HIGH DESERT HEALTH SYSTEM
AMBULATORY SURGICAL CENTER

SUBJECT: XIII-131 ULTRASOUND ENDOCA VITY PROBE HIGH LEVEL DISINFECTION	**POLICY #**: 1108
	VERSION: 1
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PURPOSE: To provide guidelines for performing safe and effective high-level disinfection (HLD) of ultrasound endocavity probes with the mechanical means of the Trophon EPR unit.

POLICY:

- There is to be procedural adherence to this policy and procedures outlined below by personnel when reprocessing the ultrasound endocavity probes.
- Ultrasound endocavity probes after each use will be pre-cleaned prior to the being high-level disinfected in accordance with the manufacturer's recommendations of the device, the disinfecting solution and the Trophon EPR unit.
- Quality control measures using chemical indicators are to be used with each disinfection cycle. Logging of the reprocessing is to occur and records maintained.
- Personnel are to receive training and competency assessment before performing reprocessing tasks. Annual competency is to also be completed.

PROCEDURES:

I. Care of the Unit

A. The Trophon unit is to be maintained plugged into the electrical outlet and in the ON mode. The unit will automatically switch into sleep mode if it is not used for extended periods in order to save power. Switching the system off for more than 24 hours will result in reduced usage from each Sonex-HL cartridge disinfectant. In the event of loss of power, tum the unit back on and follow Screen message which will indicate that the unit is warming up. The warm up cycle can take approximately 40 minutes to complete. Once completed the screen message will read: LOAD PROBE. The machine is now ready for use.

II. Pre-Cleaning

A. Personal Protective Equipment, gloves, must be worn during the cleaning process to protect against exposure to infectious agents or toxic chemicals.

B. The probe must be pre-cleaned using a low or intermediate level EPA hospital approved disinfectant (wipe or spray onto a clean soft cloth and dried with a clean

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soft cloth or towel BEFORE the High Level Disinfection process can begin in the Trophon unit.

III. Loading the probe and indicator

A. When the device is ready, screen message will say: **LOAD PROBE AND INDICATOR**

B. Open the chamber door.

C. Hold the probe by its handle; press the top of the probe gland into the gland seat.

D. Press the probe's electrical cable into the cable clamp at the top of the chamber.

E. Ensure the probe is straight and not touching the walls or the bottom of the chamber. The tip of the probe must be above the embossed line etched across the bottom of the chamber.

IV. Chemical Indicator

A. After correctly loading the probe into the chamber, place a chemical indicator into the holder on the floor of the device chamber.

B. A Chemical Indicator must be used for each disinfection cycle and can only be used once.

V. Commence disinfection cycle

A. Close the door to the chamber.

- If the door is not properly closed, screen message will say: **CLOSE CHAMBER DOOR**

B. The next screen message will say: **IS THE PROBE CLEAN AND DRY?** Respond **YES** if the probe has been pre-cleaned and dried. The unit will then check device readiness to perform a disinfection cycle. Once ready screen message displays: PRESS START TO BEGIN.

C. Press START button to initiate cycle.

D. When the cycle has been successfully completed, the device will sound an audible alarm. The next screen message will say: **CYCLE COMPLETE REMOVE AND WIPE PROBE.**

VI. Remove Probe after HLD process completed

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A. Do not touch the interior metal surfaces of the Trophon unit to avoid a burn.

B. Wearing new clean gloves, remove the used Chemical Indicator from the device and verify the chemical indicator color change from red to orange or lighter to validate successful high-level disinfection before discarding, ensure results are recorded or printed in the log and discard indicator in waste container.

C. Remove the probe after the cycle is complete. Wipe the probe with an absorbent, single-use, dry, lint-free cloth. Visually inspect the probe and ensure any peroxide residue is removed.

D. Hang and tag the disinfected probe in vertical position in a clean storage area or prepare for use on next exam.

VII. Documenting in Log

A. The Printer prints the following information and is to be adhered in the log book as a record of the quality control testing of the Trophon EPR.

1. Date
2. Trophon LCD Indicator Status (pass or fail)
3. Chemical Indicator Status (pass or fail)
4. Cycle number
5. Operator initials

VIII. Chemical Indicators Storage

A. Chemical Indicators should be stored at room temperature 59 degrees F – 86 degrees F.

B. Store in a dry and clean environment out of direct heat.

C. Do not store near chemicals such as sterilizing agents, acids, bases, bleaches and other disinfectants.

IX. Trophon SONEX-HL Cartridge:

A. Storage

1. Cartridges should be stored at temperatures between 59 degrees F and 77 degrees F.
2. Store cartridge in all original packaging in correct directional orientation until use.
3. Keep away from excessive heat, avoiding exposure to light.

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4. NEVER manually pierce or open the containers. If it is opened and needs to be disposed of, wear gloves and chemically resistant eye goggles.

B. Removing and Installing the Disinfectant Cartridge

1. The device will automatically prompt you to run a purge cycle if the cartridge has been in the device too long and has expired.
2. Screen message will say: **REPLACE THE CARTRIDGE AND CLOSE CARTRIDGE DOOR**
3. Cartridge door opens automatically. Do NOT use excessive force to pull down the cartridge door.
4. Lift the cartridge out by touching the areas exposed while the bottle is in the holder and avoid touching pierced areas.
5. Empty used cartridges should be disposed of in the nearest waste receptacle. Do not insert an empty cartridge into the unit. This may cause damage.
6. Verify the expiration date before inserting a new SONEX-HL cartridge. If expired, dispose of in Biohazard waste container.
7. Remove the cap from the new cartridge and place the cartridge neck first into the holder.
8. Ensure the locator on the cartridge is aligned with the locator keys on the door. **DO NOT FORCE THE CARTRIDGE INTO THE HOLDER.**
9. Rotate the cartridge lightly until it drops into place and cannot rotate any further. When situated in place correctly, the bottom of the cartridge has been installed the cartridge door will automatically lock and will not reopen until the cartridge is empty.

Cartridges will last for approximately one month from date of installing, depending on usage and whether the unit has been switched off The unit will automatically prompt to run a purge cycle if it detects that the disinfectant cartridge has been in the device for too long and has expired.

10. Once the cartridge is in place close the cartridge door and the unit is ready for use.
11. Document the replacement of the cartridge on the daily log sheet.

X. Purge Cycle

A. The unit will automatically prompt the user to run a purge cycle if it detects that the disinfectant cartridge has been in the unit for too long or if an error has been detected by the unit that cannot be rectified without a service call.

B. **A purge cycle must be manually initiated before lifting or moving the unit.**

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C. Screen Message: **CARTRIDGE EXPIRED**

1. Using soft key button press **PURGE** to initiate cycle.
2. Select MENU using the soft key button
3. Select PURGE
4. Screen message: **CONFIRM PURGE**
5. Select OK using soft key button
6. **ALWAYS WEAR DISPOSABLE GLOVES** when handling the waste container of the unit.
7. Ensure that the empty waste container is fully inserted into the device.
8. The Purge cycle will take about 35 minutes. Screen message: **PURGING**
9. When the purging is complete, screen message: **REMOVE AND EMPTY WASTE CONTAINER.**
10. Remove waste container from device.
11. Screen message: **LOAD WASTE CONTAINER**.
12. Screen message: **PURGE** Complete. **REMOVE CARTRIDGE**.
13. The empty cartridge can now be removed and discarded into Biohazard waste container.

XI. Warnings & Precautions:

A. Risk of bums from the hot surfaces in the internal chamber. Do NOT touch these surfaces.

B. Failure to remove the probe may result in damage to the probe. **Remove the probe immediately after the cycle is complete.**

C. Do **NOT** attempt to open the chamber door during a cycle or in the event of a power failure or system malfunction

D. All repairs must be carried out by trained personnel ONLY. Do **NOT** attempt to repair or modify any part of the device. The Trophon EPR contains no end user serviceable parts.

E. **Transporting the Device:** The device weighs approximately 38lb (17kg). Use safe lifting techniques as per your Occupational Health and Safety Lifting Guidelines for your institution. Do **not** move, relocate or transport the device if hydrogen peroxide is present; purge the device before moving or relocation.

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F. **ONLY** to be used with the Trophon EPR. Do NOT use with non-approved devices.

G. Do **NOT** use damaged and/or out-of-date indicators.

H. **Ensure** indicator is red and not exposed before use.

I. More information can be found in the Chemical Indicator Instructions for use, provided with the Chemical Indicator.

J. **Always wear disposable gloves when handling disinfectant cartridges.**

K. **It is important to wear gloves when handling probes prior and post disinfection cycle.**

L. **Always** check the expiration date on the cartridge before use. If cartridge has expired, dispose of as per local environment and government regulatory requirements. Do not attempt to open or load a damaged or distorted cartridge.

M. Do **not** manually pierce the cartridge

N. Use **ONLY** the Trophon Sonex-HL cartridges which are validated for use with the Trophon EPR

O. Each cartridge is to be used **ONCE.** Do **NOT** refill or reuse cartridges

P. Do **NOT** use the Trophon EPR to disinfect non-approved devices or instruments.

Q. **Refer to the User Manual with questions concerning care and operation of the Trophon EPR unit.**

R. **Contact the manufacturer/vendor for questions as needed.**

XII. Training

A. Training and competency review is to include review of:

1. Attachment 1: Trophon User Manual
2. Attachment B: Trophon User Guide Chemical Indicator
3. Attachment C: Trophon Sonex-HL MSDS
4. Attachment D: Trophon Quick Guide
5. Attachment E: Questions -Tool for review of the above attachments.
6. Trophon Online training and certificate completion

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REFERNCES

Centers for Disease Control and Prevention. Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

Trophon EPR User Manual

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