



KEY OPERATOR
TRAINING SERIES
ANDERSEN PRODUCTS, INC

Study guide

ECOGas[®] 3



Key Operator Training Kit

The power of knowledge



ANDERSEN
PRODUCTS

the future of gas sterilization



Thank you for using the
EOGas sterilization system.



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

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.

Certification Program Outline



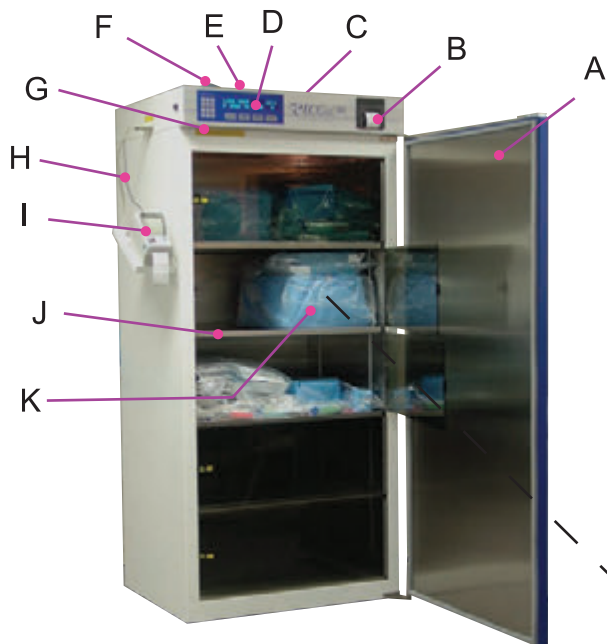
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The information in this study guide should be carefully reviewed. The Key Operator test is conducted over the telephone and requires 20 minutes. When you are ready, please call **Andersen Customer Service at (800) 523-1276** to schedule your test.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

We look forward to hearing from you!

Overview of the EOGas® Sterilization System.

- ① A typical EOGas Series 3 sterilization cycle is 16 hours at 50° C (122°F), plus a 5-minute purge cycle. This sterilization system must be installed and operated in an environment that maintains a temperature of no less than 68°F to be effective.
- 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 A relative humidity above 35% is critical to the success of the EOGas 3 cycle. The AN1071 Humidichip® and AN1072 Humiditube ensure that humidity requirements for EOGas sterilization are maintained in the sterilization bag.
- ⑤ At the end of a cycle the AN1087 Dosimeter® provides an immediate indication that adequate time, temperature, and EtO concentration for sterilization have been met.

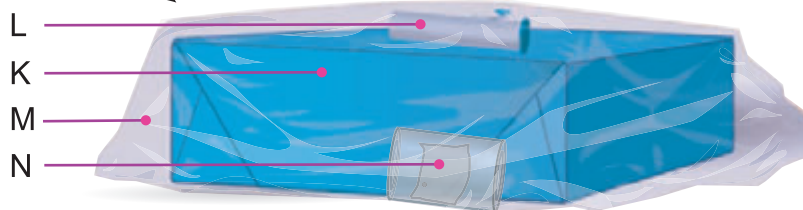


EOGas Sterilization Cabinet

- K: Wrapped Sterilization Load
- L: EOGas Cartridge
- M: Vacuum/Heat Sealed Gas Sterilization Bag
- N: Humidichip and Tube

EOGas 3 Supplies & Parts Index

- A: All Stainless Steel Interior
- B: Front Panel Printer
- C: Power Cord Socket & Switch (on rear)
- D: Cabinet Digital Display and Keypad Buttons
- E: Removable Filter
- F: Exhaust Hose
- G: Door Lock
- H: Printer Power & Data Cables
- I: Label Printer
- J: Adjustable Perforated Shelves



Loaded Sterilization Bag: Two Different Bag/Cartridge Combinations to Match Your Sterilization Needs

EOGas 3 Sterilization Accessories



AN1005 & 1006 Gas Refill Kits contain replacement gas cartridges, liner bags, Dosimeter®s, and Humidichip®s in a convenient storage/dispenser box.



AN85 Exposure Indicator Strips change color to provide immediate assurance of EOGas exposure at the end of the sterilization cycle. They include convenient self-stick backing that adheres to conventional paper or cloth wrapping.



AN1080 Steritest® Biological Indicators reliably verify that sufficient concentration of EtO killed one million *B. atrophaeus* spores, the spore most resistant to EOGas. Biological indicators are the best method to ensure sterility after a cycle.



AN1071 Humidichip & AN1072 Humiditube
These pre-moistened chips placed inside the tube ensure that relative humidity requirements are met during the sterilization cycle.



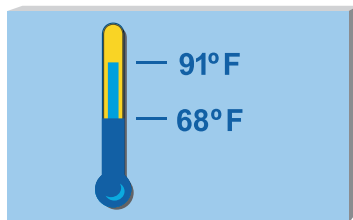
AN1087 Dosimeter Chemical Integrators present visual assurance that proper time, temperature, and EOGas concentration were reached during the sterilization cycle.



AN91,92,& 93 AirScan EtO Monitoring Badges are single use badges that measure personnel exposure to airborne concentrations of EOGas. Immediate results are provided with no extra instruments or analysis needed.

1 Preparing for Sterilization

A. Environmental Considerations



① Temperature

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



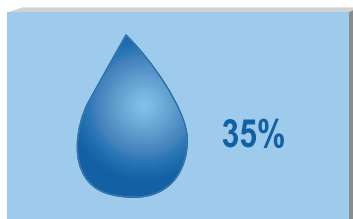
EtO FACTS: At sea level, ethylene oxide is a liquid below 51°F. Above 51°F, EtO begins to boil and converts into a gas. EtO does not become an effective sterilant until it is 68°F. Even though the EOGas 3 cabinet is heated, make sure that the room where your EOGas sterilizer is installed remains above 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 more resistant to EOGas if the RH is below 35%.

The simplest way to humidify items prior to sterilization is to wash them. Items that cannot be washed (such as laptops, cameras, and delicate electronics) should be humidified by placing the wrapped or pouched items in a plastic bag with an Andersen Humidichip® for four hours in a warm area (above 70°F). The EOGas 3 has a preconditioning cycle to facilitate this. Pressing the ZERO key twice (0,0) when the sterilizer is in standby mode initiates the preconditioning cycle.

If room RH is lower than 35% during the sterilization cycle, a Humidichip is placed into the sterilization bag to maintain proper humidity.

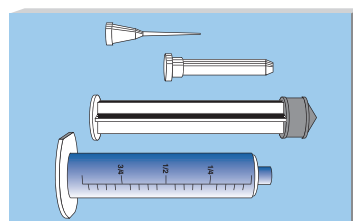


B. Four Basic Steps of Pre-cleaning

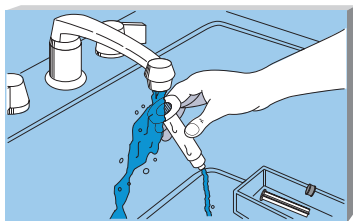
Follow manufacturer's instructions for cleaning and preparing reusable devices for EOGas sterilization whenever possible. In the absence of manufacturer's instructions, these general steps should be followed:

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 around all parts.

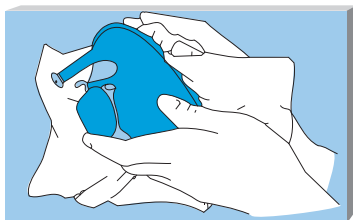


WARNING: Instruments which contain batteries must be taken apart and the batteries removed and wrapped separately to protect against a spark occurring and igniting the ethylene oxide gas.



② Wash

Presoak the items, if appropriate. Items must be washed surgically clean prior to sterilization using detergent and water.



③ Dry

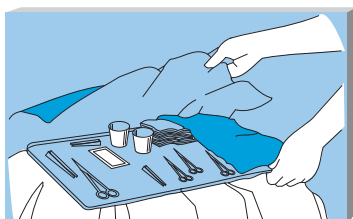
Three accepted ways to dry any item prior to sterilization with EOGas 3 are:

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



WARNING: Heat or hot air should not be used to dry an item prior to sterilizing it with EOGas because it may dehydrate or desiccate bacteria spores making them more resistant to the ethylene oxide gas.

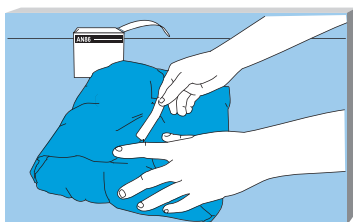
WARNING: Any water left on items may react with ethylene oxide. Items must be thoroughly dried.



④ Wrap

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

1. Heat sealed packaging such as Seal and Peel® or Tyvek® / Plastic.
 2. Self seal pouches made of paper and film.
 3. Cloth, paper, or Central Supply Room (CSR) wrap.
- ★ Always follow manufacturer's use and shelf-life guidelines for all packaging.



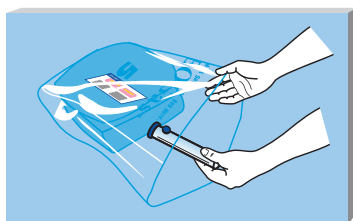
HINT: Exposure indicators such as the Andersen AN85 or AN86 are used to seal or label items. Indicators will change color in the presence of EOGas, helping to later identify items that have been sterilized. Exposure indicators DO NOT indicate sterility.

2 The Sterilization Cycle

The usual EOGas sterilization cycle is 16 hours, plus a 5-minute purge cycle.

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

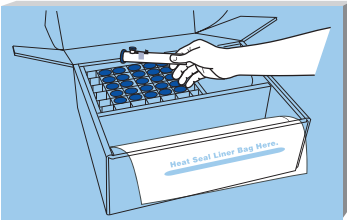
A. Bag Preparation



- ① Place prepared, wrapped items into a new medium (#5) or large (#6) EOGas sterilizing bag.



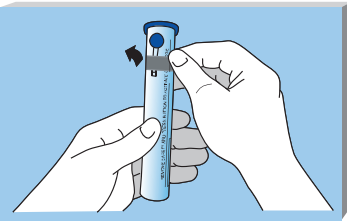
WARNING: Do not reuse sterilization liner bags. A tear in a liner bag can allow gas to escape and cause cycle failure!



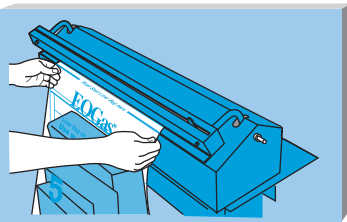
- ② Match the EOGas cartridge size (#5 or #6) with the number on the sterilizer bag. Each cartridge contains the precise amount of EOGas needed to sterilize the contents of the corresponding bag. Mismatching the bag and cartridge size may result in a non-sterile load, over saturation of product, and/or gas exposure issues.



WARNING: Use only genuine EOGas® products in your sterilizer. Use of other gas sources may result in operator injury and/or non-sterile loads.



- ③ Remove tape and safety trigger guard on the cartridge and place the cartridge in the sterilizing bag without activating it. Place it on top of items in the sterilization liner bag where it will be easy to break.
- ④ Insert appropriate controls such as a Dosimeter (chemical integrator) or a Steritest® (biological & chemical indicator) into the least accessible part of the sterilization liner bag. Place a Dosimeter and Humidtube with a Humidichip inside the EOGas sterilization bag.

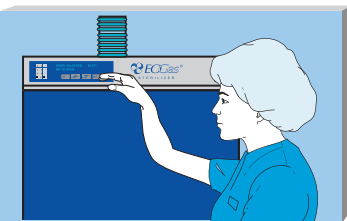


- ⑤ Press excess air out of the loaded bag, and then heat or vacuum seal it. Ensure the seal is complete with no gaps or wrinkles.



WARNING: Liquids, powders, food, and drugs should not be sterilized in ethylene oxide because it may change their chemical composition in unpredictable ways. If you have any questions about whether an item may be sterilized using EOGas, please call Andersen Customer Service.

B. Loading and Starting the Sterilizer



- ① When loading an empty sterilizer confirm that the sterilizer has power and is switched "on". Once the display reads **STANDBY** press the **LOAD** key. If required, key in your operator code and press **ENTER**.



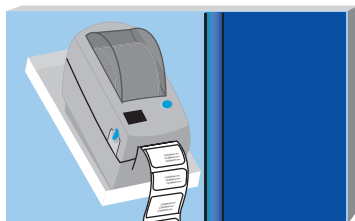
2010 models or earlier



2011 models

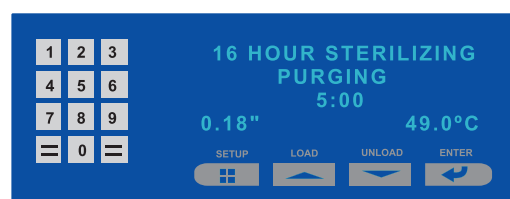
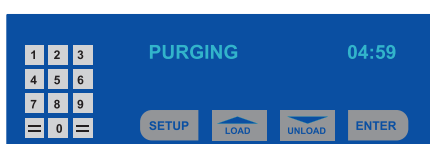
- ② On the keypad, enter the number of bags you are placing in the sterilizer. Look at the display to check that the number matches your entry and press **ENTER** to confirm.



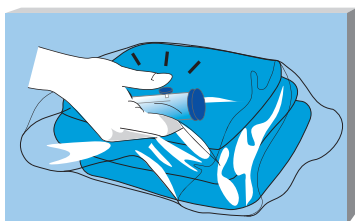
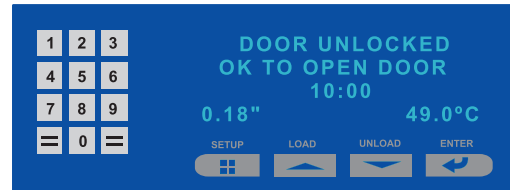
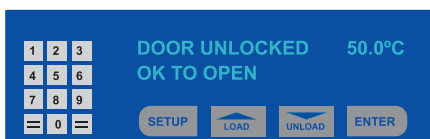


- ③ **Two labels will print for each bag.** Place one on the sterilizing bag and the other in your sterilization logbook. The labels provide a **tracking number**, a record of the time when the bag was inserted into the sterilizer and the total cycle length.

- ④ Check the display. If there were no bags in the sterilizer, the display will read **WARM UP**. If other bags have been previously loaded, it will read **PURGING** indicating the 5 minute purge cycle must complete before the door can be opened. The 5 minute purge cycle is designed to assure that the operator is not exposed to levels of EtO beyond OSHA's acceptable short term limit of five parts per million. (5.0 ppm 15 minute STEL). When the **Door Unlocked – OK to Open** message appears, open the door.



- ⑤ When the **"DOOR UNLOCKED"** message appears, open the door and immediately place the sterilizing bags into the EOGas cabinet. Do not over pack the sterilizer; air must be able to circulate around the bags. The door will remain unlocked for 3 minutes.



- ⑥ **Activate each EOGas cartridge** within the sealed sterilization bags by depressing the trigger button. Make sure that the trigger button is fully depressed.
- ⑦ **Close the door** and confirm that it is **locked**. The sterilization cycle for the loaded bags has started, and the display will read **16 HOUR STERILIZING** and show the number of bags currently being processed and time remaining.

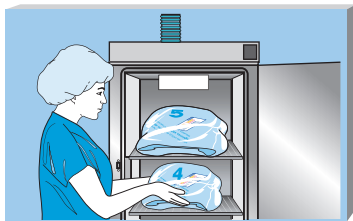


WARNING: Two reasons for never activating the EOGas cartridge without first sealing it in the EOGas sterilization bag are:

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

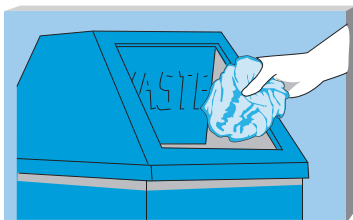
3 Unloading The Sterilizer And Determining Sterility

- ① Once the sterilization cycle is complete, unload bags by **pressing the UNLOAD button**. Key in your operator code if requested. The sterilizer will complete a five-minute purge cycle before the door will unlock.



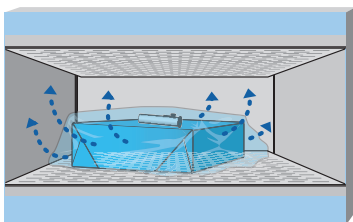
- ② Open the door when the **DOOR UNLOCKED** message appears. Confirm which sterilization bags should be unloaded by using the up and down keys on the display and **matching your log numbers to the bag numbers**.

- ③ Remove the sterilized items and **examine the Dosimeter**. Make sure the blue line has progressed up to or beyond the triangular mark. A Dosimeter that has not reached the triangular mark may indicate a problem with the cycle, such as:
 - Improperly sealed sterilization bag.
 - Failure to activate gas cartridge.
 - Overloaded sterilization bag.



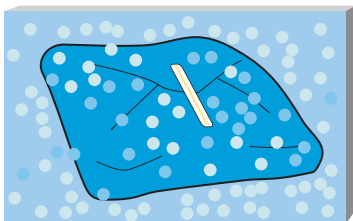
- ④ The items may be removed from the EOGas sterilization bag. Discard the sterilization bag, Humidichip, and used cartridge with ordinary trash. Incubate Biological Indicator if using one. Retain the Humiditube to use again.

A. Additional Aeration



Throughout the entire cycle, the ventilation system is always running to prevent EtO gas from entering the room. The 16-hour EOGas includes an aeration period adequate for most items. However, gas absorbent items may require additional aeration after the regular sterilization/purge cycle is finished and before they can be removed and used. Always follow Manufacturer's guidelines for the recommended aeration of specific devices. OSHA guidelines state that product aeration should take place inside of the sterilizer cabinet.

B. Guidelines for Aeration

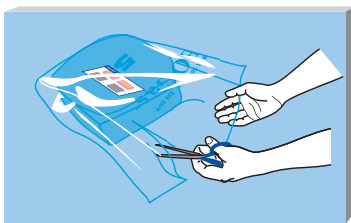


Large, gas absorbing items (especially implants, long lengths of tubing, and devices that will contact blood or living tissue) require additional aeration time:

- ① If the item's manufacturer provides guidelines on aeration required after EtO sterilization, always follow those guidelines.
- ② Two types of materials that do not require additional aeration are metal and glass. Items made of these materials do not absorb EtO.
- ③ If the item's manufacturer does not provide guidelines on aeration required after EtO sterilization, the item should remain in the EOGas sterilizer to aerate for an additional 24 hours after the sterilization and purge cycles are complete.

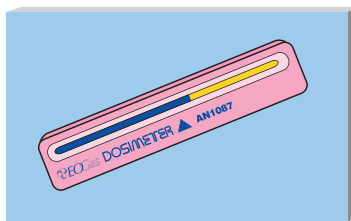
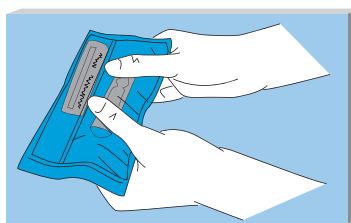
When Additional Aeration is Needed:

- ① Press the **UNLOAD** button as normal to run the initial 5 minute purge cycle and unlock the door.



- ② With the door open, carefully slit each EO Gas bag down the center to allow air to enter it easily.
- ③ Leave the slit bag in the sterilizer, and close the door. Choose 1-4 hours of additional aeration by pressing the "1", "2", "3", or "4" key respectively. The display will read **REPURGE** and count down the time until the additional aeration is complete.
- ④ After the counter reaches 00:00, remove slit bags from the cabinet and complete the remainder of the unloading process as normal.

C. IMPORTANT NOTES ABOUT INDICATORS



- ① **Biological Indicators** (BI's) such as the AN 2203 EZ Test or AN 80 Steritest use live spores and are the best confirmation of the success or failure of a sterilization cycle. Always follow manufacturer's recommendations when using BI's.
- ② **Chemical Exposure INTEGRATORS** such as the **AN87 Dosimeter** provide immediate visual confirmation that time, temperature, and EO Gas 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.

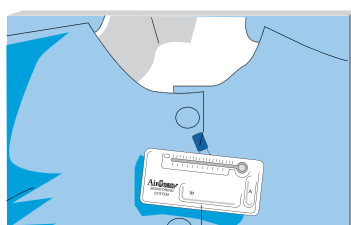
Please refer to manufacturer's instructions when using sterility or exposure indicators.

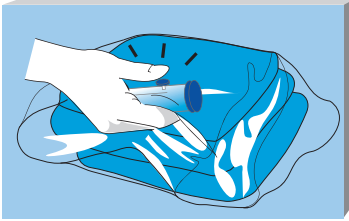
4 Safety Precautions

A. Ethylene Oxide Safety



- ① 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).
- ② Sterilization liner bags should never be reused because they may have a puncture or tear.
- ③ The sterilizer will always complete a necessary 5 minute purge cycle before the door will unlock and can be opened.
- ④ Personnel exposure to ethylene oxide can be monitored by using personal exposure badges such as the Andersen AN93 AirScan® Badges. The AN93 AirScan Kit has both STEL (15 min.) and TWA (8 hour) badges. EO Gas exposure levels should be checked 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/pppt.

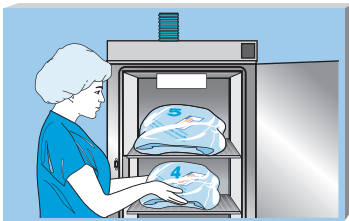




- ⑤ If a cartridge is accidentally activated outside of the sealed liner bag, immediately place it in the sterilization cabinet with the ventilation fan running and close cabinet door.
- ⑥ Always store EOGas cartridges and refill kits in a secure area that is kept cool (70° F or below) and out of direct sunlight.



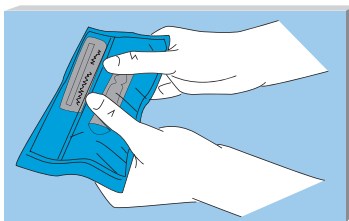
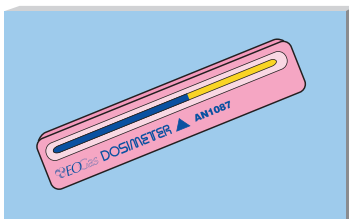
Note: No other container or sterilizer may be used with EOGas sterilizing gas.



- ⑦ Reasons 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 premature removal of a sterilization bag.
- ⑧ Three consequences of opening the EOGas bag before the 16 hour cycle has completed are:
 - The load might not be sterile.
 - The sterilization bag may still contain high levels of EOGas. Opening the bag early may expose the operator to unsafe levels of EOGas.
 - The load may not be adequately aerated. If used on a patient, the items could cause a serious chemical contact burn.

B. Malfunctions and Power Failures

If the exhaust airflow drops due to a malfunctioning fan or a blocked exhaust line, a rapid beeping alarm will sound and a **VENTILATION FAILURE** error message will be displayed. Do not turn the cabinet off if a cycle is in progress. Do not start a cycle if an alarm is sounding. If this happens, call Andersen Customer Service for assistance, (800) 523 -1276.



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 liner bag. The display will indicate when bags are **DONE**, and the items can then be unloaded normally.



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.

C. Emergency Procedures

- ① If liquid EOGas comes into contact with a part of the body, you must wash with water thoroughly for at least 15 minutes. Consult the Material Safety Data Sheet (MSDS) for further information.

- ② The **Material Safety Data Sheet** (MSDS) for EOGas gas should be readily available at your facility. Do you know where to find your MSDS?
- Operator's Manual
 - List of physical and chemical hazards is provided with each EOGas refill 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.

5 Study Guide Review

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 slit
- The required relative humidity in the room where the items are prepared
- How to prepare items for sterilization
- The types of indicators that should be 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.

Operator training records should be maintained at your facility.
Key Operator Tests will be kept on file at Andersen Products.

If you would like to have an Andersen representative come to your facility for an in person training, please contact Andersen Products for a quote on this custom service.

Many thanks for using the Andersen EOGas sterilizer. Please do not hesitate to call us if you have any questions in the future.
Andersen Customer Service 1-800-523-1276
www.anpro.com



the future of gas sterilization

www.anpro.com

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