detergents must be prepared and monitored following the manufacturer's instructions for use.
- Minimum effective concentration (MEC): The minimum concentration that a disinfectant is capable of destroying microorganisms. This must be measured and documented to ensure the effectiveness of the disinfection process.
  - Measure and document it! It will ensure the effectiveness of your efforts
- Reuse life: Maximum number of days a reusable disinfectant/sterilant might be effective.

Key Terms

- Biofilm (aka "slime"): a collection of microorganisms in which cells stick to each other on a surface.
  - These adherent cells often create their own matrix of extracellular polymeric substance (EPS)
  - EPS is the construction material that create these bacterial "structures"



Spaulding Classification System

- Items categorized on the basis of the degree of risk of infection involved in their ***use***

Body Contact	Disinfection Requirements	FDA Device Class	Example
Intact skin	Low level	Non-critical	Blood pressure cuff, stethoscope, bed rails, bedside table, bedside commode, exam table, IV Pole, telephone, computer, oximeter, EKG machine
Mucous membranes	High level	Semi-critical	Endocavitary probes, anesthesia equipment, fiber-optic endoscopes, bronchoscopes, laryngoscopes, cystoscopes, speculums
Sterile body cavity	Sterilization	Critical	Surgical and biopsy instruments, catheters, implants, needles

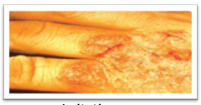
Semi-Critical Instruments and Devices

- Semi-critical items contact mucus membranes or non-intact skin
  - Examples: most endoscopes, laryngoscope blades, cystoscopes, ultrasound probes
- If these items can't be sterilized, HLD is an option
- HLD will eliminate all microorganisms in or on an instrument except for small numbers of bacterial spores
- Items that *can* be sterilized according to the manufacturer's IFU should be sterilized if possible even though the item is used as a semi-critical item (e.g., laryngoscopes)

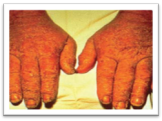
Tools: Personal Protective Equipment (PPE)

- PPE is required for cleaning and HLD of semi-critical and critical items
  - Gowns are impervious, secured at the neck and tied in back. Gloves are nitrile, (standard cuffed glove under gown and extended cuff over the cuff of the gown)
    - Double gloving is a best practice
  - Face protection suitable for chemical use (covers eyes, nose and mouth)
  - Bouffant head covers and shoe covers (not required but considered a best practice)
- Donning and doffing PPE correctly is important!
  - Don PPE when coming into contact with items that are contaminated and using chemicals
  - Doff PPE when finished processing soiled items and the use of chemicals is complete
- **Change PPE when moving from dirty to clean activities and areas**

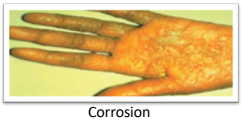
Contact with Chemicals Causes Injury



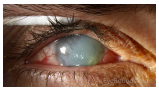
Irritation



Sensitization



Corrosion



Chemical Burn

Extended Cuff Nitrile Gloves

Yes

- Use 12 inch approved gloves for HLD chemicals and puncture resistant for handling sharp instruments
- Best practice is to double glove
  - Gown then don short glove, then don extended cuff glove
- NEVER wash or reuse disposable gloves – *they are disposable!*

No

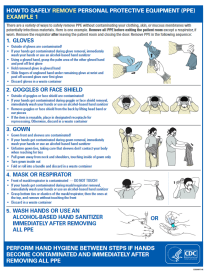
Yikes! Skin Exposure!

OSHA Code of Federal Regulations

Protect the Worker (it's the law…)

- *Improperly worn* or *inappropriate* PPE was included in the top 10 OSHA Citations in Health Care in 2010-11
- Penalties: (2016)
  - Serious: $12,471 per violation
  - Willful or repeated: $124,709 per violation
- 29 CFR 1910.130 (Bloodborne Pathogens)
- 29 CFR 1910.132 (General requirements)
- 29 CFR 1910.133 (Eye and Face)
- Many other standards (i.e. formaldehyde, glutaraldehyde)

Source: http://www.osha.gov/SLTC/personalprotectiveequipment/index.html



Solutions and Chemicals

- Sterile water for rinsing
- Detergents for washing
- Enzymatics for breaking down proteins
- Alcohol for flushing to facilitate drying
- Liquid sterilants used to kill all organisms and spores
  - Only for heat-sensitive semi-critical and critical devices
  - Powerful, toxic chemicals that require careful attention, compliance with safety precautions and appropriate use of personal protective equipment

Management and Monitoring of Chemicals

A safe place to use the words "always" and "never"

Know and follow manufacturer's recommendations for the handling and disposal of chemicals related to cleaning and HLD.

- Ensure the Safety Data Sheets (SDS) are available proximal to product use
- Always clearly label all solutions with the expiration date as instructed by the manufacturer
  - These dates must be visible on any receptacle containing a chemical (e.g., jug, bottle, bin, basin, reservoir) including tanks and reservoirs in AER machines
  - Use permanent markers such as Sharpies® for durability
- NEVER place used solutions back into original or other containers
- No "topping up" chemicals from one container to another
- Always neutralize and discard chemicals per the manufacturer's IFU
- Always store in a clean, dry location away from heat sources
- Minimize agitation of solution at all times
- Do not transport in open containers
- Ensure cap replaced tightly to prevent spills
- Clean up spills immediately following the SDS instructions
- Do not use if containers have been damaged

Monitor each container and reservoir to ensure machine is functioning properly

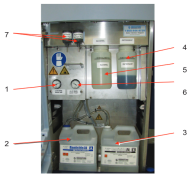


Figure 4 Chemical Reservoirs

1. **Main (High) Pressure Gauge:** Measures air pressure in the MEDIVATORS® ADVANTAGE PLUS® System. Must be set to 3 bar (45psi). Only to be adjusted by trained MEDIVATORS technicians.
2. **Disinfectant Container:** Holds disinfectant Part A used in the disinfection process.
3. **Disinfectant Container:** Holds disinfectant Part B used in the disinfection process.
4. **Detergent Reservoir:** Holds detergent used in the wash process.
5. **Alcohol Reservoir:** Holds alcohol that may be used in the alcohol/air purge process.
6. **Leak Test (Low) Pressure Gauge:** Measures air pressure in the endoscope sheath and MDS system. Must be set to 0.25 bar (3.75 psi). Only to be adjusted by trained MEDIVATORS technicians.
7. **Sample Ports:** Dispenses RAPICIDE® PA High Level Disinfectant for MRC testing at the end of each cycle.

Cidex OPA: Use Excessive Caution

- Cidex OPA should **not** be used to process any urological items or items that come in contact with mucous membranes.
  - Associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies
- If residual Cidex OPA solution remains in/on a device
  - It can cause staining, irritation or chemical burns of the mouth, throat, esophagus and/or stomach
  - This is caused by
    - Excessive soaking times (longer than one hour)
    - Inadequate rinsing
      - Rinse three times with a fresh quantity of water each time as described in manufacturer's IFU

Silicone Spray Lubricant

Special Consideration for Cleaning

- Silicone spray is a synthetic substance that adheres to endoscopes after cleaning and high-level disinfecting.
- Most enzymatic detergents used to decontaminate items are effective in breaking down blood and body fluids and organic substances *but not silicone.*
- If silicone is used, make sure you have an enzymatic detergent specifically designed to remove silicone before cleaning.

Perform QC Monitoring on HLD Test Strips

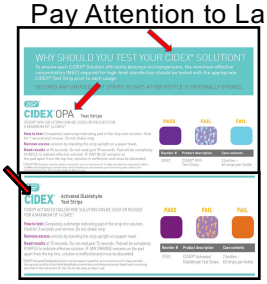
- On each test strip bottle prior to use.
  - Do they work?
- Follow manufacturers instructions on how and when to perform QC.
- Document results

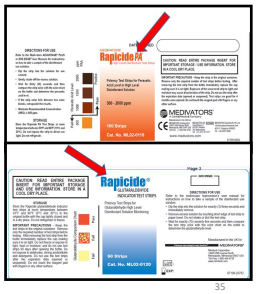
RAPACIDE
(glutaraldehyde)

Disinfectant Minimum Effective Concentration QC test strips

- Prior to ***each use*** of the disinfectant.
- Ensure use of test strips designed for ***that*** disinfectant!!
- **Never** use the disinfectant beyond the date specified *on activation*
- **Never** use the disinfectant if past the expiration date even though it meets the MEC
- Document results

Pay Attention to Labels





Managing Test Strips

- Keep 'em fresh
  - Keep caps on tight
  - Expiration dates clearly marked
  - Label all test strips with the "after opening" expiration date once opened
    - All types and brands of test strips have different expiration dates
- Dip 'em right
  - Hold straight up and down
  - Completely submerge for exactly the length of time indicated on MIFU
  - Touch end of strip to prepared paper towel and lay down gently
  - No shaking or flinging strips to get rid of "excess" chemical
- Always use a timer to accurately measure test strip QC or drying times
  - Set timer and wait, in room, for time indicated by manufacturer's IFUs
- Document results

- Temperature
  - Check ***prior to each use*** of disinfectant
  - Check actual disinfectant solution
  - Follow disinfectant manufacturer IFU for temp ranges
  - Temp range may vary from manual to automated reprocessing
  - Ensure temp on AER turned on
  - Document results

Pre-Clean Items at Point of Use

- Principles
  - Handle contaminated items as little as possible after use
  - Limit handling to those wearing the appropriate level of PPE
  - Appropriately discard sharps and disposable items
  - Always use clean gloves to transport the container to the decontamination area
- Surgical Instruments and Probes
  - Immediately wipe item with a wet gauze or sponge saturated with freshly prepared detergent solution.
  - Transport contaminated item to the reprocessing area in a covered, leak-proof, puncture-resistant container labeled as biohazard that prevents exposure to staff, patients, or the environment.

Pre-Cleaning Flexible Endoscopes

- Immediately after removing endoscope from patient and prior to disconnecting endoscope from power source:
  - Wipe insertion tube with lint free cloth or sponge saturated with freshly prepared (enzymatic) detergent solution
  - Place the distal end of the endoscope into the appropriate detergent solution and suction a large volume of detergent solution through the endoscope until clear (amount per manufacturer's IFU)
  - Flush air and water channels according to the manufacturer's IFU
  - Flush the auxiliary water channel according to the manufacturer's IFU
  - Detach the endoscope from the light source and suction pump
  - Attach protective, water-resistant video cap if using video endoscope
  - Transport soiled scope and all components to reprocessing area in a covered, leak-proof, puncture-resistant container labeled as biohazard that prevents exposure to staff, patients, or the environment

Transporting Semi-Critical and Critical Items

- One of the most frequently cited issues by Joint Commission in Ambulatory Surveys
- OSHA Law
  - From Point of use to processing room:
    - Transport must be in a leak-proof, puncture-resistant container marked biohazard
    - Container is chosen depending on the type of device being transported
      - Bins with lids
      - Enclosed or covered carts
      - Impermeable bags marked "biohazard" (not all biohazard bags are impermeable or puncture-resistant)
      - Sharps are placed in a leak-proof, puncture-resistant closeable, labeled container
      - Is able to withstand repeated cleaning and disinfection if not disposable

Important Note: Contaminated, reusable sharps must not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed (OSHA 910.1030(d)(4)(ii)(E)).

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Examples

Impermeable Humidity Pack

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Find A System that Supports Safe, Protected Transportation of Items

- Provides clear identification of clear or contaminated equipment
- Provides protected temporary storage

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Transporting (continued)

- Contaminated items should be transported to the decontamination area ***immediately*** and placed in an appropriate pre-soak solution to avoid drying.
- If immediate transport is not possible, the item is to be generously coated on all surfaces with hinges open using an enzymatic foam or gel designed for this purpose or covered with a water-soaked towel/gauze (as permitted by the manufacturer's instructions).
  - This prevents bioburden from drying on the surface of the items, which is critical to ensure disinfection/sterile processing can be achieved. The gel or foam will not splash during transport
- All non-disposable transport containers must be cleaned and disinfected between uses.
  - Wash with a mild detergent and then wipe out/spray with an EPA-registered intermediate-level disinfectant.

Transporting (continued)

- If transport is to an off-site location…
  - Plan transport process in collaboration with transporting entity, being mindful of OSHA bloodborne pathogen regulations and contract with this transporting entity.
    - Courier service must be DOT approved (separation of clean/dirty in vehicle)
  - Transport principles still apply. Transport container may require lock/more secure latch, etc.

The Processing Environment

- Use a designated processing area to control quality and ensure safety
  - Equipment processing should be performed in a dedicated reprocessing area that has a negative pressure airflow
    - Instrument processing contaminates the area in which it is performed
    - Items are only pre-cleaned at the bedside to remove visible bioburden
- Divide processing area into dedicated spaces for:
  - Receiving, cleaning and decontamination
  - Preparation
  - High-level disinfection
  - Drying
  - Sterilization
  - Storage

The Processing Environment

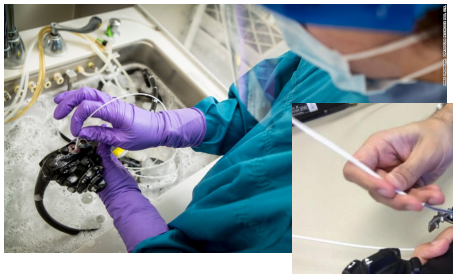
- Organized, easily accessible supplies
- No clutter
- Clearly defined purpose for the space
- Sink splashguard
- Dedicated hand washing sink
- Posted written instructions (up-to-date)
- Eyewash
- Easy to find logs in designated clean area
- Instructions laminated and posted to facilitate standardization and safety

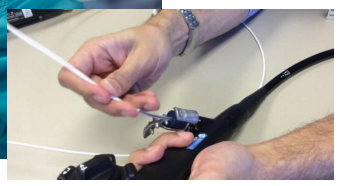
High-Level Disinfection of Semi-Critical Items

1. Don PPE
2. Perform QC Checks
3. Pre Clean (for endoscopes, this includes Leak Tests, Visual Inspection, Cleaning, Rinsing and Drying
4. Disinfect
5. Rinse and Dry
6. Inspect and Store
7. Document

Medivator®

Trophon®





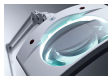
Washing and High-Level Disinfection

- Strictly follow manufacturer instructions for use (IFU)
  - Related to specific item
  - Related to enzymatic detergent/pre-soak solution
    - Be precise when measuring and timing
    - Measuring device and timer must be present!
    - More is not more, it creates a barrier on the device
- Some enzymatic detergents activate only within a specific temperature range
  - If a temperature range is listed, it must be checked before use and documented on the log

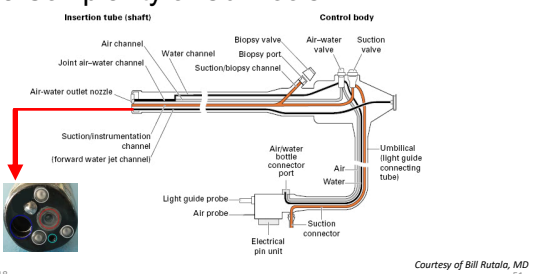
NOTE: Items are to be handled as though contaminated until processed through the full disinfection and/or sterilization cycle, unless the item has been processed with a thermal washer/disinfector that has a high-level disinfection cycle.

Visual Inspection

- High quality magnifying lamps suitable for inspecting endoscopes and other items should be used during reprocessing to identify any defects or damage to an item
- Having an adjustable arm helps focus at the correct angle



The Complexity of Our Tools



Courtesy of Bill Rutala, MD

Endoscopes

Step 1: Perform the Dry Leak Test

- Ensure the water resistant cap is secure
- Attach the leak tester to endoscope **out of water** making sure there is no water or moisture inside the cap, leak tester or tubing
- Remove valves and caps
- Insufflate leak tester to correct pressure per manufacturer's IFU
- Observes endoscope and gauge for 90 seconds watching for changes in the gauge reading and bubbles from the endoscope
- Angulates endoscope in all 4 directions while watching gauge

Don't forget the visual inspection

Endoscopes

Don't forget the visual inspection

Step 2: Perform the Wet Leak Test

- Ensure water resistant cap is secure
- Fill sink with water to measured tape line and confirm scope is fully submerged in water
- Observe endoscope and gauge for 90 seconds watching for changes in the gauge reading or constant stream of bubbles from the endoscope
- Angulate endoscope in all 4 directions while checking the bending rubber, neoprene and knobs for leaks
- Angulates elevator raiser to allow for inspection of lifter and elevator
- Endoscope remains completely submerged for entire wet leak test
- Deflate tester (30 seconds) depressing bulb to ensure all excess air has exited from endoscope
- Lift endoscope out of water to disconnect leak tester

Endoscopes

Step 3: Manual Washing

- Clean and soak the endoscope and channels
  - Use freshly prepared, approved detergent solution every time
  - Dismantle all attachments, removable parts, buttons
  - Discard any disposable attachments such as caps, buttons
  - Keep endoscope *completely* submerged during cleaning process
    - Lessens the risk of splash to you
    - The reason for the long gloves
    - It takes practice, it's not easy

  - Use Soft brushes if manufacturer's IFU allows to wash off debris and wipe with lint free soft cloth or sponge
    - Use appropriate size and bristle type to avoid ineffective cleaning or damage to the item
    - Disposable brushes are ideal but reusable brushes should be high-level disinfected after each use
  - Attach manufacturer's cleaning adapter for suction, biopsy, air, and water channels, and for any channels
  - Flush all channels with approved (enzymatic) detergent solution
  - Discard enzymatic cleaners or detergents after each use
    - They are not micro-biocidal
  - Dry items thoroughly before placing in disinfectant - wet items will dilute your chemicals

Endoscopes

Step 5: Manual High-Level Disinfection

- Completely submerge
- Ensure all lumens are flushed
  - Microorganisms require active removal by forceful flushing
  - Soaking alone without active flushing is not adequate

Soak Times	Time	Temp F	Temp C
Glutaraldehyde	20 minutes	77°F	25°C
OPA	12 minutes	68°F	20°C

Endoscopes

Step 6: Final Manual Rinsing

- Water rinse
  - Use copious amounts of filtered, sterile or tap water according to the manufacturer's IFU and national guidelines
    - Include all lumens and channels
    - Pay attention to all surfaces and removal parts
    - Don't rinse in a basin of standing water, use "running water"
    - High potential for splash exposure to you
    - May be different for ophthalmic instruments
- Alcohol Rinse (70% Isopropyl)
  - Flush all surfaces and removal parts
  - Flush all lumens and channels until the alcohol can be seen exiting the opposite end of each channel
  - This displaces water and evaporates quickly facilitating the drying process

Endoscopes

Step 7: Manual Drying

- Drying between patient procedures and before storing is required and crucial to prevent disease transmission!
- Place items to be dried on a surface that has been disinfected and covered with a lint-free cloth; replace every 12 hours or as needed if excessively moist
- Purge all channels with compressed, filtered, medical grade air to dry all lumens and channels following the manufacturer's IFU (timing is dependent on length and size of lumen as well as PSI used)
  - Use a pressure gauge to monitor air pressure to avoid excessive air pressure which can damage internal channels
- Leave all parts and attachments stored unassembled and only reassemble when ready to use

Ultrasonic Washing

- Typically used for small items and instruments
- Ultrasonic sound is sound that is transmitted at frequencies generally beyond the range of human hearing
  - As sound waves from the transducer radiate through the solution in the tank, they cause alternating high and low pressures in the solution
  - During the low pressure stage, millions of microscopic bubbles form and grow (cavitation)
  - During the high pressure stage, the bubbles collapse (implode) releasing enormous amounts of energy
    - Implosions act like an army of tiny scrub brushes working in all directions removing material from all recesses and openings

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Automated Washing and High-Level Disinfection

- Preferable method over manual
- Research has not proven AERs are superior to manual HLD
  - Increase efficiency and reliability
  - Decrease exposure risks to staff
- Concerns
  - Flushing
  - Small lumen sizes require special attention
  - Liquid chemical germicide residue
  - Water quality
  - Routine cleaning/maintenance

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Automated Washing and High-Level Disinfection

Automated Endoscope Reprocessors (AER) should have the following features:

- Fluids circulate through all channels at equal pressure without trapping air (channel flow sensors useful)
- Detergent and disinfectant cycles are followed by rinse cycles and forced air to remove all used solutions
- Disinfectants are not diluted with any fluids
- Machine is self-disinfecting
- Hoses and reservoirs are purged of any residual water
- Alcohol flush and forced air drying are ideal
- Machine has a self-contained or external water filtration system
- Machine has a method to automatically store or print data verification of cycle completion

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Automated Washing and High-Level Disinfection

- Use the correct AER designed to process the type of scope in use
- Manually clean scope well prior to placing in AER
- Operate the AER according to the manufacturer's IFU
- Place scope in AER, ensuring all channel adapters are well-attached
- Place valves and other removable parts into the soaking basin of the reprocessor
- If AER has a cycle that uses enzymatic detergent, use a product that is compatible w/AER and scope according to manufacturer's IFU
- Set the appropriate time and temperature, depending on the chemical(s) used
- Start the machine and allow it to complete all cycles/phases
  - If cycles/phases are interrupted, disinfection cannot be assured and full cycle must be repeated
- If a final alcohol rinse cycle is not a feature of the AER, this step should be done manually, followed by purging all channels w/medical-grade air until completely dry

Duodenoscopes *(Twice is Nice)*

- Duodenoscopes are different from other endoscopes because they contain an "elevator channel" at the tip that allows changes in scope angle necessary to access the ductal system
- These devices have been linked to transmission of infection because they are difficult to fully disinfect
  - Small or microscopic crevices in the elevator mechanism are difficult to reach during manual brushing and automated reprocessing steps
  - Duodenoscopes are reprocessed using meticulous manual cleaning of the elevator channel followed by washing and disinfecting in an AER
  - Raise and lower the elevator during manual cleaning to promote brushing of both sides
- **Because of the design challenges of duodenoscopes, it is recommended they be *double* reprocessed prior to use.**
  - Follow the standard automated process previously described for all endoscopes
  - Within 24 hours of the next use, reprocess following the standard automated process previously described for all endoscopes
  - It is reasonable (but not required) to follow HLD with ethylene oxide gas sterilization if this is available
    - This is not FDA approved
    - Process takes 12 – 15 hours
- If a duodenoscope is suspected as a cause of patient colonization or infection, take the duodenoscope out of service until it is confirmed as no longer contaminated

Endocavitary Probes

- ***Cleaning and HLD are still required*** **despite the use of required probe covers**
  - Probe covers simply reduce bioburden but often fail
- ***Do Not*** leave probes uncovered on ultrasound machines (before or after use)
- Recommend the use of an automatic processor such as Trophon® for immersible probes
- Replace non-immersible probes ASAP! But in the meantime:
  - Clean according to the manufacturer's IFU
  - Immerse tip of probe for prescribed time
  - Any portion of probe that can't be immersed but was exposed to mucous membranes can be wrapped with a cloth soaked in a high-level disinfectant to allow the recommended contact time

What's Wrong With This Picture?

- This Medivator is FDA-approved to process only one or two scopes per load…

What's Right With This Picture?

- Single endoscope loaded appropriately
- Accessories are stored in a mesh bag and stay with the scope throughout processing and storage

Storage of Endoscopes and Probes

- Store in a manner that will protect devices from contamination
  - Storage area should be clean, enclosed, well ventilated, and dust-free
- Devices should not be stored in the same room in which they were cleaned
- Label devices with date of reprocessing
- Hang scopes in a vertical position to facilitate drying, w/caps, valves, and other detachable components removed per manufacturer's IFU
- ***Flexible endoscopes*** should be reprocessed if they are not used within **7 days** of being properly reprocessed
- Endoscopes that are not stored vertically may be stored flat after proper processing but ***must be reprocessed prior to use***

Examples





Sterilization Methods

- Steam under pressure is the process of choice whenever possible
  - Safe, fast and most cost-effective
- Other types of sterilization techniques include:
  - Low temperature gas plasma (LTGP)
    - VPRO
    - Sterrad
  - Dry heat
  - Ethylene oxide
  - Ozone

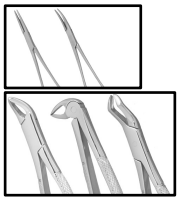
Sterilization of Critical Items

- What gets sterilized?
  - Any instrument that enters a sterile cavity or penetrates a mucosal barrier (e.g., biopsy forceps, scissors, retractors)
  - Laparoscopes, arthroscopes and other endoscopes entering sterile body tissue

- ✓ Surgical instruments
- ✓ Dental instruments
- ✓ Any item identified in the IFU that recommends it

Surgical Instruments

- Hinged, complex items made of stainless steel


Overview of the Sterilization Process

- First steps identical to HLD

Point of Use/ Removal of gross soil	Transport to Processing Area	Preparation for Cleaning/Cleaning	Inspect/ Package	Sterilization	Storage

Preparation for Cleaning/Cleaning → Manual, Automated

Prepping and Packaging

- All items are thoroughly pre-cleaned, washed and dried prior to sterilization
- Open those hinges!
- Items are packaged based on the manufacturer's IFU using FDA-approved packaging products
  - Choose the appropriate size for the item
  - Must be compatible with the type of sterilization process used
    - Peel packs
    - Rigid sterilization containers
    - Woven, non-woven textile wrappers
  - Double paper/plastic peel-pouches may be indicated per manufacturer's IFU – no folding over of the inner paper/plastic peel pouch as this may prevent sterilant from contacting the contents


Don't forget the visual inspection

Sterilizer Loading

- Do not overload the chamber
- Place items/packages one inch apart on sterilizer rack to allow full penetration of the sterilant
- Peel packs (paper to plastic) and non-perforated containers should be placed on their edge
- Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and if applicable, the expiration date

Example

- Avoid stacking or maneuvering in such a way as to tear or disrupt the integrity of the packaging

Process Times for Packaged Items

Gravity-Displacement

Table 4—Time and temperature parameters for gravity-displacement steam sterilization cycles in health care facilities

Item	Exposure time at 121°C (250°F)	Exposure time at 132°C (270°F)	Exposure time at 135°C (275°F)	Drying times
Wrapped instruments	30 minutes	15 minutes		15–30 minutes
			10 minutes	30 minutes
Textile packs	30 minutes	25 minutes		15 minutes
			10 minutes	30 minutes
Wrapped utensils	30 minutes	15 minutes		15–30 minutes
			10 minutes	30 minutes
Unwrapped nonporous items (e.g., instruments)		3 minutes	3 minutes	0–1 minute
Unwrapped nonporous and porous items in mixed load		10 minutes	10 minutes	0–1 minute

NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

ANSI/AAMI Standards 2013

Process Times for Packaged Items

Dynamic-Air-Removal

- Each sterilization process method has time and temperature parameters that must be followed depending on the type of sterilizer
- Always follow the manufacturer's IFU

Table 5—Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 132°C (270°F)	Exposure time at 135°C (275°F)	Drying times
Wrapped instruments	4 minutes		20 to 30 minutes
		3 minutes	16 minutes
Textile packs	4 minutes		5 to 20 minutes
		3 minutes	3 minutes
Wrapped utensils	4 minutes		20 minutes
		3 minutes	16 minutes
Unwrapped nonporous items (e.g., instruments)	3 minutes	3 minutes	NA
Unwrapped nonporous and porous items in mixed load	4 minutes	3 minutes	NA

NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

ANSI/AAMI Standards 2013

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Monitoring of the Sterilization Process

- Sterilization is monitored routinely by a combination of physical, chemical and biological parameters
  - Physical: cycle time, temperature, pressure
  - Chemical: heat or chemical sensitive inks that change color when germicidal-related parameters are met
  - Biological: Bacillus spores that directly indicate whether sterilization has been achieved
- Monitor each load with physical and chemical indicators
- AAMI guidelines recommend weekly (at a minimum) monitoring with biological indicators to monitor the effectiveness of sterilizers
  - Preferred: Daily
  - Best practice: With Every Load
- Use biological indicators for every load containing implantable items

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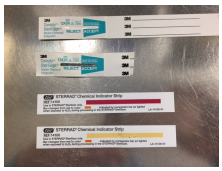
Biological Indicators and Chemical Integrators



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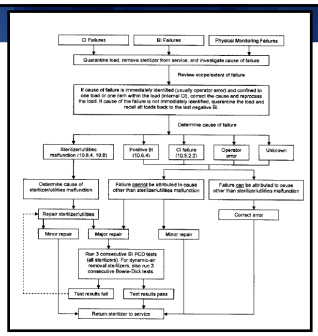
Biological and Chemical Indicator Failures Algorithm

Take the sterilizer out of service and notify the supervisor and Infection Prevention

Note: Objects other than implants do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective.



Storing Sterile Items

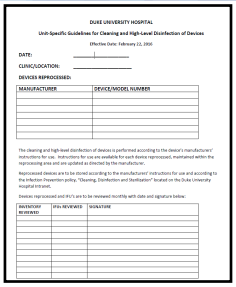
- Ensure the storage area for sterile supplies has controlled temperature, humidity and ventilation to provide protection against dust, moisture and vermin
  - Ideally the storage area is under positive pressure and has at least 4 air exchanges per hour per AAMI/ASHE
- Limit access to storage area and discourage unnecessary traffic
- Sterile supplies should be stored separately from clean supplies
  - If stored together, separate them by storing sterile items on the upper shelves and clean items on the lower shelves to prevent lint, dust and other debris from falling on the sterile items
- Items should be stored in a manner that prevents damage to packaging (punctured, torn)
  - The integrity of packaging should be evaluated prior to use
- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g. exposure to moisture)
- If using time-related shelf life, at the time of sterilization, label the pack with an expiration date

Documentation

Reprocessing Binder(s)

All documentation is kept INDEFINITELY

- Table of Contents
  - Section 1
    - Current copy of the DUHS Cleaning, Disinfection and Sterilization Policy
  - Section 2
    - Current list of items reprocessed in your area and their most recently published manufacturer's instructions for use
    - OneSource Log-in information
  - Section 3
    - Instructions for pre-cleaning process and how to send items to SPD for sterilization (include clinic code chart)
    - Competency checklist for pre-cleaning and cleaning processes
  - Section 4
    - Reprocessing logs for all items used (e.g., QC logs, HLD logs, AER logs, Trophon logs, etc.)
  - Section 5
    - Observation audit tool(s) for process monitoring
  - Section 6
    - Completed competencies for each staff member performing reprocessing activities



DUKE UNIVERSITY HOSPITAL

Unit-Specific Guidelines for Cleaning and High-Level Disinfection of Devices

Effective Date: February 22, 1990

DATE: _____

CLINIC/LOCATION: _____

DEVICES REPROCESSED:

MANUFACTURER	DEVICE/MODEL NUMBER

The cleaning and high-level disinfection of devices is performed according to the device's manufacturers' instructions for use. Instructions for use are available for each device reprocessed, maintained within the reprocessing area and are updated as directed by the manufacturer.

Reprocessed devices are to be stored according to the manufacturers' instructions for use and according to the Infection Prevention policy, "Cleaning, Disinfection and Sterilization" located on the Duke University Hospital Intranet.

Devices reprocessed and PI's are to be reviewed monthly with date and signature below:

MONTH/YEAR REVIEWED	PI'S REVIEWED	SIGNATURE

HLD Documentation

All documentation is kept INDEFINITELY

- Documentation is required for each item reprocessed
  - Endoscope/item model and serial number or other identifier
  - AER (if used) model and serial number or other identifier
  - Date item processed
  - Chemical Temperature
  - Test strip lot #
  - Dates test strips expire
  - Test strip quality check Pass or Fail if manufacturer's IFU direct
  - Date disinfectant expires
  - Disinfection MEC quality check Pass or Fail before item immersed or placed in AER
  - Soak time for manual HLD (time in solution and time out of solution)
  - Staff member(s) reprocessing the item
- Documentation is required to evidence preventative maintenance and repair per manufacturer's IFU (Clinical Engineering or equivalent)

HLD Documentation

- Each item undergoing high-level disinfection will be linked to documentation of the patient the item was used for:
  - Procedure type, date, and time
  - Patient name and MRN
  - Performing provider's name or unique ID
  - Endoscopes or probe model, serial number or other unique identifier
- It is *crucial* to be able to link each device to the patient it was used for in the event of a suspected exposure or cross-transmission of infection

HLD Documentation

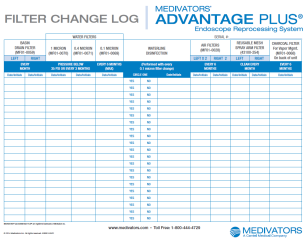
- For quality control checks:
  - Date test strip bottle opened and date to not use after
  - Test strip bottle lot number
  - Date disinfectant opened and date to not use after
  - Disinfectant bottle lot number
  - Disinfectant test date
  - Disinfectant test time
  - Temperature of disinfectant at time of test
  - MEC test results (pass/fail)
  - Staff name performing testing

Sterilization Documentation

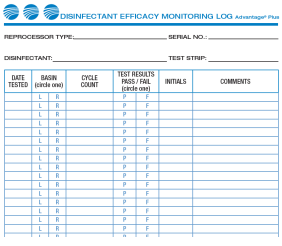
All documentation is kept INDEFINITELY

- Thorough documentation is required for each item reprocessed
  - Calendar date/time
  - Load number
  - Sterilizer number
  - Load contents
  - Temperature
  - Exposure time
  - Reviewer signature
  - Bowie-Dick testing (if indicated)
  - Chemical integrator/biological indicator results

There is a Log for Everything


FILTER CHANGE LOG

MEDIVATORS' ADVANTAGE PLUS® Endoscope Reprocessing System


DISINFECTANT EFFICACY MONITORING LOG Advantage® Plus

REPROCESSOR TYPE:_____ SERIAL NO.: _____

DISINFECTANT:_____ TEST STRIP:_____

DATE TESTED	BASIN (circle one)	CYCLE COUNT	TEST RESULTS PASS / FAIL (circle one)	INITIALS	COMMENTS
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		
	L R		P F		

There is a Log for Everything

Duke University Hospital

Manual High Level Disinfectant Quality Control Log Sheet (for new bottle of test strips)

Circle chemical used: Glutaraldehyde (Cidex™, Metricide) Cidex OPA™, Rapicide, Resert XL- AHP, (28% Hydrogen Peroxide- Trophon®)

Clinic /Location: _____

Test Date	Test Strip Lot #	Date Test Strips Expire	Date Solution Expires	Full Strength solution/Test Strip QC Pass (+) Fail (-)	Temperature of Full Strength Sol	One-half Strength Solution Test QC - Pass (+) / Fail (-)	Temperature of 1/2 Strength Sol	Staff Initials

Initials	Signature		Initials		Signature	
Initials	Signature		Initials		Signature	

There is a Log for Everything

SCOPE BUDDY® DAILY QUALITY ASSURANCE LOG

Month / Year: _____ Serial #: _____

DAY	FLOW VALIDATION TEST		INITIALS	DECONTAMINATION PROCEDURE		INITIALS	DAY	FLOW VALIDATION TEST		INITIALS	DECONTAMINATION PROCEDURE		INITIALS
1	Pass	Fail		Yes	No		17	Pass	Fail		Yes	No	
2	Pass	Fail		Yes	No		18	Pass	Fail		Yes	No	
3	Pass	Fail		Yes	No		19	Pass	Fail		Yes	No	
4	Pass	Fail		Yes	No		20	Pass	Fail		Yes	No	
5	Pass	Fail		Yes	No		21	Pass	Fail		Yes	No	
6	Pass	Fail		Yes	No		22	Pass	Fail		Yes	No	
7	Pass	Fail		Yes	No		23	Pass	Fail		Yes	No	
8	Pass	Fail		Yes	No		24	Pass	Fail		Yes	No	
9	Pass	Fail		Yes	No		25	Pass	Fail		Yes	No	
10	Pass	Fail		Yes	No		26	Pass	Fail		Yes	No	
11	Pass	Fail		Yes	No		27	Pass	Fail		Yes	No	
12	Pass	Fail		Yes	No		28	Pass	Fail		Yes	No	
13	Pass	Fail		Yes	No		29	Pass	Fail		Yes	No	
14	Pass	Fail		Yes	No		30	Pass	Fail		Yes	No	
15	Pass	Fail		Yes	No		31	Pass	Fail		Yes	No	
16	Pass	Fail		Yes	No								

Circle results and initial

If the Flow Validation Test fails, contact Medivators Customer Support at 1-800-444-4729

MEDIVATORS

10096.006 Rev A

There is a Log for Everything

High-Level Disinfection Log
For Trophon EPR Serial # _____

CARTRIDGE REPLACEMENT: Each time when using a new SONEX CARTRIDGE, document: DATE LOADED, LOT #, & EXP. DATE.
NEW CHEMICAL INDICATOR BOX: Each time when opening a new box of CHEMICAL INDICATORS, document on next available row: LOT # & EXPIRATION DATE.

CYCLE RESULTS: Manually record cycle results if printer label not utilized, otherwise place label in dotted template squares. Labels correspond to the disinfection cartridge lot opened and recorded above them.

	CARTRIDGE REPLACEMENT		CHEMICAL INDICATOR		CYCLE RESULTS		OPERATOR
Date	Date Loaded & Lot #	Expiration Date	Lot Batch #	Expiration Date	Time In & Time Out	Cycle # or Pass /Fail	Initials

There is a Log for Everything

Duke University Hospital		Disinfectant Testing Log				
Location/Department:						
Date Test Strip Bottle Opened:		Do Not Use After:				
Date Disinfectant Opened:		Do Not Use After:				
Test Strip Bottle Lot #:		Test Strip Brand & Type:				
Disinfectant Bottle Lot #		DisinfectantBrand & Name:				
Disinfectant Test Date	**Disinfectant Test Time**	**Temperature**	**MEC Test Result**		**Initials**	**Comments**
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		
			PASS	FAIL		

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There is a Log for Everything

Ultrasound Endocavity Probe: Log for Cleaning and Disinfectant

Department _____ Site _____

Initials _____ & Signature _____
Initials _____ & Signature _____
Initials _____ & Signature _____
Initials _____ & Signature _____
Initials _____ & Signature _____

Date	Probe Serial #	Patient Name	Patient Hospital Number	2 min Enzymatic Soak/Rinse Date/Time/ Initials				Odeo OPA: Test strip Initials	+ & - Control Every 7 Days	High Level Disinfection Completed Time/Initials				Rinse Initials	Rinse Initials	Rinse Initials
				Soak	Rinse	Pass	Fail	Date		Time In	Time Out	Odeo OPA Exp. Date		1 min	1 min	1 min

Place Patient Identification Sticker on Back of QA Form

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.

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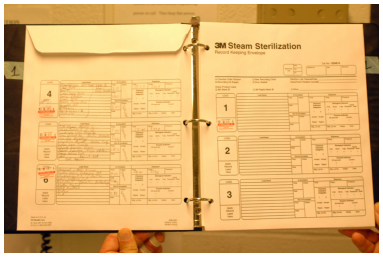

Add manual log for downtime, need standardization for compiling SPM

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Take Home Points

- Pre-Cleaning is the most important step in the reprocessing of devices
- Always refer to the current manufacturer's instructions for all devices and equipment
- HLD or sterilization process should not be rushed through
- Clearly label all products with expiration dates
- HLD and sterilization competencies should be maintained annually and with changes in equipment or processes

Resources

- American National Standards Institute (ANSI)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Centers for Disease Control and Prevention (CDC)
- Association of PeriOperative Registered Nurses (AORN)
- International Association of Healthcare Central Service Materiel Management (IAHCSMM)
- Society of Gastroenterology Nurses and Associates (SGNA)