KEY OPERATOR
TRAINING SERIES
ANDERSEN STERILIZERS, INC

ANDERSEN
STERILIZERS

ECOGas4
STERILIZER

Key Operator Training
Study Guide

sterility.com

EOGas 4 STERILIZER

APPLIES TO **EOGas 4**

Thank you for using the EOGas 4 sterilization system.

The active ingredient in the EOGas 4 system is ethylene oxide (EO). EO 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 should be properly trained and certified.

The Andersen EOGas 4 Key Operator Certification Program is available free of charge for the ten-year useful life of your sterilizer. We recommend training for all operators before they use the sterilizer for the first time.

Certification Program Outline

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 schedule your Key Operator test by calling Andersen Customer Service at **1.800.523.1276**. Shortly after successfully completing your test, you will receive a registered training certificate.

We look forward to hearing from you!

Overview of the EOGas 4 Sterilization System

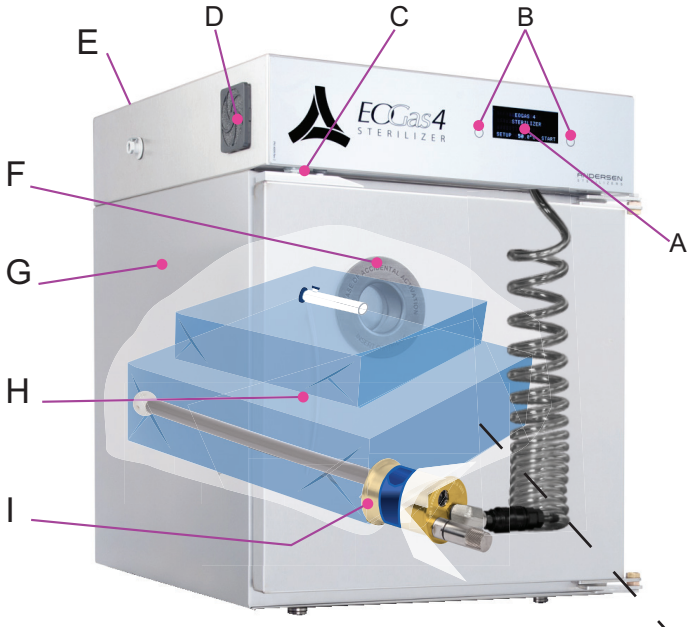
1. The EOGas 4 sterilizer is a tabletop ethylene oxide (EO) gas sterilizer. Install and operate the sterilization system in an environment with a minimum of 10 air exchanges per hour and temperature controlled between 20°- 23°C (68°-73°F). The unit should also undergo regularly scheduled maintenance by a qualified technician during its 10-year useful life.

2. The gas exposure for most devices is three hours at 50°C (122°F), followed by 30 minutes of bag ventilation. A second gas exposure for six hours at 50°C is used for endoscopes with narrow, long lumens.

3. Some absorbent devices require a minimum 24-hour additional aeration to prevent chemical burns that can be caused by premature contact with living tissue. Always follow the manufacturer's guidelines on aeration after EO sterilization.

4. Maintaining relative humidity above 35% is critical to the success of the EOGas 4 cycle. The AN1071 Humidichip® ensures that humidity requirements for EOGas 4 sterilization are maintained in the sterilization bag.

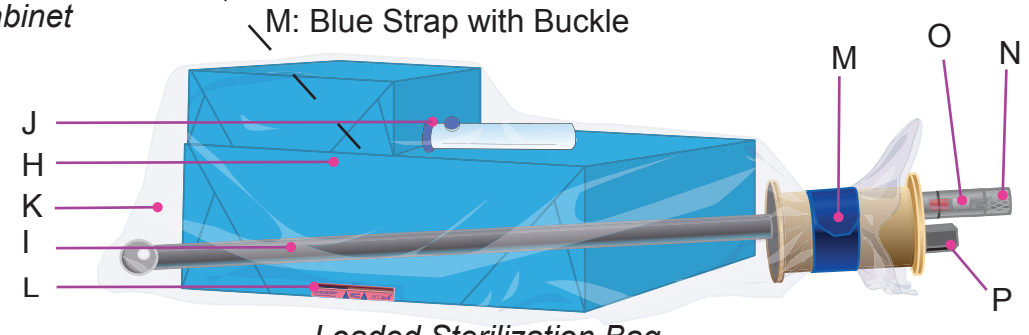
5. The AN1036 Dosimeter® provides an immediate indication at the end of a cycle that adequate time and EO gas concentration for sterilization have been met.



EOGas 4 Sterilization Cabinet

EOGas 4 Supplies & Parts Index

A: Display
B: Keypad Buttons
C: Door Lock
D: Removable Air Filter
E: Power Cord Socket and Switch (on rear)
F: Accidental Release Containment Mechanism
G: Stainless Steel Cabinet
H: Wrapped Sterilization Load
I: Purge Probe with Humidichip clip
3-Hour Gas Exposure: Use Blue Purge Probe (optional)
6-Hour Gas Exposure: Use Gold Purge Probe (included)
J: EOGas 4 AN1004 Cartridge
K: Gas Sterilization Bag
L: AN1036 Dosimeter
M: Blue Strap with Buckle
N: Process Challenge Device (PCD)
O: Biological Indicator (BI) inside PCD
P: Quick Release Connector

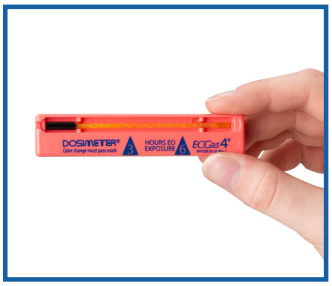


Loaded Sterilization Bag

EOGas 4 Sterilization Accessories

AN1004 Gas Refill Kit contains replacement gas cartridges, sterilization bags, Dosimeters and Humidichips in a convenient storage/dispenser box.

AN2203 EZTest® (red cap) or AN2211 Bionova® BT110 (green cap) biological indicators (BI) reliably verify that the cycle inactivated one million Bacillus atrophaeus spores, the spore most resistant to EO gas.



AN1036 Dosimeter Chemical Indicators present visual assurance that proper time and EO gas concentration were reached during either the three-hour or six-hour sterilization gas exposures.

AN85 Exposure Indicator Strips change color from yellow-green to blue to provide immediate assurance of EO exposure at the end of the sterilization cycle. They include convenient self-stick backing that adheres to sterile wrapping.

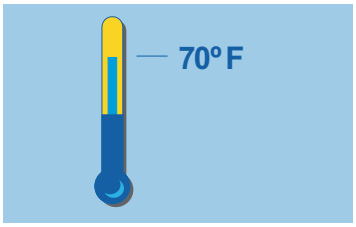
Place one **AN1071 Humidichip** inside the purge probe's Humidichip clip to ensure that relative humidity requirements are met during the sterilization cycle. Please note: when running a three-hour gas exposure, use the blue purge probe, which is purchased separately. The gold purge probe is used when running a six-hour gas exposure and is included with your purchase of the EOGas 4 sterilizer.

AN94 Vapor-Trak Monitoring Badges are single-use badges that measure personnel exposure to airborne concentrations of EO gas in the user's breathing area. U.S. postage-paid mailers are included for convenient return to the laboratory.

1. Preparing for Sterilization

A. Environmental Considerations

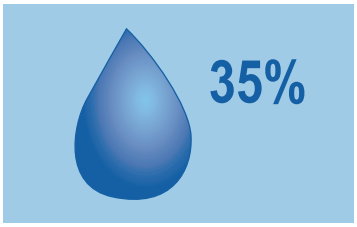
① Temperature



- Gas storage temperature: store your EOGas refill kits in a cool, secure area, out of direct sunlight. We recommend storage below 21°C (70°F).
- The sterilizer maintains a temperature of 50°C (122°F).

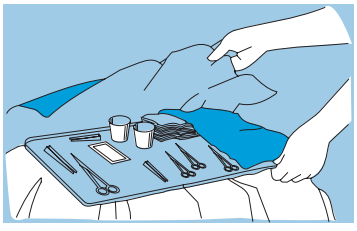
EO FACTS: At sea level, ethylene oxide is a liquid below 11°C (51°C). Above 11°C, EO begins to boil, converting into a gas. Even though the EOGas 4 cabinet is heated, make sure that the room where your EOGas sterilizer is installed is temperature-controlled.

② Humidity

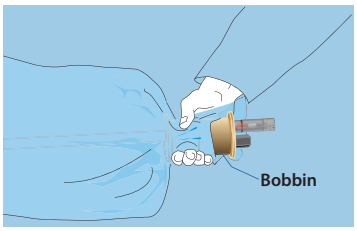


- Humidity is very important to the EOGas sterilization process. Relative Humidity (RH) should be at least 35% in the room where device preparation and sterilization take place. Spores that might be on the instruments may become desiccated and more resistant to EO gas if the RH is below 35%
- The simplest way to humidify devices prior to sterilization is to immerse them in water. Devices that cannot be immersed (such as delicate electronics) should be prehumidified.

Process for Prehumidification Using an EOGas 4 sterilization bag:



- Make sure the sterilizer is switched on so that it heats to 50°C (122° F).
- Prepare the devices in the load for sterilization.
- Place the prepared devices along with a Humidichip inside a sterilization bag. Using the blue strap, securely close the neck of the bag around the purge

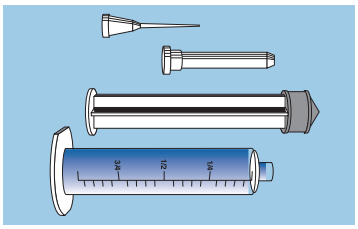


bobbin. It is not necessary to attach the purge probe to the purge tube at this time.

- Place the bag in the sterilizer for two hours, then remove the bag from the sterilizer for an additional two hours to allow for cooling.
  DO NOT ACTIVATE THE CARTRIDGE AT ELEVATED TEMPERATURE.
- After the two hours of cooling, the sterilization bag may be placed in the sterilizer and the cycle started normally.

B. Four Basic Steps of Cleaning

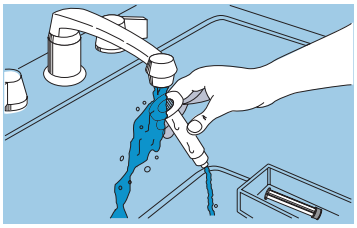
Follow the manufacturer's instructions for cleaning and preparing reusable devices for EO gas sterilization.
In the absence of manufacturer's instructions, these general steps should be followed:



① Disassemble

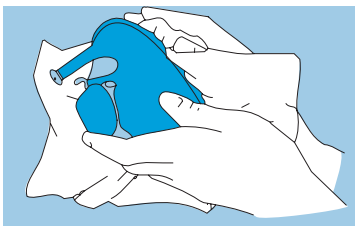
Devices containing removable parts such as syringes, caps and plugs must be taken apart before cleaning, drying and wrapping to allow the EO an unobstructed path around all parts.

> **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 Clean

Immerse the devices in water, if appropriate. Devices must be surgically clean prior to sterilization using appropriate detergent and water.



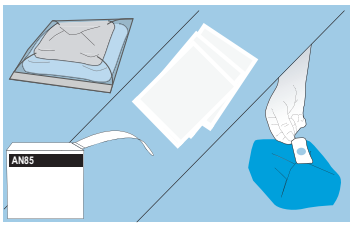
③ Dry

Three accepted ways to dry any device prior to sterilization with EOGas 4 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 devices prior to sterilizing with EO. It may dehydrate or desiccate bacterial spores making them more resistant to the ethylene oxide gas.

④ Wrap



The following wrapping materials are recommended for use with EOGas 4:

1. Heat-sealed packaging such as Tyvek® / Plastic.
2. Self-sealing pouches made of paper and film.
3. Cloth, paper or Central Supply Room (CSR) wrap.

★ Always follow the manufacturer's use and shelf life guidelines for all packaging.

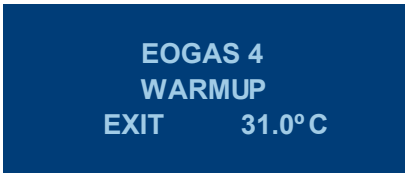
★ Never use unapproved packaging materials including household food storage bags or containers.

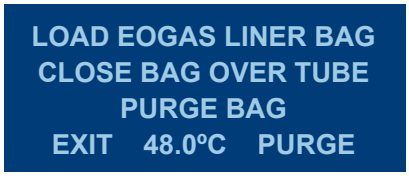
HINT: Exposure indicators such as the Andersen AN85 are used to seal or label wrapped devices. Indicators will change color in the presence of EO gas, helping to later identify devices that have been processed. **Exposure indicators do not indicate sterility.**

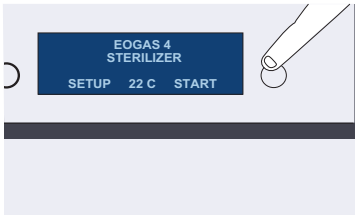
2. The Sterilization Setup

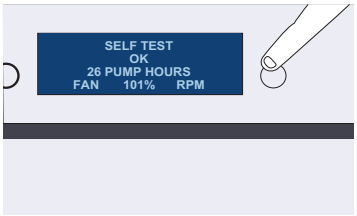
A. Warming Up the Sterilizer

① Make sure the EOGas 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 Press the button to the right of **START** on the display screen to initiate the self test.

③ When the warmup screen appears, you can exit or await the target temperature reading and prepare sterilization bag.

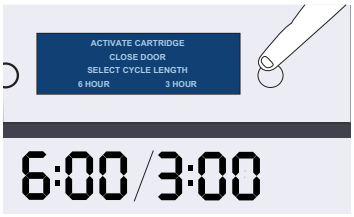
④ Once the sterilizer has warmed up, loading instructions are shown on the screen.

*This EOGas 4 comes with the gold purge probe. If you also purchased the blue probe, be sure to use the correct probe with the appropriate sterilization cycle. For more information, please refer to the user manual.

B. Selecting the Cycle Length & Purge Probe*

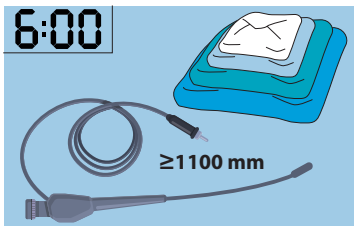
Choose the appropriate cycle for the load to be sterilized. The EOGas 4 sterilizer offers two sterilization cycles (both validated for use in human medical facilities):

Temperature	Hours of sterilization exposure	Minutes of bag vent/purge	Purge Probe color
50° C	3	30	Blue
50° C	6	60	Gold



For metal, plastic and fabric devices and endoscopes **less than** 1100mm, the **3-HOUR** gas exposure (with the blue purge probe) is used.

The **6-HOUR** gas exposure (with the gold purge probe) must be used when processing endoscopes with a working length **greater than** 1100 mm as specified in the labeling.



See the Statement of Indications for Hospital Use in the User's Manual for more details regarding validated loads in both cycles.

3. The Sterilization Cycle

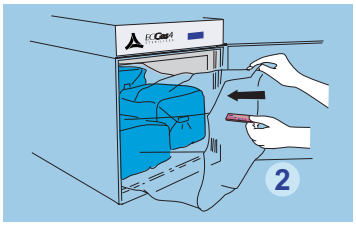
A. Loading the Sterilization Bag and Sterilizer

① Place prepared devices into a new sterilization bag.

WARNING: Use only genuine EOGas 4 products in your sterilizer. Use of other gas sources may result in operator injury and/or non-sterile loads.

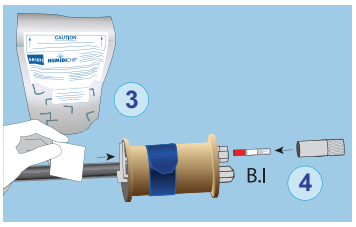
WARNING: Do not reuse sterilization bags.

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 a device may be sterilized using EO gas, please call Andersen Customer Service.



② Insert **AN1036 Dosimeter** into the least accessible part of the sterilization bag.

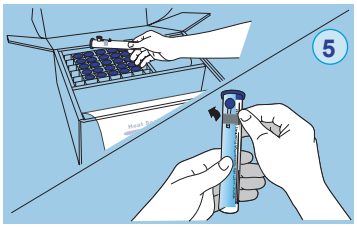
③ Insert a **Humidichip** into the purge probe's **Humidichip clip**.

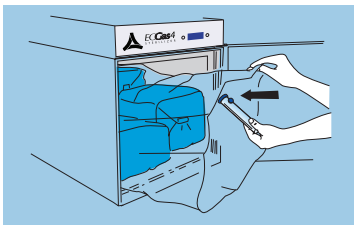


④ Unscrew the PCD cap on the purge probe. Insert the biological indicator (**EZTest or Bionova®**) into the purge probe's PCD with the cap towards the wand and ball end. Screw PCD cap back on securely.

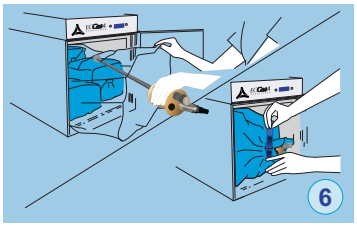
The EZTest biological indicator can be used in either gas exposure (blue or gold probe).

The Bionova biological indicator may only be used in the 6-hour gas exposure (gold purge probe).

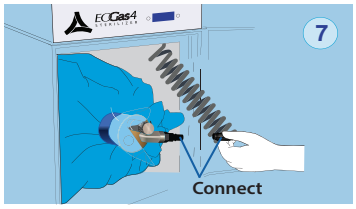




⑤ Remove one **AN1004 EOGas cartridge** from the Refill Kit. Remove the tape and safety trigger guard on the cartridge and place the cartridge on top of the wrapped devices so it can easily be manipulated through the wall of the bag (blue button facing up). **Do not activate the cartridge at this time.**



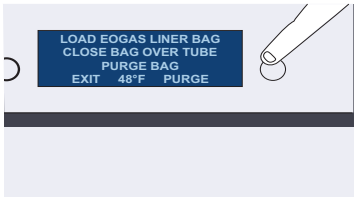
⑥ Place purge probe into the sterilization bag with the ball at the rear of the bag and bobbin and quick release fitting at the open end. Place the blue strap around the sterilization bag and the bobbin of the purge probe, and pull it snuggly through its loop to completely close the bag. The strap must tightly secure the sterilization bag around the purge probe bobbin in order to keep EO gas from escaping.



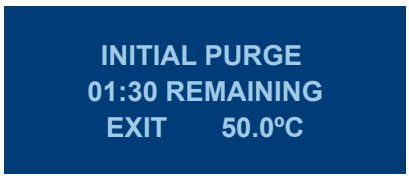
⑦ Connect the quick release connector to the purge probe tubing if it is not already connected.

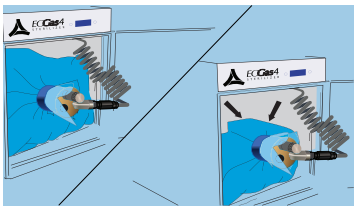
HINT: The sterilization bag may be loaded and sealed away from the sterilizer cabinet and connected to the purge tube once the sterilizer has warmed up.

B. Starting the Cycle



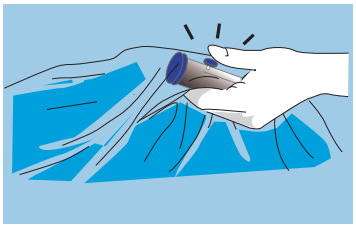
With the loaded bag sealed and connected to the purge tube, press the **PURGE** button while the cabinet door is open.





The sterilizer will purge air out of the sterilization bag for one minute and 30 seconds until the display reads '00:00:00.' The sterilization bag will vacuum down as excess air is removed.

After the initial purge has been completed, the display instructs the operator to activate the cartridge, close the door and select the cycle length:

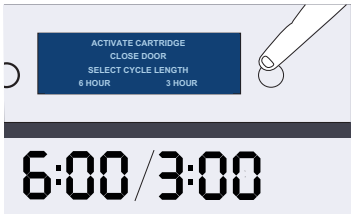


1. Activate the cartridge by pressing the trigger button on the cartridge through the wall of the closed bag. Make sure that the button is fully depressed.

Important: The EOGas 4 cartridge has the precise amount of EO needed to the sterilize contents of the EOGas 4 sterilization bag.

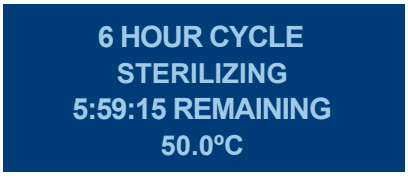
2. Close the door.

3. Select the length of the sterilization cycle (3 or 6 hours). The door will lock automatically.



Important: If a cycle time is not selected within five seconds after closing the door, a continuous alarm will sound to remind you to choose a cycle length.

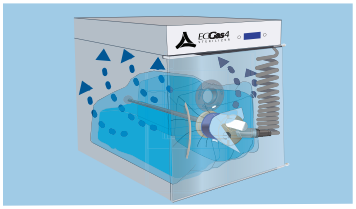
4. After the cycle length is selected, the display counts down time remaining. The door will remain locked.



WARNING: Never interrupt a cycle once the gas cartridge has been activated.

5. Log sterilization data if required.

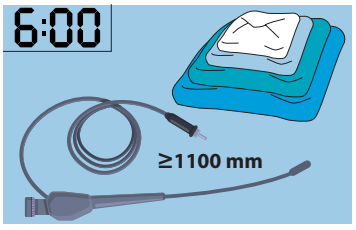
C. Additional Aeration



Throughout the entire cycle, the ventilation system runs continuously to prevent EO gas from entering the room. At the end of the sterilization cycle, the cabinet ventilation pump and the purge pump will run in two-minute intervals, purging the sterilization bag and ventilating the cabinet. This ventilation continues for 30 minutes after the three-hour gas exposure and one hour after the six-hour gas exposure.

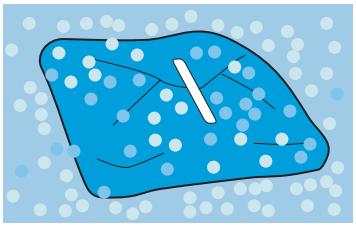
Once the ventilation is complete, the sterilizer will continue to ventilate and purge the bag. A count-up timer will begin on the sterilizer display to keep track of this additional aeration time, and the sterilizer will reset only after the door is opened and the exit button is pressed.

Gas absorbent devices may require additional aeration after the regular sterilization/ventilation cycle and before they can be removed and used. Aeration prevents chemical burns to living tissue that can be caused by residual EO absorbed during the sterilization cycle. EPA guidelines state that device aeration must take place inside the sterilizer cabinet.



D. Aeration Guidelines

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



1. If the device manufacturer provides instructions on aeration required after EO sterilization, always follow those guidelines.

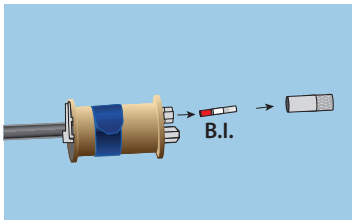
② Two materials that do not require additional aeration are metal and glass. Devices made of these materials do not absorb EO.

③ If the device manufacturer does not provide instructions on aeration required after EO sterilization, the device should remain in the EOGas sterilizer to aerate for an additional 24 hours after the sterilization and ventilation cycles are complete.

4. Unloading the Sterilizer and Determining Sterility

A. Unloading the Sterilization Bag

① When the display indicates **UNLOAD STERILIZER**, open the door and unscrew the cap on the PCD.

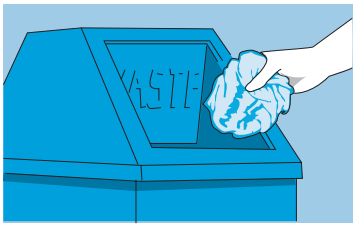


② Remove the biological Indicator from the PCD, prepare according to manufacturer's instructions and incubate:

- EZTest (red cap): 37°C for 48 hours, color change
- Bionova (green cap): 37°C for four hours, fluorescent activity or 48 hours for color change

HINT: To unload the sterilization bag away from the sterilizer, simply detach the purge probe tubing from the bag using the quick release connector.

③ Remove and examine the Dosimeter. When running a six-hour gas exposure, the blue line must at least meet the six-hour triangular calibration mark. When running a three-hour gas exposure, make sure it has reached the three-hour mark.

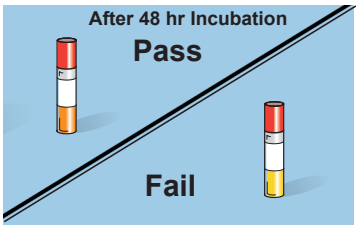


④ Discard the sterilization bag, Humidichip and used cartridge with ordinary trash.

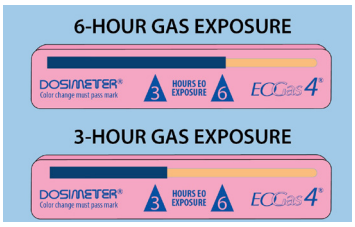
⑤ Press **EXIT** to end the cycle and return the sterilizer to the standby state. Switch the power button to off.

WARNING: Never remove devices before the full sterilization and ventilation cycles have completed. The sterilizer is designed to aerate devices sufficiently to avoid operator exposure to EO gas and to meet the OSHA short-term exposure level (STEL) of 5.0 ppm over 15 minutes.

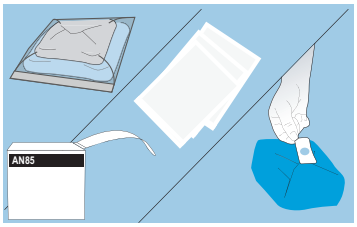
B. Important Notes About Indicators (See page 18 for additional references)



① Biological Indicators (BI) such as the **AN2203 EZTest** 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 Indicators, such as the **AN1036 Dosimeter** provide immediate visual confirmation that time and EO gas concentration were sufficient for sterilization to occur.



③ Chemical Exposure Indicators such as the **AN85** do not indicate sterility. They change color to show that the devices have been exposed to ethylene oxide.

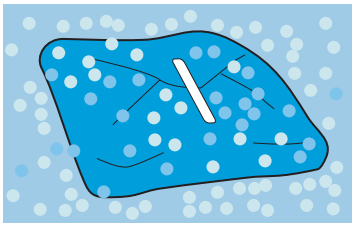
Please refer to manufacturer's instructions when using sterility or exposure indicators.

5. Safety Precautions

A. Ethylene Oxide Safety

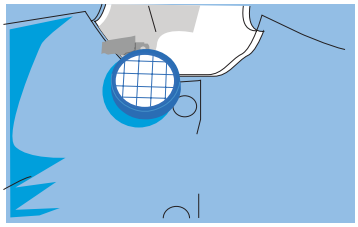
① The sterilizer should be inspected and maintained at least annually and only by an Andersen Sterilizers authorized technician.

② Do not allow open flame or sparks near the sterilizer during the sterilization cycle. Ethylene oxide gas is highly flammable.



3. Never interrupt a cycle in progress. Consequences of removing and opening the sterilization bag before a cycle is complete can include:
   - The load might not be sterile
   - The bag may still contain high levels of EO and put the operator at risk of unsafe exposure

4. Sterilization bags should never be reused because they may have a puncture or tear.

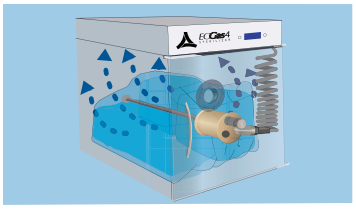


5. Personnel exposure to ethylene oxide can be monitored by using personal exposure badges such as the Andersen **AN94 Vapor-Trak Monitoring Badges**. The AN94 contains both STEL (15-min.) and TWA (eight-hour) badges. EO exposure levels should be checked upon installation of the sterilizer. We recommend exposure testing annually or whenever a sterilizer is relocated. OSHA guidelines for personal monitoring can be found at www.cdc.gov/niosh/programs/ppt.

6. If a cartridge is accidentally activated outside of the sterilization bag, immediately insert it into the **Accidental Release Containment Mechanism (ARCM)** or "safety port" located on the front door of the sterilizer cabinet. Make sure the sterilizer is turned on and immediately run a three-hour cycle. See Section 1 of the User's Manual for more detail about this procedure.

7. Always store gas cartridges and refill kits in a secure area that is kept cool (70°F or below) and out of direct sunlight.

Important: No other container or sterilizer may be used with Andersen gas cartridges.

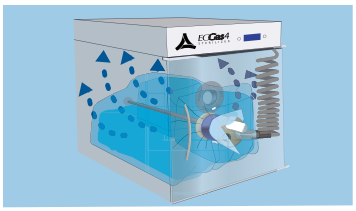


B. Malfunctions and Power Failures

In the event of a **PURGE PUMP FAILURE** error message during the **sterilization cycle**, the bag must be placed by a certified supervisor either outside or under a vent hood. The devices in the load **should not be considered sterile**.

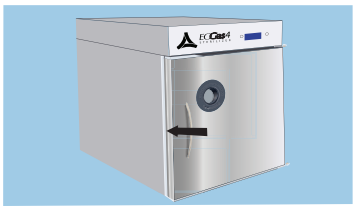
If a **PURGE PUMP FAILURE** occurs during the **ventilation cycle**, the vent pump will run and devices should be aerated for two hours in the sterilizer cabinet with the blue strap removed. The devices in the load **may still be considered sterile**.

In the event of a **VENT PUMP FAILURE** error message during the **sterilization cycle**, the purge pump will remove any remaining gas, and the cycle will be aborted. Devices in the load **should not be considered sterile**.



If a **VENT PUMP FAILURE** occurs during the **ventilation cycle**, the purge pump will remove any remaining gas and an error message will display at the end of the cycle. Devices in the load **may still be considered sterile**.

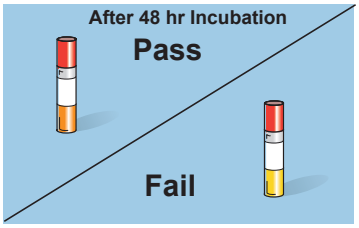
If a **POWER OUTAGE** occurs, the sterilizer is equipped with a battery backup that will keep track of elapsed cycle time. If the outage occurs during the **sterilization cycle**, the temperature of the cabinet may drop too low and the sterilizer will display **CYCLE FAILED**. If it has, the devices in the load **may not be considered sterile**.



If the **POWER OUTAGE** occurs during the **ventilation cycle**, the sterilizer will resume aeration when power returns. **Devices may still be considered sterile**.

Do not open the door of the sterilizer until power is restored and the vent/purge systems have removed any residual gas from the bag.

Call Andersen Customer Service for assistance with any malfunctions, **1.800.523.1276**. See Section 6 of the User's Manual for more details about proper troubleshooting procedures.



IMPORTANT: In the case of any sterilizer malfunction or power failure, you can determine whether sterilization was achieved by examining the indicators included in the load (such as chemical integrators and biological indicators).

1. If liquid EO comes into contact with a part of the body you must wash with water thoroughly for at least 15 minutes while removing contaminated clothing and shoes. Consult the **Safety Data Sheet** (SDS) for further information.

2. The **Safety Data Sheet** (SDS) for EO gas should be readily available. Do you know where to find your SDS?
   - User's Manual
   - List of physical and chemical hazards is provided with each EOGas Refill Kit.
   - Link on page 19

In case of emergency, please contact:

Business Hours
Monday - Friday, 8 a.m. to 5 p.m. EST
1.800.523.1276

After Hours
(for medical or chemical emergencies only)
VelocityEHS: 1.800.255.3924

Sterility Indicators References

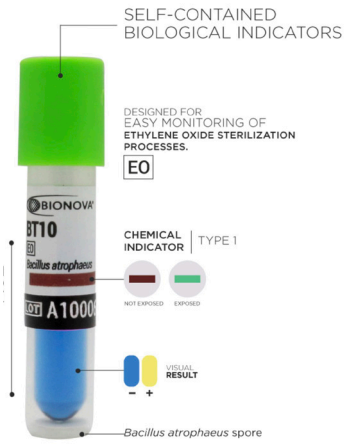
Biological Indicators: AN2203 EZTest® (red cap)

Unused

Pass

Fail

The AN2203 EZTest® can confirm sterilization cycle efficacy after 48 hours of incubation. After 48 hours of incubation, medium color change from red/orange to yellow indicates positive results (a failed sterilization cycle).



AN2211 Bionova® BT110 (green cap)

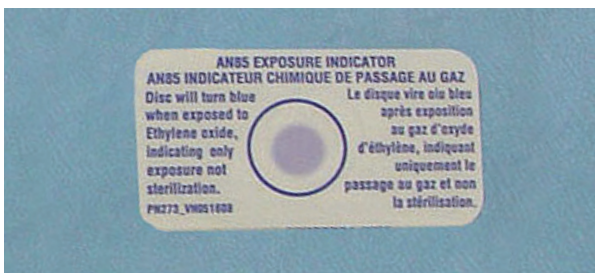
The AN2211 Bionova® BT110 can confirm sterilization cycle efficacy after 4 hours or 48 hours of incubation. After four hours incubation, a UV light can be utilized and fluorescent activity indicates positive results (a failed sterilization cycle). After 48 hours incubation, medium color change from blue to yellow indicates positive results (a failed sterilization cycle). Either method is sufficient, the 48-hour incubation is not required if the four-hour incubation method is utilized. Refer to biological indicator's instructions for use for more details.

Chemical Indicator: AN1036 Dosimeter

Pass (six-hour)

Fail (six-hour)

Exposure Indicator: AN85 *These are indicators of exposure, not of sterility.*



Pass

Fail

Other Resources

Andersen Website: sterility.com

1 SDS on ethylene oxide
https://www.sterility.com/wp-content/uploads/EtO_SDS.pdf

2 OSHA Small Business Guide to Ethylene Oxide
https://www.osha.gov/sites/default/files/publications/ethylene-oxide.pdf

3 Many other useful reference materials
https://www.sterility.com/resources/studies-and-reference/

Questions & Notes

Please use this area to list any questions that you have for your Andersen Representative regarding your EOGas 4 Sterilizer.

6. Study Guide Review

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

- The minimum temperature recommended in the room where the sterilization system is installed and operated
- The two sterilization cycle options and their corresponding purge probes
- Why the ventilation system runs continuously during the entire cycle
- Why the sterilization bag is purged at the beginning of the cycle
- The required relative humidity in the room where devices are prepared
- How to prepare devices 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 schedule your Key Operator Certification exam by giving Andersen Sterilizers a call at **1.800.523.1276**. The test takes approximately 20 minutes to complete.

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

If you would like to have an Andersen representative come to your facility for on-site training and/or a maintenance service plan, please contact Andersen Sterilizers for a quote on these custom services.

Thank you for purchasing the Andersen EOGas 4 sterilizer.
If at anytime you have questions, please do not hesitate to call.

Andersen Customer Service

1.800.523.1276

sterility.com

Revision Table			
Revision	ECN	Date	Effective for AN4000.60/AN4000.61 Lot #s
1	2025003	2025-04-16	All Lot #s