01.05.04 - Cleaning, Sterilization, High-Level Disinfection and Storage of Scopes

Purpose
To provide scopes that have been appropriately processed and are safe to use.

Audience
All those in the UTMB Health System who clean, disinfect, sterilize or store patient care instruments and other healthcare items.

Policy
All scopes will be cleaned, reprocessed and stored according to these procedures. Some areas where scopes are used will process on site while others will send scopes to SPD for sterilization.

General principles
- There are many types of scopes used by different specialties on different patient populations. Some areas as noted below are designated as sites where pre-cleaning and decontamination is performed prior to sending the scope to another area for processing. Some areas are designated as sites that perform the complete process.
- Manufacturer’s instructions for use (MFG IFU) for the scope and any equipment or supplies used in the reprocessing.
- Scopes will be sterile when introduced into a sterile field in or used in an open abdominal procedure.
- For those departments that perform high-level disinfection with chemicals, the area for reprocessing should be separated from the area where items are stored. If only two sinks other than the handwashing sink are available, one shall be designated “clean” and the other “dirty”. Work flow will support the separation of clean and dirty processes.
- If scope and/or accessories cannot be processed immediately, follow the MFG IFU for delayed processing.
- An enzymatic detergent will be utilized for cleaning all endoscopes and accessories, following MFG IFU. The scope and accessories must be thoroughly cleaned before processing either by high level disinfection or sterilization.
- All scopes and accessories will be inspected for damage and/or water leaks and will be removed from service for repair if damage has occurred that renders the equipment inoperable or poses a patient safety threat.
- An FDA-registered liquid cold sterilant/disinfectant will be used for all scopes and compatible accessories processed by high level disinfection. Accessories not processed with a cold sterilant/disinfectant will be sterilized.
- Sterilization methods: see MFG IFU. Acceptable methods include steam sterilizer, V-PRO, Steris, or Sterrad.
- Although processes are standardized to the extent feasible, detailed procedures are scope- and site-specific. Not all scopes have the same configuration and there are differences in patient population that may preclude use of certain disinfectants.
### Personnel Guidelines

- Staff involved in cleaning, disinfecting, sterilizing, or storing scopes must be trained upon hire and annually thereafter on the processes for which they are responsible. Only staff who are competent in these procedures should process scopes.

- Staff shall wear PPE appropriate for their task as described in subsequent sections.

### Procedures: All areas with scopes

All scope users, whether sending scopes to SPD or processing in the area, will perform pre-cleaning steps as appropriate to the scope (see specifics to follow) while in the procedure room. Pre-cleaning steps will be different for lumened and non-lumened scopes.

- Line transport container with appropriately-sized liner. Ensure there is a biohazard sticker on the outside of the container.

- Small pieces of equipment may be placed in a small zip-lock bag inside the larger liner to prevent damage or loss.

- Remove PPE perform hand hygiene, and don clean gloves.

- Transport scope with its components in the closed transport container to the soiled utility room

- **If the clinic/department is sending scopes to SPD for processing, the scope will be transported from the soiled utility room to SPD in the transport container.** See section below for clinics/departments where scopes are processed on site.

### SPD Process

- SPD will verify delivery and contents.

- Log in receipt of scopes and assign processing to the Clinic SPD tech.

- Clinic SPD tech will verify serial numbers.

- Process scopes per AAMI guidelines.

- Send SPD collection container through cart wash.

- Clinic SPD tech will wrap scope in the scope tray and sterilize using the V-PRO. (SPD does not perform high-level disinfection processes).

- All scopes will be wrapped for transport and placed inside a clean SPD collection container for pickup.

- Each SPD collection container will be labeled with the destination clinic and stored in an area of SPD designated for clinic scopes/instruments.

### Transportation back to Clinic

- Transporter will pick up from SPD at designated times or by request and will deliver the scopes to the appropriate clinic.

- Clinic staff will verify receipt of correct scopes and place scopes in the clean storage room.

### Storage

- Scopes processed by high-level disinfection will be stored in a well-ventilated clean area following manufacturer’s IFU for storage. General principles
  - Hang vertically with free-hanging tip
  - Scopes should be adequately dry to prevent bacterial growth and biofilm
  - Scopes must be hung with adequate space so they do not touch each other or the cabinet walls or floor.
Removable parts should be detached but kept with the scope.
Angulation lock should be in the free position.
Maximum hang time is 14 days after processing.
A “use next” tag may be employed.

- Sterilized scopes will be stored in their container or packing in which they were sterilized.
- For all scopes is 14 days.
- The maximum hang time is applicable to all UTMB Health System Areas using flexible and semi-rigid endoscopes.
- All UTMB Health System Area using flexible and semi-rigid endoscopes are required to adhere to the established maximum hang time.
- All UTMB Health System areas using flexible and semi-rigid endoscopes are required to reprocess endoscope which include the following steps:
  - Leak Testing
  - Manual Cleaning (all steps)
  - Rinsing after cleaning
  - High-Level Disinfection
  - Alcohol Flush
  - Store

- Cidex® ortho-phthalaldehyde (OPA) is used for manual high level disinfection. OPA does not irritate the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odor and requires no activation. It will stain proteins grey and must be thoroughly rinsed to prevent discoloration of the patient’s skin and inflammation of mucous membranes.

- Cidex® OPA solution should be stored in its original sealed container at controlled room temperature 15-30°C (59-86°F) in a well-ventilated, low traffic area. The expiration date of the Cidex® OPA solution is found on the original container as received from the manufacturer. Once opened the unused portion of the solution may be stored in the original container for up to 75 days until used. Calculate 75 days from when the original container was opened and record this date on the bottle. Verify that the expiration date on the original container is longer than 75 days.

- Reprocessing should be performed away from patient care areas (not in a patient room), and the area should be well-ventilated. The area must have sufficient air changes to prevent build up of vapor. Healthcare workers who process instruments in Cidex® OPA must wear PPE including face shield, fluid-resistant gown and gloves. If latex gloves are used, don 2 pair of gloves. A single pair of gloves may be used if made from 100% synthetic copolymer, nitrate rubber or
butyl rubber.

- The bucket and tray systems used for OPA disinfection must be made from polypropylene, acrylonitrile-butadiene-styrene, polyethylene, and glass-filled polypropylene and/or polycarbonate plastics.

- Prior to placement of instruments into the disinfectant solution, they must be thoroughly cleaned with a suitable detergent by brushing the surfaces to remove all blood, body fluids, tissue and any other foreign matter. Hinged instruments must be opened to permit thorough removal of all organic material. Lumens in instruments must be thoroughly brushed and irrigated until clean.

- The soaking bucket or tray containing OPA solution must be labeled with name of the solution, date of first use, and date of expiration. The instruments must be fully immersed, hinged instruments opened, instrument lumens filled with disinfectant and the cover closed. High-level disinfection requires 12 minutes for OPA.

- Checking the MEC of the OPA solution must be monitored with a chemical test strip and results documented each time the solution is used.

- The temperature of OPA solution must be checked and documented each time the solution is used. Minimum temperature required is ≥ 20ºC or ≥ 68ºF.

Specific Instructions for High-Level Disinfection of Various Scope Types

The characteristics of the scope will determine what options are available for high-level disinfection. Characteristics may include, but are not limited to, the following:

- Lumened or non-lumened
- Tolerance for processing chemicals and/or processor
- Presence of elevator channels
- Use of video and other accessories

There may also be limitations imposed by patient characteristics (see Urology Clinics).

Scope Cleaning Requirement Prior to Placement in AER

The automated cleaning cycle is not intended to replace point of use precleaning or thorough manual cleaning including brushing and flushing of all used and unused channels of the endoscope prior to placing it into the AER.

Automated Endoscope Reprocessor Use of the Medivator Advantage Plus

The Medivator Advantage Plus automated endoscope reprocessor uses Rapicide PA, a single use peracetic acid-based high-level disinfectant. The system performs the initial clean, disinfection, rinse and alcohol rinse.

Preparation of Rapicide PA: There are 2 containers: Part A and Part B. One bottle of Part A is connected to the blue cap of the processor and one bottle of Part B is connected to the white cap of the processor. Part A and Part B are mixed to achieve at least 850 ppm of peracetic acid (the minimum recommended concentration, or MRC). The machine prompts the user to replace either Part A or B when the container is empty.

Other solutions:

- The system uses Intercept Detergent for the cleaning step. The machine will
stop and prompt the user to refill the container when it is empty.

- The system utilizes 70% isopropyl alcohol for a rinse. The machine will stop and prompt the user to refill the container when it is empty.

**Procedure**

1. Follow pre-cleaning steps described previously and transport scope to reprocessing area in impermeable container labeled “biohazard”
2. Place endoscope in basin.
3. Select the correct hookup block and connect it in the basin.
4. Connect the endoscope to the hookup block.
5. Attach the channel separator to the endoscope, if required.
6. From menu, scan operator’s barcode and select endoscope
7. Scan barcode on hookup block, endoscope, and patient label (or enter manually)
8. Start cycle
9. At the end of the cycle, a yellow screen will prompt you to “Collect disinfection sample and check MRC with test strip”. Do the following:
   a) Check the Rapicide PA’s minimum recommended concentration (MRC) by taking a Rapicide PA sample from the correct sample port inside the Advantage Plus unit.
   b) Dip a Rapicide PA test strip into the sample solution for one second.
   c) Gently shake off excess solution.
   d) Wait for 30 seconds and then compare the strip color with the color chart and determine if the solution passed the MRC.
   e) Press Start to indicate a “PASS”; press Cancel to indicate a “FAILURE” of the test strip.
10. When prompted, open lid to complete the cycle and scan the operator’s barcode.
11. The lid will open and the cycle is complete.
12. Remove endoscope and hang to store.
13. Cover tip with peel pouch so that the scope tip does not touch the towel at the bottom of the cabinet, the sides of the cabinet, or other scopes.

**Sterilization**

The characteristics of the scope will determine what options are available for sterilization. Characteristics may include, but are not limited to, the following:

- Rigid or flexible
- Lumened or non-lumened
- Number and diameter of lumens
- Length of scope
- Tolerance for processing chemicals and/or processor
- Presence of elevator channels
- Use of video and other accessories

Scopes that are heat-tolerant (e.g. rigid cystoscopes) will be steam-sterilized.
Scopes requiring low temperature processing will be sterilized by one of 3 sterilizers, depending upon both the scope and sterilizer’s manufacturer’s instructions for use. The sterilizers include: Steris, V-PRO, and Sterrad.
### Sterilization in a Steris System IE

- An endoscope may be sterilized using the Steris System IE processor. The sterilizing agent is peracetic acid.
- The endoscope shall be sterilized immediately prior to introduction to the sterile field. The Steris processing system shall be used by following the manufacturer’s recommendations.
- The Steris portable case that contains the sterilized endoscope shall be retrieved by the scrub person from the Steris Room and transported directly to the operating suite. The lid shall be removed only when the endoscope is ready to be taken out of the case.
- The sterilized endoscope inside the sealed Steris portable case is considered sterile for immediate patient use only. The endoscope shall be processed again if humidity is allowed to build up inside the container.

### Fluid Containers/Water Bottles

- Wash and rinse disassembled fluid containers/water bottles.
- Submerge fluid containers in Cidex OPA for high-level disinfection.

### Mouth Guards (Bite Block)

- If the guard is disposable, discard after procedure.
- Reusable guards should be processed as follows:
  - Place in enzymatic cleaning solution.
  - Utilizing a brush, brush all surfaces thoroughly.
  - Rinse thoroughly in clean water. Inspect for damage and or cracks.
  - Send to Sterile Processing for sterilization.
  - As an alternative, in addition to cleaning and rinsing steps as described, the mouth guard may be processed through the ultrasonic system.
  - Mouth guards may also be reprocessed using high-level disinfection (Cidex OPA) instead of steam sterilization.

### Air/Water Valves, Suction Valves, Biopsy Channel Covers

- Place in enzymatic cleaning solution.
- Utilizing a cleaning brush and/or Q-tip, brush all surfaces thoroughly and remove debris from holes and crevasses.
- Remove and rinse thoroughly with clean water.
- Place in cold sterilant/disinfectant solution per manufacturer’s recommendations (Cidex OPA).
- After the recommended exposure time, remove from solution and rinse thoroughly in tap water.
- Dry thoroughly and inspect for excessive wear and/or damage.
- Using silicone oil, place a drop of oil on the slide mechanism and the O rings of the valves.
- Store in appropriate areas.

### Biopsy Forceps, Hot Biopsy Forceps and Rat Tooth Forceps

- Place in instrument milk prior to sending to SPD.
Using a cloth saturated in cleaning solution, thoroughly wash down the length of
the forceps, beginning with the handle.
• Open the cups and gently brush the inside of the cups.
• Rinse thoroughly in clean water.
• Using silicone oil, place a drop of oil on cup hinges and slide mechanism of
  handle and work the oil in by opening and closing the cups.
• Send to Sterile Processing for sterilization.

**Snares**

• Snares are disposable. Discard after use

**Tripods, Grasping Forceps and Baskets**

Place in enzymatic cleaning solution.
• Disassemble if structure allows.
• Using a cloth saturated in cleaning solution, thoroughly wash down the length of
  the forceps, beginning with the handle.
• Move handle to open position and gently brush the exposed wires.
• Remove and rinse thoroughly in clean water.
• The items are then sent to Sterile Processing for sterilization.
Sterilization in a V-PRO Max

The Steris V-PRO Max low temperature sterilizer uses vaporized hydrogen peroxide (VAPROX HC) Sterilant, which is a 59% H2O2 solution delivered in a sealed cartridge. There are 3 cycles with different uses: the non-lumen cycle, the lumen cycle, and the flexible cycle.

1. Non Lumen Cycle
The approximately 28-minute Non Lumen Cycle is used to sterilize instruments without lumens (i.e. surface sterilization) such as defibrillator paddles, cables, cords, non lumened rigid endoscopes (telescopes), Da Vinci instruments, batteries and cameras. The Non Lumen Cycle can be used to sterilize instruments with stainless steel mated surfaces such as the hinged portion of forceps or scissors.

2. Lumen Cycle
The approximately 55-minute cycle is used to sterilize rigid instruments with lumens and mated surfaces including resectoscopes, trocars, and cannulas.

3. Flexible Cycle
The approximately 35 minute cycle is used to sterilize flexible scopes including urethrosopes, cystoscopes, bronchoscopes, single channel surgical flexible endoscopes (up to 1050 mm), and dual channel surgical flexible endoscopes (up to 998 mm)

Procedure
- Prior to sterilization, clean and dry instruments.
- Select appropriate wrap/container/pouch/tray and place chemical indicator (CI) inside the tray/container/pouch. Ensure devices are placed in tray to facilitate sterilant contact.
- Place another CI on the outside of trays and containers.
- For the first cycle of the day, place 1 biological indicator (BI) and 1 CI in pouch. Place the pouch in the center of the top shelf.
- Load the chamber for proper diffusion of VAPROX® HC Sterilant. Do not stack packages and leave 1 inch space.
- Close door and select correct cycle.
- Prior to starting sterilizer, verify that printer has paper and cup has adequate sterilant. Wear gloves to handle cup.
- There are 4 stages to the process
  1. **Condition Phase (Moisture Check):** - Vacuum is pulled to remove air and moisture from chamber.
  2. **Sterilization Phase:** There are 4 pulses consisting of VAPROX sterilant injection and hold; pressure transition and hold; and vacuum pulled on chamber.
  3. **Aeration Phase** The chamber VHP is exhausted through a catalytic converter that decomposes the hydrogen peroxide to water and oxygen
- After cycle ends, don gloves, open door, and remove contents.
- Review printout. Printer is located on the front of the sterilization unit on the right
side while facing the unit. This alphanumeric impact printer provides an easy to read permanent record of the Sterilization Cycle

- Check critical parameters and save printout.

Monitors

- VERIFY® Vaporized VH2O2 Process Indicator is a vaporized hydrogen peroxide sterilization process indicator designed for use in the V-PRO® Max. It distinguishes between processed and unprocessed units when placed within sterilization wraps, trays or pouches to indicate, through a visible change from magenta to yellow, when the device has been exposed to hydrogen peroxide.

- Place the VERIFY Vaporized VH2O2 Process Indicator in the center of each pack (i.e., tray, container, pouch, etc.) to be sterilized and perform a Lumen, Non Lumen or Flexible Sterilization cycle. Upon completion of the cycle, follow department procedure for load release. Confirmation of the indicator performance should take place at time of pack use. This product has met all specifications for a Class 1 Process Indicator as described in ANSI/AAMI/ISO 11140-1, 2005.

- Prior to use of the items within the pack, remove the indicator(s) and compare its color with the yellow color standard on the indicator strip. If the color is yellow, the contents of the pack may be used. If the color is magenta, orange or any color other than yellow, the contents of the pack may not be used. Follow department procedures for reporting sterilization failures.

- Biological Indicator: VERIFY® V24 Self-Contained Biological Indicator is a completely self-contained, providing 10⁶ colony forming units (CFU) of Geobacillus stearothermophilus and an ampoule of specifically formulated growth medium with a pH indicator. It is designed to be sealed after processing, reducing the risk of contamination (and consequent false positives) and evaporation of growth medium. A chemical process indicator on each vial provides immediate proof of processing. Following incubation, a vivid color change of the growth media from orange to yellow and/or turbidity gives distinct evidence of microbial growth. If no microbial growth occurs, the media remains orange and clear (no turbidity).

Sterilization in Sterrad 100NX

Equipment that may be processed in a Sterrad 100NX is determined in part by the materials and in part by the number and size of lumens. Consult the MFG IFU if the materials are unknown.

For a list of types of equipment that can be processed in a Sterrad 100NX, see http://www.aspjj.com/emea/sites/www.aspjj.com.emea/files/pdf/EN/What_Can_I_Sterilize_in_the_STERRAD_100NX_Sterilizer_Brochure.pdf

Packaging

- Items which can be disassembled should be disassembled for sterilization
- Attach venting cap to scope.
- A chemical indicator strip must be placed inside the package
- Scope must have an external chemical indicator such as Sterrad indicator tape.
- Wrapped items should not have any gaps or openings. Peel packs are
not permitted inside any wrapped tray.
- Load Control Sticker should be applied after Sterrad sterilization cycle is complete.

Biological monitoring:
- Perform Biological Monitoring each day the sterilizer is used.
- Obtain a STERRAD CycleSure Biological Indicator (BI), peel pack in a Tyvek/Mylar pouch. Place BI test pack in the back/rear on the bottom shelf toward the back chamber wall.
- Sterilize only one (1) single-channel flexible scope at a time no other device may be run.
- Start sterilization cycle. Run on the Advanced Cycle ONLY DUO or Flex Cycle for 100NX, where available
- Approved single-channel flexible scope lumen dimensions are: Single-channel flexible scopes with a polyethylene or Teflon® lumen, inside diameter of 1 mm or larger and length of 850mm or shorter. Please refer to the Sterrad Sterility Guide for a list of NX compatible flexible scopes. http://www.sterradsterilityguide.com
- ASP Customer Care Center: 1-888-STERRAD (1-888-783-7723)
- After the sterilization cycle is complete, immediately remove the BI Test Pack from the sterilizer. Wear goggles and gloves when handling BI.
- Check the chemical indicator for color change from red to yellow (STERRAD). Press cap down until firmly seated in order to seal vial while BI is inside the peel pack.
- Remove BI from peel packaging. Using the tube crusher, squeeze the vial until glass media ampule has been crushed. Do not crush by hand because the broken glass may penetrate the BI vial and lacerate fingers.
- Keep vial in a vertical position after it has been crushed.
- Label vial with date and load number and places in incubator.
- Incubate BI in an approved incubator at 55-60 degrees Centigrade for (24) hours (STERRAD). At this time the temperature of the STERRAD incubator will be recorded.
- Crush an unprocessed vial to serve as a test Control, label with date, and place in same incubator as the processed vial.
- After twenty four (24) hours (STERRAD) interprets results and record in log book. Discard the ampules in a biohazardous sharps container.

Evotech-flexible scopes

Site or Scope-Specific Instructions

As noted previously, there are differences in scope design and MFG IFU that may dictate differences in scope processing. There are differences in the patient populations in the various sites of scope use. See below for specific considerations.
Olympus OES Endoscopes and Video Endoscopes

Pre-Cleaning Endoscope in Procedure Room
- Wipe the insertion tube with a wet, low or non-linting cloth or sponge soaked in the freshly prepared cleaning solution.
  - Note: cloth/sponge is single-use only
- Ensure that all controls are in the free/unlocked position.
- Suction solution through the suction/biopsy channel as per manufacturer’s written IFU.
- Flush the air/water channels with solution using the endoscope’s cleaning adapter or by manufacturer’s IFU.
- Flush all other channels (e.g., auxiliary water or elevator channels) with solution, if present.
- Suction the solution through the endoscope until clear.
- Detach the endoscope from the light source and suction pump.
- If applicable attach the fluid-resistant cap.
- Visually inspect the endoscope for damage.

Transportation of Endoscopes
- Isolate and transport each endoscope with its components in a closed system.
- Transport items such as forceps/wires separately
- Transport in impermeable container labeled biohazard
- Loosely coil in large loops in a transport container

Leak Testing
- Attach scope leak tester and look for a drop in the pressure gauge.
- For failures, refer to MFG IFU for modified processing steps being sure to maintain positive pressure throughout.
- Ensure fluid-resistant cap is on prior to submersion.
- Connect the suction tubing to the endoscope.
- Place the immersible endoscope in tap water.
- Angulate bending section while immersed.
- Confirm there are no continuous series of bubbles in water.

Manual Cleaning of Endoscopes
- Follow MFG IFU for mixing enzymatic solution and appropriate soak time.
- Depress the suction valve to suction the solution through the channels of the endoscope. Fill all channels with enzymatic detergent solution even if the channels were used. Scope should be completely submerged in enzymatic solution.
- After the appropriate soaking time, empty enzymatic solution and make new enzymatic solution.
- Remove the biopsy valves, and clean the various orifices with a disposable brush until clean. Place the air/water valve, suction valve and biopsy forceps cover in the cleaning solution.
- Use a lint-free cloth or sponge soaked in the enzymatic cleaning solution; thoroughly wash the entire length of the endoscope tube, beginning with the area nearest the control body with the scope completely submerged in enzymatic solution.
Utilizing a cleaning brush appropriate for channel size and length (must use brushes of the diameter and length recommended by the scope MFG), insert the brush through the biopsy channel and brush through the entire length of the channel. When the brush protrudes from the distal end of the insertion tube, clean the brush in the cleaning solution before removing brush from channel. This process should be repeated until no particulate matter is noted on the brush. Repeat the procedure for all channels even if the channels were not used.

- Only use brush for one scope and discard or clean, HLD or sterilize if reusable.
- Clean and rinse the air/water valve, biopsy forceps cover, and suction valve.
- Remove the endoscope from the cleaning solution and place in clean water for rinsing.
- Follow the same steps for rinsing the endoscope as those used for cleaning the endoscope. Use clean, fresh water for each step.
- Place the endoscope in the cold sterilant/disinfectant solution, and utilizing the all channel irrigator, fill all the channels with the solution by flushing them with at least 100cc’s of the solution. Do this for all channels even if the channel was not used.
- Soak the endoscope in a disinfectant (Cidex OPA) according to manufacturer’s recommendations (see policy: 01.05 Cleaning Sterilization High-Level Disinfection and Storage of Patient Care Devices and Other Items).
- After the recommended exposure time is completed, remove the endoscope from the cold sterilant disinfectant solution and repeat the steps for rinsing the endoscope.
- Remove the excess water from the suction channel and biopsy channel by connecting the suction tubing to the endoscope and suctioning while holding the top of the endoscope out of the water.
- Use alcohol to aid in the drying process. Utilizing the all channel irrigator, fill all the channels by flushing them with 70-80% ethyl or isopropyl alcohol. Follow MFG IFU for amount to be used.
- Dry all removable parts and do not reattach.
- Keep valves with endoscope to assure ability to trace.
- Manually dry the endoscope and hang to store.

**Urology Clinics**

- Follow MFG IFU for cystoscopes with regard to the need for leak testing.
- Rigid heat-tolerant scopes will be steam-sterilized.
- Flexible cystoscopes will be processed either by high-level disinfection with OPA or sterilization in the V-PRO. OPA must not be used to process any urological instruments used to treat patients with a history of bladder cancer. OPA may be used for other patients
- Woven Filiforms and Followers must be processed in Cidex® OPA.

**Process for Olympus cystoscopes:**

**Protocol for Pre-Cleaning at bedside immediately after procedure**

- Perform hand hygiene and don PPE (impervious gown, surgical mask, eye protection, gloves and bouffant)
- Place pan/basin lined with chuck to absorb enzymatic flush and water. Flush on table used for sterile field. (after procedure table is considered dirty).
- Remove Endozime SLR sponge from the Phase One Canister.
- Wipe exterior surface of scope, starting with the top of the insertion tube to end of insertion tube with Endozime SLR sponge.
- Discard sponge in waste pan/basin.
- Use a 30cc syringe to suck up 30cc of Endozime SLR from jar.
- Flush lumen of scope with Endozime SLR solution X3.
- Collect waste in pan/basin.
- Disassemble stop cock and place in specimen cup with remaining Endozime solution.
- Use 30cc syringe to suck up 30cc of water from culture cup. (dispose daily)
- Flush lumen of scope with water X3.
- Collect waste in pan/basin.
- Using 30cc syringe, flush lumen of scope with air X3.
- Discard waste pan/basin and syringe in regular trash.
- Place the scope and the specimen cup containing the disassembled stopcock into the lined transport/SPD collection container and close lid.
- Place a biohazard sticker on outside of transport/SPD collection container.
- Remove PPE, perform hand hygiene and don clean gloves.
- Follow Transporting Dirty Cystoscope algorithm from Procedure/Exam Room.

**Duodenoscope (ERCP)**
- Raise the elevator on the ERCP scope and carefully brush around and under the elevator mechanism.
- Lower the elevator before brushing channels.
- Brush the channels a minimum of 3 times per channel. Continue until there is no visible debris. Start by inspecting the channel cleaning brush for any damage. There are 2 portions of the suction channel that require individual brushing.
  - Extends from the valve housing to the distal tip
  - Extends from the valve housing to the light source connector.
- Brush suction channel within the insertion tube by holding channel cleaning brush at 90 degree angle and insert the brush into the opening in the side of the suction valve housing. Use short strokes to advance the brush through insertion tube until it emerges from the distal tip. Remove any debris from the bristles with fingers, gently pull the brush back through the channel, inspect and clean bristles again. Repeat this process until debris cannot be seen on the bristle tip. Inspect and clean bristles while submerged.
- Brush at 45 degree angle; insert the brush in the center of the suction valve opening. Pass the brush through the universal cord until it emerges from the suction connector. Clean the bristles and withdraw the brush.
- Brush the suction channel within the universal cord; insert the brush in the
center of the suction valve opening. Pass the brush through the universal cord until it emerges from the suction connector. Clean the bristles and withdraw the brush. Continue brushing until there is no visible debris on the bristle tip.

- Clean the channel openings. Carefully insert cleaning brush into the suction valve housing. Rotate the brush and remove. Clean the bristles. Repeat this process until no visible debris remains.
- Clean the instrument channel port. Insert brush, rotate and remove and clean the bristles. Repeat a minimum of 3 times. Continue until no visible debris remains. Flush the channels with endoscope-compatible detergent to remove any remaining debris.
- When all internal channels are filled with detergent, wipe external surfaces of the scope with a soft lint-free cloth or sponge to remove any debris.
- Soak scope and accessories for the time recommended by the manufacturer...
- Discard detergent after each scope.
- Prior to high level disinfection, rinse all channels with tap water using irrigation adapters s needed to remove all traces of detergent and debris.
  - Attach suction tubing to suction port and aspirate approximately 500 ml water through suction channel or use syringe.
  - Dry all channels with regulated forced air and dry the exterior of the scope with a soft lint-free cloth and all accessories before disinfecting to prevent dilution of the disinfectant.

Cardiac Catheterization - TEE Scope

- Pre-clean in procedure room: wipe with lint-free cloth.
- Place in lined transport container labeled biohazard.
- Transport to soiled utility room.
- Process manually: soak, clean and rinse (as previously described)
- Immerse the ultrasound transducer into the Cidex OPA cylinder.
- Perform Ultrasound transducer leakage test:
  - Plug transducer adapter into the appropriate port on the ULT 2020 Leakage Tester
  - Plug the Ultrasound Transducer Electrical Connector into the transducer adapter. The transducer electrical connector plug will click into place.
  - Plug dual prong conductivity probe into the appropriate port on the ULT 2020 Leakage Tester.
  - Place dual prong conductivity probe into Cidex OPA cylinder.
  - Turn on ULT 2020 Leakage Tester and select “Full Test”
  - Document result of test in Cidex OPA QC log book
  - Remove probe form use if leak test fails and notify NM and/or contact manufacturer. Staff documents corrective action
- Remove from OPA and rinse as previously described.
- Store in TEE cabinet
Bronchoscope Protocol for Pre-Cleaning at bedside immediately after procedure

- Perform hand hygiene and don PPE (impervious gown, surgical mask, eye protection, gloves and bouffant)
- Place pan/basin lined with chuck to absorb enzymatic flush and water. Flush on table used for sterile field (after procedure table is considered dirty).
- Remove Endozime SLR sponge from the Phase One Canister.
- Wipe exterior surface of scope, starting with the top of the insertion tube to end of insertion tube with Endozime SLR sponge.
- Discard sponge in waste pan/basin.
- Use a 30cc syringe to suck up 30cc of Endozime SLR from jar.
- Flush lumen of scope with Endozime
- SLR solution X3.
- Collect waste in pan/basin.
- Disassemble stop cock and place in specimen cup with remaining Endozime solution.
- Use 30cc syringe to suck up 30cc of water from culture cup. (dispose daily)
- Flush lumen of scope with water X3.
- Collect waste in pan/basin.
- Using 30cc syringe, flush lumen of scope with air X3.
- Discard waste pan/basin and syringe in regular trash.
- Place the scope and the specimen cup containing the disassembled stopcock into the lined transport/SPD collection container and close lid.
- Place a biohazard sticker on outside of transport/SPD collection container.
- Remove PPE, perform hand hygiene and don clean gloves. Follow Transporting Dirty Cystoscope algorithm from Procedure/Exam Room.

Off-Site Transportation of Sterile Items

Off-site transportation from SPD on the UTMB campus to the hospital/clinics will be carried out using closed containers, and closed containers will be used for items being returned to SPD.

References

CIDEX® OPA TEST STRIPS QUALITY CONTROL LOG

**Location/Department:** ____________________________

**Purpose:** Document performing quality control of the CIDEX® OPA Quality Control strips when a new bottle of strips is opened.

**Definitions:**
- **Expiration date** is printed on the label by the manufacturer
- **Discard date** is calculated by adding 90 days to the open date of the strips
- **Quality control means** both positive and negative controls are performed each time a new bottle of QC strips is opened.

**Procedure to Prepare the Positive & Negative Controls:**
- **POSITIVE Control:** use full strength, activated CIDEX® OPA (30 ml);
- **NEGATIVE Control:** one part activated CIDEX® OPA (15 ml) and one part water (15 ml). Timing is critical. Insert 3 strips into each of the two control solutions for (1) second. Remove excess solution by standing up the strips. Read results in exactly ninety (90) seconds.

**Controls Results:** To “PASS” on the positive controls, the dipped QC strip(s) must turn purple; if any blue appears on indicating pad apart from the top line, the solution did not pass (“FAILS”); to “PASS” on the negative controls, the strip color is blue or blue/purple.

**Corrective Action Key:** use the following key to denote action if either control did not pass:
- **D:** CIDEX® OPA Solution Test Strips discarded today because test failed;
- **D1:** CIDEX® OPA Solution Test Strips discarded today because bottle was left open;
- **D2:** CIDEX® OPA Solution Test Strips discarded today because bottle was not dated when opened.

**Test Date**

<table>
<thead>
<tr>
<th>Year</th>
<th>CIDEX® OPA Solution</th>
<th>CIDEX® OPA Strips</th>
<th>CIDEX® OPA Strips: Date Opened and Calculated Discard Date</th>
<th>Positive Quality Controls All 3 results: (Pass/Fail) Pass = only purple color</th>
<th>Negative Quality Controls All 3 results: (Pass/Fail) Pass = Blue or blue/purple</th>
<th>Print Employee Name performing Quality Controls</th>
<th>Corrective Action Key (use reverse side for comments)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lot</td>
<td>Lot</td>
<td>Exp: Discard Date</td>
<td></td>
<td></td>
<td>Print Employee Name performing Quality Controls</td>
<td>Corrective Action Key (use reverse side for comments)</td>
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<td>Corrective Action Key (use reverse side for comments)</td>
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</tbody>
</table>

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### CIDE® OPA Working Solution QUALITY CONTROL LOG

**Location/ Dept:**

*Note: Use backside of log for any Corrective Action taken (eg working solution temperature out-of-range), or comments. Don't forget to date and initial!*

<table>
<thead>
<tr>
<th>Working Solution Quality Test Date</th>
<th>Probe and/or Scope # and Patient MRN #</th>
<th>CIDE® OPA Gallon Bottle Manufacturer's Label Lot# and Exp Date</th>
<th>CIDE® OPA Gallon Bottle Open Date and +75 days Date (75 days = 2.5 months)</th>
<th>CIDE® OPA Working Solution (WS) Container Start Date</th>
<th>CIDE® OPA Working Solution (WS) Expiration Date (Never use WS past 14 days from start date)</th>
<th>Test Strips Lot#</th>
<th>CIDE® OPA Working Solution (before each use) Open date and +90 days Date (90 days = 3 months)</th>
<th>Strip Test Results (Circle correct response)</th>
<th>Leak Testing</th>
<th>CIDE® OPA Working Solution Temp Acceptable ≥ 20°C (68°F)</th>
<th>Processed by (Print Name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#</td>
<td>MRN:</td>
<td>Lot#</td>
<td>Exp. Date</td>
<td>Lot #</td>
<td>Open date and +90 days Date</td>
<td>Pass Fail</td>
<td>Pass Fail</td>
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<td>MRN:</td>
<td>Lot#</td>
<td>Exp. Date</td>
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<td>Open date and +90 days Date</td>
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High-Level Disinfection (CIDEX OPA)

1. Date and initial the CIDEX OPA bottle when opened. Expiration date is 75 days after bottle is opened.
2. Label CIDEX OPA pour-over containers with expiration date and initials. Expiration date is 14 days after pouring into CIDEX OPA container.
3. Don PPE before starting cleaning process:
   - Gloves
   - Fluid resistant gown
   - Mask
   - Eyewear (goggles or face shield)
   - Bouffant
4. Check CIDEX OPA solution before each use with a CIDEX OPA Test Strip dipped into the solution for 1 second.
5. Read the test strip in 90 seconds. (If solution fails by test strip, identify problem and take corrective action.)
6. Record the result of the test strip.
7. Check the CIDEX OPA solution temperature before each use. Temperature should be ≥68°F.
8. Record temperature of CIDEX OPA solution.
9. Prewash instruments with enzymatic cleaner before placing in the CIDEX OPA bath. Instruments must be TOTALLY SUBMERGED and all lumens filled with disinfectant.
10. Soak the instruments for 12 MINUTES using a timer.
11. Rinse well 3 times with a minimum of 2 gallons of 0.2u filtered water (or sterile water) each time and then air dry.

NOTE: Single use disposables must not be reprocessed. Instruments that cut or biopsy must be sterilized.
DEPARTMENT OF HEALTHCARE EPIDEMIOLOGY

QUALITY CONTROL PROCEDURE
RAPICIDE PA (Peri Acetic Acid) MONITORS

TESTING PROCEDURE
- Open the Rapicide PA Test Strips bottle and remove test strip. Close the bottle.
- For ADVANTAGE PLUS – Use the ADVANTAGE Plus sampling cups to collect the solution sample from the reprocessor. Dip the test strip indicator pad into the Rapicide PA solution in the sampling cup for exactly one (1) second and immediately remove.
- For DSD EDGE – Dip the test strip indicator pad into the Rapicide PA solution in the sample port (located inside the basin) for exactly one (1) second and immediately remove.
- Wait exactly thirty (30) seconds and then compare the test strip color with the color chart located on the side of the test strip bottle to determine peracetic acid parts per million (ppm) concentration levels.

TESTING FREQUENCY
- It is recommended that the Rapicide PA solution be tested with each endoscope reprocessing cycle to verify disinfectant is above 850 ppm MRC.

UNSATISFACTORY QC TEST PERFORMANCE
- If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. DO NOT USE. For customer support, contact Medivators at 1-800-444-4729.