INSERT THIS END

Steri-Gas™ 3M

Cartridge 4-100

Active Ingredient: Ethylene Oxide 100%•Net wt. 100gms (3.52 oz)

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 non-incinerated waste.

KEEP OUT OF REACH OF CHILDREN

DANGER

EXTREMELY FLAMMABLE — DO NOT USE NEAR FIRE OR FLAME

N Y F D C of A No 933

Use Only In Accordance With Manufacturer's Instructions In Steri-Vac™ Gas Sterilizer Models 400C/4XL/5XL.

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.

Made in U.S.A. for
3M Medical-Surgical Division
St Paul MN 55144-1000

785220

E.P.A. Reg. No. 7182-1
E.P.A. Est. No. 3657-WI-2

ACCEPTED

6

7182-1

Danger: Ethylene Oxide

Flammability

DANGER

FLAMMABILITY

Ethylene oxide is flammable in air when present in concentrations from 3% (30,000 ppm) to 100%. Keep matches, lighted cigarettes and other potential sources of ignition away from sterilizer and cartridges.

Toxicity

TOXICITY

Acute Inhalation. Overexposure may cause irritation of the respiratory tract, dizziness, weakness, nausea and vomiting (immediate or delayed), chest pain, and neurotoxic effects. Repeated overexposure may result in olfactory fatigue (i.e. increasingly difficult to smell EO.) EO is odorless except at concentrations > 500 ppm.

Chronic Inhalation. The results of animal toxicity and human epidemiology studies indicate that long-term exposure to inhaled EO may be hazardous to humans. The Occupational Safety and Health Administration (OSHA) classifies EO as a cancer and reproductive hazard.

Eye Contact. Liquid EO splashed in the eyes may cause severe injury. High concentrations of EO gas may cause severe eye irritation and injury.

Skin Contact. Liquid EO in contact with the skin may cause skin irritation, dermatitis and blisters.

Ingestion. A highly unlikely route of exposure. Liquid EO, upon ingestion, is caustic and may cause severe irritation and burns to the gastrointestinal mucosa.

APR 6 990

OSHA Limits (29 CFR 1910.1047)

A worker's exposure to EO must not exceed OSHA's Permissible Exposure Limit of 1 ppm (one part per million) measured as an 8-hour time-weighted average, or Excursion Limit of 5 ppm averaged over a sampling period of 15 minutes.

Statement of Practical Treatment/First Aid

Inhalation. Immediately get fresh air for overexposure to EO gas. Contact a physician as soon as possible.

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

Skin Contact. Thoroughly 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 Poision 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.

Steri-Gas™ Cartridge Selection

It is essential to use the correct cartridge/gas sterilizer combination.
The chart below will guide you in the proper selection of correct cartridge.

Steri-Gas Cartridge No.	Gas Sterilizer
2-67	Steri-Vac™ gas sterilizer Models 202 and 202B
4-134	Steri-Vac gas sterilizer Models 400 and 400B
4-100	Steri-Vac gas sterilizer Models 400C, 4XL and 5XL

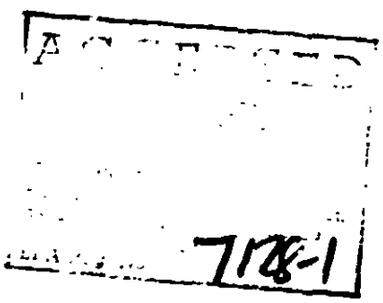
Note: This product is limited to use by health care professionals or appropriately trained personnel in health care and industrial use areas. It is a violation of Federal Law (USA) to use this product in a manner inconsistent with its labeling.

E.P.A. Reg. No. 7182-1 E.P.A. Est. No. 3657-WI-2 H.I. 4509
Made in USA for
Medical-Surgical Division 3M
3M Health Care
St. Paul, MN 55144-1000

Consumer Product Profile

Steri-Gas Cartridges EPA Reg. No. 7182-1

3M HealthCare



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H94609
Litho in U.S.A.

Medical-Surgical Division
3M Health Care

3M Center
St. Paul, MN 55144-1000

3M

1. INTRODUCTION

For over twenty years, unit dose quantities of ethylene oxide have been supplied to 3M Steri-Vac™ gas sterilizers in Steri-Gas cartridges. More than eighteen hundred health care facilities have found the 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.

2. FEATURES AND BENEFITS

Steri-Gas cartridges contain less than five (5) ounces of 100% ethylene oxide. Before a sterilization cycle is started, an operator inserts a cartridge into its holder inside the Steri-Vac chamber. The empty cartridge is easily removed from the holder after the sterilization cycle is completed, aerated with the sterilized items, and discarded with nonincinerated waste. The following are the major features and benefits of the system.

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

2.2 The cartridges deliver the proper amount of ethylene oxide for each sterilization cycle.

2.3 The system provides an easy, cost-effective and efficient method of gas sterilization.

2.4 The ethylene oxide in the cartridges is stable with a minimum shelf life of 24 months.

2.5 There are no bulky sterilant tanks to store, change and transport.

2.6 There are also no external valves and gaslines between the sterilizer and sterilant that can be sources of leaks and require time-consuming maintenance.

2.7 There are no gasline filters which can plug, need periodic changing, and can be sources of ethylene oxide exposure.

2.8 The cartridges do not contain chlorofluorocarbon diluents which are known to accelerate corrosion of certain plastics.[1]

3. STERI-GAS CARTRIDGE APPLICATIONS

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

Steri-Gas Cartridges	Steri-Vac Sterilizer models
2-67	202 & 202B
4-100	400C, 4XL & 5XL
4-134	400 & 400B

4. STERI-GAS CARTRIDGE PRODUCT SPECIFICATIONS

4.1 Cartridge Contents

Steri-Gas cartridges contain one hundred percent 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:

Boiling Point	10.7°C (51.3°F)
Vapor Pressure	1094 mm Hg at 20°C (457 g sq cm gauge)
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	Approximately 500 - 750ppm

[1]Health Devices, March-April, 1979, p. 147

4.2 Shelf Life

The minimum shelf life for Steri-Gas cartridges is twenty-four (24) months from the date stamped on the bottom of each cartridge and on the label of each Steri-Gas cartridge box. Weigh cartridges older than 24 months before use. Use cartridges with gross weights equalling or exceeding those listed in Section 4.3 in Steri-Vac sterilizers. **Do not use Steri-Gas cartridges with gross weights less than those listed below.** Follow the instructions listed in Section 9 for handling underweight cartridges.

4.3 Cartridge Weights

The following table lists the minimum acceptance gross weights of Steri-Gas cartridges before use.

Steri-Gas cartridge	Minimum Gross Weight in Grams
2-67	89
4-100	130
4-134	157

4.4 Cartridge Construction

The cartridge containing ethylene oxide is made of 0.07 cm (0.02 inch) thick seamless aluminum. The cartridge cap is valveless and composed of tin-plated steel with a thickness of 0.03 cm (0.01 inch).

5. REGISTRATION AND LISTINGS

5.1 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.

5.2 Listing With Underwriters Laboratories, Inc.

The Steri-Vac 4XL and 5XL gas sterilizers are listed with Underwriters Laboratories, Inc. (UL). As a third party testing institution, Underwriters Laboratories has evaluated the sterilization system at the request of 3M. The evaluation includes mechanical and electrical testing as well as an on-going program of factory inspections to ensure the equipment meets the requirements of UL Standard No. 544. The UL listing is located on the serial plate of the Steri-Vac 4XL and 5XL gas sterilizers.

5.3 International Listings

The Steri-Vac 4XL and 5XL gas sterilizers are also listed with two international agencies, the Technischer Uberwachungs-Verein (TUV) and the Canadian Standards Association (CSA). The TUV is an inspection agency authorized by the West German government to implement an equipment safety law. TUV conducts tests and applies certification marks to products meeting the International Electrical Commission (IEC 601-1) requirements. In a similar manner, CSA reviews equipment in light of Canadian safety standards and guidelines.[2] The CSA and TUV labels located on or near the serial plate represent sterilizer compliance.

5.4 Factory Mutual Systems Listing

Factory Mutual Systems has evaluated the electrical safety of the following Steri-Vac sterilizer/ Steri-Gas cartridge systems.

Steri-Vac sterilizers	Steri-Gas cartridge
400B	4-134
400C	4-100

Factory Mutual Systems is an internationally recognized testing laboratory similar to Underwriters Laboratories. Its tests include both electrical and mechanical tests and end-of-cycle gas concentration measurements. 3M participated with Factory Mutual in a program of periodic factory inspections and design change notifications to ensure that its safety performance requirements continued to be met. The Factory Mutual label is located near the serial plate of each Steri-Vac 400B and 400C gas sterilizer.

HEALTH AND SAFETY INFORMATION

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. 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 Material Cartridge Safety Data Sheet containing more detailed information.

⚠ DANGER

6.1 Flammability

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 cartridges.

6.2 Toxicity

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

6.2.2 Chronic inhalation. The results of animal toxicity and human epidemiology studies indicate that long term exposure to inhaled ethylene oxide may be hazardous to humans. The Occupational Safety and Health Administration (OSHA) classifies ethylene oxide as a cancer and reproductive hazard.

6.2.3 Eye Contact. Liquid ethylene oxide splashed in the eyes may cause severe injury. High concentrations of ethylene oxide gas may cause severe eye irritation and injury.

6.2.4 Skin Contact. Liquid ethylene oxide in contact with the skin may cause irritation, dermatitis, and blistering.

6.2.5 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.

6.3 OSHA LIMITS (29 CFR 1910.1047)

A worker's exposure to ethylene oxide must not exceed OSHA's Permissible Exposure Limit of 1 ppm (one part per million) measured as an 8-hour time-weighted average nor the Excursion Limit of 5 ppm averaged over a sampling period of 15 minutes. Direct contact with ethylene oxide as a liquid or in ...tions must be prevented.

6.4 STATEMENT OF PRACTICAL TREATMENT/FIRST AID

6.4.1 Inhalation. Immediately get fresh air for overexposures to ethylene oxide gas. Contact a physician as soon as possible. Repeated overexposure may result in olfactory fatigue (i.e., increasingly difficult to smell E.O.) Ethylene Oxide is odorless except at concentrations > 500 ppm.

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

6.4.3 Skin Contact. Thoroughly 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.

6.4.4 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.

STORAGE OF STERI-GAS CARTRIDGES

7.1 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, ...xcept in safety cans." Ten (10) gallons of ethylene oxide is approximately equivalent to 245 of the ...rgest Steri-Gas cartridges (No. 4-134).

7.2 3M RECOMMENDATIONS

The following are 3M's recommendations for storing Steri-Gas cartridges. These recommendations are significantly more stringent that those in the NFPA Codes. Check your local fire protection codes for additional requirements.

⚠ DANGER

7.2.1 Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilizer and cartridges.

7.2.2 Store cartridges at room temperature.

7.2.3 Keep only one day's requirement or a maximum of twelve (12) cartridges (one box) in the immediate sterilizer area.

7.2.4 Store 13-48 cartridges (2-4 boxes) in an area away from the sterilizer(s) and ignition sources.

7.2.5 Store 49 or more cartridges (more than 4 boxes) in an approved flammable liquid storage cabinet or in an area suitable for storage of flammable liquids.

8. CARTRIDGE SHIPPING

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

8.1 Red Flammable Liquid Label

8.2 UN-1040

8.3 ETHYLENE OXIDE

9. CARTRIDGE HANDLING AND DISPOSAL

9.1 Used Cartridges

9.1.1 Aerate empty (i.e. used) Steri-Gas cartridges with sterilized medical items. This procedure will ensure that any trace quantities of ethylene oxide gas are removed from the cartridges.

9.1.2 After aeration, dispose of the empty cartridges with normal, nonincinerated waste.

9.1.3 Dispose of the aerated cartridges immediately. Do not return empty cartridges to boxes containing full cartridges. This precaution will prevent the accidental disposal of full cartridges.

9.2 Unused Cartridges

Unused cartridges are pesticide wastes which are toxic. Improper disposal 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. Contact 3M Technical Service at 612/736 3861 for additional information.

10. ETHYLENE OXIDE LEAKS OR SPILLS

10.1 Characteristics of a Leak or Spill

The following indicate Steri-Gas cartridge leakage:

10.1.1 liquid ethylene oxide spurting or rapidly dripping from a cartridge,

10.1.2 a cartridge that feels very cold to the touch, and/or

10.1.3 cartridge weight loss.

10.2 Emergency Plan and Procedures

10.2.1 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 for reporting an emergency to appropriate authorities and for determining when 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. OSHA has specific requirements for installing, testing, and maintaining alarms. Direct voice communication can be used as an alarm in areas with ten or fewer employees. Consult OSHA's standards on ethylene oxide (29 CFR 1910.1047), employee emergency plans (29 CFR 1910.28), and alarm systems (29 CFR 1910 165) for more detailed information.

10.2.2 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 inputs 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:

"Good Hospital Practice: Ethylene Oxide Gas-Ventilation Recommendations and Safe Use"

Doc. No. AAMI EO-VRSU 3/81

Association for the Advancement of Medical Instrumentation
(AAMI)
1901 North Ft. Myer Drive
Suite 602
Arlington, VA 22209
Phone 703/525-4890

10.2.3 3M Recommendations for a Gas Leak or Spill Response

10.2.3.1 Avoid direct contact with liquid ethylene oxide.

10.2.3.2 Evacuate personnel from the immediate department.

10.2.3.3 Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the ethylene oxide.

10.2.3.4 Immediately contact the appropriate personnel designated in the department's emergency plan.

10.2.3.5 If necessary, follow the First Aid measures listed in Section 6.

10.2.3.6 Re-enter the department only after a qualified health and/or safety personnel has 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).

10.2.3.7 Contact the cartridge manufacturer. If the spill is associated with the sterilizer, contact the sterilizer manufacturer's representative.

10.2.3.8 Do not wear clothing contaminated with ethylene oxide until it has been laundered. Discard contaminated leather items.

11. PRECAUTIONS

11.1 Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from the sterilizer and Steri-Gas cartridges.

11.2 DO NOT INCINERATE empty or full Steri-Gas cartridges.

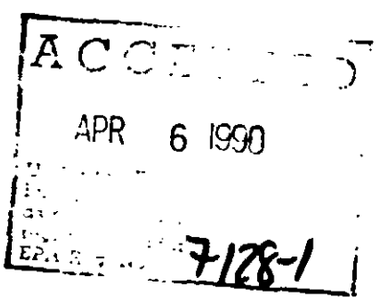
11.3 DO NOT PLACE A LEAKING CARTRIDGE IN AN AERATION CABINET. Place or leave the cartridge in the sterilizer and run a cycle to evacuate the ethylene oxide.

11.4 Do not puncture the cartridge by any means other than in the sterilizer.

11.5 In accordance with the 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 Section 10 of this Product Profile for detailed information.

,M STERI-VAC™ 5XL Gas Sterilizer/Aerator Operator's Manual

EPA Reg. No. 7182-1



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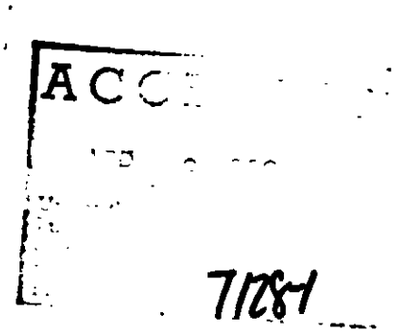


1. Introduction

Health and Safety Information

⚠ DANGER

ETHYLENE OXIDE

FLAMMABILITY

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.

TOXICITY

Acute Inhalation 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) classifies ethylene oxide (EO) as a cancer 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. 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's Permissible Exposure Limit. A worker's exposure must not exceed 1 ppm (one part per million) measured as an 8-hour time-weighted average, nor exceed 5 ppm averaged over a sampling period of 15 minutes.

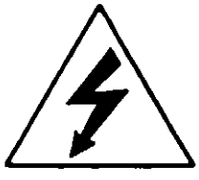
STATEMENT OF PRACTICAL TREATMENT/ FIRST AID

Inhalation. Immediately get fresh air for overexposures 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.



CAUTION

Hazardous Voltage.
Refer installation and servicing to qualified persons.

General Ethylene Oxide Data

Boiling Point:	10.7°C (51.3°F)
Vapor Pressure:	1094 mm Hg at 20° C (457 g/sq cm gauge)
Color:	Colorless
Flammable Limits:	3% (30,000 ppm) to 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:	Approximately 500 - 750 ppm

Ethylene Oxide Leaks or Spills

The following indicate ethylene oxide leakage from a 3M Steri-Gas 4-100 cartridge:

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

3M recommends an ethylene oxide area monitor for detecting short term airborne gas at concentrations that cannot be noticed by the user. The chosen monitor should be EO specific to avoid false alarms from other chemical compounds.

OSHA Requirements

The Occupational Safety and Health Administration (OSHA) requires facilities using ethylene oxide to have the following:

- Written emergency plan for spills or leaks.
- Procedures for training, alerting, evacuating, rescuing and medically treating personnel.
- Procedures for reporting an emergency to appropriate authorities and for determining when it is safe to re-enter the spill area.

Responsibilities must be clearly defined in the plan. Consult OSHA's standards on ethylene oxide (29 CFR 1910.1047 [AMENDED]), employee emergency plans (29 CFR 1910.28), and alarm systems (29 CFR 1910.165) for more detailed information.

3M Recommendations for a Gas Leak or Spill Response

- Avoid direct contact with ethylene oxide.
- Evacuate personnel from the immediate department
- Keep all sources of ignition such as matches, lighted cigarettes, sparks and static discharge away from ethylene oxide.
- Immediately contact the appropriate personnel designated in the department's emergency plan. They may then need to contact the 3M Medical-Surgical Service Representative or the 3M Medical-Surgical Service Center.
- If necessary, follow the Practical Treatment measures listed on the front panel label.
- Re-enter the department only after a qualified health and/or safety person has 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).
- Do not wear clothing contaminated with ethylene oxide until it has been laundered. Discard contaminated leather items.
- DO NOT PLACE A LEAKING CARTRIDGE IN AN AERATION CABINET.
  Place or leave the cartridge in the sterilizer and run a cycle to evacuate the ethylene oxide.

Sterilizer Listings
The Steri-Vac 5XL gas sterilizer is listed with the Underwriters Laboratories, Inc. (UL), the Canadian Standards Association (CSA) and the West German Technischer Überwachungs-Verein (TÜV). These are internationally recognized laboratories that inspected and evaluated the Steri-Vac system. Their labels are located on or near the serial plate of your sterilizer.

Sterilizer Specifications

Chamber Dimensions

Width	Depth	Height	Diagonal
43 cm	82.6 cm	38 cm	96.5 cm
(17 in)	(32.5 in)	(15 in)	(38 in)

Basket (two baskets) Dimensions

Width	Depth	Height	Diagonal
41 cm	80 cm	20 cm	N/A
(16 in)	(31-1/2 in)	(8 in)	

Note: Refer to the Steri-Vac 5XL Installation Guide for the exterior dimensions.

Chamber Volume:	136 liters (4.8 cu ft)
Chamber Material:	Anodized Aluminum
Exterior Finish:	Baked enamel black body; brushed stainless steel door.
Net Weight:	136 Kg (300 lb.)
Shipping Weight:	145 Kg (320 lb.)

Power Requirements:

Voltage:	220 Volts AC (V ~), ±10%
Frequency:	50/60 Hz
Phase:	Single (1)
Current:	15 Ampere (Dedicated)
Power Cord:	220 Volt, 15 amp plug .

Power cords furnished with sterilizers sold outside the USA will meet local electrical requirements. A circuit breaker is incorporated in the ON/OFF switch.

Compressed Air Requirements
Air Pressure:

minimum	3.5 Kg/cm^2 (50 psig)
maximum	10.5 Kg/cm^2 (150 psig)
Air Flow:	3.4 liters/second (7 scfm) at 3.5 Kg/cm^2 (50 psig)

Water Requirements
No external water connection. The operator must add distilled water to the water reservoir.

Reservoir Capacity: 1 liter (provides humidification for approximately 25 cycles)

Venting Requirement
The chamber must be vented through a dedicated copper line exhausting to the outside atmosphere or to an emission control system.

Exhaust Hood Requirements (optional)
A local exhaust hood can be built into the top panel of the sterilizer for users who need immediate access to the load at the end of the sterilization cycle. Its function is to remove residual ethylene oxide gas from the breathing zone when the door is opened at cycle completion. The hood must be connected to a dedicated exhaust system supplied by the customer.

The system must meet the following minimum specifications. *(See the 5XL Installation Guide for complete requirements)*

Air Flow Through Hood:
283 decaliters/min (100 scfm)

Air Velocity in 10.2 cm (4 in) Line to Hood:
350 meters/min (1150 fpm)

Static Pressure (Water Gauge) at Hood:
-0.15 cm (-0.06 in)

Sterilant Specifications
Use 3M Steri-Gas 4-100 unit dose cartridges containing 100% ethylene oxide. The retainer ring of the cartridge holder inside the sterilizer chamber is color coded green to match the green label on the Steri-Gas 4-100 cartridge.

Sterilant Shelf Life & Cartridge Weight
The minimum shelf life for Steri-Gas cartridges is twenty-four (24) months from the date stamped on the bottom of each cartridge and on the label of each box of Steri-Gas cartridges. Weigh cartridges

older than 24 months before use. Use Steri-Gas 4-100 cartridges with gross weights of 130 grams or more in the Steri-Vac 5XL gas sterilizer. Follow the instructions listed in the Steri-Gas Consumer Product Profile, (see Accessory Section) for handling underweight cartridges.

Steri-Gas 4-100 Cartridge Specifications

Length:	16.5 cm (6.5 in)
Diameter:	3.8 cm (1.5 in)
Minimum Weight:	130 grams

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.

II. Sterilizer Operating Procedure

Notice: User Responsibility
Only health care 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 persons or property can result unless the operating instructions are followed carefully.

Power On Continuously
Turn on the power switch located on the left side of the sterilizer. Leave the power switch on at all times. Leaving the sterilizer in standby simplifies operation and enables the sterilizer electronics monitor the operation continuously. The sterilizer will be in standby except during sterilization or aeration.

Loading the Sterilizer
Thoroughly wash and rinse all items to be sterilized to remove any mucus, dried blood, or other organic matter. Ethylene oxide will not kill microorganisms hidden and protected in dried organic matter. Remove excess moisture left from cleaning the items and package items in an EO permeable container or wrapping.

Load sterilizer baskets in a loose, orderly manner. Packages should not contact the chamber walls. Place packages on their edge to eliminate undue pressure on pouches and to facilitate gas penetration. Do not stack packages. Arrange paper-plastic pouches so plastic sides face the paper sides. If a pouch must be placed flat in the basket, place the paper side down.

When possible, sterilize full loads of items having common aeration times. Otherwise, place the items with shorter aeration times at the front of the load for easy retrieval.

Biological Monitoring
A biological indicator, such as the 3M Attest™ biological indicator for gas sterilization, should be included in each load of items sterilized with ethylene oxide to monitor the effectiveness of the sterilization process. The biological indicator should be placed in a test pack that is representative of the load and creates the greatest challenge. Another option is to use a disposable 3M Attest EO pack. Place the test pack in the center of a full load. See the Attest biological indicator for EO sterilization and the Attest EO pack package inserts for further instructions. (In countries other than the USA, additional biological tests may be required).

A number of organizations in the USA recommend the biological monitoring of every load sterilized with ethylene oxide for maximum sterilization quality assurance. These organizations include the Association for the Advancement of Medical Instrumentation (AAMI)[1], the American Hospital Association (AHA)[2], the Association of Operating Room Nurses (AORN)[3], the U.S. Army[4], and the Veterans Administration[5].

Load the Chamber
Check that the sterilizer is in standby, indicated by a light in one of the two temperature switches and all other panel lights off.

Turn the handle counter-clockwise all the way to open the sterilizer door.

If the unit has the local exhaust hood option installed, lift the DOOR RELEASE on the exhaust hood while pulling the door open.

Insert Gas Cartridge
Insert a Steri-Gas 4-100 cartridge into the retainer ring of the cartridge holder inside the chamber. Push the cartridge down and slightly inward until the cartridge is properly seated. The **green label** on the Steri-Gas 4-100 cartridge matches the **green retainer ring** of the holder.

1. AAMI, "Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers - Ethylene Oxide Test Packages", 1987.
2. AHA, "Guidelines for Hospital Central Service Department", 1978.
3. AORN, "Recommended Practices, Sterilization and Disinfection", 1987.
4. U S Army, Army Regulations (AR40-19), 1984.
5. Veterans Administration, VA Manual 61, MP-2 1985 and MP-2, Sub-Chapter E, Change 159, June 22,1983.

Insert Baskets
Place loaded baskets in the sterilizer. The upper basket slides over the lower basket to minimize the lifting required. Close the door by turning the handle clockwise until it stops.

Select Temperature and Start
Press either the WARM or COOL temperature select switch. Check that the light in the upper right corner of the selected switch is ON.

Press the START switch.

The cycle now continues automatically to completion. The cycle temperature appears in the digital display in the upper right corner of the front panel. The chamber pressure is displayed just below the temperature.

The following panel lights indicate the progression of the cycle.

PRE-CONDITION
GAS EXPOSE
AERATE

chamber temperature remains the same as selected for the sterilization cycle. A 15-second alarm sounds when the door unlocks.

NOTICE
The door unlocks immediately after the sterilization cycle for a sterilizer with a built in local exhaust hood. If no hood is installed, the sterilizer aerates for three hours before unlocking the door.

Door Opening without Local Exhaust Hood
To open the door, turn the handle counter-clockwise all the way, allow approximately 30 seconds for the chamber pressure to equalize with the room pressure, then pull the door open. The elapsed time display stops while the door is open and resumes timing when it is closed.

To continue aerating the remaining items, close the door and turn the handle clockwise. Do not press any of the switches.

Door Opening with Local Exhaust Hood
Ensure that the digital display is not flashing a "C 1" caution message. This warning indicates a malfunction of the local exhaust system. Correct the problem, or aerate for at least 3 hours before opening the sterilizer door.

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

Pull the door open to the "latched position" *(See Figure 1)*. The elapsed time display stops while the door is open and resumes timing when it is closed. Keep the door in the latched position for at least five minutes. After five minutes, pull the door fully open

The sterilizer has the following approximate cycle times.

Approximate Cycle Times

Cycle	Temperature	Cycle Time with Local Exhaust Hood	Cycle Time without Local Exhaust Hood
WARM	55 C (132 F)	2 hrs 45 min	5 hrs 45 min
COOL	37 C (99 F)	4 hrs 45 min	7 hrs 45 min

Automatic Aeration
After ethylene oxide sterilization, the load must be aerated to remove the gas that has been absorbed by the load. It is possible to leave the load in the Steri-Vac 5XL gas sterilizer/aerator or transfer the basket of items to an aeration cabinet. Use the device manufacturers' recommendations for aeration time and temperature.

After sterilization is complete, aeration begins automatically in the sterilizer. The AERATE status light comes on and the the digital display in the upper right corner of the front panel shows the elapsed time of aeration in hours and minutes. The

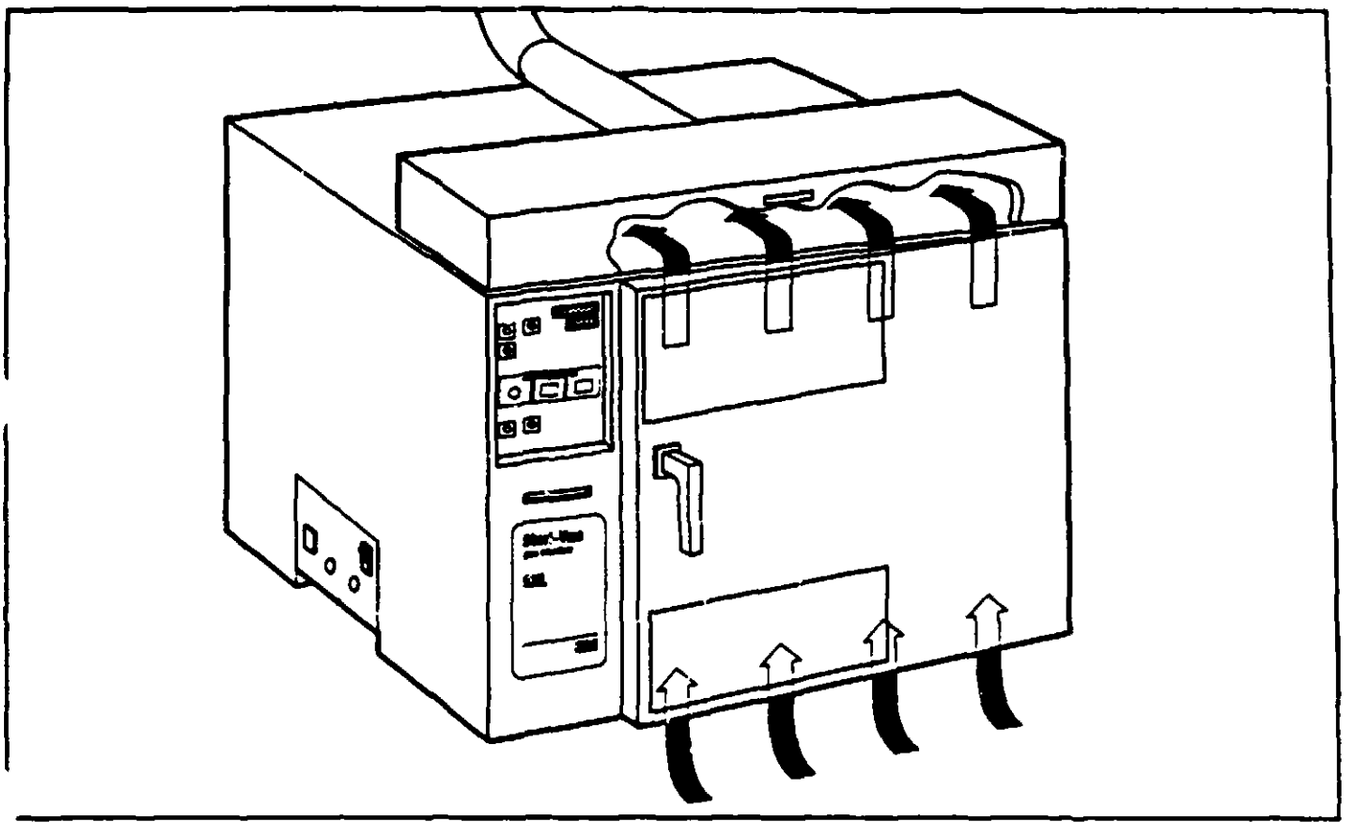


Figure 1. Optional Local Exhaust Hood. Door open to "latched position".

while lifting the DOOR RELEASE on the exhaust hood.

To continue aerating the remaining items, close the door and turn the handle clockwise. Do not press any of the switches.

NOTICE
If the door is not opened within two minutes after turning the handle, aeration resumes. Turn the door handle to the vertical position and repeat the door opening procedure.

Unloading the Sterilizer
Remove the baskets of sterilized items. Remove the empty gas cartridge from the holder. Place it on top of a basket of goods to be aerated. *(You do not need to continue to aerate an empty cartridge that has aerated in its sterilizer holder for two or more hours.)* Dispose of the aerated empty cartridge with non-incinerated waste.

Follow the instructions from the manufacturer of the biological indicator for removing the test pack from the load and incubating the biological indicator. Transfer the basket of unaerated or incompletely aerated items to an aeration cabinet.

Terminating the Cycle - Return to Standby
Press the STOP switch while the door is open to reset the sterilizer to standby. Close the sterilizer door. The sterilizer remains in standby until the next cycle is started.

III. Theory of Operation

Benefits of Ethylene Oxide Sterilization
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. The following are the major benefits of 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 used.
- Ethylene oxide is relatively noncorrosive to plastic, metal, or rubber materials.
- Ethylene oxide can penetrate and sterilize irregularly shaped items.
- Biological (e.g. Attest biological indicators) and chemical (e.g. Indox™ EO monitor tape or Comply ™EO indicators) monitoring systems can be used to ensure that sterilization parameters are met and to distinguish processed from unprocessed materials.
- Ethylene oxide can be used to sterilize those materials that cannot be immersed in liquid disinfectants or processed by steam or dry heat sterilization.

Features and Benefits of the Steri-Vac 5XL gas sterilizer/ aerator

The Steri-Vac 5XL gas sterilizer is a compact unit with a 4.8 cubic foot chamber. The sterilizer can be installed in a wall, in a specially designed rack, or on a counter top. It can be ordered with two doors to allow pass-through operation in a clean room arrangement. It can be installed with a local exhaust hood or operated with a mandatory three-hour aeration making the exhaust hood unnecessary. All versions meet current OSHA and EPA regulations concerning operator exposure and sterilization performance.

The 5XL sterilizer offers a fully automatic system of controls to ensure that proper conditions for sterilization are met and to minimize the possibility of operator exposure to high concentrations of ethylene oxide gas. The following are the major features and benefits of the system.

Negative Pressure
- Throughout the cycle the chamber remains at negative pressure relative to the room so gas cannot escape.

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

Continuous Cycle Monitoring
- The chamber temperature and vacuum are monitored continually during the sterilization cycle.
- Humidification:
  Multiple pulses of low temperature steam assure proper humidification.
- 100% EO Unit Dose Cartridge:
  A unit dose cartridge of ethylene oxide is punctured inside the chamber after the door is closed and locked with vacuum verified.
  The gas cartridge contains no chlorofluorocarbons (CFCs).
- Cycle Status Display:
  The lights on the front panel of the sterilizer show cycle status.
- Graphic Printer:
  A printer is installed to give a permanent graphic record of time, temperature, pressure and aeration time.

Manual Cycle Interrupt
- The operator can manually interrupt a cycle at any time. The final vacuum system and air purge automatically clear the chamber before the door is unlocked if the cartridge was punctured.

Reliability
- For maximum reliability, the air venturi vacuum pump has no moving parts.

Automatic Aeration
- Aeration begins automatically after the sterilization cycle. The sterilization/aeration process can be accomplished in one chamber reducing potential gas exposure due to load transfer to an aerator.

Explanation of Sterilizer Controls

Refer to Figure 2 showing the sterilizer controls.

Power Switch
Controls power to the sterilizer. The switch located on the left side of the sterilizer should be kept on at all times to simplify operation.

Temperature Select Switches
Select the chamber temperature. During the sterilization and aeration cycles, the selected temperature cannot be changed.

Start Switch
Starts the automatic sterilization cycle.

Stop Switch
Interrupts the cycle at any time. If pressed before the GAS EXPOSE light appears, the sterilizer reverts to standby and the door can be opened. If the GAS EXPOSE light is on, the sterilizer

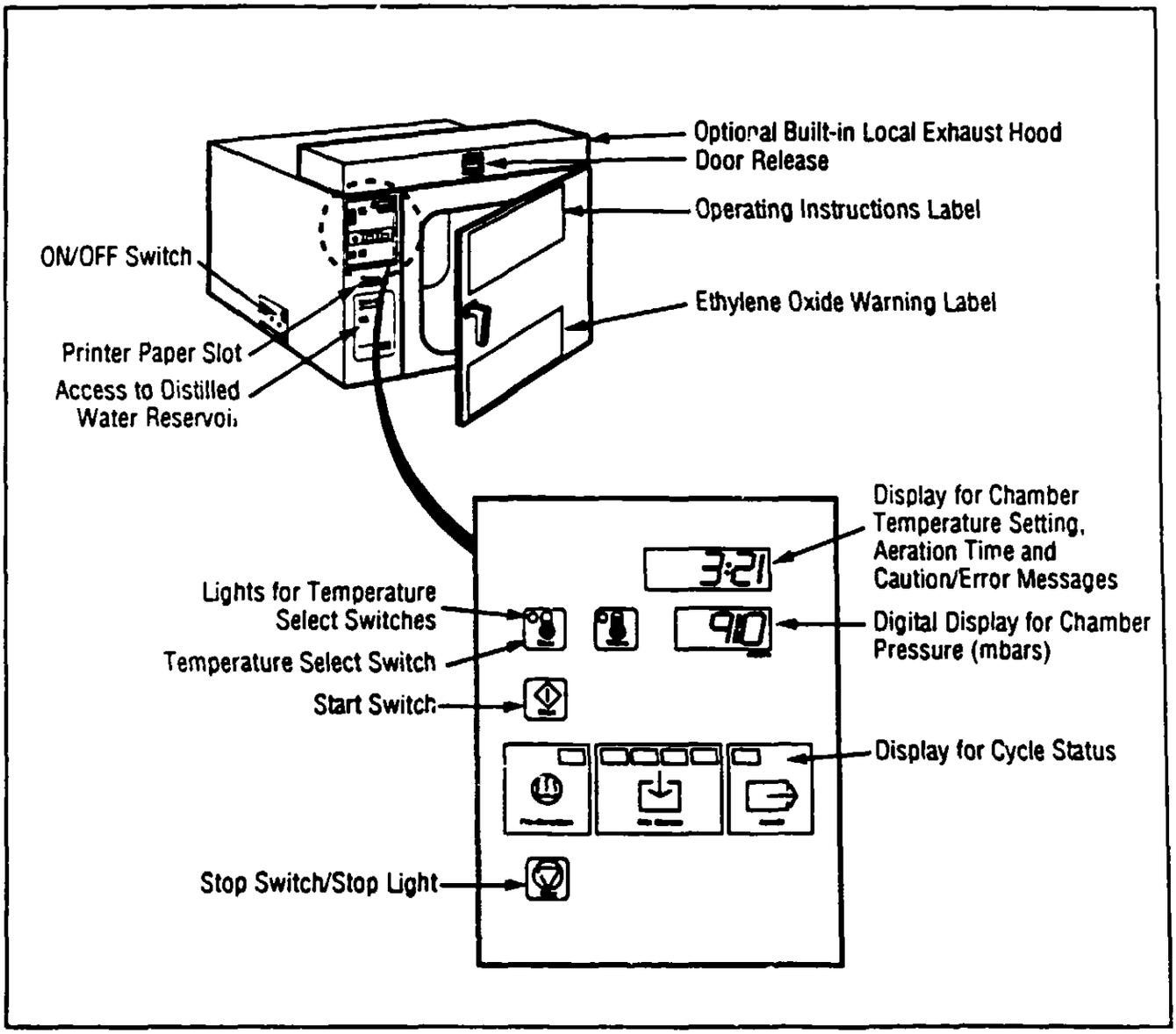


Figure 2. Sterilizer controls.

advances to final vacuum exhaust. An audible alarm then sounds, indicating cycle termination.

The sterilizer ends aeration and returns to standby if the STOP switch is pressed while the AERATE light is on and the door is open.

Upper Digital Display - Temperature Display
The upper digital display indicates chamber temperature setting in degrees Celsius. The temperature is displayed during the PRE-CONDITION and GAS EXPOSE phases.

Upper Digital Display - Aeration Time Display
The upper display indicates the elapsed time in AERATE to a maximum of 99 hours and 59 minutes. The timer replaces the temperature display when the sterilization cycle is completed. The aeration temperature remains the same as selected for sterilization.

Upper Digital Display - Caution/Error Codes
The upper display is used to indicate caution or error codes that may occur during the cycle.

Pressure Display
The lower digital display indicates the absolute pressure of the chamber in millibars during the sterilization and aeration cycles. (*1000 millibars are approximately equal to 1 atmosphere.*)

Temperature Select Switch Lights
Indicates that either WARM or COOL switch was pressed. These remain lit after cycle completion and during standby until the other temperature switch is pressed.

Precondition Status Light
Indicates start of a sterilization cycle during which vacuum is drawn and the chamber is heated and humidified. There is no gas in the chamber during this phase.

Gas Expose Status Lights
Indicates the phases during which the cartridge is punctured, the load is exposed to ethylene oxide, the gas is exhausted and the chamber is purged for 30 minutes.

Aerate Status Light
Indicates final phase when the door is unlocked and the sterilized load is being aerated.

Stop Light
Indicates the cycle was interrupted before the end of the sterilization process. The error code is displayed in the upper digital display.

Preparing for Sterilization

Humidification - Preconditioning
Cleaning and humidification is essential for ethylene oxide sterilization. The gas may not kill dessicated microorganisms. Moisture swells the microbial cells to enhance ethylene oxide penetration and aids the chemical alkylation process that kills the microorganisms.

Preconditioning Hard Surfaced Items
Plastic devices or items with hard surfaces may require more humidification than provided by the sterilizer's automatic humidification system. If possible, wash and soak these items well. Rinse and dry the articles only until there are no visible liquid droplets. Keep articles in an area with a relative humidity of 30% or greater overnight before packaging and sterilization.

NOTICE
Remove drops of water from articles before gas sterilization. The liquid and ethylene oxide may form residues of ethylene glycol and ethylene chlorohydrin during sterilization. Routine aeration does not remove these residues.

Packaging

Packaging Material Characteristics
Before sterilization, package articles that will be stored before use. Use packaging materials with the following characteristics:
- permit rapid penetration of the ethylene oxide and moisture
- permit release of the gas after sterilization
- are strong enough to withstand normal handling
- allow easy filling, sealing, removal (aseptic presentation) and handling

•are suitable barriers to bacteria and permit extended shelf life
•provide proven seals (i.e. do not delaminate or reseal if opened)

Packaging Materials
The following materials are compatible with ethylene oxide sterilization.
•Tyvek™ film
•paper/film
•glassine
•paper or nonwovens
•muslin or wovens
•sterile rigid container systems designed for EO sterilization
•polyethylene film with a maximum thickness of 5 mil (*Dampen or prehumidify items wrapped in polyethylene film which can be a barrier to water vapor and prevent sterilization.*)

Do not use the following materials for packaging! They are not suitable for ethylene oxide sterilization.
•nylon film
•polyester film
•aluminum foil
•glass or metal jars

Power On
The power switch, located on the left side of the sterilizer, should be in the ON position at all times to allow the unit to perform self checks and to simplify operation.

Standby
In the standby mode, the sterilizer is monitoring the water level, the compressed air supply and the air flow in the optional exhaust hood (if connected). The standby mode is indicated by one of the temperature select switches being lit and all other lights turned off.

Cycle Selection
The Steri-Vac 5XL gas sterilizer has two cycles: WARM (55°C) or COOL (37°C). Both cycles have been shown to be efficacious . The choice is based on the temperature sensitivity of the materials being sterilized. Since ethylene oxide is more reactant at higher temperatures, the WARM cycle requires less gas exposure time than the COOL cycle.

After loading the chamber with the prepared baskets and a gas cartridge, the door is closed and the cycle temperature is selected and the START switch pressed. The sterilizer operates automatically for the rest of the sterilization process.

Precondition
The sterilizer locks the door and begins to "precondition" the load for sterilization. The PRECONDITION phase takes approximately 45 minutes and establishes chamber vacuum, temperature and humidity.

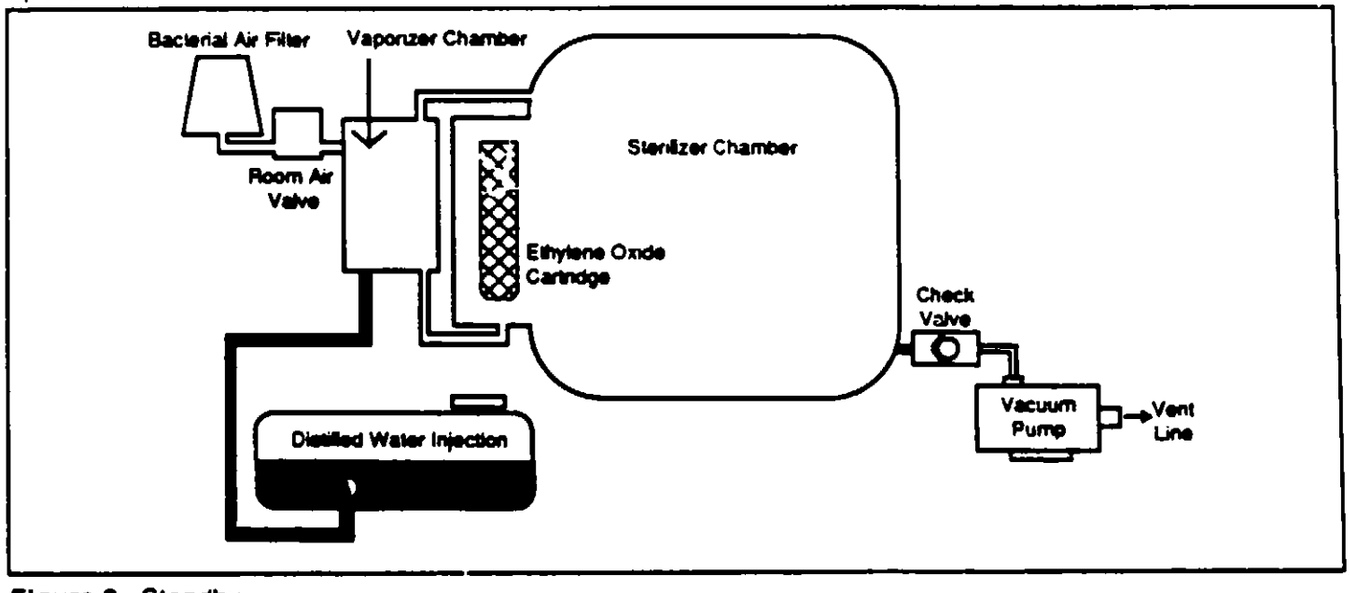


Figure 3. Standby.

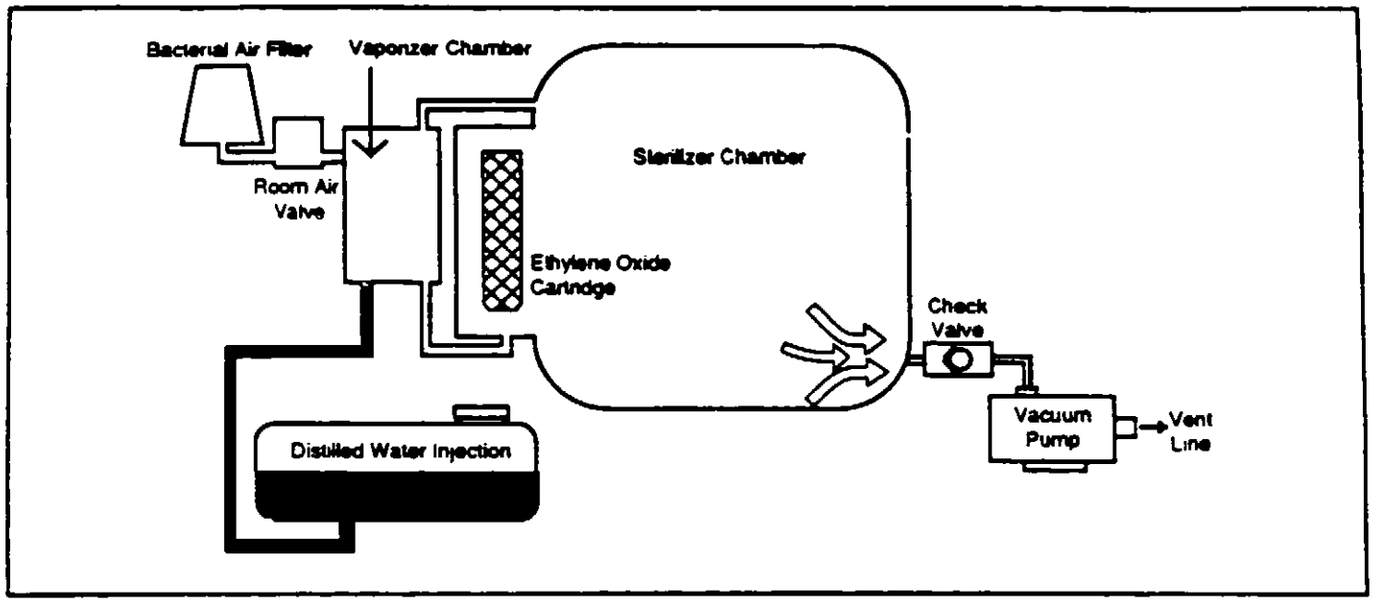


Figure 4. Initial Vacuum.

Initial Vacuum

The vacuum within the chamber serves several functions. First, it prevents any gas from escaping the chamber. Secondly, it improves the penetration of the humidity and gas into difficult to reach parts of the load by removing air that would otherwise block access. The sterilizer allows a maximum of 20 minutes for the vacuum system to draw down to the proper level.

Preheat

While the chamber vacuum is being drawn, the chamber walls are brought up to the selected temperature. The load is warmed during this time. A maximum of 45 minutes is allowed to achieve the selected temperature.

Humidification

After the proper vacuum and temperature conditions have been reached, the sterilizer injects low temperature steam to humidify the load. This improves the ethylene oxide penetration through the

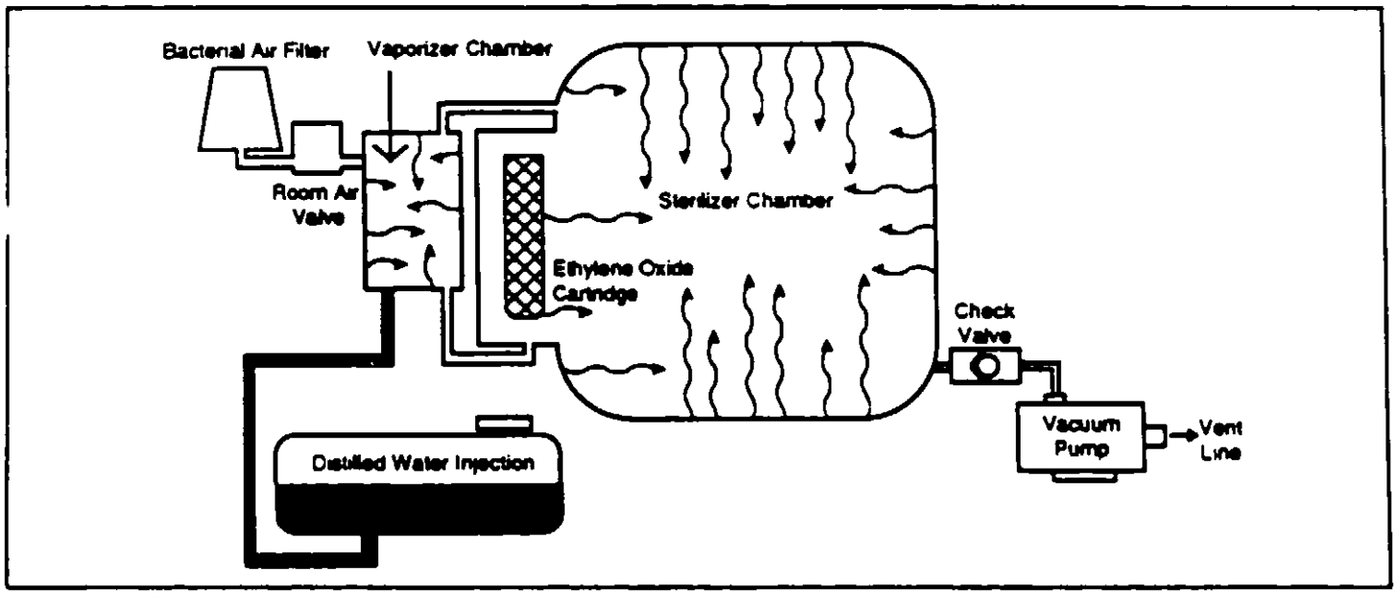


Figure 5. Preheat.

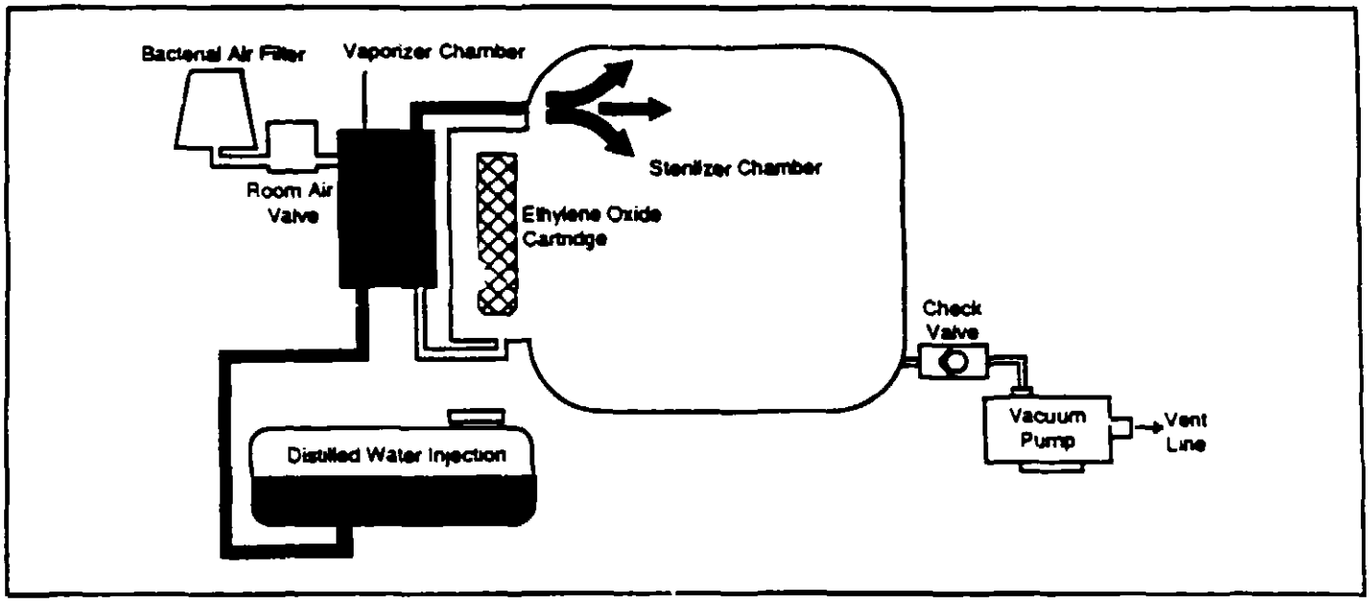


Figure 6. Humidification.

cell walls. The sterilizer injects this steam in a series of pulses that combine long soak times with additional vacuum to ensure good penetration of even hard-to-reach areas.

The COOL cycle makes three low temperature steam injections, each followed by eight minutes of soak time and three minutes of vacuum. Since warm air can hold more moisture, the WARM cycle makes four injections with 5.5 minutes of soak time and three minutes of vacuum.

Gas Expose

The GAS EXPOSE phase indicates the presence of EO in the chamber. The four status lights each represent approximately 25% of this phase. The approximate GAS EXPOSE time shown below includes the gas exposure time, final vacuum and thirty minutes of fresh air purge.

Cycle	Total Time in GAS EXPOSE
WARM	100 minutes
COOL	220 minutes

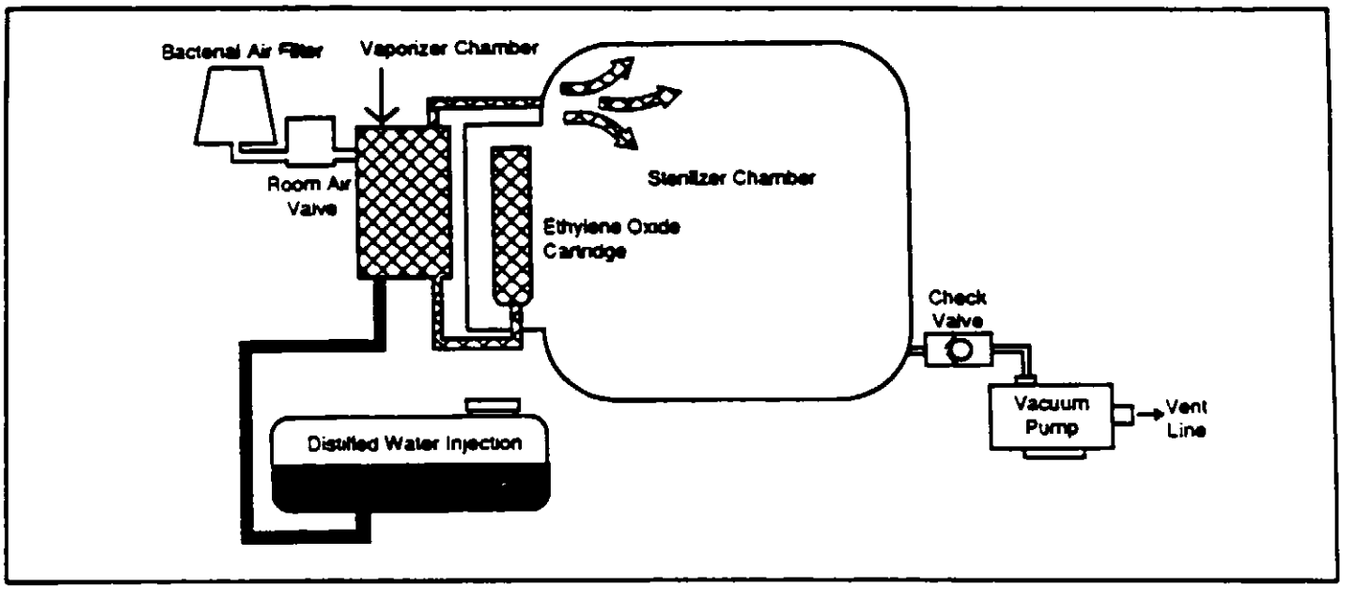


Figure 7. Gas Injection.

Gas Injection

Before puncturing the gas cartridge, the sterilizer automatically verifies the chamber temperature, the vacuum level and the door position. The difference in pressure between vacuum in the chamber and pressure outside the chamber provides the force used to puncture the cartridge. This use of pressure difference gives added assurance that the puncture cannot occur if the door is open or insufficient vacuum is in the chamber.

After puncture, the sterilizer electronics monitor the increase in chamber pressure caused by the gas being released. If this pressure does not increase, it indicates that a new cartridge was not used. If the pressure does not increase a sufficient amount, it indicates the possibility that the cartridge was not fully punctured. Both of these situations would cause the sterilizer to display an error code and stop the cycle.

Gas Exposure

Throughout the gas exposure, the sterilizer chamber is maintained at a negative pressure.

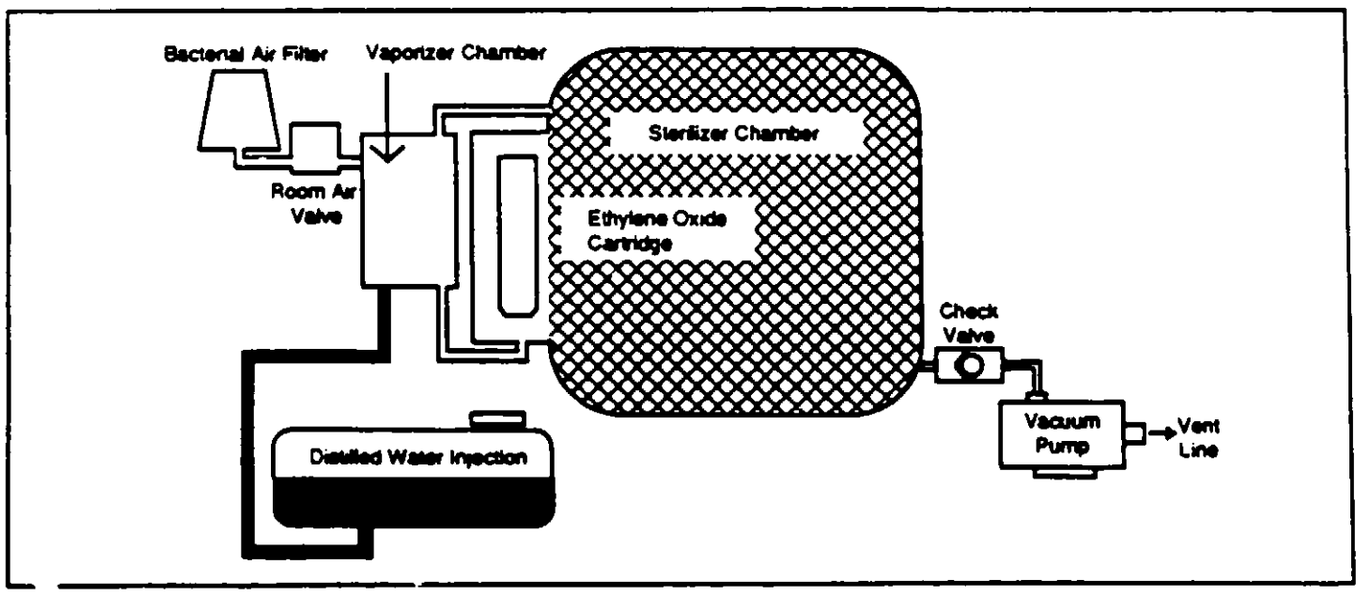


Figure 8. Gas Exposure.

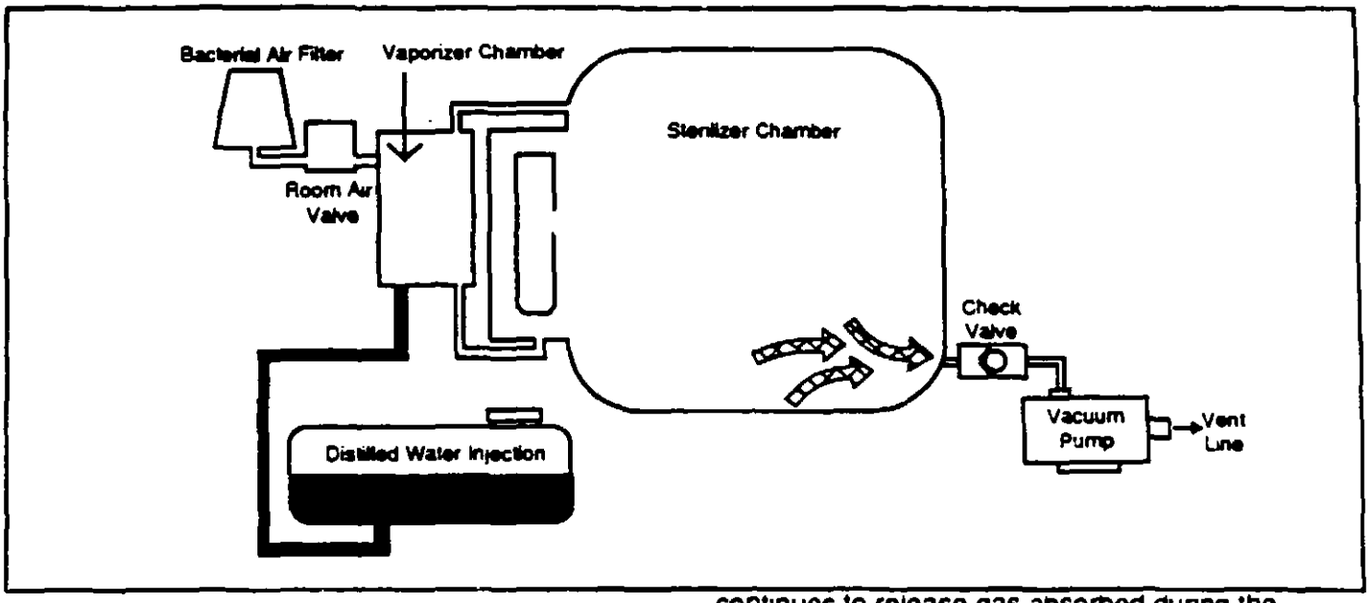


Figure 9. Final Vacuum Exhaust

This ensures that gas cannot escape the chamber. If the chamber vacuum or temperature cannot be controlled properly, the cycle will be stopped and an appropriate error code will be displayed. Four GAS EXPOSE status lights indicate the cycle progress.

Final Vacuum and 30 Minute Air Purge

After the gas exposure has been completed, the chamber is cleared of gas by combining a deep vacuum with a fresh air purge. This removes most of the airborne gas, but the material in the load continues to release gas absorbed during the exposure.

Aerate

The Steri-Vac 5XL sterilizer automatically begins aeration to remove the ethylene oxide gas as it is released from material in the load. The upper front panel becomes an elapsed time display to a maximum of 99 hours, 59 minutes. The aeration temperature is the same as the selected sterilization temperature. The unit continues to maintain a negative pressure within the chamber to keep all

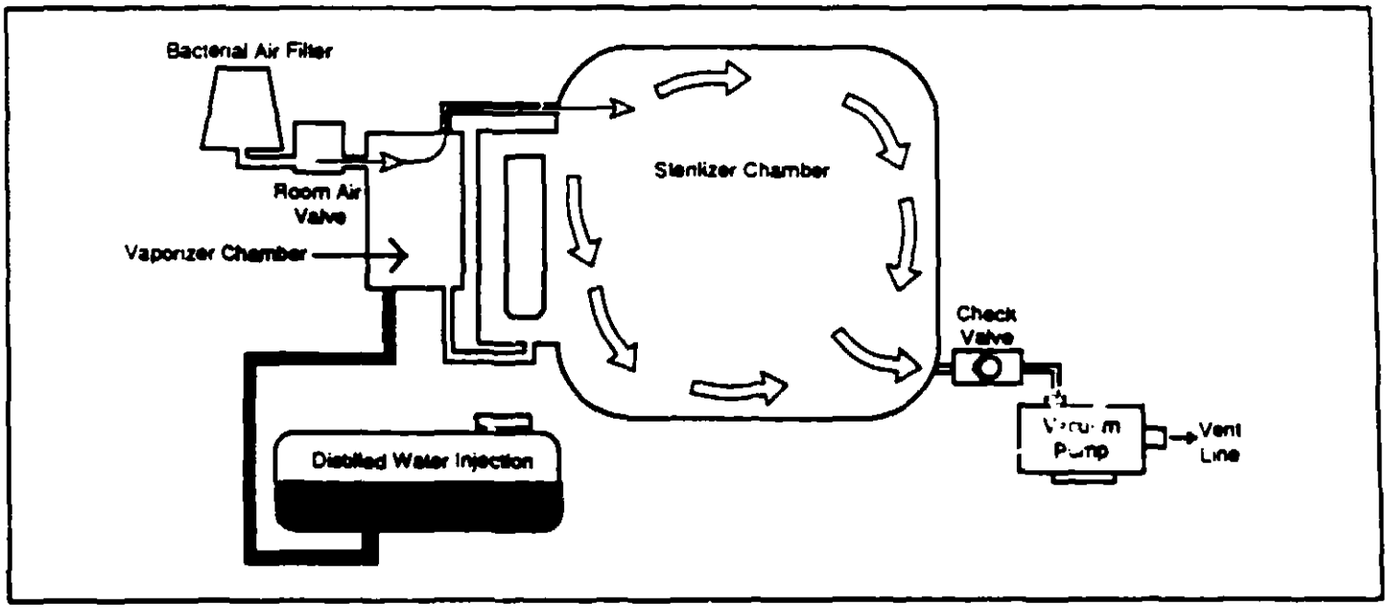


Figure 10. 30 Minute Air Purge

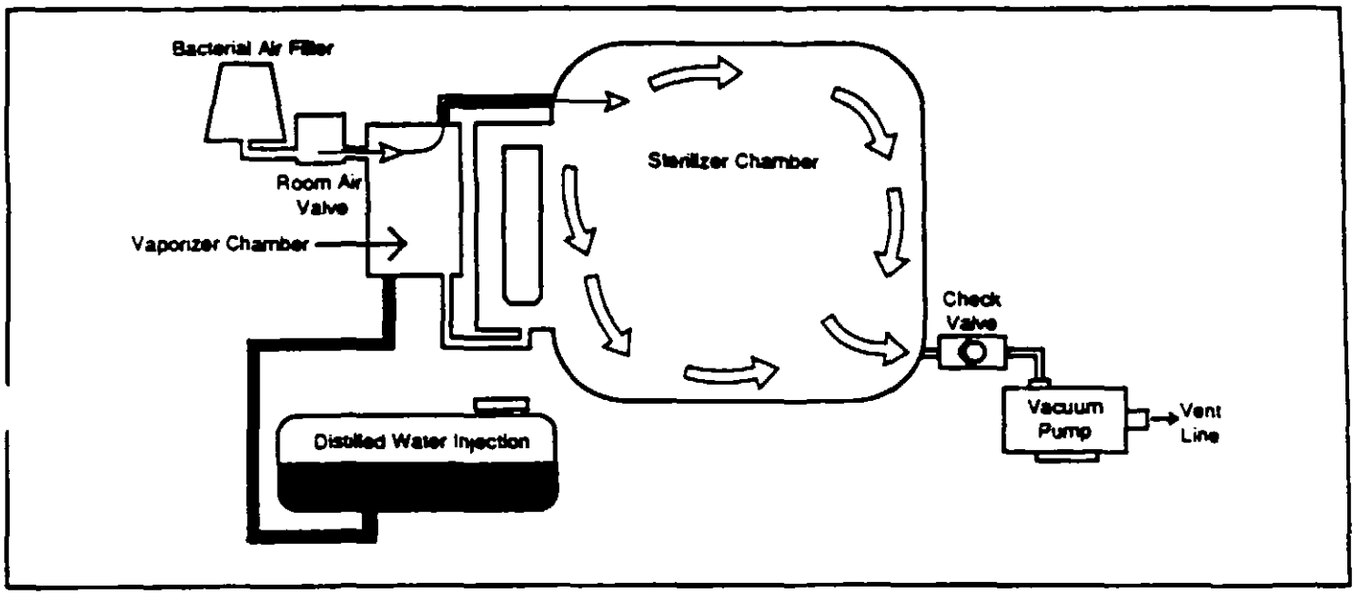


Figure 11. Continuous Aeration—Open Door

gas being released in the chamber until it is removed by the vacuum system.

The aeration time required to reduce the gas concentration in the individual items of the load depends upon material composition and aeration temperature. It is necessary to obtain recommended aeration times and temperatures for each item from the manufacturer. Only they know the composition of materials in their product and what temperatures they can withstand.

CAUTION
The load continues to release EO until it is completely aerated from the sterilized materials. If the optional local exhaust hood feature is installed and connected, the door will unlock immediately after the 30 minute purge. Fairly high levels of EO may still be within the chamber. The operator must follow the door opening instructions carefully and transfer the load quickly. The local exhaust hood will effectively remove the airborne EO from the chamber, but will not protect the operator who has moved the load away from the local exhaust hood.

If the unit is not equipped with the optional local exhaust hood, three hours mandatory aeration is required before the door will unlock. After this mandatory time the airborne EO levels within the chamber are within acceptable limits to allow transfer to an aerator if desired.

CAUTION
The load continues to release EO until it is completely aerated from the sterilized materials.

Door Opening
It is recommended that the load remain in the sterilizer for the entire aeration time. It is possible, however, to open the door at any time after it unlocks to remove the baskets for transfer to another aeration cabinet. If only some of the items are removed, aeration can be resumed by closing the door and turning the handle clockwise. The aeration timer stops while the door is open and restarts when the door closes.

Press the STOP switch while the door is opened to end the cycle after the load has been removed. The sterilizer will then return to standby, and will be ready for the next cycle.

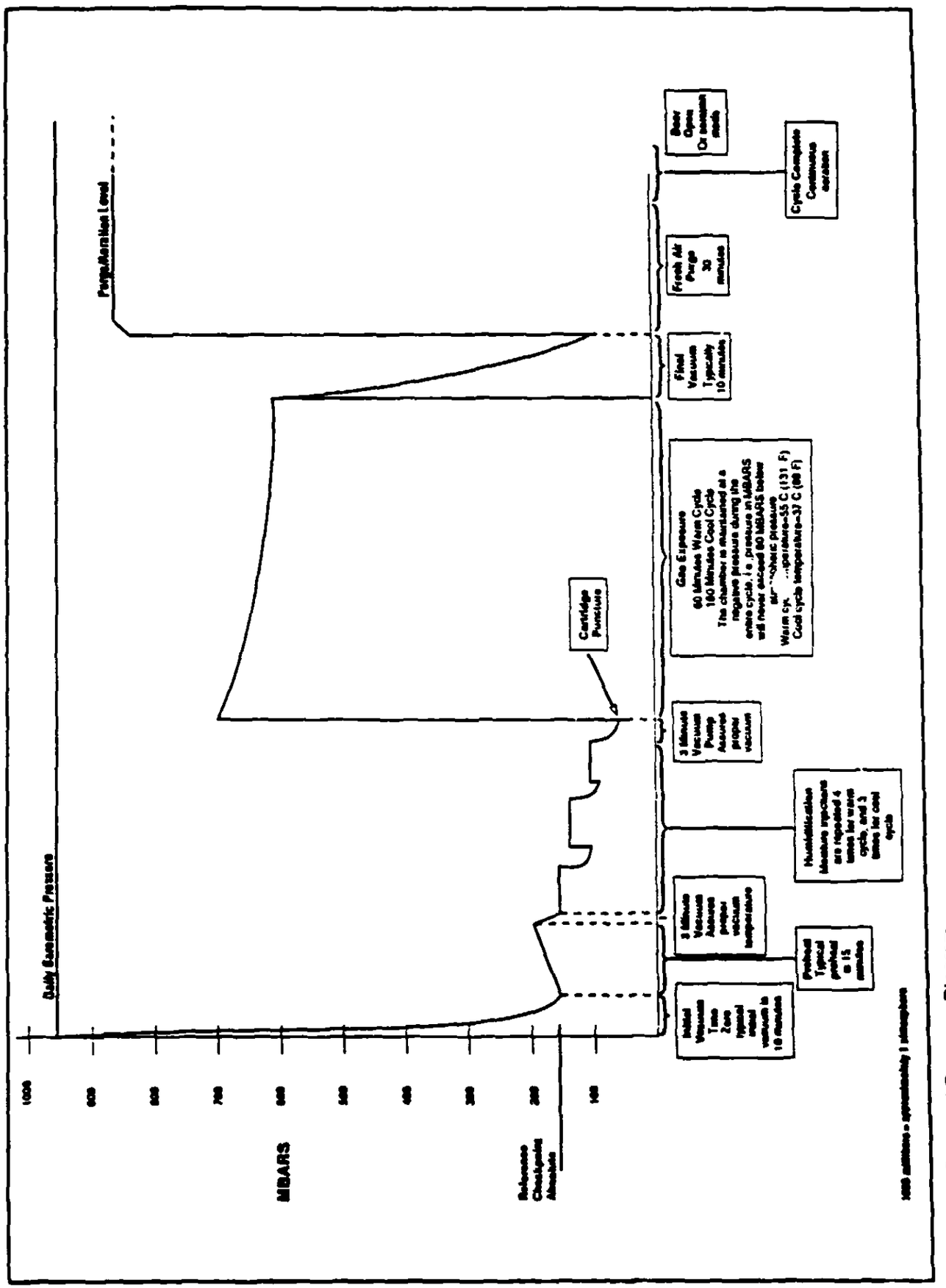


Figure 12. Time and Pressure Diagram.

Caution and Error Codes Explanation
Use the following chart to determine the cause of a caution/error message appearing in the upper digital display. Follow the corrective steps designated. Call your 3M Service Representative when indicated below, if a code appears that is not listed below, or if you have any questions.

Caution codes (e.g. c2) appear as flashing advisory messages but will not stop a cycle in progress. An operator must correct the problem indicated to clear the caution code.

Error codes (e.g. E10) appear as non-flashing error messages. The cycle in progress stops and the cycle status lights turn off. Follow the steps listed to correct the problem and clear the code.

- Codes E1 - E49 occur before cartridge puncture.

  Operator must open the door, press STOP and take the corrective steps indicated.

- Codes E50-69 occur after cartridge puncture. The STOP indicator is lit. The machine advances through final vacuum and purge then gives a constant audible alarm when the door unlocks. The operator must open door and press the STOP switch to stop the alarm and then take corrective steps.

- Codes E70-89 occur if the sterilizer cannot complete the final vacuum and purge. These codes may require a service call. Door remains locked and does not progress to the final vacuum and purge. There is no alarm. The STOP indicator is lit.

Caution and Error Codes Chart

Caution or Error Code	Message	Possible Reasons	Corrective Steps
Caution Messages - Do Not Stop Cycle			
c1	Low air in exhaust hood (only if unit is equipped with this feature)	External fan malfunction	Check fan and fan belts
		Duct plugged/disconnected	Check ductwork (Aerate 3 hrs. before opening)
		Airflow sensor failure	Call service representative
c2	Low water during standby	Reservoir needs water	Add distilled water
c3	Power interruption	Power outage	Cycle restarts automatically
c4	Compressed air lost during aeration	No compressed air	Check compressor, air lines
c5	Heater control lost during aeration	Heater control failure	Call service representative (Increase aeration time)
c6	Temperature calibration error	Electronics	Call service representative
Self -Test Errors Occurring on Power Up or at the Start of a Cycle			
E1	Processor memory failure	Electronics	Call service representative
E2	Program memory failure	Electronics	Call service representative
E3	Processor failure	Electronics	Call service representative
E4	Door locked in standby	No compressed air	Check compressor, air lines
E5	Chamber temp sensor fail	Bad sensor or connection	Call service representative
E6	Heatsink temp sensor fail	Bad sensor or connection	Call service representative
E7	Pressure sensor failure	Bad sensor or connection	Call service representative
E8	Pressure fail w/door open	Bad sensor or connection	Call service representative
Errors That Are Detected Before Puncture			
E10	Low water	Reservoir needs water	Add distilled water
		Water float switch failure	Call service representative
E20	Chamber needs to cool down	Chamber too warm	Open door, let chamber cool
E21	No vacuum	Blockage at vacuum port	Clear pkg. from vacuum port
		No compressed air	Check air lines
		Defective vacuum pump	Call service representative
E22	Initial pumpdown timeout	Improper air pressure	Check air system
		Defective vacuum pump	Call service representative
E23	Chamber preheat timeout	Defective temp. control	Call service representative
E24	Heatsink preheat timeout	Defective temp. control	Call service representative
E25	Over temp #1	Electronics	Call service representative
E26	Under temp #1	Electronics	Call service representative
E27	Pressure #1	Leak in chamber	Check door seal/call service
		Defective pressure sensor	Call service representative
E28	No water injected	Reservoir float switch stuck	Add water to reservoir
		Water system plugged	Call service representative
E29	Over temp #2	Electronics	Call service representative
E30	Under temp #2	Electronics	Call service representative

Caution and Error Codes Chart Continued

Caution or Error Code	Message	Possible Reasons	Corrective Steps
E31	Pressure #2	Leak in chamber	Check door seal/call service
		Defective pressure sensor	Call service representative
E32	Door unlocked	Door lock hung up on bolt	Turn handle to vertical position
		Control error	Call service representative
E33	Memory relay	Electronics	Call service representative
E34	Door open	Door not closed	Close door - restart
		Defective switch	Call service representative
E40	User interruption	User pressed STOP switch	Restart
Errors Found During Gas Exposure			
E50	Empty cartridge	Empty cartridge used	Use new cartridge
		Puncture mechanism failed	Call service representative
E51	Chamber vacuum leakage	Air leak in chamber	Call service representative
E52	Under temperature abort	Electronics	Call service representative
E53	Over temperature abort	Electronics	Call service representative
E54	Extended power outage	Could not restart cycle	Rerun cycle
E60	User interruption	User pressed STOP switch	Rerun cycle
Errors That Leave the Chamber Locked with Gas Possibly in the Chamber			
E71	Final pumpdown timeout	Compressed air problem	Correct and press start
		Vacuum system failure	Call service representative
E72	Obstructed air inlet	Bacterial filter plugged	Press START; if code repeats Call service representative
E73	Pressure sensor out of range	Electronics	Call service representative
E75	Low gas injected	Partial puncture	Call service representative
E76	Memory relay won't reset	Memory relay failure	Press START; if code repeats Call service representative

Error Code Clearing Procedure

When machine is showing an error code, it is necessary to return to the standby mode before running another cycle. This is accomplished by opening the door and pressing the STOP switch.

IV. Customer Maintenance

Cleaning

Clean the following parts of your Steri-Vac 5XL gas sterilizer/aerator at least weekly, preferably daily, using a damp cloth with mild soap and warm water.

- chamber floor and walls
- outer chamber lip
- inner door surface
- outer cabinet

Servicing Filters, Moisture Trap, and Vent Line Air Line Filters (if applicable)

Replace the prefilter element at least every six months and the oil removal filter at least every 12 months. Change the elements more frequently if the air supply is highly contaminated. Daily drain any moisture/oil that collects in the bottom of the air filter reservoirs.

Vent Line Moisture Trap (if applicable)

Empty the moisture trap at least monthly. Be sure the trap reservoir is screwed in securely and the sealing O-ring is in good condition and properly placed to prevent gas leakage during sterilizer discharge.

Factory Authorized Service

Only authorized personnel should repair or replace parts. Tampering or unauthorized alterations in the equipment will void the manufacturer's warranty.

3M Medical-Surgical Division has established a worldwide service organization to provide factory-trained technicians to care for your equipment. In the USA, contact your local 3M Service Representative or the 3M Medical-Surgical Service Center at the following address for servicing information.

3M Medical-Surgical Service Center
3M Center, Building 582-1E-02
St. Paul, MN 55144
(612) 733-7865

Outside the United States, contact the local 3M subsidiary. In Canada, contact:

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

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 Medical-Surgical Service Representative or the 3M Medical-Surgical Service Center at the above address for PMA information.

Service Manual

A Service Manual for the Steri-Vac 5XL gas sterilizer can be purchased. The manual contains an illustrated parts list, a troubleshooting guide, the details of operation, and an electrical schematic. Request the manual by writing or calling the 3M Medical-Surgical Service Center at the address listed above.

Steri-Vac Printer Operating Instructions

The Steri-Vac printer is built into the front of the

V. Accessory Equipment

sterilizer immediately beneath the operator control panel and behind the printer/water supply access door (Figure 13). This is a thermal printer requiring no ink or ribbon. The print quality does not deteriorate due to ink supply or ribbon related problems. The unit is designed to print high quality graphic and alpha numeric characters without the requirement of routine maintenance.

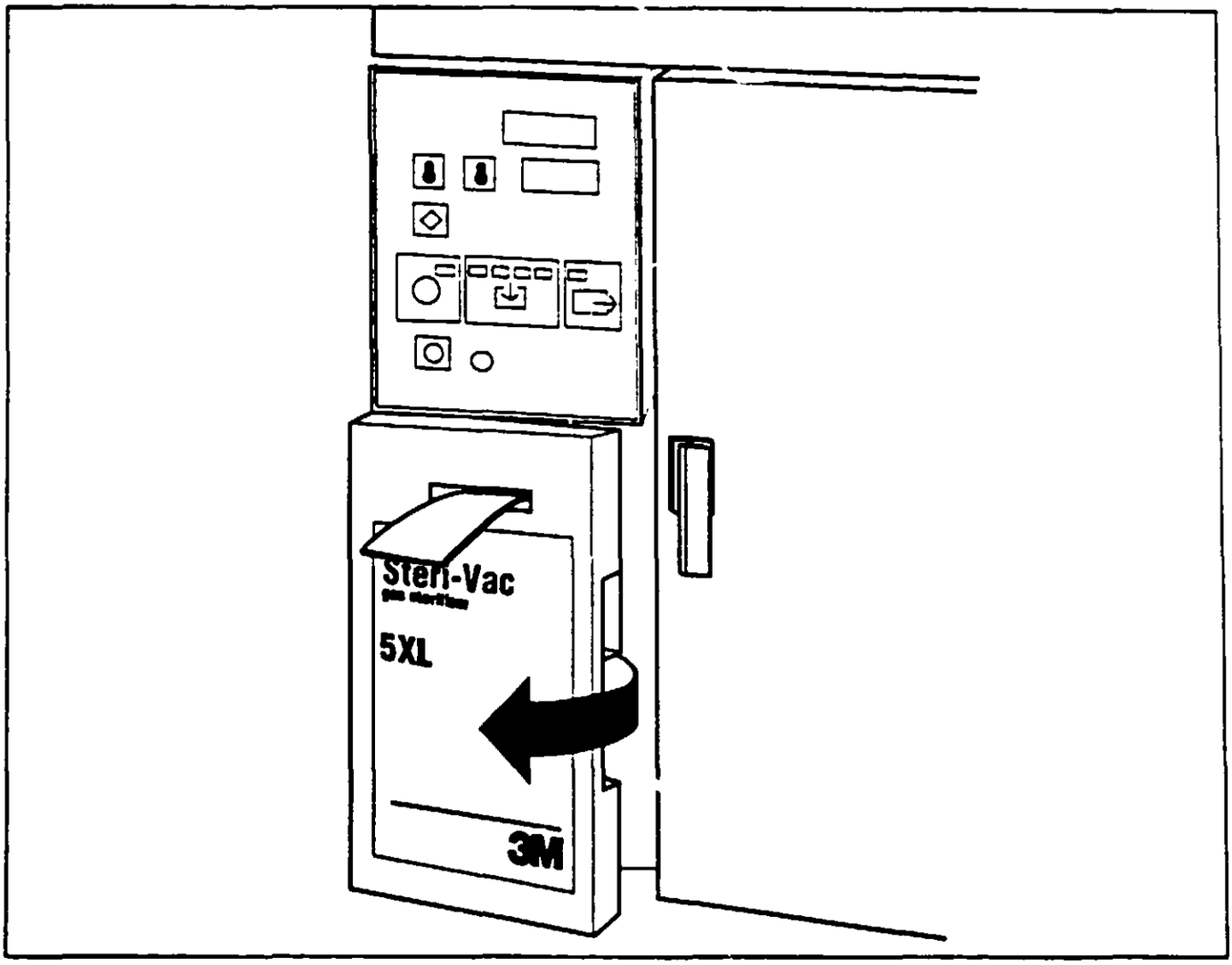


Figure 13. Printer Location.

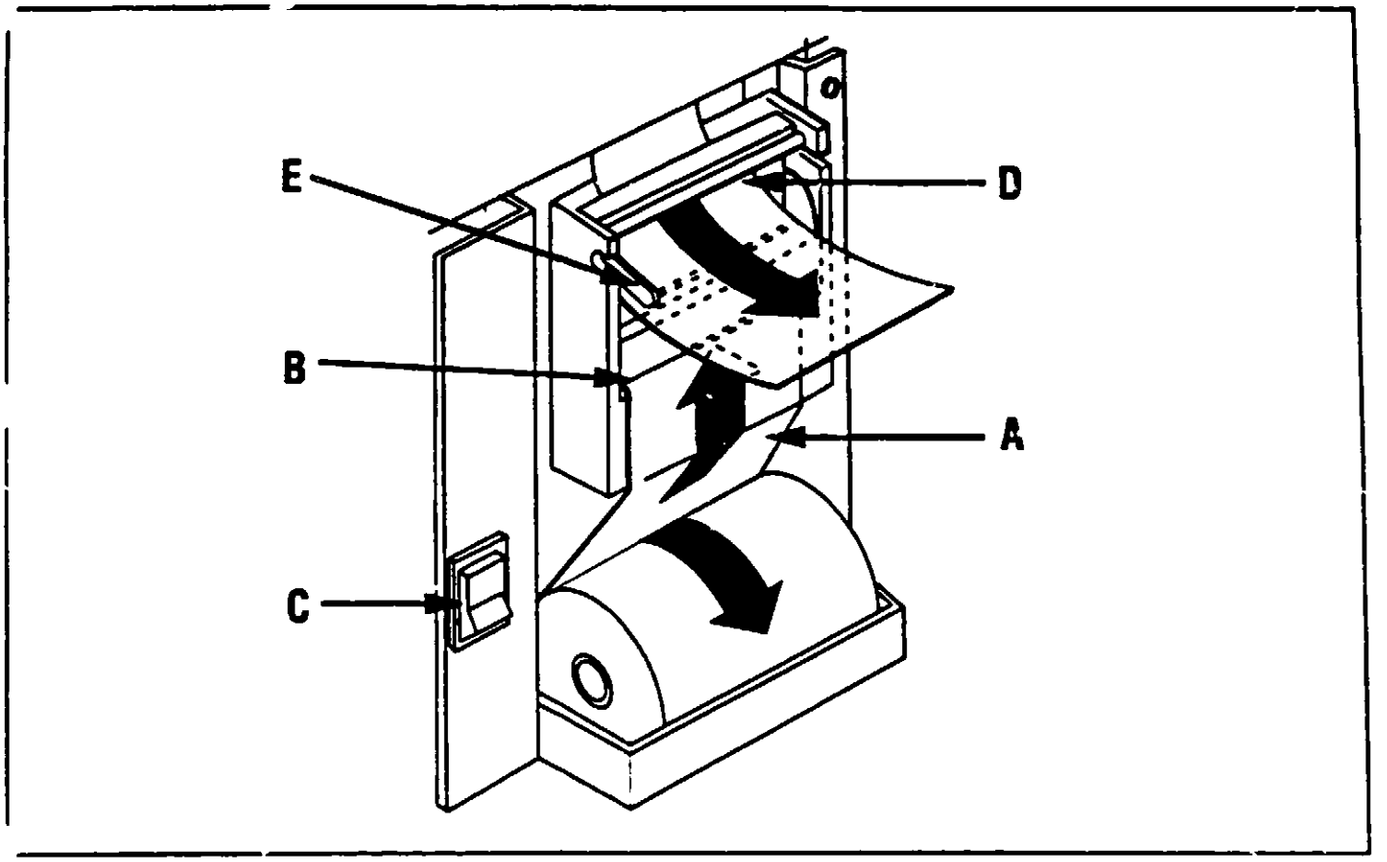


Figure 14. Loading the printer paper.

Paper Loading

Loading the printer paper is a very easy operation and should be done as indicated in Figure 14.

Note: Letters in the text refer to Figure 14.

1. Place paper roll in tray (A) so that paper rolls off the back of the roll as shown.
2. Make sure printer roller tension lever is in the DOWN position.
3. Hand-feed the paper into the lower paper slot (B).
4. Momentarily press the printer paper feed switch (C) until about 10 cm (4") of paper advances from the upper paper slot (D).
5. Feed paper through the slot in the door (E) as the door is closed .
6. To obtain cycle printout, ensure that the printer power/control switch is in the ON position before starting a cycle.

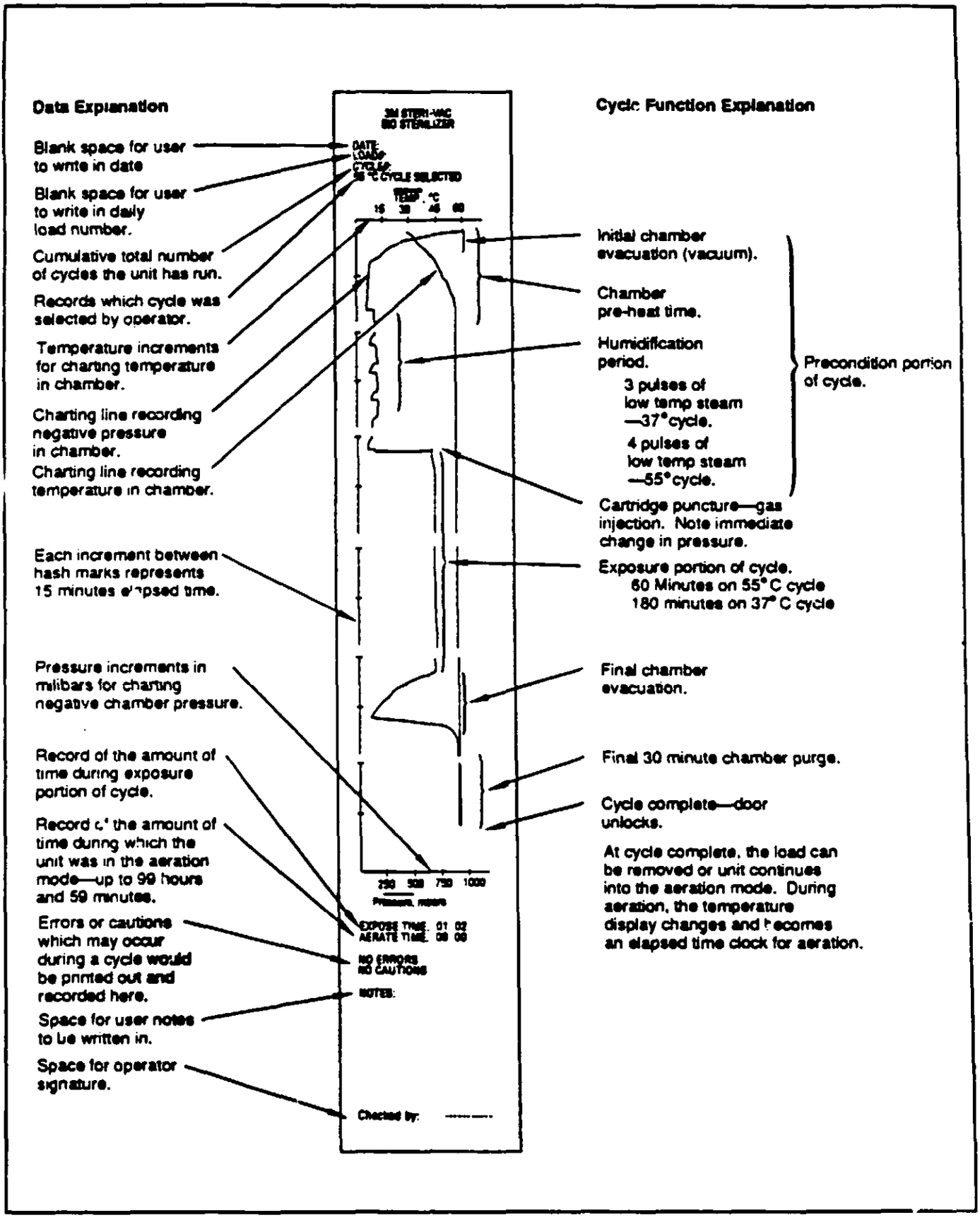


Figure 15. Printout explanation chart.

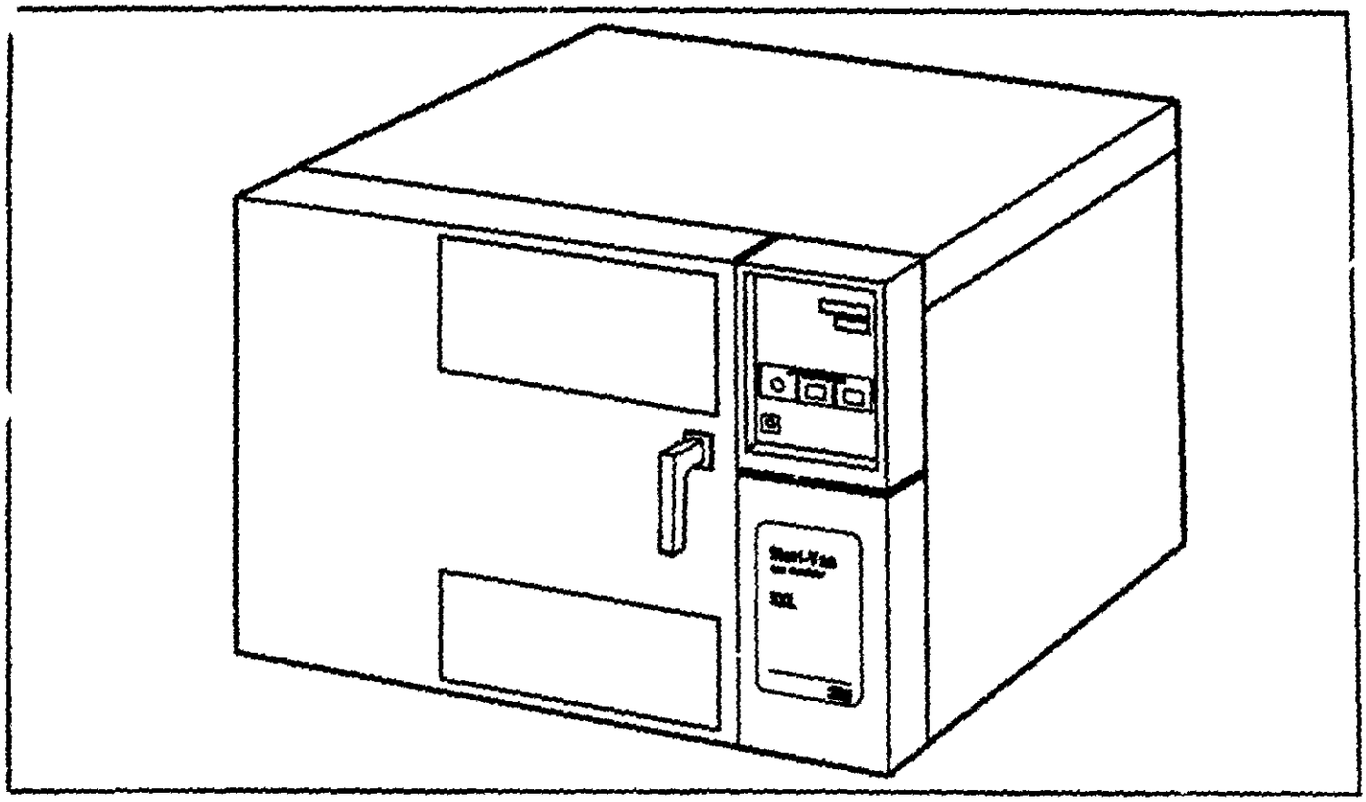


Figure 16. Unload side of two-door unit.

Optional Two Door Operation

The Steri-Vac 5XL gas sterilizer/aerator can be ordered with a second door for installations or facilities that use a clean room approach to separate sterilized goods from contaminated items. A second control panel is added to the unloading side of the two door unit. This control panel provides full cycle status information and a STOP switch to terminate the cycle after the baskets have been removed. This control panel does not have the temperature select or START switches since these are used only from the loading side.

The operation sequence of the two door sterilizer is exactly the same as that of a single door unit. In addition, the function of all the switches and the information in all the displays are the same whether they are on the load or unload side of the sterilizer. The second door gives the operator the option to unload from either side according to the policies of the hospital or clinic where the sterilizer is installed.

Optional Local Exhaust Hood
As indicated earlier in this manual, a local exhaust hood can be connected to the Steri-Vac 5XL gas sterilizer/aerator for customers that do not want to wait for the three hour mandatory aeration before removing the load from the chamber. The local exhaust hood has been shown to be effective at minimizing exposure to residual airborne EO that may be in the chamber after the final pumpdown and 30-minute purge. The hood is available for both single and double door sterilizers.
The local exhaust hood is connected to a customer supplied non-recirculating ventilation system. *(Refer to the Steri-Vac 5XL Installation Guide)* It also puts added responsibility on the proper performance of the door opening procedure and prompt handling of the basket of unaerated goods. The door must be left in the "latched" position for at least five minutes as described in the Operating Instructions. The basket must be transferred immediately to an aeration cabinet to finish aeration.

CAUTION!
The local exhaust hood will effectively remove the airborne EO from the chamber, but will not protect the operator who has moved the load away from the local exhaust hood. The load will continue to release EO until completely aerated.

VI. Installation Guide