

14-07-78

Precautions



Danger



- Keep all sources of ignition such as matches, lighted cigarettes, sparks, and static discharge away from the sterilizer and Steri-Gas cartridges.
- Do not incinerate empty or full Steri-Gas cartridges.
- To avoid an explosion hazard, do not place a leaking ethylene oxide cartridge in an aeration cabinet. Place or leave the cartridge in the sterilizer and run a cycle to evacuate the ethylene oxide.
- Re-enter the department only after qualified health and/or safety personnel have determined that re-entry is safe (e.g., air sampling or calculating the amount of time needed for the ventilation system to remove ethylene oxide).
- If the spill is associated with the Steri-Gas cartridge, contact 3M Clinical Research at 612-733-2374.
- Do not wear clothing contaminated with ethylene oxide until it has been laundered. Discard contaminated leather items.
- Do not puncture the cartridge by any means other than in the sterilizer.
- In accordance with OSHA ethylene oxide standard, develop a written emergency plan for leaks or spills. Ensure your personnel are trained in the emergency procedures. Refer to the OSHA standard, 29 CFR 1910.1047, and "Ethylene Oxide Leaks or Spills" on p. 6-7 of this Product Profile for detailed information.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 30 1995
Under the Fungicide, Insecticide,
Fungicide, and Herbicide Act
as amended, for the pesticide
registered under EPA Reg. No.
7182-1

50772

3M

Health Care

**3M Center, Building 275-4E-01
St. Paul, MN 55144-1000
U.S.A.
1-800-228-3957**

3M Canada, Inc.

**P.O. Box 5757
London, Ontario
Canada N6A4T1
1-800-563-2921**








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Health & Safety Information

⚠ DANGER

The 3M™ Steri-Vac™ Sterilizer/Aerator uses ethylene oxide gas to sterilize heat-and/or moisture-sensitive devices. Ethylene oxide is flammable and toxic. Follow all instructions and precautions carefully.

Toxicity	Statement of Practical Treatment/First Aid	Toxicity	
 <p>Acute Inhalation Overexposure may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), chest pain and neurotoxic effects.</p> <p>Chronic Inhalation The Occupational Safety and Health Administration (OSHA) classifies ethylene oxide (EO) as a probable human carcinogen and reproductive hazard.</p>	<p>Inhalation Get fresh air immediately after overexposure to ethylene oxide gas. Contact a physician as soon as possible.</p>	 <p>Skin Contact Liquid ethylene oxide may cause skin irritation, dermatitis and blistering.</p>	<p>Skin Contact Flush the area of contact with water for a minimum of 15 minutes. Remove contaminated clothing while flushing. Wash the affected area with soap and water. Contact a physician as soon as possible. Aerate contaminated clothing and launder before reuse. Discard contaminated leather items.</p>
 <p>Eye Contact Splashes of ethylene oxide may cause severe eye injury. High gas concentrations may cause severe eye irritation and injury.</p>	<p>Eye Contact For liquid ethylene oxide or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.</p>	 <p>Ingestion A highly unlikely route of exposure. Liquid ethylene oxide, upon ingestion, is caustic and may cause severe irritation and burns to the gastrointestinal mucosa.</p>	<p>Ingestion Call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.</p>
 <p>Flammability Ethylene oxide is flammable in concentrations from 3% (30,000 ppm) to 100%. Keep all sources of ignition such as matches, lighted cigarettes, sparks, and static discharge away from the sterilizer and cartridges.</p>	<p>Ethylene Oxide Leaks or Spills The following indicate Steri-Gas cartridge leakage:</p> <ul style="list-style-type: none"> • Liquid ethylene oxide spurting or rapidly dripping from a cartridge • A cartridge that feels very cold to the touch • Cartridge weight loss 		

ACCEPTED
with COMMENTS
in EPA Letter Dated:

78-8078-5088-4 Rev 1

MAR 30 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

7182-1

Operating Procedure

User Responsibility: Understand the 3M™ Steri-Vac™ Gas Sterilizer/Aerator Model 8XL, 2-Door Operator's Manual before using this product. Only trained personnel should use this equipment. To operate this product in a manner inconsistent with its labeling is a violation of Federal Law (USA)



The Steri-Vac sterilizer automatically controls the sterilization cycle.



Open sterilizer unload-side door.
Unload the sterilizer.
Take empty cartridge from basket and discard in non incinerated waste.



Return to standby.

Error Codes

See operator's manual for specific meaning

C1 to C20 Cautions

Will not stop the sterilization cycle.
The message is cleared automatically when the condition started

NOTICE

When the sterilization cycle is interrupted by an unload-side door remains locked. The error message will not clear until the cycle restarted from the load side.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the FIFRA Act of 1990, this pesticide is registered under FIFRA Reg. No.

7182-1

Operating Procedure

User Responsibility: Understand the 3M™ Steri-Vac™ Gas Sterilizer/Aerator Model 8X1, 2-Door Operator's Manual before using this product. Only trained personnel should use this equipment. To operate this product in a manner inconsistent with its labeling is a violation of Federal Law (USA)

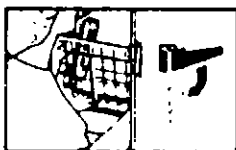


1. Place biological indicator in the sterilizer basket with load.



2. Open the sterilizer load-side door. Remove empty gas cartridge and place it in basket. Insert new 3M™ Steri-Gas™ 8-170 Cartridge.

DO NOT force the cartridge.



3. Place baskets in chamber. Close the door.



4. Select temperature (37°C or 55°C).



5. Set the aeration time (optional).



6. Start the sterilization cycle.



7. The Steri-Vac sterilizer automatically controls the sterilization cycle.



8. Open sterilizer unload-side door. Unload the sterilizer. Take empty cartridge from basket and discard in non incinerated waste.



9. Return to standby.

Error Codes

See operator's manual for specific meaning of the codes.

C1 to C20 Cautions

Will not stop the sterilization cycle.
The message is cleared automatically when the condition is corrected or a new cycle started

E1 to E20 Self-test failures

Prevents the start of a sterilization cycle. **To reset:**

- Open the door
- Press STOP
- Correct the problem

E21 to E49 Failures prior to gas puncture

Stops the cycle before gas is released. The load is not sterilized. **To reset:**

- Open the door
- Press STOP
- Correct the problem

E50 to E69 Failures during gas exposure

Stops the cycle before sterilization is complete. The door remains locked until the gas is purged from the chamber. **To reset:**

- Open the door
- Press STOP
- Correct the problem

E70 to E90 Locked chamber failures

Load not sterilized. Stops the cycle when sterilizer can not clear the gas from the chamber. **To reset:**

- Correct the problem
- Press START (if present on the display) to repeat gas removal phase.
- If gas removal again fails, call service representative

NOTICE

When the sterilization cycle is interrupted by an error code, the unload-side door remains locked. The error must be cleared and the cycle restarted from the load side

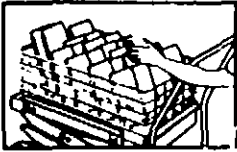
ACCEPTED
with COMMENTS
to EPA Letter B-1000

MAR 30 1995

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Fungible, and
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7182-1

Operating Procedure

User Responsibility: Understand the 3M™ Steri-Vac™ Gas Sterilizer/Aerator Model 8XL Operator's Manual before using this product. Only trained personnel should use this equipment. To operate this product in a manner inconsistent with its labeling is a violation of Federal Law (USA)

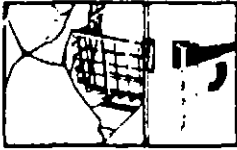


1. Place biological indicator in the sterilizer basket with load.



2. Open the sterilizer load-side door. Insert new 3M™ Steri-Gas™ 8-170 Cartridge.

DO NOT force the cartridge.



3. Place baskets in chamber. Close the door.



4. Select temperature (37°C or 55°C).



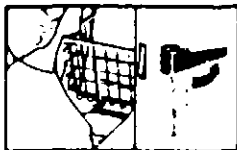
5. Set the aeration time (optional).



6. Start the sterilization cycle.



7. The Steri-Vac sterilizer automatically controls the sterilization cycle.



8. Open sterilizer door. Unload the sterilizer. Discard aerated empty cartridge in non incinerated waste.



9. Return to standby.

Error Codes

See operator's manual for specific meaning of the codes.

C1 to C20 Cautions

Will not stop the sterilization cycle.

The message is cleared automatically when the condition is corrected or a new cycle started

E1 to E20 Self-test failures

Prevents the start of a sterilization cycle.

To reset:

- Open the door
- Press STOP
- Correct the problem

E21 to E49 Failures prior to gas puncture

Stops the cycle before gas is released.

The load is not sterilized.

To reset:

- Open the door
- Press STOP
- Correct the problem

E50 to E69 Failures during gas exposure

Stops the cycle before sterilization is complete.

The door remains locked until the gas is purged from the chamber.

To reset:

- Open the door
- Press STOP
- Correct the problem

E70 to E90 Locked chamber failures

Load not sterilized.

Stops the cycle when sterilizer can not clear the gas from the chamber.

To reset:

- Correct the problem
- Press START (if present on the display) to repeat gas removal phase.
- If gas removal again fails, call service representative

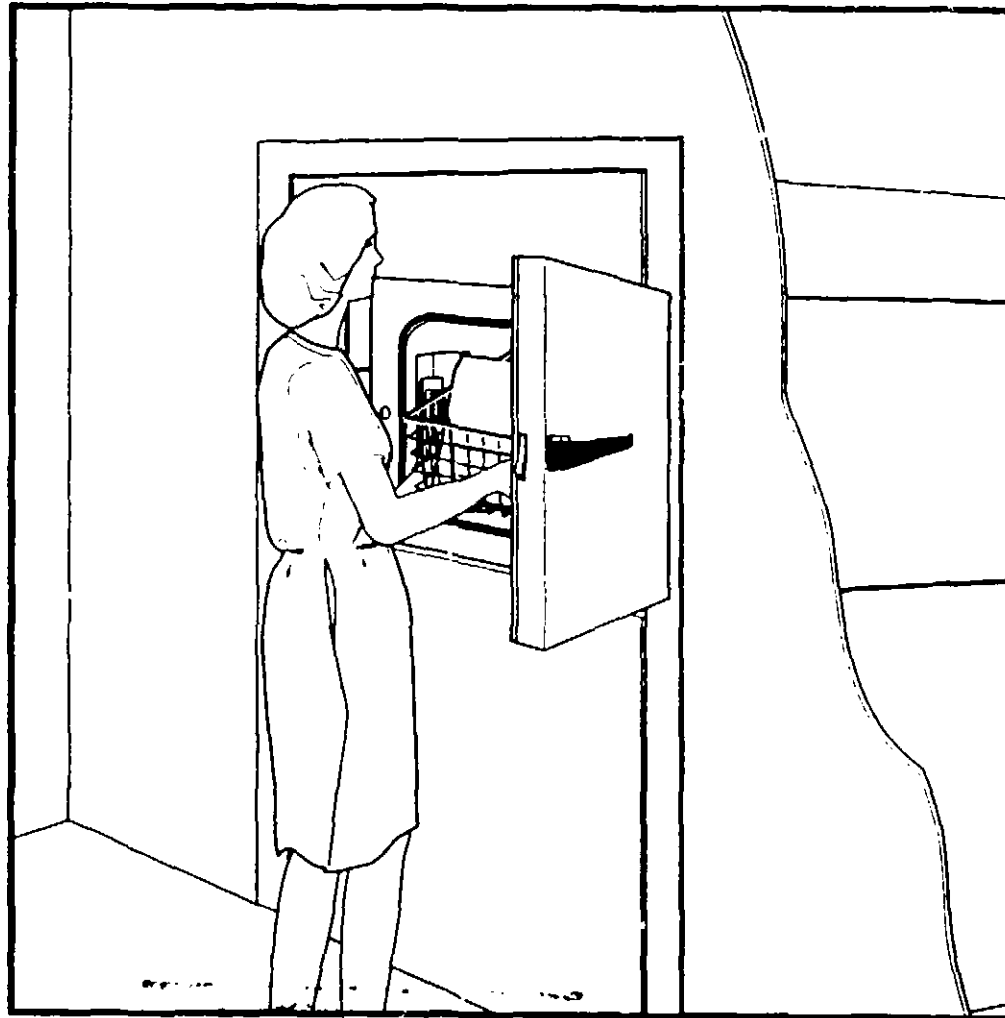
ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the provisions of the Clean Air Act
this device is registered under EPA Reg. No.
7152-1

Gas Sterilizer/Processor Model 8XL

Operator's Manual



ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

7182-1

3M Health Care

210772

Please read this manual carefully to learn how to correctly operate and maintain the 3M™ Steri-Vac™ Sterilizer/Aerator. Incorrect operation may lead to sterilization failure or serious personal injury.

This manual explains the function of the sterilizer/aerator, how to correctly sterilize heat-and/or moisture-sensitive devices, and how to maintain the sterilizer/aerator.

NOTICE
<i>Before operating the sterilizer/aerator, read and understand all of the health and safety information listed in Health & Safety Information section of this manual.</i>

ACCEPTED
with COMMENTS
by EPA LIAISON

MAR 30 1995

Under the provisions of the
Cigarette and Tobacco Tax Act
of 1933, for the products
registered under EPA Reg. No.
1182-1

INTRODUCTION

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with COMMENTS
in EPA Letter Bag
MAR 30 1995

Under the Fungicide, Insecticide,
and Herbicide Act
as amended, for the pesticide
registered under EPA Reg. No.
7182-1

FEATURES & BENEFITS

The Steri-Vac Model 8XL gas sterilizer/aerator is a compact unit designed to sterilize heat- and/or moisture-sensitive devices. It utilizes a fully automatic control system to ensure that proper sterilization conditions are met, and to minimize the possibility of operator exposure to ethylene oxide gas.

Health care facilities throughout the world have found ethylene oxide gas sterilization to be a dependable and effective method of sterilizing heat- and/or moisture-sensitive devices. There are many benefits to gas sterilization:

- All microorganisms, including resistant spores, are killed by the chemical reaction with ethylene oxide.
- Materials can be pre-packaged, then sterilized and maintained sterile until use.
- Ethylene oxide is relatively non-corrosive to plastic, metal, or rubber materials.
- Ethylene oxide can penetrate and sterilize irregular-shaped items.
- Biological monitoring systems (such as 3M™ Attest™ Biological Indicators) or chemical monitoring systems (such as 3M™ Indox™ EO Monitor Tape or 3M™ Comply™ EO Indicators) can be used to ensure that sterilization parameters are met. These monitoring systems can also be used to distinguish processed materials from unprocessed materials.
- Ethylene oxide can be used to sterilize those materials that cannot be immersed in liquid disinfectants or processed in dry heat, steam, or other chemical vapor sterilization systems.

ACCEPTED
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in EPA Letter Dated:

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7182-1

Major Features and Benefits

Following are the major features and benefits of the sterilizer/aerator:

Accurate and Dependable

The solid state electronic design provides accuracy and dependability. The electronic controller automatically stops the cycle and displays the error code if errors are detected.

Continuous Temperature Monitoring

Under normal conditions, the temperature will be maintained to within $\pm 3^{\circ}\text{C}$ of the selected cycle temperature; if the temperature sensor detects a temperature 4°C beyond the setpoint the sterilization cycle will automatically stop.

Humidification

Multiple pulses of low-temperature steam help assure proper humidification.

100% Ethylene Oxide Unit-Dose Cartridge

A unit-dose cartridge of ethylene oxide is punctured inside the chamber only when proper chamber conditions are achieved.

Negative Pressure

Throughout the cycle, the chamber remains at negative pressure relative to the room so gas can not escape into the sterilization work area. If a leak failure does occur in the chamber, room air will migrate into the chamber and the controller will automatically detect the leak and interrupt the sterilization cycle until service is performed.

Vacuum Controlled Puncture

The vacuum in the chamber provides the force to puncture the cartridge; this cannot occur unless the door is closed and a vacuum below 160 mbars exists in the chamber.

Cycle Status Display

The display on the front panel of the sterilizer shows cycle status.

2/10/78

FEATURES & BENEFITS

Manual Cycle Interrupt

The operator can manually interrupt a cycle at any time. If the cartridge of gas was punctured, the final vacuum and air purge automatically clears the chamber before the door is unlocked.

Automatic Aeration

Aeration begins automatically after the sterilization cycle. The sterilization/aeration process can be accomplished in one chamber, reducing potential gas exposure that can occur during load transfer to an aerator.

General Information

Sterilization Cycles

Temperature	Gas Exposure Time	Cycle Time <small>approx.</small>
37°C (99°F)	3 hours	4 hours 45 min
55°C (131°F)	1 hour	3 hours

NOTICE

Additional time is required after the sterilization cycle time to allow for aeration of the load. It is necessary to obtain recommended aeration times and temperatures from the device manufacturers.

Sterilant

3M Steri-Gas™ EO Cartridge 8-170 100% ethylene oxide (EO).

Weight of gas.....170 grams
Minimum gross weight.....185 grams

Sterilant Specifications

Refer to the Consumer Product Profile 3M Steri-Gas EO Cartridges.

Shelf Life and Gas Weight

Refer to the Consumer Product Profile 3M Steri-Gas EO cartridges.

Chamber Dimensions

Width..... 51 cm (20 in)
Depth..... 97 cm (38 in)
Height..... 46 cm (18 in)
Diagonal..... 117 cm (46 in)
Volume..... 224 l (7.9 cu ft)

Basket Dimensions


Width..... 46 cm (18 in)
Depth..... 91 cm (36 in)
Height..... 20 cm (8 in)






Water Requirements

Distilled water is added by the operator to a reservoir with a 7.5 liter (2 gal) capacity.

HEALTH & SAFETY

Please read and understand all instructions before using the Steri-Vac sterilizer/aerator.

 <p>DANGER</p>	<p>The Steri-Vac sterilizer/aerator uses ethylene oxide gas to sterilize heat-and/or moisture-sensitive devices. Ethylene oxide is flammable and toxic. Follow all instructions and precautions carefully.</p>
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Toxicity	Statement of Practical Treatment/First Aid	Toxicity	Statement of Practical Treatment/First Aid
 <p>Acute Inhalation Overexposure may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), chest pain and neurotoxic effects.</p> <p>Chronic Inhalation The Occupational Safety and Health Administration (OSHA) classifies ethylene oxide (EO) as a probable human carcinogen and reproductive hazard.</p>	<p>Inhalation Get fresh air immediately after overexposure to ethylene oxide gas. Contact a physician as soon as possible.</p>	 <p>Skin Contact Liquid ethylene oxide may cause skin irritation, dermatitis and blistering.</p>	<p>Skin Contact Flush the area of contact with water for a minimum of 15 minutes. Remove contaminated clothing while flushing. Wash the affected area with soap and water. Contact a physician as soon as possible. Aerate contaminated clothing and launder before reuse. Discard contaminated leather items.</p>
 <p>Eye Contact Splashes of ethylene oxide may cause severe eye injury. High gas concentrations may cause severe eye irritation and injury.</p>	<p>Eye Contact For liquid ethylene oxide or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.</p>	 <p>Ingestion A highly unlikely route of exposure. Liquid ethylene oxide, upon ingestion, is caustic and may cause severe irritation and burns to the gastrointestinal mucosa.</p>	<p>Ingestion Call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.</p>
 <p>Flammability Ethylene oxide is flammable in concentrations from 3% (30,000 ppm) to 100%. Keep all sources of ignition such as matches, lighted cigarettes, sparks, and static discharge away from the sterilizer and cartridges.</p>	<p>Ethylene Oxide Leaks or Spills The following indicate Steri-Gas cartridge leakage:</p> <ul style="list-style-type: none"> • Liquid ethylene oxide spurting or rapidly dripping from a cartridge • A cartridge that feels very cold to the touch • Cartridge weight loss 		

HEALTH**Agency Listings**

The Steri-Vac gas sterilizer/aerator is listed with the Underwriters Laboratories, Inc. (UL).

This internationally-recognized laboratory has inspected and evaluated the Steri-Vac system. They perform on-going inspections of the manufacturing facilities. Additional international approvals have also been received or are pending. All approved labels are located on or near the serial plate of the sterilizer.

EPA Registration

Manufacturers of chemical pesticides, such as ethylene oxide, are required to register their product label claims with the Environmental Protection Agency (EPA). Based on these claims, the EPA requires the manufacturer to demonstrate that the product meets certain performance standards prior to issuing a registration number. The EPA registration number, which appears on all Steri-Gas cartridges, is 7182-1.

OPERATION**Introduction**

This section of the manual describes how to correctly operate the sterilizer/aerator. Included are procedures for turning on the sterilizer, preparing items for sterilization, and correctly performing the sterilization procedure.

A detailed description of the controls and indicators is also provided. Before operating the sterilizer/aerator, read and understand the descriptions for each of the controls and indicators.

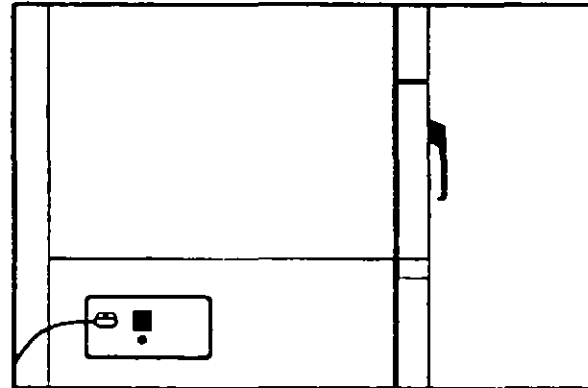
NOTICE

User Responsibility. Only healthcare professionals or other appropriately trained personnel in health care and industrial use areas should use this equipment. It is a violation of Federal Law (USA) to use this product in a manner inconsistent with its labeling. Injury to person or property can result unless the operating instructions are followed carefully.

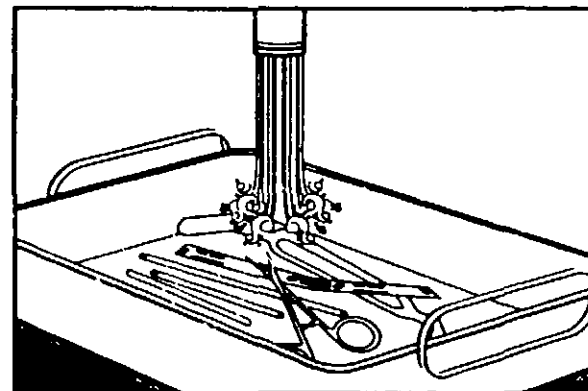
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OPERATING PROCEDURE**Step 1****Power on the sterilizer.**

Turn on the power switch (located on the left side of the sterilizer). Leave the power switch on at all times to simplify operation and allow the sterilizer electronics to continually monitor sterilizer functions.

**Step 2****Prepare items for sterilization.**

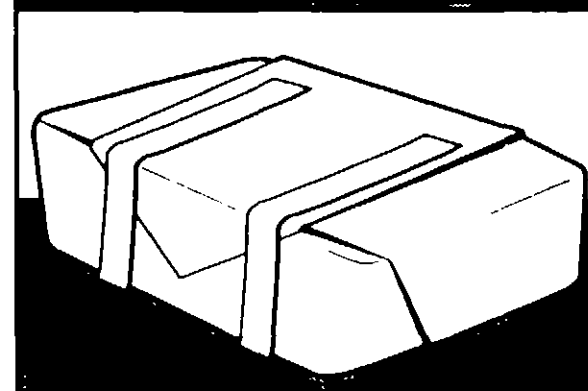
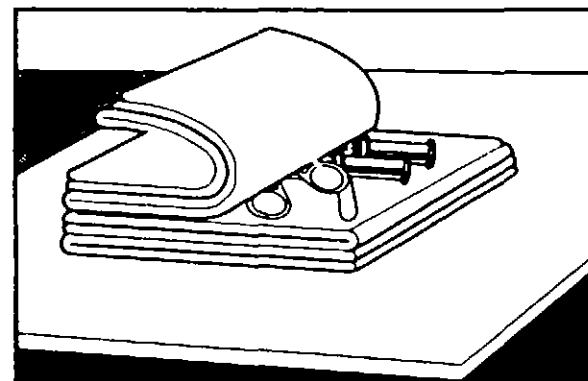
Thoroughly clean and rinse all items to be sterilized to remove mucous, dried blood, or other organic matter. Dry the items to remove water droplets.

**Step 3****Package items for storage.**

Before sterilizing, package items that will be stored before they are used. Use only packaging materials that are intended for ethylene oxide sterilization.

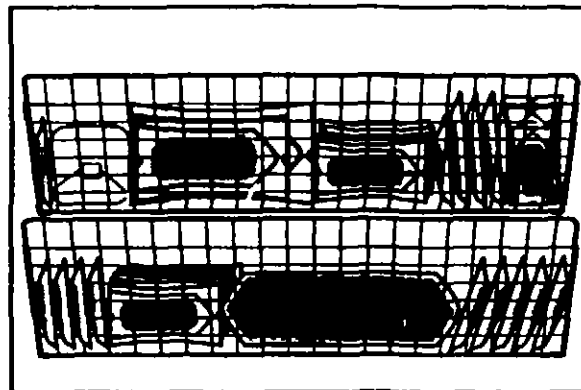
NOTICE

The packaging area should have a minimum room humidity of 35% RH.

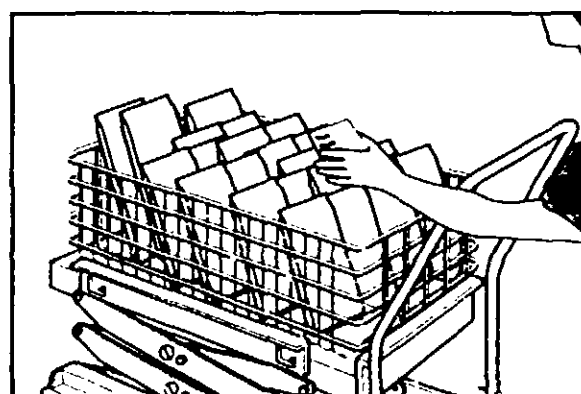


OPERATING

Step 4 Load the sterilizer baskets.
When loading items in the baskets, leave some space between each item. Place packages on edge. When arranging paper-plastic pouches, place the plastic side of one pouch against the paper side of another pouch.

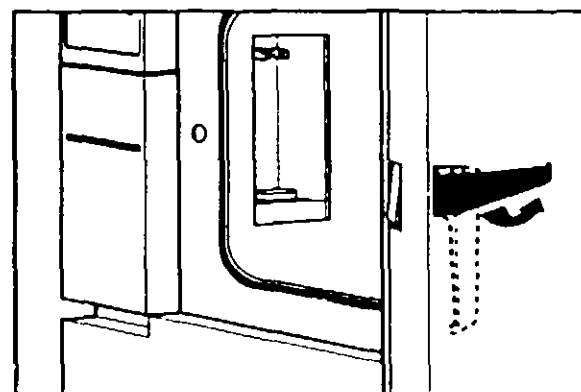


Step 5 Place biological indicator (BI) in the sterilizer basket with load.
A BI should be included with each load to monitor the sterilization process.
The BI or BI test pack should be representative of the materials being sterilized and placed in the center of the load.



⚠ DANGER
To minimize exposure to EO when retrieving the biological indicator, ensure that it is easily identifiable when unloading

Step 6 Open the sterilizer door.
Turn the handle counter-clockwise to open the door.



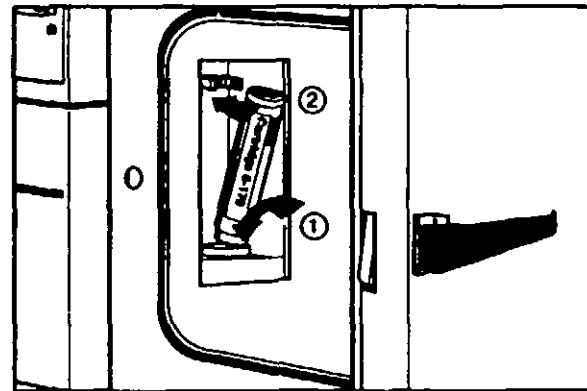
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OPERATION

Step 7

Insert gas cartridge.

Insert a Steri-Gas cartridge 8-170 into the retainer ring on the cartridge holder inside the chamber. Push the cartridge down and slightly inward until the cartridge "snaps" into position.



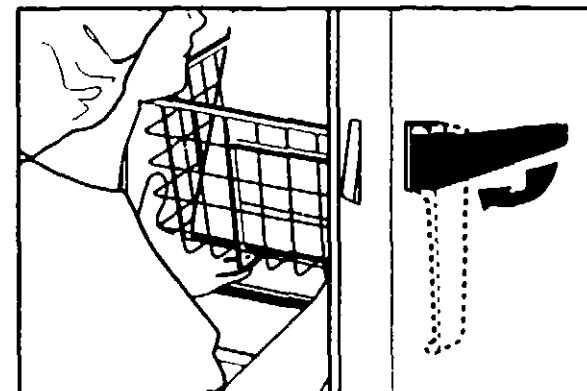
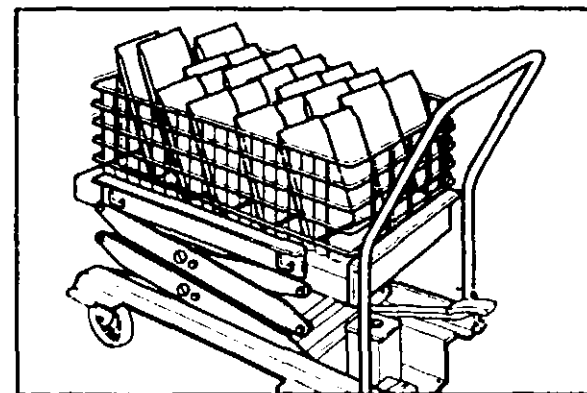
⚠ DANGER

DO NOT force the cartridge. Use of excessive force could result in premature puncture of the cartridge and subsequent exposure to ethylene oxide. Remove the cartridge from the holder and check for obstruction.

Step 8

Place baskets in chamber.

Place the loaded baskets in the sterilizer chamber. Close the door and turn the door handle clockwise until it is vertical.



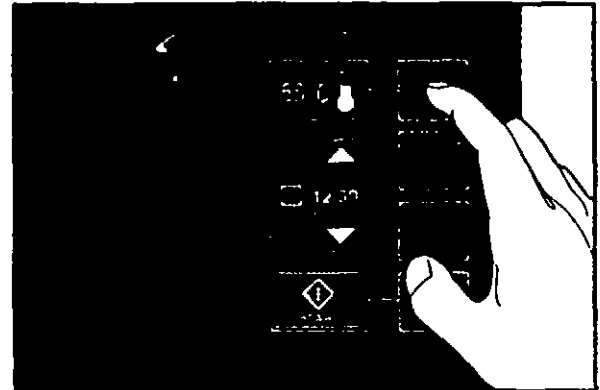
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OPERATING PROCEDURE

Step 9

Select temperature.

Press the temperature select switch until the desired sterilization/aeration temperature is displayed. Select the temperature according to manufacturer's recommendations for the devices in the load.



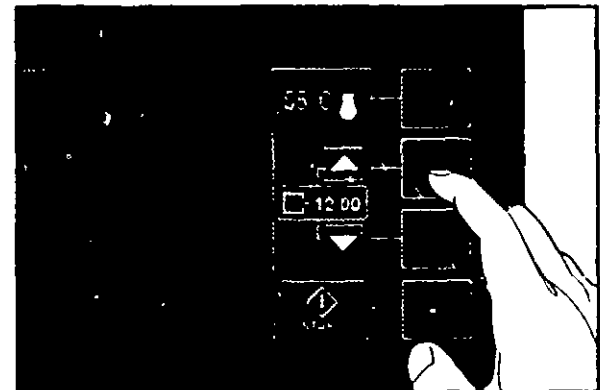
NOTICE

The cycle setup is cancelled if the start switch is not pressed within 5 minutes of setting the cycle parameters. The setup can also be cancelled by pressing the STOP switch.

Step 10

Set the aeration time.

Pressing the aeration time preset control arrows change the time in one hour increments until the desired aeration time is displayed.



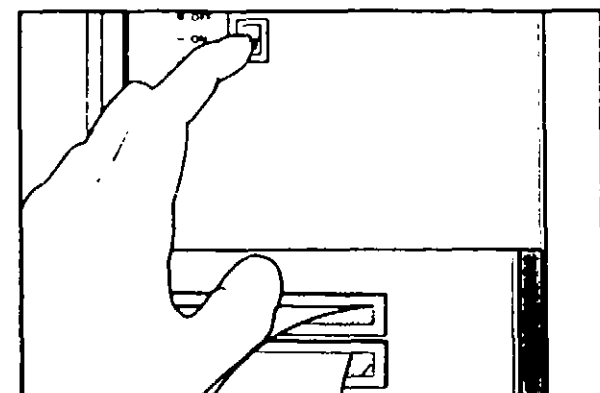
NOTICE

The sterilizer displays the aeration time used in the previous cycle. Presetting the aeration time is optional. If no aeration time is preset, the sterilizer will automatically aerate the load until the operator stops the cycle.

Step 11

Turn on printer.

Press the printer "on" switch (located behind printer/water door) before starting the cycle if a cycle printout is desired.



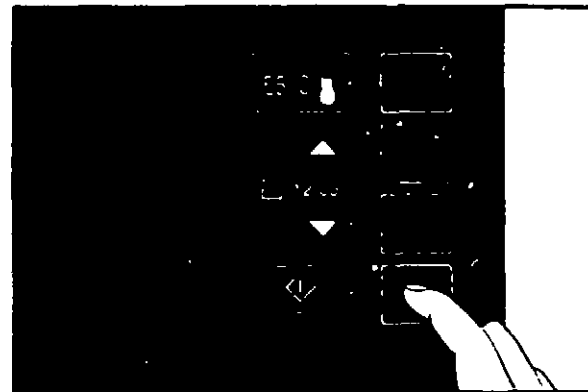
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OPERATING PROCEDURE

Step 12

Start the sterilization cycle.

Press the START switch to begin the sterilization/aeration cycle. The cycle continues automatically until completion. The front panel displays cycle information

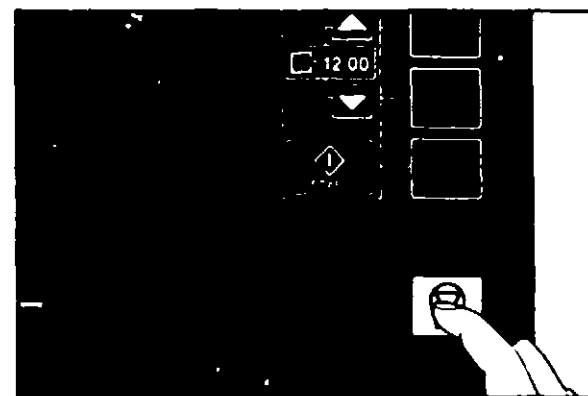


Front panel displays cycle sequence

Precondition Phase	Gas Expose Phase	Aeration Phase
<ul style="list-style-type: none"> • Preheat • Chamber vacuum • Humidification 	<ul style="list-style-type: none"> • Cartridge punctured • Gas exposure • Gas removal 	<ul style="list-style-type: none"> • Sterilization cycle complete • Aeration

Interrupting the sterilization cycle.

Press the STOP switch at any time to interrupt the cycle.



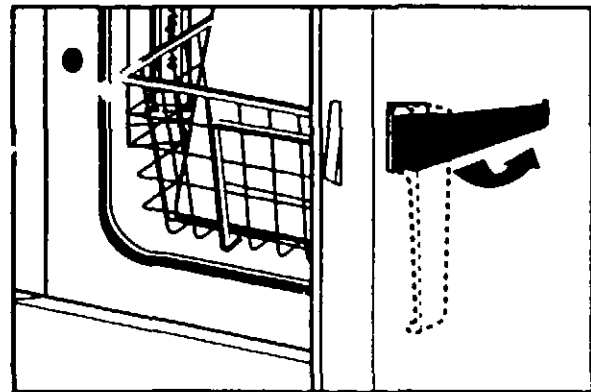
NOTICE

If the cycle is interrupted before gas exposure, the door will unlock immediately.
If the cycle is interrupted after the gas cartridge is punctured, the machine must go through final pump down and purge before the door will unlock.

OPERATING PROCEDURE**Step 13****Open sterilizer door.**

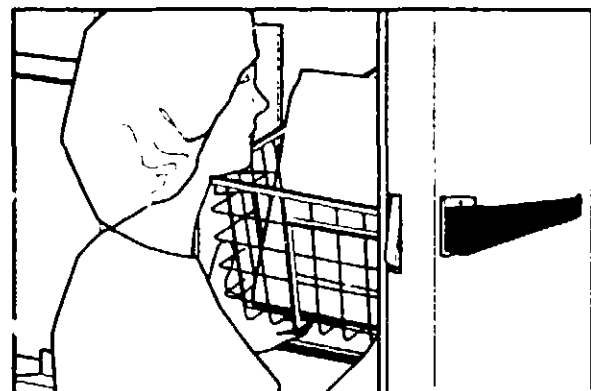
During aeration cycle, appearance of the "door unlocked" symbol will indicate when the door can be opened.

To open the door, turn the handle counter clockwise, allow approximately 30-60 seconds for the chamber pressure to equalize with the room pressure.

**Step 14****Unload the sterilizer.**

Once sterilization/aeration is complete, remove the baskets of sterilized/aerated items from the chamber.

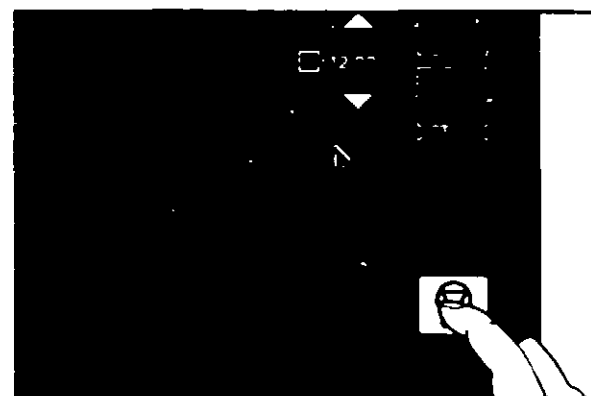
Remove and aerate the empty gas cartridge with the load. After aeration, the cartridge can be discarded with non incinerated waste.

**⚠ DANGER**

The load continues to release EO until it is completely aerated. Minimize handling or sorting an incompletely aerated load.

Step 15**Return to standby.**

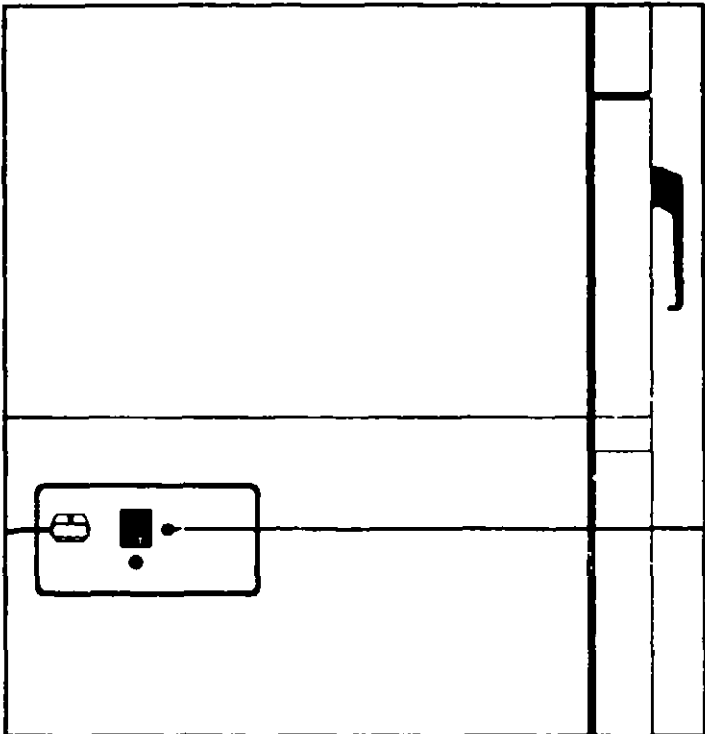
To end the cycle after the load has been removed, press the STOP switch while the door is open. This places the sterilizer in the standby mode, ready for the next cycle.



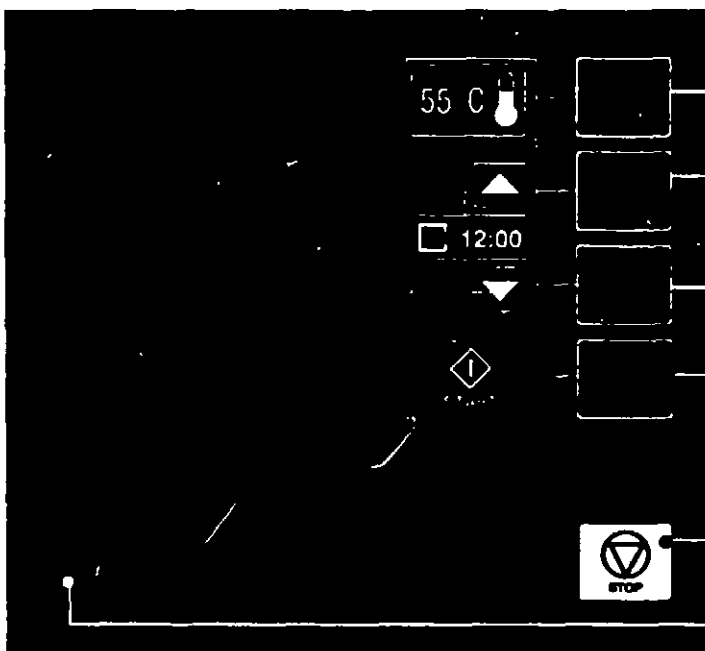
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STERILIZER & CONTROL

The following switches are used to control sterilizing operations and the control panel display shows status during sterilization:



1 Power Switch.
 Turns the power to the sterilizer on and off. This switch should be left on at all times to simplify operation.



2 Temperature Select Switch.
 Press to select the desired chamber temperature

3 Aeration Preset Time Increase Arrow.
 Press to increase the aeration time by one hour.

4 Aeration Preset Time Decrease Arrow.
 Press to decrease the aeration time by one hour.

5 START Switch.
 Press to start the automatic sterilization cycle.

6 STOP Switch.
 Press at any time to interrupt the cycle.

7 Power-On Indicator.
 Shows that power has been turned on to the sterilizer.

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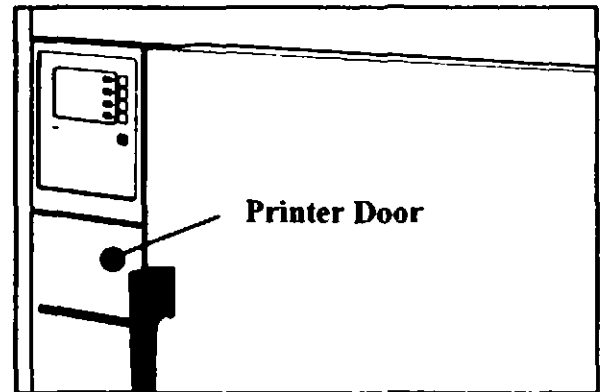
OPERATION

Introduction

The built-in thermal printer provides easy to read information on each sterilization cycle. The printout is helpful in analyzing sterilizer performance and can be retained to meet cycle verification policies.

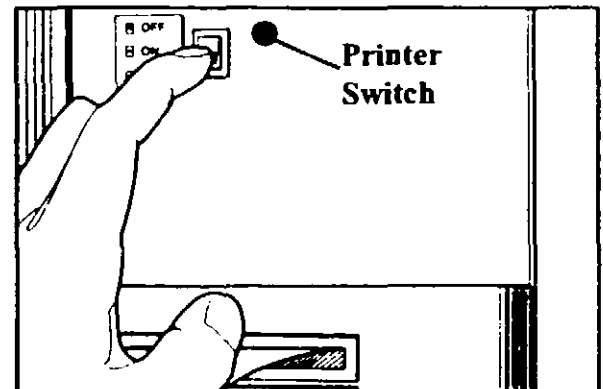
Location

The printer is installed in the front of the sterilizer behind the access door for the water reservoir.



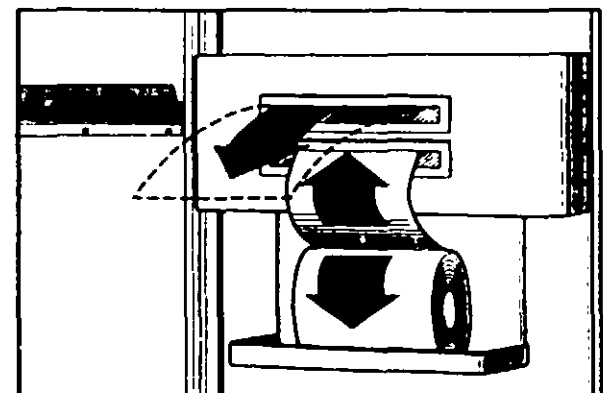
Operation

To operate the printer, press the printer switch to the ON position before starting the sterilization cycle. The switch has three positions: OFF, ON, and FEED.



Load Paper

To load printer paper, install the roll in the feed mechanism as shown in this diagram. Press the switch to the FEED position to advance the paper through the printer and the paper slot in the access door.



NOTICE

To avoid damage to the print head, use only paper intended for this printer.

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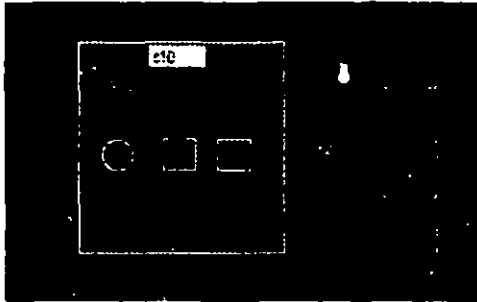
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CAUTION & ERROR CODES

Introduction

The Steri-Vac gas sterilizers use an extensive list of codes to provide information to the operator. "Cautions" do not indicate a failure, but are informational messages to alert the operator to some special situation. Other codes indicate an "error" occurred which stopped the cycle.

Often the code is sufficient to provide very specific information regarding the failure that occurred, giving the service representative enough information over the phone to indicate the likely failed component. In some of these situations, the service representative will be able to recommend a correction that may avoid a service call.

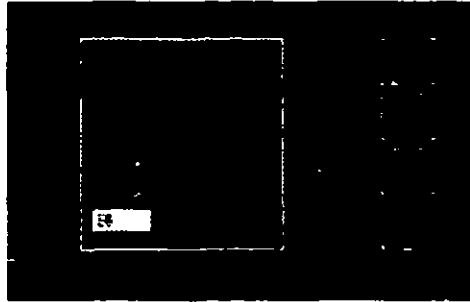


Caution Codes

C1 to C20

Will not stop the sterilization cycle.

The message is cleared automatically when the condition is corrected or a new cycle started.



Self-test Errors

E1 to E20

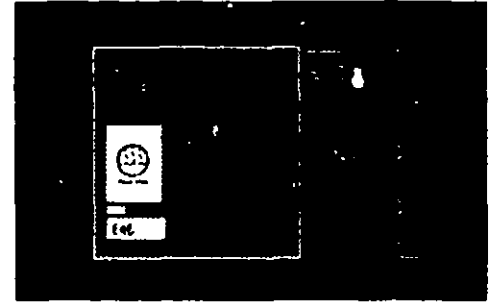
Prevents the start of a sterilization cycle.

- To reset:
- Open the door
 - Press STOP
 - Correct the problem

If error does not clear call service representative.

If the error indicates that the problem is in the controller electronics, it may be necessary to turn power off to stop the alarm.

These errors are detected before the sterilization cycle has begun, therefore, there is no gas in the chamber. The sterilizer will issue short "beeps" to alert the operator of the error. Open the door and press the STOP key to clear the error message and alarm.



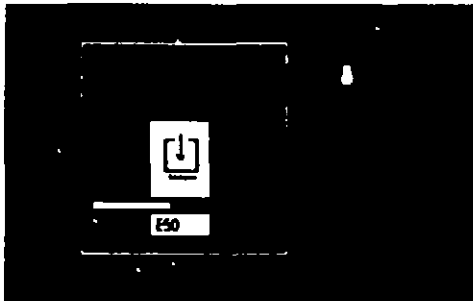
Errors in Precondition Phase

E21 to E49

Stops the cycle before gas is released. The load is not sterilized.

- To reset:
- Open the door
 - Press STOP
 - Correct the problem

These errors are detected before gas has been injected into the chamber so the load is not sterilized. The sterilizer will issue short "beeps" to alert the operator of the error. The sterilizer will automatically release any vacuum within the chamber to allow the door to be opened—this may take approximately one minute. Turning the sterilizer handle will stop the alarm while the chamber vacuum is being released. Once the door can be opened, press the STOP key to clear the error and return to standby.

CAUTION

Errors in Gas Expose Phase E50 to E69

Stops the cycle before sterilization is complete. The door remains locked until the gas is purged from the chamber.

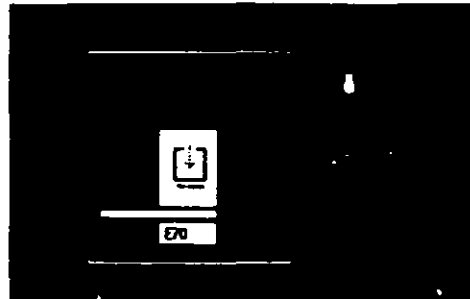
- To reset:*
- *Open the door*
 - *Press STOP*
 - *Correct the problem*

These error codes indicate that gas should have been injected into the chamber, but that the sterilization process was not correct so the load is not sterilized. The sterilizer will automatically advance to final vacuum and purge to remove gas from the chamber. This will take approximately 45 minutes.

At the end of this mandatory gas removal, the sterilizer will unlock the door following the same procedures as required for normal sterilization cycles; in other words, if the cycle was set up with a mandatory aeration time, the sterilizer will perform that mandatory aeration before unlocking the door.

When the door is unlocked, a continuous alarm is turned on while the sterilizer aerates the load. The alarm will stop when the door handle is turned to release the vacuum in the chamber.

To continue aerating the load without the alarm, turn the handle back clockwise. The alarm will sound again when the door is opened.



Locked Chamber Errors E70 to E79

Stop the cycle. The load may be sterilized, but the sterilizer cannot clear the gas from the chamber.

- To reset:*
- *Correct the problem*
 - *Press START (if present on the display) to repeat gas removal phase*
 - *If gas removal again fails, call service representative*

These error codes indicate that the gas removal could not be completed or could not be verified. The chamber is left locked. A slow "beep" alarm will come on.

If the error code allows a restart of the gas removal phase, the START switch will be active. After correcting the problem, press START to perform the gas removal. The alarm will stop and the sterilizer will automatically rerun final vacuum and purge to remove gas from the chamber.

This will take approximately 45 minutes. If the gas removal is then successful, the sterilizer will unlock the door following the same procedure as required for normal sterilization cycles; in other words, if the cycle was set up with a mandatory aeration time, the sterilizer will perform that mandatory aeration before unlocking the door.

If the sterilization cycle was complete before the problem in the gas removal phase was detected, the load is considered sterilized. If another error had been detected prior to gas removal, a continuous alarm is turned on while the sterilizer aerates the load. The alarm will stop when the door handle is turned to release the vacuum in the chamber.

To continue aerating the load without the alarm, turn the handle back clockwise. The alarm will sound again when the door is opened.

CAUTION & ERROR CODES

Use the following tables to isolate the possible causes and corrective actions for the messages displayed on the information display of the sterilizer. Call your 3M service representative when indicated on the chart, if a code appears that is not listed, or if you have any questions. Codes with "●" are used on accessories to the Steri-Vac sterilizers.

Caution Messages (Will not stop the cycle)

Code	Message	Possible Causes	Corrective Action
● C1	Low air in exhaust hood (Mandatory aeration performed automatically)	External fan malfunction Airflow sensor	Check fan and fan ducts Call service representative
C2	Low water in standby	Reservoir needs water	Add distilled water
C3	Power interruption	Power outage	Cycle restarts automatically
C4	Lost compressed air	No compressed air	Check compressor, air lines
C5	Temperature loss during aeration	Heater control failure	Call service representative (Increase aeration time)
● C6	Unload side door open	Unload-side door must be closed	Close door
C7	Door locked	Lost compressed air Switch Failure	Check compressor; air lines Call service representative
C8	Printer paper error	Printer out of paper	Replace printer paper
C9	Printer error	Printer or electronics	Call service representative
● C10	Abator caution	Abator problem during gas removal	Refer to error messages displayed after cycle complete
C11	Replace used gas cartridge	Used cartridge or cartridge missing	Install new cartridge
C12	Sensor calibration needed	Sensor is out of calibration	Call service representative

Self-Test Errors (Prevents the start of a cycle)

Code	Message	Possible Causes	Corrective Action
E1	Processor memory failure	Electronics	Call service representative
E2	Program memory failure	Electronics	Call service representative
E3	Processor failure	Electronics	Call service representative
E4	Chamber temperature sensor fail	Bad sensor or connection	Call service representative
E5	Heatsink temperature sensor fail	Bad sensor or connection	Call service representative
E6	Pressure sensor failure	Bad sensor or connection	Call service representative
E7	Pressure failure w/door open	Bad sensor or connection	Call service representative
E8	End wall temp sensor fail	Bad sensor or connection	Call service representative
E9	Middle wall temp sensor fail	Bad sensor or connection	Call service representative
E10	Low water	Reservoir needs water	Add distilled water
E11	No compressed air	Compressed air source off	Check air pressure
E12	RH sensor failure	Bad sensor or connection	Call service representative
E13	No gas cartridge	Need new gas cartridge Sensor error	Replace cartridge Call service representative
E14	Load door open	Door not closed Switch failure	Close door-restart Call service representative

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CAUTION & ERROR

Self-Test Errors (Prevents the start of a cycle) Continued from previous page...

● E15	Unload door open	Door not closed Switch failure	Close door-restart Call service representative
● E16	Unload door unlocked	Door lock hung up on bolt Switch failure	Turn handle to vertical position Call service representative
E17	Load door unlocked	Door lock hung up on bolt Switch failure	Turn handle to vertical position Call service representative
E20	Chamber needs to cool down	Recent warm cycle	Open door, let chamber cool

Errors detected in the precondition phase (Stops the cycle)

Code	Message	Possible Causes	Corrective Action
E21	No vacuum	Blockage at vacuum port No compressed air (venturi systems) Vacuum system failure	Clear chamber vacuum port Check air pressure Call service representative
E22	Initial pumpdown timeout	Improper air pressure (venturi systems) Vacuum system failure	Check air supply Call service representative
E23	Chamber preheat timeout	Temperature control failure	Call service representative
E24	Heatsink preheat timeout	Temperature control failure	Call service representative
E25	Chamber over-temp	Over temp in precondition phase	Call service representative
E26	Chamber under-temp	Under temp in precondition phase	Call service representative
E27	Vacuum failure	Leak in chamber Vacuum system failure	Call service representative
E28	No humidity injected	Humidity system failure Water level sensor failure Moisture injection failure	Call service representative
E29	Low humidity	Very dry load Moisture injection failure	Prehumidify @ 35% RH Call service representative
E30	RH sensor valve failure	Valve or control failure	Call service representative
E31	Vacuum leak test failure	Failed the vacuum leak test	Call service representative
E32	Vacuum level at puncture	Improper vacuum level before puncture	Call service representative
E33	Interlock relay failure	Electronics	Call service representative
● E38	Nitrogen empty	Nitrogen tank empty	Replace nitrogen tank
● E39	No nitrogen injection	Nitrogen pressure sensor failure Nitrogen injection failure	Replace nitrogen tank Call service representative
E40	User interruption	User pressed STOP switch	Restart the cycle

Errors detected in the gas expose phase (Stops the cycle)

Code	Message	Possible Causes	Corrective Action
E50	Empty cartridge	Empty cartridge used Puncture mechanism failure	Use new cartridge Call service representative
E51	Chamber vacuum leakage	Air leak into chamber	Call service representative
E52	Under temperature failure	Electronics	Call service representative
E53	Over temperature failure	Electronics	Call service representative
E54	Extended power outage	Could not restart the cycle	Rerun the cycle

CAUTION**Errors detected in the gas expose phase (Stops the cycle) Continued from previous page...**

E55	Undefined condition at startup	Processor error Interlock relay failure	Call service representative Call service representative
E60	User interruption	User pressed the STOP switch	Rerun the cycle

Locked chamber errors (operator or service representative must restart)

Code	Message	Possible Causes	Corrective Action
E71	Final pumpdown timeout	Improper air pressure (venturi systems) Vacuum system failure	Check air supply, press START Call service representative
E72	Obstructed air inlet	Bacterial air filter failure	Attempt restart, press START Call service representative
E73	Vacuum sensor failure	Electronics	Call service representative
E75	Low gas injected	Partial puncture	Call service representative
E76	Interlock relay failure	Electronics	Call service representative
E77	Puncture pin in up position	Puncture mechanism failure	Attempt restart, press START Call service representative
● E80	Abator lockup	Abator not operating Electronics	Check power, press START Call service representative
● E81	Abator over-temp failure	Abator heater failure	Allow to cool, press START Call service representative
● E82	Abator under-temperature failure	Abator not up to temperature	Attempt restart, press START Call service representative
● E83	Abator blower failure	Airflow system failure	Call service representative
● E84	Abator filter failure	Airflow filter plugged	Call service representative

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PREVENTIVE MAINTENANCE**Introduction**

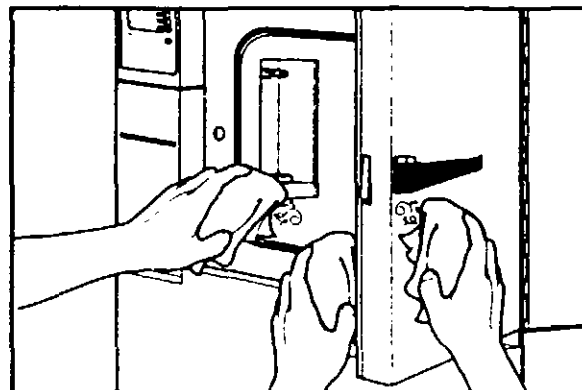
Performing preventive maintenance at scheduled intervals is a critical part of ensuring that the Steri-Vac sterilizer/aerator model 8XL continues to produce quality results. This should be done by a trained 3M service representative or a trained maintenance person from the institution.

Perform the following preventive maintenance procedures at the recommended intervals.

Daily Cleaning

Using a soft cloth dampened with mild soap and warm water, clean the following parts of the sterilizer/aerator daily:

- Chamber walls and floor
- Outer lip of chamber
- Inside surface of chamber door
- Outer surface of cabinet
- Door gasket

**Compressed Air Line Filters****Daily**

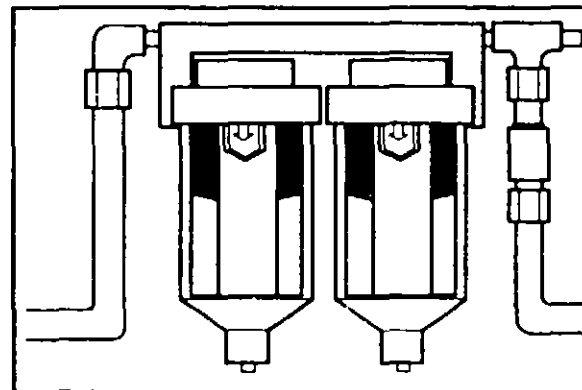
At the beginning of each work day, drain any moisture or oil that has collected in the bottom of the air filter reservoirs.

Every 6 Months

Replace the mist separator element at least every six months.

Every 12 Months

Replace the micromist separator element at least every 12 months



ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
7182-1

⚠ WARNING

These filters are provided for precautionary purposes only, and not as a replacement for a clean air supply. A contaminated air supply can quickly reduce the effectiveness of the filter element, resulting in early machine failure and possible ethylene oxide exposure to the operator. The customer is solely responsible for providing an oil-free and dry (to a dew point of 50°F) air supply

3M AUTHORIZED

3M Health Care has established a worldwide service organization to provide trained technicians to care for your equipment. For servicing information in the USA, contact your local 3M service representative or the 3M Health Care Service Center at the following address:

3M Service Center
3M Center, Building 275-4W-05
St. Paul, MN 55144-1000
800-292-6298

In Canada, contact:

3M Canada, Inc.
P.O. Box 5757
London, Ontario N6A 4T1
1-800-268-9696

For servicing information outside of the USA or Canada, contact the local 3M subsidiary.

⚠ WARNING

Only authorized personnel should repair or replace parts. Tampering or unauthorized alterations in the equipment will void the manufacturer's warranty and may result in early machine failure or personal injury.

⚠ WARNING

This equipment is operated with hazardous voltage which can shock, burn, or cause death.

Preventive Maintenance Agreement

For your convenience, 3M provides a preventive maintenance agreement (PMA) for purchase with the Steri-Vac equipment. The PMA assures you of periodic maintenance of your sterilizer and emergency services. Contact your local 3M Health Care service representative or the 3M Health Care Service Center at the above address for PMA information.

Service Manuals

Service Manuals are available for any 3M Steri-Vac gas sterilizer/aerator. These manuals contain illustrated parts lists, troubleshooting guides, details of operation, schematics, and preventive maintenance routines. Request the manuals desired in writing or by calling the 3M Health Care Service Center at the address listed above

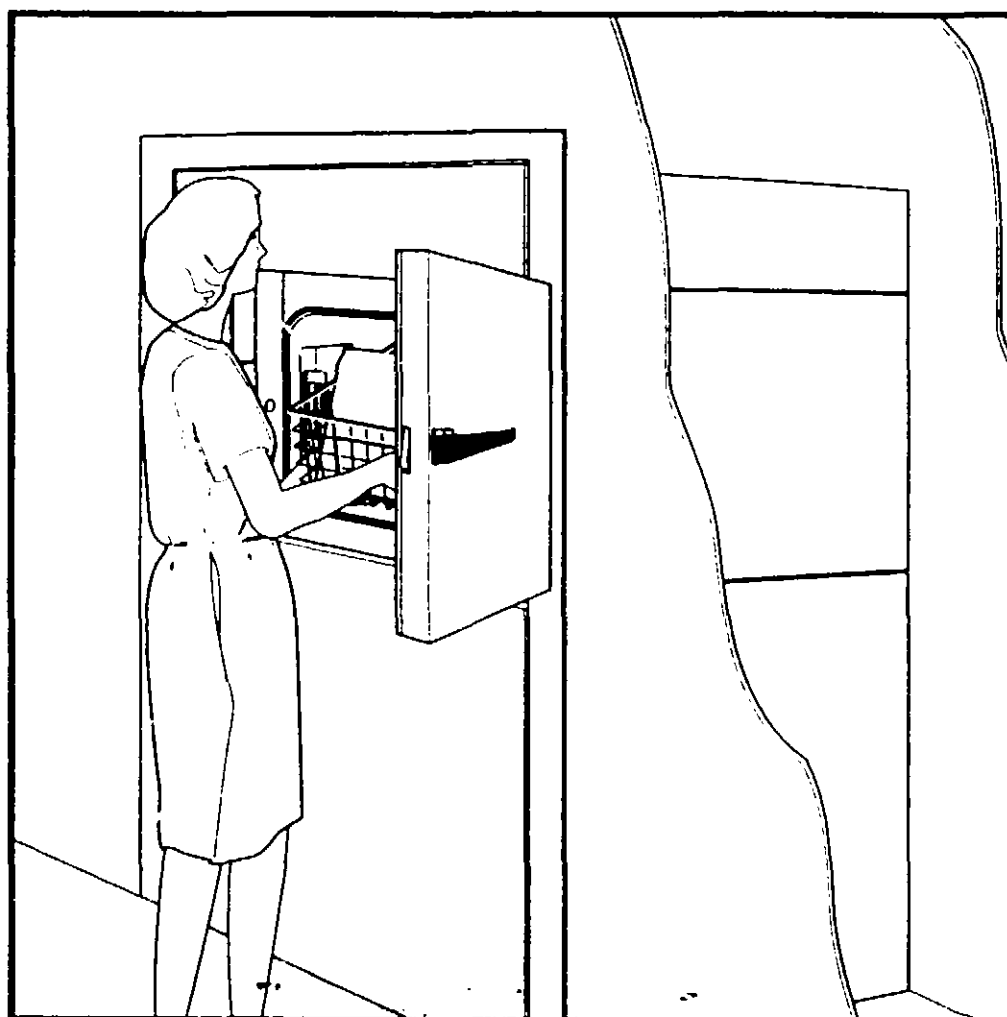
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NOTES

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3M Steri-Vac™ Gas Sterilizer/Aerator Model 8XL 2 Door

Operator's Manual



ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

3M Health Care

Under the...
Fungicide...
amended...
registered under EPA Reg. No.

7182-1

117-2710

Please read this manual carefully to learn how to correctly operate and maintain the 3M™ Steri-Vac™ Sterilizer/Aerator. Incorrect operation may lead to sterilization failure or serious personal injury.

This manual explains the function of the sterilizer/aerator, how to correctly sterilize heat-and/or moisture-sensitive devices, and how to maintain the sterilizer/aerator.

NOTICE

Before operating the sterilizer/aerator, read and understand all of the health and safety information listed in Health & Safety Information section of this manual.

ACQUISITION
WITH COMMENTS
in Liaison Dept.

MAR 30 1995

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INTRODUCTION

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APPROVED
 WITH COMMENTS
 in E.O. 12812 Dated:

 MAR 30 1995
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 as amended, this pesticide
 registered under EPA Reg. No.
7182-1

FEATURES

The Steri-Vac Model 8XL gas sterilizer/aerator is a compact unit designed to sterilize heat- and/or moisture-sensitive devices. It utilizes a fully automatic control system to ensure that proper sterilization conditions are met, and to minimize the possibility of operator exposure to ethylene oxide gas. The 2-door model allows pass through operation in clean room facilities.

Health care facilities throughout the world have found ethylene oxide gas sterilization to be a dependable and effective method of sterilizing heat- and/or moisture-sensitive devices. There are many benefits to gas sterilization:

- All microorganisms, including resistant spores, are killed by the chemical reaction with ethylene oxide.
- Materials can be pre-packaged, then sterilized and maintained sterile until use.
- Ethylene oxide is relatively non-corrosive to plastic, metal, or rubber materials.
- Ethylene oxide can penetrate and sterilize irregular-shaped items.
- Biological monitoring systems (such as 3M™ Attest™ Biological Indicators) or chemical monitoring systems (such as 3M™ Indox™ EO Monitor Tape or 3M™ Comply™ EO Indicators) can be used to ensure that sterilization parameters are met. These monitoring systems can also be used to distinguish processed materials from unprocessed materials.
- Ethylene oxide can be used to sterilize those materials that cannot be immersed in liquid disinfectants or processed in dry heat, steam, or other chemical vapor sterilization systems.

Major Features and Benefits

Following are the major features and benefits of the sterilizer/aerator:

Accurate and Dependable

The solid state electronic design provides accuracy and dependability. The electronic controller automatically stops the cycle and displays the error code if errors are detected.

Continuous Temperature Monitoring

The chamber temperature and vacuum are monitored continually during the sterilization cycle.

Humidification

Multiple pulses of low-temperature steam help assure proper humidification.

100% Ethylene Oxide Unit-Dose Cartridge

A unit-dose cartridge of ethylene oxide is punctured inside the chamber only when proper chamber conditions are achieved.

Negative Pressure

Throughout the cycle, the chamber remains at negative pressure relative to the room so gas can not escape into the sterilization work area. If a leak failure does occur in the chamber, room air will migrate into the chamber and the controller will automatically detect the leak and interrupt the sterilization cycle until service is performed.

Vacuum Controlled Puncture

The vacuum in the chamber provides the force to puncture the cartridge; this cannot occur unless the door is closed and a vacuum below 160 mbars exists in the chamber.

Cycle Status Display

The display on the front panel of the sterilizer shows cycle status.

ACCEPTED
with COMMENTS
in EPA Register Docket

MAR 30 1995

Under the Clean Air Act
Fungicide and Disinfectant Act
as amended for the pesticide
registered under EPA Reg. No.
7182-1

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FEATURES

Manual Cycle Interrupt

The operator can manually interrupt a cycle at any time. If the cartridge of gas was punctured, the final vacuum and air purge automatically clears the chamber before the door is unlocked.

Automatic Aeration

Aeration begins automatically after the sterilization cycle. The sterilization/aeration process can be accomplished in one chamber, reducing potential gas exposure that can occur during load transfer to an aerator.

General Information

Sterilization Cycles

Temperature	Gas Exposure Time	Cycle Time <small>approx.</small>
37°C (99°F)	3 hours	4 hours 45 min
55°C (131°F)	1 hour	3 hours

NOTICE

Additional time is required after the sterilization cycle time to allow for aeration of the load. It is necessary to obtain recommended aeration times and temperatures from the device manufacturers.

Sterilant

3M™ Steri-Gas™ EO Cartridge 8-170 100% ethylene oxide (EO).

Weight of gas.....170 grams
Minimum gross weight.....185 grams

Sterilant Specifications

Refer to the Consumer Product Profile 3M Steri-Gas EO Cartridges.

Shelf Life and Gas Weight

Refer to the Consumer Product Profile 3M Steri-Gas EO cartridges.

Chamber Dimensions

Width..... 51 cm (20 in)
Depth..... 97 cm (38 in)
Height..... 46 cm (18 in)
Diagonal.... 117 cm (46 in)
Volume..... 224 l (7.9 cu ft)

Basket Dimensions

Width..... 46 cm (18 in)
Depth..... 91 cm (36 in)
Height..... 20 cm (8 in)






Water Requirements

Distilled water is added by the operator to a reservoir with a 7.5 liter (2 gal) capacity.

HEALTH

Please read and understand all instructions before using the Steri-Vac sterilizer/aerator.

⚠ DANGER The Steri-Vac sterilizer/aerator uses ethylene oxide gas to sterilize heat-and/or moisture-sensitive devices. Ethylene oxide is flammable and toxic. Follow all instructions and precautions carefully.

Toxicity	Statement of Practical Treatment/First Aid	Toxicity	Statement of Practical Treatment/First Aid
 <p>Acute Inhalation Overexposure may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), chest pain and neurotoxic effects.</p> <p>Chronic Inhalation The Occupational Safety and Health Administration (OSHA) classifies ethylene oxide (EO) as a probable human carcinogen and reproductive hazard.</p>	<p>Inhalation Get fresh air immediately after overexposure to ethylene oxide gas. Contact a physician as soon as possible.</p>	 <p>Skin Contact Liquid ethylene oxide may cause skin irritation, dermatitis and blistering.</p>	<p>Skin Contact Flush the area of contact with water for a minimum of 15 minutes. Remove contaminated clothing while flushing. Wash the affected area with soap and water. Contact a physician as soon as possible. Aerate contaminated clothing and launder before reuse. Discard contaminated leather items.</p>
 <p>Eye Contact Splashes of ethylene oxide may cause severe eye injury. High gas concentrations may cause severe eye irritation and injury.</p>	<p>Eye Contact For liquid ethylene oxide or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.</p>	 <p>Ingestion A highly unlikely route of exposure. Liquid ethylene oxide, upon ingestion, is caustic and may cause severe irritation and burns to the gastrointestinal mucosa.</p>	<p>Ingestion Call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.</p>
 <p>Flammability Ethylene oxide is flammable in concentrations from 3% (30,000 ppm) to 100%. Keep all sources of ignition such as matches, lighted cigarettes, sparks, and static discharge away from the sterilizer and cartridges.</p>	<p>Ethylene Oxide Leaks or Spills The following indicate Steri-Gas cartridge leakage:</p> <ul style="list-style-type: none"> • Liquid ethylene oxide spurting or rapidly dripping from a cartridge • A cartridge that feels very cold to the touch • Cartridge weight loss 		

REGISTERED
with CARTRIDGES
In EPA 600/4-90-010
MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
7182-1

HEALTH**Agency Listings**

The Steri-Vac gas sterilizer/aerator is listed with the Underwriters Laboratories, Inc. (UL).

This internationally-recognized laboratory has inspected and evaluated the Steri-Vac system. They perform on-going inspections of the manufacturing facilities. Additional international approvals have also been received or are pending. All approved labels are located on or near the serial plate of the sterilizer.

EPA Registration

Manufacturers of chemical pesticides, such as ethylene oxide, are required to register their product label claims with the Environmental Protection Agency (EPA). Based on these claims, the EPA requires the manufacturer to demonstrate that the product meets certain performance standards prior to issuing a registration number. The EPA registration number, which appears on all Steri-Gas cartridges, is 7182-1.

OPERATION**Introduction**

This section of the manual describes how to correctly operate the sterilizer/aerator. Included are procedures for turning on the sterilizer, preparing items for sterilization, and correctly performing the sterilization procedure.

A detailed description of the controls and indicators is also provided. Before operating the sterilizer/aerator, read and understand the descriptions for each of the controls and indicators.

NOTICE

User Responsibility. Only healthcare professionals or other appropriately trained personnel in health care and industrial use areas should use this equipment. It is a violation of Federal Law (USA) to use this product in a manner inconsistent with its labeling. Injury to person or property can result unless the operating instructions are followed carefully.

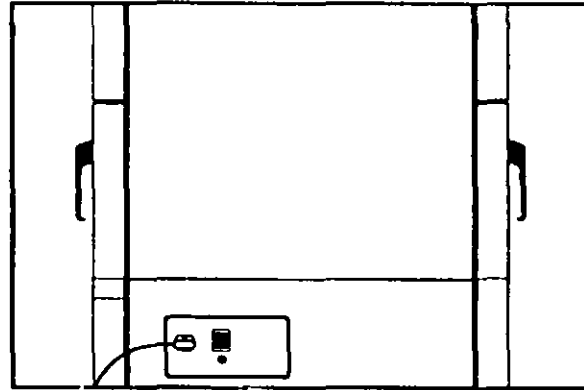
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OPERATING PROCEDURE

Step 1

Power on the sterilizer.

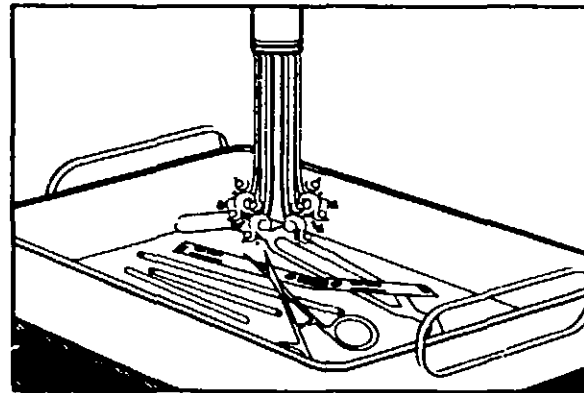
Turn on the power switch (located on the left side of the sterilizer). Leave the power switch on at all times to simplify operation and allow the sterilizer electronics to continually monitor sterilizer functions.



Step 2

Prepare items for sterilization.

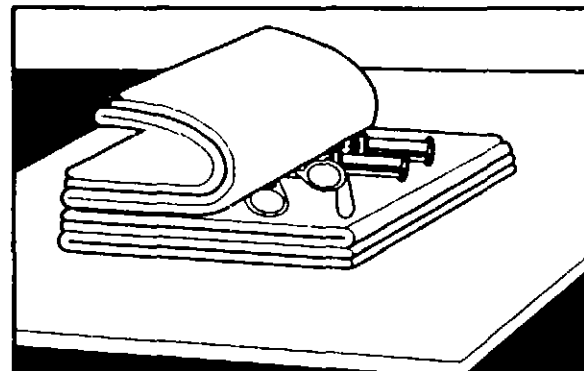
Thoroughly clean and rinse all items to be sterilized to remove mucous, dried blood, or other organic matter. Dry the items to remove water droplets.



Step 3

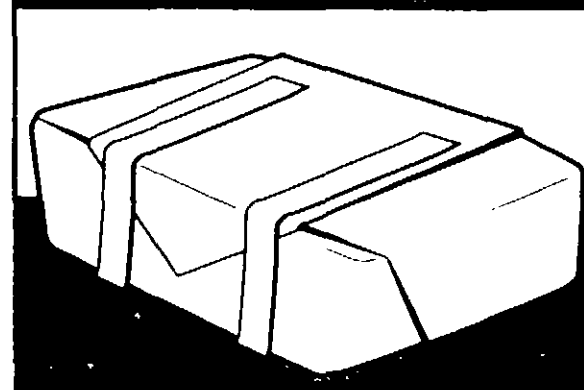
Package items for storage.

Before sterilizing, package items that will be stored before they are used. Use only packaging materials that are intended for ethylene oxide sterilization.



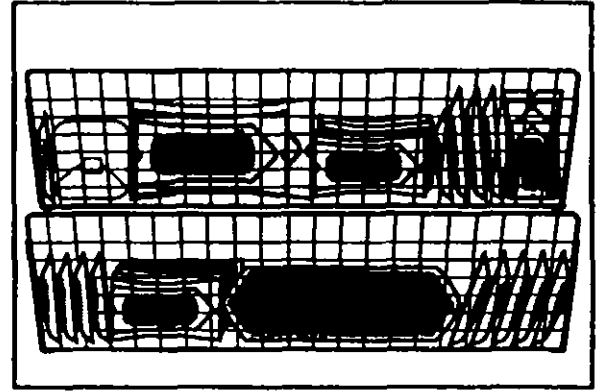
NOTICE

The packaging area should have a minimum room humidity of 35% RH.



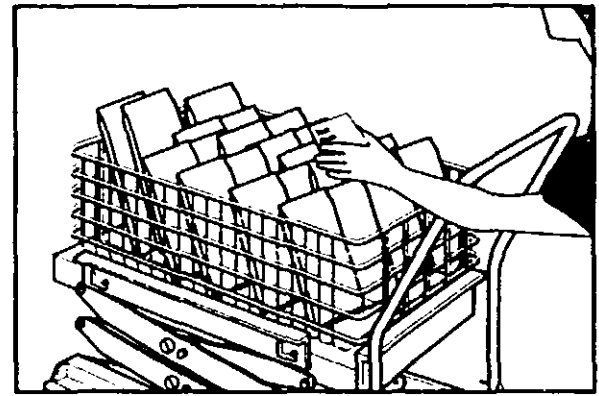
OPERATION**Step 4****Load the sterilizer baskets.**

When loading items in the baskets, leave some space between each item. Place packages on edge. When arranging paper-plastic pouches, place the plastic side of one pouch against the paper side of another pouch.

**Step 5****Place biological indicator (BI) in the sterilizer basket with load.**

A BI should be included with each load to monitor the sterilization process.

The BI or BI test pack should be representative of the materials being sterilized and placed in the center of the load.

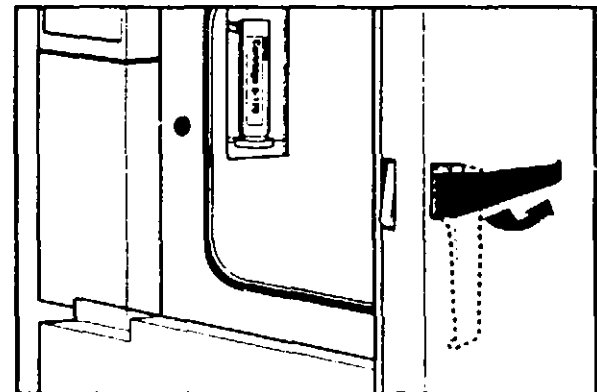
**⚠ DANGER**

To minimize exposure to EO when retrieving the biological indicator, ensure that it is easily identifiable when unloading

Step 6**Open the load-side sterilizer door.**

Turn the handle counter-clockwise to open the door.

Remove the empty gas cartridge and place in the basket to be processed.



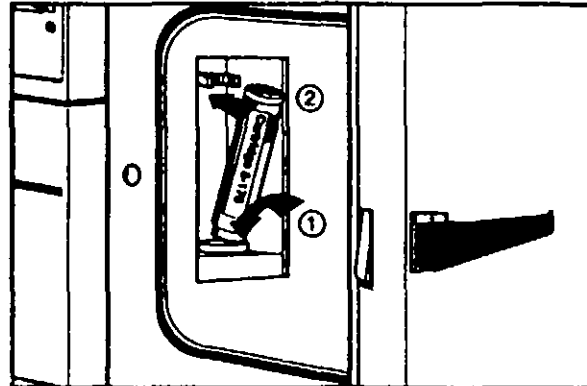
2/10/10

OPERATION

Step 7

Insert gas cartridge.

Insert a Steri-Gas cartridge 8-170 into the retainer ring on the cartridge holder inside the chamber. Push the cartridge down and slightly inward until the cartridge "snaps" into position.



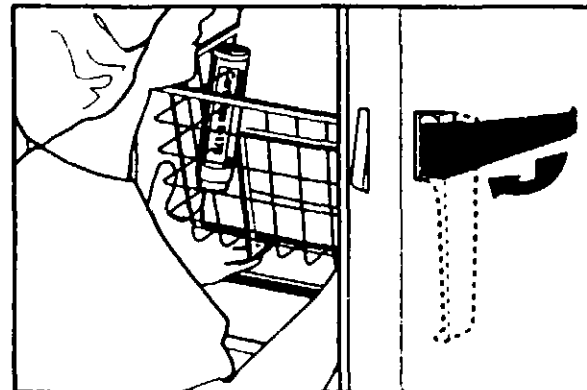
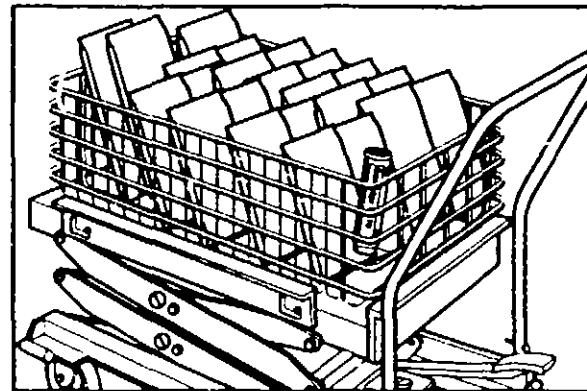
⚠ DANGER

DO NOT force the cartridge. Use of excessive force could result in premature puncture of the cartridge and subsequent exposure to ethylene oxide. Remove the cartridge from the holder and check for obstruction.

Step 8

Place baskets in chamber.

Place the loaded baskets in the sterilizer chamber. Close the door and turn the door handle clockwise until it is vertical.



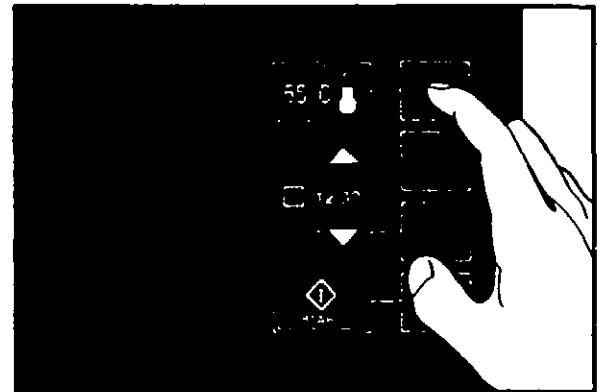
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OPERATING PROCEDURE

Step 9

Select temperature.

Press the temperature select switch until the desired sterilization/aeration temperature is displayed. Select the temperature according to manufacturer's recommendations for the devices in the load.

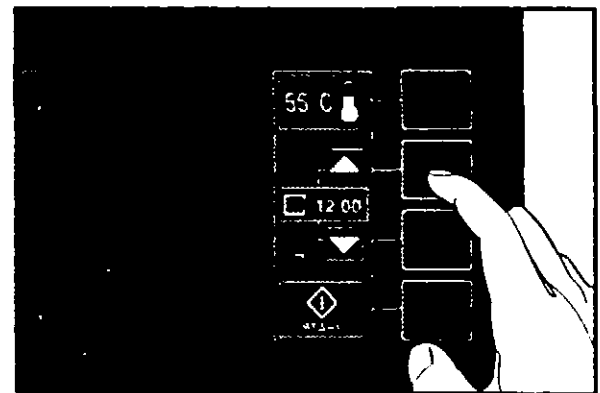


NOTICE
The cycle setup is cancelled if the start switch is not pressed within 5 minutes of setting the cycle parameters. The setup can also be cancelled by pressing the STOP switch.

Step 10

Set the aeration time.

Pressing the aeration time preset control arrows change the time in one hour increments until the desired aeration time is displayed.

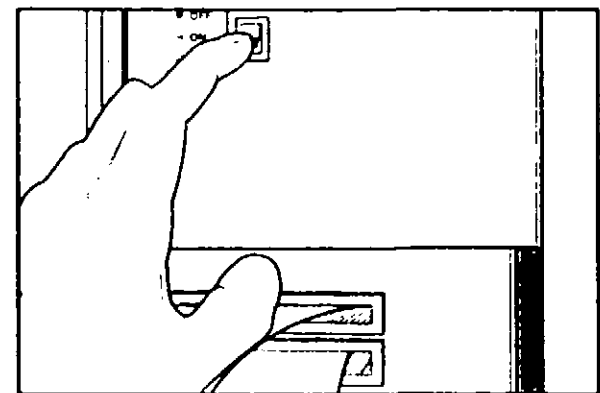


NOTICE
The sterilizer displays the aeration time used in the previous cycle. Presetting the aeration time is optional. If no aeration time is preset, the sterilizer will automatically aerate the load until the operator stops the cycle.

Step 11

Turn on printer.

Press the printer "on" switch (located behind printer/water door) before starting the cycle if a cycle printout is desired.

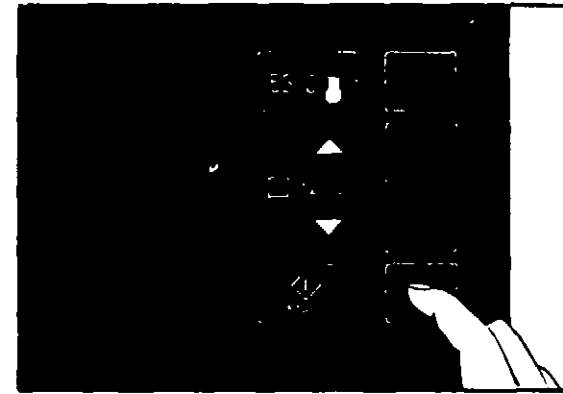


OPERATING PROCEDURE

Step 12

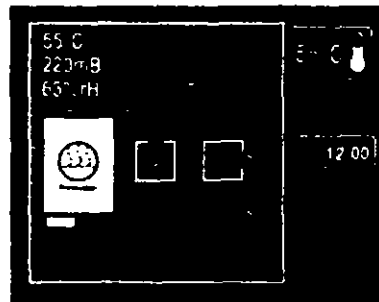
Start the sterilization cycle.

Press the START switch to begin the sterilization/aeration cycle. The cycle continues automatically until completion. The front panel displays cycle information



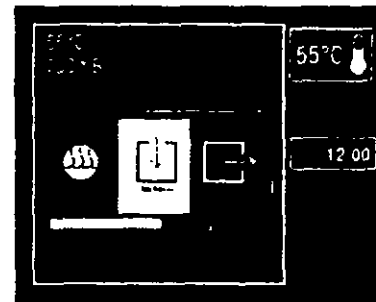
Front panel displays cycle sequence

Precondition Phase



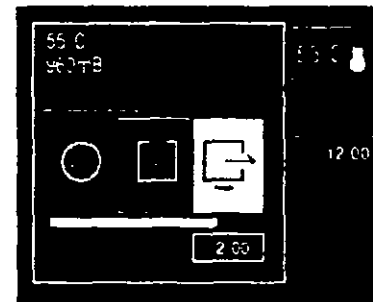
- Preheat
- Chamber vacuum
- Humidification

Gas Expose Phase



- Cartridge punctured
- Gas exposure
- Gas removal

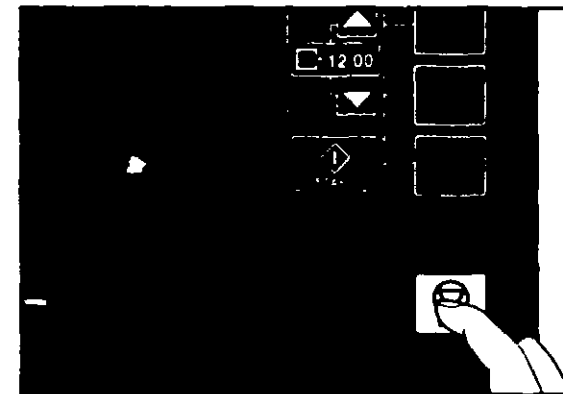
Aeration Phase



- Sterilization cycle complete
- Aeration

Interrupting the sterilization cycle.

Press the STOP switch at any time to interrupt the cycle.



NOTICE

If the cycle is interrupted before gas exposure, the door will unlock immediately.

If the cycle is interrupted after the gas cartridge is punctured, the machine must go through final pump down and purge before the door will unlock.

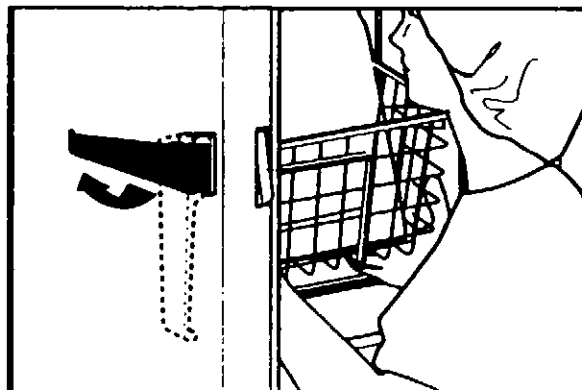
OPERATING PROCEDURE

Step 13

Open sterilizer unload-side door.

During aeration cycle, appearance of the "door unlocked" symbol will indicate when the door can be opened.

To open the door, turn the handle clockwise, allow approximately 30-60 seconds for the chamber pressure to equalize with the room pressure.

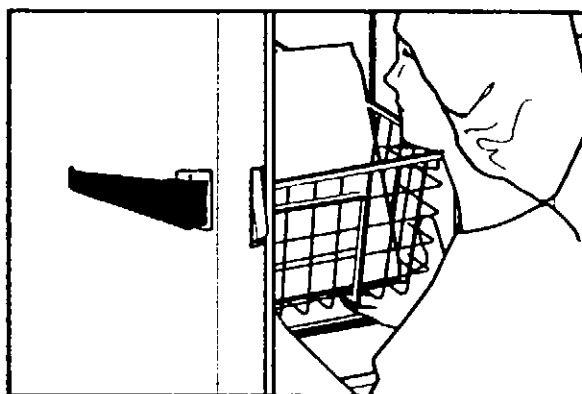


Step 14

Unload the sterilizer.

Once sterilization/aeration is complete, remove the baskets of sterilized/aerated items from the chamber.

After aeration, remove the empty cartridge placed in the basket at the start of the cycle. Discard the cartridge with nonincinerated waste.

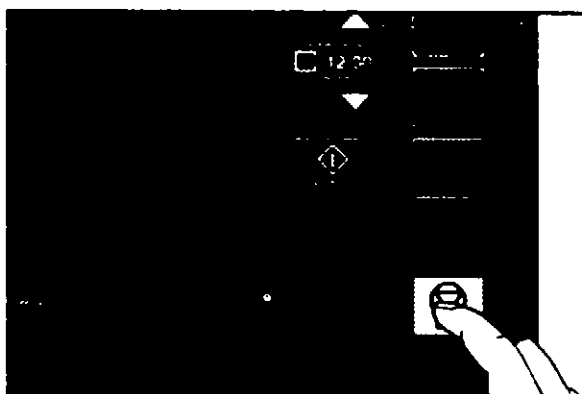
**⚠ DANGER**

The load continues to release EO until it is completely aerated. Minimize handling or sorting an incompletely-aerated load.

Step 15

Return to standby.

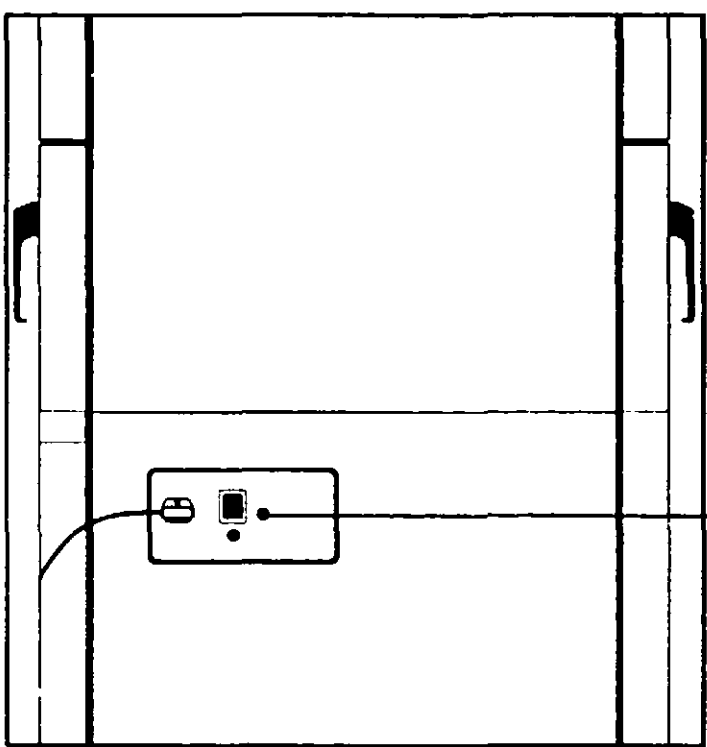
To end the cycle after the load has been removed, press the STOP switch while the door is open. Close the unload-side door. This places the sterilizer in the standby mode, ready for the next cycle.



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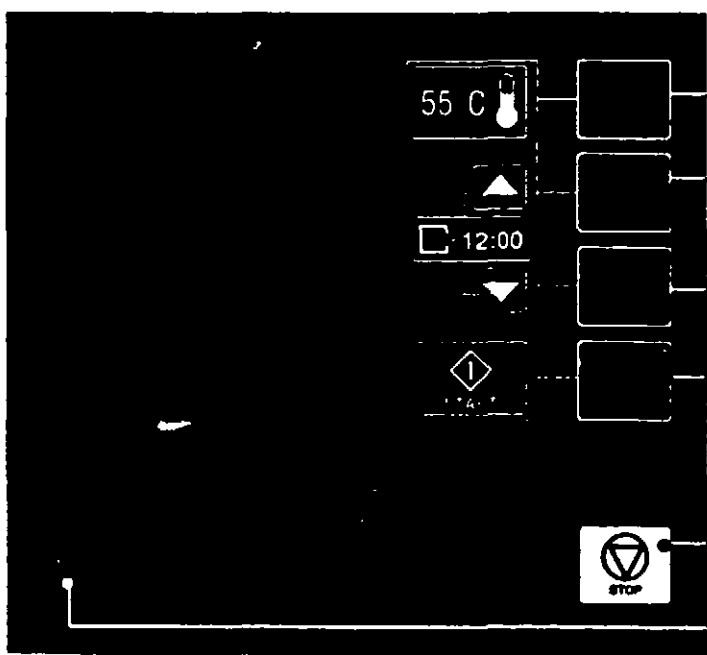
STERILIZER

The following switches are used to control sterilizing operations and the control panel display shows status during sterilization:



1

Power Switch.
Turns the power to the sterilizer on and off. This switch should be left on at all times to simplify operation.



2

Temperature Select Switch.
Press to select the desired chamber temperature.

3

Aeration Preset Time Increase Arrow.
Press to increase the aeration time by one hour

4

Aeration Preset Time Decrease Arrow.
Press to decrease the aeration time by one hour

5

START Switch.
Press to start the automatic sterilization cycle.

6

STOP Switch.
Press at any time to interrupt the cycle.

7

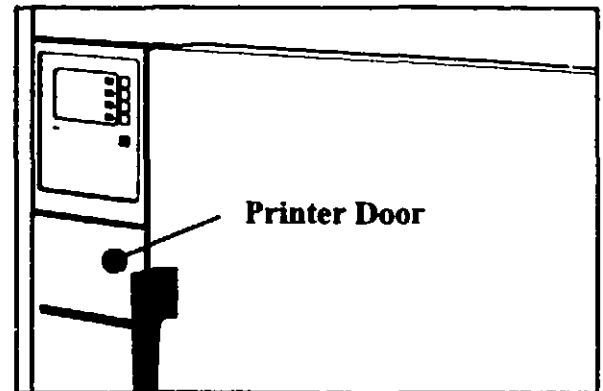
Power-On Indicator.
Shows that power has been turned on to the sterilizer.

OPERATION**Introduction**

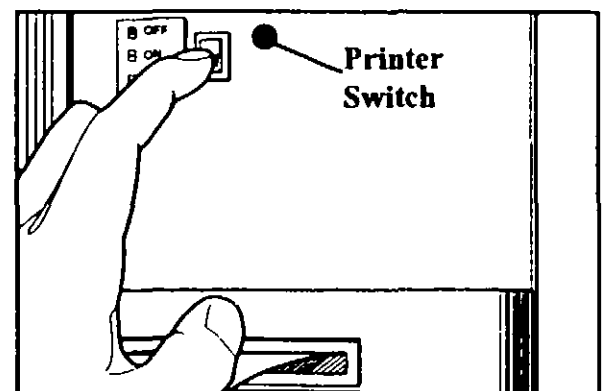
The built-in thermal printer provides easy to read information on each sterilization cycle. The printout is helpful in analyzing sterilizer performance and can be retained to meet cycle verification policies.

Location

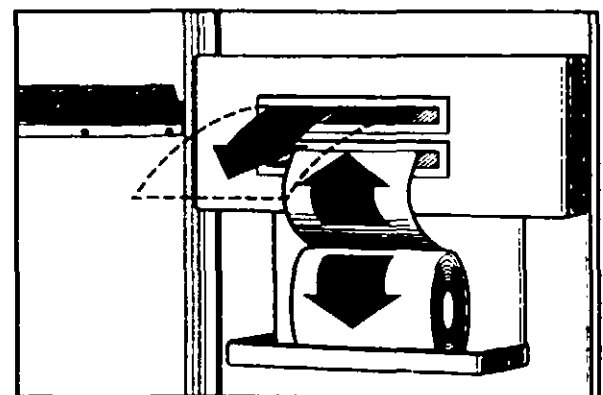
The printer is installed in the front of the sterilizer behind the access door for the water reservoir.

**Operation**

To operate the printer, press the printer switch to the ON position before starting the sterilization cycle. The switch has three positions: OFF, ON, and FEED.

**Load Paper**

To load printer paper, install the roll in the feed mechanism as shown in this diagram. Press the switch to the FEED position to advance the paper through the printer and the paper slot in the access door.

**NOTICE**

To avoid damage to the print head, use only paper intended for this printer.

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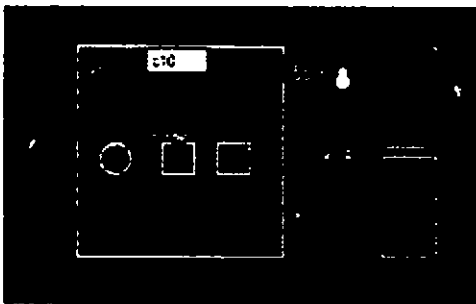
64 J72

CAUTION & ERROR CODES**Introduction**

The Steri-Vac gas sterilizers use an extensive list of codes to provide information to the operator. "Cautions" do not indicate a failure, but are informational messages to alert the operator to some special situation. Other codes indicate an "error" occurred which stopped the cycle.

Often the code is sufficient to provide very specific information regarding the failure that occurred, giving the service representative enough information over the phone to indicate the likely failed component. In some of these situations, the service representative will be able to recommend a correction that may avoid a service call.

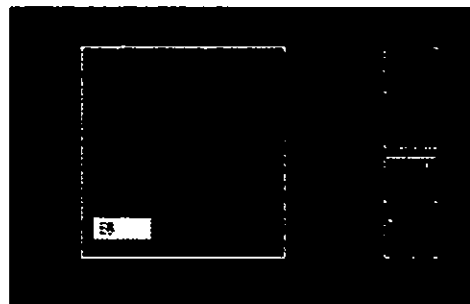
When the sterilization cycle is interrupted by an error code in a Steri-Vac 8XL 2-Door unit, the unload-side door remains locked. The error should be cleared and the cycle restarted from the load side.

**Caution Codes****C1 to C20**

Will not stop the sterilization cycle.

The message is cleared automatically when the condition is corrected or a new cycle started.

A caution alone will not prevent the successful completion of the cycle. Therefore, the unload-side will be unlocked to allow removal of a load that has completed the sterilization cycle.

**Self-test Errors****E1 to E20**

Prevents the start of a sterilization cycle.

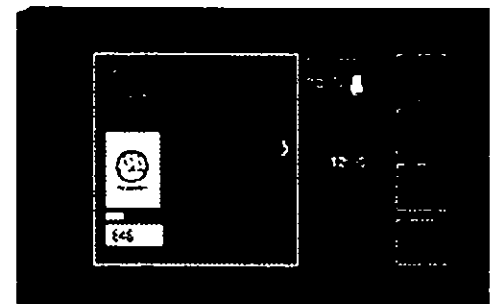
To reset:

- *Open the door*
- *Press STOP*
- *Correct the problem*

If error does not clear call service representative.

If the error indicates that the problem is in the controller electronics, it may be necessary to turn power off to stop the alarm.

These errors are detected before the sterilization cycle has begun, therefore, there is no gas in the chamber. The sterilizer will issue short "beeps" to alert the operator of the error. Open the load-side door and press the STOP key to clear the error message and alarm.

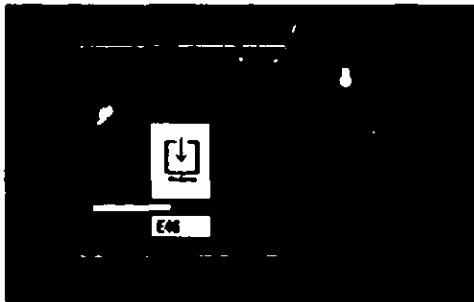
**Errors in Precondition Phase****E21 to E49**

Stops the cycle before gas is released. The load is not sterilized.

To reset:

- *Open the load-side door*
- *Press STOP*
- *Correct the problem*

These errors are detected before gas has been injected into the chamber so the load is not sterilized. The sterilizer will issue short "beeps" to alert the operator of the error. The sterilizer will automatically release any vacuum within the chamber to allow the load-side door to be opened—this may take approximately one minute. Turning the sterilizer handle will stop the alarm while the chamber vacuum is being released. Once the door can be opened, press the STOP key to clear the error and return to standby.

CAUTION

Errors in Gas Expose Phase E50 to E69

Stops the cycle before sterilization is complete. The door remains locked until the gas is purged from the chamber.

To reset:

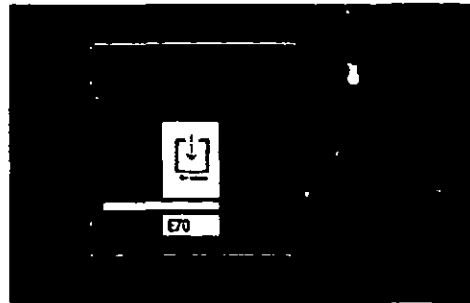
- *Open the load-side door*
- *Press STOP*
- *Correct the problem*

These error codes indicate that gas should have been injected into the chamber, but that the sterilization process was not correct so the load is not sterilized. The sterilizer will automatically advance to final vacuum and purge to remove gas from the chamber. This will take approximately 45 minutes.

At the end of this mandatory gas removal, the sterilizer will unlock the door following the same procedures as required for normal sterilization cycles; in other words, if the cycle was set up with a mandatory aeration time, the sterilizer will perform that mandatory aeration before unlocking the door.

When the load-side door is unlocked, a continuous alarm is turned on while the sterilizer aerates the load. The alarm will stop when the load-side door handle

is turned to release the vacuum in the chamber. To continue aerating the load without the alarm, turn the handle back clockwise. The alarm will sound again when the door is opened.



Locked Chamber Errors E70 to E79

Stop the cycle. The load may be sterilized, but the sterilizer cannot clear the gas from the chamber.

To reset:

- *Correct the problem*
- *Press START (if present on the display) to repeat gas removal phase*
- *If gas removal again fails, call service representative*

These error codes indicate that the gas removal could not be completed or could not be verified. The chamber is left locked. A slow "beep" alarm will come on.

If the error code allows a restart of the gas removal phase, the START switch will be active. After correcting the problem, press START to perform the gas removal. The alarm will stop and the sterilizer will automatically rerun final vacuum and purge to remove gas from the chamber.

This will take approximately 45 minutes. If the gas removal is then successful, the sterilizer will unlock the door following the same procedure as required for normal sterilization cycles; in other words, if the cycle was set up with a mandatory aeration time, the sterilizer will perform that mandatory aeration before unlocking the door.

If the sterilization cycle was complete before the problem in the gas removal phase was detected, the load is considered sterilized and the unload-side will unlock. If another error had been detected prior to gas removal, a continuous alarm is turned on when the load-side door while the sterilizer aerates the load. The alarm will stop when the door handle is turned to release the vacuum in the chamber.

To continue aerating the load without the alarm, turn the handle back clockwise. The alarm will sound again when the door is opened.

CAUTION & ERROR CODES

Use the following tables to isolate the possible causes and corrective actions for the messages displayed on the information display of the sterilizer. Call your 3M service representative when indicated on the chart, if a code appears that is not listed, or if you have any questions. Codes with "●" are used on accessories to the Steri-Vac sterilizers.

Caution Messages (Will not stop the cycle)

Code	Message	Possible Causes	Corrective Action
● C1	Low air in exhaust hood (Mandatory aeration performed automatically)	External fan malfunction Airflow sensor	Check fan and fan ducts Call service representative
C2	Low water in standby	Reservoir needs water	Add distilled water
C3	Power interruption	Power outage	Cycle restarts automatically
C4	Lost compressed air	No compressed air	Check compressor, air lines
C5	Temperature loss during aeration	Heater control failure	Call service representative (Increase aeration time)
● C6	Unload side door open	Unload-side door must be closed	Close door
C7	Door locked	Lost compressed air Switch Failure	Check compressor, air lines Call service representative
C8	Printer paper error	Printer out of paper	Replace printer paper
C9	Printer error	Printer or electronics	Call service representative
● C10	Abator caution	Abator problem during gas removal	Refer to error messages displayed after cycle complete
C11	Replace used gas cartridge	Used cartridge or cartridge missing	Install new cartridge
C12	Sensor calibration needed	Sensor is out of calibration	Call service representative

Self-Test Errors (Prevents the start of a cycle)

Code	Message	Possible Causes	Corrective Action
E1	Processor memory failure	Electronics	Call service representative
E2	Program memory failure	Electronics	Call service representative
E3	Processor failure	Electronics	Call service representative
E4	Chamber temperature sensor fail	Bad sensor or connection	Call service representative
E5	Heatsink temperature sensor fail	Bad sensor or connection	Call service representative
E6	Pressure sensor failure	Bad sensor or connection	Call service representative
E7	Pressure failure w/door open	Bad sensor or connection	Call service representative
E8	End wall temp sensor fail	Bad sensor or connection	Call service representative
E9	Middle wall temp sensor fail	Bad sensor or connection	Call service representative
E10	Low water	Reservoir needs water	Add distilled water
E11	No compressed air	Compressed air source off	Check air pressure
E12	RH sensor failure	Bad sensor or connection	Call service representative
E13	No gas cartridge	Need new gas cartridge Sensor error	Replace cartridge Call service representative
E14	Load door open	Door not closed Switch failure	Close door -restart Call service representative

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CAUTION & ERROR

Self-Test Errors (Prevents the start of a cycle) Continued from previous page...

● E15	Unload door open	Door not closed Switch failure	Close door-restart Call service representative
● E16	Unload door unlocked	Door lock hung up on bolt Switch failure	Turn handle to vertical position Call service representative
E17	Load door unlocked	Door lock hung up on bolt Switch failure	Turn handle to vertical position Call service representative
E20	Chamber needs to cool down	Recent warm cycle	Open door, let chamber cool

Errors detected in the precondition phase (Stops the cycle)

Code	Message	Possible Causes	Corrective Action
E21	No vacuum	Blockage at vacuum port No compressed air (venturi systems) Vacuum system failure	Clear chamber vacuum port Check air pressure Call service representative
E22	Initial pumpdown timeout	Improper air pressure (venturi systems) Vacuum system failure	Check air supply Call service representative
E23	Chamber preheat timeout	Temperature control failure	Call service representative
E24	Heatsink preheat timeout	Temperature control failure	Call service representative
E25	Chamber over-temp	Over temp in precondition phase	Call service representative
E26	Chamber under-temp	Under temp in precondition phase	Call service representative
E27	Vacuum failure	Leak in chamber Vacuum system failure	Call service representative
E28	No humidity injected	Humidity system failure Water level sensor failure Moisture injection failure	Call service representative
E29	Low humidity	Very dry load Moisture injection failure	Prehumidify @ 35% RH Call service representative
E30	RH sensor valve failure	Valve or control failure	Call service representative
E31	Vacuum leak test failure	Failed the vacuum leak test	Call service representative
E32	Vacuum level at puncture	Improper vacuum level before puncture	Call service representative
E33	Interlock relay failure	Electronics	Call service representative
● E38	Nitrogen empty	Nitrogen tank empty	Replace nitrogen tank
● E39	No nitrogen injection	Nitrogen pressure sensor failure Nitrogen injection failure	Replace nitrogen tank Call service representative
E40	User interruption	User pressed STOP switch	Restart the cycle

Errors detected in the gas expose phase (Stops the cycle)

Code	Message	Possible Causes	Corrective Action
E50	Empty cartridge	Empty cartridge used Puncture mechanism failure	Use new cartridge Call service representative
E51	Chamber vacuum leakage	Air leak into chamber	Call service representative
E52	Under temperature failure	Electronics	Call service representative
E53	Over temperature failure	Electronics	Call service representative
E54	Extended power outage	Could not restart the cycle	Rerun the cycle

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CAUTION & ERROR

Errors detected in the gas expose phase (Stops the cycle) Continued from previous page...

E55	Undefined condition at startup	Processor error Interlock relay failure	Call service representative Call service representative
E60	User interruption	User pressed the STOP switch	Rerun the cycle

Locked chamber errors (operator or service representative must restart)

Code	Message	Possible Causes	Corrective Action
E71	Final pumpdown timeout	Improper air pressure (venturi systems) Vacuum system failure	Check air supply, press START Call service representative
E72	Obstructed air inlet	Bacterial air filter failure	Attempt restart, press START Call service representative
E73	Vacuum sensor failure	Electronics	Call service representative
E75	Low gas injected	Partial puncture	Call service representative
E76	Interlock relay failure	Electronics	Call service representative
E77	Puncture pin in up position	Puncture mechanism failure	Attempt restart, press START Call service representative
● E80	Abator lockup	Abator not operating Electronics	Check power, press START Call service representative
● E81	Abator over-temp failure	Abator heater failure	Allow to cool, press START Call service representative
● E82	Abator under-temp failure	Abator not up to temperature	Attempt restart, press START Call service representative
● E83	Abator blower failure	Airflow system failure	Call service representative
● E84	Abator filter failure	Airflow filter plugged	Call service representative

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PREVENTIVE MAINTENANCE

Introduction

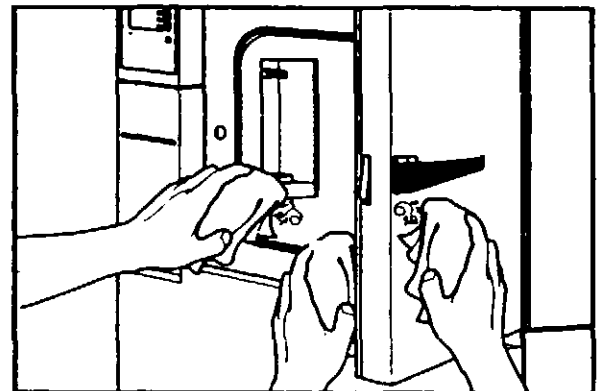
Performing preventive maintenance at scheduled intervals is a critical part of ensuring that the Steri-Vac sterilizer/aerator model 8XL continues to produce quality results. This should be done by a trained 3M service representative or a trained maintenance person from the institution.

Perform the following preventive maintenance procedures at the recommended intervals.

Daily Cleaning

Using a soft cloth dampened with mild soap and warm water, clean the following parts of the sterilizer/aerator daily:

- Chamber walls and floor
- Outer lip of chamber
- Inside surface of chamber door
- Outer surface of cabinet
- Door gasket



Compressed Air Line Filters

Daily

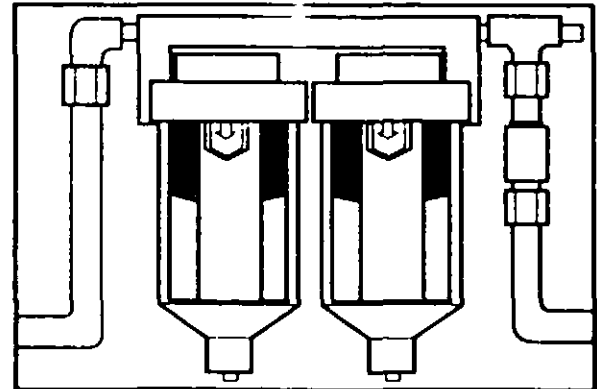
At the beginning of each work day, drain any moisture or oil that has collected in the bottom of the air filter reservoirs.

Every 6 Months

Replace the mist separator element at least every six months.

Every 12 Months

Replace the micromist separator element at least every 12 months.



ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

7182-1

⚠ WARNING

These filters are provided for precautionary purposes only, and not as a replacement for a clean air supply. A contaminated air supply can quickly reduce the effectiveness of the filter element, resulting in early machine failure and possible ethylene oxide exposure to the operator. The customer is solely responsible for providing a oil-free and dry (to a dew point of 50°F) air supply.

3M AUTHORIZED

3M Health Care has established a worldwide service organization to provide trained technicians to care for your equipment. For servicing information in the USA, contact your local 3M service representative or the 3M Health Care Service Center at the following address:

3M Service Center
3M Center, Building 275-4W-05
St. Paul, MN 55144-1000
800-292-6298

In Canada, contact:

3M Canada, Inc.
P.O. Box 5757
London, Ontario N6A 4T1
1-800-268-9696

For servicing information outside of the USA or Canada, contact the local 3M subsidiary.

⚠ WARNING

Only authorized personnel should repair or replace parts. Tampering or unauthorized alterations in the equipment will void the manufacturer's warranty and may result in early machine failure or personal injury.

⚠ WARNING

This equipment is operated with hazardous voltage which can shock, burn, or cause death.

Preventive Maintenance Agreement

For your convenience, 3M provides a preventive maintenance agreement (PMA) for purchase with the Steri-Vac equipment. The PMA assures you of periodic maintenance of your sterilizer and emergency services. Contact your local 3M Health Care service representative or the 3M Health Care Service Center at the above address for PMA information.

Service Manuals

Service Manuals are available for any 3M Steri-Vac gas sterilizer/aerator. These manuals contain illustrated parts lists, troubleshooting guides, details of operation, schematics, and preventive maintenance routines. Request the manuals desired in writing or by calling the 3M Health Care Service Center at the address listed above.

APPLICATION RATES

GARDENS AND TURF	Apply 1-2 oz. Organic Plus® Diatomaceous Earth/Pyrethrin Insecticide per 500 square feet.
POTTED PLANTS	Apply ¼ oz. (1 Tablespoon) Organic Plus® Diatomaceous Earth/Pyrethrin Insecticide per 12 inches pot diameter.
TREES AND BUSHES	Apply 1 oz. (4 Tablespoons) Organic Plus® Diatomaceous Earth/Pyrethrin Insecticide per 10 feet plant height.

FOR CONTROL OF FIRE ANT MOUNDS IN TURF AND GARDENS

Organic Plus® Diatomaceous Earth/Pyrethrin Insecticide is a contact insecticide for use on turf and gardens plots to control fire ant mounds in and around homes. Not for use on turf grown for sale or other commercial use as sod, for commercial seed production, or for research purposes.

FIRE ANT MOUNDS: Apply Organic Plus® Diatomaceous Earth/Pyrethrin Insecticide as a liquid. Drench both the mound and the area within six inches of the mound with solution. Apply gently to avoid disturbing ants. Reapply as necessary. For best results, apply in cool weather (65-80°F) or in early morning or late evening hours. Treat new mounds as they appear.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage and disposal.
STORAGE: Store in a cool, dry place away from food or feed. Keep out of reach of children.
DISPOSAL: Do not reuse empty container. Wrap in several layers of newspaper and discard in trash.

NOTICE TO USE: Seller's guarantee shall be limited to the terms of the label and subject thereto, the buyer assumes all risks to persons or property arising out of the use or handling and accepts the product on these conditions.

(LOGO) Made in USA by:
Organic Plus, Inc.
108 Dale Avenue, SE
Albuquerque, New Mexico 87105
(800) 933-2278

MAR 30 1995

3M Medical Products Group
3 Center, Bldg. 275-3E-08
St. Paul, MN 55144-1000

Attention: Marvin L. Hart, Senior
Regulatory Affairs Specialist

Subject: Steri-Gas[™] Cartridges/Steri-Vac[™] Sterilizer
EPA Registration No. 7182-1
Amendment Dated September 21, 1994 and
Letter Dated February 24, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your cartridge label for Model 8-170, will be acceptable, provided that you make the labeling changes listed below before you release the product for shipment.

1. Include the following "Directions For Use" section to read:

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is limited to use by medical professional or appropriately trained personnel for ethylene oxide sterilization in medical and industrial use areas. Use only in accordance with manufacturer's instructions in Steri-Vac Gas Sterilizer Model 8XL

2. Include a "Physical or Chemical Hazards" section to read:

Physical or Chemical Hazards

Ethylene Oxide gas is extremely flammable. Do not use near flame, electrical sparks or hot surfaces. Ground all equipment to prevent static sparks. Contents under pressure. Do not puncture or incinerate container. exposure to temperatures above 130° may cause bursting.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

3. Include a "Precautionary Hazards" statement to read:

Precautionary Statements
Hazards to Humans and Domestic Animals

DANGER

Ethylene Oxide [EO] is toxic. Exposure to EO may cause serious adverse health effects. possible hazards may include carcinogenic, mutagenic neurologic and reproductive effects. Liquid EO causes eye damage, burns to the skin, and is harmful if swallowed. Exposure to EO may cause irritative effects. Inhalation may cause neurologic effects and may be fatal. Chronic exposure may cause carcinogenic, mutagenic and reproductive effects.

4. Under the "Storage and Disposal" section, revise your instructions to include the following subheadings:

Pesticide Disposal
Container Disposal

5. Include a "Note to Physician" statement to read:

"Probable mucosal damage may contraindicate the use of gastric lavage."

6. The revised Confidential Statement of Formula dated October 21, 1994 agrees with the label and is acceptable.

NOTE: In the future, please use the correct CSF form, EPA Form 8570-4 (Rev. 8-94). A copy of the correct form is enclosed.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

ACCEPTED
with COMMENTS
to EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

7182-1

EPA Reg. No. 7182-1
EPA Est 3657-WI-2

3M

D

Steri-Gas™

EO Gas Cartridge

Active Ingredient: Ethylene Oxide 100% • Net wt. **A**

Storage and Disposal: Do not contaminate water, food or feed by storage or disposal. Store at room temperature. Do not incinerate. Avoid puncturing. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Aerate empty Steri-Gas cartridges. After aeration, dispose of immediately with normal nonincinerated waste.

top of tube

D

KEEP OUT OF REACH OF CHILDREN

DANGER

EXTREMELY FLAMMABLE—DO NOT USE NEAR FLAME

Use Only in Accordance With Manufacturer's Instructions in
Steri-Vac™ Gas Sterilizer Model

ETHYLENE OXIDE VAPOR HARMFUL • MAY CAUSE BURNS

Keep Container Closed—Avoid Breathing Vapors. Avoid inhalation and contact with skin or eyes. The product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical and industrial use areas.

Statement of Practical Treatment. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink egg whites, gelatin solution or, if these are not available, drink large quantities of water. Call a physician.

B

C

MTD NO

Made in U.S.A. for 3M Health Care, St. Paul, MN 55144-1000

©3M 1994

INSERT THIS END

D

Legend

(A) Net. Wt.	(B) Sterilizer Model No.	(C) Part No.	(D) Accent Color
100 (g)	4XL, 5XL, 400C	4-100	Green
127 (g)	400B	4-134	Red
170 (g)	8XL	8-170	Green

Steri-Gas™ Cartridges

(English)

(Svenska)

Danger: Ethylene Oxide
Flammability

DANGER



Ethylene oxide is flammable in air when present in concentrations from 3% (30,000 ppm) to 100%. Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilizer and cartridge.

Toxicity



Acute inhalation. Overexposure may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), chest pain, and neurotoxic effects.



Chronic inhalation. The Occupational Safety and Health Administration (OSHA) classified ethylene oxide (EO) as a probable human carcinogen and reproductive hazard.



Eye Contact. Splashes of EO may cause severe eye injury. High gas concentrations may cause severe eye irritation and injury.



Skin Contact. Liquid EO may cause skin irritation, dermatitis and blistering.



Ingestion. Is a highly unlikely route of exposure. Liquid ethylene oxide, upon ingestion, is caustic and may cause severe irritation and burns to the gastrointestinal mucosa.

OSHA Permissible Exposure Limits (29 CFR 1910.1047)

The OSHA Permissible Exposure Limits are 1 ppm (one part per million) measured as an 8-hour time-weighted average, and an Excursion Limit of 5 ppm averaged over a sampling period of 15 minutes.

Statement of Practical Treatment/First Aid Instructions. Get fresh air immediately after overexposure to EO gas. Contact a physician as soon as possible.

Eye Contact. For liquid EO or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.

Skin Contact. Flush the area of contact with water for a minimum of 15 minutes. Remove contaminated clothing while flushing. Wash the affected area with soap and water. Contact a physician as soon as possible. Aerate contaminated clothing and launder before reuse. Discard contaminated leather items.

Ingestion. Call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

Note: This product is limited to use by health care professionals or appropriately trained personnel in health care and industrial use areas. It is a violation of Federal Law (U.S.A.) to use this product in a manner inconsistent with its labeling.

1. Varning: Ethlenoxid.

2. Brännbarhet/Explosionsrisk.



a. Etylenoxid är brännbar i blandning med luft i koncentrationer från 3% - 100%.
b. Undvik öppen eld, brännande cigaretter och andra potentiellt genbildande källor härnär från sterilisatorns inått.

3. Toxicitet.



a. Akut inandning kan orsaka irriterande, irriterande (andningen omedelbart eller senare) smärtsam, svaghet, luft- och bröst, irritation i luftvägarna samt ge neurotoxiska effekter.
b. Upprepat överexponering kan ge andningssvårigheter och minskad tolerans för EO-gas.

4. Kronisk inandning.

a. Resultat från djurförsök och epidemiologiska studier på människor indikerar att långtidsexponering av EO-gas kan vara hälsofarlig för människor.

5. Flytande EO/Ögonkontakt.

a. Flytande EO kan irriteras och bränna ögon.
b. Höga koncentrationer av EO-gas kan orsaka ögonirritation.

6. Flytande EO/Hudkontakt.

a. Flytande EO irriterar och kan orsaka brännskador i form av blåsor.

Vid förtäring. En mycket ringa mängd etylenoxidlika vätskor starkt irriterande och kan orsaka kraftig irritation och brännskador på slemhinnor.

7. Första hjälpen.

8. Inandning.

a. Uppåt omedelbart frisk luft.
b. Om inandande och irriterande uppträder, håll personen stilla och varm samt kalla på läkare.
c. Om andningen är svår, ge syrgas.
d. Om andningen upphör, ge orsaksanpassad hjälp med mun till munandning och andning med syrgas.
e. Akut exponering vilken orsakar irriterande och irriterande skall alltid behandlas av läkare.

9. Ögonkontakt.

a. Om flytande EO eller höga koncentrationer av EO-gas kommer i kontakt med ögon skall dessa omedelbart spolas med vatten under minst 15 minuter och läkare kontaktas.

10. Hudkontakt.

a. Avlägsna omedelbart alla irriterande kläder och spola området vilken kommer i kontakt med EO med rikligt med vatten under minst 10 minuter.
b. Lufta irriterade kläder omsorgsfullt och tvätta dessa före återanvändning.
c. Skor som irriterats med EO skall kastas bort eller tvättas.

Vid förtäring. Kontakta läkare eller giftinformationscentral. Drick ett eller två glas vatten och framkalla kräkning genom att stoppa ner fingrarna i halsen. Stoppa ingenting i munnen och framkalla inte kräkning på en person som är medvetslös.

1. Pas op: Ethylen oxide.

2. Brännbar.



a. In om concentratie van 3 tot 100% ver met lucht een ontvlambaar mengtel.
b. Koem niet met lucifers, brunnende el de nabijheid van de sterilisator.

3. Toxiciteit



a. Etylen oxide is een zeer giftig gas inademing kan misselijkheid, braken of roedehand), duizeligheid, algeheel pijn in de borst, irritatie van de luchtwegs, gisgigverochijnselen veroorzaakt.
b. Regelmatig tweed inademing van dit gas vermindert gevoeligheid van het g.

4. Regelmatige inademing van ethylen oxide

a. Vergiftigingsovereen bij sterven en epidemiole hebben uitgevoerd, dat veelvuldig inademing oxide o hadelijk is voor het menselijk lichaam.

5. Vloeibaar EO in de ogen.

a. Vloeibaar ethylen oxide kan ernstige oogbeso veroorzaken.
b. Een hoge concentratie ethylen oxide kan de irriteren.

6. Vloeibaar EO op de huid.

a. Vloeibaar ethylen oxide veroorzaakt verbrandingsverschijnselen en blaren op de h.

Doorslikken. Dit is een zeer ongebruikelijke vij blootstelling aan E.O. Vloeibaar ethylen-oxide agressief en kan ernstige irritatie en brandwond in het weefsel van het maag-darmkanaal.

7. Eerste hulp.

8. Bij inademing:

a. De direct in de frisse lucht.
b. Wanneer misselijkheid en braken optreden, h slachtoffer dan rustig en roep de hulp van een c. Dien voorziet toe bij ademhalingsmoeilijkheid d. In geval van ademstilstand, pas kunstmatige r zo mogelijk mond op mond beademing. Hier toedienen.
e. Acute blootstelling, die misselijkheid en brak dient door een arts behandeld te worden.

9. Ogen.

a. Wanneer de ogen met vloeibaar EO of met ee concentratie EO gas in aanraking zijn gekoel dan minimaal 15 minuten met water en neem een arts.

10. Contact met de huid.

a. Direct besmette kleding verwijderen en de hu minstens intensief met water spolen.
b. Besmette kleding laten luchten en goed wasser voor te gebruiken.
c. Lederen schoenen enz. moeten worden gerein daarrat de EO niet kan worden verwijderd.

Doorslikken. Waarschuw direct een arts of een gespecialiseerd in vergiftiging. Drink één of twee glazen water en wolk braken vuster achter in de keel te steken. Wolk geen brakenoedingen op bij een bewusteloos geef deze niet te drinken.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
this product is registered under EPA Reg. No.
7182-1

E.P.A. Reg. No. 7182-1 E.P.A. Est. 3657-W1-1

3M

Made in U.S.A. for
3M Health Care

St. Paul, MN 55144-1000
(U.S.A.) 1-800-728-3957

Steri-Gas and Steri-Vac are
registered trademarks of 3M.
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34-7036-6432-3

Steri-Gas™

3M

Cartridge 4-134

Steri-Gas™

3M

Cartridge 8-170

Steri-Gas™

3M

Cartridge 4-100

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

7182-1

3M Health Care

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ACCEPTED
with COMMENTS
in EPA REG. NO. 7182-1

MAR 30 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
the amount for the pesticide
registered under EPA Reg. No.
7182-1

Introduction

For many years, unit dose quantities of ethylene oxide (EO) have been supplied to 3M™ Steri-Vac™ Gas Sterilizers in Steri-Gas EO gas cartridges. Several thousand health care facilities have found this system to be a reliable and cost-effective method for sterilizing medical devices.

Note: Steri-Gas cartridges are limited to use by medical professionals or appropriately trained personnel in medical and industrial use areas.



This safety alert symbol identifies important safety messages in this manual. When you see this symbol, carefully read the message that follows. It may help prevent personal injury or sterilization failure.

Features and Benefits

The largest Steri-Gas cartridge contains less than six (6) ounces of 100% ethylene oxide. Before a sterilization cycle is started, an operator inserts a cartridge into its holder inside the Steri-Vac sterilizer chamber. The spent cartridge is easily removed from the holder after the sterilization cycle is completed, aerated with the sterilized items, and discarded with nonincinerated waste.

Major features and benefits of the system are:

- Only small amounts of ethylene oxide are contained in the cartridges.

- The cartridges deliver the proper amount of ethylene oxide for each sterilization cycle.
- The system provides an easy, cost effective and efficient method of gas sterilization.
- There are no bulky sterilant tanks to store, change and transport.
- There are no external valves requiring time-

consuming maintenance. External valves can be a source of gas leaks.

- There are no gas line filters which can plug and need periodic changing. Gas line filters can also be sources of ethylene oxide exposure.
- The cartridges do not contain chlorofluorocarbon diluents implicated in the destruction of the earth's ozone layer.

7-2-72

Applications

The following cartridges are approved for use only in the Steri-Vac sterilizers listed.

Steri-Gas Cartridge

Use with Steri-Vac Sterilizer Models

4-100	400C, 4XL & 5XL
4-134	400B
8-170	8XL

Specifications

Cartridge Contents
Steri-Gas cartridges contain 100% liquid ethylene oxide. The liquid becomes a gas when released from the cartridge into the sterilization chamber. The major physical characteristics of ethylene oxide are listed to the right.

Boiling point	10.7°C (51.3°F)
Vapor pressure	1094 mm Hg at 20°C
Color	Colorless
Flammable limits	
lower	3% (30,000 ppm)
upper	100%
Ignition temperature	
in air	428.9°C (804°F)
in absence of air	571.1°C (1060°F)
Solubility in water	Complete
Liquid density (water = 1)	0.87
Vapor density (air = 1)	1.49
Detectable odor	Approx. 500-750ppm

ACCEPTED
with COMMENTS
in EPA Label Draft

MAR 30 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

748-1

Shelf Life

The shelf life of a Steri-Gas cartridge is five years from the date of manufacture. The manufacturing date for each cartridge is embossed on the side of its cap, and is printed on the label of the cartridge box.

Weight	Steri-Gas Cartridge	EO Weight*	Minimum Gross Weight
	4-100	100 grams (3.52 oz.)	117 grams (4.12 oz.)
	4-134	127 grams (4.47 oz.)	141 grams (4.98 oz.)
	8-170	170 grams (5.99 oz.)	185 grams (6.52 oz.)

* Weight of ethylene oxide in Steri-Gas cartridge.

Specifications (Continued)

Construction
The cartridge containing the ethylene oxide is made of 0.5 mm (0.02 inch) thick seamless aluminum. The valveless cartridge cap is made of 0.25 mm (0.01 inch) thick, tin-plated steel.

EPA Registration
Manufacturers of chemical pesticides, such as ethylene oxide, are required to register their product label claims with the Environmental Protection Agency (EPA).

Based on these claims, the EPA requires the manufacturer to demonstrate that the product meets certain performance standards prior to issuing a registration. The EPA registration number, which appears on all Steri-Gas cartridges, is 7182-1.

Health and Safety Information

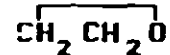
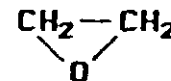
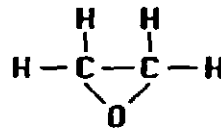


Danger



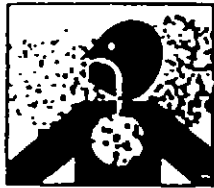
The sterilant, ethylene oxide, is both flammable and toxic. It is important that Steri-Vac sterilizer users understand the chemical's hazards and the necessary precautions. The Occupational Safety and Health Administration (OSHA), and many states and localities have Hazard Communication or Right-to-Know laws that require employers to provide this information to workers. Contact your 3M Sales or Service Representative for a Steri-Gas Cartridge Material Safety Data Sheet containing more detailed information.

Ethylene Oxide (EO, EtO)



Ethylene oxide is flammable in concentrations from 3% (30,000 ppm) to 100%. Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilizer and cartridge.

Health and Safety Information
(Continued)



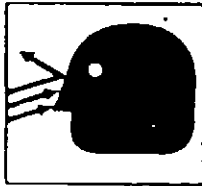
Toxicity

Statement of Practical Treatment/First Aid

Acute Inhalation. Inhalation may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), chest pain and neurotoxic effects.

Inhalation. Get fresh air immediately after over-exposure to EO gas. Contact a physician as soon as possible.

Chronic Inhalation. The Occupational Safety and Health Administration (OSHA) classifies ethylene oxide (EO) as a probable human carcinogen and reproductive hazard.



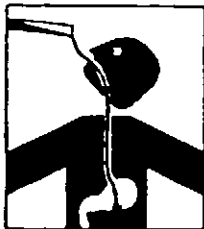
Eye Contact. Splashes of EO may cause severe eye injury. High gas concentrations may cause severe eye irritation and injury.

Eye Contact. For liquid EO or high concentrations of gas, immediately flush the eyes with water for at least 10 minutes. Contact a physician immediately.



Skin Contact. Liquid EO may cause skin irritation, dermatitis and blistering.

Skin Contact. Flush the area of contact with water for a minimum of 15 minutes. Remove contaminated clothing while flushing. Wash the affected area with soap and water. Contact a physician as soon as possible. Aerate contaminated clothing and launder before reuse. Discard contaminated leather items.



Ingestion. This is a highly unlikely route of exposure. Liquid ethylene oxide, upon ingestion, is caustic and may cause severe irritation and burns to the gastrointestinal mucosa.

Ingestion. Call a physician or Poison Control Center. Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

OSHA's Permissible Exposure Limits
(29CFR 1910.1047)

The OSHA Permissible Exposure Limits are 1 ppm (one part per million) measured as an 8-hour time-weighted average, with an Excursion Limit of 5 ppm averaged over a sampling period of 15 minutes.



National Fire Protection Association (NFPA) Codes

NFPA Article No. 30, Section 4450 outlines storage requirements for Class I flammable liquids in office, education and institutional occupancies. The requirements pertain to Steri-Gas cartridges containing 100% ethylene oxide. Subparagraph (b) of this section states: "Not more than 10 gallons of Class I and Class II liquids combined shall be stored outside of a storage cabinet or storage room, except in safety cans." Ten (10) gallons of ethylene oxide is approximately equivalent to 213 of the largest Steri-Gas cartridges (No. 8-170).

3M Recommendations

3M's recommendations for storing Steri-Gas cartridges (listed below) are more stringent than those in the NFPA Codes. Check your local fire protection codes for additional requirements.

- | | | |
|--|---|--|
| <ul style="list-style-type: none">• Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilizer and cartridges.• Store cartridges at a temperature of 0-35°C (32-95°F) in an upright position. | <ul style="list-style-type: none">• Keep only one day's requirement or a maximum of twelve (12) cartridges (one box) in the immediate sterilizer area. This area needs to have at least ten air changes per hour.• Additional Steri-Gas cartridges should be stored in an approved | <p>flammable liquid storage cabinet vented to the outside atmosphere, or in an area suitable for storage of flammable liquids appropriately vented to the outside atmosphere, or into a non-recirculating, continuously operating, dedicated exhaust system.</p> |
|--|---|--|

**Handling and
Disposal of
Cartridges**

Used Cartridges

Aerate empty (i.e. used) Steri-Gas cartridges with sterilized medical items. This procedure will remove ethylene oxide residues from the cartridges. After aeration, dispose of the empty cartridges with normal, nonincinerated waste. Dispose of the aerated cartridges immediately. Do not return empty cartridges to boxes containing full cartridges. Taking this precaution will prevent the accidental disposal of full cartridges.

Unused Cartridges

Unused cartridges contain pesticide waste which is toxic. Improper disposal is a violation of Federal Law. If these wastes cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Contact 3M Product Service at 612-733-0186 for additional information. It is the customer's responsibility to ship according to local, state and federal transportation requirements. Steri-Gas cartridges must be stored and transported in the original shipping case or intermediate package, both of which are Department

Handling and Disposal of Cartridges (Continued)

of Transportation (DOT) approved shipping containers. The following must be clearly visible on the outside packaging for transportation:

Red Flammable Gas Label
UN-1040
ETHYLENE OXIDE
Inhalation Hazard

Under DOT E-10695, 3M has been granted an extension from certain provisions of the U.S. Department of Transportation packaging regulations for transportation of Steri-Gas EO cartridges.

This exemption requires the cartons to be labeled with flammable gas labels and marked "Inhalation Hazard."

Ethylene Oxide Leaks or Spills

Characteristics of a Leak or Spill

The following indicate Steri-Gas cartridge leakage:

- liquid ethylene oxide spurting or rapidly dripping from a cartridge,
- a cartridge that feels very cold to the touch, and/or
- cartridge weight loss

Emergency Plan and Procedures

OSHA Requirements

The Occupational Safety and Health Administration (OSHA) requires facilities using ethylene oxide to have a written emergency plan for spills or leaks. Procedures for training, alerting, evacuating, rescuing, and, if necessary, medically treating personnel must be included in the plan. Procedures—from when an emergency is first reported to the time it is safe to re-enter the spill area—must also be specified. Responsibilities must be clearly defined in the plan.

OSHA requires an audible or visible alarm system to alert personnel of a spill or leak in areas with more than ten (10) employees.

A public address system, a call to the switchboard for an intercom announcement, and lights are examples of acceptable systems. The alarm can be either manually or automatically activated. An alarm connected to an air sampling system is not required. Direct voice communication can be used as an alarm in areas with ten or fewer employees.

OSHA also has specific requirements for installing, testing, and maintaining alarms.

Consult OSHA's standards on ethylene oxide (29 CFR 1910.1047), employee emergency plans (29 CFR 1910.28), and alarm systems (29 CFR 910.165) for more detailed information.

**Ethylene Oxide
Leaks or Spills
(Continued)**

Emergency Plan and Procedures (Continued)

**AAMI*
Recommended
Emergency Plan**

The emergency plan must be an integral part of employee training. All personnel likely to be involved in an EO emergency should be well versed in the procedures. Training should be scheduled during job orientation, whenever the emergency procedures change, and at least annually. Emergency drills, similar to fire drills, should be

scheduled periodically. A facility's safety officer or a member of a safety committee should develop the emergency plan with input from the departments handling ethylene oxide, an engineer, a physician and other appropriate personnel (e.g., local fire department).

3M endorses the "Action Team" concept as described in the following reference:

Association for the Advancement of Medical Instrumentation. *Good Hospital Practice: Ethylene Oxide Gas Ventilation Recommendations and Safe Use*. Doc. AAMI ST43-1993.

AAMI's address:
Suite #400
3330 Washington Blvd.,
Arlington, VA 22201-4598

**3M Recommendations
for Handling a Gas
Leak or Spill**

- Avoid direct contact with liquid ethylene oxide.
- Evacuate personnel from the immediate department.

- Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the ethylene oxide.
- Immediately contact the appropriate personnel designated in the department's emergency plan.

- If necessary, follow the First Aid measures listed in "Health and Safety Information" on p. 3 of this Product Profile.