University of California, Berkeley

OFFICE OF LABORATORY ANIMAL CARE

STANDARD OPERATING PROCEDURE

SOP Number:	**703.1**	**Ethylene Oxide Sterilizer Operation and Maintenance**	**Revision #:**	1
Date Effective:	6/15/22		**Supersedes:**	703

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PURPOSE

The following will outline the maintenance and operation of the ethylene oxide sterilization unit used to sterilize delicate instruments and supplies that would otherwise be damaged by heat sterilization.

SCOPE

These procedures apply to the OLAC veterinary staff and serve to guide the use and upkeep of the machinery.

RESPONSIBILITY

The use, maintenance, and quality control of this equipment is the responsibility of the OLAC veterinary staff.

DEFINITIONS/ACRONYMS

- EtO: Ethylene oxide
- BI: Biological Indicator

PROCEDURE

1. Prior to initial use:
    a. Ensure that you have been trained to properly use the ethylene oxide sterilization unit.
    b. Be aware that there are inherent health hazards associated with the use of ethylene oxide, specifically the carcinogenic properties and potential reproductive harm from the sterilization gas.

2. Packaging and preparation of items to be sterilized:
    a. Verify that all equipment and instruments may be safely gas sterilized.
    b. Consult manufacturer recommendations if necessary.
    c. Clean all debris from instruments and make sure they are dried completely.
    d. Open and/or uncap all items to be sterilized.
    e. Remove any batteries from all mechanical instrumentation/devices and sterilize separately to prevent ignition by sparking.
    f. Place all items in individual sterilization pouches, located in the drawer under the machine. Make sure all pouches are sealed at the perforated dotted line to ensure no gaps are created between the seal.
    g. Tear off a one-inch piece of indicator tape and adhere to the outside of the etO sterilization pouch.
    h. Put the pouches in the provided bag with an indicator strip placed toward the middle of the load.
    i. Take 1-2 ampules of ethylene oxide and put them inside of the bag, placed on top of and towards the front for easy access once the bag is vacuumed closed. The wrapper on the ampule(s) should be unwound but not opened (Figure 1 below).

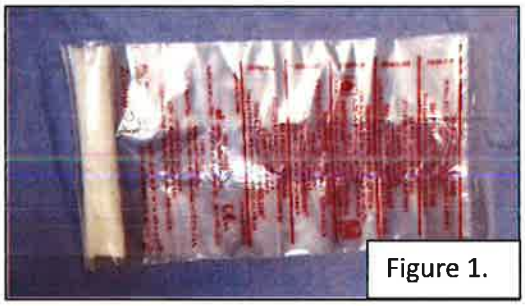


Figure 1.

    j. Check the temperature and humidity in the sterilization room using the hygrometer located on top of the EtO machine.
        i. The recommended range for operating the sterilizer is above 68° F during the entire cycle and room humidity should be above 35%.
        ii. If room humidity levels fall below 35%, a humidifying chip should be added to the bag and it should rest sealed for 4 hours **prior** to sterilization.
3. Sterilization Process:
    a. Turn on the sterilizer. A self-test cycle will commence.
    b. When the display reads "Load Sterilizer Bag":
        i. Load the bag into the chamber.
        ii. Place the purge stem and tube inside of the bag.
    c. Secure the bag tightly around the black base of the purge stem with the Velcro strap (Figure 2 below).
    d. Select Purge to begin the cycle. The bag will begin to decompress as air is suctioned for a set amount of time. Ensure that the ampule(s) in the etO bag are in an easily accessible position.
    e. Wait for the display to show "Break Ampule".
    f. Without opening the bag or removing the velcro strap, snap the ampule along the narrow neck.
    g. Select the cycle length and close/lock the sterilizer.

i. 12 hours is appropriate for a small load of instruments.
ii. 24 hours should be used for larger items or for a large load.

h. The sterilizer will run a ventilation cycle for 2 hours after the sterilization period is complete.
i. Do not open the sterilizer until the display reads "Unload Sterilizer".
j. Verify the load was successfully sterilized by looking at the sterilization indicator strip and placing it in the log book next to the record of the run (Appendix A).

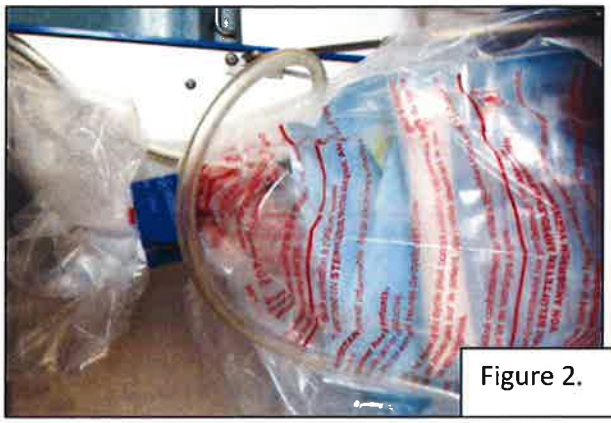


Figure 2.

4. Biological Indicator Testing:
   a. Utilize a biological indicator:
      i. For quarterly sterilization quality control (QC) checks,
      ii. When error messages are reported, or
      iii. When questionable indicator strips are reported.
   b. Label the test material tube with the date of the run and place in the sterilizer.
   c. Use the 12-hour cycle to run intermittent QC tests.
   d. Crush the indicator tube and a positive control tube which did not undergo sterilization at the bottom to mix the bacterial segment with the media.
   e. Place in an incubator (38-40 C) for 24 hours or more.
   f. Record results in the Biological indicator log (Appendix B).

Figure 3.

Control (left): rose chemical indicator prior to incubation

Gas sterilized BI (Right): brown chemical indicator prior to incubation

Figure 4.

Post incubation

Validated sterilization: Ethylene Oxide

Chemical indicator: Brown

Biological indicator: Purple

Figure 5.

Post incubation

Validated sterilization: Control

Chemical indicator: Rose

REVISION HISTORY			
REVISION NUMBER	**AUTHOR(S)**	**EFFECTIVE DATE**	**REVISION(S)**
1	Satori Le	6/15/22	Replaced Author Monica McDonald w/ Satori Le, updated revision number 2.f., 2.g., 2.i., 2.j., 3.b.ii, 3.c, 3.d, 3.f Minor grammatical corrections

Appendix A:

Sterilization Strip Test Log

Date	Results	Signature

Appendix B:

Ethylene Oxide Biological Indicator Testing Log							
Date	Initials	Cycle Length	Indicator Used (Brand/exp date)	Indicator Pass/Fail		Positive Control (+/-)	Comments
				24h	48h		

Appendix C:

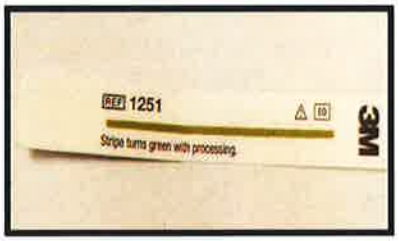
Indicator tape pre-sterilization

Indicator tape post- sterilization

Pouch pre-sterilization

Pouch post- sterilization

Indicator strip pre-sterilization



Indicator strip post- sterilization