AN 74i / AN 74ix / Anprolene® gas sterilization

OWNER'S MANUAL

CERTIFIED
ISO 9001

Accredited by the Council for Accreditation (RvA)

INTERTEK CERTIFICATION

ANSI-RAB QMS ACCREDITED
National Accreditation Program

ETHYLENE OXIDE
STERILIZATION SYSTEM

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Andersen Sterilizers, Inc. Health Science Park Haw River, NC 27258-8710

Owner's Manual

Congratulations on your purchase of an AN74*i* / AN74*ix* Anprolene® Sterilizer. For over 30 years, Andersen Products has been a leader in tabletop Ethylene Oxide sterilization. With the installation of your sterilizer, you join thousands of healthcare facilities worldwide using an Andersen Products' sterilization system.

Please read the entire Owner's Manual prior to installing and using your new machine.

The Andersen Anprolene sterilizer uses less than 20% of the amount of Ethylene Oxide gas of our nearest competitor (less than 18 grams). However, please note that Ethylene Oxide can be hazardous if not properly handled. Ethylene Oxide is also highly flammable, so precautions should be taken to avoid improper installation or operation of the equipment near spark or open flame.

Knowing how to properly use the Anprolene system is important. With this in mind, we have included the Operator Training and Education Section found in Section 4, beginning on page 17. Illustrated instructions and information on humidification are included in the training section. In addition, you will also find information concerning the Andersen Key Operator Certification Program. The Key Operator Program covers all aspects of effective use of your Anprolene sterilizer and is offered free of charge for the lifetime of the sterilizer. After reviewing the enclosed training material, please call 800-523-1276 or 336-376-3000 to schedule your exam. Outside the United States and Canada, please contact your local distributor.

A list of suggested items that can be sterilized in the Anprolene sterilizer can be found on pages 28 and 29 of this manual. **CAUTION:** Food and drugs may not be sterilized because Ethylene Oxide may change their chemical composition. If you are not certain about an item's suitability for Ethylene Oxide sterilization, please contact an Andersen Customer Service Representative.

Section 6 of this manual covers **Troubleshooting and Error Messages** and begins on page 34. Installation requirements and instructions are discussed in Appendices B through D, beginning on page 46.

Please call **Customer Service at 800-523-1276 or 336-376-3000** for repair services. Outside the United States and Canada, please contact your local distributor.

Instructions on **preparation of products prior to sterilization** appear in Section 1, beginning on page 5.

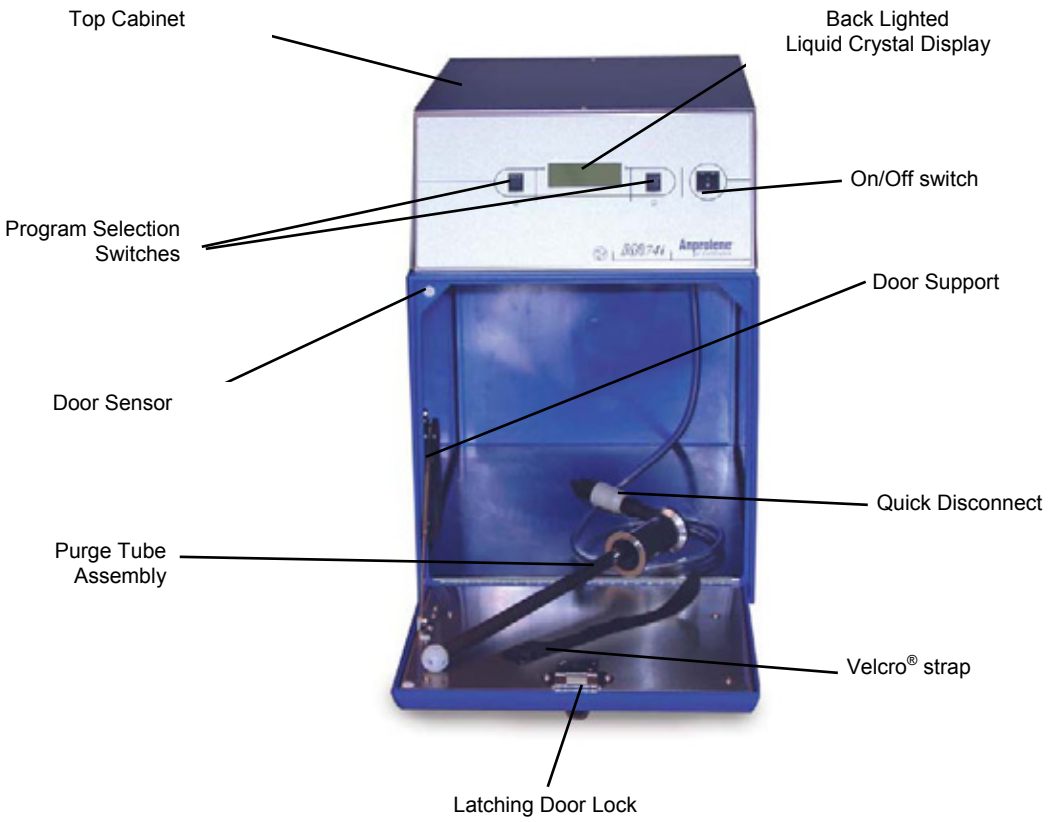
Accessories for use with your Anprolene sterilizer can be found in Section 5, beginning on page 30.

WARNING! If the Anprolene sterilizer is not installed and operated in the manner specified by Andersen Products, the protection provided by the equipment may be seriously impaired.

DANGER! Ethylene Oxide is a Cancer and Reproductive hazard. Refer to MSDS on page 68 and EPA approved labeling on all Anprolene refill kits for complete instructions and warnings.

In case of emergency, please call Andersen Products Customer Service at 336-376-3000 during regular business hours (EST). After business hours, please contact 800-255-3924.

Overview of Features



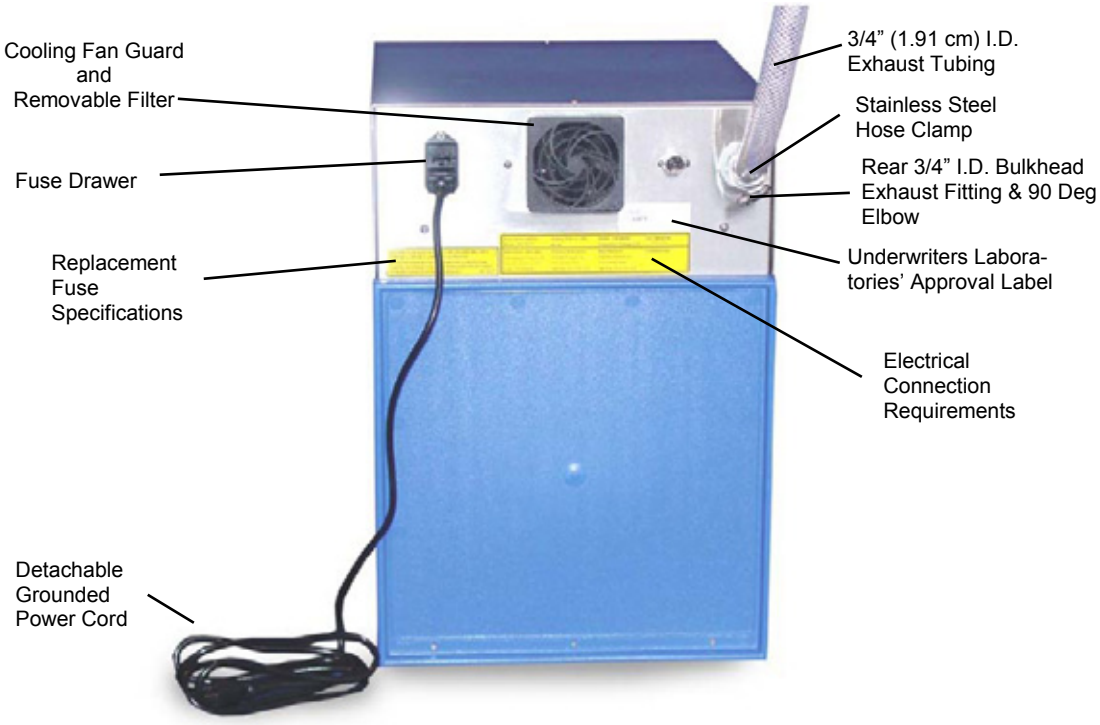


TABLE OF CONTENTS

SECTION 1

Before You Begin...

SECTION 1
Before You Begin

There are a number of conditions that can affect the operation of your sterilizer. By paying close attention to these details, you will greatly reduce the likelihood of problems.

1.1. **Installation:** Please make sure that your Anprolene sterilizer is installed correctly. Full installation instructions can be found in Appendix B, starting on page 46. Please call our Customer Service Department if you have installation questions not covered in this section.

1.2. **Environmental Factors:** Your Anprolene sterilizer is designed to operate at room temperature (68°F/20°C to 91°F/33°C). Please pay close attention to the following factors:

a. **Temperature:** Ethylene Oxide (EtO) is sensitive to temperature and becomes less effective at lower temperatures. Make sure that the room where the sterilizer is installed maintains a temperature between 68°F/20°C and 91°F/33°C for the full duration of the sterilization cycle.

b. **Humidity:** Anprolene sterilization requires at least 35% relative humidity (RH). In low humidity areas, or during the winter months when the humidity level drops, an Andersen Humidichip® may be necessary to achieve and/or maintain the proper humidity level in the sterilization liner bag. Please refer to Section 4, beginning on page 17, for more information on humidity and pre-humidification.

1.3. **Preparing Items for Sterilization:** Materials to be sterilized by all Ethylene Oxide sterilizers, including Anprolene, must be meticulously cleaned and dried. Coatings of dried proteins such as pus, blood or feces protect microorganisms and slow the sterilization process. Precautions must always be taken before sterilization with Anprolene. To prepare items for sterilization, please include the following steps:

a. **Disassemble -** Anprolene is a highly diffusible gas sterilant; nevertheless, occlusive caps, plugs and stylets must be removed from instruments so that the gas can penetrate freely. Hollow bore needles and plastic or rubber tubing must be open and free from stylets and plugs. Syringes must be packaged with the plungers removed.

b. **Wash -** Scrub the disassembled instruments in detergent and water to the most critical standard of cleanliness possible. We recommend the use of an enzymatic cleaner such as Andersen Products' AN2281 Surgical Instrument Enzymatic Detergent, which may be used with most materials.

c. **Dry -** Water on instruments at the time of exposure to Anprolene may react with the gas and reduce its effectiveness. Make sure that items to be sterilized are physically dry before wrapping and processing. Towel drying or drain drying is sufficient. **CAUTION: Do not use hot air to dry.**

d. **Wrap -** All items to be sterilized must be wrapped in cloth, paper or plastic in the manner conventional for steam sterilization, or in Andersen Seal and Peel® Packaging.

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SECTION 2

Diagrammatic Instructions for Normal Operation

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Turn on the sterilizer by pressing the on-off switch on the back right side of the top cabinet.

The Liquid Crystal Display will illuminate. The initial startup and standby screen is shown to the right.

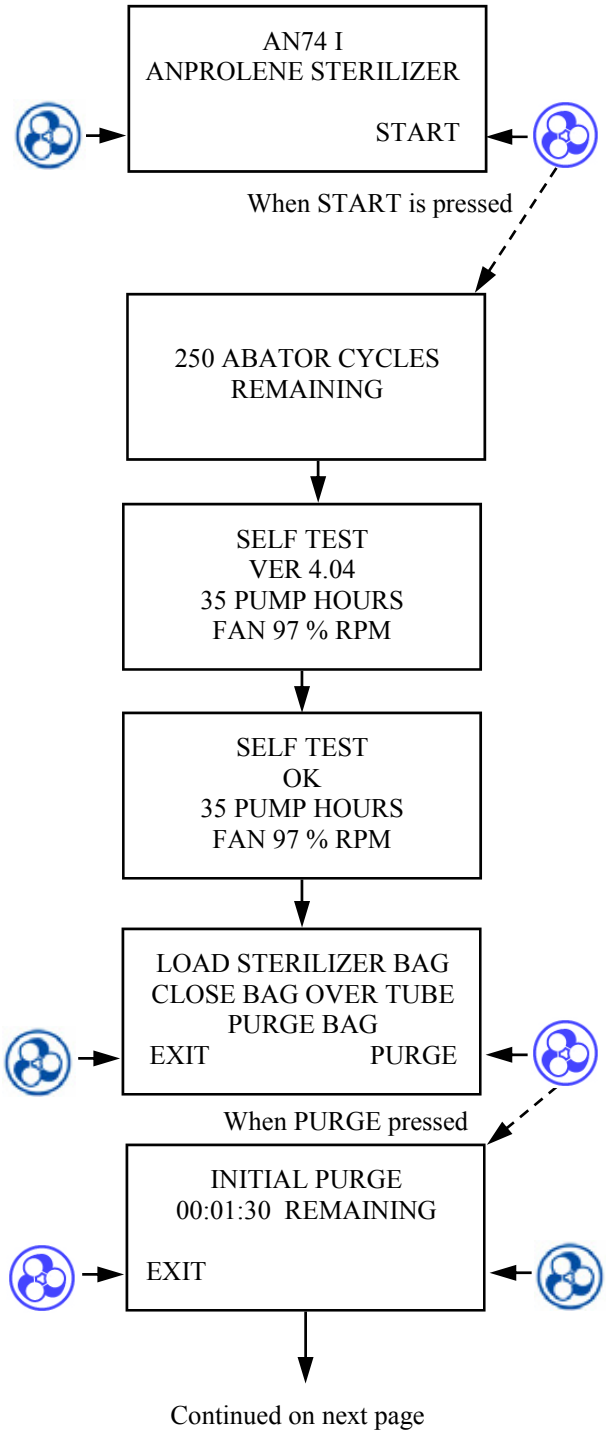
To load the sterilizer and commence a sterilization cycle, press the button immediately to the right of the word START.

If an abator is attached to the machine, the number of cycles remaining for the abator cartridge will be displayed. A new abator cartridge may be used for a maximum of 250 sterilization cycles.

The display will indicate that the sterilizer has performed a self test on the cabinet ventilation pump and ventilation switch. The version of the computer software is shown (VER 4.04). In addition, the total number of hours that the ventilation pump has been operating is shown (35 PUMP HOURS). This information is used to determine when preventive maintenance should be performed. (See Section 7). The cooling fan blade speed is displayed as a percentage of nominal operating speed (FAN 97% RPM).

Once the self test of the cabinet ventilation pump has been successfully completed, the display will show the instructions for loading the sterilizer. After the sterilization bag has been secured to the purge tube bobbin via the Velcro strap, press the button to the right of the word PURGE to evacuate air from the sterilization bag.

The display will show the initial 1 minute, 30 second initial purge is in progress. To stop the cycle and return to the standby screen, press the button to the left of the word EXIT.



Continued on next page

Diagrammatic Instructions for Normal Operation, *continued*

After the initial purge, the screen to the right will appear. If the operator breaks the ampoule and closes the door without selecting a cycle length, the sterilizer will beep after 5 seconds to remind the operator to select the appropriate cycle length. The operator should break the Anprolene ampoule, close the sterilizer door, remove the key, and select the desired cycle length.

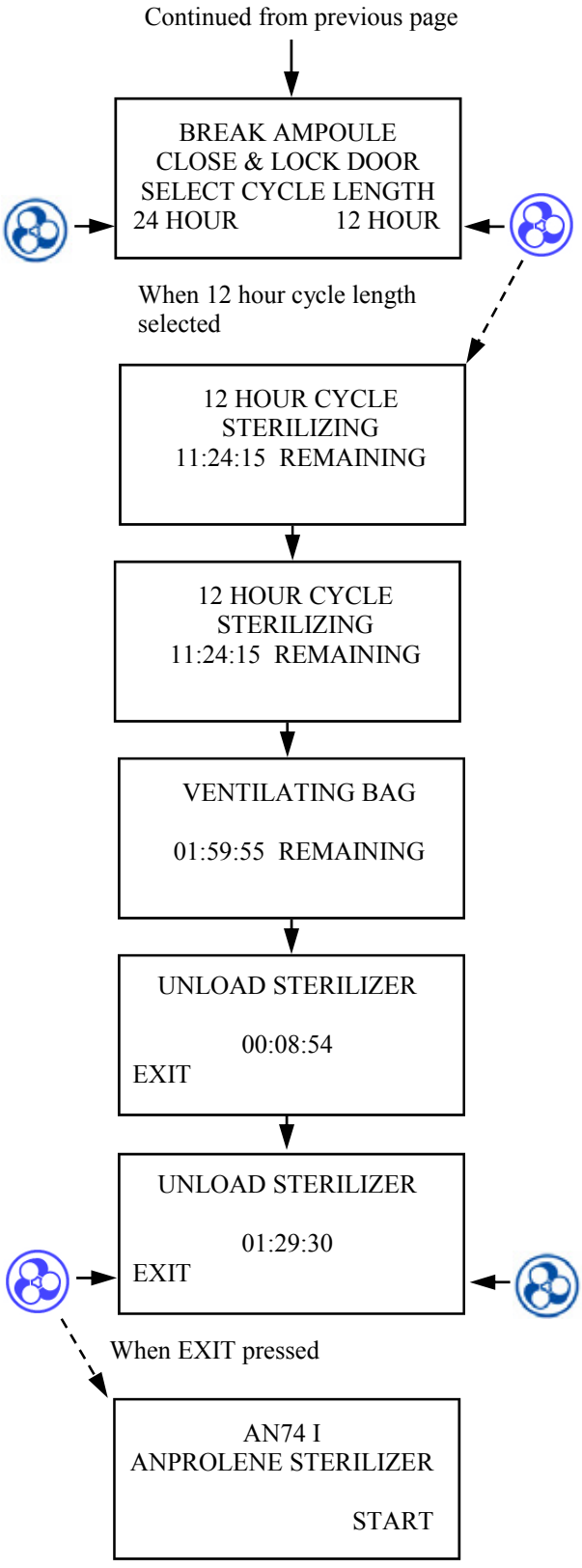
Once the sterilization cycle has been initiated, the display will show the cycle length chosen and the time remaining in the sterilization cycle.

At the end of the sterilization cycle, the unit will begin a 2 hour sterilization liner bag ventilation (purge) cycle to remove the residual Ethylene Oxide. The display will show the time remaining in the purge cycle. During this time the purge pump and cabinet ventilation pumps will run alternating two minute cycles.

At the end of the 2 hour liner bag ventilation (purge) cycle, the machine will beep once and instruct the user to UNLOAD STERILIZER, signifying the end of the cycle. The sterilizer may now be safely unloaded.

Note - Additional Aeration Option:
The ventilation pump and purge pump continue running alternating two minute cycles until the door is opened and the EXIT button is pressed. If needed, items may be left in the machine for further aeration after the cycle has ended by simply leaving the items inside the sterilizer. The count-up timer indicates the additional aeration time.

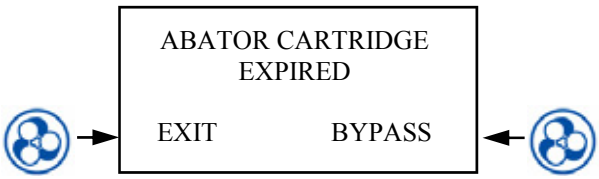
Once the cycle has been concluded by opening the door and pressing the EXIT button, both pumps will stop running and the sterilizer will return to the standby screen.



Diagrammatic Abator Instructions:
Installing Optional New Abator Cartridge, Resetting Counter

When the Abator cartridge has been used completely (250 sterilization cycles), the screen will display ABATOR CARTRIDGE EXPIRED and the alarm will sound.

Additional cycles may be completed by bypassing the screen. This is not recommended. The cartridge should be changed prior to starting a new cycle.



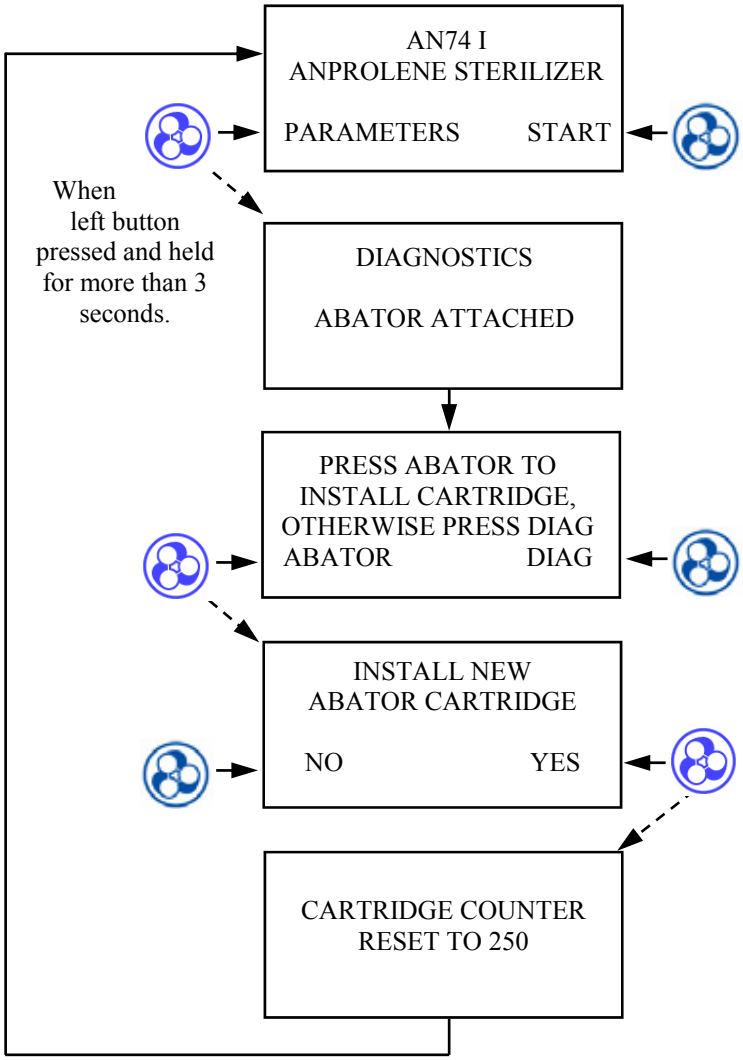
Once a new cartridge is installed, the counter must be reset.

To reset the counter:

1. Hold the left button continuously for more than 3 seconds

2. Press ABATOR button

3. Answer YES to the question: INSTALL NEW ABATOR CARTRIDGE



SECTION 3

Detailed Pictorial Instructions for Running a Sterilization Cycle

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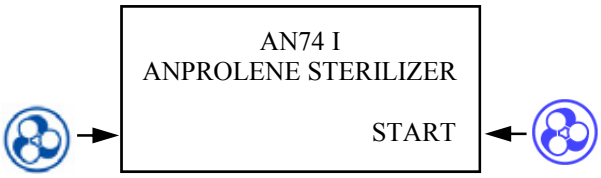
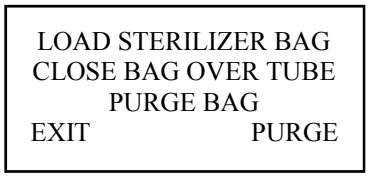
Detailed Pictorial Instructions for Running the Sterilization Cycle

Once the items to be sterilized have been disassembled, cleaned, dried and wrapped, the sterilization cycle can proceed.

3.1 Prior to loading the sterilizer: (1) Turn the power ON by pressing the right side of the black power switch located on the back right corner of the machine. This will cause the initial screen to appear. (2) Press the button to the right of START on the display screen to initiate the self test.



Upon successful completion of the self test, the following LOAD screen will be displayed:



3.2. **Preparation and loading of the sterilization liner bag:**

a. Remove a sterilization liner bag from the refill kit and place it inside the sterilizer cabinet with the open end facing you.

b. Place the wrapped items for sterilization inside of the sterilization liner bag.

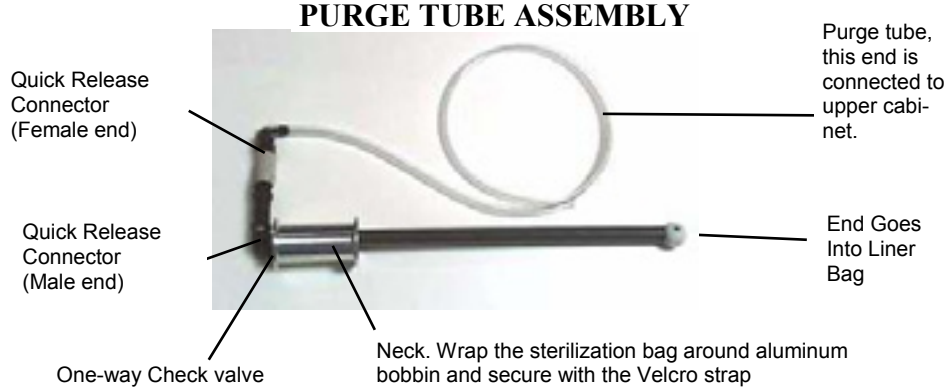
c. Unroll the gas release bag containing the gas ampoule.

d. Without opening the gas release bag, gently move the ampoule to the center of the gas release bag.

e. Place the gas release bag on top of the wrapped items so that you can easily manipulate it through the wall of the bag after the sterilization liner bag has been closed. **Do not break the ampoule at this time.**

f. Place appropriate indicators inside of the sterilization liner bag. (See Section 5 for more information concerning sterility indicators.)

PURGE TUBE ASSEMBLY



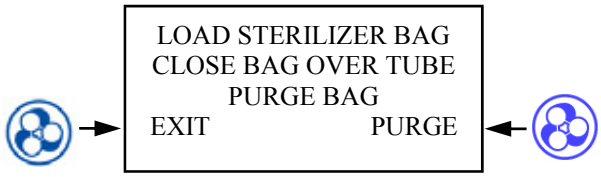
3.3. Insert the purge tube into the sterilization liner bag with the plastic ball towards the rear of the bag and the neck towards the opening. Then, gather the open end of the sterilization liner bag around the aluminum neck of the purge tube, taking care to ensure you have left no openings.

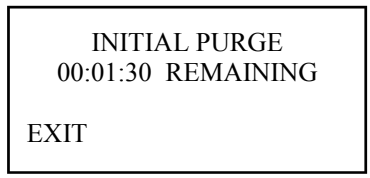
3.4. Slip the black Velcro® strap around the outside of the sterilization liner bag and thread the pointed end of the strap through the square black loop. Pull the Velcro strap firmly and then wind it back around the exposed surface of the strap. **Make sure that the Velcro strap is secure and provides an airtight seal between the aluminum neck of the purge tube and sterilization liner bag.**

3.4.a. This is how the secured sterilization liner bag and purge tube should appear.

3.5. If the purge tube has been disconnected from the sterilizer by means of the quick release, simply reattach it by pressing the male and female ends together until they click.

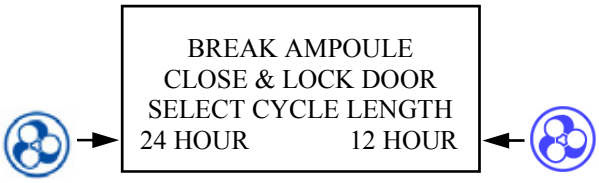
3.6. With the cabinet door open, press the PURGE button.



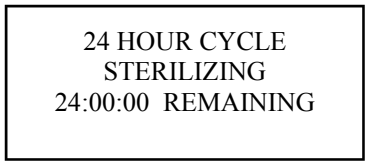


3.8. After the initial purge has been completed (timer to 00:00:00), the display instructs the operator to: (1) break the ampoule by manipulating the ampoule gas release bag through the wall of the sterilization liner bag, (2) close the door, and (3) lock the door and remove the key.

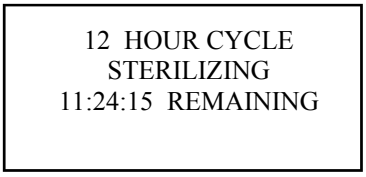
3.9. Select the length of the sterilization cycle. For most items, the 12 HOUR cycle will be adequate.



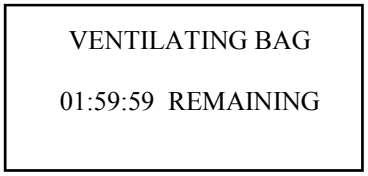
3.10. When sterilizing lengths of tubing greater than 3 feet (91.5 cm) or loads containing gas absorbent materials, the extended length 24 hour cycle should be used. Large volumes of gas absorbent materials (rubber and plastic) also require the use of an additional Anprolene ampoule and the extended 24 hour cycle. To operate the sterilizer using the extended 24 hour cycle, press the button to the left of 24 HOUR. The display will then show STERILIZING 24:00:00 REMAINING.



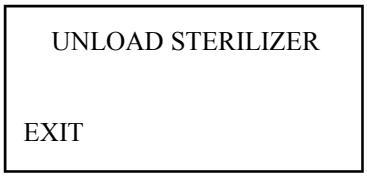
3.11. The sterilization cycle will then begin. ***Note:*** *After the ampoule is activated and the door is closed, if the operator does not select a cycle length within 5 seconds, a continuous alarm will sound to remind the operator to select the appropriate cycle time.*



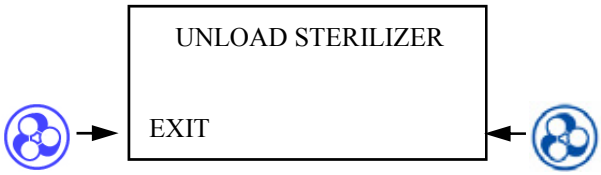
3.12. At the end of the 12 (or 24) hour cycle, the cabinet ventilation pump will stop and the purge pump will run for two minutes, flushing Ethylene Oxide from the sterilization liner bag. Then the purge pump will stop while the cabinet ventilation pump runs for two minutes. This alternating cycling of the purge and cabinet ventilation pumps will continue for a period of two hours. This will be displayed as shown below and will count down to 00:00:00.



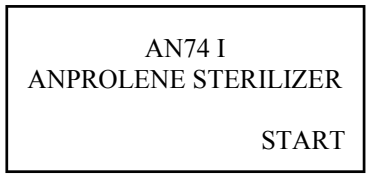
3.13. At the end of the two hour ventilation cycle, the following screen will appear, notifying the operator that the sterilizer may be unloaded.



3.14. If the operator does not unload the sterilization liner bag at the end of the two hour ventilation cycle, the purge pump and the cabinet ventilation pump continue to alternate on a two minute cycle to flush the sterilization liner bag and cabinet indefinitely until the door is opened and the EXIT button is pressed This feature may be used for **Additional Aeration**. Refer to page 45.



3.15. If the operator opens the door after the two hour purge cycle is complete and presses EXIT , both pumps will stop and the program will automatically return the sterilizer to the start screen.



3.16. To unload the sterilizer, open the door and remove the Velcro® strap from around the neck of the purge tube. Remove the purge tube from the sterilization liner bag. Unload the wrapped items from the sterilization liner bag and place them on a shelf in a well-ventilated room that has a minimum of 10 air changes per hour of fresh makeup air.

3.17. Gas absorbent materials such as rubber or plastic must be aerated in their individual packages for at least 24 additional hours before they are used.

3.18. The used gas release bag ampoule and sterilization liner bag may be disposed of in ordinary rubbish. **Never reuse sterilization liner bags**.

SECTION 4

Operator Training and Education

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Operator Training and Education

- Ethylene Oxide sterilization procedures must be supervised by personnel trained and well informed in the safe use of such sterilant materials.

- Personnel working with ethylene oxide must have had comprehensive instruction in the process. This instruction must cover the relevant health hazards (See MSDS on page 68), relevant national regulations (e.g. OSHA regulation 29 CFR Part No. 1910 Standard No. 1910.1047), methods for safe use and methods to detect escape of sterilant material (e.g. AN 93 Airscan Badges)

- Regular in-service programs relating to the process must be conducted and an attendance record and evidence of understanding must be kept for each employee (e.g. Andersen Key Operators Test).

4.1. Humidity and Pre-humidification.

It has been demonstrated repeatedly that some microorganisms are made very resistant to Ethylene Oxide sterilization systems by desiccation, which is exposure to very low relative humidity.

As a result, humidity is a very important part of the Ethylene Oxide sterilization cycle. Items that can be washed in water and towel or air dried will not need pre-humidification.

Items that may be damaged by immersion in water or a sterilization load that contains a large amount of material that will absorb water (dry paper and cloth) will need pre-humidification.

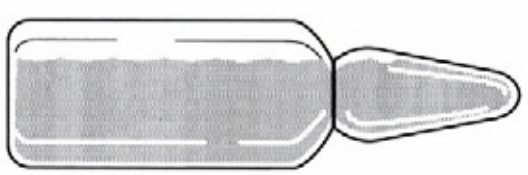
Process for Pre-Humidification Using an Anprolene Sterilization Liner Bag

a. Items that cannot be immersed in water should be disassembled and wrapped in the usual way.
b. Place the prepared items along with a Humidichip® inside a sterilization liner bag. Using a twist tie or Velcro® strap, securely close the neck of the bag.
c. Leave the items in the bag for a minimum of four hours at a temperature of 68°F /20°C or higher. Pre-humidification may take place outside the sterilizer cabinet. *Take caution not to rip or puncture the sterilization liner bag.*

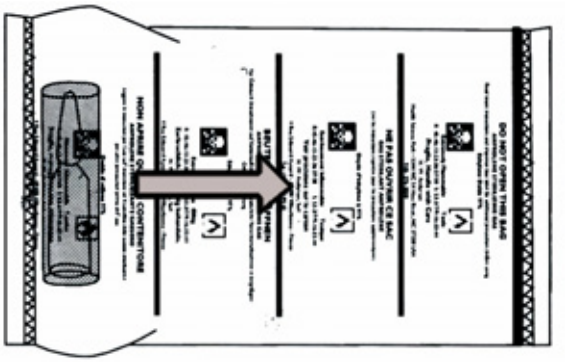
During the sterilization cycle, use a Humidichip to ensure a minimum of 35% Relative Humidity inside the sterilization liner bag. Items that did not need pre-humidification can be added to the sterilization liner bag, along with the appropriate controls such as Dosimeter®, Steritest®, or other Biological Indicators. If there is any question as to the integrity of the sterilization liner bag, use a new liner bag for the sterilization cycle.

4.2 ABRIDGED ILLUSTRATED INSTRUCTIONS

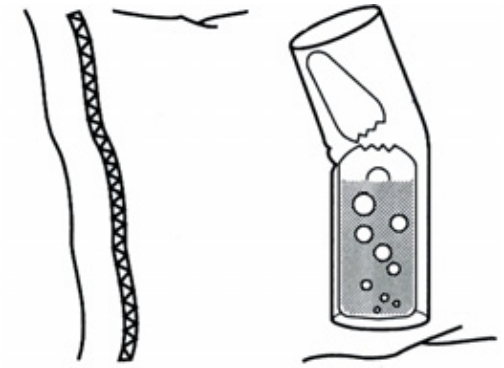
HOW ANPROLENE WORKS



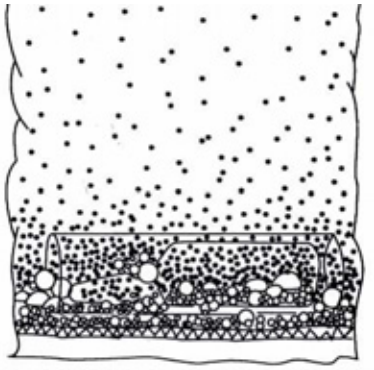
1. The glass ampoule contains liquid Ethylene Oxide (EtO) and an inert solid stabilizer. The ampoule is scored at the neck for easy opening.



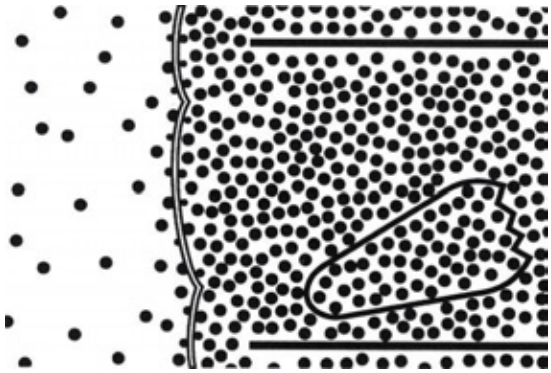
2. A plastic/fabric break shield surrounds the ampoule. The ampoule and shield are sealed inside a plastic gas-release bag, which should never be opened.
IMPORTANT! Push the ampoule to the center of the gas release bag before activating



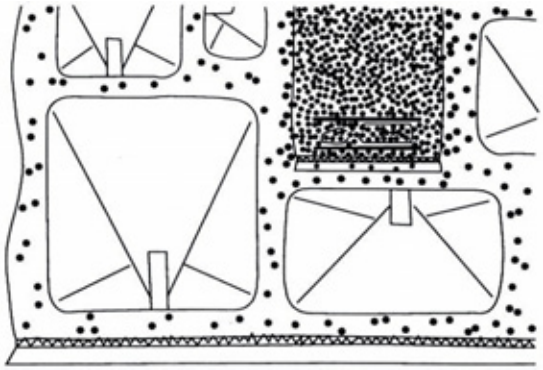
3. After the gas release bag is placed inside of the sterilization liner bag and it is secured to the purge bobbin, the sterilization bag is then vacuumed down. To release pure EtO gas, manually snap off the top of the ampoule by manipulating it through the walls of the sterilization liner bag. The plastic/fabric shield prevents the broken glass of the opened ampoule from puncturing the gas-release bag.



4. The liquid EtO then boils, releasing 100% EtO gas within the gas-release bag, leaving residual deposits of the previously dissolved inert solid stabilizer.



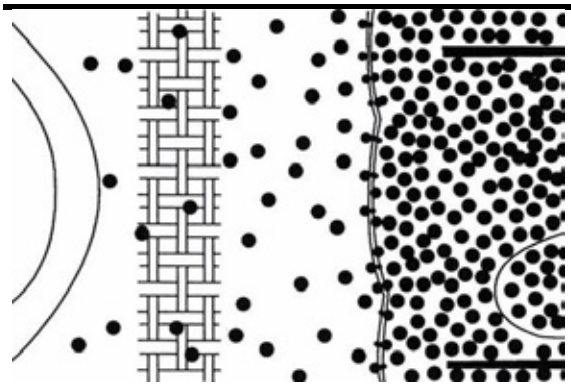
5. Since the walls of the gas-release bag are permeable only to EtO gas and not the inert solid stabilizer, only the 100% pure EtO gas diffuses through the walls of the gas-release bag and into the liner bag.



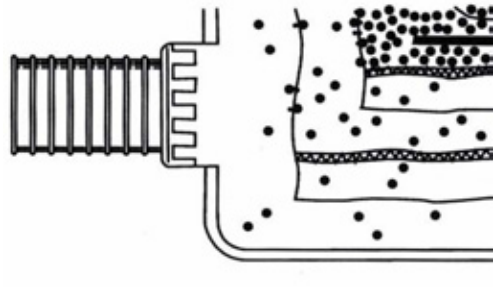
6. EtO possesses great kinetic energy, which causes the gas molecules to spread out to every cubic centimeter of the liner bag by their own velocity.

4.2 ABRIDGED ILLUSTRATED INSTRUCTIONS

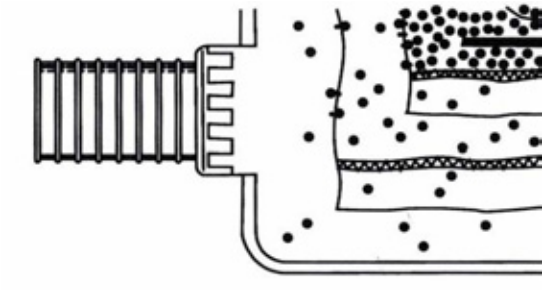
HOW ANPROLENE WORKS



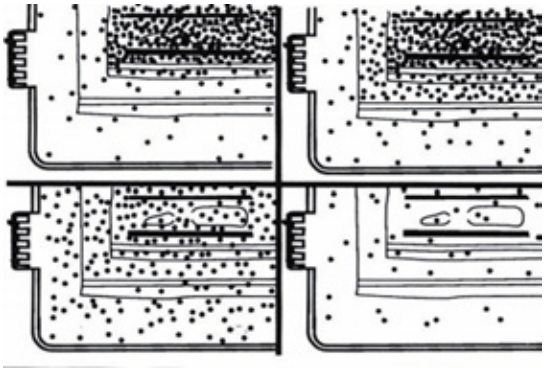
7. EtO gas readily passes through cloth, paper, and Seal and Peel® Packaging to reach the items to be sterilized.



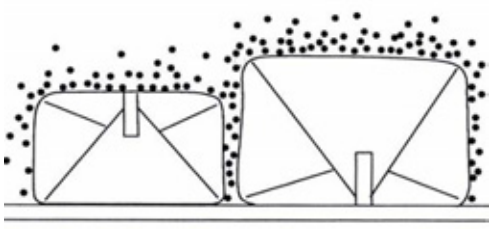
8. The walls of the sterilization bag are also porous to EtO gas. As the concentration of EtO gas in the liner bag is increased by gas diffusing from the gas-release bag, the EtO molecules also diffuse through the walls of the liner bag and into the sterilization cabinet.



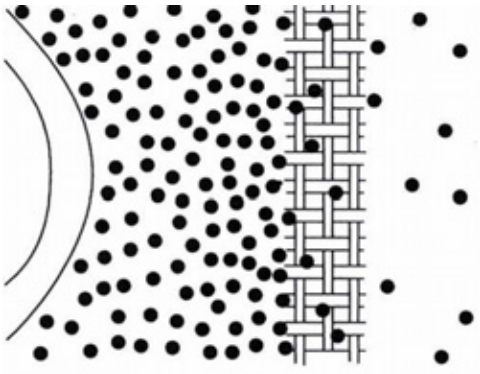
9. The EtO molecules diffusing from the liner bag into the sterilization cabinet are then evacuated to the abator, if installed. Any remaining effluent is then vented to the outside atmosphere by the sterilizer's ventilation system.



10. For about three hours there are more EtO molecules released into the liner bag than are released by the liner bag into the sterilizer. Then the rates are similar for three hours. Finally, the liquid Anprolene in the gas-release bag is exhausted. EtO molecules gradually diffuse into the sterilizer for the remainder of the cycle.



11. At 12 hours, all items are sterile, and the residual gas in the liner bag is small. The additional two-hour purge cycle is used to remove remaining residual EtO from the liner bag before the container may be opened.



12. Gas-absorbent materials, like plastic and rubber, are aired in their protective wrapping before use. The EtO gas absorbed by plastic or rubber readily escapes through cloth, paper, or Seal and Peel® Packaging.

4.3 Key Operator Study Guide: AN74I / IX Anprolene® Sterilizer

Thank you for using the Anprolene® sterilization system.

The active ingredient in Anprolene is ethylene oxide (EtO or EO), a chemical that can be hazardous if not handled properly. To ensure that you fully understand the safe operation of your sterilizer, we strongly encourage you to take advantage of our Key Operator certification program.

To begin Key Operator training, please read through this study guide thoroughly. If you do not understand any of the information in the guide, please call Andersen Customer Service for assistance. Once you are familiar with the study guide, you can call us at (800) 523-1276 to schedule a test.

The test will take approximately 20 minutes. The Key Operator test is also an excellent opportunity to ask your Andersen Representative any questions you may have about your Anprolene system or ethylene oxide.

When you successfully complete the test, you will receive a certificate and a registered key ring. We look forward to hearing from you.

Key Operator training is free of charge for the lifetime of your sterilizer. Please have all new operators of your Anprolene sterilizer contact us for training before they use the system.

A. Environmental Considerations

1) Temperature

- Store your Anprolene gas refill kits in a cool, secure area. We recommend storage below 72°F (22.2°C).
- The sterilizer must be used in an area where the temperature is not less than 68ºF (20°C) or more than 91ºF (33°C). This temperature range must be maintained during the entire sterilization cycle.

EO FACTS: *At sea level, ethylene oxide is a liquid below 51 ° F (10.6. ° C). Above 51 ° F, EO begins to boil and converts into a gas. EO does not become an effective sterilant until 68 ° F (20 ° C) Make sure that the room where your Anprolene sterilizer is installed remains above 68 ° F during the entire 12-hour sterilization cycle. This is especially important during the winter months!*

2) Humidity

- Humidity is very important to the Anprolene 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 very dry and resistant to Anprolene if the RH is below 35%.
- The simplest way to humidify items is to wash them.
- It is necessary to humidify items which cannot be washed by enclosing them in a plastic bag with an Andersen Humidichip® or a damp sponge for four hours prior to sterilization at a temperature greater than 68 ° F (20 ° C)

B. Preparing Items for Sterilization

Four basic steps must always be followed when preparing items for sterilization:

1) **Disassemble**
2) **Wash**
3) **Dry**
4) **Wrap**

1) Disassemble

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

WARNING!: ***Instruments which contain batteries should 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. For cleaning, we recommend using an enzymatic detergent such as Andersen's Sterizyme (AN2281).

3) Dry

Two accepted ways to dry any item prior to sterilization with Anprolene are:
1. Towel drying
2. Drain drying (air drying).

WARNING!: *Heat or hot air should never be used to dry an item prior to sterilizing it with Anprolene because it will dehydrate or dry out bacteria spores making them more resistant to the ethylene oxide gas.*
WARNING!: *Any water left on items may react with ethylene oxide, reducing its efficacy. Please air dry instruments thoroughly.*

4) Wrap

The following types of wrapping material are recommended for use with Anprolene:
1. Andersen Seal and Peel® Packaging (which is airtight and waterproof and greatly extends the shelf life when heat sealed at both ends)
2. Cloth (like CSR wrap) has an estimated sterile shelf life of 30 days
3. Paper (self-seal pouches) has a shelf life of 30 days
4. Tyvek-paper pouches

☺**HINT:** *Exposure indicators such as the Andersen AN85 or AN86 will turn color in the presence of EO, helping to later identify items that have been sterilized.*

C. Sterilization Cycle

1) Preparing the Sterilization Liner Bag

1. Place prepared items in a new sterilization liner bag.

WARNING!: *Do not reuse sterilization liner bags. Even a tiny pinhole in a sterilization liner bag can allow gas to escape and cause cycle failure!*
WARNING!: *Do not sterilize liquids, foods or drugs in the Anprolene sterilizer. If you have any questions about whether an item may be sterilized using Anprolene, please call Andersen Customer Service.*

2. Insert appropriate controls such as a Dosimeter (chemical indicator) or a Steritest® (biological & chemical indicator) into the least accessible part of the sterilization liner bag. Add a Humidichip® if appropriate.
3. Unroll the gas release bag containing the gas ampoule and, without opening it, gently move the ampoule to the center of the gas release bag. Place it on top of the items in the sterilization liner bag where it will be easy to break.

4. Insert the purge tube into the sterilization liner bag with the aluminum bobbin and quick release fitting at the open end. Place the black Velcro® strap around the sterilization liner bag and the bobbin of the purge tube, and pull it snug though its loop to close the sterilization liner bag. The strap must secure the sterilization liner bag tightly around the aluminum bobbin to keep gas from escaping.
5. Connect the quick release connector to the purge tube, if it is not already connected.

☺**HINT:** *The sterilization liner bag may be loaded and sealed away from the sterilizer cabinet, and connected to the purge tube once you are ready to start a cycle.*

2) Starting the Cycle

1. Make sure the AN*74 i/ix* power cord is connected. Press the right side of the power switch located on the right rear of the cabinet. Wait to see the 'AN*74 I* ANPROLENE STERILIZER' and the 'START' message to appear on the cabinet display.
2. Push the button to the right of START.
3. Wait for the SELF TEST and number of elapsed PUMP HOURS to appear. (If above 18,000 hours, call Andersen for service.)
4. Press the button to the right of the PURGE message on the display and wait for the time to count down from 1 minute 30 seconds to '00:00:00'. The sterilization liner bag should compress as excess air is removed.
5. When the display indicates "BREAK AMPOULE," carefully, so as not to puncture the sterilization liner bag, grasp the ampoule through the sterilization liner bag and activate it by snapping off the top.

3) Selecting Cycle Length

1. Close the door.
2. Lock the sterilizer and remove the key.
3. SELECT CYCLE LENGTH. (Right button = 12 Hour, Left button = 24 Hour)

WARNING: *The usual Anprolene sterilization cycle is 12 hours, plus a 2-hour purge cycle. When sterilizing lengths of tubing 3 feet (91.4 cm) or longer, or a full load of gas absorbent items, it may be necessary to increase the cycle time to 24 hours with the '24 HOUR CYCLE' button and to use two ampoules.*

4. If an electronic beep sounds, it is an alert that 5 seconds have elapsed and the AN 74 i/ix is awaiting a 12/24 hour cycle time selection.
5. Log sterilization data if required.

WARNING: *Never interrupt a cycle once the gas ampoule has been activated. An alarm will sound if the door is opened during the cycle.*

4) Unloading the Sterilizer and Determining Sterility

1. Remove the sterilized items only after the sterilization cycle and 2-hour purge cycle have been completed and the display indicates UNLOAD STERILIZER. The sterilizer will continue to aerate items that are not removed immediately. A count-up timer on the display will indicate the time that has lapsed since the final 2-hour purge cycle ended.

   ☺**HINT:** *To unload the sterilization liner bag away from the sterilizer, simply detach the purge probe hose from the bag using the quick release fitting at the base of the purge probe.*

2. Close the sterilizer door and press EXIT to turn off the AN7*4 i/ix*.
3. Unload the liner bag and check the sterility (chemical &/or biological) indicators.
   - Steritest provides an immediate indication of the success of the cycle (via the Dosimeter), and later proves sterility by showing that active spores have been killed. (Spores will require at least 48 hours of incubation to provide results.)
   - The Dosimeter shows whether time, temperature and gas concentration parameters have been met. It provides an immediate chemical indication that the cycle was successful. Dosimeters should not be used in place of biological indicators to prove sterility.
   - 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.
4. Spent ampoule may be disposed of in regular trash.

   ☺**HINT:** *While you may not reuse sterilization liner bags, they make great heavy-duty trash bags!*

D. Aeration

- The cabinet ventilator should be running during the entire sterilization cycle to prevent personnel from being exposed to more than the OSHA permitted levels of ethylene oxide. [1.0 ppm (parts per million) over an 8 hour time weighted average (TWA)] Do not remove items before the full 2-hour purge cycle. Aeration should take place in a well-ventilated area that provides at least 10 fresh air exchanges per hour so that high concentrations of gas will not build up while aerating. The purge cycle is designed to aerate most products sufficiently to meet the short-term exposure level (STEL) of 5.0 ppm for the 15-minutes (while unloading the liner bag).
- Metal and glass do not require additional aeration. However, items made of gas absorbent material must be aerated at a minimum room temperature of 68° F (20° C) for at least 24 hours prior to use. Any ethylene oxide retained in an item could cause a serious chemical contact burn to the patient.

☺ **HINT:** *The AN74 i/ix can be used for extended aeration. A count-up timer will keep track of the time that has passed since the standard cycle was completed. After the regular cycle is finished, the sterilizer will continue to ventilate and purge the liner bag until: (1) the door is opened; and (2) the EXIT button is pressed. This will turn off both pumps and end the cycle. If the door is opened and closed and the EXIT button is not pressed, the two pumps will continue to ventilate and purge the liner bag and cabinet.*

- Extended aeration can also take place outside of the sterilizer. In this case, aeration should take place in a well-ventilated area that provides at least 10 fresh air exchanges per hour so that high concentrations of gas will not build up while aerating.

E. Safety Precautions

1) Ethylene Oxide Safety

- Sterilization liner bags should never be reused because they may have a puncture or tear.
- **DANGER!** Do not allow open flame or sparks near the sterilizer during the sterilization cycle because ethylene oxide gas is highly flammable in concentrations above 3.0% (30,000 ppm).
- The 12 and 24-hour sterilization cycles both end with a 2-hour purge cycle, which flushes fresh air around the products in the sterilization load.
- The sterilization liner bag must be purged for 2 hours before the sterilized items are removed to prevent the operator from being exposed to more than the OSHA permitted level of 5.0 ppm in a 15-minute time period (STEL) while the sterilizer is being unloaded.
- Personnel exposure to ethylene oxide can be monitored by using the personal exposure badges, such as the Andersen AN93 AirScan® Badges. The AN93 AirScan Kit has both STEL and TWA badges. EO exposure levels should be checked upon installation of the sterilizer. We recommend that exposure testing be performed on an annual basis.
- **CAUTION.** If you come in contact with liquid Anprolene, you should immediately wash the affected area with water thoroughly for at least 15 minutes and obtain medical attention.

2) Malfunctions and Power Failures

- In the event of a purge pump failure, the vent pump will continue to ventilate the interior of the cabinet, exhausting gas as it diffuses through the liner bag. A PURGE PUMP FAILURE error message will be displayed, and the sterilizer will add 24 hours of aeration before the display indicates that you may remove your products. (If this happens, please call Customer Service for assistance.)
- In the event of a vent pump failure, the cycle will be aborted, and the purge pump will evacuate the liner bag of any remaining gas. (If this happens, please call Customer Service for assistance.)

- If a power outage occurs during any part of the cycle, the sterilizer is equipped with a battery back up on 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.

☺ **HINT:** *In the case of any sterilizer malfunction or power failure, you can determine whether sterilization was achieved by examining the Steritest biological indicator included in the load***.**

3) Reasons for locking the Anprolene sterilizer:

1. To protect the contents from spark or flame.
2. To protect the liner bag from puncture.
3. To ensure the Anprolene sterilizer exhausts the ethylene oxide through the ventilation system and abator, if installed, to the outside.

Note: *No other container or sterilizer can be used with Anprolene sterilizing gas.*

4) Reasons why the gas release bag containing the ampoule should never be opened:

1. To prevent the liquid ethylene oxide from coming in contact with the user or the items to be sterilized.
2. To prevent the gas from escaping too quickly to achieve sterilization.

Things that CAN be sterilized with Anprolene:

ELECTRICAL DEVICES	**SURGICAL DEVICES**	**ENDOSCOPES**
Flashlights	Scalpels & sharps	Endoscopes
Drills	Scissors	Cameras
Dremmel drills	Clamps & crimpers	Fiber optic scopes
Microdrills	Dental tools	
	Saws	
	Rulers	
	Forceps	
	Biopsy punches	
	Dermal punches	
	Dilators	
	Skin staplers	
	Speculi	
	Needles	
	Neuter clips	
	IV sets	
	Marking pens	

Things that CAN be sterilized with Anprolene but that require additional aeration:
Any items that are made of rubber, plastic, cloth, are implanted or come in direct contact with the skin, require additional aeration.

CLOTH ITEMS
Gauze
Gowns
Bandages
Cotton balls
Masks
Drape materials

TUBES
Suction tubes
Liposuction tubes
Catheters
Endotracheal tubes
Feeding tubes
Nasal tubes

IMPLANTS
Pacemakers
Nylon implants
Implants

OTHER ITEMS
Toothbrushes
Rubber bands
Rubber tourniquets
Sponges

Things that CANNOT be sterilized with Anprolene:
Liquids, food, and drugs should not be sterilized in ethylene oxide because it may change their chemical composition.

SECTION 5

Sundries *for Use with Anprolene*

SECTION 5
Accessories for Use with Anprolene

Exposure Indicator Strips

Immediate assurance of gas exposure! The strips provide a strong color change when exposed to Ethylene Oxide. Convenient self-stick backing adheres to conventional paper or cloth wrapping. Please note that these strips are not intended to be an indicator of sterility. They are a quick visual reference when placed on the outside of a package that it has been through the sterilization process.

Exposure Indicator Strips	**AN85**	**200 units/box**

Package Closure Indicator Strip

Get visual assurance of gas exposure and seal your packages in one step! Strips provide a strong color change through rapid confirmation of EtO exposure. Self-adhesive strips stick to conventional paper, CSR wrap, cloth wrapping or Andersen Seal and Peel ®.
For use with Anprolene and EOGas systems only.

Package Closure Indicator Strip	**AN86**	**200 units/box**

Dosimeter®

Time, temperature, and EtO concentration are essential to proper sterilization. The Dosimeter provides visual assurance that all of these parameters have been fulfilled during the sterilization cycle. Results can be viewed immediately after sterilization– no laboratory culture necessary. We recommend the use of one Dosimeter in the least accessible part of the load during each sterilization cycle.

Dosimeter®	**AN87**	**25 units/box**

Steritest® Biological Control and Biological Control Incubator

Steritest reliably verifies that sufficient concentration of EtO killed one million *B. subtilis* spores, the most resistant spore to EtO gas. Two control components, a Dosimeter and a bacterial spore preparation in a sterile culture medium, reduce the possibility of false positives.

The Biological Control Incubator incorporates a thermostatically controlled 98.6°F (37°C) incubator into a tabletop unit with interior dimensions of only 10"x 7"x 8" (25 cm x 17.8 cm x 20.3 cm).

Steritest®	**AN80**	**11 units/box**
Steritest Incubator (120V 60Hz)	**AN810**	**1 per box**

Mini Self-Contained Biological Indicators

Biological indicators test the effectiveness of EtO sterilization cycle using live spores. High population of spores (10^6 Bacillus subtilis) achieves accuracy. Compact size allows economical storage. Color change discloses EtO test results after 48 hours incubation at 37 °C.

Mini Self-Contained Bls.	**AN2200**	**25/box**

AirScan® Badges

Single-use badges measure 15 minute short term (STEL) or 8 hour (TWA) exposure levels to EtO. Worn in the breathing zone of the sterilizer operator, badges can document compliance with OSHA regulations. Easy to use and provides immediate results.

AirScan® EtO Monitoring Badge		
8 Hour TWA Kit	**AN91**	**1 Kit**
15 Minute STEL Kit	**AN92**	**1 Kit**
8 Hour TWA and 15 Minute STEL Kit	**AN93**	**1 Kit**

Humidichip®

Designed specifically for use with Andersen gas sterilization systems, this unique device ensures adequate Relative Humidity during the sterilization cycle. Each single-use, pre-moistened, 2"x 2" (5 cm x 5 cm) Humidichip releases up to 4 grams of water vapor.

Humidichips®	**AN1071**	**25/jar**

Self–Seal Sterilization Pouches

Uncoated paper/propylene-polyester peel pouches provide superior bacterial barrier. Packaging is printed with color change indicators for EtO and steam sterilization.

Self-Seal Sterilization Pouches		
3.25" x 6.5" (82 mm x 165 mm)	**AN2310**	**200/box**
3.25" x 12" (82 mm x 305 mm)	**AN2320**	**200/box**
5.25" x 11" (135 mm x 280 mm)	**AN2330**	**200/box**
7.5" x 14" (178 mm x 330 mm)	**AN2340**	**200/box**
10" x 15" (254 mm x 380 mm)	**AN2350**	**200/box**

Seal and Peel® Packaging / 8" Electric Impulse Heat Sealer

Supplies tough, transparent, waterproof sealed package. Provides extended shelf life. Resists pinholes, abrasion and tearing. Highly porous to EtO gas for reliable sterilization and quick aeration. Available in a wide range of widths to accommodate various instrument sizes.

Seal and Peel® Sterilization Packaging		
2"(inside) x 200 ft (5 cm x 60 m)	**AN820**	**2 rolls/box**
3"(inside) x 200 ft (7.5 cm x 60 m)	**AN830**	**2 rolls/box**
5"(inside) x 200 ft (12.5 cm x 60 m)	**AN850**	**1 roll /box**
7"(inside) x 200 ft (17.5 cm x 60 m)	**AN870**	**1 roll /box**
Seal and Peel Impulse Heat Sealer 8" Seal length 110V 60 Hz or 220V 50Hz	**AN90**	**1 per box**

If you have questions concerning Andersen Sterilization Accessories, contact an Andersen Customer Service Representative at 1-800-523-1276 or 336-376-3000 or visit our website at www.anpro.com.

SECTION 6

Warnings, Troubleshooting, Error Messages and Alarms

SECTION 6
Warnings, Troubleshooting, Error Messages and Alarms

- The AN74 *i/ix* sterilizer utilizes a maximum of 36 grams of ethylene oxide gas as the sterilizing agent in one cycle. Please refer to the MSDS for ethylene oxide included in this manual as Appendix F, on page 67, for pre-cautions and chemical properties related to toxicity and flammability.

- Do **NOT** open the sterilizer until the sterilization cycle is completed and the display indicates "UNLOAD STERILIZER".

- Personal protective equipment is not required for normal operation and maintenance of this equipment.

- The exhaust port must be properly vented to the outside as specified starting in Appendix B, page 46, and ending with Appendix D, page 54.

Pre-Cycle Error Messages (Before the ampoule is broken)

6.1. Vent Sensor Failure
6.2. Purge Sensor Failure
6.3. Pressure Sensor Failure
6.4. Vent Pump Failure
6.5. Purge Pump Failure
6.6 Cooling Fan Failure
6.7 Abator Failure

During Cycle Error Messages (After the ampoule is broken)

6.8. Close Door
6.9. Vent Pump Failure (During the initial 12/24 hours of sterilization cycle)
6.10. Vent Pump Failure (During the 2 hour purge cycle)
6.11. Purge Pump Failure (During the 2 hour purge cycle)

Audible Alarms

6.12 Ventilation Pump Alarm
6.13 Purge Pump Alarm
6.14 Abator Alarm

Power Outage

6.15 Temporary Loss of Power

Pre-Cycle Error Messages (Before the ampoule is broken): The self test portion of the cycle begins when the START button is pressed and ends after the initial purging of the sterilization liner bag. Ethylene Oxide has not been released into the sterilization liner bag during the self test. Therefore, it is safe to remove the sterilization liner bag and its contents from the machine if needed. The self test screen is shown below.

SELF TEST OK 1,000 PUMP HOURS FAN 100 % RPM

If you see this screen, the controller is indicating that the ventilation sensor, purge sensor, ventilation pump and cooling fan are all operating correctly. If an abator is attached to the sterilizer, it indicates that the abator pump is operating correctly as well. The bottom line on this display indicates that the cooling fan is running at 100% of its nominal revolutions per minute (RPM).

6.1. **VENT SENSOR FAILURE:** Failure of the ventilation sensor during the self test portion of the cycle will show the VENT SENSOR FAILURE message on the screen. A vent sensor failure during the self test is often caused by a defective sensor. In this instance, the sensor needs to be replaced.

6.2. **PURGE SENSOR FAILURE:** Failure of the purge sensor during the self test portion of the cycle will show the PURGE SENSOR FAILURE message on the screen. A purge sensor failure during the self test is often caused by a defective sensor. In this instance, the sensor needs to be replaced.

6.3. **PRESSURE SENSOR FAILURE:** Failure of the pressure sensor during the self test portion of the cycle will show the PRESSURE SENSOR FAILURE message on the screen. A pressure sensor failure during the self test is often caused by a defective sensor. In this instance, the sensor needs to be replaced.

6.4. **VENT PUMP FAILURE:** Failure of the ventilation pump during the self test potion of the cycle will show the VENT PUMP FAILURE message on the screen.

Possible causes of VENT PUMP FAILURE during self test and remedies:

- The ventilation tubing has become disconnected inside the top cabinet. Reconnect ventilation tubing.
- The ventilation vacuum pump has failed to generate the required vacuum. Replace ventilation vacuum pump.
- The exhaust tubing from the ventilation pump is blocked. Remove obstruction.

Response: The cause of failure must be identified and corrected prior to starting the sterilization cycle.

6.5. **PURGE PUMP FAILURE:** Failure of the purge pump during the self test portion of the cycle will show the PURGE PUMP FAILURE message on the screen.

Possible causes of PURGE PUMP FAILURE during self test and remedies:

- Tubing inside the bottom cabinet has become disconnected or the sterilization bag is not properly secured to the purge tube bobbin with the Velcro strap. Reconnect tubing, recheck the integrity of the sterilization liner bag and retighten the Velcro strap.
- The purge pump failed to generate the required vacuum. Replace the purge pump.
- The purge tubing became disconnected inside the top cabinet. Reconnect purge tubing.
- Exhaust tubing from purge pump is blocked. Remove obstruction.

Response: The cause of failure must be identified and corrected prior to starting the sterilization cycle.

6.6. **COOLING FAN FAILURE:** Failure of the cooling fan located in the center rear of the top cabinet during the self test portion of the cycle will show the COOLING FAN FAILURE message on the screen.

Possible causes of COOLING FAN FAILURE during self test and remedies:

- If the fan is running, the cooling fan blade may be partially or completely obstructed. This is indicated by a RPM value of less than 70% on the self test screen on the previous page. Remove the obstruction, clean the filter and reinitiate the self test.
- If the fan is running but the indicated RPM value is 0%, the white feedback wire from the fan may not be properly connected to the PC board. Check connection.
- If the fan is not running, check the connection of the red and black lead wires to the PC board. If they are properly connected, check the voltage at the PC board connector for the red and white wires. If you obtain a reading of 6 VDC, replace the fan. If you obtain a reading of 0 VDC, the PC board may need to be replaced.

6.7. **ABATOR FAILURE:** Failure of the abator pump during the self test portion of the cycle will show the ABATOR FAILURE message on the screen.

Possible causes of ABATOR FAILURE during self test and remedies:

- If the BNC Connector on the back of the AN 74 I is not attached to the sterilizer or to the Abator, the Abator pump will not start. Check the connection. Listen to the Abator to determine if the pump is starting when START is pressed.
- Check for an obstruction in the tubing between the sterilizer and abator. If there is a complete obstruction it can cause an abator failure. Remove the obstruction and repeat the self test.
- The abator pump may have failed. It will need to be replaced to continue.

Response: The cause of failure must be identified and corrected prior to starting the sterilization cycle.

Error Messages During the Cycle (After the ampoule is activated)

6.8. **CLOSE DOOR:** The CLOSE DOOR message is accompanied by a constant audible alarm and indicates that the sterilizer door is open when it should be closed. There is a magnetic sensor in the upper left corner of the door frame that senses when the door is closed. To turn off the alarm and message, close the door of the sterilizer.

6.9. **VENT PUMP FAILURE (During the initial 12 (or extended 24) hours of the sterilization cycle)**: Please note that sterilization takes place during the initial 12/24 hours of the cycle. If the vent pump fails during this time, the sterilization process has been compromised.

If the ventilation pump fails during the sterilization portion of the cycle when a substantial amount of ethylene oxide remains within the sterilizer cabinet and the sterilization liner bag, the paramount concern is the safety of the operator. If a ventilation pump failure is sensed, the sterilizer will immediately start the purge pump. The purge pump will then remove Ethylene Oxide from both the sterilization liner bag and the cabinet by drawing air from the enclosed cabinet, into the sterilization liner bag and then exhaust it to the outside thereby minimizing the risk of operator exposure. If this happens, the sterilization time and concentration of ethylene oxide inside the sterilization liner bag has been prematurely reduced and the items in the sterilizer should not be considered sterile.

Response: The sterilization cycle is halted and a purge is initiated to minimize the possibility of operator exposure to Ethylene Oxide. After the machine has completed the two hour purge and is unloaded, the cause of the failure must be identified and corrected prior to starting a new sterilization cycle.

CAUTION!: In this scenario, items in the sterilizer may not be sterile. Items must be resterilized prior to use.

6.10. **VENT PUMP FAILURE (During the purge cycle):** The sterilization process takes place in the first 12 hours of the sterilization cycle. If the vent pump fails during hours 12 to 14 (or 24 to 26 during an extended cycle), the sterilization process has not been compromised.

Instead of the vent pump and purge running alternating two minute cycles, the purge pump will run continuously. The purge pump will remove Ethylene Oxide from both the sterilization liner bag and the cabinet by drawing air from the enclosed cabinet, into the sterilization liner bag and then exhaust it to the outside thereby minimizing the risk of operator exposure.

If examination of the sterility indicators included with the load indicate adequate time/concentration exposure to ethylene oxide, the items in the sterilizer may be considered sterile. The vent pump failure message will be displayed after the entire cycle is complete, and the door has been opened to remove the load from the sterilizer.

Response: Sterilization cycle was completed normally. After the machine is unloaded, the cause of the failure must be identified and corrected prior to starting a new sterilization cycle.

6.11. **PURGE PUMP FAILURE (During the purge cycle):** The sterilization process takes place in the first 12/24 hours of the sterilization cycle. If the purge pump fails during the purge cycle, hours 12 to 14 (or hours 24 to 26 for extended cycles), the sterilization process has not been compromised. However, if the purge pump fails, there will be abnormally high concentrations of Ethylene Oxide inside the sterilization liner bag at the end of the normal 14 hour cycle. In response to this failure, the sterilizer will: (1) immediately start the vent pump, which will now run continuously until the end of the cycle; (2) add 24 hours to the total cycle time; and (3) display a PURGE PUMP FAILURE message on the screen.

During this additional 24 hour aeration time, most of the remaining Ethylene Oxide will pass through the wall of the sterilization liner bag. The sterilizer will count down 24 hours and then instruct the operator to release the Velcro strap from the neck of the sterilization liner bag and immediately close the door. The sterilizer will then count down an additional 2 hours of aeration time to remove any residual Ethylene Oxide from the opened sterilization liner bag within the cabinet. If examination of the sterility indicators included with the load indicate adequate time/concentration exposure to ethylene oxide, the items in the sterilizer may be considered sterile.

Response: Sterilization cycle was completed normally, however, the sterilization liner bag was not fully purged. The sterilizer will add 24 additional hours to the cycle to allow residual Ethylene Oxide to pass through the sterilization liner bag. After the machine is unloaded, the cause of the failure must be identified and corrected prior to starting a new sterilization cycle.

ALARMS: If a critical component of the sterilizer fails during any part of the cycle, the controller will notify the operator by means of a visual display and an audible alarm:

6.12 **Ventilation Pump Alarm**: If the cabinet ventilation pump fails to maintain an adequate vacuum for 20 consecutive seconds while the ventilation pump is running, an alarm will sound continuously and the display will read: VENT PUMP FAILURE. The audible alarm may be silenced by pressing the EXIT button.

The ventilation sensor monitors the vacuum between the cabinet ventilation pump and the interior of the cabinet. The pressure within the cabinet relative to the room is negative (vacuum) which ensures the sterilizing gas which has diffused through the walls of the sterilization liner bag is retained within the cabinet.

Before the ventilation pump is turned on at the beginning of the cycle, the controller tests to make sure the ventilation sensor is reading zero vacuum. It then turns on the ventilation pump and checks to see if there is adequate vacuum. If the vacuum is less than 0.25 inches of water vacuum, the VENT PUMP FAILURE message will be displayed.

During the entire sterilization and ventilation cycle, the amount of vacuum created by the ventilation pump is also continuously monitored while the vent pump is running. If a VENT PUMP FAILURE message is displayed, the audible alarm may be silenced by pressing the EXIT button.

As an automated safety precaution, if the cabinet ventilation pump fails at any time during the 12 (or 24) hour sterilization cycle, the purge pump will automatically start and run continuously for the remainder of the sterilization and ventilation cycle. The sterilization liner bag will be vacuumed down until the check valves in the purge tube open at 3.0" (7.6 cm) of water vacuum. At this point the check valves will open and the cabinet will then be vented through the sterilization liner bag for the remainder of the cycle.

6.13 **Purge Pump Alarm**: Similarly, the purge pump sensor monitors the vacuum within the tubing that connects the purge pump to the sterilization liner bag. Before the purge pump is turned on at the beginning of the cycle, the controller tests to make sure the purge sensor is reading zero vacuum. The purge pump is then turned on and the sterilization liner bag is vacuumed down. The controller checks to make sure the vacuum is greater than 5.00 inches of water vacuum. Otherwise, the controller will display a PURGE PUMP FAILURE message.

During the 2 hour ventilating bag cycle at the end of the 12 (or 24) hour sterilizing cycle, the amount of vacuum created by the purge pump is also continuously monitored while it is running. If the vacuum created by the purge pump is inadequate for 20 consecutive seconds, a PURGE PUMP FAILURE message is displayed.

If the purge pump fails during the 2 hour ventilation cycle, the controller will automatically add 24 hours to the cycle time to allow the remaining Ethylene Oxide contained within the sterilization liner bag to diffuse through the walls of the sterilization liner bag as opposed to being flushed with fresh air for 2 hours, as would occur during normal operation.

The first purge cycle takes place immediately prior to activation of the Anprolene ampoule and commencement of the sterilization cycle. This cycle lasts for 1 minute, 30 seconds and is displayed as the INITIAL PURGE.

The second purge cycle is automatically initiated when the sterilization cycle has reached the end of the 12 (or 24) hours. The purge cycle continues for two hours with the display showing VENTILATING BAG - 02:00:00 REMAINING and counting down to zero. At the end of the two hours, the sterilizer can be unloaded. The purge pump runs for two minutes and then turns off for two minutes, alternating with the ventilation pump during the ventilation cycle.

If the two hour VENTILATING BAG period has expired but: (1) the door to the sterilizer has not been opened; and (2) the EXIT button has not been pressed, the sterilizer will continue to intermittently purge the sterilization liner bag. It will remain on this schedule indefinitely until the door is opened and the EXIT button is pressed. In addition, the display will show a count-up timer indicating additional aeration time.

6.14 **Abator Alarm**: The alarm will beep 3 times on startup if the abator is down to 25 or fewer remaining cycles. A constant alarm sounds when the abator is down to 0 cycles remaining.

6.15 **Power Outage**: The program in the microchip is protected from power loss by a battery which is built into the clock chip mounted on the circuit board. The design enables the program to continue in the event of a power loss by using the backup battery power.

If a power outage occurs during the sterilization portion of the cycle, the program will continue without interruption as if a power outage did not occur since the items inside the sterilization liner bag will still be exposed to the Anprolene gas for the same amount of time even if the power is off.

If a power outage occurs during the ventilation portion of the cycle, the program will record how long the sterilization liner bag was ventilated prior to the power outage (for example, 30 minutes) and it will resume the countdown for the remainder of the 2 hour ventilation cycle. (in this example, an additional 1 hour, 30 minutes).

SECTION 7

Maintenance

SECTION 7
Maintenance

7.1. The cabinet ventilation pump and the sterilization liner bag purge pump have an expected life of 18,000 hours (this translates to approximately five cycles per week for five years). During this time, the pumps are designed to pump at or above minimum required volumes of exhaust air at up to 27 inches of water backpressure. The total number of hours that the pumps have run is displayed on the Liquid Crystal Display at the beginning of each sterilization cycle.

When the pumps have been in operation for more than 18,000 hours (approximately 1,300 sterilization cycles), it is recommended that the complete sterilizer unit be returned to the factory for replacement and/or refurbishment of the pumps and associated tubing. Call Andersen Products Customer Service for return authorization and pricing.

7.2. On a semi-annual basis, or every 1,800 hours of operation, the following maintenance should be performed:

a. Check the quick connect fittings and the tubing that runs from inside the upper right hand corner of the sterilizer cabinet to the purge tube.

b. All external tubing and tubing connections that are visible, and therefore accessible to the operator, should be checked to make sure they are secure and that there are no visible signs of degradation such as cracking or splitting.

c. Check the exhaust tubing connections at the back of the sterilizer and perform a leak test as detailed in Appendix D, page 55 and following.

d. The filter media attached to the cooling fan in the rear of the top cabinet should be removed, cleaned and reattached.

7.3 All exterior surfaces and the interior surfaces of the lower cabinet should be cleaned using a cotton cloth and a mild soap and water solution. Do not use abrasive pads as this may mar the finish of the stainless steel and plastic molded fittings.

APPENDIX A

Technical Features

APPENDIX A
Technical Features

A.1. **Cabinet**: The AN74*i/ix* cabinet is assembled from grain finish stainless steel with molded ABS front and rear end plates. The door is assembled from a molded polystyrene outer door and inner stainless steel liner. The door is provided with an exterior grain finish stainless steel cover panel, door support arm and latching lock with removable key. Protective rubber feet are attached to the lower cabinet panel.

A.2. **Pumps**: The lower cabinet is ventilated by means of two linear oscillating pumps located in the enclosed top cabinet. The pumps remove the air from inside of the lower cabinet and sterilization liner bag and exhaust the air to the outside. The 3/4" (1.9 cm) inside diameter braided PVC tubing may be up to 200 feet (60.96 meters) in length. During sterilization and ventilation cycles, the pumps maintain a negative pressure (vacuum) in the lower cabinet with respect to the room where the sterilizer is located. If an abator is installed it uses a third linear pump that is enclosed in the abator cabinet.

A.2.a. **Ventilation Pump**: The cabinet ventilation pump will run continuously from the time the operator pushes the START button at the beginning of the cycle until the 12 or 24 hour sterilizing cycle is complete. After that, during the 2 hour purge cycle, it will alternate with the purge pump, running for two minutes and then shutting down for two minutes until the operator:

1. Opens the door to remove the sterilized items; and
2. Presses the EXIT button.

The cabinet ventilation pump is designed to exhaust the lower cabinet at a minimum rate of 38 liters per minute. These specifications are for a cabinet equipped with a maximum of 200 feet (60.96 m) of 3/4" (1.9 cm) inside diameter braided PVC tubing with one 90º bulkhead fitting at the back of the cabinet and one 90º bulkhead fitting at the interior wall above the sterilizer.

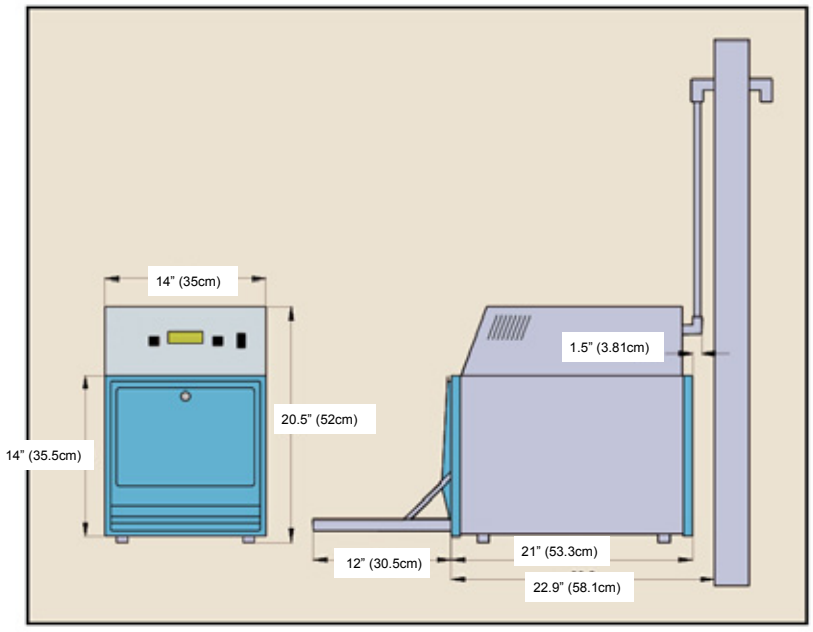
Additional Aeration: If the operator wishes to use the sterilization cabinet to further aerate the sterilized items after the normal 14/26 hour sterilization and ventilation cycles are completed, the operator may simply leave the sterilizer running when the UNLOAD STERILIZER screen appears. A count-up timer will appear on the screen showing the additional aeration time after the end of the normal 14/26 hour sterilization and aeration cycle. When the operator wishes to stop the additional aeration, they simply need to follow the steps outlined in A.2.a. above.

A.2.b. **Purge Pump**: The second exhaust pump, referred to as the purge pump, is connected to the purge tube assembly and sterilization liner bag by a tube connected to the front right corner of the lower cabinet. Purging is the intermittent flushing of the sterilization liner bag with fresh air and takes place at the beginning and end of the cycle.

APPENDIX B

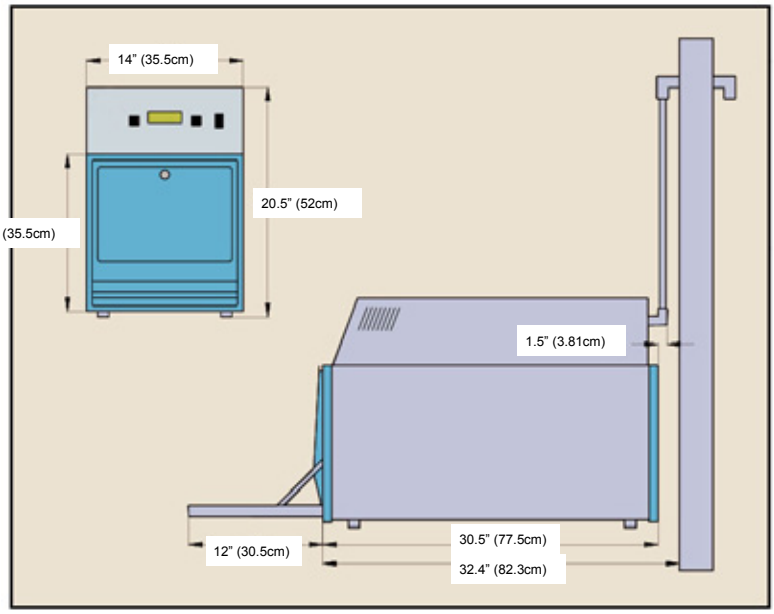
Installation Requirements

APPENDIX B
AN74i Anprolene Sterilizer
Dimensions and Clearances and Installation Requirements



Total weight is approximately 50.5 pounds (22.9kg). It is advisable to have two persons assist in the installation or moving of the machine. Refer to installation instructions in Appendix C for detailed instructions.

APPENDIX B
AN74ix Anprolene Sterilizer
Dimensions and Clearances and Installation Requirements



Total weight is approximately 60.5 pounds (27.5kg). It is advisable to have two persons assist in the installation or moving of the machine. Refer to installation instructions in Appendix C for detailed instructions.

APPENDIX B
Dimensions and Clearances and Installation Requirements

B.1 The AN74 *i/ix* Sterilizer consists of three major components: (1) a lower cabinet which is used to contain the items being sterilized; (2) an upper cabinet containing the controller, user interface display and pneumatic equipment to ventilate the lower cabinet and sterilization bag; and (3) a 3/4" (1.9 cm) I.D. exhaust tube and fittings which vent the Ethylene Oxide laden air from the lower cabinet and sterilization liner bag to the outside.

B.2 The total weight of the AN74 *i/ix* is approximately 50.5 pounds (22.9 kg) / 60.5 pounds (27.5 kg). It is advisable to have two persons assist in the installation or moving of the machine. Refer to installation instructions in Appendix C and following for detailed instructions. Place the sterilizer cabinet on a sturdy counter space or workbench at a height convenient for loading.

B.3 **CAUTION!: The Anprolene sterilizer cabinet location must be adjacent to an UNSWITCHED, GROUNDED power outlet, preferably one that is dedicated to its exclusive use.** The standard Anprolene sterilizer is fitted with a 7 foot long (220 cm) power cord.

B.4. Whenever possible, the Anprolene sterilizer should be located against an outside wall, and exhaust directly to the outside by means of 3/4" (1.9 cm) I.D. tubing to minimize the impedance of the exhaust system.

CAUTION!: The exhaust outlet should not be located near a common area.

APPENDIX C

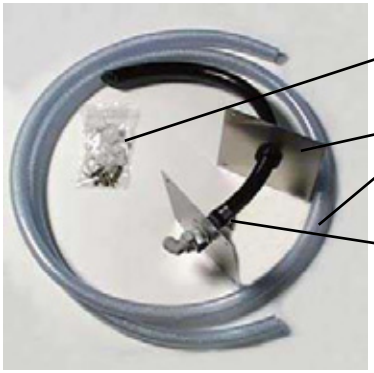
Installation Instructions for New Anprolene Users

APPENDIX C
Installation Instructions for New Anprolene Users

C.1 Unpacking - The combined upper and lower sterilization cabinet weighs approximately 50.5 pounds / 60.5 pounds. To avoid possible injury, it is recommended that two persons assist in removing the sterilizer from the shipping box and placing the sterilizer wherever it will be used.

To unpack the sterilizer, gently turn the packing box upside down on the floor. Next, slit the tape along the center edges of the bottom flaps and fold all four flaps down against the sides of the box. Leave the bottom foam packing insert in place and turn the packing box back to its original upright position. Pull the box up and off of the sterilizer. Remove the top foam packing insert.

Each side of the painted steel enclosure has a turned under bottom edge that is raised up off the ground approximately 3/4" (1.9 cm). One person should now take hold of the left bottom edge while the other takes hold of the bottom edge on the opposite side of the sterilizer and lift it up out of the bottom foam insert and place the sterilizer on the counter surface where the unit is to be installed.



Confirm that you have the following items:

- AN74 *i/ix* Anprolene sterilizer upper and lower cabinet unit
- (A) Eight toggle inserts and Phillips screws to secure the mounting plates.
- (B) Exterior wall mounting plate with black plastic bushing.
- (C) Eight foot length of 3/4" (1.9 cm) I.D. clear braided PVC tubing and two stainless hose clamps (included with sterilizer).
- (D) Interior wall mounting plate with 90° elbow fitting assembly and 20" (50.8 cm) length of black 3/4" (1.9 cm) I.D. tubing for through wall penetration
- (E) Owner's Manual

C.2 The following tools will be needed for installation of the sterilizer:

- Electric drill
- 3/8" (0.95 cm) drill for the toggles
- 1/4" to 3/8" diameter drill bit that is longer than the exterior wall is thick
- 2" (5.08 cm) hole saw
- Medium flat blade screwdriver
- Medium Phillips screwdriver
- Razor knife, and
- Soapy water solution in a squirt bottle for leak testing.

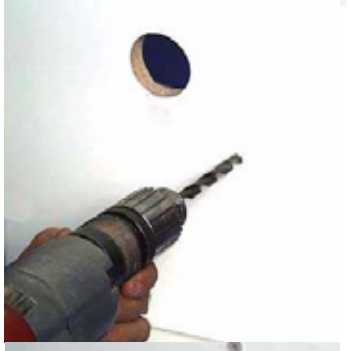
C.3 Temporarily position the sterilization cabinet in the appropriate location, as described in Appendix B.

C.4 Interior Wall Mounting: Choose a location on the wall that is directly above the exhaust bulkhead fitting coming out of the back of the sterilizer (See lower picture on page 3). This is the location where the exhaust hose will run through the wall to the outside.

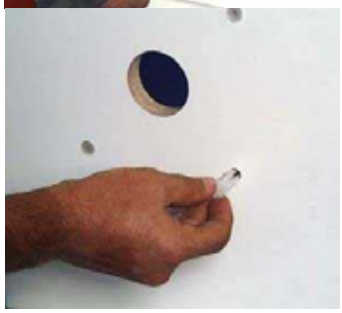
CAUTION! Make sure you are not drilling into any structural members, wires or pipes. With the long drill bit, drill all the way through to the outside.

C.5 Using a 2" hole saw bit, enlarge the pilot hole on the interior surface of the wall to 2". Repeat this process on the exterior surface of the wall using the pilot hole as the center point. You should now have a 2" hole through the entire wall.

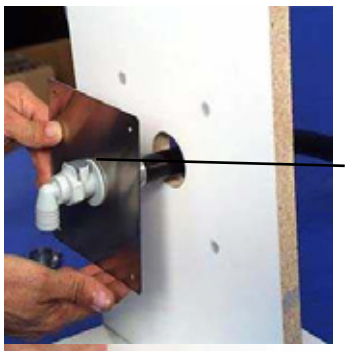
C.6 Take the Interior wall plate assembly (marked "D") with the 90 degree elbow attached and insert the black tube through the hole to the outside. Center the tube inside the 2" diameter hole and mark the location of the four plastic toggles.



C.7 Remove the interior wall plate assembly and drill the four toggle mounting holes using a 3/8" (.95 cm) bit.

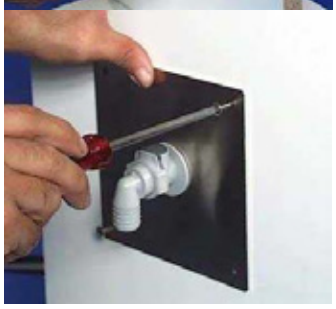


C.8 Insert four of the toggles into the interior mounting holes and tap them flush against the inside surface of the wall.



C.9 Insert the black hose that is attached to the interior plate assembly into the two inch hole and line up the four mounting holes with the four toggles.

The gray interlock button on the fitting should be facing up.



C.10 Secure the interior mounting plate assembly to the interior wall by threading the Phillips screws into the four toggles.

C.11 Take one end of the eight foot length of 3/4" (1.9 cm) I.D. clear braided PVC tubing and slip one of the stainless steel hose clamps over the end. Next, push the tubing as far as it will go onto the 90 degree hose barb connector on the back of the cabinet. Then secure the PVC hose by tightening the stainless hose clamp with a flat blade screw driver.

C.12 Move the sterilizer into its permanent location and then stretch the clear braided PVC tubing up to the 90 degree wall mount fitting. Allow for an extra inch or two and cut to length. Slip a stainless steel hose clamp over the tubing and then push the tubing as far as it will go onto the 90 degree hose barb connector. Secure the PVC tubing with the second stainless steel hose clamp.

C.13 Exterior Wall Mounting: Slide the exterior mounting plate over the black PVC tubing that extends out through the 2" hole and then mark the four mounting holes.

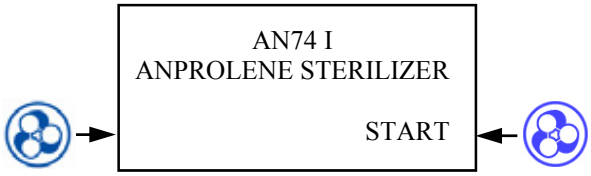
C.14 Repeat steps C.7 and C.8 by drilling the four toggle mounting holes and inserting the toggles. Secure the exterior plate to the wall with the four Phillips screws provided. Depending on the thickness of your exterior wall, you may wish to trim off excess black tubing that protrudes from the exterior plate with a utility knife. Make sure you leave at least three inches protruding out from the metal plate and make sure you cut the tubing at a 45 degree angle with the long end of the cut on the top of the tube.

C.15 Initial Operation - Once the installation of the exhaust tubing is complete, ensure that the purge tube is connected inside the cabinet. The purge tube connects the sterilizer via an acetyl quick connect fitting that is located on the front right corner of the lower cabinet's ceiling. Check to make sure the power cord is connected to the back of the sterilizer and is plugged into an un-switched, grounded power outlet.

C.16 Turn the sterilizer on with the black power switch located on the back right corner of the upper cabinet. The sterilizer will display the following screen:

AN74 I ANPROLENE STERILIZER START

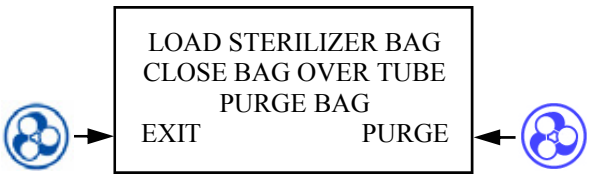
C.17 Press the button next to START and the sterilizer will perform a self test on the cabinet ventilation pump.



C.18. The display will then show the current version of the microchip program, and "OK" indicating the cabinet ventilation pump is functioning properly. It will also display the total number of hours that the evacuation pumps have been running since the unit was manufactured. The bottom line displays a number indicating the blade speed of the rear cooling fan.

SELF TEST OK (VER. 4.04) 16 PUMP HOURS FAN 100 % RPM

C.19. At the end of the initial self test, the following screen will be automatically displayed. Pressing the button to the right of PURGE will cause the sterilization bag purge pump to operate for 1 minute, 30 seconds. This, in turn, will cause air to flow through the sterilization liner bag, up the 1/4" (.64 cm) I.D. purge tube into the purge pump, and then out the 3/4" I.D. exhaust tube creating an exhaust pressure of approximately one to three inches of water inside the exhaust tube at the rear of the sterilization cabinet.



C.20 Checking Connections - The final step in the installation process is to make sure the fitting connections outside the cabinet are airtight. One method of testing for leaks is to squirt a soapy water solution onto the connections when the sterilizer pumps are running as explained below.

C.21. While the pumps are running, squirt or pour a small amount of the soapy water solution onto the visible connections. If you see any air bubbles that are growing larger, this is an indication that air is escaping from the fitting. Tighten the stainless hose clamps further until the bubbles stop getting larger.

C.22. At the end of the initial purge cycle, the following screen will appear. If you do not want to run a cycle at this time you may simply turn the power off by pressing the on/off switch on the right rear corner of the top cabinet.

The unit may now be placed into service as instructed in Section 3, beginning on page 12..

APPENDIX D

Installation Instructions for Current Anprolene Users

APPENDIX D
Installation Instructions for Current Anprolene Users

The following instructions are for current users of ventilated AN74C, D or E Anprolene® systems. The adaptor kit included with your new sterilizer allows for an easy conversion from the 2" outlet hose used with earlier Anprolene systems to the 3/4" I.D. outlet hose of the AN74 i/ix.

The following items are included in the adaptor kit:

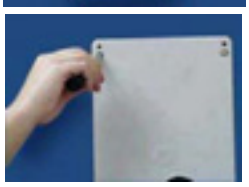
1 PVC adaptor
1 90º hose barb fitting
1 Stainless steel hose clamp

PVC glue

Section D.1. Directions To Remove Blower and Check Previous Installation of Pipe

D.1.1 Remove the existing ventilation unit from the wall by removing the 4 small metal screws at each corner.

D.1.2 This will expose the plastic mounting plate underneath.



D.1.3 At the time of initial installation, the 2" pipe leading to the outside should have been sealed with a light coat of silicone caulking and pressed firmly into the hole in the mounting plate. To check whether or not this occurred, remove the 4 remaining screws and gently test the connection between the pipe and the mounting plate by rotating the plate.

If the pipe is not secure, continue on to Section D.2. If the pipe is secure, reattach the mounting plate with the original 4 screws, and advance to Section D.3.

Section D.2. Securing the PVC

D.2.1 Clean the Mating Surfaces. Remove the mounting plate from the wall and clean the outside surface of the 2" PVC pipe as well as the interior surface of the tube extending from the back of the plate with rubbing alcohol and allow to dry.

D.2.2 Correct Position of the Wall Plate. After the PVC glue is applied as detailed in the next paragraph, you must quickly slide the mounting plate all the way onto the pipe until it bottoms out against the lip of the mounting plate. Then you must immediately align the four holes in the mounting plate with the four mounting toggle holes in the wall by rotating the mounting plate as needed.

D.2.3 Gluing the Wall Plate to the PVC Tube. Apply a thin film of PVC glue to each of the mating surfaces. **QUICKLY** press the wall plate onto the PVC pipe. The glue acts as a lubricant, so it will easily slide in. **NOTE: There can be no delay in sliding the wall plate onto the pipe after applying the glue. The glue dries in seconds and any delay may prevent correct alignment.** Wipe off any excess PVC glue from the interior of the pipe with a paper towel

D.2.4 Secure the Mounting Plate to the Wall. Screw the mounting plate to the wall using the original 4 small screws.

Section D.3. Inserting the PVC Adaptor

D.3.1 Before inserting the PVC adaptor, test the fit by placing the adaptor into the hole. If necessary, clean the mating surfaces with rubbing alcohol.

D.3.2 Apply a thin film of PVC glue to each of the mating surfaces, including the inside of the 2" PVC pipe.

D.3.3 **QUICKLY** press the adaptor all the way into the hole. The glue acts as a lubricant, so it will easily slide in. **NOTE: There can be no delay in sliding the adaptor into the hole after applying the glue. The glue dries in seconds and any delay will prevent correct placement.**

D.3.4 Screw in the black nylon 90º hosebarb fitting and align the barb end such that it is pointing down.

D.3.5 Take one end of the eight foot length of 3/4" (1.9 cm) I.D. clear braided PVC tubing and slip one of the stainless steel hose clamps over the end. Next, push the tubing as far as it will go onto the 90 degree hose barb connector on the back of the cabinet. Then secure the PVC hose by tightening the stainless hose clamp with a flat blade screw driver.

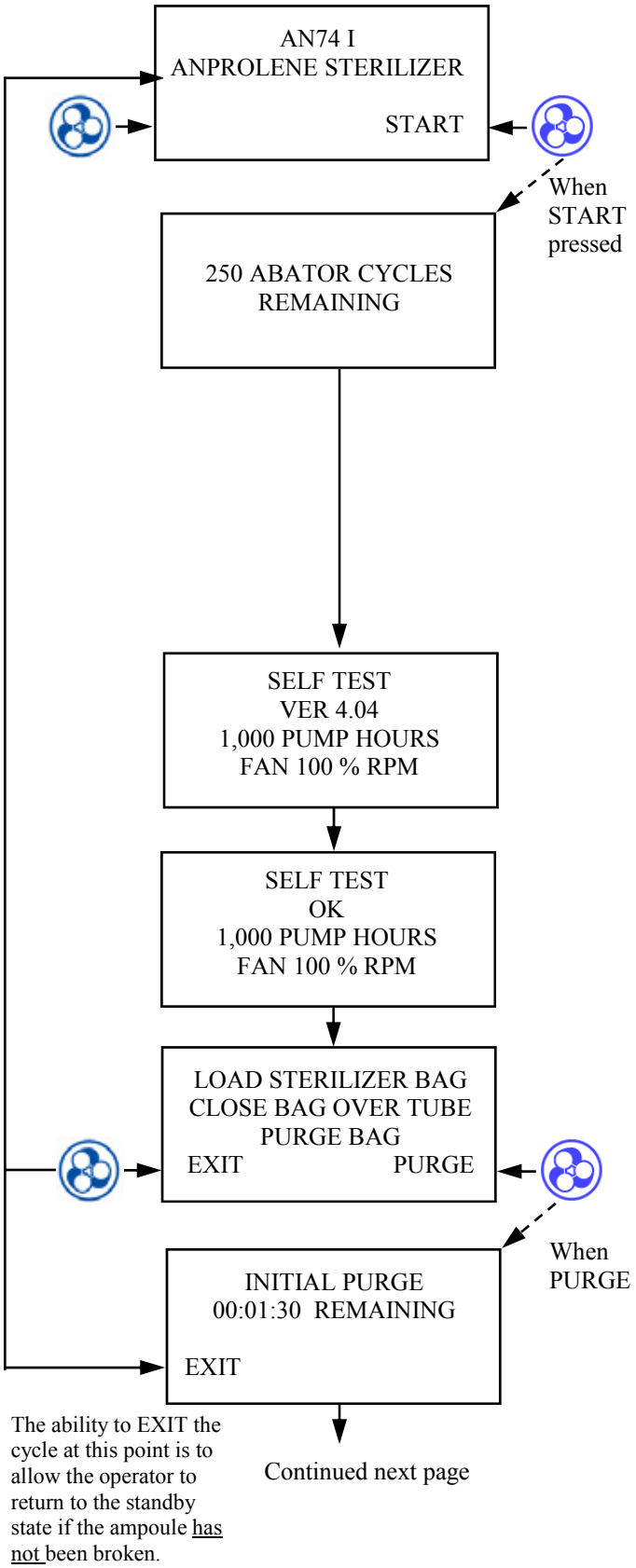
D.3.6 Move the sterilizer into its permanent location and then stretch the clear braided PVC tubing up to the 90 degree wall mount fitting. Allow for an extra inch or two and cut to length. Slip a stainless steel hose clamp over the tubing and then push the tubing as as far as it will go onto the 90 degree hose barb connector. Secure the PVC tubing with the second stainless steel hose clamp.

D.3.7 Refer to Section C.15 and the following steps on page 53 of the manual for initial operation and leak testing the connections.

APPENDIX E

Software/User Interface Flowcharts

Flowchart for Normal Operating Screens



The ability to EXIT the cycle at this point is to allow the operator to return to the standby state if the ampoule has not been broken.

Continued next page

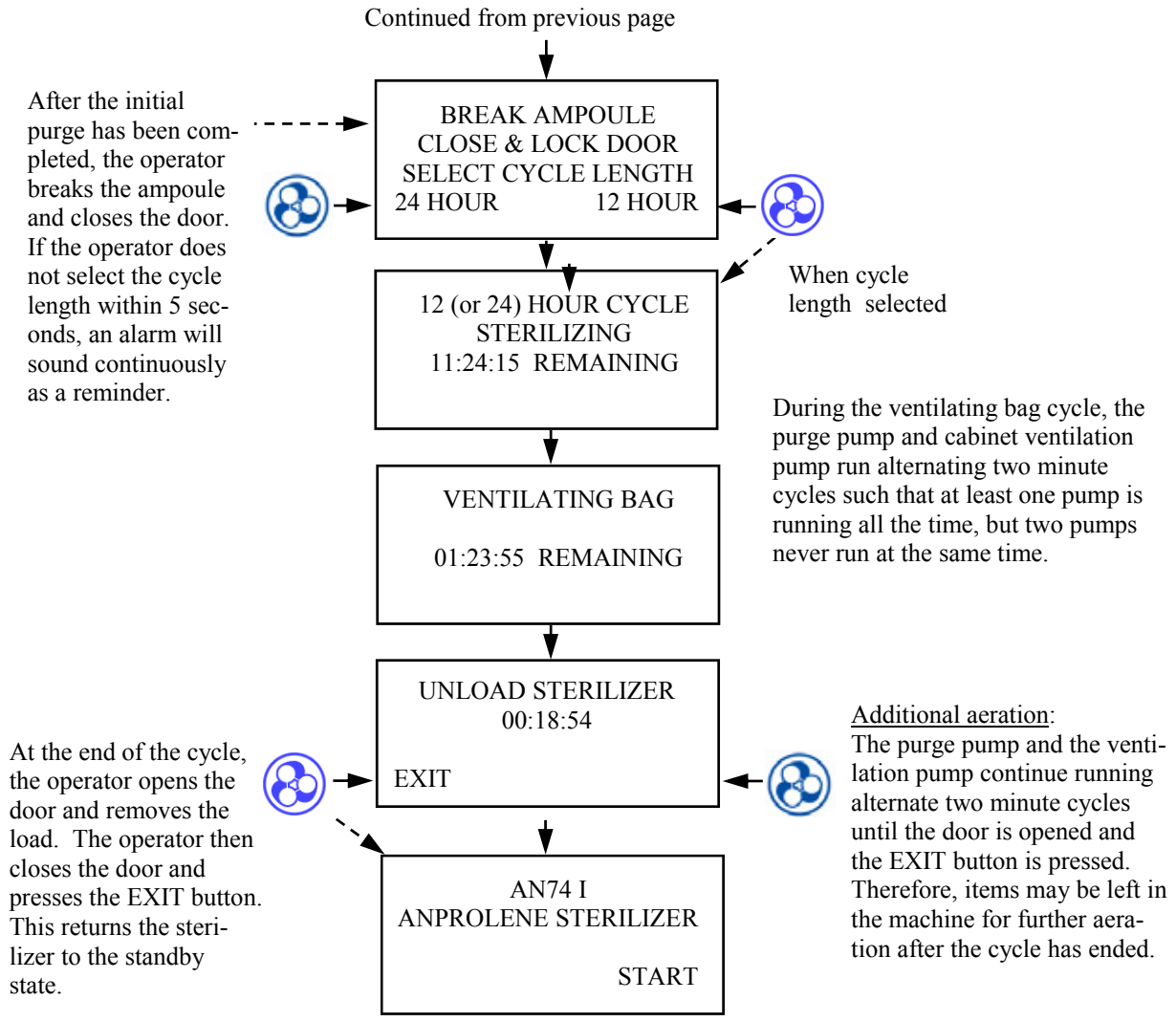
If Abator Attached (optional):
On initial startup the sterilizer will indicate the number of remaining abator cartridge cycles.

Initial Abator Self Test:
1. Abator Cartridge - checks cycles remaining (countdown). If more than 25, continues without change in display. If equal to or less than 25 cycles remaining, beeps 3 times to notify operator. If cycles remaining equals 0, the machine beeps continuously. The cartridge has expired and should be replaced. Additional cycles are not recommended but the screen may be bypassed by pressing the BYPASS button.
2. Abator Pump - tests vacuum on exhaust line

Initial Self Test:
1. Cooling Fan Speed – tests fan speed as a percentage of nominal speed
2. Purge Sensor - checks purge sensor offset value
3. Ventilation Sensor - checks ventilation sensor offset value
4. Back Pressure Sensor - checks back pressure sensor offset value
5. Purge Pump - tests vacuum on inlet to purge pump
6. Ventilation Pump - tests vacuum on input to ventilation pump
7. Back Pressure - tests pressure on exhaust line

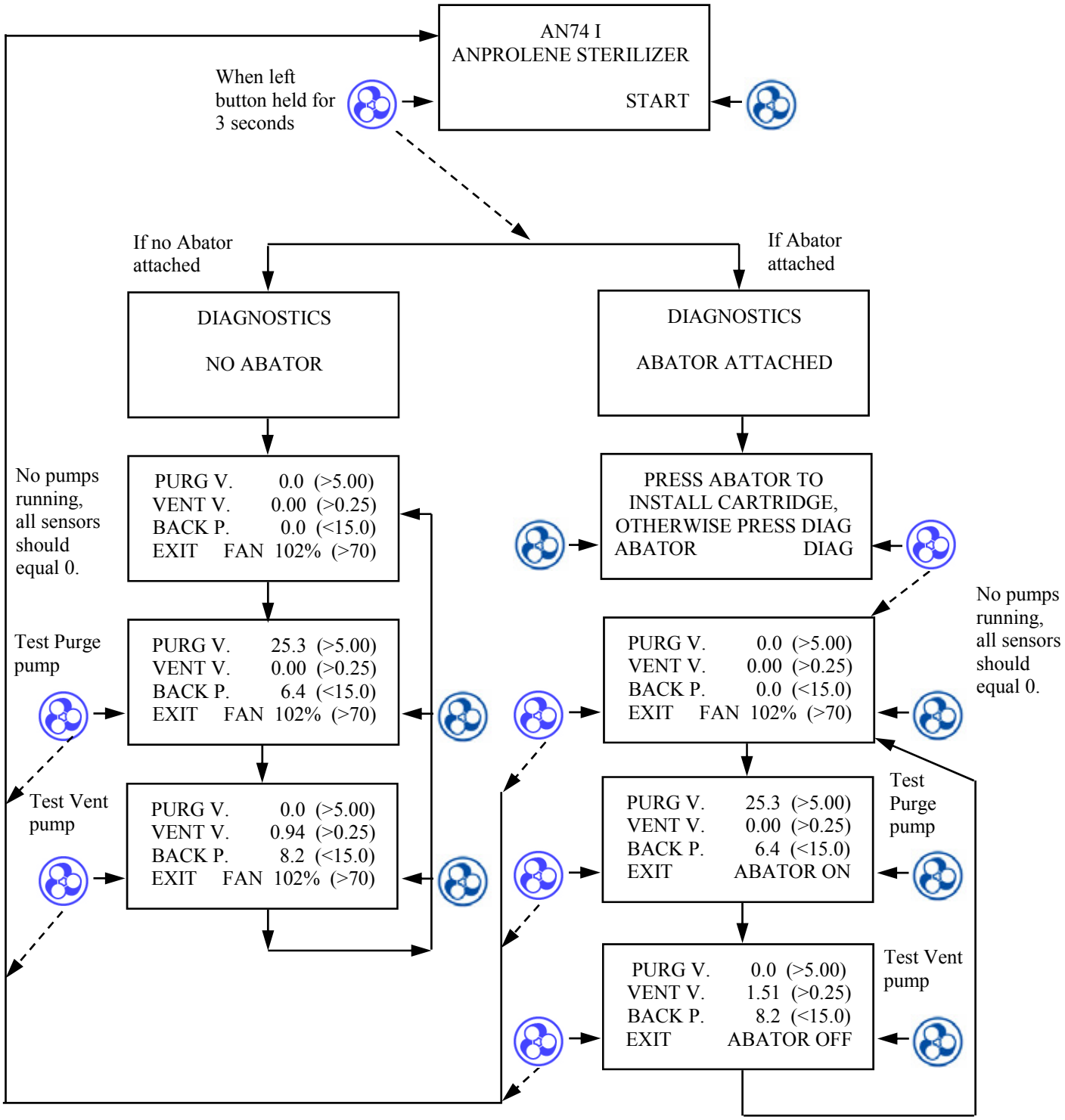
PUMP HOURS
This message is displayed every time the START button is pressed. It displays the total number of hours that the ventilation pump (VENT PUMP) has operated. The pump should be serviced or replaced on a regular schedule. See the maintenance information in Section 7 of this manual for details.

Flowchart for Normal Operating Screens, continued

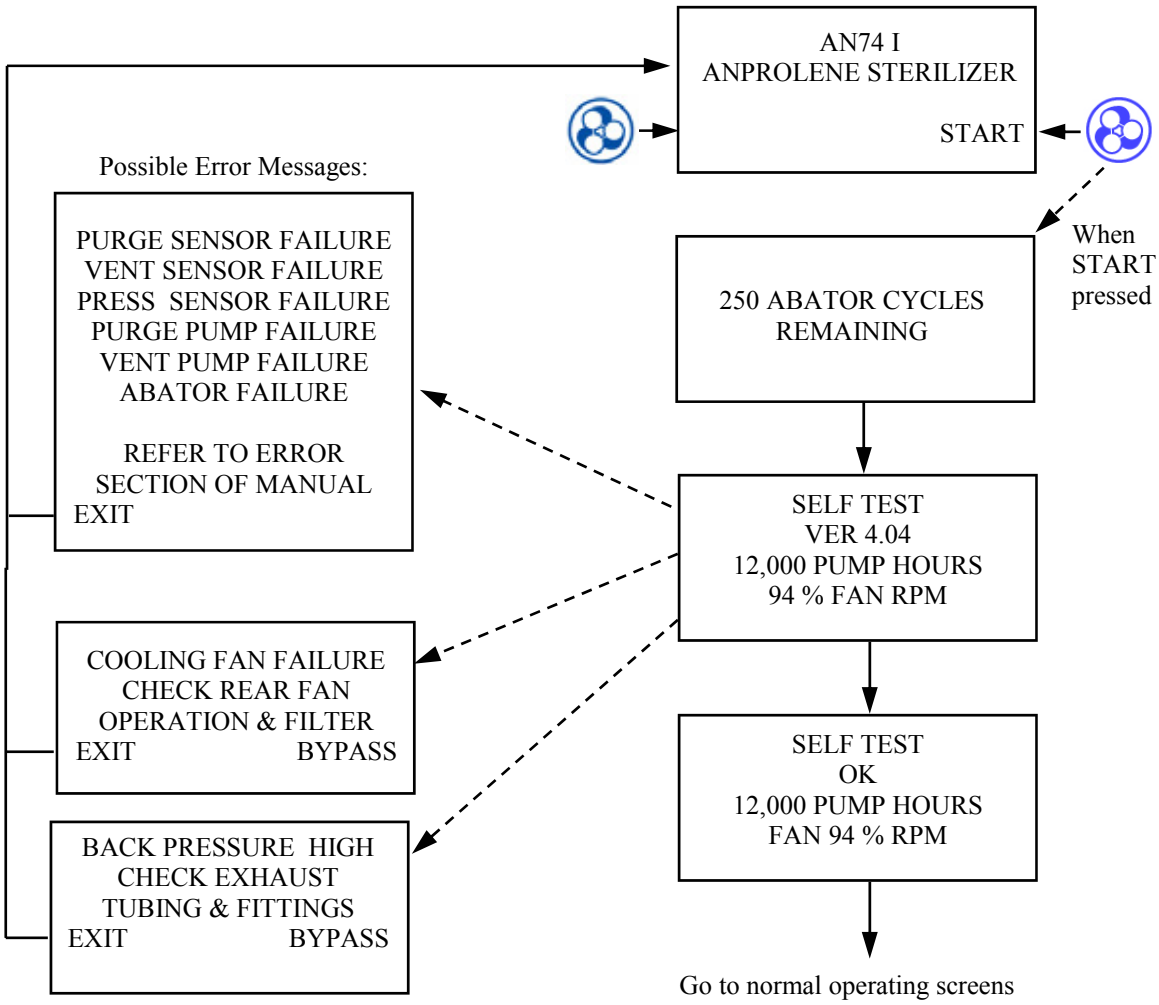


Flowchart for Technical and Diagnostic Screens

These screens are used by authorized service technicians and installers only, to check the vacuum created by the abator pump, ventilation pump and purge pump. The screens are used for diagnostic and installation purposes and would not normally be used by the operator of the machine.



Flowchart for Pre-Cycle Error Messages



COOLING FAN FAILURE indicates the cooling fan in the top did not reach the required operating speed (70% of rated speed)

PURGE SENSOR, VENT SENSOR or PRESSURE SENSOR FAILURE indicates the offset of the specified sensor was out of range (> =0.1 AND <= 0.4) prior to starting the ventilation pump.

PURGE PUMP FAILURE indicates the purge sensor or the purge pump failed or the purge tubing became disconnected.

VENT PUMP FAILURE indicates the ventilation tubing is blocked or disconnected, the ventilation sensor failed or the ventilation pump failed.

ABATOR FAILURE indicates the exhaust tubing blocked, disconnected or the abator pump failed.

BACK PRESSURE HIGH indicates the exhaust tubing is blocked.

EXIT returns to the startup screen

Flowchart for Ventilation Pump Failure During Sterilization Cycle

If a VENT PUMP FAILURE occurs during the sterilization cycle, the screen will display the error message, and the machine will beep continuously until the ALARM button is pressed. This alerts the operator to the problem. The purge pump will start and remain on for the remainder of the normal cycle time.

Press ALARM OFF to stop the alarm

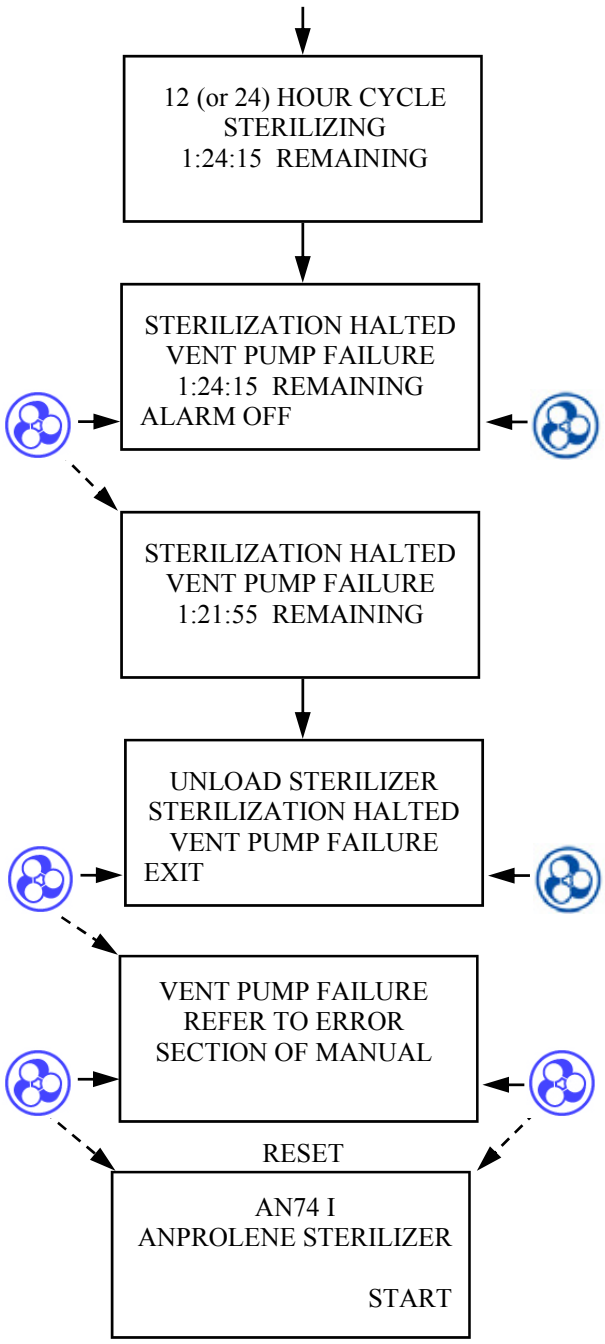
In this case, sterilization has been stopped during the cycle and the Ethylene oxide in the liner bag was removed by the purge pump.

ITEMS IN THE LINER BAG SHOULD NOT BE CONSIDERED STERILE

The machine may be unloaded once the counter reaches 0:00:00, but the items in the liner bag should be resterilized prior to use

Refer to the Error and Troubleshooting sections of the manual for information about repairing the sterilizer

To reset the machine, shut off the machine power. Then, while holding both buttons, turn on the power. Release buttons after the display shows characters.



Flowchart for Ventilation Pump Failure During Ventilation Cycle

If a VENT PUMP FAILURE occurs during ventilation cycle, the screen will display the error message, and beep continuously until the ALARM button is pressed. The purge pump will remain on for the remainder of the normal cycle time and will ventilate the cabinet.

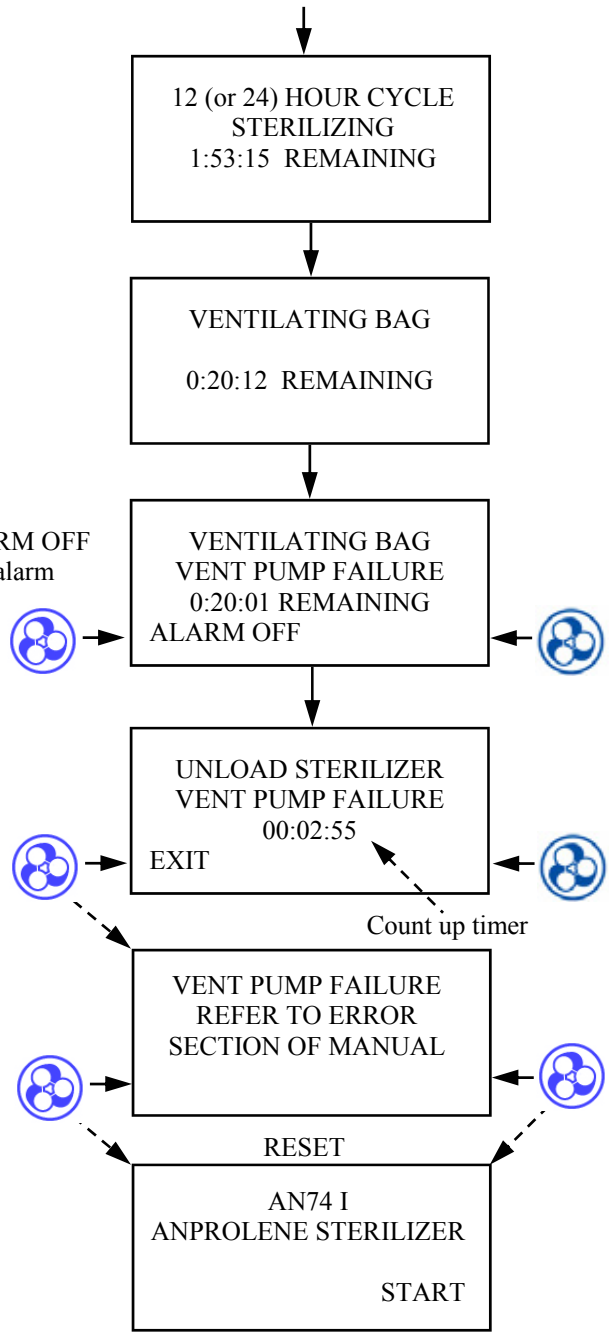
In this case, sterilization has been completed prior to the failure of the pump.

ITEMS IN THE LINER BAG MAY BE CONSIDERED STERILE

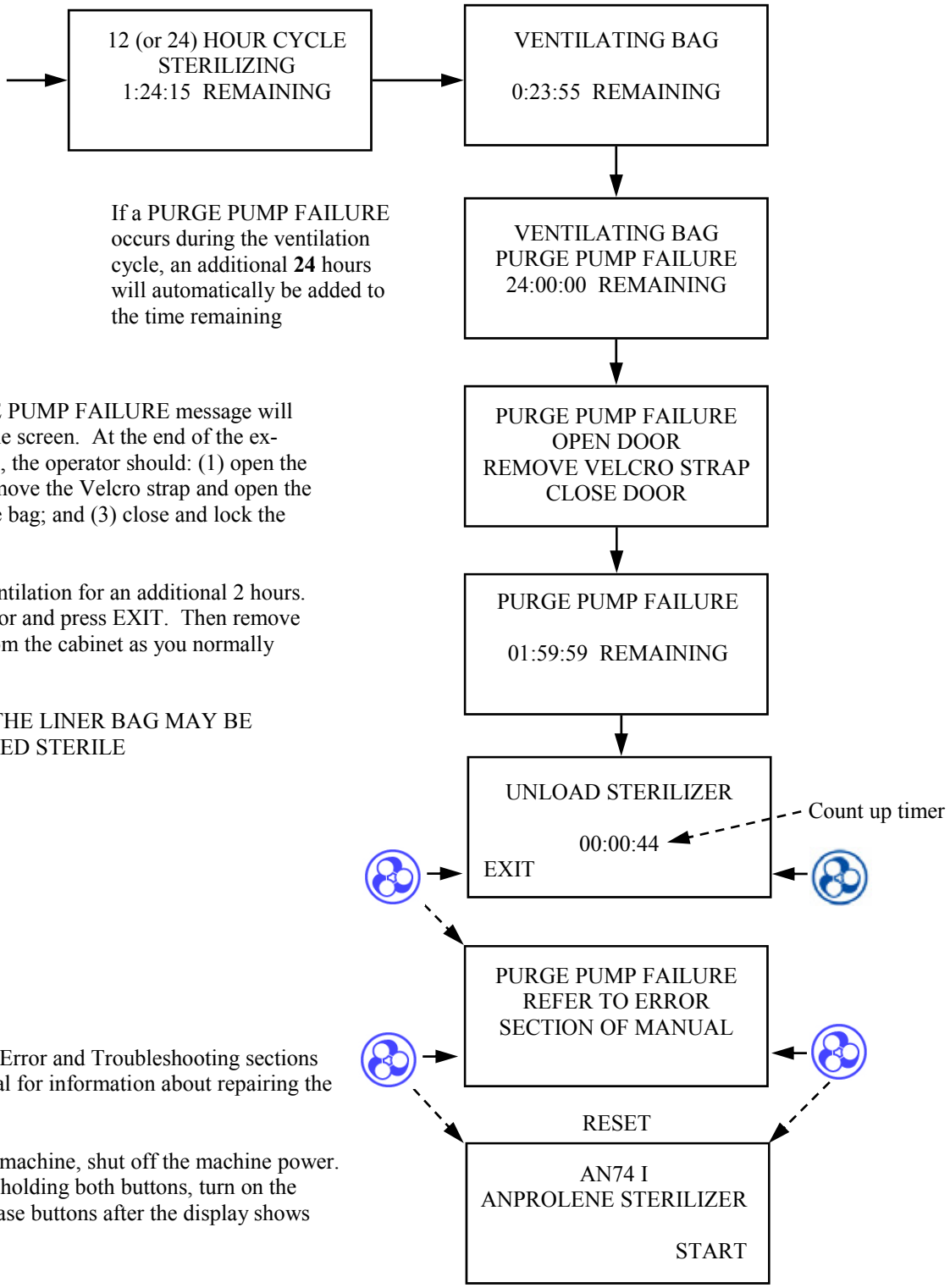
The machine may be unloaded once the counter reaches 0:00:00, and the items may be used normally

Refer to the Error and Troubleshooting sections of the manual for information about repairing the sterilizer

To reset the machine, shut off the machine power. Then, while holding both buttons, turn on the power. Release buttons after the display shows characters.



Flowchart for Purge Pump Failure During Ventilation Cycle



If a PURGE PUMP FAILURE occurs during the ventilation cycle, an additional **24** hours will automatically be added to the time remaining

The PURGE PUMP FAILURE message will remain on the screen. At the end of the extended cycle, the operator should: (1) open the door; (2) remove the Velcro strap and open the mouth of the bag; and (3) close and lock the door.

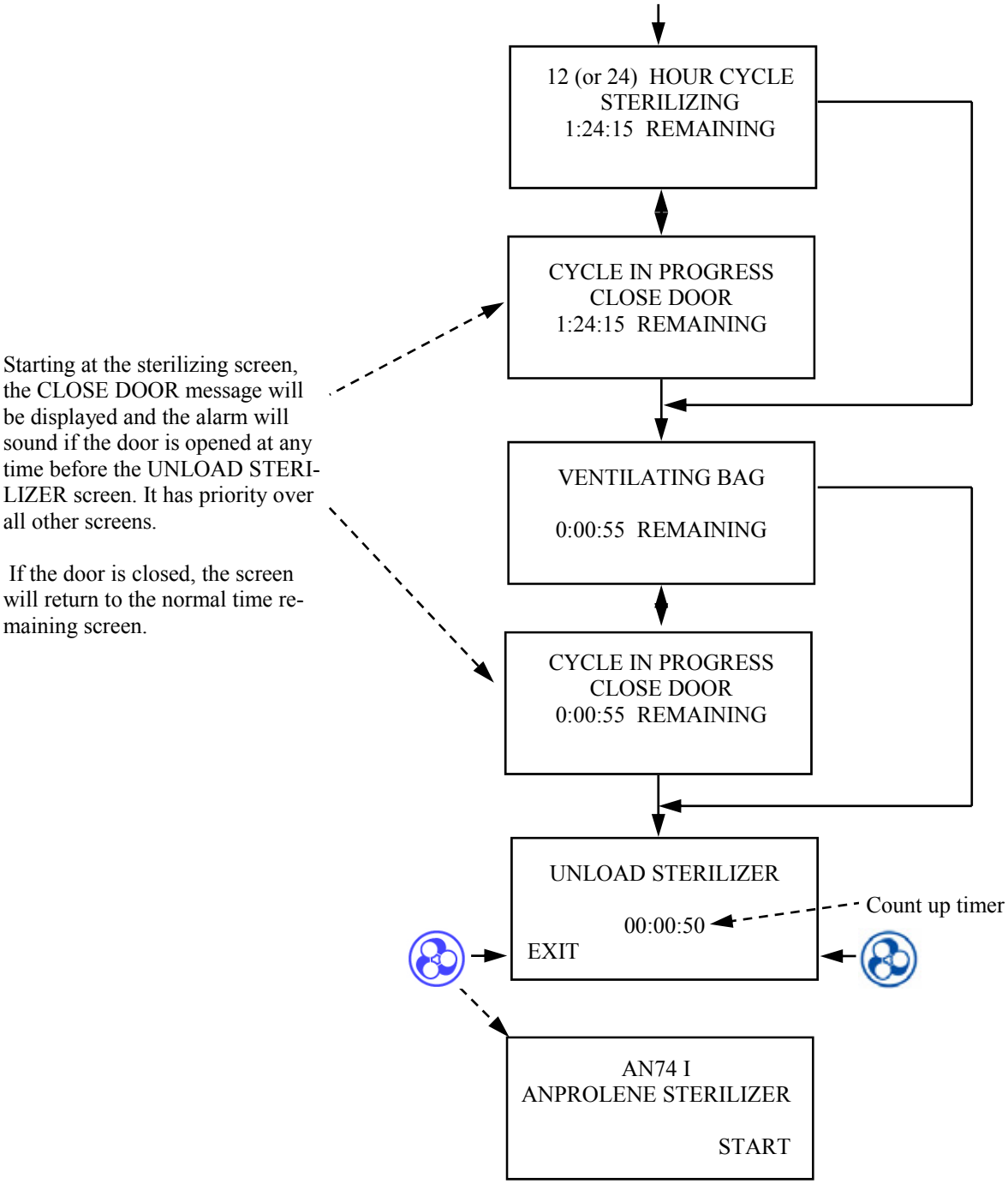
Continue ventilation for an additional 2 hours. Open the door and press EXIT. Then remove the items from the cabinet as you normally would.

ITEMS IN THE LINER BAG MAY BE CONSIDERED STERILE

Refer to the Error and Troubleshooting sections of the manual for information about repairing the sterilizer

To reset the machine, shut off the machine power. Then, while holding both buttons, turn on the power. Release buttons after the display shows characters.

Flowchart for Close Door Error Message



Starting at the sterilizing screen, the CLOSE DOOR message will be displayed and the alarm will sound if the door is opened at any time before the UNLOAD STERILIZER screen. It has priority over all other screens.

If the door is closed, the screen will return to the normal time remaining screen.

APPENDIX F

Material Safety Data Sheets

APPENDIX F
Material Safety Data Sheets—Ethylene Oxide

Section 1
Chemical Product & Company Identification

Product: ANPROLENE®

Manufactured by:

Andersen Sterilizers, Inc.
Health Science Park
3154 Caroline Drive
Haw River, NC 27258 USA

Information Telephone Number: (336) 376-8622

Emergency Telephone Number
(24 HRS, 7 DAYS PER WEEK)
CHEM-TEL (800)-255-3924

Section 2
Composition/ Information on Ingredients

Chemical Name:	Ethylene Oxide
Weight By %:	84 to 97%
Chemical Family:	Epoxide
Formula:	$(CH_2)_2O$
Molecular Weight:	44.06 gms/mole
CAS Number:	75-21-8
CAS Name:	Oxirane
Synonyms:	EO, EtO, Dihydroxirene, 1-2 Epoxyethane, Dimethylene Oxide, Oxane, Oxirane, Alkene Oxide, Alpha/ Beta-Oxidoethane, Oxacyclopropane.
Product Uses:	Chemical intermediate for production of anti-freeze, polyester resins, non-ionic surfactants and specialty solvents; sterilizing agent for controlling microorganisms in health care applications; fumigant for controlling insect infestation in whole and ground spices and cosmetics.

Section 3
Hazard Identification

EMERGENCY OVERVIEW

Colorless liquid or heavier-than-air gas with a sweet, ether-like odor. Extremely flammable liquefied gas which burns in the absence of oxygen and can explode when exposed to elevated temperatures. Toxic when inhaled. Causes severe skin and eye irritation or burns and respiratory tract irritation; effects may be delayed. Harmful if swallowed or absorbed through the skin. Contact with liquid may cause frostbite.

Statement of Hazards:

DANGER!
Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly reactive. May be harmful if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.

HAZARD RATINGS: (0 = minimum; 4 = maximum)

HMIS RATING: Health = 3
Flammability = 4
Reactivity = 3
Personal Protection Code = x (Consult your supervisor or standard operating procedures for special handling directions.)

NFPA RATING: Health = 3
Flammability = 4
Reactivity = 3

Exposure Limits:

	TWA (8 hr)	STEL (15-min)
OSHA	1 ppm	5 ppm
ACGIH	1 ppm	n/a

PRIMARY ROUTES OF EXPOSURE: Inhalation; eye contact, skin contact/absorption

SIGNS AND SYMPTOMS OF OVEREXPOSURE: Effects include skin, eye and respiratory tract irritation or burns. Central nervous system effects initially cause headache, dizziness and nausea and in extreme cases, unconsciousness and death. Peripheral nerve damage may result in muscular weakness, giddiness, irrational behavior and loss of sensation in the extremities. Dulling of the sense of smell may occur.

ACUTE HEALTH EFFECTS:

INHALATION: Inhaling concentrated vapor may cause serious health effects. Inhalation may progressively cause mucous membrane and respiratory irritation, headache, vomiting, cyanosis, drowsiness, weakness, in coordination, CNS depression, lachrymation, nasal discharge and salivation, gasping, and labored breathing. Delayed effects may include nausea, diarrhea, edema of the lungs, paralysis and convulsions. NOTE: Ethylene oxide has a high odor threshold (>250 ppm) and the sense of smell does not provide adequate protection against its toxic effects.

EYE CONTACT: Liquid ethylene oxide is severely irritating and corrosive to the eyes and contact can cause swelling of the conjunctiva and irreversible corneal injury. Contact with liquid ethylene oxide can cause frostbite. Vapors may cause eye irritation, tearing, redness and swelling of the conjunctiva.

SKIN CONTACT: Prolonged contact with liquid ethylene oxide can cause a local erythema, edema, and formation of blisters. Response is more severe on damp skin. There may be a latency period of several hours prior to the onset of symptoms. Ethylene oxide may be absorbed by the skin, and sustained contact may produce adverse effects such as headache, dizziness, nausea, and vomiting. Ethylene Oxide is a skin sensitizer and some individuals may suffer an allergic skin reaction. Skin contact may also cause allergic contact dermatitis in some exposed individuals. Liquid Ethylene oxide evaporates rapidly and may chill the skin causing frostbite.

INGESTION: This relatively unlikely route of exposure is expected to cause severe irritation and burns of the mouth and throat, abdominal pain, nausea, vomiting, collapse and coma. Aspiration may occur during swallowing or vomiting, resulting in lung damage.

CHRONIC HEALTH EFFECTS:

SKIN CONTACT: Long term effects are unknown but are expected to be similar to acute effects of skin exposure.

EYE CONTACT: Some cases of cataract formation have been reported.

INHALATION: Respiratory irritation which can result in permanent, lung injury, chromosomal aberrations and peripheral neurotoxic effects with a numbing of the sense of smell. Cognitive and CNS impairment may result from long term exposures.

INGESTION: May cause anemia, gastrointestinal irritation, effects on liver, kidneys, and adrenal glands.

CARCINOGENICITY:
OSHA classifies ethylene oxide as a cancer/ reproductive hazard and considers that, at excessive levels, ethylene oxide may present reproductive, mutagenic, genotoxic, neurologic and skin sensitization hazards.
ACGIH classifies ethylene oxide as "A2"- suspected human carcinogen.
NTP classifies ethylene oxide as a known human carcinogen.
IARC classifies ethylene oxide in Group 1 (carcinogenic to humans).
NIOSH classifies ethylene oxide as a potential human carcinogen.

Section 4
First Aid Measures

EYE CONTACT: Immediately flush eyes, including the entire surface of the eyes and under the eyelids, gently but thoroughly with plenty of running water for at least 15 minutes. Obtain medical attention immediately. NOTE: Never wear contact lenses when working with ethylene oxide.

SKIN CONTACT: Immediately flush skin thoroughly with water for at least 15 minutes while removing contaminated clothing and shoes. Obtain medical attention immediately. Wash clothing before reuse and discard contaminated leather articles such as shoes and belts.

INHALATION: Remove exposed person to fresh air. If breathing has stopped, give artificial respiration then have qualified personnel administer oxygen, if needed. Get immediate medical attention.

INGESTION: If patient is conscious give plenty of water (minimum of two glasses) but DO NOT INDUCE VOMITING. This material is corrosive. Keep head lower than hips to avoid aspiration, should vomiting occur. Get medical attention immediately.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:
Preexisting skin, eye and respiratory disorders; lung, blood, nervous system and peripheral nerve disorders.

NOTE TO PHYSICIANS: Respiratory symptoms include nausea, vomiting and irritation of the nose and throat. Pulmonary edema may occur. Respiratory effects may be delayed. Consider oxygen administration. If a chemical burn is present decontaminate skin and treat as any thermal burn. No specific antidote is known, however consider gastric lavage and administration of a charcoal slurry.

Section 5
Fire Fighting Measures

FLASH POINT (TEST METHOD):
Tag Closed Cup: -4F (-20C)

FLAMMABLE LIMITS IN AIR (% BY VOLUME);
Upper flammable limit: 100%
Lower flammable limit: 3.0% (30,000 ppm)

NEFA HAZARD RATING:
Health: 3 Flammability: 4 Reactivity: 3

AUTOIGNITION TEMPERATURE:
804 F (429C); burns in the absence of air

EXTINGUISHING MEDIA: Carbon dioxide, dry chemical or water spray for small fires. Water spray, polymer or alcohol resistant foams for large fires. Dilution of liquid ethylene oxide with 23 volumes of water should render it non-flammable. Dilution with 100 parts water to one part of ethylene oxide vapor may be required to control build up of flammable vapors in closed systems. Water spray can be used to reduce intensity of flames to cool fire-exposed containers and to dilute spills to render non-flammable.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide and carbon dioxide.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Ethylene oxide is dangerously explosive under fire condition; it is flammable over an extremely large range of concentrations in air and burns in the absence of oxygen. Liquid ethylene oxide is lighter than water (floats) and vapors are heavier than air and may travel along ground long distances to sources of ignition and then flash back. Containers should not be subject to temperatures hotter than 127F (52 C). Vapors are extremely flammable and are readily ignited by static charge, sparks and flames at concentrations above 3%.

Section 6
Accidental Release Measures

PRECAUTIONS: Treat any ethylene oxide leak as an emergency. Evacuate all personnel from the area except those directly engaged in stopping the leak or in cleaning up. If an Anprolene ampoule is inadvertently dropped and activated before it is sealed inside of the sterilization liner bag, it will still take time for the ethylene oxide

to diffuse out of the gas release bag and into the room. At one full minute after activation there is less than 1 ppm measured at a distance of 18 inches from the gas release bag. In the case of a premature activation the operator should immediately:

- Place the Anprolene ampoule inside the sterilizer
- Close the sterilizer door
- Turn the power on; and
- Press the button to the right of PURGE.

This will cause the purge and ventilation pumps to turn on and evacuate the ethylene oxide from the sterilizer and exhaust it from the workspace. Allow a full 14 hour cycle before you open the door and remove the used Anprolene ampoule and dispose of it.

Section 7
Handling and Storage

HANDLING AND STORAGE PRECAUTIONS: Have established handling and emergency response procedures in place prior to use. Make sure that the sterilizer is properly grounded. Protect containers from physical damage and regularly inspect them for cracks or leaks.

ENGINEERING CONTROLS: Ethylene oxide, a major fire hazard, can burn in the absence of oxygen. All electrical devices used in areas processing or handling ethylene oxide must be engineered and designed to the applicable local electrical/fire codes. Safeguards can include designing electrical devices as explosion proof and/or intrinsically safe. ATTENTION: Ethylene oxide vapors are colorless and odorless above OSHA'S permissible exposure level. An air monitoring system and/or AirScan® badges are recommended to determine airborne exposure levels.

STORAGE SEGREGATION: Store ethylene oxide in a cool, dry, well-ventilated area away from incompatible chemicals and sources of ignition. Store Anprolene® refill kits upright; do not drop and move in a carefully supervised manner. DO NOT STORE IN DIRECT SUNLIGHT.

SHIPPING AND STORAGE CONTAINERS: (See 49 CFR 173.4) All Anprolene® refill kits containing ethylene oxide are packaged and shipped in accordance with the small quantities exemption under 49 CFR 173.4(c) and DOT approval CA 9803005 issued April 9, 1998.

Section 8
Exposure Controls/Personal Protection

EXPOSURE LIMITS:

OSHA ACTION LEVEL (8 HR. TWA)	0.5 ppm
OSHA PEL (8 HR TWA)	1 ppm
OSHA 15 MINUTE EXCURSION LIMIT	5 ppm; 9 mg/m3
ACGIHTLV/TWA	1 ppm; 1.8 mg/m3
IDLH:	800 ppm

EYE PROTECTION: NEVER WEAR CONTACT LENSES when working with ethylene oxide.

VENTILATION: Install and operate general and local exhaust ventilation systems powerful enough to maintain airborne levels of ethylene oxide below the OSHA PEL in the worker's breathing area. AAMI / ANSI ST41 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance Guidelines, Section 3.4 recommends a minimum of 10 room makeup air changes per hour. Emission controls must be in compliance with Federal, State and local regulations.

OTHER PROTECTION: Sterilizer must be electrically grounded/bonded. Practice good personal hygiene; always wash thoroughly after using this material. Do not eat drink or smoke in work area.

Section 9
Stability and Reactivity

Boiling Point:	50.9ºF (10.5ºC)
Freezing Point	-169º F (-111.7ºC)
Specific Gravity:	0.871 at 20ºC
Vapor Pressure:	1094 mm Hg @ 20ºC
Vapor Density (Air =1)	1.5
Solubility in Water:	100%
Molecular Weight:	44.06 gms/mole
Percent Volatile by Volume	100%
Evaporation rate (Butyl Acetate = 1)	Not applicable
PH:	7, neutral (100 grams/liter in water)
Appearance and Odor:	Colorless liquid or gas with sweet ether-like odor. Odor threshold: 261 ppm (detectable); 600-700 ppm recognizable).
Log Octanol/Water Partition Coefficient (log Kow):	-0.3

STABILITY: Material is stable for extended periods in closed air-tight, pressurized containers at room temperature, under normal storage and handling conditions. Vapors may explode when exposed to common ignition sources.

CONDITIONS TO AVOID: Storage at warm temperatures or any exposure of storage or shipping containers to hot temperatures. Prevent exposure to all sources of ignition such as heat, flame, lighted tobacco products, or electrical or mechanical sparks.

HAZARDOUS DECOMPOSITION PRODUCTS: Ethylene oxide undergoes thermal decomposition to form carbon dioxide and carbon monoxide gases.

Section 10
Toxicological Information

TOXICOLOGICAL- ACUTE INHALATION: LC_{50} (1 hr. exposure)

5748 ppm (male rat)
4439 ppm (female rat)
5029 ppm (rat – combined sexes)

Various mammalian species exposed to lethal concentrations of ethylene oxide had symptoms of mucous membrane irritation, central nervous system depression, lacrimation, nasal discharge, salivation, nausea, vomiting, diarrhea, respiratory irritation, incoordination, and convulsions.

TOXICOLOGICAL-CHRONIC INHALATION: Symptoms of chronic exposure are similar to those observed in acute studies, including lung, kidney and liver damage and testicular tubule degeneration in some species. Studies demonstrated neuromuscular effects as the most sensitive indicator of ethylene oxide over exposure.

TOXICOLOGICAL-ACUTE DERMAL: No dermal LD_{50} information is available on this product. It is expected to be corrosive to rabbit skin.

TOXICOLOGICAL – CHRONIC DERMAL: No chronic dermal toxicity data are available on this product.

TOXICOLOGICAL- EYE: No eye irritation animal data are available on this product. However, it is expected to extremely irritating to rabbit eyes.

TOXICOLOGICAL-ACUTE INGESTION: The acute oral LD_{50} for This product is; 72 mg/kg, rat

TOXICOLOGICAL-CHRONIC INGESTION: The effects of chronic ingestion of this product are unknown

CARCINOGENICITY: A recent assessment of available epidemiology studies related to ethylene oxide concluded that the evidence indicates that ethylene oxide does not cause heart disease, an excess of cancers overall, or brain, stomach or pancreatic cancers which were seen in some animal and isolated human studies. The findings with respect to leukemia and non-Hodgkins lymphoma are less definitive. While the majority of the evidence does not indicate that ethylene oxide causes these cancers, there are some suggestive trends. Longer follow-up of ethylene oxide workers is needed to better clarify these relationships. Two inhalation studies with rats demonstrated carcinogenic responses consisting of increased incidences of mono-nuclear cell leukemia, peritoneal mesotheliomas , and primary brain tumors. In 2-year inhalation studies with mice there was evidence of carcinogenic activity as indicated by dose-related incidences of benign or malignant neoplasms of the uterus, mammary gland, and hematopoietic system (lymphoma).

MUTAGENICITY: While ethylene oxide has demonstrated, in epidemiological studies with exposed workers, an increased incidence of chromosomal aberrations and sister chromatid exchanges, the relevance of such effects to human health hazard evaluation is currently uncertain. In rodent studies, dose related exposure to ethylene oxide induces increases in numbers of adducts in DNA and hemoglobin. Laboratory studies with mice have shown that acute exposure to ethylene oxide at 300 ppm and above caused testicular injury as evidenced by concentration-related increased embryonic deaths following mating of exposed males to non-exposed females (Dominant-Lethal Test).

NEUROTOXICITY: Effects are similar to those of acute (short term) exposure, namely headaches, nausea, diarrhea, lethargy, and irrational behovior. Muscle weakness, loss of sensation in the extremities and a reduction in the sense of smell and/or taste may also result. Studies on workers Indicate that CNS and cognitive impairment may result from chronic exposures to ethylene oxide.

REPRODUCTIVE EFFECTS: Some limited epidemiological data suggests that women exposed to ethylene oxide have a greater incidence of miscarriages. A one-generation reproduction study in rats showed decreased number of pups at 100 ppm, but not at 33 ppm. In a two-generation reproduction study involving exposure of rats to ethylene oxide vapor for 5 hrs/day, 5 days/week, there was parental toxicity at 33 ppm and 100 ppm. The no-observable effect concentration for adult toxicity, offspring effect and reproductive effect was 10 ppm.

TERATOLOGY: Inhalation development toxicity studies with rats exposed to ethylene oxide vapor at concentrations of 50 ppm, 125 ppm and 225 ppm showed that maternal toxicity occurred at 125 and 225 ppm. Fetotoxicity, evidenced by reduced fetal body weight, occurred at all concentrations. At 225 ppm and to a lesser extent at 125 ppm an increased incidence of skeletal variants was found. There was no evidence of embryotoxicity or malformations.

TARGET ORGANS: Overexposure to this product may affect the skin, eyes, respiratory system, liver, kidneys, brain, blood, reproductive system, and central nervous system.

Section 11
Ecological Information

ECOTOXICOLOGICAL DATA: Ethylene oxide hydrolyzes to ethylene glycol. Biodegradation of ethylene oxide occurs at a moderate rate after acclimation (3-5% degradation after 5 days; 52% after 20 days). Biodegradation is expected in a wastewater treatment plant. Ethylene oxide has an estimated half-life in the atmosphere of 211 days. A high adsorptivity in soil is expected.

Section 12
Disposal Consideration

WASTE MANAGEMENT/DISPOSAL: Dispose used Anprolene ampoules, sterilization liner bags, indicators and accessories as you would ordinary trash.

However, unused Anprolene ampoules containing ethylene oxide are a RCRA hazardous waste with waste code U115 (Commercial chemical product - listed for toxicity and ignitability). Unused Anprolene ampoules containing ethylene oxide may be incinerated in an approved hazardous waste incinerator or can be biologically treated in an approved facility. Unused Anprolene ampoules containing ethylene oxide are banned from land disposal.

Dispose of waste materials in accordance with all applicable Federal, State and local laws and regulations.

Section 13
Transport Information

TRANSPORTATION DATA:

DOT Proper shipping Name:	Ethylene Oxide
DOT Class or Division:	2.3 (Poison Gas)
Identification Number	UN 1040
Packing Group:	n/a
DOT Label:	"This package conforms to 49 CFR 173.4"
DOT Packaging	See section 7, "Handling and stor age"
DOT Approval:	CA-9803005

Section 14
Regulatory Information

U.S. REGULATIONS:

TSCA status: Listed
CERCLA Section 103 (40 CFR 302.4): listed
10 lb. Reportable Quantity
SARA Section 304 (40 CFR 356.40): Listed
1 lb Reportable Quantity
SARA Section 311/312 (40 CFR 370.21) Hazard categories met:
Acute, Chronic, Fire, Reactive, Sudden Release
SARA Section 313 (40 CFR 372.65); Listed
OSHA (29 CFR 1910. 1200): Meets criteria as a hazardous material
OSHA (29 CFR 1910. 1047): Ethylene Oxide Standard
EPA list of Hazardous Air Contaminants: Listed
EPA Organic Hazardous Air Pollutant (HAP) list: Listed
EPA list of Pesticide Chemicals (40 CFR 180.151): Listed
EPA NESHAPS (40 CFR 63.360)
VOC Rule: 100% VOC

STATE RIGHT-TO-KNOW REGULATIONS:

California Proposition 65: Listed; cancer hazard; reproductive hazard
California Director's List: Listed
Florida Hazardous Substance List: Listed
Massachusetts Extraordinarily Hazardous Substance List: Listed
Minnesota Hazardous Substance List: Listed
New Jersey Hazardous Substance List: Listed on 0882
(Special Hazardous Substance: Environmental Hazardous Substance)
Pennsylvania Right-to-know List: Listed

Section 15
Other Information

GLOSSARY OF TERMS AND ABBREVIATIONS:

ACGIH- American Conference of Governmental Industrial Hygienists
CERCLA- Comprehensive Environmental Response, Compensation and Liability Act.
CAS- Chemical Abstract Service
CFR- Code of Federal Regulations
CNS- Central Nervous System
DOT- U.S. Department of Transportation
EPA- U. S. Environmental Protection Agency
HMIS- Hazardous Materials information Sheet
IARC- International Agency for Research on Cancer
IDL- ingredient Disclosure List
IDLH- Immediately dangerous to life and health
HAP- Hazardous Air Pollutant
LC_{50} - Median lethal dose that kills 50% of an exposed population by the inhalation route
LD_{50}- Median lethal dose that kills 50% of an exposed population by the oral (or dermal) route
NESHAPS- National Emission Standards for Hazardous Air Pollutants
NFPA- National Fire Protection Association
NIOSH- National Institute of Occupational Safety and Health
NTP- National Toxicology Program
OSHA- Occupational Safety and Health Administration
p/p- parts per part
PEL- Permissible exposure Limit
PVC- Polyvinyl chloride
ppm- Parts per million
p.s.i.g- Pounds per square inch (gauge pressure)
RCRA- Resource, Conservation and Recovery Act
SARA- Superfund Amendment and Reauthorization Act of 1990
STEL- Short-term exposure Limit
TDG-Transportation of Dangerous Goods
TLV- Threshold Limit Value
TSCA- Toxic Substance Control Act
TWA- Time Weighted Average
VOC- Volatile organic compound
WHMIS-Workplace Hazardous Material Information System

MSDS Revision Date: 10/23/02

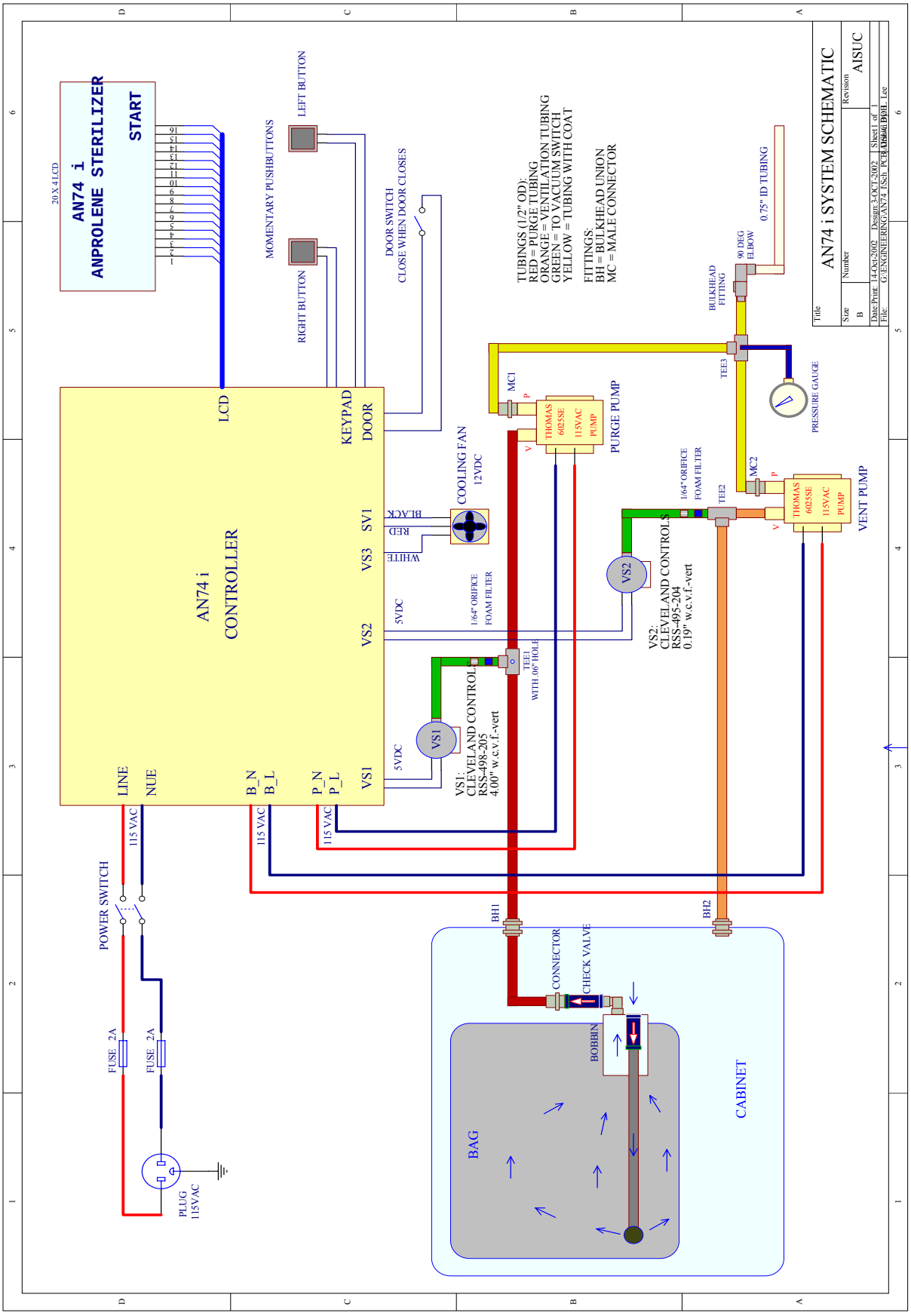
Disclaimer

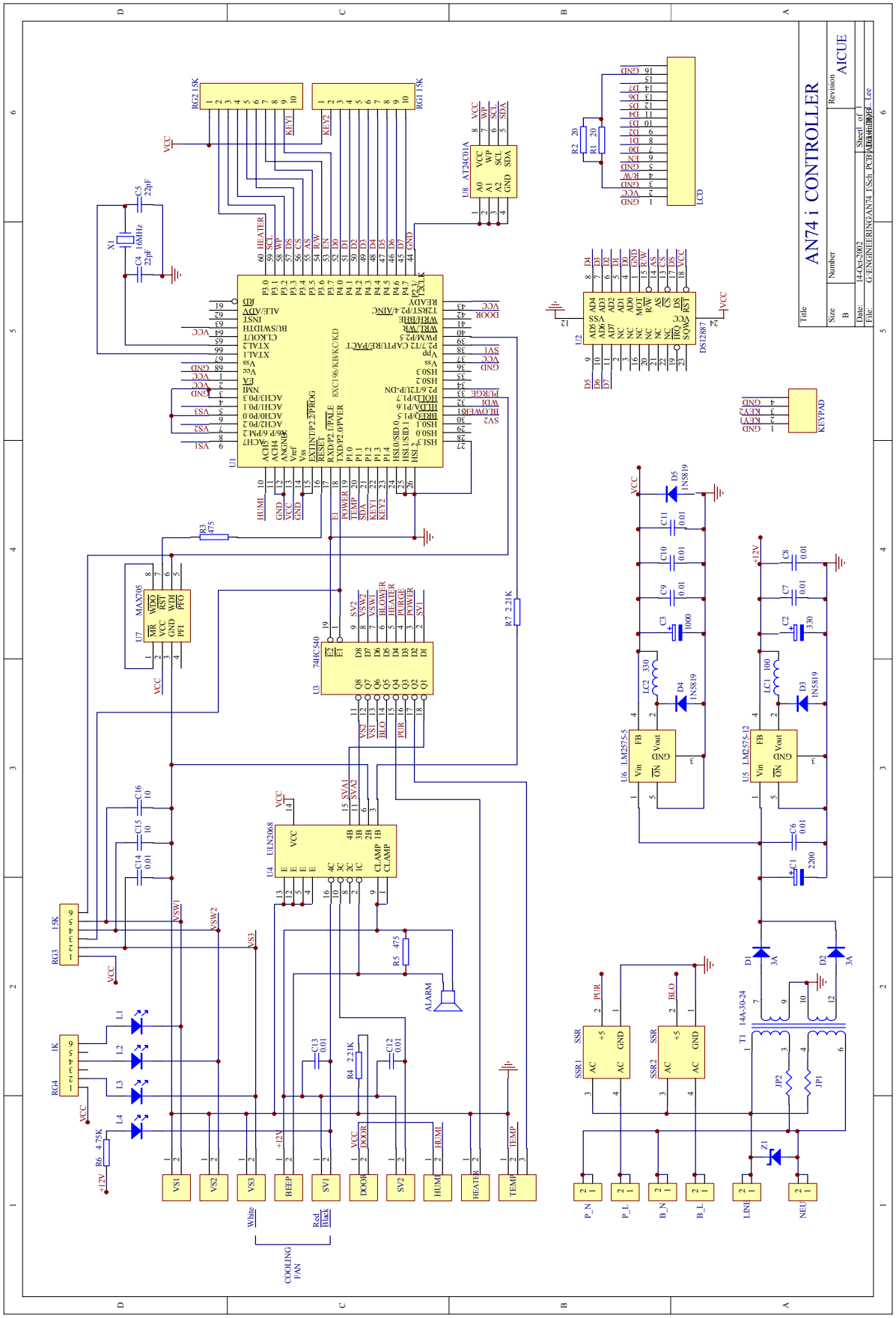
It is imperative that the user/reader be familiar with and adhere to OSHA regulations which are specific to ethylene oxide (29CFR1910.1047) as well as any other applicable Federal, State, or local government regulations. Regulations listed in Section 14 of this document may not be all inclusive and are subject to change. The data in this MSDS is furnished gratuitously independent of any sale of the product only for your investigation and independent verification. While the information is believed to be correct, Andersen makes no representation as to the accuracy of the information contained herein. Andersen shall in no event be responsible for any damages of whatsoever nature directly or indirectly resulting from publication or use of, or negligence upon data contained herein. No Warranty (either expressed or implied) of merchantability or of fitness for any purpose with respect to the product or to the data herein is made hereunder

MSDS Revision Date: 9/08/04

APPENDIX G

AN74 i/ix Specifications





APPENDIX H

Equipment Ratings Summary and Replacement Parts List

APPENDIX G
Equipment Ratings Summary

Equipment Rating

Model Ref.		Voltage	Hz.	Power	Fuse Rating
AN74.67	AN74*i*	115v +/- 10%	50/60	150 Watts	2 Amp.
AN74.68	AN74*i*	230v +/- 10%	50/60	150 Watts	2 Amp.
AN74.69	AN74*i*	100v +/- 10%	50/60	150 Watts	2 Amp.
AN74.87	AN74*ix*	115v +/- 10%	50/60	150 Watts	2 Amp.
AN74.88	AN74*i*	230v +/- 10%	50/60	150 Watts	2 Amp.
AN74.89	AN74*ix*	100v +/- 10%	50/60	150 Watts	2 Amp.

Environmental Conditions

The Anprolene Sterilizers are designed to function in an environment with these conditions:

i. Indoor use;
ii. Altitude up to 6,562 feet (2000 meters);
iii. Temperature 68°F (20º C) to 91°F (33° C);
iv. Maximum relative humidity 80% for temperatures up to 87.8° F (31° C) decreasing linearly to 50% relative humidity at 104°F (40° C);
v. Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage;
vi. Transient overvoltages according to INSTALLATION CATEGORY (OVERVOLTAGE CATEGORY) II: Local level, appliances, portable equipment, etc. capable of withstanding 1500 volts impulse;
vii. POLLUTION DEGREE 2 in accordance with EC 664.

Connections

Nominal voltage depending upon model selected connected to a grounded, un-switched power supply.

Anprolene Sterilizers Replacement Parts List

This list relates to Models:

AN74*i* Model: AN 74.67	AN74*ix* Model: AN74.87
AN74*i* Model: AN 74.68	AN74*ix* Model: AN74.88
AN74*i* Model: AN 74.69	AN74*ix* Model: AN74.89

Part No.: **Description**

AN100.04 Purge Tube Bobbin Assembly
7489 Populated Circuit Board Assembly (version AICUEG)
2929 Blue hose .250" OD, .125 ID
3875 .125" Brass Hose Barb
3876 90° Brass Elbow
4710 Check Valve 3" of H2O
7409 Strap, Velcro, Hook and Loop, 10" Long x 1" Wide
7433 Tubing, 1/2" OD, 3/8" ID, Ester Based, Poly
7434 Tubing, FP, 3/8" OD, 1/4" ID
7441 Plastic Single Barb Fittings, 3/8" ID, 1/8" NPT
7443 Acetal Union Tee, 1/2" OD
7445 Acetal Bulkhead Union, 3/8"
7446 Acetal Bulkhead Union, 1/2"
7448 Female Elbow Adapter, 1/2" OD, 3/8" NPT (AN 74.69)
7449 Acetal Stem Adapter, 1/2" OD to 3/8" NPT (AN 74.69)
7450 Insert, 1/2" OD Tube
7451 Rubber Tubing, 5/8" ID with 1/8" Wall, Amber
7452 Pump, Thomas 6025SE, 100VAC, 50 Hz, 150070
7453 Pump, Thomas 6025SE, 115VAC, 60 Hz, 150057
87455 Switch, Momentary Action, Push Button
7456 D Series Miniature Power Rocker Switch, SPDT
7458 Fuse, Buss ABC-2, 250V, 1/4" x 1 1/4", 2 Amp, Fast Acting
7460 Power Cord (AN 74.67 and AN 74.69)
7461 Cable, Single-Row Receptacle, Housing to Solder Type, 16 PIN, 4"L
7464 LED Backlight, Optrex LCD 4 x 20
7468 Magnetic Proximity Sensor, Recessed, 3/8" Magnet Included
7491 Fuse Holder Receptacle
7493 Fuse Drawer (AN 74.67 and AN 74.69)
74012 Exhaust outlet
74013 90° Exhaust Insert
74014 Gauge, 30 In. of H2O
74015 Nipple, Brass with Hose
74017 .020" Aluminum Orifice
74022 .020" Gray PVC Orifice
74027 12v DC Cooling Fan
802741 Vacuum Switch (VS0.19)
802742 Vacuum Switch (VS4.0)

APPENDIX I

Andersen One Year Limited Warranty

ANDERSEN One-Year Limited Warranty

Andersen Products, Inc. ("Andersen") warrants that this Anprolene© Sterilizer ("Product") is free from defects in material and workmanship that result in Product failure during normal usage, according to the following terms and conditions:

1. The limited warranty for the Product extends for ONE (1) year beginning on the date of the purchase of the Product.
2. The limited warranty extends to the original purchaser of the Product ("Consumer") and is not assignable or transferable to any subsequent purchaser/end-user.
3. The limited warranty extends only to Consumers who purchase the Product in the United States, Canada and Japan, Mexico, Central and South America and the Caribbean.
4. During the limited warranty period, Andersen will repair, or replace, at Andersen's option, any defective parts, or any parts that will not properly operate for their intended use with new or factory rebuilt replacement items if such repair or replacement is needed because of product malfunction or failure during normal usage. No charge will be made to the Consumer for any such parts. Andersen will also pay for the labor charges incurred by Andersen in repairing or replacing the defective parts. The limited warranty does not cover defects in appearance that are cosmetic or decorative. Andersen's limit of liability under the limited warranty shall be the actual cash value of the Product at the time the Consumer returns the Product for repair, determined by the price paid by the Consumer for the Product less a reasonable amount for usage. Andersen shall not be liable for any other losses or damages. These remedies are the Consumer's exclusive remedies for breach of warranty.
5. Upon request from Andersen, the Consumer must prove the date of the original purchase of the Product by a dated bill of sale or dated itemized receipt.
6. The Consumer shall bear the cost of shipping the Product, or any part thereof, to Andersen in Haw River, North Carolina. Andersen shall bear the cost of shipping the Product, or any part thereof, back to the Consumer after the completion of service under this limited warranty.
7. The Consumer shall have no coverage or benefits under this limited warranty if any of the following conditions are applicable:

a) The Product has been subject to abnormal use, abnormal conditions, improper storage, exposure to moisture or dampness, unauthorized modifications, unauthorized connections, un-authorized repair, misuse, neglect, abuse, accident, alteration, improper installation, or other acts which are not the fault of Andersen, including damage caused by shipping.
b) The Product has been damaged from external causes such as collision with an object, or from fire, flooding, sand, dirt, windstorm, lightning, earthquake or damage from exposure to weather conditions, an Act of God, or theft, blown fuse, or improper use of any electrical source, or damage caused by the connection to other products not recommended for interconnection by Andersen.
c) Andersen was not advised by the Consumer in writing of the alleged defect or malfunction of the Product within fourteen (14) days after the expiration of the applicable limited warranty period.
d) The Product serial number plate has been removed, defaced or altered.

8. If a problem develops during the limited warranty period, the Consumer shall take the following step-by-step procedure:

a)The Consumer shall contact the place of purchase to describe the alleged defect or malfunction of the Product and obtain a Return Authorization Number ("RMA")
b) The Consumer shall return the Product to the place of purchase for repair or replacement processing.
c) If "b" is not convenient because of distance (more than 100 miles) or for other good cause, the Consumer shall ship the Product prepaid and insured to:

Andersen, Products, Inc.
Attn: Repair Department
3202 Caroline Drive
Health Science Park
Haw River, NC 27258 USA

d) The Consumer shall include a return address, daytime phone number and/or fax number, complete description of the problem, proof of purchase and service agreement (if applicable). Expenses related to removing the Product from an installation are not covered under this limited warranty.
e) The Consumer will be billed for any parts or labor charges not covered by this limited warranty. The Consumer will be responsible for any expenses related to reinstallation of the Product.
f) Andersen will repair or authorize the repair of the Product under the limited warranty within 15 days after receipt of the Product by Andersen or an Andersen authorized service center. If Andersen cannot perform repair covered under this limited warranty within 15 days, or after a reasonable number of attempts to repair the same defect, Andersen at its option, will provide a replacement Product or refund the purchase price of the Product less a reasonable amount for usage.

g) If the Product is returned to Andersen during the limited warranty period, but the problem with the Product is not covered under the terms and conditions of this limited warranty, the Consumer will be notified and given an estimate of the charges the Consumer must pay to have the Product repaired, with all shipping charges billed to the Consumer. If the estimate is refused, the Product will be returned freight collect. If the Product is returned to Andersen after the expiration of the limited warranty period, Andersen's normal service policies shall apply and the Consumer will be responsible for all shipping charges.
9. The Product consists of newly assembled equipment that may contain used components that have been reprocessed to allow machine compliance with Product performance and reliability specifications.
10. ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OR USE, SHALL BE LIMITED TO THE DURATION OF THE FOREGOING LIMITED WRITTEN WARRANTY. OTHERWISE, THE FOREGOING LIMITED WARRANTY IS THE CONSUMER'S SOLE AND EXCLUSIVE REMEDY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. ANDERSEN SHALL NOT BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF ANTICIPATED BENEFITS OR PROFITS, LOSS OF SAVINGS OR REVENUE, PUNITIVE DAMAGES, LOSS OF USE OF THE PRODUCT OR ANY ASSOCIATED EQUIPMENT, COST OF CAPITAL, COST OF ANY SUBSTITUTE EQUIPMENT OR FACILITIES, DOWN-TIME, THE CLAIMS OF ANY THIRD PARTIES, INCLUDING CUSTOMERS, AND INJURY TO PROPERTY, RESULTING FROM THE PURCHASE OR USE OF THE PRODUCT OR ARISING FROM BREACH OF THE WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, STRICT TORT, OR ANY OTHER LEGAL OR EQUITABLE THEORY, EVEN IF ANDERSEN KNEW OF THE LIKELIHOOD OF SUCH DAMAGES. ANDERSEN SHALL NOT BE LIABLE FOR DELAY IN RENDERING SERVICE UNDER THE LIMITED WARRANTY, OR LOSS OF USE DURING THE PERIOD THAT THE PRODUCT IS BEING REPAIRED.
11. Some countries do not allow limitation of how long an implied warranty lasts, so the above one-year warranty limitation may not apply to you (the Consumer). Some countries do not allow the exclusion or limitation of incidental and consequential damages, so certain of the above limitations or exclusions may not apply to you (the Consumer). This limited warranty gives the Consumer specific legal rights and the Consumer may also have other rights which vary from country to country.
12. Andersen neither assumes nor authorizes any authorized service center or any other person or entity to assume for it any other obligation or liability beyond that which is expressly provided for in this limited warranty including the provider or seller of any extended warranty or service agreement.
13. This is the entire warranty between Andersen and the Consumer, and supersedes all prior and contemporaneous agreements or understandings, oral or written, and all communications relating to the Product, and no representation, promise or condition not contained herein shall modify these terms.
14. This limited warranty allocates the risk of failure of the Product between the Consumer and Andersen. The allocation is recognized by the Consumer and is reflected in the purchase price of the Product.
15. Any action or lawsuit for breach of warranty must be commenced within eighteen (18) months following delivery of the Product to the Consumer.
16. Questions concerning this limited warranty may be directed to:
Andersen Customer Care Center
Andersen Products, Inc.
3202 Caroline Drive
Health Science Park
Haw River, NC 27258
Telephone: 1-800-523-1276
Facsimile: (336) 376-8153
E-mail: customerservice@anpro.com
17. The limited warranty period for Andersen supplied attachments and accessories is specifically defined within their own warranty cards and packaging.

Anprolene© is a registered trademark of Andersen Products, Inc.

APPENDIX J

10 Year Useful Life of Sterilizer

APPENDIX J
10 Year Useful Life

J.1.1 The Useful Life of the Andersen AN74i and AN74iX sterilizers is ten (10) years from the date of manufacture. The Lot/Serial Number on the back of the sterilizer indicates the year the sterilizer was manufactured. For example, the first two numbers of the Lot/ Serial Number 233508 indicate that the sterilizer was manufactured in the year 2003. Useful Life refers to the time period during which Andersen Sterilizers will maintain a spare parts inventory and provide services to repair and support your sterilizer. Useful Life also refers to the time period, after which the sterilizer should be removed from service and replaced with a newer sterilizer.

J.1.2 If your sterilizer is in need of repair after the Limited One Year Warranty Period has expired and prior to the expiration of the Useful Life, you should contact your Andersen Customer representative at 800-523-1276 if you are located in the United States or Canada. If you are located outside of these two countries you should contact your local distributor.

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