LAC+ USC MEDICAL CENTER POLICY
DEPARTMENT OF NURSING SERVICES POLICY

Subject: **HIGH LEVEL DISINFECTION PROCEDURE**	Original Issue Date: 04/2018	Policy #: **1207**
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Departments/Areas Consulted:	Reviewed & Approved by:	Approved by:
Epidemiology	Professional Practice Committee Nurse Executive Council Attending Staff Association Executive Committee	(signature on file) Nancy Blake, RN Chief Nursing Officer

PURPOSE:
To ensure maximum adherence to High Level Disinfection (HLD) procedures by healthcare workers (HCWs) and to reduce the transmission of pathogenic organisms to patients and personnel in healthcare settings.

RESPONSIBILITY
All workers (employee or contract) who are involved in HLD procedures.

POLICY
It is the policy of LAC+ USC Medical Center that all employees, including contract staff, who have contact with patients or enter patient care areas will comply with expected HLD procedures as defined in this policy.

DEFINITIONS:
Decontamination is the use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Disinfection is the process that kills pathogenic and other microorganisms by physical or chemical means.

High level disinfection is the process of complete elimination of all microorganisms in or on a device, except for small numbers of bacterial spores.

PROCEDURES:

I. Probes

Trophon (Automated)

1. Don PPE (a gown, eye protection and gloves) prior to cleaning/processing contaminated equipment.

2. Clean the gel, blood, or visible contaminants from the probe using a dry towel. The probe must be clean and dry for the disinfection to be effective.
3. Place the probe inside the Trophon® device, securing at the top by the cord, and ensure that the tip of the probe is not situated below the indicated line within the chamber.
4. Place a chemical indicator disc (red circular piece of paper) inside the chamber at the designated area.
5. Close device door and press start.
6. After the (7 minutes) cycle is complete, the screen will displace “Cycle Complete.” Open the chamber door. Check the indicator disc against the color chart for color change demonstrating adequate disinfection and discard. Note that the machine will also report if disinfection is adequate.
7. Open waste drawer and dispose in the sink (bi-products are water/bio-safe).
8. If disinfection is adequate, remove the probe from the chamber, wipe with a clean, dry towel. The probe is ready for immediate use, or it can be stored for future use (place a clean sleeve over the probe if not being used immediately).
9. If disinfection is inadequate, remove the probe from the chamber; ensure that all gel or visible contaminants have been wiped from the probe and that the probe is dry. Repeat the disinfection process again. If disinfection is still inadequate after a second cycle, do not use the device: notify the departmental administration of the equipment failure, remove and secure the device for servicing.
9. Complete the log of high level disinfection after each patient. Place the sticker of the patient name, DOB, MRN and FIN. Next to the patient sticker, place the Trophon® sticker (high level disinfection date, time, and unit device number).
10. Maintain the Log for three years.

Machine Maintenance:

1. Trophon® should remain on at all times. If the machine is not used it will go into sleep mode. If the machine is turned off it can be easily turned on, however the machine may require and extended warm up time.
2. The disinfection cartridge must be changed every month. The old cartridge will need to be purged and a new cartridge will need to be inserted for this process. The machine will notify when this process is necessary. The departmental identified personnel will be responsible for the routine maintenance of the machine.

3. Trophon® will keep an internal log of all disinfections performed. The Trophon® printer confirmation stickers must be kept in an external log book for quality assurance. The provider should document the color change of the indicator strip in the logbook as well.

4. Empty the waste drawer every day.

Preventive Maintenance
Wipe the chamber with a damp cloth when cool. Do not allow liquid to come in contact with the device or power socket. Do not block or obstruct air flow into the system.
Contact manufacturer's customer service every 12 months or 5000 cycles (will display on screen) to arrange for service.

Quality Monitoring
The cycle documentation is kept by an internal log in the automated high -level disinfection system. The cycle confirmation stickers are printed out for each disinfection. A log is kept with the patient's name, the serial number of the probe, the date and time of the cycle and if the probe passed disinfection. The automated high-level disinfection system will notify user when the cartridge expires.

If chemical indicators do not change color, complete process again. After a second attempt if indicator still does not change, place the automated high-level disinfection system out of service and notify the nurse manager or nurse in charge.

Competency Training
Staff responsible will be oriented/trained on infection prevention and control plan, High Level Disinfection Policy, and operation of Trophon, upon hire and annually thereafter utilizing the skills checklist. They receive in-service training from the manufacturer or those trained by the manufacturer for all new instrumentation, devices and equipment. All orientation, on-the-job, and in-service training and competencies are documented in personnel files.

Rectal/GI Motility Probes Manual HLD

A. Pre-Cleaning

1. Don on appropriate PPE.

2. Unplug the transducer from the system.

3. Remove any cover, puncture guides or other attachments and disassemble all parts.

4. Wipe off any gel or biological material with a moist cloth or sponge moistened with detergent solution following manufacturer's instruction or water to remove all visible contamination and dispose sponge/cloth in appropriate biohazardous waste container.

5. Place the pre-cleaned device in a closed container and transport to the reprocessing area.

6. Place label on the container to indicate the patient's name, MRN, serial number and provider's name.

7. Log in device information into Processing Log.

B. Manual Cleaning By Immersion

1. Using hospital approved enzymatic solution, in accordance to its manufacturer's instructions, follow the device manufacturer's guidelines for manual cleaning instructions.

2. Immerse the transducer and all removable parts and (if applicable the cable and plug).

3. Thoroughly clean all parts of the device using a suitable soft brush, paying special attention to the tip, any built -in biopsy channels, buttons, lever, edges or grooves.

4. Soak the device following the detergent's manufacturer's specified contact time.

5. Visually inspect for any remaining soil and repeat the cleaning steps if necessary.

C. Rinse after Manual Cleaning

- Thoroughly rinse the device and all removable parts with running water with a temperature between 10 degrees C (50 degrees F) and 40 degrees C (104 degrees F) until all signs of residual debris and cleaning solution are removed for approximately 1 minute.

D. Drying after Manual Cleaning

- Remove water from the device with a clean disposable soft, lint-free cloth.

E. High Level Disinfection By Immersion

- Using hospital and device approved High Level Disinfection Solution, in accordance to its manufacturer's instructions, follow the manufacturer's guidelines for manual high level disinfections instructions. Make sure that the solution passes through any built in biopsy channels or grooves. If necessary, use a suitable brush to make sure there are no air bubbles in the channel.

F. Rinse after HLD

- Rinse off the disinfectant thoroughly with sterile water with a temperature between 10 degrees C (50 degrees F) and 40 degrees C (104 degrees F), thoroughly flushing any channels.

G. Drying

- Dry with clean soft lint free cloth.

H. Storage

1. Store in a clean, dust free environment.
2. Tag device with date processed and initial.
3. Device needs to be reprocessed if not used within 7 days, prior to use.

Vaginal Probes Manual HLD

A. Pre-Cleaning

1. Perform hand hygiene and don PPE (a gown, eye protection and gloves) prior to cleaning/processing contaminated equipment.

2. Disconnect the probe from the ultrasound console. Remove all coupling gel from the probe by wiping with a soft cloth dampened with a mild soap and rinse with flowing water. Wipe dry with a soft cloth. All visible residue must be removed during the pre-cleaning process. **Do not use excessive force when cleaning the lens face of the ultrasound transducer.**

3. Remove PPE and transport dirty probe to the processing room in a biohazard bag or container.

4. Perform hand hygiene and don appropriate PPE.

5. Inspect the probe's lens, cable, casing, and connector. Look for any damage that would allow liquid to enter the probe. If any damage is found, do not use the probe.

B. High Level Disinfection

Using hospital approved and probe manufacturer recommended High Level Disinfection Solution, in accordance to its manufacturer's instructions, follow the probe's manufacturer's guidelines for manual high- level disinfection instructions. It is imperative that the probe be immersed at the specified probe length, per probe manufacturer's guidelines. Specified surface area of the probe must be in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.

C. Rinse after HLD

1. Change and don on appropriate PPE
2. Thoroughly rinse the probe with sterile water in accordance to the manufacturer's instructions of the probe and HLD solution manufacturers. Be sure to rinse from the point where the probe was immersed and flush all visible germicide residue.
3. Allow probe to air dry.

Competency/Training

Processing personnel will be oriented/trained on infection prevention and control plan, High Level Disinfection Policy, and operation of manual high-level disinfection system, upon hire and annually thereafter utilizing the skills checklist. They receive in-service training from the manufacturer or those trained by the manufacturer for all new instrumentation, devices and equipment. All orientation, on-the-job, and in-service training and competencies are documented in personnel files.

II. Scopes without Lumen

A. Pre Cleaning

1. Perform hand hygiene and don on appropriate PPE (include eye, skin and respiration protection).

2. Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet cloth or sponge soaked in hospital approved enzymatic detergent solution and discard in appropriate waste container.

3. Place the dirty endoscope in biohazard scope bag (DO NOT COIL ENDOSCOPE TOO TIGHTLY).

4. Place label on bag to indicate the patient's name, MRN, endoscope serial number, and provider's.

5. Take endoscope to the Scope Processing Room. Remove PPE in procedure room prior to transport of endoscope to the Scope Processing Room.

6. Log in endoscope information into Scope Processing Log.

B. Leak Testing

1. Perform hand hygiene and don appropriate PPE (gown, goggles/face shield, and clean gloves).

2. Follow the Endoscope Manufacturer's guidelines on leakage test procedure, prior to immersing the endoscope.

C. Manual Cleaning

1. Using hospital approved enzymatic solution, in accordance to its manufacturer's instruction, follow endoscope manufacturer's guidelines for manual cleaning instructions.

2. Detach the endoscope from the light source (battery type), if applicable.

3. Before complete immersion, securely attach the soaking cap on the endoscope's light source socket.

4. Ensure that the battery housing cap is securely attached on the battery type light source.

D. Rinse after Manual Cleaning

1. Use clean water, immerse the entire endoscope and thoroughly rinse it to remove residual detergent solution.

2. Gently dry all external surfaces of the endoscope with a soft, lint free gauze. Dry the objective lens and the ocular lens with a cotton tip applicator.

E. Disinfection (Manual High-Level Disinfection)

1. Perform hand hygiene and change to clean gloves.

2. Using hospital approved and endoscope manufacturer recommended High Level Disinfection Solution, in accordance to its manufacturer's instructions, follow the endoscope manufacturer's guidelines for manual high- level disinfection instructions. It is imperative that all surfaces of the endoscope are in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.

F. Rinse after HLD

1. Change and don on appropriate PPE.

2. Thoroughly rinse the endoscope with sterile water in accordance to the instructions of the endoscope and HLD solution manufacturers. Ensure to rinse all internal channels and endoscope surfaces to remove all residual disinfectant solution.

G. Drying

1. Gently dry all external surfaces of the device with alcohol saturated soft gauze or lint free 4x4.

2. Dry the ocular lens and the objective lens with a cotton tip applicator. Do not put tension on the insertion tube while drying since the bending section be excessively stretched.

H. Endoscope Storage

1. Store endoscopes in a closed cabinet with high-efficiency particulate arrestance (HEPA) filtered air.

2. Hang endoscope vertically, ensuring it is not coiling or touching the bottom of the cabinet.

3. Store endoscope with all valves open and removable parts (e.g., caps, valves, battery type, or light source) detached.

4. Store in clean, well ventilated, and dust free area.

5. Tag endoscope with date processed and initial.

6. Reprocess scopes (if not used within 7 days) prior to use.

7. Storage cabinet should be cleaned and disinfected weekly.

HLD Solution Storage, Disposal and Spill
Metricide OPA Plus Solution should be stored in its original sealed container at controlled room temperature 15-30 degrees C (59-86 degrees F) in a well- ventilated low traffic area. Once opened, the unused portion of the solution stored in the original container for up to 75 days until used. Dispose of Metricide OPA Plus in a container provided and place in a designated area for pick up and final disposal by Facilities Management. Discard in accordance with federal, state and local regulations per hospital policy. Refer to SDS and Hazardous Waste Spill Policy.

Quality Monitoring
Quality monitoring of HLD solution using the solution test strips is performed prior to each use and recorded on the Scope Processing Log. Quality check of the endoscope processing is conducted using hospital approved monitoring system. Perform procedure in accordance to the manufacturer's instructions. Quality check of the endoscope processing is conducted using hospital approved monitoring system. Perform procedure in accordance to the manufacturer's instructions.

Automatic Endoscopic Reprocessor (AER) Preventive Maintenance
To ensure proper performance of equipment and AERS, preventive maintenance of the system, including performance test should be carried out according the equipment manufacturer's instructions by the vendor or a qualified engineer.

Competency/Training
Processing personnel will be oriented/trained on infection prevention and control plan, High Level Disinfection Policy, and operation of manual/automated high-level disinfection system, upon hire and annually thereafter utilizing the skills checklist. They receive in-service training from the manufacturer or those trained by the manufacturer for all new instrumentation, devices and equipment. All orientation, on-the-job, and in-service training and competencies are documented in personnel files.

III. Scopes with Lumen
A. Pre-Cleaning

1. Don on appropriate PPE
2. Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet cloth or sponge soaked in the freshly prepared detergent solution. Discard in appropriate container.

3. 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. Finish by suctioning air.

4. Detach the endoscope from the light source, suction pump, and all other connections.

5. Attach protective video cap.

6. Place dirty scope in biohazard scope bag (DO NOT COIL SCOPE TOO TIGHTLY).

7. Place label on bag to indicate the patient's name, MRN, scope serial number, and provider.

8. Take scope to Scope Processing Room. Remove PPE in procedure room prior to transport of endoscope to the Scope Processing Room.

B. Leak Testing
1. Log in scope number into Scope Processing Log (See Scope Processing Log).
2. Don personal protective equipment, gown, goggles/face shield, and clean gloves.
3. Follow Scope Manufacturer's guidelines on pre-cleaning and leakage test procedure.

C. Manual Cleaning
1. Using hospital approved enzymatic solution, in accordance to its manufacturer's instruction, follow scope manufacturer's guidelines for manual cleaning procedure.
2. Prior to disinfection all endoscope components must scrupulously cleaned including manual brushing of all brushable channels.
3. With the endoscope manufacturer approved brushes make sure to brush clean the entire suction/instrument channels, all cylinders, ports and valves.

D. Rinse after Manual Cleaning
1. Use clean water, immerse the entire endoscope and thoroughly rinse it to remove residual detergent solution.
2. It is important that all internal channels (air, water, instrument, water jet, etc), external endoscope surfaces and components be thoroughly rinsed.
3. Gently dry all external surfaces of the endoscope with a soft gauze. Dry the objective lens and the ocular lens with a cotton tip applicator.

E. High-Level Disinfection
Manual HLD
Using hospital approved and endoscope manufacturer recommended High Level Disinfection Solution, in accordance to its manufacturer's instructions, follow the endoscope manufacturer's guidelines for manual high -level disinfection instructions.

HLD Using Automatic Endoscopic Reprocessor (AER)
Using hospital approved and endoscope manufacturer recommended High Level Disinfection Solution, in accordance to its manufacturer's instructions, follow the endoscope manufacturer's guidelines for AER including for tubes connection and operation.

Using hospital approved and endoscope manufacturer recommended Liquid Chemical Sterilant, in accordance to its manufacturer's instructions, follow the endoscope manufacturer's guidelines for processing including tubes connection and operation.

F. Rinse after Manual HLD
Thoroughly rinse the endoscope with sterile water in accordance to the instructions of the endoscope and HLD solution manufacturers. Ensure to rinse all internal channels and endoscope surfaces to remove all residual disinfectant solution.

G. Drying
1. Don on fresh gown and gloves.
2. Remove endoscope from AER.
3. Follow scope manufacturer's guidelines on alcohol flush.

H. Storage
1. Store endoscopes in a closed cabinet with high-efficiency particulate arrestance (HEPA) filtered air.
2. Hang endoscope vertically, ensuring it is not coiling or touching the bottom of the cabinet.
3. Store endoscope with all valves open and removable parts (e.g., caps, valves, battery type, or light source) detached.
4. Store in clean, well ventilated, and dust free area.
5. Tag endoscope with date processed and initial.
6. Reprocess scopes (if not used within 7 days) prior to use.
7. Storage cabinet should be cleaned and disinfected weekly.

HLD Solution Storage, Disposal, Spill
Metricide OPA Plus Solution should be stored in its original sealed container at controlled room temperature 15-30 degrees C (59-86 degrees F) in a well ventilated low traffic area. Once opened, the unused portion of the solution stored in the original container for up to 75 days until used. Dispose Metricide OPA Plus in a container provided and place in a designated area for pick up and final disposal by Facilities Refer to SDS and Hazardous Waste Spill Policy Management. Discard in accordance with federal, state and local regulations per hospital policy.

Quality Monitoring
Quality monitoring of HLD solution and Test strips is recorded on the Scope Processing Log. Quality check of the endoscope processing is conducted using hospital approved monitoring system. Perform procedure in accordance to the manufacturer's instructions.

Automatic Endoscopic Reprocessor (AER) Preventive Maintenance
To ensure proper performance of equipment and AERS, preventive maintenance of the system, including performance test should be carried out according the equipment manufacturer's instructions by the vendor or a qualified engineer.

Competency/Training
Processing personnel will be oriented/trained on infection prevention and control plan, High Level Disinfection Policy, and operation of manual/automated high-level disinfection system, upon hire and annually thereafter utilizing the skills checklist. They receive in-service training from the manufacturer or those trained by the manufacturer for all new instrumentation, devices and

equipment. All orientation, on-the-job, and in-service training and competencies are documented in personnel files.

Outbreak Report
An adverse event shall be reported to the department no later than five days after it has been detected, or if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than 24 hours after the adverse event has been detected. An "adverse event" includes patient death or serious disability with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of contamination. The facility must also report deaths and serious injuries associated with the use of medical devices to the FDA. If it is a device-related death, the facility must notify the FDA, using the FDA 3500A form, within 10 work days of becoming aware of the incident. The facility must also notify the manufacturer. If it is a device-related serious injury, the facility must notify the manufacturer, and the FDA only if the manufacturer is unknown; this is to be done within 10 work days of becoming aware.

IV. Temperature and Humidity Reading

A. Areas utilizing a thermometer to monitor humidity and temperature (excluding Trophon device disinfection areas and locations that have temperature and humidity monitored by Facilities Management)

1. Before the start of the HLD process, staff will check and record the temperature and humidity reading from the thermometer, daily.

2. Normal temperature and humidity reading:
   - Temperature- 64 F- 73 F
   - Humidity- 30% - 60%

3. If the temperature or humidity is out of range, notify Supervisor; and notify and consult with Epidemiology for any actions or recommendations.

4. If the thermometer is not functioning properly, check and replace the battery.

5. If unable to continue processing, notify supervisor.

B. Areas utilizing Trophon Device

1. Before the start of the HLD process, staff will check and record the temperature reading from the thermometer daily.

2. Normal temperature reading: 68 F- 76 F.

3. If temperature is out of range, notify Supervisor; and notify and consult with Epidemiology for any actions or recommendations.

4. If the thermometer is not functioning properly, check and replace the battery.

5. If unable to continue processing, notify supervisor.

V. Recall Procedure
Refer to Department of Nursing Policy #625, Supplies and Equipment.

REFERENCES
Code of Federal Regulations
Association for the Advancement of Medical Instrumentation (AAMI)
American National standards Institute Inc. (ANSI)
Joint Commission
LAC+USC Medical Center Department of Epidemiology Policy #40
LAC+USC Medical Center Nursing Policy #1207-A. Locations of Nursing Areas Performing High Level Disinfection

REVISIONS
4/2018, 10/19, 10/21