

Cleaning and High Level Disinfection of Semi-Critical Medical Devices

I. Purpose:

A. To provide guidance for cleaning, processing and high level disinfection (HLD) of semi-critical devices using cylinders, bins/pans, or automated endoscopic reprocessors. This process is to include vaginal-rectal ultrasound probes, endoscopes, laryngoscope blades, cystoscopes, esophageal manometry probes, anorectal manometry catheters, respiratory/anesthesia equipment, all GI scopes, transesophageal echocardiogram probes and rhinoscopes. According to the Centers for Disease Control and Prevention, medical devices and equipment that contact mucous membranes or non-intact skin minimally require high level disinfection. The expected outcome is that the patient will be free from signs and symptoms of infection.

II. Policy:

A. It is the policy of Naval Medical Center Portsmouth that:

1. The manufacturer's written instructions for semi-critical medical devices will be followed regarding

- a) Cleaning processes
- b) Selection of cleaning product
- c) Selection of disinfectant/sterilization products
- d) Use of alcohol
- e) Compatibility with automatic endoscope reprocessors (AER)

2. High-level disinfectant and chemical cleaner manufacturer's written instructions will be followed regarding

- a) Compatibility with the semi-critical medical device
- b) Water quality
- c) Dilution
- d) Temperature of solution
- e) Testing for minimum effective concentration
- f) Time of exposure
- g) Rinsing

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3. Semi-critical medical devices and accessories will be pre-cleaned at the point of use before transport to the decontamination area.
4. For the purposes of this policy, the referenced HLD will be Cidex® OPA. Infection Control must approve any exception to the referenced HLD. NOTE: Urology uses Cidex® OPA Concentrate. GI clinic uses Rapicide® PA. Trophon units may be purchased and used for vaginal probe HLD AFTER approval for the entire process has been completed by Infection Control.
5. Special note regarding Glutaraldehyde User Stations (GUS):
 - Per manufacturer's guidelines, these systems require filter changes every six (6) months. It is the responsibility of each department that uses a GUS to order and replace these filters when applicable. A label should be placed on the side of the GUS units to indicate when the filter was changed and when the next change is due.
 - Turn rinse cylinders upside down on a clean, dry towel or Chux® pad to dry preferably after use but definitely at the end of the day to prevent mold from forming in the cylinders. GUS cylinders should be washed out at least monthly with hot soapy water, using a clean bottle brush then rinsed with hot water and turned upside down to dry.
6. Procedures/forms used for processing semi-critical medical devices shall be consistent throughout the command. Any change in the forms used for HLD documentation must be approved by IC before institution.

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III. Procedure: Flexible endoscopes

- A. Wash external surfaces of the flexible endoscope insertion tube with an enzymatic detergent solution using a soft cloth or gauze sponge.
- B. Prior to removing the endoscope from the patient care environment, suction copious amounts of enzymatic solution (e.g., enzymatic detergent mixed with tap water) and air through the internal suction/biopsy channels.
- C. Flush air and water channels with an enzymatic solution.
- D. Flush air and water channels using low-pressure compressed air (i.e., pressure should not exceed maximum channel pressure specified by manufacturer), if available. If low-pressure compressed air is not available, a syringe may be used for flushing with air.
- E. Flush or purge with water and/or enzymatic detergent solution as described in the manufacturer's written instructions any remaining components or channels (e.g., forward water jet channel, exposed elevator wire channels, balloon channels).
- F. Visually inspect all surfaces of the endoscope tip and working parts for damage and for cleanliness.
- G. Attach the video protective cap, if available, after removing the flexible endoscope from the light source and suction.
- H. Remove all detachable parts (e.g., hoods, valves, water bottle) and immerse in an enzymatic detergent solution until transport to the decontamination room.
- I. Discard the enzymatic detergent solution after a single use.
- J. When flexible endoscopes and accessories are used on a sterile field:
 - 1. The external surfaces should be wiped with a lint-free cloth saturated with sterile water;
 - 2. Sterile water and air should be alternately suctioned through the channels;
 - 3. The endoscope and accessories should be handed to the circulator as soon as possible, enabling steps 1 through 7 to be accomplished.
- K. Transport the contaminated flexible endoscope and accessories to the decontamination area using a closed, rigid container (e.g., enclosed inside a rigid container with a lid and has a Chux® pad or towel in the bottom to protect the instruments) that is labeled to indicate biohazardous contents.
 - 1. Before cleaning, perform pressure (i.e., leak) tests on flexible endoscopes with leak testing capabilities in the decontamination area before cleaning.

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- a) Manipulate the flexible endoscope control knobs in all directions during leak testing.
 - b) When using a leak test system requiring water, attach the leak test system to the flexible endoscope, and then submerge the entire endoscope in water that does not contain cleaning agents.
 - c) Check for the presence of bubbling in the water.
 - d) Keep the leak testing device attached to the flexible endoscope and under pressure if a leak is detected until the endoscope is removed from the water.
 - e) Complete the leak test before submersion in water or cleaning solution when using a leak test system that does not require water.
2. Manually clean the flexible endoscopes and accessories.
- a) Submerge the flexible endoscope in an enzymatic detergent solution.
 - b) Wash the insertion tube of the flexible endoscope using a soft, lint-free cloth or gauze sponge.
 - c) Flush all internal channels thoroughly with an enzymatic detergent using manufacturer-provided channel cleaning adapters.
 - d) Flush all endoscope components (e.g., shroud, valves) thoroughly with an enzymatic detergent.
 - e) Inspect brushes prior to insertion to confirm that they are sized appropriately to the channel(s), not kinked or missing bristles, and that a protective tip is present.
 - f) Insert the brush through the channel with the entire endoscope submerged.
 - g) Wipe the bristles prior to retracting the brush back through the channel.
 - h) Flush all channels thoroughly and rinse all exterior surfaces of the flexible endoscope and accessories with potable tap water in accordance with manufacturer's instructions.
 - i) Dry the flexible endoscope using low-pressure forced air through the internal channels and wipe the exterior surfaces with a soft cloth.

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3. After cleaning, high-level disinfect or sterilize flexible endoscopes and accessories.
 - a) When using a **manual process for HLD**
 - (1) Completely immerse the flexible endoscope and its' accessories in the disinfecting solution
 - (2) Flush all channels with disinfecting solution after immersion
 - b) When using an **AER for HLD**
 - (1) Insert the flexible endoscope and components into the AER and attach all the flexible endoscope channels to the unit using compatible connectors.
4. Follow the steps for manual HLD when the compatible connectors of the automatic endoscope reprocessor cannot be connected to a specific channel (i.e., the wire elevator channel of a duodenoscope), for this channel or for the entire flexible endoscope.
6. Follow the steps for manual HLD when the compatible connectors of the automatic endoscope reprocessor cannot be connected to a specific channel (i.e., the wire elevator channel of a duodenoscope), for this channel or for the entire flexible endoscope.
7. Rinse the flexible endoscope and flush the internal channels with water (e.g., sterile water, filtered or unfiltered tap water).
8. Rinse the flexible endoscope and flush the internal channels with 70% to 90% ethyl or isopropyl alcohol, unless contraindicated by the manufacturer's written instructions.
9. Dry the flexible endoscope and the internal channels using low-pressure forced air.
10. Do not store flexible endoscopes in their original shipment cases. Store clean flexible endoscopes in a closed cabinet with:

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- a) Venting that allows air circulation around the flexible endoscopes
- b) Internal surfaces composed of cleanable materials
- c) Adequate height to allow flexible endoscopes to hang without touching the bottom of the cabinet
- d) Sufficient space for storage of multiple endoscopes without touching
- e) Hanging in a secure vertical position
- f) With all removable endoscope components detached (e.g., valve mechanisms, biopsy valve covers, irrigation tubes)
- g) All accessories removed
- h) With scope protectors applied if the protector does not interfere with the flexible endoscope hanging straight or restrict the air movement around channel openings

11. Once the HLD process has been completed, transport the clean instruments/equipment in a designated rigid, clear or opaque plastic lidded container that has a label that reads **CLEAN PROCESSED EQUIPMENT ONLY**. These containers can be washed with soap and water, dried, and then disinfected using an approved germicidal wipe and observing the correct contact time. Store containers in a clean space, not on the floor or near any dirty area.

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- L. Reprocess flexible endoscopes before use if
 1. The endoscope has not been used for more than five days or
 2. Evidence of improper drying exists (e.g., evidence of discoloration, wet spots, stains, soil in the storage cabinet).

- M. Decontaminate flexible endoscope accessories (e.g., water bottle, cap, water tubing, biopsy forceps, cytology brushes, cleaning brushes) after each use.
 1. Decontaminate and sterilize endoscopic accessories (e.g., biopsy forceps, cytology brushes) that enter sterile tissue or the vascular system between uses.
 2. Brush all surfaces of accessories using brushes of the appropriate size and style.
 3. Clean reusable cleaning brushes using an ultrasonic cleaner and sterilize or high-level disinfect after each use.

- N. Inspect flexible endoscopes, accessories, and associated equipment for integrity, function, and cleanliness:
 1. Before, during, and after use
 2. Immediately after decontamination
 3. Before disinfection or sterilization

- O. Remove damaged flexible endoscopes and accessories from use.
 1. Consult the manufacturer for directions regarding actions to be taken prior to shipping for repair.
 2. Unless otherwise specified in the manufacturer's instructions, do not submerge a damaged flexible endoscope or any accessory.
 3. Before shipping, package a contaminated flexible endoscope or its accessories in impervious material in compliance with Department of Transportation shipping regulations.
 4. Label the flexible endoscope(s) and accessories returned to the manufacturer for repair with a biohazard label that is visible during shipping.

- P. Personnel should wear appropriate PPE **based on the degree of expected contact with contaminated flexible endoscopes and accessories or any other equipment/instruments that require HLD**. Appropriate PPE should include, but is not limited to,
 1. Fluid-resistant gown

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2. Disposable gloves
 3. Surgical mask
 4. Goggles or plastic face shield
- Q. Wash hands after removing PPE.
- R. Decontaminate and sterilize endoscopic accessories (e.g., biopsy forceps, cytology brushes) that enter sterile tissue or the vascular system between uses.
- S. Brush all surfaces of accessories using brushes of the appropriate size and style.
- T. Clean reusable cleaning brushes using an ultrasonic cleaner and sterilize or high-level disinfect after each use.

IV. Procedure: All other semi-critical devices to include vaginal-rectal ultrasound probes, laryngoscope blades, cystoscopes, esophageal manometry probes, anorectal manometry catheters, respiratory/anesthesia equipment, all GI scopes, trans-esophageal echocardiogram probes, tonometers, and rhinoscopes.

A. Special notes regarding tonometers used in Ophthalmology/Optometry: Infection Control recommends the use of disposable, one time use prisms.

If reusable tonometer prisms should have to be used (and this should be a rare occasion), follow the guidelines listed below:

1. ALWAYS refer to manufacturer's recommendations for disinfection of this device BEFORE reprocessing.
2. Recommended disinfection process per the Centers for Disease Control and Prevention (CDC):
 - Remove measuring prism carefully from holder.
 - Wipe prism clean.
 - Disinfect the prism by soaking it in a 10% aqueous solution of sodium hypochlorite (household bleach) i.e. 1 oz. bleach, 10 ozs. tap water, making sure the prism (s) is completely under the solution for 10 minutes. It is important to use a timer for this process.
 - Rinse the prism(s) thoroughly using cold water.
 - Allow the tonometer prism(s) to air dry on a clean field/surface.
 - Store in a clean, dry container.
 - Maintain a log book of each decon procedure which should include the date, duration of HLD, and name of person performing the HLD.
3. Special notes regarding the tonometer prism HLD process:
 - Areas performing this process can use small plastic containers for the disinfection and rinsing processes. These containers should be labeled with the contents of each such as 10% aqueous bleach solution or rinse water and the date on both containers.
 - The bleach solution must be made fresh DAILY.
 - Always use fresh water for rinsing.
 - Prisms can be processed in bulk by placing used/dirty prisms in a plastic, covered container labeled BIOHAZARD written on the lid. MAKE SURE THE PRISMS

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DO NOT OVERLAP ONE ANOTHER during the 10 min. soaking time. Label this container as USED/DIRTY Tonometer Prisms.

- Once processing is completed, clean prisms can be stored in bulk in a clean covered plastic container labeled CLEAN Tonometer Prisms.

B. Vaginal and rectal (endocavitary) probes used in sonographic scanning are considered to be semi-critical devices and require high-level disinfection prior to reuse. Though current practice mandates the use of a new condom/probe cover for each patient, because condoms/probe covers may fail, HLD of the probe is required following each procedure. The pre-cleaning/disinfecting process must be performed per the device and sterilant manufacturer's recommendations and current infection control practices. The following process must be followed with all the semi-critical medical devices mentioned previously.

1. Transport the contaminated semi-critical medical device and accessories to the decontamination area using a closed, rigid, lidded container that is labeled to indicate biohazardous contents. This same type of transport applies to vaginal probes. Using an approved germicidal wipe, cords from used vaginal probes should be wiped down after exam is completed and condom is removed from the probe. Then the ENTIRE probe & cord unit is transported to decon area in the container described in this paragraph. As part of the decon process, vaginal probe cord should be wiped down again after removing from dirty transport bin, using the approved germicidal wipe.
2. Visually inspect all surfaces of the semi-critical medical device and working parts for damage and for cleanliness.
3. Vaginal probe cords should be wiped down with a clean soft cloth using 70% isopropyl alcohol or an approved hospital grade surface disinfectant wipe/cloth. **Always check the manufacturer's recommendations prior to using any cleaning/disinfecting material on equipment.**
4. Using a soft cloth or gauze sponge, manually clean external surfaces of the semi-critical medical device and accessories with a pre-cleaner approved by the equipment manufacturer. In the case of vaginal probes, pre-cleaning can be handled by using soap and water, a hospital grade surface disinfectant wipe/cloth, which can be alcohol-free if need be, or an enzymatic detergent solution as recommended by the manufacturer of the vaginal probe. Because of the different types of vaginal probes used, resulting in different manufacturer's recommendations for pre-cleaning, each area must decide what to use as their pre-cleaner and add this to their SOP for their clinical space. **Always check the manufacturer's recommendations for type of pre-cleaning required.**

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- a) Depending on the semi-critical device, submerge the device, preferably in an enzymatic detergent solution, following the directions of the pre-cleaner of choice.
 - b) Dry the semi-critical medical device using low-pressure forced air through the internal channels, if applicable, and wipe the exterior surfaces with a soft cloth.
 - c) After cleaning, high-level disinfect or sterilize semi-critical medical devices and accessories.
- A. When using a manual process for HLD
1. Completely immerse the semi-critical medical device and its accessories in the disinfecting solution
 2. If the semi-critical medical device has channels, flush all channels with disinfecting solution after immersion.
 - a) Rinse the semi-critical medical device and, if applicable, flush the internal channels with water (e.g., sterile water, filtered or unfiltered tap water).
 - b) Rinse the semi-critical medical device and flush the internal channels with 70% to 90% ethyl or isopropyl alcohol, unless contraindicated by the manufacturer's written instructions.
 - c) Dry the semi-critical medical device with a soft cloth or gauze. Use low-pressure forced air to dry the internal channels, if applicable.
 3. Do not store semi-critical medical devices in their original shipment cases. Store clean semi-critical medical devices per manufacturer's recommendations, or wrapped in clean toweling or cloth i.e., laryngoscope blades for anticipated immediate patient use. These covered blades must be reprocessed if not used within 5 days. If the blade is sterilized, storage will be in a peel pack. If the blade is high level disinfected, storage will be in a closed (e.g., ZipLock®) plastic bag. Regarding other semi-critical medical devices that can/will be maintained in a closed cabinet, the following guidelines apply:
 - a) Venting that allows air circulation
 - b) Internal surfaces composed of cleanable materials
 - c) Adequate height to allow semi-critical medical devices to hang without touching the bottom of the cabinet
 - d) Sufficient space for storage of multiple semi-critical medical devices without touching

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- e) Hanging in a secure vertical position, covered with a clean plastic bag that contains a green tag indicating CLEANED and the date.
 - f) With all removable components detached
 - g) All accessories removed
 - h) With protectors applied if the protector does not interfere with the device hanging/lying straight or restrict the air movement around channel openings.
 - i) Reprocess the semi-critical medical device before use if
 - j) The device has not been used for more than five (5) days or
 - k) Evidence of improper drying exists (eg, evidence of discoloration, wet spots, stains, soil in the storage cabinet).
4. Decontaminate semi-critical medical device accessories after each use.
- B. Inspect semi-critical medical devices, accessories, and associated equipment for integrity, function, and cleanliness:
- 1. Before, during, and after use
 - 2. Immediately after decontamination
 - 3. Before disinfection or sterilization
- C. Remove damaged semi-critical medical devices and accessories from use.
- 1. Consult the manufacturer for directions regarding actions to be taken prior to shipping for repair.
 - 2. Unless otherwise specified in the manufacturer's instructions, do not submerge a damaged semi-critical medical device or any accessory.
 - 3. Before shipping package a contaminated semi-critical medical device or its accessories in impervious material, in compliance with Department of Transportation shipping regulations.
 - 4. Label the semi-critical medical device and accessories returned to the manufacturer for repair with a biohazardous label that is visible during shipping.
- D. Personnel should wear appropriate PPE **based on the degree of expected contact with contaminated semi-critical medical devices and accessories or any other equipment that requires HLD**. Appropriate PPE will include, but is not limited to:
- 1. Fluid-resistant gown

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2. Disposable gloves
 3. Surgical mask
 4. Goggles or plastic face shield
- E. Wash hands after removing PPE.

V. Cidex® OPA Solution Instructions (Attachments 1 & 2)

A. When opening a new container of Cidex® OPA label the container with the date, time, and initials of person opening the container. Seventy-five (75) day shelf life after opening the bottle.

B. Cidex® OPA solution must be maintained at a minimum temperature of 20°C or (68°F). A temperature strip must be added to the **OUTSIDE** of the cylinder or bin that contains the Cidex® OPA solution that is ready for use. The minimum temperature should be maintained or exceeded throughout the soaking time. The solution should not be used until the temperature is sufficient. In most cases, the ambient temperature of a reprocessing area is adequate to ensure the minimum reprocessing temperature is maintained during HLD. **Reading** of the Cidex® OPA solution temperature must be performed prior to each use of the solution and **recorded** on the NMCP Cidex® OPA Solution Testing Log (attachment 3).

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B. Follow disinfectant manufacturer's recommendations for testing the disinfectant's minimum effective concentration (MEC) and quality control testing of disinfectant test strips. When opening a new test strip bottle, label the bottle with the date, time, and initials of person opening the bottle. Bottle expires after 90 days.

C. Quality control testing of test strips will be performed upon initial bottle opening and at 30 day intervals thereafter until the 90 day expiration date has been reached for the container. Document results on the NMCP Cidex® OPA solution testing log (attachment 2).

D. Keep HLD test strip container closed. If left open greater than 30 minutes, discard test strips and obtain new bottle of strips.

E. To perform quality control testing, prepare a positive and negative control solution. (Refer to Cidex® OPA Test Strip IFU – attachment 2)

1. Thirty (30) ml of positive control solution is undiluted HLD and a negative control is a dilution of 15 ml water and 15 ml Cidex® OPA.

2. Submerge three (3) test strips in each solution for ONE (1) second, remove. Do not shake the strip(s)! Stand test strips upright on a paper towel. Read at 90 seconds.

3. The pads of the three (3) test strips dipped in the undiluted positive control solution should turn fully purple.

4. The pads of the three (3) test strips dipped in the diluted negative control solution should remain blue or exhibit an incomplete color change.

5. Document test results on the NMCP Cidex® OPA solution testing log.

F. MEC disinfectant solution testing will be performed before each use. Each solution is to be tested separately and results noted accordingly on the NMCP Cidex® OPA solution testing log. Refer to #2E above regarding how to read the test strip.

G. Each disinfectant solution will be clearly labeled with the used solution expiration/change date.

H. Washing and rinsing of semi-critical devices in hand washing sinks is not permitted. Cleaning and HLD will be performed in an appropriate Soiled Utility room.

I. Manual Processing:

1. If permitted by manufacturer, immerse device completely, filling all lumens and eliminating air pockets, in Cidex® OPA solution for a minimum of 12 minutes at 20°Celsius or 68°Fahrenheit or higher (normal room temperature) to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly following the rinsing instructions below. To prevent damage to the device surface, do not leave the equipment in the HLD for an extended (one hour or greater) period of time.

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J. AER:

1. For use in a legally marketed AER (that can be set to a minimum of 25°C or 77°F) with a minimum immersion time of 5 minutes. As with all high level disinfectants, it is critical that temperature is monitored when using Cidex® OPA solution or Cidex® OPA Concentrate in an AER. (See section D. 1 “Monitoring of Germicide” in the Cidex® OPA Instructions for Use).

K. Rinsing Instructions:

1. Manual Processing:

a) Following removal from Cidex® OPA solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume (e.g., 1-2 gallons) of fresh water. Use potable (tap) water unless sterile water rinsing is indicated e.g., bronchoscopes/cystoscopes.

b) Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.

c) Manually flush all lumens with large volumes (not less than 100 ml) (NOTE: the volume of rinse water will depend on the size of the device being rinsed e.g., using the GUS, vaginal probes are only submerged to the where the cord connects to the actual probe) of rinse water unless otherwise noted by the device manufacturer.

d) Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.

e) Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove Cidex® OPA solution residues. Residues may cause serious side effects. (See WARNINGS in Cidex® OPA Instruction for Use). THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED. Note that any Cidex® OPA residue will show up as a dark stain on the material used to dry the processed device. If this occurs, perform 3 additional rinses to insure all HLD is removed.

f) Refer to the reusable semi-critical medical device manufacturer’s labeling for additional rinsing instructions.

2. AER:

a) Select a rinse cycle on the AER that has been validated for use with this product.

b) Ensure that the automated rinse cycle selected will thoroughly rinse the semi-critical medical device including all lumens with large volumes of sterile or potable water equivalent to the reusable device manufacturer’s recommendations.

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- c) Verify that each rinse is a minimum of 1 minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh volume of water is used for each rinse. Do not reuse the water for rinsing or any other purpose.
 3. If permitted by the manufacturer, devices rinsed in tap water should be wiped with 70% to 90% ethyl or isopropyl alcohol and allowed to air dry.
 4. Use sterile water rinse if:
 - a) Device is intended for use in normally sterile areas of the body.
 - b) Device is intended for use in known immuno-compromised patients, or potentially immune-compromised patients.
 - c) When practical, bronchoscopes, due to a risk of contamination from potable water supply.
 5. Use potable water rinse:
 - a) When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with microorganisms which may be present in potable water supplies.
 - b) Water treatment systems, such as softeners or deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is recommended.
 - c) A device that is not completely dried provides an ideal situation for rapid colonization of bacteria. As these waterborne bacteria are highly resistant to drying, rapid drying will avoid possible colonization but may not result in a device free from these bacteria. A final rinse using a 70% to 90% ethyl or isopropyl alcohol solution can be used to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.
 6. Any dark or discolored area noted on semi-critical devices indicates poor or incomplete cleaning. The device should be immediately reprocessed with particular attention paid to cleaning.
- L. Re-usage for Disinfection of Cidex® OPA solution:
 1. Cidex® OPA solution has demonstrated efficacy in the presence of organic soil contamination and microbiological burden during reuse. The ortho-Phthalaldehyde concentration of Cidex® OPA solution during its use-life must be verified by the Cidex® OPA solution test strips prior to each use, to determine that the MEC of 0.3% is present. Cidex® OPA solution may be used and re-used within the limitations indicated above for up to a maximum of 14 days. Cidex®

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OPA solution must be discarded after 14 days, even if the Cidex® OPA solution test strip indicates a concentration above the MEC.

- M. Disposal of Cidex® OPA shall be in accordance with NMCP policy (attachment 6).

VI. Documentation:

A. Document the following items for each flexible endoscope or semi-critical device cleaning and processing procedure (attachment 5):

1. Test strip result
2. Flexible endoscope or semi-critical device identification
3. Leak test (if applicable)
4. Patient identification
5. Start time of HLD
6. Printed name of person starting HLD
7. Stop time of HLD
8. Printed name of person stopping HLD

B. Document all patient-specific information according to the policy and procedure for documentation for patients undergoing operative or invasive procedures.

C. Personnel removing any processed scope from a department must document in a well-maintained log the scope #, date, time, his/her printed name, and where scope is being taken (attachment 9).

D. HLD and sterilization records will be maintained for a minimum of 3 years.

VII. Competency:

A. **DEPARTMENT HEADS** are responsible for assuring that only properly trained staff perform high-level disinfection of semi-critical patient care equipment and devices. Personnel working with flexible endoscopes and semi-critical medical devices will receive orientation upon hire and ongoing education on proper care, cleaning, and processing of the instruments and related accessories. Competency training for HLD is **REQUIRED** initially before anyone can perform HLD and again annually in July of each year.

1. Personnel should demonstrate competency in the use, care, transporting, and processing of flexible endoscopes, semi-critical medical devices and related equipment.

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2. Personnel who work with flexible endoscopes and semi-critical medical devices will receive training and education on:
 - a) Cleaning and decontamination methods
 - b) Preparation and transportation of flexible endoscopes, semi-critical medical devices and related accessories for sterilization or high level disinfection
 - c) Selection of cleaning agents and methods
 - d) Proper use of cleaning agents, including an understanding of specific applications, appropriate dilution, and special precautions
 - e) Decontamination of specialized flexible endoscopes, semi-critical medical devices and related accessories
 - f) PPE required during instrument processing
 - g) Exposure risk associated with chemical cleaning agents
 - h) Locations of material safety data sheets (SDS).
 - i) It is required that each department/area that performs HLD develop and keep current a signature page (this document should contain both a printed name and legible signature of same person) of those staff who are qualified to perform HLD, keeping this log in the HLD manual.
3. Personnel will be provided education before new flexible endoscopes, semi-critical medical devices, accessories, cleaning agents, cleaning methods, and procedures are introduced.
4. The NMCP High Level Disinfection of Semi-Critical Medical Devices Competency form (attachment 7) will be used to document training and demonstration of competency. The completed form will be maintained in each individual's training record(s).

VIII. Definitions:

- A. Automatic endoscope reprocessor: A unit for mechanical cleaning, disinfecting, and rinsing of flexible endoscopes.
- B. Cleaning: A process using friction, detergent, and water to remove organic debris; the process by which any type of soil, including organic debris, is removed. Cleaning removes rather than kills microorganisms.
- C. Contaminated: The presence of potentially infectious, pathogenic organisms (eg, blood, other potentially infectious material) on or in animate or inanimate objects.

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- D. Decontamination: A process that removes contaminating infectious agents and renders reusable medical products safe for handling.
- E. Disinfection: A process that kills most forms of microorganisms on inanimate surfaces. Disinfection destroys pathogenic organisms (excluding bacterial spores) or their toxins or vectors by direct exposure to chemical or physical means.
- F. Enzymatic cleaner: A cleaner that uses enzymes to remove protein from surgical instruments.
- G. High-level disinfection: A process that kills all microorganisms with the exception of high numbers of bacterial spores and prions. High-level disinfectants have the capability to inactivate the hepatitis B and C viruses, HIV, and Mycobacterium tuberculosis, but do not inactivate the virus-like prion that causes Creutzfeld-Jakob disease. Government-registered high-level disinfection agents kill vegetative bacteria, tubercle bacilli, some spores and fungi, and lipid and nonlipid viruses, given appropriate concentration, submersion, and contact time.
- H. Personal protective equipment (PPE): Specialized equipment or clothing for eyes, face, head, body, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the worker from injury or exposure to a patient's blood, tissue, or body fluids. Used by health care workers and others whenever necessary to protect from the hazards of processes or environments, chemical hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation, or physical contact.
- I. Semi-critical: Items that come in contact with mucous membranes or non-intact skin eg scopes, laryngoscope handles and blades, reusable peak flow meters, vaginal and rectal probes, cryosurgical instruments, thermometers.

IX. References:

- A. Petersen C, ed. Perioperative Nursing Data Set. 3rd ed. Denver, CO: AORN, Inc; 2010. In Press.
- B. Recommended practices for cleaning and processing flexible endoscopes and endoscope accessories. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2011: 415-428.
- C. Recommended practices for High Level Disinfection. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2011: 399-414.
- D. APIC Text of Infection Control and Epidemiology 2009, 3rd edition, Chapter 21, Cleaning, Disinfection, and Sterilization
- E. Centers for Disease Control and Prevention Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

X. Attachments:

Cleaning and High Level Disinfection of Semi-Critical Medical Devices

1. Cidex® OPA Instructions for Use
2. Cidex® OPA Solution Test Strips IFU
3. NMCP Cidex® OPA Solution Testing Log
4. Color chart of test strip indicators
5. NMCP High Level Disinfection Control Form
6. NMCP Cidex® OPA Disposal
7. NMCP High Level Disinfection of Semi-Critical Medical Devices Competency & Key
8. List of areas/units performing HLD
9. Sign-out form for scopes

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