

Thank you for using the EOGas 3 sterilization system.

The active ingredient in EOGas 3 is ethylene oxide (EtO or EO). EtO is a powerful anti-microbial agent; it can also be dangerous if not handled correctly. To help ensure that your sterilizer is operated safely, all personnel who operate or maintain the equipment need to be properly trained.

The Andersen EOGas 3 Key Operator Certification Program provides instruction in the following areas:

- Environmental considerations for EOGas 3 sterilization
- Preparation of items to be sterilized
- Operation of the sterilizer
- Sterility Assurance
- Operator Exposure Testing and Emergency Procedures

The Andersen EOGas 3 Key Operator Certification Program is available free of charge for the lifetime of your sterilizer. We recommend that all operators at your facility are trained before they use the sterilizer for the first time.

The information in this study guide should be carefully reviewed. The Key Operator test is conducted over the telephone and requires 20 minutes. When you are ready, please call Andersen Customer Service at (800) 523-1276 to schedule your test. Shortly after completing your test, you will receive a registered training certificate.

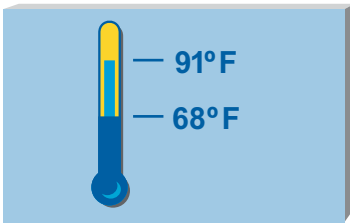
We look forward to hearing from you!



Overview of the EOGas 3 sterilization system.

- 1 The usual EOGas Series 3 sterilization cycle is 16 hours at 50° C, plus a 5-minute purge cycle.
- 2 EOGas 3 has micro-processor control and tracking capability so the operator may load new bags or unload finished bags while others are in process.
- 3 EOGas 3 provides two sterilization bag/cartridge size options (AN1005 and AN1006) to match the actual load volume and greatly reduce gas consumption.
- 4 The AN1071 Humidichip and AN1072 Humiditube ensure that humidity requirements for EOGas 3 sterilization are maintained in the sterilization bag.
- 5 The AN1087 Dosimeter provides an immediate indication at the end of a cycle of whether the conditions for sterilization have been met.

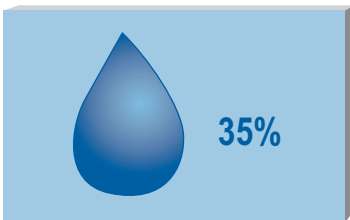
Environmental Considerations



1 Temperature

Store your EOGas 3 gas refill kits in a cool, secure area. We recommend storage below 70°F. The sterilizer must be used in an area where the temperature is not less than 68°F or more than 91°F.

EtO FACTS: At sea level, ethylene oxide is a liquid below 51°F. Above 51°F, EtO begins to boil and converts into a gas. EtO does not become an effective sterilant until 68°F. Even though the EOGas 3 cabinet is heated make sure that the room where your EOGas sterilizer is installed remains above 68°F.



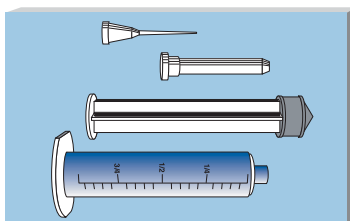
2 Humidity

Humidity is very important to the EOGas process. Relative Humidity (RH) must be at least 35% in the room where item preparation and sterilization take place. Spores that might be on the instruments may become desiccated and resistant to EOGas if the RH is below 35%.

The simplest way to humidify items is to wash them. Items that cannot be washed (like laptops, cameras, and delicate electronics) should be humidified by the following method: Place wrapped or pouched items in a plastic bag with an Andersen Humidichip® or a damp sponge for four hours in a warm area (above 70°F) prior to sterilization.

Preparing the items for sterilization

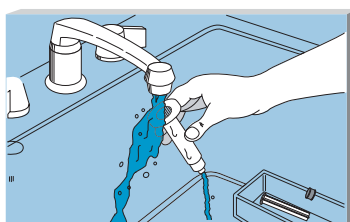
Four basic steps must always be followed:



1 Disassemble

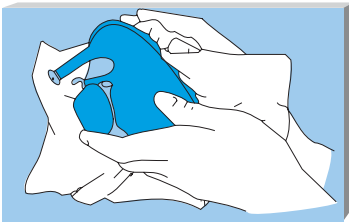
Items containing removable parts such as syringes must be taken apart before washing, drying, and wrapping them to allow the EOGas an unobstructed path.

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

Items must be washed surgically clean prior to sterilization using a detergent and water.



3 Dry

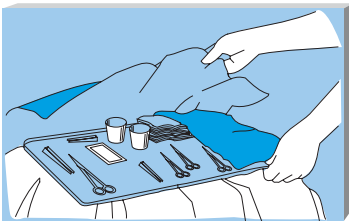
Three accepted ways to dry any item prior to sterilization with EOGas are:

1. Towel drying
2. Drain drying (air drying)
3. Compressed air for tubing and long lumens.



WARNING: Heat or hot air should never be used to dry an item prior to sterilizing it with EOGas because it will dehydrate or desiccate bacteria spores making them more resistant to the ethylene oxide gas.

WARNING: Any water left on items may react with ethylene oxide. Please air dry instruments thoroughly.



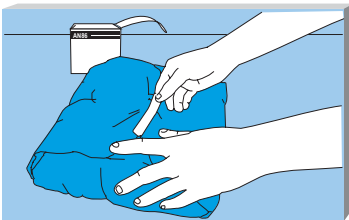
4 Wrap

The following types of wrapping material are recommended for use with EOGas:

1. Heat sealed packaging (eg Seal and Peel® or Tyvek®/Plastic).
 2. Self seal pouches (typically paper/plastic).
 3. Cloth, paper or CSR wrap.
- ★ Follow manufacturer's use and shelf-life guidelines for all packaging.



HINT: Exposure indicators such as the Andersen AN85 or AN86 are used to seal or label items. Indicators will change color in the presence of EtO, helping to later identify items that have been sterilized. Exposure indicators **DO NOT** indicate sterility.



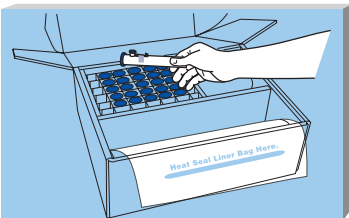
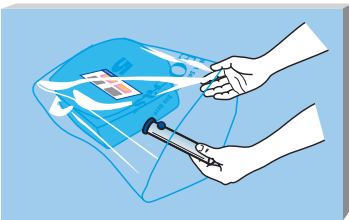
EOGas Sterilization Cycle

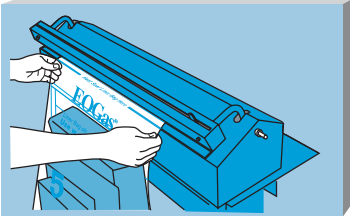
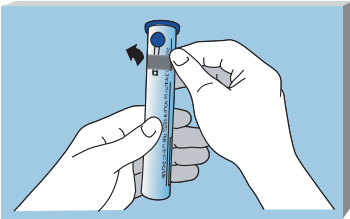
The usual EOGas sterilization and aeration cycle is 16 hours, plus a 5-minute purge cycle. Sterilization and aeration must take place in the EOGas cabinet at a temperature that is not less than 50° C (122° F).

The following are the recommended steps for a complete EOGas sterilization cycle on Standard Operating Mode:

1 Bag Preparation

- Place prepared, wrapped items into a medium (#5) or large (#6) EOGas sterilizing bag.
- Match the EOGas cartridge size (#5 or #6) with the number on the sterilizer bag. Each cartridge contains the precise amount of EtO needed to sterilize the contents of the corresponding sterilization bag. Mismatching the bag and cartridge size may result in a non-sterile load or over saturation of product and/or gas exposure issues.

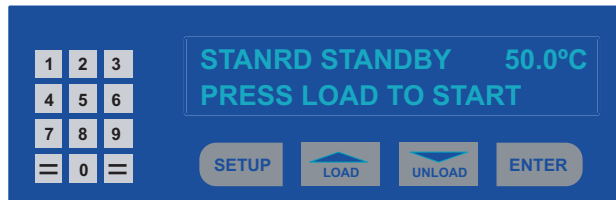
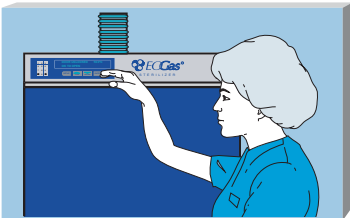




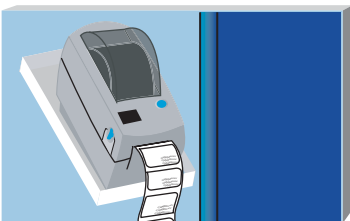
- Remove tape and safety trigger guard on the cartridge and place the cartridge in the sterilizing bag without activating the cartridge.
- Place a Dosimeter and Humidtube with a Humidichip inside the EOGas sterilization bag.
- Insert a biological control (optional but recommended).
- Press excess air out of the loaded bag.
- Heat seal or vacuum seal the sterilizing bag.

2 Loading the Sterilizer

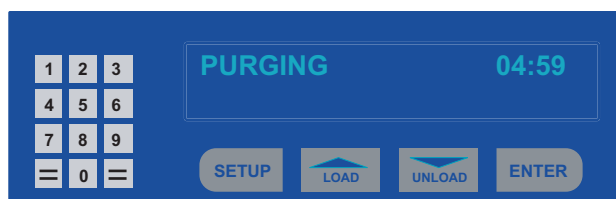
- Have your EOGas bags prepared and heat sealed.
- When loading an empty sterilizer confirm that the sterilizer has power and is switched "on". Once the display reads "Standby" press the "Load" key. This will allow the sterilizer to reach a temperature of 50° C. (If required, key in your operator code and press "Enter".)



- On the keypad, enter the number of bags you are placing in the sterilizer. Look at the display to check that the number matches your entry and press "Enter" to confirm.

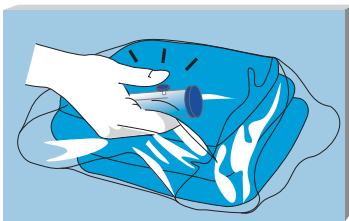
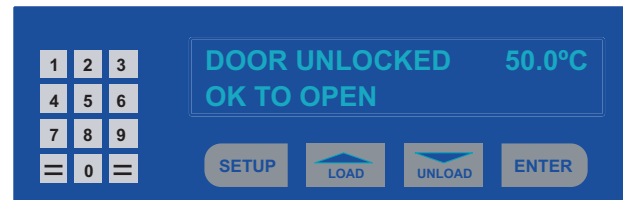


- Two labels will print for each bag. Place one on the sterilizing bag and one in your sterilization logbook. The labels provide a tracking number, along with a record of the time when the bag was inserted into the sterilizer and the cycle length.
- Check the display. If there are no bags in the sterilizer, the display will read "Warm Up". If other bags have been previously loaded, it will read "Purging".





- When the **"Door Unlocked - OK to Open"** message appears, open the door. The EOGas Sterilizer always goes through a 5 minute purge cycle before the door may be opened to assure that the operator is not exposed to levels of EtO above OSHA's acceptable short term limit of five parts per million. (5.0 ppm 15 minute STEL). The door will remain unlocked for 3 minutes.



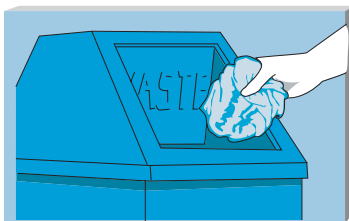
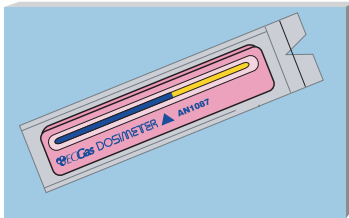
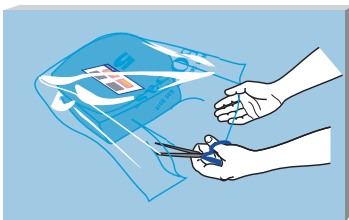
- Immediately place the sterilizing bag(s) into the EOGas cabinet. Do not over pack the sterilizer; air must be able to circulate around the bags.
- **Activate each EOGas cartridge** within the sealed sterilization bag(s) by depressing the trigger button. Make sure that the trigger button is fully depressed.
- **Close the door** and confirm that it is **locked**.

Unloading

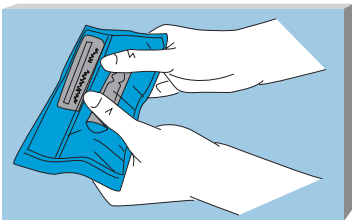
3 Unloading the Sterilizer



- To unload bag(s) after the full cycle, **press the "Unload" button**. Key in your operator code if requested. The sterilizer will complete a five-minute purge cycle before the door will unlock.
- When the **"Door Unlock - OK to Open"** message appears, open the door. Confirm which sterilization bags should be unloaded by using the up and down keys on your display. **Match your log numbers to bag numbers** to determine which have completed the 16-hour cycle.
- The 16-hour EOGas cycle at 50°C includes an aeration period adequate for most EtO absorbing materials.
- With current model sterilizers, if extended aeration is desired, slit each appropriate bag down the center to aerate. Close the door and choose 5 min., 1 hr., or 2 hr. additional aeration time. (Press "0", "1", or "2" respectively.)
- After the counter reaches 00:00, **press "unload"**. Remove slit bags from cabinet.
- Remove the sterilized items and **examine the Dosimeter**. Make sure the blue line has progressed up to or beyond the triangular mark.
- The items may be removed from the EOGas sterilization bag. Discard the sterilization bag, Humidichip, and spent cartridge with ordinary trash. Incubate Biological Indicator, if using one. Retain Humiditytube to use again.



Sterility Assurance

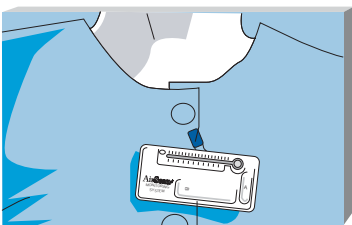


Final Word: Important Notes About EOGas

- ① **Biological Indicators (BI's)** use live spores and are the best confirmation of the success or failure of a sterilization cycle. Always follow manufacturer's recommendations when using BIs.
- ② **Chemical Exposure Integrators** such as the **Dosimeter** provide immediate visual confirmation that time, temperature, and EtO concentration were sufficient for sterilization to occur.
- ③ **Chemical Exposure Indicators** such as the AN85 or AN86, do not prove sterilization. They only change color to show that the items have been exposed to ethylene oxide.

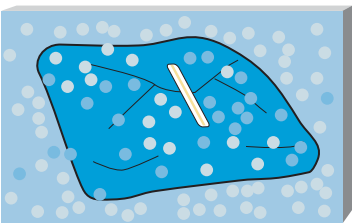
Please refer to manufacturer's instructions when using sterility or exposure indicators.

Safety Precautions



- ① Personnel exposure to ethylene oxide can be monitored by using personal exposure badges, such as the Andersen AN93 AirScan® Badge Kits with both STEL (15 min.) and TWA (8 hour) badges. EtO exposure levels should be tested upon installation of the sterilizer. We recommend that exposure testing be performed on an annual basis or whenever a sterilizer is relocated. OSHA guidelines for personal monitoring can be found at www.cdc.gov/niosh/programs/ppt.
- ② Do not allow open flame or sparks near the sterilizer during the sterilization cycle. Ethylene oxide gas is highly flammable in concentrations above 3.0% (30,000 ppm).
- ③ Always store EOGas cartridges and refill kits in a secure cabinet that is kept cool (70° F) and out of direct sunlight.

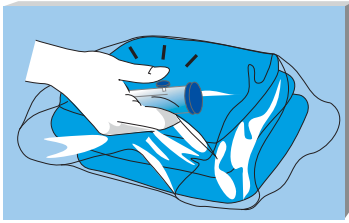
Important Considerations



- ① Two items that do not require aeration are metal and glass. Items made of these materials do not absorb EtO.
- ② Large, gas absorbing items, especially implants, long lengths of tubing, and devices that will contact blood or living tissue may require additional aeration time. Please refer to device manufacturer's guidelines on aeration after EtO sterilization.



Things that **CANNOT** be sterilized with **EOGas 3**:
Liquids, powders, food, and drugs should not be sterilized in ethylene oxide because it may change their chemical composition in unpredictable ways.



③ **Two reasons for never activating the EOGas 3 cartridge without first sealing it in the EOGas sterilization bag are:**

- To prevent the exposure to EtO in excess of OSHA's regulations.
- To assure the full amount of EtO is available for sterilization.

④ **Reason for locking the EOGas sterilizer:**

- The ventilation and purge features of the system prevent operator exposure to levels of ethylene oxide in excess of OSHA regulations.
- To prevent accidental early removal of a sterilization bag.

⑤ **Three consequences of opening the EOGas bag before the 16 hour cycle are:**

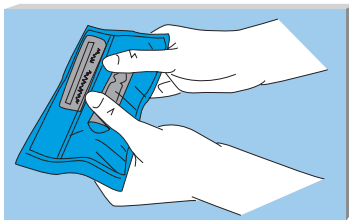
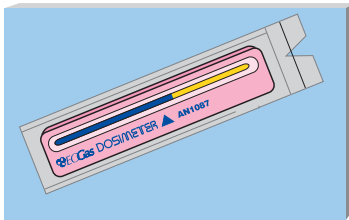
- The load might not be sterile.
- The sterilization bag might still contain high levels of EtO. Opening the bag early may expose the operator to unsafe levels of EtO.
- The load might not be adequately aerated. If used on a patient, the items might cause a serious chemical contact burn.

⑥ **Power Failures**

If a power outage occurs during any part of the cycle, the sterilizer is equipped with a battery back up to the circuit board that will keep track of elapsed cycle time. When power is restored, the cycle will continue. Do not open the door of the sterilizer until power is restored and the vent/purge systems have removed any residual gas from the sterilization bags.



HINT: In the case of any sterilizer malfunction or power failure, you can determine whether sterilization was achieved by examining the sterility indicators (biological indicator, Steritest with Dosimeter) included in the load.



⑦ **Ventilation Failures**

If the exhaust airflow drops due to a malfunctioning fan or a blocked exhaust line an alarm will sound and an error message will be displayed. Do not start a cycle if an alarm is sounding. Call Andersen Customer Service immediately to have your sterilizer repaired.

Emergency Procedures

- ① If liquid EtO comes into contact with a part of the body you must wash with water thoroughly for at least 15 minutes.
- ② The **Material Safety Data Sheet (MSDS)** for EOGas should be readily available. Do you know where to find your MSDS?
 - Operator's Manual
 - List of physical and chemical hazards provided with each EOGas kit.



In case of emergency, please contact:

During business hours M-F, 8AM - 7PM EST

1-800-523-1276

After business hours or on weekends, call

1-800-255-3924.

Finally, make a list of any questions that you have about the EOGas system. Your Andersen Representative will be happy to assist you!

Here is what you should know after reading this study guide:

- The minimum temperature needed in the room for the entire sterilization cycle
- The length (in time) of the standard cycle
- Why the ventilation system is running during the entire cycle
- Why the sterilization liner bag is purged
- The desired relative humidity in the room where the items are prepared
- How to prepare items for sterilization
- The types of indicators that are used in the EOGas system
- Ethylene oxide safety and precautions
- Basic operation of your EOGas sterilizer from start to finish

When you feel comfortable with answers to these subjects, please give Andersen Products a call at 1-800-523-1276 and schedule your Key Operator Certification exam. The test will take approximately 20 minutes.