

STANDARD OPERATING PROCEDURES
DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

SOP#: 1172.1

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TITLE:	EOGas 4® Ethylene Oxide (EO) Gas Sterilizer System
SCOPE:	All Authorized Personnel
RESPONSIBILITY:	Facility Manager, Supervisor and Technical Staff
PURPOSE:	To Outline the Proper Procedures for sterilization using the EOGas 4® Ethylene Oxide (EO) Gas System

I. PURPOSE

1. This SOP outlines the proper procedures to be followed for gas sterilization using the EOGas 4® Ethylene Oxide (EO) Gas System.

II. RESPONSIBILITY

1. It is the responsibility of the Facility Manager and/or Supervisor to ensure that all technical staff performing these methods are adequately trained in the following procedures and these procedures are adhered to.
2. It is the responsibility of the technical staff assigned to sterilization procedures to read, understand, and follow the procedures outlined below.

III. EQUIPMENT USE

III.A. Pre-Cleaning Items for Sterilization

1. **Disassemble** items containing removable parts such as syringes, caps, and plugs must be taken apart before washing, drying and wrapping them to allow the EO an unobstructed path around all parts. **WARNING:** Instruments which contain batteries must be taken apart and the batteries removed and wrapped separately to protect against a spark occurring and igniting the ethylene oxide gas.
2. **Wash**, presoak the items if appropriate. Items must be washed surgically cleaned prior to sterilization using appropriate detergent and water.
3. **Dry** items prior to sterilization. Three accepted ways to dry any item is towel drying, drain drying (air drying) and compressed air for tubing and long lumens.
4. Items must be **wrapped** before sterilization. Materials recommended for use with EOGas 4 are: heat sealed packaging such as Tyvek®/Plastic, self-seal pouches made of paper and film and cloth, paper wrap.

III.B. Warming Up the Sterilizer

1. Place exhaust hose in the hood and leave in place while cycle is running and ensure that all necessary signage is posted while the unit is in use, SC #284. Ensure that the EO Gas 4 is connected to power and turn the sterilizer on by pressing the black power switch located on the back of the cabinet. The initial startup screen will appear.
2. The temperature setting can be switched between standard (50°C) and room temperature (30°C) modes using the setup menu. Once set, press the button to the right of **START** on the display screen to initiate the self-test.
3. When the warm up screen appears, you can exit or await the target temperature reading and prepare sterilization bag if not already done.
4. Once warmed up, loading instructions are shown on the screen. **Note:** The sterilizer must be used in an area where temperature is not less than 68°F or more than 73°F. Relative humidity (RH) must be at least 35% in the room where item preparation and sterilization take place.

III.C. Sterilization Cycle

1. Place prepared items into a new sterilization bag.
2. **Insert appropriate controls** such as a chemical integrator (**Dosimeter**) into the least accessible part of the sterilization liner bag.
3. Insert a **Humidichip** into the purge probe's **Humidichip** clip and place into the sterilization liner bag.
4. Biological Indicators are run **monthly**. Unscrew the PCD cap on the purge probe. Insert the biological indicator (EZTest®) into the purge probe's PCD with the red cap towards the wand and ball end. Screw PCD cap back on securely.
5. Remove one AN1004 EO Gas cartridge from the Refill Kit. Remove the tape and safety trigger guard on the cartridge and place the cartridge on top of the wrapped items so it can easily be manipulated through the wall of the bag. **Do not activate the cartridge at this time.**
Safety Note: If EO Gas Cartridge is accidentally activated or dropped outside of the liner bag, immediately place it in the Accidental Release Containment Mechanism (ARCM) which is connected to an input on the upper left side of the sterilizer. Ensure the sterilizer pump is running. Run the appropriate cycle for this incident.
6. Place purge probe into sterilization liner bag with the ball at the rear of the bag and bobbin and quick release fitting at the open end. Place the blue hook and loop strap around the sterilization liner bag and the bobbin of the purge probe, and pull it snug through its loop to completely close the sterilization liner bag. The strap must tightly secure the sterilization liner bag around the purge probe bobbin in order to keep gas from escaping.

7. Connect the quick release connector to the purge probe hose if it is not already connected. **Warning: Never interrupt a cycle once the gas cartridge has been activated.**

III.D. Starting the Cycle

1. With the loaded bag sealed and connected to the purge tube, press the **PURGE** button while the cabinet door is open. The sterilizer will purge air out of the sterilization liner bag for 1 minute and 30 seconds. The sterilization liner bag should vacuum down as excess air is removed.
2. **Activate the cartridge** by pressing the trigger button on the cartridge through the wall of the closed liner bag. Make sure that the button is fully depressed.
3. **Close the door.**
4. **Select** the length of the **sterilization cycle**. The door will lock automatically. If a cycle is not selected within 5 seconds after closing the door, a continuous alarm will sound to remind you to choose a cycle length.
5. Choose the appropriate cycle for the load to be sterilized. The EOGas 4 sterilizer offers four different sterilization cycles. For most items, the **3 HOUR** cycle will be adequate. The **5 HOUR** cycle should be used when sterilizing lengths of tubing greater than 3 feet and with loads containing large amounts of gas absorbing materials. For temperature sensitive items use the 12 or 24 HOUR room temperature (30°C) mode.
6. After the cycle length is selected, the display counts down time remaining. The door will remain locked.

III.E. Unloading the Sterilizer and Determining Sterility

1. When the display indicated UNLOAD STERILIZER open the door and unscrew the cap on the PCD. After removing the biological indicator from the PCD or the liner bag, prepare, and incubate at 37°C for 48 hours.
2. Remove and **examine the Dosimeter**. Make sure the blue line has progressed to or beyond the triangular mark.
3. Discard the sterilization bag, Humidichip, and used cartridge with ordinary trash, but retain Humiditube to use again.
4. Press EXIT to end the cycle and return the sterilizer to the standby state. Switch the power button to off.

IV. Maintenance

1. Sterilizer should be inspected and maintained at least annually; only by an Andersen Sterilizers authorized technician.

Approved:

Date: