ANDERSEN STERILIZERS

ANPROLENE AN75

STUDY GUIDE

ANPROLENE AN75
STUDY GUIDE

Anprolene® gas sterilization

Thank you for using the Anprolene sterilisation system.

The active ingredient in the Anprolene sterilisation system is Ethylene Oxide (EO). EO is a powerful anti-microbial agent; it needs to be handled with care. To help ensure that your steriliser is operated safely, all personnel who operate or maintain the equipment must be properly trained.

The Andersen Anprolene Key Operator Certification Program is available free of charge for the life of your steriliser. We recommend that all operators at your facility successfully complete Key Operator training before they use the steriliser for the first time.

Certification Program Outline

The information in this study guide should be carefully reviewed. Training can take place either at your facility or it may be conducted over the telephone and requires 15 minutes. When you are ready, please call Andersen Customer Service on 01255 428328 to schedule your test or book an onsite visit. Shortly after successfully completing your test, you will receive a registered training certificate.

We look forward to hearing from you!

ANDERSEN STERILIZERS

ANPROLENE AN75
STUDY GUIDE

Overview of your Anprolene Sterilisation System.

The Anprolene sterilisation system is a room temperature Ethylene Oxide (EO) steriliser. This sterilisation system must be installed and operated in an environment that maintains a temperature of no lower than 20°C throughout the entire cycle to be effective.

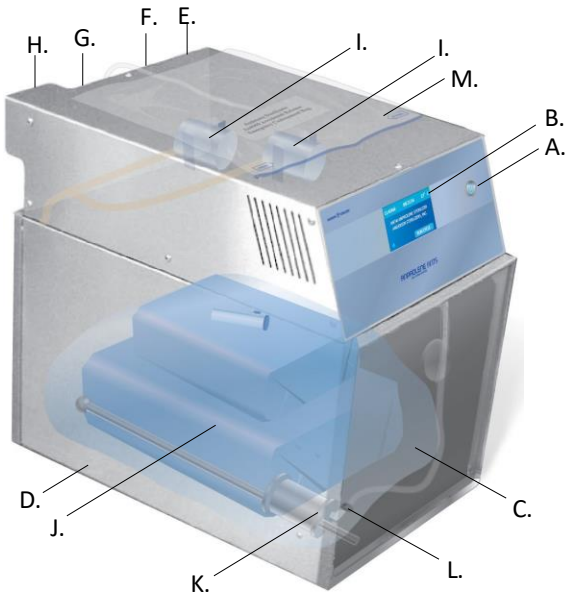
The Usual Anprolene cycle is 12 hours, plus an automatic 2 hour bag ventilation cycle to remove excess gas and prevent the operator from being exposed to the gas.

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

Maintaining a relative humidity above 30% is critical to the success of the Anprolene cycle.

The AN87 Dosimeter® provides an immediate indication at the end of a cycle that adequate time, temperature and EO concentration for sterilisation have been met.

ANPROLENE AN75
STUDY GUIDE

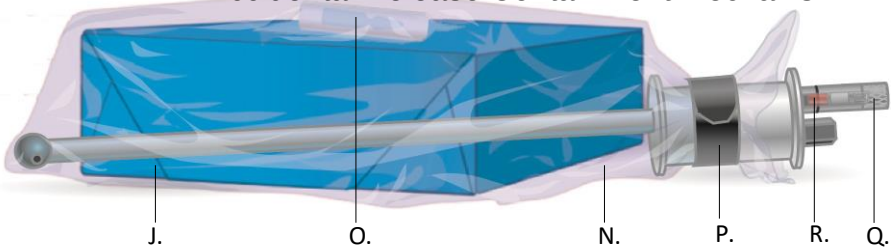


AN75 Anprolene Sterilisation Cabinet

Anprolene Sterilisation System Components

A: Front Panel
B: Cabinet Touch Screen Display
C: Impermeable Sterilisation Bag
D: Sturdy Stainless Steel Cabinet
E: Power Cord Socket (Power Supply: 115/230V) & Power Switch
F: Cooling Fan with Guard and Removable Filter
G: Abator Low Voltage Control Cable
H: Quick Connect Fitting for Exhaust Hose
I: Independent Purge and Vent Pumps
J: Wrapped Sterilisation Load
K: Purge Probe with PCD
L: Quick Release Connector
M: Accidental Release Containment Mechanism

N. Impermeable Sterilisation Bag
O. Anprolene EO Cartridge
P. Velcro® Strap with Buckle
Q. Process Challenge Device (PCD)
R. Biological Indicator (BI) inside PCD



Loaded Sterilisation Bag

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ANPROLENE AN75
STUDY GUIDE

Anprolene Sterilisation Accessories

AN7514 Anprolene Gas Refill Kits contain replacement gas cartridges, sterilisation bags, and Dosimeters in a convenient storage / dispenser box.

AN2203 *EZTEST*® Biological Indicators reliably verify that sufficient dose of EO inactivated one million Bacillus atrophaeus spores, the spore most resistant to EO gas. Biological indicators are

AN87 Dosimeter Chemical Indicators present visual Assurance that proper time, temperature and EO concentration were reached during the sterilisation cycle.

AN85 Exposure Indicator Stickers change colour to provide assurance of EO exposure at the end of the sterilisation cycle. They include convenient self-stick backing that adheres to sterile wrapping.

EO Monitoring Badges are single use badges that measure personnel exposure to airborne concentrations of EO in the user's breathing zone. Results are provided after return to Andersen for analysis.

ANDERSEN STERILIZERS

ANPROLENE AN75

Characteristics of Ethylene Oxide

- EO boils at 10.5˚C
- EO is not an effective sterilant below 20˚C
- EO is toxic
- EO is flammable
- EO is potentially human carcinogenic
- Some items sterilised in EO will require additional aeration prior to use on living tissue
- Work place exposure limits are 1ppm TWA (time weighted average)
- There are no restrictions on EO into the atmosphere, it is NOT a greenhouse gas
- At 200-700ppm you will smell EO, and you may have the following symptoms of exposure: runny eyes or nose, scratchy throat.

ANPROLENE AN75
STUDY GUIDE

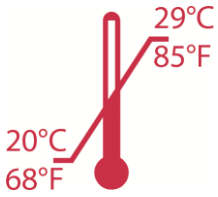
Preparing for Sterilisation

A. Environmental Considerations

1. Temperature

- Gas Storage Temperature: Store your Anprolene gas refill kits in a cool, secure area, out of direct sunlight. We recommend storage below 22°C.

- Operational Temperature: The steriliser is designed for use in an area where the temperature is not lower than 20°C or higher than 29°C.



EO FACTS: At sea level, ethylene oxide is a liquid below 10.5°C. Above 10.5°C, EO begins to boil and converts into a gas. EO does not become an effective sterilant until it is 20°C. The room where your Anprolene steriliser is installed must remain above 20°C during the entire sterilisation, ventilation *and* aeration cycle. This is especially important during the winter months!

2 Humidity

Humidity is very important to the Anprolene process. Ideal relative humidity in the preparation and packaging area is 50 % and should not be less than 35 % for best results in achieving sterilisation. Spores that might be on the instruments may become desiccated and more resistant to Anprolene sterilisation if the RH is below 30%. If humidity is below 30% use an AN1071 Humidichip in the cycle.

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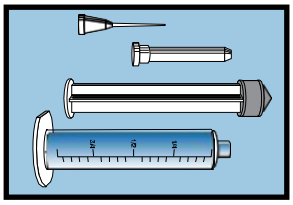
ANPROLENE AN75
STUDY GUIDE

B. Four basic steps of Pre cleaning

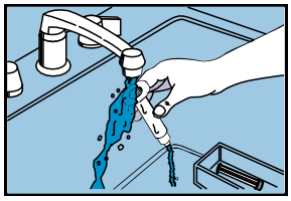
Always follow medical device manufacturer's instructions for cleaning and preparing reusable devices for EO sterilisation. In the absence of manufacturer's instructions, these general steps must be followed:



1 Disassemble

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

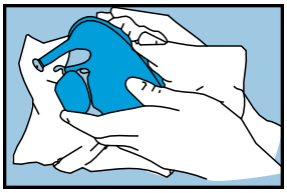
WARNING: Batteries should be removed and wrapped separately



2 Wash

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

3 Dry



Three accepted ways to dry any item prior to sterilisation with Anprolene are:

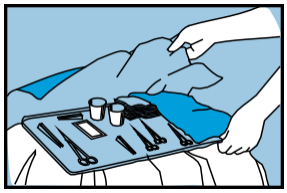
1. Towel drying;
2. Drain drying (air drying);
3. Compressed air for tubing and long lumens.

WARNING: Do not use heat or hot air to dry an item prior to sterilising it with Anprolene because it may dehydrate or desicate bacteria spores making them more resistant to the ethylene oxide gas. Any water left on an item may combine with EO to form Ethylene Glycol meaning there may be insufficient gas left to achieve sterilisation.

ANDERSEN STERILIZERS

ANPROLENE AN75
STUDY GUIDE

4. Wrap



The following types of wrapping material are approved for use with Anprolene:

- Heat sealed packaging such as non coated Tyvek®
- Sterile wrap sheets.
- Self Seal pouches (provided they are marked for EO)

Always follow manufacturer's use and shelf-life guidelines for all packaging materials.

General rule:

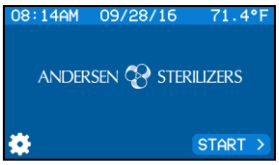
Heat sealed packaging	2 years
Self Seal pouches	6 months
Paper, cloth or wrap	30 days

HINT: Exposure indicators such as the Andersen AN85 are used to seal or label items. Indicators will change colour in the presence of EO, helping to later identify items that have been processed through an EO sterilisation cycle. They DO NOT indicate sterility

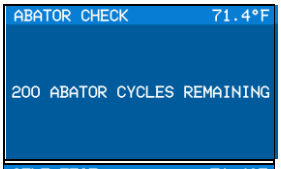
ANPROLENE AN75
STUDY GUIDE

The Sterilisation Cycle

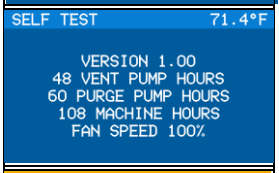
A. Performing Self Test



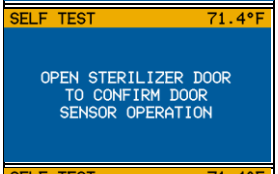
From the standby screen, press the START button to initiate a steriliser self test.

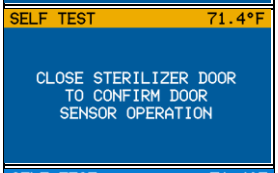


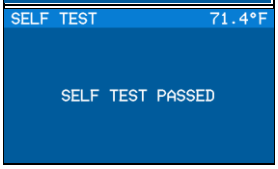
The steriliser will confirm whether an abator is attached and, if so, how many abator cycles are remaining. If the optional AN5100 Cartridge Abator is not installed, the steriliser will display a No Abator Attached screen.



Next, the steriliser will display the software version, vent pump hours, purge pump hours, machine hours, and the cooling fan speed.

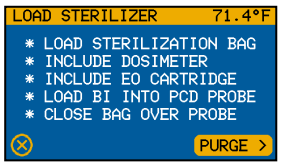






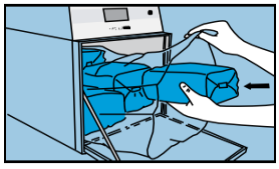
As a safety precaution, a sensor monitors the open/close state of the sterililser door during the entire sterilisation, ventilation, and aeration process. In order to confirm the sensor is functioning properly prior to initiating a cycle, the steriliser requires the user to either open or close the door as part of Self Test. Depending on the current door position, one of the screens shown at left will be displayed until a change in door state is confirmed.

If all parameters are within specification, a SELF TEST PASSED screen will appear and the user will be instructed to load the steriliser.



B. Loading the Sterilisation Bag and Steriliser

1 Place prepared items in a new sterilisation bag.



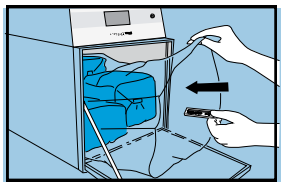
WARNING: Use only genuine Anprolene products in your steriliser. Use of other gas sources or sterilisation bags may result in operator injury and/or non-sterile loads.

WARNING: Do not reuse sterilisation bags. All items in the refill kits are for single use only.

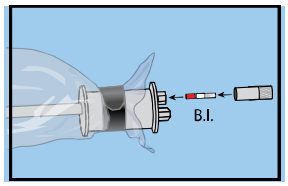
WARNING: Liquids, powders, food, and drugs may not be sterilised in ethylene oxide because it may change their chemical composition in unpredictable ways.

ANDERSEN STERILIZERS

ANPROLENE AN75
STUDY GUIDE

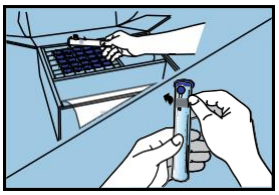


Insert chemical indicator (AN87 Dosimeter) into the least accessible part of the sterilisation bag.



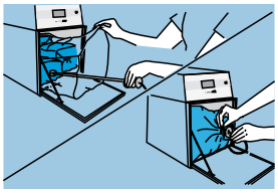
If using Process Challenge Device (PCD):Disconnect the purge probe from the purge tube by holding the bobbin with one hand and pulling the quick connect with the other hand. Load a new AN2203 Biological Indicator (BI) into the PCD chamber in the base of the purge probe.

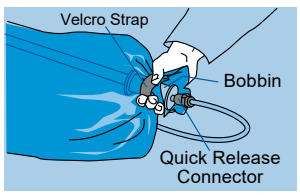
- Unscrew the aluminum cap of the PCD.
- Insert AN2203 with the red cap going in first, as shown.
- Screw the aluminum cap back onto the PCD.



Remove one Anprolene EO cartridge from the Refill Kit. Hold the trigger guard with your thumb while removing the tape; then slide the safety trigger guard down the side of the cartridge to remove it. Place the cartridge on top of the wrapped items so it can be easily manipulated through the wall of the bag. DO NOT ACTIVATE THE CARTRIDGE AT THIS TIME.

Maximum Weight for a mixed cycle 10Kg for a cycle containing absorbent materials ie large amounts of tubing, cloth or paper the maximum weight is 5Kg





Insert the purge probe into the sterilisation bag with the aluminum purge bobbin and quick release fitting at the open end of the bag. Gather the open end of the sterilisation bag around the aluminum purge bobbin. Next, wrap the Velcro strap around both the sterilisation bag opening and the purge probe bobbin, pulling it snug through its loop to completely close the sterilisation bag. If any part the sterlization bag opening is behind or under the velcro strap it could interfere with the purging cycle or allow EO to escape from the bag.

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

ANDERSEN STERILIZERS

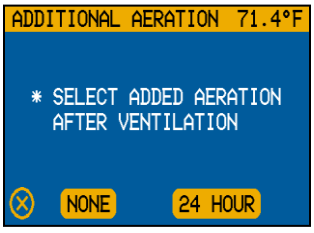
ANPROLENE AN75
STUDY GUIDE

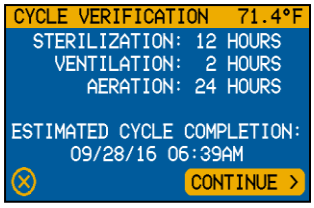
C. Starting the Cycle

1. Initial Purge With the loaded bag sealed and connected to the purge tube and the Biological Indicator loaded into the PCD that is built into the aluminum purge bobbin, excess air must now be removed from the sterilisation bag to ensure that the proper ethylene oxide concentation is achieved. Press the PURGE button to perform the initial purge.

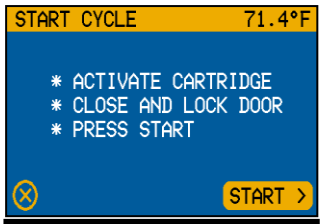
   The steriliser will purge air out of the sterilisation bag for 1 minute 30 seconds until the display reads '00:00:00'. The sterilisation bag will vacuum down and conform to the load as excess air is removed.

2. Selecting Additional Aeration After the initial purge has been completed the display instructs the operator to select the amount of Additional Aeration to perform once the 12 hour exposure and 2 hour ventilation phases are completed. If you are sterilising ítems that contain plastic and cloth fibers that are highly absorbent of EO, the 24 HOUR ADDITIONAL AERATION should always be selected. Refer to medical device manufactuer's instructions for required aeration at specified temperatures.





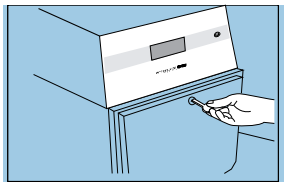
3. Cycle Verification. The steriliser then displays a screen showing the cycle options the user has selected along with an estimated cycle completion date and time. If everything is correct, the user presses the CONTINUE button to advance to the START CYCLE screen shown below. If corrections are required, the user may press the icon in the lower left hand corner of the screen to return to the previous screen or to the standby screen.



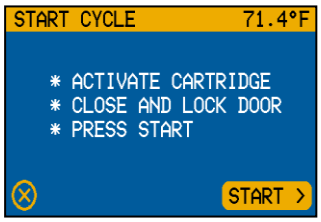
4. Starting a Cycle. Activate the cartridge by pressing the trigger button on the cartridge through the wall of the closed sterilisation bag. Make sure that the button is fully depressed. When fully depressed, the user will hear an audible click.

ANDERSEN STERILIZERS

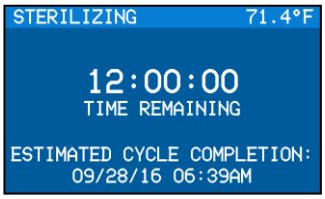
ANPROLENE AN75
STUDY GUIDE



5. Close and lock the door.



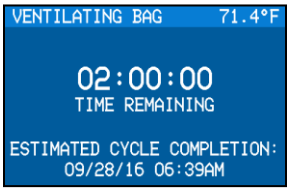
6. Press the START button. If the START button is not pressed within 5 seconds an intermittent double beep will sound at 20 second intervals to remind you to start the cycle. Once started, the ventilation system will run continuously throughout the entire cycle to prevent EO gas from entering the room.



7. Once the cycle is started, the steriliser display will count down the time remaining until the sterilisation phase of the cycle is complete along with an estimated completion date and time.

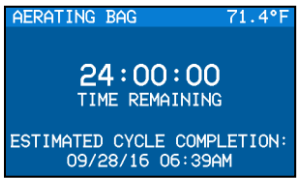
   WARNING: Never interrupt a cycle once the EO cartridge has been activated. A Close Door screen will be displayed and an alarm will sound if the door is opened during the cycle.

8. Ventilating Bag. Once the 12 hour EO exposure phase is complete, the steriliser will ventilate the sterilisation bag for 2 hours. The cabinet ventilation pump and the purge pump will run in 2 minute intervals, alternatey flushing the sterilisation bag and ventilating the cabinet.



This phase of the cycle will be displayed on the screen as shown. The steriliser display will count down the time remaining until ventilating bag phase of the cycle is complete.

Additional Aeration. If the 24 hour aditional aeration option has been selected, the unit will display an Aerating Bag screen as shown. The steriliser display will count down the time remaining until the ventilating bag phase of the cycle is complete.

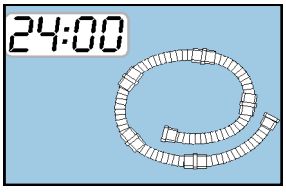


D. Extended Aeration

Once the 2 hour Ventilating Bag and 24 hour Additional Aeration (if selected) are complete, the steriliser will continue to ventilate the cabinet and flush the sterilisation bag. An Extended Aeration timer will begin on the steriliser display to keep track of the additional extended aeration time until the steriliser is unloaded. The temperature in the room must continue to remain at least 20°C during the ventilation and aeration period.

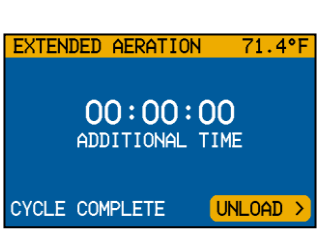
Gas absorbent items require 24 hours of Additional Aeration and, in some cases, Extended Aeration after the 12+2 hour sterilisation / ventilation cycle before they can be removed and used. This Additional and/or Extended aeration prevents chemical burns to living tissue that can be caused by residual EO absorbed during the sterilisation cycle.

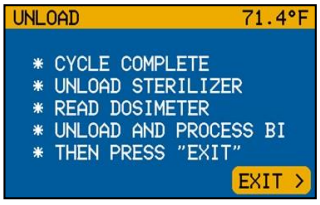
E. Aeration Guidelines



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

1. If the item's manufacturer provides instructions on aeration required after EO sterilisation, follow those guidelines.
   Two types of materials that do not require additional aeration are metal and glass.



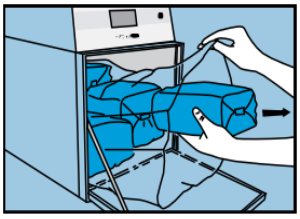


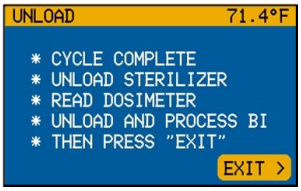
3. Unloading the Steriliser and Determining Sterility

A. Unloading The Sterilisation Bag:

1. In the Extended Aeration screen, press the UNLOAD button to display the UNLOAD screen, which will guide you through the post-sterilisation process. Follow the enumerated steps only after the 12 hour sterilisation cycle, 2-hour ventilating bag cycle, and any additional and/or extended aeration have been completed.

ANPROLENE AN75
STUDY GUIDE

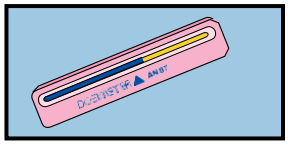


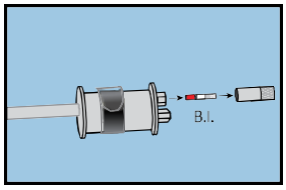


WARNING: Never remove items before the full sterilisation, ventilating bag, and aerating cycles have completed. The ventilating and aeration cycles are designed to aerate most products sufficiently, to avoid operator exposure to EO, and meet the short-term exposure level (STEL) of 5.0 ppm over 15 mins.

HINT: To unload the sterilisation bag away from the steriliser, simply detach the purge hose from the bag using the quick release connector.

2. Once you have removed all items from the sterilisation bag, read the dosimeter, and unloaded the BI (if using), press EXIT to halt the operation of the vent and purge pumps, eliminating unnecessary wear and tear, and return the steriliser to the standby screen.





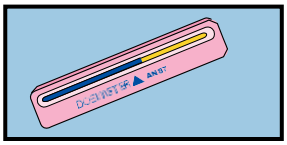
3. Examine the Dosimeter. Make sure the blue line has progressed up to or beyond the triangular calibration mark. If the blue line has *not* reached the mark, the load should not be considered sterile

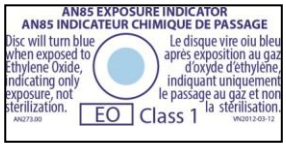
4. (IF Using)Remove Biological Indicator from PCD, activate, and incubate according to manufacturer's instructions. If the liquid changes from light orange/red to yellow after the specified incubation temperature and time, this means that viable Bacillus atrophaeus microorganisms survived the sterilisation process and indicates that one or more of the parameters for sterilisation (time, EO concentration, temperature, or relative humidity) have not been met.

5. Discard the single use sterilisation bag and spent cartridge in the ordinary trash.

ANDERSEN STERILIZERS

ANPROLENE AN75
STUDY GUIDE





B. Important Notes About Indicators:

1. Biological Indicators (BI's) The AN2203 *EZTEST* uses live spores and is the best confirmation of the success or failure of a sterilisation cycle. Always follow manufacturer's recommendations when using BI's.
2. Chemical Exposure INDICATORS such as the AN87 Dosimeter provide immediate visual confirmation that time, temperature and EO concentration were sufficient for sterilisation to occur.
3. Chemical Exposure INDICATORS such as AN85 do not prove sterilisation. The colour change only indicates that the items have been exposed to ethylene oxide.

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

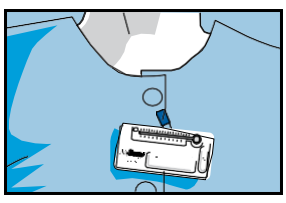
4. Safety Precautions

A. Ethylene Oxide Safety

1. Do not allow open flame or sparks near the steriliser during the sterilisaton cycle. Ethylene oxide gas is highly flammable in concentrations above 2.6% (26,000 ppm).
2. Always remove batteries from devices and wrap them separately for sterilisation.

3. Never interrupt a cycle in progress.
4. Sterilisation bags should never be reused. They are single use ítems only, as specified on the bag.

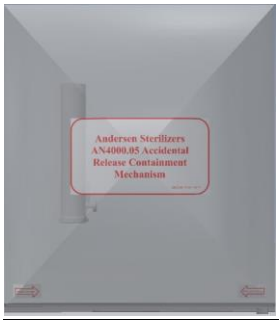
5. The 12 hour sterilisation cycle ends with a 2-hour ventilating bag cycle, which flushes fresh air around the items in the sterilisation load.

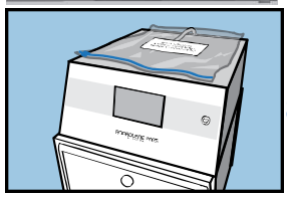


6. Personnel exposure to ethylene oxide can be monitored by using personal exposure badges. We recommend that exposure testing

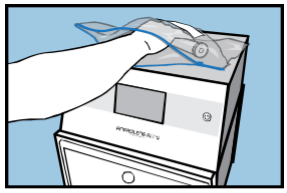
be performed on an annual basis or whenever the steriliser is relocated.

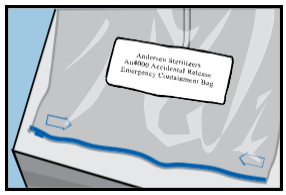
7. If an Anprolene cartridge is inadvertently activated before it is sealed inside of the sterilisation bag, it must be immediately sealed in an Andersen AN4000.05 Accidental Release Containment Mechanism (ARCM), as depicted. Immediately place the cartridge in the ARCM and seal. The ACRM should always be positioned on top of the steriliser where it is easily accessible,connected into the ARCM port on the rear of the steriliser. If the steriliser is running then the EO emitted from the cartridge will be automatically exhausted into the exhaust stack.





8. If the steriliser is not running a cycle and/or the power has been turned off, after sealing the cartridge inside the ACRM, the user must press the illuminated POWER ON button and press the START button. The steriliser will automatically conduct a SELF TEST and then turn on the vent pump which will run continuously evacuating EO from the ARCM bag containing the cartridge.





9. Leave the ARCM connected to the steriliser for a minimum of twelve hours, during which time the machine must remain powered, with the cabinet ventilation pump running. At the end of 12 hours, unseal the ARCM, and dispose of the empty cartridge.

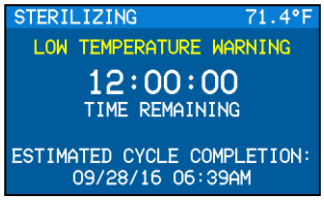
10. Always store gas cartridges and refill kits in a secure area that is kept out of direct sunlight.

ANDERSEN STERILIZERS

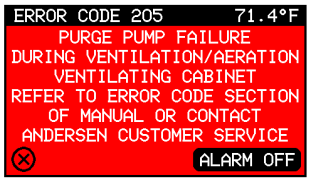
ANPROLENE AN75
STUDY GUIDE

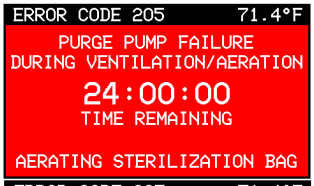
B. Malfunctions and Power Failures

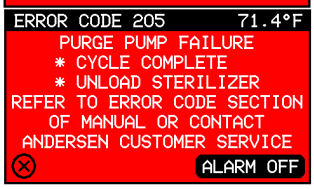
Low Temperature Warning



If at any time during the cycle the temperature around the steriliser Drops below 20°C, a low temperature warning will be displayed This may be an indication that the cycle may have been unsuccessful due to inadequate temperature. Check your sterility indicators to confirm the success or failure of the cycle.





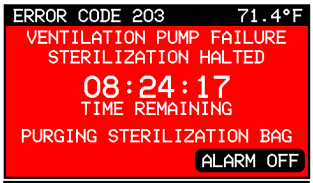


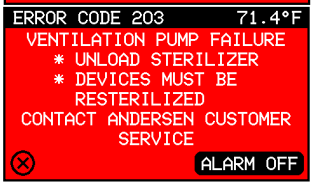
Purge Pump Failure

In the event of a purge pump failure, the vent pump will continue to ventilate the interior of the cabinet. PURGE PUMP FAILURE error message will be displayed. The sterilizer will add 24 hours of

aeration before the display indicates that you can remove

your items. **If this happens please call Customer Services for assistance on 01255 428328 or 07872 041393 out of hours.**





Vent Pump Failure

In a VENT PUMP FAILURE occurs during the sterilisation cycle, the purge pump will run continuoulsy and immediately remove EO from the sterilisation bag before the required EO exposure time is complete. **If this happens please call Customer Services for assistance on 01255 428328 or 07872 041393 out of hours.**

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Power Outage

If a POWER OUTAGE occurs, the steriliser is equipped with a battery backup that will keep track of elapsed cycle time. If the outage occurs during the sterilisation cycle, the steriliser will resume sterilisation when power returns. Items may still be considered sterile, provided there are no other errors that occur during the cycle.

If the POWER OUTAGE occurs during the ventilating bag or additional aeration cycle, the steriliser will resume aeration when power returns. Items may still be considered sterile.

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

Call Andersen Customer Service for assistance with any malfunctions,
+44 (0)1255 428328.

HINT: In the case of any steriliser malfunction or power failure, you can determine whether sterilisation has been achieved by examining the indicators included in the load (such as chemical and biological indicators).

C. Emergency Procedures

1 If liquid EO comes into contact with any part of the body, you must wash with water thoroughly for at least 15 minutes. Consult the detailed information contained on the refill kit box label and Safety Data Sheet (SDS) that appears in the user manual for further information.

2 The Safety Data Sheet (SDS) for EO Gas should be readily available at your facility.

ANDERSEN STERILIZERS

ANPROLENE AN75
STUDY GUIDE

In case of chemical emergency, please contact: Chem-Tel on 001 813 248 0585
Chem-Tel contract number MIS 0000425

For ALL other issues please call customer Services on 01255 428328
(out of hours 07872 041393)

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

- The minimum temperature needed in the room for the entire sterilisation cycle
- The length (in time) of the standard cycle
- Why the ventilation system is running during the entire cycle
- Why the sterilisation bag is purged
- How to prepare items for sterilisation
- The types of indicators that should be used in the Anprolene system
- Ethylene oxide safety and precautions
- Basic operation of your Anprolene steriliser from start to finish

Andersen Customer Service 01255 428328
www.andesensterilisers.com